

# FINAL REGISTRATION REPORT

## **Part B**

### **Section 7**

#### **Metabolism and Residues**

Detailed summary of the risk assessment

Product code: SHA 0100 Y

Product name: Decide

Chemical active substance:

Deltamethrin, 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### **CORE ASSESSMENT**

Applicant: Sharda Cropchem España S.L.

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## Version history

When	What
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## 7 Metabolism and residue data (KCA section 6)

### 7.1 Summary and zRMS Conclusion

#### **Storage stability**

EFSA conclusion (EFSA Journal 2015;13(11):4309): Storage stability of deltamethrin was demonstrated at -20 °C for a period of 24 months in high water content commodities (cabbage, lettuce and tomatoes) and at -12°C for 30 months in high oil content commodities (cotton seed) and for 9 month in dry/high starch commodities (cereals grain) (Sweden, 1998).

The available data were considered sufficient to conclude on the storage stability of deltamethrin in acidic matrices (EFSA Journal 2015;13(11):4309)

#### **Metabolism in plants and animals**

The metabolism of deltamethrin in primary crops following foliar treatment has been investigated in fruits and fruiting vegetables (apples and tomatoes), pulses and oilseeds (cotton seed and leaves) and cereals (corn).

The metabolism of deltamethrin in rotational crops – carrots, lettuce, spinach, radishes, barley - has been evaluated during the peer review.

The metabolism of deltamethrin was studied with laying hens, and lactating cows

Endpoints:

Plant and animal residue definition for monitoring (Regulation n°2018/832): deltamethrin (cis-deltamethrin))

Plant and animal residue definition for risk assessment (RD-RA): Sum of deltamethrin and its alpha-R isomer and trans-isomer (tentative).

No further data are required to support the proposed uses.

#### **Magnitude of residues in plants**

##### **Brassicas (cabbage, brussels sprouts, cauliflowers)**

Proposed GAP: BBCH 11-43; 1 application, 0.0075 kg as/ha, PHI: 7 days

Cauliflower belongs to Flowering brassicas group

Cabbage and brussels sprouts belongs to Head brassicas group

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

Residue trials on cauliflowers from NEU are available (7 trials below LOQ). Number of trials is sufficient as results are below 0.01 mg/kg.

GAP on which EU a.s. assessment is based: 3 x 7.5g as/ha, interval: 14 days, PHI 7d, outdoor (NEU)

Residues: 2 x <0.005, 5 x <0.01 mg/kg.

The residues arising from the proposed use on cauliflowers will not exceed the MRL established for cauliflower (0.1 mg/kg, Reg. (EU) 2018/832)

Extrapolation to head brassica is not possible (SANCO 7525/VI/95\_rev 10.3)

Proposed use on cauliflowers is accepted.

Proposed uses on cabbage and brussels sprouts are not accepted. Residue trials are required.

##### **Strawberry**

Proposed GAP: BBCH 11-81 1 application, 0.0075 as/ha, PHI: 3 days

6 NEU residue trials on strawberries are available (DAR addendum of deltamethrin).

GAP on which EU a.s. assessment is based: 2 x 12.5 g a.s./ha, PHI 3d, outdoor

Residues: 4 x < 0.02, 0.02, 0.03

Eight trials are required for a major crop such as strawberry.

Two new trials were conducted in Hungary in 2020 and two in Poland (2020).

Hungary:

Trials GAP: 3 x 12.5 g a.s./ha, PHI 3d, outdoor

Residues; 2 x <0.01 mg/kg

Poland:

Trials GAP: 3 x 12.5 g a.s./ha, PHI 3d, outdoor

Residues: 2 x <0.01 mg/kg

Trials are overdosed but acceptable because all the results are below LOQ.

Number of available trials is sufficient. The residues arising from the proposed use will not exceed the MRL established for strawberry (0.2 mg/kg, Reg. (EU) 2018/832). Use is accepted.

#### Tomato (field and greenhouse uses)

Proposed GAP: BBCH 11-81 1 application, 0.0075 kg as/ha, PHI: 3 days

#### Greenhouse uses

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

NEU residue trials on indoor tomatoes are available.

GAP on which EU a.s. assessment is based: 4 x 12.5 g a.s./ha, PHI 3d, indoor

Residues: 2 x <0.01, 3x0.01, 0.013, 0.014, 0.03 mg/kg

The residues arising from the proposed use on indoor tomatoes will not exceed the MRL (0.07 mg/kg, Reg. (EU) 2018/832).

Greenhouse use is accepted.

#### Field use

4 NEU residue trials on tomatoes in the open field are summarized in the DAR addendum of deltamethrin. Residues: <0.01, 2x0.01, 0.03 mg/kg

Three new trials were conducted in Hungary and three in Poland in 2020 under open field condition.

Trials GAP: 3 x 12.5 g a.s./ha, PHI 3d, outdoor

Residues: 6 x <0.01 mg/kg

The residues arising from the proposed use on outdoor tomatoes will not exceed the MRL (0.07 mg/kg, Reg. (EU) 2018/832).

Field use is accepted.

#### Ornamentals

No data is required.

#### **Magnitude of residues in livestock**

The requested uses do not modify the theoretical maximum daily intake for animals, therefore there is no risk for animal MRL to be exceeded.

#### **Processing studies**

Data/information on processing studies was reviewed during the approval of active substance and were considered acceptable.

#### **Magnitude of residues in representative succeeding crops**

The available data for the active substance sufficiently addresses aspects of the residue situation that might arise from the use of Deltamethrin 5% CS. Therefore, other special studies are not needed.

#### **Consumer risk assessment**

The accepted uses of Deltamethrin in the formulation Deltamethrin 5% Cs do not represent an unacceptable acute and chronic risks for the consumer. EFSA PRIMo rev.3.1 calculation was done.

Since no information on the residues of the two additional metabolites included in the risk assessment residue definition was available, the risk assessment values (i.e. the supervised trials median residue and the highest residue), were multiplied by the tentative conversion factor of 1.25 derived in the framework of the MRL review for vegetables.

Risk assessment is tentative because of the following elements (*EFSA Journal 2018;16(1):5153, EFSA Journal 2020;18(10):6271*):

- use of conversion factor for risk assessment instead of information on the actual occurrence of residues of trans-deltamethrin and alpha-R-deltamethrin;
- lack of information on the toxicological profile of trans-deltamethrin and alpha-R-deltamethrin;

- *lack of information on the metabolism of trans-deltamethrin and alpha-R-deltamethrin in livestock;*
- *adequate livestock feeding studies in cows and hens, investigating all relevant tissues and matrices according to the residue definitions for monitoring and risk assessment simultaneously.*

Residues in crops under consideration are minor contributors to the overall chronic consumer exposure. The short-term consumer exposure for the intended uses did not exceed the toxicological reference value.

### 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 Deltamethrin 5% CS are presented in Table 7.1-1. They have been selected from the individual GAPs in the CEU. A list of all intended uses within the SEU is given in Part B, Section 0.

#### Justification for the selection of the critical GAP

#### Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for Deltamethrin as laid down in Reg. (EU) 396/2005 is not expected.

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

As far as consumer health protection is concerned, authority, zRMS agrees with the authorization of the intended use(s) on cauliflowers, greenhouse tomatoes and ornamentals.

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

#### Data gaps

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

Noticed data gaps are:

Noticed data gaps are:

- data gap 1  
Cabbage and brussels sprouts: residue trials

**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, 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		
1	Brassicas (cabbage, Brussels sprouts, cauliflowers)	CEU	Deltamethrin 5% CS	F	Aphids	CS	50 g/L	Foliar spray	BBCH 11- 43	1	-	0.00125- 0.00375	200-600	0.0075	7	A Cauliflowers N cabbage, Brussels sprouts
2	Brassicas (cabbage, Brussels sprouts, cauliflowers)	CEU	Deltamethrin 5% CS	F	Caterpillars	CS	50 g/L	Foliar spray	BBCH 11- 43	1	-	0.00125- 0.00375	200-600	0.0075	7	A Cauliflowers N cabbage, Brussels sprouts
3	Strawberry	CEU	Deltamethrin 5% CS	F	Aphids	CS	50 g/L	Foliar spray	BBCH 11- 81	1	-	0.00125- 0.00375	200-600	0.0075	3	A
4	Strawberry	CEU	Deltamethrin 5% CS	F	Lepidoptera	CS	50 g/L	Foliar spray	BBCH 11- 81	1	-	0.00125- 0.00375	200-600	0.0075	3	A
5	Tomato	CEU	Deltamethrin 5% CS	F	Aphids	CS	50 g/L	Foliar spray	BBCH 11- 85	1	-	0.00125- 0.00375	200-600	0.0075	3	A
6	Tomato	CEU	Deltamethrin 5% CS	G	Whitefly	CS	50 g/L	Foliar spray	BBCH 11- 85	1	-	0.00125- 0.00375	200-600	0.0075	3	A
7	Ornamentals	CEU	Deltamethrin 5% CS	F	Aphids	CS	50 g/L	Foliar spray	BBCH 10- 89	1	-	0.00125- 0.00375	200-600	0.0075	-	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 Deltamethrin 5% CS is composed of Deltamethrin.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Deltamethrin					
ADI	EU	2002	0.01 mg/kg bw/d	1-year dog 90 days dog	100
ArfD	EU	2002	As the ADI: 0.01 mg/kg bw/d	As the ADI: 1-year dog 90 days dog	As the ADI: 100

### 7.1.2.1 Summary for Deltamethrin

**Table 7.1-3: Summary for Deltamethrin**

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	Yes	<del>Yes</del> No	<del>NA</del> No	<del>Yes</del> No	<del>Yes</del> No	No	No
1, 2	Brussels sprouts	Yes	<del>Yes</del> No	<del>NA</del> No	<del>Yes</del> No	<del>Yes</del> No		No
1, 2	Cauliflower	Yes	Yes	NA	Yes	Yes		No
3, 4	Strawberry	Yes	Yes	NA	Yes	Yes		No
5, 6	Tomato	Yes	Yes	NA	Yes	Yes		No
7	Ornamentals	NA	NR	NR	NR	NR		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 Deltamethrin 5% CS

**Table 7.1-4: Information on Deltamethrin 5% CS (KCA 6.8)**

Crop	PHI for Deltamethrin 5% CS proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for Deltamethrin 5% CS proposed by zRMS	zRMS Comments (if different PHI proposed)
		Deltamethrin		
Cabbage	NR	<del>NR</del> No		No data
Brussels	NR	<del>NR</del> No		No data

Crop	PHI for Del- tamethrin 5% CS proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for Del- tamethrin 5% CS proposed by zRMS	zRMS Comments (if different PHI pro- posed)
		Deltamethrin		
sprouts				
Cauliflower	NR- 7	NR Yes		
Strawberry	NR 3	NR Yes		
Tomato	NR 3	NR Yes		
Ornamentals	NR	NR		

NR: not relevant

\* Purpose of withholding period to be specified

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

**Table 7.1-5: Waiting periods before planting succeeding crops**

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for Clomazone 36% CS
Crop group	Led by Clomazone	
Leafy crops	NR	
Root crops	NR	
Fruiting crops	NR	
Pulses and oilseeds	NR	
Cereal/Grass crops	NR	

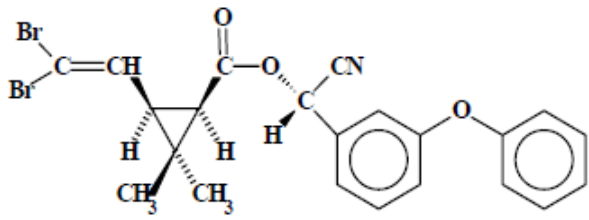
NR: not relevant

## Assessment

### 7.2 Deltamethrin

General data on Deltamethrin are summarized in the table below (last updated 2018/10/09).

