FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA 3600 B

Product name(s): LABAMBA

Chemical active substance:

Lambda cyhalothrin, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: March 2022

Update date: September 2022

MS Finalisation date: July 2022, November 2022

Version history

When	What
March 2022	
July 2022	zRMS assessment
September 2022	Applicant update
November 2022	Assessment of the applicant's supplements

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

The text highlighted in grey (comments and corrections) and yellow is provided by the evaluator.

Stability of Residues

No new data submitted in the framework of this application.

Residues of Lambda cyhalothrin in high water, high starch, high oil content products are stable for 26 months. The animal product residues are stable for 3 months.

Metabolism in plant and animal

The metabolism in plant and animal was assessed for annex 1 inclusion (approval) of the active substance. The data evaluated is sufficient to support the proposed uses.

Sharda has submitted a letter of access to Green M, 2012 study (Lambda-cyhalothrin – The metabolism of [14C]- Lambda-cyhalothrin in Lactating Goat, Syngenta, File No PP321 11503)

The residue definitions agreed for monitoring and risk assessment

Plant and animal residue definition for monitoring (Regulation (EU) 2021/590)

Lambda cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)

Plant and animal residue definition for risk assessment (EFSA 2014, 2015, 2020):

Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)

The data evaluated are sufficient to support the proposed uses.

No further data are required.

Magnitude of residues in plants

Flowering brassica (cauliflower)

Head brassica (brussels sprouts, cabbage)

Proposed uses:

1 application, BBCH 11-43, 0.0075 kg as/ha, PHI: 3 (cabbage), 7 (Brussels sprouts, cauliflower) days

Cauliflower and cabbage are a major crops in northern Europe. A minimum of eight trials of each is required.

No new residue trials were performed. Applicant refers to data of active substance.

One trial on cauliflower and four trials on cabbage are available.

There are insufficient trials to support the proposed uses. Additionally trials on cauliflower and cabbage are required.

Additional data provided by the applicant (September 2022).

- Cauliflower

One decline and one magnitude of residues trials were carried out on the open field in Poland in 2021.

Trials GAP: 2 x 7.5 g as/ha, BBCH 45, PHI 7d, outdoor

Residues: 2x< 0.01 mg/kg

Overall supporting data for cGAP (cauliflower):

Two trials carried out on the open field in Poland more critical trials than proposed uses (2 applications *versus* to 1 applications). The study can be accepted as the worst case because the residues are below LOQ.

Additionally, the applicant refers to one overdosed trial on cauliflower (DAR 1996, 4 x 10-15 g as/ha). Cauliflower was not assessed during the revision of the active substance assessment. Too little information is available to conclude on the acceptability of this study.

Use is not accepted. Data gap: one trial on cauliflower.

- Head brassica (brussels sprouts, cabbage)

8 new trials on head cabbage were provided by the applicant (Poland, Hungary, Germany).

Trials GAP: 2 x 7.5 g as/ha, BBCH 45, PHI 3d, outdoor

Trials are more critical than proposed uses (2 applications *versus* to 1 applications). The trials can be accepted as the worst case because the residues are below LOQ.

The trials from study KCP 8.3.19 (Poland) are not independent – the same localisation and dates like in the study KCP 8.3.15. These trials (KCP 8.3.19) are not considered in the assessment.

Trial CPRHU21-205-065IR/Hungary/N-EU/2021 and trial CPRHU21-210-065IR/Hungary/N-EU/2021, Kőszeg, Zip code: 97-30 are not independent. Trial CPRHU21-205-065IR/Hungary/N-EU/2021 is not considered in the assessment (KCP 8.3.21).

Acceptable residues: 5 x <0.01 mg/kg

Sufficient number of trials are available to support the proposed use on cabbage (residues <LOQ).

According to SANTE/2019/12752 extrapolation from cabbage to brussels sprouts is not possible. Use on brussels sprouts is not acceptable.

Tomato (indoor, outdoor)

Proposed uses:

1 application, BBCH 51-81, 0.0075 kg as/ha, PHI: 3

Tomato is a major crop in northern Europe. A minimum of eight trials for indoor uses and 8 for outdoor uses is required.

6 overdosed indoor trials are available . Uses are not accepted.

Additional data provided by the applicant (September 2022).

New trials were provided by the applicant.

Trials GAP: 2 x 20 g as/ha, BBCH 85, PHI 3d, outdoor.

KCP 8.3.29 - Trial 21SGS46-01/Poland/N-EU/2021, Kaczkowo ((Kujawsko-Pomorskie), Zip code:88-400 is not consider in the assessment as not independent to trial 21SGS50-01/Poland/N-EU/2021,

Study KCP 8.3.31 is not considered in the assessment as not independent to study KCP 8.3.27.

Acceptable residues:

KCP 8.3.25: <0.01, 0.02 mg/kg – open field

KCP 8.3.27: 2x<0.01 mg/kg - open field

KCP 8.3.29: <0.01 mg/kg - open field

KCP 8.3.31: - open field

KCP 8.3.33: 0.02, 0.03 mg/kg – protected

KCP 8.3.35: 2x<0.01 mg/kg - protected

Summary (outdoor): 4x<0.01, 0.02 mg/kg

Summary (protected): 2x<0.01, 0.02, 0.03 mg/kg

Additionally residues in tomatoes were assessed in the RAR.

Trials GAP (RAR, field N-EU): 2 applications at 12.5 g as/ha, BBCH 10-89, PHI: 3 days

Trials GAP (RAR, G): 2 applications at 25 g as/ha, BBCH 10-89, PHI: 3 days

These trials were performed at a more critical application rate than those intended in this dossier.

Residues (RAR, field N-EU): 8x<0.01 mg/kg

Residues (RAR, G): 4x<0.01, 2x0.01,4x0.02, 2x0.03, 0.04 mg/kg

Sufficient number of trials are available to support the proposed use on outdoor tomato. Use is acceptable.

Sufficient number of trials are available to support the proposed use on indoor tomato. Use is acceptable.

Winter cereals (wheat, barley, rye, oats, triticale)

Proposed use:

1 application, BBCH 41-75, 0.0075 kg as/ha, PHI: 28 days

Applicant refers to unprotected data from DAR and new studies.

Wheat

EFSA, 2014; Sweden 2013: N-EU GAP on which MRL/EU a.s. assessment is based: 2 x 7.5; 2 x 15 g as/ha, outdoor

Residues: 4 x <0.01 mg/kg

DAR 1996: N-EU GAP on which MRL/EU a.s. assessment is based: 3 x 10 g as/ha, , outdoor

Residues:3 x <0.01 mg/kg

New trials: N-EU Trials GAP: 2 x 7.5 g as/ha, BBCH: 82-87, PHI 28-29d, outdoor

Residues:2 x <0.01 mg/kg

Barley

DAR 1996: N-EU GAP on which MRL/EU a.s. assessment is based:3 x 10 g as/ha,

Residues:4 x <0.01, 3 x 0.02 mg/kg

New trials: N-EU Trials GAP: 2 x 7.5 g as/ha, BBCH: 73, PHI 28d

Residues:1 x <0.01 mg/kg.

Oats

DAR 1996: N-EU GAP on which MRL/EU a.s. assessment is based:3 x 10 g as/ha,

Residues:4 x <0.01 mg/kg

Presented trials are not in line with proposed used (they are overdosed). The available trials were performed with 2 applications at 7.5, 10 and 15 g a.s./ha instead of 1 applications at 7.5 g a.s./ha. Nevertheless, the studies are acceptable to cover the proposed use due to residues below LOQ except for 3 tests with the results of 0.02 mg/kg. Application times in all studies are consistent with proposed GAP.

According to the available data, the intended uses on cereals are considered acceptable. The new studies are accepted.

Winter Oilseed rape

Oilseed rape

Proposed uses:

1 application, BBCH 50-59, 0.0075 kg as/ha, PHI: 35 days

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

The object of this study was to determine the magnitude and decline of residues of lambda-CYHALOTHRIN in Oilseed rape resulting from three foliar applications at the maximum anticipated labelled rate of lambda-CYHALOTHRIN 2.5% WG (0.0075 kg as/ha).

Residues: 2 x < 0.01 mg/kg

The GAP of trials is more critical than proposed uses (3 applications *versus* to 1 applications; growth stage at last treatment are later than proposed). The study can be accepted as the worst case because the residues are below LOQ.

Additionally one residue trial on oilseed rape from Northernn Europe is available (2 x 5 g as/ha). This trial can only support GAP with application rate of 0.005 kg as/ha.

Conclusion

A number of trials on oilseed rape can be considered as insufficient (only two accepted trials).

Additional one trial is required as residues were <LOQ in the two accepted trials with non-systemic profile of the active substance.

Use is not accepted.

Additional data provided by the applicant (September 2022).

One decline trial was carried out on the open field in Czech Republic in 2021.

Residues: < 0.01 mg/kg

and

One trial was carried out on the open field in Poland in 2021.

Residues: < 0.01 mg/kg

The GAP of trials (GAP: 3 x 7.5 g as/ha, PHI 35d) is more critical than proposed uses (3 applications versus to 1 applications; growth stage at last treatment are later than proposed). The studies can be accepted as the worst case because the residues are below LOQ.

A number of available trials on oilseed rape can be considered as sufficient. Use is accepted.

Magnitude of residues in livestock

There is no risk for animal MRL to be exceeded

Magnitude of residues in processed commodities

Additional data is not required.

Magnitude of residues in representative succeeding crops

EFSA Journal 2019;17(1):5546: *This conclusion was confirmed by rotational crop field trials conducted at a total dose rate of 500 g/ha which resulted in residues of lambda-cyhalothrin and compound Ia below the LOQ in the edible parts at 30 and 60 day plant-back intervals (EFSA, 2014b)*

No residues of lambda-cyhalothrin are expected in rotational crops, provided that the active substance is applied according to the accepted uses. No risk mitigation measures are required.

Estimation of exposure through diet and other means

The accepted uses of lambda-cyhalothrin in the formulation SHA 3600 B 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 SHA 3600 B are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central zone for brassicas, tomatoes, winter cereals and winter oilseed rape. A list of all intended uses within the central zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment ~~for cereals only~~. An exceedance of the current MRL for lambda cyhalothrin (for cereals, cabbage, tomato (indoor, outdoor) and oilseed rape) as laid down in Reg. (EU) 2021/590 is not expected.
The chronic and the short-term intakes of lambda-cyhalothrin residues are unlikely to present a public health concern (in relation to cereals, cabbage, tomato (indoor, outdoor) and oilseed rape).
As far as consumer health protection is concerned, Poland agrees with the authorization of the intended use(s) on cereals, cabbage, tomato (indoor, outdoor) and oilseed rape.

Data gaps

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

Noticed data gaps are:

- one residue trial on cauliflower and residue trials on Brussels sprouts are required.

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	**Brassicas (cabbage, ~~Brussels sprouts, cauliflower~~)**	CEU	SHA 3600 B	F	Aphids	CS	100 g/L	Foliar Spray	BBCH 41-43	a) 1 b) 1		0.00125 – 0.00375	200-600	a) 0.0075 b) 0.0075	3 (cabbage), 7 (Brussels sprouts, cauliflower)	A cabbage N Brussels sprouts, cauliflower
2	**Brassicas (cabbage, ~~Brussels sprouts, cauliflower~~)**	CEU	SHA 3600 B	F	Caterpillars	CS	100 g/L	Foliar Spray	BBCH 41-43	a) 1 b) 1		0.00125 – 0.00375	200-600	a) 0.0075 b) 0.0075	3 (cabbage), 7 (Brussels sprouts, cauliflower)	A cabbage N Brussels sprouts, cauliflower
3	**Tomato**	CEU	SHA 3600 B	F	Aphids	CS	100 g/L	Foliar Spray	BBCH 51-85	a) 1 b) 1		0.00075 – 0.0025	300-1000	a) 0.0075 b) 0.0075	3	A
4	**Tomato**	CEU	SHA 3600 B	G	Whitefly	CS	100 g/L	Foliar Spray	BBCH 51-85	a) 1 b) 1		0.00075 – 0.0025	300-1000	a) 0.0075 b) 0.0075	3	A
5	**Winter cereals (wheat, barley, rye, oats, triticale)**	CEU	SHA 3600 B	F	Aphids	CS	100 g/L	Foliar Spray	BBCH 41-75	a) 1 b) 1		0.001875 – 0.00375	200-400	a) 0.0075 b) 0.0075	28	A
6	**Winter Oilseed rape**	CEU	SHA 3600 B	F	Aphids	CS	100 g/L	Foliar Spray	BBCH 50-59	a) 1 b) 1		0.00125 – 0.00375	200-600	a) 0.0075 b) 0.0075	35	A
7	**Winter Oilseed rape**	CEU	SHA 3600 B	F	Coleseed sawfly	CS	100 g/L	Foliar Spray	BBCH 50-59	a) 1 b) 1		0.00125 – 0.00375	200-600	a) 0.0075 b) 0.0075	35	A

8	**Winter Oilseed rape**	CEU	SHA 3600 B	F	Pollen beetle	CS	100 g/L	Foliar Spray	BBCH 50-59	a) 1 b) 1		0.00125 – 0.00375	200-600	a) 0.0075 b) 0.0075	35	A
9	**Winter Oilseed rape**	CEU	SHA 3600 B	F	Stem weevil	CS	100 g/L	Foliar Spray	BBCH 50-59	a) 1 b) 1		0.00125 – 0.00375	200-600	a) 0.0075 b) 0.0075	35	A

* 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 SHA 3600 B is composed of lambda-cyhalothrin

Table 7.1-2: Toxicological reference values for the dietary risk assessment of lambda cyhalothrin.

Reference value	Source	Year	Value	Study relied upon	Safety factor
Lambda cyhalothrin					
ADI	*EFSA Journal 2014;12(5):3677*	2014	0.0025 mg/kg bw/d	Multigeneration study in rat	200
ARfD	*EFSA Journal 2014;12(5):3677*	2014	0.005 mg/kg bw	1-year study in dog	100

7.1.2.1 Summary for lambda-cyhalothrin

Table 7.1-3: Summary for LABAMBA (SHA 3600 B)

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?
1-2	Cabbage, Brussels Sprouts	Yes	Yes: Cabbage No: Brussels Sprouts	Yes: Cabbage No: Brussels Sprouts	Yes	Yes: Cabbage No: Brussels Sprouts	No	No
1-2	Cauliflower	Yes	~~Yes~~ No	~~Yes~~ No	Yes	~~Yes~~ No	No	No
3	Tomato	Yes	Yes ~~No~~	Yes ~~No~~	Yes	Yes ~~No~~	No	No
4	Tomato	Yes	Yes ~~No~~	Yes ~~No~~	Yes	Yes ~~No~~	No	No
5	Wheat, rye, triticale	Yes	Yes	Yes	Yes	Yes	No	No
5	Barley, oats	Yes	Yes	Yes	Yes	Yes	No	No
6-9	Winter Oilseed rape	Yes	Yes ~~No~~	Yes ~~No~~	Yes	Yes ~~No~~	No	No

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

7.1.2.2 Summary for SHA 3600 B

Table 7.1-4: Information on SHA 3600 B (KCA 6.8)

Crop	PHI for SHA 3600 B proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for SHA 3600 B proposed by zRMS	zRMS Comments (if different PHI proposed)
		Lambda cyhalothrin		
Brassicas (cabbage)	3	Yes		
~~**Brassicas (Brussels sprouts, cauliflower)**~~	~~7~~	~~Yes~~		
Tomato	3	Yes		
Winter cereals (wheat, barley, rye, oats, triticale)	28	Yes		
Winter Oilseed rape	35	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).

Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for SHA 3600 B
Crop group	**Led by Lambda cyhalothrin**	
Leafy vegetables	NR	
Pulses and oilseeds	NR	
Cereals	NR	

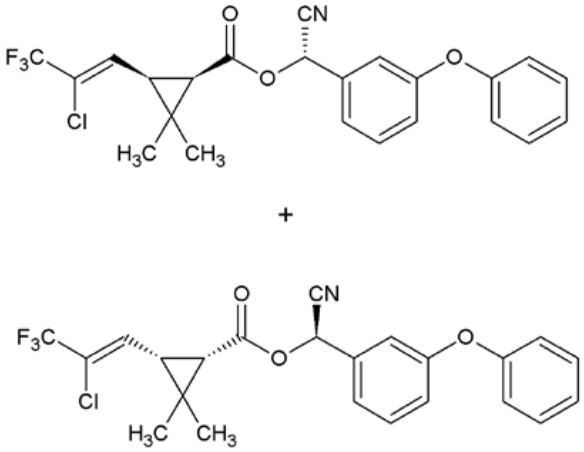
NR: not relevant

Assessment

7.2 Lambda-cyhalothrin

General data on Lambda-cyhalothrin are summarized in the table below (last updated 2022/02/16)

Table 7.2-1: General information on lambda cyhalothrin

Active substance (ISO Common Name)	Lambda-cyhalothrin
IUPAC	1:1 mixture of (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate
Chemical structure	
Molecular formula	$C_{23}H_{19}ClF_3NO_3$
Molar mass	449.9 g/mol
Chemical group	Pyrethroid
Mode of action (if available)	Contact and stomach action. Some repellant properties. Sodium channel modulator.
Systemic	Non
Company (ies)	Syngenta
Rapporteur Member State (RMS)	Original RMS: Sweden RMS: Spain Co-RMS: France
Approval status	Approved Date of (01/04/2016) and reference to decision (Regulation (EU) No 146/2016) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0146
Restriction	Only uses as insecticide may be authorised.
Review Report	SANCO/12282/2014 Rev 5 11 December 2015 17 July 2020
Current MRL regulation	Reg. (EU) 2021/590
Peer review of MRLs according to Article 12 of Reg No	Yes

396/2005 EC performed	
EFSA Journal : Conclusion on the peer review	Yes, EFSA Journal 2014;12(5):3677
EFSA Journal: conclusion on article 12	Yes, EFSA Journal 2015;13(12):4324
Current MRL applications on intended uses	EFSA-Q-2015-00058 (EMS) All Commodities Reasoned opinion available (EFSA Journal 2015;13(12):4324)

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

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Lambda cyhalothrin			
Plant products			
Apple, peach, sugar, beet rot, cabbage, potato, peas	High water content	26 months	O.J. Tummon, A Sapiets, 1988 Report No. M4845B RAR, Sweden, 2013 EFSA 2014
Wheat grain	High starch content	26 months	O.J. Tummon, A Sapiets, 1988 Report No. M4845B RAR, Sweden, 2013 EFSA 2014
Rape seed, cotton seed	High oil content	26 months	O.J. Tummon, A Sapiets, 1988 Report No. M4845B RAR, Sweden, 2013 EFSA 2014
Animal Products			
Poultry	Liver	3 months	A. Sapiets, D. Priestley 1986 Report No. M4300B RAR, Sweden, 2013 EFSA 2014
Poultry	Eggs	3 months	A. Sapiets, D. Priestley 1986 Report No. M4300B RAR, Sweden, 2013

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
			EFSA 2014
Poultry	Fat	3 months	A. Sapiets, D. Priestley 1986 Report No. M4300B RAR, Sweden, 2013 EFSA 2014
Poultry	Muscle	3 months	A. Sapiets, D. Priestley 1986 Report No. M4300B RAR, Sweden, 2013 EFSA 2014
Ruminant	Milk	4 months	A. Sapiets, 1985 Report No. M3893B RAR, Sweden, 2013 EFSA 2014
Compounds Ia, V, XXIII			
Milk		43 months	A. Sapiets, D. M. Clarke, 1994 Report No. RJ1568B RAR, Sweden, 2013 EFSA 2014
Muscle		36 months	A. Sapiets, D. M. Clarke, 1994 Report No. RJ1568B RAR, Sweden, 2013 EFSA 2014
Fat		40 months	A. Sapiets, D. M. Clarke, 1994 Report No. RJ1568B RAR, Sweden, 2013 EFSA 2014
Egg		41 months	A. Sapiets, D. M. Clarke, 1994 Report No. RJ1568B RAR, Sweden, 2013 EFSA 2014
Liver		40 months	A. Sapiets, D. M. Clarke, 1994 Report No. RJ1568B RAR, Sweden, 2013 EFSA 2014
Kidney		38 months	A. Sapiets, D. M. Clarke, 1994 Report No. RJ1568B RAR, Sweden, 2013 EFSA 2014

Conclusion on stability of residues during storage

All plant product residues trials samples reported in the study were stored for 26 months between -18 and -20 °C. The animal product residues reported in the study were stored for more or equal to 3 months be-

tween -18 and -20 °C. Degradation of residues during storage of samples is therefore not expected.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

No data was submitted and required at EU level during the EU Review of Lambda-cyhalothrin.

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	No	Sampling (DAT)	
EU data							
Fruits and fruiting vegetable	Apple	[Cyclopropane-^{14}C]-cyhalothrin	Spotting, F	33 µg/apple	1	0, 7, 14, 28 and 56 days	J. S. Hall, J. P. Leahey 1979 Report No. TMJ 1728B RAR, Sweden, 2013 EFSA 2015
Leafy vegetables	Cabbage	[Cyclopropane-^{14}C]-cyhalothrin	Spotting, F	26 µg/leaf	1	2, 4, 5, 6 and 7 weeks	E. A. Curl, J. P. Leahey, 1983 Report No. RJ0308B RAR, Sweden 2013 EFSA 2015
			Spraying, F	55 g as/ha	4-8	7 days	
Pulses and oilseeds	Soya	[Cyclopropane-^{14}C]-lambda-cyhalothrin; [benzyl-^{14}C]-lambda-cyhalothrin	Spraying, G	20 g as/ha	2	39 days leaves 51 days beans	D. A. French, J. P. Leahey, 1986 Report no. RJ0438B, RJ0507B RAR, Sweden, 2013 EFSA 2015
	Cotton leaves	[Cyclopropane-^{14}C]-lambda-cyhalothrin;	Spraying, F	66 g as/ha	3	30 days leaves 50 days seeds	J. P. Leahey, D. A. French,

		[benzyl-^{14}C]-lambda-cyhalothrin					1985, 1986 J. P. Leahey, W. M. D. Collis, D. A. French, 1986 Report No. RJ0393B, RJ0526B, RJ0497B RAR, Sweden, 2013 EFSA 2015
Cereals	Wheat	Cyclopropane-^{14}C]-lambda-cyhalothrin; [phenyl-^{14}C]-lambda-cyhalothrin	Spraying, F	224 g as/ha	2	14 days	S. J. Grout, D. A. French, 1990 Report no. RJ0836B, RJ0889B RAR, Sweden, 2013 EFSA 2015
					2	85 days	
					3	30 days	

Summary of plant metabolism studies reported in the EU

The metabolism of lambda-cyhalothrin in primary crops was investigated in cereals (wheat) and in pulses/oilseeds (soya bean and cotton leaves). Metabolism studies conducted with the racemate cyhalothrin were also submitted in fruits (apple) and leafy crops (cabbage). Lambda-cyhalothrin was radiolabelled either in the cyclopropyl ring, phenoxyphenyl ring or benzyl ring. Cyhalothrin was radiolabelled in the cyclopropyl ring only. Based on the metabolism data for lambda-cyhalothrin and cyhalothrin, the bridging between these data is considered as acceptable since the metabolic pathway was demonstrated to be similar, with the parent compound being the predominant compound of the total residues in all the crops under investigation (37 - 95 % TRR). Besides, the metabolite Ia resulting from the cleavage of the parent compound and containing the cyclopropyl moiety was identified as a significant metabolite in soya bean and cotton leaves only (17 - 25 % TRR). Since the metabolic pathway of lambda-cyhalothrin and cyhalothrin was considered to be similar and the bridging of data between lambda-cyhalothrin and cyhalothrin was considered acceptable to support the metabolism in the three crop categories fruits (apple), leafy crops (cabbage) and cereals (wheat).

