

REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: 102000028562

Product name: Deltamethrin + Flupyradifurone EC 85 (10+75 g/L)

Chemical active substances:

Deltamethrin, 10 g/L

Flupyradifurone, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Extension of use)

Applicant: Bayer Crop Science Division

Submission date: 31/08/2021

MS Finalisation date: February 2023 (initial Core Assessment)

June 2023 (final Core Assessment)

Version history

When	What
31/08/2021	Original Bayer Crop Science Division submission
February 2023	Initial zRMS assessment. The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey . Not agreed or not relevant information are struck through and shaded for transparency .
June 2023	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow . Information no longer relevant is struck through and shaded .

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The product Deltamethrin + flupyradifurone EC 85 (10+75 g/L) (DLT+FPF EC 85 / Product Code 102000028562) has been submitted at zonal level to Poland as ZRMS in October 2019 for its use in oilseed rape. However, because the evaluation of the initial dossier submitted in October 2019 is not finished, no final Registration Report from the ZRMS is available yet.

This present dossier is for an extension of use. For such dossier, only new information should be submitted. Currently, there is new information to submit in the present section.

zRMS comment:

The product Deltamethrin + flupyradifurone EC 85 (10+75 g/L) (DLT+FPF EC 85 / Product Code 102000028562) has been submitted and evaluated by Poland as zRMS in February 2022 for its use in oilseed rape. The final Registration Report from the zRMS is available yet.

During the evaluation process, the applicant resigned from the use of the product 102000028562 / Deltamethrin + Flupyradifurone EC 85 on sunflower, however this use was evaluated.

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs of the central registration zone with respect to consumer intake and risk assessment for the preparation Sivanto Energy (DLT+FPF EC 85) in grape, sunflower, barley, oat, wheat, field corn, sorghum, millet and sweet corn are presented in Table 7.1-1. A list of all intended uses within the central zone is given in Part B, Section 0.

Overall conclusion

Flupyradifurone

The data available are considered sufficient for risk assessment.

Considering the intended uses in grape, sunflower, barley, oat, wheat, field corn/maize, millet, sorghum and sweet corn, an exceedance of the default MRL of 0.01* mg/kg for flupyradifurone (expressed as flupyradifurone), as established in Commission Regulation (EU) 2022/1324, is expected for sunflower and oat.

The current MRLs for DFA (expressed as DFA) in grape, sunflower, barley, oat, wheat, field corn/maize, millet, sorghum and sweet corn will not be exceeded.

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

Deltamethrin

The data available are considered sufficient for risk assessment. Considering the intended uses in grape, potato, oilseed rape, mustard, sunflower, barley, wheat, rye, field corn (maize), millet, sorghum and sweet corn, an exceedance of the current MRLs deltamethrin, as established in Commission Regulation (EU) 2018/832, is not expected for none of the supported crops in this dossier.

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

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

Data gaps

Data gaps identified for **flupyradifurone** (including its metabolite difluoroacetic acid (DFA)) in the framework of the EU pesticides peer review (EFSA Journal 2015; 13(2):4020) have been sufficiently addressed as summarized in the most recent MRL assessment (EFSA Journal 2020;18(6):6133). The EFSA Reasoned Opinion also states that the confirmatory data gap as set for DFA and flupyradifurone MRLs in the Commission Regulation (EU) 2016/1902 can be deleted.

Data gaps identified for **deltamethrin** in the EFSA Reasoned opinion on the 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). The expected confirmatory data were submitted in an Evaluation Report in October 2018. The rapporteur Member State AGES is currently reviewing these data.

Table 7.1-1: Acceptability of critical GAPS (central zone, only)

[illegible]

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	Crop and/ or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	g as/hL min max	water L/ha min max	g as/ha min max		
262	Corn, field (maize) (0500030)	C ¹	Sivanto Energy (DLT+FPF EC 85)	F	RHOPPA, RHOPMA, MACSAV, METODR, PYRUNU, HELIAR, DIABVI	EC	085	spray	BBCH 51- 75	1	-	DLT: 0.75- 3.75 FPF: 6.625- 28.125	200-1000	DLT: 7.5 FPF: 56.25	as per growth stage	A
218	Millet (0500040)															
264	Sorghum (0500080)				RHOPPA, RHOPMA MACSAV, METODR PYRUNU, HELIAR id											

* 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

¹ For more detailed information regarding the pests to be controlled within the different GAPs please see the list of all intended GAPs in Part B, Section 0

It should be noted that there is no sufficient data to support application of DLT+FPF EC 85 at flowering sunflower and grapes. Following the review done by zRMS, the applicant would like to request to restrict the uses of the product to applications outside of flowering.

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 DLT+FPF EC 85 is composed of deltamethrin and flupyradifurone.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of flupyradifurone and deltamethrin

Reference value	Source	Year	Value	Study relied upon	Safety factor
Parent compound flupyradifurone					
ADI	EFSA	2015	0.064 mg/kg bw day	2-generation reproductive toxicity study in rats	100
ARfD	EFSA	2015	0.15 mg/kg bw	rabbit developmental toxicity study	100
Metabolite DFA (from flupyradifurone)					
ADI	EFSA	2015	0.064 mg/kg bw day ¹	2-generation reproductive toxicity study in rats	100
ARfD	EFSA	2015	0.15 mg/kg bw ¹	rabbit developmental toxicity study	100
Parent compound cis-deltamethrin					
ADI	Review report 6504/VI/99-final	2002	0.01 mg/kg bw/d	1 year dog and 90 days dog	100
ARfD	Review report 6504/VI/99-final	2002	0.01 mg/kg bw/d	1 year dog and 90 days dog	100

¹ After an expert consultation it was concluded that the reference values of the parent flupyradifurone are also applicable to DFA (when DFA residues are expressed in flupyradifurone equivalents)

7.1.2.1 Summary for flupyradifurone

Table 7.1-3: Summary for flupyradifurone

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance (FPF/DFA)	Chronic risk for consumers identified?	Acute risk for consumers identified?
201, 352, 371, 104, 202, 353, 372, 103, 252, 253	Grape	Yes	Yes ² 4 NEU (+ 4 SEU)	Yes	Yes	Yes/Yes	No	No
105, 219, 335, 354, 373, 254	Sunflower	Yes	Yes 8 NEU (+ 8 SEU)	Yes	Yes	No ¹ / No ¹	No	No

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance (FPF/DFA)	Chronic risk for consumers identified?	Acute risk for consumers identified?
106, 107, 203, 204, 255, 336, 337, 355, 356, 374, 375, 108, 109, 205, 206, 256, 338, 339, 357, 358, 376, 377, 110, 111, 207, 208, 257, 340, 341, 112, 113, 209, 210, 342, 343, 359, 360, 378, 379, 361, 362, 380, 381	Barley / Oat	Yes	Yes 8 NEU (+ 7 SEU)	Yes	Yes	Barley: No ¹ Yes/Yes ³ Oat: No ¹ / No ² Yes ¹	No	No
114, 115, 211, 212, 258, 344, 345, 363, 364, 382, 383, 116, 117, 213, 214, 260, 261, 346, 347, 365, 366, 384, 385, 259	Wheat	Yes	Yes 8 NEU (+ 8 SEU)	Yes	Yes	No ¹ Yes ¹ /Yes ³	No	No
118, 215, 262, 348, 367, 386, 218, 216, 119, 263, 349, 368, 387, 120, 264, 350, 369, 388	Field corn / Millet / Sorghum	Yes	Yes maize 8 NEU (+ 7 SEU)	Yes	Yes	Yes/ No ² Yes Yes/ No ² Yes Yes/Yes ³	No	No
217, 351, 370, 389, 121, 265	Sweet corn	Yes	Yes 8 NEU (+ 7 SEU)	Yes	Yes	Yes/Yes	No	No

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

¹ Draft Evaluation Reports have already been submitted to cover these uses of Sivanto Energy in sunflower, oat, field corn and millet.

² Bridging trials (reduced number of trials) in order to show that the GAP is covered by the cGAP of the straight formulation

³ Import tolerances will be available for flupyradifurone and DFA which will cover the intended EU uses in barley, wheat and sorghum (EFSA Journal 2020;18(6):6133)

The intended use patterns supported for Sivanto Energy in sunflower, barley, oat, wheat, field corn (maize) and millet will not be covered by the currently approved MRLs for flupyradifurone and/or its metabolite DFA (Commission Regulation (EU) 2016/1902). Consequently, an MRL Evaluation Report (dER) has been submitted to the Netherlands (Ctgb) as designated EMS in December 2020 (update March

2021) in order to support the current submission. This dER considers the recently published EFSA Reasoned Opinion which supports import tolerances for grapes, sweet corn, barley, sorghum, wheat and field corn (EFSA Journal 2020;18(6):6133). These MRLs are expected to be authorized by the end of 2020/beginning of 2021 latest.

Considering the intended uses in grape, sunflower, barley, oat, wheat, field corn/maize, millet, sorghum and sweet corn, an exceedance of the default MRL of 0.01 mg/kg for flupyradifurone (expressed as flupyradifurone), as established in Commission Regulation (EU) 2022/1324, is expected for sunflower and oat. The current MRLs for DFA (expressed as DFA) in all intended uses will not be exceeded.

The effects of processing on the nature of flupyradifurone residues have been tested and evaluated. In addition, numerous studies investigating the effect of processing on the magnitude of flupyradifurone-related residues have been conducted. For the crops relevant to this dRR, no additional processing studies are triggered. Processing studies are available for grapes, barley, wheat and field corn (maize) and for the oilseeds soybean and cotton.

Numerous field rotational crop trials have been conducted to support the use of flupyradifurone. Apart from the "main" field study (containing data for three rotations with three crop groups: leafy, root, and cereal crops), further data on individual crops after one rotation simulating crop failure ("small" rotational crop studies on tuber, stem, fruiting, bulb, and legume vegetables, as well as on pulses and oilseeds) have been submitted for the approval of the active substance. These studies have been assessed and summarized in the EFSA Peer Review (EFSA Journal 2015;13(2):4020). The amount of flupyradifurone, applied either to bare soil or lettuce as target crop, amounted to 200 or 250 g a.s./ha (which was based on the worst-case application rate in the "home & garden" uses, which are more critical as compared to the corresponding agricultural uses).

The design of the field rotational crop studies was discussed at EU level (Pesticides Peer Review expert meeting TC 107). It was questioned if the applied application rate reflects the plateau concentration of flupyradifurone reached in soil following several years of consecutive applications as flupyradifurone is a persistent compound. Moreover, the experts were of the opinion that testing a single plant back interval (PBI) of 30 days (worst-case: crop failure) reflects an unrealistic situation for several crops. It was therefore concluded that further studies conducted at realistic PBIs and providing information on the flupyradifurone and DFA residue levels in soil are required.

In order to overcome above mentioned deficiencies, an assessment was done to identify the most reasonable plateau concentration of flupyradifurone reached in soil following several years of consecutive applications. Based on the results, additional field rotational studies (including soil sampling) were initiated in selected crops in the seasons 2016, 2017 and 2018.

Two scenarios were considered: The multi-year use of flupyradifurone in a "home & garden" product and the multi-year use of flupyradifurone by farmers. New field rotational crop studies were conducted in cereals, field corn (maize) and oilseed rape after application of 175 g a.s./ha and in potato, brassica vegetables and strawberries after application of 300 g a.s./ha to bare soil. This approach considers that crops like cereals, field corn and oilseed rape are generally not grown in gardens and thus the agricultural application rates have to be used as reference. In contrast for all crops which can be grown by non-professionals, the "home & garden" use rate has to be taken into account. Considering the possible accumulation of flupyradifurone after multi-year use, exaggerated rates of 175 g a.s./ha and 300 g a.s./ha were chosen to represent the agricultural use rates and the "home & garden" use rates, respectively as agreed with the RMS ([Spiegel, K.; 2016; M-617654-01-1](#)). The rates tested cover all the intended uses of this dRR.

According to EFSA, the submitted rotational crop studies addressed the data gap set in Commission Regulation (EU) 2016/1902 and appropriate DFA MRLs for rotational crops have been proposed in the Article 12 MRL review for flupyradifurone and DFA (EFSA Journal 2020;18(6):6133).

The uses in sunflower, barley, oat, wheat, field corn, millet and sorghum- relevant to this submission - modified slightly the theoretical maximum daily intake for animals as compared to the intake estimated in the EFSA MRL Article 12 review (EFSA, 2020) and will result in an increase of some MRLs in animal commodities. All increased MRLs will be covered by the Evaluation Report that has been submitted in December 2020 (update March 2021) to support the intended uses of this dRR.

Considering the intended uses and taking into account the estimated maximum residue an exceedance of the MRLs for

- flupyradifurone (expressed as flupyradifurone as established in Commission Regulation (EU) 2022/1324) for swine liver (MRL of 0.08 mg/kg) and the for swine kidney (MRL of 0.09 mg/kg)

- difluoroacetic acid (DFA) (Reg. (EU) 2021/1842) for fat of sheep (MRL of 0.15 mg/kg), fat of swine (MRL of 0.1 mg/kg) and fat of poultry (MRL of 0.03 mg/kg), liver of swine (MRL of 0.1 mg/kg), sheep milk (MRL of 0.03 mg/kg) and poultry eggs (MRL of 0.1 mg/kg)

is expected.

Therefore, in our opinion, until the new MRLs for flupyradifurone and DFA come into force, feeding animals will not be possible.

It should be noted that there is no sufficient data to support application of DLT+FPF EC 85 at flowering sunflower and grapes. Following the review done by zRMS, the applicant would like to request to restrict the uses of the product to applications outside of flowering.

The proposed uses of flupyradifurone in the formulation Sivanto Energy (DLT+FPF EC 85) do not represent unacceptable chronic or acute risks for the consumer.

7.1.2.2 Summary for deltamethrin

Table 7.1-4: 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?
201, 352, 371, 104, 202, 353, 372, 103, 252, 253	Grape	Yes	Yes 4 NEU (+ 4 SEU)	Yes	Yes	Yes/Yes	No	No
105, 219, 335, 354, 373, 254	Sunflower	Yes	Yes 8 NEU (+ 8 SEU)	Yes	Yes	Yes/Yes	No	No
106, 107, 203, 204, 255, 336, 337, 355, 356, 374, 375, 108, 109, 205, 206, 256, 338, 339, 357, 358, 376, 377, 110, 111, 207, 208, 257, 340, 341, 112, 113, 209, 210, 342, 343, 359, 360, 378, 379, 361, 362, 380, 381	Barley / Oat	Yes	Yes 8 NEU (+ 7 SEU)	Yes	Yes	Yes/Yes	No	No

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?
114, 115, 211, 212, 258, 344, 345, 363, 364, 382, 383, 116, 117, 213, 214, 260, 261, 346, 347, 365, 366, 384, 385, 259	Wheat	Yes	Yes 8 NEU (+ 8 SEU)	Yes	Yes	Yes/Yes	No	No
118, 215, 262, 348, 367, 386, 218, 216, 119, 263, 349, 368, 387, 120, 264, 350, 369, 388	Field corn / Millet / Sorghum	Yes	Yes maize 8 NEU (+ 7 SEU)	Yes	Yes	Yes/Yes	No	No
217, 351, 370, 389, 121, 265	Sweet corn	Yes	Yes 8 NEU (+ 7 SEU)	Yes	Yes	Yes/Yes	No	No

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

The intended use patterns supported for Sivanto Energy in grape, sunflower, barley, oat, wheat, field corn (maize)/millet/sorghum and sweet corn are covered by the currently approved MRLs for deltamethrin (Commission Regulation (EU) 2018/832).

It should be noted that there is no sufficient data to support application of DLT+FPF EC 85 at flowering sunflower and grapes. Following the review done by zRMS, the applicant would like to request to restrict the uses of the product to applications outside of flowering.

The proposed uses of deltamethrin in the formulation Sivanto Energy (DLT+FPF EC 85) do not represent unacceptable chronic or acute risks for the consumer.

7.1.2.3 Summary for DLT+FPF EC 85

Table 7.1-5: Information on DLT+FPF EC 85 (KCA 6.8)

Crop	PHI for DLT+FPF EC 85 proposed by applicant	PHI/ Withholding period sufficiently supported for		PHI for DLT+FPF EC 85 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Deltamethrin	Flupyradifurone		
Sweet corn	7 days	Yes	Yes	7 days	-
Grape	14 days	Yes	Yes	14 days	-
Sunflower	NR	NR	NR	NR	-
Cereals (barley/oat/wheat)	30 days	Yes	Yes	30 days	-
Field corn/millet/	NR	NR	NR	NR	-

Crop	PHI for DLT+FPF EC 85 proposed by applicant	PHI/ Withholding period sufficiently supported for		PHI for DLT+FPF EC 85 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Deltamethrin	Flupyradifurone		
sorghum					

NR: not relevant (application based on growth stage)

Table 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for DLT+FPF EC 85
Crop group	Deltamethrin	Flupyradifurone	
Sweet corn	NR	NR	NR
Sunflower	NR	NR	NR
Cereals (barley/oat/wheat)	NR	NR	NR
Field corn/millet/sorghum	NR	NR	NR

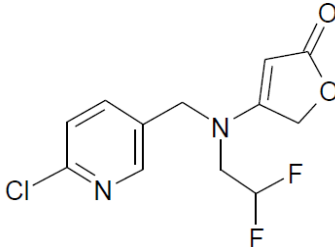
NR: not relevant

Assessment

7.2 Flupyradifurone

General data on flupyradifurone are summarized in the table below.

Table 7.2-1: General information on flupyradifurone

Active substance (ISO Common Name)	Flupyradifurone
IUPAC	4-[(6-chloro-3-pyridylmethyl)(2,2-difluoroethyl)amino]furan-2(5H)-one
Chemical structure	
Molecular formula	C ₁₂ H ₁₁ Cl F ₂ N ₂ O ₂
Molar mass	288.68 g/mol
Chemical group	Butenolide
Mode of action (if available)	Nicotinic acetylcholine receptor (nAChR) agonist
Systemic	Yes
Company (ies)	Bayer AG, Crop Science Division*
Rapporteur Member State (RMS)	The Netherlands
Approval status	Approved Commission Regulation 2015/2084 of 18 Nov. 2015 (entry into force: 9 Dec 2015)
Restriction (e.g. is restricted to use as "...")	None (confirmatory data submitted were considered sufficient to address the data gaps related to residues which were identified in the framework of the EU pesticides peer review, EFSA Journal 2020;18(6):6133)
Review Report	SANTE/11649/2015 rev 1 (Oct 9, 2015)
Current MRL regulation	Commission Regulation (EU) 2016/1902 of 27 October 2016, (entry into force: 24 November 2016); SANTE/10757/2016 [Annex IIIA] Flupyradifurone - Reg. (EU) 2022/1324 Difluoroacetic acid (DFA) - Reg. (EU) 2021/1842
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal: Conclusion on the peer review	Yes, EFSA Journal 2015; 13(2):4020 (updated version of March 2016)
EFSA Journal: conclusion on article 12	Yes, EFSA Journal 2020;18(6):6133
Current MRL applications on intended uses	An MRL application was submitted to the NL (EMS) in December 2020 (update March 2021) in order to apply for modifications of the MRLs in sunflower, oat and millet and in several livestock commodities. EFSA Journal 2020;18(11):6298

* Notifier in the EU process to whom the a.s. belong(s)

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

The stability of flupyradifurone and its metabolite difluoroacetic acid (DFA) during storage was evaluated in the final addendum to the DAR (NL, February 2015) and peer reviewed by EFSA (EFSA Journal 2015;13(2):4020). The submitted data (interim and final report) confirm freezer storage stability of both compounds at $\leq -18^{\circ}\text{C}$ for 52 months in matrices with high water content (spinach, tomato, sugarcane), high acid content (orange fruit), high oil content (soyabean), high protein content (bean), high starch content (wheat grain) and in coffee beans (EFSA Journal 2020;18(6):6133).

Excerpt from EFSA Reasoned Opinion, 2020:

The storage stability of flupyradifurone and DFA has been investigated in the EU pesticides peer review; on the basis of an interim study report, it was concluded that both compounds are stable for at least 18 months in high water, high acid, high oil, high protein and high starch content matrices when stored frozen at approximately $\leq -18^{\circ}\text{C}$ (EFSA, 2015).

The applicant now submitted the final report of the above-mentioned study, where stability of flupyradifurone and DFA residues was investigated for longer storage periods of 35 and 52 months.

The submitted data confirm freezer storage stability of both compounds at $\leq -18^{\circ}\text{C}$ for 52 months in matrices with high water content (spinach, tomato, sugarcane), high acid content (orange fruit), high oil content (soyabean), high protein content (bean), high starch content (wheat grain) and coffee beans.

During the transport of samples from supervised residue trials of maize (study 16-2100), storage temperature deviations occurred. The worst-case deviation was a temperature raise during a time period of 24.5 hours, with a maximum temperature of -12°C , resulting in an average temperature of -15°C during these 24.5 hours. Since none of the samples thawed, the stability of residues can be assumed, particularly when considering that several short-term temperature increases $\geq 0^{\circ}\text{C}$ (up to 6.5°C) were also observed in the long-term stability study.

In addition, a short-term storage stability study at exaggerated temperatures is available, which shows the stability of flupyradifurone and DFA residues in matrices of high water (green material) and high starch content (kernels and seeds) under more critical conditions ([Lakaschus, S.; Gizler, A.; 2017; M-480441-06-1](#)). Stability of flupyradifurone and DFA residues was shown for samples stored for 8 hours at $+1^{\circ}\text{C}$, followed by 6-8 days at -7°C . The study is summarized in [Appendix 2](#).

The available storage stability studies for flupyradifurone and DFA at exaggerated temperatures confirmed the storage stability of relevant flupyradifurone residues during storage and validate the residue results of the maize residue studies.

The longest storage duration relevant to this submission was detected for sunflower and amounted for 635 days (approx. 21 months). Therefore, the maximum storage duration relevant to this submission is well covered by storage stability data for flupyradifurone and DFA.

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
Data relied on in EU			
Plant products			
Sugar cane Spinach leaves Tomato fruit	High water content	Flupyradifurone (BYI 02960), Difluoroacetic acid (DFA): 18 months	
Soybean seed Coffee bean	High oil content		

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Bean seed	High protein content	Flupyradifurone (BYI 02960), Difluoroacetic acid (DFA): 52 months	Netzband, D.; Timberlake, B. C.; Harbin, A. M.; 2012 xxx; M-428412-02-1 RARVP046-1
Wheat grain	High starch content		DAR, NL, 2015 EFSA Journal 2015; 13(2):4020
Orange fruit	High acid content		Netzband, D.; 2015; M-428412-03-1 RARVP046-2 (amended version of RARVP046-1) EFSA Journal 2020;18(6):6133
Animal Products			
Poultry For parent flupyradifurone and metabolite DFA, no storage stability testing in poultry matrices is required, as the longest storage duration of the samples was < 1 month in the poultry feeding study.			
Ruminant For parent flupyradifurone, no storage stability testing for ruminant matrices is required, as the longest storage duration of the samples was < 1 month in the cattle feeding study.			
Bovine	Muscle	Difluoroacetic acid (DFA): 43 days	xxx; M-428416-02-1 , RARVP050 DAR, NL, 2015 EFSA Journal 2015; 13(2):4020
Bovine	Liver		
Bovine	Kidney		
Bovine	Fat		
Poultry/Ruminant Storage at exaggerated temperature			
Poultry	Eggs	Difluoroacetic acid (DFA): 2 days (at refrigerator conditions)	Williams, J.; Jerkins, E.; 2017; M-611007-01-1 RARVN150 EFSA Journal 2020;18(6):6133
Poultry	Muscle		
Poultry	Liver		
Poultry	Fat		
Dairy cow	Milk		
Dairy cow	Kidney		
New data			
Plant products Storage at exaggerated temperature			
Tomato fruit Wheat green material	High water content	Flupyradifurone (BYI 02960), Difluoroacetic acid (DFA): 8 hours at +1°C followed by 6-8 days of storage at -7°C	Lakaschus, S.; Gizler, A.; 2017; M-480441-06-1 S13-03307 Appendix 2
Peas, dry	High protein content		
Wheat grain Potato tuber	High starch content		
Grape bunches	High acid content		

Conclusion on stability of residues during storage

Residues of flupyradifurone and its metabolite difluoroacetic acid (DFA) were shown to be stable for up to 52 months in soybean (seed), coffee (bean), sugarcane, spinach (leaves) and tomato (fruit), bean seed, wheat grain and orange fruit in frozen storage at $\leq -18^{\circ}\text{C}$.

The maximum storage period of frozen samples obtained from the plant residue studies (field residue,

rotational crop or processing studies) included in this dRR are shown in the table below.

The maximum storage period of sunflower seeds in residue studies was 635 days (approx. 21 months) and is the longest storage duration relevant to this submission.

Hence, the results of the storage stability studies validate the residue values with respect to the stability of flupyradifurone and its metabolite DFA in deep-frozen samples relevant to this submission.

One additional study performed at exaggerated temperatures during storage validates the results of the residue studies with respect to stability of flupyradifurone and DFA in maize.

Sample material		Longest storage duration (d)	Report No.	Study dRR
Crop	Matrix			
Grape	bunch of grapes	275	14-2096	A 2.1.3.1.1
	berries	249		
	bunch of grapes	286	14-2095	A 2.1.3.1.2
	berries	260		
Sunflower	seed	635	16-2145	A 2.1.3.2.1
	kernel	532	16-2194	A 2.1.3.2.2
	seed	589		
	kernel	569	16-2195	A 2.1.3.2.3
Barley	seed	550		
	kernel	534	15-2131	A 2.1.3.3.1
	whole plant without roots	316		
	straw	294		
	grain	289	16-2035	A 2.1.3.3.2
	whole plant without roots	541		
	straw	513		
	grain	513	15-2130	A 2.1.3.3.3
	whole plant without roots	224		
	straw	291		
Wheat	grain	187	16-2034	A 2.1.3.3.4
	ear	195		
	whole plant without roots	569		
	straw	539	15-2129	A 2.1.3.4.1
	grain	539		
	whole plant without roots	182		
	straw	239	16-2033	A 2.1.3.4.2
	rest of plant	139		
	grain	160		
	ear	138	15-2127	A 2.1.3.4.3
	whole plant without roots	512		
	straw	481		
Maize	grain	489	16-2032	A 2.1.3.4.4
	whole plant without roots	212		
	straw	274		
	grain	188	15-2134	A 2.1.3.5.1
	whole plant without roots	554		
	straw	524		
	grain	524	16-2192	A 2.1.3.5.2
	rest of plant	197		
	kernel, immature	230		
	kernel	195		
	green material	239		
	rest of plant	218		
	kernel, immature	226		
	kernel	189		
	green material	246		

Evaluator comment:

The product Deltamethrin + flupyradifurone EC 85 (10+75 g/L) (DLT+FPF EC 85 / Product Code 102000028562) has been submitted and evaluated by Poland as ZRMS in February 2022 for its use in oilseed rape. The final Registration Report from the zRMS is available yet.

Information given by the Applicant is sufficient and acceptable. The studies of Netzband, D. (2015; M-428412-03-1) and Lakaschus, S.; Gizler, A.; 2017 (M-480441-06-1, S13-03307) have been evaluated and accepted (see RR for 102000028562 / DLT+FPF EC 85 (zRMS-PL, February 2022).

The submitted data confirm freezer storage stability of flupyradifurone and DFA at -18°C for 52 months in matrices with high water content (spinach, tomato, sugarcane), high acid content (orange fruit), high oil content (soyabean), high protein content (bean), high starch content (wheat grain) and coffee beans.

It should be noted that address storage stability in one commodity from each of the five commodity categories, an extrapolation to all other crops is possible (in line with paragraph 25 of OECD Guideline 506) and accepted.

The residue trial samples of crops under consideration were stored under conditions for which the stability of flupyradifurone and DFA residues has been demonstrated.

No further data are required.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Since the validity of the methods depends on factors such as reproducibility and the possibility of interruption during the work process, it must be ensured that the stability of relevant residues during possible storage of extracts is always guaranteed. The storage stability of flupyradifurone-related residues in extracts was tested during development of the analytical methods.

During the course of the method validations, stability was shown in all tested matrix extracts for at least 4-8 days, when stored in the dark in a refrigerator at $4^{\circ}\text{C} \pm 3^{\circ}\text{C}$.

Additionally, relevant information on the stability of residues in the final or any intermediate extracts can be derived from the fortification experiments performed during sample analysis. Every analytical batch does contain at least one freshly fortified sample for concurrent recovery determination. The extracts of the fortified samples and of the study samples are handled and stored in parallel. If the recoveries in the fortified samples are within acceptable ranges, the stability of the sample extracts is considered as sufficiently proven.

Conclusion on stability of residues in sample extracts

It can be concluded, that flupyradifurone and its metabolite DFA were stable for at least 4-8 days when stored in the dark in a refrigerator at $4^{\circ}\text{C} \pm 3^{\circ}\text{C}$. In addition, relevant information on the stability of residues in the final or any intermediate extracts can be derived from the fortification experiments performed during sample analysis. Every analytical batch contained at least one freshly fortified sample for concurrent recovery determination. The extracts of the fortified samples and of the study samples were handled and stored in parallel. Since the recoveries in the fortified samples were within acceptable ranges, the stability of the sample extracts was considered to be sufficiently proven.

Evaluator comment:

Information given by the Applicant is sufficient and acceptable.
No further data are required.

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

The metabolism of flupyradifurone has been investigated in apple, tomato, potato, cotton, and rice (representing five diverse crops) after foliar, soil, or seed treatment application with ¹⁴C-fluprydifurone. These studies have already been reported and evaluated in the final addendum to the DAR (NL, 2015) and peer reviewed by EFSA (EFSA Journal 2015;13(2):4020). The results are summarized in [Table 7.2-3](#).

During the last assessment EFSA requested information on metabolism in genetically modified crops, i.e. data on the nature and magnitude of flupyradifurone in GM crops compared with conventional crops. The applicant analysed different genetically modified crops (maize, cotton, soybean and potato with genetical modifications to introduce herbicide tolerance, insect resistance, modified product qualities and marker genes inserted to allow monitoring of gene expressions in plant cells). The applicant provided sufficient evidence that, based on the mode of action or structural conformity of targets in the GM crops, the metabolism of flupyradifurone in these GM crops will not be altered.

For the authorized and the intended uses under consideration, it has been concluded that the metabolic behaviour in primary crops is addressed (EFSA Journal 2020;18(6):6133).

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

Table 7.2-3: Summary of plant metabolism studies

Table 7.2-5: Summary of plant metabolism studies								
Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (g a.s./ha)	No	Sampling (DALT)	Remarks	
EU data								
Fruits and fruiting vegetable	Apple	[furanone-4- ¹⁴ C]	Foliar, F ^I	86 g a.s./ha x mCH)	1	leaves and fruit: 98 days; BBCH 87-89	-	Justus, K.; 2011; M-422562-01-1 MEF-11/499
				86 g a.s./ha x mCH)	2	leaves and fruit: 14 days; BBCH 87-89		
		[pyridinyl-methyl- ¹⁴ C]	Foliar, F ^I	87 g a.s./ha x mCH)	1	leaves and fruit: 98 days; BBCH 87-89	-	Justus, K.; 2011; M-414678-01-2 MEF-11/198
				86 g a.s./ha x mCH)	2	leaves and fruit: 14 days; BBCH 87-89		

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (g a.s./ha)	No	Sampling (DALT)	Remarks	
Fruits and fruiting vegetable (cont.)	Tomato	[furanone-4- ¹⁴ C]	Soil drench, G	300	2	flowers: 6-36 days ² ; BBCH 61-69 fruit: 69-92 days; BBCH 81-89	-	Justus, K.; 2011; M-411352-01-3 MEF-11/016 DAR, NL, 2015 EFSA Journal 2015; 13(2):4020
		[pyridinyl-methyl- ¹⁴ C]		300	2	flowers: 3-36 days ² ; BBCH 61-69 fruit: 73-92 days; BBCH 81-89	-	Justus, K.; 2011; M-411500-01-2 MEF-11/498 DAR, NL, 2015 EFSA Journal 2015; 13(2):4020
		[ethyl-1- ¹⁴ C]		300	2	flowers: 1-32 days ² ; BBCH 61-69 fruit: 56-86 days; BBCH 81-89	-	Unold, M.; Justus, K.; 2011; M-413996-01-2 MEF-11/016 DAR, NL, 2015 EFSA Journal 2015; 13(2):4020
Root and tuber vegetables	Potato	[furanone-4- ¹⁴ C]	Tuber treatment, F ¹	10 g a.s./dt = 254 g a.s./ha	1	tuber: 97 days; BBCH 97	-	Justus, K.; 2011; M-415234-01-2 MEF-10/769 DAR, NL, 2015 EFSA Journal 2015; 13(2):4020
			In-furrow appl. at planting, F ¹	626	1	tuber: 97 days, BBCH 97		
		[pyridinyl-methyl- ¹⁴ C]	Tuber treatment, F ¹	10 g a.s./dt = 254 g a.s./ha	1	tuber: 97 days, BBCH 97	-	Justus, K.; 2011; M-415078-01-2 MEF-10/710 DAR, NL, 2015 EFSA Journal 2015; 13(2):4020
			In-furrow appl. at planting, F ¹	626	1	tuber: 97 days, BBCH 97		

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (g a.s./ha)	No	Sampling (DALT)	Remarks	
Pulses and oilseeds	Cotton	[furanone-4- ¹⁴ C]	Foliar, G	209	1	intermediate: 28 days BBCH 22-24 gin trash, lint, seed: 169 days; BBCH 99	-	Schmeling, S.; Weber, E.; 2011; M-421625-01-1 MEF-11/392 DAR, NL, 2015 EFSA Journal 2015; 13(2):4020
			Foliar, G	193	2	gin trash, lint, seed: 14 days; BBCH 99		
		[pyridinyl-methyl- ¹⁴ C]	Foliar, G	1) 206 2) 176	1	intermediate: 28 days BBCH 22-24 gin trash, lint, seed: 169 days; BBCH 99	-	Schmeling, S.; Weber, E.; 2011; M-421691-01-1 MEF-11/393 DAR, NL, 2015 EFSA Journal 2015; 13(2):4020
			Foliar, G	1) 206 2) 177	2	gin trash, lint, seed: 15 days; BBCH 99		
Cereals	Paddy rice	[furanone-4- ¹⁴ C]	Soil granule at transplanting, G	0.409	1	kernels, husks, straw: 127 days, BBCH 89-92	-	Schmeling, S.; Weber, E.; 2011; M-414219-01-2 MEF-11/058 DAR, NL, 2015 EFSA Journal 2015; 13(2):4020
			Foliar, G	1) 175 2) 240	2	kernels, husks, straw: 29 days, BBCH 89-92		
		[pyridinyl-methyl- ¹⁴ C]	Soil granule at transplanting, G	0.434	1	kernels, husks, straw: 127 days, BBCH 89-92	-	Schmeling, S.; Weber, E.; 2011; M-414328-01-2 MEF-11/059 DAR, NL, 2015 EFSA Journal 2015; 13(2):4020
			Foliar, G	1) 178 2) 236	2	kernels, husks, straw: 29 days, BBCH 89-92		

¹ The plants were grown in the glass-roofed vegetation area of the test facility which allows cultivation similar to natural temperature and light conditions, but protected from rainfall.

² Tomato: newly opened tomato flowers were sampled 2-3 times a week starting at 6 days after the last application and continuing over a period of 30 days (until end of flowering). Fully ripe fruits were harvested 2-3 times a week from the remaining three plants, until no fruits were produced anymore (BBCH 89).

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

(b) F or G not reported

Summary of plant metabolism studies reported in the EU

Excerpt from EFSA Conclusion on the peer review, 2015:

Flupyradifurone metabolism in primary crops was investigated in four crop groups either by foliar applications (apple, cotton, rice), by soil granule/drench applications (tomato, potato, rice) and by seed dressing (potato). Studies were conducted using ¹⁴C-flupyradifurone labelled on the pyridinyl or furanone moiety and using application rates representative of the supported uses. One study on tomato using soil drench application and a ¹⁴C-labelling on the difluoroethyl amino group was also submitted.

The metabolism in primary crops was seen to be similar in all plant groups investigated. Flupyradifurone was consistently observed as the major component of the radioactive residues, accounting for ca. 25% to 88% TRR in all plant parts analysed. Besides flupyradifurone, the following metabolites were identified in different plant matrices:

- the conjugate flupyradifurone-hydroxy-glycoside, up to 36%TRR in apple leaves,

- the conjugate *CHPM*-diglycoside, up to 37% TRR (0.06 mg/kg) and the metabolite 6-CNA in the range of 13% to 22% TRR in tomato fruit, potato tuber and cotton seed at ca. 0.02 mg/kg, both resulting from the cleavage of the molecule at ethylamine bond and containing the pyridinyl moiety.

In contrast, metabolites containing the furanone moiety were almost not detected and the radioactivity in the ^{14}C -furanone studies was mostly recovered as incorporated in natural glucoside and carbohydrate components, indicating an extensive degradation of the furanone counterpart. In addition, information was given by the study conducted on tomato with the ^{14}C -labelling on the difluoroethyl amino group that, following soil drench application, significant proportions (87% TRR) and levels (0.17 mg/kg) of difluoroacetic acid (DFA) are present in tomato fruits. Samples from the radiolabelled studies were therefore re-analysed for non-radiolabelled DFA and residues, expressed as DFA equivalent, were measured in the range of 0.04 to 0.23 mg/kg in apple fruits, potato tuber, cotton seed and rice grain, irrespective of the mode of application. (...)

In primary crops, flupyradifurone is not extensively degraded and the metabolism in plant proceed via the hydroxylation of the furanone ring leading to the M8 metabolite and its glycoside conjugates and via the cleavage of the parent molecule at the ethylamine bond resulting in the formation of metabolites containing the pyridinyl moiety (*CHMP*-diglycoside, 6-CNA free and conjugated). The furanone counterpart is extensively metabolised and incorporated in natural glycoside or carbohydrate components. (...)

Based on these studies, and considering the outcome of the Peer Review Meeting 122 on toxicology where it was concluded that the toxicological reference values set for flupyradifurone are also applicable to DFA, the residue definition for risk assessment was proposed as “sum of flupyradifurone and DFA expressed as flupyradifurone”. For enforcement, the residue definition was intensively discussed in the teleconference meeting 107 (...). It was finally agreed that two separate residue definitions would be required, as “flupyradifurone”; to consider the residues resulting from the uses of the active substance on primary crops, and as “DFA, expressed as DFA”; to consider DFA residues in rotational crops.

Conclusion on metabolism in primary crops

Target crop metabolism studies have been performed on apple, tomato, potato, cotton, and rice (representing five diverse crops from four different crop groups) using foliar, soil, or seed treatment application with ^{14}C -flupyradifurone (labelled in the furanone ring or pyridinylmethyl position) formulated as 200 SL (for foliar and soil applications) and 480 FS (for seed treatment applications).

The metabolism studies were conducted at rates covering the anticipated worst case GAPs. The submitted foliar treatment uses on grape, sweet corn, sunflower, wheat, barley, oat, field corn, millet and sorghum are covered by the available metabolism studies.

Evaluator comment:

Information given by the Applicant is sufficient.

Flupyradifurone metabolism in primary crops was investigated in the framework of the EU pesticides peer review in four crop groups either by foliar applications (apple, cotton, rice), by soil granule/drench applications (tomato, potato, rice) and by seed treatment (potato). Studies were conducted using ^{14}C -flupyradifurone labelled on the pyridinyl and furanone moiety. One study on tomato using soil drench application and a ^{14}C -labelling on the difluoroethyl amino group was also submitted (EFSA, 2015). The metabolism in primary crops was seen to be similar in all plant groups investigated.

In EFSA Journal 2020;18(6):6133 it is stated that based on the metabolic pattern identified in primary and rotational crop metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and/or degradation products, the capabilities of enforcement analytical methods, the following **residue definitions** were agreed by the EU pesticides peer review (EFSA, 2015):

- Residue definition for risk assessment: Sum of flupyradifurone and DFA, expressed as flupyradifurone.
- Residue definition for enforcement: 1) Flupyradifurone; 2) DFA, expressed as DFA.

The same residue definitions are applicable to rotational crops and processed products.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition for enforcement.

No further data are required.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

The nature of the residues in rotational crops has been investigated in three representative crop types, a leafy crop, a root crop and a cereal after application of either [pyridinylmethyl-¹⁴C]flupyradifurone or [furanone-4-¹⁴C]flupyradifurone to bare soil. These studies have already been reported and evaluated in the final addendum to the DAR (NL, 2015) and peer reviewed by EFSA (EFSA Journal 2015; 13(2):4020). A summary of the confined rotational crop studies is presented in [Table 7.2-4](#).

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

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

Summary of metabolism studies in rotational crops								
Crop group	Crop	Label position	Application and sampling details				Remarks	Reference
			Method, F or G *	Rate (g a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		
EU data								
Leafy vegetables	Swiss chard	[furanone-4- ¹⁴ C]	Bare soil, F ¹ , G	436	29, 135 and 296	immature SC DAT: 58, 170, 344 days, BBCH 44-46 mature SC DAT: 76, 197, 359 days BBCH 49	-	Klempner, A.; 2011; M-421861-01-1 MEF 11/365 DAR, NL, 2015 EFSA Journal 2015; 13(2):4020
Root and tuber vegetables	Turnips					turnip leaves and roots DAT: 85, 209, 380 days BBCH 45-47		
Cereals	Wheat					wheat forage DAT: 69, 167, 350 days, BBCH 29-31 wheat hay DAT: 101, 237, 401 days, BBCH 79-83 wheat grain and straw DAT:134, 294, 440 BBCH 87-92		

Crop group	Crop	Label position	Application and sampling details				Remarks	Reference
			Method, F or G *	Rate (g a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		
Leafy vegetables	Swiss chard	[pyridinyl-methyl- ¹⁴ C]	Bare soil, F ¹ , G	436	29, 135 and 296	immature SC DAT: 58, 170, 344 days, BBCH 44-46 mature SC DAT: 76, 197, 359 days BBCH 49	-	Breuer-Rehm, M.; 2012: M-419853-02-1 MEF 10/892 DAR, NL, 2015 EFSA Journal 2015; 13(2):4020
Root and tuber vegetables	Turnips					turnip leaves and roots DAT: 85, 209, 380 days BBCH 45-47		
Cereals	Wheat					wheat forage DAT: 69, 167, 350 days, BBCH 29-31 wheat hay DAT: 100, 237, 401 days, BBCH 79-83 wheat grain and straw DAT: 134, 294, 440 BBCH 87-92		

F¹, G Depending on the season, the different rotations were either conducted in the vegetation hall (F) or in the greenhouse (G) of the test facility.

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

Summary of plant metabolism studies reported in the EU

Excerpt from EFSA Conclusion on the peer review, 2015:

A similar metabolic profile [compared to primary crops] was observed in the confined rotational studies conducted with a ¹⁴C-pyridinyl and ¹⁴C-furanone labelling, where flupyradifurone and its metabolites flupyradifurone-hydroxy, 6-CNA and their conjugates were seen to be the major components of the radio-active residues. These radiolabelled studies are however incomplete as they did not include a labelling on the difluoroethyl amino group. Information provided by rotational crop field studies, indicates that DFA is the major component of the residues in rotational crops. The presence of DFA is mostly the result of a preferential uptake from soil, where this metabolite was identified as a major metabolite. (...)

Based on these studies, and considering the outcome of the Peer Review Meeting 122 on toxicology where it was concluded that the toxicological reference values set for flupyradifurone are also applicable to DFA, the residue definition for risk assessment was proposed as “sum of flupyradifurone and DFA expressed as flupyradifurone”. For enforcement, the residue definition was intensively discussed in the teleconference meeting 107 (...). It was finally agreed that two separate residue definitions would be required, as “flupyradifurone”; to consider the residues resulting from the uses of the active substance on primary crops, and as “DFA, expressed as DFA”; to consider DFA residues in rotational crops.

Additional information:

The metabolism of flupyradifurone was investigated in the rotational crops wheat, Swiss chard and turnips from three consecutive rotations in two separate experiments with [furanone-4-¹⁴C]flupyradifurone and [pyridinylmethyl-¹⁴C]flupyradifurone.

Since no confined rotational crop study with [ethyl-1-¹⁴C]flupyradifurone was available, all samples from the confined rotational crop study with [furanone-4-¹⁴C]flupyradifurone were analyzed in addition by LC-MS/MS for difluoroacetic acid (DFA). The analyses revealed that DFA was the main metabolite in wheat grains (all rotations) and in turnip roots (1st rotation) and was a major metabolite in all other RACs. As a consequence, DFA was included in the data collection method for the field rotational crop studies.

The plant metabolism studies have shown a reasonably consistent metabolic profile across both foliar and soil application. The only residues of flupyradifurone that were consistently observed at significant levels across all primary and succeeding crops were the parent compound flupyradifurone and its metabolite DFA, both of which are specific to flupyradifurone use.

Conclusion on metabolism in rotational crops

These data were peer reviewed as part of the registration decision and were considered to be acceptable (see EFSA Journal 2015;13(2):4020). No additional confined rotational crop studies need to be conducted to support the submitted foliar treatment uses on grape, sweet corn, sunflower, wheat, barley, oat, field corn, millet and sorghum.

Evaluator comment:

Information given by the Applicant is sufficient.

The nature of flupyradifurone in rotational crops (turnips, Swiss chard and wheat) was investigated in the framework of the EU pesticides peer review. Flupyradifurone, labelled at ¹⁴C-pyridinyl and ¹⁴C-furanone moiety, was applied on a bare soil at an application rate of 436 g/ha. Rotational crops were planted 29, 135 and 296 days after the soil treatment. In rotational crops, flupyradifurone and its metabolites Flupyradifurone-hydroxy, 6-CNA and their conjugates were found to be the major components of the radioactive residues (EFSA, 2015). These radiolabelled studies did not include the labelling on the difluoroethyl amino group. Additional field rotational crop studies indicated that DFA is the major component of the residues in rotational crops. The presence of DFA is mostly resulting from the uptake from soil, where this metabolite was identified as a major metabolite (EFSA, 2015).

No further data are required.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

Studies investigating the nature of flupyradifurone residues in processed commodities were reported and evaluated in the final addendum to the DAR (NL, 2015) and peer reviewed by EFSA (EFSA Journal 2015;13(2):4020). A summary of the nature of the residues in processed commodities is presented in [Table 7.2-5](#).

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

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

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Parent (100%)	Weber, E.; 2011; M-402311-01-2
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Parent (100%)	MEF-10/856 DAR, NL, 2015
Sterilisation (20 minutes, 120°C, pH 6)	Parent (100%)	EFSA Journal 2015; 13(2):4020

The test compound flupyradifurone was stable under all representative conditions of high temperature hydrolysis for simulation of food processing. No significant hydrolysis products of flupyradifurone were detected above an estimated LOD of 0.5% of the total radioactivity.

It was also confirmed that no additional high-temperature hydrolyses have to be conducted with DFA since no additional metabolites will be expected in significant amounts.

Excerpt from EFSA Conclusion on the peer review, 2015:

Flupyradifurone was seen to be stable under standard hydrolysis conditions.

Excerpt from EFSA Reasoned Opinion (Article 12 MRL review for flupyradifurone and DFA, 2020):

Studies investigating the effect of processing on the nature of flupyradifurone (hydrolysis studies) demonstrated that the active substance is stable. Studies investigating the effect of processing on the nature of DFA are not available. However, considering the structural similarity of DFA with trifluoroacetic acid (TFA), which is very stable under hydrolysis conditions, EFSA agrees with the applicant and EMS that DFA is unlikely to degrade under standard hydrolytic conditions.

Conclusion on nature of residues in processed commodities

The conditions of high temperature hydrolysis tested (pasteurization, baking, brewing, boiling and sterilisation) are also representative for the processing of the crops relevant to this dossier, such as preparation of pasteurised juice from grape, oil from sunflower seed, beer from barley and bread from wheat. Thus, for the central zone, the use to be supported on grape, sunflower, wheat, barley and corn (field/sweet) is sufficiently covered by the metabolism studies on the nature of residues in processed commodities.

Evaluator comment:

Information given by the Applicant is sufficient.

In the EFSA Journal 2020;18(6):6133 it is stated that the effect of processing on the nature of flupyradifurone was investigated in the framework of the EU pesticides peer review (EFSA, 2015). Standard hydrolysis studies showed that flupyradifurone is hydrolytically stable under standard processing conditions of pasteurisation, baking/brewing/boiling and sterilisation. The effect of processing on the nature of difluoroacetic acid (DFA) has not been investigated.

EFSA agrees with the EMS that there is sufficient evidence that difluoroacetic acid is stable under standard hydrolysis conditions.

No further data are required.

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

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

Endpoints	
Plant groups covered	Fruits and fruiting vegetable: Tomato (soil drench application), apple (foliar application) Root and tuber vegetables: Potato (seed treatment and in-furrow spray application) Pulses and oilseeds: Cotton (foliar application) Cereals: Paddy rice (foliar application and granule application at transplanting) (EFSA Journal 2015;13(2):4020)
Rotational crops covered	Leafy vegetable: Swiss chard Root and tuber vegetable: Turnip Cereal: Wheat (EFSA Journal 2015;13(2):4020)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes (EFSA Journal 2015; 13(2):4020)
Processed commodities	Hydrolysis studies simulating pasteurisation, boiling and sterilisation: Flupyradifurone was shown to be stable under standard hydrolysis conditions (EFSA Journal 2015; 13(2):4020)
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes (EFSA Journal 2015;13(2):4020)
Plant residue definition for monitoring	Two separate residue definitions (EFSA Journal 2015;13(2):4020; Reg. (EU) 2022/1324 for Flupyradifurone and Reg. (EU) 2021/1842 for Difluoroacetic acid (DFA)): 1) Flupyradifurone (expressed as flupyradifurone) 2) DFA (expressed as DFA)

Plant residue definition for risk assessment	Sum of flupyradifurone and DFA, expressed as flupyradifurone (EFSA Journal 2015;13(2):4020)
Conversion factor from enforcement to RA	not appropriate (EFSA Journal 2015;13(2):4020)

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

Available data

The metabolism of flupyradifurone has been investigated in lactating goats and laying hens using flupyradifurone radiolabelled in the pyridinylmethyl or the furanone moiety. These studies have already been reported and evaluated in the final addendum to the DAR (NL, 2015) and peer reviewed by EFSA (EFSA Journal 2015;13(2):4020). The results are summarized in [Table 7.2-7](#).

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

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[furanone-4- ¹⁴ C]	1	1.0	5	Milk	Twice daily ¹	Bongartz, R.; Koester, J.; 2011; M-419701-01-1 MEF-11/269 DAR, NL, 2015; EFSA Journal 2015;13(2):4020
						Urine and faeces	Daily	
						Tissues (liver, kidney, round and loin muscle, perirenal and omental fat)	After sacrifice	
		[pyridinyl-methyl- ¹⁴ C]	1	1.0	5	Milk	Twice daily ¹	Bongartz, R.; Koester, J.; 2011; M-421995-01-1 MEF-11/268 DAR, NL, 2015 EFSA Journal 2015;13(2):4020
						Urine and faeces	Daily	
						Tissues (liver, kidney, round and loin muscle, perirenal and omental fat)	After sacrifice	
Laying poultry	Laying hen	[furanone-4- ¹⁴ C]	6	1.05	14	Eggs	Daily ²	Bongartz, R.; Koester, J.; 2012; M-422263-01-1 MEF-11/200 DAR, NL, 2015 EFSA Journal 2015;13(2):4020
						Excreta	Daily	
						Tissues (leg and breast muscle, fat, liver, kidney, skin and eggs from ovary/oviduct)	After sacrifice	
Laying poultry	Laying hen	[pyridinyl-methyl- ¹⁴ C]	6	1.02	14	Eggs	Daily ³	Bongartz, R.; Koester, J.; 2012; M-422162-01-1 MEF-11/199 DAR, NL, 2015 EFSA Journal 2015;13(2):4020
						Excreta	Daily ³	
						Tissues (leg and breast muscle, fat, liver, kidney, skin and eggs from ovary/oviduct)	After sacrifice	

¹ Milk was collected twice per day (morning milk directly before the administration and evening milk approx. 8 h after the

administration), milk collected 24 to 102 hours after the first administration was pooled and used for metabolic profiling

² Eggs were collected every morning before administration; for metabolic profiling, two egg pools were prepared: eggs of days 2 to 7 and eggs of day 8 to sacrifice,

Excreta was collected daily, but only the excreta collected 13 days after the first administration was used for metabolic profiling

³ Eggs were collected every morning before administration; for metabolic profiling, an egg pool was prepared from eggs collected 3 days after the first administration to sacrifice;

Excreta was collected daily, but only the excreta collected 13 days after the first administration was used for metabolic profiling

Summary of animal metabolism studies reported in the EU

EFSA Journal 2015;13(2):4020 summarises and concludes on the livestock metabolism studies.

Excerpt from EFSA Conclusion on the peer review, 2015:

Livestock metabolism studies conducted with ¹⁴C-flupyradifurone labelled on the pyridinyl [pyridinylmethyl] or furanone moiety at the dose rate of ca. 1 mg/kg bw over 5-6 days (goat) or 14 days (hen) were submitted. In ruminant, the degradation of the parent compound was limited, flupyradifurone accounting for 24%-35% in milk and kidney up to 81%-99% in fat. The metabolism was more extensive in hen, and flupyradifurone almost not detected in any poultry matrices in the ¹⁴C-furanone study (<3% TRR) and in the range of 1% (liver) to 20% TRR (eggs) in the ¹⁴C-pyridinyl study. The main components identified in hen were the hydroxy-flupyradifurone metabolites (18% TRR in eggs) and its sulphate conjugated in fat and liver (16-23% TRR) and the acetyl-AMCP metabolite in egg, fat and muscle (23 to 40% TRR). As for plants, the metabolic picture given by these studies is incomplete as the ¹⁴C labelling on the difluoroethyl amino group is missing. The feeding studies conducted with animals dosed with flupyradifurone alone, revealed that DFA is a major marker of the residues in poultry matrices and in a lesser extent, in ruminant matrices. Based on these studies the residue definitions were proposed as “sum of flupyradifurone and DFA expressed as flupyradifurone” for risk assessment and as flupyradifurone and as DFA as for plant two separate residue definitions were proposed for enforcement respectively.

Additional information and correction of typos in EFSA Conclusion:

Livestock metabolism studies conducted with ¹⁴C-flupyradifurone labelled on the pyridinylmethyl or furanone moiety at the dose rate of approx. 1 mg/kg bw over 5-6 days (goat) or 14 days (hen) were submitted. In ruminant, the degradation of the parent compound was less pronounced compared to poultry: In the ¹⁴C-pyridinylmethyl study, flupyradifurone accounted for 89% of the TRR in milk and for 85-99% in liver, muscle and fat; in kidney 35% of the TRR was identified as flupyradifurone. In the ¹⁴C-furanone study, flupyradifurone accounted for 24% in milk, the major radioactive residue was assigned to a natural compound (lactose). In fat and muscle again high percentages of flupyradifurone were detected (81-88%), in kidney and liver flupyradifurone accounted for 51-60%. The metabolism was more extensive in hen, and flupyradifurone was almost not detected in any poultry matrices in the ¹⁴C-furanone study (<3% of TRR) and in the range of <1% (liver) to 20% (eggs) in the ¹⁴C-pyridinyl study. The main components identified the ¹⁴C-pyridinylmethyl study was the hydroxy-flupyradifurone metabolite (up to 18% of the TRR in eggs) and its sulphate conjugate (16-23% in fat and liver), as well as the acetyl-AMCP metabolite, which was mainly detected in egg, fat and muscle (23 to 40% of TRR). In the ¹⁴C-furanone study, again the instability of the furanone ring was seen resulting in incorporation of C1 and C2-fragments in natural compounds. Endogenous fatty acids accounted for 52-96% in liver, eggs and fat. Since no metabolism studies were conducted with [ethyl-1-¹⁴C]flupyradifurone, selected livestock samples were analyzed for difluoroacetic acid (DFA) by high resolution LC-MS. The analysis revealed rather high DFA concentrations and thus it was concluded that DFA has to be included in the data collection method for livestock matrices, besides parent compound, the hydroxy and the acetyl-AMCP metabolite.

Conclusion on metabolism in livestock

Livestock metabolism studies have been conducted in goat and hen. These data were peer reviewed as part of the approval process and were considered to be acceptable (EFSA Journal 2015;13(2):4020).

As straw of the cereals including stover of maize, and as well sunflower and wheat meal can be fed to cattle and laying hens, the transfer of flupyradifurone and DFA residues into edible animal matrices cannot be excluded. However, the dose levels in the livestock metabolism studies (approx. 1 mg/kg bw/d) were significantly higher compared to the dietary burdens expected after feeding of the relevant matrices which were treated with Sivanto Energy (DLT+FPF EC 85) according to the label.

Evaluator comment:

Information given by the Applicant is sufficient.

The nature of flupyradifurone residues in livestock was investigated in the framework of the EU pesticides peer review (EFSA, 2015).

Based on these studies, the residue definitions were proposed as ‘**Sum of flupyradifurone and DFA, expressed as flupyradifurone**’ for risk assessment. For enforcement, to align with the residue definition set for plants, two separate residue definitions were established: **1) flupyradifurone** and **2) DFA, expressed as DFA** (EFSA, 2015; Reg. (EU) 2022/1324 for Flupyradifurone and Reg. (EU) 2021/1842 for Difluoroacetic acid (DFA)).

No further data are required.

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

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

	Endpoints
Animals covered	Lactating goats (EFSA Journal 2015; 13(2):4020)
	Laying hens (EFSA Journal 2015; 13(2):4020)
Time needed to reach a plateau concentration	9 days in milk, confirmed by cattle feeding study (EFSA Journal 2015; 13(2):4020)
	6 days in eggs, confirmed by feeding study (EFSA Journal 2015; 13(2):4020)
Animal residue definition for monitoring	Two separate residue definitions (EFSA Journal 2015; 13(2):4020; Reg. (EU) 2022/1324 for Flupyradifurone and Reg. (EU) 2021/1842 for Difluoroacetic acid (DFA)): 1) Flupyradifurone (expressed as flupyradifurone) 2) DFA (expressed as DFA)
Animal residue definition for risk assessment	Sum of flupyradifurone and DFA, expressed in flupyradifurone (EFSA Journal 2015; 13(2):4020)
Conversion factor	Not applicable (EFSA Journal 2015;13(2):4020)
Metabolism in rat and ruminant similar	Yes (EFSA Journal 2015;13(2):4020)
Fat soluble residue	No (EFSA Journal 2015;13(2):4020)

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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

In order to support the intended uses of Sivanto Energy EC 85 in grape, four bridging trials were conducted in the northern residue zone which demonstrated that the intended use is less critical with regard to possible flupyradifurone-related residues as compared to the "home & garden" uses on which the MRLs of flupyradifurone and DFA are currently based. In near future, the authorized flupyradifurone MRL for table and wine grapes will be even higher based on an import tolerance (EFSA Journal 2020;18(6):6133).

For all other intended uses (in sweet corn, sunflower, cereals and field corn), eight residue trials were conducted per residue zone in order to propose MRLs and to support the use in the respective registration zones.

zRMS comments:

In response to comments received from cMS-SI, the SEU trials from the Table 7.2-9 have been removed. Only trials from NEU are relevant for Central zone.

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of DLT+FPF EC 85 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) ¹	MRL compliance
Grape (table and wine grapes)	EFSA, 2015	EU	GAP on which MRL/EU a.s. assessment is based (Home & garden uses with SL 50 and SL 25 from N-EU**): 2 x 100 g a.s./ha, interval = 14d, PHI = 14d E (FPF): 0.11; 0.18*; 0.18*; 0.20; 0.21; 0.26; 0.38*; 0.42*; 0.46 E (DFA): 0.0095*, 0.019*, 2 x 0.020*, 0.022*, 0.031*, 0.035*, 0.041*, 0.049* RA /sum): 0.17*, 0.22, 0.24, 0.24*, 0.26*, 0.37*, 0.45*, 0.50*, 0.51	n.a.			FPF: 0.8 3.0 DFA: 0.15	
	EFSA, 2020	outside EU (USA/ Canada)	GAP on which MRL (import tolerance) /EU a.s. assessment is based (Article 12 Review): 2 x 205 g a.s./ha, interval = 10d, PHI = 0d E (FPF): 0.31; 0.32; 0.39; 0.44*; 0.46; 0.52; 0.57*; 0.58; 0.69*; 0.80; 1.02*; 1.13; 1.9 E (DFA): 9 x <0.017; 0.020*; 0.030*; 0.031*; 0.044*; 0.063* RA (sum): .36; 0.37; 0.44; 0.49*; 0.51; 0.58; 0.62*; 0.63*; 0.74*; 0.86; 1.1*; 1.2; 2.0	n.a.			FPF: 3.0 ³ DFA: 0.15 ³	
	New trials** 14-2096 (M-559743-01-1)	N-EU	GAP (EC 85): 2 x 30 g a.s./ha, interval = 14d, PHI = 14d E (FPF): 2 x 0.043; 0.072*; 0.096 E (DFA): 0.008*; 0.011*; 0.013*; 0.016* RA (sum): 0.063; 0.071; 0.10*; 0.12	0.058 0.012 0.086	0.096 0.016 0.12	0.191 (0.2) 0.036 (0.04)		
	New trials** 14-2095 (M-560047-01-1)	S-EU	GAP (EC 85): 2 x 30 g a.s./ha, interval = 14d, PHI = 14d E (FPF): 0.012*; 0.020*; 0.029*; 0.053* E (DFA): 2 x <0.007; 0.012*; 0.015* RA (sum): 0.032*; 0.040*; 0.058*; 0.097*	0.025 0.010 0.049	0.053 0.015 0.097	0.099 (0.1) 0.026 (0.03)		
Grape (table and wine grapes) continued	Overall supporting data for cGAPs of this dRR	EU (N-EU + S-EU)	E (FPF): 0.012*; 0.020*; 0.029*; 2 x 0.043; 0.053*; 0.072*; 0.096 E (DFA): 2 x <0.007; 0.008*; 0.011*; 0.012*; 0.013; 0.015*; 0.016* RA (sum): 0.032*; 0.040*; 0.058*; 0.063; 0.071; 0.097*; 0.10*; 0.12	0.043 0.058 0.012 0.067	0.096 0.016 0.12	0.157 (0.2) 0.028 (0.03)	FPF: 0.8 3.0 ¹ DFA: 0.15 ¹ IT FPF: 3.0 ³ DFA: 0.15 ³	yes yes

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) ¹	MRL compliance
Sunflower (seeds = kernels with shells)	EFSA, 2015	EU	GAP on which DFA MRL/EU a.s. assessment is based (rotational crop study, oilseed rape): 2 x 125 g a.s./ha on bare soil, re-cropping after 27-41d E (FPF): 0.01 E (DFA): 0.017; 0.024; 0.030; 0.051	n.a.			FPF: 0.01 DFA: 0.05 ⁽⁺⁾	
	EFSA, 2020	EU	GAP on which DFA MRL/EU a.s. assessment is based according to Article 12 Review (rotational crop study, oilseed rape): 1 x 175 g a.s./ha on bare soil, re-cropping after 137-147d E (FPF): 4 x <0.01 E (DFA): 0.0091; 0.014; 0.022 (measured values) 0.019; 0.029; 0.045 (scaled values) ⁴	0.01 0.029	0.01 0.045	- 0.045	FPF: 0.01 DFA: 0.05 ³	
	New trials 16-2145 (M-645130-01-1)	N-EU	GAP: 2 x 56.25 g a.s./ha, interval = 14d, BBCH 30-69, PHI n.a. E (FPF): 3 x 0.011; 0.015; 0.024; 0.046; 0.086; 0.10 E (DFA): 2 x 0.008; 0.015; 0.016; 2 x 0.022; 0.025; 0.042 RA (sum): 0.035; 0.044; 0.059; 0.076; 0.085; 0.090; 0.12; 0.23	0.020 0.019 0.081	0.10 0.042 0.23	0.183 (0.2) 0.064 (0.07)		
	New trials 16-2194 (M-643135-01-1) 16-2195 (M-629954-01-1)	S-EU	GAP: 2 x 56.25 g a.s./ha, interval = 14d, BBCH 30-69, PHI n.a. E (FPF): 2 x <0.01; 0.014; 0.025; 0.026; 0.027; 0.032; 0.043 E (DFA): 0.008; 0.009; 0.013; 0.023; 0.024; 0.036; 0.043; 0.049 RA (sum): 0.038; 0.048; 0.061; 0.096; 0.12; 0.13; 0.14; 0.16	0.026 0.024 0.108	0.043 0.049 0.16	0.069 (0.07) 0.088 (0.09)		
Sunflower, continued (seeds = kernels with shells)	Overall supporting data for cGAPs of this dRR	EU (N-EU + S-EU)	E (FPF): 2 x <0.01; 3 x 0.011; 0.014; 0.015; 0.024; 0.025; 0.026; 0.027; 0.032; 0.043; 0.046; 0.086; 0.10 E (DFA): 2 x 0.008; 0.009; 0.013; 0.015; 0.016; 2 x 0.022; 0.023; 0.024; 0.025; 0.036; 0.042; 0.043; 0.049 RA (sum): 0.035; 0.038; 0.044; 0.048; 0.059; 0.061; 0.076; 0.085; 0.090; 0.096; 2 x 0.12; 0.13; 0.14; 0.16; 0.23 GAP for residue uptake via roots (rotational crop study, oilseed rape): 1 x 175 g a.s./ha on bare soil, re-cropping after 137-147d E (FPF): 4 x <0.01 E (DFA): 0.0091; 0.014; 0.022 (measured values) 0.019; 0.029; 0.045 (scaled values) ⁴	0.025 0.022 0.019 0.088 0.081	0.10 0.049 0.042 0.23	0.139 (0.15) [0.076 (0.08)] 0.125 (0.15) ⁶	FPF: 0.01 DFA: 0.05 ⁽⁺⁾ IT: FPF: 0.01 DFA: 0.05 ³	no ² no ² no ² no ²
				0.01 0.029	0.01 0.045	- 0.045 ⁴		

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	STM (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) ¹	MRL compliance
Sunflower (kernel)	New trials 16-2045 (M-645130-01-1)	N-EU	GAP: 2 x 56.25 g a.s./ha, interval = 14d, BBCH 30-69, PHI n.a. E (FPF): 5 x <0.01; 2 x 0.010; 0.016 E (DFA): 0.009; 0.010; 0.012; 0.014; 0.022; 0.025; 0.030; 0.031 RA (sum): 0.036; 0.041; 0.046; 0.053; 0.076; 0.092; 2x 0.10	0.010 0.018 0.065	0.016 0.031 0.10			
	New trials 16-2194 (M-643135-01-1) 16-2195 (M-629954-01-1)	S-EU	GAP: 2 x 56.25 g a.s./ha, interval = 14d, BBCH 30-69, PHI n.a. E (FPF): 7 x <0.01; 0.012 E (DFA): 0.008; 0.010; 0.018; 0.019; 0.028; 0.046; 0.062; 0.068 RA (sum): 0.033; 0.040; 0.063; 0.066; 0.096; 0.15; 0.20; 0.21	0.010 0.024 0.081	0.012 0.068 0.21			
	Overall supporting data for cGAPs of this dRR	EU (N-EU + S-EU)	E (FPF): 12 5 x <0.01; 2 x 0.010; 0.012 ; 0.016 E (DFA): 0.008 ; 0.009; 2 x 0.010; 0.012; 0.014; 0.018; 0.019 ; 0.022; 0.025; 0.028 ; 0.030; 0.031; 0.046; 0.062; 0.068 RA (sum): 0.033 ; 0.036; 0.040 ; 0.041; 0.046; 0.053; 0.063 ; 0.066 ; 0.076; 0.092; 0.096 ; 2 x 0.10; 0.15; 0.20 ; 0.21	0.010 0.021 0.018 0.071 0.065	0.016 0.068 0.031 0.21 0.1			

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) ¹	MRL compliance
Barley (grain)	EFSA, 2015	EU	GAP on which MRL/EU a.s. assessment is based (rotational crop study, barley): 2 x 0.125 kg a.s./ha on bare soil, re-cropping after 27-41d E (FPF): 4 x <0.01 E (DFA): 0.017; 0.024; 0.030; 0.051	n.a.			FPF: 0.01 3.0 DFA: 0.3 ⁽⁺⁾ 0.8	
	EFSA, 2020	outside EU USA/ Canada	GAP on which import tolerance/ a.s. assessment is based according to Article 12 Review: 2 x 205 g a.s./ha, interval = 7d, PHI = 21d E (FPF): 0.038; 0.065; 0.096; 0.21; 0.24; 0.25; 0.27; 0.30; 0.31*; 0.44; 0.46*; 0.48; 2 x 0.68; 0.71; 0.81; 0.84; 1.2; 1.7; 2.3 E (DFA): 2 x <0.017; 0.026; 0.027; 0.029; 0.033; 0.059; 0.080; 0.085; 0.10; 0.11*; 0.11; 0.12; 0.13; 0.16; 0.17; 0.18; 0.27*; 0.36; 0.38 GAP for residue uptake via roots (rotational crop study, barley): 1 x 175 g a.s./ha on bare soil, re-cropping after 107-174d, E (FPF): 4 x <0.01 E (DFA): 0.038; 0.047; 0.088; 0.12 (measured values) 0.053; 0.066; 0.12; 0.17 (scaled values) ⁵	0.45	2.3	2.887 (3.0)	FPF: 3.0 ³	DFA: 0.8 ³
				0.11	0.38	[0.551 (0.6)] 0.77 (0.8) ⁶		
				0.01	0.01	-		
				0.093	0.17	0.17 ⁵		
New trials 15-2131 M-580973-04-1 16-2035 M-634410-01-1	N-EU		GAP: 2 x 56.25 g a.s./ha, interval = 14d, PHI = 30d E (FPF): <0.01; 0.022; 0.034; 0.053*; 0.081*; 0.082*; 0.099*; 0.16 E (DFA): 0.011; 0.031*; 0.036*; 0.039; 0.052; 0.059*; 0.064; 0.080 RA (sum): 0.12*; 0.15*; 0.18; 0.20; 0.21*; 0.26*; 2 x 0.27	0.067	0.16	0.263 (0.3)		
				0.046	0.080	0.140 (0.15)		
				0.21	0.27			

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) ¹	MRL compliance
Barley (grain), continued	New trials 15-2130 M-572779-03-1 16-2034 M-634112-01-1	S-EU	Tested GAP: 2 x 75.0 g a.s./ha, interval = 14d, PHI = 30d E (FPF): <0.01; 0.012*; 0.016*; 0.042*; 0.044*; 0.13; 0.19 E (DFA): <0.007; 0.029; 0.037*; 0.064; 0.072*; 0.091*; 0.13* RA (sum): 0.064*; 0.13*; 0.23; 0.23*; 0.28; 0.39; 0.41*					
	Scaled residues 15-2130 M-572779-03-1 16-2034 M-634112-01-1	S-EU	Intended GAP (scaled residues; scaling factor = 56.25/75 = 0.75): 2 x 56.25 g a.s./ha, interval = 14d, PHI = 30d E (FPF): <0.01; <0.01*; 0.012*; 0.032*; 0.033*; 0.098; 0.14 E (DFA): <0.007; 0.022; 0.028*; 0.048; 0.054*; 0.068*; 0.098* RA (sum): 0.048*; 0.098*; 0.17*; 0.17; 0.21; 0.29; 0.31*	0.032 0.048 0.17	0.14 0.098 0.31	0.252 (0.3) 0.169 (0.2)		
	Overall supporting data for cGAPs of this dRR	EU (N-EU + S-EU)	E (FPF): 2 x <0.01; <0.01*; 0.012*; 0.022; 0.032*; 0.033*; 0.034; 0.053*; 0.081*; 0.082*; 0.098*; 0.099; 0.14; 0.16 E (DFA): <0.007; 0.011; 0.022; 0.028*; 0.031*; 0.036*; 0.039; 0.048; 0.052; 0.054*; 0.059; 0.064; 0.068*; 0.080; 0.098* RA (sum): 0.048*; 0.098*; 0.12*; 0.15*; 0.17; 0.17*; 0.18; 0.20; 0.21; 0.21*; 0.26*; 2 x 0.27; 0.29; 0.31* GAP for residue uptake via roots (rotational crop study, barley): 1 x 175 g a.s./ha on bare soil, re-cropping after 107-174d, E (FPF): 4 x <0.01 E (DFA): 0.038; 0.047; 0.088; 0.12 (measured values) 0.078; 0.097; 0.18; 0.25 (scaled values) ⁴	0.034 0.067 0.048 0.046 0.205 0.01 0.14	0.16 0.098 0.080 0.31 0.27 0.01 0.25	0.255 (0.3) 0.148 (0.15) 0.140 (0.15) 0.40 (0.4) ⁶ 0.25 ⁴	FPF: 0.01 3.0 DFA: 0.3 ⁽⁺⁾ 0.8 IT FPF: 3.0 ³ DFA: 0.8 ³	no ¹ yes no ¹ no ¹ yes yes yes

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) ¹	MRL compliance
Oat (grain) Barley → extrapolated to oat (grain)	EFSA, 2015	EU	GAP on which MRL/EU a.s. assessment is based (rotational crop study, barley): 2 x 0.125 kg a.s./ha on bare soil, re-cropping after 27-41d E (FPF): 4 x <0.01 E (DFA): 0.017; 0.024; 0.030; 0.051	n.a.			FPF: 0.01 DFA: 0.3 ⁽⁺⁾	
	EFSA, 2020 (barley)	outside EU	GAP on which MRL (import tolerance)/EU a.s. assessment is based: 2 x 205 g a.s./ha, interval = 7d, PHI = 21d E (FPF): 0.038; 0.065; 0.096; 0.21; 0.24; 0.25; 0.27; 0.30; 0.31*; 0.44; 0.46*; 0.48; 2 x 0.68; 0.71; 0.81; 0.84; 1.2; 1.7; 2.3 E (DFA): 2 x <0.017; 0.026; 0.027; 0.029; 0.033; 0.059; 0.080; 0.085; 0.10; 0.11*; 0.11; 0.12; 0.13; 0.16; 0.17; 0.18; 0.27*; 0.36; 0.38	0.45	2.3	2.887 (3.0)	FPF: 0.01	
		USA/ Canada		0.11	0.38	[0.551 (0.6)] 0.77 (0.80)⁶	DFA: 0.3 ⁽⁺⁾	
			GAP for residue uptake via roots (rotational crop study, barley): 1 x 175 g a.s./ha on bare soil, re-cropping after 107-174d, E (FPF): 4 x <0.01 E (DFA): 0.038; 0.047; 0.088; 0.12 (measured values) 0.053; 0.066; 0.12; 0.17 (scaled values) ⁵	0.01 0.093	0.01 0.17	- 0.17 ⁵		
	New trials 15-2131 M-580973-04-1 16-2035 M-634410-01-1	N-EU	GAP: 2 x 56.25 g a.s./ha, interval = 14d, PHI = 30d E (FPF): <0.01; 0.022; 0.034; 0.053*; 0.081*; 0.082*; 0.099*; 0.16 E (DFA): 0.011; 0.031*; 0.036*; 0.039; 0.052; 0.059*; 0.064; 0.080 RA (sum): 0.12*; 0.15*; 0.18; 0.20; 0.21*; 0.26*; 2 x 0.27	0.067 0.046 0.21	0.16 0.080 0.27	0.263 (0.3) 0.140 (0.15)	FPF: 0.01 DFA: 0.3 ⁽⁺⁾	

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	STM (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) ¹	MRL compliance
Oat (grain) Barley → extrapolated to oat (grain) continued	Overall supporting data for cGAPs of this dRR	N-EU	E (FPF): <0.01; 0.022; 0.034; 0.053*; 0.081*; 0.082*; 0.099*; 0.16 E (DFA): 0.011; 0.031*; 0.036*; 0.039; 0.052; 0.059*; 0.064; 0.080 RA (sum): 0.12*; 0.15*; 0.18; 0.20; 0.21*; 0.26*; 2 x 0.27 GAP for residue uptake via roots (rotational crop study, barley): 1 x 175 g a.s./ha on bare soil, re-cropping after 107-174d, E (FPF): 4 x <0.01 E (DFA): 0.038; 0.047; 0.088; 0.12 (measured values) 0.078; 0.097; 0.18; 0.25 (scaled values) ⁴	0.067 0.046 0.21 0.01 0.14	0.16 0.080 0.27 0.01 0.25	0.263 (0.3) [0.140 (0.15)] 0.40 (0.4) ⁶ - 0.25 ⁴	FPF: 0.01 DFA: 0.3 (+)	no ² no ² yes

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) ¹	MRL compliance
Barley (straw)	New trials 15-2131 M-580973-04-1 16-2035 M-634410-01-1	N-EU	GAP: 2 x 56.25 g a.s./ha, interval = 14d, PHI = 30d E (FPF): 0.087; 2 x 0.11; 2 x 0.17; 0.28; 0.41*; 0.69 E (DFA): 0.016; 2 x <0.017; 0.017*; 0.025; 0.027; 0.027*, 0.040* RA (sum): 0.13; 2 x 0.19; 2 x 0.22; 0.37; 0.46*; 0.75	0.170 0.021 0.220	0.69 0.040 0.75			
	New trials 15-2130 M-572779-03-1 16-2034 M-634112-01-1	S-EU	Tested GAP: 2 x 75.0 g a.s./ha, interval = 14d, PHI = 30d E (FPF): 0.020*; 0.096; 0.18; 0.66; 0.72; 4.5; 6.4 E (DFA): 2 x 0.018; 0.022; 0.024*; 0.036; 0.046*; 0.77 RA (sum): 0.075*; 0.21*; 0.25; 0.77; 0.79; 6.4; 6.8					
	Scaled residues 15-2130 M-580973-04-1 16-2034 M-634410-01-1	S-EU	Intended GAP (scaled residues; scaling factor = 56.25/75 = 0.75): 2 x 56.25 g a.s./ha, interval = 14d, PHI = 30d E (FPF): 0.015*; 0.072; 0.14; 0.50; 0.54; 3.4; 4.8 E (DFA): 2 x 0.014; 0.017; 0.018*; 0.027; 0.035*; 0.58 RA (sum): 0.056*; 0.16*; 0.19; 0.58; 0.59; 4.8; 5.1	0.500 0.018 0.58	4.8 0.58 5.1			
	Overall supporting data for cGAPs of this dRR	EU (N-EU + S-EU)	E (FPF): 0.015*; 0.072; 0.087; 2 x 0.11; 0.14; 2 x 0.17; 0.28; 0.41*; 0.50; 0.54; 0.69; 3.4; 4.8 E (DFA): 2 x 0.014; 0.016; 2 2 x <0.017; 0.017*; 0.018*; 0.025; 0.027; 0.027*; 0.035*; 0.040*; 0.58 RA (sum): 0.056*; 0.13; 0.16*; 3 x 0.19; 2 x 0.22; 0.37; 0.46*; 0.58; 0.59; 0.75, 4.8; 5.1	0.170 0.021 0.22	4.8 0.69 0.58 0.040 5.1			
Oat (straw) Barley (N-EU) → extrapolated to oat (straw)	New trials 15-2131 M-580973-04-1 16-2035 M-634410-01-1	N-EU	GAP: 2 x 56.25 g a.s./ha, interval = 14d, PHI = 30d E (FPF): 0.087; 2 x 0.11; 2 x 0.17; 0.28; 0.41*; 0.69 E (DFA): 0.016; 2 x <0.017; 0.017*; 0.025; 0.027; 0.027*, 0.040* RA (sum): 0.13; 2 x 0.19; 2 x 0.22; 0.37; 0.46*; 0.75	0.170 0.021 0.220	0.69 0.040 0.75			

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) ¹	MRL compliance
Wheat (grain)	EFSA, 2015	EU	GAP on which MRL/EU a.s. assessment is based (rotational crop study, barley): 2 x 125 g a.s./ha on bare soil, re-cropping after 27-41d E (FPF): 4 x <0.01 E (DFA): 0.017; 0.024; 0.030; 0.051	n.a.			FPF: 0.01 1.0 DFA: 0.3 ⁽⁺⁾ 1.5	
	EFSA, 2020	outside EU USA/ Canada	GAP on which import tolerance/ a.s. assessment is based according to Article 12 Review: 2 x 205 g a.s./ha, interval = 7d, PHI = 21d E (FPF): 0.017; 0.019; 0.024; 0.031; 2 x 0.034; 0.041; 0.051; 0.059; 0.074; 2 x 0.090; 2 x 0.10; 2 x 0.15; 0.17*; 2 x 0.17; 0.18; 0.21*; 0.22; 0.23; 0.26; 0.34; 0.37; 0.59; 0.61; 0.73 E (DFA): 4 x <0.017; 0.017; 0.021; 0.039; 0.044; 0.059; 0.088; 0.090; 0.094; 0.11; 0.14; 2 x 0.16; 0.17*; 0.18; 0.18*; 0.20; 0.22; 0.24; 0.28; 2 x 0.33; 0.47; 0.55*; 0.65; 0.72 RA (sum): 0.069; 0.084; 0.091; 0.10; 0.21; 0.24; 0.26; 0.29; 0.30; 0.37; 0.56; 0.59; 0.65*; 2 x 0.65; 0.67;; 0.74; 0.75; 0.76*; 0.77; 0.81; 0.87; 0.90; 1.1; 1.2; 1.5; 1.8*; 2.5; 2.7 GAP for residue uptake via roots (rotational crop study, barley): 1 x 175 g a.s./ha on bare soil, re-cropping after 107-174d, E (FPF): 4 x <0.01 E (DFA): 0.038; 0.047; 0.088; 0.12 (measured values) 0.053; 0.066; 0.12; 0.17 (scaled values) ⁵	0.15	0.73	0.925 (1.0)	FPF: 1.0 ³	
				0.16	0.72	[0.961 (1.0)] 1.17 (1.5)⁶	DFA: 1.5 ³	
				0.01		-		
				0.093	0.17	0.17 ⁵		

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) ¹	MRL compliance
Wheat (grain) continued	New trials 15-2129 M-580528-03-1 16-2033 M-634190-01-1	N-EU	GAP: 2 x 56.25 g a.s./ha, interval = 14d, PHI = 30d E (FPF): 2 x <0.01; 0.010; 0.011; 0.012*; 0.015*; 0.032*; 0.061 E (DFA): 0.018; 0.067; 0.074; 0.10; 0.14*; 0.16; 0.20; 0.34 RA (sum): 0.12; 2 x 0.23; 0.32; 0.42*; 0.48; 0.62; 1.0	0.012 0.12 0.37	0.061 0.34 1.0	0.09 (0.1) 0.54 (0.6)		
	New trials 15-2127 M-580063-03-1 16-2032 M-633925-01-1	S-EU	Tested GAP: 2 x 75.0 g a.s./ha, interval = 14d, PHI = 30d E (FPF): 5 x <0.01; 0.014; 0.028*; 0.078 E (DFA): 0.070*; 0.082; 0.098; 0.12; 0.14; 0.17*; 0.19; 0.24* RA (sum): 0.22*; 0.30; 0.33; 0.36; 0.45*; 0.53*; 0.58; 0.74*					
	Scaled residues 15-2127 M-580063-03-1 16-2032 M-633925-01-1	S-EU	Intended GAP (scaled residues; scaling factor = 56.25/75 = 0.75): 2 x 56.25 g a.s./ha, interval = 14d, PHI = 30d E (FPF): 5 x <0.01; 0.011; 0.021*; 0.059 E (DFA): 0.053*; 0.062; 0.074; 0.090; 0.11; 0.13*; 0.14; 0.18* RA (sum): 0.17*; 0.23; 0.25; 0.27; 0.34*; 0.40*; 0.44; 0.56*	0.010 0.100 0.31	0.059 0.18 0.56	0.086 (0.09) 0.315 (0.4)		
	Overall supporting data for cGAPs of this dRR	EU (N-EU + S-EU)	E (FPF): 7 2 x <0.01; 0.010; 2 x 0.011; 0.012*; 0.015*; 0.021* ; 0.032*; 0.059 ; 0.061 E (DFA): 0.018; 0.053* ; 0.062 ; 0.067; 2 x 0.074; 0.090 ; 0.10; 0.11 ; 0.13*; 2 x 0.14*; 0.16; 0.18* ; 0.20; 0.34 RA (sum): 0.12; 0.17* ; 3 2 x 0.23; 0.25 ; 0.27 ; 0.32; 0.34* ; 0.40* ; 0.42*; 0.44 ; 0.48; 0.56* ; 0.62; 1.0 GAP for residue uptake via roots (rotational crop study, barley): 1 x 175 g a.s./ha on bare soil, re-cropping after 107-174d, E (FPF): 4 x <0.01 E (DFA): 0.038; 0.047; 0.088; 0.12 (measured values) 0.078; 0.097; 0.18; 0.25 (scaled values) ⁴	0.011 0.11 0.33 0.37 0.012 0.12 0.37 0.01 0.14	0.061 0.34 1.0 0.01 0.25	0.087 (0.09) [0.427 (0.5)] 0.75 (0.8) 0.25 ⁴	FPF: 0.01 1.0 DFA: 0.3 ⁽⁺⁾ 1.5 IT: FPF: 1.0 ³ DFA: 1.5 ³	no ⁺ yes no ⁺ yes yes yes

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) ¹	MRL compliance
Wheat (straw)	New trials 15-2129 M-580528-03-1 16-2033 M-634190-01-1	N-EU	GAP: 2 x 56.25 g a.s./ha, interval = 14d, PHI = 30d E (FPF): 0.12; 0.18*; 0.27; 0.31; 0.41; 0.43*; 0.81; 1.2 E (DFA): 0.022*; 0.025; 0.030; 0.039; 0.042*; 0.053; 0.11*; 0.17* RA (sum): 0.21; 0.30*; 0.38; 0.49*; 0.57; 0.76; 1.1; 1.2	0.36 0.041 0.53	1.2 0.17 1.2			
	New trials 15-2127 M-580063-03-1 16-2032 M-633925-01-1	S-EU	Tested GAP: 2 x 75.0 g a.s./ha, interval = 14d, PHI = 30d E (FPF): 0.066; 0.11; 0.44*; 0.71; 0.78; 1.5; 2.4*; 3.5 E (DFA): 0.029; 0.032; 2 x 0.033; 0.070*; 0.080*; 0.089*; 0.11 RA (sum): 0.17; 0.21; 0.78*; 0.80; 0.87; 1.7*; 2.7*; 3.8					
	Scaled residues 15-2127 M-580063-03-1 16-2032 M-633925-01-1	S-EU	Intended GAP (scaled residues; scaling factor = 56.25/75 = 0.75): 2 x 56.25 g a.s./ha, interval = 14d, PHI = 30d E (FPF): 0.050; 0.083; 0.33*; 0.53; 0.59; 1.1; 1.8*; 2.6 E (DFA): 0.022; 0.024; 2 x 0.025; 0.053*; 0.060*; 0.067*; 0.083 RA (sum): 0.13; 0.16; 0.59*; 0.60; 0.65; 1.3*; 2.0*; 2.9	0.56 0.039 0.63	2.6 0.083 2.9			
	Overall supporting data for cGAPs of this dRR	EU (N-EU + S-EU)	E (FPF): 0.050; 0.083; 0.12; 0.18*; 0.27; 0.31; 0.33*; 0.41; 0.43*; 0.53; 0.59; 0.81; 1.1; 1.2; 1.8*; 2.6 E (DFA): 0.022; 0.022*; 0.024; 3 x 0.025; 0.030; 0.039; 0.042*; 2 x 0.053; 0.060*; 0.067*; 0.083; 0.11*; 0.17* RA (sum): 0.13; 0.16; 0.21; 0.30*; 0.38; 0.49*; 0.57; 0.59*; 0.60; 0.65; 0.76; 1.1; 1.2; 1.3*; 2.0*; 2.9	0.42 0.36 0.041 0.60 0.665	2.6 1.2 0.17 2.9 1.2			

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) ¹	MRL compliance
Maize (kernel)	EFSA, 2015	EU	GAP on which MRL/EU a.s. assessment is based (rotational crop study, maize): 2 x 125 g a.s./ha on bare soil, re-cropping after 27-41d E (FPF): 4 x <0.01 E (DFA): 0.017; 0.024; 0.030; 0.051	n.a.			FPF: 0.01 0.02 DFA: 0.3 ⁽⁺⁾ 0.1	
	EFSA, 2020	outside EU USA/ Canada	GAP on which import tolerance/ a.s. assessment is based according to Article 12 Review: 2 x 205 g a.s./ha, interval = 7d, PHI = 21d E (FPF): 19 x <0.01; 0.011 E (DFA): 19 x <0.017; 0.041 GAP for residue uptake via roots (rotational crop study, maize): 1 x 175 g a.s./ha on bare soil, re-cropping after 131-204d, E (FPF): 4 x <0.01 E (DFA): <0.007; 0.021; 0.035; 0.037 (measured values) <0.01; 0.029; 0.049; 0.052 (scaled values) ⁵	0.01 0.017 0.01 0.039	0.011 0.041 0.01 0.052	0.011 (0.015) [0.041 (0.05)] 0.102 (0.1) ⁶ - 0.052 ⁵	FPF: 0.02 ³ DFA: 0.1 ³	
	New trials 15-2134 M-574350-02-1 16-2192 M-628803-01-1	N-EU	Tested GAP: 1 x 93.75 g a.s./ha, BBCH 51-75, PHI n.a. E (FPF): 8 x <0.01 E (DFA): 2x <0.007; 0.008; 0.013; 0.016; 0.018; 0.021; 0.026 RA (sum): 2 x <0.03; 0.035; 0.050; 0.057; 0.064; 0.072; 0.088	0.010 0.015 0.054	0.010 0.026 0.088			
	Scaled residues 15-2134 M-574350-02-1 16-2192 M-628803-01-1	N-EU	Intended GAP (scaled residues; scaling factor = 56.25/93.75 = 0.6): 1 x 56.25 g a.s./ha, BBCH 51-75, PHI n.a. E (FPF): 8 x <0.01 E (DFA): 3 x <0.007; 0.008; 0.010; 0.011; 0.013; 0.016 RA (sum): 3 x <0.03; 0.030; 0.034; 0.038; 0.043; 0.053	0.010 0.009 0.032	0.010 0.016 0.053	0.01 (0.01) 0.023 (0.03)		

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) ¹	MRL compliance
Maize (kernel) continued	Overall supporting data for cGAPs of this dRR	N-EU	E (FPF): 8 x <0.01 E (DFA): 3 x <0.007; 0.008; 0.010; 0.011; 0.013; 0.016 RA (sum): 3 x <0.03; 0.030; 0.034; 0.038; 0.043; 0.053 GAP for residue uptake via roots (rotational crop study, maize): 1 x 175 g a.s./ha on bare soil, re-cropping after 131-204d, E (FPF): 4 x <0.01 E (DFA): <0.007; 0.021; 0.035; 0.037 (measured values) <0.014; 0.043; 0.072; 0.076 (scaled values) ⁴	0.010 0.009 0.032 0.01 0.058	0.010 0.016 0.053 0.01 0.076	0.01 (0.01) [0.023 (0.03)] 0.106 (0.15)⁶ 0.076 ⁴	FPF: 0.01 0.02 DFA: 0.3 ⁽⁺⁾ 0.1 <u>IT:</u> FPF: 0.02 ³ DFA: 0.1 ³	yes yes yes no ²
Millet (kernel) Maize → extrapolated to millet	EFSA, 2015	EU	GAP on which MRL/EU a.s. assessment is based (rotational crop study, maize): 2 x 125 g a.s./ha on bare soil, re-cropping after 27-41d E (FPF): 4 x <0.01 E (DFA): 0.017; 0.024; 0.030; 0.051	n.a.			0.01 0.3 ⁽⁺⁾	
	EFSA, 2020 (maize)	outside EU USA/ Canada	GAP on which import tolerance/ a.s. assessment is based according to Article 12 Review: 2 x 205 g a.s./ha, interval = 7d, PHI = 21d E (FPF): 19 x <0.01; 0.011 E (DFA): 19 x <0.017; 0.041 GAP for residue uptake via roots (rotational crop study, maize): 1 x 175 g a.s./ha on bare soil, re-cropping after 131-204d, E (FPF): 4 x <0.01 E (DFA): <0.007; 0.021; 0.035; 0.037 (measured values) <0.01; 0.029; 0.049; 0.052 (scaled values) ⁵	0.01 0.017 0.01 0.039	0.011 0.041 0.01 0.052	0.011 (0.02) [0.041 (0.05)] 0.102 (0.1)⁶ - 0.052 ⁵	FPF: 0.01 DFA: 0.3 ⁽⁺⁾	

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) ¹	MRL compliance
Millet (kernel) Maize → extrapolated to millet continued	New trials 15-2134 M-574350-02-1 16-2192 M-628803-01-1	N-EU	Tested GAP: 1 x 93.75 g a.s./ha, BBCH 51-75, PHI n.a. E (FPF): 8 x <0.01 E (DFA): 2x <0.007; 0.008; 0.013; 0.016; 0.018; 0.021; 0.026 RA (sum): 2 x <0.03; 0.035; 0.050; 0.057; 0.064; 0.072; 0.088	0.010 0.015 0.054	0.010 0.026 0.088			
	Scaled residues 15-2134 M-574350-02-1 16-2192 M-628803-01-1	N-EU	Intended GAP (scaled residues; scaling factor = 56.25/93.75 = 0.6): 1 x 56.25 g a.s./ha, BBCH 51-75, PHI n.a. E (FPF): 8 x <0.01 E (DFA): 3 x <0.007; 0.008; 0.010; 0.011; 0.013; 0.016 RA (sum): 3 x <0.03; 0.030; 0.034; 0.038; 0.043; 0.053	0.010 0.009 0.032	0.010 0.016 0.053	0.01 (0.01) 0.023 (0.03)		
	Overall supporting data for cGAPs of this dRR	N-EU	E (FPF): 8 x <0.01 E (DFA): 3 x <0.007; 0.008; 0.010; 0.011; 0.013; 0.016 RA (sum): 3 x <0.03; 0.030; 0.034; 0.038; 0.043; 0.053 GAP for residue uptake via roots (rotational crop study, maize): 1 x 175 g a.s./ha on bare soil, re-cropping after 131-204d, E (FPF): 4 x <0.01 E (DFA): <0.007; 0.021; 0.035; 0.037 (measured values) <0.014; 0.043; 0.072; 0.076 (scaled values) ⁴	0.010 0.009 0.032 0.01 0.058	0.010 0.016 0.053 0.01 0.076	0.01 (0.01) [0.023 (0.03)] 0.106 (0.15)⁶ 0.076 ⁴	0.01 0.3 ⁽⁺⁾ <u>IT:</u> FPF: 0.02 ² DFA: 0.1 ²	yes yes yes no ²

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) ¹	MRL compliance
Maize (stover) → also extrapolated to millet and sorghum (stover)	New trials 15-2134 M-574350-02-1 16-2192 M-628803-01-1	N-EU	Tested GAP: 1 x 93.75 g a.s./ha, PHI n.a. E (FPF): 0.057; 0.059; 0.084; 0.16; 0.36; 0.39; 0.53; 0.75 E (DFA): 2 x <0.007; 2 x 0.007; 0.008; 0.009; 0.012; 0.015 RA (sum): 0.077; 0.10; 0.12; 0.18; 0.38; 0.41; 0.55; 0.77	0.26 0.008 0.28	0.75 0.015 0.77			
	Scaled residues 15-2134 M-574350-02-1 16-2192 M-628803-01-1	N-EU	Intended GAP (scaled residues; scaling factor = 56.25/93.75 = 0.6): 1 x 56.25 g a.s./ha, BBCH 51-75, PHI n.a. E (FPF): 0.034; 0.035; 0.050; 0.096; 0.22; 0.23; 0.32; 0.45 E (DFA): 6 x <0.007; 0.0072; 0.0090 RA (sum): 0.046; 0.060; 0.072; 0.11; 0.23; 0.25; 0.33; 0.46	0.16 0.007 0.17	0.45 0.009 0.46			
	Overall supporting data for cGAPs of this dRR	N-EU	E (FPF): 0.034; 0.035; 0.050; 0.096; 0.22; 0.23; 0.32; 0.45 E (DFA): 6 x <0.007; 0.0072; 0.0090 RA (sum): 0.046; 0.060; 0.072; 0.11; 0.23; 0.25; 0.33; 0.46	0.16 0.007 0.17	0.45 0.009 0.46			

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) ¹	MRL compliance
Sorghum (grain)	EFSA, 2015	EU	GAP on which MRL/EU a.s. assessment is based (rotational crop study, maize): 2 x 125 g a.s./ha on bare soil, re-cropping after 27-41d E (FPF): 4 x <0.01 E (DFA): 0.017; 0.024; 0.030; 0.051	n.a.			0.01 3.0 0.3 ⁽⁺⁾	
	EFSA, 2020	outside EU USA/ Canada	GAP on which MRL (import tolerance)/EU a.s. assessment is based: 2 x 205 g a.s./ha, interval = 7d, PHI = 21d E (FPF): 0.34; 2 x 0.46; 0.50; 0.51; 0.80; 0.86; 1.4; 1.5* E (DFA): 4 x <0.017; 0.018*; 0.018; 0.019; 0.043; 0.044 GAP for residue uptake via roots (rotational crop study, maize): 1 x 175 g a.s./ha on bare soil, re-cropping after 131-204d, E (FPF): 4 x <0.01 E (DFA): <0.007; 0.021; 0.035; 0.037 (measured values) <0.01; 0.029; 0.049; 0.052 (scaled values) ⁵	0.51 0.013	1.5 0.041	2.465 (3.0) [0.061 (0.07)] 0.122 (0.15)⁶	FPF: 3.0 ³ DFA: 0.3 ³	
			GAP for residue uptake via roots (rotational crop study, maize): 1 x 175 g a.s./ha on bare soil, re-cropping after 131-204d, E (FPF): 4 x <0.01 E (DFA): <0.007; 0.021; 0.035; 0.037 (measured values) <0.01; 0.029; 0.049; 0.052 (scaled values) ⁵	0.01 0.039	0.01 0.052	- 0.052 ⁵		
	New trials 15-2134 M-574350-02-1 16-2192 M-628803-01-1	N-EU	Tested GAP: 1 x 93.75 g a.s./ha, BBCH 51-75, PHI n.a. E (FPF): 8 x <0.01 E (DFA): 2x <0.007; 0.008; 0.013; 0.016; 0.018; 0.021; 0.026 RA (sum): 2 x <0.03; 0.035; 0.050; 0.057; 0.064; 0.072; 0.088	0.010 0.015 0.054	0.010 0.026 0.088			
	Scaled residues 15-2134 M-574350-02-1 16-2192 M-628803-01-1	N-EU	Intended GAP (scaled residues; scaling factor = 56.25/93.75 = 0.6): 1 x 56.25 g a.s./ha, BBCH 51-75, PHI n.a. E (FPF): 8 x <0.01 E (DFA): 3 x <0.007; 0.008; 0.010; 0.011; 0.013; 0.016 RA (sum): 3 x <0.03; 0.030; 0.034; 0.038; 0.043; 0.053	0.010 0.009 0.032	0.010 0.016 0.053	0.01 (0.01) 0.023 (0.03)		

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) ¹	MRL compliance
Sorghum (grain) continued	Overall supporting data for cGAPs of this dRR	N-EU	E (FPF): 8 x <0.01 E (DFA): 3 x <0.007; 0.008; 0.010; 0.011; 0.013; 0.016 RA (sum): 3 x <0.03; 0.030; 0.034; 0.038; 0.043; 0.053	0.010 0.009 0.032	0.010 0.016 0.053	0.01 (0.01) [0.023 (0.03)] 0.106 (0.15)⁶	FPF: 0.01 3.0 DFA: 0.3 ⁽⁺⁾	yes yes
			GAP for residue uptake via roots (rotational crop study, maize): 1 x 175 g a.s./ha on bare soil, re-cropping after 131-204d, E (FPF): 4 x <0.01 E (DFA): <0.007; 0.021; 0.035; 0.037 (measured values) <0.014; 0.043; 0.072; 0.076 (scaled values) ⁴	0.01 0.058	0.01 0.076	 0.076 ⁴	IT: FPF: 3.0 ³ DFA: 0.3 ³	yes yes
Sweet corn	EFSA, 2015		GAP on which MRL/EU a.s. assessment is based (rotational crop study in cucumber): 2 x 0.125 kg a.s./ha on bare soil, PBI 30d E (FPF): 4 x <0.01 E (DFA): 0.02; 0.09; 0.11; 0.14	n.a.			0.01 0.05 0.15 0.2	
	EFSA, 2020	outside EU	GAP on which MRL (import tolerance)/EU a.s. assessment is based: 2 x 205 g a.s./ha, interval = 7d, PHI = 7d E (FPF): 9 x <0.01; 0.016; 0.018; 0.027; 0.038 E (DFA): 3x 0.017; 0.019; 0.03; 3 x 0.037; 0.039; 0.056; 0.061*; 0.075; 0.080*	0.01 0.013	0.038 0.041	0.049 (0.05) [0.136 (0.15)] 0.202 (0.2)⁶	FPF: 0.05 ³ DFA: 0.2 ³	
		USA/ Canada	GAP for residue uptake via roots (rotational crop study, maize): 1 x 175 g a.s./ha on bare soil, re-cropping after 131-204d, E (FPF): 4 x <0.01 E (DFA): <0.007; 0.021; 0.035; 0.037 (measured values) <0.01; 0.029; 0.049; 0.052 (scaled values) ⁵	0.01 0.039	0.01 0.052	- 0.052 ⁵		

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) ¹	MRL compliance
Sweet corn continued	New trials 15-2134 M-574350-02-1 16-2192 M-628803-01-1	N-EU	Tested GAP: 1 x 93.75 g a.s./ha, BBCH 51-75, PHI = 7d E (FPF): 8 x <0.01 E (DFA): 4 x <0.007; 0.007; 2 x 0.009; 0.015 RA (sum): 4 x <0.03; 0.032; 2 x 0.038; 0.056	0.010 0.007 0.031	0.010 0.015 0.056			
	Scaled residues 15-2134 M-574350-02-1 16-2192 M-628803-01-1	N-EU	Intended GAP (scaled residues; scaling factor = 56.25/93.75 = 0.6): 1 x 56.25 g a.s./ha, BBCH 51-75, PHI = 7d E (FPF): 8 x <0.01 E (DFA): 7x <0.007; 0.009 RA (sum): 7 x <0.03; 0.034	0.010 0.007 0.030	0.010 0.009 0.034	0.01 (0.01) 0.01 (0.01)	FPF: 0.05 ³ DFA: 0.2 ³	yes yes
	Overall supporting data for cGAPs of this dRR	N-EU	E (FPF): 8 x <0.01 E (DFA): 7x <0.007; 0.009 RA (sum): 7 x <0.03; 0.034 GAP for residue uptake via roots (rotational crop study, maize): 1 x 175 g a.s./ha on bare soil, re-cropping after 131-204d, E (FPF): 4 x <0.01 E (DFA): <0.007; 0.021; 0.035; 0.037 (measured values) <0.014; 0.043; 0.072; 0.076 (scaled values) ⁴	0.010 0.007 0.030 0.01 0.058	0.010 0.009 0.034 0.01 0.076	0.01 (0.01) [0.01 (0.01)] 0.086 (0.09)⁶ - 0.076 ⁴	FPF: 0.01 0.05 DFA: 0.15 0.1 0.2 IT: FPF: 0.05 ³ DFA: 0.2 ³	yes yes yes yes

¹ according to ~~SANTE/10757/2016 [Annex IIIA]~~ and Commission Regulation (EU) 2016/1902 Flupyradifurone - Reg. (EU) 2022/1324; Difluoroacetic acid (DFA) - Reg. (EU) 2021/1842

² A dER was submitted in Q1 2019 (updated in March 2019) to apply for adequate MRLs for oilseed rape/mustard and a dER was submitted in August 2020 to apply for adequate MRLs for sunflower, oat, maize and millet

³ MRL according to Article 12 MRL review (EFSA Journal 2020;18(6):6133);

⁴ DFA residue concentrations measured in the rotational crop residue trials was multiplied by the EU scaling factor of 2.06 in order to determine the residues at the estimated soil plateau level of flupyradifurone after multi-year use (EFSA Journal 2020;18(6):6133).