**Table 7.2-1: General information on Deltamethrin**

Active substance (ISO Common Name)	Deltamethrin
IUPAC	(S)- $\alpha$ -cyano-3-phenoxybenzyl (1R, 3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate
Chemical structure	
Molecular formula	C <sub>22</sub> H <sub>19</sub> Br <sub>2</sub> NO <sub>3</sub>
Molar mass	505.2
Chemical group	Pyrethroids insecticide
Mode of action (if available)	It prevents the transmission of nervous impulses in harmful organisms thereby disrupting their nervous system.
Systemic	Yes
Companies	Hoechst Schering AgrEvo GmbH Aventis CropScience
Rapporteur Member State (RMS)	Original RMS: Sweden RMS: United-Kingdom Co-RMS: Austria
Approval status	Approved Date of (01/11/2003) and reference to decision (REGULATION (EU) No 2018/1262, (EU) No 540/2011 and (EU) No 823/2012) <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1262&amp;from=EN">https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1262&amp;from=EN</a> <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0540&amp;from=EN">https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0540&amp;from=EN</a> <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0823&amp;from=EN">https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0823&amp;from=EN</a>
Restriction	Only uses as insecticides may be authorised
Review Report	SANCO/6504/VI/99-final 17/10/2002
Current MRL regulation	Regulation (EC) No 2018/832
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes (EFSA Journal 2015;13(11):4309)
EFSA Journal: Conclusion on the peer review	No
EFSA Journal : conclusion on article 12	No

Current MRL applications on intended uses	EFSA-Q-2008-523 (EMS) Reasoned opinion available (EFSA Journal 2015;13(11):4309)
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\* 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  $\leq -18^{\circ}\text{C}$  (unless stated otherwise)**

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
<b>Data relied on in EU</b>			
<b>Plant products</b>			
Lettuce	High water content	8 months	Addendum to the Monograph, Annex B, 2002
Hops (and beer)	High oil content	5.5 months	Addendum to the Monograph, Annex B, 2002
Ginned cotton seeds	High oil content	38 months	Addendum to the Monograph, Annex B, 2002
Crude cotton oil (and soap stock)	High oil content	24 months	Addendum to the Monograph, Annex B, 2002
Cotton hull	High oil content	13 months	Addendum to the Monograph, Annex B, 2002
Corn, rice, sorghum and wheat grain	High starch content	9 months	Addendum to the Monograph, Annex B, 2002
<b>Animal Products</b>			
Poultry	Eggs	11 months	Addendum to the Monograph, Annex B, 2002
Poultry	Fat	11 months	Addendum to the Monograph, Annex B, 2002
Poultry	Muscle	11 months	Addendum to the Monograph, Annex B, 2002
Poultry	Liver, kindey	11 months	Addendum to the Monograph, Annex B, 2002
Ruminant	Milk	7 months	Addendum to the Monograph, Annex B, 2002

#### Conclusion on stability of residues during storage

Conclusions drawn from Deltamethrin – Addendum to Monograph Annex B, 2002 are reported below:  
*In the monograph it was concluded that stability studies had shown that deltamethrin was stable (no significant degradation, > 30%) under deep frozen conditions below  $-12^{\circ}\text{C}$  to  $-27^{\circ}\text{C}$ . The samples and stor-*

age periods were hops and beer (5.5 months), ginned cottonseed (38 months), cottonseed hull (13 months), crude cottonseed oil (24 months), grains (9 months) and poultry tissues and eggs (11-13 months). The storage time of lettuce (8 months) can now be added.

### 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 Deltamethrin.

## 7.2.2 Nature of residues in plants, livestock and processed commodities

### 7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

#### Available data

No new data submitted in the framework of this application.

**Table 7.2-3: Summary of plant metabolism studies**

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Apple	<sup>14</sup> C-dimethyl and <sup>14</sup> C-benzyl	foliar treatment, F	0.06 kg as/ha	2	28	-	(Periasamy et al., 1994) DAR, 1998
	Tomatoes	<sup>14</sup> C-gem dimethyl and <sup>14</sup> C-benzyl	foliar treatment, G	0.05 kg as/ha	2	4, 14, 28	-	(Merrick and North, 1985), DAR, 1998
Cereals	Field corn	<sup>14</sup> C-dimethyl and <sup>14</sup> C-benzyl	foliar treatment, F	0.112 kg as/ha	2	0, 14, 42	-	(Periasamy et al., 1994) DAR, 1998
Pulses and oilseeds/leafy vegetables	Cotton	<sup>14</sup> C-gem-dimethyl and <sup>14</sup> C-benzyl	Foliar treatment, F	0.224 kg as/ha	2	4, 10, 28	-	(O’Grodnick and Larson, 1990) Ad-dendum to Monograph Annex B, 2002

### Summary of plant metabolism studies reported in the EU

Conclusions drawn from DAR, 1998 are reported below:

*The major compound found in apples or rinses was the unmetabolized deltamethrin, with varying amounts of αR and trans-isomers present. Metabolites were each <0.01 mg/kg and < 10% of TRR. The*

*proposed degradation pathway consists of isomerisation, hydrolysis, ester cleavage, reduction, oxidation and hydroxylation.*

*In forage, foliage and husk, 80-100% of total residues was deltamethrin (4-20 mg/kg) or deltamethrin-isomers ( $\alpha$ R or trans). Minor metabolites were generally  $\leq 0.01$  mg/kg. Grain and cob contained only minor total residues ( $\leq 0.06$  mg/kg). A large part (32% and 59%) of the radioactivity in grain was not extracted.*

*28 days after spraying, parent deltamethrin constituted more than 79% of the residues in tomatoes. Minor residues were each less than 0.5%.*

Conclusions drawn from Deltamethrin – Addendum to the Monograph Annex B, 2002 are reported below:

*The residues found as  $> 10\%$  were deltamethrin ( $\alpha$ R-deltamethrin) and (trans-deltamethrin). No other components greater than 10% of  $^{14}\text{C}$ -residues were found in any matrix. The study is considered representative for the 'leafy crop' group.*

### Conclusion on metabolism in primary crops

Conclusion drawn from Deltamethrin – Addendum to the Monograph Annex B, 2002 are reported below:

*The following studies showed that parent deltamethrin was the main residue and that the degradation was similar in these crops: Field studies at exaggerated GAP (apple, field corn, tomato and cotton).*

*The major identified products of deltamethrin metabolism in plants are analogous to those in mammals but differ in the conjugated moieties involved. The proposed degradation pathway consists of isomerisation, hydrolysis, ester cleavage, reduction, oxidation and hydroxylation.*

*It is concluded that the submitted studies give sufficient information to propose a definition of the residue in plants, as deltamethrin. The definition proposed in the monograph and agreed at ECCO 83 is thus confirmed.*

### 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	<sup>14</sup> C-benzyl	Spraying, F	10 x 0.045 kg as/ha	30, 120	Half maturity and normal terminal harvest	-	(Erstfeld, Larson and Lange, 1991) DAR, 1998
	Spinach		Spraying, F	1 x 0.1175 kg as/ha	0	At maturity	-	(Krebs, Eickhoff and Raquet, 1986) DAR, 1998
Root and tuber vegetables	Carrots	<sup>14</sup> C-benzyl	Spraying, F	10 x 0.045 kg as/ha	30, 120	Half maturity and normal	-	(Erstfeld, Larson and Lange,

						terminal hervest		1991) DAR, 1998
			Spraying, F	1 x 0.1175 kg as/ha	0	At maturity	-	(Krebs, Eickhoff and Raquet, 1986) DAR, 1998
	Radishes		Spraying, F	1 x 0.1175 kg as/ha	0	At maturity	-	(Krebs, Eickhoff and Raquet, 1986) DAR, 1998
<b>Cereals</b>	Barley	<sup>14</sup> C- benzyl	Spraying, F	10 x 0.045 kg as/ha	30, 120	Half maturity and normal terminal hervest	-	(Erstfeld, Larson and Lange, 1991) DAR, 1998

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

### Summary of plant metabolism studies reported in the EU

Conclusions drawn from DAR, 1998 are reported below:

*Following the final of 10 applications of deltamethrin to soil, the decrease in radioactivity (deltamethrin equivalents) was 41% after 30 days and 63% after 120 days).*

*The only residues in soil, spinach, carrots or radishes ( $\geq 0.01$  mg/kg) following soil application of deltamethrin were in soil from the spinach field on the treatment day (0.02 mg/kg) and 28 days later (0.01 mg/kg)*

### Conclusion on metabolism in rotational crops

Conclusions drawn from DAR, 1998 are reported below:

*With the exception of barley straw, no significant residues ( $>0.01$  mg/kg) were found in edible parts of succeeding 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
<b>EU data</b>		
<b>Pasteurisation</b> (20 minutes, 90°C, pH 4)	Parent (from 91 to 97%), mPBaldehyde (0.9 to 5.2%)	(Maurer, 2001) Addendum to the Monograph Annex B
<b>Baking, boiling, brewing</b> (60 minutes, 100°C, pH 5)	Parent (from 91 to 97%), mPBaldehyde (0.9 to 5.2%)	(Maurer, 2001) Addendum to the Monograph Annex B
<b>Sterilisation</b> (20 minutes, 120°C, pH 6)	mPBaldehyde (59 to 75%), BR <sub>2</sub> CA (39 to 47%)	(Maurer, 2001) Addendum to the



Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
		Monograph Annex B

### Conclusion on nature of residues in processed commodities

Conclusions drawn from Deltamethrin – Addendum to the Monograph annex B, 2002 are reported below:  
*The results of the study showed that under simulated pasteurisation (90°C, pH 4, 20 minutes), brewing, baking and boiling (100°C, pH 5, 60 minutes), deltamethrin is stable. The parent compound represented 91 to 97% of the applied radioactivity remaining after hydrolysis. Very small quantities, 0.9 to 5.2% of the applied radioactivity remaining after hydrolysis. Very small quantities; 0.9 to 5.2% of applied radioactivity, of a plant metabolite (mPBaldehyde) were detected.*

*Results of the sterilisation process (120°C, pH6, 20 minutes) showed that deltamethrin was degraded under this condition mainly to two metabolites: mPBaldehyde and BR<sub>2</sub>CA. The former was detected in quantities from 59 to 75% and the latter one in quantities from 39 to 47% of applied radioactivity. These two substances are well known plant metabolites and none of them is considered as a relevant residue.*