Conclusion on metabolism in primary crops

The metabolism of Lambda-cyhalothrin was sufficiently investigated in different crop groups. The data available cover the crops of interest. The residue for enforcement and risk assessment in all plant commodities following foliar application is defined as lambda-cyhalothrin only.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	^{14}C-cyclopropane-lambda-cyhalothrin; ^{14}C-phenyl-lambda-cyhalothrin	Application on bare soil, G	470g as/ha	30, 60, 120 days	At maturity	-	D. B. Priestley, J. P. Leahey, 1987 Report No. RJ0593B RAR, Sweden, 2013 EFSA 2015
		^{14}C-cyclopropane-lambda-cyhalothrin	Application on bare soil, G	110g as/ha	30, 120 days	At maturity	-	S. J. Lloyd, E. A. Curl, J. P. Leahey, 1984 Report No. RJ0381B RAR, Sweden, 2013 EFSA 2015
Root and tuber vegetables	Carrot	^{14}C-cyclopropane-lambda-cyhalothrin; ^{14}C-phenyl-lambda-cyhalothrin	Application on bare soil, G	470g as/ha	30, 60, 120 days	At maturity	-	D. B. Priestley, J. P. Leahey, 1987 Report No. RJ0593B RAR, Sweden, 2013 EFSA 2015
		^{14}C-cyclopropane-lambda-cyhalothrin	Application on bare soil, G	110g as/ha	30, 120 days	At maturity	-	S. J. Lloyd, E. A. Curl, J. P. Leahey, 1984 Report No. RJ0381B RAR, Sweden,

								2013 EFSA 2015
Cereals	Wheat	^{14}C-cyclopropane-lambda-cyhalothrin; ^{14}C-phenyl-lambda-cyhalothrin	Application on bare soil, G	470g as/ha	30, 60, 120 days	At maturity	-	D. B. Priestley, J. P. Leahey, 1987 Report No. RJ0593B RAR, Sweden, 2013 EFSA 2015
		^{14}C-cyclopropane-lambda-cyhalothrin	Application on bare soil, G	110g as/ha	30, 120 days	At maturity	-	S. J. Lloyd, E. A. Curl, J. P. Leahey, 1984 Report No. RJ0381B RAR, Sweden, 2013 EFSA 2015

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

Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2015;13(12):4324 are reported below:
Confined rotational crop studies were conducted with cyclopropyl- and phenoxyphenyl-labelled lambda-cyhalothrin in wheat, lettuce and carrots after a bare soil treatment at a dose rate of 0.47 kg a.s./ha (9 N rate). The total radioactive residues were significantly higher in rotational crops conducted with the cyclopropyl labelling, indicating a preferential uptake of metabolites containing the cyclopropyl moiety, thereof metabolite Ia being the major compound of the total residues in carrot root (52 % TRR), lettuce (61 % TRR) and wheat straw (34 % TRR). The parent compound was either not detected or present at a negligible proportion (<1 % TRR) in wheat straw only. No metabolites identification was conducted in wheat grain.

Conclusion on metabolism in rotational crops

Metabolism studies showed a different metabolism than in directly treated plants. However it is not considered relevant since no residue are expected in rotated crops.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

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

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
[^{14}C-phenyl]-lambda-cyhalothrin labelled		
Pasteurisation (20 minutes, 90°C, pH 4)	Lambda-cyhalothrin* (87.8%), Compound IV (2.0%)	K. Richardson, 2006 Report No. T000767-05-REG RAR, Sweden 2013 EFSA 2014
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Lambda-cyhalothrin* (86.3%), Compound IV (2.4%), Compound V (1.2%)	
Sterilisation (20 minutes, 120°C, pH 6)	Lambda-cyhalothrin* (18.5%), compound IV (63.7%), Compound V (1.9%)	
[^{14}C-cyclopropyl]-lambda-cyhalothrin labelled		
Pasteurisation (20 minutes, 90°C, pH 4)	Lambda-cyhalothrin* (90.5%), Compound Ia (4.5%)	K. Richardson, 2006 Report No. T000767-05-REG RAR, Sweden 2013 EFSA 2014
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Lambda-cyhalothrin* (82.6%), Compound Ia (3.7%)	
Sterilisation (20 minutes, 120°C, pH 6)	Lambda-cyhalothrin* (7.5%), Compound Ia (59.2%), Gamma lactone (14.6%),	

*Sum of lambda-cyhalothrin and enantiomer pair A

Conclusion on nature of residues in processed commodities

Lambda-cyhalothrin remained stable under hydrolytic conditions representative of pasteurisation and baking, brewing and boiling (82 - 91 % TRR), whilst a significant degradation occurred at sterilisation by hydrolytic cleavage of the parent molecule into metabolites Ia (cyclopropyl label specific) (59 % TRR), IV (phenyl label specific) (63 % TRR) and gamma-lactone (15 % TRR). The residue (tentative) for enforcement and risk assessment in all processed commodities is defined as lambda-cyhalothrin only.

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

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

Endpoints	
Plant groups covered	Fruits and fruiting vegetables, leafy crops, pulses and oilseeds (indicative information on leaves only), cereals
Rotational crops covered	Leafy vegetables, root and tuber vegetables, cereals
Metabolism in rotational crops similar to metabolism in primary crops?	No but not considered relevant since no residues are expected in rotated crops
Processed commodities	Plums, tomato, beans with pods, cotton, soya bean, sorghum, wheat, corn
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes for pasteurisation and baking, brewing and boiling Sterilisation: Extensive degradation of lambda-cyhalothrin into metabolites Ia, IV, gamma-lactone (R947650) However the residue for enforcement and risk assesment in all processed commodities is defined as lambda-cyhalothrin

	only
Plant residue definition for monitoring	Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers) (Reg. (EU) 2021/590)
Plant residue definition for risk assessment	Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers) (EFSA 2014, EFSA 2015, EFSA 2020)
Conversion factor from enforcement to RA	Not applicable

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 7.2-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[phenoxy-^{14}C]-lambda-cyhalothrin; [cyclopropyl-^{14}C]-lambda-cyhalothrin	2	12 mg in total diet	7 days	Milk	daily	2012 Report No. 32458 RAR, Sweden, 2013 EFSA 2015
						Urine and faeces	daily	
						Tissues	at sacrifice	
	Goat	[cyclopropane-^{14}C]-lambda cyhalothrin	1	0.36	7 days	Milk	daily	Leahey, French, Heath, 1985 Report No. RJ0435B RAR, Sweden, 2013 EFSA 2015
						Urine and faeces	daily	
						Tissues	at sacrifice	
	Cow	[benzyl-^{14}C]-Cypermethrin	2	0.2	7 days	Milk	daily	D. H. Hutson, 1980 Report No. TLGR.80.121 RAR, Sweden, 2013 EFSA 2015
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	[cyclopropane-^{14}C]-lambda cyhalothrin (acid moiety)	2	10.8 mg in total diet	14	Eggs	Daily	Heath, Leahey, 1985 Report No. RJ0453B RAR, Sweden,
						Excreta	Daily	
						Tissues	At sacrifice	

								2013 EFSA 2015
		[phenoxy-^{14}C]-cypermehrin (alcohol moiety)	4	0.7	14	Eggs	Daily	Hutson, 1982 Report no. SBER.82.002 RAR, Sweden, 2013 EFSA 2015
						Excreta	Daily	
						Tissues	At sacrifice	

Summary of animal metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2015;13(12):4324 are reported below:
The nature of lambda-cyhalothrin residues in commodities of animal origin was investigated in two studies on lactating goats performed with ^{14}C-cyclopropyl-labelled and ^{14}C-phenoxy-labelled lambda-cyhalothrin and in one study in laying hens using ^{14}C-cyclopropyl-labelled lambda-cyhalothrin. Additional studies performed with ^{14}C-benzyl- and ^{14}C-phenoxy-labelled cypermethrin were also reported (Sweden, 1996, 2014). Lambda-cyhalothrin was the predominant compound in all tissues, except in liver and kidney, where the metabolites Ia, XI, V (PBA), XXIII (PBA(OH)) and XIII were recovered predominantly. A change in the ratio of enantiomers within the cis B pair of diastereoisomers (lambda-cyhalothrin) was observed in milk, muscle and fat. However this was considered not relevant.

Conclusion on metabolism in livestock

The general metabolic pathways in rodents and ruminants were found to be comparable. The metabolic pattern of lambda-cyhalothrin in ruminants can therefore be extrapolated to pigs. The residue definition for monitoring and risk assessment in livestock matrices is set as lambda-cyhalothrin.

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

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

	Endpoints
Animals covered	Lactating goats
	Lactating cow
	Laying hens
Time needed to reach a plateau concentration	4 days in milk
	7-9 days in eggs
Animal residue definition for monitoring	Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers) (Reg. (EU) 2021/590)
Animal residue definition for risk assessment	Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers) (EFSA 2014, EFSA 2015, EFSA 2020)
Conversion factor	NR
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of SHA 3600 B 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
Oilseed rape	DAR 1996	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 5 g as/ha, outdoor <0.01	N/A				
	New trials KCP 8.3.1 KCP 8.3.2 KCP 8.3.9 KCP 8.3.10 KCP 8.3.11 KCP 8.3.12	N-EU	Trials GAP: 3 x 7.5 g as/ha, PHI 30, 34, 35d, outdoor 2x <LOD, <LOQ (0.004), <LOQ (0.005)					
	Overall supporting data for cGAP	N-EU	2x <LOD, <LOQ (0.004), <LOQ (0.005), <0.01	0.01	0.01		0.2	Yes
Wheat grain→ rye, triticale	EFSA, 2014 Sweden 2013	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 7.5; 2 x 15 g as/ha, outdoor 4 x <0.01	N/A				

	DAR 1996	N-EU	GAP on which MRL/EU a.s. assessment is based: 3 x 10 g as/ha, outdoor 3 x <0.01					
	New trials KCP 8.3.3 KCP 8.3.4 KCP 8.3.5 KCP 8.3.6	N-EU	Trials GAP: 2 x 7.5 g as/ha, PHI 28, 29d, outdoor n.d., <LOQ (0.005), <LOQ (0.007)					
	Overall supporting data for cGAP	N-EU	n.d., <LOQ (0.005), <LOQ (0.007), 7 x <0.01	0.01	0.01		0.05	Yes
Wheat straw→ rye, triticale	DAR 1996	N-EU	GAP on which MRL/EU a.s. assessment is based: 3 x 10 g as/ha, outdoor 0.20, 0.61	N/A				
	EFSA, 2014 Sweden 2013	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 7.5; 2 x 15 g as/ha, outdoor 0.05, 0.12, 0.16, 0.23, 0.34, 0.50, 0.51, 0.80					
	New trials KCP 8.3.3 KCP 8.3.4 KCP 8.3.5 KCP 8.3.6	N-EU	Trials GAP: 2 x 7.5 g as/ha, PHI 28, 29d, outdoor n.d., 0.126, 0.265					
	Overall supporting data for cGAP	N-EU	n.d., 0.05, 0.12, 0.126, 0.16, 0.20, 0.23, 0.265, 0.34, 0.50, 0.51, 0.61, 0.80	0.23	0.80		NR	NR
Barley grain	DAR 1996	N-EU	GAP on which MRL/EU a.s. assessment is based:3 x 10 g as/ha, 4 x <0.01, 3 x 0.02	N/A				
	New trials KCP 8.3.7 KCP 8.3.8	N-EU	Trials GAP: 2 x 7.5 g as/ha, PHI 28d n.d.					
	Overall	N-EU	n.d., 4 x <0.01, 3 x 0.02	0.01	0.02		0.5	Yes

	supporting data for cGAP							
Barley straw	DAR 1996	N-EU	GAP on which MRL/EU a.s. assessment is based: 3 x 10 g as/ha, 0.02, 0.24, 0.41, 0.37, 0.41, 0.39, 0.34	N/A				
	New trials KCP 8.3.5 KCP 8.3.6	N-EU	Trials GAP: 2 x 7.5 g as/ha, PHI 28d n.d.					
	Overall supporting data for cGAP	N-EU	n.d. 0.02, 0.24, 0.34, 0.37, 0.39, 0.41, 0.41	0.36	0.41		NR	NR
Oats grain	DAR 1996	N-EU	GAP on which MRL/EU a.s. assessment is based:3 x 10 g as/ha, 4 x <0.01	N/A				
	Overall supporting data for cGAP	N-EU	4 x <0.01	0.01	0.01		0.3	yes
Cauliflower	DAR 1996	N-EU	GAP on which MRL/EU a.s. assessment is based: 4 x 10-15 g as/ha, 0.01	N/A				
	New trials KCP 8.3.13 KCP 8.3.14	N-EU	Trials GAP: 2 x 7.5 g as/ha, PHI 7d, outdoor 2x <LOD					
	Overall supporting data for cGAP	N-EU	2x <LOD, 0.01	0.01	0.01		0.1	yes
Cabbage → brussels sprouts	DAR 1996	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 15 g as/ha, 0.05, 0.06, 0.08, 0.09	N/A				
	New trials KCP 8.3.15 KCP 8.3.16 KCP 8.3.17 KCP 8.3.18 KCP 8.3.19 KCP 8.3.20	N-EU	Trials GAP: 2 x 7.5 g as/ha, PHI 3d, outdoor ~~7x <LOD, <LOQ (0.0054)~~ Outdoor: 5x<0.01 mg/kg					

	KCP 8.3.21 KCP 8.3.22 KCP 8.3.23 KCP 8.3.24							
	Overall supporting data for cGAP	N-EU	7x <LOD, <LOQ (0.0054), 0.05, 0.06, 0.08, 0.09	~~0.07~~ 0.01	0.09		0.15	yes
Tomato	New trials KCP 8.3.25 KCP 8.3.26 KCP 8.3.27 KCP 8.3.28 KCP 8.3.29 KCP 8.3.30 KCP 8.3.31 KCP 8.3.32	N-EU	Trials GAP: 2 x 20 g as/ha, PHI 3d, outdoor ~~2x < LOD, < LOQ (0.0052), < LOQ (0.0064) , < LOQ (0.0075), < LOQ (0.0076) , < LOQ (0.0079), 0.02~~ KCP 8.3.25: <0.01, 0.02 mg/kg – open field KCP 8.3.27: 2x<0.01 mg/kg - open field KCP 8.3.29: <0.01 mg/kg - open field, one trial not independent KCP 8.3.31: - open field – not independent	NA				
	Overall supporting data for cGAP	N-EU	~~2x < LOD, < LOQ (0.0052), < LOQ (0.0064) , < LOQ (0.0075), < LOQ (0.0076) , < LOQ (0.0079), 0.02~~ Summary (outdoor): 4x<0.01, 0.02 mg/kg Residues (RAR, field N-EU): 8x<0.01 mg/kg	0.01	0.02		0.07	yes
	DAR 1996	EU	GAP on which MRL/EU a.s. assessment is based: 2 x 20 g as/ha, PHI 2d, indoor 3 x 0.01, 0.02	N/A				
	EFSA, 2014 Sweden 2013	EU	GAP on which MRL/EU a.s. assessment is based: 2 x 18 g as/ha, 2 x 18 g as/ha, indoor <0.01, 0.02					
	New trials KCP 8.3.33 KCP 8.3.34 KCP 8.3.35 KCP 8.3.36	EU	Trials GAP: 2 x 20 g as/ha, PHI 3d, indoor 2x < LOD, 0.021, 0.031 KCP 8.3.33: 0.02, 0.03 mg/kg – protected KCP 8.3.35: 2x<0.01 mg/kg - protected					
	Overall supporting data for cGAP	EU	2x < LOD, <0.01, 3 x 0.01, 2x 0.02, 0.021, 0.031 Residues (RAR, G): 4x<0.01, 2x0.01,4x0.02, 2x0.03, 0.04 mg/kg	0.01	~~0.02~~ ~~0.031~~ 0.04		0.07	yes

* Source of EU MRL: Reg. (EU) 2021/590

7.2.3.2 Conclusion on the magnitude of residues in plants

The data submitted show that no exceedance of the MRL will occur for acceptable uses.
The uses on cereals, cabbage, tomato (indoor, outdoor) and oilseed rape are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-10: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment (EFSA, 2015)	Input value (mg/kg)	Comment (EFSA, 2015)
Lambda-cyhalothrin				
Barley straw	0.69	Median residue	1.62	Highest residue
Beet, sugar tops	0.15	Median residue	0.21	Highest residue
Cabbage, heads leaves	0.03	Median residue	0.09	Highest residue
Kale leaves	0.08	Median residue	0.11	Highest residue
Oat straw	0.69	Median residue	1.62	Highest residue
Rye straw	0.64	Median residue	1.20	Highest residue
Wheat straw	0.64	Median residue	1.20	Highest residue
Potato culls	0.01	Median residue	0.01	Median residue
Swede roots	0.01	Median residue	0.03	Highest residue
Turnip roots	0.01	Median residue	0.03	Highest residue
Barley grain	0.09	Median residue	0.09	Median residue
Bean seed (dry)	0.01	Median residue	0.01	Median residue

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment (EFSA, 2015)	Input value (mg/kg)	Comment (EFSA, 2015)
Corn, field (Maize)	0.01	Median residue	0.01	Median residue
Corn, pop grain	0.01	Median residue	0.01	Median residue
Cotton, undelinted seed	0.01	Median residue	0.01	Median residue
Oat grain	0.09	Median residue	0.09	Median residue
Pea (Field pea) seed (dry)	0.01	Median residue	0.01	Median residue
Rye grain	0.01	Median residue	0.01	Median residue
Wheat grain	0.01	Median residue	0.01	Median residue
Apple pomace, wet	0.15	Median residue (0.03) * PF(5)	0.15	Median residue (0.03) * PF(5)
Beet, sugar dried pulp	0.01	Median residue (0.01) * PF(1)	0.01	Median residue (0.01) * PF(1)
Beet, sugar ensiled pulp	0.01	Median residue (0.01) * PF(1)	0.01	Median residue (0.01) * PF(1)
Beet, sugar molasses	0.01	Median residue (0.01) * PF(1)	0.01	Median residue (0.01) * PF(1)
Brewer’s grain dried	0.30	Median residue (0.09) * PF(3.3)	0.30	Median residue (0.09) * PF(3.3)
Canola (rape seed) meal	0.01	Median residue (0.01) * PF(1)	0.01	Median residue (0.01) * PF(1)
Citrus dried pulp	0.12	Median residue (0.012) * PF(10)	0.12	Median residue (0.012) * PF(10)
Corn, field milled by-pdts	0.01	Median residue (0.01) * PF(1)	0.01	Median residue (0.01) * PF(1)
Corn, field hominy meal	0.01	Median residue (0.01) * PF(1)	0.01	Median residue (0.01) * PF(1)
Corn, field gluten feed	0.01	Median residue (0.01) * PF(1)	0.01	Median residue (0.01) * PF(1)
Corn, field gluten, meal	0.01	Median residue (0.01) * PF(1)	0.01	Median residue (0.01) * PF(1)
Cotton meal	0.01	Median residue (0.01) * PF(1)	0.01	Median residue (0.01) * PF(1)
Distiller’s grain	0.01	Median residue (0.01) * PF(1)	0.01	Median residue (0.01) * PF(1)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment (EFSA, 2015)	Input value (mg/kg)	Comment (EFSA, 2015)
Flaxseed/Linseed meal	0.01	Median residue (0.01) * PF(1)	0.01	Median residue (0.01) * PF(1)
Potato process waste	0.01	Median residue (0.01) * PF(1)	0.01	Median residue (0.01) * PF(1)
Potato dried pulp	0.01	Median residue (0.01) * PF(1)	0.01	Median residue (0.01) * PF(1)
Rape meal	0.01	Median residue (0.01) * PF(1)	0.01	Median residue (0.01) * PF(1)
Wheat gluten meal	0.01	Median residue (0.01) * PF(1)	0.01	Median residue (0.01) * PF(1)
Wheat milled by-pdts	0.01	Median residue (0.01) * PF(1)	0.01	Median residue (0.01) * PF(1)

Table 7.2-11: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Lambda cyhalothrin					
Cattle (all diets)	0.013	0.027	Barley straw	0.75	Y
Cattle (dairy only)	0.013	0.027	Barley straw	0.69	Y
Sheep (all diets)	0.023	0.052	Barley straw	1.22	Y
Sheep (ewe only)	0.018	0.041	Barley straw	1.22	Y
Swine (all diets)	0.004	0.007	Beet, sugar tops	0.28	Y
Poultry (all diets)	0.013	0.018	Wheat straw	0.27	Y
Poultry (layer only)	0.013	0.018	Wheat straw	0.27	Y

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

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

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

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	Calculated MRL (mg/kg)	CF for RA[d]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforce-ment		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (Sweden, 2013; EFSA, 2015)												
Lambda cyhalothrin												
Pig meat	0.004	0.007	0.036		<0.01	0.01	<0.01	0.01	0.01	0.01	0.01	1
Pig fat			0.036		0.25	0.50	0.25	0.50	0.09	0.29	0.3	1
Pig liver			0.036		0.02	0.03	0.02	0.03	0.01	0.02	0.02	1
Pig kidney			0.036		0.01	0.02	0.01	0.02	0.01	0.01	0.015	1
Ruminant meat	0.013	0.027	0.036		<0.01	0.01	<0.01	0.01	0.01	0.02	0.02	1
Ruminant fat			0.036		0.25	0.50	0.25	0.50	0.21	0.71	0.8	1
Ruminant liver			0.036		0.02	0.03	0.02	0.03	0.01	0.03	0.03	1
Ruminant kidney			0.036		0.01	0.02	0.01	0.02	0.01	0.03	0.03	1
Ruminant milk			0.036		0.02	N/A	0.02	N/A	0.01	0.016	0.02	1
Poultry meat	0.013	0.018	0.063		<0.02	n.r.	<0.02	n.r.	0.01	0.01	0.01	1
Poultry fat			0.063		0.028	n.r.	0.028	n.r.	0.01	0.01	0.01	1
Poultry liver			0.063		<0.005	n.r.	<0.005	n.r.	0.01	0.01	0.01	1
Poultry eggs			0.063		0.01	n.r.	0.01	n.r.	0.01	0.01	0.01	1

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.
n.r.: Not reported
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): MRL is expressed as mg/kg of fat contained in the whole product.
(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between

the relevant feeding groups of the study (FAO, 2009).
(d): The median conversion factor for enforcement to risk assessment.
(e): Mean residue level from day X until day XX (X cows, Y sampling days).

Conclusion on feeding studies

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

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

7.2.5.1 Available data for all crops under consideration

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

Table 7.2-13: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Lambda cyhalothrin					
Cotton seed, crude oil	1	0.20	1		EFSA 2015
Cotton seed, hulls	1	0.10	1		EFSA 2015
Cotton seed, refined oil	1	0.10	1		EFSA 2015
Cotton seed, meal/press cake	1	<0.1	1		EFSA 2015
Soya bean, meal	1	<1	1		EFSA 2015
Soya bean, crude oil	1	<1	1		EFSA 2015
Soya bean, refined oil	1	<1	1		EFSA 2015
Tomatoes, canned	4	<0.10	1		EFSA 2015
Tomatoes, paste	5	<0.11	1		EFSA 2015
Tomatoes, ketchup	1	0.22	1		EFSA 2015
Tomatoes, juice	5	<0.13	1		EFSA 2015
Tomatoes, puree	5	<0.09	1		EFSA 2015
Tomatoes, sun dried	4	5.07	1		EFSA 2015
Tomatoes, washed	8	0.90	1		EFSA 2015
Scarole, cooked	8	1.70	1		EFSA 2015
Wheat, low grade flour	1	0.5	1		EFSA 2015
Wheat, patent flour	1	0.5	1		EFSA 2015
Wheat, shorts and germ	1	1.5	1		EFSA 2015
Wheat, bran	1	4.0	1		EFSA 2015
Rye, bran	1	4.0	1		EFSA 2015

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

** The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

7.2.5.2 Conclusion on processing studies

Studies to assess the magnitude of Lambda cyhalothrin residues during processing have been assessed in the framework of the peer review and the Article 12 MRL review and processing factors were derived for several crops (EFSA, 2014, 2015).

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Data dealing with magnitude of residues in succeeding crops are available/have been submitted and are summarized hereafter.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Table 7.2-14: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
EU data					
Cotton	12x42 g as/ha (weekly intervals)	Leafy vegetables	Lettuce	30	R. Hoag, A. Sapiets, 1988 Report No. RSR/032/87/B; D. Murnane, A. Sapiets, 1988, Report No. RJ0653B RAR, Sweden, 2013 EFSA 2014
			Spinach	60	
		Root and tuber vegetables	Radish	60	
			Turnip	30, 60	
		Cereals	Barley	30, 60	
			Alfalfa	30, 60	
Cotton	12x42 g as/ha (weekly intervals)	Leafy vegetables	Mustard leaves	31, 61	R. Hoag, A. Sapiets, 1988 Report No. RSR-033-87/B; A. Sapiets, O. J. Tummon, 1988 Report No. RJ0663B RAR, Sweden, 2013 EFSA 2014
		Root and tuber vegetables	Radish	61	
			Turnip	31, 61	
		Cereals	Winter wheat	45, 61	

Conclusion on rotational crops studies

Conclusions drawn from EFSA Journal 2014;12(5):3677 are reported below:
Rotational crop field trials were conducted on radish/turnip, lettuce/spinach, barley/wheat, alfalfa and mustard leaves following harvest of a treated primary crop (cotton) at a total dose rate of 0.5 kg a.s./ha (1.2 N rate considering the PEC soil for lambda-cyhalothrin) and resulted in residues of lambda-cyhalothrin and metabolite Ia below the LOQ in the edible parts at 30 and 60 day plant-back intervals.

~~No significant residue levels (<0.01 mg.kg) in the edible parts of the rotated crops are expected, provided that lambda-cyhalothrin is applied in compliance with the GAPs proposed.~~ No residues of lambda-cyhalothrin are expected in rotational crops, provided that the active substance is applied according to the accepted uses. No risk mitigation measures are required.

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of SHA 3600 B. 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

Input values for the consumer risk assessment were adopted from MRLs based on Reg. (EU) 2021/590. The refinement of consumer risk assessment with GAPs under assessment was calculated using the values presented in the Table below.