⁵ DFA residue concentrations measured in the rotational crop residue trials was multiplied by the NA scaling factor of 1.4 in order to determine the residues at the estimated soil plateau level of flupyradifurone after multi-year use (EFSA Journal 2020;18(6):6133).

(+) Temporary MRL according to Commission Regulation (EU) 2016/1902, 27 October 2016.

In the meantime, revised MRLs have been proposed by the European Food Safety Authority (EFSA Journal 2020;18(6):6133). The EFSA Reasoned Opinion states that the confirmatory data gap as set for DFA and flupyradifurone MRLs in the Commission Regulation (EU) 2016/1902 can be deleted.

* Peak residues detected after PHI.

** The critical “home & garden uses” of Flupyradifurone SL 25 / SL 50 were the basis of the supervised residue trials evaluated by EFSA (agricultural use of FPF SL 200: 1 x 100 g a.s./ha). The new residue studies were performed as bridging trials in order to demonstrate that the residue situation does not alter with the EC 85 formulation compared to the SL200 formulation evaluated by EFSA.

FPF = Flupyradifurone (BYI 02960);

DFA = difluoroacetic acid;

HR = Highest residue;

STMR = Supervised Trials Median Residue;

IT = import tolerance

n.a. = not applicable

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on grape, ~~sunflower~~, barley, ~~oat~~, sorghum, wheat, field corn (maize), millet and sweet corn are considered acceptable in the central zone.

In case of grapes, the additional studies presented in the dRR in hand were performed in order to demonstrate that the intended use with the EC 85 formulation is less critical with regard to potential residues as compared to the already registered uses with the SL 25 or SL 50 formulation (“home and garden” uses). For field corn (maize) and sweet corn, the residue trials of the northern European residue zone were conducted according to the more critical GAP of the southern European residue zone and therefore the residue values were downscaled in order to represent the intended GAP of the central registration zone.

According to ~~EU guidance document SANCO 7525/VI/95 rev. 10.3~~ **Technical Guidelines SANTE/2019/12752**, extrapolation from barley to oat is possible, as well as from field corn to millet and sorghum (8 trials per crop are available). Therefore the uses should be extended to oat, millet and sorghum.

~~The data submitted show that the current MRLs for flupyradifurone and/or DFA are exceeded for sunflower seed, and barley, oat and wheat grain (Commission Regulation (EU) 2016/1902). As an Article 12 review is already available (EFSA Journal 2020;18(6):6133) which proposes more critical import tolerances for barley and wheat, the residues in the respective EU uses are deemed to be covered. For the intended uses in sunflower (new use) and oat (extrapolation from barley) an MRL application has already been submitted to the Netherlands as EMS. For field corn and millet, the temporary DFA MRL (0.3 mg/kg) has to be lowered based on the new data, however has to be higher than the proposed import tolerances of 0.1 mg/kg.~~

The intended EU GAPs of grape, sweet corn, barley, wheat, and sorghum are less critical as compared to the authorized GAPs in North America. Consequently, the MRLs of these crops are based on import tolerances (EFSA Journal 2020;18(6):6133) and the dietary risk assessment has to be performed with these more critical residues. For oat and millet no import tolerances are available yet, however extrapolation from barley to oat is possible, as well as from field corn to millet. As uses of these crops are also authorized in North America, the risk assessment has been conducted based on the more critical residues expected from the imported crops.

The intended GAP of sunflower is identical in N-EU and S-EU. As the supervised residue trials showed comparable residue levels in the two residue regions, the MRL and the dietary risk assessments have been based on the combined datasets.

Evaluator comment:

1. Grape

Wine grapes are the major crops in Northern Europe (Technical Guidelines SANTE/2019/12752). A minimum of eight independent trials representative of the proposed growing area for outdoor are required.

Table grapes are the minor crops in Northern Europe (Technical Guidelines SANTE/2019/12752). Therefore, 4 NEU trials are therefore required to support the use of Deltamethrin + Flupyradifurone EC 85 on table grapes in NEU.

Sufficient residue trials are available to determine flupyradifurone residues on/in grapes.

The proposed GAP of this dRR submission for the central zone for grapes is as follows:

2 x 30 g FPF/ha, interval 14 d, BBCH 57-81, PHI 14 d

Four bridging trials (14-2096) were conducted in the northern residue zone which demonstrated that the intended use is less critical with regard to possible flupyradifurone-related residues as compared to the "home & garden" uses on which the MRLs of flupyradifurone and DFA are currently based (GAP: 2 x 100 g a.s./ha, interval = 14d; PHI 14 d).

The study of Schoening, R.; Bouhamadi, S.; Sosniak, A.; Czaja, C.; 2016; 14-2096; M-559743-01-1

Residue results (mg/kg):

FPF: 2 x 0.043; 0.072*; 0.096;

DFA: 0.008*; 0.011*; 0.013*; 0.016*;

sum: 0.063; 0.071; 0.10*; 0.12.

* Peak residues detected after PHI

Available results of residue trials show that the in force MRLs of flupyradifurone on grapes of 3.0 mg/kg (Reg. (EU) 2022/1324) and DFA on grapes of 0.15 mg/kg (Reg. (EU) 2021/1842) will not be exceeded. The current EU MRLs for flupyradifurone and DFA are sufficient to support the proposed uses.

In response to comments received from cMS-SI during the commenting period, the Applicant submitted your position:

The grape residue studies for flupyradifurone referenced as EFSA 2015 have been submitted in 2012 to rapporteur Member State The Netherlands in the framework of Regulation (EC) No 1107/2009 as an application from Bayer CropScience AG for approval of the active substance flupyradifurone (BYI 029690) and have already been evaluated at EU level (DAR, NL, 2015 and EFSA, 2015).

References:

- The Netherlands, 2015: Final addendum to the draft assessment report on the active substance flupyradifurone prepared by the rapporteur Member State the Netherlands in the framework of Regulation (EC) No 1107/2009, February, 2015
- EFSA, 2015: Conclusion on the peer review of the pesticide risk assessment of the active substance flupyradifurone; EFSA Journal 2015; 13(2):4020.

The grape residue studies for deltamethrin referenced as EFSA 2015 were made available in the Article 12 process for deltamethrin (EFSA Journal 2015;13(11):4309). Sweden, as the designated rapporteur Member State (RMS) was asked by EFSA to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 22 December 2014 and finalised on 3 March 2015. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 10 April 2015 resulting in an EFSA Reasoned Opinion from November 2015. In this Reasoned Opinion data gaps were identified and laid down in regulation EU 2016/1822 as confirmatory data necessary to confirm the tentative MRLs of deltamethrin specifically relevant to the new proposed residue definition for risk assessment covering *cis*-, *alpha(R)*- and *trans*-deltamethrin. The applicant provided all new information available to the new RMS Austria until 18 October 2018 who provided an evaluation report in 2020 as background document for the Reasoned Opinion EFSA, 2022 providing an updated consumer risk assessment. The huge data set made available in the context of confirmatory data request (EFSA, 2022) showed high evidence on fruit crops that residues of *alpha*-R-isomer and *trans*-isomer are below <0.01 mg/kg and that a conversion factor of 1 between residue definition for monitoring and risk assessment applies. The consumer risk assessment performed clearly shows that, the MRL of 0.2 mg/kg for grapes based on S-EU data proposed already in EFSA, 2015 is safe for the consumer.

References:

- EFSA, 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
- EFSA, 2022: Evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for deltamethrin in tomatoes and okra/lady's fingers, EFSA Journal 2022;20(3):7107

The residue data are sufficient to support the proposed uses on grapes.

2. Sunflower

Sunflower is the major crop in Northern Europe (Technical Guidelines SANTE/2019/12752). A minimum of eight independent trials representative of the proposed growing area for outdoor are required.

Sufficient residue trials are available to determine flupyradifurone residues on/in sunflower. The proposed GAP of this dRR submission for the central zone for sunflower is as follows:
2 x 56.25 g FPF/ha, interval 14 d, BBCH 30-69, PHI n.a.

The study of Miara, C.; Kowalski, N.; 2018; 16-2145; M-645130-01-1

Residue results (mg/kg) for seeds:

E (FPF): 3 x 0.011; 0.015; 0.024; 0.046; 0.086; 0.10

E (DFA): 2 x 0.008; 0.015; 0.016; 2 x 0.022; 0.025; 0.042

RA (sum): 0.035; 0.044; 0.059; 0.076; 0.085; 0.090; 0.12; 0.23

The current MRL for sunflower is 0.01* mg/kg for flupyradifurone (Reg. (EU) 2022/1324) and 0.05 mg/kg for DFA (Reg. (EU) 2021/1842).

Available results of residue trials show that the in force MRL of DFA on sunflower of 0.05 mg/kg (Reg. (EU) 2021/1842) will not be exceeded.

Considering the intended use in sunflower, an exceedance of the default MRL of 0.01 mg/kg for flupyradifurone (expressed as flupyradifurone), as established in Commission Regulation (EU) 2022/1324, is expected. Therefore until the new MRL for flupyradifurone come into force, authorisation of the GAP (sunflower) will not be possible.

3. Barley

Barley is the major crop in Northern Europe (Technical Guidelines SANTE/2019/12752). A minimum of eight independent trials representative of the proposed growing area for outdoor are required.

Sufficient residue trials are available to determine flupyradifurone residues on/in barley.

The proposed GAP of this dRR submission for the central zone for barley is as follows:

2 x 56.25 g FPF/ha, interval 14 d, BBCH 41-83, PHI - 30 days.

The study of Schulte, G.; 2017; 15-2131; M-580973-04-1

Residue results (mg/kg) for grain (PHI: 29-33 days):

E (FPF): 0.034; 0.053*; 0.082*; 0.16

E (DFA): 0.011; 0.031*; 0.039; 0.080

RA (sum): 0.12*; 0.15*; 2 x 0.27

* Peak residues detected after PHI.

The study of Kaussmann, M.; 2018; 16-2035; M-634410-01-1

Residue results (mg/kg) for grain (PHI: 27-33 days):

E (FPF): <0.01; 0.022; 0.081*; 0.099*

E (DFA): 0.036*; 0.052; 0.059*; 0.064

RA (sum): 0.18; 0.20; 0.21*; 0.26*

* Peak residues detected after PHI.

Available results of residue trials show that the in force MRLs of flupyradifurone on barley of 3.0 mg/kg (Reg. (EU) 2022/1324) and DFA on barley of 0.8 mg/kg (Reg. (EU) 2021/1842) will not be exceeded. The current EU MRLs for flupyradifurone and DFA are sufficient to support the proposed uses.

4. Oat

Oat is the major crop in Northern Europe (Technical Guidelines SANTE/2019/12752). A minimum of eight independent trials representative of the proposed growing area for outdoor are required.

Applicant has not submitted residue trials on oat.

In accordance with Technical Guidelines SANTE/2019/12752 eight residue trials on barley (0500010) for foliar treatments before and after forming of the edible part can be extrapolated to oat (0500050). Therefore the data cover the use on oat.

HR results (mg/kg) for grain for barley:

HR (FPF): 0.16 mg/kg

HR (DFA): 0.080 mg/kg

HR (sum): 0.27 mg/kg

The current MRL for oat is 0.01* mg/kg for flupyradifurone (Reg. (EU) 2022/1324) and 0.3 mg/kg for DFA Reg. (EU) 2021/1842). **Considering the intended use in oat and taking into account the HR value for FDF (0.16 mg/kg), an exceedance of the default MRL of 0.01 mg/kg for flupyradifurone (expressed as flupyradifurone), as established in Commission Regulation (EU) 2022/1324, is expected. Therefore until the new MRL for flupyradifurone for oat come into force, authorisation of the GAP (oat) will not be possible.**

5. Wheat

Wheat is the major crop in Northern Europe (Technical Guidelines SANTE/2019/12752). A minimum of eight independent trials representative of the proposed growing area for outdoor are required.

Sufficient residue trials are available to determine flupyradifurone residues on/in wheat.

The proposed GAP of this dRR submission for the central zone for wheat is as follows:
2 x 56.25 g FPF/ha, interval 14 d, BBCH 41-83, PHI - 30 days.

The study of Schulte, G.; 2017; 15-2129; M-580528-03-1

Residue results (mg/kg) for grain (PHI: 30 days):

E (FPF): 2 x <0.01; 0.011; 0.015*

E (DFA): 0.10; 0.16; 0.20; 0.34

RA (sum): 0.32; 0.48; 0.62; 1.0

* Peak residues detected after PHI.

The study of Kaussmann, M.; Kerkerling, S.; 2018; 16-2033; M-634190-01-1

Residue results (mg/kg) for grain (PHI: 30 days):

E (FPF): 0.010; 0.012*; 0.032*; 0.061

E (DFA): 0.018; 0.067; 0.074; 0.14*

RA (sum): 0.12; 2 x 0.23; 0.42*

* Peak residues detected after PHI.

Available results of residue trials show that the in force MRLs of flupyradifurone on wheat of 1.0 mg/kg (Reg. (EU) 2022/1324) and DFA on wheat of 1.5 mg/kg (Reg. (EU) 2021/1842) will not be exceeded. The current EU MRLs for flupyradifurone and DFA are sufficient to support the proposed uses.

6. Maize and sweet corn

Maize is the major crop in Northern Europe (Technical Guidelines SANTE/2019/12752). A minimum of eight independent trials representative of the proposed growing area for outdoor are required.

Sweet corn is the minor crop in Northern Europe (Technical Guidelines SANTE/2019/12752). Therefore, 4 NEU trials are therefore required to support the use of Deltamethrin + Flupyradifurone EC 85 on sweet corn in NEU.

Sufficient residue trials are available to determine flupyradifurone residues on/in maize (kernel).

In accordance with Technical Guidelines SANTE/2019/12752 eight residue trials on immature maize for foliar treatments before and after forming of the edible part can be extrapolated to sweet corn (0234000). Therefore the data cover the use on sweet corn.

The proposed GAP of this dRR submission for the central zone for maize is as follows:

1 x 56.25 g FPF/ha, BBCH 51-75, PHI -as per growth stage.

In order to support the GAP for maize and sweet corn, Applicant proposes and zRMS-PL agrees to apply the proportionality principle to potentially account for residues in maize and sweet corn at a lower application rate of 56.25 g FPF/ha.

The study of Schulte, G.; 2017; 15-2134; M-574350-02-1

a) Maize - kernel

Tested GAP: 1 x 93.75 g a.s./ha, BBCH 51-75, PHI n.a.

Residue results (mg/kg) for kernel:

E (FPF): 4 x <0.01

E (DFA): 0.013; 0.016; 0.021; 0.026

RA (sum): 0.050; 0.057; 0.072; 0.088

Intended GAP (scaled residues; scaling factor = $56.25/93.75 = 0.6$):

1 x 56.25 g a.s./ha, BBCH 51-75, PHI n.a.

Residue results (mg/kg) for kernel:

E (FPF): 4 x <0.01

E (DFA): 0.008; 0.010; 0.013; 0.016

RA (sum): 0.030; 0.034; 0.043; 0.053

b) Maize – immature kernel

Tested GAP: 1 x 93.75 g a.s./ha, BBCH 51-75, PHI n.a.

Residue results (mg/kg) for kernel, immature:

E (FPF): 4 x <0.01

E (DFA): <0.007; 0.007; 0.009; 0.015

RA (sum): <0.03; 0.032; 0.038; 0.056

Intended GAP (scaled residues; scaling factor = $56.25/93.75 = 0.6$):

1 x 56.25 g a.s./ha, BBCH 51-75, PHI = 7d
E (FPF): 4 x <0.01
E (DFA): 2x <0.007; 0.009
RA (sum): 3 x <0.03; 0.034

The study of Schulte, G.; Kerkerling, S.; 2018; 16-2192; M-628803-01-1

a) Maize - kernel

Tested GAP: 1 x 93.75 g a.s./ha, BBCH 51-75, PHI n.a.

Residue results (mg/kg) for kernel:

E (FPF): 4 x <0.01
E (DFA): 2x <0.007; 0.008; 0.018;
RA (sum): 2 x <0.03; 0.035; 0.064.

Intended GAP (scaled residues; scaling factor = 56.25/93.75 = 0.6):

1 x 56.25 g a.s./ha, BBCH 51-75, PHI n.a.

Residue results (mg/kg) for kernel:

E (FPF): 4 x <0.01
E (DFA): <0.007; 0.011;
RA (sum): 3 x <0.03; 0.038.

b) Maize – immature kernel

Tested GAP: 1 x 93.75 g a.s./ha, BBCH 51-75, PHI n.a.

Residue results (mg/kg) for kernel, immature:

E (FPF): 4 x <0.01
E (DFA): 3 x <0.007; 0.009;
RA (sum): 3 x <0.03; 0.038.

Intended GAP (scaled residues; scaling factor = 56.25/93.75 = 0.6):

1 x 56.25 g a.s./ha, BBCH 51-75, PHI = 7d

E (FPF): 4 x <0.01;
E (DFA): 4x <0.007;
RA (sum): 4 x <0.03.

Available results of residue trials show that the in force MRLs of flupyradifurone on maize of 0.02 mg/kg (Reg. (EU) 2022/1324) and on sweet corn of 0.05 mg/kg and DFA on maize of 0.1 mg/kg and on sweet corn of 0.2 mg/kg (Reg. (EU) 2021/1842) will not be exceeded. The current EU MRLs for flupyradifurone and DFA are sufficient to support the proposed uses.

7. Common millet/proso millet

Common millet/proso millet is the minor crop in Northern Europe (Technical Guidelines SANTE/2019/12752). Therefore, 4 NEU trials are therefore required to support the use of Deltamethrin + Flupyradifurone EC 85 on common millet/proso millet in NEU. Applicant has not submitted residue trials on common millet/proso millet.

In accordance with Technical Guidelines SANTE/2019/12752 eight residue trials on maize (0500030) for foliar treatments before and after forming of the edible part can be extrapolated to common millet/proso millet (0500040). Sufficient residue trials are available to determine flupyradifurone residues on/in maize (kernel).

Therefore the data cover the use on common millet/proso millet.

Available results of residue trials show that the in force MRLs of flupyradifurone on maize of 0.02 mg/kg (Reg. (EU) 2022/1324) and on common millet/proso millet of 0.01 mg/kg and DFA on maize of 0.1 mg/kg and on common millet/proso millet of 0.3 mg/kg (Reg. (EU) 2021/1842) will not be exceeded. The current EU MRLs for flupyradifurone and DFA are sufficient to support the proposed uses.

8. Sorghum

Sorghum is the minor crop in Northern Europe (Technical Guidelines SANTE/2019/12752). Therefore, 4 NEU trials are therefore required to support the use of Deltamethrin + Flupyradifurone EC 85 on sorghum in NEU. Applicant has not submitted residue trials on sorghum.

In accordance with Technical Guidelines SANTE/2019/12752 eight residue trials on maize (0500030) for foliar treatments before and after forming of the edible part can be extrapolated to sorghum (0500080). Sufficient residue trials are available to determine flupyradifurone residues on/in maize (kernel). Therefore the data cover the use on sorghum.

Available results of residue trials show that the in force MRLs of flupyradifurone on maize of 0.02 mg/kg (Reg. (EU) 2022/1324) and on sorghum of 3 mg/kg and DFA on maize of 0.1 mg/kg and on sorghum of 0.3 mg/kg (Reg. (EU) 2021/1842) will not be exceeded. The current EU MRLs for flupyradifurone and DFA are sufficient to support the proposed uses.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

The dietary burden estimated in the most recent EFSA evaluation (Article 12 MRL review, EFSA, 2020) was updated by adding the potential feed items of the uses supported in this draft Registration Report (dRR). In the EFSA Reasoned Opinion, two different scenarios were considered in order to determine the worst case dietary exposure of livestock to flupyradifurone-related residues.

- (1) Feeding of animals in Europe considering primary and rotational crops grown in the EU as well as imported feed items from the US and their by-products (EU scenario)
- (2) Feeding of animals in the US/Canada (North America) to estimate residues in livestock matrices potentially exported to Europe (US scenario)

Only the first scenario (EU scenario) is of relevance for this dRR – it will account for the additional EU uses intended in cereals and sunflower.

For the EU scenario, median and maximum dietary burdens were estimated for parent flupyradifurone and separately for its metabolite DFA. DFA residues in primary crops were added to residue levels of DFA estimated in the respective rotational crop (grown in soil at the estimated plateau level of flupyradifurone after multi-year usage). For flupyradifurone, only residues in primary crops and processed commodities were considered as rotational crops showed generally no or negligible residues of the parent compound.

Dietary burden calculations were performed using the Excel calculator proposed by EFSA (Animal model 2017a.xls), which considers a total of 9 animal species. Input values are summarized in [Table 7.2-10](#) for flupyradifurone and in [Table 7.2-11](#) for DFA. In agreement with the information given in the calculator, flupyradifurone-related residues in forage/silage of cereals were not considered for the primary uses as no specific GAP on forage is intended (the proposed GAP supports the harvest of mature seeds in the case of the cereals). If residues in the EU feed items were equivalent or less critical as compared to the residues in the imported feed items, the residues in the imported crops were used as input values.

Table 7.2-10: Input values for the dietary burden calculation of flupyradifurone (considering primary and rotational crops grown in the EU as well as imported feed items from the USA and their by-products = EU scenario)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Feed items related to previous evaluations				
Apple, wet pomace	0.18	STMR (apple:0.11) x PF (1.6) (EFSA, 2015)	0.18	STMR x PF (1.6) (EFSA, 2015)
Citrus, dried pulp	2.07	STMR (mandarin: 0.45) x PF (4.6) (EFSA, 2020)	2.07	STMR (mandarin) x PF (4.6) (EFSA, 2020)
Head cabbage	0.05	STMR (SEU; EFSA, 2020)	0.13	HR (SEU; EFSA 2020)
Kale	0.66	STMR (EU; EFSA, 2020)	1.9	HR (EU; EFSA 2020)
Potato culls, cassava/tapioca roots	0.01	STMR (US; EFSA, 2020)	0.04	HR (US; EFSA, 2020)
Potato process waste	0.20	STMR x PF (20) ^(a) (US; EFSA, 2020)	0.20	STMR x PF (20) ^(a) (EFSA, 2020)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Potato, dried pulp	0.38	STMR x PF (38) ^(a) (US; EFSA 2020)	0.38	STMR x PF (38) ^(a) (EFSA 2020)
Carrot culls, swede and turnip roots	0.02	STMR (US; EFSA, 2020)	0.60	HR (US; EFSA, 2020)
Dry beans, lupins, cowpeas, peas	0.57	STMR (dry pea, US; EFSA, 2020)	0.57	STMR (US; EFSA, 2020)
Lupin seed, meal	0.63	STMR (dry pea) x PF (1.1) ^(a) (US; EFSA, 2020)	0.63	STMR (dry pea) x PF (1.1) ^(a) (US; EFSA, 2020)
Peanut, meal	0.02	STMR x PF (2) ^(a) (US; EFSA, 2020)	0.02	STMR x PF (2) ^(a) (US; EFSA, 2020)
Soybean seed	0.06	STMR (US; EFSA, 2020)	0.06	STMR (US; EFSA, 2020)
Soybean meal	0.07	STMR x PF (1.1) (US; EFSA, 2020)	0.07	STMR x PF (1.1) (US; EFSA, 2020)
Soybean hulls	0.04	STMR x PF (0.6) (US; EFSA, 2020)	0.04	STMR x PF (0.6) (US; EFSA, 2020)
Cotton seed	0.02	STMR (US; EFSA, 2020)	0.02	STMR (US; EFSA, 2020)
Cotton seed, meal	0.02	STMR x PF (1) ^(b) (US; EFSA, 2020)	0.02	STMR x PF (1) ^(b) (US; EFSA, 2020)
Barley grain (see also below)	0.45	STMR (US; EFSA, 2020)	0.45	STMR (US; EFSA, 2020)
Barley, brewer`s grain	0.45	STMR x PF (1) ^(b) (US; EFSA, 2020)	0.45	STMR x PF (1) ^(b) (US; EFSA, 2020)
Maize grain (see also below)	0.01	STMR (US; EFSA, 2020)	0.01	STMR (US; EFSA, 2020)
Maize, milled by-products, hominy meal, gluten feed, gluten meal	0.01	STMR x PF (1) ^(b) (US; EFSA, 2020)	0.01	STMR x PF (1) ^(b) (US; EFSA, 2020)
Sorghum grain (see also below)	0.51	STMR (US; EFSA, 2020)	0.51	STMR (US; EFSA, 2020)
Wheat/triticale grain (see also below)	0.15	STMR (US; EFSA, 2020)	0.15	STMR (US; EFSA, 2020)
Distiller's grain dried (from wheat)	0.50	STMR x PF (3.3) ^(a) (US; EFSA, 2020)	0.50	STMR x PF (3.3) ^(a) (US; EFSA, 2020)
Wheat gluten meal	0.15	STMR x PF (1) ^(b) (US; EFSA, 2020)	0.15	STMR x PF (1) ^(b) (US; EFSA, 2020)
Wheat, milled by-products	0.36	STMR x PF (2.4, bran) (US; EFSA, 2020)	0.36	STMR x PF (2.4, bran) (US; EFSA, 2020)
Feed items relevant to this submission				
Barley grain	0.45	STMR (US; cf. Table 7.2-9 & EFSA, 2020)	0.45	STMR (US; cf. Table 7.2-9 & EFSA, 2020)
Barley straw	0.17	STMR (EU; cf. Table 7.2-9)	4.8	HR (EU; cf. Table 7.2-9)
Maize grain	0.01	STMR (US; cf. Table 7.2-9 & EFSA, 2020)	0.01	STMR (US; cf. Table 7.2-9 & EFSA, 2020)
Maize stover	0.16	STMR (NEU; cf. Table 7.2-9)	0.45	HR (NEU; cf. Table 7.2-9)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Millet grain → extrapolated from maize grain (US)	0.01	STMR (maize, US; cf. Table 7.2-9)	0.01	STMR (maize, US; cf. Table 7.2-9)
Millet straw → extrapolated from maize stover (NEU)	0.16	STMR (maize, NEU; cf. Table 7.2-9)	0.45	HR (maize, NEU; cf. Table 7.2-9)
Oat grain → extrapolated from barley grain (US)	0.45	STMR (barley, US; cf. Table 7.2-9)	0.45	STMR (barley, US; cf. Table 7.2-9)
Oat straw → extrapolated from barley straw (NEU)	0.17	STMR (barley, NEU; cf. Table 7.2-9)	0.69	HR (barley, NEU; cf. Table 7.2-9)
Sorghum grain	0.51	STMR (US; cf. Table 7.2-9 & EFSA, 2020)	0.51	STMR (US; cf. Table 7.2-9 & EFSA, 2020)
Sorghum stover → extrapolated from maize straw (NEU)	0.16	STMR (maize, NEU; cf. Table 7.2-9)	0.45	HR (maize, NEU; cf. Table 7.2-9)
Sunflower, meal	0.05	STMR (0.025) x PF (2) ^(a) (cf. Table 7.2-9)	0.05	STMR (0.025) x PF (2) ^(a) (cf. Table 7.2-9)
Wheat/triticale grain	0.15	STMR (US; cf. Table 7.2-9 & EFSA, 2020)	0.15	STMR (US; cf. Table 7.2-9 & EFSA, 2020)
Wheat/triticale straw	0.42	STMR (EU; cf. Table 7.2-9)	2.6	HR (EU; cf. Table 7.2-9)

STMR = supervised trials median residue

HR = highest residue

PF = processing factor

(a) For potato process waste, potato dried pulp, sunflower meal, lupin seed meal, peanut meal, and distiller's grain in the absence of processing factors supported by data, default processing factors were used to consider the potential concentration of residues in these commodities.

(b) No concentration of residues expected according to processing studies provided for Article 12 MRL review (EFSA, 2020)

Table 7.2-11: Input values for the dietary burden calculation of DFA (expressed as DFA) (considering primary and rotational crops grown in the EU as well as imported feed items from the USA and their by-products = EU scenario)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Feed items related to previous evaluations				
Apple, wet pomace	0.08	STMR (apple) x PF (1) ^(b) (EFSA, 2015)	0.08	STMR (apple) x PF (1) ^(b) (EFSA, 2015)
Citrus, dried pulp	0.03	STMR (mandarin) x PF (1.5) (EFSA, 2020)	0.03	STMR (mandarin) x PF (1.5) (EFSA, 2020)
Head cabbage	0.15	STMR PC+ STMR RC (brassica) (EU; EFSA, 2020)	0.22	HR PC+ HR RC (brassica) (EU; EFSA, 2020)
Kale	0.23	STMR PC+ STMR RC (brassica) (EU; EFSA, 2020)	0.33	HR PC+ HR RC (brassica) (EU; EFSA, 2020)
Potato, culls cassava/tapioca roots	0.07	STMR RC (potato) (EU; EFSA, 2020)	0.18	HR RC (potato) (EU; EFSA, 2020)
Potato, process waste	0.07	STMR RC (potato) x PF (1) ^(b) , (EU; EFSA, 2020)	0.07	STMR RC (potato) x PF (1) ^(b) , (EU; EFSA, 2020)
Potato, dried pulp	0.07	STMR RC (potato) x PF (1) ^(b) , (EU; EFSA, 2020)	0.07	STMR RC (potato) x PF (1) ^(b) , (EU; EFSA, 2020)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Carrot culls, swede, roots, turnip roots	0.07	STMR PC + STMR RC (carrot/turnip) (US; EFSA, 2020)	0.25	HR PC + HR RC (carrot/turnip) (US; EFSA, 2020)
Dry beans, lupins, cowpeas, peas	1.2	STMR PC (field pea) + STMR RC (field pea) (EU; EFSA, 2020)	1.2	STMR PC + STMR RC (field pea) (EU; EFSA, 2020)
Lupin seed, meal	1.3	STMR PC (field pea) + STMR RC (field pea) (EU; EFSA, 2020) x PF (1.1) ^(a)	1.3	STMR PC (field pea) + STMR RC (field pea) (EU; EFSA, 2020) x PF (1.1) ^(a)
Peanut, meal	0.08	STMR PC (peanut) + STMR RC (rape) (US; EFSA, 2020) x PF (2) ^(a)	0.08	STMR PC (peanut) + STMR RC (rape) (US; EFSA, 2020) x PF (2) ^(a)
Linseed, rapeseed, safflower meal	0.06	STMR RC (rape) x PF (2) ^(a) (EU; EFSA, 2020)	0.06	STMR RC (rape) x PF (2) ^(a) (EU; EFSA, 2020)
Soybean seed	0.05	STMR PC (soybean) + STMR RC (rape) (US; EFSA, 2020)	0.05	STMR PC (soybean) + STMR RC (rape) (US; EFSA, 2020)
Soybean meal	0.07	STMR PC (soybean) + STMR RC (rape) x PF (1.3) (US; EFSA, 2020)	0.07	STMR PC (soybean) + STMR RC (rape) x PF (1.3) (US; EFSA, 2020)
Soybean hulls	0.05	STMR PC (soybean) + STMR RC (rape) x PF (0.9) (US; EFSA, 2020)	0.05	STMR PC (soybean) + STMR RC (rape) x PF (0.9) (US; EFSA, 2020)
Cotton seed	0.04	STMR PC (cotton) + STMR RC (rape) (EU; EFSA, 2020)	0.04	STMR PC (cotton) + STMR RC (rape) (EU; EFSA, 2020)
Cotton seed, meal	0.05	STMR PC (cotton) + STMR RC (rape) x PF (1.3) (EU; EFSA, 2020)	0.05	STMR PC (cotton) + STMR RC (rape) x PF (1.3) (EU; EFSA, 2020)
Canola/rape meal	0.06	STMR RC (rape) x PF (2) ^(a) (EU; EFSA, 2020)	0.06	STMR RC (rape) x PF (2) ^(a) (EU; EFSA, 2020)
Barley / oat grain (see also below)	0.19	STMR PC (barley) + STMR RC (barley) (US; EFSA, 2020)	0.19	STMR PC (barley) + STMR RC (barley) (US; EFSA, 2020)
Barley, brewer's grain	0.19	STMR PC (barley) + STMR RC (barley) x PF (1) ^(b) (US; EFSA, 2020)	0.19	STMR PC (barley) + STMR RC (barley) x PF (1) ^(b) (US; EFSA, 2020)
Maize grain (see also below)	0.07	STMR PC (maize) + STMR RC (maize) (US; EFSA, 2020)	0.07	STMR PC (maize) + STMR RC (maize) (US; EFSA, 2020)
Maize, milled by-products, hominy meal, gluten feed, gluten meal	0.07	STMR PC (maize) + STMR RC (maize) x PF (1) ^(b) (US; EFSA, 2020)	0.07	STMR PC (maize) + STMR RC (maize) x PF (1) ^(b) (US; EFSA, 2020)
Sorghum grain	0.11	STMR PC (sorghum) + STMR RC (barley) (US; EFSA, 2020)	0.11	STMR PC (maize) + STMR RC (barley) (US; EFSA, 2020)
Wheat grain (see also below)	0.25	STMR PC (wheat) + STMR RC (barley) (US; EFSA, 2020)	0.25	STMR PC (wheat) + STMR RC (barley) (US; EFSA, 2020)
Triticale grain / millet grain	0.09	STMR RC (barley) (US; EFSA, 2020)	0.09	STMR RC (barley) (US; EFSA, 2020)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Distiller's grain dried (from wheat)	0.83	STMR PC (wheat) + STMR RC (barley) x PF (3.3) ^(a) (US; EFSA, 2020)	0.83	STMR PC (wheat) + STMR RC (barley) x PF (3.3) ^(a) (US; EFSA, 2020)
Wheat gluten meal	0.10	STMR PC (wheat) + STMR RC (barley) x PF (0.4) (US; EFSA, 2020)	0.10	STMR PC (wheat) + STMR RC (barley) x PF (0.4) (US; EFSA, 2020)
Wheat, milled by-products	0.27	STMR PC (wheat) + STMR RC (barley) x PF (1.07, bran) (US; EFSA, 2020)	0.27	STMR PC (wheat) + STMR RC (barley) x PF (1.07, bran) (US; EFSA, 2020)
Forages of alfalfa, clover, trefoil, grass, cereals (except maize) and legumes / clover silage	0.04	STMR RC (barley forage) (EU; EFSA, 2020)	0.09	HR RC (barley forage) (EU; EFSA, 2020)
Alfalfa hay / alfalfa meal	0.10	STMR RC (barley forage) x PF (2.5) ^(a) (EU; EFSA, 2020)	0.23	HR RC (barley forage) x PF (2.5) ^(a) (EU; EFSA, 2020)
Alfalfa silage	0.04	STMR RC (barley forage) x PF (1.1) ^(a) (EU; EFSA, 2020)	0.10	HR RC (barley forage) x PF (1.1) ^(a) (EU; EFSA, 2020)
Rape forage	0.07	STMR RC (rape forage) (EU; EFSA, 2020)	0.18	HR RC (rape forage) (EU; EFSA, 2020)
Maize forage / silage	0.03	STMR RC (maize forage) (EU; EFSA, 2020)	0.04	HR RC (maize forage) (EU; EFSA, 2020)
Triticale straw	0.06	STMR RC (barley straw) (EU; EFSA, 2020)	0.07	HR RC (barley straw) (EU; EFSA, 2020)
Barley silage	0.05	STMR RC (barley forage) x PF (1.3) ^(a) (EU; EFSA, 2020)	0.12	HR RC (barley forage) x PF (1.3) ^(a) (EU; EFSA, 2020)
Grass / pea silage	0.06	STMR RC (barley forage) x PF (1.6) ^(a) (EU; EFSA, 2020)	0.14	HR RC (barley forage) x PF (1.6) ^(a) (EU; EFSA, 2020)
Lespedeza, hay	0.16	STMR RC (barley forage) x PF (4.0) ^(a) (EU; EFSA, 2020)	0.36	HR RC (barley forage) x PF (4.0) ^(a) (EU; EFSA, 2020)
Sorghum silage	0.02	STMR RC (barley forage) x PF (0.6) ^(a) (EU; EFSA, 2020)	0.05	HR RC (barley forage) x PF (0.6) ^(a) (EU; EFSA, 2020)
Soybean silage	0.02	STMR RC (barley forage) x PF (0.5) ^(a) (EU; EFSA, 2020)	0.05	HR RC (barley forage) x PF (0.5) ^(a) (EU; EFSA, 2020)
Clover hay / oat hay	0.12	STMR RC (barley forage) x PF (3) ^(a) (EU; EFSA, 2020)	0.27	HR RC (barley forage) x PF (3) ^(a) (EU; EFSA, 2020)
Cowpea hay/ triticale hay	0.12	STMR RC (barley forage) x PF (2.9) ^(a) (EU; EFSA, 2020)	0.26	HR RC (barley forage) x PF (2.9) ^(a) (EU; EFSA, 2020)
Grass hay/ pea hay/ wheat hay	0.14	STMR RC (barley forage) x PF (3.5) ^(a) (EU; EFSA, 2020)	0.32	HR RC (barley forage) x PF (3.5) ^(a) (EU; EFSA, 2020)
Soybean hay	0.06	STMR RC (barley forage) x PF (1.5) ^(a) (EU; EFSA, 2020)	0.14	HR RC (barley forage) x PF (1.5) ^(a) (EU; EFSA, 2020)
Trefoil hay	0.11	STMR RC (barley forage) x PF (2.8) ^(a) (EU; EFSA, 2020)	0.25	HR RC (barley forage) x PF (2.8) ^(a) (EU; EFSA, 2020)
Tops of beets and turnips	0.03	STMR RC (lettuce) (EU; EFSA, 2020)	0.08	HR RC (lettuce) (EU; EFSA, 2020)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Feed items relevant to this submission				
Barley grain	0.19	STMR PC (barley grain) + STMR RC (barley grain) (EU; cf. Table 7.2-9 & EFSA, 2020)	0.19	STMR PC (barley grain) + STMR RC (barley grain) (EU; cf. Table 7.2-9 & EFSA, 2020)
Barley straw	0.08	STMR PC (barley straw) + STMR RC (barley straw) (EU; cf. Table 7.2-9 & Table 7.2-23)	0.65	HR PC (barley straw) + HR RC (barley straw) (EU; cf. Table 7.2-9 & Table 7.2-23)
Maize grain → also extrapolated to millet grain	0.07	STMR PC (maize) + STMR RC (maize) (EU; cf. Table 7.2-9 & EFSA, 2020)	0.07	STMR PC (maize) + STMR RC (maize) (EU; cf. Table 7.2-9 & EFSA, 2020)
Maize stover → also extrapolated to millet straw / sorghum stover	0.03	STMR PC (maize stover) + STMR RC (barley straw) (NEU; cf. Table 7.2-9 & Table 7.2-23)	0.05	HR PC (maize stover) + HR RC (maize stover) (NEU; cf. Table 7.2-9 & Table 7.2-23)
Oat grain	0.19	STMR PC (barley grain) + STMR RC (barley grain) (NEU; cf. Table 7.2-9 & Table 7.2-23)	0.19	STMR PC (barley grain) + STMR RC (barley grain) (NEU; cf. Table 7.2-9 & Table 7.2-23)
Oat straw	0.08	STMR PC (barley straw) + STMR RC (barley straw) (NEU; cf. Table 7.2-9 & Table 7.2-23)	0.11	HR PC (barley straw) + STMR RC (barley straw) (NEU; cf. Table 7.2-9 & Table 7.2-23)
Sunflower, meal	0.10	STMR PC + STMR RC (rape) x PF (2) ^(a) (cf. Table 7.2-9 & Table 7.2-23)	0.10	STMR PC + STMR RC (rape) x PF (2) ^(a) (cf. Table 7.2-9 & Table 7.2-23)
Wheat grain	0.25	STMR PC (wheat) + STMR RC (barley) (US; cf. Table 7.2-9 & Table 7.2-23 & EFSA, 2020)	0.25	STMR PC (wheat) + STMR RC (barley) (US; cf. Table 7.2-9 & Table 7.2-23 & EFSA, 2020)
Wheat straw	0.10	STMR PC (wheat straw) + STMR RC (barley straw) (EU; cf. Table 7.2-9 & Table 7.2-23)	0.24	HR PC (wheat straw) + HR RC (barley straw) (EU; cf. Table 7.2-9 & Table 7.2-23)

PC = primary crop

RC = rotational crop

STMR = supervised trials median residue

HR = highest residue

PF = processing factor

(a) Default processing factors according to the Excel calculator proposed by EFSA (Animal model 2017a.xls).

Remark: Values in *italics* deviate slightly from the EFSA RO (EFSA, 2020) as the values estimated by EFSA could not be confirmed.

Results of the animal burden calculations are reported for flupyradifurone in [Table 7.2-12](#) and for DFA in [Table 7.2-13](#) (automatically generated by Excel calculator).



FPF_after feeding
FPF_NEU scenario.xl



DFA_after feeding
DFA_NEU scenario.x

Table 7.2-12: Results of the dietary burden calculation for flupyradifurone

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)	Previous assessment (EFSA, 2020)
	mg/kg bw per day		mg/kg DM						
	Median	Maximum	Median	Maximum					
								0.004 mg/kg bw	Max burden mg/kg bw
Cattle (all diets)	0.063	0.170	1.78	5.60	Dairy cattle	Kale	leaves	Yes	0.170
Cattle (dairy only)	0.063	0.170	1.64	4.41	Dairy cattle	Kale	leaves	Yes	0.170
Sheep (all diets)	0.047	0.221	1.36	5.20	Lamb	Swede	roots	Yes	0.155
Sheep (ewe only)	0.045	0.173	1.36	5.20	Ram/Ewe	Swede	roots	Yes	0.129
Swine (all diets)	0.028	0.097	1.21	4.22	Swine (breeding)	Kale	leaves	Yes	0.097
Poultry (all diets)	0.037	0.095	0.52	1.38	Poultry layer	Swede	roots	Yes	0.078
Poultry (layer only)	0.035	0.095	0.51	1.38	Poultry layer	Swede	roots	Yes	0.074

(a) When several diets are relevant (e.g. cattle, sheep, and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"

(b) The most critical commodity is the major contributor identified from the maximum dietary burden burdens expressed as "mg/kg bw per day"

Table 7.2-13: Results of the dietary burden calculation for DFA (expressed as DFA)

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)	Previous assessment (EFSA, 2020)
	mg/kg bw per day		mg/kg DM						
	Median	Maximum	Median	Maximum				0.004 mg/kg bw	Max burden mg/kg bw
Cattle (all diets)	0.040	0.059	1.17	2.02	Dairy cattle	Swede	roots	Yes	0.057
Cattle (dairy only)	0.040	0.059	1.03	1.52	Dairy cattle	Swede	roots	Yes	0.057
Sheep (all diets)	0.040	0.066	1.02	1.63	Lamb	Swede	roots	Yes	0.065
Sheep (ewe only)	0.034	0.054	1.02	1.63	Ram/Ewe	Swede	roots	Yes	0.053
Swine (all diets)	0.023	0.045	0.89	1.67	Swine (finishing)	Swede	roots	Yes	0.044
Poultry (all diets)	0.037	0.051	0.55	0.75	Poultry layer	Swede	roots	Yes	0.050
Poultry (layer only)	0.037	0.051	0.55	0.75	Poultry layer	Swede	roots	Yes	0.050

(a) When several diets are relevant (e.g. cattle, sheep, and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"

(b) The most critical commodity is the major contributor identified from the maximum dietary burden burdens expressed as "mg/kg bw per day"

Evaluator comment:

Information given by the Applicant is sufficient.

The median and maximum dietary burdens for livestock were estimated for parent flupyradifurone and separately for its metabolite DFA and were calculated using the animal model calculator developed by EFSA (Animal model 2017).

The calculated dietary burdens for flupyradifurone and for its metabolite DFA were found to exceed the trigger value of 0.1 mg/kg DM (or 0.004 mg/kg bw/d, respectively) for all groups. Further investigation of residues is therefore required.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

Livestock feeding studies were provided with flupyradifurone and DFA, respectively for poultry and ruminants. The studies were used to derive MRL proposals for flupyradifurone and for DFA considering the expected dietary burdens estimated for EU livestock and as well for livestock fed in North America (in order to take into account that commodities of animal origin can be imported into the EU).

Data/information on livestock feeding studies were evaluated at EU level and were considered to be acceptable (Article 12 MRL review for flupyradifurone and DFA, EFSA Journal 2020;18(6):6133).

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

Flupyradifurone:

Based on the updated dietary burden calculation for flupyradifurone (i.e. considering the intended uses of this dRR for the EU scenario) the following flupyradifurone MRLs (cf. [Table 7.2-14](#)) were estimated. All MRLs are covered by the MRLs proposed in the most recent EFSA evaluation (EFSA, 2020), except for the flupyradifurone MRL in liver and kidney of swine. For these two commodities, new flupyradifurone MRLs were proposed in the draft Evaluation Report submitted in December 2020 (update March 2021).

New MRL proposals (as indicated in red in [Table 7.2-14](#)) are as follows:

Swine: 0.09 mg/kg for liver
0.15 mg/kg for kidney

Table 7.2-14: Flupyradifurone expressed as flupyradifurone: Risk assessment values and MRL proposals for EU scenario; comparison with MRLs proposed in Article 12 review (EFSA, 2020)

Animal commodity	Residues at the closet feeding level (mg/kg)		Estimated value at 1N level		MRL proposal (EU scenario) (mg/kg)	MRL (EFSA, 2020) (mg/kg)
			STMR _{Mo} (mg/kg)	HR _{Mo} (mg/kg)		
	Mean	Highest				
Cattle (all diets)						
Closest feeding level ^(a) :	0.184	mg/kg bw	1.1	N Dairy cattle (highest diet)		
Muscle	0.043	0.048	0.015	0.044	0.05	0.3
Fat	0.021	0.028	0.007	0.026	0.03	0.2
Liver	0.145	0.172	0.050	0.334 ⁽²⁾	0.4	1.0
Kidney	0.159	0.222	0.054	0.205	0.2	1.0
Cattle (dairy only)						
Closest feeding level ^(a) :	0.184	mg/kg bw	1.1	N Dairy cattle		
Milk ^(b)	0.023	0.026	0.008	0.021	0.03	0.15
Sheep (all diets)^(d)						
Closest feeding level ^(a) :	0.184	mg/kg bw	0.8	N Lamb (highest diet)		
Muscle	0.043	0.048	0.011	0.059	0.06	0.3
Fat	0.021	0.028	0.005	0.034	0.04	0.2
Liver	0.145	0.172	0.037	0.374	0.4	1.0
Kidney	0.159	0.222	0.040	0.267	0.3	1.0

Animal commodity	Residues at the closest feeding level (mg/kg)		Estimated value at 1N level		MRL proposal (EU scenario) (mg/kg)	MRL (EFSA, 2020) (mg/kg)
	Mean	Highest	STMR _{Mo} (mg/kg)	HR _{Mo} (mg/kg)		
Sheep (dairy only) ^(d)						
Closest feeding level ^(a) :	0.184	mg/kg bw	1.1	N Ewe		
Milk ^(b)	0.023	0.026	0.006	0.022	0.03	0.15
Swine ^(d)						
Closest feeding level ^(a) :	0.184	mg/kg bw	1.9	N Breeding (highest diet)		
Muscle	0.043	0.048	0.006	0.025	0.03	0.03
Fat	0.021	0.028	0.003	0.015	0.015	0.015
Liver	0.145	0.172	0.022	0.091	0.09	0.08
Kidney	0.159	0.222	0.024	0.117	0.15	0.09
Poultry (all diets)						
Closest feeding level ^(a) :	0.1	mg/kg bw	1.1	N Layer (highest diet)		
Muscle	0.004	0.004	0.004	0.004	0.01*	0.01*
Fat	0.003	0.003	0.003	0.003	0.01*	0.01*
Liver	0.003	0.003	0.003	0.003	0.01*	0.01*
Poultry (layer only)						
Closest feeding level ^(a) :	0.1	mg/kg bw	1.1	N Layer		
Eggs ^(c)	0.004	0.004	0.004	0.004	0.01*	0.01*

* Indicates that the MRL is proposed at the limit of quantification.

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level.

(a): Closest feeding level and N dose rate related to the maximum dietary burden

(b): Highest residue level from day D1 to day D28 (daily mean of 3 cows).

(c): Highest residue level from day D1 to day D28 (daily mean of 12 laying hens).

(d): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

Remark: For the MRL estimations, three different approaches [transfer factor (1), linear regression (2) and interpolation between the two closest feeding levels (3)] were applied as recommended in the OECD Guidance 73 on residues in livestock. The highest value resulting from the 3 different calculation approaches was chosen as the basis for the MRL estimation. The value derived by linear regression is disregarded when $R^2 < 0.9$. In such a case, the highest value derived by the transfer factor or interpolation approach is selected.

If not stated otherwise the transfer factor approach (closest level) was used for estimating the residues.



FPF_after feeding
FPF_NEU scenario.xl

Diffuoroacetic acid (DFA):

When estimating the residues of DFA in the animal matrices, it has to be considered that the DFA residues can have two sources; either DFA is directly taken up via the feed and can be transferred into the edible matrices, or parent compound flupyradifurone is taken up via the feed and is metabolized to DFA in the animal. Thus the contribution of direct feeding of DFA, as well as the contribution due to degradation of flupyradifurone has to be considered when estimating MRLs for DFA in animal matrices.

However when considering the estimated dietary burdens based on the authorized and intended EU uses, the contribution of DFA after feeding of flupyradifurone is negligible in most matrices ([Table 7.2-15](#)). At the estimated 1N level, DFA residues were always below the LOQ except in the poultry matrices and in kidney of cattle and sheep. When adding the estimated DFA residues (LOQ for values below the LOQ) formed after feeding of flupyradifurone (after conversion of the residues to DFA equivalents) to the values estimated after direct feeding with DFA, the DFA MRLs proposed in the most recent EFSA evaluation (EFSA, 2020) will be exceeded for fat of sheep, swine and poultry, liver of swine, sheep milk and poultry eggs. For these commodities, new MRLs were proposed in the draft Evaluation Report submitted in

December 2020 (update March 2021)

The residues after direct feeding of DFA are summarized in [Table 7.2-16](#) and the combined DFA residues after feeding of flupyradifurone and after feeding of DFA are summarized in [Table 7.2-17](#).

Table 7.2-15: DFA expressed as flupyradifurone: Overview of the values derived from livestock feeding studies with flupyradifurone

Animal commodity	Residues at the closet feeding level (mg/kg)		Estimated value at 1N level (a.s. equivalent)		Estimated value at 1N level (DFA equivalent)	
			STMR _{Mo} (mg/kg)	HR _{Mo} (mg/kg)	STMR _{Mo} (mg/kg)	HR _{Mo} (mg/kg)
	Mean	Highest				
Cattle (all diets)						
Closest feeding level ^(a) :	0.184	mg/kg bw	1.1	N Dairy cattle (highest diet)		
Muscle	0.012	0.014	0.013	0.013	<0.007	<0.007
Fat	0.011	0.013	0.012	0.012	<0.007	<0.007
Liver	0.012	0.014	0.014	0.014	<0.007	<0.007
Kidney	0.017	0.022	0.006	0.020	<0.007	0.007
Cattle (dairy only)						
Closest feeding level ^(a) :	0.184	mg/kg bw	1.1	N Dairy cattle		
Milk ^(b)	0.004	0.005	0.004	0.004	<0.007	<0.007
Sheep (all diets)						
Closest feeding level ^(a) :	0.184	mg/kg bw	0.8	N Lamb (highest diet)		
Muscle	0.012	0.014	0.013	0.017	<0.007	<0.007
Fat	0.011	0.013	0.012	0.015	<0.007	<0.007
Liver	0.012	0.014	0.014	0.017	<0.007	<0.007
Kidney	0.017	0.022	0.004	0.026	<0.007	0.009
Sheep (dairy only)						
Closest feeding level ^(a) :	0.184	mg/kg bw	1.1	N Ewe		
Milk ^(b)	0.004	0.005	0.004	0.004	<0.007	<0.007
Swine						
Closest feeding level ^(a) :	0.184	mg/kg bw	1.9	N Breeding (highest diet)		
Muscle	0.012	0.014	0.013	0.013	<0.007	<0.007
Fat	0.011	0.013	0.012	0.012	<0.007	<0.007
Liver	0.012	0.014	0.014	0.014	<0.007	<0.007
Kidney	0.017	0.022	0.003	0.012	<0.007	<0.007
Poultry (all diets)						
Closest feeding level ^(a) :	0.1	mg/kg bw	1.1	N Layer (highest diet)		
Muscle	0.083	0.096	0.030	0.091	0.010	0.030
Fat	0.029	0.035	0.011	0.033	<0.007	0.011
Liver	0.104	0.112	0.038	0.112	0.013	0.037
Poultry (layer only)						
Closest feeding level ^(a) :	0.1	mg/kg bw	1.1	N Layer		
Eggs ^(c)	0.047	0.051	0.016	0.062	<0.007	0.021



DFA after feeding
FPF_NEU scenario.xl

Table 7.2-16: DFA expressed as DFA: Overview of the values derived from livestock feeding studies with DFA

Animal commodity	Residues at the closet feeding level (mg/kg)		Estimated value at 1N level (DFA equivalent)		Estimated value at 1N level (a.s. equivalent)	
	Mean	Highest	STMR _{Mo} (mg/kg)	HR _{Mo} (mg/kg)	STMR _{Mo} (mg/kg)	HR _{Mo} (mg/kg)
Cattle (all diets)						
Closest feeding level ^(a) :	0.032	mg/kg bw	0.5	N Dairy cattle (highest diet)		
Muscle	0.070	0.090	0.086	0.164	0.259	0.493
Fat	0.074	0.131	0.092	0.240	0.276	0.722
Liver	0.053	0.065	0.067	0.119	0.201	0.357
Kidney	0.106	0.119	0.132	0.219	0.395	0.657
Cattle (dairy only)						
Closest feeding level ^(a) :	0.032	mg/kg bw	0.5	N Dairy cattle		
Milk ^(b)	0.015	0.020	0.019	0.028	0.056	0.083
Sheep (all diets)						
Closest feeding level ^(a) :	0.032	mg/kg bw	0.5	N Lamb (highest diet)		
Muscle	0.070	0.090	0.087	0.185	0.263	0.556
Fat	0.074	0.131	0.093	0.271	0.280	0.814
Liver	0.053	0.065	0.068	0.134	0.204	0.402
Kidney	0.106	0.119	0.134	0.246	0.402	0.740
Sheep (dairy only)						
Closest feeding level ^(a) :	0.032	mg/kg bw	0.6	N Ewe		
Milk ^(b)	0.015	0.020	0.016	0.026	0.048	0.077
Swine						
Closest feeding level ^(a) :	0.032	mg/kg bw	0.7	N Finishing (highest diet)		
Muscle	0.070	0.090	0.049	0.125	0.147	0.377
Fat	0.074	0.131	0.052	0.184	0.157	0.552
Liver	0.053	0.065	0.038	0.091	0.113	0.273
Kidney	0.106	0.119	0.075	0.167	0.225	0.502
Poultry (all diets)						
Closest feeding level ^(a) :	0.054	mg/kg bw	1.1	N Layer (highest diet)		
Muscle	0.094	0.103	0.066	0.101	0.198	0.305
Fat	0.021	0.022	0.014	0.023	0.043	0.070
Liver	0.175	0.188	0.123	0.199	0.370	0.598
Poultry (layer only)						
Closest feeding level ^(a) :	0.054	mg/kg bw	1.1	N Layer		
Eggs ^(c)	0.083	0.093	0.061	0.089	0.183	0.268



DFA_after feeding
DFA_NEU scenario.x

Table 7.2-17: Overview of the DFA values derived from livestock feeding studies with flupyradifurone and DFA

Animal matrix	Estimated median residue [mg/kg]				Estimated maximum residue [mg/kg]				MRL [mg/kg]
	feeding of FPF		feeding of DFA	Sum DFA	feeding of FPF		feeding of DFA	Sum DFA	EFSA, 2020
	expr. as FPF	expr. as DFA	expr. as DFA	expr. as DFA	expr. as FPF	expr. as DFA	expr. as DFA	expr. as DFA	expr. as DFA
Ruminant muscle	0.013	<0.007	0.086	0.093	0.013	<0.007	0.164	0.171	0.40
Ruminant fat	0.012	<0.007	0.092	0.099	0.012	<0.007	0.240	0.247	0.50
Ruminant liver	0.014	<0.007	0.067	0.074	0.014	<0.007	0.119	0.126	0.40
Ruminant kidney	0.006	<0.007	0.132	0.139	0.020	0.007	0.219	0.226	0.50
Ruminant milk	0.004	<0.007	0.019	0.026	0.004	<0.007	0.028	0.035	0.07
Sheep muscle	0.013	<0.007	0.087	0.094	0.017	<0.007	0.185	0.192	0.20
Sheep fat	0.012	<0.007	0.093	0.100	0.015	<0.007	0.271	0.278	0.15
Sheep liver	0.014	<0.007	0.068	0.075	0.017	<0.007	0.134	0.141	0.15
Sheep kidney	0.004	<0.007	0.134	0.141	0.026	0.009	0.246	0.255	0.30
Sheep milk	0.004	<0.007	0.016	0.023	0.004	<0.007	0.026	0.033	0.03
Swine muscle	0.013	<0.007	0.049	0.056	0.013	<0.007	0.125	0.132	0.15
Swine fat	0.012	<0.007	0.052	0.059	0.012	<0.007	0.184	0.191	0.10
Swine liver	0.014	<0.007	0.038	0.045	0.014	<0.007	0.091	0.098	0.09
Swine kidney	0.003	<0.007	0.075	0.082	0.012	<0.007	0.167	0.174	0.20
Poultry muscle	0.030	0.010	0.066	0.076	0.091	0.030	0.101	0.131	0.15
Poultry fat	0.011	<0.007	0.014	0.021	0.033	0.011	0.023	0.034	0.03
Poultry liver	0.038	0.013	0.123	0.136	0.112	0.037	0.119	0.236	0.30
Poultry eggs	0.016	<0.007	0.061	0.068	0.062	0.021	0.089	0.110	0.10

Remark: DFA values <LOQ are indicated as <0.007 mg/kg when expressed as DFA. When calculating the sum, values below the LOQ are considered to be at the LOQ.

When adding the estimated DFA residues (LOQ for values below the LOQ) formed after feeding of flupyradifurone (after conversion of the residues to DFA equivalents) to the values estimated after direct feeding with DFA, the MRLs proposed for DFA in the most recent EFSA evaluation (EFSA, 2020) will be exceeded for fat of sheep, swine and poultry, liver of swine, sheep milk and poultry eggs.

New MRLs proposed in the draft Evaluation Report submitted in December 2020 (update March 2021):

Sheep: 0.3 mg/kg for fat
0.04 mg/kg for milk
Swine: 0.2 mg/kg for fat
0.1 mg/kg for liver
Poultry: 0.04 mg/kg for fat
0.15 mg/kg for egg

For the dietary risk assessment the sum of flupyradifurone and DFA residues has to be considered. As a consequence, the estimated residues for flupyradifurone and DFA detected after feeding of flupyradifurone were added to the DFA residues detected after feeding of DFA, only. The total residue (expressed as flupyradifurone equivalents) is shown in [Table 7.2-18](#).

Table 7.2-18: Sum of flupyradifurone and DFA residues (expressed as flupyradifurone) in ruminant and poultry matrices calculated for dietary risk assessment

Animal matrix	Estimated median residue [mg a.s. equiv./kg]				Estimated maximum residue [mg a.s. equiv./kg]			
	feeding of a.s.		feeding of DFA	Total residue	feeding of a.s.		feeding of DFA	Total residue
	a.s.	DFA	DFA		a.s.	DFA	DFA	
Ruminant muscle	0.015	<0.02	0.259	0.293	0.044	<0.02	0.493	0.557
Ruminant fat	<0.01	<0.02	0.276	0.306	0.026	<0.02	0.722	0.768
Ruminant liver	0.050	<0.02	0.201	0.270	0.334	<0.02	0.357	0.711
Ruminant kidney	0.054	<0.02	0.395	0.470	0.205	<0.02	0.657	0.882
Ruminant milk	<0.01	<0.02	0.056	0.086	0.021	<0.02	0.083	0.124
Sheep muscle	0.011	<0.02	0.263	0.294	0.059	<0.02	0.556	0.635
Sheep fat	<0.01	<0.02	0.280	0.310	0.034	<0.02	0.814	0.867
Sheep liver	0.037	<0.02	0.204	0.261	0.374	<0.02	0.402	0.796
Sheep kidney	0.040	<0.02	0.402	0.462	0.267	0.026	0.740	1.034
Sheep milk	<0.01	<0.02	0.048	0.078	0.022	<0.02	0.077	0.119
Swine muscle	<0.01	<0.02	0.147	0.177	0.025	<0.02	0.377	0.422
Swine fat	<0.01	<0.02	0.157	0.187	0.015	<0.02	0.552	0.587
Swine liver	0.022	<0.02	0.113	0.155	0.091	<0.02	0.273	0.384
Swine kidney	<0.01	<0.02	0.225	0.269	0.117	<0.02	0.502	0.640
Poultry muscle	0.024	0.030	0.198	0.238	<0.01	0.091	0.305	0.406
Poultry fat	<0.01	<0.02	0.043	0.073	<0.01	0.033	0.070	0.113
Poultry liver	<0.01	0.038	0.370	0.418	<0.01	0.112	0.598	0.720
Poultry eggs	<0.01	<0.02	0.183	0.213	<0.01	0.062	0.268	0.340

Remark: Flupyradifurone and DFA values below the LOQ are indicated as <0.01 or <0.02 mg/kg, respectively when expressed as parent equivalent. When calculating the sum, values below the LOQ are considered to be at the LOQ.

Conclusion on feeding studies

The requested uses in potential feed items relevant to this submission modified the theoretical maximum daily intake for animals compared to the intake estimated in the EFSA Reasoned Opinion in 2020 (Article 12 MRL review for flupyradifurone and DFA). As a result, some MRLs for animal commodities have to be adapted. A Draft Evaluation Report (dER) has been submitted in December 2020 (update March 2021) in order to propose higher MRLs for the corresponding commodities.

Evaluator comment:

Information given by the Applicant is sufficient.

Animal metabolism studies showed that flupyradifurone (BYI 02960) its metabolite DFA are the major contributors to the relevant residue in animals.

The livestock exposure was calculated separately for flupyradifurone and the DFA according to the OECD methodology using the EFSA Animal model 2017. The results indicate that the trigger value of 0.004 mg/kg body weight (bw) per day is exceeded for all livestock species, both for flupyradifurone and DFA for relevant livestock diets. Considering the results of livestock dietary burden calculations, the nature and magnitude of flupyradifurone and DFA in animal matrices were further investigated.

The nature of flupyradifurone residues in livestock was investigated in the framework of the EU pesticides peer review (EFSA, 2015).

In the Annex II dossier, feeding studies conducted with the parent flupyradifurone have been provided. These feeding studies were evaluated by EFSA and considered to be acceptable (EFSA, 2015). Additional feeding studies were conducted with DFA at three different feeding levels in poultry (laying hens) and ruminants (cattle). These studies were submitted to Ctgb-NL as confirmatory data (March 2018) and have already been evaluated.

EFSA concluded that the existing EU MRLs for flupyradifurone and DFA should be raised in all animal matrices, except for flupyradifurone in poultry commodities (EFSA Journal 2020;18(6):6133). The data gap identified by the peer review for the livestock feeding studies with DFA was sufficiently addressed.

More details are presented in Appendix 2, point A 2.1.4.1.

In the meantime new MRLs were set for animal commodities for flupyradifurone in Reg. (EU) 2022/1324 and DFA in Reg. 2021/1842:

1000000	PRODUCTS OF ANIMAL ORIGIN - TERRESTRIAL ANIMALS	Flupyradifurone Reg. (EU) 2022/1324	Difluoroacetic acid (DFA) Reg. (EU) 2021/1842
1010000	Commodities from		
1011000	(a) swine		
1011010	Muscle	0.03	0.15
1011020	Fat	0.015	0.1
1011030	Liver	0.08	0.1
1011040	Kidney	0.09	0.2
1011050	Edible offals (other than liver and kidney)	0.09	0.2
1011990	Others (2)	0.09	0.2
1012000	(b) bovine		
1012010	Muscle	0.3	0.4
1012020	Fat	0.2	0.5
1012030	Liver	1	0.4
1012040	Kidney	1	0.5
1012050	Edible offals (other than liver and kidney)	1	0.5
1012990	Others (2)	1	0.5
1013000	(c) sheep		
1013010	Muscle	0.3	0.2
1013020	Fat	0.2	0.15
1013030	Liver	1	0.15
1013040	Kidney	1	0.3
1013050	Edible offals (other than liver and kidney)	1	0.3
1013990	Others (2)	1	0.3
1014000	d) goat		
1014010	Muscle	0.3	0.2
1014020	Fat	0.2	0.15
1014030	Liver	1	0.15
1014040	Kidney	1	0.3
1014050	Edible offals (other than liver and kidney)	1	0.3
1014990	Others (2)	1	0.3
1015000	(e) equine		
1015010	Muscle	0.3	0.4
1015020	Fat	0.2	0.5
1015030	Liver	1	0.4
1015040	Kidney	1	0.5
1015050	Edible offals (other than liver and kidney)	1	0.5
1015990	Others (2)	1	0.5
1016000	(f) poultry	0.01*	
1016010	Muscle	0.01*	0.15
1016020	Fat	0.01*	0.03
1016030	Liver	0.01*	0.3
1016040	Kidney	0.01*	0.02*
1016050	Edible offals (other than liver and kidney)	0.01*	0.02*

1016990	Others (2)	0.01*	0.02*
1017000	(g) other farmed terrestrial animals		
1017010	Muscle	0.3	0.4
1017020	Fat	0.2	0.5
1017030	Liver	1	0.4
1017040	Kidney	1	0.5
1017050	Edible offals (other than liver and kidney)	1	0.5
1017990	Others (2)	1	0.5
1020000	Milk		
1020010	Cattle	0.15	0.07
1020020	Sheep	0.15	0.03
1020030	Goat	0.15	0.03
1020040	Horse	0.01*	0.03
1020990	Others (2)	0.01*	0.03
1030000	Birds eggs	0.01*	0.1
1030010	Chicken	0.01*	0.1
1030020	Duck	0.01*	0.1
1030030	Geese	0.01*	0.1
1030040	Quail	0.01*	0.1
1030990	Others (2)	0.01*	0.1

Considering the intended uses and taking into account the estimated maximum residue an exceedance of the MRLs for

- flupyradifurone (expressed as flupyradifurone as established in Commission Regulation (EU) 2022/1324) for swine liver (MRL of 0.08 mg/kg) and the for swine kidney (MRL of 0.09 mg/kg)
- difluoroacetic acid (DFA) (Reg. (EU) 2021/1842) for fat of sheep (MRL of 0.15 mg/kg), fat of swine (MRL of 0.1 mg/kg) and fat of poultry (MRL of 0.03 mg/kg), liver of swine (MRL of 0.1 mg/kg), sheep milk (MRL of 0.03 mg/kg) and poultry eggs (MRL of 0.1 mg/kg) is expected.

Therefore, in our opinion, until the new MRLs for flupyradifurone and DFA come into force, feeding animals will not be possible.

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

Numerous studies investigating the effect of processing on the magnitude of flupyradifurone-related residues have been conducted to support the use of flupyradifurone. Representative processing studies were conducted with field samples collected from supervised residue trials conducted in Europe, USA or Canada. In an extensive package of processing data, separate Processing Factors (PF) were elucidated for parent flupyradifurone, metabolite DFA and the total residue (sum of flupyradifurone and DFA). These data on processing studies were already reviewed during the approval of active substance (EFSA, 2015) and in the Article 12 MRL review for flupyradifurone and DFA (EFSA, 2020). No further studies have been performed.

Excerpt from EFSA Conclusion on the peer review of flupyradifurone, 2015:

Flupyradifurone was seen to be stable under standard hydrolysis conditions. Processing studies were submitted and processing and conversion factors were proposed for flupyradifurone and DFA respectively, for lettuce, hops, and for the crops included in MRL application (apple, grape, tomato and cucumber).

Excerpt from EFSA Reasoned Opinion (Article 12 MRL review for flupyradifurone and DFA, 2020):

In the framework of the current application the applicant submitted a wide range of studies where the effect of processing on the magnitude of flupyradifurone and DFA was investigated in processed products of oranges, soybean, potato, barley, wheat, maize, cotton, peanut, coffee (Netherlands, 2017), melons, mustard greens, broccoli, carrots, courgettes, peas, olives, cocoa beans (Netherlands, 2019). The raw and processed commodities were analysed for flupyradifurone and DFA individually and results were presented according to currently applicable enforcement and risk assessment residue definitions. The processing factors give the ratio of residues in processed products to residues in unprocessed products. Separate PF were calculated for parent flupyradifurone (PF_F), for DFA (PF_{DFA}) and for the sum of flupyradifurone and DFA, expressed as DFA (PF_{sum}). Hence, the PF_F and PF_{DFA} are intended for enforcement purpose, while PF_{sum} is to be used for risk assessment purposes.

7.2.5.1 Available data for all crops under consideration

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

Table 7.2-19: Overview of the available processing studies

Table 7.2-17: Overview of the available processing studies						
Processed commodity	Number of studies	Median PF			Comments	Reference
		FPF	DFA	Sum		
Risk assessment residue definition: Sum of flupyradifurone and DFA, expressed as flupyradifurone Enforcement residue definition: 1) flupyradifurone; 2) DFA, expressed as DFA						
Grape, red wine	2	0.7	1.0 ^{a)}	0.7 ^{b)}	Data from EU trials (PHI 14 d) Residues of DFA <LOQ in one trial	EFSA, 2015
Grape, white wine	2	0.3	1.0 ^{a)}	0.3 ^{b)}	Data from EU trials (PHI 14 d) Residues of DFA <LOQ in one trial	
Grape, juice (pasteurized)	2	0.7	1.0	0.7 ^{b)}		
Grape, jelly	2	0.3	0.7	0.3 ^{b)}		EFSA, 2015
Grape, raisin	2	2.5	2.3 ^{a)}	2.5 ^{b)}	Data from EU trials (PHI 14 d) Residues of DFA <LOQ in one trial	
Potato, peeled	3	-	1.07	1.12	Residues of FPF	EFSA, 2020

Processed commodity	Number of studies	Median PF			Comments	Reference
		FPF	DFA	Sum		
					<LOQ in the RAC	
Potato, flakes	4	1.1 ^{a)}	1.7	1.5	Residues of FPF <LOQ in the RAC in all trials. Concentration of FPF residues on the basis of one trial cannot be confirmed.	EFSA, 2020
Potato, chips	4	-	1.75	1.5	Residues of FPF <LOQ in the RAC	
Potato, dried waste	2	-	<0.8	<0.85		
Potato, dry pulp Potato, starch	2	-	<0.8	<0.86		
Barley, brewer`s grain (dried)	2	0.05 ^{a)}	<0.6	0.7	PFs for FPF differ more than 50%, however concentration can be excluded	EFSA, 2020
Barley, malt sprouts	2	0.4	12.5	0.8		EFSA, 2020
Barley, brewer`s yeast	2	0.09	<0.6	0.1		
Barley, beer	2	0.06	<0.6	0.08		
Barley, pearl barley	2	0.1	0.7	0.1		
Barley, pear barley rub-off	2	2.9	1.8	2.9		
Wheat, semolina	2	0.9	1.5 ^{a)}	0.95	PFs for FPF differ more than 50%, therefore a third processing study should be initiated. Residues of DFA <LOQ in RAC of one trial.	EFSA, 2020
Wheat, white flour	4	0.2	0.8	0.5	EU and US trials combined	EFSA, 2020
Wheat, white flour bran	2	6	12	7	PFs for DFA differ more than 50%, therefore a third processing study should be initiated.	
Wheat, bran	2	2.4	1.07	1.5		
Wheat, white bread	4	0.2	0.7	0.3	EU and US trials combined	
Wheat, whole meal flour	4	1.4	1.1	1.3	EU and US trials combined	EFSA, 2020
Wheat, whole meal bread	4	0.8	0.7	0.8	EU and US trials combined	
Wheat, germ	4	1.45	0.99	1.25	EU and US trials combined	
Wheat, aspirated grain fraction	2	18	7	11		
Wheat, gluten	2	0.4	0.4	0.4		
Wheat, starch	2	0.01	0.04	0.03		
Wheat, fresh pasta	2	0.2	0.7	0.5		

Processed commodity	Number of studies	Median PF			Comments	Reference
		FPF	DFA	Sum		
Wheat, dry pasta	2	0.3	0.89	0.7		
Wheat, shorts	2	0.9	0.9	0.94		
Wheat, middlings	2	0.7	0.9	0.84		
Maize, aspirated grain fraction	2	23	-	-	Residues of DFA <LOQ in the RAC and in processed commodity. Trials performed at 1.5-2.5N of authorized GAP. For the risk assessment it can be concluded that concentration of DFA residues in processed commodities are not expected.	EFSA, 2020
Maize, bran	2	2.7	-	-		
Maize, germ (dry milling)	2	1	-	-		
Maize, germ (wet milling)	2	0.7	-	-		
Maize, refined oil/starch/grits/flour	2	<0.6	-	-		

a) tentative PF is derived based on a limited dataset

b) data (based on DAR, 2015) added in order to align with EFSA evaluation of 2020

7.2.5.2 Conclusion on processing studies

For the crops of interest in this dossier, adequate processing studies have already been evaluated at EU level (EFSA, 2015 and EFSA, 2020). Some processing factors could not be estimated as FPF or DFA residues were below the LOQ in the RACs (despite the fact that the trials were conducted at exaggerated rates) or differed significantly (>50%). In some of these cases, EFSA recommended to conduct additional processing trials to clarify the situation.

Food items: Concentration of flupyradifurone and/or DFA residues was only detected in some processed food items like raisins, and semolina, bran and whole meal flour of wheat and in defatted flour of soybean.

Feed items: Concentration of flupyradifurone and/or DFA residues was only detected in the following feed items:

The processing study with soybean indicated a slight concentration of flupyradifurone and DFA residues in the processed product meal. As the experimentally determined processing factors for soybean are equivalent or lower as compared to the default processing factors proposed by EFSA (Animal model 2017a.xls), the default processing factor were used when estimating the dietary burden of livestock.

The processing studies for barley, wheat, field corn (maize), cotton - where processed commodities are potential feed items - indicated no concentration of flupyradifurone and DFA residues in any of the EU feed items (brewer's grain, milled by-products and gluten of wheat, flour, grits and meal (dry milled) of maize/corn as well as process waste and dried pulp of potatoes), except for DFA in cotton meal where a slight increase of DFA was indicated.

As the raw agricultural commodity (cotton, seed) did not show any DFA residues, no reasonable processing factor could be estimated and therefore the default processing factor was applied when calculating the dietary burden of livestock.

Evaluator comment:

The studies on processing have been evaluated and accepted (see RR for 102000028562 / DLT+FPF EC 85 (zRMS-PL, February 2022)). The intended uses are covered with the available processing studies. Information given by the Applicant is sufficient and acceptable. No further data are required.

7.2.6 Magnitude of residues in representative succeeding crops

Several of the crops under consideration can be grown in rotation and therefore the possible occurrence of residues in succeeding crops resulting from a primary use has to be taken into account. Data dealing with the magnitude of residues in succeeding crops have already been submitted and evaluated at EU level (EFSA, 2015 and EFSA 2020). A short summary of the evaluation is given below.

Numerous field rotational crop trials have been conducted in Europe to support the use of flupyradifurone. Apart from the “main” field study (containing data for three rotations with three crop groups: leafy, root, and cereal crops), further data on individual crops after one rotation simulating crop failure (“small” rotational crop studies on tuber, stem, fruiting, bulb, and legume vegetables, as well as on pulses and oilseeds) have been submitted. These studies have already been assessed and summarized in the EFSA peer review (EFSA, 2015). The amount of flupyradifurone, applied either to bare soil or lettuce as target crop, amounted to 200 or 250 g a.s./ha (based on the worst-case application rate in the “home & garden” uses, which are more critical than the corresponding agricultural uses).

The design of these field rotational crop studies was discussed at EU level (Pesticides Peer Review expert meeting TC 107). It was questioned if the applied application rate reflects the plateau concentration of flupyradifurone reached in soil following several years of consecutive applications as flupyradifurone is a persistent compound. Moreover, the experts were of the opinion that testing a single plant back interval (PBI) of 30 days (worst-case: crop failure) reflects an unrealistic situation for several crops which can lead to an overestimation of MRLs. It was therefore concluded that further studies – conducted at realistic PBIs and providing information on the flupyradifurone and DFA residue levels in soil – are required. Provisionally and since significant DFA residues are expected in rotational crops, it was agreed to derive default MRLs values for rotational crops from the available trials conducted at a dose rate of 200-250 g a.s./ha and considering the plant back interval of 30 days and the highest residue values.

In order to overcome the above mentioned deficiencies, an assessment was done to identify the most reasonable plateau concentration of flupyradifurone reached in soil following several years of consecutive applications. Based on the results, additional field rotational studies (including soil sampling) were initiated in selected crops in the seasons 2016, 2017 and 2018. Only realistic plant back intervals were considered and soil samples were collected before each re-cropping interval to determine the flupyradifurone and DFA levels in the relevant soil layer (plough layer, 0-20 cm).

These studies sufficiently addressed the data gap set in Commission Regulation (EU) 2016/1902 as summarized in EFSA Journal 2020;18(6):6133. The respective MRLs were adapted.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

The available studies – all already evaluated at EU level - are summarized in [Table 7.2-20](#).