### 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 fruitng vegetable (apple, tomato) Grain vegetables (corn) Pulses and oilseeds/Leafy vegetables (cotton)
Rotational crops covered	Leafy vegetables (lettuce, spinach) Root and tuber vegetables (carrots and radishes) Cereals (barley)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Deltmethrin is stable under pasteurisation nad boling/brewing/baking. Under sterilisation deltamethrin represented 21-48% of the AR and degraded mainly into two metabolites.
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Deltamethrin ( <i>cis</i> -deltamethrin) (Regulation n°2018/832)
Plant residue definition for risk assessment	Deltamethrin (DAR, 1998)
Conversion factor from enforcement to RA	-

### 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	Cow	<sup>14</sup> C-gem-dimethyl and <sup>14</sup> C-benzyl	2	10 mg/kg b/d	3 days	Milk	twice daily	(Akhtar and al., 1986) DAR, 1998
						Urine and faeces	daily	
						Tissues	at sacrifice	
		<sup>14</sup> C-gem-dimethyl and <sup>14</sup> C-benzyl	2	1.64 mg/kg bw and 1.58 mg/kg	3 days	Milk	twice daily	(Struble and Singh, 1990) Addendum to Monograph Annex B, 2002
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	<sup>14</sup> C-gem-dimethyl and <sup>14</sup> C-benzyl	4	7.5 mg/hen/d	3 days	Eggs	daily	(Akhtar and al., 1985) DAR, 1998
						Excreta	daily	
						Tissues	at sacrifice	

### Summary of plant metabolism studies reported in the EU

Conclusion drawn from DAR, 1998 are reported below:

*In livestock metabolism studies with cows and chickens, metabolites were present in significant amounts. In edible tissues from cows, major residues (>10% of TRR) besides deltamethrin (23-90% TRR), were Br2CA and Pbacid. In chickens, deltamethrin was 19-65% TRR, and identified major metabolites in kidneys were c-Br2CA and c- and t-COOH-c-Br2CA (together 22% TRR), and c-CH2OH-c-Br2CA, and t-COOH-c-CH2OH-c-Br2CA-lactone (together 15-22% TRR), and an unidentified polar component (0-18% TRR).*

*The basic metabolic reactions were cleavage of the ester bond, by oxidation and/or hydrolysis, followed by oxidation of both acid and alcohol moieties. The acid moiety (Br2CA) was transformed into conjugates chiefly in the form of glucuronide and excreted in urine. It could also be hydroxylated at one of the gem-methyl groups, which is in turn conjugated and excreted. The unstable alcohol moiety was transformed via the aldehyde into the acid (Pbacid). Pbacid undergoes further oxidation by hydroxylation of aromatic rings and then extensively excreted in urine mainly as the 4OH sulphate conjugate. Minor metabolic pathways lead to some hydroxylated parent compounds which are found with intact deltamethrin in faeces. In contrast no intact deltamethrin nor compound bearing the ester bond can be found in urine. Thus complete ester cleavage and extensive conjugation of released oxidised moieties are required prior to excretion in urine. The cyano group is mainly converted to thiocyanate and also to ITCA by reaction with ysteine (fig. 6.2.a).*

*The major metabolism pathways leading to the metabolites excreted were the same in rats and cows.*

### Conclusion on metabolism in livestock

Conclusions drawn from DAR, 1998 are reported below:

*In livestock, several metabolites were identified in liver and kidney of cow, and in kidney of hen. Recovery from muscle was low in both species. No regular toxicity studies were supplied by the notifier on the me-*

*tabolite residues (Pbacid and cBr2CA in cow and cBr2CA, c/t-COOH-cBr2CA, cCH2OH-cBr2CA and tCOOH-c-CH2OH-c-Br2CA-lactone), although they should be regarded as relevant residues due to their relatively high prevalence in the tissue. However, the deltamethrin metabolites are, in similarity with metabolites of other pyrethroid with similar structures, regarded as being considerably less toxic than the parent compound. This is to some extent supported by LD50 data. The notifier has also submitted unpublished data on Br2CA, indicating negative results in genotoxicity tests (mouse micronucleus test and Ames test) and oral LD50 values in male and female rats of 1682 and > 2000 mg/kg body weight, respectively.*

*Due to the generally recognised decrease in toxicity by biotransformation of the pyrethroids, we conclude that the residue in livestock should be defined as deltamethrin, despite the lack of properly conducted toxicity studies of the metabolites.*

Conclusion drawn from Deltamethrin – Addendum to Monograph Annex B, 2002 are reported below:  
*The definition of the residue in the monograph, deltamethrin alone is confirmed.*

#### **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 cow
	Laying hens
Time needed to reach a plateau concentration	2 days (eggs).
Animal residue definition for monitoring	Deltamethrin ( <i>cis</i> -deltamethrin) (Regulation n°2018/832)
Animal residue definition for risk assessment	Deltamethrin (DAR, 1998)
Conversion factor	-
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes (log Pow = 4.6)

## 7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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

**Table 7.2-9: Summary of EU reported and new data supporting the intended uses of Deltamethrin 5% CS 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
Strawberry	New trials	N-EU	Trials GAP: 3 x 12.5 g a.s./ha, PHI 3d, outdoor 2 x <LOQ, 2 x n.d. 4 x <0.01					
	List of endpoints, 2002	N-EU	GAP on which EU a.s. assessment is based: 2 x 12.5 g a.s./ha, PHI 3d, outdoor RA: 4 x < 0.02, 0.02, 0.03	N/A				
	List of endpoints, 2002	S-EU	GAP on which EU a.s. assessment is based: 3 x 12.5 g a.s./ha, PHI 3d, outdoor RA: <0.01, 2 x 0.02, 0.025, 3 x 0.03, 0.04, 0.05, 0.06, 0.085					
		EU	RA: 2 x n.d. 3 x <0.01 5 x <0.01, 4 x <0.02, 3 x 0.02, 0.025, 4 x 0.03, 0.04, 0.05, 0.06, 0.085	0.03 0.02	0.085	-	0.2	Yes
Tomato (outdoor)	New trials	N-EU	Trials GAP: 3 x 12.5 g a.s./ha, PHI 3d, outdoor 6 x n.d. 6 x <0.01					
	List of endpoints, 2002	N-EU	GAP on which EU a.s. assessment is based: 3 x 12.5 g a.s./ha, PHI 3d outdoor RA: <0.01, 2 x 0.01, 0.03	N/A				
	List of endpoints, 2002	S-EU	GAP on which EU a.s. assessment is based: 3 x 12.5 g a.s./ha, PHI 3d outdoor					

			RA: 0.009, 0.01, 8 x <0.02					
		EU	RA: <del>6 x n.d.</del> 6 x <0.01 0.009, <0.01, 3 x 0.01, 8 x <0.02, 0.03	<del>0.02</del> 0.01	0.03	-	0.07	Yes
Tomato (indoor)	List of endpoints, 2002	EU	GAP on which EU a.s. assessment is based: 4 x 12.5 g a.s./ha, PHI 3d, indoor RA: 2 x <0.01, 3x0.01, 0.013, 0.014, 0.03	0.01	0.03	-	0.07	Yes
Brassicas (cauliflowers)	List of endpoints, 2002	N-EU	GAP on which EU a.s. assessment is based: 3 x 7.5 g as/ha, , PHI 7d, outdoor RA: 2 x <0.005, 5 x <0.01	N/A				
	List of endpoints, 2002	S-EU	GAP on which EU a.s. assessment is based: 2 x 12.5 g as/ha, PHI 7d, outdoor RA: 6 x <0.02					
		EU	RA: 2 x <0.005, 5 x <0.01, 6 x <0.02	0.01	0.02	-	0.1	Yes

\* Source of EU MRL: Reg. (EU) 2018/832

### 7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on strawberry, tomato and brassicas are considered acceptable, for outdoor use (and indoor uses for tomato).

Based on residue trials on tomatoes in/on field and greenhouses, it can be assumed that there is no significant differences between residue levels, therefore results in outdoor and indoor conditions can be considered as comparable.

Residue trials on cabbage are on-going.

### 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 (the uses under consideration)**

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cabbage	0.03	STMR <sub>Mo</sub> x CF	0.08	HR <sub>Mo</sub> x CF

**Table 7.2-11: Results of the dietary burden calculation – considering intended uses (pesticides\_mrl\_guidelines\_animal\_model\_2017)**

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)
Cattle (all diets)	0.002	0.004	Cabbage, heads (leaves)	0.11	Y
Cattle (dairy only)	0.002	0.004	Cabbage, heads (leaves)	0.11	Y
Sheep (all diets)	0.001	0.002	Cabbage, heads (leaves)	0.05	N
Sheep (ewe only)	0.001	0.002	Cabbage, heads (leaves)	0.05	N
Swine (all diets)	0.000	0.001	Cabbage, heads (leaves)	0.05	N
Poultry (all diets)	0.001	0.002	Cabbage, heads (leaves)	0.03	N
Poultry (layer only)	0.001	0.002	Cabbage, heads (leaves)	0.03	N

**Table 7.2-12: Results of the dietary burden calculation - EFSA Journal 2015;13(11):4309**

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)
Dairy ruminants	0.086	0.099	Kale	2.8	Y
Meat ruminants	0.102	0.110	Wheat grain	2.6	Y
Poultry	0.076	0.116	Wheat grain	1.8	Y
Pigs	0.077	0.089	Wheat grain	2.2	Y

#### 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 7.2-13: Overview of the values derived from livestock feeding studies**

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) <sup>(b)</sup>	Highest residue (mg/kg) <sup>(c)</sup>	Calculated MRL (mg/kg)	CF for RA <sup>(d)</sup>
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) <sup>(a)</sup>	No	Result for enforce-ment		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (DAR, 1998 and Addendum to Monograph Annex B, 2002)												
Ruminant meat	0.102	0.110	0.07	3	< 0.01	0.01	n.r.	n.r.		0.01	Not proposed	-
			0.20	3	< 0.01	< 0.01	n.r.	n.r.				
			0.60	3	< 0.01	0.01	n.r.	n.r.				
Ruminant fat			0.07	3	0.04	0.04	n.r.	n.r.		0.04	Not proposed	-
			0.20	3	0.02	0.02	n.r.	n.r.				
			0.60	3	0.03	0.03	n.r.	n.r.				
Ruminant liver			0.07	3	< 0.01	0.01	n.r.	n.r.		0.01	Not proposed	-
			0.20	3	< 0.01	< 0.01	n.r.	n.r.				
			0.60	3	< 0.01	0.01	n.r.	n.r.				
Ruminant kidney			0.07	3	< 0.01	0.01	n.r.	n.r.		0.01	Not proposed	-
			0.20	3	< 0.01	< 0.01	n.r.	n.r.				
			0.60	3	< 0.01	0.01	n.r.	n.r.				
Poultry meat	0.076	0.116	0.093	20	< 0.02	< 0.02	n.r.	n.r.		0.02	Not proposed	-
			0.275	20	< 0.02	< 0.02	n.r.	n.r.				
			0.927	20	< 0.02	< 0.02	n.r.	n.r.				
Poultry fat			0.093	20	< 0.05	< 0.05	n.r.	n.r.		0.553	Not proposed	-
			0.275	20	0.258	0.258	n.r.	n.r.				