Table 7.2-15: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Lambda-cyhalothrin				
Citrus fruits	0.003	Median residue*PF (EFSA, 2015)	0.01	Highest residue*PF (EFSA, 2015)
Almonds Chestnuts Hazelnuts Walnuts	0.01*	Median residue (EFSA, 2015)	0.01*	Highest residue (EFSA, 2015)
Apples Pears	0.02	Median residue (EFSA, 2015)	0.05	Highest residue (EFSA, 2015)
Quinces Medlar Loquat	0.03	Median residue (EFSA, 2015)	0.13	Highest residue (EFSA, 2015)
Apricots	0.03	Median residue (EFSA, 2015)	0.07	Highest residue (EFSA, 2015)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cherries	0.04	Median residue (EFSA, 2015)	0.08	Highest residue (EFSA, 2015)
Peaches	0.03	Median residue (EFSA, 2015)	0.07	Highest residue (EFSA, 2015)
Plums	0.01	Median residue (EFSA, 2015)	0.04	Highest residue (EFSA, 2015)
Table & wine grapes	0.02	Median residue (EFSA, 2015)	0.05	Highest residue (EFSA, 2015)
Strawberries	0.02	Median residue (EFSA, 2015)	0.06	Highest residue (EFSA, 2015)
Cane fruits	0.03	Median residue (EFSA, 2015)	0.08	Highest residue (EFSA, 2015)
Currants	0.06	Median residue (EFSA, 2015)	0.12	Highest residue (EFSA, 2015)
Blueberries Cranberries Gooseberries Elderberries Azarole	0.02	Median residue (EFSA, 2015)	0.08	Highest residue (EFSA, 2015)
Table olives	0.11	Median residue (EFSA, 2015)	0.30	Highest residue (EFSA, 2015)
Persimmon	0.02	Median residue (EFSA, 2015)	0.04	Highest residue (EFSA, 2015)
Bananas	0.02	Median residue*PF (EFSA, 2015)	0.03	Highest residue*PF (EFSA, 2015)
Mangoes	0.02	Median residue*PF (EFSA, 2015)	0.02	Highest residue*PF (EFSA, 2015)
Kiwi	0.01	Median residue (EFSA, 2015)	0.03	Highest residue (EFSA, 2015)
Potatoes Sweet potatoes Yams	0.01*	Median residue (EFSA, 2015)	0.01*	Highest residue (EFSA, 2015)
Beetroot	0.01	Median residue (EFSA, 2015)	0.03	Highest residue (EFSA, 2015)
Carrots Horseradish Jerusalem artichokes Parsnips Parsley root Salsify Swedes Turnips	0.01	Median residue (EFSA, 2015)	0.03	Highest residue (EFSA, 2015)
Celeriac	0.03	Median residue (EFSA, 2015)	0.03	Highest residue (EFSA, 2015)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Radishes	0.02	Median residue (EFSA, 2015)	0.05	Highest residue (EFSA, 2015)
Garlic	0.01*	Median residue (EFSA, 2015)	0.01*	Highest residue (EFSA, 2015)
Onions Shallots	0.01	Median residue (EFSA, 2015)	0.03	Highest residue (EFSA, 2015)
Spring onions	0.01	Median residue (EFSA, 2015)	0.04	Highest residue (EFSA, 2015)
Tomatoes	0.02	Median residue (EFSA, 2015)	0.05	Highest residue (EFSA, 2015)
Peppers	0.02	Median residue (EFSA, 2015)	0.09	Highest residue (EFSA, 2015)
Aubergines	0.01	Median residue (EFSA, 2015)	0.02	Highest residue (EFSA, 2015)
Okra	0.05	Median residue (EFSA, 2015)	0.07	Highest residue (EFSA, 2015)
Cucumbers	0.01	Median residue (EFSA, 2015)	0.03	Highest residue (EFSA, 2015)
Courgettes Gherkins	0.04	Median residue (EFSA, 2015)	0.06	Highest residue (EFSA, 2015)
Cucurbits with inedible peel	0.01	Median residue*PF (EFSA, 2015)	0.02	Highest residue*PF (EFSA, 2015)
Sweet corn	0.01	Median residue (EFSA, 2015)	0.03	Highest residue (EFSA, 2015)
Broccoli Cauliflower	0.02	Median residue (EFSA, 2015)	0.07	Highest residue (EFSA, 2015)
Brussels sprouts	0.02	Median residue (EFSA, 2015)	0.02	Highest residue (EFSA, 2015)
Head cabbage	0.03	Median residue (EFSA, 2015)	0.09	Highest residue (EFSA, 2015)
Chinese cabbage	0.08	Median residue (EFSA, 2015)	0.13	Highest residue (EFSA, 2015)
Kale	0.08	Median residue (EFSA, 2015)	0.11	Highest residue (EFSA, 2015)
Kohlrabi	0.01*	Median residue (EFSA, 2015)	0.01*	Highest residue (EFSA, 2015)
Lamb's lettuce	0.34	Median residue (EFSA, 2015)	0.63	Highest residue (EFSA, 2015)
Cress Land cress Rocket Leaves and sprouts of Brassica spp	0.23	Median residue (EFSA, 2015)	0.42	Highest residue (EFSA, 2015)
Lettuce	0.03	Median residue	0.06	Highest residue (EFSA,

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Scarole		(EFSA, 2015)		2015)
Scarole	0.02	Median residue (EFSA, 2015)	0.04	Highest residue (EFSA, 2015)
Spinach	0.20	Median residue (EFSA, 2015)	0.28	Highest residue (EFSA, 2015)
Beet leaves (chard)	0.05	Median residue (EFSA, 2015)	0.08	Highest residue (EFSA, 2015)
Fresh herbs	0.23	Median residue (EFSA, 2015)	0.42	Highest residue (EFSA, 2015)
Beans (fresh, with pods)	0.11	Median residue (EFSA, 2015)	0.17	Highest residue (EFSA, 2015)
Beans (fresh, without pods)	0.01	Median residue (EFSA, 2015)	0.03	Highest residue (EFSA, 2015)
Peas (fresh, with pods)	0.01	Median residue (EFSA, 2015)	0.02	Highest residue (EFSA, 2015)
Peas (fresh, without pods)	0.01*	Median residue (EFSA, 2015)	0.01*	Highest residue (EFSA, 2015)
Asparagus	0.01*	Median residue (EFSA, 2015)	0.01*	Highest residue (EFSA, 2015)
Celery	0.01	Median residue (EFSA, 2015)	0.02	Highest residue (EFSA, 2015)
Fennel	0.05	Median residue (EFSA, 2015)	0.09	Highest residue (EFSA, 2015)
Globe artichokes	0.04	Median residue (EFSA, 2015)	0.07	Highest residue (EFSA, 2015)
Leek	0.02	Median residue (EFSA, 2015)	0.04	Highest residue (EFSA, 2015)
Wild fungi	0.17	Median residue (EFSA, 2015)	0.23	Highest residue (EFSA, 2015)
Pulses (dry)	0.01*	Median residue (EFSA, 2015)	0.01*	Highest residue (EFSA, 2015)
Sunflower seed	0.20	MRL	0.20	MRL
Rape seed Mustard seed Gold of pleasure Borage Poppy seed Linseed	0.01*	Median residue (EFSA, 2015)	0.01*	Highest residue (EFSA, 2015)
Soya bean	0.05	MRL	0.05	MRL
Cotton seed	0.05	Median residue (EFSA, 2015)	0.05	Highest residue (EFSA, 2015)
Olives for oil production	0.11	Median residue (EFSA, 2015)	0.30	Highest residue (EFSA, 2015)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Barley grain	0.09	Median residue (EFSA, 2015)	0.33	Highest residue (EFSA, 2015)
Oats grain	0.09	Median residue (EFSA, 2015)	0.11	Highest residue (EFSA, 2015)
Maize & sorghum grain	0.01*	Median residue (EFSA, 2015)	0.01*	Highest residue (EFSA, 2015)
Wheat & rye grain	0.01*	Median residue (EFSA, 2015)	0.01*	Highest residue (EFSA, 2015)
Tea	0.01	MRL	0.01	MRL
Hops	3.30	Median residue (EFSA, 2015)	3.60	Highest residue (EFSA, 2015)
Sugar beet (root)	0.01*	Median residue (EFSA, 2015)	0.01*	Highest residue (EFSA, 2015)
Chicory root	0.01*	Median residue (EFSA, 2015)	0.01*	Highest residue (EFSA, 2015)
Swine meat	0.03	0.8*Median muscle + 0.2*Median fat (EFSA, 2015)	0.07	0.8*Highest muscle + 0.2*Highest fat (EFSA, 2015)
Swine fat	0.09	Median residue (EFSA, 2015)	0.29	Highest residue (EFSA, 2015)
Swine liver	0.01	Median residue (EFSA, 2015)	0.02	Highest residue (EFSA, 2015)
Swine kidney	0.01	Median residue (EFSA, 2015)	0.01	Highest residue (EFSA, 2015)
Ruminant meat	0.05	0.8*Median muscle + 0.2*Median fat (EFSA, 2015)	0.16	0.8*Highest muscle + 0.2*Highest fat (EFSA, 2015)
Ruminant fat	0.21	Median residue (EFSA, 2015)	0.71	Highest residue (EFSA, 2015)
Ruminant liver	0.01	Median residue (EFSA, 2015)	0.03	Highest residue (EFSA, 2015)
Ruminant kidney	0.01	Median residue (EFSA, 2015)	0.03	Highest residue (EFSA, 2015)
Poultry meat	0.01*	0.9*Median muscle + 0.1*Median fat (EFSA, 2015)	0.01*	0.9*Highest muscle + 0.1*Highest fat (EFSA, 2015)
Poultry fat	0.01*	Median residue (EFSA, 2015)	0.01*	Highest residue (EFSA, 2015)
Poultry liver	0.01*	Median residue (EFSA, 2015)	0.01*	Highest residue (EFSA, 2015)
Ruminant milk	0.01	Median residue (EFSA, 2015)	0.02	Highest residue (EFSA, 2015)
Bird’s eggs	0.01*	Median residue (EFSA, 2015)	0.01*	Highest residue (EFSA, 2015)

* Indicates that the input value is proposed at the limit of quantification.

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-16: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	277 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	83 % (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	**Unprocessed commodities:** **- results for children** 530.48% Oranges 436.55% Bovine: Edible offals (other than liver and kidney) 314.51% Mangoes 314.00% Grapefruits 291.18% Bananas 285.09% Peaches 271.21% Spinaches 237.13% Mandarins 221.58% Pears 192.81% Chinese cabbages/pe-tsai 182.02% Melons 180.00% Swine: Edible offals (other than liver and kidney) 172.45% Apples 168.53% Plums 150.00% Aubergines/egg plants **- results for adults** 199.20% Bovine: Edible offals (other than liver and kidney) 162.49% Aubergines/egg plants 156.60% Swine: Edible offals (other than liver and kidney) 151.88% Chinese cabbages/pe-tsai 126.15% Head cabbages 122.66% Oranges 121.80% Swine: Fat tissue 111.83% Florence fennels 103.53% Mangoes 94.87% Wine grapes 75.59% Chards/beet leaves 71.83% Mandarins 71.54% Grapefruits 71.26% Plums 69.85% Courgettes **Processed commodities:** **- results for children** 272.0% Florence fennels / boiled 211.0% Oranges / juice 174.6% Wine grapes / juice 166.9% Spinaches / frozen; boiled 157.5% Broccoli / boiled 139.2% Cauliflowers / boiled 124.5% Chards/beet leaves / boiled 114.3% Currants (red, black and white) / juice 106.4% Pumpkins / boiled 106.3% Courgettes / boiled

	100.3% Beans (with pods) / boiled 92.8% Escaroles/broad-leaved endives / boiled 86.6% Apples / juice 80.2% Leeks / boiled 78.0% Peaches / canned **- results for adults** 135.0% Celeries / boiled 116.28% Florence fennels / boiled 99.32% Spinaches / frozen; boiled 83.33% Cauliflowers / boiled 83.20% Wine grapes / juice 72.00% Barley / beer 68.61% Courgettes / boiled 66.29% Pumpkins / boiled 60.48% Oranges / juice 53.33% Apples / juice 51.00% Currants (red, black and white) / juice 50.06% Chards/beet leaves / boiled 48.15% Broccoli / boiled 43.45% Grapefruits / juice 37.83% Wine grapes / wine **Consumer risk assesment after the refinement with input values from EFSA 2015 with GAPs under assessment is presented below.** **Unprocessed commodities:** **- results for children** 81.10% Cauliflowers 79.63% Head cabbages 58.15% Tomatoes 10.10% Barley 3.36% Brussels sprouts 2.89% Wheat 2.00% Oat 1.26% Rye 0.28% Rapeseeds/canola seeds **- results for adults** 75.69% Head cabbages 32.46% Cauliflowers 15.86% Tomatoes 8.70% Barley 2.40% Brussels sprouts 1.68% Wheat 1.15% Oat 0.97% Rye 0.11% Rapeseeds/canola seeds **Processed commodities:** **- results for children** 97.5% Cauliflowers / boiled 7.6% Tomatoes / juice 6.5% Oat / boiled 6.5% Barley / cooked 5.4% Oat / milling (flakes) 4.1% Brussels sprouts / boiled 3.8% Tomatoes / sauce/puree 3.5% Head cabbages / canned 3.3% Barley / milling (flour) 2.4% Wheat / milling (flour)

	1.1% Wheat / milling (wholemeal)-baking 0.7% Rye / boiled 0.7% Rye / milling (wholemeal)-baking 0.1% Rapeseeds / oils **- results for adults** 58.3% Cauliflowers / boiled 12.96% Barley / beer 5.64% Head cabbages / canned 3.28% Tomatoes / sauce/puree 2.74% Oat / boiled 0.88% Wheat / bread/pizza 0.76% Wheat / pasta 0.70% Wheat / bread (wholemeal)
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 lambda-cyhalothrin in the formulation SHA 3600 B do not represent unacceptable acute and chronic risks for the consumer.

7.3 Combined exposure and risk assessment

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

7.4 References

Draft Renewal Assessment Report on Lambda-cyhalothrin, Sweeden, February 2013

EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance Lambda-cyhalothrin. EFSA Journal 2014;12(5):3677

EFSA (European Food Safety Authority), 2015. Revision of the review of the existing maximum residue levels for the active substance lambda-cyhalothrin. EFSA Journal 2015;13(12):4324

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.3.1	K. Rump	2016	Determination of residues at harvest and decline of lambda-cyhalothrin in Oilseed rape, following broadcast applications of lambda-cyhalothrin 2.5% WG, under open field conditions Central Europe – Season 2016 Report No. FRS 068/16 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.2	P. Sikorski	2018	Determination of lambda-cyhalothrin residues in oilseed rape samples after application of "Lambda-cyhalothrin 2.5% WG" in two trials (1 DCS and 1 HS), Germany 2016 Report No. ZBBZ-2016/19DPL/2DE GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.3	K. Rump	2016	Determination of residues at harvest and decline of lambda-cyhalothrin in wheat, following broadcast applications of lambda-cyhalothrin 2.5% WG, under open field conditions Central Europe – Season 2016 Report No. FRS 070/16 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.4	P. Sikorski	2018	Determination of lambda-cyhalothrin residues in winter wheat samples after application of "Lambda-cyhalothrin 2.5% WG" Report No. ZBBZ-2016/19DPL/4DE GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.5	C. Thirkell	2020	Field Residue Trials to Determine Levels of Lambda-cyhalothrin 2.5% WG on Cereals in Northern Europe Report No. SHA006-17	N	Sharda Cropchem Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCP 8.3.6	M. Rubino	2018	Determination of p Lambda Cyhalothrin (CAS: 91465-08-6) in cereals by LC-MS according to SOPa-190-LABCHI-Rev. 2 Report No. 18.618098.0002 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.7	T. Roehl	2018	Residue study (Harvest) in barley following two applications with Lambda 2.5 WG in Germany 2017 Report No. CT17-1-42 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.8	M. Rubino	2018	Determination of p lambda cyhalothrin (CAS: 91465-08-6) in cereals by LC-MS according to SOPa-190-LABCHI-Rev.2 Report No. FR 18.618095.0001 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.9	M. Figurski	2022	Magnitude of the residue of lambda cyhalothrin (CAS 91465-08-6) in winter oilseed rape (Raw Agricultural Commodity - RAC) grown in open field conditions after three applications of a formulated product Lambda cyhalothrin 10% CS - one harvest trial in Northern Europe - Poland (2021) Report No. 21FRT-38BRSNNLACY GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.10	A. Markowicz	2022	Determination of the magnitude of the residues of lambda-cyhalothrin in winter oilseed rape (raw agricultural commodity-rac) grown in open field conditions after three applications of lambda cyhalothrin 10% CS – one harvest trial in northern Europe - Poland (2021) Report No. 21/FSL/08/5PL GLP Unpublished	N	Sharda Cropchem Ltd.
KCP	J. Hrabovský	2022	Determine of Lambda cyhalothrin 10 % CS residues in winter rape following three sequential applica-	N	Sharda

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
8.3.11			tions. Type D under field conditions in The Czech Republic in 2021 – field part Report No. KUJ21RO24 GLP Unpublished		Cropchem Ltd.
KCP 8.3.12	A. Markowicz	2022	Determination of the residues of lambda-cyhalothrin in winter oilseed rape after three applications of lambda cyhalothrin 10% CS – decline under field conditions in in the Czech Republic in 2021 Report No. 21/FSL/08/5CZ GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.13	T. Peda	2022	Magnitude of the residue of Lambda-cyhalothrin in Cauliflower (Raw Agricultural Commodity) after two applications of Lambda cyhalothrin 10% CS - one harvest and one decline curve trial in Poland - 2021 Report No. 21SGS48 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.14	A. Markowicz	2022	Determination of the magnitude of the residues of lambda-cyhalothrin in cauliflower (raw agricultural commodity) after two applications of lambda cyhalothrin 10% CS – one harvest and one decline curve trial in Poland – 2021 Report No. 21/FSL/08/2PL GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.15	T. Peda	2022	Magnitude of the residues of lambda-cyhalothrin in cabbage (raw agricultural commodity) after two applications of lambda cyhalothrin 10% CS – one harvest and one decline curve trial in Poland - 2021 Report No. 21SGS47 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.16	A. Markowicz	2022	Determination of the magnitude of the residues of lambda-cyhalothrin in cabbage (raw agricultural commodity) after two applications of lambda cyhalothrin 10% CS – one harvest and one decline curve trial in Poland - 2021 Report No. 21/FSL/08/1PL1 GLP	N	Sharda Cropchem Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 8.3.17	G. Wágner	2022	Determination of the residues of lambda cyhalothrin in/on cabbage after two applications of lambda cyhalothrin 10% CS in northern Europe - Hungary in 2021 Report No. 065CPRHU21R05 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.18	A. Markowicz	2022	Determination of the residues of lambda-cyhalothrin in/on cabbage after two applications of lambda cyhalothrin 10% CS in northern Europe – Hungary in 2021 Report No. 21/FSL/08/1HU1 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.19	T. Peda	2022	Magnitude of the residues of lambda cyhalothrin in cabbage (raw agricultural commodity) after two applications of lambda cyhalothrin 2.5% WG – one harvest and one decline curve trial in Poland - 2021 Report No. 21SGS44 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.20	A. Markowicz	2022	Determination of the magnitude of the residues of lambda-cyhalothrin in cabbage (raw agricultural commodity) after two applications of lambda cyhalothrin 2.5% WG – one harvest and one decline curve trial in Poland - 2021 Report No. 21/FSL/08/1PL2 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.21	G. Wágner	2022	Determination of the residues of lambda cyhalothrin in/on cabbage after two applications of lambda cyhalothrin 2.5% WG in northern Europe - Hungary in 2021 Report No. 065CPRHU21R02 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.22	A. Markowicz	2022	Determination of the residues of lambda-cyhalothrin in/on cabbage after two applications of lambda cyhalothrin 2.5% WG in northern Europe – Hungary in 2021	N	Sharda Cropchem

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report No. 21/FSL/08/1HU2 GLP Unpublished		Ltd.
KCP 8.3.23	K. Rump	2022	Determination of residues at harvest of lambda-cyhalothrin in Cabbage, following two applications of lambda-cyhalothrin 2.5% WG, under open field conditions Germany- Season 2021 Report No. FRS 009/21 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.24	A. Markowicz	2022	Determination of the residues at harvest of lambda-cyhalothrin in cabbage following two applications of lambda cyhalothrin 2.5% WG under open field conditions Germany - season 2021 Report No. 21/FSL/08/1DE GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.25	T. Peda	2022	Magnitude of the residues of lambda cyhalothrin in tomato (raw agricultural commodity) after two applications of lambda cyhalothrin 10% CS – one harvest and one decline curve trial in Poland - 2021 Report No. 21SGS50 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.26	A. Markowicz	2022	Determination of the magnitude of the residues of lambda-cyhalothrin in tomato (raw agricultural commodity) after two applications of lambda cyhalothrin 10% CS – one harvest and one decline curve trial in Poland - 2021 Report No. 21/FSL/08/4PL1 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.27	G. Wágner	2022	Determination of the residues of lambda cyhalothrin in/on tomato after two applications of lambda cyhalothrin 10 % CS in northern Europe - Hungary in 2021 Report No. 065CPRHU21R07 GLP Unpublished	N	Sharda Cropchem Ltd.

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 8.3.28	A. Markowicz	2022	Determination of the residues of lambda-cyhalothrin in/on tomato after two applications of lambda cyhalothrin 10% CS in northern Europe – Hungary in 2021 Report No. 21/FSL/08/4HU1 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.29	T. Peda	2022	Magnitude of the residues of lambda-cyhalothrin in tomato (raw agricultural commodity) after two applications of lambda cyhalothrin 2.5% WG – one harvest and one decline curve trial in Poland - 2021 Report No. 21SGS46 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.30	A. Markowicz	2022	Determination of the magnitude of the residues of lambda-cyhalothrin in tomato (raw agricultural commodity) after two applications of lambda cyhalothrin 2.5% WG – one harvest and one decline curve trial in Poland - 2021 Report No. 21/FSL/08/4PL3 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.31	G. Wágner	2022	Determination of the residues of lambda cyhalothrin in/on tomato after two applications of lambda cyhalothrin 2.5 % WG in northern Europe - Hungary in 2021 Report No. 065CPRHU21R04 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.32	A. Markowicz	2022	Determination of the residues of lambda-cyhalothrin in/on tomato after two applications of lambda cyhalothrin 2.5% WG in northern Europe – Hungary in 2021 Report No. 21/FSL/08/4HU3 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.33	T. Peda	2022	Magnitude of the residues of lambda cyhalothrin in tomato (raw agricultural commodity) after two applications of lambda cyhalothrin 10% CS under protected conditions – one harvest and one decline curve trial in Poland - 2021 Report No. 21SGS51	N	Sharda Cropchem Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCP 8.3.34	A. Markowicz	2022	Determination of the magnitude of the residues of lambda-cyhalothrin in tomato (raw agricultural commodity) after two applications of lambda cyhalothrin 10% CS under protected conditions – one harvest and one decline curve trial in Poland - 2021 Report No. 21/FSL/08/4PL2 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.35	G. Wágner	2022	Determination of the residues of lambda cyhalothrin in/on indoor tomato after two applications of lambda cyhalothrin 10 % CS in northern Europe - Hungary in 2021 Report No. 065CPRHU21R08 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.36	A. Markowicz	2022	Determination of the residues of lambda-cyhalothrin in/on indoor tomato after two applications of lambda cyhalothrin 10% CS in northern Europe – Hungary in 2021 Report No. 21/FSL/08/4HU2 GLP Unpublished	N	Sharda Cropchem Ltd.

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 Lambda cyhalothrin

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

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

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

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

A 2.1.2.1.2 Nature of residue in rotational crops

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

A 2.1.2.1.3 Nature of residues in processed commodities

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

A 2.1.2.2 Nature of residues in livestock

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

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Oilseed rape

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, 2015)	1-3	0.0075 kg a.s./ha	14 days		35
Intended cGAP (6, 7, 8, 9)	1	0.0075 kg a.s./ha		BBCH 50-59	35

* 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:	Study is accepted

Reference:	KCP 8.3.1
Report	Determination of residues at harvest and decline of lambda-cyhalothrin in Oilseed rape, following broadcast applications of lambda-cyhalothrin 2.5% WG, under open field conditions. Central Europe – Season 2016. K. Rump, 2016, Report No. FRS 068/16, Germany 2016 (Field phase)
Guideline(s):	EC Commission Directive 2004/10/EC of 11 February 2004 OECD Principles of Good Laboratory Practice (as revised in 1997) and Compliance Monitoring No 1, ENV/MC/CHEM(98)17 The application of the GLP Principles to Field Studies, Compliance Monitoring No. 6, ENV/JM/MONO(99)22 National GLP reference guideline: Chemikaliengesetz, § 19a-d (Germany)
Deviations:	No

GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

MATERIALS
Test material: Lambda cyhalothrin 2.5% WG
Batch #: SCL- 458625
Actual content: Lambda-cyhalothrin 2.5% (w/w)
CAS #: 91465-08-6

Test Commodity/Crop: Oilseed rape
Crop parts(s) or processed: whole plant, seeds

STUDY DESIGN AND METHODS
The object of this study was to determine the magnitude and decline of residues of lambda-CYHALOTHRIN in Oilseed rape resulting from three foliar applications at the maximum anticipated labelled rate of lambda-CYHALOTHRIN 2.5% WG.
Raw agricultural commodity specimens have been generated from Oilseed rape plants harvested from treated and untreated plots 1, 5(±1), 10(±2), 20(±2) days after last application (DALA) and at grain harvest 35(±2) DALA for the decline trial and at grain harvest 35(±2) DALA for the harvest trial.
The study wasconducted under field conditions in Central Europe.