Table 7.2-20: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
EU data (at max. application rate of flupyradifurone)					
Bare soil/ Lettuce	1 x 0.200 (BBCH 19)	Root and tuber vegetable	Carrot/ turnip (root and top)	1 st rotation: 25-30 2 nd rotation: 61-145 3 rd rotation: 279-329	EFSA, 2015
Bare soil/ Lettuce	1 x 0.200 (BBCH 19)	Leafy vegetable	Lettuce (head)	1 st rotation: 25-30 2 nd rotation: 64-145 3 rd rotation: 279-328	
Bare soil/ Lettuce	1 x 0.200 (BBCH 19)	Small grain cereal	Barley (green material, grain and straw)	1 st rotation: 25-33 2 nd rotation: 116-195 3 rd rotation: 266-295	EFSA, 2015 1 st rotation identified as unrealistic re- cropping scenario
Bare soil	2 x 0.125 (10 day interval)	Root and tuber vegetable	Potato (tuber)	1 st rotation: 25-33	EFSA, 2015 identified as unrealistic re- cropping scenario
Bare soil	2 x 0.125 (10 day interval)	Stem vegetable	Leek (whole plant without root)	1 st rotation: 26-33	EFSA, 2015
Bare soil	2 x 0.125 (10 day interval)	Fruiting vegetable	Cucumber (fruit)	1 st rotation: 25-30	EFSA, 2015
Bare soil	2 x 0.125 (10 day interval)	Bulb vegetable	Onion (bulb)	1 st rotation: 25-33	EFSA, 2015
Bare soil	2 x 0.125 (10 day interval)	Legume vegetable	Bean (pods)	1 st rotation: 25-30	EFSA, 2015
Bare soil	2 x 0.125 (10 day interval)	Pulses	Field pea (dry seed)	1 st rotation: 25-35	EFSA, 2015
Bare soil	2 x 0.125 (10 day interval)	Oilseeds	Oilseed rape (seed)	1 st rotation: 27-41	EFSA, 2015
EU data (considering plateau rate of flupyradifurone in soil)					
Bare soil	1 x 0.300	Root and tuber vegetable	Potato (tuber)	2 nd rotation: 138-181 3 rd rotation: 295-343	EFSA, 2020
Bare soil	1 x 0.175	Oilseeds	Oilseed rape (seed)	2 nd rotation: 137 3 rd rotation: 335	EFSA, 2020
Bare soil	1 x 0.175	Oilseeds	Oilseed rape (seed)	2 nd rotation: 158-167 3 rd rotation: 273	EFSA, 2020
Bare soil	1 x 0.175	Small grain cereal	Barley (green material, grain and straw)	2 nd rotation: 137-174 3 rd rotation: 335-337	EFSA, 2020
Bare soil	1 x 0.175	Small grain cereal	Barley (green material, grain and straw)	2 nd rotation: 107-163 3 rd rotation: 281-283	EFSA, 2020
Bare soil	1 x 0.175	Cereals	Maize (green material, kernel, rest of plant)	2 nd rotation: 131-167 3 rd rotation: 291-365	EFSA, 2020

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
Bare soil	1 x 0.175	Cereals	Maize (green material, kernel, rest of plant)	2 nd rotation: 139-204 3 rd rotation: 313-324	EFSA, 2020
Bare soil	1 x 0.300	Fruits	Strawberry (fruit)	2 nd rotation: 22 3 rd rotation: 139-141	EFSA, 2020
Bare soil	1 x 0.300	Fruits	Strawberry (fruit)	1 st rotation: 29 2 nd rotation: 133 3 rd rotation: 363	EFSA, 2020
Bare soil	1 x 0.300	Brassica vegetables	Cauliflower and broccoli (curd)	1 st rotation: 21-30 2 nd rotation: 129-161 3 rd rotation: 321-339	EFSA, 2020

An overview on the residue levels of flupyradifurone and DFA detected in all available field rotational crop studies is provided in [Table 7.2-21](#). Unrealistic re-cropping scenarios which do not have to be considered – however were submitted for the approval of flupyradifurone – are shown with grey background. In order to comply with the most recent EFSA evaluation (EFSA 2020), always the worst-case residue levels were considered for crops which were collected at two sampling points as an early harvest before maturity cannot be excluded (e.g. potatoes were collected at BBCH 45 and 49, the worst-case residue was selected for each trial, independent if the crop was collected at maturity or at BBCH 45).

Table 7.2-21: Summary of residues detected in field rotational crop studies

Crop group	Crop	Application			Residue levels (mg/kg)	
		PBI (day)	g/ha	on bare soil or primary crop	flupyradifurone [mg FPF/kg]	DFA [mg DFA/kg]
Root crop	Potato (tuber)	25-33	250	bare soil	4 x <0.01	0.0094; 0.012; 0.064; 0.082
		138-181	300	bare soil	<u>BBCH 45:</u> 4 x <0.01 <u>BBCH 49:</u> 4 x <0.01	<u>BBCH 45: 0.012; 0.042;</u> 0.088 ; 0.016 <u>BBCH 49: 0.011; 0.028;</u> 0.071; 0.023
		295-343	300	bare soil	4 x <0.01	<u>BBCH 45: <0.007; 0.018;</u> 0.019 ; 0.011 <u>BBCH 49: <0.007; 0.014;</u> 0.015; 0.012
	Turnip/ carrot (root/cull)	25-30	200	lettuce	4 x <0.01	0.0090; 0.018; 0.020; 0.035
		61-145	200	bare soil	4 x <0.01	<0.007; 0.0092; 0.010; 0.013
		284-328	200	bare soil	4 x <0.01	<0.007; 0.0088; 0.011; 0.014
Bulb veg.	Onion	25-33	250	bare soil	4 x <0.01	<0.007; 0.019; 0.024; 0.054
Stem veg.	Leek	26-33	250	bare soil	4 x <0.01	0.007; 0.013; 0.032; 0.077

Crop group	Crop	Application			Residue levels (mg/kg)	
		PBI (day)	g/ha	on bare soil or primary crop	flupyradifurone [mg FPF/kg]	DFA [mg DFA/kg]
Fruits	Strawberry (fruits)	22-29	300	bare soil	<u>BBCH 85:</u> 4 x <0.01 <u>BBCH 87:</u> 4 x <0.01	<u>BBCH 85:</u> 0.056; 0.083; 0.009 ; 0.078 <u>BBCH 87:</u> 0.068 ; 0.098 ; <0.007; 0.12
		133-158	300	bare soil	<u>BBCH 85:</u> 4 x <0.01 <u>BBCH 87:</u> 4 x <0.01	<u>BBCH 85:</u> 0.040; 0.12; <0.007; 0.068 <u>BBCH 87:</u> 0.046 ; 0.12 ; 0.012 ; 0.059
		270-341	300	bare soil	<u>BBCH 85:</u> 4 x <0.01 <u>BBCH 87:</u> 4 x <0.01	<u>BBCH 85:</u> 0.024 ; 0.026; <0.007; 0.017 <u>BBCH 87:</u> 0.023; 0.076 ; < 0.007 ; <0.007
Fruiting veg.	Cucumber	25-30	250	bare soil	4 x <0.01	0.016; 0.093; 0.11; 0.14
Leafy veg.	Lettuce	25-30	200	lettuce	2 x <0.01; 0.01; 0.03	<0.007; 0.011; 0.016; 0.037
		64-145	200	bare soil	3 x <0.01; 0.01	3 x <0.007; 0.028
		279-329	200	bare soil	4 x <0.01	3 x <0.007; 0.015
Brassica veg.	Cauliflower/ broccoli (curd)	21-30	300	bare soil	<u>BBCH 45:</u> 4 x <0.01 <u>BBCH 49:</u> 4 x <0.01	<u>BBCH 45:</u> 0.025 ; 0.059; 0.042 ; 0.056 <u>BBCH 49:</u> 0.023; 0.065 ; 0.021; 0.054
		129-161	300	bare soil	<u>BBCH 45:</u> 4 x <0.01 <u>BBCH 49:</u> 4 x <0.01	<u>BBCH 45:</u> 0.015 ; 0.048 ; 0.029; 0.061 <u>BBCH 49:</u> 0.012; 0.035; 0.037 ; 0.058
		321-339	300	bare soil	<u>BBCH 45:</u> 4 x <0.01 <u>BBCH 49:</u> 4 x <0.01	<u>BBCH 45:</u> 0.007; 0.041 ; 0.016; 0.018 <u>BBCH 49:</u> 0.008 ; 0.033; 0.023 ; 0.015
Cereals	Maize (kernel)	131-204	175	bare soil	4 x <0.01	<0.007; 0.021; 0.035; 0.037
		291-365	175	bare soil	4 x <0.01	<0.007; 0.013; 0.019; 0.030
Cereals	Maize (forage)	131-204	175	bare soil	3 x <0.01; 0.030	<0.007; 0.011; 0.015; 0.020
		291-365	175	bare soil	3 x <0.01; 0.012	<0.007; 0.007; 0.008; 0.009
Cereals	Maize (stover)	131-204	175	bare soil	<0.01; 0.01 2 x 0.020	<0.007; 0.007; 0.014; 0.022
		291-365	175	bare soil	3 x <0.01; 0.010	3 x <0.007; 0.008
Cereals	Barley (grain)	107-174	175	bare soil	4 x <0.01	0.038; 0.047; 0.088; 0.12
		281-337	175	bare soil	4 x <0.01	0.025; 0.040; 0.056; 0.088
		25-33	200	lettuce	3 x <0.01	0.030; 0.11; 0.21
		116-195	200	bare soil	4 x <0.01	0.012; 0.030; 0.034; 0.088
		266-295	200	bare soil	4 x <0.01	0.020; 0.030; 0.032; 0.12
Cereals	Barley (forage)	25-33	200	lettuce	3 x <0.01; 0.02	0.0092; 0.014; 0.038; 0.12
		116-195	200	bare soil	3 x <0.01; 0.01	0.0093; 0.010; 0.012; 0.034
		266-295	200	bare soil	3 x <0.01; 0.030	2 x <0.007; 0.0078; 0.049
		107-174	175	bare soil	3 x <0.01; 0.013	0.008; 0.014; 0.028; 0.045
		281-337	175	bare soil	3 x <0.01; 0.010	<0.007; 0.020; 0.025; 0.027
Cereals	Barley (straw)	25-33	200	lettuce	<0.01; 0.01; 0.02, 0.04	<0.017; 0.018; 0.042; 0.11
		116-195	200	bare soil	3 x <0.01; 0.02	3 x <0.017; 0.033
		266-295	200	bare soil	4 x <0.01	2 x <0.017; 0.017; 0.055
		107-174	175	bare soil	2 x <0.01, 0.018; 0.032	3 x <0.03; 0.036
		281-337	175	bare soil	4 x <0.01	4 x <0.03
Oilseeds	Rape (seed)	27-41	200	bare soil	4 x <0.01	0.017; 0.024; 0.030; 0.051
		137-167	175	bare soil	3 x <0.01	0.0091, 0.014; 0.022
		273-335	175	bare soil	3 x <0.01	0.007; 0.008; 0.013
Oilseeds	Rape (forage)	137-167	175	bare soil	4 x <0.01	0.010; 0.015; 0.056; 0.085
		273-335	175	bare soil	4 x <0.01	0.007; 0.008; 0.044; 0.046
Pulses	Field pea	25-35	250	bare soil	4 x <0.01	0.22; 0.33; 0.69; 0.76

Crop group	Crop	Application			Residue levels (mg/kg)	
		PBI (day)	g/ha	on bare soil or primary crop	flupyradifurone [mg FPF/kg]	DFA [mg DFA/kg]
Legume veg.	green bean	25-30	250	bare soil	4 x <0.01	0.087; 0.13; 0.19; 0.36

Remark: Values in bold indicate worst-case DFA residues in samples collected at two sampling points (shortly before and at maturity). These values were used for STMR and HR estimations.

In contrast to the applicant, EFSA did not rely on the DFA residues determined in the field rotational crop studies which have been conducted at application rates which were calculated based on the plateau concentration of flupyradifurone reached in soil following several years of consecutive applications plus the maximum annual application rate (two different maximum application rates were considered: 175 g a.s./ha for agricultural crops and 300 g a.s./ha for home and garden crops). EFSA used the soil concentration of flupyradifurone determined at the different plant back intervals as reference. This concentration was compared to the worst-case long-term flupyradifurone soil plateau concentration (C_{min}) which was modelled following an approach to determine PEC_{soil} values. The worst-case long-term flupyradifurone soil plateau concentration (C_{min}) for authorized and intended EU application rates (2 x 125 g/ha) was estimated in the framework of the EU pesticides peer review (EFSA, 2015) as **0.062 mg/kg** (DT₅₀ 462 days, indoor application on lettuce at 2 x 0.125 kg/ha, crop interception 25%, residue distribution over 20 cm soil; assumed degradation kinetics: Double First Order in Parallel (DFOP)). Since the determined geometrical mean soil concentration of flupyradifurone in soil from the rotational crop residue trials was 0.029 mg/kg (highest, at the PBI of 107-204 days, after application of 300 g flupyradifurone/ha), the residue trials are considered underdosed and a scaling factor of **2.06** was derived.

In analogy, the worst-case long-term flupyradifurone soil plateau concentration (C_{min}) from critical authorized uses in North America (410 g a.s./ha) was estimated by EFSA using the EU soil dissipation data. This concentration was calculated to estimate worst-case DFA residues in rotational crops being imported to Europe. As the North American uses represent the most critical uses globally, this approach will cover imported crops from all regions. The following input parameters were used: DT₅₀ 462 days, application of 2 x 210 g/ha, interval between applications 7 days, crop interception 70%, residue distribution over 20 cm soil; method of calculation: Double First Order in Parallel (DFOP). The C_{min} was calculated at **0.0416 mg/kg**. Since the determined geometrical mean soil concentration of flupyradifurone in soil is 0.029 mg/kg, the residue trials are underdosed. Hence, a scaling factor of **1.4** was derived.

A summary of the measured and scaled DFA residues in rotational crops (with STMR and HR values) is shown in [Table 7.2-23](#).

Soil samples collected in the most recent trials prior to re-cropping showed that the only soil residue that can be detected is parent flupyradifurone. Residues of the metabolite DFA were always below the LOQ of 0.005 mg/kg (expressed as DFA). This result is well in agreement with the degradation behaviour of DFA revealed in the Efate studies. DFA degradation follows a single first order kinetic and shows a rather short half-live (<150 days).

As rotational crops show only very rarely flupyradifurone (BYI 02960) residues (only in some feed items and in lettuce at very low levels), but in almost all cases DFA residues, an immediate uptake of DFA from the soil – as soon as it is formed in soil – by the plants could provide an explanation for the DFA residues in the plant commodities. An alternative explanation would be uptake of flupyradifurone from the soil and immediate degradation to DFA in the plant.

As expected, the lowest flupyradifurone residues in soil were detected before sowing/planting the crops of the third rotation (273-365 days after treatment of the bare soil). Equivalent flupyradifurone concentrations were detected in soil before sowing/planting the crops of the first and second rotation. The overall highest residue detected in the plough layer (0-20 cm) was detected before sowing/planting the crops of the first rotation (21-30 days after treatment of the bare soil) and accounted for 0.1 mg/kg of parent flupyradifurone. The geometrical mean soil concentrations of flupyradifurone ranged from 0.016 mg/kg to 0.030 mg/kg after application of 300 g a.s./ha (1st to 3rd rotation) and from 0.020 mg/kg to 0.029 mg/kg after application of 175 g a.s./ha (2nd and 3rd rotation). The results indicate that mean soil residues are at the same order of magnitude for the two application rates tested (175 or 300 g/ha). The overall geometric mean concentrations ranged from 0.018 to 0.029 mg/kg. The summary of soil residue data is given in the table below.

Table 7.2-22: Summary of flupyradifurone (FPF) and DFA residues in soil of field rotational crop studies

Rotation	Plant-back interval [days]	Residues in soil (0-20 cm) [mg/kg]*		Overall geomean [mg/kg]
		FPF (BYI 02960)	DFA	FPF (BYI 02960)
1 st rotation	21-30	<0.005-0.10	<0.005	0.027
2 nd rotation	107-204	<0.005-0.074	<0.005	0.029
3 rd rotation	273-365	<0.005-0.064	<0.005	0.018

* expressed in analyte equivalents

Table 7.2-23: Summary of DFA residues in field rotational crop studies conducted in the EU (EFSA, 2015 & EFSA 2020)

Crop group	Crop	Application			DFA residues [mg DFA/kg]						
					Field data			Extrapolated to EU soil plateau level		Extrapolated to US soil plateau level	
		PBI (day)	g/ha	on bare soil or primary crop	Field data	STMR	HR	STMR	HR	STMR	HR
Root crop	Potato (tuber)	138-181	300	bare soil	BBCH 45: 0.012; 0.042; 0.088 ; 0.016 BBCH 49 (mature): 0.011; 0.028; 0.071; 0.023	0.033	0.088	0.067	0.18	0.046	0.12
		295-343	300	bare soil	BBCH 45: <0.007; 0.018; 0.019 ; 0.011 BBCH 49 (mature): < 0.007 ; 0.014; 0.015; 0.012	0.015	0.019	0.031	0.039	0.021	0.027
	Turnip/ carrot (root/cull)	25-30	200	lettuce	0.0090; 0.018; 0.020; 0.035	0.019	0.035	0.039	0.072	0.027	0.049
		61-145	200	bare soil	<0.007; 0.0092; 0.010; 0.013	0.0096	0.013	0.020	0.027	0.013	0.018
		284-328	200	bare soil	<0.007; 0.0088; 0.011; 0.014	0.0099	0.014	0.020	0.029	0.014	0.020
Bulb veg.	Onion	25-33	250	bare soil	<0.007; 0.019; 0.024; 0.054	0.022	0.054	0.044	0.11	0.030	0.076
Stem veg.	Leek	26-33	250	bare soil	0.007; 0.013; 0.032; 0.077	0.023	0.077	0.046	0.16	0.032	0.11
Fruits	Strawberry (fruits)	22	300	bare soil	BBCH 85: 0.056; 0.083; 0.009 ; 0.078 BBCH 87 (mature): 0.068; 0.098 ; <0.007; 0.12	0.083	0.12	0.17	0.25	0.12	0.17
		139-141	300	bare soil	BBCH 85: 0.040; 0.12; <0.007; 0.068 BBCH 87 (mature): 0.046; 0.12; 0.012 ; 0.059	0.057	0.12	0.12	0.25	0.080	0.17
		301-337	300	bare soil	BBCH 85: 0.024 ; 0.026; <0.007; 0.017 BBCH 87 (mature): 0.023; 0.076 ; < 0.007 ; <0.007	0.021	0.076	0.042	0.16	0.029	0.11
Fruiting veg.	Cucumber	25-30	250	bare soil	0.016; 0.093; 0.11; 0.14	0.10	0.14	0.21	0.29	0.14	0.20
Leafy veg.	Lettuce	25-30	200	lettuce	<0.007; 0.011; 0.016; 0.037	0.014	0.037	0.03	0.076	0.019	0.052
		64-145	200	bare soil	3 x <0.007; 0.028	0.007	0.028	0.014	0.058	0.010	0.039
		279-329	200	bare soil	3 x <0.007; 0.015	0.007	0.015	0.014	0.031	0.010	0.021
Brassica veg.	Cauliflower/ broccoli (curd)	21-30	300	bare soil	BBCH 45: 0.025 ; 0.059; 0.042; 0.056 BBCH 49 (mature): 0.023; 0.065 ; 0.021; 0.054	0.049	0.065	0.10	0.13	0.069	0.091
		138-161	300	bare soil	BBCH 45: 0.015; 0.048 ; 0.029; 0.061 BBCH 49 (mature): 0.012; 0.035; 0.037 ; 0.058	0.043	0.061	0.088	0.13	0.060	0.085

Crop group	Crop	Application			DFA residues [mg DFA/kg]						
					Field data			Extrapolated to EU soil plateau level		Extrapolated to US soil plateau level	
		PBI (day)	g/ha	on bare soil or primary crop	Field data	STMR	HR	STMR	HR	STMR	HR
		321-336	300	bare soil	BBCH 45: 0.007; 0.041 ; 0.016; 0.018 BBCH 49 (mature): 0.008 ; 0.033; 0.023 ; 0.015	0.021	0.041	0.042	0.084	0.029	0.057
Cereals	Maize (kernel)	131-204	175	bare soil	<0.007; 0.021; 0.035; 0.037	0.028	0.037	0.058	0.076	0.039	0.052
		291-365	175	bare soil	<0.007; 0.013; 0.019; 0.030	0.016	0.030	0.033	0.062	0.022	0.042
Cereals	Maize (forage)	131-204	175	bare soil	<0.007; 0.011; 0.015; 0.020	0.013	0.020	0.027	0.041	0.018	0.028
		291-365	175	bare soil	<0.007; 0.007; 0.008; 0.009	0.008	0.009	0.015	0.019	0.011	0.013
Cereals	Maize (stover)	131-204	175	bare soil	<0.007; 0.007; 0.014; 0.022	0.011	0.022	0.022	0.045	0.015	0.031
		291-365	175	bare soil	2 x <0.007; 0.007; 0.008	0.007	0.008	0.014	0.016	0.010	0.011
Cereals	Barley (grain)	107-174	175	bare soil	0.038; 0.047; 0.088; 0.12	0.068	0.12	0.14	0.25	0.095	0.17
		281-337	175	bare soil	0.025; 0.040; 0.056; 0.088	0.048	0.088	0.099	0.18	0.067	0.12
Cereals	Barley (forage)	107-174	175	bare soil	0.008; 0.014; 0.028; 0.045	0.021	0.045	0.043	0.093	0.029	0.063
		281-337	175	bare soil	<0.007; 0.020; 0.025; 0.027	0.023	0.027	0.046	0.056	0.032	0.038
Cereals	Barley (straw)	107-174	175	bare soil	3 x <0.03; 0.036	0.030	0.036	0.062	0.074	0.042	0.050
		281-337	175	bare soil	4 x <0.03	0.030	0.030	0.062	0.062	0.042	0.042
Oilseeds	Rape (seed)	137-147	175	bare soil	0.0091; 0.014; 0.022	0.014	0.022	0.029	0.045	0.020	0.031
		330-335	175	bare soil	<0.007; 0.007; 0.013	0.007	0.013	0.014	0.027	0.010	0.018
Oilseeds	Rape (forage)	137-167	175	bare soil	0.0097; 0.015; 0.056; 0.085	0.036	0.085	0.073	0.18	0.050	0.12
		273-335	175	bare soil	0.007; 0.0076; 0.044; 0.046	0.026	0.046	0.053	0.095	0.036	0.064
Pulses	Field pea	25-35	250	bare soil	0.22; 0.33; 0.69; 0.76	0.51	0.76	1.1	1.6	0.71	1.1
Legume veg.	green bean	25-30	250	bare soil	0.087; 0.13; 0.19; 0.36	0.16	0.36	0.330	0.74	0.22	0.50

Conclusion on rotational crops studies

Parent compound flupyradifurone was generally not detected above the LOQ of 0.01 mg/kg in rotational crops that are food items, except in one lettuce trial which showed residues at 0.03 mg/kg in the first rotation. Thus the flupyradifurone MRL is always driven by the residues in the primary crop. Consequently, if no use is registered in a primary crop, the default MRL of 0.01 mg/kg can be applied for flupyradifurone to crops grown in rotation..

In contrast, almost all field rotational crop trials showed residues of the metabolite DFA. For several annual crops, the uptake of DFA residues from soil via roots can be more pronounced as compared to the DFA residues resulting from the primary/direct crop treatment. Therefore the portion taken up from the soil has to be taken into consideration in the risk assessment and when setting MRLs for DFA. DFA residues determined in rotational crop studies (considering the flupyradifurone soil plateau concentration after multi-year usage) have to be added to the DFA residues detected in the primary crops. For MRL setting, the highest residues estimated in the rotational crop is added to the MRL estimated for the primary crop and the result is then rounded up to the next MRL class.

The DFA residues (STMR and HR values) estimated in the rotational crops under consideration in this dRR are summarized in [Table 7.2-24](#). The DFA residues used to propose DFA MRLs are shown in [Table 7.2-25](#).

Table 7.2-24: Summary of DFA residues in rotational crops estimated at the plateau soil concentrations of flupyradifurone [mg a.s./kg]

Crop	Difluoroacetic acid (DFA)		Representative crop in field rotational crop study
	STMR (at EU plateau soil conc., cf. Table 7.2-23)	HR (at EU plateau soil conc., cf. Table 7.2-23)	
Sunflower	0.029	0.045	rapeseed
Barley grain	0.14	0.25	barley
Oat grain	0.14	0.25	barley
Wheat grain	0.14	0.25	barley
Maize kernel	0.058	0.076	maize
Millet grain	0.058	0.076	maize
Sorghum grain	0.058	0.076	maize
Sweet corn	0.058	0.076	maize

RC = Rotational Crop

PC = Primary Crop

STMR = Supervised Trials Median Residue

HR = Highest Residue

Table 7.2-25: Summary of the DFA residues arising at plateau soil concentrations as a basis to estimate DFA MRLs [mg a.s./kg]

Crop	HR RC (at EU plateau soil conc., cf. Table 7.2-23)	HR PC Table 7.2-9	PC MRL proposal (EU) Table 7.2-9	PC MRL + HR RC (EU)	MRL estimate (EU, only)	MRL proposal (considering also import tolerances)
Sunflower	0.045 (rapeseed)	0.049	0.08	0.125	0.15	0.15^{b)}
Barley grain	0.25 (barley)	0.098	0.15	0.40	0.4^{a)}	0.8
Oat grain	0.25 (barley)	0.080	0.15	0.40	0.4^{a)}	0.8^{b)}
Wheat grain	0.25 (barley)	0.34	0.5	0.75	0.8^{a)}	1.5
Maize kernel	0.076 (maize)	0.016	0.03	0.106	0.15	0.15^{b)}
Millet grain	0.076 (maize)	0.016	0.03	0.106	0.15	0.15^{b)}
Sorghum grain	0.076 (maize)	0.016	0.03	0.106	0.15^{a)}	0.3
Sweet corn	0.076 (maize)	0.009	0.01	0.086	0.09^{a)}	0.2

RC = Rotational Crop

PC = Primary Crop

HR = Highest Residue

^{a)} Residues in imported crops are higher and thus the EU MRL is based on the import tolerance (EFSA, 2020)

^{b)} A dER has already been submitted to the Netherlands as EMS to adapt the MRL

Evaluator comment:

Information given by the Applicant is sufficient.

Excerpt from EFSA Journal 2020;18(11):6298:

“A wide range of rotational crop field studies were submitted for the EU pesticides peer review and in the framework of the previous EFSA assessments (EFSA, 2015, 2020; Netherlands, 2017). Flupyradifurone was either applied on a bare soil or on a primary crop lettuce at application rates ranging from 125 to 300 g/ha. Studies

indicate a significant uptake of metabolite DFA in rotational crops. Consequently, the EU pesticide peer review derived provisional MRLs for difluoroacetic acid in rotational crops (EFSA, 2015). These provisional MRLs were further assessed by EFSA in the light of rotational crop studies which were submitted by the EMS Netherlands for the assessment of Article 12 confirmatory data and for the setting of MRLs for flupyradifurone and DFA (EFSA, 2020).

Since the total annual application rate in the intended use GAPs on oilseed rape and mustard is significantly lower than the application rates on primary crops for which the residues of DFA in rotational crops were estimated in the previous EFSA assessment (EFSA, 2020), the magnitude of DFA residues in rotational crops was not re-assessed and the conclusions of the previous EFSA opinion are applicable.”

Proposed uses can be grown in a crop rotation (except grapes).

New field rotational crop studies were conducted in cereals, maize and oilseed rape after application of 175 g a.s./ha and in potato, brassica vegetables and strawberries after application of 300 g a.s./ha to bare soil. More details are presented in Appendix 2, point A 2.1.6.

It should be noted that *parent compound flupyradifurone* was generally not detected above the LOQ of 0.01 mg/kg in rotational crops, except in one lettuce trial which showed residues at 0.03 mg/kg in the first rotation. Thus the flupyradifurone MRL is always driven by the residues in the primary crop.

In contrast, almost all field rotational crop trials showed residues of the metabolite DFA. Therefore DFA MRLs have to be established in all crops that can be grown in rotation. In some cases, the DFA residues in primary crops were higher as compared to the DFA residues detected in the rotational crops.

The new MRL proposals were submitted in 2018.

EMS-The Netherlands concluded in Evaluation report on MRLs for flupyradifurone in imported commodities, February 2019:

“As rotational crops show only very rarely flupyradifurone (BYI 02960) residues (only in some feed items and in lettuce at very low levels), but in almost all cases DFA residues, an immediate uptake of DFA from the soil – as soon as it is formed in soil – by the plants could provide an explanation for the DFA residues in the plant commodities. An alternative explanation would be uptake of flupyradifurone from the soil and immediate degradation to DFA in the plant.”

No waiting periods beyond normal agricultural practice are proposed for succeeding crops to be planted.

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of Sivanto Energy (mixture of flupyradifurone and deltamethrin). Therefore, other special studies are not needed.

Evaluator comment:

According to the SANTE/11956/2016 rev. 9, 14 September 2018, the residues are expected in honey after pesticide application when a substance is applied during the flowering stage (BBCH 60-69) of a crop which is foraged by bees and when a substance with systemic properties is applied prior to the flowering stage (before BBCH 60), including treatment of seeds, of a crop which is foraged by bees.

According to Appendix 2 of the guidance SANTE/11956/2016 rev. 9, 14 September 2018 maize, sweet corn, millet, sorghum, barley, oat and wheat aren't melliferous crops. Therefore, no residues are expected in honey after pesticides application.

There is no sufficient data to support the application of DLT+FPF EC 85 on flowering sunflowers and grapes. Flupyradifurone has systemic properties and additional data should be provided (data gap).

In response, the Applicant provided the following information:

Sivanto Energy is used in non-bee attractive crops (cereals, maize) there is no risk if we take the below risk mitigation measures into account:

- Do not use the product during the flowering period (BBCH 61-69) of bee-attractive crops.
- In order to protect bees in case of pre-flowering application of the product, the last application must be performed not later than at BBCH 57, but not less than 10 days before beginning of the flowering (BBCH 60). Application date must be thus determined on the basis of the expected number of days to flowering, estimated with consideration of the expected weather conditions, variety, agricultural practices and the BBCH stage on the day when the decision is taken.

- Do not apply when flowering weeds are present.
- Regardless of the developmental stage of the treated crop, apply in the evening after the bee flight in order to exclude accidental exposure to the spray drift of bees foraging on flowering weeds outside the field or in adjacent crops.

Additionally:

A study was conducted in Europe to measure the magnitude of flupyradifurone and DFA residues in honey from *Phacelia tanacetifolia* that was treated with Flupyradifurone SL 200 during flowering under semi-field conditions. The most critical EU GAP of flupyradifurone registered in a melliferous crop was tested, with 2 applications at a target rate of 180 g a.s./ha (related to the use in pome fruit with 2 applications at 60 g a.s. per ha and meter crop height [up to 3 meter crop height]).

(Study reference: Appeltauer, A. (2019). Determination of residues of flupyradifurone in honey after two applications of FPF SL 200 in *Phacelia tanacetifolia* at 4 sites in Northern and Southern Europe in 2019.)

In addition, in a second study, the potential residues of flupyradifurone and DFA in honey were determined after application of Flupyradifurone SL 200 to the bare soil (application rate 1 x 300 g a.s./ha, related to worst case use in lettuce [2 x 125 g a.s./ha] and considering persistence of FPF), followed by sowing of *Phacelia tanacetifolia* on the plots as rotational crop.

(Study reference: Appeltauer, A. (2021). Determination of residues of flupyradifurone in honey after one application of FPF SL 200 to bare soil and growing *Phacelia tanacetifolia* as field rotational crop at 4 sites in Northern and Southern Europe in 2019 and 2020.)

Based on the two studies, MRLs of 2.0 and 0.05 mg/kg were proposed in honey for flupyradifurone and DFA, respectively, by Bayer in 2020 and are still under evaluation. The eMS (Ctgb, the Netherlands) has finalized their evaluation and currently the risk assessment deadline by EFSA has been set on April 10, 2023. The applicant was informed by Ctgb that the relevant documents for this application were uploaded on EFSA DMS.

It should be noted that the trials were all performed at a much higher application rate (2 x 180 g as/ha) at flowering or at higher rate to soil (1 x 300 g as/ha) compared to the intended use of Sivanto Energy in grape (2 x 30 g as/ha). Therefore, the honey residue trials are considered a worst-case scenario.

Summary of residues data in honey

Commodity	Region/ Indoor	Residue levels observed in the supervised residue trials (mg/kg)	Comments / Source	STMR (mg/kg)	HR (mg/kg)	Current EU MRL (mg/kg)	Proposed MRL (mg/kg)
Honey	NEU	Mo (FPF): 0.064; 0.44 Mo (DFA): <0.0067; 0.0094 RA: 0.084; 0.47	Application to <i>Phacelia tanacetifolia</i> at GAP of 2 x 0.18 kg as/ha shortly before or at flowering	Mo (FPF): 0.34 Mo (DFA): 0.01 RA: 0.36	Mo (FPF): 0.89 Mo (DFA): 0.0094 RA: 0.92	FPF: 0.05* DFA: 0.05*	FPF: 2.0 DFA: 0.05
	SEU	Mo (FPF): 0.23; 0.89 Mo (DFA): <0.0067; 0.0086 RA: 0.25; 0.92					
Honey (from rotational crop)	NEU	Mo (FPF): 2 x 0.01 Mo (DFA): <0.0067; 0.0118 RA: <0.03; 0.0455	Application to bare soil at GAP of 1 x 0.3 kg as/ha and sowing of <i>Phacelia tanacetifolia</i> at 3 different rotations	Mo (FPF): 0.010 Mo (DFA): 0.01 RA: 0.04	Mo (FPF): 0.0218 Mo (DFA): 0.0118 RA: 0.0455		
	SEU	Mo (FPF): <0.01; 0.0218 Mo (DFA): 0.00712; 0.00843 RA: 0.0314; 0.0418					

* Indicates that the MRL is set at the limit of quantification

Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.

NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

Conclusions:

Following the review done by zRMS, the Applicant would like to request to restrict the use of the product to applications outside of flowering. The table GAP has been corrected.

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

The residue definition for risk assessment comprises the parent compound flupyradifurone and its metabolite DFA (sum of both components, expressed as flupyradifurone).

No TMDI calculations – based on MRLs – have been performed as the two residue definitions for monitoring/enforcement of MRLs are not in agreement with the residue definition for risk assessment.

In order to evaluate the potential chronic and acute exposure to flupyradifurone residues through the diet, the respective International Estimated Daily Intakes (IEDI) and International Estimated Short-Term Intakes (IESTI) were estimated using EFSA PRIMo rev. 3.1 (Pesticide Residue Intake Model). All crops were considered for which there are registered uses within the EC. An ADI of 0.064 mg/kg bw/d and an ARfD of 0.15 mg/kg bw (EFSA, 2015) were used as toxicological reference values.

According to the most recent EFSA evaluation (EFSA, 2020), two separate consumer exposure calculation scenarios were performed in order to estimate the exposure to flupyradifurone and DFA residues from 1) animal commodities and treated primary crops and 2) rotational crops.

The chronic exposure was calculated based on the median residue values reported in the previously issued EFSA Reasoned Opinion on the MRL assessment of flupyradifurone and DFA according to Article 12 (EFSA Journal 2020;18(6):6133) and the median residues (STMR values) detected in the supervised field trials of primary or field rotational crop trials submitted in this dRR. For citrus fruits, the peeling factor of 0.4 was applied to refine the exposure calculation.

The acute exposure assessment was performed based on the median residues for sunflower, barley, oat, wheat and maize/corn, sorghum and millet, and the highest residue values (HR) of grape (table and wine grapes), sweet corn, and all matrices of animal origin (as requested by Primo rev.3.1).

The input values used for the dietary exposure calculation are summarized in Table 7.2-26 (scenario 1) and in Table 7.2-27 (scenario 2).

Table 7.2-26: Input values for the consumer risk assessment considering primary crops and commodities of animal origin (scenario 1)

Commodity	Chronic risk assessment (IEDI)		Acute risk assessment (IESTI)	
	Input value ^{a)} (mg/kg)	Comment	Input value ^{a)} (mg/kg)	Comment
Risk assessment residue definition (sum of flupyradifurone and DFA, expressed as flupyradifurone)				
Oranges, grapefruit	0.14	STMR (IT) x PF (0.4)	-	Acute risk assessment undertaken only with regard to crops under consideration
Lemons, limes	0.14	STMR (IT) x PF (0.4)	-	
Mandarins	0.20	STMR (IT) x PF (0.4)	-	
Tree nuts	0.06	STMR (IT)	-	
Pome fruit	0.28	STMR (IT)	-	

Commodity	Chronic risk assessment (IEDI)		Acute risk assessment (IESTI)	
	Input value ^{a)} (mg/kg)	Comment	Input value ^{a)} (mg/kg)	Comment
Grapes (Table and wine grapes)	0.62 [0.067]	STMR (IT) STMR (EU)	1.95 0.12	HR (IT) HR (EU)]
Strawberries	0.15	STMR (EU) (EFSA, 2016)	-	Acute risk assessment undertaken only with regard to crops under consideration
Blackberries, raspberries	0.39	STMR (EU) (EFSA, 2016)	-	
Blueberries	0.86	STMR (IT)	-	
Table olives	0.50	STMR (EU)	-	
Potatoes	0.06	STMR (IT)	-	HR (IT)
Tropical root and tuber vegetables	0.06	STMR (IT)	-	Acute risk assessment undertaken only with regard to crops under consideration
Root and tuber vegetables, except sugar beets	0.15	STMR (IT)	-	
Tomato, aubergines	0.20	STMR (IT) STMR (EU)	-	
Peppers	0.24	STMR (IT)	-	
Cucurbits (edible peel)	0.13	STMR (EU) (EFSA, 2015)	-	
Watermelon	0.065	STMR pulp (EU) (EFSA, 2015)	-	
Melon	0.17	STMR (IT)	-	
Sweet corn	0.13 [0.030]	STMR (IT) STMR (NEU)	0.25 0.034	HR (IT) HR (NEU)]
Broccoli, cauliflower	0.27	STMR (EU)	-	Acute risk assessment undertaken only with regard to crops under consideration
Brussels sprouts	0.16	STMR (EU)	-	
Head cabbage	0.21	STMR (EU)	-	
Kale	0.97	STMR (EU)	-	
Kohlrabi	0.19	STMR (EU)	-	
Lettuce	1.12	STMR (EU)	-	
Lettuce and other salad plants, except lettuce and escarole	1.36	STMR (EU)	-	
Herbs and edible flowers, spinach and similar	1.36	STMR (EU)	-	
Escaroles	-	no primary crop treatment	-	
Legume vegetables (with pods)	0.19	STMR (EU)	-	
Legume vegetables (without pods)	0.16	STMR (EU)	-	

Commodity	Chronic risk assessment (IEDI)		Acute risk assessment (IESTI)	
	Input value ^{a)} (mg/kg)	Comment	Input value ^{a)} (mg/kg)	Comment
Pulses	0.79	STMR (IT)	-	
Peanuts	0.06	STMR (IT)	-	
Soybean	0.15	STMR (IT)	-	
Cotton seed	0.17	STMR (IT)	-	
Olives for oil production	0.50	STMR (EU)	-	
Sunflower seeds	0.088	STMR (EU), cf. Table 7.2-9	0.23	HR (EU), cf. Table 7.2-9
Barley grain	0.81 [0.20]	STMR (IT) STMR (EU); cf. Table 7.2-9	0.81 0.20	STMR (IT) STMR (EU); cf. Table 7.2-9
Oat grain	0.81 [0.21]	STMR (IT) STMR (EU); cf. Table 7.2-9	0.81 0.21	STMR (IT) STMR (EU); cf. Table 7.2-9
Sorghum grain	0.64 [0.032]	STMR (IT) STMR (EU); cf. Table 7.2-9	0.64 0.032	STMR (IT) STMR (EU); cf. Table 7.2-9
Wheat grain	0.65 [0.33]	STMR (IT) STMR (EU); cf. Table 7.2-9	0.65 0.33	STMR (IT) STMR (EU); cf. Table 7.2-9
Maize grain	0.06 [0.032]	STMR (IT) STMR (EU); cf. Table 7.2-9	0.06 0.032	STMR (IT) STMR (EU); cf. Table 7.2-9
Coffee beans	0.24	STMR (IT)	-	Acute risk assessment undertaken only with regard to crops under consideration
Cocoa beans	0.07	STMR (IT)	-	
Hops	1.08	STMR (EU) (EFSA, 2015)	-	
Cattle, equine muscle	1.10	FPF MRL (US) + DFA STMR (US) (sum of DFA after feeding FPF and after feeding DFA)	1.22	FPF MRL (US) + DFA HR (US) (sum of DFA after feeding FPF and after feeding DFA)
Cattle, equine fat	1.03		1.48	
Cattle, equine liver	1.74		1.91	
Cattle, equine kidney, edible offal	2.24		2.39	
Cattle, equine milk	0.34	FPF MRL (US) + DFA STMR (US) (sum of DFA after feeding FPF and after feeding DFA)	0.34	FPF MRL (US) + DFA STMR (US) (sum of DFA after feeding FPF and after feeding DFA)
Sheep, goat muscle	0.54	FPF MRL (US) + DFA STMR (US) (sum of DFA after feeding FPF and after feeding DFA)	0.84	FPF MRL (US) + DFA HR (US) (sum of DFA after feeding FPF and after feeding DFA) (EFSA, 2020), except for sheep/goat fat where EU value is more critical, cf. Table 7.2-18
Sheep, goat fat	0.38		0.87	
Sheep, goat liver	1.21		1.39	
Sheep, goat kidney, edible offal	1.39		1.72	
Sheep, goat milk	0.18	FPF MRL (US) + DFA STMR (US) (sum of DFA after feeding FPF and after feeding DFA)	0.18	FPF MRL (US) + DFA STMR (US) (sum of DFA after feeding FPF and after feeding DFA)
Swine muscle	0.18	FPF STMR (EU) + DFA STMR (EU), cf. Table 7.2-18	0.42	FPF HR (EU) + DFA HR (EU), cf. Table 7.2-18
Swine fat	0.19		0.59	
Swine liver	0.16		0.38	
Swine kidney,	0.27		0.64	

Commodity	Chronic risk assessment (IEDI)		Acute risk assessment (IESTI)	
	Input value ^{a)} (mg/kg)	Comment	Input value ^{a)} (mg/kg)	Comment
edible offal				
Poultry muscle	0.32	FPF STMR (US) + DFA STMR (US) (sum of DFA after feeding FPF and after feeding DFA)	0.41	FPF HR (EU) + DFA HR (EU), cf. Table 7.2-18
Poultry fat	0.09		0.11	
Poultry liver, kidney, edible offal	0.68	FPF STMR (EU) + DFA STMR (EU) (sum of DFA after feeding FPF and after feeding DFA)	0.72	
Eggs	0.25	FPF STMR (US) + DFA STMR (US) (sum of DFA after feeding FPF and after feeding DFA)	0.34	
Honey	0.35	Submitted in dER, 2020	-	Acute risk assessment undertaken only with regard to crops under consideration

a) if not stated otherwise, input values were taken from EFSA, 2020 (EFSA RO: Setting of import tolerances, modification of existing maximum residue levels and evaluation of confirmatory data following the Article 12 MRL review for flupyradifurone and DFA (EFSA Journal 2020;18(6):6133))

EFSA, 2015: EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance flupyradifurone, published March 21, 2016 (EFSA Journal 2015;13(2):4020), replaces version of February 10, 2015

EFSA, 2016: EFSA RO: Setting of new maximum residue levels for flupyradifurone in strawberries, blackberries and raspberries, published March 16, 2016 (EFSA Journal 2016;14(3):4423)

dER, 2020: dER prepared in order to support the uses of this dRR included also tunnel studies with phacelia to estimate MRLs in honey and to conduct a risk assessment

Table 7.2-27: Input values for the consumer risk assessment considering rotational crops (scenario 2)

Commodity	Chronic risk assessment (IEDI)		Acute risk assessment (IESTI)	
	Input value ^{a)} (mg/kg)	Comment ^{b)}	Input value ^{a)} (mg/kg)	Comment
Risk assessment residue definition (sum of flupyradifurone and DFA, expressed as flupyradifurone)				
Strawberries	0.51	STMR DFA, RC strawberry (EU plateau)	-	Acute risk assessment undertaken only with regard to crops under consideration
Potatoes	0.20	STMR DFA RC potato (EU plateau)	-	
Tropical root and tuber vegetables	0.20	STMR DFA RC potato (EU plateau)	-	
Root and tuber vegetables, except sugar beets	0.12	STMR DFA RC carrot/turnip (EU plateau)	-	
Bulb vegetables	0.13	STMR DFA RC onion (EU plateau)	-	
Tomato, aubergines, peppers	0.63	STMR DFA RC cucumber (EU plateau)	-	
Cucurbits (edible peel)	0.63	STMR DFA RC cucumber (EU plateau)	-	
Cucurbits (inedible peel)	0.63	STMR DFA RC cucumber (EU plateau)	-	
Sweet corn	0.17	STMR DFA RC maize (EU plateau)	0.17	STMR DFA RC maize (EU plateau)

Commodity	Chronic risk assessment (IEDI)		Acute risk assessment (IESTI)	
	Input value ^{a)} (mg/kg)	Comment ^{b)}	Input value ^{a)} (mg/kg)	Comment
Brassica vegetables	0.30	STMR DFA RC broccoli/cauliflower (EU plateau)	-	Acute risk assessment undertaken only with regard to crops under consideration
Lettuces and other salad plants	0.09	STMR FPF + STMR DFA RC lettuce (EU plateau)	-	
Herbs and edible flowers, spinach and similar	0.09	STMR FPF + STMR DFA RC lettuce (EU plateau)	-	
Legume vegetables	0.99	STMR DFA RC beans with pods (EU plateau)	-	
Stem vegetables	0.14	STMR DFA RC leek (EU plateau)	-	
Pulses	3.16	STMR DFA RC dry peas (EU plateau)	-	
Oilseeds, except sunflower	0.09	STMR DFA RC rapeseed (EU plateau)	-	STMR DFA RC rapeseed (EU plateau)
Sunflower seeds	0.09	STMR DFA RC rapeseed (EU plateau)	0.09	
Cereals grains, except maize, millet and sorghum	0.42	STMR DFA RC barley (EU plateau)	0.42	STMR DFA RC barley (EU plateau)
Maize, millet and sorghum grain	0.17	STMR DFA RC maize (EU plateau)	0.17	STMR DFA RC maize (EU plateau)

a) if not stated otherwise, input values were taken from EFSA, 2020 (EFSA RO: Setting of import tolerances, modification of existing maximum residue levels and evaluation of confirmatory data following the Article 12 MRL review for flupyradifurone and DFA (EFSA, 2020)

b) STMR values are summarized in [Table 7.2-23](#)

Remark:

Values marked in *italic* typeface slightly differ from the values presented in the EFSA Reasoned Opinion (EFSA, 2020), probably due to rounding.

7.2.8.2 Conclusion on consumer risk assessment

For the scenario 1 (consumer exposure to flupyradifurone and DFA residues resulting from treated primary crops and animal commodities) the estimated long-term dietary exposure (IEDI), calculated according to the EFSA model, amounts to between 2% (PL general) and 53% (NL toddler) of the ADI. All ADI usage values in this evaluation are well below 100%, and thus no risk to the consumer was identified.

For the scenario 2 (consumer exposure to flupyradifurone-related residues [generally DFA] resulting from rotational crops) the estimated long-term dietary exposure amounts to between 2% (IE child) and 16% (GEMS/Food G06) of the ADI. All ADI usage values in this evaluation are well below 100%, and thus no risk to the consumer was identified.

The combined exposure to flupyradifurone and DFA residues from the intake of food commodities following primary crop treatments, animal commodities and untreated food commodities containing residues due to the uptake via soil accounts for a maximum of 69% of the ADI (without considering a special diet), whereas the most critical diet (NL toddler) amounts to 65% of the ADI. As a consequence no additional refinement was considered to be necessary. The overall exposure to flupyradifurone and DFA is unlikely to pose a chronic consumer intake concern.

The EU uses for grape, sunflower, barley, oat, wheat, corn (field/sweet), millet, and sorghum which are

intended for submission did not result in an exceedance of the ARfD.

Extensive calculation sheets are presented in [Appendix 3](#).

Table 7.2-28: Consumer risk assessment



TMDI (% ADI) according to EFSA PRIMo 3.1	Not conducted, please refer to IEDI
IEDI (% ADI) according to EFSA PRIMo 3.1	<p>Scenario 1 (primary crops and animal commodities): 53% (NL toddler)</p> <p>Scenario 2 (rotational crops): 16% (GEMS/Food G06) 12% (NL toddler)</p>
IESTI (% ARfD) according to EFSA PRIMo 3.1	<p>Scenario 1:</p> <p><u>Results for children (>1% of ARfD):</u> unprocessed commodities: table grapes: 95% sweet corn 14% wine grapes: 12% wheat: 6% barley: 3% processed commodities: wine grapes / juice: 18% wheat / milling (flour): 5% wheat / milling (wholemeal): 2% oat / boiled: 2% barley / cooked: 2% oat / milling (flakes): 2%</p> <p><u>Results for adults (>1% of ARfD):</u> unprocessed commodities: table grapes: 44% wine grapes: 31% sweet corn: 5% wheat: 4% barley: 3% processed commodities: wine grapes / wine: 12% wine grapes / juice: 9% table grapes / raisin: 7% barley / beer: 4% wheat / bread/pizza: 2% wheat / pasta: 2% wheat / bread: 2%</p> <p>Scenario 2:</p> <p><u>Results for children (>1% of ARfD):</u> unprocessed commodities: sweet corn: 5% wheat: 4% barley: 2% processed commodities: wheat / milling (flour): 3% maize / oil: 3% wheat / milling (wholemeal): 2%</p> <p><u>Results for adults (>1% of ARfD):</u> unprocessed commodities: wheat: 2% sweet corn: 2% processed commodities: barley / beer: 2%</p>
TMDI (% ADI) **	Not relevant
NEDI (% ADI)**	

NESTI (% ARfD)**	
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* include raw and processed commodities if both values are required for PRIMo

** if national model is available

The proposed use of flupyradifurone in the formulation DLT+FPF EC 85 does not represent unacceptable acute and chronic risks for the consumer.

	
scenario	scenario
1_efsa_primo_rev3.1	2_efsa_primo_rev3.1

Evaluator comment:

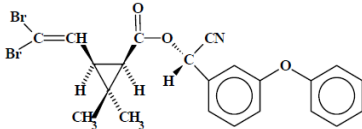
Information given by the Applicant is sufficient and acceptable.

The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of flupyradifurone residues are unlikely to present a public health concern.

7.3 Deltamethrin

General data on deltamethrin are summarized in the table below.

Table 7.3-1: General information on deltamethrin

Deltamethrin (ISO Common Name)	Active substance
IUPAC	(S)-a-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2- dibromovinyl)-2,2-dimethylcyclopropane carboxylate
Chemical structure	
Molecular formula	C ₂₂ H ₁₉ Br ₂ NO ₃
Molar mass	505.2
Chemical group	Pyrethroids
Mode of action (if available)	Nervous system
Systemic	No
Company (ies)	Bayer
Rapporteur Member State (RMS)	HUN
Approval status	Approved Date of (01/11/2003) and reference to decision (COMMISSION DIRECTIVE 2003/5/EC. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003L0005&from=EN
Restriction (e.g. is restricted to use as "...")	Only uses as insecticide
Review Report	6504/VI/99-final 17 October 2002
Current MRL regulation	Reg. (EU) 2018/832 Reg. (EU) 2018/687 Reg. (EU) 2017/1016 Reg. (EU) 2016/1822 Reg. SANTE/10024/2016 Reg. (EU) No 441/2012 Reg. (EU) No 524/2011 Reg. (EC) No 839/2008

	Reg. (EC) No 149/2008
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes
EFSA Journal: conclusion on article 12	Yes (EFSA 2015)
Current MRL applications on intended uses	None

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

One new stability study has been submitted by the applicant in the framework of this application. Results are summarized in the Table below. The detailed assessment of these studies is presented in [Appendix 2](#).

Table 7.3-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Table 7.5.2: Summary of stability data achieved at $\pm 10^{\circ}\text{C}$ (unless stated otherwise)			
Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Tomato, cherry tomato	High water content	13.5 months 24 months	Czarnecki, J. J.; 1992, M-152267-01-1 report A73998, FAO 2002
Cabbage	High water content	24 months	Williams, L.; 2000, M-238621-01-1 , report B002954, FAO 2002
Ginned cotton	Dry matrices	38 months	McKinney, F. R. ; 1995, M-149576-01-1 report A71103, Sweden 1998
Cotton oil	High oil content	36 months	
Cotton soap stock	High oil content	24 months	
Cotton seed	High oil content	38 months	
Corn grain	High protein content	36 months	Czarnecki, J. J.; 1996, M-139715-01-1 , report A55828, submitted in AIR dossier
Corn Forage	High water content	36 months	
Corn Starch	High starch content	36 months	
Corn Flour	Dry matrices	36 months	
Corn Oil	High oil content	36 months	
Animal Products			
Poultry	Muscle	11 months at -12°C	FAO 2002; Sweden 2002
Poultry	Liver	11 months at -12°C	
Poultry	Kidney	11 months at -12°C	
Poultry	Egg	11 months at -12°C	
Cow	Milk	7 months at -20°C	
New data submitted during the renewal process			
Plant products			
Orange	High acid content	24 months	Ballesteros, C., 2012, M-441996-01-1 , report Nr 09-07, Appendix 2

Conclusion on stability of residues during storage

Data are sufficient to cover the trials supporting intended GAPs of DLT+FPF EC 85.

Crop	Sample material Matrix	Longest storage duration (d)	Report No.	Study dRR
Grape	bunch of grapes	273	14-2096	A 2.2.3.1.1
	berries	234		
Sunflower	seed	354	16-2145	A 2.2.3.2.1
	kernel	347		
Barley	whole plant without roots	295	15-2131	A 2.2.3.3.1
	straw	313		
	grain	272		
	whole plant without roots	431	16-2035	A 2.2.3.3.2
Wheat	straw	402		
	grain	403		
	whole plant without roots	177	15-2129	A 2.2.3.4.1
	straw	149		
	grain	154		
Maize	ear	132	16-2033	A 2.2.3.4.2
	whole plant without roots	450		
	straw	420		
	grain	417	15-2134	A 2.2.3.5.1
Maize	rest of plant	175		
	kernel, immature	212		
	kernel	177		
	green material	218	16-2192	A 2.2.3.5.2
Maize	rest of plant	309		
	kernel, immature	345		
	kernel	308		
	green material	343		

Evaluator comment:

The endpoints, as presented in EFSA Journal 2015;13(11):4309 are summarized below:

“Storage stability of deltamethrin was demonstrated at -20 °C for a period of 24 months in high water content commodities (cabbage and tomatoes) (FAO, 2002) and at -12°C for 30 months in high oil content commodities (cotton seed) and for 9 month in dry commodities (cereals grain) (Sweden, 1998). Storage stability studies on high acid content commodities are not available. However, considering that storage stability in tomatoes (which is borderline between a high water and a high acid content commodity) has been demonstrated for up to 24 months and that in samples from acidic commodities stored for up to 16 months residue levels were not significant different from samples stored for shorter period, a storage stability study on acidic commodities is only desirable.”

Additional stability study (Ballesteros, C.; 2012) has been submitted by the Applicant in the framework of this application. The study of Ballesteros, C.; 2012 has been evaluated and accepted (see RR for 102000028562 / DLT+FPF EC 85 (zRMS-PL, February 2022).

Deltamethrin and its isomers (AE F108569 and AE 0035073) were shown to be stable in orange (fruit) for at least 25 months (751 days) under freezer conditions at about -18 °C.

It should be noted that address storage stability in one commodity from each of the five commodity categories, an extrapolation to all other crops is possible (in line with paragraph 25 of OECD Guideline 506) and accepted.

The residue trial samples of crops under consideration were stored under conditions for which the stability of deltamethrin and its isomers (AE F108569 and AE 0035073) residues has been demonstrated.

No further data are required.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

The stability of *trans*-, *cis*-, α -(R)-deltamethrin in strawberry (fruit), tomato (fruit), lambs lettuce, green peas, wheat (grain and straw), barley (whole plant) and oilseed rape (seed) was tested at approximately 4°C in the dark after 7 days of storage in analytical method 00855/M004 ([Lakaschus, S.; Winter, O.; 2009; M-356934-01-1](#)). A stability check was performed by fortifying control extracts of each matrix in toluene (or acetonitrile for OSR) at 50 ng/mL with *trans*-, *cis*-, α -(R)-deltamethrin. At day 0 and after 7 days aliquots

of these extracts were evaporated to dryness and re-constituted in the HPLC solvent containing the internal standards. The average recoveries were found within the range of 70-110% with a deviation between initial analysis and days of reanalysis of -11% (internal criterion at $\pm 20\%$).

Additionally, relevant information on the stability of residues in the final or any intermediate extracts can be derived from the fortification experiments performed during sample analysis. Every analytical batch does contain at least one freshly fortified sample for concurrent recovery determination. The extracts of the fortified samples and of the study samples are handled and stored in parallel. If the recoveries in the fortified samples are within acceptable ranges, the stability of the sample extracts is considered as sufficiently proven.

Conclusion on stability of residues in sample extracts

It can be concluded, that *trans*-, *cis*-, and α -(R)-deltamethrin were stable for at least 7 days when stored in the dark at $4^{\circ}\text{C} \pm 3^{\circ}\text{C}$. However in all studies, recovery experiments were performed concurrently with the analyzed samples. The recovery rates for the studies presented in this dossier were all in the range of 70-110% range, meaning that residues were stable in the sample extracts.

Evaluator comment:

Information given by the Applicant is sufficient.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

The metabolism of flupyradifurone has been investigated in apple, tomato, cotton, and maize (representing four diverse crops) after foliar treatment application with ^{14}C -deltamethrin. These studies have already been reported and evaluated by FAO (2002) and peer reviewed by EFSA (2015). The results are summarized in Table 7.3-3.

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

Table 7.3-3: Summary of plant metabolism studies

Table A2.3: 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	[gem-dimethyl- ¹⁴ C]- and [¹⁴ C-benzyl]-deltamethrin	Foliar, F	0.06	2	28	-	Periasamy, R.; Kimmel, E. C.; Toia, R. F. (1994), M-149515-01-1 ; FAO, 2002; EFSA, 2015
	Tomato		Foliar, F	0.05	1	4, 14, 28	-	Merricks, L.; Swidersky, P., (1985), M-125042-01-1 FAO 2002; EFSA, 2015
			Local, G	14 µg/tomato	1			
Pulses and oilseeds	Cotton*	[¹⁴ C-benzyl]-deltamethrin	G	Foliar: 0.009 mg/plant Soil: 0.18 mg/plant hydroponic: 6.7 mg/plant	1	1, 3, 7	Translocation study	Salmon, J.; van Assche, C. J.; Salmon, M., (1977), M-149605-01-2 , FAO 2002; EFSA, 2015

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
	Cotton leaf*	[Dibromo- ¹⁴ C-vinyl]-, ¹⁴ C-cyano- and [¹⁴ C-benzyl]-deltamethrin	F, G	3-15 mg/kg leaf	1	14, 42	-	xxx, M-093407-01-1 , FAO, 2002; EFSA, 2015
	Cotton	[gem-dimethyl- ¹⁴ C]- and [¹⁴ C-benzyl]-deltamethrin	Foliar, F	0.22	2	4, 10, 28	-	O'Grodnick, J. S.; Larson, J. D. (1990 and 1994), M-149567-01-1 and M-191128-02-1 , FAO 2002; EFSA, 2015
Cereals	Maize/corn	[gem-dimethyl- ¹⁴ C]- and [¹⁴ C-benzyl]-deltamethrin	Foliar, F	0.11	2		-	Periasamy, R., Kimmel, E.C., Toia, R.F. (1994), M-149571-01-1 , FAO 2002; EFSA, 2015

(a) Outdoor/field application (F) or glasshouse/protected/indoor application (G) * covers also leafy vegetables

Summary of plant metabolism studies reported in the EU

As stated in EFSA, 2015:

“The metabolism of deltamethrin in primary crops was investigated in the framework of the peer review (Sweden, 1998, 2002). The same studies have been considered in the JMPR Evaluation of deltamethrin (FAO, 2002).

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).

Deltamethrin was the predominant compound in all the crops tested accounting for up to 77% total radioactive residue (TRR) (forage corn). In the studies analysing for the single isomers (apples, corn and cotton), the alpha-R-isomer and the trans-isomer accounted for up to 34% TRR (apple) and for up to 19% TRR (apples), respectively. In all crops investigated, residues of metabolite 3-phenoxybenzylaldehyde (mPB aldehyde) were found but their levels were never relevant compared to parent and its isomers.

In the study on cotton investigating translocation, hydroponic and soil treatments resulted in a significant root uptake while, after foliar treatment, only a limited translocation throughout the plant was observed. After local applications on cotton leaves, deltamethrin was degraded to its trans-isomer more rapidly under field conditions than under glasshouse conditions.

No studies investigating the metabolism of deltamethrin following post-harvest treatment are available. However, considering the similar metabolic pathway of deltamethrin observed in all crops investigated, it can be assumed that, when applied in post-harvest treatments, deltamethrin will not undergo a more extensive metabolism. EFSA therefore concludes that no additional metabolism studies are required to support post-harvest treatments.”

Conclusion on metabolism in primary crops

Sufficient data have been provided to acknowledge the metabolism of deltamethrin in primary crops.

As stated in EFSA, 2015:

“The metabolism of deltamethrin was investigated in apples, tomatoes, cotton seed and leaves, corn. Similar metabolic patterns were observed in these studies and a general residue definition for monitoring is proposed as deltamethrin.”

Evaluator comment:

The metabolism of deltamethrin in primary crops was investigated in the framework of the peer review (Sweden, 1998, 2002). Information given by the Applicant is sufficient.

According to the EFSA Journal 2020;18(10):6271: *The metabolism of deltamethrin in primary crops belonging to*

the group of fruits (apples and tomatoes), pulses and oilseeds (cotton seed) and cereals (maize) was investigated in the framework of the MRL review. The metabolism studies after foliar and local treatment showed that the metabolic pathway is similar in all crop groups investigated. Deltamethrin was the main component of residues (up to 77% of the total radioactive residue (TRR)) with alpha-R-isomer and trans-isomer accounting for approximately 30–40% of the TRR.

Residue definitions:

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of deltamethrin relevant isomers and the capabilities of enforcement analytical methods, the following residue definitions were proposed by the MRL review (EFSA, 2015).

- residue definition for enforcement: deltamethrin (cis-deltamethrin);
- residue definition for risk assessment: sum of cis-deltamethrin and its alpha-R isomer and trans-isomer (provisional).

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

The same residue definitions are applicable to rotational crops and processed products (EFSA, 2015).

The risk assessment residue definition should be considered on a provisional basis, pending the assessment of further toxicological data investigating the toxicological properties of the alpha-R isomer and trans-isomer of deltamethrin (EFSA, 2015).

Taking into account of the proposed uses assessed in this application, it can be concluded that these residue definitions are appropriate and no further information is required.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

A new metabolism study in rotational crops has been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.3-4: Summary of metabolism studies in rotational crops

Table 7.3-4. Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data**								
Leafy vegetables	Lettuce	[¹⁴ C-benzyl]-deltamethrin	F	10 x 0.045	30, 120	139, 176, 190	Bare soil application	Erstfeld, K. M.; Larson, J. D.; Lange, B. D. (1991 / 1994), M-136651-02-2 , FAO, 2002; EFSA, 2015
Root and tuber vegetables	Carrot					205, 254		
Cereals	Barley					139, 164, 196, 226		
New data submitted during the renewal process								
Leafy vegetables	Swiss chard	[gem-dimethyl- ¹⁴ C]-deltamethrin	G	0.041	30, 134	69, 80, 174, 188	Bare soil application	Schmeling, S.; Breuer-Rehm, M. (2012); M-431769-01-1 , Appendix 2
Root and tuber vegetables	Turnip					86, 202		
Cereals	Wheat					69, 101, 127, 175, 234, 280		

* Outdoor/field application (F) or glasshouse/protected/indoor application (G) ** another study is mentioned in EFSA, 2015 but it is not a confined rotational crop study but a rotational study (1986, Krebs, *et al.*, [M-115043-01-2](#)).

Summary of plant metabolism studies reported in the EU

As stated in EFSA, 2015:

“The metabolism of deltamethrin in rotational crops – carrots, lettuce, barley - has been evaluated during the peer review (Sweden, 1998). One confined rotational crop study investigating the nature of residues following different plant-back intervals is available.

Following treatment of a bare soil at 10×0.45 kg a.s./ha, residues in rotational crops at harvest were generally found to be below 0.01 mg eq/kg, except in barley straw and foliage where residues amounted to 0.023 and 0.016 mg eq/kg, respectively. Consequently, considering the overdosing factor of the confined study (86N), no significant residues are expected in crops grown in rotation and a specific residue definition for rotational crops is not required.”

Summary of new studies in rotational crops

In 2012, a confined rotational crop study was performed with [^{14}C]-gemdimethyl deltamethrin.

The objective of this study was to investigate the metabolism of deltamethrin in rotational crops after one pre-emergent spray application onto bare soil. The application rate of the test compound [gemdimethyl- ^{14}C] deltamethrin was aimed to be about 10% above the highest annual field dose of approx. 37.5 g a.s./ha. The rotational crops used were Swiss chard, turnips and spring wheat. The intended timeframe for sowing was approx. 30, 150 and 365 days after soil treatment for the first, the second and the third rotation, respectively. The study was concluded after two rotations due to the very low TRRs (< 0.01 mg/kg) in all of the collected matrices.

No extraction of plant matrices was conducted during this study because of the very low TRR values. The radioactivity in all samples was exclusively determined by combustion followed by LSC. There was no significant metabolism of deltamethrin detectable in confined rotational crops.

Conclusion on metabolism in rotational crops

Sufficient data have been provided to acknowledge the metabolism of deltamethrin in rotated crops. There is no need for a specific residue definition.

Evaluator comment:

Information given by the Applicant is sufficient.

Additionally metabolism study in rotational crops (Schmeling, S.; Breuer-Rehm, M.; 2012; MEF-11/669; M-431769-01-1) has been submitted by the Applicant in the framework of this application. This study has been evaluated and accepted (please refer RR for 102000028562 / DLT+FPF EC 85 (zRMS-PL, February 2022)).
Summary:

The metabolism of deltamethrin was investigated in the rotational crops Swiss chard, turnips and spring wheat after one soil treatment with radiolabelled [gemdimethyl- ^{14}C] deltamethrin. The actual application rate corresponded to 41 g a.s./ha, which was slightly above the anticipated maximal seasonal treatment rate for pre-emergent use.

Two rotations were sown at plant-back intervals of 30 and 134 days. The study was concluded after two rotations due to the very low TRRs (< 0.01 mg/kg) in all of the collected matrices.

The TRR values of all samples were very low and ranged from values < LOQ in turnip leaves and roots and wheat forage of the 2nd rotation to 0.009 mg/kg in wheat straw of the 1st rotation. They showed a decrease from the 1st to the 2nd rotation.

No extraction of plant matrices was conducted during this study; the radioactivity in all samples was determined exclusively by combustion followed by LSC.

As this study is not required for this assessment then this is provided for information only.

No further data are required at the moment.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

Studies investigating the nature of deltamethrin residues in processed commodities were reported and evaluated in the peer review (Sweden, 2002). A summary of the nature of the residues in processed commodities is presented in Table 7.3-5.

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

Table 7.3-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	-Parent (94-96), - 3-phenoxybenzaldehyde (1-2)	Maurer, T., (2001), M-204204-01-1 ; EFSA, 2015
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	-Parent (91-97), - 3-phenoxybenzaldehyde (3-5)	
Sterilisation (20 minutes, 120°C, pH 6)	-Parent (21-30) -3-phenoxybenzaldehyde (59-75) -(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylic acid (Br ₂ CA) (39-47)	

Conclusion on nature of residues in processed commodities

Three different hydrolysis conditions were applied simulating pasteurisation; brewing / baking / boiling and sterilisation. The sterilisation condition was carried out with two different label positions, [¹⁴C]-benzyl deltamethrin and [¹⁴C]-gemdimethyl deltamethrin. Analysis was performed with LSC and HPLC. The results of the study showed that under simulated pasteurisation (90°C, pH 4, 20 min.), brewing, baking and boiling (100°C, pH 5, 60 min.), deltamethrin is stable. Results of the sterilisation process (120°C, pH 6, 20 min) showed that deltamethrin was degraded under this conditions mainly to two metabolites; 3-phenoxybenzaldehyde and (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylic acid (Br₂CA).

Evaluator comment:

Information given by the Applicant is sufficient.

Excerpt from EFSA Journal 2015;13(11):4309:

“The effect of processing on the nature of deltamethrin was investigated in the framework of the peer review (Sweden, 2002). Studies were conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). Under simulated pasteurisation and brewing, baking and boiling, deltamethrin is stable and only small quantities (0.9 to 5.2% of applied radioactivity) of the plant metabolite 3-phenoxybenzylaldehyde (mPB aldehyde) were detected. Following sterilisation process, deltamethrin represented 21-48% of the applied radioactivity (AR) and it was degraded mainly into two metabolites: mPB aldehyde (59-75% of the AR) and (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylic acid (Br₂CA) (39-47% of AR). During the peer review these two substances were considered well known plant metabolites with no toxicological relevance. Although their toxicological relevance may be reconsidered during the renewal of the approval of the active substance, the conclusions derived during the initial peer review were applied in the framework of this MRL review. It is also noted that in the hydrolysis studies, residues were always reported as deltamethrin and it is not clear if the analytical method used analysed for the sum of all isomers.”

No further data are required at the moment.

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

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

Endpoints	
Plant groups covered	Fruit crops (tomato, apple), cereal (maize/corn), pulses and oilseeds (cotton)
Rotational crops covered	Yes
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	a.s. is stable under pasteurisation and baking/boiling /brewing conditions and not stable under sterilisation conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Parent deltamethrin (tentative, EFSA, 2015); Deltamethrin (cis-deltamethrin) Reg. (EU) 2018/832)
Plant residue definition for risk assessment	Based on Regulation EU 2016/1822, the sum of <i>cis</i> -deltamethrin parent and its isomers <i>alpha</i> -R-deltamethrin and <i>trans</i> -deltamethrin
Conversion factor from enforcement to RA	1.25 (except asparagus: 1) (EFSA, 2015) Not relevant in the framework of this application for oil seed rape.

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

Available data

No new data submitted in the framework of this application.

Table 7.3-7: Summary of animal metabolism studies

Table 7.3-7. 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								
Laying poultry	Hen	[gem-dimethyl- ¹⁴ C]- and [14C-benzyl]-deltamethrin	3 groups	5	3	Eggs	daily	xxx (1985), M-116708-01-1 , FAO, 2002; EFSA, 2015
						Excreta	daily	
						Tissues	at sacrifice	
Lactating ruminants	Cow	[gem-dimethyl- ¹⁴ C]- and [14C-benzyl]-deltamethrin	2	10	3	Milk	twice daily	xxx (1986), M-115057-01-1 , FAO, 2002; EFSA, 2015
						Urine and faeces	daily	
						Tissues	at sacrifice	

Summary of animal metabolism studies reported in the EU

As stated in EFSA, 2015:

Metabolism of deltamethrin in poultry was investigated in the framework of Directive 91/414/EEC (Sweden, 1998, 2002). Hens were dosed for three consecutive days with 5 mg/kg bw per day (also labelled on both rings). In poultry tissues and eggs, deltamethrin was the main compound found (19-65% of the TRR), except in kidney where, apart for deltamethrin (25-28% TRR), metabolites c-Br₂CA and c/t-COOH-c-Br₂CA (together 22% TRR), and c-CH₂OH-c-Br₂CA and t-COOH-c-CH₂OH-c-Br₂CA-lactone (together 15-22% TRR) were also identified.”

“Metabolism of deltamethrin in ruminants was investigated in the framework of Directive 91/414/EEC (Sweden, 1998, 2002). Cows were dosed for three consecutive days with 10 mg/kg body weight (bw) per day (labelled on both the benzyl- and dimethyl-rings, one cow for each label). Deltamethrin was the major compound in all tissues accounting for up to 90% of the TRR in fat. Metabolites Br₂CA and PB acid were present at the same level as parent in liver and kidney (23 and 33% of the TRR, respectively).

Conclusion on metabolism in livestock

Sufficient data have been provided to acknowledge the metabolism of deltamethrin in animal commodities. As stated in EFSA, 2015:

“The metabolism of deltamethrin was investigated in cows and laying hens. As metabolic pathways are expected to be similar in ruminants and rodents, the results of the cow metabolism study could be extrapolated to pigs. From these studies it was proposed to consider, on a tentative basis, deltamethrin as a sufficient marker for monitoring in livestock commodities.”

Evaluator comment:

Information given by the Applicant is sufficient.

Excerpt from EFSA Journal 2015;13(11):4309:

EFSA proposes on a tentative basis, to define the residue for enforcement as deltamethrin only. For risk assessment, the residue definition is proposed as the sum of deltamethrin and its trans-isomer and alpha R-isomer. As metabolic pathways are expected to be similar in ruminants and rodents, the results of the cow metabolism study could be extrapolated to pigs.

No further data are required at the moment.

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

Table 7.3-8: 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	Not stated (peak after 3 days)
	2 days in eggs
Animal residue definition for monitoring	Parent deltamethrin (tentative, EFSA, 2015) Deltamethrin (cis-deltamethrin) Reg. (EU) 2018/832
Animal residue definition for risk assessment	Based on Regulation EU 2016/1822, the sum of <i>cis</i> -deltamethrin parent and its isomers <i>alpha</i> -R-deltamethrin and <i>trans</i> -deltamethrin
Conversion factor	Data do not allow to derive CFs
Metabolism in rat and ruminant similar	Yes (EFSA, 2015)
Fat soluble residue	Yes (EFSA, 2015)

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

New studies measuring the 3 isomers of deltamethrin according to the new residue definition for risk assessment, have been submitted by the applicant in the framework of this application. These **new** studies are summarized in the Table below. The detailed assessment of these **new** studies is presented in Appendix 2.

zRMS comments:

In response to comments received from cMS-SI, the SEU trials from the Table 7.3-9 have been removed. Only trials from NEU are relevant for Central zone.

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of DLT+FPF EC 85 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) ¹	MRL compliance
Grape (Table and wine grape)	EFSA 2015 01R059 01R060 DR00EUS411	S-EU	GAP on which MRL/EU a.s. assessment is based 1 x 7.5 g/ha + 2 x 17.5 g/ha, interval 14, PHI 7d (table grape and wine grape) E: 0.06, 0.06, 0.01, 0.01, <0.02, 0.04, 0.07, 0.07, 0.09, 0.09, 0.11 RA: no data	0.06 -	0.11 -	0.2	0.2	
	EFSA, 2015 C024717, 01R061	N-EU	GAP 1x 7.5 g a.s./ha + 2x 17.5 g a.s./ha, interval 14 d, PHI 14 d (wine grape) E: <0.01, 0.01, 0.01 and 0.02 RA: no data	0.01	0.02	0.02*		yes
	New trials 14-2096 (M-559743-01-1)	N-EU	GAP (EC 85): 2 x 4 g a.s./ha, interval = 14 d, PHI = 14 d E (deltamethrin): <0.01, 0.011, 0.013, 0.015, 0.015* RA (sum): <0.03, 0.031, 0.033, 0.035, 0.035*	0.014 0.034	0.015 0.035			
	New trials 14-2095 (M-560047-01-1)	S-EU	GAP (EC 85): 2 x 4 g a.s./ha, interval = 14 d, PHI = 14 d E (deltamethrin): <0.01, 0.010, 0.011, 0.029 RA (sum): <0.03, 0.030, 0.031, 0.049	0.011 0.031	0.029 0.049			
	Overall supporting data for cGAPs of this dRR	EU (N-EU + S-EU)	E (deltamethrin): 2 x <0.01, 2 x 0.010, 1 x 0.011, 0.013, 0.015, 0.015*, 0.02 0.029 RA (sum): 2 x <0.03, 0.030, 1 x 0.031, 0.033, 0.035, 0.035*, 0.049	0.012 0.034	0.029 0.02 0.049 0.035	0.040 (0.04)	0.2	yes

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) ¹	MRL compliance
Sunflower (seeds = kernels with shells)	EFSA 2015 ER98ECS727 DR00EUS751	S-EU	GAP on which MRL/EU a.s. assessment is based 1 x 7.5g/ha, PHI 60 d E: 8 x <0.05 RA: no data	0.05	0.05		0.05	
	New trials 16-2145 (M-645130-01-1)	N-EU	GAP: 2 x 7.5 g a.s./ha, interval = 14 d, BBCH 69, n.a. E (deltamethrin): 8 x <0.01 RA (sum): 8 x <0.03	0.01 0.03	0.01 0.03			
	New trials 16-2194 (M-643135-01-1) 16-2195 (M-629954-01-1)	S-EU	GAP: 2 x 7.5 g a.s./ha, interval = 14 d, BBCH 69, n.a. E (deltamethrin): 8 x <0.01 RA (sum): 8 x <0.03	0.01 0.03	0.01 0.03			
	Overall supporting data for cGAPs of this dRR	EU (N-EU + S-EU)	E (deltamethrin): 16 x <0.01 RA (sum): 16 x 8 x <0.03	0.01 0.03	0.01 0.03	0.01	0.05	yes
Sunflower (kernel)	New trials 16-2145 (M-645130-01-1)	N-EU	GAP: 2 x 7.5 g a.s./ha, interval = 14 d, BBCH 69, n.a. E (deltamethrin): 8 x <0.01 RA (sum): 8 x <0.03	0.01 0.03	0.01 0.03			
	New trials 16-2194 (M-643135-01-1) 16-2195 (M-629954-01-1)	S-EU	GAP: 2 x 7.5 g a.s./ha, interval = 14 d, BBCH 69, n.a. E (deltamethrin): 8 x <0.01 RA (sum): 8 x <0.03	0.01 0.03	0.01 0.03			
	Overall supporting data for cGAPs of this dRR	EU (N-EU + S-EU)	E (deltamethrin): 16 x <0.01 RA (sum): 16 x 8 x <0.03	0.01 0.03	0.01 0.03	0.01	0.05	yes
Barley (grain)	EFSA 2015 LEAHI180/711-B	N-EU	GAP on which MRL/EU a.s. assessment is based 2 x 7.5 g/ha, PHI 21 d Barley E: 0.01, 2 x 0.03, 0.05 RA: no data	0.03	0.05			

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) ¹	MRL compliance
	EFSA 2015 S10-00005, 10-2032	S-EU	GAP on which MRL/EU a.s. assessment is based 1 x 12.5 g/ha, PHI 30 d Barley E: 2 x <0.01, 2 x 0.01, 0.02, 0.03, 0.05, 0.08 RA: no data	0.02	0.08			
	EFSA 2015 A71928 FP-83.20.12/AF FP-80.05.02/F FP-78.07.12/A	Indoor (post-harvest) combined data set	GAP on which MRL/EU a.s. assessment is based 1 g/ton Wheat Mo: 0.205; 0.31; 0.35; 0.364; 0.40; 0.42; 0.429; 0.45; 0.467; 0.474; 0.50; 0.50; 0.50; 0.521; 0.53; 0.58; 0.63; 0.85; 1.0; 1.10; 1.432 Wheat RA: no data Maize Mo: 0.338; 0.40; 0.60; 0.70; 0.734	0.50	1.43	1.74	2 (existing CXL)	
	New trials 15-2131 (M-580973-04-1) 16-2035 (M-634410-01-1)	N-EU	GAP: 2 x 7.5 g a.s./ha, interval = 14 d, BBCH 73-85, PHI 30 d E (deltamethrin): <0.01, 0.013, 0.014*, 0.019*, 0.030, 0.042, 0.044*, 0.048 RA (sum): <0.03, 0.033, 0.034*, 0.039*, 0.051, 0.070, 0.070*, 0.073	0.025 0.045	0.048 0.073			
	New trials 15-2130 (M-572779-03-1) 16-2034 (M-634112-01-1)	S-EU	Tested GAP: 2 x 10 g a.s./ha, interval = 14 d, BBCH 69-87, PHI 30 d E (deltamethrin): 3 x <0.01, 0.014*, 0.031, 0.037, 0.053* RA (sum): 3 x <0.03, 0.034*, 0.053, 0.071, 0.090*	0.014 0.034	0.053 0.090			
	Scaled residues 15-2130 (M-572779-03-1) 16-2034 (M-634112-01-1)	S-EU	Intended GAP (scaled residues; scaling factor = 7.5/10 = 0.75): 2 x 7.5 g a.s./ha, interval = 14 d, PHI 30 d E (deltamethrin): 3 x <0.008, 0.011, 0.023, 0.028, 0.040 RA (sum): 3 x <0.023, 0.026, 0.040, 0.053, 0.068	0.011 0.026	0.040 0.068			
	Overall supporting data for cGAPs of this dRR	EU (N-EU + S-EU)	E (deltamethrin): 3 x <0.008 , <0.01, 0.011 , 0.013, 0.014*, 0.019*, 0.023 , 0.028, 0.030, 0.040 , 0.042, 0.044*, 0.048 RA (sum): 3 x <0.023 , 0.026 , <0.03, 0.033, 0.034*, 0.039*, 0.040 , 0.051, 0.053 , 0.068 , 0.070, 0.070*, 0.073	0.019 0.0245 0.039 0.045	0.048 0.073	0.081 (0.09)	2	yes

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) ¹	MRL compliance
Barley (straw)	New trials 15-2131 (M-580973-04-1) 16-2035 (M-634410-01-1)	N-EU	GAP: 2 x 7.5 g a.s./ha, interval = 14 d, BBCH 73-85, PHI 30 d E (deltamethrin): 0.17*, 0.21*, 0.21*, 0.22*, 0.25, 0.27, 0.49, 0.70 RA (sum): 0.28*, 0.31*, 0.31*, 0.33*, 0.37, 0.44, 0.68, 0.95	0.35	0.95			
	New trials 15-2130 (M-572779-03-1) 16-2034 (M-634112-01-1)	S-EU	Tested GAP: 2 x 10 g a.s./ha, interval 14 d, BBCH 69-87, PHI 30 d E (deltamethrin): <0.05, 0.11*, 0.16*, 0.24, 0.36, 0.48, 0.58 RA (sum): < 0.15, 0.22*, 0.27*, 0.38, 0.62, 0.80, 0.82					
	Scaled residues 15-2130 (M-580973-04-1) 16-2034 (M-634410-01-1)	S-EU	Intended GAP (scaled residues; scaling factor = 7.5/10 = 0.75): 2 x 7.5 g a.s./ha, interval 14 d, PHI 30 d E (deltamethrin): <0.038, 0.083, 0.12, 0.18, 0.27, 0.36, 0.44 RA (sum): <0.11, 0.17, 0.20, 0.29, 0.47, 0.60, 0.62					
	Overall supporting data for cGAPs of this dRR	EU (N-EU + S-EU)	E (deltamethrin): <0.038, 0.083, 0.12, 0.17, 0.18, 0.21*, 0.21*, 0.22*, 0.25, 0.27, 0.36, 0.44, 0.49, 0.70 RA (sum): <0.11, 0.17, 0.20, 0.28*, 0.29, 0.31*, 0.31*, 0.33*, 0.37, 0.44, 0.47, 0.60, 0.62, 0.68, 0.95	0.24 0.32	0.70 0.95			
Wheat (grain)	EFSA 2015 ER95ECN795	N-EU	GAP on which MRL/EU a.s. assessment is based 2 x 6.25-7.5 g/ha, PHI 30 d E: 4 x <0.02 RA: no data	0.02	0.02			
	EFSA 2015 10-2233 S10-00006	S-EU	GAP on which MRL/EU a.s. assessment is based 1 x 12.5 g a.s./ha, PHI 30 d E: 7 x <0.01, 0.02 RA: no data	0.01	0.02			
	EFSA 2015 08-2014 08-2015	Indoor (post-harvest) combined data set	GAP on which MRL/EU a.s. assessment is based 0.5 g a.s./ton Wheat E: 0.44, 0.45, 0.33, 0.49 RA: no data Barley E: 0.32, 0.40, 0.58, 0.54 RA: no data	0.45	0.58	1.33	1	

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) ¹	MRL compliance
	New trials 15-2129 (M-580528-03-1) 16-2033 (M-634190-01-1)	N-EU	GAP: 2 x 10 g a.s./ha, interval 14 d, BBCH 71-87, PHI 30 d E (deltamethrin): 8 x <0.01 RA (sum): 8 x <0.03	0.01 0.03	0.01 0.03			
	New trials 15-2127 (M-580063-03-1) 16-2032 (M-633925-01-1)	S-EU	Tested GAP: 2 x 10 g a.s./ha, interval 14 d, BBCH 69-83, PHI 30 d E (deltamethrin): 7 x <0.01, 0.01 RA (sum): 7 x <0.03, 0.03	0.01 0.03	0.01 0.03			
	Scaled residues 15-2127 (M-580063-03-1) 16-2032 (M-633925-01-1)	S-EU	Intended GAP (scaled residues, scaling factor = 7.5/10 = 0.75): 2 x 7.5 g a.s./ha, interval 14 d, BBCH 69-83, PHI 30 d E (deltamethrin): 7 x <0.008, 0.008 RA (sum): 7 x <0.023, 0.023	0.008 0.023	0.008 0.023			
	Overall supporting data for cGAPs of this dRR	EU (N-EU + S-EU)	E (deltamethrin): 7 x <0.008, 0.008, 8 x <0.01 RA (sum): 7 x <0.023, 0.023, 8 x <0.03	0.009 0.01 0.027 0.03	0.01 0.03	0.013 (0.015)	1	yes
Wheat (straw)	New trials 15-2129 (M-580528-03-1) 16-2033 (M-634190-01-1)	N-EU	GAP: 2 x 10 g a.s./ha, interval 14 d, BBCH 71-87, PHI 30 d E (deltamethrin): 0.12, 0.12*, 0.13, 2 x 0.17, 0.20, 0.21, 0.44* RA (sum): 0.22, 0.22*, 0.23, 0.29, 0.30, 0.31, 0.32, 0.63*	0.17 0.30	0.44 0.63			
	New trials 15-2127 (M-580063-03-1) 16-2032 (M-633925-01-1)	S-EU	Tested GAP: 2 x 10 g a.s./ha, interval 14 d, BBCH 69-83, PHI 30 d E (deltamethrin): 0.10, 0.15, 0.31, 0.31*, 0.39, 0.48, 0.53, 0.68 RA (sum): 0.20, 0.29, 0.42, 0.57, 0.57*, 0.72, 0.78, 1.0	0.35 0.57	0.68 1.0			
	Scaled residues 15-2127 (M-580063-03-1) 16-2032 (M-633925-01-1)	S-EU	Intended GAP (scaled residues, scaling factor = 7.5/10 = 0.75): 2 x 7.5 g a.s./ha, interval 14 d, BBCH 69-83, PHI 30 d E (deltamethrin): 0.075, 0.11, 0.23, 0.23*, 0.29, 0.36, 0.40, 0.51 RA (sum): 0.15, 0.22, 0.32, 0.43, 0.43*, 0.54, 0.59, 0.75	0.26 0.43	0.51 0.75			

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) ¹	MRL compliance
	Overall supporting data for cGAPs of this dRR	EU (N-EU + S-EU)	E (deltamethrin): 0.075, 0.11 , 0.12, 0.12*, 0.13, 2 x 0.17, 0.20, 0.21, 0.23 , 0.23* , 0.29, 0.36, 0.40, 0.44, 0.51 RA (sum): 0.15 , 2 x 0.22 , 0.22*, 0.23, 0.29, 0.30, 0.31, 2 x 0.32 , 0.43 , 0.43* , 0.54 , 0.59 , 0.63*, 0.75	0.21 0.17 0.31	0.51 0.44 0.75 0.63			
Maize (kernel) → also extrapolated to millet and sorghum (kernel)	EFSA 2015 S10-00012 10-2042	S-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 12.5 g a.s./ha + 1 x 17.5 g a.s./ha, PHI 30 d E: 8 x <0.01 RA: no data	0.01	0.01			
	EFSA 2015 FP-82.12.07/AF	Indoor (post-harvest)	GAP on which MRL/EU a.s. assessment is based: 1 g a.s./ton E: 0.34, 0.40, 0.60, 0.70, 0.73 RA: no data	0.6	0.73		2 (existing CXL)	
	New trials 15-2134 (M-574350-02-1) 16-2192 (M-628803-01-1)	N-EU	GAP: 1 x 12.5 g a.s./ha, BBCH 75, PHI n.a. E (deltamethrin): 8 x <0.01 RA (sum): 8 x <0.03	0.01 0.03	0.01 0.03			
	New trials 15-2133 (M-574144-02-1) 16-2100 (M-621728-01-1)	S-EU	GAP: 1 x 12.5 g a.s./ha, BBCH 73-75, PHI n.a. E (deltamethrin): 7 x <0.01 RA (sum): 7 x <0.03	0.01 0.03	0.01 0.03			
	Overall supporting data for cGAPs of this dRR	EU (N-EU + S-EU)	E (deltamethrin): 15 8 x <0.01 RA (sum): 15 8 x <0.03	0.01 0.03	0.01 0.03	0.01	2 (existing CXL)	yes
Maize (stover) → also extrapolated to millet and sorghum (stover)	New trials 15-2134 (M-574350-02-1) 16-2192 (M-628803-01-1)	N-EU	GAP: 1 x 12.5 g a.s./ha, BBCH 75, PHI n.a. E (deltamethrin): 4 x <0.05, 0.066, 0.081, 0.086, 0.13 RA (sum): 4 x <0.15, 0.17, 0.18, 0.19, 0.23	0.06 0.16	0.13 0.23			
	New trials 15-2133 (M-574144-02-1) 16-2100 (M-621728-01-1)	S-EU	GAP: 1 x 12.5 g a.s./ha, BBCH 73-75, PHI n.a. E (deltamethrin): 7 x <0.05 RA (sum): 7 x <0.15	0.05 0.15	0.05 0.15			

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) ¹	MRL compliance
	Overall supporting data for cGAPs of this dRR	EU (N-EU + S-EU)	E (deltamethrin): 1.4 x <0.05, 0.066, 0.081, 0.086, 0.13 RA (sum): 1.4 x <0.15, 0.17, 0.18, 0.19, 0.23	0.056 0.156	0.13 0.23			
Sweet corn	EFSA, 2015 DR00EUN424 M-201828-01-1	N-EU	GAP on which MRL/EU a.s. assessment is based 2 x 12.5 g a.s./ha , PHI 3 E (deltamethrin): 5 x <0.02 RA (sum):-	0.02	0.02			
	EFSA, 2015 DR00EUS410 M-207608-01-1	S-EU	GAP on which MRL/EU a.s. assessment is based 2 x 12.5 g a.s./ha , PHI 3 E (deltamethrin): 5 x <0.02 RA (sum):-	0.02	0.02			
	New trials 15-2134 (M-574350-02-1) 16-2192 (M-628803-01-1)	N-EU	GAP: 1 x 12.5 g a.s./ha, BBCH 75, PHI = 7 d E (deltamethrin): 8 x <0.01 RA (sum): 8 x <0.03	0.01 0.03	0.01 0.03			
	New trials 15-2133 (M-574144-02-1) 16-2100 (M-621728-01-1)	S-EU	GAP: 1 x 12.5 g a.s./ha, BBCH 73-75, PHI = 7 d E (deltamethrin): 8 x <0.01 RA (sum): 8 x <0.03	0.01 0.03	0.01 0.03			
	Overall supporting data for cGAPs of this dRR	EU (N-EU + S-EU)	E (deltamethrin): 1.6 8 x <0.01 RA (sum): 1.6 8 x <0.03	0.01 0.03	0.01 0.03	0.01	0.02	yes

¹ according to ~~SANTE/10757/2016 [Annex IIIA]~~ and Commission Regulation (EU) ~~2016/1902~~ **Reg. (EU) 2018/832**

* Peak residues detected after PHI

7.3.3.2 Conclusion on the magnitude of residues in plants

In case of grapes, the additional studies presented in the dRR in hand were performed in order to demonstrate that the intended use with the EC 85 formulation is less critical with regard to potential residues as compared to the already registered uses of Deltamethrin solo formulations and also to demonstrate the negligible exposure to both isomers, *trans*-isomer and *alpha*-R isomer.