			0.927	20	0.553	0.553	n.r.	n.r.				
<b>Poultry liver</b>			0.093	20	< 0.02	< 0.02	n.r.	n.r.		0.02	Not proposed	-
			0.275	20	< 0.02	< 0.02	n.r.	n.r.				
			0.927	20	< 0.02	< 0.02	n.r.	n.r.				
<b>Milk</b>	0.086	0.099	0.07	3	0.02 <sup>(e)</sup>	N/A	n.r.	n.r.		0.03	Not proposed	-
			0.20	3	0.01 <sup>(e)</sup>	N/A	n.r.	n.r.				
			0.60	3	0.03 <sup>(e)</sup>	N/A	n.r.	n.r.				
<b>Eggs</b>	0.076	0.116	0.093	20	< 0.015	< 0.015	n.r.	n.r.		0.037	Not proposed	-
			0.275	20	0.018	0.018	n.r.	n.r.				
			0.927	20	0.037	0.037	n.r.	n.r.				

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

n.r.: Not reported

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

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

(a): Based on a 550 kg animal consuming 17.5 kg feed DM/day.

(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 1 until day 3 (3 cows, 2 sampling days).

## Conclusion on feeding studies

The requested uses (or the new mode of calculation) do not modify the theoretical maximum daily intake for animals, therefore 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 7.2-14: Overview of the available processing studies**

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
<b>EU data</b>					
Strawberry, jam	-	0.67	1.25		List of endpoints, 2002; Addendum to the Monograph Annex B, 2002 and DAR, 1998
Peaches, syrup	-	0.25	1.25		
Apricots, syrup	-	0.33	1.25		
Cherries, syrup	-	< 0.01	1.25		
Leek, cooked	-	0.85	1.25		
Aubergines, cooked	-	< 0.01	1.25		
Lettuce, cooked	-	0.5	1.25		
Spinach, cooked	-	0.75	1.25		
Haricot verts, cooked	-	0.5	1.25		
Peas, cooked	-	0.5	1.25		
Carrot, cooked	-	< 0.01	1.25		
Artichokes, cooked	1	0.33	1.25		
Apples, wet pomace	1	5.7	1.25		
Apples, juice	1	0.09	1.25		
Tomatoes, dry pomace	1	7	1.25		
Tomatoes, wet pomace, puree, ketchup, paste, juice	1	< 1	1.25		
Tomatoes, paste	1	0.4	1.25		
Tomatoes, puree	1	0.4	1.25		
Pulses, cooked	1	0.1	1.25		
Hops, beverages	1	0.01	1.25		
Tea, beverage	1	0.01	1.25		
Potatoes, peeled	1	0	1.25		
Potatoes, washed	2	0.86	1.25		
Potatoes, cooked	4	0.62	1.25		

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
Coffee, roasted	1	0	1.25		
Wheat/flour, bread	1	0.2	1.25		
Barley/malt, beer	1	0	1.25		
Maize, oil	1	20	1.25		
Rape seed/oil	1	10	1.25		
Soya bean/oil	1	10	1.25		
Sunflower seed/oil	1	10	1.25		
Olives/oil	1	1.6	1.25		

\* 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

Conclusions drawn from DAR, 1998 are reported below:

*Peeling of potatoes, preparation of white flour, and cooking of pulses removes more than 80% of the residues. The submitted studies were published papers with limited background information.*

Conclusions drawn from Addendum to the Monograph Annex B, 2002 are reported below:

*No concentration occurred in processing tomatoes to puree and paste. In processing apples to wet pomace and juice, it was found that deltamethrin-derived residues were concentrated by a factor of 5.7 between apples and wet pomace, while no concentration occurred in the apple juice process.*

### 7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

#### 7.2.6.1 Field rotational crop studies (KCA 6.6.2)

##### Available data

No new data submitted in the framework of this application.

##### Conclusion on rotational crops studies

Conclusions drawn from DAR, 1998 are reported below:

*Following the final of 10 applications of deltamethrin to soil, the decrease in radioactivity (deltamethrin equivalents) was 41% after 30 days, and 63% after 120 days.*

*The only residues in soil, spinach, carrots or radishes (<0.01 mg/kg) following soil application of deltamethrin were in soil from the spinach field on the treatment day (0.02 mg/kg) and 28 days later (0.01 mg/kg).*

*With the exception of barley straw, no significant residues (>0.01 mg/kg) were found in edible parts of succeeding crops.*

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

The available data for the active substance sufficiently addresses aspects of the residue situation that might arise from the use of Deltamethrin 5% CS. Therefore, other special studies are not needed.

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

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

### 7.2.8.1 Input values for the consumer risk assessment

**Table 7.2-15: Input values for the consumer risk assessment (Art. 12 - EFSA Journal 2015;13(11):4309) without consideration of the existing CXLs**

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Citrus fruits	0.01	STMR <sub>M0</sub> x CF (tentative)
Pome fruits	0.04	STMR <sub>M0</sub> x CF (tentative)
Apricots	0.03	STMR <sub>M0</sub> x CF (tentative)
Cherries	0.04	STMR <sub>M0</sub> x CF (tentative)
Peaches	0.03	STMR <sub>M0</sub> x CF (tentative)
Plums	0.01	STMR <sub>M0</sub> x CF (tentative)
Table and wine grapes	0.08	STMR <sub>M0</sub> x CF (tentative)
Strawberries	0.03	STMR <sub>M0</sub> x CF (tentative)
Cane fruit	0.03	STMR <sub>M0</sub> x CF (tentative)
Other small fruits and berries	0.10	STMR <sub>M0</sub> x CF (tentative)
Table olives	0.26	STMR <sub>M0</sub> x CF (tentative)
Kiwi	0.03	STMR <sub>M0</sub> x CF (tentative)
Potatoes	0.02	STMR <sub>M0</sub> x PF x CF (tentative)
Garlic	0.03	STMR <sub>M0</sub> x CF (tentative)
Onions	0.03	STMR <sub>M0</sub> x CF (tentative)
Shallots	0.03	STMR <sub>M0</sub> x CF (tentative)
Spring onions	0.07	STMR <sub>M0</sub> x CF (tentative)
Tomatoes	0.03	STMR <sub>M0</sub> x CF (fall-back, tentative)
Peppers	0.04	STMR <sub>M0</sub> x CF (tentative)
Aubergines (egg plants)	0.07	STMR <sub>M0</sub> x CF (tentative)
Cucurbits edible peel	0.03	STMR <sub>M0</sub> x CF (tentative)
Cucurbits inedible peel	0.03	STMR <sub>M0</sub> x CF (tentative)
Sweet corn	0.03	STMR <sub>M0</sub> x CF (tentative)
Flowering brassica	0.03	STMR <sub>M0</sub> x CF (tentative)
Head cabbage	0.03	STMR <sub>M0</sub> x CF (tentative)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Chinease cabbage	0.02	STMR <sub>M0</sub> x CF (tentative)
Kale	0.40	STMR <sub>M0</sub> x CF (tentative)
Lamb's lettuce	0.43	STMR <sub>M0</sub> x CF (tentative)
Lettuce	0.19	STMR <sub>M0</sub> x CF (fall-back, tentative)
Scarole (broad-leaf endive)	0.04	STMR <sub>M0</sub> x CF (fall-back, tentative)
Cress	0.43	STMR <sub>M0</sub> x CF (tentative)
Land cress	0.43	STMR <sub>M0</sub> x CF (tentative)
Rocket, Rucola	0.43	STMR <sub>M0</sub> x CF (tentative)
Red mustard	0.43	STMR <sub>M0</sub> x CF (tentative)
Leaves and sprouts of Brassica	0.33	STMR <sub>M0</sub> x CF (tentative)
Witloof	0.03	STMR <sub>M0</sub> x CF (tentative)
Herbs	0.43	STMR <sub>M0</sub> x CF (tentative)
Beans (fresh, with pods)	0.02	STMR <sub>M0</sub> x CF (tentative)
Beans (fresh, without pods)	0.03	STMR <sub>M0</sub> x CF (tentative)
Peas (fresh, with pods)	0.02	STMR <sub>M0</sub> x CF (tentative)
Peas (fresh, without pods)	0.02	STMR <sub>M0</sub> x CF (tentative)
Lentils (fresh)	0.02	STMR <sub>M0</sub> x CF (tentative)
Celery	0.06	EU MRL x CF
Globe artichokes	0.07	STMR <sub>M0</sub> x CF (tentative)
Leek	0.07	STMR <sub>M0</sub> x CF (tentative)
Cultivated fungi	0.03	STMR <sub>M0</sub> x CF (tentative)
Pulses	0.25	STMR <sub>M0</sub> x CF (tentative)
Poppy seed	0.06	STMR <sub>M0</sub> x CF (tentative)
Sesame seed	0.01	STMR <sub>M0</sub> x CF (tentative)
Rape seed	0.06	STMR <sub>M0</sub> x CF (tentative)
Mustard seed	0.06	STMR <sub>M0</sub> x CF (tentative)
Cotton seed	0.01	STMR <sub>M0</sub> x CF (tentative)
Pumpkin seed	0.01	STMR <sub>M0</sub> x CF (tentative)
Safflower	0.01	STMR <sub>M0</sub> x CF (tentative)
Borage	0.06	STMR <sub>M0</sub> x CF (tentative)
Gold of pleasure	0.06	STMR <sub>M0</sub> x CF (tentative)
Hempseed	0.06	STMR <sub>M0</sub> x CF (tentative)
Castor bean	0.06	STMR <sub>M0</sub> x CF (tentative)
Olives for oil production	0.26	STMR <sub>M0</sub> x CF (tentative)
Barley grain	0.56	STMR <sub>M0</sub> x CF (fall-back, tentative)
Buckwheat grain	0.63	STMR <sub>M0</sub> x CF (tentative)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Maize grain	0.56	STMR <sub>Mo</sub> x CF (fall-back, tentative)
Millet grain	0.63	STMR <sub>Mo</sub> x CF (tentative)
Oats grain	0.63	STMR <sub>Mo</sub> x CF (tentative)
Rye grain	0.56	STMR <sub>Mo</sub> x CF (fall-back, tentative)
Rye grain	0.56	STMR <sub>Mo</sub> x CF (fall-back, tentative)
Sorghum grain	0.63	STMR <sub>Mo</sub> x CF (tentative)
Wheat grain	0.03	STMR <sub>Mo</sub> x CF (fall-back, tentative)
Herbal infusions (dried, flowers)	1.31	STMR <sub>Mo</sub> x CF (tentative)
Herbal infusions (dried, leaves)	1.31	STMR <sub>Mo</sub> x CF (tentative)
Herbal infusions (dried, roots)	0.09	STMR <sub>Mo</sub> x CF (tentative)
Spices (seeds)	0.06	EU MRL x CF
Spices (fruits and berries)	1.31	STMR <sub>Mo</sub> x CF (tentative)
Species (roots and rhizome)	0.09	STMR <sub>Mo</sub> x CF (tentative)
Spices (buds)	1.31	STMR <sub>Mo</sub> x CF (tentative)
Spices (flower stigma)	1.31	STMR <sub>Mo</sub> x CF (tentative)
Chicory roots	0.01	STMR <sub>Mo</sub> x CF (tentative)
Swine fat (free of lean meat)	0.06	STMR <sub>Mo</sub> (tentative)
Swine liver	0.02	STMR <sub>Mo</sub> (tentative)
Ruminant meat	0.03	0.8 x STMR <sub>Mo</sub> muscle + 0.2 x STMR <sub>Mo</sub> fat (tentative)
Ruminant fat	0.08	STMR <sub>Mo</sub> (tentative)
Ruminant liver	0.02	STMR <sub>Mo</sub> (tentative)
Poultry fat	0.04	STMR <sub>Mo</sub> (tentative)
Ruminant milk	0.02	STMR <sub>Mo</sub> (tentative)