Reference:	KCP 8.3.2
Report	Determination of lambda-cyhalothrin residues in oilseed rape samples after application of “Lambda-cyhalothrin 2.5% WG” in two trials (1 DCS and 1 HS), Germany – 2016. P. Sikorski, 2018, Report No. ZBBZ-2016/19DPL/2DE (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of seeds or whole plant protection products on the market andrepealing council Directives 79/117/EEC and 91/414/EC EU Directive 96/46/EC Amending Directive 91/414/EEC, Annex II, section 4 of Part A EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No

GLP: Yes

Acceptability: Yes

STUDY DESIGN AND METHODS

The objective of this study was to determine the magnitude of residues of Lambda-Cyhalothrin in rape seeds and rape plant taken from the field trial following application of Lambda-Cyhalothrin 2.5% WG. The general principles of the analytical procedure were based on the AOAC Official Method 2007.01. In brief, samples of rape seeds and rape plant were extracted with acidified acetonitrile after addition of water. After addition of a buffer-salt mixture containing magnesium sulphate and sodium acetate the extract was shaken. Following centrifugation, an aliquot of the acetonitrile phase was dehydrated by magnesium sulphate, cleaned by primary secondary amine (PSA).

An aliquot of the sample solution was injected into the high-performance liquid chromatography and subjected to reversed phase chromatography coupled with tandem mass spectrometry (MS/MS). The MS/MS instrument was operated in the Multiple Reaction Monitoring mode (MRM). The ammonium adduct ion of the Lambda-Cyhalothrin (precursor ion) generated in electrospray ionization source (ESI) was isolated by the first quadrupole by mass/charge (m/z) ratio and subjected to collision induced dissociation (CID) which occurs in collision cell (second quadrupole). The resulting fragment ions (product ions) were separated according to their m/z ratio in third quadrupole.

SAMPLE EXTRACTION

- 5.00 g ± 0.05 g of homogenized matrix was weighed into a 50 mL Teflon® centrifuge tube. Sample weight was recorded.
- If necessary fortification of the concurrent recovery sample(s) by aliquoting the fortification standard onto the matrix was carried out at this step. The tube was shaken for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	**Matrix**	**Concentration (µg/mL) of lambda-Cyhalothrin**	**Volume used (µL)**
LOQ (0.01 mg/kg)	Seeds	1	50
10 x LOQ (0.1 mg/kg)		10	50
LOQ (0.01 mg/kg	Plant	1	50
100 x LOQ (1 mg/kg)		100	50

- Using glass volumetric pipettes 10 mL of water and 10 mL of acidified acetonitrile (+1 Vol% acetic acid) was added.
- The Teflon® centrifuge tube was closed tightly and shaken thoroughly for 1 min.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Lambda-Cyhalothrin in rape seeds and plant matrices.

The LOD was set at < 30 % of the LOQ (0.002 mg/kg for rape seeds and plant). The chromatographic peaks at the LOD were more than three times the background noise.

ACCURACY
The mean recovery values at the fortification levels of 0.01 mg/kg, 0.1 mg/kg and 1 mg/kg for both ion mass transitions of Lambda-Cyhalothrin were all in the range of 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANCO/825/00 rev. 8.1. and SANCO/3029/99 rev. 4.

Table A 2: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalothrin		
	(a)	(b)				(c)				(d)	(e)
FRS 068/16-V1/ Germany/N-EU/2016	Oilseed rape	01 September 15 April 16 22 July 16	7.5	200		03 June 16 14 June 16 22 June 16	BBCH 76-77 BBCH 77-79 BBCH 81	Seeds	<LOQ (0.004)	30	LOD = 0.002 mg/kg LOQ = 0.01 mg/kg
FRS 068/16-V2/ Germany/N-EU/2016	Oilseed rape	06 September 15 April 16 25 July 16	7.5	200		03 June 16 13 June 16 21 June 16	BBCH 73 BBCH 75-76 BBCH 76-77	Plant Plant Plant Plant Seeds	0.238 0.203 0.121 0.084 <LOQ (0.005)	1 5 10 21 34	LOD = 0.002 mg/kg LOQ = 0.01 mg/kg

A 2.1.3.1.2 Study 2

Comments of zRMS:	Study is acceped. Field phase is accepted. Acceptable validated in accordance to the guidance document: SANTE/2020/12830, Rev.1, (2021) method was used. Study is acceptable with regard to storage stability data.

Reference: KCP 8.3.9

Report: Magnitude of the residue of lambda cyhalothrin (CAS 91465-08-6) in winter oilseed rape (Raw Agricultural Commodity - RAC) grown in open field conditions after three applications of a formulated product Lambda cyhalothrin 10% CS -

	one harvest trial in Northern Europe - Poland (2021). M. Figurski, 2022, Report No. 21FRT-38BRSNNLACY (Field phase)
Guideline(s):	Regulation (EC) N°1107/2009 of 21 October 2009 (Repealing the Council Directive 91/414/EEC) concerning the placing of plant protection products on the market The OECD Principles of Good Laboratory Practice (as Revised in 1997), OECD Series on Principles of GLP and Compliance Monitoring Number 1, ENV/MC/CHEM(98)17 The Application of GLP Principles to Field Studies, OECD Series on Principles of GLP and Compliance Monitoring Number 6 (Revised 1999), ENV/JM/MONO(99)22
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

MATERIALS
Test material: Lambda cyhalothrin 10% CS
Batch #: SCL-34763
Actual content: Lambda cyhalothrin 10.2% (w/v)
CAS #: 91465-08-6

Test Commodity/Crop: Winter oilseed rape
Crop parts(s) or processed: seeds

STUDY DESIGN AND METHODS
The objective of the field phase was to provide an analytical laboratory with treated specimens resulting from three applications at rate of 0.075 L*ha^{-1} of Lambda cyhalothrin 10% CS, regarding open field conditions. All aspects of a field work will be performed in accordance with typical Good Agricultural Practices.
The field phase happened as anticipated in the study plan and amendments. One harvest trial was established in central Poland. Trial consisted of one untreated plot C and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negatively impacted on the integrity and validity of this study. Three foliar applications of Lambda cyhalothrin 10% CS were performed with a boom sprayer on the treated plot at the target dose rate of 0.075 L*ha^{-1} (equivalent to 7.5 g a.s.*ha^{-1} of lambda cyhalothrin). The target spray volume was 200-1000 litres per hectare according to Good Agricultural Practices.
Applications were performed at the following timing:

– A1 - 10÷1 days before A2 (>BBCH 75);

– A2 - 10÷1 days before A3 (>BBCH 75);
– at BBCH 81/ 35 days before harvest.

The spray mixture volumes remaining after applications were measured and the volumes applied to the treated plot were calculated to verify delivery rates. The calculations and the delivery rates were verified by the Study Director. Deviations from the target rate were between ±5% as requested in the study plan.
RAC specimens for analyses were collected at a normal commercial harvest. Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site. RAC specimens were put in deep freezing conditions at a target temperature of ≤-18°C on the day of sampling, within 12 hours after sampling. All specimens remained deep frozen during storage at the test facility and during shipment to the analytical laboratory Research Institute of Horticulture, Pomologiczna 18St., 96-100 Skierniewice.

Reference:	KCP 8.3.10
Report	Determination of the magnitude of the residues of lambda-cyhalothrin in winter oilseed rape (raw agricultural commodity-rac) grown in open field conditions after three applications of lambda cyhalothrin 10% CS – one harvest trial in northern Europe - Poland (2021). A. Markowicz, 2022, Report No. 21/FSL/08/5PL (Analytical phase)
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 repeating Council Directives 79/117/EEC and 91/414/EEC EC Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830, Rev.1, (2021) OECD: Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17, (2007)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS
The objective of this study was to determine the decline and the magnitude of residues lambda-Cyhalothrin in oilseed rape (whole plant and seeds) samples taken from the field trial, after three applications of LAMBDA CYHALOTHRIN 10% CS, under open field conditions. To achieve the objective appropriate analytical method for determination of lambda-Cyhalothrin in target matrix was used. The reference method was validated for oilseed rape (whole plant and seed) as representative oil and very low water matrix in accordance to the guidance document: SANTE/2020/12830, Rev.1 of the European Commission. The validated limit of quantification is 0.01 mg/kg.
The general principles of the analytical procedure were based on the normalized method EN 15662:2018. In brief, samples of oilseed rape were extracted with acetonitrile. After addition of a buffer-salt mixture containing magnesium sulphate, sodium chloride and sodium citrate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulphate addition.
Quantification was performed by use of highly selective gas chromatography coupled with tandem mass spectrometry (GC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention time of analyte in extracts corresponds to that of the

calibration standard with a tolerance of < ± 0.1 min. Confirmation ion ratio for lambda-Cyhalothrin in all samples were within ± 30 % of the average found for the standards. Determination was performed using matrix-matched calibration standards.

SAMPLE EXTRACTION

- 5.00 g ± 0.05 g of homogenized matrix was weighed into a 50 mL Teflon® centrifuge tube. Sample weight was recorded.
- If necessary fortification of the concurrent recovery sample(s) by aliquoting the fortification standard onto the matrix was carried out at this step. The tube was shaken for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	Matrix	Concentration (µg/mL) of lambda-Cyhalothrin	Volume used (µL)
LOQ (0.01 mg/kg)	Seeds	1	50

- Using glass volumetric pipettes 10 mL of water were added.
- Using glass volumetric pipettes 10 mL of acetonitrile were added.
- The Teflon® centrifuge tube was closed tightly and shaken vigorously by QuEChERS Hand Motion Shaker for 1 min.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION
The limit of quantification (LOQ) was established at 0.01 mg/kg for lambda-Cyhalothrin, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for oilseed rape.

ACCURACY AND PRECISION
The mean recovery values at the fortification level of 0.01 mg/kg for both ion mass transitions were all in the range 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, Rev.1 of the European Commission. All precision values at the fortification level of 0.01 mg/kg for both ion mass transitions were < 20%.

Table A 3: Summary of the study 2 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat-ment or no. of treatments and last date (c)	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalo-thrin		

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: g a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): Lambda cyhalothrin	PHI (days) (d)	Details on trial (e)
21FRT-38BRSNNLACY-01/ Poland/N-EU/2021	Oilseed rape	22.08.2020 15.05.2021-28.05.2021 07.08.2021	7.2 7.5 7.1			12.06.2021 23.06.2021 03.07.2021	BBCH 75 BBCH 79 BBCH 81	Seeds	<LOD	35	LOD = 0.002 mg/kg LOQ = 0.01 mg/kg

A 2.1.3.1.3 Study 3

Comments of zRMS:	Study is accepted. Field phase is accepted. Acceptable validated in accordance to the guidance document: SANTE/2020/12830, Rev.1, (2021) method was used. Study is acceptable with regard to storage stability data.

Reference:	KCP 8.3.11
Report	Determine of Lambda cyhalothrin 10 % CS residues in winter rape following three sequential applications. Type D under field conditions in The Czech Republic in 2021 – field part. J. Hrabovský, 2022, Report No. KUJ21RO24 (Field phase)
Guideline(s):	OECD Principles on Good Laboratory Practice (as revised in 1997) (ENV/MC/CHEM98)17 Quality assurance and GLP, ENV/JM/MONO(99)20 The Application of the GLP Principles to Field Studies (ENV/JM/MONO(99)22) The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO(2002)9 OECD Guidelines for the testing of chemicals, 509; Crop field trial, 07/09/2009 SANCO 7029/VI/95 rev. 5, 22/07/1997 – General recommendation for the design, preparation and realisation of residue trials
Deviations:	No
GLP:	Yes

Acceptability:	Yes

MATERIAL AND METHODS

MATERIALS
Test material: Lambda cyhalothrin 10% CS
Batch #: SCL-34763
Actual content: Lambda cyhalothrin 10.2% (w/v)
CAS #: 91465-08-6

Test Commodity/Crop: Winter oilseed rape
Crop parts(s) or processed: whole plant, seeds

STUDY DESIGN AND METHODS
The purpose of the study was to generate specimens for the determination of residues after three sequential applications with Lambda cyhalothrin 10% CS in winter oilseed rape, variety DK Sequel in the Czech Republic 2021. The study consisted of a decline trial.
The study was carried out according to the study plan KUJ21RO24, the guideline document SANCO 7029/V1/95 rev. 5, 22.07.1997, and the guidelines mentioned in the "Statement of Compliance".
One decline trial KUJ21RO24 was carried out on the open field in Kujavy (Moravian-Silesian region). Two plots were measured out in the crop winter oilseed rape: one untreated control plot (U) and one treated plot (T). T plot was treated three times with the test item Lambda cyhalothrin 10% CS with the rate of 0.075 l/ha. The used water volume was 200 L/ha. Application A was conducted at BBCH 65-67 80%-20%); application B at BBCH 69-75-77 (5%-80%-15%) and last application C was provided at BBCH 79 (100%) of the crop.
Specimens of the whole plant (without roots) from the untreated and treated plot were collected 0 days after the last application (0 DALA), 7 days after the last application (7 DALA), 14 days after the last application (14 DALA), 21 days after last application (21 DALA) and 35 days after last application (35 DALA).
The specimens were stored frozen (-18°C to – 20.0 °C) at the test facility in ZZS Kujavy.
The specimens were shipped frozen to the analytical laboratory Food Safety Laboratory, Research Institute of Horticulture, Pomologiczna 13b, 96-100 Skierniewice, Poland for residue analysis.

Reference:	KCP 8.3.12
Report	Determination of the residues of lambda-cyhalothrin in winter oilseed rape after three applications of lambda cyhalothrin 10% CS – decline under field conditions in in the Czech Republic in 2021. A. Markowicz, 2022, Report No. 21/FSL/08/5CZ (Analytical phase)
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/EEC
EC Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830, Rev.1, (2021)
OECD: Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17, (2007)

Deviations: No

GLP: Yes

Acceptability: Yes

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues lambda-Cyhalothrin in oilseed rape (whole plant and seeds) samples taken from the field trial, after three applications of LAMBDA CYHALOTHRIN 10% CS, under open field conditions. To achieve the objective appropriate analytical method for determination of lambda-Cyhalothrin in target matrix was used. The reference method was validated for oilseed rape (whole plant and seed) as representative oil and very low water matrix in accordance to the guidance document: SANTE/2020/12830, Rev.1 of the European Commission. The validated limit of quantification is 0.01 mg/kg.

The general principles of the analytical procedure were based on the normalized method EN 15662:2018. In brief, samples of oilseed rape were extracted with acetonitrile. After addition of a buffer-salt mixture containing magnesium sulphate, sodium chloride and sodium citrate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulphate addition.

Quantification was performed by use of highly selective gas chromatography coupled with tandem mass spectrometry (GC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention time of analyte in extracts corresponds to that of the calibration standard with a tolerance of < ± 0.1 min. Confirmation ion ratio for lambda-Cyhalothrin in all samples were within ± 30 % of the average found for the standards. Determination was performed using matrix-matched calibration standards.

SAMPLE EXTRACTION

- 5.00 g ± 0.05 g of homogenized matrix was weighed into a 50 mL Teflon® centrifuge tube. Sample weight was recorded.
- If necessary fortification of the concurrent recovery sample(s) by aliquoting the fortification standard onto the matrix was carried out at this step. The tube was shaken for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	Matrix	Concentration (µg/mL) of lambda-Cyhalothrin	Volume used (µL)
LOQ (0.01 mg/kg)	Seeds	1	50

- Using glass volumetric pipettes 10 mL of water were added.

– Using glass volumetric pipettes 10 mL of acetonitrile were added.
– The Teflon® centrifuge tube was closed tightly and shaken vigorously by QuEChERS Hand Motion Shaker for 1 min.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION

The limit of quantification (LOQ) was established at 0.01 mg/kg for lambda-Cyhalothrin, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for oilseed rape.

ACCURACY AND PRECISION

The mean recovery values (Table 16) at the fortification level of 0.01 mg/kg for both ion mass transitions were all in the range 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, Rev.1 of the European Commission. All precision values at the fortification level of 0.01 mg/kg for both ion mass transitions were < 20%.

Table A 4: Summary of the study 3 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat-ment or no. of treatments and last date	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalo-thrin		
	(a)	(b)				(c)				(d)	(e)
KUJ21RO24/ TheCzechRep./N-EU/2021	Oilseed rape	25.08.2020 - 21.07.2021	7.57 7.49 7.57	200		27.05.2021 06.06.2021 16.06.2021	BBCH 65-67 BBCH 69-77 BBCH 79	Whole plant Whole plant Whole plant Whole plant Seeds	<LOQ (0.0027) <LOQ (0.0022) <LOD <LOD <LOD	0 7 14 21 35	LOD = 0.002 mg/kg LOQ = 0.01 mg/kg

Table A 5: Summary of the study in N-EU (DAR 1996)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat-ment or no. of treatments and last date	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalo-thrin		
	(a)	(b)				(c)				(d)	(e)

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				Lambda cyhalothrin		
	(a)	(b)				(c)				(d)	(e)
M4718B/UK/N-EU/1987	Oilseed rape		5			2			<0.01	175	

A 2.1.3.2 Winter wheat

Table A 6: 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, 2015)	1-2	0.0075-0.015 kg a.s./ha			30
Intended cGAP (5)	1	0.0075 kg a.s./ha		BBCH 41-75	28

* 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:	Study is accepted

Reference: KCP 8.3.3

Report: Determination of residues at harvest and decline of lambda-cyhalothrin in wheat, following broadcast applications of lambda-cyhalothrin 2.5% WG, under open field conditions. Central Europe – Season 2016. K. Rump, 2016, Report no. FRS 070/16, Germany 2016 (Field phase)

Guideline(s): EC Commission Directive 2004/10/EC of 11 February 2004

	OECD Principles of Good Laboratory Practice (as revised in 1997) and Compliance Monitoring No 1, ENV/MC/CHEM(98)17 The application of the GLP Principles to Field Studies, Compliance Monitoring No. 6, ENV/JM/MONO(99)22 National GLP reference guideline: Chemikaliengesetz, § 19a-d (Germany)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

MATERIALS
Test material: Lambda cyhalothrin 2.5% WG
Batch #: SCL- 458625
Actual content: Lambda-cyhalothrin 2.5% (w/w)
CAS #: 91465-08-6

Test Commodity/Crop: winter wheat
Crop parts(s) or processed: grain, straw, whole plant

STUDY DESIGN AND METHODS
The object of this study was to determine the magnitude and decline of residues of lambda-CYHALOTHRIN in wheat resulting from two foliar applications at the maximum anticipated labelled rate of lambda-CYHALOTHRIN 2.5% WG.
Raw agricultural commodity specimens have been generated from wheat plants harvested from treated and untreated plots 1, 5(±1), 10(±2), 20(±2) days after last application (DALA) and at grain harvest 28(±2) DALA for the decline trial and at grain harvest 28(±2) DALA for the harvest trial.
The study was conducted under field conditions in Central Europe.

Reference:	KCP 8.3.4
Report	Determination of lambda-cyhalothrin residues in winter wheat samples after application of “Lambda-cyhalothrin 2.5% WG”. P. Sikorski, 2018, Report ZBBZ-2016/19DPL/4DE (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of seeds or whole plant protection products on the market andrepealing council Directives 79/117/EEC and 91/414/EC

EU Directive 96/46/EC Amending Directive 91/414/EEC, Annex II, section 4 of Part A
EU Guidance Document SANCO/3029/99 rev. 4
EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No

GLP: Yes

Acceptability: Yes

STUDY DESIGN AND METHODS

The objective of this study was to determine the magnitude of residues of Lambda-Cyhalothrin in winter wheat plant, grain and straw taken from the field trial following application of Lambda-Cyhalothrin 2.5% WG. To achieve the objective appropriate analytical method for determination of target analyte in winter wheat plant, grain and straw was validated in accordance to the guidance document SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validated limit of quantification is 0.01 mg/kg. In brief, samples of winter wheat plant, grain and straw were extracted with acidified acetonitrile after addition of water. After addition of a buffer-salt mixture containing magnesium sulphate and sodium acetate the extract was shaken. Following centrifugation, an aliquot of the acetonitrile phase was dehydrated by magnesium sulphate, cleaned by primary secondary amine (PSA).
An aliquot of the sample solution was injected into the high-performance liquid chromatography and subjected to reversed phase chromatography coupled with tandem mass spectrometry (MS/MS). The MS/MS instrument was operated in the Multiple Reaction Monitoring mode (MRM). The ammonium adduct ion of the Lambda-Cyhalothrin (precursor ion) generated in electrospray ionization source (ESI) was isolated by the first quadrupole by mass/charge (m/z) ratio and subjected to collision induced dissociation (CID) which occurs in collision cell (second quadrupole). The resulting fragment ions (product ions) were separated according to their m/z ratio in third quadrupole.

SAMPLE EXTRACTION

- 5.00 g ± 0.05 g of homogenized winter wheat grain or 2.00 g ± 0.02 g winter wheat plant and straw was weighed into a 50 mL Teflon® centrifuge tube. Sample weight was recorded.
- If necessary fortification of the concurrent recovery sample(s) by aliquoting the fortification standard onto the matrix was carried out at this step. The tube was shaken for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	**Matrix**	**Concentration (µg/mL) of lambda-Cyhalothrin**	**Volume used (µL)**
LOQ (0.01 mg/kg)	Plant	0.2	100
100 x LOQ (0.1 mg/kg)		10	200
LOQ (0.01 mg/kg	Grain	1	50
10 x LOQ (1 mg/kg)		10	50
LOQ (0.01 mg/kg)	Straw	0.2	100

100 x LOQ (0.1 mg/kg)		10	200

- Using glass volumetric pipettes 10 mL of water and 10 mL of acidified acetonitrile (+1 Vol% acetic acid) was added.
- The Teflon® centrifuge tube was closed tightly and shaken thoroughly for 1 min.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION
The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Lambda-Cyhalothrin in winter wheat plant, grain and straw matrices.
The LOD was set at < 30 % of the LOQ (0.002 mg/kg for wheat grain and 0.003 mg/kg for wheat plant and straw. The chromatographic peaks at the LOD were more than three times the background noise.

ACCURACY
The mean recovery values at the fortification levels of 0.01 mg/kg, 0.1 mg/kg and 1 mg/kg for both ion mass transitions of Lambda-Cyhalothrin were all in the range of 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANCO/825/00 rev. 8.1. and SANCO/3029/99 rev. 4

Table A 7: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalothrin		
	(a)	(b)				(c)				(d)	(e)
FRS 070/16-V1/ Germany/N-EU/2016	Winter wheat/Tobak	01 October 15 - 10 August 16	7.5	200		01 July 16 12 July 16	BBCH 75 BBCH 82	Grain Straw	<LOQ (0.005) 0.265	29 29	
FRS 070/16-V2/ Germany/N-EU/2016	Winter wheat/Lear	05 October 15 June 16 11August 16	7.5	200		04 July 16 14 July 16	BBCH 75-77 BBCH 85-87	Whole plant Whole plant Whole plant Whole plant Grain Straw	0.164 0.150 0.140 0.116 <LOQ (0.007) 0.126	1 5 11 20 28 28	

A 2.1.3.2.2 Study 2

Comments of zRMS:	Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information

Reference:	KCP 8.3.5
Report	Field Residue trials to Determine Levels of Lambda-cyhalothrin 2.5% WG on Cereals in Northern Europe. C. Thirkell, 2020, Report No. SHA006-17 (Field Phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of seeds or whole plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC EU Directive 96/46/EC Amending Directive 91/414/EEC, Annex II, section 4 of Part A ENV/JM/MONO(99)22
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS

A study on the residue level of Lambda-cyhalothrin 2.5% WG following 2 applications on cereals in Northern Europe. The field phase of this study comprised 1 location in the United Kingdom which was representative for this test crop. One decline trial was conducted consisting of two plots: 1 untreated plot (plot U) and 1 plot treated with Lambda-cyhalothrin 2.5% WG (plot T). The applications were carried out using a boom sprayer to reproduce a normal agricultural application technique on a small-scale size. The first application was made at BBCH 65 and application two was made at BBCH 71. There were 5 sampling events, the first sampling event was on the day of application, the second sampling event was 4 DALA, the third sampling event was 7 (+/- 1) DALA, the fourth sampling event was 14 (+/- 1) DALA and the fifth sampling event was 28 (+/- 1) DALA. At sampling event one, two, three and four, 2 samples were collected from each plot (Plot U and Plot T). At sampling event five, 4 samples were collected from each plot (Plot U and Plot T).