The actual MRL for grapes is set based on the southern European residue data for grape and wine grapes which is more critical in comparison to the northern European cGAP. Registrations for both residue zones and the corresponding residue data package were available in Article 12 MRL review (for details see residue data in EFSA RO, 2015 (EFSA Journal 2015;13(11):4309).

Residue data for N-EU available in the Article 12 process followed a higher application rate in comparison to the N-EU cGAP supported in this submission, but clearly showed a lower residue situation in comparison to the S-EU cGAP. The S-EU data package is clearly the driver for the EU-MRL and resulted in an EU-MRL of 0.2 mg/kg which is equal to the CXL derived in 2004 also based on S-EU cGAP.

Therefore, overall data, including residue data following the N-EU critical GAP reported during the MRL review, suffices to confirm the MRL compliance for wine and table grapes when DLT + FPF EC 85 is applied following the use relevant to this submission.

Please note residue data available in Article 12 process were available following residue definition for monitoring only. However, the huge data set made available in the context of confirmatory data request (EFSA Journal 2022;20(3):7107) showed high evidence on fruit crops that residues of *alpha*-R-isomer and *trans*-isomer are below <0.01 mg/kg and that a conversion factor of 1 between residue definition for monitoring and risk assessment applies. The consumer risk assessment performed clearly shows that, the MRL of 0.2 mg/kg for grapes is safe for the consumer.

The data submitted for all intended crops show that the current MRLs for deltamethrin have no need to be changed to cover these new uses.

Evaluator comment:

1. Grape

Wine grapes are the major crops in Northern Europe (Technical Guidelines SANTE/2019/12752). A minimum of eight independent trials representative of the proposed growing area for outdoor are required.

Table grapes are the minor crops in Northern Europe (Technical Guidelines SANTE/2019/12752). Therefore, 4 NEU trials are therefore required to support the use of Deltamethrin + Flupyradifurone EC 85 on table grapes in NEU.

Sufficient residue trials are available to determine deltamethrin residues on/in grapes.

The proposed GAP of this dRR submission for the central zone for grapes is as follows:

2 x 4 g a.s./ha, interval 14 d, BBCH 57-81, PHI 14 d

Four bridging trials (14-2096) were conducted in the northern residue zone which demonstrated that the intended use is less critical with regard to potential residues as compared to the already registered uses of Deltamethrin solo formulations (GAP: 1 x 7.5 g/ha + 2 x 17.5 g/ha, interval 14, PHI 7d).

The study of Schoening, R.; Bouhamadi, S.; Sosniak, A.; Czaja, C.; 2016; 14-2096; M-559743-01-1

Residue results (mg/kg):

E (deltamethrin): <0.01, 0.011, 0.013, 0.015, 0.015*

RA (sum): <0.03, 0.031, 0.033, 0.035, 0.035*

* Peak residues detected after PHI

Available results of residue trials show that the in force MRLs of deltamethrin on grapes of 0.2 mg/kg (Reg. (EU) 2018/832) will not be exceeded. The current EU MRL for deltamethrin is sufficient to support the proposed use.

2. Sunflower

Sunflower is the major crop in Northern Europe (Technical Guidelines SANTE/2019/12752). A minimum of eight independent trials representative of the proposed growing area for outdoor are required.

Sufficient residue trials are available to determine deltamethrin residues on/in sunflower.

The proposed GAP of this dRR submission for the central zone for sunflower is as follows:
2 x 7.5 g a.s./ha, interval 14 d, BBCH 30-69, PHI n.a.

The study of Miara, C.; Kowalski, N.; 2018; 16-2145; M-645130-01-1

Residue results (mg/kg) in seeds:

E (deltamethrin): 8 x <0.01

RA (sum): 8 x <0.03

Available results of residue trials show that the in force MRL of deltamethrin on sunflower of 0.05* mg/kg (Reg. (EU) 2018/832) will not be exceeded. The current EU MRL for deltamethrin is sufficient to support the proposed use.

3. Barley

Barley is the major crop in Northern Europe (Technical Guidelines SANTE/2019/12752). A minimum of eight independent trials representative of the proposed growing area for outdoor are required.

Sufficient residue trials are available to determine deltamethrin residues on/in barley.

The proposed GAP of this dRR submission for the central zone for barley is as follows:

2 x 7.5 g a.s./ha, interval 14 d, BBCH 41-83, PHI - 30 days.

The study of Schulte, G.; 2017; 15-2131; M-580973-04-1

Residue results (mg/kg) for grain (PHI: 29-33 days):

E (deltamethrin): 0.013, 0.030, 0.042, 0.044*

RA (sum): 0.033, 0.051, 0.070, 0.070*

* Peak residues detected after PHI.

The study of Kaussmann, M.; 2018; 16-2035; M-634410-01-1

Residue results (mg/kg) for grain (PHI: 27-33 days):

E (deltamethrin): <0.01, 0.014*, 0.019*, 0.048

RA (sum): <0.03, 0.034*, 0.039*, 0.073

* Peak residues detected after PHI.

Available results of residue trials show that the in force MRL of deltamethrin on barley of 2.0 mg/kg (Reg. (EU) 2018/832) will not be exceeded. The current EU MRL for deltamethrin is sufficient to support the proposed use.

4. Oat

Oat is the major crop in Northern Europe (Technical Guidelines SANTE/2019/12752). A minimum of eight independent trials representative of the proposed growing area for outdoor are required.

Applicant has not submitted residue trials on oat.

In accordance with Technical Guidelines SANTE/2019/12752 eight residue trials on barley (0500010) for foliar treatments before and after forming of the edible part can be extrapolated to oat (0500050). Therefore the data cover the use on oat.

HR results (mg/kg) for barley grain:

HR (deltamethrin): 0.048 mg/kg

HR (sum): 0.073 mg/kg

The current MRL for oat is 2.0 mg/kg for deltamethrin (Reg. (EU) 2018/832). Considering the intended use in oat and taking into account the HR value for deltamethrin for barley (0.048 mg/kg), an exceedance of the MRL of 2.0 mg/kg for oat (Reg. (EU) 2018/832) is not expected.

5. Wheat

Wheat is the major crop in Northern Europe (Technical Guidelines SANTE/2019/12752). A minimum of eight independent trials representative of the proposed growing area for outdoor are required.

Sufficient residue trials are available to determine deltamethrin residues on/in wheat.

The proposed GAP of this dRR submission for the central zone for wheat is as follows:

2 x 7.5 g a.s./ha, interval 14 d, BBCH 41-83, PHI - 30 days.

The study of Schulte, G.; 2017; 15-2129; M-580528-03-1

Residue results (mg/kg) in grain:

E (deltamethrin): 4 x <0.01
RA (sum): 4 x <0.03

The study of Kaussmann, M.; Kerkerling, S.; 2018; 16-2033; M-634190-01-1

Residue results (mg/kg) in grain:

E (deltamethrin): 4 x <0.01
RA (sum): 4 x <0.03

Available results of residue trials show that the in force MRLs of deltamethrin on wheat of 1.0 mg/kg (Reg. (EU) 2018/832) will not be exceeded. The current EU MRL for deltamethrin is sufficient to support the proposed use.

6. Maize and sweet corn

Maize is the major crop in Northern Europe (Technical Guidelines SANTE/2019/12752). A minimum of eight independent trials representative of the proposed growing area for outdoor are required.

Sweet corn is the minor crop in Northern Europe (Technical Guidelines SANTE/2019/12752). Therefore, 4 NEU trials are therefore required to support the use of Deltamethrin + Flupyradifurone EC 85 on sweet corn in NEU.

Sufficient residue trials are available to determine deltamethrin residues on/in maize (kernel).

In accordance with Technical Guidelines SANTE/2019/12752 eight residue trials on immature maize for foliar treatments before and after forming of the edible part can be extrapolated to sweet corn (0234000). Therefore the data cover the use on sweet corn.

The proposed GAP of this dRR submission for the central zone for maize is as follows:
1 x 7.5 g PPF/ha, BBCH 51-75, PHI -as per growth stage.

The study of Schulte, G.; 2017; 15-2134; M-574350-02-1

a) Maize - kernel

Residue results (mg/kg) for kernel:

E (deltamethrin): 4 x <0.01
RA (sum): 4 x <0.03

b) Maize – immature kernel

Residue results (mg/kg) for kernel, immature:

E (deltamethrin): 4 x <0.01
RA (sum): 4 x <0.03

The study of Schulte, G.; Kerkerling, S.; 2018; 16-2192; M-628803-01-1

c) Maize - kernel

Residue results (mg/kg) for kernel:

E (deltamethrin): 4 x <0.01
RA (sum): 4 x <0.03

d) Maize – immature kernel

Residue results (mg/kg) for kernel, immature:

E (deltamethrin): 4 x <0.01
RA (sum): 4 x <0.03

Available results of residue trials show that the in force MRLs of deltamethrin on maize of 2 mg/kg (Reg. (EU) 2018/832) and on sweet corn of 0.02 mg/kg will not be exceeded. The current EU MRLs for deltamethrin are sufficient to support the proposed uses.

7. Common millet/proso millet

Common millet/proso millet is the minor crop in Northern Europe (Technical Guidelines SANTE/2019/12752). Therefore, 4 NEU trials are therefore required to support the use of Deltamethrin + Flupyradifurone EC 85 on common millet/proso millet in NEU. Applicant has not submitted residue trials on common millet/proso millet.

In accordance with Technical Guidelines SANTE/2019/12752 eight residue trials on maize (0500030) for foliar treatments before and after forming of the edible part can be extrapolated to common millet/proso millet (0500040). Sufficient residue trials are available to determine deltamethrin residues on/in maize (kernel). Therefore the data cover the use on common millet/proso millet.

Available results of residue trials show that the in force MRLs of deltamethrin on maize of 2 mg/kg (Reg. (EU) 2018/832) and on common millet/proso millet of 2 mg/kg will not be exceeded. The current EU MRLs for deltamethrin are sufficient to support the proposed uses.

8. Sorghum

Sorghum is the minor crop in Northern Europe (Technical Guidelines SANTE/2019/12752). Therefore, 4 NEU trials are therefore required to support the use of Deltamethrin + Flupyradifurone EC 85 on sorghum in NEU. Applicant has not submitted residue trials on sorghum.

In accordance with Technical Guidelines SANTE/2019/12752 eight residue trials on maize (0500030) for foliar treatments before and after forming of the edible part can be extrapolated to sorghum (0500080). Sufficient residue trials are available to determine deltamethrin residues on/in maize (kernel). Therefore the data cover the use on sorghum.

Available results of residue trials show that the in force MRLs of deltamethrin on maize of 2 mg/kg (Reg. (EU) 2018/832) and on sorghum of 2 mg/kg. The current EU MRLs for deltamethrin are sufficient to support the proposed uses.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

New input values were taken into account in the dietary burden calculation based on the model OECD according to Regulation (EU) No 283/2013. In 2018, a new study was performed on stored maize grain in order to support the critical GAP of Deltamethrin as post-harvest use on cereals. In this study, Deltamethrin EC 275 was applied at 0.5 g/ton, the current registered GAP. The residue was analysed according to the new residue definition for risk assessment, including the 3 isomers. As expected, the isomers *trans* and *alpha*-R, were in a situation of no residue. This observation is in line with the current knowledge of the isomerization conditions, photoisomerization of *cis*-deltamethrin in *trans* deltamethrin and acidic conditions for isomerization in *alpha*-R. The confirmation of this behavior, by these results allow us to consider the values get for the parent compound to be representative of the actual exposure in the case of a post-harvest use. A conversion factor of 1 was applied to the deltamethrin residue value as input value for cereals grains.

Besides in the case of no residue situation, a conversion factor of 1 was applied to the Deltamethrin residue value, as mentioned in the following table.

The supported uses in this dossier are less critical than the ones reviewed in the frame of the Article 12 of regulation 396/2005. Consequently no change in the transfer of Deltamethrin and its isomers is anticipated in animal matrices. The current MRLs don't need to be modified.

Table 7.3-10: Input values for the dietary burden calculation (considering the uses reviewed in Art. 12 procedure and the use under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition <i>Cis</i> -deltamethrin + <i>Trans</i> isomer + <i>Alpha</i> -R isomer (EFSA RO 2015)				
Alfalfa (fresh and silage)	0.11	STMRMo × CF (EFSA 2015)	0.23	HRMo × CF (EFSA 2015)
Clover (fresh and silage)	0.11	STMRMo × CF (EFSA 2015)	0.23	HRMo × CF (EFSA 2015)
Grass (fresh and silage)	0.05	STMRMo × CF (EFSA 2015)	0.08	HRMo × CF (EFSA 2015)
Cabbage	0.03	STMRMo × CF (EFSA 2015)	0.08	HRMo × CF (EFSA 2015)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sugar beet leaves	0.03	STMR _{Mo} × CF (EFSA 2015)	0.03	HR _{Mo} × CF (EFSA 2015)
Fodder beet leaves	0.03	STMR _{Mo} × CF (EFSA 2015)	0.03	HR _{Mo} × CF (EFSA 2015)
Citrus pomace	0.03	STMR _{Mo} × CF × 2.5 (EFSA 2015)	0.03	STMR _{Mo} × CF × 2.5 (EFSA 2015)
Apple pomace	0.21	STMR _{Mo} × CF × 2.5 (EFSA 2015)	0.21	STMR _{Mo} × CF × 2.5 (EFSA 2015)
Alfalfa hay	0.43	STMR _{Mo} × CF × 4 (EFSA 2015)	0.90	HR _{Mo} × CF × 4 (EFSA 2015)
Clover hay	0.43	STMR _{Mo} × CF × 4 (EFSA 2015)	0.90	HR _{Mo} × CF × 4 (EFSA 2015)
Grass hay	0.20	STMR _{Mo} × CF × 4 (EFSA 2015)	0.30	HR _{Mo} × CF × 4 (EFSA 2015)
Cereal grain	0.44	STMR Post-harvest use	0.58	HR Post-harvest use
Cereal bran	3.6	STMR × 8 Post-harvest use	4.64	HR × 8 Post-harvest use
Wheat and rye straw	0.43	STMR EUS spray use	0.75	HR EUS spray use
Barley and oat straw	0.35	STMR EUN spray use	0.95	HR EUN spray use
Pulses	0.25	STMR _{Mo} (EFSA 2015) Post-harvest use	0.33	HR _{Mo} × CF (EFSA 2015) Post-harvest use
Potatoes	0.01 *	No residue situation	0.01 *	No residue situation
Turnips	0.01 *	No residue situation	0.01 *	No residue situation
Swedes	0.01 *	No residue situation	0.01 *	No residue situation
Sugar beet	0.01 *	No residue situation	0.01 *	No residue situation
Fodder beet	0.01 *	No residue situation	0.01 *	No residue situation
Rape seed meal	0.01 *	No residue situation	0.01 *	No residue situation
Cotton seed meal	0.01 *	No residue situation	0.01 *	No residue situation
Linseed meal	0.01 *	No residue situation	0.01 *	No residue situation

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sunflower seed meal	0.01 *	No residue situation	0.01 *	No residue situation

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

STMRMo: supervised trials median residue according to the monitoring residue definition

HRMo: highest residue according to the monitoring residue definition

CF: conversion factor for risk assessment

PF: processing factor

(a): For cotton, rapeseed and linseed meals no default processing factor was applied because residues are expected to be below the LOQ in the raw commodities. Concentration of residues in these commodities is therefore not expected (considering fat solubility of the compound).

(b): For fruit pomace, forage hay and cereal bran, in the absence of processing factors supported by data, default processing factors of 2.5, 4 and 8 were respectively included in the calculation in order to consider the potential concentration of Delatmethrin in those fractions.

Table 7.3-11: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition <i>Cis</i> -deltamethrin + <i>Trans</i> -isomer + <i>Alpha-R</i> -isomer (EFSA RO 2015)					
Beef cattle*	0.0336	0.036	Wheat milled by product	1.51	Y
Dairy cattle*	0.0526	0.063	Wheat milled by product	1.63	Y
Ram/ewe	0.0560	0.068	Wheat milled by product	2.0	Y
Lamb	0.085	0.097	Wheat milled by product	2.28	Y
Breeding swine	0.046	0.049	Wheat milled by product	2.10	Y
Finishing swine*	0.060	0.062	Wheat milled by product	2.08	Y
Broiler poultry	0.075	0.084	Wheat milled by product	1.19	Y
Layer poultry*	0.075	0.085	Wheat milled by product	1.24	Y
Turkey	0.073	0.081	Wheat milled by product	1.13	Y

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

Evaluator comment:

The dietary burden has been calculated with the EFSA Animal Model 2017. Since crops treated with deltamethrin might be fed to livestock, the median and maximum dietary burdens were calculated for different groups of livestock using the agreed European methodology. The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore required in all commodities of animal origin.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

Poultry:

In EFSA's recent Reasoned Opinion (EFSA Journal 2015;13(11):4309) on the review of the existing maximum residue levels (MRLs), it is stated :

For poultry, although the maximum dietary burden exceeded the threshold of 0.1 mg/kg DM, no residues above the LOQ were expected in poultry matrices at the calculated dietary burden and no feeding study was triggered. Therefore, MRLs can be established at the LOQ in all poultry commodities and no default conversion factors for risk assessment need to be derived.

Ruminant:

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

Conclusion on feeding studies

The requested uses in potential feed items relevant to this submission and the new mode of calculation the theoretical maximum daily intake for animals compared to the intake estimated in the EFSA Conclusion on the peer review (2015) do not lead to a modification of the existing MRLs of Deltamethrin in animal products.

Evaluator comment:

Information given by the Applicant is sufficient.

Excerpt from EFSA Journal 2015;13(11):4309:

Deltamethrin is authorised for use on several crops that might be fed to livestock and the dietary burden calculations exceeded the trigger values for all groups of livestock. The metabolism of deltamethrin was investigated in cows and laying hens. As metabolic pathways are expected to be similar in ruminants and rodents, the results of the cow metabolism study could be extrapolated to pigs. From these studies it was proposed to consider, on a tentative basis, deltamethrin as a sufficient marker for monitoring in livestock commodities. A validated analytical method for enforcement of the proposed residue definition is available but not fully validated. For risk assessment, the residue definition was tentatively proposed as the sum of deltamethrin and its trans-isomer and alpha R-isomer. Available livestock feeding studies were sufficient only for deriving tentative MRLs in all relevant tissues of ruminants, pigs (except for kidney) and hens, as well as milk and eggs.

The feeding data available show that no exceedance of the MRL for animal commodities (Reg. (EU) 2018/832) will occur and the intended uses are considered acceptable.

No further data are required at the moment.

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

7.3.5.1 Available data for all crops under consideration

The new data submitted in the framework of this application do not call for additional new processing studies. Nevertheless for comprehensiveness sake all existing processing studies are mentioned hereafter - however not summarized in Appendix 2 as not relevant for this dRR.

The following table summarises all the existing processing studies that were already reviewed by EFSA in the frame of the Article 12 review of the MRLs and new data that were submitted in the frame of the renewal process and reviewed by the UK rapporteur Member State.

Table 7.3-12: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Cis-deltamethrin					
Potatoes, unpeeled and boiled	4	0.26			EFSA 2015
Potatoes, fried	4	0.04			EFSA 2015
Apples, juice	1	0.01			EFSA 2015
Apples, wet pomace	1	5.70			EFSA 2015
Strawberries, canned	1	0.65			EFSA 2015
Tomatoes, paste	1	0.40			EFSA 2015

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
Tomatoes, juice	1	1.00			EFSA 2015
Tomatoes, ketchup	1	1.00			EFSA 2015
Dry pulses, cooked	1	0.10			EFSA 2015
Sunflower seed, crude oil	1	10			EFSA 2015
Rape seed, crude oil	1	10			EFSA 2015
Cotton seed, crude oil	1	0.02			EFSA 2015
Olives, crude oil after warm press	1	1.60			EFSA 2015
Barley, beer	1	0.02			EFSA 2015
Maize, crude oil	1	20			EFSA 2015
Rice, polished	1	0.2			EFSA 2015
New data submitted during renewal process					
Cis-deltamethrin					
Wheat flour (type 55)	1	0.27			Billian, P.; Reineke, A.; 2010, M-363957-01-1 , 08-3214
White flour bran	1	3.3			
White bread	1	0.06			
wholemeal	1	1.2			
Wholemeal bread	1	0.41			
Germ	1	0.81			
Semolina	1	0.13			
Semolina bran	1	0.69			
Pasta, fresh	1	0.09			
Pasta, cooked	1	0.03			
Pasta, dry	1	0.05			
Pasta, dried and cooked	1	0.03			
Brewer's malt	1	0.5			Billian, P.; Reineke, A.; 2009, M-361937-01-1 , 08-3215
Brewer's grain	1	0.2			
Beer	1	0.03*			
Pearl barley	1	0.03			

* 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.

7.3.5.2 Conclusion on processing studies

New data were submitted in the frame of the renewal process. Wheat and barley are part of this dossier, and the processing of wheat into bread and semolina and the processing of barley into beer illustrated that Deltamethrin is diluted in the final processed fractions. Deltamethrin stays located into bran fractions.

Evaluator comment:

Information given by the Applicant is sufficient and acceptable. No additional data are required.

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

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

Deltamethrin showed a relatively fast to moderate dissipation from soil under field conditions (field DT_{50} = 8 – 28 days), even after multiple application of exaggerated rates. The respective DT_{90} was calculated to be in a range of 25-94 days. The main soil metabolite Br_2CA was not detected above the limit of quantification (LOQ = 0.01 mg/kg soil) under field conditions. These field dissipation studies demonstrated that deltamethrin and its metabolites are fully degradable under field conditions.

Furthermore, deltamethrin shows a very high adsorption to soil particles with an average K_{oc} of 10 240 000 mL/g. Deltamethrin is not systemic in plants and was not translocated from the application site to other plant parts. Therefore, by considering these results together with the very low uptake of deltamethrin derived soil residues by plants as shown in confined rotational crop studies, the presence of residues in succeeding crops under field conditions is unlikely.

Conclusion on rotational crops studies

No field rotational crop study is considered necessary.

Evaluator comment:

Information given by the Applicant is sufficient.

Excerpt from EFSA Journal 2015;13(11):4309:

“Most of the crops under consideration may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, period required for 90 percent dissipation (DT_{90}) value of deltamethrin is expected to range between 30 and 390 days which is higher than the trigger value of 100 days (European Commission, 2002). According to the European guidelines on rotational crops (European Commission, 1997b), further investigation of residues in rotational crops is relevant.

The results of the confined rotational crop study is confirmed by a field rotational crop study analysing residues in spinach, carrots and radishes planted in soil treated once at 0.12 kg a.s./ha. Considering that deltamethrin was applied to a bare soil (interception of active substance by the plants is expected in practice), it can be concluded that residue levels in rotational commodities are not expected to exceed 0.01 mg/kg provided that deltamethrin is used according to the GAPs assessed in the present review.”

No waiting periods beyond normal agricultural practice are proposed for succeeding crops to be planted.

No additional data are required.

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of Deltamethrin + Flupyradifurone EC 85. Therefore, other special studies are not needed.

Evaluator comment:

According to the SANTE/11956/2016 rev. 9, 14 September 2018, the residues are expected in honey after pesticide application when a substance is applied during the flowering stage (BBCH 60-69) of a crop which is foraged by bees.

There is no sufficient data to support the application of DLT+FPF EC 85 on flowering sunflowers and grapes. Following the review done by zRMS, the Applicant would like to request to restrict the use of the product to applications outside of flowering. The table GAP has been corrected.

In response, the Applicant provided the following information:

Sivanto Energy is used in non-bee attractive crops (cereals, maize, grapes) there is no risk if we take the below risk mitigation measures into account:

- Do not use the product during the flowering period (BBCH 61-69) of bee-attractive crops.

- In order to protect bees in case of pre-flowering application of the product, the last application must be performed not later than at BBCH 57, but not less than 10 days before beginning of the flowering (BBCH 60). Application date must be thus determined on the basis of the expected number of days to flowering, estimated with consideration of the expected weather conditions, variety, agricultural practices and the BBCH stage on the day when the decision is taken.

- Do not apply when flowering weeds are present.

- Regardless of the developmental stage of the treated crop, apply in the evening after the bee flight in order to exclude accidental exposure to the spray drift of bees foraging on flowering weeds outside the field or in adjacent crops.

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

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

7.3.8.1 Input values for the consumer risk assessment

In its reasoned opinion EFSA has proposed to change the residue definition for risk assessment adding to the parent compound *cis*-deltamethrin its 2 isomers, *trans*-isomer and *alpha*-R-isomer. Consequently EFSA has performed the consumer chronic and acute risk assessment applying a conservative conversion factor of 1.25 to STMR and HR values. Residues arising directly from the intended uses in grape, sweet corn, sunflower, barley, wheat, rye, corn, millet and sorghum are considered. The conversion factor of 1.25 was not applied as the supporting residue trials were analyzed according to the new residue definition for risk assessment, *cis*-deltamethrin, *trans*-deltamethrin and *alpha*-R-deltamethrin.

In the frame of this submission, neither for chronic nor acute risk assessment the post-harvest uses of Deltamethrin on cereals were taken into consideration since a spray use of the formulation DLT+FPF EC 85 on wheat, barley and maize is intended in this dossier.

An ADI of 0.01 mg/kg bw/d and an ARfD of 0.01 mg/kg bw were used as toxicological reference values (EFSA, 2015).

For potatoes a processing factor (PF = 0.26 for unpeeled, boiled potatoes) was also applied.

The input values used for the dietary exposure calculation are summarized below.

Table 7.3-13: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cis-deltamethrin+ <i>trans</i> -deltamethrin+ <i>alpha</i> -R deltamethrin				
Citrus fruit	0.01	STMRxCF (EFSA, 2015)	-	Acute risk assessment undertaken only with regard to crops under consideration
Tree nuts	0.03	STMRxCF (EFSA, 2015)	-	
Pome fruits	0.04	STMRxCF (EFSA, 2015)	-	
Apricots	0.03	STMRxCF (EFSA, 2015)	-	
Peaches	0.03	STMRxCF (EFSA, 2015)	-	
Cherries	0.04	STMRxCF (EFSA, 2015)	-	
Plums	0.01	STMRxCF (EFSA, 2015)	-	
Cane fruit	0.03	STMRxCF (EFSA, 2015)	-	
Other small fruits and berries	0.10	STMRxCF (EFSA, 2015)	-	
Table and wine grapes	0.033	STMR-RA	0.035	HR-RA
Strawberries	0.03	STMRxCF (EFSA, 2015)	-	Acute risk assessment undertaken only with regard to crops under
Table olives	0.26	STMRxCF (EFSA, 2015)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Kiwi	0.03	STMRxCF (EFSA, 2015)	-	consideration
Potatoes	0.03	STMR-RA	-	
Other root and tuber vegetables	0.03	STMRxCF (EFSA, 2015)	-	
Garlic	0.03	STMRxCF (EFSA, 2015)	-	
Onions	0.03	STMRxCF (EFSA, 2015)	-	
Shallots	0.03	STMRxCF (EFSA, 2015)	-	
Spring onions	0.07	STMRxCF (EFSA, 2015)	-	
Tomatoes	0.03	STMRxCF (EFSA, 2015)	-	
Peppers	0.04	STMRxCF (EFSA, 2015)	-	
Aubergines (egg plants)	0.07	STMRxCF (EFSA, 2015)	-	
Cucurbits edible peel	0.03	STMRxCF (EFSA, 2015)	-	
Cucurbits inedible peel	0.03	STMRxCF (EFSA, 2015)	-	
Sweet corn	0.03	STMR-RA	0.03	HR-RA
Flowering brassica	0.03	STMRxCF (EFSA, 2015)	-	Acute risk assessment undertaken only with regard to crops under consideration
Brussels sprouts	0.01	STMRxCF (EFSA, 2015)	-	
Head cabbage	0.03	STMRxCF (EFSA, 2015)	-	
Chinese cabbage	0.02	STMRxCF (EFSA, 2015)	-	
Kale	0.05	STMRxCF (EFSA, 2018)	-	
Kohlrabi	0.01	STMRxCF (EFSA, 2015)	-	
Lamb's lettuce	0.43	STMRxCF (EFSA, 2015)	-	
Lettuce	0.19	STMRxCF (EFSA, 2015)	-	
Scarole	0.04	STMRxCF (EFSA, 2015)	-	
Cress	0.43	STMRxCF (EFSA, 2015)	-	
Land cress	0.43	STMRxCF (EFSA, 2015)	-	
Rocket rucola	0.43	STMRxCF (EFSA, 2015)	-	
Red mustard	0.43	STMRxCF (EFSA, 2015)	-	
Leaves and sprouts of Brassica spp	0.33	STMRxCF (EFSA, 2015)	-	
Spinach and similar leaves	0.43	STMRxCF (EFSA, 2015)	-	
Witloof	0.03	STMRxCF (EFSA, 2015)	-	
Herbs	0.43	STMRxCF (EFSA, 2015)	-	
Beans (fresh, with pods)	0.02	STMRxCF (EFSA, 2015)	-	
Beans (fresh, without pods)	0.03	STMRxCF (EFSA, 2015)	-	
Peas (fresh, with pods)	0.02	STMRxCF (EFSA, 2015)	-	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Peas (fresh, without pods)	0.02	STMRxCF (EFSA, 2015)	-	
Lentils (fresh)	0.02	STMRxCF (EFSA, 2015)	-	
Asparagus	0.02	STMRxCF (EFSA, 2015)	-	
Celery	0.08	STMRxCF (EFSA, 2017)	-	
Florence fennel	0.08	STMRxCF (EFSA, 2017)	-	
Rhubarb	0.08	STMRxCF (EFSA, 2017)	-	
Globe artichokes	0.07	STMRxCF (EFSA, 2015)	-	
Leek	0.07	STMRxCF (EFSA, 2015)	-	
Cultivated fungi	0.03	STMRxCF (EFSA, 2015)	-	
Pulses	0.25	STMRxCF (EFSA, 2015)	-	
Linseed	0.03	STMR-RA	-	
Poppy seed	0.06	STMRxCF (EFSA, 2015)	-	
Sesame seed	0.01	STMRxCF (EFSA, 2015)	-	
Sunflower seed	0.03	STMR-RA	0.03	HR-RA
Rape seed	0.03	STMR-RA	-	
Mustard seed	0.03	STMR-RA	-	
Cotton seed	0.01	STMRxCF (EFSA, 2015)		
Pumpkin seed	0.01	STMRxCF (EFSA, 2015)	-	
Safflower	0.01	STMRxCF (EFSA, 2015)	-	
Borage	0.06	STMRxCF (EFSA, 2015)	-	
Gold of pleasure	0.06	STMRxCF (EFSA, 2015)	-	
Hempseed	0.06	STMRxCF (EFSA, 2015)	-	
Castor bean	0.06	STMRxCF (EFSA, 2015)	-	
Olives for oil production	0.26	STMRxCF (EFSA, 2015)	-	
Barley grain	0.045	STMR-RA	0.073	HR-RA
Buckwheat grain	0.63	STMRxCF (EFSA, 2015)	-	
Maize grain	0.03	STMR-RA	0.03	HR-RA
Millet grain	0.03	STMR-RA	0.03	HR-RA
Oats grain	0.63	STMRxCF (EFSA, 2015)	-	
Rice grain	0.56	STMRxCF (EFSA, 2015)	-	
Rye grain	0.03	STMR-RA	0.03	HR-RA
Sorghum grain	0.03	STMR-RA	0.03	HR-RA
Wheat grain	0.03	STMR-RA	0.03	HR-RA
Herbal infusions (dried flowers)	1.31	STMRxCF (EFSA, 2015)	-	Acute risk assessment undertaken only with

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Herbal infusions (dried leaves)	1.31	STMR _x CF (EFSA, 2015)	-	regard to crops under consideration
Herbal infusions (dried roots)	0.09	STMR _x CF (EFSA, 2015)	-	
Spices (seeds)	0.06	EUMRL _x CF (EFSA, 2015)	-	
Spices (fruits and berries)	1.31	STMR _x CF (EFSA, 2015)	-	
Spices (roots and rhizome)	0.09	STMR _x CF (EFSA, 2015)	-	
Spices (buds)	1.31	STMR _x CF (EFSA, 2015)	-	
Spices (flower stigma)	1.31	STMR _x CF (EFSA, 2015)	-	
Sugar beet (root)	0.03	STMR _x CF (EFSA, 2015)	-	
Chicory roots	0.01	STMR _x CF (EFSA, 2015)	-	
Swine meat	0.03	0.8xSTMR _{muscle} +0.2 STMR _{fat} (EFSA, 2015)	0.03	
Swine fat (free of lean meat)	0.06	STMR (EFSA, 2015)	0.06	
Swine liver	0.02	STMR (EFSA, 2015)	0.02	
Swine kidney	0.03	EUMRL (EFSA, 2015)	0.03	
Ruminant meat	0.03	0.8xSTMR _{muscle} +0.2 STMR _{fat} (EFSA, 2015)	0.03	
Ruminant fat	0.08	STMR (EFSA, 2015)	0.08	
Ruminant liver	0.02	STMR (EFSA, 2015)	0.02	
Ruminant kidney	0.03	EUMRL (EFSA, 2015)	0.03	
Poultry meat	0.02	0.9xSTMR _{muscle} +0.1STMR _{fat} (EFSA, 2015)	0.02	
Poultry fat	0.04	STMR (EFSA, 2015)	0.04	
Poultry liver	0.02	STMR (EFSA, 2015)	0.02	
Ruminant milk	0.02	STMR (EFSA, 2015)	0.02	
Birds' eggs	0.02	STMR (EFSA, 2015)	0.02	

CF: Conversion factor (tentative). For all crops except asparagus, a tentative CF of 1.25 has been proposed for risk assessment (EFSA, 2015)

EFSA, 2015: EFSA Journal 2015;13(11):4309 [104 pp.].Review of the existing maximum residue levels for deltamethrin according to Article 12 of Regulation (EC) No 396/2005.

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-14: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	Not conducted, please refer to IEDI
IEDI (% ADI) according to EFSA PRIMo Rev.3.1	31% (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo Rev.3.1	Table grape: 26 % (based on children)

*include raw and processed commodities if both values are required for PRIMo

** if national model is available

The proposed uses of deltamethrin in the formulation DLT+FPF EC 85 do not represent unacceptable acute and chronic risks for the consumer.

Evaluator comment:

Information given by the Applicant is sufficient and acceptable.

The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of deltamethrin residues are unlikely to present a public health concern.

7.4 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

Evaluator comment:

Information given by the Applicant is sufficient.

7.5 References

FAO 2002 Deltamethrin. In: Pesticide residues in food – 2002- Evaluations – Part I: Residues. Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 175/1, 2002.

Sweden, 1998. Draft assessment report on the active substance deltamethrin prepared by the rapporteur Member State Sweden in the framework of Council Directive 91/414/EEC, October 1998.

Sweden, 2002. Addendum to the draft assessment report on the active substance deltamethrin prepared by the rapporteur Member State Sweden in the framework of Council Directive 91/414/EEC, June 2002.

EFSA Journal 2015;13(11):4309 [104 pp.]. Review of the existing maximum residue levels for deltamethrin according to Article 12 of Regulation (EC) No 396/2005.

EC (European Commission), 2011: Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs; SANCO 7525/VI/95-rev.10.3

Commission Regulation (EU) 2016/1902 of 27 October 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, ametoctradin, azoxystrobin, cyfluthrin, difluoroacetic acid, dimethomorph, fenpyrazamine, flonicamid, fluazinam, fludioxonil, flupyradifurone, flutriafol, fluxapyroxad, metconazole, proquinazid, prothioconazole, pyriproxyfen, spiroticlofen and trifloxystrobin in or on certain products

Commission Regulation (EU) 2016/486 of 29 March 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyazofamid, cycloxydim, difluoroacetic acid, fenoxycarb, flumetralin, fluopicolide, flupyradifurone, fluxapyroxad, kresoxim-methyl, mandestrobin, mepanipyrim, metalaxyl-M, pendimethalin and tefluthrin in or on certain products

EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance flupyradifurone, EFSA Journal 2015; 13(2):4020 (doi:10.2903/j.efsa.2015.4020)

EFSA (European Food Safety Authority), 2016. Reasoned Opinion on setting of new maximum residue levels for flupyradifurone in strawberries, blackberries and raspberries, EFSA Journal 2016;14(3):4423 (doi:10.2903/j.efsa.2016.4423)

The Netherlands, 2014: Draft assessment report on the active substance flupyradifurone prepared by the

rapporteur Member State the Netherlands in the framework of Regulation (EC) No 1107/2009. February, 2014

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Netherlands (Ctgb), 2018a: Evaluation Report - MRL application on the setting of MRLs in various rotational crops and animal commodities (confirmatory data), under evaluation (draft prepared by Bayer AG: March 26, 2018; [M-618206-01-1](#); final document submitted by Ctgb to EFSA in February 2019 as combined document including the import tolerances)

Netherlands (Ctgb), 2018b: Evaluation Report - MRL application on the setting of flupyradifurone MRLs and Import tolerances in various imported commodities, under evaluation (draft prepared by Bayer AG, June 25, 2018; updated July 9 and August 22, 2018; [M-626821-04-1](#); final document submitted by Ctgb to EFSA in February 2019 as combined document including the confirmatory data)

Netherlands (Ctgb), 2019: MRL application on the setting of MRLs for flupyradifurone in oilseed rape (OSR), under evaluation (draft prepared by Bayer AG: January 31, updated March 19, 2019; [M-650217-01-1](#))

OECD (Organisation for Economic Co-operation and Development), 2011: OECD MRL Calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011; In: Pesticide Publications/Publications on Pesticide Residues

OECD (Organisation for Economic Co-operation and Development), 2013: Guidance document on residues in livestock; Series on Pesticides No 73, 10 July 2013, 77 pp.; ENV/JM/MONO(2013)8

EFSA (European Food Safety Authority), 2015: Estimation of animal intakes and HR, STMR and MRL calculation for products of animal origin, September 2015

FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner	Previously used Y/N If yes, for which data point?
KCA 6.1 / 01 ... also filed: KCP 5.1 / 23	Lakaschus, S.; Gizler, A.	2017	Amendment no. 3 to final report - 7 days freezer storage stability study with different combinations of a total of 61 analytes (parent and metabolite molecules) and five matrix types (high water / acidic / starch / protein / oil) Report No.: S13-03307, Edition Number: M-480441-06-1 Eurofins Agroscience Services Chem GmbH (EAS Chem), Hamburg, Germany ... amended: 2017-08-16 GLP/GEP: Yes unpublished	No	Bayer	Y evaluated in the RR for DLT+FPF EC 85 on 02.2022
KCA 6.1 / 02	Ballesteros, C.	2012	Storage stability of residues of deltamethrin (AE F032640) and its isomers AE F108569 and AE 0035073 in orange during deep freeze storage for up to 24 months Report No.: 09-07, Edition Number: M-441996-01-1 Bayer S.A.S., Bayer CropScience, Lyon, France GLP/GEP: Yes unpublished	No	Bayer	Y evaluated in the RR for DLT+FPF EC 85 on 02.2022
KCA 6.1 / 03	Winter, O.; Amann, S.; Giesler, W.	2018	Storage stability of deltamethrin and flupyradifurone in oilseed rape (seed and straw) Report No.: S17-05312, Edition Number: M-626405-01-1 Eurofins Agroscience Services Chem GmbH, Hamburg, Germany GLP/GEP: Yes unpublished	No	Bayer	Y evaluated in the RR for DLT+FPF EC 85 on 02.2022
KCA 6.3.1.1 / 01 ... also filed: KCA 6.3.1.2 / 01 KCP 5.1 / 05	Schoening, R.; Bouhamadi, S.; Sosniak, A.; Czaja, C.	2016	Determination of the residues of BYI 02960 and deltamethrin in/on grape after high and low-volume spray application of deltamethrin & flupyradifurone EC 085 in Germany and France (North) Report No.: 14-2096, Edition Number: M-559743-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	N
KCA 6.3.1.1 / 02 ... also filed: KCP 5.1 / 04	Schoening, R.; Bouhamadi, S.; Sosniak, A.; Czaja, C.	2016	Determination of the residues of BYI 02960 and deltamethrin in/on grape after high or low-volume spray application of deltamethrin & flupyradifurone EC 085 in southern France, Spain and Italy Report No.: 14-2095, Edition Number: M-560047-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	N

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner	Previously used Y/N If yes, for which data point?
KCA 6.3.1.2 / 01 ... also filed: KCA 6.3.1.1 / 01 KCP 5.1 / 05	Schoening, R.; Bouhamadi, S.; Sosniak, A.; Czaja, C.	2016	Determination of the residues of BYI 02960 and deltamethrin in/on grape after high and low-volume spray application of deltamethrin & flupyradifurone EC 085 in Germany and France (North) Report No.: 14-2096, Edition Number: M-559743-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	N
KCA 6.3.2.1 / 01 ... also filed: KCA 6.3.2.2 / 01 KCP 5.1 / 07	Miara, C.; Kowalski, N.	2018	Determination of the residues of BYI 02960 and deltamethrin in/on sunflower after spray application of deltamethrin & flupyradifurone EC 085 in northern France, Hungary, The United Kingdom and Poland Report No.: 16-2145, Edition Number: M-645130-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	N
KCA 6.3.2.1 / 02 ... also filed: KCP 5.1 / 06	Kaussmann, M.; Kowalski, N.	2018	Determination of the residues of BYI 02960 and deltamethrin in/on sunflower after spray application of deltamethrin & flupyradifurone EC 085 in Italy, southern France, Spain and Greece Report No.: 16-2194, Edition Number: M-634135-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	
KCA 6.3.2.1 / 03 ... also filed: KCP 5.1 / 08	Kaussmann, M.; Kowalski, N.	2018	Determination of the residues of BYI 02960 and deltamethrin in/on sunflower after spray application of deltamethrin & flupyradifurone EC 085 in southern France, Spain and Italy Report No.: 16-2195, Edition Number: M-629954-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	
KCA 6.3.2.2 / 01 ... also filed: KCA 6.3.2.1 / 01 KCP 5.1 / 07	Miara, C.; Kowalski, N.	2018	Determination of the residues of BYI 02960 and deltamethrin in/on sunflower after spray application of deltamethrin & flupyradifurone EC 085 in northern France, Hungary, The United Kingdom and Poland Report No.: 16-2145, Edition Number: M-645130-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	N
KCA 6.3.3.1 / 01 ... also filed: KCA 6.3.3.2 / 01 KCP 5.1 / 10	Schulte, G.	2017	Amendment no. 3 to final report - Determination of the residues of BYI 02960 and deltamethrin in/on winter and spring barley after spray application of deltamethrin & flupyradifurone EC 085 in Germany, Belgium and United Kingdom Report No.: 15-2131, Edition Number: M-580973-04-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2017-09-22 GLP/GEP: Yes unpublished	No	Bayer	N

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner	Previously used Y/N If yes, for which data point?
KCA 6.3.3.1 / 02 ... also filed: KCA 6.3.3.2 / 02 KCP 5.1 / 12	Kaussmann, M.	2018	Determination of the residues of BYI 02960 and deltamethrin in/on winter and spring barley after spray application of deltamethrin & flupyradifurone EC 085 in the Netherlands, Germany and Belgium Report No.: 16-2035, Edition Number: M-634410-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	N
KCA 6.3.3.1 / 03 ... also filed: KCP 5.1 / 09	Noss, G.	2017	Determination of the residues of BYI 02960 and deltamethrin in/on barley after spray application of deltamethrin & flupyradifurone EC 085 in France (South), Italy, Spain and Greece Report No.: 15-2130, Edition Number: M-572779-03-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2017-10-17 GLP/GEP: Yes unpublished	No	Bayer	
KCA 6.3.3.1 / 04 ... also filed: KCP 5.1 / 11	Kaussmann, M.; Miara, C.	2018	Determination of the residues of BYI 02960 and deltamethrin in/on barley after spray application of deltamethrin & flupyradifurone EC 085 in southern France, Italy, Spain and Greece Report No.: 16-2034, Edition Number: M-634112-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	
KCA 6.3.3.2 / 01 ... also filed: KCA 6.3.3.1 / 01 KCP 5.1 / 10	Schulte, G.	2017	Amendment no. 3 to final report - Determination of the residues of BYI 02960 and deltamethrin in/on winter and spring barley after spray application of deltamethrin & flupyradifurone EC 085 in Germany, Belgium and United Kingdom Report No.: 15-2131, Edition Number: M-580973-04-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2017-09-22 GLP/GEP: Yes unpublished	No	Bayer	N
KCA 6.3.3.2 / 02 ... also filed: KCA 6.3.3.1 / 02 KCP 5.1 / 12	Kaussmann, M.	2018	Determination of the residues of BYI 02960 and deltamethrin in/on winter and spring barley after spray application of deltamethrin & flupyradifurone EC 085 in the Netherlands, Germany and Belgium Report No.: 16-2035, Edition Number: M-634410-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	N

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner	Previously used Y/N If yes, for which data point?
KCA 6.3.4.1 / 01 ... also filed: KCA 6.3.4.2 / 01 KCP 5.1 / 14	Schulte, G.	2017	Amendment no. 2 to final report - Determination of the residues of BYI 02960 and deltamethrin in/on spring wheat and winter wheat after spray application of deltamethrin & flupyradifurone EC 085 in Germany, the Netherlands and Belgium Report No.: 15-2129, Edition Number: M-580528-03-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2017-09-22 GLP/GEP: Yes unpublished	No	Bayer	N
KCA 6.3.4.1 / 02 ... also filed: KCA 6.3.4.2 / 02 KCP 5.1 / 16	Kaussmann, M.; Kerkering, S.	2018	Determination of the residues of BYI 02960 and deltamethrin in/on winter and spring wheat after spray application of deltamethrin & flupyradifurone EC 085 in Belgium, Germany and the Netherlands Report No.: 16-2033, Edition Number: M-634190-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	N
KCA 6.3.4.1 / 03 ... also filed: KCP 5.1 / 13	Schulte, G.	2017	Amendment no. 2 to final report - Determination of the residues of BYI 02960 and deltamethrin in/on wheat after spray application of deltamethrin & flupyradifurone EC 085 in Italy, Spain and Portugal Report No.: 15-2127, Edition Number: M-580063-03-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2017-09-22 GLP/GEP: Yes unpublished	No	Bayer	
KCA 6.3.4.1 / 04 ... also filed: KCP 5.1 / 15	Kaussmann, M.; Kerkering, S.	2018	Determination of the residues of BYI 02960 and deltamethrin in/on wheat after spray application of deltamethrin & flupyradifurone EC 085 in southern France, Italy and Spain Report No.: 16-2032, Edition Number: M-633925-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	
KCA 6.3.4.2 / 01 ... also filed: KCA 6.3.4.1 / 01 KCP 5.1 / 14	Schulte, G.	2017	Amendment no. 2 to final report - Determination of the residues of BYI 02960 and deltamethrin in/on spring wheat and winter wheat after spray application of deltamethrin & flupyradifurone EC 085 in Germany, the Netherlands and Belgium Report No.: 15-2129, Edition Number: M-580528-03-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2017-09-22 GLP/GEP: Yes unpublished	No	Bayer	N

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner	Previously used Y/N If yes, for which data point?
KCA 6.3.4.2 / 02 ... also filed: KCA 6.3.4.1 / 02 KCP 5.1 / 16	Kaussmann, M.; Kerkering, S.	2018	Determination of the residues of BYI 02960 and deltamethrin in/on winter and spring wheat after spray application of deltamethrin & flupyradifurone EC 085 in Belgium, Germany and the Netherlands Report No.: 16-2033, Edition Number: M-634190-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	N
KCA 6.3.5.1 / 01 ... also filed: KCA 6.3.5.2 / 01 KCP 5.1 / 20	Schulte, G.	2017	Amendment no. 1: Determination of the residues of BYI 02960 and deltamethrin in/on maize/corn after spray application of deltamethrin & flupyradifurone EC 085 in Germany, Belgium and the Netherlands Report No.: 15-2134, Edition Number: M-574350-02-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2017-05-03 GLP/GEP: Yes unpublished	No	Bayer	N
KCA 6.3.5.1 / 02 ... also filed: KCA 6.3.5.2 / 02 KCP 5.1 / 18	Schulte, G.; Kerkering, S.	2018	Determination of the residues of BYI 02960 and deltamethrin in/on maize/corn after spray application of deltamethrin & flupyradifurone EC 085 in Germany, Belgium and the Netherlands Report No.: 16-2192, Edition Number: M-628803-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	N
KCA 6.3.5.2 / 01 ... also filed: KCA 6.3.5.1 / 01 KCP 5.1 / 20	Schulte, G.	2017	Amendment no. 1: Determination of the residues of BYI 02960 and deltamethrin in/on maize/corn after spray application of deltamethrin & flupyradifurone EC 085 in Germany, Belgium and the Netherlands Report No.: 15-2134, Edition Number: M-574350-02-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2017-05-03 GLP/GEP: Yes unpublished	No	Bayer	N
KCA 6.3.5.2 / 02 ... also filed: KCA 6.3.5.1 / 02 KCP 5.1 / 18	Schulte, G.; Kerkering, S.	2018	Determination of the residues of BYI 02960 and deltamethrin in/on maize/corn after spray application of deltamethrin & flupyradifurone EC 085 in Germany, Belgium and the Netherlands Report No.: 16-2192, Edition Number: M-628803-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	N

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner	Previously used Y/N If yes, for which data point?
KCA 6.6.1 / 01	Schmeling, S.; Breuer-Rehm, M.	2012	Metabolism of [gemdimethyl-14C] deltamethrin in confined rotational crops Report No.: MEF-11/669, Edition Number: M-431769-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer	Y evaluated in the RR for DLT+FPF EC 85 on 02.2022

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

Please note that all data mentioned as part of DAR, RAR, or EFSA journals are considered as relied on.

Flupyradifurone

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
KIIA 6.1.1 /01	Netzband, D.; Timberlake, B. C.; Harbin, A. M.	2012	Storage stability of BYI 02960, difluoroacetic acid, and difluoroethyl-amino-furanone in plant matrices (18-month data) Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVP046-1, Edition Number: M-428412-02-1 EPA MRID No.: 48977401 Date: 2012-04-03 ...Amended: 2012-11-01 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.1.1 /02	Moore, S. M.; Harbin, A. M.	2012	BYI 02960 - Magnitude of the residue in dairy cows - Amended report Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVP050-1, Edition Number: M-428416-02-1 EPA MRID No.: 48843842 Date: 2012-04-03 ...Amended: 2012-05-31 GLP/GEP: yes, unpublished ...also filed: KIIA 4.3 /08 ...also filed: KIIA 6.4.2 /01	Y	Bayer
KIIA 6.2.1 /01	Justus, K.	2011	Metabolism of [furanone-4-14C]BYI 02960 in tomatoes Bayer CropScience, Report No.: MEF-11/016, Edition Number: M-411352-01-3 EPA MRID No.: 48843801 Date: 2011-07-25 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.2.1 /02	Justus, K.	2011	Metabolism of [pyridinylmethyl-14C]BYI 02960 in tomatoes Bayer CropScience, Report No.: MEF-11/182, Edition Number: M-411500-01-2 EPA MRID No.: 48843802 Date: 2011-07-26 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.2.1 /03	Unold, M.; Justus, K	2011	Metabolism of [ethyl-1-14C]BYI 02960 in tomatoes Bayer CropScience, Report No.: MEF-11/498, Edition Number: M-413996-01-2 EPA MRID No.: 48843803 Date: 2011-09-05 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.2.1 /04	Justus, K.	2011	Metabolism of [furanone-4-14C]BYI 02960 in potatoes Bayer CropScience, Report No.: MEF-10/769, Edition Number: M-415234-01-2 EPA MRID No.: 48843804 Date: 2011-09-14 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.2.1 /05	Justus, K.	2011	Metabolism of [pyridinylmethyl-14C]BYI 02960 in potatoes Bayer CropScience, Report No.: MEF-10/710, Edition Number: M-415078-01-2 EPA MRID No.: 48843805 Date: 2011-09-14 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.2.1 /06	Justus, K.	2011	Metabolism of [furanone-4-14C]BYI 02960 in apples Bayer CropScience, Report No.: MEF-11/499, Edition Number: M-422562-01-1 EPA MRID No.: 48843806 Date: 2011-12-29 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.2.1 /07	Justus, K.	2011	Metabolism of [pyridinylmethyl-14C]BYI 02960 in apples Bayer CropScience, Report No.: MEF-11/198, Edition Number: M-414678-01-2 EPA MRID No.: 48843807 Date: 2011-09-09 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.2.1 /08	Schmeling, S.; Weber, E.	2011	Metabolism of [furanone-4-14C]BYI 02960 in cotton after spray application Bayer CropScience, Report No.: MEF-11/392, Edition Number: M-421625-01-2 EPA MRID No.: 48843808 Date: 2011-12-12 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.2.1 /09	Schmeling, S.; Weber, E.	2011	Metabolism of [pyridinylmethyl-14C]BYI 02960 in cotton after spray application Bayer CropScience, Report No.: MEF-11/393, Edition Number: M-421691-01-2 EPA MRID No.: 48843809 Date: 2011-12-12 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.2.1 /10	Schmeling, S.; Weber, E.	2011	Metabolism of [furanone-4-14C]BYI 02960 in paddy rice Bayer CropScience, Report No.: MEF-11/058, Edition Number: M-414219-01-2 EPA MRID No.: 48843810 Date: 2011-09-09 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.2.1 /11	Schmeling, S.; Weber, E.	2011	Metabolism of [pyridinylmethyl-14C]BYI 02960 in paddy rice Bayer CropScience, Report No.: MEF-11/059, Edition Number: M-414328-01-2 EPA MRID No.: 48843811 Date: 2011-09-09 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.2.1 /12	Schoening, R.; Ruhl, S.	2012	Determination of residues of difluoroacetic acid in extracts of samples from plant metabolism and confined rotational crops studies after application of BYI 02960 Bayer CropScience, Report No.: MR-11/050, Edition Number: M-422550-01-1 EPA MRID No.: 48843812 Date: 2012-01-17 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.2.2 /01	Bongartz, R.; Koester, J.	2012	[Pyridinylmethyl-14C]BYI 02960: Metabolism in the laying hen Bayer CropScience, Report No.: MEF-11/199, Edition Number: M-422162-01-2 EPA MRID No.: 48843814 Date: 2012-01-10 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 6.2.2 /02	Bongartz, R.; Koester, J.	2012	[Furanone-4-14C]BYI 02960: Metabolism in the laying hen Bayer CropScience, Report No.: MEF-11/200, Edition Number: M-422263-01-2 EPA MRID No.: 48843813 Date: 2012-01-10 GLP/GEP: yes, unpublished	Y	Bayer

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
KIIA 6.2.3 /01	Bongartz, R.; Koester, J.	2011	[Pyridinylmethyl-14C]BYI 02960: Metabolism in the lactating goat Bayer CropScience, Report No.: MEF-11/269, Edition Number: M-419701-01-2 EPA MRID No.: 48843816 Date: 2011-12-07 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 6.2.3 /02	Bongartz, R.; Koester, J.	2011	[Furanone-4-14C]BYI 02960: Metabolism in the lactating goat Bayer CropScience, Report No.: MEF11/268, Edition Number: M-421995-01-2 EPA MRID No.: 48843815 Date: 2011-12-16 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 6.3.1.1 /01	Noss, G.; Bauer, J.	2012	Determination of the residues of BYI 02960 in/on lettuce after spraying of BYI 02960 SL 200 in the field in the Netherlands, Belgium, France (North) and Germany Bayer CropScience, Report No.: 10-2223, Report includes Trial Nos.: 10-2223-01 10-2223-02 10-2223-03 10-2223-04 10-2223-05 Edition Number: M-424742-01-1 Date: 2012-02-08 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.1.1 /02	Uceda, L.	2012	Amendment No. 1 - Determination of the residues of BYI 02960 in/on lettuce after spray application of BYI 02960 SL 200 in the field in Germany, northern France and Belgium Bayer S.A.S., Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 11-2082, Report includes Trial Nos.: 11-2082-01 11-2082-02 11-2082-03 11-2082-04 Edition Number: M-425941-02-1 Date: 2012-02-23 ...Amended: 2012-03-05 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.1.1 /03	Schoening, R.; Bauer, J.	2011	Determination of the residues of BYI 02960 in/on lettuce, head after spray application of BYI 02960 SL 200 in the field in France (South), Spain and Italy - Amendment no. 0001 to report no. 10-2213 Bayer CropScience, Report No.: 10-2213, Report includes Trial Nos.: 10-2213-01 10-2213-02 10-2213-03 10-2213-04 10-2213-05 Edition Number: M-425913-02-1 Date: 2011-09-14 ...Amended: 2012-02-27 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.1.1 /04	Uceda, L.	2012	Amendment No.1 - Determination of the residues of BYI 02960 in/on lettuce after spray application of BYI 02960 SL 200 in the field in Spain, Italy, Southern France and Portugal Bayer S.A.S., Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 11-2071, Report includes Trial Nos.: 11-2071-01 11-2071-02 11-2071-03 11-2071-04 Edition Number: M-425784-02-1 Date: 2012-02-23 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.1.1 /05	Schulte, G.	2012	Determination of the residues of BYI 02960 in/on lettuce after spraying of BYI 02960 SL 200 in the greenhouse in France (North), Germany, the Netherlands and Italy Bayer CropScience, Report No.: 10-2212, Report includes Trial Nos.: 10-2212-01 10-2212-02 10-2212-03 10-2212-04 10-2212-05 Edition Number: M-425829-01-1 Date: 2012-02-22 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.1.1 /06	Uceda, L.	2012	Determination of the residues of BYI 02960 in/on lettuce after spray application of BYI 02960 SL 200 in the greenhouse in northern France, Italy, Spain and Germany Bayer S.A.S., Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 11-2070, Report includes Trial Nos.: 11-2070-01 11-2070-02 11-2070-03 11-2070-04 Edition Number: M-425786-01-1 Date: 2012-02-23 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.1.2 /01	Noss, G.; Ballmann, C.	2012	Determination of the residues of BYI 02960 in/on hop after spraying of BYI 02960 SL 200 in the field in Germany Bayer CropScience, Report No.: 10-2225, Report includes Trial Nos.: 10-2225-01 10-2225-02 10-2225-03 10-2225-04 Edition Number: M-425351-01-1 Date: 2012-02-13 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.1.2 /02	Noss, G.; Ballmann, C.	2012	Determination of the residues of BYI 02960 in/on hop after spray application of BYI 02960 SL 200 in Germany Bayer CropScience, Report No.: 11-2076, Report includes Trial Nos.: 11-2076-01 11-2076-02 11-2076-03 11-2076-04 Edition Number: M-425339-01-1 Date: 2012-02-13 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.1.3 /01	Bauer, J.; Schulte, G.	2012	Determination of the residues of BYI 02960 in/on apple after spraying of BYI 02960 SL 200 in the field in Germany, France (north), the Netherlands and Belgium Bayer CropScience, Report No.: 10-2171, Report includes Trial Nos.: 10-2171-01 10-2171-02 10-2171-03 10-2171-04 10-2171-05 10-2171-06 Edition Number: M-434587-01-1 Date: 2012-07-05 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.1.3 /02	Schulte, G.; Bauer, J.	2012	Determination of the residues of BYI 02960 in/on apple after spray application of BYI 02960 SL 200 in the field in Germany, northern France and the United Kingdom Bayer CropScience, Report No.: 11-2077, Report includes Trial Nos.: 11-2077-01 11-2077-02 11-2077-03 11-2077-04 Edition Number: M-438329-01-1 Date: 2012-09-10 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.1.3 /03	Bauer, J.; Schulte, G.	2012	Determination of the residues of BYI 02960 in/on apple after spraying of BYI 02960 SL 200 in the field in France (south), Italy and Spain Bayer CropScience, Report No.: 10-2172, Report includes Trial Nos.: 10-2172-01 10-2172-02 10-2172-03 10-2172-04 10-2172-05 10-2172-06 Edition Number: M-434603-01-1 Date: 2012-07-05 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.1.3 /04	Schulte, G.; Bauer, J.; Ruhl, S.	2012	Determination of the residues of BYI 02960 in/on apple after spray application of BYI 02960 SL 200 in the field in southern France, Spain, Italy and Portugal Bayer CropScience, Report No.: 11-2078, Report includes Trial Nos.: 11-2078-01 11-2078-02 11-2078-03 11-2078-04 Edition Number: M-439845-01-1 Date: 2012-10-16 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.1.4 /01	Rosati, D.; Ratajczak, M.	2012	Determination of the residues of BYI 02960 in/on grape after spraying and spraying, low-volume of BYI 02960 SL 200 in the field in Germany, France (North) and Belgium Bayer S.A.S., Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 10-2218, Report includes Trial Nos.: 10-2218-01 10-2218-02 10-2218-03 10-2218-04 10-2218-05 Edition Number: M-437138-01-1 Date: 2012-08-22 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.1.4 /02	Meilland-Berthier, I.	2012	Determination of the residues of BYI 02960 in/on grape after high or low-volume spray application of BYI 02960 SL 200 in Germany and northern France Bayer CropScience, Report No.: 11-2089, Report includes Trial Nos.: 11-2089-01 11-2089-02 11-2089-03 11-2089-04 Edition Number: M-436857-01-1 Date: 2012-08-17 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.1.4 /03	Rosati, D.; Ratajczak, M.	2012	Determination of the residues of BYI 02960 in/on grape after spraying and spraying, low-volume of BYI 02960 SL 200 in the field in France (South), Spain and Italy Bayer S.A.S., Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 10-2219, Report includes Trial Nos.: 10-2219-01 10-2219-02 10-2219-03 10-2219-04 Edition Number: M-437131-01-1 Date: 2012-08-22 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.1.4 /04	Meilland-Berthier, I.	2012	Determination of the residues of BYI 02960 in/on grape after high or low-volume spray application of BYI 02960 SL 200 in Southern France, Spain and Italy Bayer S.A.S., Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 11-2090, Report includes Trial Nos.: 11-2090-01 11-2090-02 11-2090-03 11-2090-04 Edition Number: M-438482-01-1 Date: 2012-09-18 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.1.5 /01	Schulte, G.; Bauer, J.	2012	Determination of the residues of BYI 02960 in/on tomato after spraying of BYI 02960 SL 200 in the field in France (south), Italy, Spain and Portugal Bayer CropScience, Report No.: 10-2186, Report includes Trial Nos.: 10-2186-01 10-2186-02 10-2186-03 10-2186-04 Edition Number: M-438184-01-1 Date: 2012-09-06 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.1.5 /02	Meilland-Berthier, I.	2012	Determination of the residues of BYI 02960 in/on tomato after spray application of BYI 02960 SL 200 in the field in Spain, Italy, Portugal and Greece Bayer S.A.S., Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 11-2087, Report includes Trial Nos.: 11-2087-01 11-2087-02 11-2087-03 11-2087-04 Edition Number: M-438275-01-1 Date: 2012-01-17 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.1.5 /03	Schoening, R.; Ballmann; C.	2012	Determination of the residues of BYI 02960 in/on tomato after spray application of BYI 02960 SL 200 in the greenhouse in Germany, the Netherlands, France (North) and Belgium Bayer CropScience, Report No.: 10-2190, Report includes Trial Nos.: 10-2190-01 10-2190-02 10-2190-03 10-2190-04 Edition Number: M-426300-01-1 Date: 2012-03-01 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.1.5 /04	Meilland-Berthier, I.	2012	Determination of the residues of BYI 02960 in/on tomato and cherry tomato after spray application of BYI 02960 SL 200 in the greenhouse in Germany, the Netherlands, Italy and Spain Bayer S.A.S., Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 11-2085, Report includes Trial Nos.: 11-2085-01 11-2085-02 11-2085-03 11-2085-04 Edition Number: M-427056-01-1 Date: 2012-03-08 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.1.3.6 /01	Schulte, G.	2012	Determination of the residues of BYI 02960 in/on sweet pepper after spraying of BYI 02960 SL 200 in the field in France (south), Italy, Spain and Portugal Bayer CropScience, Report No.: 10-2187, Report includes Trial Nos.: 10-2187-01 10-2187-02 10-2187-03 10-2187-04 Edition Number: M-439089-01-1 Date: 2012-09-27 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.1.3.6 /02	Schulte, G.	2012	Determination of the residues of BYI 02960 in/on sweet pepper after spray application of BYI 02960 SL 200 in the field in southern France, Spain and Italy Bayer CropScience, Report No.: 11-2083, Report includes Trial Nos.: 11-2083-01 11-2083-02 11-2083-03 11-2083-04 Edition Number: M-439083-01-1 Date: 2012-09-25 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.1.3.6 /03	Fargeix, G.	2012	Determination of the residues of BYI 02960 in/on sweet pepper after spraying of BYI 02960 SL 200 in the greenhouse in France, Spain, Italy, Greece and the Netherlands Bayer S.A.S., Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 11-2081, Report includes Trial Nos.: 11-2081-01 11-2081-02 11-2081-03 11-2081-04 11-2081-05 11-2081-06 11-2081-07 11-2081-08 Edition Number: M-436855-01-1 Date: 2012-08-17 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.1.3.7 /01	Schulte, G.; Ruhl, S.	2012	Determination of the residues of BYI 02960 in/on cucumber after spraying of BYI 02960 SL 200 in the field in France (south), Spain and Italy Bayer CropScience, Report No.: 10-2184, Report includes Trial Nos.: 10-2184-01 10-2184-02 10-2184-03 10-2184-04 Edition Number: M-438188-01-1 Date: 2012-09-06 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.1.3.7 /02	Schulte, G.; Diehl, P.	2012	Determination of the residues of BYI 02960 in/on gherkin after spray application of BYI 02960 SL 200 in the field in southern France, Spain and Italy Bayer CropScience, Report No.: 11-2066, Report includes Trial Nos.: 11-2066-01 11-2066-02 11-2066-03 11-2066-04 Edition Number: M-438326-01-1 Date: 2012-09-10 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.1.3.7 /03	Schoening, R.; Oel, D.	2012	Determination of the residues of BYI 02960 in/on cucumber after spray application of BYI 02960 SL 200 in the greenhouse in France (South), the Netherlands, Germany and Italy Bayer CropScience, Report No.: 10-2189, Report includes Trial Nos.: 10-2189-01 10-2189-02 10-2189-03 10-2189-04 Edition Number: M-435235-01-1 Date: 2012-07-23 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.1.3.7 /04	Schulte, G.; Diehl, P.	2012	Determination of the residues of BYI 02960 in/on cucumber after spray application of BYI 02960 SL 200 in the greenhouse in Greece, Italy, Spain and Portugal Bayer CropScience, Report No.: 11-2067, Report includes Trial Nos.: 11-2067-01 11-2067-02 11-2067-03 11-2067-04 Edition Number: M-439079-01-1 Date: 2012-09-24 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.1.3.8 /01	Schoening, R.; Ballmann, C.	2012	Determination of the residues of BYI 02960 in/on melon after spray application of BYI 02960 SL 200 in the field in Spain, Italy, France (South) and Portugal Bayer CropScience, Report No.: 10-2185, Report includes Trial Nos.: 10-2185-01 10-2185-02 10-2185-03 10-2185-04 Edition Number: M-439328-01-1 Date: 2012-10-01 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.1.3.8 /02	Fargeix, G.	2012	Determination of the residues of BYI 02960 in/on water melon after spray application of BYI 02960 SL 200 in the field in Portugal, Italy and Spain Bayer S.A.S., Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 11-2074, Report includes Trial Nos.: 11-2074-01 11-2074-02 11-2074-03 11-2074-04 11-2074-05 Edition Number: M-438099-01-1 Date: 2012-09-10 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.1.3.8 /03	Uceda, L.	2012	Determination of the residues of BYI 02960 in/on melon after spray application of BYI 02960 SL 200 in the greenhouse in the Netherlands, Italy and Spain Bayer S.A.S., Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 10-2188, Report includes Trial Nos.: 10-2188-01 10-2188-02 10-2188-03 Edition Number: M-425792-01-1 Date: 2012-02-23 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.1.3.8 /04	Fargeix, G.	2012	Determination of the residues of BYI 02960 in/on water melon after spraying application of BYI 02960 SL 200 in the greenhouse in Spain and Italy Bayer S.A.S., Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 11-2075, Report includes Trial Nos.: 11-2075-01 11-2075-02 11-2075-03 11-2075-04 11-2075-05 11-2075-06 Edition Number: M-437681-01-1 Date: 2012-09-04 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.1 /01	Beedle, E.; Niczyporowicz, L. M.	2012	BYI 02960 200 SL - Magnitude of the residue in/on citrus (crop group 10) Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY012, Edition Number: M-433259-01-1 EPA MRID No.: 48843913 Date: 2012-06-27 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.2.1 /02	Woodard, D. L.; Timberlake, B.	2012	BYI 02960 200 SL - Magnitude of the residue in/on mandarin orange (CG 10) Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVP064, Edition Number: M-432184-01-2 EPA MRID No.: 48843914 Date: 2012-06-05 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.1 /03	Dallstream, K. A.	2012	BYI 02960 200 SL - Magnitude of the residue in/on citrus (including bridging trials to Brazil import tolerance) Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVP076, Edition Number: M-432687-01-1 EPA MRID No.: 48843915 Date: 2012-06-15 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.1 /04	Resende, G.	2012	Amendment 01 to the final report - Determination of residues of BYI 02960 and its metabolites, in citrus culture after drench application at the base of the plants, followed by foliar spray application of BYI 02960 (200 SL) in field trials in Brazil Bayer CropScience, São Paulo, SP, Brazil Bayer CropScience, Report No.: I11-022, Report includes Trial Nos.: I11-022-01 I11-022-02 I11-022-03 I11-022-04 I11-022-05 Edition Number: M-427041-02-3 EPA MRID No.: 48843945 Date: 2012-03-06 ...Amended: 2012-07-11 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.2.1 /05	Resende, G.	2012	Amendment 01 to the final report - Determination of residues of BYI 02960 and its metabolites, in citrus after foliar spray application of BYI 02960 (200 SL) in field trials in Brazil Departamento de Registro Bayer CropScience, São Paulo, Brazil Bayer CropScience, Report No.: I11-006, Report includes Trial Nos.: I11-006-03 I11-006-04 I11-006-05 I11-006-06 I11-006-07 Edition Number: M-427468-02-3 EPA MRID No.: 48843946 Date: 2012-03-09 ...Amended: 2012-07-10 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.2 /01	Niczyporowicz, L. M.; Netzband, D.	2012	BYI 02960 200 SL - Magnitude of the residue in/on tree nuts (Crop Group 14) Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY016, Edition Number: M-433350-01-1 EPA MRID No.: 48843920 Date: 2012-06-27 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.3 /01	Lam, C.	2012	BYI 02960 200 SL - Magnitude of the residue in/on pome fruits (crop group 11) Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY013, Edition Number: M-432703-01-1 EPA MRID No.: 48843916 Date: 2012-06-18 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.2.4 /01	Dallstream, K. A.	2012	BYI 02960 200 SL - Magnitude of the residue in/on small fruit vine climbing (except Fuzzy kiwifruit) Crop Subgroup 13-07F Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY007, Edition Number: M-432181-01-2 EPA MRID No.: 48843918 Date: 2012-06-04 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.2.5 /01	Dorschner, K. W.	2012	BYI 02960: Magnitude of the residue on blueberry Rutgers, The State University of New Jersey, Princeton, NJ, USA TF- BCS-IR4, Report No.: IR-4 PR No. 10637, Report includes Trial Nos.: 10637.11-AU01 10637.11-AU02 10637.11-AU04 10637.11-CL01 10637.11-CL02 10637.11-CL03 10637.11-DK01 10637.11-IT01 10637.11-MI01 10637.11-MI02 10637.11-MI03 10637.11-NC01 10637.11-NC02 10637.11-NJ01 10637.11-NJ02 10637.11-NS01 10637.11-NS02 10637.11-NS03 10637.11-NZ01 10637.11-NZ02 10637.11-OR01 10637.11-QC16 10637.11-SP01 10637.11-UK01 10637.11-UK02 Edition Number: M-435476-01-1 EPA MRID No.: 48843917 Date: 2012-07-17 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.2.6 /01	Dorschner, K.	1996	BYI 02960: Magnitude of the residue on prickly pear cactus U.S. Department of Agriculture, Salinas, CA, USA TF- BCS-IR4, Report No.: IR-4 PR NO. 10722, Report includes Trial Nos.: 10722.11-CA*01 10722.11-CA*02 10722.11-CA*143 10722.11-CA*144 10722.11-CA*160 10722.11-CA*161 10722.11-CA*162 10722.11-CA*163 Edition Number: M-432542-01-1 EPA MRID No.: 48843931 Date: 1996-10-24 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.7 /01	Krolski, M. E.; Harbin, A. M.	2012	BYI 02960 200 SL - Magnitude of the residue in potato - Tuberous and corm vegetables (Crop Subgroup 1C) Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY015, Edition Number: M-430532-01-2 EPA MRID No.: 48843902 Date: 2012-05-08 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.7 /02	Ellis, A.	2011	Amendment no.1 - Determination of residues of BYI 02960 in potatoes and sweet potatoes following two or three applications of BYI 02960 200 SL at rates of 100, 150 or 200 g a.i./ha seven days apart Bayer CropScience Pty. Ltd., Eight Mile Plains, QLD, Australia Bayer CropScience, Report No.: BCS-0352, Edition Number: M-415292-02-1 EPA MRID No.: 48843940 Date: 2011-09-30 ...Amended: 2012-07-09 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.2.7 /03	Ellis, A.	2012	Amendment no.1 - Determination of residues of BYI 02960 in potatoes and sweet potatoes following two or three applications of BYI 02960 200 SL at rates of 100, 150 or 200 g a.i./ha seven days apart Bayer CropScience Pty. Ltd., Residue Laboratory, Eight Mile Plains, QLD, Australia Bayer CropScience, Report No.: BCS-0358, Report includes Trial Nos.: C538 C539 C541 C632 Edition Number: M-426841-02-1 EPA MRID No.: 48843941 Date: 2012-02-27 ...Amended: 2012-07-09 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.8 /01	Miller, A.; Helfrich, K. K.	2012	BYI 02960 200 SL - Magnitude of the residue in/on fruiting vegetables (CG 8); US / Canada import tolerance Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY022, Edition Number: M-433126-01-1 EPA MRID No.: 48843911 Date: 2012-06-22 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.8 /02	Ellis, A.	2011	Amendment no.1 - Determination of residues of BYI 02960 following three foliar applications of BYI 02960 200 SL to trellis and bush tomatoes at rates of 100, 150 or 200 g a.i./ha seven days apart, and in glass house tomatoes at rates of 10, 15 and 20 g a.i./100L seven days apart Bayer CropScience Pty. Ltd., Residue Laboratory, Eight Mile Plains, QLD, Australia Bayer CropScience, Report No.: BCS-0348.02, Edition Number: M-411773-02-1 EPA MRID No.: 48843936 Date: 2011-07-20 ...Amended: 2012-07-09 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.2.8 /03	Ellis, A.	2011	Amendment no. 1 - Determination of residues of BYI 02960 following three foliar applications of BYI 02960 200 SL to capsicums at rates of 100, 150 or 200 g a.i./ha seven days apart Bayer CropScience Pty. Ltd., Residue Laboratory, Eight Mile Plains, QLD, Australia Bayer CropScience, Report No.: BCS-0349.02, Edition Number: M-430274-02-1 EPA MRID No.: 48843937 Date: 2011-08-11 ...Amended: 2012-07-09 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.8 /04	Ellis, A.	2012	Determination of residues of BYI 02960 following three foliar applications of BYI 02960 200 SL to trellis and bush tomatoes at rates of 100, 150 or 200 g a.i./ha seven days apart, and in glass house tomatoes at rates of 10, 15 and 20 g a.i./ 100 L seven days apart - Amendment no. 1 to the report BCS-0354 Bayer CropScience Pty. Ltd., Residue Laboratory, Eight Mile Plains, QLD, Australia Bayer CropScience, Report No.: BCS-0354, Report includes Trial Nos.: C525 C526 C683 Edition Number: M-433790-02-1 EPA MRID No.: 48843938 Date: 2012-05-31 ...Amended: 2012-07-09 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.8 /05	Ellis, A.	2012	Determination of residues of BYI 02960 following three foliar applications of BYI 02960 200 SL to capsicums at rates of 100, 150 or 200 g a.i./ha seven days apart - Amendment no. 1 to the report BCS-0355 Bayer CropScience Pty. Ltd., Residue Laboratory, Eight Mile Plains, QLD, Australia Bayer CropScience, Report No.: BCS-0355, Edition Number: M-432144-02-1 EPA MRID No.: 48843939 Date: 2012-05-11 ...Amended: 2012-07-09 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.2.9 /01	Netzband, D.; Niczyporowicz, L. M.	2012	BYI 02960 SL 200 - Magnitude of the residue in/on leafy vegetables (Crop Group 4) Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY005, Edition Number: M-433317-01-1 EPA MRID No.: 48843904 Date: 2012-06-27 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.10 /01	Hoag, R. E.; Arthur, E. L.; Woodard, D. L.	2012	BYI 02960 200 SL - Magnitude of the residue in/on dried, shelled pea and bean (except soybean), foliage of legume vegetables (except soybean); (CG 6C and 7A) Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY028, Edition Number: M-433260-01-1 EPA MRID No.: 48843909 Date: 2012-06-26 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.11 /01	Krolski, M. E.; Harbin, A. H.	2012	BYI 02960 200 SL - Magnitude of the residue in peanut Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY010, Edition Number: M-424313-01-2 EPA MRID No.: 48843930 Date: 2012-01-30 GLP/GEP: no, unpublished	N	Bayer
KIIA 6.3.2.12 /01	Sturdivant, D. W.	2012	BYI 02960 200 SL and BYI 02960 480 FS - Magnitude of the residue in/on soybeans Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY011, Edition Number: M-431214-01-2 EPA MRID No.: 48843910 Date: 2012-05-15 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.2.13 /01	Timberlake, B. C.; Harbin, A. M.	2012	BYI 02960 200 SL and BYI 02960 480 FS - Magnitude of the residue in/on cotton (Crop Subgroup 20C) Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY009, Edition Number: M-431910-01-2 EPA MRID No.: 48843925 Date: 2012-06-01 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.14 /01	Hoag, R. E.	2012	BYI 02960 200 SL and BYI 02960 480 FS - Magnitude of the residue in/on barley Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY001, Edition Number: M-431905-01-2 EPA MRID No.: 48843921 Date: 2012-04-19 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.15 /01	Fisher, D. R.	2012	BYI 02960 200 SL and BYI 02960 480 FS - Magnitude of the residue in/on corn Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY002, Edition Number: M-432754-01-1 EPA MRID No.: 48843922 Date: 2012-06-18 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.16 /01	Krolski, M. E.; Dallstream, K. A.	2012	BYI 02960 200 SL and BYI 02960 480 FS - Magnitude of the residue in/on sorghum Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY004, Edition Number: M-427048-01-2 EPA MRID No.: 48843923 Date: 2012-03-14 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.2.17 /01	Fischer, D. R.; Niczyporowicz, L. M.	2012	BYI 02960 200 SL and BYI 02960 480 FS - Magnitude of the residue in/on wheat Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY003, Edition Number: M-433258-01-1 EPA MRID No.: 48843924 Date: 2012-06-27 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.18 /01	Hoag, R. E.	2012	BYI 02960 200 SL - Magnitude of the residue in/on coffee; U.S., Canada and E.U. import tolerance Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVP074, Edition Number: M-433257-01-1 EPA MRID No.: 48843928 Date: 2012-06-27 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.3.2.18 /02	Resende, G.	2012	Amendment 01 to the final report - Determination of residues of BYI 02960 and its metabolites, in coffee after drench application at the base of the plants, followed by foliar application of BYI 02960 (200 SL) in field trials in Brazil Departamento de Registro Bayer CropScience, São Paulo, Brazil Bayer CropScience, Report No.: I11-008, Report includes Trial Nos.: I11-008-01 I11-008-02 I11-008-04 I11-008-05 Edition Number: M-427469-03-2 EPA MRID No.: 48843944 Date: 2012-03-09 ...Amended: 2012-07-02 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.3.2.19 /01	Krolski, M. E.	2012	BYI 02960 200 SL - Magnitude of the residue in/on hops Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY008, Report includes Trial Nos.: RV047-11HA RV048-11HA RV049-11HA Edition Number: M-432695-01-1 EPA MRID No.: 48843929 Date: 2012-06-12 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.4.1 /01	Wade, J. M.; Netzband, D. J.	2012	BYI 02960 - Magnitude of the residue in laying hens Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVP041, Edition Number: M-428933-01-1 Date: 2012-04-05 GLP/GEP: yes, unpublished ...also filed: KIIA 4.3 /09	Y	Bayer
KIIA 6.4.2 /01	xxx	2012	BYI 02960 - Magnitude of the residue in dairy cows - Amended report xxx Report No.: RARVP050-1, Edition Number: M-428416-02-1 EPA MRID No.: 48843842 Date: 2012-04-03 ...Amended: 2012-05-31 GLP/GEP: yes, unpublished ...also filed: KIIA 4.3 /08 ...also filed: KIIA 6.1.1 /02	Y	Bayer
KIIA 6.5.1 /01	Weber, E.	2011	Nature of the residues of [pyridinylmethyl-14C]BYI02960 in processed commodities - High temperature hydrolysis Bayer CropScience, Report No.: MEF-10/856, Edition Number: M-402311-01-2 EPA MRID No.: 48843966 Date: 2011-02-09 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.5.4 /01	Schulte, G.; Bauer, J.	2012	Determination of the residues of BYI 02960 in/on lettuce and head lettuce and the processed fractions (head, inner parts; leaf, outer; leaf, inner; leaf, inner, washed and washings) after spraying of BYI 02960 SL 200 in the field in the Netherlands, Belgium and Germany Bayer CropScience, Report No.: 10-3223, Report includes Trial Nos.: 10-3223-01 10-3223-02 10-3223-04 10-3223-05 Edition Number: M-426982-01-2 EPA MRID No.: 48843947 Date: 2012-03-07 GLP/GEP: no, unpublished ...also filed: KIIA 6.5.4.1 /01	N	Bayer
KIIA 6.5.4 /02	Schulte, G.; Bauer, J.	2012	Determination of the residues of BYI 02960 in/on hop (cone, green and cone, kiln-dried) and the processed fractions (hops draff, brewer's yeast and beer) after spraying of BYI 02960 SL 200 in the field in Germany Bayer CropScience, Report No.: 10-3407, Report includes Trial Nos.: 10-3407-01 10-3407-02 Edition Number: M-425311-01-1 Date: 2012-02-13 GLP/GEP: yes, unpublished ...also filed: KIIA 6.5.4.2 /01	N	Bayer

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
KIIA 6.5.4.1 /01	Schulte, G.; Bauer, J.	2012	Determination of the residues of BYI 02960 in/on lettuce and head lettuce and the processed fractions (head, inner parts; leaf, outer; leaf, inner; leaf, inner, washed and washings) after spraying of BYI 02960 SL 200 in the field in the Netherlands, Belgium and Germany Bayer CropScience, Report No.: 10-3223, Report includes Trial Nos.: 10-3223-01 10-3223-02 10-3223-04 10-3223-05 Edition Number: M-426982-01-2 EPA MRID No.: 48843947 Date: 2012-03-07 GLP/GEP: no, unpublished ...also filed: KIIA 6.5.4 /01	N	Bayer
KIIA 6.5.4.2 /01	Schulte, G.; Bauer, J.	2012	Determination of the residues of BYI 02960 in/on hop (cone, green and cone, kiln-dried) and the processed fractions (hops draff, brewer's yeast and beer) after spraying of BYI 02960 SL 200 in the field in Germany Bayer CropScience, Report No.: 10-3407, Report includes Trial Nos.: 10-3407-01 10-3407-02 Edition Number: M-425311-01-1 Date: 2012-02-13 GLP/GEP: yes, unpublished ...also filed: KIIA 6.5.4 /02	N	Bayer
KIIA 6.5.4.3 /01	Schulte, G.; Teubner, L.	2012	Processing Study - Determination of the residues of BYI 02960 in/on orange (fruit and pulp) and the processed fractions (fruit, stored; whole fruit, washed; washings; raw juice; pomace, wet; pomace, dried; juice; marmalade; pulp; peel; peel washed; peel without oil; oil) after spraying of BYI 02960 SL 200 in the field in Spain Bayer CropScience, Report No.: 10-3405, Report includes Trial Nos.: 10-3405-01 10-3405-02 Edition Number: M-439410-01-1 Date: 2012-10-01 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.5.4.3 /02	Lenz, C.	2012	BYI 02960 200 SL - Magnitude of the residue in/on orange processed commodities Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY035, Edition Number: M-432186-01-2 EPA MRID No.: 48843954 Date: 2012-06-01 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.5.4.4 /01	Schulte, G.; Bauer, J.	2012	Amendment No. 1 - Determination of the residues of BYI 02960 in/on apple and the processed fractions (whole fruit, washed; washings; raw sauce; strain rest; sauce; pomace, wet; pomace, dried; raw juice; juice, retentate; peel; fruit peeled; fruit, dried) after spraying of BYI 02960 SL 200 in the field in Germany and Belgium Bayer CropScience, Report No.: 10-3171, Report includes Trial Nos.: 10-3171-03 10-3171-06 Edition Number: M-434004-02-1 Date: 2012-07-05 ...Amended: 2012-09-28 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.5.4.4 /02	Schulte, G.; Ballmann, C.	2012	Determination of the residues of BYI 02960 in/on apple and the processed fractions (whole fruit, washed; washings; raw sauce; strain rest; sauce; pomace, wet; pomace, dried; raw juice; retentate; and juice) after spray application of BYI 02960 SL 200 in the field in Italy and Spain Bayer CropScience, Report No.: 10-3172, Report includes Trial Nos.: 10-3172-03 10-3172-06 Edition Number: M-434006-01-2 Date: 2012-07-05 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.5.4.5 /01	Noss, G.; Teubner, L.	2012	Determination of the residues of BYI 02960 in/on peach and the processed fractions (whole fruit, washed; washings; peel; fruit, peeled and preserve) after spraying of BYI 02960 SL of BYI 02960 SL 200 in the field in Spain and Italy Bayer CropScience, Report No.: 10-3216, Report includes Trial Nos.: 10-3216-02 10-3216-03 Edition Number: M-439376-01-1 Date: 2012-10-08 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.5.4.6 /01	Noss, G.; Bauer, J.; Ruhl, S.	2011	Determination of the residues of BYI 02960 in/on grape and the processed fractions (pomace, grape; must; wine at bottling; wine at first taste test, juice, pasteurised; jelly; washings; raisin waste; raisin) after spraying of BYI 02960 SL 200 in the field in Germany Bayer CropScience, Report No.: 10-3406, Report includes Trial Nos.: 10-3406-01 10-3406-02 10-3406-03 10-3406-04 Edition Number: M-433545-01-1 EPA MRID No.: 48843953 Date: 2011-09-07 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.5.4.7 /01	Schulte, G.; Ruhl, S.	2012	Processing study - Determination of the residues of BYI 02960 in/on beet, sugar and processed fractions (body, washed; washings; pulp; raw juice; thin juice; cake, lime; thick juice; molasses; raw sugar; white sugar; pulp, extracted, wet; press liquor; pulp, extracted, pressed; pulp, extracted, dry; pulp, extracted, ensiled; and refined sugar) after spraying and incorporation of BYI 02960 SL 200 in the field in Germany Bayer CropScience, Report No.: 10-3408, Report includes Trial Nos.: 10-3408-01 10-3408-02 Edition Number: M-439824-01-1 Date: 2012-10-18 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.5.4.8 /01	Schulte, G.; Ballmann, C.	2012	Amendment No. 2 - Determination of the residues of BYI 02960 in/on tomato and the processed fractions (whole fruit, washed; washings; strain rest; raw juice; juice; raw puree; puree; paste; peel; peeling water; fruit peeled; preserve and tomato, dried) after spraying of BYI 02960 SL 200 in the field in southern France, Italy, Spain and Portugal Bayer CropScience, Report No.: 10-3186, Report includes Trial Nos.: 10-3186-01 10-3186-02 10-3186-03 10-3186-04 Edition Number: M-427003-03-1 Date: 2012-03-08 ...Amended: 2012-09-28 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.5.4.9 /01	Schulte, G.; Ruhl, S.	2012	Determination of the residues of BYI 02960 in/on cucumber and the processed fractions (washings; whole fruit, washed; preserve; brine; and fruit, fermented) after spraying of BYI 02960 SL 200 in the field in France (south) - Processing study Bayer CropScience, Report No.: 10-3184, Report includes Trial Nos.: 10-3184-01 10-3184-04 Edition Number: M-438180-01-1 Date: 2012-09-06 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.5.4.10 /01	Schulte, G.; Ruhl, S.	2012	Processing study - Determination of the residues of BYI 02960 in/on spring barley and the processed fractions (malt sprouts; brewer's malt; brewer's grain, hops draff; brewer's yeast; beer; pearl barley; pearl barley rub off) after spraying of BYI 02960 SL 200 in the field in Germany Bayer CropScience, Report No.: 10-3410, Report includes Trial Nos.: 10-3410-01 10-3410-02 Edition Number: M-439853-01-1 Date: 2012-10-16 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.5.4.11 /01	Schulte, G.; Bauer, J.	2012	Processing study - Determination of the residues of BYI 02960 in/on wheat and the processed fractions (semolina; semolina bran; whiteflour bran; white flour; white bread; whole meal; wholemeal bread and wheat germ) after spraying of BYI 02960 SL 200 in the field in Germany Bayer CropScience, Report No.: 10-3409, Report includes Trial Nos.: 10-3409-01 10-3409-02 Edition Number: M-440307-01-1 Date: 2012-10-30 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.5.4.11 /02	Lenz, C.; Fischer, D. R.	2012	BYI 02960 200 SL - Magnitude of the residue in/on wheat processed commodities Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY031, Edition Number: M-427047-01-2 EPA MRID No.: 48843959 Date: 2012-03-13 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.5.4.12 /01	Hoag, R. E.	2012	BYI 02960 200 SL - Magnitude of the residue in/on processed commodities for coffee; U.S., Canada and E.U. import tolerance Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVP075, Edition Number: M-433200-01-1 EPA MRID No.: 48843950 Date: 2012-06-26 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.5.4.13 /01	Lenz, C.	2012	BYI 02960 200 SL - Magnitude of the residue in/on field corn processed commodities Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY030, Edition Number: M-424774-01-1 EPA MRID No.: 48843951 Date: 2012-02-09 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.5.4.14 /01	Lenz, C.; Beedle, E.	2012	BYI 02960 200 SL - Magnitude of the residue in cotton processed commodities (crop subgroup 20C) Bayer Corporation, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY033, Edition Number: M-433122-01-1 EPA MRID No.: 48843952 Date: 2012-06-22 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.5.4.15 /01	Lenz, C.	2012	BYI 02960 200 SL - Magnitude of the residue in/on peanut processed commodities Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY032, Report includes Trial Nos.: RV274-10PA RV275-10PA Edition Number: M-430523-01-2 EPA MRID No.: 48843955 Date: 2012-05-08 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.5.4.16 /01	Lenz, C.	2012	BYI 02960 200 SL - Magnitude of the residue in/on potato processed commodities Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY038, Edition Number: M-430542-01-2 EPA MRID No.: 48843956 Date: 2012-05-07 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.5.4.17 /01	Lenz, C.	2012	BYI 02960 200 SL - Magnitude of the residue in/on soybean processed commodities Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVY029, Report includes Trial Nos.: RV268-10PA RV269-10PA Edition Number: M-428939-01-2 EPA MRID No.: 48843957 Date: 2012-04-04 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.5.4.18 /01	Fischer, D. R.	2012	BYI 02960 200 SL - Request for Waiver of the requirements for the BYI 02960 magnitude of the residue in sugarcane processed commodities in Florida (rotational crop regional tolerance) Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RARVX001, Report includes Trial Nos.: RV288-10PA Edition Number: M-432700-01-1 EPA MRID No.: 48843960 Date: 2012-06-18 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.6.2 /01	A. Klemptner	2011	Metabolism of [furanone-4-14C]BYI 02960 in confined rotational crops Bayer CropScience, Report No.: MEF-11/365, Edition Number: M-421861-01-3 EPA MRID No.: 48843961 Date: 2011-12-16 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.6.2 /02	Breuer-Rehm, M.	2011	Metabolism of [pyridinylmethyl-14C]BYI 02960 in confined rotational crops Bayer CropScience, Report No.: MEF-10/892, Edition Number: M-419853-02-1 EPA MRID No.: 48843962 Date: 2011-12-02 ...Amended: 2012-02-22 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.6.3 /01	Schoening, R.; Bauer, J.	2012	Determination of the residues of BYI 02960 in/on the field rotational crops barley, carrot, lettuce and turnip after spray application of BYI 02960 SL 200 on lettuce and soil in the field in Germany, the Netherlands, France (South) and Spain Bayer CropScience, Report No.: 10-2503, Report includes Trial Nos.: 10-2503-01 10-2503-02 10-2503-03 10-2503-04 Edition Number: M-429091-02-1 Date: 2012-04-11 ...Amended: 2013-01-24 GLP/GEP: yes, unpublished ...also filed: KIIA 6.6.3.1.1 /01	N	Bayer
KIIA 6.6.3.1.1 /01	Schoening, R.; Bauer, J.	2012	Determination of the residues of BYI 02960 in/on the field rotational crops barley, carrot, lettuce and turnip after spray application of BYI 02960 SL 200 on lettuce and soil in the field in Germany, the Netherlands, France (South) and Spain Bayer CropScience, Report No.: 10-2503, Report includes Trial Nos.: 10-2503-01 10-2503-02 10-2503-03 10-2503-04 Edition Number: M-429091-02-1 Date: 2012-04-11 ...Amended: 2013-01-24 GLP/GEP: yes, unpublished ...also filed: KIIA 6.6.3 /01	N	Bayer