### 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	301 % (based on NL toddler) 196% (based on DK child) 154% (based on GEMS/FoodG06) 150% (based on DE child) 131% (based on GEMS/food G08) 121% (based on GEMS/Food G15) 119% (based on GEMS/Food G10) 111% (based on GEMS/Food G11) 111% (based on GEMS/Food G07) 108% (based on NL child) 107% (based on RO general) 104% (based on UK infant)
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	102% (based on FR child 3-15 year)
IEDI (% ADI) according to EFSA PRIMo rev.3.1	80 % (based on NL toddler)
IENTI (% ARfD) according to EFSA PRIMo rev.3.1	<p><b>Unprocessed commodities:</b></p> <p>Results for children</p> <p>57.93% Cauliflowers</p> <p>44.24% Head cabbages</p> <p>40.70% Tomatoes</p> <p>32.69% Strawberries</p> <p>0.84% Brussels sprouts</p> <p>Results for adults</p> <p>42.05% Head cabbages</p> <p>23.19% Cauliflowers</p> <p>18.66% Strawberries</p> <p>11.10% Tomatoes</p> <p>0.60% Brussels sprouts</p> <p><b>Processed commodities:</b></p> <p>Results for children</p> <p>69.6% Cauliflowers / boiled</p> <p>13.3% Tomatoes / juice</p> <p>6.7% Tomatoes / sauce/puree</p> <p>5.8% Head cabbages / canned</p> <p>1.0% Brussels sprouts / boiled</p> <p>Results for adults</p> <p>41.7% Cauliflowers / boiled</p> <p>9.40% Head cabbages / canned</p> <p>5.75% Tomatoes / sauce/puree</p>
NTMDI (% ADI)	-
NEDI (% ADI)	-
NESTI (% ARfD)	-

The proposed uses of Deltamethrin in the formulation Deltamethrin 5% Cs do not represents an unacceptable acute and chronic risks for the consumer.

### 7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

### 7.4 References

Draft Assessment Report (DAR) Sweden, 1998. Annex B B6-Residues

Deltamethrin - Addendum to Monograph Annex B B6-Residues, 2002

EFSA (European Food Safety Authority), 2015. Review of the existing maximum residue levels for deltamethrin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(11)4309

## Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.3.1.1	G. XXX	2021	Determination of the residues of deltamethrin in/on strawberries after three applications of Deltamethrin 5% CS in Northern Europe – Hungary in 2020. Report No. 065CPRHU20R24 GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.1.2	S. XXX	2021	Determination of the Residues of Deltamethrin in/on Strawberries after three applications of Deltamethrin 5% CS in Northern Europe – Hungary in 2020. Report No. DPL/169/2020 GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.1.3	R. XXX	2021	Magnitude of the residue of deltamethrin in strawberry (Raw Agricultural Commodity – RAC) grown in open field conditions after three applications of formulated product Deltamethrin 5% CS – one harvest and one decline curve trial in Northern Europe – Poland, 2020 Report No. D-2020-23 GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.1.4	G. XXX	2021	Magnitude of the residue of Deltamethrin in strawberry (Raw Agriculture Commodity – RAC) grown in open field conditions after three applications of formulated product Deltamethrin 5% CS – one harvest and one decline curve trial in Northern Europe – Poland, 2020 Report No. DPL/170/2020	N	Sharda Cropchem Limited



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCP 8.3.2.1	G. XXX	2021	Determination of the residues of Deltamethrin in/on tomato after three applications of Deltamethrin 5% CS in Northern Europe – Hungary in 2020. Report No. 065CPRHU20R25 GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.2.2	G. XXX	2021	Magnitude of the residues of Deltamethrin in/on Tomato after three applications of Deltamethrin 5% CS in Northern Europe – Hungary, 2020. Report No. DPL/174/2020 GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.2.3	R. XXX	2021	Magnitude of the residue of deltamethrin in tomato (Raw Agricultural Commodity – RAC) grown in open field conditions after three applications of formulated product Deltamethrin 5% CS – one harvest and two decline curve trials in Northern Europe. Report No. D-2020-24 GLP Unpublished	N	Sharda Cropchem Limited
KCP 8.3.2.4	S. XXX	2021	Magnitude of the residue of deltamethrin in tomato (Raw Agricultural Commodity – RAC) grown in open field conditions after three applications of formulated product Deltamethrin 5% CS – one harvest and two decline curve trials in Northern Europe – Poland, 2020 Report No. DPL/171/2020 GLP Unpublished	N	Sharda Cropchem Limited

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

The following tables are to be completed by MS.

**List of data submitted by the applicant and not relied on**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

## **Appendix 2 Detailed evaluation of the additional studies relied upon**

### **A 2.1 Deltamethrin**

#### **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 submitted in the framework of this application.

###### **A 2.1.1.1.2 Storage stability of residues in animal products**

No new data 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 submitted in the framework of this application.

#### A 2.1.2.1.2 Nature of residue in rotational crops

No new data submitted in the framework of this application.

#### A 2.1.2.1.3 Nature of residues in processed commodities

No new data submitted in the framework of this application.

#### A 2.1.2.2 Nature of residues in livestock

No new data submitted in the framework of this application.

#### A 2.1.3 Magnitude of residues in plants

No new data submitted in the framework of this application.

#### A 2.1.3.1 Cauliflower

**Table A 1: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment (g ai/ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU	2	12.5			7
cGAP EU (Art. 12, EFSA, 2015)	2	12.5	14		7
Intended cGAP (1-2)	2 1	12.5 7.5	10-14	BBCH 11 – 43	7

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

**Table A 2: Summary of the study 1 trials**

Trial No./ Location/ EU zone/ Year	Commodi- ty/ 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 treat- ment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl						

Germany / 1981	Cauliflower		7.5		3			0.005 <0.005 <0.005 <0.005	0 3 5 7	De Wilde, 1995q
Germany / 1981	Cauliflower		7.5		3			0.02 0.008 <0.005 <0.005	0 3 5 7	De Wilde, 1995q
Germany / 1981	Cauliflower		7.5		3			<0.01 <0.01 <0.01 <0.01	0 3 5 7	De Wilde, 1995q
Germany / 1981	Cauliflower		7.5		3			<0.01 <0.01 <0.01 <0.01	0 3 5 7	De Wilde, 1995q
Germany / 2000	Cauliflower		7.5		3			<0.01 <0.01 <0.01 <0.01	0 2 4 7	Davies, 2001c
Germany / 2000	Cauliflower		7.5		3			<0.01 <0.01 <0.01 <0.01	0 2 4 7	Davies, 2001c
Germany / 2000	Cauliflower		7.5		3			<0.01 <0.01 <0.01 <0.01	0 2 4 7	Davies, 2001c
Spain / 1997	Cauliflower		12.5		2			<0.02 <0.02	0 7	Klein, 1999a
Greece / 1997	Cauliflower		12.5		2			<0.02 <0.02	0 7	Klein, 1999a
Italy / 1997	Cauliflower		12.5		2			<0.02 <0.02	0 7	Klein, 1999a
Spain / 1998	Cauliflower		12.5		2			<0.02 <0.02	0 7	Klein & Burstell, 1999b
S France / 1998	Cauliflower		12.5		2			<0.02 <0.02	0 7	Klein & Burstell, 1999b
Greece / 1998	Cauliflower		12.5		2			<0.02 <0.02	0 7	Klein & Burstell, 1999b

### A 2.1.3.2 Strawberries

**Table A 3: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment (g ai/ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU	3	12.5			3
cGAP EU (Art. 12, EFSA, 2015)	3	12.5	14		3
Intended cGAP (3-4)	3 1	12.5 7.5	10-14	BBCH 11 - 81	3

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

**Table A 4: Summary of the study 1 trials**

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl						
N France / 1993	Strawberries		12.5			4			0.02	3	De Wilde, 1995g
Germany / 2000	Strawberries		12.5			2			<0.02 <0.02 <0.02	0 1 3	Klein, 2001h
Germany / 2000	Strawberries		12.5			2			0.04 <0.02 <0.02	0 1 3	Klein, 2001h
Germany / 2000	Strawberries		12.5			2			<0.02 <0.02 <0.02	0 1 3	Klein, 2001h
N France / 1993	Strawberries		12.5			2			<0.02 <0.02 <0.02	0 1 3	Klein, 2001h
United Kingdom / 2000	Strawberries		12.5			2			0.05 0.04 0.03	0 1 3	Klein, 2001h

S France / 1993	Strawberries		12.5			4			0.05	3	De Wilde, 1995g
S France / 1993	Strawberries		12.5			4			0.03	3	De Wilde, 1995g
S France / 1993	Strawberries		12.5			4			0.04	3	De Wilde, 1995g
Spain / 1995	Strawberries		12.5			3			0.05 0.07 0.085	0 1 3	Klein & Moede, 1996f
Spain / 1995	Strawberries		12.5			3			0.055 0.045 0.03	0 1 3	Klein & Moede, 1996f
S France / 1994	Strawberries		12.5			3			0.035 0.02 0.03	0 1 3	Klein & Moede, 1996f
S France / 1994	Strawberries		12.5			3			0.03 0.035 0.025	0 1 3	Klein & Moede, 1996f
Spain / 1995	Strawberries		12.5			3			0.07 0.08 0.06	0 1 3	Klein & Burstell, 1996a
S France / 1995	Strawberries		12.5			3			0.03 0.02 0.02	0 1 3	Klein & Burstell, 1996a
Italy / 1995	Strawberries		12.5			3			0.02 0.01 <0.01	0 1 3	Klein & Burstell, 1996a

#### A 2.1.3.2.1 Study 1

Comments of zRMS:	Study is accepted. Trials are independent and accepted with respect to stability data.
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#### Reference:

#### KCP 8.3.1.1

#### Report

Determination of the residues of Deltamethrin in/on strawberries after three applications of Deltamethrin 5% CS in Northern Europe – Hungary in 2020. G. XXX, 2021, Report No. 065CPRHU20R24



**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

Two trials were conducted in Hungary in 2020. The field phase was performed in Gelse (CPRHU20-213-065IR) and in Sé (CPRHU20-214-065IR).  
 Three applications (between 81-85 BBCH) of the formulated product Deltamethrin 5% CS were applied at a rate of 0.256 L formulated product/ha (12.5 g active ingredient of deltamethrin/ha) onto the crop, under open field condition.  
 Specimens (fruits) were collected at 0, 1 and 3 days after last application (DALA) in decline trial and at 3 DALA in harvest trial, frozen and shipped deep frozen to analytical facility of SGS Polska Sp. z o.o. for residue analysis. There was no unusual event that affected this phase of the study.