Reference:	KCP 8.3.6
Report	Determination of p Lambda Cyhalothrin (CAS: 91465-08-6) in cereals by LC-MS according to SOPa-190-LABCHI-Rev. 2. M. Rubino, 2018, Report No. 18.618098.0002 (Analytical phase)
Guideline(s):	OECD (1988) The OECD Principles of Good Laboratory Practice (as revised in 1997), ENV/MC/CH EM (98)17 OECD (2002) The application of the OECD Principles of Good Laboratory Practice to the organisation and management of multi-side studies, ENV/JM/MON0 (2002)9 Italian Legislative Decree (D.L. No. 50 dated Match 2nd, 2007) as published in G. U. No. 86 of April 13th, 2007

	Annex II, Regulation EC 1107/2009 concerning the placing of Plant Protection Products on the market OECD 204/2014 Guidance document for single laboratory validation of quantitative analytical methods – guidance used in suport of pre- and post- registration. Data requirements for plant protection and biocidal products. 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 analytical phase of the study 18.618098.0002 was conducted to determine the residual level of Lambda cyhalothrin in cereals by LC-MS according to the in-house validated method.

SAMPLE EXTRACTION
About 5 g of sample grinded were introduced into a 50 mL plastic tube, 7.5 mL of milliQ water and 10 mL of extraction mixture were added to the sample. After vortexing for about 1 min about 6 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1 min. The tube was centrifugedat 4750 rpm for 5 min and kept at about -20°C for about 2 hours. Then, the tube was centrifuged at 4750 rpm for 5 min and it was proceed to puridication of the supernatant.
6 mL of supernatant were transferred into a 10 mL plastic tube, containing about 900 mg of magnesium sulphate anhydrous and 300 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.
1 mL of the purified sample was transferred into a 2 mL volumetric flask and diluted to volume with mobile phase A, filtered and transferred into an HPLC vial and injected.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION
The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed.
The LOD was set at 0.003 mg/kg.

ACCURACY
Accuracy evaluation was performed on sample aliquots spiked with Lambda Cyhalothrin at LOQ (about 0.01 mg/kg). 3 replicate analyses were performed for each spiking level.
Mean recovery was 93.3% with RSD = 2% for first mass transition and 80.4% with RSD = 5% for the second mass transition.

Table A 8: Summary of the study 2 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat-ment or no. of treatments and last date	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalo-thrin		
	(a)	(b)				(c)				(d)	(e)
SHA006-17-RES0037/UK/N-EU/2017	Spring wheat/Mulika	17/03/17 06-07/17 08/17	7.5 7.5	402 401	1.9 1.9	05/07/17 14/07/17	BBCH 65 BBCH 71	Whole plant Whole plant Whole plant Whole plant Grain Straw	n.d. n.d. n.d. n.d. n.d. n.d.	0 4 6 14 28 28	

Table A 9: Summary of the study in N-EU (RAR 2013, DAR 1996)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat-ment or no. of treatments and last date	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalo-thrin		
	(a)	(b)				(c)				(d)	(e)

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				Lambda cyhalothrin		
	(a)	(b)				(c)				(d)	(e)
17705/UK/N-EU/1997-98	Winter wheat/Soissons	22.19.1997 - 10.08.1998	7.5 7.5	200 200		28.06.1998 14.07.1998	BBCH 75-77 BBCH 83	Whole plant Whole plant Whole plant Whole plant Whole plant Straw Grain	0.19 0.14 0.24 0.10 0.16 0.34 <0.01	0 3 7 10 14 27 27	Spraying, spray interval: 16 days
			15 15	200 200		28.06.1998 14.07.1998	BBCH 75-77 BBCH 83	Whole plant Whole plant Whole plant Whole plant Whole plant Straw Grain	0.42 0.23 0.19 0.30 0.18 0.50 <0.01	0 3 7 10 14 27 27	
17705/UK/N-EU/1997-98	Winter wheat/Consort	12.09.1997 - 31.08.1998	7.5 7.5	200 200		29.06.1998 14.07.1998	BBCH 75-77 BBCH 83	Whole plant Whole plant Whole plant Whole plant Whole plant Straw Grain	0.18 0.09 0.11 0.09 0.08 0.23 <0.01	0 3 7 10 14 48 48	Spraying, spray interval: 15 days
			15 15	200 200		29.06.1998 14.07.1998	BBCH 75-77 BBCH 83	Whole plant Whole plant Whole plant Whole plant Whole plant Straw Grain	0.30 0.16 0.20 0.22 0.25 0.51 <0.01	0 3 7 10 14 48 48	
17950/Netherlands/N-EU/1997-98	Winter wheat/Vivant (animal feed)	29.10.1997 - 14.08.1998	8.4 9.4	400 400		30.06.1998 10.07.1998	Zadoks 78 Zadoks 85	Whole plant Whole plant Whole plant Whole plant Whole plant Straw Grain	0.24 0.16 0.15 0.12 0.09 0.05 <0.01	0 3 7 10 25 35 35	Spraying, spray interval: 10 days
			15.9	400		30.06.1998	Zadoks 78	Whole plant	0.31	0	

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				Lambda cyhalothrin		
	(a)	(b)				(c)				(d)	(e)
			16.4	400		10.07.1998	Zadoks 85	Whole plant Whole plant Whole plant Whole plant Straw Grain	0.22 0.33 0.22 0.19 0.12 <u><0.01</u>	3 7 10 25 35 35	
17950/Netherlands/N-EU/1997-98	Winter wheat/Bercy (baking)	15.10.1997 - 11.08.1998	8.3 8.3	250 250		21.06.1998 06.07.1998	Zadoks 76 Zadoks 85	Whole plant Whole plant Whole plant Whole plant Whole plant Straw Grain	0.22 0.11 0.13 0.09 0.11 0.08 <u><0.01</u>	0 3 7 10 14 36 36	Spraying, spray interval: 15 days
			17.3 16.5	250 250		21.06.1998 06.07.1998	Zadoks 76 Zadoks 85	Whole plant Whole plant Whole plant Whole plant Whole plant Straw Grain	0.24 0.29 0.25 - 0.22 0.16 <u><0.01</u>	0 3 7 10 14 36 36	
M4013B/Germany/N-EU/1984	Wheat/Turbo		10			3	BBCH 87	Grain	<u><0.01</u>	35	
RJ1464B/Germany/N-EU/1992	Wheat/Ambral		10			3	BBCH 69	Grain Straw	<u><0.01</u> <u>0.20</u>	42	
RJ1464B/Germany/N-EU/1992	Wheat/Borenos		10			3	BBCH 69	Grain Straw	<u><0.01</u> <u>0.61</u>	41	

A 2.1.3.3 Barley

Table A 10: 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, 2015)	1-2	0.0075-0.015 kg a.s./ha			30
Intended cGAP (5)	1	0.0075 kg a.s./ha		BBCH 41-75	28

* 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:	Study is accepted

Reference: KCP 8.3.7

Report: Residue study (Harvest) in barley following two applications with Lambda 2.5 WG in Germany 2017, T. Roehl, 2018, Report CT17-1-42, Germany 2018 (Field phase)

Guideline(s): OECD Guidelines for the testing of chemicals, No 509: Crop Field Trials (2009)
EEC document 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97, rev. 2, 1999: General recommendation for the design, preparation and realisation of residue trials
The Principles of Good Laboratory Practice, ChemG 25.07.1994, § 19, Annex 1 (BGBL 21, I, 2001, p. 843-855)
OECD-Principles of Good Laboratory Practice, No. 4: Quality Assurance and GLP (as revised in 1999), ENV/JM/MONO (1999) 20, Paris 2002
The Application of the GLP Principles to Field Studies, OECD Consensus Document, 6, revised, ENV/JM/MONO (1999) 22, Paris 2002
The Application of the OECD Principles of GLP to the Organisation and Management of Multi-site Studies, OECD Consensus Document, 13, ENV/JM/MONO (2002) 9
Rückstandsversuche, Teil 1 Prüfungen an Pflanzen, A: Allgemeiner Teil, B: Spezieller Teil, IVA-Guideline, Industrieverband Agrar e. V. 1992

Deviations: No

GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

MATERIALS
Test material: Lambda cyhalothrin 2.5% WG
Batch #: SCL- 33624
Actual content: Lambda-cyhalothrin 2.5% (w/w)
CAS#: 91465-08-6

Test Commodity/Crop: barley
Crop parts(s) or processed: grain, straw

STUDY DESIGN AND METHODS
The purpose of the study was to generate specimens for the determination of residues after two applications with Lambda 2.5 WG in barley in Germany 2017. One harvest trial CT17-1-42DE1 was carried out in North Germany. Two plots were measured out on open field on the crop winter barley: one untreated control plot and one treated plot. Plot 2 was treated twice with the test item Lambda 2.5 WG with the rate of 0.3 kh/ha at a sprawy interval of 10 days. Application B was performed 28 days before harvest. The used water volume was 300 L/ha.
The applications were conducted with a knapsack sprayer with boom. The spraying equipment was cleaned with water before and after use. The output of the nozzles was checked for uniformity before start of application. The speed of walk was adapted to the output of the sprayer and test runs were performed before start of application
Whole plants were collected from the central area of each plot 28 days after the second application / at the time of commercial harvest. The specimens from the untreated plots were taken prior to the specimens of the treated plots. Each specimen “whole plant” was placed in a plastic bag labelled with the specimen identification number. The plastic bag was placed in a second bag. Specimens were frozen within a maximum of 2:50 hours after start of collection. 16 days later, grain was separated from straw at the storage of the test facility by using a research size combine harvester. The sample preparation was performer without thawing of samples. Each specimen “grain” and “straw” was placed in a plastic bag labelled with the specimen identification number. The plastic bag was placed in a second bag. Ship and retain specimens were taken.

Reference:	KCP 8.3.8
Report	Determination of p lambda cyhalothrin (CAS: 91465-08-6) in cereals by LC-MS according to SOPa-190-LABCHI-rev. 2. M. Rubino, 2018, Report FR 18.618095.0001 (Analytical phase)

Guideline(s):	OECD (1988) The OECD Principles of Good Laboratory Practice (as revised in 1997), ENV/MC/CH EM (98)17 OECD (2002) The application of the OECD Principles of Good Laboratory Practice to the organisation and management of multi-side studies, ENV/JM/MON0 (2002)9 Italian Legislative Decree (D.L. No. 50 dated Match 2nd, 2007) as published in G. U. No. 86 of April 13th, 2007 Annex II, Regulation EC 1107/2009 concerning the placing of Plant Protection Products on the market OECD 204/2014 Guidance document for single laboratory validation of quantitative analytical methods – guidance used in suport of pre- and post- registration. Data requirements for plant protection and biocidal products. EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS
The analitycal phase of the study 18.618095.0001 was conducted to determine the residua level of Lambda cyhalothrin in cereals by LC-MS according to the in-house validated method codified as SOPa-190-LABCHI-Rev.2.

SAMPLE EXTRACTION
About 5.00 g of sample grinded were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture were added to the sample. After vortexing for about 1 min, about 66 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1min. The tube was cetriduged at 4750 rpm for 5min and kept at about -20°C for abour 2 hours. Then, the tube was cetrifuged at 4750 rpm for 5min and it was proceed to purification of the supernatant.
6 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5min.
1ml of the purified sample was transferred into a 2 ml volumetric flask and diluted to volume with mobile phase A, filtered and transfered into an HPLC vial and injected.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION
The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Lambda-Cyhalothrin in barley grain and straw matrices.
The LOD was set at 0.003 mg/kg.

ACCURACY
Accuracy evaluation was performed on sample aliquots spiked with Lambda Cyhalothrin at LOQ (about 0.01 mg/kg). 3 replicate analyses were performed for each

spiking level.
Mean recovery was 85.6% with RSD = 2% for first mass transition and 88.2% with RSD = 7% for the second mass transition in grain.
Mean recovery was 92.9% with RSD = 11% for first mass transition and 92.8% with RSD = 14% for the second mass transition in straw.

Table A 11: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalothrin		
	(a)	(b)				(c)				(d)	(e)
CT17-1-42DE1/Germany/N-EU/2017	Barley	30.09.2016 11.10.2016 06.07.2017	7.8 7.5	300 300		2		Grain Straw	n.d. n.d.	28	LOD = 0.003 mg/kg LOQ = 0.01 mg/kg

Table A 12: Summary of the study in N-EU (DAR 1996)

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				Lambda cyhalothrin		
	(a)	(b)				(c)				(d)	(e)

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalothrin		
M4013B/Germany/N-EU/1984	Barley/Tapir		10			3	BBCH 59	Grain Straw	0.02 0.02	48	
M4013B/Germany/N-EU/1984	Barley/Cerise		10			3	BBCH 59	Grain Straw	<0.01 0.24	47	
M4013B/Germany/N-EU/1984	Barley/Cerise		10			3	BBCH 69	Grain Straw	0.02 0.41	33	
M4013B/Germany/N-EU/1984	Barley/Trumpf		10			3	BBCH 51-59	Grain Straw	<0.01 0.37	52	
M4013B/Germany/N-EU/1984	Barley/Trumpf		10			3	BBCH 61	Grain Straw	<0.01 0.41	49	
M4013B/Germany/N-EU/1984	Barley/Trumpf		10			3	BBCH 69-71	Grain Straw	<0.01 0.39	43	
RJ1464B/Germany/N-EU/1992	Barley/Nixe		10			3	BBCH 69	Grain Straw	0.02 0.34	34	

A 2.1.3.4 Oats

Table A 13: 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, 2015)	1-2	0.0075-0.015 kg a.s./ha			30
Intended cGAP (5)	1	0.0075 kg a.s./ha		BBCH 41-75	28

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

Table A 14: Summary of the study in N-EU (DAR 1996)

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				Lambda cyhalothrin		
	(a)	(b)				(c)				(d)	(e)
M4013B/Germany/N-EU/1984	Oats/Alfred		10			3	BBCH 71	Grain Straw	<0.01 0.09	31	
M4013B/Germany/N-EU/1984	Oats/Alfred		10			3	BBCH 65	Grain Straw	<0.01 0.23	56	
M4013B/Germany/N-EU/1984	Oats/Alfred		10			3	BBCH 59	Grain Straw	<0.01 0.25	65	
RJ1464B/Germany/N-EU/1992	Oats/Alfred		10			3	BBCH 65	Grain Straw	<0.01 0.06	36	

A 2.1.3.5 Cauliflower

Table A 15: 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, 2015)	1-2	0.02 kg a.s./ha		BBCH 45	7
cGAP EU (Art. 12, EFSA, 2015)	1-2	0.01 kg a.s./ha			7
Intended cGAP (1-2)	1	0.0075 kg a.s./ha		BBCH 41-43	7

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

A 2.1.3.5.1 Study 1

Comments of zRMS:	Study is accepted. Field phase is accepted. Acceptable validated in accordance to the guidance document: SANTE/2020/12830, Rev.1, (2021) method was used. Trials are independent and acceptable with regard to storage stability data.

Reference:	KCP 8.3.13
Report	Magnitude of the residue of Lambda-cyhalothrin in Cauliflower (Raw Agricultural Commodity) after two applications of Lambda cyhalothrin 10% CS - one harvest and one decline curve trial in Poland - 2021. T. Peda, 2022, Report No. 21SGS48 (Field phase)
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029Nl/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
Deviations:	No
GLP:	Yes

Acceptability:	Yes

MATERIAL AND METHODS

MATERIALS
Test material: Lambda cyhalothrin 10% CS
Batch #: SCL-34763
Actual content: Lambda cyhalothrin 10.2% (w/v)
CAS #: 91465-08-6

Test Commodity/Crop: Cauliflower
Crop parts(s) or processed: Inflorescences

STUDY DESIGN AND METHODS
The objective of the study was to generate specimens of cauliflower (Raw Agricultural Commodity) after two applications of Lambda cyhalothrin 10% CS under cultural practice typical for cauliflower production.
Lambda cyhalothrin 10% CS was mixed only with water, no adjuvant was added to the spray mixture. The target dose rate of the test item at each application according to Study Plan was 0.075 l/ha, equivalent to 7.5 g a. s./ha. Target water volume for each application was 200-1000 l/ha according to Good Agricultural Practice.
RAC specimens were shipped deep frozen at a target temperature below -18°C to the following analytical laboratory: InHort lnstytut Ogrodnictwa - Panstwowy lnstytut Badawczy, Zaktad Badania Bezpieczeristwa Zywnosci ul. Pomologiczna 138, 96-100 Skierniewice Poland.

Reference:	KCP 8.3.14
Report	Determination of the magnitude of the residues of lambda-cyhalothrin in cauliflower (raw agricultural commodity) after two applications of lambda cyhalothrin 10% CS – one harvest and one decline curve trial in Poland – 2021. A. Markowicz, 2022, Report No. 21/FSL/08/2PL (Analytical phase)
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 repeating Council Directives 79/117/EEC and 91/414/EEC EC Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830, Rev.1, (2021) OECD: Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17, (2007)
Deviations:	No
GLP:	Yes

Acceptability: Yes

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues lambda-Cyhalothrin in cauliflower (inflorescences) samples taken from the field trials, after two applications of LAMBDA CYHALOTHRIN 10% CS, under open field conditions. To achieve the objective appropriate analytical method for determination of lambda-Cyhalothrin in target matrix was used. The reference method was validated for head cabbage as representative high-water content matrix in accordance to the guidance document: SANTE/2020/12830, Rev.1 of the European Commission. The validated limit of quantification is 0.01 mg/kg.

The general principles of the analytical procedure were based on the normalized method EN 15662:2018. In brief, samples of cauliflower were extracted with acetonitrile. After addition of a buffer-salt mixture containing magnesium sulphate, sodium chloride and sodium citrate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulphate addition.

Quantification was performed by use of highly selective gas chromatography coupled with tandem mass spectrometry (GC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention time of analyte in extracts corresponds to that of the calibration standard with a tolerance of < ± 0.1 min. Confirmation ion ratio for lambda-Cyhalothrin in all samples were within ± 30 % of the average found for the standards. Determination was performed using matrix-matched calibration standards.

SAMPLE EXTRACTION

- 10 g ± 0.1 g of homogenized cauliflower was weighed into a 50 mL Teflon® centrifuge tube. Sample weight was recorded.
- If necessary, fortification of the concurrent recovery sample(s) by aliquoting the fortification standard onto the matrix was carried out at this step. The tube was shaken in a vortex mixer for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	**Matrix**	**Concentration (µg/mL) of lambda-Cyhalothrin**	**Volume used (µL)**
LOQ (0.01 mg/kg)	Cauliflower (inflorescences)	1	100

- Using glass volumetric pipettes 10 mL of acetonitrile were added.
- The Teflon® centrifuge tube was closed tightly and shaken vigorously by QuEChERS Hand Motion Shaker for 1 min.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION

The limit of quantification (LOQ) was established at 0.01 mg/kg for lambda-Cyhalothrin, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for cauliflower.

ACCURACY AND PRECISION

The mean recovery values at the fortification level of 0.01 mg/kg for both ion mass transitions were all in the range 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, Rev.1 of the European Commission. All precision values at the fortification level of 0.01 mg/kg for both ion mass transitions were < 20%.

Table A 16: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalothrin		
21SGS48-01/ Poland/N-EU/2021 Chwastnica (Dolnośląskie) Zip code: 55-216	Cauliflower/Almagro	28/04/2021 - 27/07/2021	7.6 7.3			08/07/2021 19/07/2021	BBCH 41 BBCH 45	Inflorescences	<LOD	7	LOD = 0.002 mg/kg LOQ = 0.01 mg/kg
21SGS48-02/ Poland/N-EU/2021 Światkowo (Kujawsko-Pomorskie) Zip code: 88-430	Cauliflower/Fortaleza	21/06/2021 - 06/09/2021	7.2 7.6			20/08/2021 30/08/2021	BBCH 43 BBCH 45	Inflorescences	<LOD <LOD <LOD	1 3 7	LOD = 0.002 mg/kg LOQ = 0.01 mg/kg

Table A 17: Summary of the study in N-EU (DAR 1996)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalothrin		
M4226B/Germany/N-EU/1985	Cauliflower/White top		10-15			4			0.01	0	

A 2.1.3.6 Cabbage

Table A 18: 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, 2015)	1-2	0.0125 kg a.s./ha			7
Intended cGAP (1-2)	1	0.0075 kg a.s./ha		BBCH 41-43	3

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

A 2.1.3.6.1 Study 1

Comments of zRMS:	Study is acceptable. Field phase is accepted. Acceptable validated in accordance to the guidance document: SANTE/2020/12830, Rev.1, (2021) method was used. Trials are independent and acceptable with regard to storage stability data.

Reference:	KCP 8.3.15
Report	Magnitude of the residues of lambda-cyhalothrin in cabbage (raw agricultural commodity) after two applications of lambda cyhalothrin 10% CS – one harvest and one decline curve trial in Poland - 2021. T. Peda, 2022, Report No. 21SGS47 (Field phase)
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029Nl/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
Deviations:	No
GLP:	Yes

Acceptability:	Yes

MATERIAL AND METHODS

MATERIALS
Test material: Lambda cyhalothrin 10% CS
Batch #: SCL-34763
Actual content: Lambda cyhalothrin 10.2% (w/v)
CAS #: 91465-08-6

Test Commodity/Crop: Cabbage
Crop parts(s) or processed: Head cabbage

STUDY DESIGN AND METHODS
The objective of the study was to generate specimens of cabbage (Raw Agricultural Commodity) after two applications of Lambda cyhalothrin 10% CS under cultural practice typical for cabbage production.
Lambda cyhalothrin 10% CS was mixed only with water, no adjuvant was added to the spray mixture. The target dose rate of the test item at each application according to Study Plan was 0.075 l/ha, equivalent to 7.5 g a. s./ha. Target water volume for each application was 200-1000 l/ha according to Good Agricultural Practice.
RAC specimens were shipped deep frozen at a target temperature below -18°C to the following analytical laboratory: InHort lnstytut Ogrodnictwa - Panstwowy lnstytut Badawczy, Zaktad Badania Bezpieczeristwa Zywnosci ul. Pomologiczna 138, 96-100 Skierniewice Poland.

Reference:	KCP 8.3.16
Report	Determination of the magnitude of the residues of lambda-cyhalothrin in cabbage (raw agricultural commodity) after two applications of lambda cyhalothrin 10% CS – one harvest and one decline curve trial in Poland - 2021. A. Markowicz, 2022, Report No. 21/FSL/08/1PL1 (Analytical phase)
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 repeating Council Directives 79/117/EEC and 91/414/EEC EC Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830, Rev.1, (2021) OECD: Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17, (2007)
Deviations:	No
GLP:	Yes

Acceptability: Yes

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues lambda-Cyhalothrin in head cabbage (head) samples taken from the field trials, after two applications of LAMBDA CYHALOTHRIN 10% CS, under open field conditions. To achieve the objective appropriate analytical method for determination of lambda-Cyhalothrin in target matrix was used. The reference method was validated for head cabbage as representative high-water content matrix in accordance to the guidance document: SANTE/2020/12830, Rev.1 of the European Commission. The validated limit of quantification is 0.01 mg/kg.

The general principles of the analytical procedure were based on the normalized method EN 15662:2018. In brief, samples of head cabbage were extracted with acetonitrile. After addition of a buffer-salt mixture containing magnesium sulphate, sodium chloride and sodium citrate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulphate addition.

Quantification was performed by use of highly selective gas chromatography coupled with tandem mass spectrometry (GC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention time of analyte in extracts corresponds to that of the calibration standard with a tolerance of < ± 0.1 min. Confirmation ion ratio for lambda-Cyhalothrin in all samples were within ± 30 % of the average found for the standards. Determination was performed using matrix-matched calibration standards.

SAMPLE EXTRACTION

- 10 g ± 0.1 g of homogenized head cabbage was weighed into a 50 mL Teflon® centrifuge tube. Sample weight was recorded.
- If necessary, fortification of the concurrent recovery sample(s) by aliquoting the fortification standard onto the matrix was carried out at this step. The tube was shaken in a vortex mixer for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	Matrix	Concentration (µg/mL) of lambda-Cyhalothrin	Volume used (µL)
LOQ (0.01 mg/kg)	Head cabbage	1	100

- Using glass volumetric pipettes 10 mL of acetonitrile were added.
- The Teflon® centrifuge tube was closed tightly and shaken vigorously by QuEChERS Hand Motion Shaker for 1 min.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION

The limit of quantification (LOQ) was established at 0.01 mg/kg for lambda-Cyhalothrin, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for head cabbage.

ACCURACY AND PRECISION

The mean recovery values at the fortification level of 0.01 mg/kg for both ion mass transitions were all in the range 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, Rev.1 of the European Commission. All precision values at the fortification level of 0.01 mg/kg for both ion mass transitions were < 20%.