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
KIIA 6.6.3.1.2 /01	Schulte, G.	2012	Determination of the residues of BYI 02960 in/on the field rotational crop potato after spray application of BYI 02960 SL 200 to bare soil in the field in northern France, the Netherlands, Spain and Italy - Limited rotational crop study Bayer CropScience, Report No.: 11-2550, Report includes Trial Nos.: 11-2550-01 11-2550-02 11-2550-03 11-2550-04 Edition Number: M-438341-01-1 Date: 2012-09-10 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.6.3.1.3 /01	Schulte, G.	2012	Determination of the residues of BYI 02960 in/on the field rotational crop leek after spray application of BYI 02960 SL 200 to bare soil in the field in northern France, Germany, Spain and Italy - Limited rotational crop study Bayer CropScience, Report No.: 11-2551, Report includes Trial Nos.: 11-2551-01 11-2551-02 11-2551-03 11-2551-04 Edition Number: M-438384-01-1 Date: 2012-09-13 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.6.3.1.4 /01	Schulte, G.	2012	Determination of the residues of BYI 02960 in/on the field rotational crop cucumber after spray application of BYI 02960 SL 200 to bare soil in the field in northern France, Germany, Spain and Italy - Limited rotational crop study Bayer CropScience, Report No.: 11-2552, Report includes Trial Nos.: 11-2552-01 11-2552-02 11-2552-03 11-2552-04 Edition Number: M-438343-01-1 Date: 2012-09-13 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.6.3.1.5 /01	Schulte, G.	2012	Determination of the residues of BYI 02960 in/on the field rotational crop onion after spray application of BYI 02960 SL 200 on bare soil in the field in France (North), Germany, Italy and Spain - Limited rotational crop study Bayer CropScience, Report No.: 11-2553, Report includes Trial Nos.: 11-2553-01 11-2553-02 11-2553-03 11-2553-04 Edition Number: M-438397-01-1 Date: 2012-09-14 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.6.3.1.6 /01	Schulte, G.	2012	Amendment no. 1 to report no: 11.2555 - Determination of the residues of BYI 02960 in/on the field rotational crop french bean after spray application of BYI 02960 SL 200 to bare soil in the field in northern France, Germany, Italy and Spain - Limited rotational crop study Bayer CropScience, Report No.: 11-2555, Report includes Trial Nos.: 11-2555-01 11-2555-02 11-2555-03 11-2555-04 Edition Number: M-438394-02-1 Date: 2012-09-14 ...Amended: 2012-09-27 GLP/GEP: yes, unpublished	N	Bayer

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
KIIA 6.6.3.1.7 /01	Schulte, G.	2012	Determination of the residues of BYI 02960 in/on the field rotational crop pea after spray application of BYI 02960 SL 200 on bare soil in the field in France (North), Germany, Italy and Spain - Limited rotational crop study Bayer CropScience, Report No.: 11-2556, Report includes Trial Nos.: 11-2556-01 11-2556-02 11-2556-03 11-2556-04 Edition Number: M-438582-01-1 Date: 2012-09-17 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.6.3.1.8 /01	Schulte, G.	2012	Determination of the residues of BYI 02960 in/on the field rotational crop rape after spray application of BYI 02960 SL 200 on bare soil in the field in northern France, Germany, Italy and Spain Bayer CropScience, Report No.: 11-2554, Report includes Trial Nos.: 11-2554-01 11-2554-02 11-2554-03 11-2554-04 Edition Number: M-443092-01-1 Date: 2012-12-07 GLP/GEP: yes, unpublished	N	Bayer
KIIA 6.6.3.2 /01	Krolski, M. E.; Dallstream, K. A.	2012	BYI 02960, fenamidone, fluopyram, and spiromesifen - Magnitude of the residue in sugarcane in Florida (rotational crop regional Tolerance) Bayer CropScience LP, RTP, NC, USA Bayer CropScience, Report No.: RARVP030, Report includes Trial Nos.: RV001-11RA RV002-11RA RV286-10RA RV287-10RB Edition Number: M-432179-01-2 EPA MRID No.: 48843964 Date: 2012-05-25 GLP/GEP: yes, unpublished	N	Bayer

Deltamethrine

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1 / 01	Grigor, A. F.	1990	Storage stability study for combined residues of tralomethrin, deltamethrin and trans-deltamethrin in lettuce in a freezer stability study. Chemalysis, Inc., USA Bayer Report No.: A73531 Edition Number: M-151815-01-1 Date: 1990-03-01 GLP/GEP: No, unpublished	No	Bayer
KCA 6.1 / 02	Grigor, A. F.	1991	Supplement to: Determination of the combined residues of tralomethrin, deltamethrin and trans-deltamethrin in lettuce in a freezer stability study. Chemalysis, Inc., USA Bayer Report No.: A71112 Edition Number: M-149583-01-1 Date: 1991-11-11 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.1 / 03	Ballesteros, C.	2012	Storage stability of residues of deltamethrin (AE F032640) and its isomers AE F108569 and AE 0035073 in orange during deep freeze storage for up to 24 months Bayer Report No.: 09-07 Edition Number: M-441996-01-1 Date: 2012-11-19 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.1 / 04	Czarnecki, J. J.	1996	Amended summary report covering submission guidelines for magnitude of the residue (171-4(k)), processed food/feed (171-4(l)), residue methodology (171-4(c)) and storage stability (171-4(e)) for residues of deltamethrin and its metabolites AgrEvo USA Company, Pikeville, NC, USA Bayer Report No.: A55828 Edition Number: M-139715-01-1 Date: 1996-10-22 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.1 / 05	Anon.	2015	Deltamethrin - AIR 3 renewal Bayer - 014/01279 - UK CRD request on residues (dated 09-10-2015) Bayer Report No.: M-536440-01-1 Date: 2015-10-09 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1 / 06	Sadler, T.	2019	Linearity data for method HRAV-10 and method DGM F01/97-0 Bayer Report No.: M-646787-01-1 Date: 2019-01-18 GLP/GEP: n.a., unpublished ... also filed: KCA 4.1.2 / 58	No	Bayer
KCA 6.1 / 07	Rose, S. J.	1985	One-year storage stability of tralomethrin and deltamethrin in soybean seeds. Tegeris Laboratories, Inc., Laurel, MD, USA Bayer Report No.: A73611 Edition Number: M-151894-01-1 Date: 1985-05-06 GLP/GEP: No, unpublished	No	Bayer
KCA 6.1 / 08	Czarnecki, J. J.	1996	Amended summary report covering submission guidelines for magnitude of the residue, processed food/feed, storage stability, and residue methodology for residues of deltamethrin, and metabolites, trans-deltamethrin and alpha-R-deltamethrin, AgrEvo USA Company, Pikeville, NC, USA Bayer Report No.: A55837 Edition Number: M-139724-01-1 Date: 1996-10-22 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.1 / 09	Hsu, R. S.; Czarnecki, J. J.; Kwiatkoski, D. M.	1993	Summary report covering submission guidelines for magnitude of the residue [171-4 (k)], processed food/feed [171-4 (l)], storage stability [171-4(e)] and residue methodology [171-4 (c)] for residues of tralomethrin and its metabolites delta Huntingdon Analytical Services, Middleport, NY, USA Bayer Report No.: A73997 Edition Number: M-152266-01-1 Date: 1993-08-02 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1 / 10	Czarnecki, J. J.; Hsu, R. S.; Kwiatkoski, D. M.	1992	Summary report covering magnitude of the residue, storage stability and residue analytical method for residues of tralomethrin and its metabolites (deltamethrin and trans-deltamethrin) in or on tomatoes. Huntingdon Analytical Services, Middleport, NY, USA Bayer Report No.: A73998 Edition Number: M-152267-01-1 Date: 1992-12-21 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.1 / 11	Singer, G. M.	1999	At harvest deltamethrin-derived residues in cabbage following eight applications of DECIS (R) at the maximum proposed rate and the shortest proposed PHI, USA, 1998 AgrEvo USA Company, Pikeville, NC, USA Bayer Report No.: C002732 Edition Number: M-184972-01-1 Date: 1999-04-23 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.1 / 12	McKinney, F. R.; Clayton, F. B.	1991	Stability of Tralomethrin, cis-Deltamethrin and trans-Deltamethrin in cottonseed under freezer storage conditions [with alpha-R-Deltamethrin and stability in processed commodities (cottonseed fractions) added by amendment] EN-CAS Analytical Laboratories, Winston-Salem, NC, USA Bayer Report No.: C038177 Report includes Trial Nos.: ECRCNC91ENCAA1US890011 Edition Number: M-224446-01-1 Date: 1991-10-09 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.1 / 13	Williams, L.	2000	Stability of Deltamethrin Residues in Cabbage During Frozen Storage, USA, 1999 Aventis CropScience USA LP, RTP, NC, USA Bayer Report No.: B002954 Report includes Trial Nos.: BP99R001 Edition Number: M-238621-01-1 Date: 2000-09-13 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2 / 01	Ruzo, L. O.; Casida, J. E.	1979	Degradation of Decamethrin on Cotton Plants Journal: Journal of Agricultural and Food Chemistry Volume: 27 Issue: 3 Pages: 572-575 Year: 1979 Report No.: A20237 Edition Number: M-093407-01-1 GLP/GEP: n.a., published	No	published
KCA 6.2 / 02	Salmon, J.; van Assche, C. J.; Salmon, M.	1977	Etude preliminaire de l'absorption et du transport de RU 22974 sur coton. Procida, Les Algorithmes, Gif sur Yvette, France Bayer Report No.: A71134 Edition Number: M-149605-01-1 Date: 1977-09-13 GLP/GEP: No, unpublished	No	Bayer
KCA 6.2 / 03	Merricks, L.; Swidersky, P.	1985	Identification of the residues of (14C)-labeled deltamethrin, Decis, in the tomato plant Agriseach UK Ltd., Melbourne, United Kingdom Bayer Report No.: A41994 Edition Number: M-125042-01-1 Date: 1985-04-24 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.2 / 04	Krebs, B.; Eickhoff, H.; Raquet, H.; Thier, W.	1986	Deltamethrin - Bestimmung von Rueckstaenden in Gemuesekulturen nach Aufnahme aus kontaminiertem Boden Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A34266 Edition Number: M-115043-01-1 Date: 1986-06-06 GLP/GEP: No, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2 / 05	Erstfeld, K. M.; Larson, J. D.; Lange, B. D.	1994	C-14 Deltamethrin: Confined Accumulation in Rotational Crops 30 and 120 Day Experiment Pan-Agricultural Laboratories, Inc., Madera, CA, USA Bayer Report No.: A47914 Report includes Trial Nos.: 89-0101 Edition Number: M-136651-02-1 Date: 1991-08-26 ... amended: 1994-05-06 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.2 / 06	Periasamy, R.; Kimmel, E. C.; Toia, R. F.	1994	Metabolism of [14C-acid] and [14C-alcohol] Decis (deltamethrin) in apples PTRL West, Inc., Richmond, CA, USA Bayer Report No.: A71034 Edition Number: M-149515-01-1 Date: 1994-01-18 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.2 / 07	Periasamy, R.; Kimmel, E. C.; Toia, R. F.	1994	Metabolism of [14C-Acid] and [14C-Alcohol] Decis (deltamethrin) in field corn. PTRL West, Inc., Richmond, CA, USA Bayer Report No.: A71098 Edition Number: M-149571-01-1 Date: 1994-02-11 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.2 / 08	Timme, G.; Frehse, H.; Laska, V.	1986	Statistical interpretation and graphic representation of the degradational behaviour of pesticide residues. II. Journal: Pflanzenschutz-Nachrichten Bayer Volume: 39 Issue: 2 Pages: 188-204 Year: 1986 Report No.: A53503 Edition Number: M-121089-01-2 GLP/GEP: n.a., published	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2 / 09	Fisher, P. J.	2000	Conversion of tralomethrin to deltamethrin in mammals (expert summary) Aventis CropScience S.A., Lyon, France Bayer Report No.: C009954 Edition Number: M-199580-01-1 Date: 2000-10-02 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.2 / 10	xxx	1982	Pyrethroid metabolism: comparative fate in rats of tralomethrin, traloccythrin, deltamethrin and (1R,α S)-cis- cypermethrin. xxx Volume: 30 Pages: 631-636 Year: 1982 Report No.: A71114 Edition Number: M-149585-01-1 GLP/GEP: n.a., published ... also filed: KCA 5.1 / 01	Yes	published
KCA 6.2 / 11	xxx	1990	Metabolism of 14C-tralomethrin in rats. xxx Bayer Report No.: A73039 Edition Number: M-151332-01-1 Date: 1990-04-05 GLP/GEP: Yes, unpublished ... also filed: KCA 5.1.1 / 01	Yes	Bayer
KCA 6.2 / 12	xxx	2016	Deltamethrin - Additional information on residues and metabolism xxx Report No.: M-560007-01-1 Date: 2016-07-21 GLP/GEP: n.a., unpublished	Yes	Bayer
KCA 6.2 / 13	Christian, I.	2019	Deltamethrin - Occurrence of metabolites in the rat, plants and livestock Bayer Report No.: M-646371-01-1 Date: 2019-01-03 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2 / 14	Christian, I.	2019	Summary of the toxicological and metabolism studies for Ddmethrin - ADME studies already evaluated during previous Annex I inclusion Bayer Report No.: M-646370-01-1 Date: 2019-01-14 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.2.1 / 01	O'Grodnick, J. S.; Larson, J. D.	1990	14C-deltamethrin: Nature of the residue in cotton. Hazleton Laboratories America, Inc., USA Bayer Report No.: A71094 Edition Number: M-149567-01-1 Date: 1990-09-12 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.2.1 / 02	Larson, J. D.	1994	14C-deltamethrin: Nature of the residue in cotton (analytical phase - supplements number 1 and 2) Hazleton Laboratories America, Inc., USA Bayer Report No.: A71095 Edition Number: M-191128-02-1 Date: 1991-08-26 ... amended: 1994-05-06 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.2.1 / 03	Salmon, J.; van Assche, C. J.; Salmon, M.	1977	Preliminary uptake - Translocation studies of Ru 22974 in cotton. Procida, Les Algorithmes, Gif sur Yvette, France Bayer Report No.: A41995 Edition Number: M-149605-01-2 Date: 1977-09-13 GLP/GEP: No, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2.2 / 01	xxx	1985	Metabolism, distribution, and excretion of deltamethrin by leghorn hens. xxx Volume: 33 Issue: 4 Pages: 610-617 Year: 1985 Report No.: A35015 Edition Number: M-116708-01-1 GLP/GEP: n.a., published ... also filed: KCA 5.1.1 / 06 KCA 5.1.2 / 06	Yes	published
KCA 6.2.2 / 02	xxx	1994	Equivalent mixture of (14C-phenyl)-cypermethrin, (14C-benzyl)-deltamethrin and (14C-phenoxyphenyl)-fenvaterate: Distribution - kinetics and excretion after single oral administration to laying hens xxx Report No.: A52315 Edition Number: M-133155-01-1 Date: 1994-03-30 GLP/GEP: Yes, unpublished ... also filed: KCA 5.1.1 / 03	Yes	Bayer
KCA 6.2.2 / 03	xxx	1993	(14C-Benzyl)-deltamethrin: Distribution - Kinetics and Excretion after single intravenous Administration to laying Hens xxx Report No.: A51514 Edition Number: M-132448-01-1 Date: 1993-08-05 GLP/GEP: Yes, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2.3 / 01	xxx	1986	Fate of 14C-Deltamethrin in lactating dairy cows. xxx Volume: 34 Issue: 4 Pages: 753-758 Year: 1986 Report No.: A34280 Edition Number: M-115057-01-1 GLP/GEP: n.a., published ... also filed: KCA 5.1.1 / 07 KCA 5.1.2 / 07	Yes	published
KCA 6.2.3 / 02	xxx	1995	Metabolism of 14C-benzyl-tralomethrin and 14C-gem-dimethyl-tralomethrin in lactating dairy cattle and storage stability of tralomethrin and deltamethrin in cow milk and tissues. xxx Report No.: A70045 Report includes Trial Nos.: HR-01-88 Edition Number: M-148609-02-1 Date: 1991-09-27 ... amended: 1995-11-07 GLP/GEP: Yes, unpublished ... also filed: KCA 6.4.2 / 05	Yes	Bayer
KCA 6.2.5 / 01	xxx	1993	Deltamethrin: Bioconcentration exposure with Bluegill Sunfish (Lepomis macrochirus) and identification of resulting metabolites. xxx Report No.: A70918 Report includes Trial Nos.: 1719.0393.6231.140 Edition Number: M-149401-01-1 Date: 1993-12-20 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 6.3 / 01	Fuchsbichler, G.	1990	Hoe 032640 (deltamethrin): Storage stability in hops and beer (storage interval 5 1/2 months). Bayer Report No.: A71869 Edition Number: M-150246-01-1 Date: 1990-03-29 GLP/GEP: No, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 02	McKinney, F. R.; Clayton, F. B.	1995	Stability of tralomethrin, cis-deltamethrin and trans-deltamethrin in cottonseed under freezer storage conditions (with alpha- R-Deltamethrin and stability in processed commodities, cottonseed fractions, added by amendment). EN-CAS Analytical Laboratories, Winston-Salem, NC, USA Bayer Report No.: A71103 Edition Number: M-149576-01-1 Date: 1995-01-11 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 03	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in animal feed. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71894 Edition Number: M-150269-01-1 Date: 1995-03-22 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 04	de Wilde, G.	1995	Deltamethrin: Residue data summary from supervised trials in legume vegetables (fresh): Beans and peas with pods. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71733 Edition Number: M-150126-01-1 Date: 1995-03-21 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 05	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in stem vegetables: Asparagus. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71770 Edition Number: M-150158-01-1 Date: 1995-03-27 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 06	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in pulses: dry bean, dry lentils, dry peas. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71886 Edition Number: M-150261-01-1 Date: 1995-04-03 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 07	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in hops. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71842 Edition Number: M-150219-01-1 Date: 1995-03-21 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 08	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in cacao. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71872 Edition Number: M-150249-01-1 Date: 1995-03-21 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 09	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in coffee. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71895 Edition Number: M-150270-01-1 Date: 1995-03-30 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 10	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in Citrus. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71438 Edition Number: M-149870-01-1 Date: 1995-03-13 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 11	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in stone fruits: Apricots, cherries, peaches, plums. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71519 Edition Number: M-149932-01-1 Date: 1995-03-15 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 12	de Wilde, G.	1995	Deltamethrin: Residues data summary trials in berries: Grapes (wine and table grapes). Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71536 Edition Number: M-149946-01-1 Date: 1995-03-15 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 13	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in leaf vegetables and fresh herbs: Lettuce and similar. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71692 Edition Number: M-150086-01-1 Date: 1995-03-17 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 14	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in leaf vegetables, fresh herbs - Celery. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71730 Edition Number: M-150123-01-1 Date: 1995-03-20 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 15	Moede, J.	1996	Report on plant protection residue trial. (Hoe 032640, Prunus persica var persica and var nucipersica) AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom Bayer Report No.: A56981 Edition Number: M-140755-01-1 Date: 1996-06-11 GLP/GEP: No, unpublished	No	Bayer
KCA 6.3 / 16	Klein, E. H. J.; Buerstell, H.	1996	Deltamethrin; Emulsifiable granules 6.25 % w/w; Code: AE F032640 00 EG06 A103 -Residue trials in peas (canning) to confirm maximum residue level compliance. Determination of active substance at harvest following three applications. European Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A56787 Edition Number: M-140572-01-1 Date: 1996-10-07 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 17	Klein, E. H. J.; Martens, R.	1997	Residues trials in peaches to confirm Maximum Residue Level compliance. Determination of active substance following 3 applications. European Union, Southern zone, 1996. Deltamethrin - emulsifiable granules 62.5 a.s./kg. Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A74186 Edition Number: M-152437-01-1 Date: 1997-08-11 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 18	Klein, E. H. J.; Martens, R.	1997	Residue trials in green beans to confirm Maximum Residue Level compliance. Determination of active substance following two applications. European Union, Northern zone 1996. Deltamethrin - EG emulsifiable granules 62.5 g as/kg Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A74188 Edition Number: M-152439-01-1 Date: 1997-07-25 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 19	Klein, E. H. J.; Martens, R.	1997	Residue trials in green beans to confirm Maximum Residue Level compliance. Determination of active substance following two applications. European Union, Southern zone 1996. Deltamethrin - emulsifiable granules 62.5 g a.s./kg. Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A74187 Edition Number: M-152438-01-1 Date: 1997-07-28 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 20	Klein, E. H. J.; Moede, J.	1996	Deltamethrin EG (emulsifiable granules) 6.25 %; Code: Hoe 032640 00 EG06 A102 -Determination of residues of Hoe 032640 to verify the existing maximum residue level following 3 applications in lettuce under field and plastic covered green ho Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A55221 Edition Number: M-139191-01-1 Date: 1996-05-03 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 21	Klein, E. H. J.; Moede, J.	1996	Deltamethrin; emulsifiable granules 6.25 % w/w; Code: AE F032640 00 EG06 A103 -Determination of residues of AE F032640 to verify the existing maximum residue level following three applications in lettuce under field conditions. 1995 Europea Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A56782 Edition Number: M-140567-01-1 Date: 1996-09-17 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 22	McKinney, F. R.	1994	Determination of freezer residue stability for deltamethrin (alpha-R, cis, and trans) and tralomethrin in poultry tissues. EN-CAS Analytical Laboratories, Winston-Salem, NC, USA Bayer Report No.: A54085 Edition Number: M-134680-01-1 Date: 1994-08-12 GLP/GEP: Yes, unpublished ... also filed: KCA 6.4.1 / 02	No	Bayer
KCA 6.3 / 23	Klein, E. H. J.	2001	Residues at harvest in kidney beans, green European Union, Southern zone 2000 Deltamethrin, AE F032640 emulsifiable concentrate (EC) 2.81 % w/w (= 25 g/L) Code: AE F032640 00 EC03 B005 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C016472 Edition Number: M-202465-01-1 Date: 2001-11-28 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 24	Klein, E. H. J.; Martens, R.	2000	Residues at harvest in walnuts European Union (northern zone) 1999 Deltamethrin emulsifiable granule (EG) 6.25 % w/w Code: AE F032640 00 EG06 A107 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C009200 Edition Number: M-198192-01-1 Date: 2000-09-28 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 25	Klein, E. H. J.; Martens, R.	2000	Residues at harvest in hazel-and walnuts European union (southern zone),1999 Deltamethrin, AE F032640 emulsifiable granule 6.25 % w/w Code: AE F032640 00 EG06 A107 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C009201 Edition Number: M-198193-01-1 Date: 2000-10-12 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 26	Davies, P.	2001	Residues at harvest in hazelnuts European Union (Southern zone), 2000 Deltamethrin emulsifiable concentrate (EC) 2.81 % w/w (25 g/L) Code: AE F032640 00 EC03 B007 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C014846 Edition Number: M-207403-01-1 Date: 2001-11-15 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 27	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in tree nuts: Walnut. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71823 Edition Number: M-150203-01-1 Date: 1995-12-15 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 28	Luttringer, M.; Boltz, V.	1995	Rapport d'essai residus. Analyses de residus de deltamethrine sur noix. Institut National de la Recherche Agronomique, France Bayer Report No.: A70667 Edition Number: M-149168-01-1 Date: 1995-03-10 GLP/GEP: No, unpublished	No	Bayer
KCA 6.3 / 29	Neuss, B.	2001	Residue data summary from supervised trials Tree nuts: Hazelnuts and walnuts Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015915 Edition Number: M-201403-01-1 Date: 2001-11-05 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 30	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in pome fruits (apples and pears). Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71460 Edition Number: M-149883-01-1 Date: 1995-03-13 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 31	Kurzmeier, E.	1998	Residues data summary from supervised trials in pome fruit (apples). Additional data Deltamethrin Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C005438 Edition Number: M-192078-01-1 Date: 1998-01-28 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 32	Neuss, B.	2001	Residues data summary from supervised trials - apples Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015916 Edition Number: M-201404-01-1 Date: 2001-11-21 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 33	Klein, E. H. J.	2001	Decline of residues in apples (bridging data) European Union, Southern zone 2000 Deltamethrin emulsifiable concentrate (EC) emulsifiable granule (EG) oil in water formulation (EW) 25 g/L / 6.25 %/ 15 g/L Codes: AE F032640 00 EC03 B005; AE F Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C017035 Edition Number: M-203523-01-1 Date: 2001-11-26 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 34	Klein, E. H. J.; Buerstell, H.	1997	Residue trials in apples to confirm MRL compliance. Determination of a.i. following 5 applications. EU, Southern zone 1996 DT EG 62.5 g/kg Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A74166 Edition Number: M-152417-01-1 Date: 1997-07-02 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 35	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in berries and small fruits: Strawberries. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71556 Edition Number: M-149963-01-1 Date: 1995-03-15 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 36	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in Cane fruits: Raspberries, Blackberries. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71565 Edition Number: M-149972-01-1 Date: 1995-03-15 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 37	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in other small fruits and berries: currants and wild berries. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71567 Edition Number: M-149974-01-1 Date: 1995-03-15 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 38	Klein, E. H. J.	2001	Decline of residues in strawberries (bridging data) European Union, Northern Zone 2000 Deltamethrin EC (emulsifiable concentrate) 25 g/L EG (emulsifiable granule) 6.25 % EW (oil in water emulsion) 15 g/L Codes: AE F032640 00 EC03 B005; AE F Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C016894 Edition Number: M-203252-01-1 Date: 2001-11-27 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 39	Kurzmeier, E.	1998	Residues data summary from supervised trials in berries and small fruits: Strawberries. additional data Deltamethrin Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C005441 Edition Number: M-192084-01-1 Date: 1998-01-30 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 40	Klein, E. H. J.; Buerstell, H.	1996	Deltamethrin; EG (emulsifiable granule) 6.25 % w/w; Code: AE F032640 00 EG06 A102 -Residue trials in strawberries to confirm MRL compliance. Determination of active substance at harvest following 3 applications under field conditions. Europ Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A56783 Edition Number: M-140568-01-1 Date: 1996-09-17 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 41	Klein, E. H. J.; Moede, J.	1996	Deltamethrin EG (emulsifiable granule) 6.25 %; Code: Hoe 032640 00 EG06 A102 - Determination of residues of Hoe 032640 to verify the existing maximum residue level following 3 applications in strawberries under field conditions. Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A55222 Edition Number: M-139192-01-1 Date: 1996-04-26 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 42	Neuss, B.	2001	Residues data summary from supervised trials Berries and small fruit: strawberries Additional data Deltmethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C017004 Edition Number: M-203463-01-1 Date: 2001-11-19 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 43	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in miscellaneous fruits (figs, kiwi, ananas, olives). Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71572 Edition Number: M-149979-01-1 Date: 1995-03-15 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 44	Klein, E. H. J.; Martens, R.	1999	Decline of residues in olives European Union (Southern zone) 1998 Deltamethrin emulsifiable granule (EG) 6.25 % w/w Code: AE F032640 00 EG06 A106 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C005160 Edition Number: M-191497-01-1 Date: 1999-12-21 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 45	Davies, P.	2001	Decline of residues in olives European Union southern zone 2000 deltamethrin emulsifiable concentrate (EC) 2.81 % w/w (25 g/L) Code: AE F032640 00 EC03 B007; AE F032640 00 EC03 B005 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C016290 Edition Number: M-202111-01-1 Date: 2001-12-04 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 46	Neuss, B.	2001	Residues data summary from supervised trials on olives Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015755 Edition Number: M-201124-01-1 Date: 2001-11-19 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 47	Klein, E. H. J.; Martens, R.	2000	Residues at harvest in olives and processed fractions. European Union, Southern zone 1997 Deltamthrin, AE F032640 emulsifiable granule 6.25 % w/W Code: AE F032640 00 EG06 A105 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C010147 Edition Number: M-238971-01-1 Date: 2000-09-21 GLP/GEP: Yes, unpublished ... also filed: KCA 6.5.3 / 03	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 48	Klein, E. H. J.	2001	Residues at harvest in carrots European Union (Southern zone) 2000 Deltamethrin emulsifiable concentrate (EC), 2.81 % w/w = 25 g/L Code: AE F032640 00 EC03 B005 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C016257 Edition Number: M-202047-01-1 Date: 2001-11-05 GLP/GEP: No, unpublished	No	Bayer
KCA 6.3 / 49	Davies, P.	2001	Decline of residues in carrots European Union (Northern zone) 2000 Deltamethrin emulsifiable concentrate (EC) 2.81 % w/w (25 g/L) Code: AE F032640 00 EC03 B007 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C016078 Edition Number: M-201688-01-1 Date: 2001-11-14 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 50	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in bulb vegetables: Onions, Shallots, Garlic. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71606 Edition Number: M-150006-01-1 Date: 1995-03-17 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 51	Holzwarth, U.	2001	Residues data summary from supervised trials Bulb vegetables: Bulb onions - Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015720 Edition Number: M-201054-01-1 Date: 2001-11-02 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 52	Klein, E. H. J.; Martens, R.	1999	Decline of residues in onions European Union, northern zone 1998 Deltamethrin emulsifiable granule (EG) 6.25% w/w Code: AE F032640 00 EG06 A106 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C004595 Edition Number: M-188229-01-1 Date: 1999-10-25 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 53	Klein, E. H. J.; Martens, R.	1999	Decline of residues in onions European Union, southern zone 1998 Deltamethrin emulsifiable granule (EG) 6.25% w/w Code: AE F032640 00 EG06 A106 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C004596 Edition Number: M-188231-01-1 Date: 1999-10-26 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 54	Welcker, H.	1999	Residues at harvest in onions; European Union (northern zone) 1997 - Deltamethrin emulsifiable granule (EG) 6.25% w/w (Code: AE F032640 00 EG06 A105). Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A74344 Edition Number: M-152577-01-1 Date: 1999-02-18 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 55	Klein, E. H. J.	1999	Residues at harvest in onions European Union (southern zone) 1997 Deltamethrin emulsifiable granule (EG) 6.25% w/w Code: AE F032640 00 EG06 A105 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C001500 Edition Number: M-182781-01-1 Date: 1999-02-15 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 56	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in fruiting vegetables: Solanacea (Tomatoes, Peppers, Aubergines). Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71610 Edition Number: M-150010-01-1 Date: 1995-03-20 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 57	Davies, P.	2001	Decline of residues in protected tomatoes European Union (indoor) 2000 Deltamethrin emulsifiable concentrate (EC) 2.81 % w/w (25 g/L) Code: AE F032640 00 EC03 B007 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C016111 Edition Number: M-201758-01-1 Date: 2001-11-23 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 58	Klein, E. H. J.; Buerstell, H.	1997	Residue trials in field tomatoes (industrial use) to confirm MRL compliance. Determination of a.i. substance at harvest following 4 applications. EU Southern zone 1996. Deltamethrin EG 62.5 g/kg Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A74164 Edition Number: M-152415-01-1 Date: 1997-06-24 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 59	Neuss, B.	2001	Residues data summary from supervised trials - tomatoes Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C017003 Edition Number: M-203461-01-1 Date: 2001-11-20 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 60	Klein, E. H. J.	1998	Residue trials in tomatoes to reconfirm a maximum residue level. Determination of a.s. decline following 4 applications under field conditions. European Union (southern zone) 1997 Deltamethrin emulsifiable granule 6.25% Code: AE F032640 00 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C001247 Edition Number: M-182154-01-1 Date: 1998-11-09 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 61	de Wilde, G.	1995	Deltamethrin: Residues data summary supervised trials in Cucurbits with edible peel (Cucumber and gherkin). Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71645 Edition Number: M-150039-01-1 Date: 1995-03-13 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 62	Klein, E.H.-J.	1999	Decline of residues in cucumbers or zucchini European Union (southern zone) 1997 Deltamethrin emulsifiable granule (EG) 6.25% w/w Code: AE F032640 00 EG06 A105 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C002581 Edition Number: M-184758-01-1 Date: 1999-03-16 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 63	Klein, E. H. J.; Buerstell, H.	1999	Residues at harvest in cucumber/zucchini European Union, Southern zone 1998 Deltamethrin emulsifiable granule (EG) 6.25 % w/w Code: AE F032640 00 EG06 A106 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C005161 Edition Number: M-191499-01-1 Date: 1999-11-11 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 64	Davies, P.	2001	Decline of residues in protected cucumbers 2000 Deltamethrin emulsifiable concentrate (EC) 2.81 % w/w (25 g/L) Code: AE F032640 00 EC03 B007 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015571 Edition Number: M-200743-01-1 Date: 2001-11-15 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 65	Neuss, B.	2001	Residue data summary from supervised trials Fruit vegetables: cucurbits with edible peel: cucumber and zucchini Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015759 Edition Number: M-201132-01-1 Date: 2001-11-07 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 66	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in fruiting vegetables with inedible peel: Melon. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71654 Edition Number: M-150048-01-1 Date: 1995-03-13 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 67	Klein, E. H. J.; Martens, R.	1999	Decline of residues in melons European Union, southern zone 1998 Deltamethrin emulsifiable granule (EG) 6.25% w/w Code: AE F032640 00 EG06 A106 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C005490 Edition Number: M-192157-01-1 Date: 1999-10-28 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 68	Holzwarth, U.	2001	Residues data summary from supervised trials Fruiting vegetables: Cucurbits with inedible peel melon - Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015719 Edition Number: M-201052-01-1 Date: 2001-11-02 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 69	Klein, E. H. J.	1998	Residue trials in melons to reconfirm an maximum residue level. Determination of a.s. decline following 4 applications under field conditions. European union (southern zone) 1997 Deltamethrin emulsifiable granule 62.5 g a.s./kg Code: AE F03 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A56781 Edition Number: M-140566-01-1 Date: 1998-09-24 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 70	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in sweet corn. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71661 Edition Number: M-150055-01-1 Date: 1995-03-13 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 71	Klein, E. H. J.	2001	Residues at harvets in sweet corn European Union, Northern zone 2000 Deltamethrin emulsifiable concentrate (EC), 2.81 % w/w (=25 g/L) Code: AE F032640 00 EC03 B005 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C016147 Edition Number: M-201828-01-1 Date: 2001-10-31 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 72	Klein, E. H. J.	2001	Residues at harvest in sweet corn European Union (Southern zone) 2000 Deltamethrin emulsifiable concentrate (EC) 2.81 % w/w (= 25 g/L) Code: AE F032640 00 EC03 B005 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C014943 Edition Number: M-207608-01-1 Date: 2001-10-25 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 73	Holzwarth, U.	2001	Residues data summary from supervised trials Sweet corn - Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015919 Edition Number: M-201410-01-1 Date: 2001-11-02 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 74	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in vegetables - Brassica, Leafy brassica. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71689 Edition Number: M-150083-01-1 Date: 1995-03-20 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 75	Holzwarth, U.	2001	Residues data summary from supervised trials Leaf brassica: Curly kale - Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015756 Edition Number: M-201126-01-1 Date: 2001-11-03 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 76	Klein, E. H. J.; Martens, R.	2000	Residue on harvest in curly kale , European union (northern zone) 1999 Deltamethrin, AE F032640 emulsifiable granule (EG), 6.25 % w/w Code: AE F032640 00 EG06 A107 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C009198 Edition Number: M-198190-01-1 Date: 2000-10-12 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 77	Klein, E. H. J.; Moede, J.	1996	Deltamethrin; emulsifiable granules 6.25 % w/w; Code: Hoe 032640 00 EG06 A103 - Deltamethrin; emulsifiable concentrate 25 g/l; Code: Hoe 032640 00 EC03 B001 - Residue trials in curly kale to confirm maximum residue level compliance. Determi Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A56790 Edition Number: M-140575-01-1 Date: 1996-09-17 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 78	Klein, E. H. J.; Martens, R.	1999	Decline of residues in curly kale European Union, Northern zone 1998 Deltamethrin emulsifiable granule (EG) 6.25 % w/w Code: AE F032640 00 EG06 A106 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C005491 Edition Number: M-192159-01-1 Date: 1999-12-07 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 79	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in leaf vegetables and herbs: Spinach and similar. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71710 Edition Number: M-150104-01-1 Date: 1995-03-17 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 80	Neuss, B.	2001	Residue data summary from supervised trials Leaf vegetables and fresh herbs: Spinach Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015920 Edition Number: M-201412-01-1 Date: 2001-11-06 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 81	Klein, E. H. J.	2001	Residues at harvest in spinach European Union (Southern zone) 2000 Deltamethrin emulsifiable concentrate (EC) 25 g/L, emulsifiable granule (EG) 6.25 g/L, oil in water formulation (EW) 15 g/L Code: AE F032640 00 EC03 B005, AE F032640 00 EG06 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015002 Edition Number: M-199679-01-1 Date: 2001-10-31 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 82	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in leaf vegetables: Witlof (endives). Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71726 Edition Number: M-150119-01-1 Date: 1995-03-17 GLP/GEP: No, unpublished	No	Bayer
KCA 6.3 / 83	Holzwarth, U.	2001	Residues data summary from supervised trials Leaf vegetables and fresh herbs: Witloof (chickory) - Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015722 Edition Number: M-201058-01-1 Date: 2001-11-02 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 84	Klein, E. H. J.	1998	Residue trials on chicory to reconfirm an maximum residue level. Determination of a.s. decline following 3 applications. European Union (Northern zone) 1997 Deltamethrin emulsifiable granule 6.25 % Code: AE F032640 00 EG06 A105 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C001246 Edition Number: M-182150-01-1 Date: 1998-11-24 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 85	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in stem vegetables: Artichokes. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71771 Edition Number: M-150159-01-1 Date: 1995-03-17 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 86	Holzwarth, U.	2001	Residues data summary from supervised trials Leaf and stem vegetables: Garden artichoke - Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015723 Edition Number: M-201060-01-1 Date: 2001-11-02 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 87	Klein, E. H. J.; Buerstell, H.	1996	Deltamethrin; Emulsifiable granules 6.25 % w/w; Code: AE F032640 00 EG06 A103 - Residue trials in artichokes to confirm maximum residue level compliance Determination of active substance at harvest following four applications European Union Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A56780 Edition Number: M-140565-01-1 Date: 1996-10-11 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 88	Klein, E. H. J.; Buerstell, H.	1997	Deltamethrin EG 62.5 g/kg - Residue trials in artichokes to confirm MRL compliance following 4 applications (EU, Southern zone 1996) Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A74152 Edition Number: M-152404-01-1 Date: 1997-06-02 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 89	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in Stem vegetables: Leeks. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71781 Edition Number: M-150169-01-1 Date: 1995-03-21 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 90	Holzwarth, U.	2001	Residues data summary from supervised trials Stem vegetables: Leek Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015758 Edition Number: M-201130-01-1 Date: 2001-11-02 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 91	Klein, E. H. J.	1999	Residues at harvest in leeks European Union (southern zone) 1997 Deltamethrin emulsifiable granule (EG) 6.25% w/w Code: AE F032640 00 EG06 A105 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C001463 Edition Number: M-182694-01-1 Date: 1999-02-15 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 92	Klein, E. H. J.; Martens, R.	1999	Decline of residues in leek European Union (Northern zone) 1998 Deltamethrin emulsifiable granule (EG) 6.25 % w/w Code: AE F032640 00 EG06 A106 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C005162 Edition Number: M-191501-01-1 Date: 1999-12-20 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 93	Klein, E. H. J.; Martens, R.	2000	Residues at harvest in leek European Union (northern zone) 1999 Deltamethrin emulsifiable granule (EG) 6.25 % w/w Code: AE F032640 00 EG06 A107 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C009199 Edition Number: M-198191-01-1 Date: 2000-08-28 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 94	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in Fungi vegetables: Cultivated mushroom. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71788 Edition Number: M-150175-01-1 Date: 1995-03-21 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 95	Holzwarth, U.	2001	Residues data summary from supervised trials Fungi: Cultivated mushroom - Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015925 Edition Number: M-201419-01-1 Date: 2001-11-03 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 96	Balluff, M.	2000	Determination of residues of deltamethrin in mushrooms following two applications of AE F032640 00 EG06 (common name: Decis EG 06) at 2 locations in Germany and France respectively, 1998 Arbeitsgemeinschaft GAB GmbH & IFU GmbH, Germany Bayer Report No.: C008388 Edition Number: M-197450-01-1 Date: 2000-05-02 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 97	Holzwarth, U.	2001	Residues data summary from supervised trials Rape - Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015921 Edition Number: M-201414-01-1 Date: 2001-11-03 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 98	Klein, E. H. J.; Moede, J.	1996	Deltamethrin; Emulsifiable granules 6.25 % w/w; Code: Hoe 032640 00 EG06 A102 - Residue trials in rape to confirm maximum residue level compliance determination of active substance decline following 4 applications European Union (Northern z Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A55220 Edition Number: M-139190-01-1 Date: 1996-08-12 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 99	Neuss, B.	2001	Residue data summary from supervised trials - sunflower Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015923 Edition Number: M-201417-01-1 Date: 2001-12-11 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 100	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in oilseeds: Sunflower seed, Rape seed, Soja bean, Cotton seed. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71790 Edition Number: M-150177-01-1 Date: 1995-03-21 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 101	Klein, E. H. J.; Martens, R.	1999	Decline of residues in sunflower European Union, southern zone, 1998 Deltamethrin emulsifiable granule (EG) 6.25% w/w Code: AE F032640 00 EG06 A106 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C004594 Edition Number: M-188226-01-1 Date: 1999-10-27 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 102	Klein, E. H. J.	2001	Residues at harvest sunflowers European Union, Northern zone 2000 Deltamethrin, AE F032640 emulsifiable concentrate (EC 2.81 % w/w (= 25 g/L) Code: AE F032640 00 EC03 B005 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C016321 Edition Number: M-202174-01-1 Date: 2001-11-28 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 103	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in Oilseeds: Sunflower seed, Rape seed, Soja bean, Cotton seed. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71810 Edition Number: M-150194-01-1 Date: 1995-03-21 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 104	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in potatoes. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71877 Edition Number: M-150252-01-1 Date: 1995-04-03 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 105	Neuss, B.	2001	Residue data summary from supervised trials Potatoes Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015924 Edition Number: M-201418-01-1 Date: 2001-11-12 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 106	Kalter, G. J.; Merz, H. D.	1994	Pirimicarb (100 g/l) und Deltamethrin (7.5 g/l) -Emulgierbares Konzentrat- (Code: Hoe 032640 03 EC11 A202) Untersuchung der Rueckstaende in Kartoffeln nach fuenfmaliger Anwendung von Hoe 032640 03 EC11 A202 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A52611 Edition Number: M-133421-01-1 Date: 1994-12-16 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 107	Klein, E. H. J.; Moede, J.	1996	Deltamethrin; Emulsifiable granules 6.25 % w/w; Code: Hoe 032640 00 EG06 A103 - Residue trials in potatoes to confirm maximum residue level compliance. Determination of active substance at harvest following four applications European Union Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A56789 Edition Number: M-140574-01-1 Date: 1996-08-15 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 108	Klein, E. H. J.; Martens, R.; Werner, H. J.	1999	Decline of residues in potatoes European Union (southern zone) 1998 Deltamethrin emulsifiable granule (EG) 6.25 % w/w Code: AE F032640 00 EG06 A106 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C004453 Edition Number: M-187966-01-1 Date: 1999-08-27 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 109	Davies, P.	2001	Residues at harvest in potatoes European Union (Southern zone) 2000 Deltamethrin emulsifiable concentrate (EC) 25 g/L (2.81 %) Code: AE F032640 00 EC03 B007, AE F032640 00 EC03 B005 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015284 Edition Number: M-200206-01-1 Date: 2001-11-14 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 110	Mestres, R.	1982	Residues Analysis; Commercial Product, K-Othrine 0.05 dust; Decamethrine 0.05%; Potatoes (stored) University of Montpellier, Faculte de Pharmacie, Montpellier, France Bayer Report No.: A97788 Edition Number: M-175301-01-1 Date: 1982-07-01 GLP/GEP: No, unpublished	No	Bayer
KCA 6.3 / 111	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in tea. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71829 Edition Number: M-150208-01-1 Date: 1995-03-21 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 112	Klein, E. H. J.	2001	Decline of residues in tea and processed fractions South East Asia 2000/2001 Deltamethrin, AE F032640 emulsifiable concentrate (EC) 2.81 % w/w (= 25 g/L) Code: AE F032640 00 EC03 B0007 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C016591 Edition Number: M-202700-01-1 Date: 2001-11-30 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 113	Neuss, B.	2001	Residues data summary from supervised trials - tea Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C017005 Edition Number: M-203465-01-1 Date: 2001-11-23 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 114	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in Brassica vegetables - Head brassica: Brussels sprout and Head cabbage. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71678 Edition Number: M-150072-01-1 Date: 1995-03-20 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 115	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in Brassica vegetables: Kohlrabi. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71691 Edition Number: M-150085-01-1 Date: 1995-03-20 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 116	Thier, W.; Gorbach, S.	1978	Pflanzenschutzmittel-Rueckstaende. (Kohlrabi). Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A13420 Edition Number: M-065112-01-1 Date: 1978-02-09 GLP/GEP: No, unpublished	No	Bayer
KCA 6.3 / 117	Thier, W.; Gorbach, S.	1978	Pflanzenschutzmittel-Rueckstaende. (Kohlrabi). Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A13421 Edition Number: M-065116-01-1 Date: 1978-02-09 GLP/GEP: No, unpublished	No	Bayer
KCA 6.3 / 118	Thier, W.; Gorbach, S.	1978	Pflanzenschutzmittel-Rueckstaende. (Kohlrabi). Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A13422 Edition Number: M-065120-01-1 Date: 1978-02-09 GLP/GEP: No, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 119	Thier, W.; Gorbach, S.	1978	Pflanzenschutzmittel-Rueckstaende. (Kohlrabi). Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A13423 Edition Number: M-065124-01-1 Date: 1978-02-09 GLP/GEP: No, unpublished	No	Bayer
KCA 6.3 / 120	Neuss, B.	2001	Residue data summary from supervised trials Root and tuber vegetables: Carrots Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015917 Edition Number: M-201406-01-1 Date: 2001-11-05 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 121	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in 4/ Cereals: Rice. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71984 Edition Number: M-150348-01-1 Date: 1995-04-05 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 122	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in: 3/ Cereals: Corn (Maize). Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71957 Edition Number: M-150324-01-1 Date: 1995-04-05 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3 / 123	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in: 2) Cereals: Sorghum (Millet). Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71951 Edition Number: M-150318-01-1 Date: 1995-04-05 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 124	Block, H.	2010	Determination of residues of deltamethrin in/on barley after spraying of Decis EC 025 in the field in Germany 2009 Eurofins Agrosience Services GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S09-00281 Edition Number: M-398036-01-1 Date: 2010-11-25 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 125	Block, H.	2010	Determination of residues of deltamethrin in/on corn after spraying of Decis EC 025 in the field in Germany 2009 Eurofins Agrosience Services GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S09-00285 Edition Number: M-398043-01-1 Date: 2010-11-25 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 126	Ballesteros, C.; Meilland-Berthier, I.	2011	Determination of the residues of deltamethrin and imidacloprid in/on pea, field after spraying of imidacloprid & deltamethrin in the field in France (South) Bayer Report No.: 10-2056 Report includes Trial Nos.: 10-2056-01 Edition Number: M-405310-01-1 Date: 2011-04-12 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 127	Ballesteros, C.	2011	Determination of the residues of deltamethrin and imidacloprid in/on pea, field after spraying of imidacloprid & deltamethrin in the field in France (South) and Italy Bayer Report No.: 09-2007 Report includes Trial Nos.: 09-2007-01 09-2007-03 09-2007-04 Edition Number: M-409261-01-1 Date: 2011-06-14 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 128	Block, H.	2011	Determination of residues of deltamethrin in/on tomato after spraying of deltamethrin EC 25AK G or deltamethrin EC 25 AF G in the greenhouse in France, Spain, Poland and Germany 2010 Eurofins Agrosience Services GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S10-00016 Edition Number: M-410061-01-1 Date: 2011-06-28 GLP/GEP: No, unpublished	No	Bayer
KCA 6.3 / 129	Meilland-Berthier, I.	2011	Determination of the residues of deltamethrin in/on spinach after spray application of Decis EC 025 in the field in United Kingdom and Belgium Bayer Report No.: 10-2029 Report includes Trial Nos.: 10-2029-01 10-2029-02 Edition Number: M-410009-01-1 Date: 2011-06-30 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 130	Block, H.	2011	Determination of residues of deltamethrin in/on lettuce after spraying of Decis EC 025 in the greenhouse in France 2009 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S09-00290 Report includes Trial Nos.: S09-00290-02 Edition Number: M-411438-01-1 Date: 2011-07-01 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 131	Block, H.	2011	Determination of residues of deltamethrin in/on oilseed rape after spraying of Decis EC 025 in the field in Spain and France 2010 Eurofins Agrosience Services GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S10-00002 Report includes Trial Nos.: S10-00002-01 S10-00002-02 Edition Number: M-410870-01-1 Date: 2011-07-07 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 132	Block, H.	2011	Determination of residues of deltamethrin in/on spinach and the processed fractions (washings, leaf washed, cooking water, leaf cooked) after spraying of Decis EC 025 in the field in Poland and Germany 2010 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S10-00001 Report includes Trial Nos.: S10-00001-01 S10-00001-02 S10-00001-03 Edition Number: M-411380-01-1 Date: 2011-07-19 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 133	Block, H.	2011	Determination of residues of Deltamethrin in/on currant after spraying of Decis EC 025 in the field in France and Italy 2010 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S10-00003 Report includes Trial Nos.: S10-00003-01 S10-00003-02 S10-00003-03 Edition Number: M-413402-01-1 Date: 2011-07-22 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 134	Block, H.	2011	Determination of residues of deltamethrin in/on barley after spraying of Decis EC 025 in the field in UK and Germany 2010 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S10-00007 Report includes Trial Nos.: S10-00007-01 S10-00007-02 S10-00007-03 Edition Number: M-411372-01-1 Date: 2011-07-22 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 135	Block, H.	2011	Determination of residues of deltamethrin in/on lettuce after spraying of Decis EC 025 in the greenhouse in Germany 2010 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S10-00014 Edition Number: M-415853-01-1 Date: 2011-07-22 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 136	Block, H.	2011	Determination of residues of deltamethrin in/on barley after spraying of Decis EC 025 in the field in France and Spain 2010 Bayer Report No.: S10-00008 Report includes Trial Nos.: S10-00008-01 S10-00008-02 S10-00008-03 S10-00008-04 Edition Number: M-411558-01-1 Date: 2011-07-29 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 137	Block, H.	2011	Determination of residues of deltamethrin in/on corn after spraying of Decis EC 025 in the field in Bulgaria and France (south) 2010 Bayer Report No.: S10-00012 Report includes Trial Nos.: S10-00012-01 S10-00012-02 S10-00012-03 S10-00012-04 Edition Number: M-411562-01-1 Date: 2011-07-29 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 138	Block, H.	2011	Determination of residues of deltamethrin in/on raspberries after spraying of Decis EC 025 in the field in France, Spain and Italy 2010 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S10-00013 Report includes Trial Nos.: S10-00013-01 S10-00013-02 S10-00013-03 Edition Number: M-411569-01-1 Date: 2011-07-29 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 139	Block, H.	2011	Determination of residues of deltamethrin in/on sweet cherry after spraying of Decis EC 025 in the field in Spain and Italy 2010 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S10-00004 Report includes Trial Nos.: S10-00004-01 S10-00004-02 Edition Number: M-411417-02-1 Date: 2010-07-07 ... amended: 2011-08-15 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 140	Block, H.	2011	Determination of residues of deltamethrin in/on barley after spraying of Decis EC 025 in the field in France and Spain 2010 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S10-00005 Report includes Trial Nos.: S10-00005-01 S10-00005-02 S10-00005-03 S10-00005-04 Edition Number: M-412389-01-1 Date: 2011-08-17 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 141	Block, H.	2011	Determination of residues of deltamethrin in/on olive and the processed fractions (washings; whole fruit, washed; pomace, wet; vegetation water; oil, crude, oil virgin) after spraying of decis EC 025 in the field in Spain and Italy 2009 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S09-00291 Report includes Trial Nos.: S09-00291-01 S09-00291-02 S09-00291-03 Edition Number: M-412393-01-1 Date: 2011-08-18 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 142	Block, H.	2011	Determination of residues of deltamethrin in/on raspberries after spraying of Decis EC 025 in the field in Germany 2009 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S09-00288 Report includes Trial Nos.: S09-00288-01 Edition Number: M-413294-01-1 Date: 2011-08-25 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 143	Block, H.	2011	Determination of residues of deltamethrin in/on olive after spraying of Decis EC 025 in the field in France and Italy 2010 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S10-00015 Report includes Trial Nos.: S10-00015-03 S10-00015-04 Edition Number: M-413291-01-1 Date: 2011-08-25 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 144	Ballesteros, C.	2011	Determination of the residues of deltamethrin and imidacloprid in/on kale, curly after spraying of imidacloprid & deltamethrin in the field in Italy and Spain Bayer Report No.: 09-2002 Report includes Trial Nos.: 09-2002-01 09-2002-02 Edition Number: M-413003-01-1 Date: 2011-08-26 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 145	Block, H.	2011	Determination of residues of deltamethrin in/on currant after spraying of Decis EC 025 in the field in Germany 2009 Eurofins Agrosience Services GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S09-00277 Report includes Trial Nos.: S09-00277-01 Edition Number: M-414546-01-1 Date: 2011-08-26 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 146	Schulz, H.	2011	Study on the residue behaviour of deltamethrin in oranges after treatment with Decis Fluxx EC 025 under field conditions in Spain, 2010 SGS Institut Fresenius GmbH, Taunusstein, Germany Bayer Report No.: 10-2302 Report includes Trial Nos.: 10-ES-067 10-ES-068 10-ES-069 10-ES-070 Edition Number: M-421031-01-1 Date: 2011-09-22 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 147	Block, H.	2011	Determination of residues of deltamethrin in/on spinach and the processed fractions (washings, leaf washed, cooking water, leaf cooked) after spraying of Decis EC 025 in the field in Germany 2009 Eurofins-GAB GmbH, Stade, Germany Bayer Report No.: S09-00274 Report includes Trial Nos.: S09-00274-02 Edition Number: M-415862-01-1 Date: 2011-10-17 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 148	Block, H.	2011	Determination of residues of deltamethrin in/on green peas after spraying of deltamethrin EW 15A G in the open field in France and Spain 2009 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S09-00293 Report includes Trial Nos.: S09-00293-01 S09-00293-02 S09-00293-03 S09-00293-04 Edition Number: M-415856-01-1 Date: 2011-10-17 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 149	Block, H.	2011	Determination of residues of deltamethrin in/on corn after spraying of Decis EC 025 in the field in Hungary and Germany 2010 Eurofins-GAB GmbH, Stade, Germany Bayer Report No.: S10-00011 Report includes Trial Nos.: S10-00011-1 S10-00011-2 S10-00011-3 Edition Number: M-415871-01-1 Date: 2011-10-17 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 150	Meilland-Berthier, I.	2011	Determination of the residues of deltamethrin in/on maize/corn after spray application of Decis EC 025 in the field in Germany, northern France, United Kingdom, the Netherlands, southern France, Spain and Portugal Bayer Report No.: 10-2042 Report includes Trial Nos.: 10-2042-01 10-2042-02 10-2042-03 10-2042-04 10-2042-05 10-2042-06 10-2042-07 10-2042-08 Edition Number: M-416542-01-1 Date: 2011-10-27 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 151	Noss, G.; Krusell, L.; Ruhl, S.	2011	Determination of residues of deltamethrin in/on barley after spraying of Decis EC 025 in the field in France (South), Spain, Italy and Portugal Bayer Report No.: 10-2032 Report includes Trial Nos.: 10-2032-01 10-2032-02 10-2032-03 10-2032-04 Edition Number: M-418208-01-1 Date: 2011-11-23 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 152	Block, H.	2012	Determination of residues of deltamethrin in/on strawberries and the processed Fractions (whole fruit, washings and preserve) after spraying of Decis EC 025 in the field in France and Spain 2009 Eurofins Agrosience Services GmbH, Stade, Germany Bayer Report No.: S09-00275 Report includes Trial Nos.: S09-00275-01 S09-00275-02 S09-00275-03 S09-00275-04 Edition Number: M-414534-02-1 Date: 2011-09-20 ... amended: 2012-06-08 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 153	Meilland-Berthier, I.	2012	Determination of the residues of deltamethrin in/on winter wheat after spray application of Decis EC 025 in the field in Belgium, northern France, United Kingdom, Germany, southern France, Italy, Spain and Portugal Bayer Report No.: 10-2036 Report includes Trial Nos.: 10-2036-01 10-2036-02 10-2036-03 10-2036-04 10-2036-05 10-2036-06 10-2036-07 10-2036-08 Edition Number: M-435250-01-1 Date: 2012-07-18 GLP/GEP: Yes, unpublished ... also filed: KCA 6.3.3 / 07	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 154	Meilland-Berthier, I.	2012	Determination of the residues of deltamethrin in/on winter barley after spray application of Decis EC 025 in the field in Germany, northern France, United Kingdom, southern France, Portugal, Italy and Spain Bayer Report No.: 10-2035 Report includes Trial Nos.: 10-2035-01 10-2035-02 10-2035-03 10-2035-04 10-2035-05 10-2035-07 10-2035-08 Edition Number: M-435247-01-1 Date: 2012-07-19 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 155	Meilland-Berthier, I.	2012	Determination of the residues of deltamethrin in/on tomato after spray application of Decis EC 025 in the field in southern France, Spain, Portugal, Greece and Italy Bayer Report No.: 11-2047 Report includes Trial Nos.: 11-2047-01 11-2047-02 11-2047-03 11-2047-04 11-2047-05 11-2047-06 Edition Number: M-442495-01-1 Date: 2012-11-22 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 156	Meilland-Berthier, I.	2012	Determination of the residues of deltamethrin in/on tomato and cherry tomato after spray of Decis EC 025 in the field in northern France, Germany and Belgium Bayer Report No.: 11-2048 Report includes Trial Nos.: 11-2048-01 11-2048-02 11-2048-03 11-2048-04 Edition Number: M-442496-01-1 Date: 2012-11-26 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 157	Schoening, R.; Diehl, P.	2013	Determination of the residues of deltamethrin and imidacloprid in/on lettuce after spray application of imidacloprid & deltamethrin OD 85 in Spain, Italy, France (south) and Portugal Bayer Report No.: 11-2052 Report includes Trial Nos.: 11-2052-01 11-2052-02 11-2052-03 11-2052-04 Edition Number: M-448490-02-1 Date: 2013-03-04 ... amended: 2013-04-04 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 158	Meilland-Berthier, I.	2013	Determination of the residues of deltamethrin in/on garden pea after spray application of deltamethrin EW 015 in southern France, Spain, Italy and Greece Bayer Report No.: 12-2063 Report includes Trial Nos.: 12-2063-01 12-2063-02 12-2063-03 12-2063-04 Edition Number: M-451494-01-1 Date: 2013-04-16 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 159	Meilland-Berthier, I.	2013	Determination of the residues of deltamethrin in/on winter barley after spray application of Decis EC 025 in the field in the Netherlands and southern France Bayer Report No.: 11-2107 Report includes Trial Nos.: 11-2107-01 11-2107-02 11-2107-03 11-2107-04 Edition Number: M-456339-01-1 Date: 2013-06-06 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3 / 160	Meilland-Berthier, I.	2013	Amendment No. 1 to Final Report No: 12-2064 - Determination of the residues of deltamethrin in/on cauliflower after spray application of deltamethrin EW 015 in southern France, Spain, Italy and Greece Bayer Report No.: 12-2064 Report includes Trial Nos.: 12-2064-01 12-2064-02 12-2064-03 12-2064-04 Edition Number: M-451517-02-1 Date: 2013-04-16 ... amended: 2013-10-17 GLP/GEP: Yes, unpublished ... also filed: KCA 6.3.1 / 16	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3 / 161	Block, H.	2015	Determination of residues of deltamethrin in/on chinese cabbage and curly kale after spraying of Deltamethrin EW 15A G in the field in France (North and South), Italy, Poland and Germany 2009 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S09-00289 Report includes Trial Nos.: S09-00289-01 S09-00289-02 S09-00289-03 S09-00289-04 S09-00289-05 S09-00289-06 S09-00289-07 S09-00289-08 Edition Number: M-411407-02-1 Date: 2011-06-29 ... amended: 2015-09-25 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3.1 / 01	Krebs, B.; Gorbach, S.	1983	Berichtsbogen fuer Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln (Blumenkohl). Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A25151 Edition Number: M-098086-01-1 Date: 1983-01-18 GLP/GEP: No, unpublished	No	Bayer
KCA 6.3.1 / 02	Krebs, B.; Gorbach, S.	1983	Berichtsbogen fuer Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln (Blumenkohl). Handelslabor Dr. Koerl und Dr. Specht, Hamburg, Germany Bayer Report No.: A25152 Edition Number: M-098087-01-1 Date: 1983-01-18 GLP/GEP: No, unpublished	No	Bayer
KCA 6.3.1 / 03	Krebs, B.; Gorbach, S.	1983	Berichtsbogen fuer Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln (Blumenkohl). LUFA, DEU; Bayer Report No.: A25153 Edition Number: M-098088-01-1 Date: 1983-01-18 GLP/GEP: No, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.1 / 04	Krebs, W.; Gorbach, S.	1983	Berichtsbogen fuer Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln (Blumenkohl). Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A25154 Edition Number: M-098089-01-1 Date: 1983-01-18 GLP/GEP: No, unpublished	No	Bayer
KCA 6.3.1 / 05	Davies, P.	2001	Decline of residues in cauliflower European Union (Northern zone) 2000 Deltamethrin emulsifiable concentrate (EC) 2.81 % w/w (25 g/L) Code: AE F032640 00 EC03 B007 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015567 Edition Number: M-200735-01-1 Date: 2001-11-14 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3.1 / 06	Klein, E. H. J.	1999	Residues at harvest in cauliflowers / broccoli European Union (southern zone) 1997 Deltamethrin emulsifiable granule (EG) 6.25% w/w Code: AE F032640 00 EG06 A105 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C001462 Edition Number: M-182691-01-1 Date: 1999-02-15 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3.1 / 07	Klein, E. H. J.; Buerstell, H.	2006	Residues at harvest in cauliflower and broccoli European Union, Southern zone 1998 Deltamethrin emulsifiable granule (EG) 6.25 % w/w Code: AE F032640 00 EG06 A106 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C005163 Edition Number: M-191503-02-1 Date: 1999-11-15 ... amended: 2006-08-07 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.1 / 08	de Wilde, G.	1995	Deltamethrine: Residues data summary from supervised trials in vegetables - Brassica: Broccoli and Cauliflower. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71668 Edition Number: M-150062-01-1 Date: 1995-03-20 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3.1 / 09	Neuss, B.	2001	Residue data summary from supervised trials Flowering brassicas: cauliflower and broccoli Additional data Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C015757 Edition Number: M-201128-01-1 Date: 2001-11-14 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3.1 / 10	Idstein, H.; Bock, K. D.	1989	Berichtsbogen fuer Rueckstandsuntersuchungen (Hoe 032640, Brassica oleracea var sabellica) Universitaet Muenchen, Muenchen, Germany Bayer Report No.: A41457 Edition Number: M-124552-01-1 Date: 1989-06-01 GLP/GEP: No, unpublished	No	Bayer
KCA 6.3.1 / 11	Idstein, H.; Bock, K. D.	1989	Berichtsbogen fuer Rueckstandsuntersuchungen (Hoe 032640, Brassica oleracea var sabellica) Universitaet Muenchen, Muenchen, Germany Bayer Report No.: A41456 Edition Number: M-124551-01-1 Date: 1989-06-01 GLP/GEP: No, unpublished	No	Bayer
KCA 6.3.1 / 12	Idstein, H.; Bock, K. D.	1989	Berichtsbogen fuer Rueckstandsuntersuchungen (Hoe 032640, Brassica oleracea var sabellica) Universitaet Muenchen, Muenchen, Germany Bayer Report No.: A41458 Edition Number: M-124553-01-1 Date: 1989-06-01 GLP/GEP: No, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.1 / 13	Sole, C.	2002	Residue study with deltamethrin in cauliflower European Union (Northern Zone) 2001 Deltamethrin emulsifiable concentrate (EC) 24.8 g/L (25 g/L nominal) Code: AE F032640 00 EC03 B018 (= EXP05610A) ADME Bioanalyses S.A., Vergeze, France Bayer Report No.: C023140 Report includes Trial Nos.: 01R054 Edition Number: M-214429-01-1 Date: 2002-05-17 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3.1 / 14	Noss, G.; Schneeberg-Seeba, C.	2008	Determination of the residues of deltamethrin in/on cauliflower after spraying of deltamethrin EW 15 (015 EW) in the field in Spain and Italy Bayer Report No.: RA-2555/06 Report includes Trial Nos.: R 2006 0305/3 = 0305 - 06 R 2006 0306/1 = 0306 - 06 Edition Number: M-303449-01-1 Date: 2008-06-24 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3.1 / 15	Noss, G.; Wolters, A.	2008	Determination of the residues of deltamethrin in/on cauliflower after spraying of deltamethrin EW 15 (015 EW) in the field in Spain and Italy Bayer Report No.: RA-2547/07 Report includes Trial Nos.: R 2007 0048/2 = 0048 - 07 R 2007 0049/0 = 0049 - 07 Edition Number: M-308923-01-1 Date: 2008-09-30 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.1 / 16	Meilland-Berthier, I.	2013	Amendment No. 1 to Final Report No: 12-2064 - Determination of the residues of deltamethrin in/on cauliflower after spray application of deltamethrin EW 015 in southern France, Spain, Italy and Greece Bayer Report No.: 12-2064 Report includes Trial Nos.: 12-2064-01 12-2064-02 12-2064-03 12-2064-04 Edition Number: M-451517-02-1 Date: 2013-04-16 ... amended: 2013-10-17 GLP/GEP: Yes, unpublished ... also filed: KCA 6.3 / 160	No	Bayer
KCA 6.3.2 / 01	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in root and tuber vegetables. Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71585 Edition Number: M-149986-01-1 Date: 1995-03-16 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3.2 / 02	Klein, E. H. J.	2001	Residues at harvest in sugar beets European Union, Northern zone 2000 Deltamethrin, AE F032640 emulsifiable concentrate (EC) 2.81 % w/w (= 25 g/L) Code: AE F032640 00 EC03 B005 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C017186 Edition Number: M-203812-01-1 Date: 2001-12-12 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3.2 / 03	Sole, C.	2002	Residue study with deltamethrin in sugar beets European Union (Northern zone) 2001 Deltamethrin emulsifiable concentrate (EC) 24.8 g/L (25 g/L nominal) Code: AE F032640 00 EC03 B018 (=EXP05610A) ADME Bioanalyses S.A., Mougins, France Bayer Report No.: C023401 Edition Number: M-214930-01-1 Date: 2002-05-24 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.2 / 04	Klein, E. H. J.	2001	Residues at harvest in sugar beets European Union, Southern szone 2000 Deltamethrin, AE F032640 emulsifiable concentrate (EC) 2.81 % w/w (= 25 g/L) Code: AE F032640 00 EC03 B005 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C017408 Edition Number: M-204224-01-1 Date: 2001-12-06 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3.2 / 05	Sole, C.	2002	Residue study with deltamethrin in sugar beets European Union (Southern zone) 2001 Deltamethrin emulsifiable concentrate (EC) 24.8 g/L (25 g/L nominal) Code: AE F032640 00 EC03 B018 (EXP05610A) ADME Bioanalyses S.A., Mougins, France Bayer Report No.: C024054 Report includes Trial Nos.: 01R052 Edition Number: M-216175-01-1 Date: 2002-06-13 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3.3 / 01	McKinney, F. R.	1993	Determination of cis-deltamethrin, trans-deltamethrin and alpha-R-deltamethrin in various grains, grain fractions and grain dusts under 20.C, 30.C and frozen storage conditions. EN-CAS Analytical Laboratories, Winston-Salem, NC, USA Bayer Report No.: A71102 Edition Number: M-149575-01-1 Date: 1993-08-10 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3.3 / 02	de Wilde, G.	1995	Deltamethrin: Residues data summary from supervised trials in 1/ Cereals: Wheat, Barley, Oats... Hoechst Schering AgrEvo S.A., France Bayer Report No.: A71908 Edition Number: M-150279-01-1 Date: 1995-04-06 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.3 / 03	Wiesener, G.	1998	Residues data summary from supervised trials in cereals (wheat, winter variety). Additional data Deltamethrin Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C005447 Edition Number: M-192094-01-1 Date: 1998-02-06 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.3.3 / 05	Billian, P.; Krusell, L.	2009	Determination of the residues of deltamethrin in/on winter wheat after mixing of Deltamethrin & Piperonylbutoxide EC 275 in the Room, hall, store, ... in Germany, Greece, Portugal and the United Kingdom Bayer Report No.: 08-2214 Report includes Trial Nos.: 08-2214-01 08-2214-02 08-2214-03 08-2214-04 Edition Number: M-360719-01-1 Date: 2009-12-15 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3.3 / 06	Block, H.	2011	Determination of residues of deltamethrin in/on wheat after spraying of Decis EC 025 in the field in UK and Poland 2010 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S10-00009 Edition Number: M-411373-01-1 Date: 2011-07-22 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.3 / 07	Meilland-Berthier, I.	2012	Determination of the residues of deltamethrin in/on winter wheat after spray application of Decis EC 025 in the field in Belgium, northern France, United Kingdom, Germany, southern France, Italy, Spain and Portugal Bayer Report No.: 10-2036 Report includes Trial Nos.: 10-2036-01 10-2036-02 10-2036-03 10-2036-04 10-2036-05 10-2036-06 10-2036-07 10-2036-08 Edition Number: M-435250-01-1 Date: 2012-07-18 GLP/GEP: Yes, unpublished ... also filed: KCA 6.3 / 153	No	Bayer
KCA 6.3.3 / 08	Meilland-Berthier, I.	2011	Determination of the residues of deltamethrin in/on wheat after spray application of Decis EC 025 in the field in Southern France, Italy, Spain and Greece Bayer Report No.: 10-2233 Report includes Trial Nos.: 10-2233-01 10-2233-02 10-2233-03 10-2233-04 Edition Number: M-413097-01-1 Date: 2011-08-30 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3.3 / 09	Block, H.	2011	Determination of residues of deltamethrin in/on wheat after spraying of Decis EC 025 in the field in France and Italy 2010 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S10-00006 Edition Number: M-411367-01-1 Date: 2011-07-22 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.3 / 10	Block, H.	2011	Determination of residues of deltamethrin in/on wheat after spraying of Decis EC 025 in the field in France and Spain 2010 Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer Report No.: S10-00010 Report includes Trial Nos.: S10-00010-01 S10-00010-04 S10-00010-05 Edition Number: M-433851-01-1 Date: 2011-09-20 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.3.3 / 04	Klein, E. H. J.; Buerstell, H.	1997	Deltamethrin; emulsifiable granules 6.25 % w/w; Code: AE F032640 00 EG06 A103 - Residue trials in winter-wheat to confirm maximum residue level compliance. Determination of active substance at harvest following two applications. European un Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A56788 Edition Number: M-140573-01-1 Date: 1997-01-13 GLP/GEP: Yes, unpublished ... also filed: Document MCA / 01 KCA 6.4.2 / 06	No	Bayer
KCA 6.4 / 01	Anon.	2015	Deltamethrin - AIR 3 renewal Bayer - 2014/01279: UK CRD request (dated 13-10-2015): Residues - Livestock metabolism Bayer Report No.: M-536726-01-1 Date: 2015-10-23 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.4 / 02	Mousques, A.	2016	Compilation of dRR tables for deltamethrin residue studies from 2009 onwards - Results displayed for cis-deltamethrin, trans isomer and alpha-R isomer Bayer Report No.: M-559648-01-1 Date: 2016-07-13 GLP/GEP: n.a., unpublished ... also filed: KCA 5.8.1 / 09	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.4 / 03	Christian, I; Mousquès, A.	2018	Deltamethrin - Information on the behaviour of the alpha-R isomer and the trans-isomer of cis-deltamethrin in livestock matrices Bayer Report No.: M-628340-01-1 Date: 2018-06-29 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.4.1 / 01	xxx	1995	Effects of a supplemented deltamethrin and piperonyl butoxide diet on levels of residues in products of animal origin.~a2. Feeding studies in poultry. xxx Volume: 43 Pages: 1039-1043 Year: 1995 Report No.: A70891 Edition Number: M-149375-01-1 GLP/GEP: n.a., published	Yes	published
KCA 6.4.1 / 02	McKinney, F. R.	1994	Determination of freezer residue stability for deltamethrin (alpha-R, cis, and trans) and tralomethrin in poultry tissues. EN-CAS Analytical Laboratories, Winston-Salem, NC, USA Bayer Report No.: A54085 Edition Number: M-134680-01-1 Date: 1994-08-12 GLP/GEP: Yes, unpublished ... also filed: KCA 6.3 / 22	No	Bayer
KCA 6.4.1 / 03	xxx	1994	Magnitude of the residues in meat and eggs for tralomethrin (RU 25474) and its major metabolite deltamethrin (RU 22974) in white Leghorn chickens. xxx Report No.: A71106 Edition Number: M-149579-01-1 Date: 1994-08-24 GLP/GEP: Yes, unpublished ... also filed: KCA 6.5.1 / 01	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.4.2 / 01	xxx	2000	Feeding study of a mixture of tralomethrin and deltamethrin in dairy cows and magnitude of the combined residues of tralomethrin, deltamethrin and trans-deltamethrin in milk and tissues of dairy cattle. (2 volumes). xxx Report No.: A70946 Report includes Trial Nos.: HRAV Proj. #87-0123 HRAV Project No. 87-0123 Edition Number: M-149428-03-1 Date: 1988-11-04 ... amended: 2000-05-23 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 6.4.2 / 02	Akhtar, M. H.; Danis, C.; Trenholm, H. L.; Hartin, K. E.	1992	Deltamethrin residues in milk and tissues of lactating dairy cows. Journal: Journal of Environmental Science and Health : Part B Volume: B27 Issue: 3 Pages: 235-253 Year: 1992 Report No.: A70892 Edition Number: M-149376-01-1 GLP/GEP: n.a., published	No	published
KCA 6.4.2 / 03	Martens, R.	2000	Calculation of the 1x dosage rate for deltamethrin in a ruminant livestock feeding study (according to EU-document 7031/VI/95 rev.4, 22.07.1996 (draft)) Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C009557 Edition Number: M-198796-01-1 Date: 2000-09-06 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.4.2 / 04	Singer, S. S.; Hurst, K.	2001	Survey of Reports on Analysis for Deltamethrin in Milk from Cows and Humans Bayer Report No.: B003480 Edition Number: M-240501-01-1 Date: 2001-09-24 GLP/GEP: n.a., unpublished ... also filed: KCA 5.6 / 04 KCA 6.9 / 01	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.4.2 / 05	xxx	1995	Metabolism of 14C-benzyl-tralomethrin and 14C-gem-dimethyl-tralomethrin in lactating dairy cattle and storage stability of tralomethrin and deltamethrin in cow milk and tissues. xxx Report No.: A70045 Report includes Trial Nos.: HR-01-88 Edition Number: M-148609-02-1 Date: 1991-09-27 ... amended: 1995-11-07 GLP/GEP: Yes, unpublished ... also filed: KCA 6.2.3 / 02	Yes	Bayer
KCA 6.4.2 / 06	Klein, E. H. J.; Buerstell, H.	1997	Deltamethrin; emulsifiable granules 6.25 % w/w; Code: AE F032640 00 EG06 A103 - Residue trials in winter-wheat to confirm maximum residue level compliance. Determination of active substance at harvest following two applications. European un Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A56788 Edition Number: M-140573-01-1 Date: 1997-01-13 GLP/GEP: Yes, unpublished ... also filed: Document MCA / 01 KCA 6.3.3 / 04	No	Bayer
KCA 6.4.3 / 01	xxx	1993	Effects of a supplemented deltamethrin and piperonyl butoxide diet on residues in products of animal origin. I. Feeding study in pigs. xxx Volume: 41 Pages: 2416-2420 Year: 1993 Report No.: A70890 Edition Number: M-149374-01-1 GLP/GEP: n.a., published	Yes	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.5 / 01	Mestres, G.; Espinoza, C.; Chevallier, C.	1986	Effets sur les residus de Deltamethrine de la transformation des produits agricoles en vue de leur consommation Journal: Med.et Nutr. Volume: 22 Issue: 3 Pages: 181-184 Year: 1986 Report No.: A41874 Edition Number: M-124937-01-1 GLP/GEP: n.a., published	No	published
KCA 6.5 / 02	Mestres, G.; Espinoza, C.; Chevallier, C.	1986	Effects of edible crop processing on deltamethrin residues Journal: Unknown Pages: 1;14 Year: 1986 Report No.: A72063 Edition Number: M-150406-01-1 GLP/GEP: n.a., published	No	published
KCA 6.5 / 03	Thier, W.; Gorbach, S.	1980	Berichtsbogen fuer Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln (Spinat). Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A20420 Edition Number: M-093631-01-1 Date: 1980-11-17 GLP/GEP: No, unpublished	No	Bayer
KCA 6.5 / 04	Thier, W.; Krebs, B.	1983	Berichtsbogen fuer Rueckstandsuntersuchungen mit Pflanzenbehandlungsmitteln (Spinat). Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A25427 Edition Number: M-098339-01-1 Date: 1983-02-15 GLP/GEP: No, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.5 / 05	Maurer, T.	2001	Investigation of the nature of the potential residue in the products of industrial processing or household preparation Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C017397 Edition Number: M-204204-01-1 Date: 2001-11-27 GLP/GEP: Yes, unpublished ... also filed: KCA 6.5.3 / 04	No	Bayer
KCA 6.5 / 06	Martens, R.	1999	Statement on the acute dietary risk assessment for deltamethrin Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C006040 Edition Number: M-193192-01-1 Date: 1999-11-18 GLP/GEP: n.a., unpublished ... also filed: KCA 6.9 / 07	No	Bayer
KCA 6.5.1 / 01	xxx	1994	Magnitude of the residues in meat and eggs for tralomethrin (RU 25474) and its major metabolite deltamethrin (RU 22974) in white Leghorn chickens. xxx Report No.: A71106 Edition Number: M-149579-01-1 Date: 1994-08-24 GLP/GEP: Yes, unpublished ... also filed: KCA 6.4.1 / 03	Yes	Bayer
KCA 6.5.1 / 02	Christian, I.	2013	Deltamethrin: Metabolic behaviour of 3-phenoxybenzaldehyde Bayer Report No.: M-466413-01-1 Date: 2013-10-03 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.5.3 / 01	Brady, S. S.	1999	Magnitude of deltamethrin residues in or on apples and processed apple commodities resulting from three applications of Decis (R) insecticide USA, 1998 AgrEvo USA Company, Pikeville, NC, USA Bayer Report No.: C002139 Edition Number: M-183978-01-1 Date: 1999-03-30 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.5.3 / 02	Brady, S. S.	1999	Magnitude of deltamethrin residues in or on tomatoes and processed tomato commodities resulting from six applications of Decis (R) insecticide, USA, 1998 AgrEvo USA Company, Pikeville, NC, USA Bayer Report No.: C002859 Edition Number: M-185190-01-1 Date: 1999-04-20 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.5.3 / 03	Klein, E. H. J.; Martens, R.	2000	Residues at harvest in olives and processed fractions. European Union, Southern zone 1997 Deltamthrin, AE F032640 emulsifiable granule 6.25 % w/W Code: AE F032640 00 EG06 A105 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C010147 Edition Number: M-238971-01-1 Date: 2000-09-21 GLP/GEP: Yes, unpublished ... also filed: KCA 6.3 / 47	No	Bayer
KCA 6.5.3 / 04	Maurer, T.	2001	Investigation of the nature of the potential residue in the products of industrial processing or household preparation Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C017397 Edition Number: M-204204-01-1 Date: 2001-11-27 GLP/GEP: Yes, unpublished ... also filed: KCA 6.5 / 05	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.5.3 / 05	Billian, P.; Reineke, A.	2010	Determination of the residues of deltamethrin in/on winter wheat and processed fractions after mixing of Deltamethrin & Piperonylbutoxide EC 275 in the room, hall store ... in Germany, Greece, Portugal and the United Kingdom Bayer Report No.: 08-3214 Report includes Trial Nos.: 08-3214-01 08-3214-02 08-3214-03 08-3214-04 Edition Number: M-363957-01-1 Date: 2010-02-17 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.5.3 / 06	Schulte, G.	2016	Additional chromatograms of study report 08-3214; Determination of the residues of deltamethrin in/on winter wheat and processed fractions after mixing of deltamethrin & piperonylbutoxide EC 275 in the room, hall store ... in Germany, Greece, Portugal and the United Kingdom Bayer Report No.: M-559765-01-1 Date: 2016-07-19 GLP/GEP: No, unpublished	No	Bayer
KCA 6.6.1 / 01	Schmeling, S.; Breuer-Rehm, M.	2012	Metabolism of [gemdimethyl-14C] deltamethrin in confined rotational crops Bayer Report No.: MEF-11/669 Edition Number: M-431769-01-1 Date: 2012-05-14 GLP/GEP: Yes, unpublished	No	Bayer
KCA 6.6.1 / 02	Erstfeld, K. M.; Larson, J. D.; Lange, B. D.	1994	C-14 Deltamethrin - Confined accumulation in rotational crops 30 and 120 Day Experiment - including - Supplement to the report (amendment) Pan-Agricultural Laboratories, Inc., Madera, CA, USA Bayer Report No.: A73873 Report includes Trial Nos.: 89-0101 Edition Number: M-136651-02-2 Date: 1991-08-26 ... amended: 1994-05-06 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.9 / 01	Singer, S. S.; Hurst, K.	2001	Survey of Reports on Analysis for Deltamethrin in Milk from Cows and Humans Bayer Report No.: B003480 Edition Number: M-240501-01-1 Date: 2001-09-24 GLP/GEP: n.a., unpublished ... also filed: KCA 5.6 / 04 KCA 6.4.2 / 04	No	Bayer
KCA 6.9 / 02	CRD	2012	Data requirements handbook (version 2.2, June 2012) Chemicals Regulation Directorate, CRD, York, United Kingdom Bayer Report No.: M-449685-01-1 Date: 2012-06-30 GLP/GEP: n.a., unpublished	No	Bayer
KCA 6.9 / 03	xxx	1999	Analysis of polychlorinated biphenyls, pyrethroid insecticides and fragrances in human milk using a laminar cup liner in the GC injector xxx Volume: 212 Pages: 247-251 Year: 2001 Report No.: M-449790-01-1 GLP/GEP: n.a., published	Yes	published
KCA 6.9 / 04	xxx	1996	The environmental fate of xenobiotics - Pesticides contamination in animal tissues and foods, monitoring results 1993-1994-1995 xxx Pages: 473-481 Year: 1996 Report No.: M-449809-01-1 GLP/GEP: n.a., published	Yes	published
KCA 6.9 / 05	Anon.	1997	Guidelines for predicting dietary intake of pesticide residues (revised) Publisher: WHO - World Health Organization Year: 1997 Report No.: M-449680-01-1 GLP/GEP: n.a., published	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.9 / 06	xxx	2001	Addendum to monograph Annex B, presented by RMS Sweden, draft dated November 26, 2001 Aventis comments on dietary intake calculations (sections B.6.15.3, page 28) Deltamethrin xxx Report No.: C017841 Edition Number: M-205036-01-1 Date: 2001-12-06 GLP/GEP: n.a., unpublished	Yes	Bayer
KCA 6.9 / 07	Martens, R.	1999	Statement on the acute dietary risk assessment for deltamethrin Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: C006040 Edition Number: M-193192-01-1 Date: 1999-11-18 GLP/GEP: n.a., unpublished ... also filed: KCA 6.5 / 06	No	Bayer
KCA 6.9 / 08	Shipp, E.	2019	Deltamethrin - In silico assessment of the plant metabolite 3-phenoxybenzaldehyde Bayer Report No.: M-646818-01-1 Date: 2019-01-18 GLP/GEP: n.a., unpublished ... also filed: KCA 5.8.1 / 12	No	Bayer
KCA 6.10.1 / 01	Miles, M.; Radix, P.; Brink, H.	2017	Statement: Label extension Decis forte (EC100): Additional information concerning the presence of residues in nectar and honey following applications in flowering oil seed rape Bayer Report No.: M-598954-01-2 Date: 2017-08-29 GLP/GEP: n.a., unpublished	No	Bayer

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
KCA 6.3.2.1 / 02 ... also filed: KCP 5.1 / 06	Kaussmann, M.; Kowalski, N.	2018	Determination of the residues of BYI 02960 and deltamethrin in/on sunflower after spray application of deltamethrin & flupyradifurone EC 085 in Italy, southern France, Spain and Greece Report No.: 16-2194, Edition Number: <u>M-634135-01-1</u> Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.2.1 / 03 ... also filed: KCP 5.1 / 08	Kaussmann, M.; Kowalski, N.	2018	Determination of the residues of BYI 02960 and deltamethrin in/on sunflower after spray application of deltamethrin & flupyradifurone EC 085 in southern France, Spain and Italy Report No.: 16-2195, Edition Number: <u>M-629954-01-1</u> Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.3.1 / 03 ... also filed: KCP 5.1 / 09	Noss, G.	2017	Determination of the residues of BYI 02960 and deltamethrin in/on barley after spray application of deltamethrin & flupyradifurone EC 085 in France (South), Italy, Spain and Greece Report No.: 15-2130, Edition Number: <u>M-572779-03-1</u> Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2017-10-17 GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.3.1 / 04 ... also filed: KCP 5.1 / 11	Kaussmann, M.; Miara, C.	2018	Determination of the residues of BYI 02960 and deltamethrin in/on barley after spray application of deltamethrin & flupyradifurone EC 085 in southern France, Italy, Spain and Greece Report No.: 16-2034, Edition Number: <u>M-634112-01-1</u> Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.4.1 / 03 ... also filed: KCP 5.1 / 13	Schulte, G.	2017	Amendment no. 2 to final report - Determination of the residues of BYI 02960 and deltamethrin in/on wheat after spray application of deltamethrin & flupyradifurone EC 085 in Italy, Spain and Portugal Report No.: 15-2127, Edition Number: <u>M-580063-03-1</u> Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2017-09-22 GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.4.1 / 04	Kaussmann, M.; Kerkerling, S.	2018	Determination of the residues of BYI 02960 and deltamethrin in/on wheat after spray application of deltamethrin & flupyradifurone EC 085 in southern France, Italy and Spain	No	Bayer

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
... also filed: KCP 5.1 / 15			Report No.: 16-2032, Edition Number: <u>M-633925-01-1</u> Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished		

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 Flupyradifurone

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

Within one residue study (16-2100) on maize the temperatures during storage increased. Therefore, one storage stability study at exaggerated temperatures was performed and summarized within this submission.