<b>Comments of zRMS:</b>	Study is accepted
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**Reference:** KCP 8.3.1.2

**Report** Determination of the residues of Deltamethrin in/on Strawberries after three applications of Deltamethrin 5% CS in Northern Europe – Hungary in 2020. S. XXX, 2021, Report No. DPL/169/2020

**Guideline(s):** Regulation (EC) No 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  
 Guidane Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, SANTE/2020/12830 Rev. 1, 24 February 2021

**Deviations:** No

**GLP:** Yes

**Acceptability:** Yes

The objective of the study was the determination of residues of deltamethrin (+alpha R isomer + trans isomer+ in strawberry after three applications of Deltamethrin

5% CS.

Specimen extraction and determination of residues of deltamethrin (sum of three isomers) was performed using the Quechers technique.

Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each of compound.

#### Extraction

10 g of the homogenized sample was weighed into a 50 mL centrifuge tube, 10 mL of acetonitrile was added together with 100 µL of internal standard solution and the mixture was shaken vigorously by hand for one minute, then was added 6.5 g mixture of buffered salts and shaking was repeated. The sample was centrifuged at 4700 rpm for 10 min for phase separation. Next, extract was filtered through a membrane filter. After, the final extract was directly employed for LC-MS/MS analysis.

**Table A 5: Summary of the study 1 trials**

Trans-de	Commodity/ Variety	Date of 1.Sowing or planting 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				Trans- deltamethrin	Cis- deltamethrin	Alfa R- deltamethrin		
CPRHU20-213-065IR/N- EU/Hungary/2020	Strawbery/Clery	March 2017 April 2020 June 2020	12 12 13	292 295 304		31/05/2020 23/05/2020 02/06/2020	BBCH 81 BBCH 85 BBCH 85	Fruit	n.d.	<0.01	n.d.	3	Analytical report DPL/169/2020  LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
CPRHU20-214-065IR/N- EU/Hungary/2020	Strawbery/Elsanta	March 2018 April 2020 June 2020	13 13 13	314 311 306		31/05/2020 23/05/2020 02/06/2020	BBCH 81 BBCH 85 BBCH 85	Fruit	n.d. n.d. n.d.	0.012 0.012 <0.01	n.d. n.d. n.d.	0 1 3	Analytical report DPL/169/2020  LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

## A 2.1.3.2.2 Study 2

Comments of zRMS:	Study is accepted. Trials are independent and accepted with respect to stability data.
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Reference:	KCP 8.3.1.3
Report	Magnitude of the residue of deltamethrin in strawberry (Raw Agricultural Commodity – RAC) grown in open field conditions after three applications of formulated product Deltamethrin 5% CS – one harvest and one decline curve trial in Northern Europe – Poland, 2020. R. XXX, 2021, Report No. D-2020-23
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

The field phase was happened as anticipated in the study plan and amendments. One harvest trial and one decline curve trial were established in central Poland. Trials consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have a negatively impact the integrity and validity of this study. Three foliar applications of Deltamethrin 5% CS were performed with a boom sprayer on the treated plot at a target dose rate of 0,256 L\*ha<sup>-1</sup> (equivalent to 12,5 g a.s.\*ha<sup>-1</sup> of deltamethrin). The reported dose rates actually ranging from 0,216 to 0,232 L\*ha<sup>-1</sup>.

The target spray volume was 200-600 litres per hectare according to Good Agricultural Practices.

Applications were performed at the following timing:

- 1<sup>st</sup> application A1 - 23±1 days before a normal commercial harvest,
- 2<sup>nd</sup> application A2 - 13±1 days before a normal commercial harvest,
- 3<sup>rd</sup> application A3 - 3±1 days before a normal commercial harvest.

The spray mixture volumes remaining after applications were measured and volumes applied to the treated plot were calculated to verify the delivery rates. The calculations and the delivery rates were verified by the Study Director.

In HS trial, RAC specimens for analyses were collected at normal commercial harvest. In decline curve trials (DCS), RAC specimens for analyses (fruit) were collected as follows:

- at 0 days after application (just after the last application; U+T),
- at 1 day after the last application (U+T),
- at 3±1 days after the application (U+T).

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.1.4
Report	Magnitude of the residue of Deltamethrin in strawberry (Raw Agricultural Commodity – RAC) grown in open field conditions after three applications of formulated product Deltamethrin 5% CS – one harvest and one decline curve trial in Northern Europe – Poland, 2020. G. XXX, 2021, Report No. DPL/170/2020
Guideline(s):	Regulation (EC) No 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 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, SANTE/2020/12830 Rev. 1, 24 February 2021
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was the determination of residues of deltamethrin (+alpha R isomer + trans isomer+ in strawberry after three applications of Deltamethrin 5% CS.

Specimen extraction and determination of residues of deltamethrin (sum of three isomers) was performed using the Quechers technique.

Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each of compound.

#### Extraction

10 g of the homogenized sample was weighed into a 50 mL centrifuge tube, 10 mL of acetonitrile was added together with 100 µL of internal standard solution and the mixture was shaken vigorously by hand for one minute, then was added 6.5 g mixture of buffered salts and shaking was repeated. The sample was centrifuged at 4700 rpm for 10 min for phase separation. Next, extract was filtered through a membrane filter. After, the final extract was directly employed for LC-MS/MS analy-

sis.

**Table A 6: Summary of the study 2 trials**

Trans-de	Commodity/ Variety	Date of 1.Sowing or planting 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				Trans- deltamethrin	Cis- deltamethrin	Alfa R- deltamethrin		
D-2020-23-F01/N- EU/Poland/2020	Strawberry/Senga Sengana	28/09/2018 10/06/2020 20/06/2020	11 12 12	478 511 507		27/05/2020 05/06/2020 16/06/2020	BBCH 56 BBCH 71 BBCH 81	Fruit	n.d.	n.d.	n.d.	3	Analytical report DPL/170/2020  LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
D-2020-23-F02/N- EU/Poland/2020	Strawberry/Aprica	08/2019 08/06/2020 22/06/2020	11 11 11	314 311 306		20/05/2020 30/05/2020 09/06/2020	BBCH 67 BBCH 74 BBCH 81	Fruit	n.d. n.d. n.d.	<0.01 n.d. n.d.	n.d. n.d. n.d.	0 1 3	Analytical report DPL/170/2020  LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

### A 2.1.3.3 Tomato - outdoor

**Table A 7: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treat- ment (g ai/ha)	Interval between applica- tion	Growth stage at last appli- cation	PHI (days)
cGAP EU	3	12.5			3
cGAP EU (Art. 12, EFSA, 2015)	3	12.5	14		3

Type of GAP	Number of applications	Application rate per treatment (g ai/ha)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (5-6)	3 1	12.5 7.5	10-14	BBCH 11 – 81 85	3

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

**Table A 8: Summary of the study 1 trials**

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of 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						
Germany / 1980	Tomatoes		12.5			3			<0.01 0.02 <0.01 0.03	0 1 2 3	De Wilde, 1995m
Germany / 1980	Tomatoes		12.5			3			<0.01 <0.01 0.02 0.01	0 1 2 3	De Wilde, 1995m
Germany / 1980	Tomatoes		12.5			3			0.07 0.06 0.05 0.01	0 1 2 3	De Wilde, 1995m
Germany / 1980	Tomatoes		12.5			3			0.01 0.02 0.01 <0.01	0 1 2 3	De Wilde, 1995m
S France / 1977	Tomatoes		10			3			0.009 0.009	2 5	De Wilde, 1995m
S France / 1977	Tomatoes		10			3			0.010 0.007	2 5	De Wilde, 1995m
Spain / 1996	Tomatoes		125			4			<0.02 <0.02	0 3	Klein & Burstell, 1997b
S France / 1996	Tomatoes		125			4			<0.02 <0.02	0 3	Klein & Burstell, 1997b

Greece / 1996	Tomatoes		125			4			<0.02 <0.02	0 3	Klein & Burstell, 1997b
Italy / 1996	Tomatoes		125			4			<0.02 <0.02	0 3	Klein & Burstell, 1997b
Spain / 1997	Tomatoes		125			4			<0.02 <0.02 <0.02	0 3 7	Klein 1998c
Spain / 1997	Tomatoes		125			4			<0.02 <0.02 <0.02	0 3 7	Klein 1998c
Greece / 1997	Tomatoes		125			4			<0.02 <0.02 <0.02	0 3 7	Klein 1998c
Italy / 1997	Tomatoes		125			4			<0.02 <0.02 <0.02	0 3 7	Klein 1998c
Italy / 1997	Tomatoes		125			4			<0.02 <0.02 <0.02	0 3 7	Klein 1998c

#### A 2.1.3.3.1 Study 1

Comments of zRMS:	Study is accepted. Trials are independent and accepted with respect to stability data.
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#### Reference:

#### KCP 8.3.2.1

#### Report

Determination of the residues of Deltamethrin in/on tomato after three application of Deltamethrin 5% CS in Northern Europe – Hungary in 2020. G. XXX, 2021, Report No. 065CPRHU20R25

#### 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

Three trials were conducted in Hungary in 2020. The field phase was performed in Vép (CPRHU20-215-065IR) in Kőszeg (CPRHU20-216-065IR), and in Szatymaz (CPRHU20-217-065IR).  
 Three application (between 85-88 BBCH) of the formulated product Deltamethrin 5% CS (containing nominal concentration of 5 % deltamethrin) were applied at a rate of 0.256 L formulated product/ha (12.5 g active ingredient/ha) onto the crop, under open field condition.  
 Specimens (fruits) were collected at 0 ,1 and 3 (NCH) days after last application (DALA) in decline trials and at harvest in harvest trial, frozen and shipped deep frozen to analytical facility of SGS Polska Sp.z o.o. for residue analysis. There was no unusual event that affected this phase of the study.

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.2.2  
 Report Magnitude of the residues of Deltamethrin in/on Tomato after three applications of Deltamethrin 5% CS in Northern Europe – Hungary, 2020. G. XXX, 2021, Report No. DPL/174/2020  
 Guideline(s): Regulation (EC) No 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  
 Guidane Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, SANTE/2020/12830 Rev. 1, 24 February 2021  
 Deviations: No  
 GLP: Yes  
 Acceptability: Yes

The objective of the study was the determination of residues of deltamethrin (+alpha R isomer + trans isomer) in tomato after three applications of Deltamethrin 5% CS.

Specimen extraction and determination of residues of deltamethrin (sum of three isomers) was performed using the Quechers technique.

Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each of compound.



### Extraction

10 g of the homogenized sample was weighed into a 50 mL centrifuge tube, 10 mL of acetonitrile was added together with 100 µL of internal standard solution and the mixture was shaken vigorously by hand for one minute, then was added 6.5 g mixture of buffered salts and shaking was repeated. The sample was centrifuged at 4700 rpm for 10 min for phase separation. Next, extract was filtered through a membrane filter. After, the final extract was directly employed for LC-MS/MS analysis.