Table A 19: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: g a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): Lambda cyhalothrin	PHI (days) (d)	Details on trial (e)
21SGS47-01/ Poland/N-EU/2021 Chwastnica (Dolnośląskie) Zip code: 55-216	Cabbage/Gregorian	28/04/2021 - 13/07/2021	7.3 7.6			01/07/2021 10/07/2021	BBCH 43 BBCH 45	Head cabbage	< LOD	3	LOD = 0.002 mg/kg LOQ = 0.01 mg/kg
21SGS47-02/ Poland/N-EU/2021 Kaczkowo ((Kujawsko-Pomorskie) Zip code:88-400	Cabbage/Liberator	28/05/2021 - 19/08/2021	7.4 7.5			06/08/2021 16/08/2021	BBCH 43 BBCH 45	Head cabbage	< LOQ (0.0033) < LOD < LOD	0 1 3	LOD = 0.002 mg/kg LOQ = 0.01 mg/kg

A 2.1.3.6.2 Study 2

Comments of zRMS:	Study is acceptable. Field phase is accepted. Acceptable validated in accordance to the guidance document: SANTE/2020/12830, Rev.1, (2021) method was used. Trials are independent and acceptable with regard to storage stability data.

Reference:	KCP 8.3.17
Report	Determination of the residues of lambda cyhalothrin in/on cabbage after two applications of lambda cyhalothrin 10% CS in northern Europe - Hungary in 2021. G. Wágner, 2022, Report No. 065CPRHU21R05 (Field phase)
Guideline(s):	Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC) No. 1107/2009 of the European Parlia-

	ment Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

MATERIALS
Test material: Lambda cyhalothrin 10% CS
Batch #: SCL-34763
Actual content: Lambda cyhalothrin 10.2% (w/v)
CAS #: 91465-08-6

Test Commodity/Crop: Cabbage
Crop parts(s) or processed: Head cabbage

STUDY DESIGN AND METHODS
Lambda cyhalothrin 10% CS is an insecticide developed by Sharda Cropchem Ltd. for pest control in different crops. The objective of this study is to provide results from the magnitude of residues of lambda cyhalothrin in/on cabbage, grown in open field conditions, 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 2021. The field phase was performed in Kőszeg (CPRHU21-210-065IR) and in Szatymaz (CPRHU21-211-065IR).
Two applications (first at 10 days before application 2, second at 3 days before harvest, at BBCH 45) of the formulated product Lambda cyhalothrin 10% CS were applied at a rate of 0.075 L formulated product/ha (7.5 g active ingredient of lambda cyhalothrin /ha) onto the crop, under open field condition.
Specimens (cabbage head) were collected at 0, 1 and 3 (NCH) days after last application (DALA) in decline trial and at 3 days after last application (DALA) in harvest trial, frozen and shipped deep frozen to analytical facility of Food Safety Laboratory Research Institute of Horticulture for residue analysis.

Reference:	KCP 8.3.18
Report	Determination of the residues of lambda-cyhalothrin in/on cabbage after two applications of lambda cyhalothrin 10% CS in northern Europe – Hungary in 2021. A. Markowicz, 2022, Report No. 21/FSL/08/1HU1 (Analytical phase)

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 repeating Council Directives 79/117/EEC and 91/414/EEC EC Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830, Rev.1, (2021) OECD: Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17, (2007)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues lambda-Cyhalothrin in head cabbage (head) samples taken from the field trials, after two applications of LAMBDA CYHALOTHRIN 10% CS, under open field conditions. To achieve the objective appropriate analytical method for determination of lambda-Cyhalothrin in target matrix was used. The reference method was validated for head cabbage as representative high-water content matrix in accordance to the guidance document: SANTE/2020/12830, Rev.1 of the European Commission. The validated limit of quantification is 0.01 mg/kg.

The general principles of the analytical procedure were based on the normalized method EN 15662:2018. In brief, samples of head cabbage were extracted with acetonitrile. After addition of a buffer-salt mixture containing magnesium sulphate, sodium chloride and sodium citrate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulphate addition.

Quantification was performed by use of highly selective gas chromatography coupled with tandem mass spectrometry (GC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention time of analyte in extracts corresponds to that of the calibration standard with a tolerance of < ± 0.1 min. Confirmation ion ratio for lambda-Cyhalothrin in all samples were within ± 30 % of the average found for the standards. Determination was performed using matrix-matched calibration standards.

SAMPLE EXTRACTION

- 10 g ± 0.1 g of homogenized head cabbage was weighed into a 50 mL Teflon® centrifuge tube. Sample weight was recorded
- If necessary, fortification of the concurrent recovery sample(s) by aliquoting the fortification standard onto the matrix was carried out at this step. The tube was shaken in a vortex mixer for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	Matrix	Concentration (µg/mL) of lambda-Cyhalothrin	Volume used (µL)
LOQ (0.01 mg/kg)	Head cabbage	1	100

- Using glass volumetric pipettes 10 mL of acetonitrile were added.

– The Teflon® centrifuge tube was closed tightly and shaken vigorously by QuEChERS Hand Motion Shaker for 1 min.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION
The limit of quantification (LOQ) was established at 0.01 mg/kg for lambda-Cyhalothrin, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for head cabbage.

ACCURACY AND PRECISION
The mean recovery values at the fortification level of 0.01 mg/kg for both ion mass transitions were all in the range 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, Rev.1 of the European Commission. All precision values at the fortification level of 0.01 mg/kg for both ion mass transitions were < 20%.

Table A 20: Summary of the study 2 trials

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: g a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): Lambda cyhalothrin	PHI (days) (d)	Details on trial (e)
CPRHU21-210-065IR/ Hungary/N-EU/2021 Kőszeg Zip code: 97-30	Cabbage/Gloria F1	29 Apr 2021 - 11 Aug 2021	7.33 7.75			29 Jul 2021 08 Aug 2021	BBCH 43 BBCH 45	Head cabbage	< LOD	3	LOD = 0.002 mg/kg LOQ = 0.01 mg/kg
CPRHU21-211-065IR/ Hungary/N-EU/2021 Szatymaz Zip code: 67-63	Cabbage/Braunschweigi	22 Apr 2021 - 27 Aug 2021	7.83 7.65			14 Aug 2021 24 Aug 2021	BBCH 43 BBCH 45	Head cabbage	< LOD < LOD < LOD	0 1 3	LOD = 0.002 mg/kg LOQ = 0.01 mg/kg

A 2.1.3.6.3 Study 3

Comments of zRMS:	The trials are not independent – the same localisation and dates like in the study KCP 8.3.15 Not considered in the assessment.

Reference:	KCP 8.3.19
Report	Magnitude of the residues of lambda-cyhalothrin in cabbage (raw agricultural commodity) after two applications of lambda cyhalothrin 2.5% WG – one harvest and one decline curve trial in Poland - 2021. T. Peda, 2022, Report No. 21SGS44 (Field phase)
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029Nl/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

MATERIALS
Test material: Lambda cyhalothrin 2.5% WG
Batch #: SCL-34762
Actual content: Lambda cyhalothrin 2.6% (w/w)
CAS #: 91465-08-6

Test Commodity/Crop: Cabbage
Crop parts(s) or processed: Head cabbage

STUDY DESIGN AND METHODS
The objective of the study was to generate specimens of cabbage (Raw Agricultural Commodity) after two applications of Lambda cyhalothrin 2,5% WG under cultural practice typical for cabbage production.
Lambda cyhalothrin 2.5% WG was mixed only with water, no adjuvant was added to the spray mixture. The target dose rate of the test item at each application according to Study Plan was 0.3 kg/ha, equivalent to 7.5 g a. s./ha. Target water volume for each application was 200-1000 l/ha according to Good Agricultural Practice.
RAC specimens were shipped deep frozen at a target temperature below -18°C to the following analytical laboratory: InHort Instytut Ogrodnictwa - Panstwowy

lnstytut Badawczy, Zaktad Badania Bezpieczeristwa Zywnosci ul. Pomologiczna 138, 96-100 Skierniewice Poland.

Reference:	KCP 8.3.20
Report	Determination of the magnitude of the residues of lambda-cyhalothrin in cabbage (raw agricultural commodity) after two applications of lambda cyhalothrin 2.5% WG – one harvest and one decline curve trial in Poland - 2021. A. Markowicz, 2022, Report No. 21/FSL/08/1PL2 (Analytical phase)
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 repeating Council Directives 79/117/EEC and 91/414/EEC EC Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830, Rev.1, (2021) OECD: Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17, (2007)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues lambda-Cyhalothrin in head cabbage (head) samples taken from the field trials, after two applications of LAMBDA CYHALOTHRIN 2.5% WG, under open field conditions. To achieve the objective appropriate analytical method for determination of lambda-Cyhalothrin in target matrix was used. The reference method was validated for head cabbage as representative high-water content matrix in accordance to the guidance document: SANTE/2020/12830, Rev.1 of the European Commission. The validated limit of quantification is 0.01 mg/kg.

The general principles of the analytical procedure were based on the normalized method EN 15662:2018. In brief, samples of head cabbage were extracted with acetonitrile. After addition of a buffer-salt mixture containing magnesium sulphate, sodium chloride and sodium citrate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulphate addition.

Quantification was performed by use of highly selective gas chromatography coupled with tandem mass spectrometry (GC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention time of analyte in extracts corresponds to that of the calibration standard with a tolerance of < ± 0.1 min. Confirmation ion ratio for lambda-Cyhalothrin in all samples were within ± 30 % of the average found for the standards. Determination was performed using matrix-matched calibration standards.

SAMPLE EXTRACTION

- 10 g ± 0.1 g of homogenized head cabbage was weighed into a 50 mL Teflon® centrifuge tube. Sample weight was recorded.
- If necessary, fortification of the concurrent recovery sample(s) by aliquoting the fortification standard onto the matrix was carried out at this step. The tube was shaken in a vortex mixer for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	Matrix	Concentration	Volume used

		(µg/mL) of lambda-Cyhalothrin	(µL)
LOQ (0.01 mg/kg)	Head cabbage	1	100

– Using glass volumetric pipettes 10 mL of acetonitrile were added.
– The Teflon® centrifuge tube was closed tightly and shaken vigorously by QuEChERS Hand Motion Shaker for 1 min.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION
The limit of quantification (LOQ) was established at 0.01 mg/kg for lambda-Cyhalothrin, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for head cabbage.

ACCURACY AND PRECISION
The mean recovery values at the fortification level of 0.01 mg/kg for both ion mass transitions were all in the range 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, Rev.1 of the European Commission. All precision values at the fortification level of 0.01 mg/kg for both ion mass transitions were < 20%.

Table A 21: Summary of the study 3 trials

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: g a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): Lambda cyhalothrin	PHI (days) (d)	Details on trial (e)
21SGS44-01/ Poland/N-EU/2021 Chwastnica (Dolnośląskie) Zip code: 55-216	Cabbage/Gregorian	28/04/2021 - 13/07/2021	7.65 7.23			01/07/2021 10/07/2021	BBCH 43 BBCH 45	Head cabbage	< LOD	3	LOD = 0.002 mg/kg LOQ = 0.01 mg/kg
21SGS44-02/ Poland/N-EU/2021 Kaczkowo ((Kujawsko-Pomorskie) Zip code:88-400	Cabbage/Liberator	28/05/2021 - 19/08/2021	7.63 7.58			06/08/2021 16/08/2021	BBCH 43 BBCH 45	Head cabbage	< LOQ (0.0022) < LOD < LOD	0 1 3	LOD = 0.002 mg/kg LOQ = 0.01 mg/kg

A 2.1.3.6.4 Study 4

A 2.1.3.6.5

Comments of zRMS:	Trial CPRHU21-205-065IR/Hungary/N-EU/2021 and trial CPRHU21-210-065IR/Hungary/N-EU/2021, Kőszeg, Zip code: 97-30 are not independent. Trial CPRHU21-205-065IR/Hungary/N-EU/2021 is not considered in the assessment.

Reference:	KCP 8.3.21
Report	Determination of the residues of lambda cyhalothrin in/on cabbage after two applications of lambda cyhalothrin 2.5% WG in northern Europe - Hungary in 2021. G. Wágner, 2022, Report No. 065CPRHU21R02 (Field phase)
Guideline(s):	Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC) No. 1107/2009 of the European Parliament Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

MATERIALS
Test material: Lambda cyhalothrin 2.5% WG
Batch #: SCL-34762
Actual content: Lambda cyhalothrin 2.6% (w/w)
CAS #: 91465-08-6

Test Commodity/Crop: Cabbage
Crop parts(s) or processed: Head cabbage

STUDY DESIGN AND METHODS
Lambda cyhalothrin 2.5% WG is an insecticide developed by Sharda Cropchem Ltd. for pest control in different crops. The objective of this study is to provide results from the magnitude of residues of lambda cyhalothrin in/on cabbage, grown in open field conditions, in order to support the registration of the plant protection

product applied according to Good Laboratory Practice (GLP).
One trial was conducted in Hungary in 2021. The field phase was performed in Kőszeg (CPRHU21-205-065IR).
Two applications (first at 10 days before application 2, second at 3 days before harvest, at BBCH 45) of the formulated product Lambda cyhalothrin 2.5% WG was applied at a rate of 0.3 kg formulated product/ha (7.5 g active ingredient of lambda cyhalothrin /ha) onto the crop, under open field condition.
Specimens (cabbage) were collected at 0, 1 and 3 (NCH) days after last application (DALA) in decline trial, frozen and shipped deep frozen to analytical facility of Food Safety Laboratory Research Institute of Horticulture for residue analysis.

Reference:	KCP 8.3.22
Report	Determination of the residues of lambda-cyhalothrin in/on cabbage after two applications of lambda cyhalothrin 2.5% WG in northern Europe – Hungary in 2021. A. Markowicz, 2022, Report No. 21/FSL/08/1HU2 (Analytical phase)
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 repeating Council Directives 79/117/EEC and 91/414/EEC EC Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830, Rev.1, (2021) OECD: Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17, (2007)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS
The objective of this study was to determine the decline and the magnitude of residues lambda-Cyhalothrin in head cabbage (head) samples taken from the field trial, after two applications of LAMBDA CYHALOTHRIN 2.5% WG, under open field conditions. To achieve the objective appropriate analytical method for determination of lambda-Cyhalothrin in target matrix was used. The reference method was validated for head cabbage as representative high-water content matrix in accordance to the guidance document: SANTE/2020/12830, Rev.1 of the European Commission. The validated limit of quantification is 0.01 mg/kg.
The general principles of the analytical procedure were based on the normalized method EN 15662:2018. In brief, samples of head cabbage were extracted with acetonitrile. After addition of a buffer-salt mixture containing magnesium sulphate, sodium chloride and sodium citrate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulphate addition.
Quantification was performed by use of highly selective gas chromatography coupled with tandem mass spectrometry (GC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention time of analyte in extracts corresponds to that of the calibration standard with a tolerance of < ± 0.1 min. Confirmation ion ratio for lambda-Cyhalothrin in all samples were within ± 30 % of the average found for the standards. Determination was performed using matrix-matched calibration standards.

SAMPLE EXTRACTION

– 10 g ± 0.1 g of homogenized head cabbage was weighed into a 50 mL Teflon® centrifuge tube. Sample weight was recorded.
– If necessary, fortification of the concurrent recovery sample(s) by aliquoting the fortification standard onto the matrix was carried out at this step. The tube was shaken in a vortex mixer for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	Matrix	Concentration (µg/mL) of lambda-Cyhalothrin	Volume used (µL)
LOQ (0.01 mg/kg)	Head cabbage	1	100

– Using glass volumetric pipettes 10 mL of acetonitrile were added.
– The Teflon® centrifuge tube was closed tightly and shaken vigorously by QuEChERS Hand Motion Shaker for 1 min.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION
The limit of quantification (LOQ) was established at 0.01 mg/kg for lambda-Cyhalothrin, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for head cabbage.

ACCURACY AND PRECISION
The mean recovery values at the fortification level of 0.01 mg/kg for both ion mass transitions were all in the range 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, Rev.1 of the European Commission. All precision values at the fortification level of 0.01 mg/kg for both ion mass transitions were < 20%.

Table A 22: Summary of the study 4 trials

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: g a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): Lambda cyhalothrin	PHI (days) (d)	Details on trial (e)
CPRHU21-205-065IR/ Hungary/N-EU/2021	Cabbage/ Gloria F1	29 Apr 2021 - 11 Aug 2021	7.18 7.68			29 Jul 2021 08 Aug 2021	BBCH 43 BBCH 45	Head cabbage	< LOD < LOD < LOD	0 1 3	LOD = 0.002 mg/kg LOQ = 0.01 mg/kg

A 2.1.3.6.6 Study 5

Comments of zRMS:	Study is acceptable (field phase and analytical method used)

Reference:	KCP 8.3.23
Report	Determination of residues at harvest of lambda-cyhalothrin in Cabbage, following two applications of lambda-cyhalothrin 2.5% WG, under open field conditions Germany- Season 2021. K. Rump, 2022, Report No. FRS 009/21 (Field phase)
Guideline(s):	EC Commission Directive 2004/10/EC of 11 February 2004 OECD Principles of Good Laboratory Practice (as revised in 1997) and Compliance Monitoring No 1, ENV/MC/CHEM(98)17 The application of the GLP Principles to Field Studies, Compliance Monitoring No. 6, ENV/JM/MONO(99)22 National GLP reference guideline: Chemikaliengesetz, § 19a-d (Germany)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

MATERIALS
Test material: Lambda cyhalothrin 2.5% WG
Batch #: SCL-34762
Actual content: Lambda cyhalothrin 2.6% (w/w)
CAS #: 91465-08-6

Test Commodity/Crop: Cabbage
Crop parts(s) or processed: Head cabbage

STUDY DESIGN AND METHODS
The object of this study was to determine the magnitude of residues of lambda-CYHALOTHRIN in Cabbage resulting from two applications at the maximum anticipated labelled rate of lambda-CYHALOTHRIN 2.5% WG. Raw agricultural commodity specimens were be generated from plants harvested from untreated and treated plots at 3 DALA (days after last application) at commercial harvest for a harvest study. The study will be conducted under field conditions in Germany.

Reference:	KCP 8.3.24
Report	Determination of the residues at harvest of lambda-cyhalothrin in cabbage following two applications of lambda cyhalothrin 2.5% WG under open field conditions Germany - season 2021. A. Markowicz, 2022, Report No. 21/FSL/08/1DE (Analytical phase)
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 repeating Council Directives 79/117/EEC and 91/414/EEC EC Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830, Rev.1, (2021) OECD: Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17, (2007)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues lambda-Cyhalothrin in head cabbage (head) samples taken from the field trial, after two applications of LAMBDA CYHALOTHRIN 2.5% WG, under open field conditions. To achieve the objective appropriate analytical method for determination of lambda-Cyhalothrin in target matrix was used. The reference method was validated for head cabbage as representative high-water content matrix in accordance to the guidance document: SANTE/2020/12830, Rev.1 of the European Commission. The validated limit of quantification is 0.01 mg/kg.

The general principles of the analytical procedure were based on the normalized method EN 15662:2018. In brief, samples of head cabbage were extracted with acetonitrile. After addition of a buffer-salt mixture containing magnesium sulphate, sodium chloride and sodium citrate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulphate addition.

Quantification was performed by use of highly selective gas chromatography coupled with tandem mass spectrometry (GC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention time of analyte in extracts corresponds to that of the calibration standard with a tolerance of < ± 0.1 min. Confirmation ion ratio for lambda-Cyhalothrin in all samples were within ± 30 % of the average found for the standards. Determination was performed using matrix-matched calibration standards.

SAMPLE EXTRACTION

- 10 g ± 0.1 g of homogenized head cabbage was weighed into a 50 mL Teflon® centrifuge tube. Sample weight was recorded.
- If necessary, fortification of the concurrent recovery sample(s) by aliquoting the fortification standard onto the matrix was carried out at this step. The tube was shaken in a vortex mixer for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	Matrix	Concentration (µg/mL) of lambda-Cyhalothrin	Volume used (µL)

LOQ (0.01 mg/kg)	Head cabbage	1	100

– Using glass volumetric pipettes 10 mL of acetonitrile were added.
– The Teflon® centrifuge tube was closed tightly and shaken vigorously by QuEChERS Hand Motion Shaker for 1 min.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION
The limit of quantification (LOQ) was established at 0.01 mg/kg for lambda-Cyhalothrin, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for head cabbage.

ACCURACY AND PRECISION
The mean recovery values at the fortification level of 0.01 mg/kg for both ion mass transitions were all in the range 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, Rev.1 of the European Commission. All precision values at the fortification level of 0.01 mg/kg for both ion mass transitions were < 20%.

Table A 23: Summary of the study 5 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat-ment or no. of treatments and last date	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalo-thrin		
	(a)	(b)				(c)				(d)	(e)
FRS009/21 / Germany/N-EU/2021	Cabbage/Lion	20/05/2021 - 05/08/2021	7.0 8.2	200		23/07/2021 02/08/2021	BBCH 43 BBCH 45	Head cabbage	< LOQ (0.0054)	3	LOD = 0.002 mg/kg LOQ = 0.01 mg/kg

Table A 24: Summary of the study in N-EU (DAR 1996)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat-ment or no. of treatments and last date	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalo-thrin		
	(a)	(b)				(c)				(d)	(e)

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalothrin		
M3933B/UK/N-EU/1984	Cabbage/January King		15			1			0.05	3	
M3933B/UK/N-EU/1984	Cabbage/Golden Cross		15			1			0.08	3	
M3933B/UK/N-EU/1984	Cabbage/Polinyus		15			1			0.06	3	
M278B/UK/1985	Cabbage/Dutch White		15			1			0.09	3	

A 2.1.3.7 Tomato

Table A 25: 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, 2015)	2	0.02 kg a.s./ha	10	BBCH 81	3
Intended cGAP (3, 4)	1	0.0075 kg a.s./ha		BBCH 51-85	3

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

A 2.1.3.7.1 Study 1

Comments of zRMS:	Study is acceptable. Field phase is accepted. Acceptable validated in accordance to the guidance document: SANTE/2020/12830, Rev.1, (2021) method was used. Trials are independent and acceptable with regard to storage stability data.

Reference:	KCP 8.3.25
Report	Magnitude of the residues of lambda cyhalothrin in tomato (raw agricultural commodity) after two applications of lambda cyhalothrin 10% CS – one harvest and one decline curve trial in Poland - 2021. T. Peda, 2022, Report No. 21SGS50 (Field phase)
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029Nl/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

MATERIALS
Test material: Lambda cyhalothrin 10% CS
Batch #: SCL-34763
Actual content: Lambda cyhalothrin 10.2% (w/v)
CAS #: 91465-08-6

Test Commodity/Crop: Tomato
Crop parts(s) or processed: Fruit without calyx

STUDY DESIGN AND METHODS
The objective of the study was to generate specimens of tomato (Raw Agricultural Commodity) after two applications of Lambda cyhalothrin 10% CS under cultural practice typical for tomato production.
Lambda cyhalothrin 10% CS was mixed only with water, no adjuvant was added to the spray mixture. The target dose rate of the test item at each application according to Study Plan was 0.2 l/ha, equivalent to 20 g a. s./ha. Target water volume for each application was 200-1000 l/ha according to Good Agricultural Practice.

RAC specimens were shipped deep frozen at a target temperature below -18°C to the following analytical laboratory: InHort Instytut Ogrodnictwa - Panstwowy Instytut Badawczy, Zaktad Badania Bezpieczeristwa Zywnosci ul. Pomologiczna 138, 96-100 Skierniewice Poland.

Reference:	KCP 8.3.26
Report	Determination of the magnitude of the residues of lambda-cyhalothrin in tomato (raw agricultural commodity) after two applications of lambda cyhalothrin 10% CS – one harvest and one decline curve trial in Poland - 2021. A. Markowicz, 2022, Report No. 21/FSL/08/4PL1 (Analytical phase)
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 repeating Council Directives 79/117/EEC and 91/414/EEC EC Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830, Rev.1, (2021) OECD: Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17, (2007)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues lambda-Cyhalothrin in tomato (fruit without calyx) samples taken from the field trials, after two applications of LAMBDA CYHALOTHRIN 10% CS, under open field conditions. To achieve the objective appropriate analytical method for determination of lambda-Cyhalothrin in target matrix was used. The reference method was validated for head cabbage as representative high-water content matrix in accordance to the guidance document: SANTE/2020/12830, Rev.1 of the European Commission. The validated limit of quantification is 0.01 mg/kg.

The general principles of the analytical procedure were based on the normalized method EN 15662:2018. In brief, samples of tomato were extracted with acetonitrile. After addition of a buffer-salt mixture containing magnesium sulphate, sodium chloride and sodium citrate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulphate addition.

Quantification was performed by use of highly selective gas chromatography coupled with tandem mass spectrometry (GC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention time of analyte in extracts corresponds to that of the calibration standard with a tolerance of < ± 0.1 min. Confirmation ion ratio for lambda-Cyhalothrin in all samples were within ± 30 % of the average found for the standards. Determination was performed using matrix-matched calibration standards.