A 2.1.1.1.1.1 Study report S13-03307

Comments of zRMS:	The study of Lakaschus, S.; Gizler, A.; (2017; S13-03307; M-480441-06-1) has been evaluated in Registration Report for 102000028562 / DLT+FPF EC 85 in February 2022 by zRMS- PL and the summary is presented below: <i>According to the storage stability results it can be concluded that residues of flupyradifurone and DFA in the plant matrices of high water, high acid, high starch and high protein content were stable (<30% decomposition) after storage at + 1°C for 8 hours, following a storage of 6 - 8 days at -7°C.</i> <i>The study is acceptable.</i>
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Reference:	KCA 6.1/01
Title:	Amendment no. 3 to final report - 7 days freezer storage stability study with different combinations of a total of 61 analytes (parent and metabolite molecules) and five matrix types (high water / acidic / starch / protein / oil)
Report:	Lakaschus, S.; Gizler, A.; 2017; S13-03307; M-480441-06-1
Authority registration No:	
Guideline(s):	Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances US EPA Residue Chemistry Test Guideline OPPTS 860.1380: Storage Stability Data OECD Test Guideline 506, adopted 16 October 2007
Deviations:	see report
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Materials and methods

To determine the storage stability of relevant residues of flupyradifurone for a period of 8 hours at +1°C followed by 6-8 days of storage at -7°C in tomato fruit, wheat green material (high water content), grape bunches (high acid content), wheat grain, potato tuber (high starch content) and dry peas (high protein content). Individual 5-g control samples of the respective sample material were spiked with a mixture of the relevant analytes flupyradifurone parent compound (separately) or DFEAF, DFA and 6-CNA (jointly) at a fortification level of 1.0 mg/kg of each analyte.

(Results of DFEAF and 6-CNA are not shown in this summary since these metabolites are not a part of the residue definition; for details please refer to the report).

Except for the day-0 analysis, samples were stored in plastic containers at an average temperature of +1°C for eight hours, following 6-8 days at -7°C. For day-0 analysis, five treated samples of each material were chosen, as well as two control samples of each. Samples were then also analyzed after 6, 7 or 8 days of storage.

At each storage interval, five stored samples were analyzed. In addition two concurrent recoveries per commodity were conducted.

Flupyradifurone was analytically determined using analytical method 01207 ([Schoening, R.; Willmes, J.; 2014; M-476845-01](#)) and its metabolites DFA, DFEAF and 6-CNA were analytically determined using analytical method 01304 ([Li, Y.; Schoening, R.; 2012; M-415504-02](#)).

For the analysis of flupyradifurone, samples were adjusted with water followed by addition of acetonitrile leading to an acetonitrile/water ratio of (4/1, v/v). The samples fortified with flupyradifurone were left to soak for 15 minutes and then shaken for 15 minutes to enhance the extraction. Afterwards, a salt mixture ($\text{Mg}_2\text{SO}_4/\text{NaCl}/\text{Na}_3\text{ citrate } 2 \text{ H}_2\text{O}/\text{Na}_2\text{H citrate } 6 \text{ H}_2\text{O}$) (4/1/1/0.5, w/w/w/w) was added and the extracts were centrifuged. The extracts were submitted to LC-MS/MS-analysis and quantification was done using matrix-matched standards.

For DFA the samples were extracted twice with acidified acetonitrile/water (4/1, v/v). After centrifugation the clear supernatant was transferred into a volumetric flask and filled up to volume. An aliquot of the crude extract was evaporated to the aqueous remainder and purified using Bond Elut C_{18} SPE cartridges followed by the addition of internal standards. The final extracts were submitted to LC-MS/MS analysis with quantification using matrix-matched standards.

The methods were successfully validated at a level of 1 mg/kg relevant to this study in/on samples of tomato (fruit), wheat (green material), grape (bunches), wheat (grain), potato (tuber) and peas (dry peas) in the presented study. For further information on validation of the two methods please refer to Section 5, Appendix A 2.1.1.1).

Results and discussions

In the control samples, the residues were always below 30% of the LOQ.

Summaries of concurrent recoveries conducted as a part of the study are presented in Table A 1. The mean of the recoveries for each matrix were in an acceptable range (mean recoveries were 74% to 105%). The RSDs were in the range of 5.2 to 20%.

Summaries of residues recovered in stored samples are presented in Table A 2 for flupyradifurone and DFA.

Residues of flupyradifurone and DFA were stable (<30% decomposition) in tomato fruit, wheat green material, grape bunches, wheat grain, potato tuber and dry peas after storage for 8 hours at +1°C followed by 6-8 days of storage at -7°C frozen storage.

For flupyradifurone in dry peas the mean recovery in stored samples was at 69% (day 6 analysis). However, after correction for concurrent recoveries, flupyradifurone in dry peas can be considered as stable. The corrected mean recovery amounted to 88%.

Table A 1: Summary of concurrent recoveries of flupyradifurone and DFA in plant matrices

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
<i>Flupyradifurone</i>					
Tomato fruit	1.0	0	5	83, 106, 82, 84, 88	89±11
		8	2	86, 83	85
Wheat green material	1.0	0	5	90, 91, 94, 101, 103	96±6.1
		8	2	76, 72	74
Grapes bunches	1.0	0	5	79, 93, 97, 95, 109	95±11
		7	2	96, 88	92
Wheat grain	1.0	0	5	78, 94, 95, 100, 103	94±10
		7	2	76, 81	79
Potato tuber	1.0	0	5	91, 94, 95, 84, 87	90±5.2
		7	2	64, 93	79
Peas, dry	1.0	0	5	117, 107, 86, 132, 81	105±20
		6	2	78, 79	79
<i>DFA</i>					
Tomato fruit	1.0	0	5	102, 79, 68, 99, 84	86±16
		7	2	105, 96	101
Wheat green material	1.0	0	5	89, 80, 77, 61, 75	76±13
		7	2	83, 110	97
Grapes bunches	1.0	0	5	69, 90, 73, 99, 107	88±19
		7	2	85, 92	89
Wheat grain	1.0	0	5	99, 99, 80, 71, 91	88±14
		7	2	92, 87	90
Potato tuber	1.0	0	5	65, 104, 93, 111, 111	97±20
		7	2	91, 90	91
Peas, dry	1.0	0	5	74, 99, 72, 96, 67	82±18
		7	2	88, 76	82

Table A 2: Stability of flupyradifurone and DFA residues in plant matrices following storage at + 1°C for eight hours, following 6 to 8 days at -7°C

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)
<i>Flupyradifurone</i>				
Tomato fruit	1.0	0	0.833, 1.061, 0.816, 0.837, 0.875	83, 106, 82, 84, 88
		8	0.883, 0.904, 0.972, 0.885, 0.949	88, 90, 97, 89, 95
Wheat green material	1.0	0	0.896, 0.911, 0.941, 1.007, 1.031	90, 91, 94, 101, 103
		8	0.919, 0.755, 0.801, 0.830, 0.869	92, 76, 80, 83, 87
Grapes bunches	1.0	0	0.791, 0.933, 0.967, 0.950, 1.095	79, 93, 97, 95, 109
		7	0.957, 1.016, 0.952, 1.005, 1.055	96, 102, 95, 100, 105
Wheat grain	1.0	0	0.782, 0.938, 0.953, 1.001, 1.029	78, 94, 95, 100, 103
		7	0.720, 0.917, 0.826, 1.061, 0.883	72, 92, 83, 106, 88
Potato tuber	1.0	0	0.914, 0.940, 0.954, 0.842, 0.865	91, 94, 95, 84, 87
		7	0.945, 0.973, 1.024, 1.017, 0.981	94, 97, 102, 102, 98
Peas dry	1.0	0	1.168, 1.070, 0.856, 1.325, 0.812	117, 107, 86, 132, 81
		6	0.778, 0.665, 0.499, 0.727, 0.778	78, 66, 50, 73, 78
<i>DFA</i>				
Tomato fruit	1.0	0	1.025, 0.788, 0.682, 0.989, 0.844	102, 79, 68, 99, 84
		7	0.843, 0.970, 0.778, 0.907, 0.753	84, 97, 78, 91, 75
Wheat green material	1.0	0	0.892, 0.798, 0.765, 0.608, 0.749	89, 80, 77, 61, 75
		7	0.826, 0.788, 0.926, 1.059, 0.928	83, 79, 93, 106, 93
Grapes bunches	1.0	0	0.691, 0.905, 0.731, 0.991, 1.069	69, 90, 73, 99, 107
		7	1.038, 0.932, 1.017, 0.893, 1.021	104, 93, 102, 89, 102
Wheat grain	1.0	0	0.987, 0.991, 0.802, 0.714, 0.911	99, 99, 80, 71, 91
		7	0.999, 0.968, 0.892, 1.184, 1.067	100, 97, 89, 118, 107
Potato tuber	1.0	0	0.645, 1.036, 0.932, 1.110, 1.106	65, 104, 93, 111, 111
		7	0.872, 1.001, 1.072, 1.033, 0.948	87, 100, 107, 103, 95
Peas dry	1.0	0	0.739, 0.986, 0.716, 0.963, 0.673	74, 99, 72, 96, 67
		7	0.821, 0.746, 0.845, 0.653, 0.841	82, 75, 84, 65, 84

Conclusion

Residues of flupyradifurone and DFA in the plant matrices of high water, high acid, high starch and high protein content were stable (<30% decomposition) after storage at + 1°C for 8 hours, following a storage of 6 - 8 days at -7°C.

A 2.1.1.1.2 Storage stability of residues in animal products

No additional studies are required.

A 2.1.1.2 Stability of residues in sample extracts

A 2.1.1.2.1 Storage stability of residues in plant sample extracts

No additional studies are required.

A 2.1.1.2.2 Storage stability of residues in animal sample extracts

No additional studies are required.

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

A 2.1.2.1 Nature of residue in primary crops

No additional studies are required.

A 2.1.2.2 Nature of residue in rotational crops

No additional studies are required.

A 2.1.2.3 Nature of residues in processed commodities

No additional studies are required.

A 2.1.2.4 Nature of residues in livestock

No additional studies are required.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Grape

The critical GAP (cGAP) for the proposed use of Sivanto Energy (DLT+FPF EC 85) in grape is summarized in Table A 3.

Table A 3: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Home & Garden GAP, N-EU) (EFSA, 2015)	2	100	14	BBCH 57-81	14
Intended cGAP (number 103, 104, 201, 202, 252, 253, 352, 353, 371, 372*)	2	30	14	BBCH 57-81	14

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

A 2.1.3.1.1 Study report 14-2096

Comments of zRMS:	<p>Four field residue trials were conducted in northern Europe in 2014 to determine the magnitude of the relevant residues of BYI 02960 (flupyradifurone) and deltamethrin in/on grape (berry and bunch of grapes) after two spray applications with Deltamethrin & Flupyradifurone EC 085, an emulsifiable concentrate (EC) formulation containing 10 g/L deltamethrin and 75 g/L BYI 02960 each at a rate of 0.4 L/ha, corresponding to 30 g /ha BYI 02960 and 4 g /ha of deltamethrin with an interval of 13-15 days. The last application was done at a crop growth stage BBCH 83-89.</p> <p>Residues of BYI 02960 and its metabolites (difluoroacetic acid, BYI 02960-difluoroethylaminofuranone and 6-chloronicotinic acid) were determined by HPLC-MS/MS according to method 01212.</p> <p>The LOQ are 0.01 mg/kg for BYI 02960 and BYI 02960-difluoroethylaminofuranone calculated as BYI 02960 and 0.02 mg/kg for difluoroacetic acid calculated as BYI 02960. For BYI 02960 and its metabolites the average recoveries per fortification level were within the acceptable range of 70 – 110% and the RSD values were below 20% except for: BYI 02960 at the LOQ level (116%) in bunch of grapes and BYI 02960-difluoroethylaminofuranone at the LOQ level (117%) in bunch of grapes.</p> <p>Residue results (mg/kg): FPF: 2 x 0.043; 0.072*; 0.096, DFA: 0.008*; 0.011*; 0.013*; 0.016*, sum: 0.063; 0.071; 0.10*; 0.12. * Peak residues detected after PHI</p> <p>The storage period of deep-frozen samples intended for the analysis of BYI 02960 and its metabolites (AG01) in the treated samples ranged between 234 and 275 days and the storage period of the corresponding control samples ranged between 237 and 275 days.</p> <p>Residues of deltamethrin and its isomers AE 0035073 and AE F108569 were determined by HPLC-MS/MS according to method 00855/M004 with LOQ of 0.01 mg/kg for each compound in each sample material of the study.</p> <p>For deltamethrin and its two isomers average recoveries were at each fortification level within the acceptable range of 70 – 110% and the RSD values were below 20%.</p> <p>Residue results (mg/kg): E (deltamethrin): <0.01, 0.011, 0.013, 0.015, 0.015* RA (sum): <0.03, 0.031 0.033, 0.035, 0.035* * Peak residues detected after PHI</p>
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	The storage period of deep-frozen samples intended for the analysis of deltamethrin and its metabolites (AG02) in the treated and control samples ranged between 222 and 273 days.
	The study is acceptable.

Reference:	KCA 6.3.1.1/01
Title:	Determination of the residues of BYI 02960 and deltamethrin in/on grape after high and low-volume spray application of deltamethrin & flupyradifurone EC 085 in Germany and France (North)
Report:	Schoening, R.; Bouhamadi, S.; Sosniak, A.; Czaja, C.; 2016; 14-2096; M-559743-01-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP Guideline No. 860.1500 on Crop Field Trials
Deviations:	yes, see report
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Validity of the study:

Materials and methods

In 2014, 4 field trials were conducted in northern Europe (Germany [2] and northern France [2]) to support the use of Sivanto Energy EC 085 in grapes. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960). At each trial site there was one untreated plot in addition to three treated plots (T1- T3). Two applications were made at an interval of 13-15 days, each at a rate of 0.4 L/ha, corresponding to 30 g /ha BYI 02960. The last application was done at a crop growth stage BBCH 83-89 (BBCH 83: early dough; BBCH 89: berries ripe for harvest). The applications were performed as either low-volume (Trial 03 + 04) or high volume applications (Trial 01 + 02).

The trials were designed as reverse decline trials in order to harvest mature fruits (bunch of grapes) at different time points, ranging from 0 to 35 days after the second application. All samples were frozen within 24 hours after sampling and stored at a temperature of or below -18°C until analysis (max. 275 days). The maximum storage period of 275 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 52 months ([Netzbund, D.; 2015; M-428412-03-1](#)).

The samples were analysed according to method 01212 ([Rosati, D.; 2012; M-428017-01-1](#)) by LC-MS/MS using stable isotopically labelled internal standards. The LOQ in all sample materials was 0.01 mg/kg for BYI 02960 and 0.02 mg/kg for DFA when expressed as BYI 02960. The calculated LOQ for the total residue (sum of BYI 02960 and DFA, expressed as BYI 02960) was 0.03 mg/kg.

Residues of DFEAF and 6-CNA have been also determined during the study, but since they are not relevant to the residue definition for risk assessment, they are not reported here.

Results

During the course of this study, the method performance was checked/validated by concurrent recoveries. The average recoveries per fortification level and analyte were within the acceptable range of 70 – 110% except for BYI 02960 at the LOQ level (116%), which is considered acceptable since the overall mean is in the 70 - 110% range. If applicable, the RSD values were always well below 20% ([Table A 4](#)). Full validation of method 01212 was done and documented for matrices representing the 5 major crop groups, including tomato (fruit), grape (bunch of grape), kidney bean (dry seed), barley (grain) and summer rape (seed) when developing the method.

Details of the application and residue information are summarized in [Table A 5](#)
No residues above the LOQ were found in the control samples.

Table A 4: Recovery data for BYI 02960 and its metabolite DFA in grape

Study Trial No. Plot No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortifica tion level* (mg/kg)	Recovery (%) Individual recoveries	Min	Max	Mean	RSD
14-2096 14-2096-01 14-2096-01- T1 GLP: yes 2014	Grape	bunch of grapes	BYI 02960	2	0.01	105; 126	105	126	116	4.8
				3	0.1	99; 104; 109	99	109	104	
				1	0.5	100	100	100	100	
				6	overall		99	126	107	
			DFA	2	0.02	91; 129	91	129	110	9.8
				3	0.2	95; 99; 114	95	114	103	
				1	1.0	99	99	99	99	
				6	overall		91	129	105	

* expressed as BYI 02960

Table A 5: Residue trials on grapes

GAP Summary of the trials of study 14-2096

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL			
(a)	(b)	(b)				(c)	(d)	(f)
14-2096-01 14-2096-01-T1 Germany 76889 Steinfeld Europe, North F 2014	Grape Müller- Thurgau; withe variety	1) 03.05.2005 2) 06.06.2014 - 13.06.2014 3) 08.09.2014 - 03.10.2014	30 30	800 800	3.8 3.8	04.08.2014/0 18.08.2014/14	85	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
14-2096-01 14-2096-01-T2 Germany 76889 Steinfeld Europe, North F 2014	Grape Müller- Thurgau; withe variety	1) 03.05.2005 2) 06.06.2014 - 13.06.2014 3) 08.09.2014 - 03.10.2014	30 30	800 800	3.8 3.8	18.08.2014/0 01.09.2014/14	85	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
14-2096-01 14-2096-01-T3 Germany 76889 Steinfeld Europe, North F 2014	Grape Müller- Thurgau; withe variety	1) 03.05.2005 2) 06.06.2014 - 13.06.2014 3) 08.09.2014 - 03.10.2014	30 30	800 800	3.8 3.8	29.08.2014/0 13.09.2014/15	85	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
14-2096-02 14-2096-02-T1 Germany 67281 Bissersheim Europe, North F 2014	Grape Dornfelder; red variety	1) 14.06.2001 2) 06.06.2014 - 13.06.2014 3) 08.09.2014 - 03.10.2014	30 30	800 800	3.8 3.8	04.08.2014/0 18.08.2014/14	85	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL			
14-2096-02 14-2096-02-T2 Germany 67281 Bissersheim Europe, North F 2014	Grape Dornfelder; red variety	1) 14.06.2001 2) 06.06.2014 - 13.06.2014 3) 08.09.2014 - 03.10.2014	30 30	800 800	3.8 3.8	18.08.2014/0 01.09.2014/14	85	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
14-2096-02 14-2096-02-T3 Germany 67281 Bissersheim Europe, North F 2014	Grape Dornfelder; red variety	1) 14.06.2001 2) 06.06.2014 - 13.06.2014 3) 08.09.2014 - 03.10.2014	30 30	800 800	3.8 3.8	29.08.2014/0 13.09.2014/15	85	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
14-2096-03 14-2096-03-T1 France, north 37270 Athée sur Cher Europe, North F 2014	Grape Chardonnay; white variety	1) 01.01.1994 2) 03.06.2014 - 13.06.2014 3) 15.09.2014 - 25.09.2014	30 30	200 200	15 15	05.08.2014/0 19.08.2014/14	83	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying, low-volume
14-2096-03 14-2096-03-T2 France, north 37270 Athée sur Cher Europe, North F 2014	Grape Chardonnay; white variety	1) 01.01.1994 2) 03.06.2014 - 13.06.2014 3) 15.09.2014 - 25.09.2014	30 30	200 200	15 15	19.08.2014/0 02.09.2014/14	85	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying, low-volume

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL			
(a)	(b)	(b)				(c)	(d)	(f)
14-2096-03 14-2096-03-T3 France, north 37270 Athée sur Cher Europe, North F 2014	Grape Chardonnay; white variety	1) 01.01.1994 2) 03.06.2014 - 13.06.2014 3) 15.09.2014 - 25.09.2014	30 30	200 200	15 15	02.09.2014/0 16.09.2014/14	89	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying, low-volume
14-2096-04 14-2096-04-T1 France, north 37140 Saint Nicolas de Bourgueil Europe, North F 2014	Grape Cabernet Franc; red variety	1) 01.01.1986 2) 06.06.2014 - 18.06.2014 3) 20.09.2014 - 30.09.2014	30 30	200 200	15 15	13.08.2014/0 27.08.2014/14	85	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying, low-volume
14-2096-04 14-2096-04-T2 France, north 37140 Saint Nicolas de Bourgueil Europe, North F 2014	Grape Cabernet Franc; red variety	1) 01.01.1986 2) 06.06.2014 - 18.06.2014 3) 20.09.2014 - 30.09.2014	30 30	200 200	15 15	27.08.2014/0 10.09.2014/14	85	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying, low-volume
14-2096-04 14-2096-04-T3 France, north 37140 Saint Nicolas de Bourgueil Europe, North F 2014	Grape Cabernet Franc; red variety	1) 01.01.1986 2) 06.06.2014 - 18.06.2014 3) 20.09.2014 - 30.09.2014	30 30	200 200	15 15	10.09.2014/0 23.09.2014/13	89	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying, low-volume

Analytical part 14-2096

Analyte 1: BYI 02960 (determined as BYI 02960, calculated as BYI 02960), Analyte 2: DFA (determined as DFA, calculated as BYI 02960), Analyte 3: sum of BYI 02960 and DFA (calculated value. calculated as BYI 02960), Analyte 4: DFA (determined as DFA, calculated as DFA)

Trial No. / Location / EU zone / Year	Commodity/ Variety	Portion analysed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
(a)			(d)					(e)	(f)
14-2096-01 14-2096-01-T1 Germany 76889 Steinfeld Europe, North F 2014	Grape Müller- Thurgau; white variety	bunch of grapes	85 89 89	0.14 0.054 0.071	<0.02 0.024 0.034	0.16 0.078 <u>0.10</u>	<0.0067 0.0079 <u>0.011</u>	0 28 35	(g) 14-2096 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 274 days
14-2096-01 14-2096-01-T2 Germany 76889 Steinfeld Europe, North F 2014	Grape Müller- Thurgau; white variety	bunch of grapes	85 89 89	0.089 0.061 <u>0.072</u>	<0.02 0.021 0.031	0.11 0.082 0.10	<0.0067 0.0070 0.010	0 <u>14</u> 21	(g) 14-2096 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 260 days
14-2096-01 14-2096-01-T3 Germany 76889 Steinfeld Europe, North F 2014	Grape Müller- Thurgau; white variety	bunch of grapes berry	85 85 85 89 89 85 89	0.038 0.11 0.11 0.10 0.074 0.11 0.10	<0.02 <0.02 <0.02 <0.02 <0.02 <0.02 <0.02	0.058 0.13 0.13 0.12 0.094 0.13 0.12	<0.0067 <0.0067 <0.0067 <0.0067 <0.0067 <0.0067 <0.0067	0* 0 1 3 7 1 3	(g) 14-2096 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 248 days Analyte 1, 2 berry: 249 days

Trial No. / Location / EU zone / Year	Commodity/ Variety (a)	Portion analysed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
14-2096-02 14-2096-02-T1 Germany 67281 Bissersheim Europe, North F 2014	Grape Dornfelder; red variety	bunch of grapes	85 89 89	0.13 0.080 0.061	<0.02 0.036 0.048	0.15 0.12 0.11	<0.0067 0.012 <u>0.016</u>	0 28 35	(g) 14-2096 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 274 days
14-2096-02 14-2096-02-T2 Germany 67281 Bissersheim Europe, North F 2014	Grape Dornfelder; red variety	bunch of grapes	85 89 89 89	0.13 <u>0.096</u> 0.082	<0.02 <0.02 0.026	0.15 <u>0.12</u> 0.11	<0.0067 <0.0067 0.0087	0 <u>14</u> 21	(g) 14-2096 (j) Analytical method:01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 260 days
14-2096-02 14-2096-02-T3 Germany 67281 Bissersheim Europe, North F 2014	Grape Dornfelder; red variety	bunch of grapes berry	85 85 85 89 89 85 89	0.038 0.13 0.10 0.10 0.098 0.13 0.072	<0.02 <0.02 <0.02 <0.02 <0.02 <0.02 <0.02	0.058 0.15 0.12 0.12 0.12 0.15 0.092	<0.0067 <0.0067 <0.0067 <0.0067 <0.0067 <0.0067 <0.0067	0* 0 1 3 7 1 3	(g) 14-2096 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 249 days Analyte 1, 2 berry: 249 days

Trial No. / Location / EU zone / Year	Commodity/ Variety	Portion analysed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
	(a)		(d)					(e)	(f)
14-2096-03 14-2096-03-T1 France, north 37270 Athée sur Cher Europe, North F 2014	Grape Chardonnay; white variety	bunch of grapes	83 89 89	0.057 0.031 0.020	<0.02 0.038 0.030	0.077 0.069 0.051	<0.0067 0.013 0.010	0 28 35	(g) 14-2096 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 275 days
14-2096-03 14-2096-03-T2 France, north 37270 Athée sur Cher Europe, North F 2014	Grape Chardonnay; white variety	bunch of grapes	85 89 89	0.066 0.043 0.038	<0.02 0.028 0.026	0.086 0.071 0.064	<0.0067 0.0094 0.0087	0 14 21	(g) 14-2096 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 261 days
14-2096-03 14-2096-03-T3 France, north 37270 Athée sur Cher Europe, North F 2014	Grape Chardonnay; white variety	bunch of grapes berry	89 89 89 89 89 89 89	0.022 0.084 0.070 0.073 0.035 0.035 0.063	<0.02 <0.02 <0.02 <0.02 <0.02 <0.02 <0.02	0.042 0.10 0.090 0.093 0.055 0.055 0.083	<0.0067 <0.0067 <0.0067 <0.0067 <0.0067 <0.0067 <0.0067	0* 0 1 3 7 1 3	(g) 14-2096 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 247 days Analyte 1, 2 berry: 246 days

Trial No. / Location / EU zone / Year	Commodity/ Variety	Portion analysed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
(a)	(a)		(d)					(e)	(f)
14-2096-04 14-2096-04-T1 France, north 37140 Saint Nicolas de Bourgueil Europe, North F 2014	Grape Cabernet Franc; red variety	bunch of grapes	85 89 89	0.11 0.039 0.035	<0.02 0.022 0.025	0.13 0.061 0.060	<0.0067 0.0073 <u>0.0084</u>	0 28 34	(g) 14-2096 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 268 days
14-2096-04 14-2096-04-T2 France, north 37140 Saint Nicolas de Bourgueil Europe, North F 2014	Grape Cabernet Franc; red variety	bunch of grapes	85 89 89	0.13 <u>0.043</u> 0.043	<0.02 0.022 0.025	0.15 <u>0.063</u> 0.063	<0.0067 0.0067 0.0067	0 14 20	(g) 14-2096 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 254 days
14-2096-04 14-2096-04-T3 France, north 37140 Saint Nicolas de Bourgueil Europe, North F 2014	Grape Cabernet Franc; red variety	bunch of grapes berry	89 89 89 89 89 89 89	0.017 0.12 0.067 0.038 0.033 0.082 0.042	<0.02 0.022 0.022 0.022 0.022 0.022 0.022	0.037 0.14 0.087 0.058 0.053 0.10 0.062	<0.0067 0.0067 0.0067 0.0067 0.0067 0.0067 0.0067	0* 0 1 3 7 1 3	(g) 14-2096 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 241 days Analyte 1, 2 berry: 239 days

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control
(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.1.3.1.2 Study report 14-2095 (for information only)

Comments of zRMS:	This study has not been evaluated by zRMS-PL because it was conducted in southern Europe.
Reference:	KCA 6.3.1.1/02
Title:	Determination of the residues of BYI 02960 and deltamethrin in/on grape after high or low-volume spray application of deltamethrin & flupyradifurone EC 085 in southern France, Spain and Italy
Report:	Schoening, R.; Bouhamadi, S.; Sosniak, A.; Czaja, C.; 2016; 14-2095; M-560047-01-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP Guideline No. 860.1500 on Crop Field Trials
Deviations:	yes, see report
GLP/GEP:	yes
Acceptability:	-
Duplication (if vertebrate study):	

Validity of the study:

Materials and methods

In 2014, 4 field trials were conducted in southern Europe (southern France, Spain and Italy [2]) to support the use of Sivanto Energy EC 085 in grapes. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960). At each trial site there was one untreated plot in addition to three treated plots (T1- T3). Two applications were made at an interval of 13-14 days, each at a rate of 0.4 L/ha, corresponding to 30 g /ha BYI 02960. The last application was done at a crop growth stage BBCH 81-89 (BBCH 89: berries ripe for harvest). The applications were performed as either low-volume (Trial 02) or high volume applications (Trial 01, 03 and 04).

The trials were designed as reverse decline trials in order to harvest mature fruits (berries or bunch of grapes) at different time points, ranging from 0 to 35 days after the second application. All samples were frozen within 24 hours after sampling and stored at a temperature of or below -18°C until analysis (max. 286 days). The maximum storage period of 286 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 52 months ([Netzbänd, D.; 2015; M-428412-03-1](#)).

The samples were analysed according to method 01212 ([Rosati, D.; 2012; M-428017-01-1](#)) by LC-MS/MS using stable isotopically labelled internal standards. The LOQ in all sample materials was 0.01 mg/kg for BYI 02960 and 0.02 mg/kg for DFA when expressed as BYI 02960. The calculated LOQ for the total residue (sum of BYI 02960 and DFA, expressed as BYI 02960) was 0.03 mg/kg.

Residues of DFEAF and 6-CNA have been also determined during the study, but since they are not relevant to the residue definition for risk assessment, they are not reported here.

Results

During the course of this study, the method performance was checked/validated by concurrent recoveries. The average recoveries per fortification level and analyte were within the range of 70 – 120%. Recoveries above 110% were also accepted at the higher fortification levels (0.5 or 1.0 mg/kg) since all residue values in the treated samples were generally at lower levels. RSD values were always well below 20% (Table A 6). Full validation of method 01212 was done and documented for matrices representing the 5 major crop groups, including tomato (fruit), grape (bunch of grape), kidney bean (dry seed), barley (grain) and summer rape (seed) when developing the method.

Details of the application and residue information are summarized in [Table A 7](#).

No residues above the LOQ were found in the control samples.

Table A 6: Recovery data for BYI 02960 and its metabolite DFA in grape

Study Trial Plot No. GLP Year	No.	Crop	Portion analysed	a.s./ metabolite	n	Fortifica tion level* (mg/kg)	Recovery (%) Individual recoveries	Min	Max	Mean	RSD
14-2095 14-2095-01 14-2095-01-T1 to T3 to 14-2095-04 14-2095-04-T1 to T3 GLP: yes 2014		Grape	bunch of grapes	BYI 02960	4 2 1 7	0.01 0.1 0.5 overall	108;111;111;117 103;110 123 103	108 103 123 103	117 110 123 123	112 107 123 112	3.4 5.8
				DFA	4 2 1 7	0.02 0.2 1.0 overall	112;115;121;121 103;104 120 103	112 103 120 103	121 104 120 121	117 104 120 114	3.8 6.8
14-2095 14-2095-01 14-2095-01-T3 to 14-2095-04 14-2095-04-T3 GLP: yes 2014			berry	BYI 02960	3 1 4	0.01 0.5 overall	105;106;108 126 105	105 126 105	108 126 126	106 126 111	1.4 8.9
				DFA	3 1 4	0.02 1.0 overall	105;105;113 120 105	105 120 105	113 120 120	108 120 111	4.3 6.5

* expressed as BYI 02960

Table A 7: Residue trials on grapes

GAP Summary of the trials of study 14-2095

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL			
(a)	(a)	(b)				(c)	(d)	(f)
14-2095-01 14-2095-01-T1 Italy 40128 Bologna Europe, South F 2014	Grape Pinot Grigio; white variety	1) 01.01.2000 2) 15.05.2014 - 30.07.2014 3) 25.08.2014 - 05.09.2014	30.00 30.00	1000 1000	3.0 3.0	11.07.2014/0 25.07.2014/14	81	(g) 14-2095 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
14-2095-01 14-2095-01-T2 Italy 40128 Bologna Europe, South F 2014	Grape Pinot Grigio; white variety	1) 01.01.2000 2) 15.05.2014 - 30.07.2014 3) 25.08.2014 - 05.09.2014	30.00 30.00	1000 1000	3.0 3.0	25.07.2014/0 08.08.2014/14	83	(g) 14-2095 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
14-2095-01 14-2095-01-T3 Italy 40128 Bologna Europe, South F 2014	Grape Pinot Grigio; white variety	1) 01.01.2000 2) 15.05.2014 - 30.07.2014 3) 25.08.2014 - 05.09.2014	30.00 30.00	1000 1000	3.0 3.0	05.08.2014/0 19.08.2014/14	85	(g) 14-2095 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
14-2095-02 14-2095-02-T1 France, south 30290 Laudun Europe, South F 2014	Grape Grenache blanc; white variety	1) 01.04.1955 2) 25.05.2014 - 05.06.2014 3) 20.09.2014 - 30.09.2014	30.0 30.0	200 200	15 15	13.08.2014/0 27.08.2014/14	85	(g) 14-2095 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying, low-volume

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL			
14-2095-02 14-2095-02-T2 France, south 30290 Laudun Europe, South F 2014	Grape Grenache blanc; white variety	1) 01.04.1955 2) 25.05.2014 - 05.06.2014 3) 20.09.2014 - 30.09.2014	30.0 30.0	200 200	15 15	27.08.2014/0 10.09.2014/14	85	(g) 14-2095 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying, low-volume
14-2095-02 14-2095-02-T3 France, south 30290 Laudun Europe, South F 2014	Grape Grenache blanc; white variety	1) 01.04.1955 2) 25.05.2014 - 05.06.2014 3) 20.09.2014 - 30.09.2014	30.0 30.0	200 200	15 15	08.09.2014/0 22.09.2014/14	89	(g) 14-2095 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying, low-volume
14-2095-03 14-2095-03-T1 Spain 08784 Piera Europe, South F 2014	Grape Tempranillo; red variety	1) 01.01.1997 2) 15.05.2014 - 25.05.2014 3) 25.08.2014 - 10.09.2014	30.0 30.0	500 500	6.0 6.0	18.07.2014/0 31.07.2014/13	83	(g) 14-2095 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
14-2095-03 14-2095-03-T2 Spain 08784 Piera Europe, South F 2014	Grape Tempranillo; red variety	1) 01.01.1997 2) 15.05.2014 - 25.05.2014 3) 25.08.2014 - 10.09.2014	30.0 30.0	500 500	6.0 6.0	31.07.2014/0 14.08.2014/14	85	(g) 14-2095 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
14-2095-03 14-2095-03-T3 Spain 08784 Piera Europe, South F 2014	Grape Tempranillo; red variety	1) 01.01.1997 2) 15.05.2014 - 25.05.2014 3) 25.08.2014 - 10.09.2014	30.0 30.0	500 500	6.0 6.0	12.08.2014/0 26.08.2014/14	85	(g) 14-2095 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL			
14-2095-04 14-2095-04-T1 Italy 76123 Andria Europe, South F 2014	Grape Nero di troia; red variety	1) 05.02.1996 2) 31.05.2014 - 15.06.2014 3) 01.09.2014 - 15.09.2014	30.0 30.0	800 800	3.8 3.8	24.07.2014/0 07.08.2014/14	81	(g) 14-2095 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
14-2095-04 14-2095-04-T2 Italy 76123 Andria Europe, South F 2014	Grape Nero di troia; red variety	1) 05.02.1996 2) 31.05.2014 - 15.06.2014 3) 01.09.2014 - 15.09.2014	30.0 30.0	800 800	3.8 3.8	07.08.2014/0 21.08.2014/14	85	(g) 14-2095 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
14-2095-04 14-2095-04-T3 Italy 76123 Andria Europe, South F 2014	Grape Nero di troia; red variety	1) 05.02.1996 2) 31.05.2014 - 15.06.2014 3) 01.09.2014 - 15.09.2014	30.0 30.0	800 800	3.8 3.8	18.08.2014/0 02.09.2014/15	89	(g) 14-2095 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying

Analyte 1: BYI 02960 (determined as BYI 02960, calculated as BYI 02960), Analyte 2: DFA (determined as DFA, calculated as BYI 02960), Analyte 3 (calculated value): sum of BYI 02960 and DFA (calculated as BYI 02960), Analyte 4: DFA (determined as DFA, calculated as DFA)

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 difluoroacetic acid as BYI 02960	Analyte 3 sum of BYI 02960 and difluoroacetic acid as BYI 02960	Analyte 4 difluoroacetic acid as difluoroacetic acid		
(a)			(d)					(e)	(f)
14-2095-01 14-2095-01-T1 Italy 40128 Bologna Europe, South F 2014	Grape Pinot Grigio; white variety	bunch of grapes	81 89 89	0.061 0.013 0.014	<0.02 0.026 0.036	0.081 0.039 0.050	<0.0067 0.0087 <u>0.012</u>	0 28 35	(g) 14-2095 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2, 4 bunch of grapes: 286 days
14-2095-01 14-2095-01-T2 Italy 40128 Bologna Europe, South F 2014	Grape Pinot Grigio; white variety	bunch of grapes	83 89 89	0.14 0.027 <u>0.029</u>	<0.02 0.023 0.028	0.16 0.050 <u>0.058</u>	<0.0067 0.0076 0.0095	0 <u>14</u> 21	(g) 14-2095 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2, 4 bunch of grapes: 272 days
14-2095-01 14-2095-01-T3 Italy 40128 Bologna Europe, South F 2014	Grape Pinot Grigio; white variety	bunch of grapes	85 85 85 89 89	0.028 0.067 0.050 0.051 0.035	<0.02 <0.02 <0.02 <0.02 <0.02	0.048 0.087 0.070 0.071 0.055	<0.0067 <0.0067 <0.0067 <0.0067 <0.0067	0* 0 1 3 10	(g) 14-2095 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 261 days Analyte 1, 2 berry: 260 days
		berry	85 89	0.053 0.032	<0.02 <0.02	0.073 0.052	<0.0067 <0.0067	1 3	

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 difluoroacetic acid as BYI 02960	Analyte 3 sum of BYI 02960 and difluoroacetic acid as BYI 02960	Analyte 4 difluoroacetic acid as difluoroacetic acid		
14-2095-02 14-2095-02-T1 France, south 30290 Laudun Europe, South F 2014	Grape Grenache blanc; white variety	bunch of grapes	85 89 89	0.045 <0.01 <u>0.012</u>	<0.02 <0.02 <0.02	0.065 <0.03 <u>0.032</u>	<0.0067 <0.0067 <0.0067	0 28 35	(g) 14-2095 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 253 days
14-2095-02 14-2095-02-T2 France, south 30290 Laudun Europe, South F 2014	Grape Grenache blanc; white variety	bunch of grapes	85 85 89 89 89	0.049 <0.01 <0.01	<0.02 <0.02 <0.02	0.069 <0.03 <0.03	<0.0067 <u><0.0067</u> <0.0067	0 <u>14</u> 21	(g) 14-2095 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 239 days
14-2095-02 14-2095-02-T3 France, south 30290 Laudun Europe, South F 2014	Grape Grenache blanc; white variety	bunch of grapes berry	89 89 89 89 89 89 89	<0.01 0.037 0.017 0.015 0.014 0.028 0.014	<0.02 <0.02 <0.02 <0.02 <0.02 <0.02 <0.02	<0.03 0.057 0.037 0.035 0.034 0.048 0.034	<0.0067 <0.0067 <0.0067 <0.0067 <0.0067 <0.0067 <0.0067	0* 0 1 3 7 1 3	(g) 14-2095 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 231 days Analyte 1, 2 berry: 230 days

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 difluoroacetic acid as BYI 02960	Analyte 3 sum of BYI 02960 and difluoroacetic acid as BYI 02960	Analyte 4 difluoroacetic acid as difluoroacetic acid		
14-2095-03 14-2095-03-T1 Spain 08784 Piera Europe, South F 2014	Grape Tempranillo; red variety	bunch of grapes	83 89 89	0.19 <u>0.053</u> 0.046	<0.02 0.044 0.044	0.21 <u>0.097</u> 0.090	<0.0067 <u>0.015</u> 0.015	0 29 35	(g) 14-2095MAN (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 284 days
14-2095-03 14-2095-03-T2 Spain 08784 Piera Europe, South F 2014	Grape Tempranillo; red variety	bunch of grapes	85 89 89	0.13 0.037 0.027	<0.02 0.028 0.026	0.15 0.065 0.053	<0.0067 0.0094 0.0087	0 15 21	(g) 14-2095 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 270 days
14-2095-03 14-2095-03-T3 Spain 08784 Piera Europe, South F 2014	Grape Tempranillo; red variety	bunch of grapes berry	85 85 85 89 89 85 89	0.028 0.13 0.063 0.061 0.050 0.085 0.070	<0.02 <0.02 <0.02 <0.02 <0.02 <0.02 <0.02	0.048 0.15 0.083 0.081 0.070 0.11 0.090	<0.0067 <0.0067 <0.0067 <0.0067 <0.0067 <0.0067 <0.0067	0* 0 1 3 7 1 3	(g) 14-2095 (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 258 days Analyte 1, 2 berry: 257 days

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 difluoroacetic acid as BYI 02960	Analyte 3 sum of BYI 02960 and difluoroacetic acid as BYI 02960	Analyte 4 difluoroacetic acid as difluoroacetic acid		
14-2095-04 14-2095-04-T1 Italy 76123 Andria Europe, South F 2014	Grape Nero di troia; red variety	bunch of grapes	81 89 89	0.087 <u>0.020</u> 0.018	<0.02 <0.02 <0.02	0.11 <u>0.040</u> 0.038	<0.0067 <0.0067 <0.0067	0 28 35	(g) 14-2095MAN (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 277 days
14-2095-04 14-2095-04-T2 Italy 76123 Andria Europe, South F 2014	Grape Nero di troia; red variety	bunch of grapes	85 89 89	0.087 0.018 0.017	<0.02 <0.02 <0.02	0.11 0.038 0.037	<0.0067 <u><0.0067</u> <0.0067	0 <u>14</u> 21	(g) 14-2095MAN (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 263 days
14-2095-04 14-2095-04-T3 Italy 76123 Andria Europe, South F 2014	Grape Nero di troia; red variety	bunch of grapes berry	89 89 89 89 89 89 89	<0.01 0.089 0.037 0.050 0.029 0.049 0.034	<0.02 <0.02 <0.02 <0.02 <0.02 <0.02 <0.02	<0.03 0.11 0.057 0.070 0.049 0.069 0.054	<0.0067 <0.0067 <0.0067 <0.0067 <0.0067 <0.0067 <0.0067	0* 0 1 3 7 1 3	(g) 14-2095MAN (j) Analytical method: 01212 (k) LOQ: Analyte 1 berry, bunch of grapes: 0.01 mg/kg Analyte 2 berry, bunch of grapes: 0.02 mg/kg Analyte 3 berry, bunch of grapes: 0.03 mg/kg Analyte 4 berry, bunch of grapes: 0.0067 mg/kg (l) Method Validation Data: 01212, 14-2096 (m) Storage: Analyte 1, 2 bunch of grapes: 251 days Analyte 1, 2 berry: 252 days

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control
(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.1.3.2 Sunflower

The critical GAP (cGAP) for the proposed use of Sivanto Energy (DLT+FPF EC 85) in sunflower is summarized in [Table A 8](#).

Table A 8: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU	Currently there is no EU cGAP in place on sunflower seeds for flupyradifurone.				
Intended cGAP* (number 105, 219, 254, 335, 354, 373)	2	56.25	14	BBCH 30-69	As per growth stage

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

A 2.1.3.2.1 Study report 16-2145

Comments of zRMS:	<p>Eight field residue trials were conducted in northern Europe in 2016 to determine the magnitude of the residues of deltamethrin and BYI 02960 (common name flupyradifurone) in/on sunflower seeds (kernel with shell) and kernels (shelled seeds) after two spray applications and with Deltamethrin & Flupyradifurone EC 085, an emulsifiable concentrate (EC) formulation containing 10 g/L deltamethrin and 75 g/L BYI 02960 each at a rate of 0.75 L/ha, corresponding to 56.25 g BYI 02960/ha and 7.5 g/ha of deltamethrin with an interval of 13-14 days. The last application was done at a crop growth stage BBCH 69..</p> <p>Residues of BYI 02960 and difluoroacetic acid were determined by HPLC-MS/MS according to method 01304.</p> <p>The individual LOQs for BYI 02960 and difluoroacetic acid in seed and kernel are 0.01 mg/kg and 0.02 mg/kg (expressed as BYI 02960), respectively.</p> <p>The average recoveries per fortification level were within the range of 70 – 110%. The RSD values were below 20%.</p> <p>Residue results (mg/kg) for seeds (PHI: 29-56): E (FPF): 3 x 0.011; 0.015; 0.024; 0.046; 0.086; 0.10 E (DFA): 2 x 0.008; 0.015; 0.016; 2 x 0.022; 0.025; 0.042 RA (sum): 0.035; 0.044; 0.059; 0.076; 0.085; 0.090; 0.12; 0.23</p> <p>The storage period of samples (deepfrozen) used for the analysis of BYI 02960 and its metabolites was between 489 and 635 days.</p> <p>Residues of deltamethrin and its isomers AE 0035073 and AE F108569 were determined by HPLC-MS/MS according to method 00855/M004 with LOQ of 0.01 mg/kg for each compound.</p> <p>For deltamethrin and its two isomers average recoveries were at each fortification level within the acceptable range of 70 – 110% and the RSD values were below 20%.</p> <p>Residue results (mg/kg) in seeds: E (deltamethrin): 8 x <0.01 RA (sum): 8 x <0.03</p> <p>The storage period of samples (deep-frozen) used for the analysis of deltamethrin and its isomers was between 298 and 354 days.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.2.1/01
Title:	Determination of the residues of BYI 02960 and deltamethrin in/on sunflower after spray application of deltamethrin & flupyradifurone EC 085 in northern France, Hungary, The United Kingdom and Poland
Report:	Miara, C.; Kowalski, N.; 2018; 16-2145; M-645130-01-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial
Deviations:	None
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Validity of the study:

Materials and methods

In 2016, 8 field trials were conducted in northern Europe (northern France [3], Hungary [2], The United Kingdom and Poland [2]) to support the use of Sivanto Energy EC 085 in sunflower. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960). Two applications were made at an interval of 13-14 days, each at a rate of 0.75 L/ha, corresponding to 56.25 g BYI 02960/ha. The last application was done at a crop growth stage of BBCH 69 (end of flowering: most disc florets have finished flowering, ray florets dry or fallen).

Mature seed (kernel with shell) samples were collected at BBCH 85, 87 and 89, corresponding to 12-42, 21-46 and 29-56 days after the last treatment, respectively. An additional sample of mature seeds was taken 7 days after sampling at BBCH 89 (BBCH 89-92, 29-63 days after last treatment). All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 635 days). For the preparation of seeds into kernels the samples were defrosted, dried, if necessary, and stored at room temperature until start of preparation. After the preparation (cleaning, shelling and fractionation) all samples were stored at ambient conditions until separation of the kernel fraction. All kernel samples were deep-frozen immediately after separation (at or below -18°C within 24 h). The maximum storage period of 635 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 52 months ([Netzband, D.; 2015; M-428412-03-1](#)).

The residues of BYI 02960 and DFA were determined according to method 01304 ([Li, Y.; Schoening, R.; 2012; M-415504-02-1](#)). The LOQ in all sample matrices was 0.01 mg/kg for BYI 02960 and 0.02 mg/kg for DFA when expressed as BYI 02960 (corresponding to an LOQ of 0.0067 mg/kg, when expressed as DFA). The calculated LOQ for the total residue (sum of BYI 02960 and DFA, expressed as BYI 02960) was 0.03 mg/kg.

Residues of DFEAF and 6-CNA have been also determined during the study, but since they are not relevant to the residue definition for risk assessment, they are not reported here.

Results

During the course of this study, the method performance was checked/validated by at least 3 concurrent recoveries at two fortification levels. The average recoveries per fortification level and analyte were within the acceptable range of 70 – 110%. If applicable, the RSD values were always well below 20% ([Table A 9](#)).

Details of the application and residue information are summarized in [Table A 10](#).

No residues above the LOQ were found in the control samples except for BYI 02960 in seed (0.027 mg/kg) from trial 16-2145-06 and difluoroacetic acid in seed (up to 0.047 mg/kg) from trials 16-2145-01 and 16-2145-06 and kernel (0.043 mg/kg) from trial 16-2145-01.

Table A 9: Recovery data for flupyradifurone and its metabolite DFA in matrices of sunflower

Study Trial No. Plot No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortifica tion level * (mg/kg)	Recovery (%)				
						Individual recoveries	Min	Max	Mean	RSD
16-2145 16-2145-01 16-2145-01-T to 16-2145-08 16-2145-08-T GLP: yes 2016	Sunflower	kernel	BYI 02960	3	0.01	92; 94; 96	92	96	94	2.1
				3	0.1	92; 94; 96	92	96	94	2.1
				1	5.0	92	92	92	92	
				7	overall		92	96	94	1.9
			DFA	3	0.02	91; 97; 101	91	101	96	5.2
				3	0.2	74; 75; 78	74	78	76	2.8
				1	10	77	77	77	77	
				7	overall		74	101	85	13.4
		seed	BYI 02960	3	0.01	96; 96; 99	96	99	97	1.8
				3	0.1	90; 92; 99	90	99	94	5.0
				1	5.0	96	96	96	96	
				7	overall		90	99	95	3.5
			DFA	3	0.02	73; 80; 88	73	88	80	9.3
				3	0.2	79; 82; 83	79	83	81	2.6
				1	10	85	85	85	85	
				7	overall		73	88	81	5.9

* expressed as BYI 02960

Table A 10: Residue trials on sunflower

GAP summary of the trials of study16-2145

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL			
16-2145-01 16-2145-01-T France, north 71570 LA CHAPELLE DE GUINCHAY Europe, North F 2016	Sunflower Valento	1) 09.06.2016 2) 01.08.2016 - 25.08.2016 3) 15.09.2016 - 31.10.2016	56.25 56.25	350 350	16 16	12.08.2016/0 25.08.2016/13	69	(g) 16-2145 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
16-2145-02 16-2145-02-T Hungary 9600 Sarvar Europe, North F 2016	Sunflower Subaro	1) 19.05.2016 2) 18.07.2016 - 06.08.2016 3) 15.09.2016 - 30.09.2016	56.25 56.25	300 300	18.75 18.75	20.07.2016/0 03.08.2016/14	69	(g) 16-2145 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
16-2145-03 16-2145-03-T Hungary 7987 Istvandi Europe, North F 2016	Sunflower LG 54.92 HO-CL	1) 01.05.2016 2) 07.07.2016 - 24.07.2016 3) 01.09.2016 - 20.09.2016	56.25 56.25	250 250	22.5 22.5	07.07.2016/0 21.07.2016/14	69	(g) 16-2145 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
16-2145-04 16-2145-04-T France, north 63260 Montpensier Europe, North F 2016	Sunflower Symphonie	1) 25.04.2016 2) 18.07.2016 - 08.08.2016 3) 15.09.2016 - 15.10.2016	56.25 56.25	350 350	16.07 16.07	26.07.2016/0 08.08.2016/13	69	(g) 16-2145 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL			
16-2145-05 16-2145-05-T France, north 71290 Simandre Europe, North F 2016	Sunflower PR64E118	1) 05.05.2016 2) 21.07.2016 - 08.08.2016 3) 23.09.2016 - 07.10.2016	56.25 56.25	300 300	18.75 18.75	02.08.2016/0 16.08.2016/14	69	(g) 16-2145 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
16-2145-06 16-2145-06-T United Kingdom IP31 2NG BURY ST EDMUNDS Europe, North F 2016	Sunflower Sunspot	1) 26.05.2016 2) 21.08.2016 - 10.09.2016 3) 22.09.2016 - 20.10.2016	56.25 56.25	200 200	28.125 28.125	25.08.2016/0 08.09.2016/14	69	(g) 16-2145 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
16-2145-07 16-2145-07-T Poland 99-423 Oszkowice Europe, North F 2016	Sunflower Wielkopolski	1) 06.06.2016 2) 14.08.2016 - 28.08.2016 3) 15.09.2016 - 15.10.2016	56.25 56.25	300 300	18.75 18.75	13.08.2016/0 26.08.2016/13	69	(g) 16-2145 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
16-2145-08 16-2145-08-T Poland 88-400 Murczyn Europe, North F 2016	Sunflower MAS83.R	1) 25.05.2016 2) 07.08.2016 - 21.08.2016 3) 15.09.2016 - 15.10.2016	56.25 56.25	300 300	18.75 18.75	05.08.2016/0 19.08.2016/14	69	(g) 16-2145 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying

Analytical part 16-2145

Analyte 1: BYI 02960 (determined as BYI 02960, calculated as BYI 02960), Analyte 2: DFA (determined as DFA, calculated as BYI 02960), Analyte 3 (calculated value): sum of BYI 02960 and DFA (calculated as BYI 02960), Analyte 4: DFA (determined as DFA, calculated as DFA)

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
16-2145-01 16-2145-01-T France, north 71570 LA CHAPELLE DE GUINCHAY Europe, North F 2016	Sunflower Valento	Seed	85	0.041	0.034	0.075	0.011	35	(g) 16-2145 (j) Analytical method: 01304 (k) LOQ: Analyte 1: 0.01 mg/kg Analyte 2: 0.02 mg/kg Analyte 3: 0.03 mg/kg Analyte 4: 0.007 mg/kg (l) Method Validation Data: 01304, 16-2145 (m) Storage: Analyte 1, 2, 3 seed: 607 days Analyte 1, 2, 3 kernel: 490 days
			87	0.045	0.034	0.079	0.011	46	
			89	0.011	0.023/0.029**	0.034/0.039**	0.008/0.010**	56	
			89	<u>0.015</u>	0.020	<u>0.035</u>	0.007	63	
		Kernel	89	<u>0.010</u>	0.043/0.043**	<u>0.053/0.053**</u>	<u>0.014/0.014**</u>	56	
16-2145-02 16-2145-02-T Hungary 9600 Sarvar Europe, North F 2016	Sunflower Subaro	Seed	85	0.016	0.024	0.040	0.008	40	(g) 16-2145 (j) Analytical method: 01304 (k) LOQ: Analyte 1: 0.01 mg/kg Analyte 2: 0.02 mg/kg Analyte 3: 0.03 mg/kg Analyte 4: 0.007 mg/kg (l) Method Validation Data: 01304, 16-2145 (m) Storage: Analyte 1, 2, 3 seed: 624 days Analyte 1, 2, 3 kernel: 521 days
			87	0.017	0.026	0.043	0.009	43	
			89	<u>0.011</u>	0.026	0.037	0.009	47	
			89	<0.01	0.066	<u>0.076</u>	<u>0.022</u>	54	
		Kernel	89	<u><0.01</u>	0.031	<u>0.041</u>	<u>0.010</u>	47	
16-2145-03 16-2145-03-T Hungary 7987 Istvandi Europe, North F 2016	Sunflower LG 54.92 HO-CL	Seed	85	0.014	<0.02	0.034	<0.007	42	(g) 16-2145 (j) Analytical method: 01304 (k) LOQ: Analyte 1: 0.01 mg/kg Analyte 2: 0.02 mg/kg Analyte 3: 0.03 mg/kg Analyte 4: 0.007 mg/kg (l) Method Validation Data: 01304, 16-2145 (m) Storage: Analyte 1, 2, 3 seed: 635 days Analyte 1, 2, 3 kernel: 532 days
			87	0.016	0.020	0.036	0.007	46	
			89	0.016	0.020	0.036	0.007	49	
			89	<u>0.046</u>	0.044	<u>0.090</u>	<u>0.015</u>	56	
		Kernel	89	<u><0.01</u>	0.026	<u>0.036</u>	<u>0.009</u>	49	

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
16-2145-04 16-2145-04-T France, north 63260 Montpensier Europe, North F 2016	Sunflower Symphonie	Seed	85 87 89 89	0.013 <0.01 <u>0.011</u> <0.01	0.057 0.053 0.074 0.065	0.069 0.063 <u>0.085</u> 0.075	0.019 0.018 <u>0.025</u> 0.022	31 36 44 51	(g) 16-2145 (j) Analytical method: 01304 (k) LOQ: Analyte 1: 0.01 mg/kg Analyte 2: 0.02 mg/kg Analyte 3: 0.03 mg/kg Analyte 4: 0.007 mg/kg (l) Method Validation Data: 01304, 16-2145 (m) Storage: Analyte 1, 2, 3 seed: 628 days Analyte 1, 2, 3 kernel: 519 days
16-2145-05 16-2145-05-T France, north 71290 Simandre Europe, North F 2016	Sunflower PR64E118	Seed	85 87 89 89	0.059 0.062 <u>0.10</u> 0.054	0.039 0.063 0.13 0.081	0.098 0.12 <u>0.23</u> 0.13	0.013 0.021 <u>0.042</u> 0.027	23 34 43 50	(g) 16-2145 (j) Analytical method: 01304 (k) LOQ: Analyte 1: 0.01 mg/kg Analyte 2: 0.02 mg/kg Analyte 3: 0.03 mg/kg Analyte 4: 0.007 mg/kg (l) Method Validation Data: 01304, 16-2145 (m) Storage: Analyte 1, 2, 3 seed: 634 days Analyte 1, 2, 3 kernel: 512 days
16-2145-06 16-2145-06-T United Kingdom IP31 2NG BURY ST EDMUNDS Europe, North F 2016	Sunflower Sunspot	Seed	85 87 89 89	0.031 0.072 0.054/0.027** <u>0.086</u>	<0.02 0.041 0.067/0.047** 0.033	0.051 0.11 0.12/0.074** <u>0.12</u>	<0.007 0.014 <u>0.022</u> /0.016** 0.011	12 21 29 36	(g) 16-2145 (j) Analytical method: 01304 (k) LOQ: Analyte 1: 0.01 mg/kg Analyte 2: 0.02 mg/kg Analyte 3: 0.03 mg/kg Analyte 4: 0.007 mg/kg (l) Method Validation Data: 01304, 16-2145 (m) Storage: Analyte 1, 2, 3 seed: 622 days Analyte 1, 2, 3 kernel: 503 days
16-2145-07 16-2145-07-T Poland 99-423	Sunflower Wielkopolski	Seed	85 87 89 92	0.022 0.016 <u>0.024</u> 0.016	<0.02 <0.02 <0.02 0.024	0.042 0.036 <u>0.044</u> 0.040	<0.007 <0.007 <0.007 <u>0.008</u>	21 27 35 42	(g) 16-2145 (j) Analytical method: 01304 (k) LOQ: Analyte 1: 0.01 mg/kg

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
Oszkowice Europe, North F 2016		Kernel	89	<u><0.01</u>	0.036	<u>0.046</u>	<u>0.012</u>	35	Analyte 2: 0.02 mg/kg Analyte 3: 0.03 mg/kg Analyte 4: 0.007 mg/kg (l) Method Validation Data: 01304, 16-2145 (m) Storage: Analyte 1, 2, 3 seed: 626 days Analyte 1, 2, 3 kernel: 510 days
16-2145-08 16-2145-08-T Poland 88-400 Murczyn Europe, North F 2016	Sunflower MAS83.R	Seed Kernel	85 87 89 92 89	0.012 0.012 <u>0.011</u> <0.01 <u><0.01</u>	0.020 0.032 0.048 0.026 0.066	0.032 0.044 <u>0.059</u> 0.036 <u>0.076</u>	0.007 0.011 <u>0.016</u> 0.009 <u>0.022</u>	25 32 40 47 40	(g) 16-2145 (j) Analytical method: 01304 (k) LOQ: Analyte 1: 0.01 mg/kg Analyte 2: 0.02 mg/kg Analyte 3: 0.03 mg/kg Analyte 4: 0.007 mg/kg (l) Method Validation Data: 01304, 16-2145 (m) Storage: Analyte 1, 2, 3 seed: 629 days Analyte 1, 2, 3 kernel: 512 days

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.1.3.2.2 Study report 16-2194 (for information only)

Comments of zRMS:	This study has not been evaluated by zRMS-PL because it was conducted in southern Europe.
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Reference:	KCA 6.3.2.1/02
Title:	Determination of the residues of BYI 02960 and deltamethrin in/on sunflower after spray application of deltamethrin & flupyradifurone EC 085 in Italy, southern France, Spain and Greece
Report:	Kaussmann, M.; Kowalski, N.; 2018; 16-2194; M-634135-01-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSP 860.1500, Crop Field Trial
Deviations:	None
GLP/GEP:	yes
Acceptability:	-
Duplication (if vertebrate study):	

Validity of the study:

Materials and methods

In 2016, 5 field trials were conducted in southern Europe (Spain, Greece, southern France and Italy [2]) to support the use of Sivanto Energy EC 085 in sunflower. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960).

Two applications were made at an interval of 14-15 days, each at a rate of 0.75 L/ha, corresponding to 56.25 g BYI 02960/ha. The last application was done at a crop growth stage of BBCH 69 (BBCH69: end of flowering, most disc florets have finished flowering ray florets dry or fallen) with the exception of trial 16-2194-04 where the second application was done at BBCH 63. However the interval between last treatment and harvest of mature kernels was in the same range as for the other trials (even slightly shorter). The residues in the mature kernel seeds of all trials were comparable and no significant difference could be observed.

Seed samples (kernel with shell) were collected at BBCH 85, 87 and 89, corresponding to 10-43, 23-49 and 48-66 days after the last treatment, respectively. An additional sample of mature seeds was taken 7 days after sampling at BBCH 89 (BBCH 89-92, 57-73 days after last treatment), except for trial 16-2194-04. All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 589 days). The maximum storage period of 589 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 52 months ([Netzband, D.; 2015; M-428412-03-1](#)).

The samples were analysed according to method 01304 ([Li, Y.; Schoening, R.; 2012; M-415504-02-1](#)). The LOQ in all sample matrices was 0.01 mg/kg for BYI 02960 and 0.02 mg/kg for DFA when expressed as BYI 02960 (corresponding to an LOQ of 0.0067 mg/kg, when expressed as DFA). The calculated LOQ for the total residue (sum of BYI 02960 and DFA, expressed as BYI 02960) was 0.03 mg/kg.

Residues of DFEAF and 6-CNA have been also determined during the study, but since they are not relevant to the residue definition for risk assessment, they are not reported here.

Results

During the course of this study, the method performance was checked/validated by concurrent recoveries. Full validation of method 01304 was done and documented for matrices representing the 5 major crop groups, including dry seeds of beans, cereal forage, orange fruit, soybean seeds, tomato fruit, and wheat grain when developing the method. For sunflower seed and kernel a limited set (1 control, 3

repetitions each at two fortification levels) of additional validation recoveries was done within this study. The average recoveries per fortification level and analyte were within the acceptable range of 70 – 110%. If applicable, the RSD values were always well below 20% (Table A 12).

Details of the application and residue information are summarized in Table A 11. No residues of BYI 02960 or DFA at or above the limit of quantification of the method were found in any of the untreated samples.

Table A 12: Recovery data for flupyradifurone and its metabolite DFA in sunflower

Study Trial Plot No. GLP Year	No.	Crop	Portion analysed	a.s./ metabolite	n	Fortific ation level (mg/kg) *	Individual recoveries	Recovery (%)			
								Min	Max	Mean	RSD
16-2194 16-2194-01 16-2194-01-T to 16-2194-05 16-2194-05-T GLP: yes 2016		Sunflower	kernel	BYI 02960	3	0.01	95; 96; 98	95	98	96	1.6
					3	0.1	95; 96; 98	95	98	96	1.6
					1	3.0	98	98	98	98	-
					7	overall		95	98	97	1.4
			DFA		3	0.02	79; 81; 86	79	86	82	4.4
					3	0.2	76; 77; 79	76	79	77	2
					1	6.0	81	81	81	81	-
					7	overall		76	86	80	4.1
		seed	BYI 02960		3	0.01	92; 92; 96	92	96	93	2.5
					3	0.1	89; 89; 89	89	89	89	0
					1	5.0	90	90	90	90	-
					7	overall		89	96	91	2.8
			DFA		3	0.02	91; 99; 100	91	100	97	5.1
					3	0.2	73; 73; 73	73	73	73	0
					1	10	78	78	78	78	-
					7	overall		73	100	84	14.8

* expressed as BYI 02960

Table A 13: Residue trials on sunflower

GAP summary of the 16-2194 trials

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL			
(a)	(b)	(b)				(c)	(d)	(f)
16-2194-01 16-2194-01-T Italy 00052 Furbara di Cerveteri (RM) Europe, South F 2016	Sunflower P63HH79	1) 07.04.2016 2) 27.06.2016 - 11.07.2016 3) 15.08.2016 - 15.09.2016	56.25 56.25	350 350	16.07 16.07	27.06.2016/0 11.07.2016/14	69	(g) 16-2194 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
16-2194-02 16-2194-02-T Italy 45020 Lusia Rovigo Europe, South F 2016	Sunflower P64LE25	1) 01.04.2016 2) 21.06.2016 - 04.07.2016 3) 18.08.2016 - 06.09.2016	56.25 56.25	500 500	11.25 11.25	21.06.2016/0 05.07.2016/14	69	(g) 16-2194 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
16-2194-03 16-2194-03-T France, south 31620 Gargas Europe, South F 2016	Sunflower Sy Talento	1) 05.04.2016 2) 10.07.2016 - 23.07.2016 3) 12.09.2016 - 30.09.2016	56.25 56.25	300 300	18.75 18.75	06.07.2016/0 20.07.2016/14	69	(g) 16-2194 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
16-2194-04 16-2194-04-T Spain 41610 Paradas Europe, South F 2016	Sunflower Duet	1) 10.03.2016 2) 02.06.2016 - 17.06.2016 3) 10.07.2016 - 20.08.2016	56.25 56.25	300 300	18.75 18.75	23.05.2016/0 07.06.2016/15	63	(g) 16-2194 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
16-2194-05 16-2194-05-T Greece	Sunflower NK Adagio	1) 10.04.2016 2) 14.07.2016 - 29.07.2016	56.25 56.25	500 500	11.25 11.25	15.07.2016/0 29.07.2016/14	69	(g) 16-2194 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method:

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL			
	(a)	(b)				(c)	(d)	(f)
GR - 501 00 Kissa, Thymaria - Kozani Europe, South F 2016		3) 03.10.2016 - 03.10.2016						Spraying

Analytical part 16-2194

Analyte 1: BYI 02960 (determined as BYI 02960, calculated as BYI 02960), Analyte 2: DFA (determined as DFA, calculated as BYI 02960), Analyte 3 (calculated value): sum of BYI 02960 and DFA (calculated as BYI 02960), Analyte 4: DFA (determined as DFA, calculated as DFA)

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
	(a)		(d)					(e)	(f)
16-2194-01 16-2194-01-T Italy 00052 Furbara di Cerveteri (RM) Europe, South F 2016	Sunflower P63HH79	seed	85 87 89 89	0.026 0.018 0.021 <u>0.025</u>	0.044 0.088 0.093 0.11	0.070 0.11 0.11 <u>0.13</u>	0.015 0.029 0.031 <u>0.036</u>	10 23 50 57	(g) 16-2194 (j) Analytical method: seed, kernel: 01304 (k) LOQ:
		kernel	89	<u><0.01</u>	0.14	<u>0.15</u>	<u>0.046</u>	50	Analyte 1 seed, kernel: 0.01 mg/kg Analyte 2 seed, kernel: 0.02 mg/kg Analyte 3 seed, kernel: 0.03 mg/kg Analyte 4 seed, kernel: 0.007 mg/kg (l) Method Validation Data: 01304, 16-2194 (m) Storage: seed: 580 days kernel: 533 days

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
16-2194-02 16-2194-02-T Italy 45020 Lusia Rovigo Europe, South F 2016	Sunflower P64LE25	seed	85 87 89 89	0.015 0.035 0.023 <u>0.032</u>	0.020 0.023 0.020 0.028	0.035 0.058 0.044 <u>0.061</u>	0.007 0.008 0.007 <u>0.009</u>	43 49 56 63	(g) 16-2194 (j) Analytical method: seed, kernel: 01304 (k) LOQ: Analyte 1 seed, kernel: 0.01 mg/kg Analyte 2 seed, kernel: 0.02 mg/kg Analyte 3 seed, kernel: 0.03 mg/kg Analyte 4 seed, kernel: 0.007 mg/kg (l) Method Validation Data: 01304, 16-2194 (m) Storage: seed: 553 days kernel: 533 days
16-2194-03 16-2194-03-T France, south 31620 Gargas Europe, South F 2016	Sunflower Sy Talento	seed	85 87 89 89	<0.01 <0.01 <u><0.01</u> <0.01	0.035 0.037 0.038 0.029	0.045 0.047 <u>0.048</u> 0.039	0.012 0.012 <u>0.013</u> 0.010	34 44 54 61	(g) 16-2194 (j) Analytical method: seed, kernel: 01304 (k) LOQ: Analyte 1 seed, kernel: 0.01 mg/kg Analyte 2 seed, kernel: 0.02 mg/kg Analyte 3 seed, kernel: 0.03 mg/kg Analyte 4 seed, kernel: 0.007 mg/kg (l) Method Validation Data: 01304, 16-2194 (m) Storage: seed: 547 days kernel: 520 days
16-2194-04 16-2194-04-T Spain 41610 Paradas Europe, South F 2016	Sunflower Duet	seed	85 87 89	<0.01 0.011 <u><0.01</u>	0.096 0.13 0.13	0.11 0.14 <u>0.14</u>	0.032 0.042 <u>0.043</u>	35 41 48	(g) 16-2194 (j) Analytical method: seed, kernel: 01304 (k) LOQ: Analyte 1 seed, kernel: 0.01 mg/kg Analyte 2 seed, kernel: 0.02 mg/kg Analyte 3 seed, kernel: 0.03 mg/kg Analyte 4 seed, kernel: 0.007 mg/kg (l) Method Validation Data: 01304, 16-2194 (m) Storage: seed: 589 days kernel: 569 days
		kernel	89	<u><0.01</u>	0.20	<u>0.21</u>	<u>0.068</u>	48	

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)		
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA				
16-2194-05 16-2194-05-T Greece GR - 501 00 Kissa, Thymaria - Kozani Europe, South F 2016	Sunflower NK Adagio	seed	85 87 89 92	0.028 0.028 <u>0.014</u> 0.014	<0.02 <0.02 0.024 0.022	0.048 0.048 <u>0.038</u> 0.035	<0.007 <0.007 <u>0.008</u> 0.007	21 28 66 73	(g) 16-2194 (j) Analytical method: seed, kernel: 01304 (k) LOQ: Analyte 1 seed, kernel: 0.01 mg/kg Analyte 2 seed, kernel: 0.02 mg/kg Analyte 3 seed, kernel: 0.03 mg/kg Analyte 4 seed, kernel: 0.007 mg/kg (l) Method Validation Data: 01304, 16-2194 (m) Storage: seed: 551 days kernel: 499 days		
		kernel	89	<u><0.01</u>	0.023	<u>0.033</u>	<u>0.008</u>	66			
(a)	According to CODEX Classification / Guide			(e)	Days after last application (Label pre-harvest interval, PHI, underline)			(h)	Formulation type	(l)	Method validation
(b)	Only if relevant			(f)	Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included			(i)	Application method	(m)	Storage (max)
(c)	Year must be indicated							(j)	Method information		! based on date of analysis
(d)	Either growth stage description or BBCH Code			(g)	Study reference			(k)	LOQ		P based on production date
G	greenhouse	F field	*	prior to last treatment			**	residue in control	#	no data available	

A 2.1.3.2.3 Study report 16-2195 (for information only)

Comments of zRMS:	This study has not been evaluated by zRMS-PL because it was conducted in southern Europe.
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Reference:	KCA 6.3.2.1/03
Title:	Determination of the residues of BYI 02960 and deltamethrin in/on sunflower after spray application of deltamethrin & flupyradifurone EC 085 in southern France, Spain and Italy
Report:	Kaussmann, M.; Kowalski, N.; 2018; 16-2195; M-629954-01-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPG Guideline No. 860.1500 on Crop Field Trial
Deviations:	None
GLP/GEP:	yes
Acceptability:	-
Duplication (if vertebrate study):	

Validity of the study:

Materials and method

In 2016, 3 field trials were conducted in southern Europe (southern France, Spain and Italy) to support the use of Sivanto Energy EC 085 in sunflower. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960). Two applications were made at an interval of 14-16 days, each at a rate of 0.75 L/ha, corresponding to 56.25 g BYI 02960/ha. The last application was done at a crop growth stage of BBCH 69 (end of flowering: most disc florets have finished flowering ray florets dry or fallen).

Mature seed (kernel with shell) samples were collected at BBCH 85, 87 and 89, corresponding to 18-31, 25-34 and 36-41 days after the last treatment, respectively. An additional sample of mature seeds was taken 7 days after sampling at BBCH 89 (BBCH 89-92, 43-48 days after last treatment). All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 550 days). For the preparation of seeds into kernels the samples were defrosted, dried, if necessary, and stored at room temperature until further preparation. After the preparation (cleaning, shelling and fractionation) all samples were stored at ambient conditions for separation of the kernel fraction. All kernel samples were deep-frozen immediately after separation (at or below -18°C within 24 h). The maximum storage period of 550 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 52 months ([Netzband, D.; 2015; M-428412-03-1](#)).

The samples were analysed according to method 01304 ([Li, Y.; Schoening, R.; 2012; M-415504-02-1](#)). The LOQ in all sample matrices was 0.01 mg/kg for BYI 02960 and 0.02 mg/kg for DFA when expressed as BYI 02960 (corresponding to an LOQ of 0.0067 mg/kg, when expressed as DFA). The calculated LOQ for the total residue (sum of BYI 02960 and DFA, expressed as BYI 02960) was 0.03 mg/kg.

Residues of DFEAF and 6-CNA have been also determined during the study, but since they are not relevant to the residue definition for risk assessment, they are not reported here.

Results

During the course of this study, the method performance was checked/validated by concurrent recoveries. Full validation of method 01304 was done and documented for matrices representing the 5 major crop groups, including dry seeds of beans, cereal forage, orange fruit, soybean seeds, tomato fruit,

and wheat grain when developing the method. For sunflower seed and kernel a limited set (1 control, 3 repetitions each at two fortification levels) of additional validation recoveries was done within this study. The average recoveries per fortification level and analyte were within the acceptable range of 70 – 110%. If applicable, the RSD values were always well below 20% (Table A 14).

Details of the application and residue information are summarized in Table A 15.

No residues of BYI 02960 or DFA at or above the limit of quantification of the method were found in any of the untreated samples.

Table A 14: Recovery data for flupyradifurone and its metabolite DFA in sunflower

Study Trial No. Plot No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortifi- cation level * (mg/kg)	Individual recoveries	Recovery (%)			RSD
							Min	Max	Mean	
16-2195 16-2195-01 16-2195-01-T to 16-2195-03 16-2195-03-T GLP: yes 2016	Sun- flower	seed	BYI 02960	3	0.01	99;100; 102	99	102	100	1.5
				3	0.1	96;97;104	96	104	99	4.4
				6	overall		96	104	100	3.0
			DFA	3	0.02	81;84;85	81	85	83	2.5
				3	0.2	72;74;91	72	91	79	13.2
				6	overall		72	91	81	8.8
		kernel	BYI 02960	3	0.01	105;108; 108	105	108	107	1.6
				3	0.1	96;99;105	96	105	100	4.6
				6	overall		96	108	104	4.8
			DFA	3	0.02	94;104; 104	94	104	101	5.7
				3	0.2	86;86;87	86	87	86	0.7
				6	overall		86	104	94	9.3

* expressed as BYI 02960

Table A 15: Residue trials on sunflower

GAP Summary of the 16-2195 trials

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL			
(a)	(b)	(b)				(c)	(d)	(f)
16-2195-01 16-2195-01-T France, south 32490 Monferran-Savès Europe, South F 2016	Sunflower Tutti	1) 28.04.2016 2) 20.07.2016 - 08.08.2016 3) 07.09.2016 - 17.09.2016	56.25 56.25	300 300	18.75 18.75	25.07.2016/0 08.08.2016/14	69	(g) 16-2195 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
16-2195-02 16-2195-02-T Spain E-02220 Motiveja Europe, South F 2016	Sunflower Talento	1) 08.06.2016 2) 01.08.2016 - 17.08.2016 3) 27.09.2016 - 04.10.2016	56.25 56.25	560 560	10.04 10.04	01.08.2016/0 17.08.2016/16	69	(g) 16-2195 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
16-2195-03 16-2195-03-T Italy 15028 Refrancore Europe, South F 2016	Sunflower Olival SIS	1) 28.04.2016 2) 07.07.2016 - 19.07.2016 3) 20.08.2016 - 10.09.2016	56.25 56.25	400 400	14.06 14.06	05.07.2016/0 19.07.2016/14	69	(g) 16-2195 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying

Analytical part 16-2195

Analyte 1: BYI 02960 (determined as BYI 02960, calculated as BYI 02960), Analyte 2: DFA (determined as DFA, calculated as BYI 02960), Analyte 3 (calculated value): sum of BYI 02960 and DFA (calculated as BYI 02960), Analyte 4: DFA (determined as DFA, calculated as DFA)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
16-2195-01 16-2195-01-T France, south 32490 Monferran-Savès Europe, South F 2016	Sunflower Tutti	seed	85	0.016	0.064	0.080	0.021	18	(g) 16-2195 (j) Analytical method: Analyte 2, 3, 4 seed: 01304 Analyte 2, 3, 4 kernel: 01304 (k) LOQ: Analyte 1 seed/kernel: 0.01 mg/kg Analyte 2 seed/kernel: 0.02 mg/kg Analyte 3 seed/kernel: 0.03 mg/kg Analyte 4 seed/kernel: 0.0067 mg/kg (l) Method Validation Data: 01304, 16-2195 (m) Storage: Analyte 1, 2, 4 seed: 543 days Analyte 1, 2, 4 kernel: 519 days
			87	0.019	0.055	0.074	0.018	25	
			89	0.014	0.043	0.057	0.014	36	
			92	<u>0.026</u>	0.070	<u>0.096</u>	<u>0.023</u>	43	
		kernel	89	<u><0.01</u>	0.056	<u>0.066</u>	<u>0.019</u>	36	
16-2195-02 16-2195-02-T Spain E-02220 Mottileja Europe, South F 2016	Sunflower Talento	seed	85	0.018	0.076	0.094	0.025	21	(g) 16-2195 (j) Analytical method: Analyte 2, 3, 4 seed: 01304 Analyte 2, 3, 4 kernel: 01304 (k) LOQ: Analyte 1 seed/kernel: 0.01 mg/kg Analyte 2 seed/kernel: 0.02 mg/kg Analyte 3 seed/kernel: 0.03 mg/kg Analyte 4 seed/kernel: 0.0067 mg/kg (l) Method Validation Data: 01304, 16-2195 (m) Storage: Analyte 1, 2, 4 seed: 531 days Analyte 1, 2, 4 kernel: 505 days
			87	0.017	0.084	0.10	0.028	29	
			89	0.014	0.15	<u>0.16</u>	<u>0.049</u>	41	
			92	<u>0.027</u>	0.11	0.14	0.038	48	
		kernel	89	<u><0.01</u>	0.19	<u>0.20</u>	<u>0.062</u>	41	

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
16-2195-03 16-2195-03-T Italy 15028 Refrancore Europe, South F 2016	Sunflower Olival SIS	seed	85	0.028	0.061	0.089	0.020	31	(g) 16-2195 (j) Analytical method: Analyte 2, 3, 4 seed: 01304 Analyte 2, 3, 4 kernel: 01304 (k) LOQ: Analyte 1 seed/kernel: 0.01 mg/kg Analyte 2 seed/kernel: 0.02 mg/kg Analyte 3 seed/kernel: 0.03 mg/kg Analyte 4 seed/kernel: 0.0067 mg/kg (l) Method Validation Data: 01304, 16-2195 (m) Storage: Analyte 1, 2, 4 seed: 550 days Analyte 1, 2, 4 kernel: 534 days
			87	0.038	0.075	0.11	0.025	34	
			89	<u>0.043</u>	0.073	<u>0.12</u>	<u>0.024</u>	41	
			89	0.033	0.070	0.10	0.023	48	
		kernel	89	<u>0.012</u>	0.084	<u>0.096</u>	<u>0.028</u>	41	

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control
(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.1.3.3 Barley

The critical GAP (cGAP) for the proposed use of Sivanto Energy (DLT+FPF EC 85) in barley is summarized in [Table A 16](#).

Table A 16: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU	Currently there is no EU cGAP in place on barley for flupyradifurone.				
Intended cGAP* (number 107, 109, 204, 206, 337, 339, 356, 358, 375, 377)	2	56.25	14	BBCH 41-83	30

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

A 2.1.3.3.1 Study report 15-2131

Comments of zRMS:	<p>Four field residue trials were conducted in northern Europe in 2015 to determine the magnitude of the residues of deltamethrin and BYI 02960 (common name flupyradifurone) in/on winter and spring barley (grain, straw and whole plant without root) after two spray applications with Deltamethrin & Flupyradifurone EC 085, an EC formulation containing 10 g/L deltamethrin and 75 g/L BYI 02960 each at a rate of 0.75 L/ha, corresponding to 56.25 g BYI 02960/ha and 7.5 g/ha of deltamethrin with an interval of 13-14 days. The last application was done at a crop growth stage BBCH 73-85. The PHI was 30 days.</p> <p>Residues of BYI 02960 and difluoroacetic acid were determined by HPLC-MS/MS according to method 01212.</p> <p>The individual LOQs for BYI 02960 and difluoroacetic acid are 0.01 and 0.02 mg/kg, respectively in the sample materials barley (grain) and barley (whole plant without root). For the sample material barley (straw) the individual LOQs are 0.05 mg/kg for each analyte.</p> <p>The average recoveries per fortification level were within the range of 70 – 110%. The RSD values were below 20%.</p> <p>Residue results (mg/kg) for grain (PHI: 29-33 days): E (FPF): 0.034; 0.053*; 0.082*; 0.16 E (DFA): 0.011; 0.031*; 0.039; 0.080 RA (sum): 0.12*; 0.15*; 2 x 0.27 * Peak residues detected after PHI.</p> <p>The storage period of deep-frozen samples intended for the analysis of BYI 02960 and its metabolites in the treated samples ranged between 247 and 316 days and the storage period of the corresponding control samples ranged between 252 and 314 days.</p> <p>Residues of deltamethrin and its isomers AE 0035073 and AE F108569 were determined by HPLC-MS/MS according to method 00855/M004 with LOQ of 0.01 mg/kg for grain and for each compound and 0.05 mg/kg for straw and whole plant without root for each compound.</p> <p>For deltamethrin and its two isomers average recoveries were at each fortification level within the acceptable range of 70 – 110% and the RSD values were below 20%.</p> <p>Residue results (mg/kg) in grain: E (deltamethrin): 0.013, 0.030, 0.042, 0.044* RA (sum): 0.033, 0.051, 0.070, 0.070*</p> <p>The storage period of deep-frozen samples intended for the analysis of deltamethrin and its isomers in the treated samples ranged between 230 and 313 days and the storage period of the corresponding control samples ranged between 235 and 306 days.</p>
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	The study is acceptable.
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Reference:	KCA 6.3.3.1/01
Title:	Amendment no. 3 to final report - Determination of the residues of BYI 02960 and deltamethrin in/on winter and spring barley after spray application of deltamethrin & flupyradifurone EC 085 in Germany, Belgium and United Kingdom
Report:	Schulte, G.; 2017; 15-2131; M-580973-04-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial
Deviations:	none
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Validity of the study:

Materials and methods

In 2015, 4 field trials were conducted in northern Europe (United Kingdom, Germany [2] and Belgium) to support the use of Sivanto Energy EC 085 in spring and winter barley. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960). Two applications were made at an interval of 13-14 days, each at a rate of 0.75 L/ha, corresponding to 56.25 g BYI 02960/ha. The last application was done at a crop growth stage of BBCH 73-85 (fruit development stages, BBCH 73: early milk; BBCH 85 soft dough). The envisaged PHI was 30 days.

Samples of barley, whole plant without root were collected immediately before and after the last treatment, as well as 6-7 and 13-14 days after the last treatment. Mature grain samples and barley straw were collected 21-22, 29-33 and 34-37 days after the last treatment. All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 316 days). The maximum storage period of 316 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 52 months ([Netzband, D.; 2015; M-428412-03-1](#)).

The samples were analysed according to method 01212 ([Rosati, D.; 2012; M-428017-01-1](#)) by LC-MS/MS using stable isotopically labelled internal standards. The LOQ in the sample materials barley (grain) and barley (whole plant without root) was 0.01 mg/kg for BYI 02960 and 0.02 mg/kg for DFA when expressed as BYI 02960. The calculated LOQ for the total residue (sum of BYI 02960 and DFA, expressed as BYI 02960) was 0.03 mg/kg. For the sample material barley (straw) the individual LOQs are 0.05 mg/kg for each analyte, and thus a theoretical LOQ of 0.10 mg/kg results for the sum of the two analytes. Residues of DFEAF and 6-CNA have been also determined during the study, but since they are not relevant to the residue definition for risk assessment, they are not reported here.

Results

The method performance was validated by concurrent recoveries during the conduct of study 15-2130 which was analysed in parallel. During the course of the present study, the method performance was confirmed by concurrent recoveries. The apparent residues in the control samples used for recoveries at LOQ level were below 30% of the LOQ except for difluoroacetic acid (15-2131-03-0015E and 15-2131-03-0031E with 33% and 41% of LOQ, respectively). The recoveries conducted with the affected control samples were corrected. Since spring barley and winter barley are two varieties of the same crop, it is appropriate for the calculation of the average recoveries and the RSD values to combine the results obtained for each variety. The average recoveries per fortification level and analyte were within the acceptable range of 70 – 110%. The overall RSD values were always below 20% ([Table A 17](#)).

Details of the application and residue information are summarized in [Table A 18](#). No residues of BYI 02960 or DFA at or above the limit of quantification of the method were found in any of the untreated samples.

Table A 17: Recovery data for flupyradifurone and its metabolite DFA in matrices of barley

Study Trial No. Plot No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortification level * (mg/kg)	Recovery (%) Individual recoveries	Min	Max	Mean	RSD
15-2131 15-2131-01 15-2131-01-T to 15-2131-04 15-2131-04-T GLP: yes 2015	Barley	whole plant without roots	BYI 02960	1	0.01	92	92	92	92	6.0
				1	0.1	99	99	99	99	
				1	1.0	106	106	106	106	
				1	8.0	96	96	96	96	
				4	overall		92	106	98	
			DFA	1	0.02	90 ^a	90	90	90	1.3
				1	0.2	92 ^b	92	92	92	
				1	16	90	90	90	90	
				3	overall		90	92	91	
		grain	BYI 02960	1	0.01	95	95	95	95	4.2
				1	0.1	97	97	97	97	
				1	0.5	103	103	103	103	
				3	overall		95	103	98	
			DFA	1	0.02	78 ^c	78	78	78	6.0
				1	0.2	84 ^d	84	84	84	
				1	1.0	88	88	88	88	
				3	overall		78	88	83	
		straw	BYI 02960	1	0.05	100	100	100	100	5.1
				1	0.5	92	92	92	92	
				1	4.0	101	101	101	101	
				3	overall		92	101	98	
			DFA	1	0.05	89 ^e	89	89	89	4.1
				1	0.5	90 ^f	90	90	90	
				1	4.0	96	96	96	96	
				3	overall		89	96	92	

* expressed as BYI 02960

The control 15-2131-03-0015E (0.00664 mg/kg expressed as BYI 02960) was used for fortification for the following values:

^a This value was corrected with the value of the respective control sample. The uncorrected value was 123%.

^b This value was corrected with the value of the respective control sample. The uncorrected value was 95%.

The control 15-2131-04-0030E (0.00589 mg/kg expressed as BYI 02960) was used for fortification for the following values:

^c This value was corrected with the value of the respective control sample. The uncorrected value was 108%.

^d This value was corrected with the value of the respective control sample. The uncorrected value was 87%.

The control 15-2131-03-0031E (0.0202 mg/kg expressed as BYI 02960) was used for fortification for the following values:

^e This value was corrected with the value of the respective control sample. The uncorrected value was 129%.

^f This value was corrected with the value of the respective control sample. The uncorrected value was 94%.