**Table A 9: Summary of the study 1 trials**

Trans-de	Commodity/ Variety	Date of 1.Sowing or planting 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				Trans- deltamethrin	Cis- deltamethrin	Alfa R- deltamethrin		
CPRHU20-215-065IR/N- EU/Hungary/2020	Tomato/Kecskemeti Jubileum	22/05/2020 July 2020 06/09/2020	14 13 14	324 316 325		14/08/2020 24/08/2020 03/09/2020	BBCH 81 BBCH 83 BBCH 85	Fruit	n.d. n.d. n.d.	n.d. n.d. n.d.	n.d. n.d. n.d.	3	Analytical report DPL/174/2020  LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
CPRHU20-216-065IR/N- EU/Hungary/2020	Tomato/Kecskemeti 549	20/06/2020 June 2020 06/09/2020	13 13 12	321 301 299		14/08/2020 24/08/2020 03/09/2020	BBCH 82 BBCH 83 BBCH 85	Fruit	n.d. n.d. n.d.	<0.01 n.d. n.d.	n.d. n.d. n.d.	0 1 3	Analytical report DPL/174/2020  LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
CPRHU20-217-065IR/N- EU/Hungary/2020	Tomato/Uno	29/05/2020 July 2020 09/09/2020	14 14 12	246 248 225		17/08/2020 27/08/2020 06/09/2020	BBCH 81 BBCH 83 BBCH 85	Fruit	n.d. n.d. n.d.	<0.01 <0.01 n.d.	n.d. n.d. n.d.	0 1 3	Analytical report DPL/174/2020  LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

### A 2.1.3.3.2 Study 2

Comments of zRMS:	Study is accepted. Trials are independent and accepted with respect to stability data.
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Reference:	KCP 8.3.2.3
Report	Magnitude of the residue of deltamethrin in tomato (Raw Agricultural Commodity – RAC) grown in open field conditions after three applications of formulated product Deltamethrin 5% CS – one harvest and two decline curve trials in Northern Europe – Poland, 2020. R. XXX, 2021, Report No. D-2020-24
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

The field phase happened as anticipated in the study plan and amendments. One harvest trial and two decline curve trials were established in central Poland. Trials consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negatively impacted the integrity and validity of this study. Three foliar applications of Deltamethrin 5% CS were performed with a boom sprayer on the treated plot at the target dose rate of 0,256 L\*ha<sup>-1</sup> (equivalent to 12,5 g a.s.\*ha<sup>-1</sup> of deltamethrin).

The target spray volume was 300-1000 litres per hectare according to Good Agricultural Practices.

Application was performed at the following timing:

- 1<sup>st</sup> application A1 - 23±1 days before a normal commercial harvest,
- 2<sup>nd</sup> application A2 - 13±1 days before a normal commercial harvest,
- 3<sup>rd</sup> application A3 - 3±1 days before a normal commercial harvest.

In HS trial, RAC specimens for analyses were collected at normal commercial harvest. In decline curve trials (DCS), RAC specimens for analyses (fruit) were collected as follows:

- at 0 days after application (just after the last application; U+T),
- at 1 day after the last application (U+T),
- at 3±1 days after the application (U+T).

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site.

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.2.4

Report Magnitude of the residue of deltamethrin in tomato (Raw Agricultural Commodity – RAC) grown in open field conditions after three applications of formulated product Deltamethrin 5% CS – one harvest and two decline curve trials in Northern Europe – Poland, 2020. S. XXX, 2021, Report No. DPL/171/2020

Guideline(s): Regulation (EC) No 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  
 Guidane Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, SANTE/2020/12830 Rev. 1, 24 February 2021

Deviations: No

GLP: Yes

Acceptability: Yes

The objective of the study was the determination of residues of deltamethrin (+alpha R isomer + trans isomer) in tomato after three applications of Deltamethrin 5% CS.

Specimen extraction and determination of residues of deltamethrin (sum of three isomers) was performed using the Quechers technique.

Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each of compound.

#### Extraction

10 g of the homogenized sample was weighed into a 50 mL centrifuge tube, 10 mL of acetonitrile was added together with 100 µL of internal standard solution and the mixture was shaken vigorously by hand for one minute, then was added 6.5 g mixture of buffered salts and shaking was repeated. The sample was centrifuged at 4700 rpm for 10 min for phase separation. Next, extract was filtered through a membrane filter. After, the final extract was directly employed for LC-MS/MS analysis.

**Table A 10: Summary of the study 2 trials**

Trans-de	Commodity/ Variety	Date of 1.Sowing or planting 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				Trans- deltamethrin	Cis- deltamethrin	Alfa R- deltamethrin		
D-2020-24-F01/N- EU/Poland/2020	Tomato/Calista F1	16/05/2020 05/08/2020 30/09/2020	12 12 12	613 619 617		22/07/2020 31/07/2020 11/08/2020	BBCH 71 BBCH 75 BBCH 85	Fruit	n.d.	n.d.	n.d.	3	Analytical report DPL/171/2020  LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
D-2020-24-F02/N- EU/Poland/2020	Tomato/Rediana	19/05/2020 07/08/2020 13/09/2020	12 11 12	620 590 626		03/08/2020 13/08/2020 24/08/2020	BBCH 72 BBCH 75 BBCH 85	Fruit	n.d. n.d. n.d.	n.d. n.d. n.d.	n.d. n.d. n.d.	0 1 3	Analytical report DPL/171/2020  LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
D-2020-24-F02/N- EU/Poland/2020	Tomato/Hapynet	08/05/2020 16/07/2020 05/09/2020	11 11 12	582 893 615		22/07/2020 31/07/2020 11/08/2020	BBCH 72 BBCH 75 BBCH 85	Fruit	n.d. n.d. n.d.	<0.01 n.d. n.d.	n.d. n.d. n.d.	0 1 3	Analytical report DPL/171/2020  LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

#### A 2.1.3.4 Tomato - indoor

**Table A 11: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment (g ai/ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU	4	17.5			3
cGAP EU (Art. 12, EFSA, 2015)	3	17.5	7		3
Intended cGAP (5 6)	3 1	12.5 7.5	10-14	BBCH 11 – 84 85	3

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

**Table A 12: 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						

Germany / 1981	Tomatoes		18.75			4			0.1 0.2 0.2 0.2	0 1 2 3	De Wilde, 1995m
Germany / 1981	Tomatoes		18.75			4			0.08 0.2 0.1 0.08	0 1 2 3	De Wilde, 1995m
Germany / 1981	Tomatoes		18.75			4			0.06 0.1 0.1 0.2	0 1 2 3	De Wilde, 1995m
Germany / 1981	Tomatoes		18.75			4			0.06 0.02 0.07 0.1	0 1 2 3	De Wilde, 1995m
Spain / 2000	Tomatoes		12.5			4			0.016 <0.01 <0.01	0 1 3	Davies, 2001f
Greece / 2000	Tomatoes		12.5			4			0.014 <0.01 0.01	0 1 3	Davies, 2001f
Italy / 2000	Tomatoes		12.5			4			0.02 0.05 0.03	0 1 3	Davies, 2001f
Netherlands / 2000	Tomatoes		12.5			4			0.02 0.02 <0.01	0 1 3	Davies, 2001f
Netherlands / 2000	Tomatoes		12.5			4			0.02 0.02 0.01	0 1 3	Davies, 2001f
Netherlands / 2000	Tomatoes		12.5			4			0.01 0.015 0.01	0 1 3	Davies, 2001f
Netherlands / 2000	Tomatoes		12.5			4			0.02 0.01 0.013	0 1 3	Davies, 2001f
Portugal / 2000	Tomatoes		12.5			4			0.02 0.01 0.013	0 1 3	Davies, 2001f

#### **A 2.1.4            Magnitude of residues in livestock**

##### **A 2.1.4.1            Livestock feeding studies**

No new data submitted in the framework of this application.

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

##### **A 2.1.5.1            Distribution of the residue in peel/pulp**

No new data submitted in the framework of this application.

##### **A 2.1.5.2            Processing studies on a core set of representative processes**

No new data submitted in the framework of this application.

#### **A 2.1.6            Magnitude of residues in representative succeeding crops**


No new data submitted in the framework of this application.

#### **A 2.1.7            Other/Special Studies**

No new data submitted in the framework of this application.

## Appendix 3 Pesticide Residue Intake Model (PRIMo)

### A 3.1 TMDI calculations



European Food Safety Authority  
EFSA PRIMo revision 3.0; 2017/12/11

**Deltamethrin (F)**

LOQs (mg/kg) range from: **0.01** to: **0.10**

**Toxicological reference values**

ADI (mg/kg bw/day): **0.01** ARPD (mg/kg bw): **0.01**

Source of ADI: **EU** Source of ARPD: **EU**

Year of evaluation: **2002** Year of evaluation: **2002**

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)**

Calculated exposure		Exposure	Highest contributor	Commodity /	2nd contributor to	Commodity /	3rd contributor to	Commodity /	Exposure resulting from	
(in % of ADI)	MS Diet	(µg/kg bw per day)	to MS diet (in % of ADI)	group of commodities	MS diet (in % of ADI)	group of commodities	MS diet (in % of ADI)	group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
		No of diets exceeding the ADI :		13						
TMDI(NED)/IEDI calculation (based on average food consumption)	301%	NL toddler	30.13	Maize/corn	33%	Wheat	30%	Milk: Cattle	3%	301%
	136%	DK child	19.58	Rye	44%	Wheat	8%	Oat	0.8%	136%
	154%	GEMS/Food G06	15.43	Wheat	25%	Maize/corn	16%	Rice	2%	154%
	150%	DE child	15.04	Wheat	25%	Apples	16%	Rye	2%	150%
	131%	GEMS/Food G08	13.07	Wheat	18%	Barley	12%	Rye	2%	131%
	121%	GEMS/Food G15	12.05	Wheat	16%	Barley	13%	Maize/corn	2%	121%
	119%	GEMS/Food G10	11.92	Wheat	13%	Maize/corn	13%	Rice	2%	119%
	111%	GEMS/Food G11	11.15	Wheat	16%	Barley	12%	Potatoes	2%	111%
	111%	GEMS/Food G07	11.07	Wheat	12%	Barley	11%	Potatoes	2%	111%
	108%	NL child	10.82	Wheat	12%	Milk: Cattle	12%	Apples	3%	108%
	107%	RO general	10.71	Wheat	19%	Maize/corn	11%	Potatoes	1%	107%
	104%	UK infant	10.41	Wheat	21%	Maize/corn	19%	Milk: Cattle	1%	104%
	102%	FR child 3-15 yr	10.16	Wheat	11%	Milk: Cattle	8%	Maize/corn	2%	102%
	32%	PT general	3.21	Wheat	16%	Potatoes	10%	Maize/corn	0.4%	32%
	30%	ES child	3.01	Wheat	6%	Milk: Cattle	6%	Maize/corn	1%	30%
	86%	UK toddler	8.61	Wheat	10%	Potatoes	10%	Milk: Cattle	1%	86%
	83%	IE adult	8.31	Wheat	7%	Potatoes	7%	Tes (dried leaves of Camellia sinensis)	2%	83%
	82%	IT toddler	8.20	Wheat	3%	Potatoes	2%	Rice	0.5%	82%
	82%	FR toddler 2-3 yr	8.19	Wheat	15%	Milk: Cattle	6%	Apples	2%	82%
	73%	SE general	7.34	Wheat	13%	Potatoes	6%	Milk: Cattle	0.7%	73%
	76%	DE general	7.55	Wheat	12%	Rye	10%	Barley	2%	76%
	71%	DE women 14-50 yr	7.08	Wheat	10%	Rye	6%	Milk: Cattle	2%	71%
	63%	FI 3 yr	6.86	Potatoes	13%	Rye	12%	Wheat	0.7%	63%
	62%	LT adult	6.20	Rye	11%	Wheat	10%	Potatoes	0.3%	62%
	60%	ES adult	5.97	Wheat	10%	Barley	3%	Potatoes	0.7%	60%
	59%	NL general	5.88	Wheat	7%	Potatoes	6%	Barley	2%	59%
	55%	IT adult	5.54	Wheat	2%	Lettuces	2%	Potatoes	0.3%	55%
	54%	FI 6 yr	5.43	Rye	12%	Potatoes	10%	Wheat	0.6%	54%
	53%	FR adult	5.32	Wheat	7%	Tes (dried leaves of Camellia sinensis)	5%	Vine grapes	1%	53%
	45%	UK vegetarian	4.48	Wheat	4%	Potatoes	4%	Rice	0.3%	45%
	40%	DK adult	4.03	Wheat	11%	Rye	4%	Potatoes	0.3%	40%
	39%	UK adult	3.86	Wheat	4%	Potatoes	4%	Rice	0.4%	39%
	37%	FI adult	3.69	Rye	6%	Coffee beans	4%	Potatoes	6%	37%
	34%	FR infant	3.44	Milk: Cattle	8%	Wheat	6%	Potatoes	0.8%	34%
	22%	IE child	2.16	Wheat	3%	Rice	2%	Potatoes	0.1%	22%
19%	PL general	1.89	Potatoes	4%	Apples	0.6%	Table grapes	0.2%	19%	