SAMPLE EXTRACTION

- 10 g ± 0.1 g of homogenized tomato was weighed into a 50 mL Teflon® centrifuge tube. Sample weight was recorded.
- If necessary, fortification of the concurrent recovery sample(s) by aliquoting the fortification standard onto the matrix was carried out at this step. The tube was shaken in a vortex mixer for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	Matrix	Concentration (µg/mL) of lambda-Cyhalothrin	Volume used (µL)
LOQ (0.01 mg/kg)	Tomato (fruit without calyx)	1	100

- Using glass volumetric pipettes 10 mL of acetonitrile were added.
- The Teflon® centrifuge tube was closed tightly and shaken vigorously by QuEChERS Hand Motion Shaker for 1 min.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION

The limit of quantification (LOQ) was established at 0.01 mg/kg for lambda-Cyhalothrin, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for tomato.

ACCURACY AND PRECISION

The mean recovery values at the fortification level of 0.01 mg/kg for both ion mass transitions were all in the range 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, Rev.1 of the European Commission. All precision values at the fortification level of 0.01 mg/kg for both ion mass transitions were < 20%.

Table A 26: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat-ment or no. of treatments and last date (c)	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalo-thrin		
21SGS50-01/Poland/N-EU/2021 Kaczkowo ((Kujaw-sko-Pomorskie) Zip code:88-400	Tomato/Docet field	27/05/2021 - 22/08/2021	19.6 20.3			09/08/2021 19/08/2021	BBCH 83 BBCH 85	Fruit without calyx	< LOD	3	Outdoor LOD = 0.002 mg/kg LOQ = 0.01 mg/kg
21SGS50-02/Poland/N-EU/2021 Czarnolas (Dolnośląskie) Zip code:48-320	Tomato/Pietrarossa field	17/05/2021 - 24/09/2021	20.1 19.7			11/09/2021 21/09/2021	BBCH 83 BBCH 85	Fruit without calyx	0.028 0.023 0.020	0 1 3	Outdoor LOD = 0.002 mg/kg LOQ = 0.01 mg/kg

A 2.1.3.7.2 Study 2

Comments of zRMS:	Study is acceptable. Field phase is accepted. Acceptable validated in accordance to the guidance document: SANTE/2020/12830, Rev.1, (2021) method was used. Trials are independent and acceptable with regard to storage stability data.

Reference:	KCP 8.3.27
Report	Determination of the residues of lambda cyhalothrin in/on tomato after two applications of lambda cyhalothrin 10 % CS in northern Europe - Hungary in 2021. G. Wágner, 2022, Report No. 065CPRHU21R07 (Field phase)
Guideline(s):	Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC) No. 1107/2009 of the European Parliament Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)

Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

MATERIALS
Test material: Lambda cyhalothrin 10% CS
Batch #: SCL-34763
Actual content: Lambda cyhalothrin 10.2% (w/v)
CAS #: 91465-08-6

Test Commodity/Crop: Tomato
Crop parts(s) or processed: Tomato (fruit)

STUDY DESIGN AND METHODS
Lambda cyhalothrin 10 % CS is an insecticide developed by Sharda Cropchem Ltd. for plant growth control in different crops. The objective of this study is to provide results from the magnitude of residues of lambda cyhalothrin in/on tomato 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 2021. The field phase was performed in Kőszeg (CPRHU21-214-065IR) and in Ják (CPRHU21-215-065IR).
Two applications (first at 10 days before application 2, second at 3 days before harvest, at BBCH 85) of the formulated product Lambda cyhalothrin 10 % CS (containing nominal concentration of 10 % lambda cyhalothrin) were applied at a rate of 0.2 L formulated product/ha (20 g active ingredient/ha) onto the crop, under open field condition.
Specimens (fruit) were collected at 0, 1 and 3 (NCH) days after last application (DALA) in decline trial and at 3 DALA in harvest trial, frozen and shipped deep frozen to analytical facility of Food Safety Laboratory, Research Institute of Horticulture for residue analysis.

Reference:	KCP 8.3.28
Report	Determination of the residues of lambda-cyhalothrin in/on tomato after two applications of lambda cyhalothrin 10% CS in northern Europe – Hungary in 2021. A. Markowicz, 2022, Report No. 21/FSL/08/4HU1 (Analytical phase)
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 repeating Council Directives 79/117/EEC and 91/414/EEC EC Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830, Rev.1, (2021)

	OECD: Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17, (2007)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues lambda-Cyhalothrin in tomato (fruit) samples taken from the field trials, after two applications of LAMBDA CYHALOTHRIN 10% CS, under open field conditions. To achieve the objective appropriate analytical method for determination of lambda-Cyhalothrin in target matrix was used. The reference method was validated for head cabbage as representative high-water content matrix in accordance to the guidance document: SANTE/2020/12830, Rev.1 of the European Commission. The validated limit of quantification is 0.01 mg/kg.

The general principles of the analytical procedure were based on the normalized method EN 15662:2018. In brief, samples of tomato were extracted with acetonitrile. After addition of a buffer-salt mixture containing magnesium sulphate, sodium chloride and sodium citrate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulphate addition.

Quantification was performed by use of highly selective gas chromatography coupled with tandem mass spectrometry (GC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention time of analyte in extracts corresponds to that of the calibration standard with a tolerance of < ± 0.1 min. Confirmation ion ratio for lambda-Cyhalothrin in all samples were within ± 30 % of the average found for the standards. Determination was performed using matrix-matched calibration standards.

SAMPLE EXTRACTION

- 10 g ± 0.1 g of homogenized tomato was weighed into a 50 mL Teflon® centrifuge tube. Sample weight was recorded.
- If necessary, fortification of the concurrent recovery sample(s) by aliquoting the fortification standard onto the matrix was carried out at this step. The tube was shaken in a vortex mixer for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	Matrix	Concentration (µg/mL) of lambda-Cyhalothrin	Volume used (µL)
LOQ (0.01 mg/kg)	Tomato (fruit)	1	100

- Using glass volumetric pipettes 10 mL of acetonitrile were added.
- The Teflon® centrifuge tube was closed tightly and shaken vigorously by QuEChERS Hand Motion Shaker for 1 min.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION

The limit of quantification (LOQ) was established at 0.01 mg/kg for lambda-Cyhalothrin, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for tomato.

ACCURACY AND PRECISION
The mean recovery values at the fortification levels (0.01 mg/kg and 0.1 mg/kg) for both ion mass transitions were all in the range 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, Rev.1 of the European Commission. All precision values at the fortification levels (0.01 mg/kg and 0.1 mg/kg) for both ion mass transitions were < 20%.

Table A 27: Summary of the study 2 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: g a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): Lambda cyhalothrin	PHI (days) (d)	Details on trial (e)
CPRHU21-214-065IR/Hungary/N-EU/2021 Kőszeg	Tomato/ Kecskeméti Jubileum field	28 May 2021 - 26 Aug 2021	20.80 21.87			13 Aug 2021 23 Aug 2021	BBCH 83 BBCH 85	Tomato (fruit)	< LOD	3	Outdoor LOD = 0.002 mg/kg LOQ = 0.01 mg/kg
CPRHU21-215-065IR/Hungary/N-EU/2021 Ják	Tomato/ Kecskeméti 549 field	27 May 2021 - 30 Aug 2021	20.73 21.80			17 Aug 2021 27 Aug 2021	BBCH 83 BBCH 85	Tomato (fruit)	< LOD < LOD < LOD	0 1 3	Outdoor LOD = 0.002 mg/kg LOQ = 0.01 mg/kg

A 2.1.3.7.3 Study 3

Comments of zRMS:	Trial 21SGS46-01/Poland/N-EU/2021, Kaczkowo ((Kujawsko-Pomorskie), Zip code:88-400 is not consider in the assessment as not independent to trial 21SGS50-01/Poland/N-EU/2021, Trial 21SGS46-02/Poland/N-EU/2021 is acceptable.

Reference:	KCP 8.3.29
Report	Magnitude of the residues of lambda-cyhalothrin in tomato (raw agricultural commodity) after two applications of lambda cyhalothrin 2.5% WG – one harvest and one decline curve trial in Poland - 2021. T. Peda, 2022, Report No. 21SGS46 (Field phase)

Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029Nl/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

MATERIALS
Test material: Lambda cyhalothrin 2.5% WG
Batch #: SCL-34762
Actual content: Lambda cyhalothrin 2.6% (w/w)
CAS #: 91465-08-6

Test Commodity/Crop: Tomato
Crop parts(s) or processed: Fruit without calyx

STUDY DESIGN AND METHODS
The objective of the study was to generate specimens of tomato (Raw Agricultural Commodity) after two applications of Lambda cyhalothrin 2.5% WG under cultural practice typical for tomato production.
Lambda cyhalothrin 2.5% WG was mixed only with water, no adjuvant was added to the spray mixture. The target dose rate of the test item at each application according to Study Plan was 0.8 kg/ha, equivalent to 20 g a. s./ha. Target water volume for each application was 200-1000 l/ha according to Good Agricultural Practice.
RAC specimens were shipped deep frozen at a target temperature below -18°C to the following analytical laboratory: InHort lnstytut Ogrodnictwa - Panstwowy lnstytut Badawczy, Zaktad Badania Bezpieczeristwa Zywnosci ul. Pomologiczna 138, 96-100 Skierniewice Poland.

Reference:	KCP 8.3.30
Report	Determination of the magnitude of the residues of lambda-cyhalothrin in tomato (raw agricultural commodity) after two applications of lambda cyhalothrin 2.5% WG – one harvest and one decline curve trial in Poland - 2021. A. Markowicz,

	2022, Report No. 21/FSL/08/4PL3 (Analytical phase)
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 repeating Council Directives 79/117/EEC and 91/414/EEC EC Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830, Rev.1, (2021) OECD: Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17, (2007)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues lambda-Cyhalothrin in tomato (fruit without calyx) samples taken from the field trials, after two applications of LAMBDA CYHALOTHRIN 2.5% WG, under open field conditions. To achieve the objective appropriate analytical method for determination of lambda-Cyhalothrin in target matrix was used. The reference method was validated for head cabbage as representative high-water content matrix in accordance to the guidance document: SANTE/2020/12830, Rev.1 of the European Commission. The validated limit of quantification is 0.01 mg/kg.

The general principles of the analytical procedure were based on the normalized method EN 15662:2018. In brief, samples of tomato were extracted with acetonitrile. After addition of a buffer-salt mixture containing magnesium sulphate, sodium chloride and sodium citrate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulphate addition.

Quantification was performed by use of highly selective gas chromatography coupled with tandem mass spectrometry (GC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention time of analyte in extracts corresponds to that of the calibration standard with a tolerance of < ± 0.1 min. Confirmation ion ratio for lambda-Cyhalothrin in all samples were within ± 30 % of the average found for the standards. Determination was performed using matrix-matched calibration standards.

SAMPLE EXTRACTION

- 10 g ± 0.1 g of homogenized tomato was weighed into a 50 mL Teflon® centrifuge tube. Sample weight was recorded.
- If necessary, fortification of the concurrent recovery sample(s) by aliquoting the fortification standard onto the matrix was carried out at this step. The tube was shaken in a vortex mixer for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	Matrix	Concentration (µg/mL) of lambda-Cyhalothrin	Volume used (µL)
LOQ (0.01 mg/kg)	Tomato (fruit without calyx)	1	100

– Using glass volumetric pipettes 10 mL of acetonitrile were added.
– The Teflon® centrifuge tube was closed tightly and shaken vigorously by QuEChERS Hand Motion Shaker for 1 min.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION
The limit of quantification (LOQ) was established at 0.01 mg/kg for lambda-Cyhalothrin, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for tomato.

ACCURACY AND PRECISION
The mean recovery values at the fortification level of 0.01 mg/kg for both ion mass transitions were all in the range 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, Rev.1 of the European Commission. All precision values at the fortification level of 0.01 mg/kg for both ion mass transitions were < 20%.

Table A 28: Summary of the study 3 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalothrin		
21SGS46-01/Poland/N-EU/2021 Kaczkowo ((Kujawsko-Pomorskie) Zip code:88-400	Tomato/Dyne field	28/05/2021 - 22/08/2021	20.2 19.6			09/08/2021 19/08/2021	BBCH 83 BBCH 85	Fruit without calyx	< LOQ (0.0064)	3	Outdoor LOD = 0.002 mg/kg LOQ = 0.01 mg/kg
21SGS46-02/Poland/N-EU/2021 Chwastnica (Dolnośląskie) Zip code: 55-216	Tomato/Asterix field	20/05/2021 - 23/08/2021	20.2 19.7			11/08/2021 20/08/2021	BBCH 83 BBCH 85	Fruit without calyx	0.015 0.015 < LOQ (0.0076)	0 1 3	Outdoor LOD = 0.002 mg/kg LOQ = 0.01 mg/kg

A 2.1.3.7.4 Study 4

Comments of zRMS:	Study KCP 8.3.31 is not considered in the assessment as not independent to study KCP 8.3.27.

Reference:	KCP 8.3.31
Report	Determination of the residues of lambda cyhalothrin in/on tomato after two applications of lambda cyhalothrin 2.5 % WG in northern Europe - Hungary in 2021. G. Wágner, 2022, Report No. 065CPRHU21R04 (Field phase)
Guideline(s):	Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC) No. 1107/2009 of the European Parliament Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

MATERIALS
Test material: Lambda cyhalothrin 2.5% WG
Batch #: SCL-34762
Actual content: Lambda cyhalothrin 2.6% (w/w)
CAS #: 91465-08-6

Test Commodity/Crop: Tomato
Crop parts(s) or processed: Tomato (fruit)

STUDY DESIGN AND METHODS
Lambda cyhalothrin 2.5 % WG is an insecticide developed by Sharda Cropchem Ltd. for pest control in different crops. The objective of this study is to provide results from the magnitude of residues of lambda cyhalothrin in/on tomato 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 2021. The field phase was performed in Kőszeg (CPRHU21-208-065IR) and in Ják (CPRHU21-209-065IR).
Two applications (first at 10 days before application 2, second at 3 days before harvest, at BBCH 85) of the formulated product Lambda cyhalothrin 2.5 % WG (containing nominal concentration of 2.5 % lambda cyhalothrin) were applied at a rate of 0.8 kg formulated product/ha (20 g active ingredient/ha) onto the crop, under open field condition.
Specimens (fruit) were collected at 0, 1 and 3 (NCH) days after last application (DALA) in decline trial and at 3 DALA in harvest trial, frozen and shipped deep

frozen to analytical facility of Food Safety Laboratory, Research Institute of Horticulture for residue analysis.

Reference:	KCP 8.3.32
Report	Determination of the residues of lambda-cyhalothrin in/on tomato after two applications of lambda cyhalothrin 2.5% WG in northern Europe – Hungary in 2021. A. Markowicz, 2022, Report No. 21/FSL/08/4HU3 (Analytical phase)
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 repeating Council Directives 79/117/EEC and 91/414/EEC EC Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830, Rev.1, (2021) OECD: Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17, (2007)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues lambda-Cyhalothrin in tomato (fruit) samples taken from the field trials, after two applications of LAMBDA CYHALOTHRIN 2.5% WG, under open field conditions. To achieve the objective appropriate analytical method for determination of lambda-Cyhalothrin in target matrix was used. The reference method was validated for head cabbage as representative high-water content matrix in accordance to the guidance document: SANTE/2020/12830, Rev.1 of the European Commission. The validated limit of quantification is 0.01 mg/kg.

The general principles of the analytical procedure were based on the normalized method EN 15662:2018. In brief, samples of tomato were extracted with acetonitrile. After addition of a buffer-salt mixture containing magnesium sulphate, sodium chloride and sodium citrate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulphate addition.

Quantification was performed by use of highly selective gas chromatography coupled with tandem mass spectrometry (GC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention time of analyte in extracts corresponds to that of the calibration standard with a tolerance of < ± 0.1 min. Confirmation ion ratio for lambda-Cyhalothrin in all samples were within ± 30 % of the average found for the standards. Determination was performed using matrix-matched calibration standards.

SAMPLE EXTRACTION

- 10 g ± 0.1 g of homogenized tomato was weighed into a 50 mL Teflon® centrifuge tube. Sample weight was recorded.
- If necessary, fortification of the concurrent recovery sample(s) by aliquoting the fortification standard onto the matrix was carried out at this step. The tube was shaken in a vortex mixer for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	Matrix	Concentration	Volume used

		(µg/mL) of lambda-Cyhalothrin	(µL)
LOQ (0.01 mg/kg)	Tomato (fruit)	1	100

– Using glass volumetric pipettes 10 mL of acetonitrile were added.
– The Teflon® centrifuge tube was closed tightly and shaken vigorously by QuEChERS Hand Motion Shaker for 1 min.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION
The limit of quantification (LOQ) was established at 0.01 mg/kg for lambda-Cyhalothrin, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for tomato.

ACCURACY AND PRECISION
The mean recovery values at the fortification level of 0.01 mg/kg for both ion mass transitions were all in the range 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, Rev.1 of the European Commission. All precision values at the fortification level of 0.01 mg/kg for both ion mass transitions were < 20%.

Table A 29: Summary of the study 4 trials

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: g a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): Lambda cyhalothrin	PHI (days) (d)	Details on trial (e)
CPRHU21-208-065IR/Hungary/N-EU/2021 Kőszeg	Tomato/ Kecskeméti Jubileum field	28 May 2021 - 26 Aug 2021	19.01 20.62			13 Aug 2021 23 Aug 2021	BBCH 83 BBCH 85	Tomato (fruit)	< LOQ (0.0052)	3	Outdoor LOD = 0.002 mg/kg LOQ = 0.01 mg/kg
CPRHU21-209-065IR/Hungary/N-EU/2021 Ják	Tomato/ Kecskeméti 549 field	26 May 2021 - 30 Aug 2021	19.12 20.28			17 Aug 2021 27 Aug 2021	BBCH 83 BBCH 85	Tomato (fruit)	0.012 < LOQ (0.0090) < LOQ (0.0079)	0 1 3	Outdoor LOD = 0.002 mg/kg LOQ = 0.01 mg/kg

A 2.1.3.7.5 Study 5

Comments of zRMS:	Field phase is accepted (protected conditions). Acceptable validated in accordance to the guidance document: SAN-

	TE/2020/12830, Rev.1, (2021) method was used. Trials are independent and acceptable with regard to storage stability data. Study is accepted.

Reference:	KCP 8.3.33
Report	Magnitude of the residues of lambda cyhalothrin in tomato (raw agricultural commodity) after two applications of lambda cyhalothrin 10% CS under protected conditions – one harvest and one decline curve trial in Poland - 2021. T. Peda, 2022, Report No. 21SGS51 (Field phase)
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029Nl/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

MATERIALS
Test material: Lambda cyhalothrin 10% CS
Batch #: SCL-34763
Actual content: Lambda cyhalothrin 10.2% (w/v)
CAS #: 91465-08-6

Test Commodity/Crop: Tomato
Crop parts(s) or processed: Fruits without calvx

STUDY DESIGN AND METHODS
The objective of the study was to generate specimens of tomato (Raw Agricultural Commodity) after two applications of Lambda cyhalothrin 10% CS under cultural practice typical for tomato production in protected conditions.

Lambda cyhalothrin 10% CS was mixed only with water, no adjuvant was added to the spray mixture. The target dose rate of the test item at each application according to Study Plan was 0.2 l/ha, equivalent to 20 g a. s./ha. Target water volume for each application was 200-1000 l/ha according to Good Agricultural Practice.
RAC specimens were shipped deep frozen at a target temperature below -18°C to the following analytical laboratory: InHort lnstytut Ogrodnictwa - Panstwowy lnstytut Badawczy, Zaktad Badania Bezpieczeristwa Zywnosci ul. Pomologiczna 138, 96-100 Skierniewice Poland.

Reference:	KCP 8.3.34
Report	Determination of the magnitude of the residues of lambda-cyhalothrin in tomato (raw agricultural commodity) after two applications of lambda cyhalothrin 10% CS under protected conditions – one harvest and one decline curve trial in Poland - 2021. A. Markowicz, 2022, Report No. 21/FSL/08/4PL2 (Analytical phase)
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 repeating Council Directives 79/117/EEC and 91/414/EEC EC Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830, Rev.1, (2021) OECD: Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17, (2007)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS
The objective of this study was to determine the decline and the magnitude of residues lambda-Cyhalothrin in tomato (fruit without calyx) samples taken from the field trials, after two applications of LAMBDA CYHALOTHRIN 10% CS, under open field conditions. To achieve the objective appropriate analytical method for determination of lambda-Cyhalothrin in target matrix was used. The reference method was validated for head cabbage as representative high-water content matrix in accordance to the guidance document: SANTE/2020/12830, Rev.1 of the European Commission. The validated limit of quantification is 0.01 mg/kg.
The general principles of the analytical procedure were based on the normalized method EN 15662:2018. In brief, samples of tomato were extracted with acetonitrile. After addition of a buffer-salt mixture containing magnesium sulphate, sodium chloride and sodium citrate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulphate addition.
Quantification was performed by use of highly selective gas chromatography coupled with tandem mass spectrometry (GC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention time of analyte in extracts corresponds to that of the calibration standard with a tolerance of < ± 0.1 min. Confirmation ion ratio for lambda-Cyhalothrin in all samples were within ± 30 % of the average found for the standards. Determination was performed using matrix-matched calibration standards.

SAMPLE EXTRACTION
- 10 g ± 0.1 g of homogenized tomato was weighed into a 50 mL Teflon® centrifuge tube. Sample weight was recorded.

– If necessary, fortification of the concurrent recovery sample(s) by aliquoting the fortification standard onto the matrix was carried out at this step. The tube was shaken in a vortex mixer for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	Matrix	Concentration (µg/mL) of lambda-Cyhalothrin	Volume used (µL)
LOQ (0.01 mg/kg)	Tomato (fruit without calyx)	1	100

– Using glass volumetric pipettes 10 mL of acetonitrile were added.
– The Teflon® centrifuge tube was closed tightly and shaken vigorously by QuEChERS Hand Motion Shaker for 1 min.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION
The limit of quantification (LOQ) was established at 0.01 mg/kg for lambda-Cyhalothrin, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for tomato.

ACCURACY AND PRECISION
The mean recovery values at the fortification level of 0.01 mg/kg for both ion mass transitions were all in the range 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, Rev.1 of the European Commission. All precision values at the fortification level of 0.01 mg/kg for both ion mass transitions were < 20%.

Table A 30: Summary of the study 5 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat-ment or no. of treatments and last date (c)	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalo-thrin		

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: g a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): Lambda cyhalothrin	PHI (days) (d)	Details on trial (e)
21SGS51-01/Poland/N-EU/2021 Piskorzówek (Dolnośląskie) Zip-code: 55-216	Tomato/Clarosa protected	22/06/2021 - 03/10/2021	20.1 19.8			20/09/2021 30/09/2021	BBCH 83 BBCH 85	Fruit without calyx	0.021	3	Indoor LOD = 0.002 mg/kg LOQ = 0.01 mg/kg
21SGS51-02/Poland/N-EU/2021 Zamarłe (Kujawsko-Pomorskie) Zip-code: 89-430	Tomato/Honey moon protected	07/05/2021 - 03/09/2021	19.1 19.7			20/08/2021 31/08/2021	BBCH 79-81 BBCH 85	Fruit without calyx	0.064 0.044 0.031	0 1 3	Indoor LOD = 0.002 mg/kg LOQ = 0.01 mg/kg

A 2.1.3.7.6 Study 6

Comments of zRMS:	Field phase is accepted (protected conditions). Acceptable validated in accordance to the guidance document: SANTE/2020/12830, Rev.1, (2021) method was used. Trials are independent and acceptable with regard to storage stability data. Study is accepted.

Reference:	KCP 8.3.35
Report	Determination of the residues of lambda cyhalothrin in/on indoor tomato after two applications of lambda cyhalothrin 10 % CS in northern Europe - Hungary in 2021. G. Wágner, 2022, Report No. 065CPRHU21R08 (Field phase)
Guideline(s):	Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC) No. 1107/2009 of the European Parliament Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)

Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

MATERIALS
Test material: Lambda cyhalothrin 10% CS
Batch #: SCL-34763
Actual content: Lambda cyhalothrin 10.2% (w/v)
CAS #: 91465-08-6

Test Commodity/Crop: Tomato
Crop parts(s) or processed: Tomato (fruit)

STUDY DESIGN AND METHODS
Lambda cyhalothrin 10 % CS is an insecticide developed by Sharda Cropchem Ltd. for pest control in different crops. The objective of this study is to provide results from the magnitude of residues of lambda cyhalothrin in/on indoor tomato, grown in protected conditions, 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 2021. The field phase was performed in trial location (CPRHU21-216- 065IR) and in trial location (CPRHU21-217-065IR).
Two applications (first at 10 days before application 2, second at 3 days before harvest, at BBCH 85) of the formulated product Lambda cyhalothrin 10 % CS were applied at a rate of 0.2 L formulated product/ha (20 g active ingredient of lambda cyhalothrin/ha) onto the crop, under indoor condition.
Specimens (fruit) were collected 0, 1 and 3 (NCH) days after last application (DALA) in decline trial and at 3 days after last application (DALA) in harvest trial, frozen and shipped deep frozen to analytical facility of Food Safety Laboratory Research Institute of Horticulture for residue analysis.