Table A 18: Residue trials on barley

GAP Summary of the 15-2131 trials

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL			
(a)	(b)					(c)	(d)	(f)
15-2131-01 15-2131-01-T Germany 04824 Beucha OT Wolfshain Europe, North F 2015	Barley, winter Meridian	1) 29.09.2014 2) 13.05.2015 - 21.05.2015 3) 08.07.2015 - 15.10.2015	56.25 56.25	300 300	18.75 18.75	27.05.2015/0 10.06.2015/14	73	(g) 15-2131 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
15-2131-02 15-2131-02-T Belgium 1450 Cortil- Noirmont Europe, North F 2015	Barley, winter Meridian	1) 30.09.2014 2) 15.05.2015 - 26.05.2015 3) 10.07.2015 - 24.07.2015	56.25 56.25	300 300	18.75 18.75	05.06.2015/0 19.06.2015/14	85	(g) 15-2131 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
15-2131-03 15-2131-03-T United Kingdom CB22 5EU Little Shelford, Cambridge Europe, North F 2015	Barley, spring Tipple	1) 12.03.2015 2) 08.06.2015 - 26.06.2015 3) 31.07.2015 - 20.08.2015	56.25 56.25	200 200	28.125 28.125	26.06.2015/0 09.07.2015/13	77	(g) 15-2131 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
15-2131-04 15-2131-04-T Germany 49838 Gersten Europe, North F 2015	Barley, spring Vespa	1) 05.03.2015 2) 07.06.2015 - 18.06.2015 3) 10.07.2015 - 28.07.2015	56.25 56.25	300 300	18.75 18.75	10.06.2015/0 24.06.2015/14	75	(g) 15-2131 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying

Analytical part 15-2131

Analyte 1: BYI 02960 (determined as BYI 02960, calculated as BYI 02960), Analyte 2: DFA (determined as DFA, calculated as BYI 02960), Analyte 3 (calculated value): sum of BYI 02960 and DFA (calculated as BYI 02960), Analyte 4: DFA (determined as DFA, calculated as DFA)

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
15-2131-01 15-2131-01-T Germany 04824 Beucha OT Wolfshain Europe, North F 2015	Barley, winter Meridian	whole plant without root grain straw	73 73 75 77 83 89 89 83 89 89	0.15 1.1 0.24 0.12 0.041 0.053 <u>0.053</u> 0.18 <u>0.17</u> 0.17	0.024 0.023 0.042 0.044 0.093 0.087 0.093 <0.05 <0.05 <0.05	0.17 1.1 0.28 0.17 0.13 0.14 <u>0.15</u> 0.23 <u>0.22</u> 0.22	0.0079 0.0077 0.014 0.015 0.031 0.029 <u>0.031</u> <0.017 <u><0.017</u> <0.017	0* 0 7 14 21 <u>30</u> 35 21 <u>30</u> 35	(g) 15-2131 (j) Analytical method: 01212 (k) LOQ: Analyte 1 whole plant without roots, grain: 0.01 mg/kg Analyte 1,2 straw: 0.05 mg/kg Analyte 2 whole plant without roots, grain: 0.02 mg/kg Analyte 3 straw: 0.1 mg/kg Analyte 3 whole plant without roots, grain: 0.03 mg/kg Analyte 4 straw: 0.017 mg/kg Analyte 4 whole plant without roots, grain: 0.0067 mg/kg (l) Method Validation Data: 01212, 15-2130 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 316 days Analyte 1, 2, 3 straw: 294 days Analyte 1, 2, 3 grain: 289 days DFA as DFA: Values were taken from the raw data
15-2131-02 15-2131-02-T Belgium 1450 Cortil- Noirmont Europe, North F 2015	Barley, winter Meridian	whole plant without root grain straw	85 85 87 87 89 89 89 89 89 89	0.062 1.6 0.18 0.32 0.16 0.075 <u>0.082</u> 0.31 <u>0.17</u> 0.17	<0.02 <0.02 0.024 0.037 0.042 0.033 0.034 0.057 <0.05 <0.05	0.082 1.7 0.21 0.35 0.20 0.11 <u>0.12</u> 0.37 <u>0.22</u> 0.22	<0.0067 <0.0067 0.0080 0.012 0.014 <u>0.011</u> 0.011 0.019 <u><0.017</u> <0.017	0* 0 7 14 21 33 35 21 33 35	(g) 15-2131 (j) Analytical method: 01212 (k) LOQ: Analyte 1 whole plant without roots, grain: 0.01 mg/kg Analyte 1,2 straw: 0.05 mg/kg Analyte 2 whole plant without roots, grain: 0.02 mg/kg Analyte 3 straw: 0.1 mg/kg Analyte 3 whole plant without roots, grain: 0.03 mg/kg Analyte 4 straw: 0.017 mg/kg Analyte 4 whole plant without roots, grain: 0.0067 mg/kg (l) Method Validation Data: 01212, 15-2130 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 307 days Analyte 1, 2, 3 straw: 285 days Analyte 1, 2, 3 grain: 280 days DFA as DFA: Values were taken from the raw data

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
15-2131-03 15-2131-03-T United Kingdom CB22 5EU Little Shelford, Cambridge Europe, North F 2015	Barley, spring Tipple	whole plant without root grain straw	77 77 87 87 89 89 89 89 89 89	0.31 1.9 1.6 0.86 0.12 <u>0.16</u> 0.12 0.43 0.40 <u>0.41</u>	0.060 0.059 0.087 0.11 0.11 0.12 0.10 <0.05 <0.05 0.050	0.37 2.0 1.7 0.96 0.23 <u>0.27</u> 0.22 0.48 0.45 <u>0.46</u>	0.020 0.020 0.029 0.036 0.036 <u>0.039</u> 0.033 <0.017 <0.017 <u>0.017</u>	0* 0 6 13 22 29 34 22 29 34	(g) 15-2131 (j) Analytical method: 01212 (k) LOQ: Analyte 1 whole plant without roots, grain: 0.01 mg/kg Analyte 1,2 straw: 0.05 mg/kg Analyte 2 whole plant without roots, grain: 0.02 mg/kg Analyte 3 straw: 0.1 mg/kg Analyte 3 whole plant without roots, grain: 0.03 mg/kg Analyte 4 straw: 0.017 mg/kg Analyte 4 whole plant without roots, grain: 0.0067 mg/kg (l) Method Validation Data: 01212, 15-2130 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 287 days Analyte 1, 2, 3 straw: 264 days Analyte 1, 2, 3 grain: 259 days DFA as DFA: Values were taken from the raw data
15-2131-04 15-2131-04-T Germany 49838 Gersten Europe, North F 2015	Barley, spring Vespa	whole plant without root grain straw	75 75 77 85 87 89 89 87 89 89	0.34 1.9 0.72 0.47 0.034 <u>0.034</u> 0.034 0.35 <u>0.11</u> <0.05	0.048 0.055 0.10 0.12 0.24 0.24 0.15 0.20 0.081 0.054	0.38 2.0 0.83 0.59 0.28 <u>0.27</u> 0.19 0.55 <u>0.19</u> 0.10	0.016 0.018 0.034 0.040 0.081 <u>0.080</u> 0.051 0.067 <u>0.027</u> 0.018	0* 0 7 14 21 <u>30</u> 37 21 <u>30</u> 37	(g) 15-2131 (j) Analytical method: 01212 (k) LOQ: Analyte 1 whole plant without roots, grain: 0.01 mg/kg Analyte 1,2 straw: 0.05 mg/kg Analyte 2 whole plant without roots, grain: 0.02 mg/kg Analyte 3 straw: 0.1 mg/kg Analyte 3 whole plant without roots, grain: 0.03 mg/kg Analyte 4 straw: 0.017 mg/kg Analyte 4 whole plant without roots, grain: 0.0067 mg/kg (l) Method Validation Data: 01212, 15-2130 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 302 days Analyte 1, 2, 3 straw: 280 days Analyte 1, 2, 3 grain: 275 days DFA as DFA: Values were taken from the raw data

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control
(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.1.3.3.2 Study report 16-2035

Comments of zRMS:	<p>Four field residue trials were conducted in northern Europe in 2016 to determine the magnitude of the residues of deltamethrin and BYI 02960 (common name flupyradifurone) in/on winter and spring barley (grain, straw and whole plant without root) after two spray applications with Deltamethrin & Flupyradifurone EC 085, an EC formulation containing 10 g/L deltamethrin and 75 g/L BYI 02960 each at a rate of 0.75 L/ha, corresponding to 56.25 g BYI 02960/ha and 7.5 g/ha of deltamethrin with an interval of 14-15 days. The last application was done at a crop growth stage BBCH 73-89. The PHI was 30 days.</p> <p>Residues of BYI 02960 and difluoroacetic acid were determined by HPLC-MS/MS according to method 01304.</p> <p>The individual LOQs for BYI 02960 and difluoroacetic acid are 0.01 and 0.02 mg/kg, respectively in the sample materials whole plant without root, grain and straw.</p> <p>The average recoveries per fortification level were within the range of 70 – 110%. The RSD values were below 20%.</p> <p>Residue results (mg/kg) for grain (PHI: 29-33 days): E (FPF): <0.01; 0.022; 0.081*; 0.099* E (DFA): 0.036*; 0.052; 0.059*; 0.064 RA (sum): 0.18; 0.20; 0.21*; 0.26* * Peak residues detected after PHI.</p> <p>The storage period of deep frozen samples used for the analysis of BYI 02960 and its metabolites was between 476 and 541 days.</p> <p>Residues of deltamethrin and its isomers AE 0035073 and AE F108569 were determined by HPLC-MS/MS according to method 00855/M004 with LOQ of 0.01 mg/kg for grain and for each compound and 0.05 mg/kg for straw and whole plant without root for each compound.</p> <p>For deltamethrin and its two isomers average recoveries were at each fortification level within the acceptable range of 70 – 110% and the RSD values were below 20%.</p> <p>Residue results (mg/kg) in grain: E (deltamethrin): <0.01, 0.014*, 0.019*, 0.048 RA (sum): <0.03, 0.034*, 0.039*, 0.073</p> <p>The storage period of deep frozen samples used for the analysis of deltamethrin and its isomers was between 365 and 431 days.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.3.1/02
Title:	Determination of the residues of BYI 02960 and deltamethrin in/on winter and spring barley after spray application of deltamethrin & flupyradifurone EC 085 in the Netherlands, Germany and Belgium
Report:	Kaussmann, M.; 2018; 16-2035; M-634410-01-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP 860.1500, Crop Field Trial
Deviations:	None
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Validity of the study:

Materials and methods

In 2016, 4 field trials were conducted in northern Europe (the Netherlands, Germany [2] and Belgium) to support the use of Sivanto Energy EC 085 in winter and spring barley. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960). Two applications were made at an interval of 14-15 days, each at a rate of 0.75 L/ha, corresponding to 56.25 g BYI 02960/ha. The last application was done at a crop growth stage of BBCH 73-83 (fruit development stages, BBCH 73: early milk; BBCH 83 early dough). The envisaged PHI was 30 days.

Samples of barley, whole plant without root were collected immediately before and after the last treatment. Mature grain samples and barley straw were collected 27-33 and 31-35 days after the last treatment. All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 541 days). The maximum storage period of 541 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 52 months ([Netzband, D.; 2015; M-428412-03-1](#)).

The samples were analysed according to method 01304 ([Li, Y.; Schoening, R.; 2012; M-415504-02-1](#)). The LOQ in all sample matrices was 0.01 mg/kg for BYI 02960 and 0.02 mg/kg for DFA when expressed as BYI 02960 (corresponding to an LOQ of 0.0067 mg/kg, when expressed as DFA). The calculated LOQ for the total residue (sum of BYI 02960 and DFA, expressed as BYI 02960) was 0.03 mg/kg.

Residues of DFEAF and 6-CNA have been also determined during the study, but since they are not relevant to the residue definition for risk assessment, they are not reported here.

Results

The method performance was validated by at least 3 concurrent recoveries at two fortification levels during the conduct of study 16-2034 which was analysed in parallel. During the course of the present study, the method performance was confirmed by concurrent recoveries. Since spring barley and winter barley are two varieties of the same crop, it is appropriate for the calculation of the average recoveries and the RSD values to combine the results obtained for each variety. The average recoveries per fortification level and analyte were within the acceptable range of 70 – 110%. If applicable, the RSD values were always well below 20% ([Table A 19](#)).

Details of the application and residue information are summarized in [Table A 20](#)

No residues of BYI 02960 or DFA at or above the limit of quantification of the method were found in any of the untreated samples.

Table A 19: Recovery data for flupyradifurone and its metabolite DFA in matrices of barley

Study Trial No. Plot No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortification level * (mg/kg)	Recovery (%) Individual recoveries	Min	Max	Mean	RSD
16-2035 16-2035-01 16-2035-01-T to 16-2035-04 16-2035-04-T GLP: yes 2016	Barley	whole plant without roots	BYI 02960	2	0.01	93;99	93	99	96	5.1
				1	0.1	89	89	89	89	
				1	5.0	89	89	89	89	
				4	overall		89	99	93	
			DFA	2	0.02	96;99	96	99	98	5.0
				1	0.2	88	88	88	88	
				1	10	93	93	93	93	
				4	overall		88	99	94	
		grain	BYI 02960	2	0.01	90;92	90	92	91	4.8
				1	0.1	94	94	94	94	
				1	5.0	84	84	84	84	
				4	overall		84	94	90	
			DFA	2	0.02	94;101	94	101	98	6.9
				1	0.2	86	86	86	86	
				1	10	90	90	90	90	
				4	overall		86	101	93	
		straw	BYI 02960	2	0.01	87;91	87	91	89	5.4
				1	0.1	96	96	96	96	
				1	5.0	85	85	85	85	
				4	overall		85	96	90	
			DFA	2	0.02	96;99	96	99	98	6.4
				1	0.2	94	94	94	94	
				1	10	85	85	85	85	
				4	overall		85	99	94	

* expressed as BYI 02960

Table A 20 Residue trials on barley

GAP Summary of the 16-2035 trials

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL			
(a)	(b)	(b)				(c)	(d)	(f)
16-2035-01 16-2035-01-T Netherlands 1437 EG Rozenburg Europe, North F 2016	Barley, winter Cassiopée	1) 15.10.2015 2) 06.06.2016 - 13.06.2016 3) 18.07.2016 - 23.07.2016	56.25 56.25	400 400	14.06 14.06	06.06.2016/0 21.06.2016/15	83	(g) 16-2035 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
16-2035-02 16-2035-02-T Germany 59609 Anröchte- Berge Europe, North F 2016	Barley, winter Keeper	1) 29.09.2015 2) 22.05.2016 - 30.05.2016 3) 05.07.2016 - 25.07.2016	56.25 56.25	300 300	18.75 18.75	30.05.2016/0 13.06.2016/14	73	(g) 16-2035 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
16-2035-03 16-2035-03-T Belgium 6211 Mellet Europe, North F 2016	Barley, spring Hilford	1) 18.03.2016 2) 16.06.2016 - 19.06.2016 3) 26.07.2016 - 01.08.2016	56.25 56.25	300 300	18.75 18.75	14.06.2016/0 28.06.2016/14	83	(g) 16-2035 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
16-2035-04 16-2035-04-T Germany 51399 Burscheid Europe, North F 2016	Barley, spring Vespa	1) 04.04.2016 2) 16.06.2016 - 21.06.2016 3) 01.08.2016 - 31.08.2016	56.25 56.25	300 300	18.75 18.75	29.06.2016/0 13.07.2016/14	83	(g) 16-2035 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying

Analytical part

Analyte 1: BYI 02960 (determined as BYI 02960, calculated as BYI 02960), Analyte 2: DFA (determined as DFA, calculated as BYI 02960), Analyte 3 (calculated value): sum of BYI 02960 and DFA (calculated as BYI 02960), Analyte 4: DFA (determined as DFA, calculated as DFA)

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
	(a)		(d)					(e)	(f)
16-2035-01 16-2035-01-T Netherlands 1437 EG Rozenburg Europe, North F 2016	Barley, winter Cassiopée	whole plant without root	83	0.048	0.035	0.083	0.012	0*	(g) 16-2035 (j) Analytical method: 01304 (k) LOQ: Analyte 1: 0.01 mg/kg Analyte 2: 0.02 mg/kg Analyte 3: 0.03 mg/kg Analyte 4: 0.007 mg/kg (l) Method Validation Data: 01304, 16-2034 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 533 days Analyte 1, 2, 3 straw: 506 days Analyte 1, 2, 3 grain: 506 days
			83	1.1	0.036	1.1	0.012	0	
		grain	89	<u>≤0.01</u>	0.19	<u>0.20</u>	<u>0.064</u>	27	
			89	<u><0.01</u>	0.11	<u>0.12</u>	<u>0.036</u>	31	
		straw	89	0.070	0.042	0.11	0.014	27	
			89	<u>0.087</u>	0.048	<u>0.13</u>	<u>0.016</u>	31	
16-2035-02 16-2035-02-T Germany 59609 Anröchte- Berge Europe, North F 2016	Barley, winter Keeper	whole plant without root	73	0.093	0.035	0.13	0.012	0*	(g) 16-2035 (j) Analytical method: 01304 (k) LOQ: Analyte 1: 0.01 mg/kg Analyte 2: 0.02 mg/kg Analyte 3: 0.03 mg/kg Analyte 4: 0.007 mg/kg (l) Method Validation Data: 01304, 16-2034 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 541 days Analyte 1, 2, 3 straw: 513 days Analyte 1, 2, 3 grain: 513 days
			73	1.2	0.041	1.3	0.014	0	
		grain	89	<u>0.022</u>	0.16	<u>0.18</u>	<u>0.052</u>	28	
			89	<u>0.015</u>	0.14	<u>0.15</u>	<u>0.045</u>	32	
		straw	89	<u>0.11</u>	0.076	<u>0.19</u>	<u>0.025</u>	28	
			89	<u>0.089</u>	0.070	<u>0.16</u>	<u>0.023</u>	32	

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
(a)			(d)					(e)	(f)
16-2035-03 16-2035-03-T Belgium 6211 Mellet Europe, North F 2016	Barley, spring Hilford	whole plant without root	83 83	0.061 1.6	0.044 0.047	0.11 1.7	0.015 0.016	0* 0	(g) 16-2035 (j) Analytical method: 01304 (k) LOQ: Analyte 1: 0.01 mg/kg Analyte 2: 0.02 mg/kg Analyte 3: 0.03 mg/kg Analyte 4: 0.007 mg/kg (l) Method Validation Data: 01304, 16-2034 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 526 days Analyte 1, 2, 3 straw: 497 days Analyte 1, 2, 3 grain: 497 days
		grain	89 89	0.075 <u>0.081</u>	0.17 0.18	0.24 <u>0.26</u>	0.055 <u>0.059</u>	29 34	
		straw	89 89	<u>0.69</u> 0.49	0.067 0.082	<u>0.75</u> 0.57	0.022 <u>0.027</u>	29 34	
16-2035-04 16-2035-04-T Germany 51399 Burscheid Europe, North F 2016	Barley, spring Vespa	whole plant without root	83 83	0.15 1.7	0.047 0.042	0.19 1.8	0.016 0.014	0* 0	(g) 16-2035 (j) Analytical method: 01304 (k) LOQ: Analyte 1: 0.01 mg/kg Analyte 2: 0.02 mg/kg Analyte 3: 0.03 mg/kg Analyte 4: 0.007 mg/kg (l) Method Validation Data: 01304, 16-2034 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 511 days Analyte 1, 2, 3 straw: 478 days Analyte 1, 2, 3 grain: 478 days
		grain	89 89	0.095 <u>0.099</u>	0.075 0.11	0.17 <u>0.21</u>	0.025 <u>0.036</u>	33 35	
		straw	89 89	<u>0.28</u> 0.24	0.087 0.12	<u>0.37</u> 0.36	0.029 <u>0.040</u>	33 35	

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control
(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.1.3.3.3 Study report 15-2130 (for information only)

Comments of zRMS:	This study has not been evaluated by zRMS-PL because it was conducted in southern Europe.
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Reference:	KCA 6.3.3.1/03
Title:	Determination of the residues of BYI 02960 and deltamethrin in/on barley after spray application of deltamethrin & flupyradifurone EC 085 in France (South), Italy, Spain and Greece
Report:	Noss, G.; 2017; 15-2130; M-572779-03-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	-
Duplication (if vertebrate study):	

Validity of the study:

Materials and methods

In 2015, 4 field trials were conducted in southern Europe (southern France, Italy, Spain and Greece) to support the use of Sivanto Energy EC 085 in barley. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960). Two applications were made at an interval of 13-14 days, each at a rate of 1.0 L/ha, corresponding to 75.0 g BYI 02960/ha. The last application was done at a crop growth stage of BBCH 69-87 (BBCH 69: end of flowering; BBCH 87: fruit development stage hard dough). The envisaged PHI was 30 days.

Samples of barley, whole plant without root were collected immediately before and after the last treatment as well as 6-7 and 14 days after treatment. Grain and straw samples were collected 20-21, 29-31 and 34-36 days after the last treatment with two exceptions. In trial 15-2130-01 the plots were accidentally harvested by the farmer before the final PHI samples could be taken. In trial 15-2130-04 samples of barley, whole plant without root and ear were harvested at harvest time 21 days after treatment instead of grain and straw as the growth stage of the crop was only BBCH 83 (no separation of grain and straw is possible). All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 291 days). The maximum storage period of 291 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 52 months ([Netzband, D.; 2015; M-428412-03-1](#)).

The samples were analysed according to method 01212 ([Rosati, D.; 2012; M-428017-01-1](#)) by LC-MS/MS using stable isotopically labelled internal standards. The LOQ in barley, ear, grain and whole plant without root was 0.01 mg/kg for BYI 02960 and 0.02 mg/kg for DFA when expressed as BYI 02960. The calculated LOQ for the total residue (sum of BYI 02960 and DFA, expressed as BYI 02960) was 0.03 mg/kg. For the sample material barley (straw) the individual LOQs are 0.05 mg/kg for each analyte, and thus a theoretical LOQ of 0.10 mg/kg results for the sum of the two analytes.

Residues of DFEAF and 6-CNA have been also determined during the study, but since they are not relevant to the residue definition for risk assessment, they are not reported here.

Results

During the course of this study, the method performance was checked/validated by concurrent recoveries. Full validation of method 01212 was done and documented for matrices representing the 5 major crop groups, including tomato (fruit), grape (bunch of grape), kidney bean (dry seed), barley (grain) and summer rape (seed) when developing the method. For barley whole plant without root and straw a limited set (1

control, ≥ 3 repetitions each at two fortification levels) of additional validation recoveries was done within this study. The apparent residues in the control samples used for recoveries at LOQ level were below 30% of the LOQ except for difluoroacetic acid (for controls 15-2130-01-0015E with 33% of the LOQ). Recoveries conducted with affected control sample were corrected. In addition, recoveries at the LOQ level were corrected in those cases where the residues in the control samples were above 10% of the LOQ. Corrections done are indicated in the recovery tables below. The average recoveries per fortification level and analyte were within the acceptable range of 70 – 110%. If applicable, the RSD values were always well below 20% (Table A 21).

Details of the application and residue information are summarized in Table A 22.

No residues of BYI 02960 or DFA at or above the limit of quantification of the method were found in any of the untreated samples.

Table A 21: Recovery data for flupyradifurone and its metabolite DFA in matrices of barley

Study Trial No. Plot No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortification level * (mg/kg)	Individual recoveries	Recovery (%)			
							Min	Max	Mean	RSD
15-2130 15-2130-01 to 15-2130-04 GLP: yes 2015	Barley	whole plant without roots	BYI 02960	4	0.01	99;100;101;101	99	101	100	1.0
				3	0.1	99;99;99	99	99	99	0.0
				1	4.0	98	98	98	98	
				8	overall		98	101	100	1.1
			DFA	4	0.02	93 ⁱ ;103; 105;107	93	107	102	6.1
				3	0.2	93;95;95	93	95	94	1.2
				1	8.0	92	92	92	92	
				8	overall		92	107	98	6.2
		grain	BYI 02960	1	0.01	98	98	98	98	
				1	0.1	103	103	103	103	
				1	1.0	101	101	101	101	
				1	4.0	103	103	103	103	
				4	overall		98	103	101	2.3
			DFA	1	0.02	91	91	91	91	
				1	0.2	83	83	83	83	
				1	2.0	86	86	86	86	
				1	8.0	81	81	81	81	
				4	overall		81	91	85	5.1
		straw	BYI 02960	4	0.05	80 ^a ;88;91; 97	80	97	89	7.9
				3	0.5	92;94;96	92	96	94	2.1
				2	4.0	91;95	91	95	93	
				9	overall		80	97	92	5.7
			DFA	4	0.05	83 ^b ;86 ^c ;87 ^d ;87 ^e	83	87	86	2.2
				3	0.5	93 ^f ;93 ^g ;93 ^h	93	93	93	0.0
				2	4.0	94;97	94	97	96	
				9	overall		83	97	90	5.2

* expressed as BYI 02960

The control 15-2130-02-0031E (0.00144 mg/kg expressed as BYI 02960) was used for fortification for the following value:

^a This value was corrected with the value of the respective control sample. The uncorrected value was 109%.

The control 15-2130-04-0031E (0.00959 mg/kg expressed as BYI 02960) was used for fortification for the following values:

^b This value was corrected with the value of the respective control sample. The uncorrected value was 102%.

^c This value was corrected with the value of the respective control sample. The uncorrected value was 104%.

^d This value was corrected with the value of the respective control sample. The uncorrected value was 106%.

^f This value was corrected with the value of the respective control sample. The uncorrected value was 95%.

^g This value was corrected with the value of the respective control sample. The uncorrected value was 95%.

^h This value was corrected with the value of the respective control sample. The uncorrected value was 95%.

The control 15-2130-02-0031E (0.0129 mg/kg expressed as BYI 02960) was used for fortification for the following value:

^e This value was corrected with the value of the respective control sample. The uncorrected value was 113%.

The control 15-2130-01-0015E (0.00661 mg/kg expressed as BYI 02960) was used for fortification for the following value:

ⁱ This value was corrected with the value of the respective control sample. The uncorrected value was 126%.

Table A 22: Residue trials on barley

GAP Summary of the 15-2130 trials

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL			
(a)	(b)	(b)				(c)	(d)	(f)
15-2130-01 15-2130-01-T France, south 13123 Albaron Europe, South F 2015	Barley SY Tepee	1) 23.10.2014 2) 15.04.2015 - 22.04.2015 3) 08.06.2015	75.0 75.0	300 300	25.0 25.0	04.05.2015/0 18.05.2015/14	83	(g) 15-2130 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
15-2130-02 15-2130-02-T Italy 20080 Zibido San Giacomo Europe, South F 2015	Barley Reni	1) 30.10.2014 2) 03.05.2015 - 08.05.2015 3) 19.06.2015 - 25.06.2015	75.0 75.0	350 350	21.4 21.4	08.05.2015/0 21.05.2015/13	75	(g) 15-2130 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
15-2130-03 15-2130-03-T Spain 29200 Antequerra Europe, South F 2015	Barley Scrabble	1) 29.12.2014 2) 23.04.2015 - 06.05.2015 3) 16.07.2015 - 20.07.2015	75.0 75.0	300 300	25.0 25.0	02.06.2015/0 16.06.2015/14	87	(g) 15-2130 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying
15-2130-04 15-2130-04-T Greece 57020 Appolonia Europe, South F 2015	Barley Mucho	1) 15.11.2014 2) 30.04.2015 - 10.05.2015 3) 05.06.2015 - 15.06.2015	75.0 75.0	200 200	37.5 37.5	22.04.2015/0 06.05.2015/14	69	(g) 15-2130 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying

Analyte 1: BYI 02960 (determined as BYI 02960, calculated as BYI 02960), Analyte 2: DFA (determined as DFA, calculated as BYI 02960), Analyte 3 (calculated value): sum of BYI 02960 and DFA (calculated as BYI 02960), Analyte 4: DFA (determined as DFA, calculated as DFA)

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
	(a)		(d)					(e)	(f)
15-2130-01 15-2130-01-T France, south 13123 Albaron Europe, South F 2015	Barley SY Tepee	whole plant without root	83 83 85 87	0.50 1.9 1.8 2.0	0.068 0.072 0.098 0.13	0.56 1.9 1.9 2.2	0.023 0.024 0.033 0.045	0* 0 7 14	(g) 15-2130 (j) Analytical method: 01212 (k) LOQ: Analyte 1 whole plant without roots: 0.01 mg/kg Analyte 2 whole plant without roots: 0.02 mg/kg Analyte 3 whole plant without roots: 0.03 mg/kg Analyte 4 whole plant without roots: 0.0067 mg/kg (l) Method Validation Data: 0212, 15-2130 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 212 days
15-2130-02 15-2130-02-T Italy 20080 Zibido San Giacomo Europe, South F 2015	Barley Reni	whole plant without root grain straw	75 75 79 81 87 89 89 87 89 89	0.018 1.9 0.29 0.17 0.021 <0.01 <u>0.016</u> 0.62 <u>0.66</u> 0.43	0.029 0.045 0.083 0.055 0.11 0.097 0.11 0.10 0.11 0.095	0.047 2.0 0.37 0.22 0.13 0.11 <u>0.13</u> 0.72 <u>0.77</u> 0.53	0.0095 0.015 0.028 0.018 0.036 0.032 <u>0.037</u> 0.035 <u>0.036</u> 0.032	0* 0 7 14 21 29 35 21 29 35	(g) 15-2130 (j) Analytical method: 01212 (k) LOQ: Analyte 1 whole plant without roots, grain: 0.01 mg/kg Analyte 1,2 straw: 0.05 mg/kg Analyte 2 whole plant without roots, grain: 0.02 mg/kg Analyte 3 straw: 0.1 mg/kg Analyte 3 whole plant without roots, grain: 0.03 mg/kg Analyte 4 straw: 0.017 mg/kg Analyte 4 whole plant without roots, grain: 0.0067 mg/kg (l) Method Validation Data: 0212, 15-2130 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 209 days Analyte 1, 2, 3 straw: 286 days Analyte 1, 2, 3 grain: 182 days

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
15-2130-03 15-2130-03-T Spain 29200 Antequerra Europe, South F 2015	Barley Scrabble	whole plant without root	87	1.3	<0.02	1.3	<0.0067	0*	(g) 15-2130 (j) Analytical method: 01212 (k) LOQ: Analyte 1 whole plant without roots, grain: 0.01 mg/kg Analyte 1,2 straw: 0.05 mg/kg Analyte 2 whole plant without roots, grain: 0.02 mg/kg Analyte 3 straw: 0.1 mg/kg Analyte 3 whole plant without roots, grain: 0.03 mg/kg Analyte 4 straw: 0.017 mg/kg Analyte 4 whole plant without roots, grain: 0.0067 mg/kg (l) Method Validation Data: 0212, 15-2130 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 183 days Analyte 1, 2, 3 straw: 261 days Analyte 1, 2, 3 grain: 163 days
			87	5.5	<0.02	5.5	<0.0067	0	
			87	5.6	<0.02	5.7	<0.0067	6	
			87	5.4	<0.02	5.4	<0.0067	14	
		grain	87	0.032	<0.02	0.052	<0.0067	20	
			89	0.043	<0.02	0.063	<0.0067	30	
			89	<u>0.044</u>	<0.02	<u>0.064</u>	<u><0.0067</u>	34	
		straw	87	6.3	<0.05	6.3	<0.017	20	
			89	<u>6.4</u>	0.055	<u>6.4</u>	<u>0.018</u>	30	
			89	4.8	<0.05	4.9	<0.017	34	
15-2130-04 15-2130-04-T Greece 57020 Appolonia Europe, South F 2015	Barley Mucho	whole plant without root	69	0.073	0.069	0.14	0.023	0*	(g) 15-2130 (j) Analytical method:01212 (k) LOQ: Analyte 1 ear, whole plant without roots, grain: 0.01 mg/kg Analyte 1,2 straw: 0.05 mg/kg Analyte 2 ear, whole plant without roots, grain: 0.02 mg/kg 3 ear, whole plant without roots, grain: 0.03 mg/kg 01212 Analyte 3 straw: 0.1 mg/kg Analyte 4 ear, whole plant without roots, grain: 0.0067 mg/kg Analyte 4 straw: 0.017 mg/kg (l) Method Validation Data: 0212, 15-2130 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 224 days Analyte 1, 2, 3 straw: 291 days Analyte 1, 2, 3 grain: 187 days Analyte 1, 2, 3 ear: 195 days
			69	2.5	0.063	2.5	0.021	0	
			69	0.46	0.13	0.59	0.044	7	
			77	0.25	0.15	0.40	0.051	14	
		ear	83	0.041	0.041	0.082	0.014	23	
			83	0.10	0.25	0.35	0.084	23	
			85	<0.01	0.28	0.29	0.092	31	
		grain	89	<u>0.012</u>	0.39	<u>0.41</u>	<u>0.13</u>	36	
			85	<u>0.096</u>	0.099	0.19	0.033	31	
			89	0.072	0.14	<u>0.21</u>	<u>0.046</u>	36	
		straw	85	<u>0.096</u>	0.099	0.19	0.033	31	
			89	0.072	0.14	<u>0.21</u>	<u>0.046</u>	36	

(a)	According to CODEX Classification / Guide	(e)	Days after last application (Label pre-harvest interval, PHI, underline)	(h)	Formulation type	(l)	Method validation
(b)	Only if relevant	(f)	Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included	(i)	Application method	(m)	Storage (max)
(c)	Year must be indicated	(g)	Study reference	(j)	Method information		! based on date of analysis
(d)	Either growth stage description or BBCH Code	*	prior to last treatment	(k)	LOQ		P based on production date
G	greenhouse F field			**	residue in control	#	no data available

A 2.1.3.3.4 Study report 16-2034 (for information only)

Comments of zRMS:	This study has not been evaluated by zRMS-PL because it was conducted in southern Europe.
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Reference:	KCA 6.3.3.1/04
Title:	Determination of the residues of BYI 02960 and deltamethrin in/on barley after spray application of deltamethrin & flupyradifurone EC 085 in southern France, Italy, Spain and Greece
Report:	Kaussmann, M.; Miara, C.; 2018; 16-2034; M-634112-01-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP 860.1500, Crop Field Trial
Deviations:	Yes (see report)
GLP/GEP:	yes
Acceptability:	-
Duplication (if vertebrate study):	

Validity of the study:

Materials and methods

In 2016, 4 field trials were conducted in southern Europe (southern France, Italy, Spain and Greece) to support the use of Sivanto Energy EC 085 in barley. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960).

Two applications were made at an interval of 14 days, each at a rate of 1.0 L/ha, corresponding to 75.0 g BYI 02960/ha, with the exception of trial 16-2034-03 for which the interval between the applications was 19 days due to bad weather conditions. The last application was done at a crop growth stage of BBCH 71-77 (fruit development stages: watery ripe to late milk). The envisaged PHI was 30 days.

Samples of barley, whole plant without root were collected immediately before and after the last treatment. Mature grain and straw samples were collected 28-30 and 34-35 days after the last treatment. All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 569 days). The maximum storage period of 569 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 52 months ([Netzband, D.; 2015; M-428412-03-1](#)).

The samples were analysed according to method 01304 ([Li, Y.; Schoening, R.; 2012; M-415504-02-1](#)). The LOQ in all sample matrices was 0.01 mg/kg for BYI 02960 and 0.02 mg/kg for DFA when expressed as BYI 02960 (corresponding to an LOQ of 0.0067 mg/kg, when expressed as DFA). The calculated LOQ for the total residue (sum of BYI 02960 and DFA, expressed as BYI 02960) was 0.03 mg/kg.

Residues of DFEAF and 6-CNA have been also determined during the study, but since they are not relevant to the residue definition for risk assessment, they are not reported here.

Results

During the course of this study, the method performance was checked/validated by concurrent recoveries. Full validation of method 01304 was done and documented for matrices representing the 5 major crop groups, including dry seeds of beans, cereal forage, orange fruit, soybean seeds, tomato fruit, and wheat grain when developing the method. For barley grain, straw and whole plant without root a limited set (1 control, ≥3 repetitions each at two fortification levels) of additional validation recoveries was done within this study. The average recoveries per fortification level and analyte were within the acceptable range of 70 – 110%. If applicable, the RSD values were always well below 20% ([Table A 23](#)).

Details of the application and residue information are summarized in [Table A 24](#).

No residues of BYI 02960 or DFA at or above the limit of quantification of the method were found in any of the untreated samples.

Table A 23: Recovery data for flupyradifurone and its metabolite DFA in matrices of barley

Study Trial No. Plot No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortification level * (mg/kg)	Individual recoveries	Recovery (%)				RSD
							Min	Max	Mean		
16-2034 16-2034-01 16-2034-01-T to 16-2034-04 16-2034-04-T GLP: yes 2016	Barley	whole plant without roots	BYI 02960	5	0.01	93; 94; 100; 100; 104	93	104	98	4.7	
				4	0.1	93; 108; 108; 109	93	109	105	7.4	
				1	1.0	94	94	94	94		
				1	6.0	92	92	92	92		
				11	overall		92	109	100	6.8	
			DFA	5	0.02	88; 94; 96; 98; 101	88	101	95	5.1	
				4	0.2	88; 92; 95; 99	88	99	94	5.0	
				1	2.0	92	92	92	92		
				1	12	89	89	89	89		
				11	overall		88	101	94	4.8	
		grain	BYI 02960	5	0.01	95; 93; 105; 107; 108	93	108	102	6.9	
				4	0.1	95; 108; 108; 110	95	110	105	6.6	
				1	1.0	98	98	98	98		
				10	overall		93	110	103	6.5	
			DFA	5	0.02	90; 92; 94; 95; 101	90	101	94	4.4	
				4	0.2	80; 88; 88; 89	80	89	86	4.9	
				1	2.0	84	84	84	84		
				10	overall		80	101	90	6.5	
		straw	BYI 02960	5	0.01	90; 92; 98; 104; 109	90	109	99	8.1	
				4	0.1	89; 108; 108; 110	89	110	104	9.5	
				1	1.0	91	91	91	91		
				1	6.0	91	91	91	91		
				11	overall		89	110	99	8.8	
			DFA	5	0.02	80; 84; 86; 95; 98	80	98	89	8.6	
				4	0.2	87; 90; 96; 97	87	97	93	5.2	
				1	2.0	87	87	87	87		
				1	12	89	89	89	89		
				11	overall		80	98	90	6.5	

* expressed as BYI 02960

Table A 24: Residue trials on barley

GAP Summary of the 16-2034 trials

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL			
(a)	(b)	(b)				(c)	(d)	(f)
16-2034-01 16-2034-01-T France, south 13103 St Etienne du gres Europe, South F 2016	Barley Augusta	1) 17.11.2015 2) 25.04.2016 - 30.04.2016 3) 15.06.2016 - 20.06.2016	75.0 75.0	300 300	25.0 25.0	04.05.2016/0 18.05.2016/14	75	(g) 16-2034 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
16-2034-02 16-2034-02-T Italy 44124 Cona Ferrara Europe, South F 2016	Barley Cometa	1) 30.11.2015 2) 26.04.2016 - 10.05.2016 3) 01.06.2016 - 15.06.2016	75.0 75.0	400 400	18.75 18.75	20.04.2016/0 04.05.2016/14	71	(g) 16-2034 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
16-2034-03 16-2034-03-T Spain 41600 Arahal Europe, South F 2016	Barley Odissey	1) 10.12.2015 2) 14.04.2016 - 22.04.2016 3) 25.05.2016 - 30.06.2016	75.0 75.0	300 300	25.0 25.0	25.04.2016/0 14.05.2016/19	77	(g) 16-2034 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
16-2034-04 16-2034-04-T Greece GR - 611 00 Kristoni, Kilis Europe, South F 2016	Barley Prestige	1) 02.11.2015 2) 03.05.2016 - 07.05.2016 3) 14.06.2016 - 14.06.2016	75.0 75.0	300 300	25.0 25.0	26.04.2016/0 10.05.2016/14	73	(g) 16-2034 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying

Analytical part 16-2034

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
16-2034-01 16-2034-01-T France, south 13103 St Etienne du gres Europe, South F 2016	Barley Augusta	whole plant without root	75	0.29	0.043	0.34	0.014	0*	(g) 16-2034 (j) Analytical method: 01304 (k) LOQ: Analyte 1: 0.01 mg/kg Analyte 2: 0.02 mg/kg Analyte 3: 0.03 mg/kg Analyte 4: 0.007 mg/kg (l) Method Validation Data: 01304; 16-2034 (m) Storage: Analyte 1, 2, 4 whole plant without roots: 558 days Analyte 1, 2, 4 straw: 527 days Analyte 1, 2, 4 grain: 527 days
			75	2.0	0.43	2.4	0.14	0	
		grain	89	0.033	0.19	<u>0.23</u>	<u>0.064</u>	28	
			89	<u>0.042</u>	0.18	0.22	0.060	35	
		straw	89	<u>0.18</u>	0.063	<u>0.25</u>	0.021	28	
			89	0.13	0.071	0.20	<u>0.024</u>	35	
16-2034-02 16-2034-02-T Italy 44124 Cona Ferrara Europe, South F 2016	Barley Cometa	whole plant without root	71	0.031	0.020	0.051	0.007	0*	(g) 16-2034 (j) Analytical method: 01304 (k) LOQ: Analyte 1: 0.01 mg/kg Analyte 2: 0.02 mg/kg Analyte 3: 0.03 mg/kg Analyte 4: 0.007 mg/kg (l) Method Validation Data: 01304; 16-2034 (m) Storage: Analyte 1, 2, 4 whole plant without roots: 569 days Analyte 1, 2, 4 straw: 539 days Analyte 1, 2, 4 grain: 539 days
			71	1.9	0.21	2.1	0.070	0	
		grain	87	<u><0.01</u>	0.20	0.21	0.065	<u>30</u>	
			89	<u><0.01</u>	0.22	<u>0.23</u>	<u>0.072</u>	35	
		straw	87	0.017	0.053	0.070	<u>0.018</u>	<u>30</u>	
			89	<u>0.020</u>	0.055	<u>0.075</u>	0.018	35	

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial		
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA				
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)		
16-2034-03 16-2034-03-T Spain 41600 Arahal Europe, South F 2016	Barley Odyssey	whole plant without root	77	0.080	0.095	0.17	0.032	0*	(g) 16-2034 (j) Analytical method: 01304 (k) LOQ: Analyte 1: 0.01 mg/kg Analyte 2: 0.02 mg/kg Analyte 3: 0.03 mg/kg Analyte 4: 0.007 mg/kg (l) Method Validation Data: 01304; 16-2034 (m) Storage: Analyte 1, 2, 4 whole plant without roots: 559 days Analyte 1, 2, 4 straw: 531 days Analyte 1, 2, 4 grain: 531 days		
			77	3.5	0.92	4.4	0.31				
		grain	89	<u>0.13</u>	0.26	<u>0.39</u>	0.087	28			
			89	0.098	0.27	0.37	<u>0.091</u>				
		straw	89	<u>4.5</u>	2.3	<u>6.8</u>	<u>0.77</u>	28			
			89	4.2	2.3	6.5	0.77				
		16-2034-04 16-2034-04-T Greece GR - 611 00 Kristoni, Kilkis Europe, South F 2016	Barley Prestige	whole plant without root	73	0.50	0.042	0.54		0.014	0*
					73	2.2	0.40	2.6		0.13	
grain	89			<u>0.19</u>	0.087	<u>0.28</u>	<u>0.029</u>	30			
	92			0.14	0.078	0.22	0.026				
straw	89			<u>0.72</u>	0.065	<u>0.79</u>	<u>0.022</u>	30			
	92			0.72	0.067	0.79	0.022				

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control
(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.1.3.4 Wheat

The critical GAP (cGAP) for the proposed use of Sivanto Energy (DLT+FPF EC 85) in wheat is summarized in [Table A 25](#).

Table A 25: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU	Currently there is no EU cGAP in place on wheat for flupyradifurone.				
Intended cGAP* (number 115, 117, 212, 214, 259, 261, 345, 347, 364, 366, 383, 385)	2	56.25	14	BBCH 41-83	30

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

A 2.1.3.4.1 Study report 15-2129

Comments of zRMS:	<p>Four field residue trials were conducted in northern Europe in 2015 to determine the magnitude of the residues of deltamethrin and BYI 02960 (common name flupyradifurone) in/on winter and spring wheat (grain, straw and whole plant without root, ear and rest of plant) after two spray applications with Deltamethrin & Flupyradifurone EC 085, an EC formulation containing 10 g/L deltamethrin and 75 g/L BYI 02960 each at a rate of 0.75 L/ha, corresponding to 56.25 g BYI 02960/ha and 7.5 g/ha of deltamethrin with an interval of 13-14 days. The last application was done at a crop growth stage BBCH 73-85. The PHI was 30 days.</p> <p>Residues of BYI 02960 and difluoroacetic acid were determined by HPLC-MS/MS according to method 01212.</p> <p>The individual LOQs for BYI 02960 and difluoroacetic acid are 0.01 and 0.02 mg/kg respectively in the sample materials wheat (grain), wheat (ear), wheat (rest of plant) and wheat (whole plant without root). For the sample material wheat (straw) the individual LOQs are 0.05 mg/kg for each analyte.</p> <p>The average recoveries per fortification level were within the range of 70 – 110%. The RSD values were below 20%.</p> <p>Residue results (mg/kg) for grain (PHI: 30 days): E (FPF): 2 x <0.01; 0.011; 0.015* E (DFA): 0.10; 0.16; 0.20; 0.34 RA (sum): 0.32; 0.48; 0.62; 1.0 * Peak residues detected after PHI.</p> <p>The storage period of deep-frozen samples intended for the analysis of BYI 02960 and its metabolites in the treated samples ranged between 123 and 239 days and the storage period of the corresponding control samples ranged between 128 and 230 days.</p> <p>Residues of deltamethrin and its isomers AE 0035073 and AE F108569 were determined by HPLC-MS/MS according to method 00855/M004 with LOQ of 0.01 mg/kg for grain and ear for each compound and 0.05 mg/kg for straw, rest of plant and whole plant without root for each compound.</p> <p>For deltamethrin and its two isomers average recoveries were at each fortification level within the acceptable range of 70 – 110% and the RSD values were below 20%.</p> <p>Residue results (mg/kg) in grain: E (deltamethrin): 4 x <0.01 RA (sum): 4 x <0.03</p>
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	The storage period of deep-frozen samples intended for the analysis of deltamethrin and its isomers in the treated samples ranged between 112 and 177 days and the storage period of the corresponding control samples ranged between 117 and 177 days.
	The study is acceptable.

Reference:	KCA 6.3.4.1/01
Title:	Amendment no. 2 to final report - Determination of the residues of BYI 02960 and deltamethrin in/on spring wheat and winter wheat after spray application of deltamethrin & flupyradifurone EC 085 in Germany, the Netherlands and Belgium
Report:	Schulte, G.; 2017; 15-2129; M-580528-03-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial
Deviations:	none
GLP/GEP:	Yes
Acceptability:	yes
Duplication (if vertebrate study):	

Validity of the study:

Materials and methods

In 2015, 4 field trials were conducted in northern Europe (Germany [2], the Netherlands and Belgium) to support the use of Sivanto Energy EC 085 in wheat. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960). Two applications were made at an interval of 14-16 days, each at a rate of 0.75 L/ha, corresponding to 56.25 g BYI 02960/ha. The last application was done at a crop growth stage of BBCH 71-75 (BBCH 71: watery ripe, first grains have reached half their final size; BBCH 75: medium milk, grain content milky, grains reached final size, still green). The envisaged PHI was 30 days.

Samples of whole plant without root were collected before and after the last treatment and 7 and 14 days after last treatment. Samples of grain and straw were collected 21, 30 and 35-36 days after the last treatment, except in trial 15-2129-01 where the sampling at 21 days after last treatment was changed from grain and straw to ear and rest of plant due to an unexpected slow development of the crop (amendment to the study plan). All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 239 days). The maximum storage period of 239 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 52 months ([Netzband, D.; 2015; M-428412-03-1](#)).

The samples were analysed according to method 01212 ([Rosati, D.; 2012; M-428017-01-1](#)) by LC-MS/MS using stable isotopically labelled internal standards. The LOQ in whole plant without roots, ear, rest of plant and grain was 0.01 mg/kg for BYI 02960 and 0.02 mg/kg for DFA when expressed as BYI 02960 (corresponding to 0.0067 mg/kg when expressed as DFA). The calculated LOQ for the total residue (sum of BYI 02960 and DFA, expressed as BYI 02960) was 0.03 mg/kg. For straw the LOQ was 0.05 mg/kg for BYI 02960 and for DFA when expressed as BYI 02960 (corresponding to 0.017 mg/kg when expressed as DFA). The calculated LOQ for the total residue (sum of BYI 02960 and DFA, expressed as BYI 02960) was 0.1 mg/kg.

Residues of DFEAF and 6-CNA have been also determined during the study, but since they are not relevant to the residue definition for risk assessment, they are not reported here.

Results

The method performance was validated by at least three recoveries at two fortification levels during the conduct of study 15-2127 which was analysed in parallel. During the course of the present study, the method performance was confirmed by concurrent recoveries. The apparent residues in the control samples used for recoveries at LOQ level were below 30% of the LOQ except for difluoroacetic acid (15-2129-01-0028E

and 15-2129-03-0014E with 31% and 38% of LOQ, respectively). The recoveries conducted with the affected control samples were corrected. In addition, recoveries at the LOQ level were corrected in those cases where the residues in the control samples were above 10% of the LOQ. Corrections done are indicated in the recovery tables below. The average recoveries per fortification level and analyte were within the acceptable range of 70–110%. The RSD values were always below 20% (Table A 26).

Details of the application and residue information are summarized in Table A 27.

Low amounts of DFA were detected in three untreated samples, however the levels were always below the limit of quantification of the method.

Table A 26: Recovery data for flupyradifurone and its metabolite DFA in matrices of wheat

Study Trial No. Plot No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortification level * (mg/kg)	Individual recoveries	Recovery (%)			
							Min	Max	Mean	RSD
15-2129 15-2129-01 15-2129-01-T to 15-2129-04 15-2129-04-T GLP: yes 2015	Wheat	whole plant without roots	BYI 02960	1	0.01	103	103	103	103	0.6
				1	0.1	102	102	102	102	
				1	4.0	102	102	102	102	
				3	overall		102	103	102	
			DFA	1	0.02	78 ^a	78	78	78	9.6
				1	0.2	93	93	93	93	
				1	8.0	92	92	92	92	
				3	overall		78	93	88	
		grain	BYI 02960	1	0.01	105	105	105	105	5.2
				1	0.1	95	95	95	95	
				1	1.0	103	103	103	103	
				3	overall		95	105	101	
			DFA	1	0.02	74 ^b	74	74	74	5.3
				1	0.2	80	80	80	80	
				1	2.0	82	82	82	82	
				3	overall		74	82	79	
		straw	BYI 02960	1	0.05	96	96	96	96	5.5
				1	0.5	106	106	106	106	
				1	4.0	97	97	97	97	
				3	overall		96	106	100	
			DFA	1	0.05	95 ^c	95	95	95	3.6
				1	0.5	101	101	101	101	
				1	4.0	95	95	95	95	
				3	overall		95	101	97	

* expressed as BYI 02960

The control 15-2129-03-0014E (0.00589 mg/kg expressed as BYI 02960) was used for fortification for the following value:

^a This value was corrected with the value of the respective control sample. The uncorrected value was 116%.

The control 15-2129-01-0028E (0.00403 mg/kg expressed as BYI 02960) was used for fortification for the following value:

^b This value was corrected with the value of the respective control sample. The uncorrected value was 104%.

The control 15-2129-04-0029E (0.00574 mg/kg expressed as BYI 02960) was used for fortification for the following value:

^c This value was corrected with the value of the respective control sample. The uncorrected value was 119%.

Table A 27: Residue trials on wheat

GAP Summary of the 15-2129 trials

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL			
(a)	(b)					(c)	(d)	(f)
15-2129-01 15-2129-01-T Germany 49377 Vechta, OT Deindrup Europe, North F 2015	Wheat, spring Granus	1) 11.04.2015 2) 08.07.2015 - 17.07.2015 3) 10.08.2015 - 20.08.2015	56.25 56.25	300 300	18.75 18.75	29.06.2015/0 15.07.2015/16	71	(g) 15-2129 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
15-2129-02 15-2129-02-T Netherlands 1775 PN Middenmeer Europe, North F 2015	Wheat, spring Tybalt	1) 18.03.2015 2) 20.06.2015 - 30.06.2015 3) 20.08.2015 - 27.08.2015	56.25 56.25	400 400	14.06 14.06	30.06.2015/0 14.07.2015/14	75	(g) 15-2129 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
15-2129-03 15-2129-03-T Germany 04720 Lüttewitz Europe, North F 2015	Wheat, winter Kerubino	1) 09.10.2014 2) 03.06.2015 - 07.06.2015 3) 20.07.2015 - 12.08.2015	56.25 56.25	300 300	18.75 18.75	09.06.2015/0 23.06.2015/14	73	(g) 15-2129 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
15-2129-04 15-2129-04-T Belgium 6210 Villers- Perwin Europe, North F 2015	Wheat, winter Edgar	1) 20.10.2014 2) 01.06.2015 - 16.06.2015 3) 24.07.2015 - 03.08.2015	56.25 56.25	300 300	18.75 18.75	10.06.2015/0 24.06.2015/14	73	(g) 15-2129 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying

Analytical part 15-2129

Analyte 1: BYI 02960 (determined as BYI 02960, calculated as BYI 02960), Analyte 2: DFA (determined as DFA, calculated as BYI 02960), Analyte 3 (calculated value): sum of BYI 02960 and DFA (calculated as BYI 02960), Analyte 4: DFA (determined as DFA, calculated as DFA)

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
(a)			(d)					(e)	(f)
15-2129-01 15-2129-01-T Germany 49377 Vechta, OT Deindrup Europe, North F 2015	Wheat, spring Granus	whole plant	71	0.080	0.16	0.24	0.054	0*	(g) 15-2129
			71	1.7	0.17	1.9	0.057	0	(j) Analytical method: 01212
		without root	77	0.39	0.35	0.73	0.12	7	(k) LOQ:
			83	0.22	0.38	0.60	0.13	14	Analyte 1 whole plant without roots, ear, rest of plant,
		ear	85	0.22	0.72	0.94	0.24	21	grain: 0.01 mg/kg
			85	0.064	0.10	0.16	0.033	21	Analyte 1,2 straw: 0.05 mg/kg
		rest of plant	85	0.064	0.10	0.16	0.033	21	Analyte 2 whole plant without roots, ear, rest of plant,
			89	<0.01	1.0	1.0	0.34	30	grain: 0.02 mg/kg
		straw	89	0.015	0.91	0.92	0.30	35	Analyte 3 straw: 0.1 mg/kg
			89	0.31	0.44	0.76	0.15	30	Analyte 3 whole plant without roots, ear, rest of plant,
			89	0.19	0.50	0.69	0.17	35	grain: 0.03 mg/kg
			89	0.19	0.50	0.69	0.17	35	Analyte 4 straw: 0.017 mg/kg
			89	0.19	0.50	0.69	0.17	35	Analyte 4 whole plant without roots, ear, rest of plant,
			89	0.19	0.50	0.69	0.17	35	grain: 0.0067 mg/kg
			89	0.19	0.50	0.69	0.17	35	(l) Method Validation Data: 01212, 15-2127
			89	0.19	0.50	0.69	0.17	35	(m) Storage:
			89	0.19	0.50	0.69	0.17	35	Analyte 1, 2, 3 whole plant without roots: 160 days
			89	0.19	0.50	0.69	0.17	35	Analyte 1, 2, 3 straw: 208 days
			89	0.19	0.50	0.69	0.17	35	Analyte 1, 2, 3 rest of plant: 139 days
			89	0.19	0.50	0.69	0.17	35	Analyte 1, 2, 3 grain: 129 days
			89	0.19	0.50	0.69	0.17	35	Analyte 1, 2, 3 ear: 138 days

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
	(a)		(d)					(e)	(f)
15-2129-02 15-2129-02-T Netherlands 1775 PN Middenmeer Europe, North F 2015	Wheat, spring Tybalt	whole plant without root grain straw	75 75 77 77 83 87 89 83 87 89	0.087 0.93 0.26 0.11 0.022 <u>≤0.01</u> 0.47 0.37 0.066 <u>0.12</u> 0.089 0.05	0.083 0.075 0.16 0.18 0.35 0.47 0.37 0.078 0.089 0.05	0.17 1.0 0.42 0.29 0.37 <u>0.48</u> 0.38 0.14 <u>0.21</u> 0.05	0.028 0.025 0.053 0.059 0.12 <u>0.16</u> 0.12 0.026 <u>0.030</u> 0.017	0* 0 7 14 21 <u>30</u> 36 21 <u>30</u> 36	(g) 15-2129 (j) Analytical method: 01212 (k) LOQ: Analyte 1 whole plant without roots, grain: 0.01 mg/kg Analyte 1,2 straw: 0.05 mg/kg Analyte 2 whole plant without roots, grain: 0.02 mg/kg Analyte 3 straw: 0.1 mg/kg Analyte 3 whole plant without roots, grain: 0.03 mg/kg Analyte 4 straw: 0.017 mg/kg Analyte 4 whole plant without roots, grain: 0.0067 mg/kg (l) Method Validation Data: 01212, 15-2127 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 161 days Analyte 1, 2, 3 straw: 218 days Analyte 1, 2, 3 grain: 139 days
15-2129-03 15-2129-03-T Germany 04720 Lüttewitz Europe, North F 2015	Wheat, winter Kerubino	whole plant without root grain straw	73 73 73 75 83 89 89 83 89 89	0.10 0.99 0.27 0.15 0.040 <u>≤0.01</u> 0.31 0.10 0.088 0.12 <u>0.18</u>	0.051 0.051 0.10 0.15 0.24 0.31 0.31 0.060 0.10 0.13	0.16 1.0 0.37 0.30 0.28 <u>0.32</u> 0.32 0.15 0.22 <u>0.30</u>	0.017 0.017 0.034 0.050 0.079 <u>0.10</u> 0.10 0.020 0.034 <u>0.042</u>	0* 0 7 14 21 <u>30</u> 35 21 <u>30</u> 35	(g) 15-2129 (j) Analytical method: 01212 (k) LOQ: Analyte 1 whole plant without roots, grain: 0.01 mg/kg Analyte 1,2 straw: 0.05 mg/kg Analyte 2 whole plant without roots, grain: 0.02 mg/kg Analyte 3 straw: 0.1 mg/kg Analyte 3 whole plant without roots, grain: 0.03 mg/kg Analyte 4 straw: 0.017 mg/kg Analyte 4 whole plant without roots, grain: 0.0067 mg/kg (l) Method Validation Data: 01212, 15-2127 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 182 days Analyte 1, 2, 3 straw: 239 days Analyte 1, 2, 3 grain: 160 days

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial		
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA			(e)	(f)
15-2129-04 15-2129-04-T Belgium 6210 Villers- Perwin Europe, North F 2015	Wheat, winter Edgar	whole plant without root grain straw	73 73 73 83 85 89 89 85 89 89	0.15 0.94 0.42 0.30 0.033 <u>0.011</u> 0.011 0.20 <u>0.27</u> 0.27	0.063 0.063 0.16 0.20 0.40 0.60 0.59 0.097 0.12 0.098	0.22 1.0 0.58 0.50 0.44 <u>0.62</u> 0.60 0.29 <u>0.38</u> 0.37	0.021 0.021 0.053 0.067 0.13 <u>0.20</u> 0.20 0.032 <u>0.039</u> 0.033	0* 0 7 14 21 <u>30</u> 35 21 <u>30</u> 35	(g) 15-2129 (j) Analytical method: 01212 (k) LOQ: Analyte 1 whole plant without roots, grain: 0.01 mg/kg Analyte 1,2 straw: 0.05 mg/kg Analyte 2 whole plant without roots, grain: 0.02 mg/kg Analyte 3 straw: 0.1 mg/kg Analyte 3 whole plant without roots, grain: 0.03 mg/kg Analyte 4 straw: 0.017 mg/kg Analyte 4 whole plant without roots, grain: 0.0067 mg/kg (l) Method Validation Data: 01212, 15-2127 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 181 days Analyte 1, 2, 3 straw: 238 days Analyte 1, 2, 3 grain: 159 days		
(a)	According to CODEX Classification / Guide			(e)	Days after last application (Label pre-harvest interval, PHI, underline)			(h)	Formulation type	(l)	Method validation
(b)	Only if relevant			(f)	Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included			(i)	Application method	(m)	Storage (max)
(c)	Year must be indicated							(j)	Method information		! based on date of analysis
(d)	Either growth stage description or BBCH Code			(g)	Study reference			(k)	LOQ		P based on production date
G	greenhouse	F field	*	prior to last treatment			**	residue in control	#	no data available	

A 2.1.3.4.2 Study report 16-2033

Comments of zRMS:	<p>Four field residue trials were conducted in northern Europe in 2016 to determine the magnitude of the residues of deltamethrin and BYI 02960 (common name flupyradifurone) in/on winter and spring wheat (grain, straw and whole plant without root) after two spray applications with Deltamethrin & Flupyradifurone EC 085, an EC formulation containing 10 g/L deltamethrin and 75 g/L BYI 02960 each at a rate of 0.75 L/ha, corresponding to 56.25 g BYI 02960/ha and 7.5 g/ha of deltamethrin with an interval of 13-14 days. The last application was done at a crop growth stage BBCH 77-87. The PHI was 30 days.</p> <p>Residues of BYI 02960 and difluoroacetic acid were determined by HPLC-MS/MS according to method 01304.</p> <p>The individual LOQs for BYI 02960 and difluoroacetic acid are 0.01 and 0.02 mg/kg, respectively in the sample materials whole plant without root, grain and straw.</p> <p>The average recoveries per fortification level were within the range of 70 – 110%. The RSD values were below 20%.</p> <p>Residue results (mg/kg) for grain (PHI: 30 days): E (FPF): 0.010; 0.012*; 0.032*; 0.061 E (DFA): 0.018; 0.067; 0.074; 0.14* RA (sum): 0.12; 2 x 0.23; 0.42* * Peak residues detected after PHI.</p> <p>The storage period of deep-frozen samples intended for the analysis of BYI 02960 and its metabolites in the treated samples ranged between 455 and 512 days.</p> <p>Residues of deltamethrin and its isomers AE 0035073 and AE F108569 were determined by HPLC-MS/MS according to method 00855/M004 with LOQ of 0.01 mg/kg for grain for each compound and 0.05 mg/kg for straw and whole plant without root for each compound. For deltamethrin and its two isomers average recoveries were at each fortification level within the acceptable range of 70 – 110% and the RSD values were below 20%.</p> <p>Residue results (mg/kg) in grain: E (deltamethrin): 4 x <0.01 RA (sum): 4 x <0.03</p> <p>The storage period of deep-frozen samples intended for the analysis of deltamethrin and its isomers in the treated samples ranged between 391 and 450 days.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.4.1/02
Title:	Determination of the residues of BYI 02960 and deltamethrin in/on winter and spring wheat after spray application of deltamethrin & flupyradifurone EC 085 in Belgium, Germany and the Netherlands
Report:	Kaussmann, M.; Kerkering, S.; 2018; 16-2033; M-634190-01-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP 860.1500, Crop Field Trial
Deviations:	None
GLP/GEP:	Yes
Acceptability:	yes
Duplication (if vertebrate study):	

Validity of the study:

In 2016, 4 field trials were conducted in northern Europe (Belgium, Germany [2] and the Netherlands) to support the use of Sivanto Energy EC 085 in wheat. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960). Two applications were made at an interval of 13-14 days, each at a rate of 0.75 L/ha, corresponding to 56.25 g BYI 02960/ha. The last application was done at a crop growth stage of BBCH 77-87 (BBCH 77: late milk ; BBCH 87: hard dough, grain content solid. Fingernail impression held). The envisaged PHI was 30 days.

Samples of whole plant without root were collected before and after the last treatment. Samples of mature grain and wheat straw were collected 30-31 and 35-36 days after the last treatment. All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 512 days). The maximum storage period of 512 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 52 months ([Netzband, D.; 2015; M-428412-03-1](#)).

Residues of DFEAF and 6-CNA have been also determined during the study, but since they are not relevant to the residue definition for risk assessment, they are not reported here.

The method performance was validated by at least 3 concurrent recoveries at two fortification levels during the conduct of study 16-2032 which was analysed in parallel. During the course of the present study, the method performance was confirmed by concurrent recoveries. The average recoveries per fortification level and analyte were within the acceptable range of 70–110%. The RSD values were always below 20% (Table A 28).

Details of the application and residue information are summarized in [Table A 29](#). No residues of BYI 02960 or DFA at or above the limit of quantification of the method were found in any of the untreated samples.

Study Trial No. Plot No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortification level * (mg/kg)	Recovery (%) Individual recoveries	Min	Max	Mean	RSD
16-2033	Wheat	whole plant without roots	BYI 02960	1	0.01	91	91	91	91	2.8
1				1.0	89	89	89			
1				2.5	94	94	94			
3				overall	89	94	91			
DFA			1	0.02	97	97	97	97	2.2	
			1	2.0	94	94	94			
			1	5.0	98	98	98			
			3	overall	94	98	96			
grain		BYI 02960	3	0.01	95; 96; 114	95	114	102	10.5	
			1	0.1	95	95	95			
			2	1.0	95;96	95	96			
			6	overall	95	114	99			
		DFA	1	0.02	101	101	101	101	7.7	
			1	2.0	88	88	88			
			2	overall	88	101	95			
straw		BYI 02960	2	0.01	81; 98	81	98	90	7.8	
			1	0.1	92	92	92			
			1	1.0	83	83	83			
			1	2.5	90	90	90			
	5	overall	81	98	89					
DFA	2	0.02	87; 91	87	91	89				
	1	0.2	85	85	85					

			1	2.0	87	87	87	87	
			1	5.0	90	90	90	90	
			5	overall		85	91	88	2.8

* expressed as BYI 02960

Table A 29: Residue trials on wheat

GAP Summary of the 16-2033 trials

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL			
(a)	(b)					(c)	(d)	(f)
16-2033-01 16-2033-01-T Belgium 6211 Mellet Europe, North F 2016	Wheat, spring Triso	1) 18.03.2016 2) 15.06.2016 - 24.06.2016 3) 10.08.2016 - 17.08.2016	56.25 56.25	250 250	22.5 22.5	22.06.2016/0 06.07.2016/14	83	(g) 16-2033 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
16-2033-02 16-2033-02-T Germany 42799 Leichlingen Europe, North F 2016	Wheat, spring Tybalt	1) 15.03.2016 2) 10.06.2016 - 16.06.2016 3) 15.08.2016 - 31.08.2016	56.25 56.25	300 300	18.75 18.75	06.07.2016/0 20.07.2016/14	85	(g) 16-2033 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
16-2033-03 16-2033-03-T Netherlands 1606 MG Venhuizen Europe, North F 2016	Wheat, winter Mediator	1) 19.10.2015 3) 15.08.2016 - 25.08.2016	56.25 56.25	400 400	14.06 14.06	06.07.2016/0 20.07.2016/14	87	(g) 16-2033 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
16-2033-04 16-2033-04-T Germany 59457 Werl- Niederbergstraße Europe, North F 2016	Wheat, winter Winnetou	1) 25.10.2015 2) 30.05.2016 - 08.06.2016 3) 27.07.2016 - 24.08.2016	56.25 56.25	300 300	18.75 18.75	15.06.2016/0 28.06.2016/13	77	(g) 16-2033 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying

Analyte 1: BYI 02960 (determined as BYI 02960, calculated as BYI 02960), Analyte 2: DFA (determined as DFA, calculated as BYI 02960), Analyte 3 (calculated value): sum of BYI 02960 and DFA (calculated as BYI 02960), Analyte 4: DFA (determined as DFA, calculated as DFA)

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
	(a)		(d)					(e)	(f)
16-2033-01	Wheat, spring Triso	whole plant without root	83	0.25	0.070	0.32	0.023	0*	(g) 16-2033
16-2033-01-T			83	1.6	0.066		0.022	0	(j) Analytical method:
Belgium		grain							whole plant without roots, straw; grain: 01304
6211 Mellet									(k) LOQ:
Europe, North			87	<u>0.010</u>	0.39	0.40	0.13	<u>30</u>	Analyte 1 whole plant without roots, straw, grain:
F			89	<0.01	0.41	<u>0.42</u>	<u>0.14</u>	35	0.01 mg/kg
2016		straw							Analyte 2 whole plant without roots, straw, grain:
			87	0.37	0.040	0.41	0.013	<u>30</u>	0.02 mg/kg
		89	<u>0.43</u>	0.065	<u>0.49</u>	<u>0.022</u>	35	Analyte 3 whole plant without roots, straw, grain:	
								Analyte 4 whole plant without roots, straw, grain:	
								0.0067 mg/kg	
								(l) Method Validation Data	
								01304, 16-2032	
								(m) Storage:	
								whole plant without roots: 504 days	
								straw: 474 days	
								grain: 482 days	

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
16-2033-02 16-2033-02-T Germany 42799 Leichlingen Europe, North F 2016	Wheat, spring Tybalt	whole plant without root	85 85	0.91 1.9	0.18 0.18	1.1 2.0	0.060 0.060	0* 0	(g) 16-2033 (j) Analytical method: whole plant without roots, straw; grain: 01304 (k) LOQ: Analyte 1 whole plant without roots, straw, grain: 0.01 mg/kg Analyte 2 whole plant without roots, straw, grain: 0.02 mg/kg Analyte 3 whole plant without roots, straw, grain: 0.03 mg/kg Analyte 4 whole plant without roots, straw, grain: 0.0067 mg/kg (l) Method Validation Data 01304, 16-2032 (m) Storage: whole plant without roots: 490 days straw: 460 days grain: 468 days
		grain	89 89	0.027 0.032	0.20 0.17	0.23 0.20	0.067 0.055	30 35	
		straw	89 89	0.81 0.66	0.26 0.34	1.1 1.0	0.086 0.11	30 35	
16-2033-03 16-2033-03-T Netherlands 1606 MG Venhuizen Europe, North F 2016	Wheat, winter Mediator	whole plant without root	87 87	0.61 1.7	0.052 0.051	0.66 1.8	0.017 0.017	0* 0	(g) 16-2033 (j) Analytical method: whole plant without roots, straw; grain: 01304 (k) LOQ: Analyte 1 whole plant without roots, straw, grain: 0.01 mg/kg Analyte 2 whole plant without roots, straw, grain: 0.02 mg/kg Analyte 3 whole plant without roots, straw, grain: 0.03 mg/kg Analyte 4 whole plant without roots, straw, grain: 0.0067 mg/kg (l) Method Validation Data 01304, 16-2032 (m) Storage: whole plant without roots: 490 days straw: 460 days grain: 468 days
		grain	89 92	0.061 0.042	0.055 0.054	0.12 0.096	0.018 0.018	30 35	
		straw	89 92	1.2 0.79	0.074 0.065	1.2 0.85	0.025 0.022	30 35	
	Wheat, winter Winnetou	whole plant without root	77 77	0.028 0.99	0.041 0.042	0.069 1.0	0.014 0.014	0* 0	

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
16-2033-04 16-2033-04-T Germany 59457 Werl- Niederbergstraße Europe, North F 2016		grain	89	<0.01	0.22	<u>0.23</u>	<u>0.074</u>	<u>31</u>	(g) 16-2033 (j) Analytical method: whole plant without roots, straw; grain: 01304 (k) LOQ: Analyte 1 whole plant without roots, straw, grain: 0.01 mg/kg Analyte 2 whole plant without roots, straw, grain: 0.02 mg/kg Analyte 3 whole plant without roots, straw, grain: 0.03 mg/kg Analyte 4 whole plant without roots, straw, grain: 0.0067 mg/kg (l) Method Validation Data 01304, 16-2032 (m) Storage: whole plant without roots: 512 days straw: 481 days grain: 489 days
			89	<u>0.012</u>	0.18	0.19	0.059	36	
		straw	89	<u>0.41</u>	0.16	<u>0.57</u>	<u>0.053</u>	<u>31</u>	
			89	0.28	0.12	0.40	0.040	36	

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Either growth stage description or BBCH Code

G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)

(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

(g) Study reference

* prior to last treatment

(h) Formulation type

(i) Application method

(j) Method information

(k) LOQ

** residue in control

(l) Method validation

(m) Storage (max)

! based on date of analysis

P based on production date

no data available

A 2.1.3.4.3 Study report 15-2127 (for information only)

Comments of zRMS:	This study has not been evaluated by zRMS-PL because it was conducted in southern Europe.
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Reference:	KCA 6.3.4.1/03
Title:	Amendment no. 2 to final report - Determination of the residues of BYI 02960 and deltamethrin in/on wheat after spray application of deltamethrin & flupyradifurone EC 085 in Italy, Spain and Portugal
Report:	Schulte, G.; 2017; 15-2127; M-580063-03-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial
Deviations:	none
GLP/GEP:	yes
Acceptability:	-
Duplication (if vertebrate study):	

Validity of the study:

Materials and methods

In 2015, 4 field trials were conducted in southern Europe (Italy [2], Spain and Portugal) to support the use of Sivanto Energy EC 085 in wheat. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960). Two applications were made at an interval of 14 days, each at a rate of 1.0 L/ha, corresponding to 75 g BYI 02960/ha. The last application was done at a crop growth stage of BBCH 69-83 (BBCH 69: end of flowering; BBCH 83: early dough stage). The envisaged PHI was 30 days.

Samples of whole plant without root were collected before and after the last treatment and 7-8 and 14 days after the last treatment. Samples of mature grain and wheat straw were collected 21, 29-30 and 35 days after the last treatment, except in trial 15-2127-02 where sampling at 21 days after last treatment was changed from grain and straw to whole plant without root due to delayed plant development. All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 274 days). The maximum storage period of 274 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 52 months ([Netzband, D.; 2015; M-428412-03-1](#)).

The samples were analysed according to method 01212 ([Rosati, D.; 2012; M-428017-01-1](#)) by LC-MS/MS using stable isotopically labelled internal standards. The LOQ in whole plant without roots and grain was 0.01 mg/kg for BYI 02960 and 0.02 mg/kg for DFA when expressed as BYI 02960 (corresponding to 0.0067 mg/kg when expressed as DFA). The calculated LOQ for the total residue (sum of BYI 02960 and DFA, expressed as BYI 02960) was 0.03 mg/kg. For straw the LOQ was 0.05 mg/kg for BYI 02960 and for DFA when expressed as BYI 02960 (corresponding to 0.017 mg/kg when expressed as DFA). The calculated LOQ for the total residue (sum of BYI 02960 and DFA, expressed as BYI 02960) was 0.1 mg/kg. Residues of DFEAF and 6-CNA have been also determined during the study, but since they are not relevant to the residue definition for risk assessment, they are not reported here.

Results

During the course of this study, the method performance was checked/validated by concurrent recoveries. Full validation of method 01212 was done and documented for matrices representing the 5 major crop groups, including tomato (fruit), grape (bunch of grape), kidney bean (dry seed), barley (grain) and summer rape (seed) when developing the method. For wheat grain, straw and whole plant without root a limited set (1 control, ≥ 3 repetitions each at two fortification levels) of additional validation recoveries was done within this study. The apparent residues in the control samples used for recoveries at LOQ level were below 30%

of the LOQ except for DFA (15-2127-01-0030E, 15-2127-03-0014E and 15-2127-04-0030E with 34%, 40% and 34% of LOQ, respectively). The recoveries conducted with these affected control samples were corrected. In addition, recoveries at the LOQ level were corrected in those cases where the residues in the control samples were above 10% of the LOQ. Corrections done are indicated in the recovery tables below. The average recoveries per fortification level and analyte were within the acceptable range of 70–110% and the RSD values were always below 20% (Table A 30).

Details of the application and residue information are summarized in Table A 31. Low amounts of BYI 02960 and DFA were detected in untreated samples, however the levels were always below the limit of quantification of the method. Corresponding recoveries were corrected for these residues.

Table A 30: Recovery data for flupyradifurone and its metabolite DFA in matrices of wheat

Study Trial No. Plot No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortification level * (mg/kg)	Recovery (%)				
						Individual recoveries	Min	Max	Mean	RSD
15-2127 15-2127-01 15-2127-01-T to 15-2127-04 15-2127-04-T GLP: yes 2015	Wheat	whole plant without roots	BYI 02960	4	0.01	94;99;102;107	94	107	101	5.4
				3	0.1	100; 101; 103	100	103	101	1.5
				1	1.0	108	108	108	108	
				1	10	97	97	97	97	
				9	overall		94	108	101	4.4
			DFA	4	0.02	84 ^f ; 88 ^g ; 91 ^h ; 96 ⁱ	84	96	90	5.6
				3	0.2	90; 90; 93	90	93	91	1.9
				1	2.0	95	95	95	95	
				8	overall		84	96	91	4.3
		grain	BYI 02960	4	0.01	97; 104; 108; 109	97	109	105	5.2
				3	0.1	106; 106; 110	106	110	107	2.2
				1	4.0	104	104	104	104	
				8	overall		97	110	106	3.9
			DFA	4	0.02	76; 82; 87; 95	76	95	85	9.5
				3	0.2	78; 80; 80	78	80	79	1.5
				1	8.0	82	82	82	82	
				8	overall		76	95	83	7.3
		straw	BYI 02960	6	0.05	91 ^a ; 92; 102 ^b ; 104 ^c ; 106 ^d ; 107 ^f	91	107	100	7
				6	0.5	98; 98; 100; 102; 103; 103	98	103	101	2.3
				1	2.5	103	103	103	103	
				1	4.0	99	99	99	99	
				14	overall		91	107	101	4.7
			DFA	6	0.05	83 ^j ; 83 ^k ; 85 ^l ; 88 ^m ; 91 ⁿ ; 107 ^o	83	107	90	10.2
				6	0.5	92; 96; 98; 98; 98; 104	92	104	98	4
				1	2.5	100	100	100	100	
				13	overall		83	107	94	8.3

* expressed as BYI 02960

The control 15-2127-01-0030E (0.00666 mg/kg expressed as BYI 02960) was used for fortification for the following values:

- ^a This value was corrected with the value of the respective control sample. The uncorrected value was 104%.
- ^b This value was corrected with the value of the respective control sample. The uncorrected value was 115%.
- ^c This value was corrected with the value of the respective control sample. The uncorrected value was 116%.
- ^d This value was corrected with the value of the respective control sample. The uncorrected value was 119%.
- ^e This value was corrected with the value of the respective control sample. The uncorrected value was 119%.

The control 15-2127-03-0014E (0.00800 mg/kg expressed as BYI 02960) was used for fortification for the following values:

- ^f This value was corrected with the value of the respective control sample. The uncorrected value was 124%.
- ^g This value was corrected with the value of the respective control sample. The uncorrected value was 128%.
- ^h This value was corrected with the value of the respective control sample. The uncorrected value was 131%.

The control 15-2127-01-0014E (0.00352 mg/kg expressed as BYI 02960) was used for fortification for the following value:

- ⁱ This value was corrected with the value of the respective control sample. The uncorrected value was 111%.

The control 15-2127-01-0030E (0.0167mg/kg expressed as BYI 02960) was used for fortification for the following value:

- ^j This value was corrected with the value of the respective control sample. The uncorrected value was 117%.
- ^k This value was corrected with the value of the respective control sample. The uncorrected value was 116%.
- ^l This value was corrected with the value of the respective control sample. The uncorrected value was 118%.
- ^m This value was corrected with the value of the respective control sample. The uncorrected value was 121%.
- ⁿ This value was corrected with the value of the respective control sample. The uncorrected value was 124%.

The control 15-2127-04-0030E (0.0172 mg/kg expressed as BYI 02960) was used for fortification for the following value:

- ^o This value was corrected with the value of the respective control sample. The uncorrected value was 141%.

Table A 31: Residue trials on wheat

GAP Summary of the 15-2127 trials

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL			
(a)	(b)	(b)				(c)	(d)	(f)
15-2127-01 15-2127-01-T Italy 76123 Andria Europe, South F 2015	Wheat Saragolla; Durum wheat	1) 22.01.2015 2) 05.05.2015 - 15.05.2015 3) 20.06.2015 - 10.07.2015	75 75	300 300	25.0 25.0	08.05.2015/0 23.05.2015/15	73	(g) 15-2127 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
15-2127-02 15-2127-02-T Italy 95100 C.da Reitana; Catania (CT) Europe, South F 2015	Wheat Mongibello	1) 15.01.2015 2) 30.04.2015 - 15.05.2015 3) 01.06.2015 - 20.06.2015	75 75	400 400	18.75 18.75	21.04.2015/0 05.05.2015/14	69	(g) 15-2127 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
15-2127-03 15-2127-03-T Spain 08520 Llerona - Les Franqueses del Valles Europe, South F 2015	Wheat Moncada	1) 15.11.2014 2) 28.04.2015 - 10.05.2015 3) 15.06.2015 - 30.06.2015	75 75	400 400	18.75 18.75	05.05.2015/0 18.05.2015/13	83	(g) 15-2127 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
15-2127-04 15-2127-04-T Portugal 2005-024 Santarem Europe, South F 2015	Wheat Jordão; Winter variety	1) 16.12.2014 2) 01.05.2015 - 11.05.2015 3) 15.06.2015 - 15.07.2015	75 75	300 300	25.0 25.0	18.05.2015/0 01.06.2015/14	75	(g) 15-2127 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying

Analyte 1: BYI 02960 (determined as BYI 02960, calculated as BYI 02960), Analyte 2: DFA (determined as DFA, calculated as BYI 02960), Analyte 3 (calculated value): sum of BYI 02960 and DFA (calculated as BYI 02960), Analyte 4: DFA (determined as DFA, calculated as DFA)

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
(a)			(d)					(e)	(f)
15-2127-01 15-2127-01-T Italy 76123 Andria Europe, South F 2015	Wheat Saragolla; Durum wheat	whole	73	0.28	0.057	0.34	0.019	0*	(g) 15-2127
		plant	73	2.1	0.059	2.2	0.020	0	(j) Analytical method: 01212
		without	75	0.67	0.077	0.75	0.026	7	(k) LOQ:
		root	77	0.77	0.094	0.86	0.031	14	Analyte 1 whole plant without roots, grain: 0.01 mg/kg
									Analyte 1,2 straw: 0.05 mg/kg
		grain	87	<0.01	0.19	0.20	0.064	21	Analyte 2 whole plant without roots, grain: 0.02 mg/kg
			89	<u><0.01</u>	0.20	0.21	0.068	<u>30</u>	Analyte 3 straw: 0.1 mg/kg
			89	<0.01	0.21	<u>0.22</u>	<u>0.070</u>	<u>35</u>	Analyte 3 whole plant without roots, grain: 0.03 mg/kg
	straw	87	0.64	0.076	0.72	0.025	21	Analyte 4 straw: 0.017 mg/kg	
		89	<u>0.78</u>	0.096	<u>0.87</u>	<u>0.032</u>	<u>30</u>	Analyte 4 whole plant without roots, grain: 0.0067 mg/kg	
		89	0.22	0.050	0.27	0.017	<u>35</u>	(l) Method Validation Data: 01212, 15-2127	
								(m) Storage: Analyte 1, 2, 3 whole plant without roots: 194 days Analyte 1, 2, 3 straw: 265 days Analyte 1, 2, 3 grain: 179 days	

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
15-2127-02 15-2127-02-T Italy 95100 C.da Reitana; Catania (CT) Europe, South F 2015	Wheat Mongibello	whole plant without root	69	0.40	0.070	0.47	0.023	0*	(g) 15-2127 (j) Analytical method: 01212 (k) LOQ: Analyte 1 whole plant without roots, grain: 0.01 mg/kg Analyte 1,2 straw: 0.05 mg/kg Analyte 2 whole plant without roots, grain: 0.02 mg/kg Analyte 3 straw: 0.1 mg/kg Analyte 3 whole plant without roots, grain: 0.03 mg/kg Analyte 4 straw: 0.017 mg/kg Analyte 4 whole plant without roots, grain: 0.0067 mg/kg (l) Method Validation Data:01212, 15-2127 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 212 days Analyte 1, 2, 3 straw: 274 days Analyte 1, 2, 3 grain: 188 days
			69	2.0	0.069	2.1	0.023	0	
			71	0.82	0.14	0.95	0.045	7	
			75	0.95	0.19	1.1	0.062	14	
			85	0.67	0.22	0.89	0.072	21	
		grain	87	<0.01	0.48	0.49	0.16	30	
			89	<0.01	0.52	0.53	0.17	35	
		straw	87	2.1	0.24	2.3	0.081	30	
			89	2.4	0.27	2.7	0.089	35	
15-2127-03 15-2127-03-T Spain 08520 Llerona - Les Franqueses del Valles Europe, South F 2015	Wheat Moncada	whole plant without root	83	0.94	0.21	1.2	0.070	0*	(g) 15-2127 (j) Analytical method: 01212 (k) LOQ: Analyte 1 whole plant without roots, grain: 0.01 mg/kg Analyte 1,2 straw: 0.05 mg/kg Analyte 2 whole plant without roots, grain: 0.02 mg/kg Analyte 3 straw: 0.1 mg/kg Analyte 3 whole plant without roots, grain: 0.03 mg/kg Analyte 4 straw: 0.017 mg/kg Analyte 4 whole plant without roots, grain: 0.0067 mg/kg (l) Method Validation Data:01212, 15-2127 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 199 days Analyte 1, 2, 3 straw: 270 days Analyte 1, 2, 3 grain: 184 days
			83	3.3	0.23	3.5	0.075	0	
			83	0.96	0.22	1.2	0.072	8	
			85	1.3	0.23	1.6	0.078	14	
		grain	87	<0.01	0.33	0.34	0.11	21	
			89	<0.01	0.29	0.30	0.098	29	
		straw	89	<0.01	0.28	0.29	0.095	35	
			87	2.5	0.38	2.9	0.13	21	
			89	1.5	0.15	1.6	0.050	29	
			89	1.5	0.21	1.7	0.070	35	

15-2127-04	Wheat	whole	75	0.62	0.13	0.75	0.044	0*	(g) 15-2127
15-2127-04-T	Jordão;	plant	75	1.7	0.12	1.8	0.039	0	(j) Analytical method: 01212
Portugal	Winter	without	83	1.7	0.20	1.8	0.065	7	(k) LOQ:
2005-024	variety	root	85	1.5	0.20	1.7	0.068	14	Analyte 1 whole plant without roots, grain: 0.01 mg/kg
Santarem		grain	87	0.020	0.41	0.43	0.14	21	Analyte 1,2 straw: 0.05 mg/kg
Europe, South			89	0.020	0.41	0.44	0.14	30	Analyte 2 whole plant without roots, grain: 0.02 mg/kg
F			89	0.028	0.42	0.45	0.14	35	Analyte 3 straw: 0.1 mg/kg
2015		straw	87	3.5	0.21	3.7	0.071	21	Analyte 3 whole plant without roots, grain: 0.03 mg/kg
			89	3.5	0.23	3.8	0.075	30	Analyte 4 straw: 0.017 mg/kg
			89	3.3	0.24	3.5	0.080	35	Analyte 4 whole plant without roots, grain: 0.0067 mg/kg

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.1.3.4.4 Study report 16-2032 (for information only)

Comments of zRMS:	This study has not been evaluated by zRMS-PL because it was conducted in southern Europe.
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Reference:	KCA 6.3.4.1/04
Title:	Determination of the residues of BYI 02960 and deltamethrin in/on wheat after spray application of deltamethrin & flupyradifurone EC 085 in southern France, Italy and Spain
Report:	Kaussmann, M.; Kerkerling, S.; 2018; 16-2032; M-633925-01-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP 860.1500, Crop Field Trial
Deviations:	None
GLP/GEP:	yes
Acceptability:	-
Duplication (if vertebrate study):	

Validity of the study:

Materials and methods

In 2016, 4 field trials were conducted in southern Europe (southern France, Italy [2] and Spain) to support the use of Sivanto Energy EC 085 in wheat. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960). Two applications were made at an interval of 14 days, each at a rate of 1.0 L/ha, corresponding to 75.0 g BYI 02960/ha. For trial 16-2032-03 the interval between the two applications was prolonged (19 days instead of 14 days) due to bad weather conditions (heavy rain); nevertheless, the planned sampling (at day -0, 0, 30 and 35) remained unchanged. The last application was done at a crop growth stage of BBCH 75-83 (BBCH 75: medium milk, grain content milky, grains reached final size, still green; BBCH 83: early dough stage). The envisaged PHI was 30 days.

Samples of whole plant without root were collected before and after the last treatment. Samples of mature grain and wheat straw were collected 28-30 and 34-36 days after the last treatment. All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 554 days). The maximum storage period of 554 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 52 months ([Netzband, D.; 2015; M-428412-03-1](#)).

The samples were analysed according to method 01304 ([Li, Y.; Schoening, R.; 2012; M-415504-02-1](#)). The LOQ in all sample matrices was 0.01 mg/kg for BYI 02960 and 0.02 mg/kg for DFA when expressed as BYI 02960 (corresponding to an LOQ of 0.0067 mg/kg, when expressed as DFA). The calculated LOQ for the total residue (sum of BYI 02960 and DFA, expressed as BYI 02960) was 0.03 mg/kg.

Residues of DFEAF and 6-CNA have been also determined during the study, but since they are not relevant to the residue definition for risk assessment, they are not reported here.

Results

During the course of this study, the method performance was checked/validated by concurrent recoveries. Full validation of method 01304 was done and documented for matrices representing the 5 major crop groups, including dry seeds of beans, cereal forage, orange fruit, soybean seeds, tomato fruit, and wheat grain when developing the method. For wheat grain, straw and whole plant without root a full set (1 control, ≥5 repetitions each at two fortification levels) of additional validation recoveries was done within this study. The average recoveries per fortification level and analyte were within the acceptable range of 70–110% and the RSD values were always below 20% ([Table A 32](#)).

Details of the application and residue information are summarized in [Table A 33](#). No residues of BYI 02960 or DFA at or above the limit of quantification of the method were found in any of the untreated samples.

Table A 32: Recovery data for flupyradifurone and its metabolite DFA in matrices of wheat

Study Trial No. Plot No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortification level * (mg/kg)	Recovery (%) Individual recoveries	Min	Max	Mean	RSD
16-2032 16-2032-01 16-2032-01-T 16-2032-02 16-2032-02-T 16-2032-03 16-2032-03-T 16-2032-04 16-2032-04-T GLP: yes 2016	Wheat	whole plant without roots	BYI 02960	6	0.01	95; 102; 103; 104; 106; 108	95	108	103	4.3
				6	0.1	96; 98; 98; 106; 106; 109	96	109	102	5.3
				1	4.5	95	95	95	95	
				13	overall		95	109	102	4.9
			DFA	6	0.02	92; 94; 96; 97; 102; 103	92	103	97	4.5
				6	0.2	86; 87; 88; 92; 93; 94	86	94	90	3.8
				1	9.0	70	70	70	70	
				13	overall		70	103	92	9.1
		grain	BYI 02960	6	0.01	96; 100; 101; 101; 104; 107	96	107	102	3.7
				6	0.1	95; 96; 96; 107; 108; 109	95	109	102	6.7
				1	1.0	97	97	97	97	
				13	overall		95	109	101	5.1
			DFA	6	0.02	90; 93; 93; 96; 100; 100	90	100	95	4.3
				6	0.2	81; 81; 81; 83; 84; 86	81	86	83	2.5
				1	2.0	87	87	87	87	
				13	overall		81	100	89	7.9
		straw	BYI 02960	6	0.01	94; 95; 96; 101; 101; 104	94	104	99	4.1
				6	0.1	89; 93; 94; 101; 107; 109	89	109	99	8.2
				1	1.0	95	95	95	95	
				13	overall		89	109	98	6.0
			DFA	6	0.02	94; 97; 100; 100; 103; 106	94	106	100	4.2
				6	0.2	89; 91; 91; 91; 92; 95	89	95	92	2.2
				1	2.0	96	96	96	96	
				13	overall		89	106	96	5.4

* expressed as BYI 02960

Table A 33: Residue trials on wheat

GAP Summary of the 16-2032 trials

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL			
(a)	(b)	(b)				(c)	(d)	(f)
16-2032-01 16-2032-01-T France, south 13103 St Etienne du Gres Europe, South F 2016	Wheat Arezzo	1) 17.11.2015 2) 09.05.2016 - 15.05.2016 3) 01.07.2016 - 10.07.2016	75 75	300 300	25.0 25.0	18.05.2016/0 01.06.2016/14	77	(g) 16-2032 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
16-2032-02 16-2032-02-T Italy 94100 C.da San Benedetto; Enna (EN) Europe, South F 2016	Wheat Avvento	1) 28.12.2015 2) 21.04.2016 - 28.04.2016 3) 10.06.2016 - 25.06.2016	75 75	400 400	18.75 18.75	27.04.2016/0 11.05.2016/14	83	(g) 16-2032 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
16-2032-03 16-2032-03-T Spain 41610 Paradas Europe, South F 2016	Wheat Arthur Nick	1) 27.11.2015 2) 01.04.2016 - 10.04.2016 3) 01.06.2016 - 30.06.2016	75 75	300 300	25.0 25.0	25.04.2016/0 14.05.2016/19	83	(g) 16-2032 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
16-2032-04 16-2032-04-T Italy 44042 Cento Ferrara Europe, South F 2016	Wheat Forblanc	1) 28.10.2015 2) 02.05.2016 - 11.05.2016 3) 13.06.2016 - 30.06.2016	75 75	400 400	18.75 18.75	03.05.2016/0 17.05.2016/14	75	(g) 16-2032 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying

Analytical part 16-2032

Analyte 1: BYI 02960 (determined as BYI 02960, calculated as BYI 02960), Analyte 2: DFA (determined as DFA, calculated as BYI 02960), Analyte 3 (calculated value): sum of BYI 02960 and DFA (calculated as BYI 02960), Analyte 4: DFA (determined as DFA, calculated as DFA)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
16-2032-01 16-2032-01-T France, south 13103 St Etienne du Gres Europe, South F 2016	Wheat Arezzo	whole plant without root grain straw	77 77 89 89 89 89	0.23 1.6 <u>0.014</u> 0.012 <u>0.71</u> 0.67	0.068 0.090 0.57 0.51 0.087 0.079	0.29 1.7 <u>0.58</u> 0.53 <u>0.80</u> 0.75	0.023 0.030 <u>0.19</u> 0.17 <u>0.029</u> 0.026	0* 0 28 35 28 35	(g) 16-2032 (j) Analytical method: whole plant without roots; straw; grain: 01304 (k) LOQ: Analyte 1 whole plant without roots, straw; grain: 0.01 mg/kg Analyte 2 whole plant without roots, straw; grain: 0.02 mg/kg Analyte 3 whole plant without roots, straw; grain: 0.03 mg/kg Analyte 4 whole plant without roots, straw; grain: 0.0067 mg/kg (l) Method Validation Data: 01304, 16-2032 (m) Storage: whole plant without roots: 533 days straw: 505 days grain: 505 days
16-2032-02 16-2032-02-T Italy 94100 C.da San Benedetto; Enna (EN) Europe, South F 2016	Wheat Avvento	whole plant without root grain straw	83 83 89 89 89 89	0.38 2.0 <u><0.01</u> <u><0.01</u> <u>0.11</u> 0.048	0.069 0.075 0.35 0.31 0.10 0.10	0.45 2.1 <u>0.36</u> 0.32 <u>0.21</u> 0.15	0.023 0.025 <u>0.12</u> 0.10 <u>0.033</u> 0.033	0* 0 30 36 30 36	(g) 16-2032 (j) Analytical method: whole plant without roots; straw; grain: 01304 (k) LOQ: Analyte 1 whole plant without roots, straw; grain: 0.01 mg/kg Analyte 2 whole plant without roots, straw; grain: 0.02 mg/kg Analyte 3 whole plant without roots, straw; grain: 0.03 mg/kg Analyte 4 whole plant without roots, straw; grain: 0.0067 mg/kg (l) Method Validation Data: 01304, 16-2032 (m) Storage: whole plant without roots: 554 days straw: 524 days grain: 524 days

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)		
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA				
16-2032-03 16-2032-03-T Spain 41610 Paradas Europe, South F 2016	Wheat Arthur Nick	whole plant without root	83	0.45	0.16	0.61	0.052	0* 0 28 34 28 34	(g) 16-2032 (j) Analytical method: whole plant without roots; straw; grain: 01304 (k) LOQ: Analyte 1 whole plant without roots, straw; grain: 0.01 mg/kg Analyte 2 whole plant without roots, straw; grain: 0.02 mg/kg Analyte 3 whole plant without roots, straw; grain: 0.03 mg/kg Analyte 4 whole plant without roots, straw; grain: 0.0067 mg/kg (l) Method Validation Data: 01304, 16-2032 (m) Storage: whole plant without roots: 551 days straw: 523 days grain: 523 days		
			83	4.1	0.15	4.2	0.049				
		grain	89	<u>0.078</u>	0.25	<u>0.33</u>	<u>0.082</u>				
			89	0.040	0.24	0.28	0.080				
		straw	89	0.41	0.34	0.75	<u>0.11</u>				
			89	<u>0.44</u>	0.34	<u>0.78</u>	0.11				
		16-2032-04 16-2032-04-T Italy 44042 Cento Ferrara Europe, South F 2016	Wheat Forblanc	whole plant without root	75	0.18	0.10			0.28	0.034
					75	1.6	0.11			1.7	0.038
grain	89			<u><0.01</u>	0.69	0.70	0.23				
	89			<u><0.01</u>	0.73	<u>0.74</u>	<u>0.24</u>				
straw	89			<u>0.066</u>	0.099	<u>0.17</u>	<u>0.033</u>				
	89			<u>0.046</u>	0.079	0.12	0.026				

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control
(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.1.3.5 Maize/Corn

The critical GAPs (cGAP) for the proposed use of Sivanto Energy (DLT+FPF EC 85) in maize/corn (field/sweet) are summarized in [Table A 34](#).