**Conclusion:**  
The estimated TMDI(NED)/IEDI was in the range of 0 % to 301.3 % of the ADI.  
For 13 diet(s) the ADI is exceeded.



### **A 3.2 IEDI calculations**



Deltamethrin (cis-deltamethrin) (F) (F)			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):		0.01	ARfD (mg/kg bw): 0.01
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 :						Exposure resulting from					
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	80%	NL toddler	8.02	39%	Maize/corn	12%	Milk: Cattle	4%	Apples		0.6%
	47%	DK child	4.73	31%	Rye	3%	Swine: Muscle/meat	3%	Milk: Cattle		0.2%
	32%	GEMS/Food G06	3.23	9%	Rice	7%	Maize/corn	3%	Tea (dried leaves of Camellia sinensis)		1%
	31%	GEMS/Food G08	3.06	5%	Barley	3%	Rye	2%	Maize/corn		0.5%
	30%	GEMS/Food G10	2.97	7%	Rice	4%	Maize/corn	3%	Barley		0.6%
	29%	UK infant	2.93	8%	Milk: Cattle	6%	Maize/corn	4%	Rice		0.3%
	29%	DE child	2.90	5%	Apples	4%	Rye	4%	Milk: Cattle		0.5%
	25%	IE adult	2.53	7%	Tea (dried leaves of Camellia sinensis)	2%	Buckwheat and other pseudo-cereals	1%	Rice		0.3%
	25%	GEMS/Food G15	2.50	4%	Barley	4%	Maize/corn	2%	Swine: Muscle/meat		0.6%
	25%	GEMS/Food G07	2.47	3%	Barley	2%	Tea (dried leaves of Camellia sinensis)	2%	Rice		0.4%
	24%	FR child 3 15 yr	2.38	5%	Milk: Cattle	2%	Rice	2%	Maize/corn		0.4%
	24%	NL child	2.37	5%	Milk: Cattle	2%	Apples	2%	Sugar beet roots		0.4%
	24%	GEMS/Food G11	2.36	4%	Barley	2%	Tea (dried leaves of Camellia sinensis)	2%	Rice		0.4%
	20%	FR toddler 2 3 yr	2.02	6%	Milk: Cattle	3%	Rice	2%	Bovine: Muscle/meat		0.3%
	20%	DE general	1.95	3%	Rye	3%	Barley	2%	Milk: Cattle		0.3%
	19%	ES child	1.94	3%	Rice	2%	Milk: Cattle	2%	Olives for oil production		0.3%
	19%	RO general	1.89	5%	Maize/corn	2%	Milk: Cattle	2%	Wheat		1%
	18%	UK toddler	1.83	4%	Milk: Cattle	3%	Rice	2%	Beans		0.3%
	18%	SE general	1.80	5%	Bovine: Muscle/meat	2%	Milk: Cattle	2%	Rice		0.5%
	17%	FR adult	1.73	7%	Tea (dried leaves of Camellia sinensis)	2%	Wine grapes	0.9%	Milk: Cattle		0.2%
	17%	DE women 14-50 yr	1.73	3%	Rye	2%	Milk: Cattle	1%	Tea (dried leaves of Camellia sinensis)		0.3%
	17%	PT general	1.66	4%	Rice	3%	Maize/corn	2%	Wine grapes		0.3%
	15%	FI 3 yr	1.53	4%	Oat	4%	Rye	3%	Rice		0.3%
	15%	NL general	1.51	2%	Tea (dried leaves of Camellia sinensis)	2%	Milk: Cattle	2%	Barley		0.3%
	15%	LT adult	1.46	6%	Rye	1%	Buckwheat and other pseudo-cereals	1%	Rice		0.3%
	14%	ES adult	1.38	3%	Barley	1%	Rice	1%	Olives for oil production		0.3%
	13%	FI adult	1.34	6%	Coffee beans	4%	Rye	0.8%	Oat		0.3%
	12%	FI 6 yr	1.20	3%	Rye	2%	Rice	2%	Oat		0.3%
	10%	UK vegetarian	1.04	2%	Tea (dried leaves of Camellia sinensis)	2%	Rice	0.9%	Beans		0.3%
	10%	UK adult	1.02	3%	Tea (dried leaves of Camellia sinensis)	2%	Rice	0.9%	Wine grapes		0.2%
	10%	DK adult	1.01	3%	Rye	1%	Swine: Muscle/meat	1%	Milk: Cattle		0.2%
	8%	FR infant	0.83	3%	Milk: Cattle	0.7%	Apples	0.4%	Swine: Muscle/meat		0.2%
	7%	IT toddler	0.69	2%	Wheat	1%	Rice	0.6%	Lettuces		0.5%
	6%	IT adult	0.58	1%	Wheat	1%	Rice	0.7%	Lettuces		0.4%
	4%	IE child	0.41	2%	Rice	0.7%	Milk: Cattle	0.3%	Wheat		0.0%
	3%	PL general	0.31	0.8%	Apples	0.7%	Potatoes	0.3%	Tomatoes		0.4%
<b>Conclusion:</b> The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Deltamethrin (cis-deltamethrin) (F) (F) is unlikely to present a public health concern.											

### A 3.3 IESTI calculations - Raw commodities

Acute risk assessment /children				Acute risk assessment / adults / general population				Acute risk assessment /children				Acute risk assessment / adults / general population				
Details - acute risk assessment /children				Details - acute risk assessment/adults				Hide IESTI new calculations				Show IESTI new calculations				
<p>The acute risk assessment is based on the ARfD.</p> <p>The calculation is based on the large portion of the most critical consumer group.</p>								<p><b>IESTI new calculations:</b></p> <p>The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.</p> <p>Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.</p>								
<p><b>Show results of IESTI calculation only for crops with GAPs under assessment</b></p>																
Unprocessed commodities	<p><b>Results for children</b></p> <p>No. of commodities for which ARfD/ADI is exceeded (IESTI): ---</p>				<p><b>Results for adults</b></p> <p>No. of commodities for which ARfD/ADI is exceeded (IESTI): ---</p>				<p><b>IESTI new Results for children</b></p> <p>No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---</p>				<p><b>IESTI new Results for adults</b></p> <p>No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---</p>			
	<b>IESTI</b>				<b>IESTI</b>				<b>IESTI new</b>				<b>IESTI new</b>			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	58%	Cauliflowers	0.1 / 0.1	5.8	42%	Head cabbages	0.1 / 0.1	4.2	35%	Cauliflowers	0.1 / 0.1	3.5	25%	Head cabbages	0.1 / 0.1	2.5
	44%	Head cabbages	0.1 / 0.1	4.4	23%	Cauliflowers	0.1 / 0.1	2.3	33%	Strawberries	0.2 / 0.2	3.3	19%	Strawberries	0.2 / 0.2	1.9
	41%	Tomatoes	0.07 / 0.07	4.1	19%	Strawberries	0.2 / 0.2	1.9	27%	Head cabbages	0.1 / 0.1	2.7	14%	Cauliflowers	0.1 / 0.1	1.4
33%	Strawberries	0.2 / 0.2	3.3	11%	Tomatoes	0.07 / 0.07	1.1	21%	Tomatoes	0.07 / 0.07	2.1	14%	Tomatoes	0.07 / 0.07	1.4	
0.8%	Brussels sprouts	0.01 / 0.01	0.08	0.6%	Brussels sprouts	0.01 / 0.01	0.06	0.8%	Brussels sprouts	0.01 / 0.01	0.08	0.6%	Brussels sprouts	0.01 / 0.01	0.06	
Expand/collapse list																
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)								

### A 3.4 IESTI calculations - Processed commodities

Processed commodities	Results for children				Results for adults				Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI new):				No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARfD/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)
	70%	Cauliflowers / boiled	0.1 / 0.1	7.0	42%	Cauliflowers / boiled	0.1 / 0.1	4.2	42%	Cauliflowers / boiled	0.1 / 0.1	4.2	25%	Cauliflowers / boiled	0.1 / 0.1	2.5
	13%	Tomatoes / juice	0.07 / 0.07	1.3	9%	Head cabbages / canned	0.1 / 0.1	0.94	13%	Tomatoes / juice	0.07 / 0.07	1.3	9%	Head cabbages / canned	0.1 / 0.1	0.94
	7%	Tomatoes / sauce/puree	0.07 / 0.07	0.67	6%	Tomatoes / sauce/puree	0.07 / 0.07	0.57	7%	Tomatoes / sauce/puree	0.07 / 0.07	0.67	6%	Tomatoes / sauce/puree	0.07 / 0.07	0.57
	6%	Head cabbages / canned	0.1 / 0.1	0.58	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	6%	Head cabbages / canned	0.1 / 0.1	0.58	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	1%	Brussels sprouts / boiled	0.01 / 0.01	0.10	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	1%	Brussels sprouts / boiled	0.01 / 0.01	0.10	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list																
<b>Conclusion:</b> No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Deltamethrin (cis-deltamethrin) (F) (F) is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.																

## **Appendix 4    Additional information provided by the applicant**

No additional data submitted.