Reference:	KCP 8.3.36
Report	Determination of the residues of lambda-cyhalothrin in/on indoor tomato after two applications of lambda cyhalothrin 10% CS in northern Europe – Hungary in 2021. A. Markowicz, 2022, Report No. 21/FSL/08/4HU2 (Analytical phase)
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 repeating Council Directives 79/117/EEC and 91/414/EEC EC Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830, Rev.1, (2021)

	OECD: Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17, (2007)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues lambda-Cyhalothrin in tomato (fruit) samples taken from the field trials, after two applications of LAMBDA CYHALOTHRIN 10% CS, under open field conditions. To achieve the objective appropriate analytical method for determination of lambda-Cyhalothrin in target matrix was used. The reference method was validated for head cabbage as representative high-water content matrix in accordance to the guidance document: SANTE/2020/12830, Rev.1 of the European Commission. The validated limit of quantification is 0.01 mg/kg.

The general principles of the analytical procedure were based on the normalized method EN 15662:2018. In brief, samples of tomato were extracted with acetonitrile. After addition of a buffer-salt mixture containing magnesium sulphate, sodium chloride and sodium citrate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulphate addition.

Quantification was performed by use of highly selective gas chromatography coupled with tandem mass spectrometry (GC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention time of analyte in extracts corresponds to that of the calibration standard with a tolerance of < ± 0.1 min. Confirmation ion ratio for lambda-Cyhalothrin in all samples were within ± 30 % of the average found for the standards. Determination was performed using matrix-matched calibration standards.

SAMPLE EXTRACTION

- 10 g ± 0.1 g of homogenized tomato was weighed into a 50 mL Teflon® centrifuge tube. Sample weight was recorded.
- If necessary, fortification of the concurrent recovery sample(s) by aliquoting the fortification standard onto the matrix was carried out at this step. The tube was shaken in a vortex mixer for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	Matrix	Concentration (µg/mL) of lambda-Cyhalothrin	Volume used (µL)
LOQ (0.01 mg/kg)	Tomato (fruit)	1	100

- Using glass volumetric pipettes 10 mL of acetonitrile were added.
- The Teflon® centrifuge tube was closed tightly and shaken vigorously by QuEChERS Hand Motion Shaker for 1 min.

LIMIT OF QUANTIFICATION AND LIMIT OF DETEECTION

The limit of quantification (LOQ) was established at 0.01 mg/kg for lambda-Cyhalothrin, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for tomato.

ACCURACY AND PRECISION

The mean recovery values at the fortification level of 0.01 mg/kg for both ion mass transitions were all in the range 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, Rev.1 of the European Commission. All precision values at the fortification level of 0.01 mg/kg for both ion mass transitions were < 20%.

Table A 31: Summary of the study 6 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat-ment or no. of treatments and last date	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalo-thrin		
	(a)	(b)				(c)				(d)	(e)
CPRHU21-216-065IR/Hungary/N-EU/2021 KÖSZEG ZIP CODE: 9730	Tomato/Lugas F1 protected	05 Jun 2021 - 19 Aug 2021	19.73 20.53			06 Aug 2021 16 Aug 2021	BBCH 83 BBCH 85	Tomato (fruit)	< LOD	3	Indoor LOD = 0.002 mg/kg LOQ = 0.01 mg/kg
CPRHU21-217-065IR/Hungary/N-EU/2021 SZATYMAZ ZIP CODE: 6763	Tomato/Lugas F1 protected	22 Apr 2021 - 19 Aug 2021	20.38 19.42			06 Aug 2021 16 Aug 2021	BBCH 83 BBCH 85	Tomato (fruit)	< LOD < LOD < LOD	0 1 3	Indoor LOD = 0.002 mg/kg LOQ = 0.01 mg/kg

Table A 32: Summary of the study in EU (DAR 1996, RAR 2013)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat-ment or no. of treatments and last date	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalo-thrin		
	(a)	(b)				(c)				(d)	(e)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat-ment or no. of treatments and last date	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Lambda cyhalo-thrin		
	(a)	(b)				(c)				(d)	(e)
RJ1626B/Italy/S-EU/1983	Tomato/HP244		20			2			0.02	2	Indoor
RJ1626B/Italy/S-EU/1983	Tomato/UC 82		20			2			0.01	2	Indoor
RJ1626B/Italy/S-EU/1983	Tomato/Red Setter		20			2			0.01	2	Indoor
RJ1626B/Italy/S-EU/1983	Tomato/Red Setter		20			2			0.01	2	Indoor
AF/4162/France/N-EU/1998	Tomato/Pegase	10.06.1998 - 28.08.1998	18 18	879 886	2 2	11.08.1998 21.08.1998	BBCH 79 BBCH 81	Fruit	<0.01 <0.01	3 7	Indoor
AF/4162/France/N-EU/1998	Tomato/Palmiro	12.03.1998 - 04.08.1998	20 20	998 1002	2 2	16.07.1998 28.07.1998	BBCH 73 BBCH 79-81	Fruit	0.02 0.02	3 7	Indoor

A 2.1.4 Magnitude of residues in livestock

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

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

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

A 2.1.6 Magnitude of residues in representative succeeding crops

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

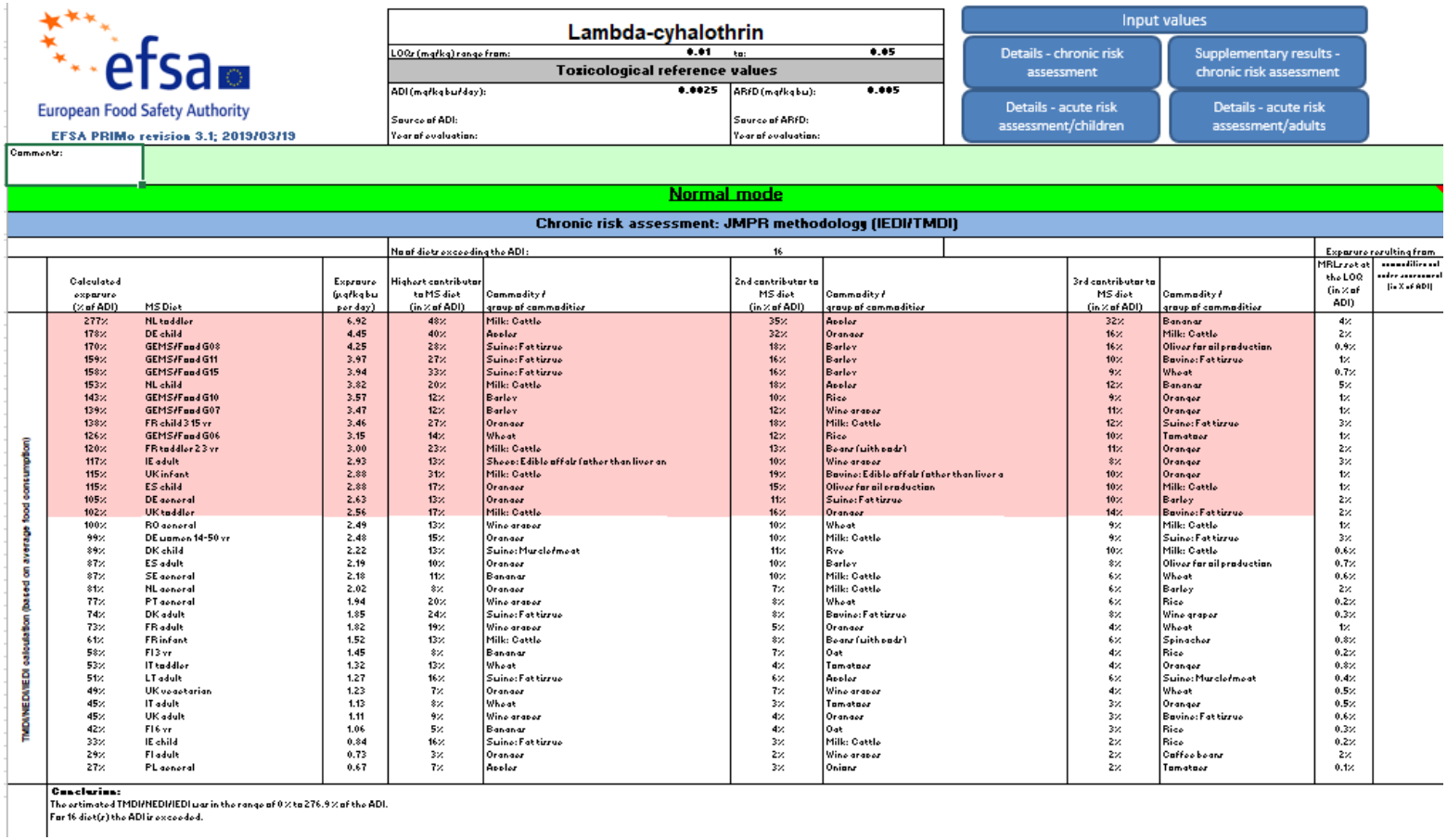
A 2.1.7 Other/Special Studies

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

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Chronic risk assessment calculated with EFSA PRIMo model for Lambda-cyhalothrin using MRLs Reg. (EU) 2021/590.



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

Lambda-cyhalothrin

LOQr (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw/day):	0.0025	ARfD (mg/kg bw):	0.005
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: 16

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg b.w. 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)
	277%	NL toddler	6.92	48%	Milk: Cattle	35%	Apples	32%	Bananas	4%	
	178%	DE child	4.45	40%	Apples	32%	Oranges	16%	Milk: Cattle	2%	
	170%	GEMS/Food G08	4.25	28%	Suine: Fat tissue	18%	Barley	16%	Olives for oil production	0.9%	
	159%	GEMS/Food G11	3.97	27%	Suine: Fat tissue	16%	Barley	10%	Bovine: Fat tissue	1%	
	158%	GEMS/Food G15	3.94	33%	Suine: Fat tissue	16%	Barley	9%	Wheat	0.7%	
	153%	NL child	3.82	20%	Milk: Cattle	18%	Apples	12%	Bananas	5%	
	143%	GEMS/Food G10	3.57	12%	Barley	10%	Rice	9%	Oranges	1%	
	139%	GEMS/Food G07	3.47	12%	Barley	12%	Wine grapes	11%	Oranges	1%	
	138%	FR child 3 15 yr	3.46	27%	Oranges	18%	Milk: Cattle	12%	Suine: Fat tissue	3%	
	126%	GEMS/Food G06	3.15	14%	Wheat	12%	Rice	10%	Tomatoes	1%	
	120%	FR toddler 2 3 yr	3.00	23%	Milk: Cattle	13%	Beans (with pods)	11%	Oranges	2%	
	117%	IE adult	2.93	13%	Sheep: Edible offals (other than liver an	10%	Wine grapes	8%	Oranges	3%	
	115%	UK infant	2.88	31%	Milk: Cattle	19%	Bovine: Edible offals (other than liver a	10%	Oranges	1%	
	115%	ES child	2.88	17%	Oranges	15%	Olives for oil production	10%	Milk: Cattle	1%	
	105%	DE general	2.63	13%	Oranges	11%	Suine: Fat tissue	10%	Barley	2%	
	102%	UK toddler	2.56	17%	Milk: Cattle	16%	Oranges	14%	Bovine: Fat tissue	2%	
	100%	RO general	2.49	13%	Wine grapes	10%	Wheat	9%	Milk: Cattle	1%	
	99%	DE women 14-50 yr	2.48	15%	Oranges	10%	Milk: Cattle	9%	Suine: Fat tissue	3%	
	89%	DK child	2.22	13%	Suine: Muscle/meat	11%	Rye	10%	Milk: Cattle	0.6%	
	87%	ES adult	2.19	10%	Oranges	10%	Barley	8%	Olives for oil production	0.7%	
	87%	SE general	2.18	11%	Bananas	10%	Milk: Cattle	6%	Wheat	0.6%	
	81%	NL general	2.02	8%	Oranges	7%	Milk: Cattle	6%	Barley	2%	
	77%	PT general	1.94	20%	Wine grapes	8%	Wheat	6%	Rice	0.2%	
	74%	DK adult	1.85	24%	Suine: Fat tissue	8%	Bovine: Fat tissue	8%	Wine grapes	0.3%	
	73%	FR adult	1.82	19%	Wine grapes	5%	Oranges	4%	Wheat	1%	
	61%	FR infant	1.52	13%	Milk: Cattle	8%	Beans (with pods)	6%	Spinaches	0.8%	
	58%	FI 3 yr	1.45	8%	Bananas	7%	Oat	4%	Rice	0.2%	
	53%	IT toddler	1.32	13%	Wheat	4%	Tomatoes	4%	Oranges	0.8%	
	51%	LT adult	1.27	16%	Suine: Fat tissue	6%	Apples	6%	Suine: Muscle/meat	0.4%	
	49%	UK vegetarian	1.23	7%	Oranges	7%	Wine grapes	4%	Wheat	0.5%	
	45%	IT adult	1.13	8%	Wheat	3%	Tomatoes	3%	Oranges	0.5%	
	45%	UK adult	1.11	9%	Wine grapes	4%	Oranges	3%	Bovine: Fat tissue	0.6%	
	42%	FI 6 yr	1.06	5%	Bananas	4%	Oat	3%	Rice	0.3%	
	33%	IE child	0.84	16%	Suine: Fat tissue	3%	Milk: Cattle	2%	Rice	0.2%	
	29%	FI adult	0.73	3%	Oranges	2%	Wine grapes	2%	Coffee beans	2%	
	27%	PL general	0.67	7%	Apples	3%	Onions	2%	Tomatoes	0.1%	

Conclusion:
The estimated TMDI/NEDI/IEDI is in the range of 0 % to 276.9 % of the ADI.
For 16 diet(s) the ADI is exceeded.

A 3.2 IEDI calculations

Lambda-cyhalothrin

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw/day):	0.0025	ARfD (mg/kg bw):	0.005
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: ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (mg/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)
83%	NL toddler	2.08	24%	Milk: Cattle	9%	Apples	6%	Spinach	1%	
54%	UK infant	1.34	19%	Bovine: Edible offal (other than liver and l	15%	Milk: Cattle	5%	Rice	0.2%	
46%	GEMS/Food G10	1.14	10%	Rice	7%	Soybeans	3%	Sugar canes	0.4%	
45%	NL child	1.13	10%	Milk: Cattle	5%	Apples	3%	Sugar beet roots	0.8%	
43%	DE child	1.07	10%	Apples	8%	Milk: Cattle	2%	Rice	0.7%	
42%	GEMS/Food G06	1.06	12%	Rice	3%	Sugar canes	3%	Wheat	0.5%	
42%	GEMS/Food G11	1.04	7%	Soybeans	4%	Sugar canes	3%	Milk: Cattle	0.9%	
41%	GEMS/Food G08	1.03	4%	Soybeans	4%	Sunflower seeds	4%	Olives for oil production	0.5%	
39%	FR child 3 15 yr	0.97	9%	Milk: Cattle	4%	Rice	3%	Bovine: Muscle/meat	0.7%	
39%	IE adult	0.97	13%	Sheep: Edible offal (other than liver and k	2%	Rice	2%	Milk: Cattle	0.9%	
38%	FR toddler 2 3 yr	0.96	12%	Milk: Cattle	5%	Rice	3%	Beans (with pods)	0.5%	
38%	GEMS/Food G15	0.94	4%	Sunflower seeds	3%	Soybeans	3%	Milk: Cattle	0.3%	
37%	GEMS/Food G07	0.93	4%	Soybeans	3%	Sunflower seeds	3%	Sugar canes	0.6%	
33%	UK toddler	0.82	8%	Milk: Cattle	5%	Bovine: Edible offal (other than liver and	5%	Rice	0.2%	
31%	ES child	0.79	5%	Milk: Cattle	4%	Rice	3%	Olives for oil production	0.3%	
30%	SE general	0.75	9%	Bovine: Muscle/meat	5%	Milk: Cattle	3%	Rice	0.2%	
28%	RO general	0.71	5%	Sunflower seeds	5%	Milk: Cattle	2%	Wheat	0.0%	
26%	DK child	0.66	5%	Milk: Cattle	3%	Swine: Muscle/meat	3%	Bovine: Muscle/meat	0.0%	
23%	DE general	0.58	5%	Milk: Cattle	2%	Apples	2%	Barley	0.4%	
23%	NL general	0.57	3%	Milk: Cattle	2%	Sunflower seeds	1%	Bovine: Muscle/meat	0.6%	
22%	DE women 14-50 yr	0.54	5%	Milk: Cattle	2%	Apples	2%	Sugar beet roots	0.4%	
22%	PT general	0.54	6%	Rice	2%	Sunflower seeds	2%	Potatoes	0.1%	
21%	ES adult	0.53	2%	Milk: Cattle	2%	Rice	2%	Olives for oil production	0.2%	
21%	FR adult	0.53	3%	Bovine: Edible offal (other than liver and l	2%	Swine: Edible offal (other than liver and l	2%	Wine grapes	0.5%	
20%	FR infant	0.49	7%	Milk: Cattle	2%	Spinach	2%	Beans (with pods)	0.1%	
16%	FI 3 yr	0.41	4%	Rice	2%	Oat	2%	Potatoes	0.2%	
12%	LT adult	0.30	2%	Rice	2%	Milk: Cattle	1%	Apples	0.1%	
12%	UK adult	0.30	3%	Rice	1%	Bovine: Muscle/meat	1%	Milk: Cattle	0.1%	
12%	IT toddler	0.30	3%	Wheat	2%	Rice	1%	Tomatoes	0.7%	
12%	FI 6 yr	0.30	3%	Rice	2%	Potatoes	1%	Oat	0.3%	
12%	DK adult	0.30	2%	Milk: Cattle	1%	Bovine: Muscle/meat	1%	Swine: Muscle/meat	0.0%	
12%	UK vegetarian	0.29	3%	Rice	1%	Milk: Cattle	0.8%	Wheat	0.1%	
11%	IT adult	0.26	2%	Wheat	1%	Rice	0.9%	Tomatoes	0.5%	
8%	FI adult	0.20	2%	Coffee beans	1%	Rice	0.5%	Oat	2%	
7%	IE child	0.17	2%	Rice	1%	Milk: Cattle	0.5%	Swine: Fat tissue	0.0%	
6%	PL general	0.16	2%	Apples	1%	Potatoes	0.7%	Tomatoes	0.1%	

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

A 3.3 IESTI calculations - Raw commodities

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 27

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
530%	Oranges	0.2 / 0.2	27
437%	Bovine: Edible offals	3 / 3	22
315%	Mangoes	0.2 / 0.2	16
314%	Grapefruits	0.2 / 0.2	16
291%	Bananas	0.15 / 0.15	15
285%	Peaches	0.15 / 0.15	14
271%	Spinaches	0.6 / 0.6	14
237%	Mandarins	0.2 / 0.2	12
222%	Pears	0.08 / 0.08	11
193%	Chinese cabbages/pe-tsai	0.3 / 0.3	9.6
182%	Melons	0.06 / 0.06	9.1
180%	Swine: Edible offals (other	3 / 3	9.0
172%	Apples	0.08 / 0.08	8.6
169%	Plums	0.2 / 0.2	8.4
150%	Aubergines/egg plants	0.3 / 0.3	7.5

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 28

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): 9

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
199%	Bovine: Edible offals	3 / 3	10.0
162%	Aubergines/egg plants	0.3 / 0.3	8.1
157%	Swine: Edible offals (other	3 / 3	7.8
152%	Chinese cabbages/pe-tsai	0.3 / 0.3	7.6
126%	Head cabbages	0.15 / 0.15	6.3
123%	Oranges	0.2 / 0.2	6.1
122%	Swine: Fat tissue	3 / 3	6.1
112%	Florence fennels	0.3 / 0.3	5.6
104%	Mangoes	0.2 / 0.2	5.2
95%	Wine grapes	0.2 / 0.2	4.7
76%	Chards/beet leaves	0.2 / 0.2	3.8
72%	Mandarins	0.2 / 0.2	3.6
72%	Grapefruits	0.2 / 0.2	3.6
71%	Plums	0.2 / 0.2	3.6
70%	Courgettes	0.15 / 0.15	3.5

Chronic consumer risk assesment after the refinement with input values from EFSA 2015 with GAPs under assessment is presented below.

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)
81%	Cauliflowers	0.1 / 0.07	4.1
80%	Head cabbages	0.15 / 0.09	4.0
58%	Tomatoes	0.07 / 0.05	2.9
10%	Barley	0.5 / 0.09	0.51
3%	Brussels sprouts	0.04 / 0.02	0.17
3%	Wheat	0.05 / 0.01	0.14
2%	Oat	0.3 / 0.09	0.10
1%	Rye	0.05 / 0.01	0.06
0.3%	Rapeseeds/canola seeds	0.2 / 0.01	0.01

Expand/collapse list

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)
76%	Head cabbages	0.15 / 0.09	3.8
32%	Cauliflowers	0.1 / 0.07	1.6
16%	Tomatoes	0.07 / 0.05	0.79
9%	Barley	0.5 / 0.09	0.44
2%	Brussels sprouts	0.04 / 0.02	0.12
2%	Wheat	0.05 / 0.01	0.08
1%	Oat	0.3 / 0.09	0.06
1.0%	Rye	0.05 / 0.01	0.05
0.1%	Rapeseeds/canola seeds	0.2 / 0.01	0.01

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

A 3.4 IESTI calculations - Processed commodities

Processed commodities

Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			11	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			2
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)
272%	Florence fennels / boiled	0.3 / 0.3	14	135%	Celeries / boiled	0.2 / 0.2	6.8
211%	Oranges / juice	0.2 / 0.2	11	116%	Florence fennels / boiled	0.3 / 0.3	5.8
175%	Wine grapes / juice	0.2 / 0.2	8.7	99%	Spinaches / frozen; boiled	0.6 / 0.6	5.0
167%	Spinaches / frozen; boiled	0.6 / 0.6	8.3	83%	Cauliflowers / boiled	0.1 / 0.1	4.2
158%	Broccoli / boiled	0.1 / 0.1	7.9	83%	Wine grapes / juice	0.2 / 0.2	4.2
139%	Cauliflowers / boiled	0.1 / 0.1	7.0	72%	Barley / beer	0.5 / 0.1	3.6
124%	Chards/beet leaves / boilec	0.2 / 0.2	6.2	69%	Courgettes / boiled	0.15 / 0.15	3.4
114%	Currants (red, black and	0.2 / 0.2	5.7	66%	Pumpkins / boiled	0.06 / 0.06	3.3
106%	Pumpkins / boiled	0.06 / 0.06	5.3	60%	Oranges / juice	0.2 / 0.2	3.0
106%	Courgettes / boiled	0.15 / 0.15	5.3	53%	Apples / juice	0.08 / 0.08	2.7
100%	Beans (with pods) / boiled	0.4 / 0.4	5.0	51%	Currants (red, black and	0.2 / 0.2	2.6
93%	Escaroles/broad-leaved er	0.07 / 0.07	4.6	50%	Chards/beet leaves /	0.2 / 0.2	2.5
87%	Apples / juice	0.08 / 0.08	4.3	48%	Broccoli / boiled	0.1 / 0.1	2.4
80%	Leeks / boiled	0.07 / 0.07	4.0	43%	Grapefruits / juice	0.2 / 0.2	2.2
78%	Peaches / canned	0.15 / 0.15	3.9	38%	Wine grapes / wine	0.2 / 0.2	1.9
Expand/collapse list							

Acute consumer risk assesment after the refinement with input values from EFSA 2015 with GAPs under assessment is presented below.

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)
97%	Cauliflowers / boiled	0.1 / 0.07	4.9
8%	Tomatoes / juice	0.07 / 0.02	0.38
7%	Oat / boiled	0.3 / 0.09	0.33
7%	Barley / cooked	0.5 / 0.09	0.33
5%	Oat / milling (flakes)	0.3 / 0.09	0.27
4%	Brussels sprouts / boiled	0.04 / 0.02	0.20
4%	Tomatoes / sauce/puree	0.07 / 0.02	0.19
3%	Head cabbages / canned	0.15 / 0.03	0.17
3%	Barley / milling (flour)	0.5 / 0.09	0.16
2%	Wheat / milling (flour)	0.05 / 0.01	0.12
1%	Wheat / milling (wholemeal)-	0.05 / 0.01	0.06
0.7%	Rye / boiled	0.05 / 0.01	0.04
0.7%	Rye / milling (wholemeal)-ba	0.05 / 0.01	0.04
0.1%	Rapeseeds / oils	0.2 / 0.02	0.01
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

Expand/collapse list

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)
58%	Cauliflowers / boiled	0.1 / 0.07	2.9
13%	Barley / beer	0.5 / 0.02	0.65
6%	Head cabbages / canned	0.15 / 0.03	0.28
3%	Tomatoes / sauce/puree	0.07 / 0.02	0.16
3%	Oat / boiled	0.3 / 0.09	0.14
0.9%	Wheat / bread/pizza	0.05 / 0.01	0.04
0.8%	Wheat / pasta	0.05 / 0.01	0.04
0.7%	Wheat / bread (wholemeal)	0.05 / 0.01	0.03
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

Appendix 4 Additional information provided by the applicant