Table A 34: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU	Currently there is no EU cGAP in place on maize/corn for flupyradifurone.				
Intended cGAP* (field corn) (number 118, 215, 262, 348, 367, 386)	1	56.25	-	BBCH 51-75	As per growth stage
Intended cGAP* (sweet corn) (number 121, 217, 265, 351, 370, 389)	1	56.25	-	BBCH 51-75	7

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

A 2.1.3.5.1 Study report 15-2134

Comments of zRMS:	<p>Four field residue trials were conducted in northern Europe in 2015 to determine the magnitude of the residues of deltamethrin and BYI 02960 (common name flupyradifurone) in/on maize/corn (green material, kernel (immature), kernel and rest of plant) after one spray application with Deltamethrin & Flupyradifurone EC 085, an EC formulation containing 10 g/L deltamethrin and 75 g/L BYI 02960 at a rate of 1.25 L/ha, corresponding to 93.75 g BYI 02960/ha and 12.5 g/ha of deltamethrin. The last application was done at a crop growth stage BBCH 75. The PHI for immature kernel samples was 7-8 days.</p> <p>Residues of BYI 02960 and difluoroacetic acid were determined by HPLC-MS/MS according to method 01212.</p> <p>The individual LOQs for BYI 02960 and difluoroacetic acid are 0.01 and 0.02 mg/kg, respectively in the sample materials green material, kernel (immature), kernel and rest of plant.</p> <p>The average recoveries per fortification level were within the range of 70 – 110%. The RSD values were below 20%.</p> <p>Residue results (mg/kg) for kernel: E (FPF): 4 x <0.01 E (DFA): 0.013; 0.016; 0.021; 0.026 RA (sum): 0.050; 0.057; 0.072; 0.088</p> <p>Residue results (mg/kg) for kernel, immature: E (FPF): 4 x <0.01 E (DFA): <0.007; 0.007; 0.009; 0.015 RA (sum): <0.03; 0.032; 0.038; 0.056</p> <p>The storage period of deep-frozen samples intended for the analysis of BYI 02960 and its metabolites in the treated samples ranged between 152 and 239 days.</p> <p>Residues of deltamethrin and its isomers AE 0035073 and AE F108569 were determined by HPLC-MS/MS according to method 00855/M004 with LOQ of 0.01 mg/kg for kernel for each compound and 0.05 mg/kg for green material and rest of plant for each compound. For deltamethrin and its two isomers average recoveries were at each fortification level within the acceptable range of 70 – 110% and the RSD values were below 20%.</p> <p>Residue results (mg/kg) in kernel: E (deltamethrin): 4 x <0.01</p>
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	RA (sum): 4 x <0.03 Residue results (mg/kg) in kernel, immature: E (deltamethrin): 4 x <0.01 RA (sum): 4 x <0.03 The storage period of deep-frozen samples intended for the analysis of deltamethrin and its isomers in the treated samples ranged between 132 and 218 days. The study is acceptable.
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Reference:	KCA 6.3.5.1/01
Title:	Amendment no. 1: Determination of the residues of BYI 02960 and deltamethrin in/on maize/corn after spray application of deltamethrin & flupyradifurone EC 085 in Germany, Belgium and the Netherlands
Report:	Schulte, G.; 2017; 15-2134; M-574350-02-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSP Guideline No. 860.1500 on Crop Field Trial
Deviations:	yes, see report
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Validity of the study:

Materials and methods

In 2015, 4 field trials were conducted in northern Europe (Germany [2], Belgium and the Netherlands) to support the use of Sivanto Energy EC 085 in field and sweet corn (kernels). Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960).

One application was made at a rate of 1.25 L/ha, corresponding to 93.75 g BYI 02960/ha. The application was done at a crop growth stage of BBCH 75 (BBCH 75: kernels in middle of cob yellowish-white (variety-dependent), content milky, about 40% dry matter).

Samples of green material were collected immediately after treatment and 7-8 and 17-24 days after application. Immature kernel samples were collected 7-8 days after the treatment in order to represent sweet corn. Mature samples (BBCH 89) of kernel and rest of plant were sampled on day 27-73. All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 239 days). The maximum storage period of 239 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 52 months ([Netzband, D.; 2015; M-428412-03-1](#)).

The samples were analysed according to method 01212 ([Rosati, D.; 2012; M-428017-01-1](#)) by LC-MS/MS using stable isotopically labelled internal standards. The LOQ in all sample matrices was 0.01 mg/kg for BYI 02960 and 0.02 mg/kg for DFA when expressed as BYI 02960 (corresponding to 0.0067 mg/kg when expressed as DFA). The calculated LOQ for the total residue (sum of BYI 02960 and DFA, expressed as BYI 02960) was 0.03 mg/kg.

Residues of DFEAF and 6-CNA have been also determined during the study, but since they are not relevant to the residue definition for risk assessment, they are not reported here.

Results

The method performance was validated by at least three concurrent recoveries at two fortification levels during the conduct of study 15-2133 which was analysed in parallel. During the course of the present study, the method performance was confirmed by concurrent recoveries. The apparent residues in the control

samples used for recoveries at LOQ level were below 30% of the LOQ except for difluoroacetic acid (15-2134-02-0022E with 38% of LOQ). The recoveries conducted with the affected control samples were corrected. In addition, recoveries at the LOQ level were corrected in those cases where the residues in the control samples were above 10% of the LOQ. Corrections done are indicated in the recovery tables below. The average recoveries per fortification level and analyte were within the acceptable range of 70–110%. The RSD values were always below 20% ([Table A 35](#)).

Details of the application and residue information are summarized in [Table A 36](#). Low amounts of DFA were detected in one untreated samples, however the level was below the limit of quantification of the method. Recoveries at the LOQ level were corrected in those cases where the residues in the control samples were above 10% of the LOQ.

Table A 35: Recovery data for flupyradifurone and its metabolite DFA in matrices of maize/corn

Study Trial No. Plot No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortification level * (mg/kg)	Individual recoveries	Recovery (%)			
							Min	Max	Mean	RSD
15-2134 15-2134-01 to 15-2134-04 GLP: yes 2015	Maize/Corn	green material	BYI 02960	1	0.01	102	102	102	102	2.2
				1	0.1	97	97	97	97	
				1	1.0	99	99	99	99	
				1	2.0	98	98	98	98	
				4	overall		97	102	99	
			DFA	1	0.02	106	106	106	106	7.4
				1	0.2	93	93	93	93	
				1	4.0	94	94	94	94	
				3	overall		93	106	98	
		kernel	BYI 02960	1	0.01	107	107	107	107	3.6
				1	0.1	101	101	101	101	
				1	2.0	108	108	108	108	
				3	overall		101	108	105	
			DFA	1	0.02	96 ^a	96	96	96	2.6
				1	0.2	93	93	93	93	
				1	4.0	98	98	98	98	
				3	overall		93	98	96	
		rest of plant	BYI 02960	1	0.01	92	92	92	92	3.4
				1	0.1	98	98	98	98	
				1	1.0	97	97	97	97	
				3	overall		92	98	96	
			DFA	1	0.02	79 ^b	79	79	79	10.9
				1	0.2	96 ^c	96	96	96	
				1	2.0	96	96	96	96	
				3	overall		79	96	90	

* expressed as BYI 02960

The sample material maize/corn (kernel, immature) is covered by sample material maize/corn (kernel).

The control 15-2134-02-0021E (0.00301 mg/kg expressed as BYI 02960) was used for fortification for the following values:

^a This value was corrected with the value of the respective control sample. The uncorrected value was 111%.

The control 15-2134-02-0022E (0.00767 mg/kg expressed as BYI 02960) was used for fortification for the following value:

^b This value was corrected with the value of the respective control sample. The uncorrected value was 118%.

^c This value was corrected with the value of the respective control sample. The uncorrected value was 100%.

Table A 36: Residue trials on maize/corn

GAP Summary of the 15-2134 trials

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL			
(a)	(b)	(b)				(c)	(d)	(f)
15-2134-01 15-2134-01-T Germany 49377 Vechta, OT Deindrup Europe, North F 2015	Maize / Corn, field Galbi CS Hybrid	1) 04.05.2015 2) 31.07.2015 - 14.08.2015 3) 15.10.2015 - 30.11.2015	93.75	400	23.4	31.08.2015/0	75	(g) 15-2134 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
15-2134-02 15-2134-02-T Germany 51399 Burscheid Europe, North F 2015	Maize / Corn, field LG30.222	1) 12.05.2015 2) 28.07.2015 - 05.08.2015 3) 30.09.2015 - 30.10.2015	93.75	300	31.3	19.08.2015/0	75	(g) 15-2134 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
15-2134-03 15-2134-03-T Belgium 6221 Saint- Amand Europe, North F 2015	Maize / Corn, field Tokala Classic	1) 12.05.2015 2) 23.07.2015 - 05.08.2015 3) 22.10.2015 - 10.11.2015	93.75	350	26.8	19.08.2015/0	75	(g) 15-2134 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
15-2134-04 15-2134-04-T Netherlands 1771 SC Wieringerwerf Europe, North F 2015	Maize / Corn, field Ricardinio	1) 20.05.2015 2) 01.07.2015 - 01.08.2015 3) 01.10.2015 - 01.11.2015	93.75	600	15.6	11.09.2015/0	75	(g) 15-2134 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying

Analytical part 15-2134

Analyte 1: BYI 02960 (determined as BYI 02960, calculated as BYI 02960), Analyte 2: DFA (determined as DFA, calculated as BYI 02960), Analyte 3 (calculated value): sum of BYI 02960 and DFA (calculated as BYI 02960), Analyte 4: DFA (determined as DFA, calculated as DFA)

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
15-2134-01 15-2134-01-T Germany 49377 Vechta, OT Deindrup Europe, North F 2015	Maize / Corn, field Galbi CS Hybrid	green material	75 79 85	0.56 0.23 0.20	<0.02 0.023 0.037	0.58 0.25 0.24	<0.0067 0.0077 0.012	0 8 24	(g) 15-2134 (j) Analytical method: 01212 (k) LOQ:
		kernel, immature	79	<0.01	0.046	0.056	0.015	8	Analyte 1 kernel, immature, green material, kernel, rest of plant: 0.01 mg/kg
		kernel	89	<0.01	0.078	0.088	0.026	73	Analyte 2 kernel, immature, green material, kernel, rest of plant: 0.02 mg/kg
		rest of plant	89	0.059	0.045	0.10	0.015	73	Analyte 3 kernel, immature, green material, kernel, rest of plant: 0.03 mg/kg
									Analyte 4 kernel, immature, green material, kernel, rest of plant: 0.0067 mg/kg
									(l) Method Validation Data: 01212, 15-2133
(m) Storage: Analyte 1, 2, 3 rest of plant: 154 days Analyte 1, 2, 3 kernel, immature: 217 days Analyte 1, 2, 3 kernel: 152 days Analyte 1, 2, 3 green material: 226 days									
DFA as DFA: Values were taken from the raw data.									

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
	(a)		(d)					(e)	(f)
15-2134-02	Maize / Corn, field LG30.222	green material	75	0.66	<0.02	0.68	<0.0067	0	(g) 15-2134
15-2134-02-T			79	0.37	0.023	0.39	0.0075	7	(j) Analytical method:01212
Germany			85	0.14	0.032	0.17	0.011	21	(k) LOQ:
51399 Burscheid		kernel, immature	79	<0.01	0.028	0.038	0.0094	7	Analyte 1 kernel, immature, green material, kernel, rest of plant: 0.01 mg/kg
Europe, North F			kernel	89	<0.01	0.062	0.072	0.021	42
2015		rest of plant	89	0.084	0.035	0.12	0.012	42	Analyte 3 kernel, immature, green material, kernel, rest of plant: 0.03 mg/kg Analyte 4 kernel, immature, green material, kernel, rest of plant: 0.0067 mg/kg (l) Method Validation Data: 01212, 15-2133 (m) Storage: Analyte 1, 2, 3 rest of plant: 197 days Analyte 1, 2, 3 kernel, immature: 230 days Analyte 1, 2, 3 kernel: 195 days Analyte 1, 2, 3 green material: 238 days
									DFA as DFA: Values were taken from the raw data.

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
15-2134-03 15-2134-03-T Belgium 6221 Saint- Amand Europe, North F 2015	Maize / Corn, field Tokala Classic	green material	75	0.95	<0.02	0.97	<0.0067	0	(g) 15-2134 (j) Analytical method: 01212 (k) LOQ: Analyte 1 kernel, immature, green material, kernel, rest of plant: 0.01 mg/kg Analyte 2 kernel, immature, green material, kernel, rest of plant: 0.02 mg/kg Analyte 3 kernel, immature, green material, kernel, rest of plant: 0.03 mg/kg Analyte 4 kernel, immature, green material, kernel, rest of plant: 0.0067 mg/kg (l) Method Validation Data: 01212, 15-2133 (m) Storage: Analyte 1, 2, 3 rest of plant: 175 days Analyte 1, 2, 3 kernel, immature: 230 days Analyte 1, 2, 3 kernel: 173 days Analyte 1, 2, 3 green material: 239 days DFA as DFA: Values were taken from the raw data.
			79	0.35	<0.02	0.37	<0.0067	7	
			85	0.20	0.024	0.22	0.0080	23	
		kernel, immature	79	<0.01	0.022	0.032	0.0074	7	
		kernel	89	<0.01	0.047	0.057	0.016	64	
		rest of plant	89	0.057	0.021	0.077	0.0069	64	
15-2134-04 15-2134-04-T Netherlands 1771 SC Wieringerwerf Europe, North F 2015	Maize / Corn, field Ricardinio	green material	75	1.2	<0.02	1.2	<0.0067	0	(g) 15-2134 (j) Analytical method: 01212 (k) LOQ: Analyte 1 kernel, immature, green material, kernel, rest of plant: 0.01 mg/kg Analyte 2 kernel, immature, green material, kernel, rest of plant: 0.02 mg/kg Analyte 3 kernel, immature, green material, kernel, rest of plant: 0.03 mg/kg Analyte 4 kernel, immature, green material, kernel, rest of plant: 0.0067 mg/kg (l) Method Validation Data: 01212, 15-2133 (m) Storage: Analyte 1, 2, 3 rest of plant: 189 days Analyte 1, 2, 3 kernel, immature: 207 days Analyte 1, 2, 3 kernel: 187 days Analyte 1, 2, 3 green material: 216 days DFA as DFA: Values were taken from the raw data.
			79	0.54	<0.02	0.56	<0.0067	7	
			85	0.44	<0.02	0.46	<0.0067	17	
		kernel, immature	79	<0.01	<0.02	<0.03	<0.0067	7	
		kernel	89	<0.01	0.040	0.050	0.013	27	
		rest of plant	89	0.39	<0.02	0.41	<0.0067	27	

(a) According to CODEX Classification / Guide
(b) Only if relevant

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and

(h) Formulation type
(i) Application method
(l) Method validation
(m) Storage (max)

(c)	Year must be indicated				(j)	Method information		! based on date of analysis
(d)	Either growth stage description or BBCH Code	(g)	information which metabolites are included		(k)	LOQ		P based on production date
G	greenhouse F field	*	Study reference prior to last treatment		**	residue in control	#	no data available

A 2.1.3.5.2 Study report 16-2192

Comments of zRMS:	<p>Four field residue trials were conducted in northern Europe in 2016 to determine the magnitude of the residues of deltamethrin and BYI 02960 (common name flupyradifurone) in/on maize/corn (green material, kernel (immature), kernel and rest of plant) after one spray application with Deltamethrin & Flupyradifurone EC 085, an EC formulation containing 10 g/L deltamethrin and 75 g/L BYI 02960 at a rate of 1.25 L/ha, corresponding to 93.75 g BYI 02960/ha and 12.5 g/ha of deltamethrin. The last application was done at a crop growth stage BBCH 75. The PHI for immature kernel samples was 7 days.</p> <p>Residues of BYI 02960 and difluoroacetic acid were determined by HPLC-MS/MS according to method 01304.</p> <p>The individual LOQs for BYI 02960 and difluoroacetic acid are 0.01 and 0.02 mg/kg, respectively in the sample materials green material, kernel (immature), kernel and rest of plant.</p> <p>The average recoveries per fortification level were within the range of 70 – 110%. The RSD values were below 20%.</p> <p>Residue results (mg/kg) for kernel: E (FPF): 4 x <0.01 E (DFA): 2x <0.007; 0.008; 0.018; RA (sum): 2 x <0.03; 0.035; 0.064;</p> <p>Residue results (mg/kg) for kernel, immature: E (FPF): 4 x <0.01 E (DFA): 3 x <0.007; 0.009; RA (sum): 3 x <0.03; 0.038.</p> <p>The storage period of deep-frozen samples intended for the analysis of BYI 02960 and its metabolites in the treated samples ranged between 141 and 246 days.</p> <p>Residues of deltamethrin and its isomers AE 0035073 and AE F108569 were determined by HPLC-MS/MS according to method 00855/M004.</p> <p>The individual LOQs for deltamethrin and its isomers are 0.05 mg/kg in green material and rest of plant and 0.01 mg/kg in mature and immature kernel.</p> <p>For deltamethrin and its two isomers average recoveries were at each fortification level within the acceptable range of 70 – 110% and the RSD values were below 20%.</p> <p>Residue results (mg/kg) in kernel: E (deltamethrin): 4 x <0.01 RA (sum): 4 x <0.03</p> <p>Residue results (mg/kg) in kernel, immature: E (deltamethrin): 4 x <0.01 RA (sum): 4 x <0.03</p> <p>The storage period of deep-frozen samples intended for the analysis of deltamethrin and its isomers in the treated samples ranged between 260 and 345 days.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.5.1/02
Title:	Determination of the residues of BYI 02960 and deltamethrin in/on maize/corn after spray application of deltamethrin & flupyradifurone EC 085 in Germany, Belgium and the Netherlands
Report:	Schulte, G.; Kerkerling, S.; 2018; 16-2192; M-628803-01-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP 860.1500, Crop Field Trial
Deviations:	None
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Validity of the study:

Materials and methods

In 2016, 4 field trials were conducted in northern Europe (Germany [2], Belgium and the Netherlands) to support the use of Sivanto Energy EC 085 in field and sweet corn (kernels). Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960).

One application was made at a rate of 1.25 L/ha, corresponding to 93.75 g BYI 02960/ha. In deviation the application rate in trial 16-2192-03 was underdosed by 6.4%, resulting in an actual rate of 1.17 L/ha, corresponding to 87.75 g BYI 02960/ha. As this deviation is less than 25% and well within the European acceptance criteria for use pattern equality, the trial is considered valid. The application was done at a crop growth stage of BBCH 75 (BBCH 75: kernels in middle of cob yellowish-white (variety-dependent), content milky, about 40% dry matter).

Samples of green material were collected immediately after the treatment and 7 and 17-29 days (BBCH 85) after application. Immature kernel samples were collected 7 days after the treatment in order to represent sweet corn. Mature samples (BBCH 89) of kernel and rest of plant were sampled on day 28-61. All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 246 days). The maximum storage period of 246 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 52 months ([Netzband, D.; 2015; M-428412-03-1](#)).

The samples were analysed according to method 01304 ([Li, Y.; Schoening, R.; 2012; M-415504-02-1](#)). The LOQ in all sample matrices was 0.01 mg/kg for BYI 02960 and 0.02 mg/kg for DFA when expressed as BYI 02960 (corresponding to an LOQ of 0.0067 mg/kg, when expressed as DFA). The calculated LOQ for the total residue (sum of BYI 02960 and DFA, expressed as BYI 02960) was 0.03 mg/kg.

Residues of DFEAF and 6-CNA have been also determined during the study, but since they are not relevant to the residue definition for risk assessment, they are not reported here.

Results

During the course of this study, the method performance was checked/validated by concurrent recoveries. Full validation of method 01304 was done and documented for matrices representing the 5 major crop groups, including dry seeds of beans, cereal forage, orange fruit, soybean seeds, tomato fruit, and wheat grain when developing the method. For maize kernel and maize stover (rest of plant) a limited set (1 control, ≥3 repetitions each at two fortification levels) of additional validation recoveries was done within this study. Due to the similarity of the plant matrices, the validation results for kernel are considered to be representative for kernel, immature. The average recoveries per fortification level and analyte were within the acceptable range of 70 – 110% and the RSD values were always below 20%. ([Table A 37](#)).

Details of the application and residue information are summarized in [Table A 38](#). No residues of BYI 02960

or DFA at or above the limit of quantification of the method were found in any of the untreated samples.

Table A 37: Recovery data for flupyradifurone and its metabolite DFA in matrices of maize/corn

Study Trial No. Plot No. GLP Year	Crop	Portion analysed	a.s./ metabolite	n	Fortifica tion level * (mg/kg)	Recovery (%) Individual recoveries	Min	Max	Mean	RSD
16-2192 16-2192-01 to 16-2192-04 GLP: yes 2016	Maize/ Corn	kernel, immature	BYI 02960	1	0.01	103	103	103	103	
				1	0.1	104	104	104	104	
				2	overall		103	104	104	
			DFA	1	0.02	91	91	91	91	
				1	0.2	84	84	84	84	
				2	overall		84	91	88	
		green material	BYI 02960	3	0.01	106; 106; 109	106	109	107	1.6
				3	0.1	101; 105; 106	101	106	104	2.5
				1	2.0	87	87	87	87	
				7	overall		87	109	103	7.2
			DFA	3	0.02	85; 88; 88	85	88	87	2
				3	0.2	86; 87; 90	86	90	88	2.4
				1	4.0	83	83	83	83	
				7	overall		83	90	87	2.6
		kernel	BYI 02960	3	0.01	100; 101; 105	100	105	102	2.6
				3	0.1	104; 104; 105	104	105	104	0.6
				6	overall		100	105	103	2.1
			DFA	3	0.02	93; 95; 98	93	98	95	2.6
				3	0.2	78; 80; 84	78	84	81	3.8
				6	overall		78	98	88	9.6
		rest of plant	BYI 02960	4	0.01	98; 102; 103; 104	98	104	102	2.6
				3	0.1	100; 105; 105	100	105	103	2.8
				1	1.0	95	95	95	95	
				8	overall		95	105	102	3.5
			DFA	4	0.02	99; 101; 102; 105	99	105	102	2.5
				3	0.2	89; 91; 92	89	92	91	1.7
				7	overall		89	105	97	6.4

* expressed as BYI 02960

Table A 38: Residue trials on maize/corn

GAP Summary of the 16-2192 trials

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment / Application interval	Growth stage at last treatment	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL			
(a)	(b)	(b)				(c)	(d)	(f)
16-2192-01 16-2192-01-T Germany 49377 Vechta, OT Langförden Europe, North F 2016	Maize/Corn Amball	1) 07.05.2016 2) 20.07.2016 - 10.08.2016 3) 15.10.2016 - 30.11.2016	93.75	400	23.4	25.08.2016/0	75	(g) 16-2192 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
16-2192-02 16-2192-02-T Germany 51399 Burscheid Europe, North F 2016	Maize/Corn LG 30222	1) 09.05.2016 2) 25.07.2016 - 03.08.2016 3) 01.10.2016 - 31.10.2016	93.75	600	15.6	23.08.2016/0	75	(g) 16-2192 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
16-2192-03 16-2192-03-T Belgium 6211 Mellet Europe, North F 2016	Maize/Corn Avalon	1) 27.05.2016 2) 12.08.2016 - 28.08.2016 3) 15.11.2016	87.75	467	18.8	15.09.2016/0	75	(g) 16-2192 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying
16-2192-04 16-2192-04-T Netherlands 1771 SC Wieringerwerf Europe, North F 2016	Maize/Corn LG 30.224	1) 21.04.2016 2) 20.07.2016 - 10.08.2016 3) 24.09.2016 - 15.10.2016	93.75	600	15.6	31.08.2016/0	75	(g) 16-2192 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying

Analytical part 16-2192

Analyte 1: BYI 02960 (determined as BYI 02960, calculated as BYI 02960), Analyte 2: DFA (determined as DFA, calculated as BYI 02960), Analyte 3 (calculated value): sum of BYI 02960 and DFA (calculated as BYI 02960), Analyte 4: DFA (determined as DFA, calculated as DFA)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
16-2192-01 16-2192-01-T Germany 49377 Vechta, OT Langförden Europe, North F 2016	Maize/Corn Amball	green material	75	0.85	<0.02	0.87	<0.0067	0	(g) 16-2192 (j) Analytical method: rest of plant, kernel, immature, kernel, green material: 01304 (k) LOQ: Analyte 1 rest of plant, kernel, immature, kernel, green material: 0.01 mg/kg Analyte 2 rest of plant, kernel, immature, kernel, green material: 0.02 mg/kg Analyte 3 rest of plant, kernel, immature, kernel, green material: 0.03 mg/kg Analyte 4 rest of plant, kernel, immature, kernel, green material: 0.0067 mg/kg (l) Method Validation Data 01304, 16-2192 (m) Storage: Analyte 1, 2, 3 rest of plant: 186 days Analyte 1, 2, 3 kernel, immature: 224 days Analyte 1, 2, 3 kernel: 163 days Analyte 1, 2, 3 green material: 224 days
			79	0.95	<0.02	0.97	<0.0067	7	
			85	0.93	0.032	0.96	0.011	29	
		kernel, immature	79	<u><0.01</u>	<0.02	<u><0.03</u>	<u><0.0067</u>	7	
			89	<u><0.01</u>	0.025	<u>0.035</u>	<u>0.0083</u>	60	
		rest of plant	89	<u>0.53</u>	0.023	<u>0.55</u>	<u>0.0077</u>	60	

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA		
16-2192-02 16-2192-02-T Germany 51399 Burscheid Europe, North F 2016	Maize/Corn LG 30222	green material	75	0.99	<0.02	1.0	<0.0067	0	(g) 16-2192 (j) Analytical method: rest of plant, kernel, immature, kernel, green material: 01304 (k) LOQ: Analyte 1 rest of plant, kernel, immature, kernel, green material: 0.01 mg/kg Analyte 2 rest of plant, kernel, immature, kernel, green material: 0.02 mg/kg Analyte 3 rest of plant, kernel, immature, kernel, green material: 0.03 mg/kg Analyte 4 rest of plant, kernel, immature, kernel, green material: 0.0067 mg/kg (l) Method Validation Data 01304, 16-2192 (m) Storage: Analyte 1, 2, 3 rest of plant: 205 days Analyte 1, 2, 3 kernel, immature: 226 days Analyte 1, 2, 3 kernel: 182 days Analyte 1, 2, 3 green material: 246 days
			79	0.30	<0.02	0.32	<0.0067	7	
			85	0.24	0.032	0.27	0.011	17	
		kernel, immature	79	<0.01	0.028	0.038	0.0093	7	
		kernel	89	<0.01	0.054	0.064	0.018	43	
		rest of plant	89	0.36	0.028	0.38	0.0093	43	
16-2192-03 16-2192-03-T Belgium 6211 Mellet Europe, North F 2016	Maize/Corn Avalon	green material	75	1.0	<0.02	1.0	<0.0067	0	(g) 16-2192 (j) Analytical method: rest of plant, kernel, immature, kernel, green material: 01304 (k) LOQ: Analyte 1 rest of plant, kernel, immature, kernel, green material: 0.01 mg/kg Analyte 2 rest of plant, kernel, immature, kernel, green material: 0.02 mg/kg Analyte 3 rest of plant, kernel, immature, kernel, green material: 0.03 mg/kg Analyte 4 rest of plant, kernel, immature, kernel, green material: 0.0067 mg/kg (l) Method Validation Data 01304, 16-2192 (m) Storage: Analyte 1, 2, 3 rest of plant: 164 days Analyte 1, 2, 3 kernel, immature: 203 days Analyte 1, 2, 3 kernel: 141 days Analyte 1, 2, 3 green material: 203 days
			79	0.18	<0.02	0.20	<0.0067	7	
			85	0.17	<0.02	0.19	<0.0067	18	
		kernel, immature	79	<0.01	<0.02	<0.03	<0.0067	7	
		kernel	89	<0.01	<0.02	<0.03	<0.0067	61	
		rest of plant	89	0.16	<0.02	0.18	<0.0067	61	

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)				PHI (days)	Details on trial		
				Analyte 1 BYI 02960 as BYI 02960	Analyte 2 DFA as BYI 02960	Analyte 3 sum of BYI 02960 and DFA as BYI 02960	Analyte 4 DFA as DFA			(e)	(f)
16-2192-04 16-2192-04-T Netherlands 1771 SC Wieringerwerf Europe, North F 2016	Maize/Corn LG 30.224	green material	75	1.2	<0.02	1.3	<0.0067	0	(g) 16-2192		
			79	0.42	<0.02	0.44	<0.0067	7	(j) Analytical method:		
			85	0.42	<0.02	0.44	<0.0067	19	rest of plant, kernel, immature, kernel, green material: 01304		
		kernel, immature	79	<0.01	<0.02	<0.03	<0.0067	7	(k) LOQ: Analyte 1 rest of plant, kernel, immature, kernel, green material: 0.01 mg/kg		
			kernel	89	<0.01	<0.02	<0.03	<0.0067	28	Analyte 2 rest of plant, kernel, immature, kernel, green material: 0.02 mg/kg	
		rest of plant		89	0.75	0.022	0.77	0.0073	28	Analyte 3 rest of plant, kernel, immature, kernel, green material: 0.03 mg/kg	
			Analyte 4 rest of plant, kernel, immature, kernel, green material: 0.0067 mg/kg								
			(l) Method Validation Data 01304, 16-2192								
		(m) Storage: Analyte 1, 2, 3 rest of plant: 218 days Analyte 1, 2, 3 kernel, immature: 218 days Analyte 1, 2, 3 kernel: 189 days Analyte 1, 2, 3 green material: 218 days									
(a)	According to CODEX Classification / Guide			(e)	Days after last application (Label pre-harvest interval, PHI, underline)			(h)	Formulation type	(l)	Method validation
(b)	Only if relevant			(f)	Remarks may include: Climatic conditions; Reference to analytical method and			(i)	Application method	(m)	Storage (max)
(c)	Year must be indicated				information which metabolites are included			(j)	Method information		! based on date of analysis
(d)	Either growth stage description or BBCH Code			(g)	Study reference			(k)	LOQ		P based on production date
G	greenhouse			*	prior to last treatment			**	residue in control	#	no data available
	F field										

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No additional studies are required.

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 additional studies are submitted.

A 2.1.5.2 Processing studies on a core set of representative processes

No additional studies are required.

A 2.1.6 Magnitude of residues in representative succeeding crops

No additional studies are required.

A 2.1.7 Other/Special Studies

No additional studies are submitted.

A 2.2 Deltamethrin

A 2.2.1 Stability of residues

A 2.2.1.1 Stability of residues during storage of samples

A 2.2.1.1.1 Storage stability of residues in plant products

The stability of deltamethrin-related residues during freezer storage up to 24 months in orange fruit is summarized in the study below.

Within some residue studies on oilseed rape the temperatures during storage increased. Therefore, two storage stability studies at exaggerated temperatures were performed and summarized within this submission.

A 2.2.1.1.1.1 Study report 09-07

Comments of zRMS:	<p>The study of Ballesteros, C.; (2012; 09-07; M-441996-01-1) has been evaluated in Registration Report for 102000028562 / DLT+FPF EC 85 in February 2022 by zRMS- PL and the summary is presented below:</p> <p><i>The study was conducted to evaluate the stability of deltamethrin and its isomers (AE F108569 and AE 0035073) in frozen condition ($\leq -18^{\circ}\text{C}$) for a period of 24 months in orange (fruit). Individual aliquots of orange (fruit) were fortified with deltamethrin, AE F108569, AE 0035073 at 0.20 mg/kg. The samples stored in HDPE Nalgene containers at an average temperature of -18°C or below, were analyzed at the nominal storage intervals of 0, 6, 12, 18 and 25 months.</i></p> <p><i>Residues of deltamethrin and its isomers AE F108569 and AE 0035073 were determined by HPLC-MS/MS according to method 00855/M004.</i></p> <p><i>The limits of quantitation (LOQ) for deltamethrin and its isomers (AE F108569 and AE 0035073) are 0.01 mg/kg, for the sample material tested, corresponding to the lowest fortification level of successfully conducted recovery experiments.</i></p> <p><i>For deltamethrin, AE F108569, AE 0035073 all the recovery means were within the acceptable range of 70-110% with corresponding RSD (relative standard deviation) < 20%. All method validation data are in compliance with the guideline requirements for data collection methods.</i></p> <p><i>Deltamethrin and its isomers (AE F108569 and AE 0035073) were shown to be stable in orange (fruit) for at least 25 months (751 days) under freezer conditions at about -18°C or below, after correction of the results by the mean of concurrent recoveries.</i></p> <p><i>The study is acceptable.</i></p>
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Reference:	KCA 6.1/02
Title:	Storage stability of residues of deltamethrin (AE F032640) and its isomers AE F108569 and AE 0035073 in orange during deep freeze storage for up to 24 months
Report:	Ballesteros, C.; 2012; 09-07; M-441996-01-1
Authority registration No:	
Guideline(s):	Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, No. 7032/VI/95 rev.5: Appendix H Storage Stability of Residues Samples, July, 1997; Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances; US EPA Residue Chemistry Test Guidelines, OPPTS 860.1380: Storage Stability Data, August 1996; OECD Guideline for the Testing of Chemicals No. 506, adopted 16 October 2007
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Materials and methods

The purpose of this study was to determine the storage stability of Deltamethrin, *alpha-R*-deltamethrin and *trans*-deltamethrin in orange stored 25 months in frozen conditions ($\leq -18^{\circ}\text{C}$).

Individual aliquots of orange (fruit) were fortified with Deltamethrin, *alpha-R*-deltamethrin and *trans*-deltamethrin at 0.20 mg/kg. The samples stored in plastic containers at an average temperature of -18°C or below, were analysed at the nominal storage intervals of 0, 6, 12, 18 and 25 months.

At each storage interval deltamethrin and its isomers were determined in the stored control samples and in the stored spiked samples according to the analytical method 00855/M004 ([Lakaschus, S.; Winter, O.; 2009; M-356934-01-1](#)). Concurrent recovery experiments at fortification levels of 0.01 mg/kg and 0.20 mg/kg were also performed for each analyte at each storage intervals. Samples were extracted with a mixture of acetone:dichloromethan:*n*-hexan (1:1:1, v:v:v) using a high speed blender. After the extraction step, the extract was evaporated to dryness and re-dissolved first with ethyl acetate. Then the obtained extract (Extract A) was directly diluted 20 times, adding the internal standard in a mixture of acetonitrile/10 mM aqueous ammonium acetate (9:1,v:v) in order to obtain the final extract. The residues are quantified by reversed phase HPLC with Electrospray and MS/MS-detection in a single run for the determination of all of the three analytes. The quantification was carried out by internal standardization using internal stable labelled standard for each corresponding analyte. Validation recoveries on orange fruit were conducted in the study. Concurrent recoveries were conducted at 0.01 mg/kg (except at storage interval 0 days) and 0.20 mg/kg at each analytical point.

Results and discussions

As required, in this summary only uncorrected recovery values will be discussed. The recovery values of the concurrent recovery rates per compound, storage interval and fortification level of 0.2 mg/kg were in the range of 90-100%. In case of fortification level of 0.01 mg/kg these recoveries ranged between 74-122% (except for Day-0 for which procedural recoveries were not measured).

At day 0, individual recoveries of Deltamethrin ranged between 107-113% (with an average recovery of 110%), between 103-109%, for *alpha-R*-deltamethrin (with an average recovery of 106%), and between 112-115% for *trans*-deltamethrin (with an average recovery of 114%)

Details of recovery data in orange fruit are shown in the table below.

Over the whole period of storage (25 months), the average recoveries of Deltamethrin ranged between 87-110%, whereas the average concurrent recoveries (for the same fortification level of 0.2 mg/kg) ranged between 92-100%.

Over the whole period of storage (25 months), the average recoveries of *alpha-R*-deltamethrin ranged between 77-106%, whereas the average concurrent recoveries (for the same fortification level of 0.2 mg/kg) ranged between 92-98%.

The average recoveries of *trans*-deltamethrin during the whole storage period of orange fruit ranged between 81-114%, whereas the average concurrent recoveries of *trans*-deltamethrin (for the same fortification level of 0.2 mg/kg) ranged between 90-97%.

The average recovery results after 25 months of storage of fortified samples were 91% for Deltamethrin, 78% for *alpha-R*-deltamethrin, and 97% for *trans*-deltamethrin.

Table A 39: Summary of concurrent recoveries of deltamethrin residues in plant matrices

Matrix	Spike level (mg/kg)	Storage Interval (months)	Sample size (n)	Individual procedural recoveries (%)	Mean \pm RSD (%)
<i>cis</i> -deltamethrin					
Orange fruit	0.01	6	1	91	-
		12	1	100	-
		18	1	106	-
		25	1	87	-

Matrix	Spike level (mg/kg)	Storage Interval (months)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD (%)
	0.2	0	3	101; 99; 100	100±1.0
		6	3	95; 96; 86	92 ±6.0
		12	5	96; 92; 94; 104; 103	98±5.5
		18	3	102; 94; 94	97±4.8
		25	3	85; 95; 99	93±7.8
alpha-R-deltamethrin					
Orange fruit	0.01	6	1	93	-
		12	1	100	-
		18	1	105	-
		25	1	84	-
	0.2	0	3	96; 99; 95	97±2.2
		6	3	95; 96; 87	93±5.3
		12	5	96; 93; 94; 104; 102	98±5.0
		18	3	101; 94; 94	96±4.2
		25	3	85; 94; 96	92±6.4
trans-deltamethrin					
Orange fruit	0.01	6	1	96	-
		12	1	122	-
		18	1	74	-
		25	1	86	-
	0.2	0	3	102; 100; 79	94±13.6
		6	3	95; 97; 86	93±6.3
		12	5	99; 94; 91; 105; 97	97±5.5
		18	3	103; 92; 92	96±6.6
		25	3	83; 93; 95	90±7.1

alpha-R-deltamethrin as AE F108569

trans-deltamethrin as AE 0035073

Table A 40: Stability of deltamethrin residues in plant matrices following storage at ≤ -18°C

Matrix	Spike level (mg/kg)	Storage interval (months)	Individual recovered residues (mg/kg)	Individual recoveries (%)
<i>cis-deltamethrin</i>				
Orange fruit	0.2	0	0.222; 0.226; 0.213	111; 113; 106
		6	0.173; 0.176; 0.169	86; 88; 84
		12	0.172; 0.191; 0.196	86; 95; 98
		18	0.194; 0.193; 0.186	97; 97; 93
		25	0.181; 0.188; 0.177	91; 94; 89
<i>alpha-R-deltamethrin</i>				
Orange fruit	0.2	0	0.206; 0.214; 0.218	103; 107; 109
		6	0.164; 0.168; 0.173	82; 84; 86
		12	0.146; 0.122; 0.161; 0.182; 0.141; 0.179	73; 61; 81; 91; 71; 89

Matrix	Spike level (mg/kg)	Storage interval (months)	Individual recovered residues (mg/kg)	Individual recoveries (%)
		18	0.155; 0.135; 0.169	77; 68; 85
		25	0.155; 0.141; 0.169	78; 71; 84
<i>trans-deltamethrin</i>				
Orange fruit	0.2	0	0.227; 0.230; 0.224	114; 115; 112
		6	0.161; 0.164; 0.165	80; 82; 82
		12	0.215; 0.212; 0.211; 0.228; 0.219; 0.213	108; 106; 106; 114; 110; 107
		18	0.177; 0.171; 0.178	88; 85; 89
		25	0.200; 0.178; 0.202	100; 89; 101

alpha-R-deltamethrin as AE F108569

trans-deltamethrin as AE 0035073

Conclusion

For the sample material orange (fruit), Deltamethrin, *alpha-R-deltamethrin* and *trans-deltamethrin* were shown to be stable for at least 25 months (751 days) under freezer conditions at about -18°C or below.

A 2.2.1.1.1.2 Study report S13-03307

Comments of zRMS:	<p>The study of Lakaschus, S.; Gizler, A.; (2017; S13-03307; M-480441-06-1) has been evaluated in Registration Report for 102000028562 / DLT+FPF EC 85 in February 2022 by zRMS- PL and the summary is presented below:</p> <p><i>According to the storage stability results it can be concluded that residues of deltamethrin and its isomers, alpha-R-deltamethrin and trans-deltamethrin, in the plant matrices of high water and high protein content were stable (<30% decomposition) after storage at + 1°C for 8 hours, following a storage of 6 days at -7°C.</i></p> <p><i>The study is acceptable.</i></p>
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Reference:	KCA 6.1/01
Title:	Amendment no. 3 to final report - 7 days freezer storage stability study with different combinations of a total of 61 analytes (parent and metabolite molecules) and five matrix types (high water / acidic / starch / protein / oil)
Report:	Lakaschus, S.; Gizler, A.; 2017; S13-03307; M-480441-06-1
Authority registration No:	
Guideline(s):	Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances US EPA Residue Chemistry Test Guideline OPPTS 860.1380: Storage Stability Data OECD Test Guideline 506, adopted 16 October 2007
Deviations:	see report
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Materials and methods

The purpose of this study was to determine the storage stability of relevant residues of deltamethrin for a period of 8 hours at +1°C followed by 6-8 days of storage at -7°C in tomato fruit, wheat green material (high water content) and dry peas (high protein content). Individual 5-g control samples of the respective sample material were spiked with the relevant analytes deltamethrin or *alpha-R-deltamethrin* or *trans-deltamethrin* (separately) at a fortification level of 0.1 mg/kg of each analyte.

Except for the day-0 analysis, samples were stored in plastic containers at an average temperature of +1°C

for eight hours, following 6-8 days at -7°C. For day-0 analysis, five treated samples of each material were chosen, as well as two control samples of each. Samples were then also analyzed after 6, 7 or 8 days of storage.

At each storage interval, five stored samples were analyzed. In addition two concurrent recoveries per commodity were conducted.

Deltamethrin and its isomers, *alpha-R*-deltamethrin and *trans*-deltamethrin, were analytically determined using analytical method 01207 ([Schoening, R.; Willmes, J.; 2014; M-476845-01](#)).

For the analysis of deltamethrin, samples were adjusted with water followed by addition of acetonitrile leading to an acetonitrile/water ratio of (4/1, v/v). The samples fortified with deltamethrin were left to soak for 15 minutes and then shaken for 15 minutes to enhance the extraction. Afterwards, a salt mixture (Mg₂SO₄/NaCl/Na₃ citrate 2 H₂O/Na₂H citrate 6 H₂O) (4/1/1/0.5, w/w/w/w)) was added and the extracts were centrifuged. The extracts were submitted to LC-MS/MS-analysis and quantification was done using matrix-matched standards.

The methods were successfully validated at a level of 0.10 mg/kg relevant to this study in/on samples of tomato (fruit), wheat (green material) and peas (dry peas) in the presented study. For further information on validation of the two methods please refer to Section 5, Appendix A 2.1.1.1).

Results and discussions

In the control samples, the residues were always below 30% of the LOQ.

Summaries of concurrent recoveries conducted as a part of the study are presented in [Table A 39](#). The mean of the recoveries for each matrix were in an acceptable range (mean recoveries were 89% to 102%). The RSDs were in the range of 1.2 to 7.3%.

Summaries of residues recovered in stored samples are presented in [Table A 40](#) for deltamethrin and its isomers, *alpha-R*-deltamethrin and *trans*-deltamethrin.

Residues of deltamethrin and its isomers, *alpha-R*-deltamethrin and *trans*-deltamethrin were stable (<30% decomposition) in tomato fruit, wheat green material and dry peas after storage for 8 hours at +1°C followed by 6 days of storage at -7°C frozen storage.

Table A 41: Summary of concurrent recoveries of deltamethrin residues in plant matrices

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
<i>cis-deltamethrin</i>					
Tomato fruit	0.1	0	5	94; 94;97; 98; 93	95±2.3
		6	2	93; 95	94
Wheat green material	0.1	0	5	100; 98; 99; 97; 98	98±1.2
		6	2	100; 97	99
Peas, dry	0.1	0	5	91; 88; 92; 91; 88	90±2.1
		6	2	87; 90	89
<i>alpha-R-deltamethrin</i>					
Tomato fruit	0.1	0	5	94; 90; 95; 95; 91	93±2.5
		6	2	100; 89	95
Wheat green material	0.1	0	5	101; 115; 98; 96; 102	102±7.3
		6	2	95; 101	98
Peas, dry	0.1	0	5	89; 83; 99; 96; 87	91±7.2
		6	2	91; 95	93
<i>trans-deltamethrin</i>					
Tomato fruit	0.1	0	5	100; 97; 97; 104; 96	99±3.3
		6	2	97; 90	94
Wheat green material	0.1	0	5	101; 106; 97; 102; 97	101±3.8
		6	2	101; 96	99
Peas, dry	0.1	0	5	93; 87; 96; 93; 92	92±3.5
		6	2	95; 97	96

Table A 42: Stability of deltamethrin residues in plant matrices following storage at + 1°C for eight hours, following 6 days at -7°C

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)
<i>cis-deltamethrin</i>				
Tomato fruit	0.1	0	0.094; 0.094; 0.097; 0.098; 0.093	94; 94; 97; 98; 93
		6	0.085; 0.081; 0.082; 0.082; 0.084	85; 81; 82; 82; 84
Wheat green material	0.1	0	0.100; 0.098; 0.099; 0.097; 0.098	100; 98; 99; 97; 98
		6	0.096; 0.097; 0.101; 0.097; 0.098	96; 97; 101; 97; 98
Peas dry	0.1	0	0.091; 0.088; 0.092; 0.091; 0.088	91; 88; 92; 91; 88
		6	0.080; 0.079; 0.082; 0.080; 0.076	80; 79; 82; 80; 76
<i>alpha-R-deltamethrin</i>				
Tomato fruit	0.1	0	0.094; 0.090; 0.095; 0.095; 0.091	94; 90; 95; 95; 91
		6	0.076; 0.082; 0.085; 0.084; 0.074	76; 82; 85; 84; 74
Wheat green material	0.1	0	0.101; 0.115; 0.098; 0.096; 0.102	101; 115; 98; 96; 102
		6	0.091; 0.106; 0.113; 0.088; 0.090	91; 106; 113; 88; 90
Peas dry	0.1	0	0.089; 0.083; 0.099; 0.096; 0.087	89; 83; 99; 96; 87
		6	0.081; 0.073; 0.074; 0.070; 0.070	81; 73; 74; 70; 70
<i>trans-deltamethrin</i>				
Tomato fruit	0.1	0	0.100; 0.097; 0.097; 0.104; 0.096	100; 97; 97; 104; 96
		6	0.085; 0.074; 0.085; 0.084; 0.082	85; 74; 85; 84; 82
Wheat green material	0.1	0	0.101; 0.106; 0.097; 0.102; 0.097	101; 106; 97; 102; 97
		6	0.106; 0.096; 0.107; 0.099; 0.097	106; 96; 107; 99; 97
Peas dry	0.1	0	0.093; 0.087; 0.096; 0.093; 0.092	93; 87; 96; 93; 92
		6	0.086; 0.081; 0.079; 0.080; 0.084	86; 81; 79; 80; 84

Conclusion

Residues of deltamethrin and its isomers, *alpha-R-deltamethrin* and *trans-deltamethrin*, in the plant matrices of high water and high protein content were stable (<30% decomposition) after storage at + 1°C for 8 hours, following a storage of 6 days at -7°C.

A 2.2.1.1.1.3 Study report S17-05312

Comments of zRMS:	<p>The study of Winter, O.; Amann, S.; Giesler, W.; 2018; (S17-05312; M-626405-01-1) has been evaluated in Registration Report for 102000028562 / DLT+FPF EC 85 in February 2022 by zRMS- PL and the summary is presented below:</p> <p><i>The stability of cis-deltamethrin, its isomers AE 0035073 (trans-deltamethrin) and AE F018569 (α-(R)-deltamethrin) was investigated in oilseed rape (seed and straw) after 10 days at -8.5°C (target) plus 5 hours at +6°C (target) in the dark.</i></p> <p><i>The residues of deltamethrin were determined in oilseed rape (seed and straw) according to BCS Method 00855/M004. The final determination was performed with HPLC-MS/MS. The Limit of Quantitation (LOQ), defined as the lowest validated fortification level, was 0.01 mg/kg for deltamethrin (cis-, trans- and α-(R)-) in oilseed rape (seed) and 0.05 mg/kg in oilseed rape (straw). All method validation data are in compliance with the guideline requirements for data generation methods.</i></p> <p><i>After 10 days of storage at -8.5°C (target) followed by 5 hours at +6°C (target) the mean recovery in oilseed rape (seed) was 78 % for cis-deltamethrin, 89 % for trans-deltamethrin, 84 % for α-(R)-deltamethrin. After 10 days of storage at -8.5°C (target) followed by 5 hours at +6°C (target) the mean recovery in oilseed rape (straw) was 92 % for cis-deltamethrin, 96 % for trans-deltamethrin, 97 % for α-(R)-deltamethrin.</i></p> <p><i>Furthermore the mean concurrent recoveries of day 0 to day 10 in oilseed rape (seed) determined from freshly fortified samples were in the range of 80-85 % for cis-deltamethrin, 84-86 % for trans-deltamethrin, 80-83 % for α-(R)-deltamethrin.</i></p> <p><i>In oilseed rape (straw) the mean concurrent recoveries of day 0 to day 10 determined from freshly fortified samples were in the range of 90-95 % for cis-deltamethrin, 91-93 % for trans-deltamethrin, 91-93 % for α-(R)-deltamethrin.</i></p> <p><i>The study results demonstrate that the residues of deltamethrin (cis-, trans- and α-(R)-) are stable in oilseed rape (seed and straw) when stored for 10 days at -8.5°C (target) plus 5 hours at +6°C (target).</i></p> <p><i>The study is acceptable.</i></p>
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Reference:	KCA 6.1/03
Title:	Storage stability of deltamethrin and flupyradifurone in oilseed rape (seed and straw)
Report:	Winter, O.; Amann, S.; Giesler, W.; 2018; S17-05312; M-626405-01-1
Authority registration No:	
Guideline(s):	<p>Regulation (EC) No 1107/2009 of the European Parliament and 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</p> <p>EC Guideline 7032/VI/95, rev. 5, July 1997; Appendix H of working document 1607/VI/97, rev. 2, June 1999 – Storage Stability of Residue Samples</p> <p>OECD 506, 2007; OECD Guideline for the Testing of Chemicals – Stability of Pesticide Residues in Stored Commodities</p>
Deviations:	None
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Materials and methods

To determine the storage stability after 10 days at -8.5°C followed by 5 hours at +6°C in the dark of the relevant residues of deltamethrin in oilseed rape seed and straw, control samples of the respective sample material were spiked with Deltamethrin or *alpha-R*-deltamethrin or *trans*-deltamethrin (separately) at a fortification level of 1.0 mg/kg.

Except for the day-0 analysis, samples were stored in glass containers in a cooling box at an average temperature of - 8.5°C for ten days, then they were transferred to +6°C in the dark.

For day-0 analysis, five treated samples of each material were chosen, as well as two control samples of

each. At the 10-day storage interval, four aliquots of the stored control and five aliquots of fortified crop matrix were removed from storage.

Samples were extracted with acetone/dichloromethane/ n-hexane (1/1/1, v/v/v) followed by liquid-liquid partition with acetonitrile and n-hexane (seed) or GPC-clean up using cyclohexane/ethyl acetate as eluent (straw). The final determination was performed with HPLC-MS/MS. All samples were analysed by single extraction and single injection to the detection system. The residues were quantified by internal standardisation using stable-labelled internal standards. The responses of the LC-MS/MS system to each analyte and its internal standard were measured in samples and in standards, and a relative response was calculated (calculated as the ratio of the analyte and the stable isotopically labelled internal standard responses). The relative response of the analyte in each sample was compared to the relative response of the analyte in the standards.

Deltamethrin and its isomers were analytically determined using analytical method 00855/M004 ([Lakaschus, S.; Winter, O.; 2009; M-356934-01-1](#)). The method was successfully validated in oilseed rape seeds and straw (equivalent to green material) in the storage stability study. The limits of quantitation (LOQs) were 0.01 mg/kg for deltamethrin residues in all matrices.

Results and discussions

In the control samples, the residues were always below 30% of the LOQ.

Summaries of concurrent recoveries conducted as a part of the study are presented in [Table A 43](#). The mean of the recoveries for each matrix were in an acceptable range (mean recoveries were 80% to 95%). The RSDs were in the range of 1.0 to 4.0%. Additional concurrent recoveries were determined at day 10 for samples spiked at 0.1 mg/kg, these values are not presented in the following table. Recoveries were 92% and 88% in seed and straw respectively, for deltamethrin, 86% and 92% in seed and straw, respectively for *alpha-R*-deltamethrin and 93% and 91% in seed and straw, respectively, for *trans*-deltamethrin.

Summaries of residues recovered in stored samples are presented in [Table A 44](#).

Residues of deltamethrin and its isomers, *alpha-R*-deltamethrin and *trans*-deltamethrin were stable (<30% decomposition) in oilseed rape seed and straw for 10 days of storage at -8.5°C followed by 5 hours at +6°C.

Table A 43: Summary of concurrent recoveries of deltamethrin residues in plant matrices

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD (%)
<i>cis</i> -deltamethrin					
Seed	1.0	0	5	77;79; 80; 81; 83	80±2.8
		10	1	78	-
Straw	1.0	0	5	92; 92; 94; 99; 100	95±4.0
		10	1	91	-
<i>alpha-R</i> -deltamethrin					
Seed	1.0	0	5	79; 79; 80; 80; 81	80±1.0
		10	1	80	-
Straw	1.0	0	5	90; 90; 92; 97; 97	93±3.8
		10	1	90	-
<i>trans</i> -deltamethrin					
Seed	1.0	0	5	82; 83; 84; 84; 85	84±1.4
		10	1	79	-
Straw	1.0	0	5	90; 91; 92; 96; 98	93±3.7
		10	1	91	-

Only concurrent recoveries for 1.0 mg/kg spiked samples are presented here. In addition samples were also fortified at a level of 0.1 mg/kg. For details, please refer to the report.

RSD values calculated from rounded values of the report.

Table A 44: Stability of deltamethrin residues in oilseed rape matrices following storage at -8.5°C for ten days, then +6°C for 5 hours

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)
<i>cis-deltamethrin</i>				
Seed	1.0	0	0.79; 0.77; 0.80; 0.81; 0.83	79; 77; 80; 81; 83
		10	0.78; 0.77; 0.79; 0.78; 0.78	78; 77; 79; 78; 78
Straw	1.0	0	0.94; 0.92; 1.00; 0.92; 0.99	94; 92; 100; 92; 99
		10	0.89; 0.89; 1.00; 0.91; 0.91	89; 89; 100; 91; 91
<i>alpha-R-deltamethrin</i>				
Seed	1.0	0	0.80; 0.79; 0.81; 0.79; 0.80	80; 79; 81; 79; 80
		10	0.90; 0.94; 0.81; 0.83; 0.73	90; 94; 81; 83; 73
Straw	1.0	0	0.92; 0.90; 0.97; 0.90; 0.97	92; 90; 97; 90; 97
		10	0.94; 0.96; 0.96; 0.99; 0.98	94; 96; 96; 99; 98
<i>trans-deltamethrin</i>				
Seed	1.0	0	0.82; 0.83; 0.84; 0.84; 0.85	82; 83; 84; 84; 85
		10	0.95; 0.88; 0.89; 0.91; 0.84	95; 88; 89; 91; 84
Straw	1.0	0	0.91; 0.92; 0.98; 0.90; 0.96	91; 92; 98; 90; 96
		10	0.91; 1.01; 0.96; 0.94; 0.98	91; 101; 96; 94; 98

Conclusion

Residues of deltamethrin and its isomers, *alpha-R-deltamethrin* and *trans-deltamethrin* in the plant matrices of oilseed rape (seed and straw) were stable during 10 days of storage at -8.5°C followed by 5 hours at +6°C.

A 2.2.1.1.2 Storage stability of residues in animal products

No additional studies are required.

A 2.2.1.2 Stability of residues in sample extracts

A 2.2.1.2.1 Storage stability of residues in plant sample extracts

No additional studies are required.

A 2.2.1.2.2 Storage stability of residues in animal sample extracts

No additional studies are required.

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

A 2.2.2.1 Nature of residue in primary crops

No additional studies are required.

A 2.2.2.2 Nature of residue in rotational crops

In 2012, a confined rotational crop study was performed with [¹⁴C]-gemdimethyl deltamethrin. It is presented below.

A 2.2.2.2.1 Study report MEF-11/669

Comments of zRMS:	<p>The study of Schmeling, S.; Breuer-Rehm, M.; 2012; (MEF-11/669; M-431769-01-1) has been evaluated in Registration Report for 102000028562 / DLT+FPF EC 85 in February 2022 by zRMS- PL and the summary is presented below:</p> <p><i>The metabolism of deltamethrin was investigated in the rotational crops Swiss chard, turnips and spring wheat after one soil treatment with radiolabelled [gemdimethyl-¹⁴C] deltamethrin. The actual application rate corresponded to 41 g a.s./ha, which was slightly above the anticipated maximal seasonal treatment rate for pre-emergent use.</i></p> <p><i>Two rotations were sown at plant-back intervals of 30 and 134 days. The study was concluded after two rotations due to the very low TRRs (< 0.01 mg/kg) in all of the collected matrices.</i></p> <p><i>The TRR values of all samples were very low and ranged from values < LOQ in turnip leaves and roots and wheat forage of the 2nd rotation to 0.009 mg/kg in wheat straw of the 1st rotation. They showed a decrease from the 1st to the 2nd rotation.</i></p> <p><i>No extraction of plant matrices was conducted during this study; the radioactivity in all samples was determined exclusively by combustion followed by LSC.</i></p>
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Reference:	KCA 6.6.1/01
Title:	Metabolism of [gemdimethyl- ¹⁴ C] deltamethrin in confined rotational crops
Report:	Schmeling, S.; Breuer-Rehm, M.; 2012; MEF-11/669; M-431769-01-1
Authority registration No:	
Guideline(s):	OECD Guideline for the Testing of Chemicals 502: Metabolism in Rotational Crops US EPA Residue Chemistry Test Guideline OPPTS 860.1850: Confined Accumulation in Rotational Crops European Parliament and Council Regulation (EC) no. 1107/2009
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Materials and methods

The objective of this study was to investigate the metabolism of deltamethrin in rotational crops after one pre-emergent spray application onto bare soil. The application rate of the test compound [gemdimethyl-¹⁴C] deltamethrin, formulated as an EW015, was aimed to be about 10% above the highest annual field dose of approx. 37.5 g a.s./ha to compensate for possible losses during treatment. The rotational crops used were Swiss chard, turnips and spring wheat. The intended timeframe for sowing was approx. 30, 150 and 365 days after soil treatment for the first, the second and the third rotation, respectively.

Immature raw agricultural commodities (RACs) investigated were Swiss chard intermediate leaves and forage and hay of wheat. All other RACs (Swiss chard leaves, turnip leaves and roots and wheat straw and grain) were harvested at maturity. The study was concluded after two rotations due to the very low TRRs (< 0.01 mg/kg) in all of the collected matrices.

Results and discussion

The TRR values were generally very low and ranged from values below the LOD (=LOQ) in turnip leaves and roots and wheat forage of the 2nd rotation to 0.009 mg/kg in wheat straw of the 1st rotation. The TRRs in the edible RACs were very low. The TRRs of all samples showed a more or less noticeable decrease from the 1st to the 2nd rotation.

The TRR values for all matrices are shown in the following table:

Table A 45: Total Radioactive Residues (TRRs) in Swiss chard, turnip and wheat matrices

Matrix	TRR (mg/kg)	
	First rotation	Second rotation
Swiss chard intermediate leaves	0.007	0.001
Swiss chard leaves	0.002	0.001
Turnip leaves	0.002	<0.001
Turnip roots	0.001	<0.001
Wheat forage	0.002	<0.001
Wheat hay	0.006	0.002
Wheat straw	0.009	0.002
Wheat grain	0.003	0.002

No extraction of plant matrices was conducted during this study because of the very low TRR values. The radioactivity in all samples was exclusively determined by combustion followed by LSC.

Conclusions

There was no significant metabolism of deltamethrin detectable in confined rotational crops. Results from earlier studies show that uptake and translocation of the parent compound and potential metabolites seems to be very limited in plants. It is also known that under aerobic conditions deltamethrin is rapidly metabolised in soil and that the formed metabolites are readily mineralised to carbon dioxide.

A 2.2.2.3 Nature of residues in processed commodities

No additional studies are required.

A 2.2.2.4 Nature of residues in livestock

No additional studies are required.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Grape

The critical GAP (cGAP) for the proposed use of Sivanto Energy (DLT+FPF EC 85) in grape is summarized in .

Table A 46: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2015)	3	1 x 7.5 + 2 x 17.5	14	-	7 (table grape)
Intended cGAP (number 103, 104, 201, 202, 252, 253, 352, 353, 371, 372*)	2	4	14	BBCH 57-81	14

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

A 2.2.3.1.1 Study report 14-2096

Comments of zRMS:	<p>Four field residue trials were conducted in northern Europe in 2014 to determine the magnitude of the relevant residues of BYI 02960 (flupyradifurone) and deltamethrin in/on grape (berry and bunch of grapes) after two spray applications with Deltamethrin & Flupyradifurone EC 085, an emulsifiable concentrate (EC) formulation containing 10 g/L deltamethrin and 75 g/L BYI 02960 each at a rate of 0.4 L/ha, corresponding to 30 g /ha BYI 02960 and 4 g /ha of deltamethrin with an interval of 13-15 days. The last application was done at a crop growth stage BBCH 83-89.</p> <p>Residues of BYI 02960 and its metabolites (difluoroacetic acid, BYI 02960-difluoroethylaminofuranone and 6-chloronicotinic acid) were determined by HPLC-MS/MS according to method 01212.</p> <p>The LOQ are 0.01 mg/kg for BYI 02960 and BYI 02960-difluoroethylaminofuranone calculated as BYI 02960 and 0.02 mg/kg for difluoroacetic acid calculated as BYI 02960. For BYI 02960 and its metabolites the average recoveries per fortification level were within the acceptable range of 70 – 110% and the RSD values were below 20% except for: BYI 02960 at the LOQ level (116%) in bunch of grapes and BYI 02960-difluoroethylaminofuranone at the LOQ level (117%) in bunch of grapes.</p> <p>Residue results (mg/kg): FPF: 2 x 0.043; 0.072*; 0.096, DFA: 0.008*; 0.011*; 0.013*; 0.016*, sum: 0.063; 0.071; 0.10*; 0.12. * Peak residues detected after PHI</p> <p>The storage period of deep-frozen samples intended for the analysis of BYI 02960 and its metabolites (AG01) in the treated samples ranged between 234 and 275 days and the storage period of the corresponding control samples ranged between 237 and 275 days.</p> <p>Residues of deltamethrin and its isomers AE 0035073 and AE F108569 were determined by HPLC-MS/MS according to method 00855/M004 with LOQ of 0.01 mg/kg for each compound in each sample material of the study.</p> <p>For deltamethrin and its two isomers average recoveries were at each fortification level within the acceptable range of 70 – 110% and the RSD values were below 20%.</p> <p>Residue results (mg/kg): E (deltamethrin): <0.01, 0.011, 0.013, 0.015, 0.015* RA (sum): <0.03, 0.031, 0.033, 0.035, 0.035* * Peak residues detected after PHI</p>
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	The storage period of deep-frozen samples intended for the analysis of deltamethrin and its metabolites in the treated and control samples ranged between 222 and 273 days. The study is acceptable.
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Reference:	KCA 6.3.1.2/01
Title:	Determination of the residues of BYI 02960 and deltamethrin in/on grape after high and low-volume spray application of deltamethrin & flupyradifurone EC 085 in Germany and France (North)
Report:	Schoening, R.; Bouhamadi, S.; Sosniak, A.; Czaja, C.; 2016; 14-2096; M-559743-01-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP Guideline No. 860.1500 on Crop Field Trials
Deviations:	yes, see report
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Validity of the study: yes

Materials and methods

In 2014, 4 field trials were conducted in northern Europe (Germany [2] and northern France [2]) to support the use of Sivanto Energy EC 085 in grapes. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960). At each trial site there was one untreated plot in addition to three treated plots (T1- T3). Two applications were made at an interval of 13-15 days, each at a rate of 0.4 L/ha, corresponding to 4 g /ha of deltamethrin. The last application was done at a crop growth stage BBCH 83-89 (BBCH 83: early dough; BBCH 89: berries ripe for harvest). The applications were performed as either low-volume (Trials 03 and 04) or high volume applications (Trials 01 and 02).

The trials were designed as reverse decline trials in order to harvest mature fruits (bunch of grapes) at different time points, ranging from 0 to 35 days after the second application. All samples were frozen within 24 hours after sampling and stored at a temperature of or below -18°C until analysis (max. 273 days). The maximum storage period of 273 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 24 months ([Ballesteros, C.; 2012; M-441996-01-1](#)).

The samples were analyzed according to method 00855/M004 ([Lakaschus, S.; Winter, O.; 2009; M-356934-01-1](#)) by LC-MS/MS using stable isotopically labelled internal standards. The LOQ in bunch of grapes and berries was 0.01 mg/kg for deltamethrin (*cis*-deltamethrin), AE F108569 (α -(*R*)-deltamethrin) and AE 0035073 (*trans*-deltamethrin). The LOQ of the isomers is not expressed as deltamethrin. The calculated LOQ for the total residue (sum of deltamethrin and its isomers AE F108569 and AE 0035073) was 0.03 mg/kg.

Results

During the course of this study, the method performance was checked/validated by concurrent recoveries. The average recoveries per fortification level and analyte were within the range of 70 – 110%. If applicable, the RSD values were always below 20%. Full validation of method 00855/M004 was done and documented for matrices representing the 5 major crop groups, including strawberry (fruit), tomato (fruit), lambs lettuce, green peas, wheat (grain), wheat (straw), barley (whole plant) and oilseed rape (seed) when developing the method. A full set (2 control, 5 repetitions each at two fortification levels) of additional validation recoveries were analyzed for grape (bunches of grapes) and a limited set (1 control, 3 repetitions each at

two fortification levels) of additional validation recoveries for grape (berry) within the course of the study 14-2095. The average recoveries per fortification level and analyte were within the acceptable range of 70 – 110% and the RSD values were always below 20%.

Details of the application and residue information are summarized in [Table A 47](#).

No residues of deltamethrin (cis-deltamethrin) and its isomers AE F108569 (α -(R)-deltamethrin) and AE 0035073 (*trans*-deltamethrin) at or above the limit of quantification of the method were found in any of the untreated samples.

Table A 47: Summary of the trials of study 14-2096

Analyte 1: deltamethrin (determined as deltamethrin, calculated as deltamethrin), Analyte 2: AE F108569 (determined as AE F108569, calculated as AE F108569), Analyte 3: AE 0035073 (determined as AE 0035073, calculated as AE 0035073)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum*		
14-2096-01 14-2096-01- T1 Germany 76889 Steinfeld Europe, North F 2014	Grape Müller- Thurgau; with variety	1) 03.05.2005 2) 06.06.2014 - 13.06.2014 3) 08.09.2014 - 03.10.2014	4.0 4.0	800 800	0.50 0.50	04.08.2014/0 18.08.2014/14	85	bunch of grapes	85 89 89	0.015 0.011 0.013	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	0.035 0.031 0.033	0 28 35	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2095 (m) Storage: Analyte 1, 2, 3 bunch of grapes: 262 days
14-2096-01 14-2096-01- T2 Germany 76889 Steinfeld Europe, North F 2014	Grape Müller- Thurgau; with variety	1) 03.05.2005 2) 06.06.2014 - 13.06.2014 3) 08.09.2014 - 03.10.2014	4.0 4.0	800 800	0.50 0.50	18.08.2014/0 01.09.2014/14	85	bunch of grapes	85 89 89	0.012 0.013 <u>0.015</u>	<0.01 <0.01 <u><0.01</u>	<0.01 <0.01 <u><0.01</u>	0.032 0.033 <u>0.035</u>	0 <u>14</u> 21	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2095 (m) Storage: Analyte 1, 2, 3 bunch of grapes: 248 days
14-2096-01 14-2096-01- T3 Germany 76889 Steinfeld Europe, North F 2014	Grape Müller- Thurgau; with variety	1) 03.05.2005 2) 06.06.2014 - 13.06.2014 3) 08.09.2014 - 03.10.2014	4.0 4.0	800 800	0.50 0.50	29.08.2014/0 13.09.2014/15	85	bunch of grapes berry	85 85 85 89 89 85 89	<0.01 0.016 0.014 0.016 0.012 0.016 0.016	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.03 0.036 0.034 0.036 0.032 0.036 0.036	0* 0 1 3 7 1 3	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2095 (m) Storage: Analyte 1, 2, 3 bunch of grapes: 236 days Analyte 1, 2, 3 berry: 234 days

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated

- (e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

- (h) Formulation type
(i) Application method
(j) Method information

- (l) Method validation
(m) Storage (max)
! based on date of analysis

(d) Either growth stage description or BBCH Code G greenhouse F field		(g) Study reference * prior to last treatment	(k) LOQ ** residue in control				# P based on production date no data available								
Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum*		
14-2096-02 14-2096-02-T1 Germany 67281 Bissersheim Europe, North F 2014	Grape Dornfelder; red variety	1) 14.06.2001 2) 06.06.2014 - 13.06.2014 3) 08.09.2014 - 03.10.2014	4.0 4.0	800 800	0.50 0.50	04.08.2014/0 18.08.2014/14	85	bunch of grapes	85 89 89	0.019 0.015 0.012	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	0.039 0.035 0.032	0 28 35	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2095 (m) Storage: Analyte 1, 2, 3 bunch of grapes: 273 days
14-2096-02 14-2096-02-T2 Germany 67281 Bissersheim Europe, North F 2014	Grape Dornfelder; red variety	1) 14.06.2001 2) 06.06.2014 - 13.06.2014 3) 08.09.2014 - 03.10.2014	4.0 4.0	800 800	0.50 0.50	18.08.2014/0 01.09.2014/14	85	bunch of grapes	85 89 89	0.017 0.015 0.012	<0.01 0.01 <0.01	<0.01 0.01 <0.01	0.037 0.035 0.032	0 14 21	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2095 (m) Storage: Analyte 1, 2, 3 bunch of grapes: 259 days
14-2096-02 14-2096-02-T3 Germany 67281 Bissersheim Europe, North F 2014	Grape Dornfelder; red variety	1) 14.06.2001 2) 06.06.2014 - 13.06.2014 3) 08.09.2014 - 03.10.2014	4.0 4.0	800 800	0.50 0.50	29.08.2014/0 13.09.2014/15	85	bunch of grapes berry	85 85 85 89 89 85 89	<0.01 0.017 0.015 0.014 0.013 0.017 0.012	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.03 0.037 0.035 0.034 0.033 0.037 0.032	0* 0 1 3 7 1 3	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2095 (m) Storage: Analyte 1, 2, 3 bunch of grapes: 247 days Analyte 1, 2, 3 berry: 234 days

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

- (e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

- (h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

- (l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum*		
14-2096-03 14-2096-03- T1 France, north 37270 Athée sur Cher Europe, North F 2014	Grape Chardonnay; white variety	1) 01.01.1994 2) 03.06.2014 - 13.06.2014 3) 15.09.2014 - 25.09.2014	4.0 4.0	200 200	2.0 2.0	05.08.2014/0 19.08.2014/14	83	bunch of grapes	83 89 89	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.03 <0.03 <0.03	0 28 35	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying, low-volume (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2095 (m) Storage: Analyte 1, 2, 3 bunch of grapes: 273 days
14-2096-03 14-2096-03- T2 France, north 37270 Athée sur Cher Europe, North F 2014	Grape Chardonnay; white variety	1) 01.01.1994 2) 03.06.2014 - 13.06.2014 3) 15.09.2014 - 25.09.2014	4.0 4.0	200 200	2.0 2.0	19.08.2014/0 02.09.2014/14	85	bunch of grapes	85 89 89	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.03 <0.03 <0.03	0 14 21	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying, low-volume (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2095 (m) Storage: Analyte 1, 2, 3 bunch of grapes: 259 days
14-2096-03 14-2096-03- T3 France, north 37270 Athée sur Cher Europe, North F 2014	Grape Chardonnay; white variety	1) 01.01.1994 2) 03.06.2014 - 13.06.2014 3) 15.09.2014 - 25.09.2014	4.0 4.0	200 200	2.0 2.0	02.09.2014/0 16.09.2014/14	89	bunch of grapes berry	89 89 89 89 89 89	<0.01 0.011 0.013 0.015 <0.01 <0.01 0.012	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.03 0.031 0.033 0.035 <0.03 <0.03 0.032	0* 0 1 3 7 1 3	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying, low-volume (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2095 (m) Storage: Analyte 1, 2, 3 bunch of grapes: 245 days Analyte 1, 2, 3 berry: 231 days

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

- | | | | |
|--|---|-------------------------|-----------------------------|
| (a) According to CODEX Classification / Guide | (e) Days after last application (Label pre-harvest interval, PHI, underline) | (h) Formulation type | (l) Method validation |
| (b) Only if relevant | (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included | (i) Application method | (m) Storage (max) |
| (c) Year must be indicated | (g) Study reference | (j) Method information | ! based on date of analysis |
| (d) Either growth stage description or BBCH Code | (*) prior to last treatment | (k) LOQ | P based on production date |
| G greenhouse | | (**) residue in control | # no data available |

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum*		
14-2096-04 14-2096-04- T1 France, north 37140 Saint Nicolas de Bourgueil Europe, North F 2014	Grape Cabernet Franc; red variety	1) 01.01.1986 2) 06.06.2014 - 18.06.2014 3) 20.09.2014 - 30.09.2014	4.0 4.0	200 200	2.0 2.0	13.08.2014/0 27.08.2014/14	85	bunch of grapes	85 89 89	0.015 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	0.035 <0.03 <0.03	0 28 34	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying, low-volume (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2095 (m) Storage: Analyte 1, 2, 3 bunch of grapes: 265 days
14-2096-04 14-2096-04- T2 France, north 37140 Saint Nicolas de Bourgueil Europe, North F 2014	Grape Cabernet Franc; red variety	1) 01.01.1986 2) 06.06.2014 - 18.06.2014 3) 20.09.2014 - 30.09.2014	4.0 4.0	200 200	2.0 2.0	27.08.2014/0 10.09.2014/14	85	bunch of grapes	85 89 89	0.017 <u>0.013</u> 0.010	<0.01 <u><0.01</u> <0.01	<0.01 <u><0.01</u> <0.01	0.037 <u>0.033</u> 0.030	0 <u>14</u> 20	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying, low-volume (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg; 14-2095 (l) Method Validation Data (m) Storage: Analyte 1, 2, 3 bunch of grapes: 251 days
14-2096-04 14-2096-04- T3 France, north 37140 Saint Nicolas de Bourgueil Europe, North F 2014	Grape Cabernet Franc; red variety	1) 01.01.1986 2) 06.06.2014 - 18.06.2014 3) 20.09.2014 - 30.09.2014	4.0 4.0	200 200	2.0 2.0	10.09.2014/0 23.09.2014/13	89	bunch of grapes berry	89 89 89 89 89 89	<0.01 0.019 0.016 0.011 0.011 0.017 0.013	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.03 0.039 0.036 0.031 0.031 0.037 0.033	0* 0 1 3 7 1 3	(g) 14-2096 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying, low-volume (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2095 (m) Storage: Analyte 1, 2, 3 bunch of grapes: 238 days Analyte 1, 2, 3 berry: 224 days

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated

- (e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and
information which metabolites are included

- (h) Formulation type
(i) Application method
(j) Method information

- (l) Method validation
(m) Storage (max)
! based on date of analysis

(d)	Either growth stage description or BBCH Code	(g)	Study reference	(k)	LOQ		P based on production date
G	greenhouse F field	*	prior to last treatment	**	residue in control	#	no data available

A 2.2.3.2 Sunflower

The critical GAP (cGAP) for the proposed use of Sivanto Energy (DLT+FPF EC 85) in sunflower is summarized in [Table A 48](#).

Table A 48: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2015)	1	7.5			60
Intended cGAP* (number 105, 219, 254, 335, 354, 373)	2	7.5	14	BBCH 30-69	as per growth stage

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

A 2.2.3.2.1 Study report 16-2145

Comments of zRMS:	<p>Eight field residue trials were conducted in northern Europe in 2016 to determine the magnitude of the residues of deltamethrin and BYI 02960 (common name flupyradifurone) in/on sunflower seeds (kernel with shell) and kernels (shelled seeds) after two spray applications and with Deltamethrin & Flupyradifurone EC 085, an emulsifiable concentrate (EC) formulation containing 10 g/L deltamethrin and 75 g/L BYI 02960 each at a rate of 0.75 L/ha, corresponding to 56.25 g BYI 02960/ha and 7.5 g/ha of deltamethrin with an interval of 13-14 days. The last application was done at a crop growth stage BBCH 69..</p> <p>Residues of BYI 02960 and difluoroacetic acid were determined by HPLC-MS/MS according to method 01304.</p> <p>The individual LOQs for BYI 02960 and difluoroacetic acid in seed and kernel are 0.01 mg/kg and 0.02 mg/kg (expressed as BYI 02960), respectively.</p> <p>The average recoveries per fortification level were within the range of 70 – 110%. The RSD values were below 20%.</p> <p>Residue results (mg/kg) for seeds (PHI: 29-56): E (FPF): 3 x 0.011; 0.015; 0.024; 0.046; 0.086; 0.10 E (DFA): 2 x 0.008; 0.015; 0.016; 2 x 0.022; 0.025; 0.042 RA (sum): 0.035; 0.044; 0.059; 0.076; 0.085; 0.090; 0.12; 0.23</p> <p>The storage period of samples (deepfrozen) used for the analysis of BYI 02960 and its metabolites was between 489 and 635 days.</p> <p>Residues of deltamethrin and its isomers AE 0035073 and AE F108569 were determined by HPLC-MS/MS according to method 00855/M004 with LOQ of 0.01 mg/kg for each compound.</p> <p>For deltamethrin and its two isomers average recoveries were at each fortification level within the acceptable range of 70 – 110% and the RSD values were below 20%.</p> <p>Residue results (mg/kg) in seeds: E (deltamethrin): 8 x <0.01 RA (sum): 8 x <0.03</p> <p>The storage period of samples (deep-frozen) used for the analysis of deltamethrin and its isomers was between 298 and 354 days.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.2.2/01
Title:	Determination of the residues of BYI 02960 and deltamethrin in/on sunflower after spray application of deltamethrin & flupyradifurone EC 085 in northern France, Hungary, The United Kingdom and Poland
Report:	Miara, C.; Kowalski, N.; 2018; 16-2145; M-645130-01-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial
Deviations:	None
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Validity of the study: yes

Materials and methods

In 2016, 8 field trials were conducted in northern Europe (northern France [3], Hungary [2], The United Kingdom and Poland [2]) to support the use of Sivanto Energy EC 085 in sunflower. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960). Two applications were made at an interval of 13-14 days, each at a rate of 0.75 L/ha, corresponding to 7.5 g/ha of deltamethrin. The last application was done at a crop growth stage of BBCH 69 (end of flowering: most disc florets have finished flowering, ray florets dry or fallen).

Mature seed (kernel with shell) samples were collected at BBCH 85, 87 and 89, corresponding to 12-42, 21-46 and 29-56 days after the last treatment, respectively. An additional sample of mature seeds was taken 7 days after sampling at BBCH 89 (BBCH 89-92, 29-63 days after last treatment). All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 354 days). For the preparation of seeds into kernels the samples were defrosted, dried, if necessary, and stored at room temperature until start of preparation. After the preparation (cleaning, shelling and fractionation) all samples were stored at ambient conditions until separation of the kernel fraction. All kernel samples were deep-frozen immediately after separation (at or below -18°C within 24 h). The maximum storage period of 354 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 38 months ([McKinney, F. R.; Clayton, F. B.; 1995; M-149576-01-1](#)).

The samples were analyzed according to method 00855/M004 ([Lakaschus, S.; Winter, O.; 2009; M-356934-01-1](#)) by LC-MS/MS using stable isotopically labelled internal standards. The LOQ in kernel and seed was 0.01 mg/kg for deltamethrin (cis-deltamethrin), AE F108569 (α -(R)-deltamethrin) and AE 0035073 (*trans*-deltamethrin). The LOQ of the isomers is not expressed as deltamethrin. The calculated LOQ for the total residue (sum of deltamethrin and its isomers AE F108569 and AE 0035073) was 0.03 mg/kg.

Results

During the course of this study, the method performance was checked/validated by concurrent recoveries. Full validation of method 00855/M004 was done and documented for matrices representing the 5 major crop groups, including strawberry (fruit), tomato (fruit), lambs lettuce, green peas, wheat (grain), wheat (straw), barley (whole plant) and oilseed rape (seed) when developing the method. For sunflower kernel a limited set (one control sample, 4 repetitions each at two fortification levels) of additional validation recoveries was done within this study. The average recoveries per fortification

level and analyte were within the acceptable range of 70 – 110% and the RSD values were always below 20%.

Details of the application and residue information are summarized in [Table A 49](#).

No residues of deltamethrin (cis-deltamethrin) and its isomers AE F108569 (α -(R)-deltamethrin) and AE 0035073 (*trans*-deltamethrin) at or above the limit of quantification of the method were found in any of the untreated samples.

Table A 49: Summary of the trials of study 16-2145

Analyte 1: deltamethrin (determined as deltamethrin, calculated as deltamethrin), Analyte 2: AE F108569 (determined as AE F108569, calculated as AE F108569), Analyte 3: AE 0035073 (determined as AE 0035073, calculated as AE 0035073)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum		
16-2145-01 France, north 71570 La Chapelle De Guinchay Europe, North F 2016	Sunflower Valento	1) 09.06.2016 2) 01.08.2016 - 25.08.2016 3) 15.09.2016 - 31.10.2016	7.5	350	2.1	12.08.2016/0 25.08.2016/13	69	seed	85	<0.01	<0.01	<0.01	<0.03	35	(g) 16-2145 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 16- 2145 (m) Storage: Analyte 1, 2, 3 seed: 326 days Analyte 1, 2, 3 kernel: 305 days
			7.5	350	2.1				87	<0.01	<0.01	<0.01	<0.03	46	
									89	<0.01	<0.01	<0.01	<0.03	56	
									89	<0.01	<0.01	<0.01	<0.03	63	
								kernel	89	<0.01	<0.01	<0.01	<0.03	56	
16-2145-02 Hungary 9600 Sarvar Europe, North F 2016	Sunflower Subaro	1) 19.05.2016 2) 18.07.2016 - 06.08.2016 3) 15.09.2016 - 30.09.2016	7.5	300	2.5	20.07.2016/0 03.08.2016/14	69	seed	85	<0.01	<0.01	<0.01	<0.03	40	(g) 16-2145 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 16- 2145 (m) Storage: Analyte 1, 2, 3 seed: 343 days Analyte 1, 2, 3 kernel: 336 days
			7.5	300	2.5				87	<0.01	<0.01	<0.01	<0.03	43	
									89	<0.01	<0.01	<0.01	<0.03	47	
									89	<0.01	<0.01	<0.01	<0.03	54	
								kernel	89	<0.01	<0.01	<0.01	<0.03	47	

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

- | | | | |
|--|---|------------------------|-----------------------------|
| (a) According to CODEX Classification / Guide | (e) Days after last application (Label pre-harvest interval, PHI, underline) | (h) Formulation type | (l) Method validation |
| (b) Only if relevant | (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included | (i) Application method | (m) Storage (max) |
| (c) Year must be indicated | (g) Study reference | (j) Method information | ! based on date of analysis |
| (d) Either growth stage description or BBCH Code | * | (k) LOQ | P based on production date |
| G greenhouse | F field | ** residue in control | # no data available |

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum		
16-2145-03 Hungary 7987 Istvandi Europe, North F 2016	Sunflower LG 54.92 HO-CL	1) 01.05.2016 2) 07.07.2016 - 24.07.2016 3) 01.09.2016 - 20.09.2016	7.5	250	3.0	07.07.2016/0 21.07.2016/14	69	seed	85	<0.01	<0.01	<0.01	<0.03	42	(g) 16-2145 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 16- 2145 (m) Storage: Analyte 1, 2, 3 seed: 354 days Analyte 1, 2, 3 kernel: 347 days
			7.5	250	3.0				87	<0.01	<0.01	<0.01	<0.03	46	
									89	<0.01	<0.01	<0.01	<0.03	49	
									89	<0.01	<0.01	<0.01	<0.03	56	
	kernel							89	<0.01	<0.01	<0.01	<0.03	49		
16-2145-04 France, north 63260 Montpensier Europe, North F 2016	Sunflower Symphonie	1) 25.04.2016 2) 18.07.2016 - 08.08.2016 3) 15.09.2016 - 15.10.2016	7.5	350	2.1	26.07.2016/0 08.08.2016/13	69	seed	85	<0.01	<0.01	<0.01	<0.03	31	(g) 16-2145 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 16- 2145 (m) Storage: Analyte 1, 2, 3 seed: 347 days Analyte 1, 2, 3 kernel: 334 days
			7.5	350	2.1				87	<0.01	<0.01	<0.01	<0.03	36	
									89	<0.01	<0.01	<0.01	<0.03	44	
									89	<0.01	<0.01	<0.01	<0.03	51	
	kernel							89	<0.01	<0.01	<0.01	<0.03	44		
16-2145-05 France, north 71290 Simandre Europe, North F 2016	Sunflower PR64E118	1) 05.05.2016 2) 21.07.2016 - 08.08.2016 3) 23.09.2016 - 07.10.2016	7.5	300	2.5	02.08.2016/0 16.08.2016/14	69	seed	85	<0.01	<0.01	<0.01	<0.03	23	(g) 16-2145 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 16- 2145 (m) Storage: Analyte 1, 2, 3 seed: 348 days Analyte 1, 2, 3 kernel: 328 days
			7.5	300	2.5				87	<0.01	<0.01	<0.01	<0.03	34	
									89	<0.01	<0.01	<0.01	<0.03	43	
									89	<0.01	<0.01	<0.01	<0.03	50	
	kernel							89	<0.01	<0.01	<0.01	<0.03	43		

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated

- (e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

- (h) Formulation type
(i) Application method
(j) Method information

- (l) Method validation
(m) Storage (max)
! based on date of analysis

(d) G	Either growth stage description or BBCH Code greenhouse F field	(g) *	Study reference prior to last treatment	(k) **	LOQ residue in control	#	P based on production date no data available
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Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum		
16-2145-06 United Kingdom IP31 2NG Bury ST Edmunds Europe, North F 2016	Sunflower Sunspot	1) 26.05.2016 2) 21.08.2016 - 10.09.2016 3) 22.09.2016 - 20.10.2016	7.5	200	3.8	25.08.2016/0 08.09.2016/14	69	seed	85	<0.01	<0.01	<0.01	<0.03	12	(g) 16-2145 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 16- 2145 (m) Storage: Analyte 1, 2, 3 seed: 336 days Analyte 1, 2, 3 kernel: 319 days
			7.5	200	3.8				87	<0.01	<0.01	<0.01	<0.03	21	
									89	<0.01	<0.01	<0.01	<0.03	29	
									89	<0.01	<0.01	<0.01	<0.03	36	
16-2145-07 Poland 99-423 Oszkowie Europe, North F 2016	Sunflower Wielkopolski	1) 06.06.2016 2) 14.08.2016 - 28.08.2016 3) 15.09.2016 - 15.10.2016	7.5	300	2.5	13.08.2016/0 26.08.2016/13	69	seed	85	<0.01	<0.01	<0.01	<0.03	21	(g) 16-2145 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 16- 2145 (m) Storage: Analyte 1, 2, 3 seed: 341 days Analyte 1, 2, 3 kernel: 327 days
			7.5	300	2.5				87	<0.01	<0.01	<0.01	<0.03	27	
									89	<0.01	<0.01	<0.01	<0.03	35	
									92	<0.01	<0.01	<0.01	<0.03	42	
16-2145-08 Poland 88-400 Murczyn Europe, North F 2016	Sunflower MAS83.R	1) 25.05.2016 2) 07.08.2016 - 21.08.2016 3) 15.09.2016 - 15.10.2016	7.5	300	2.5	05.08.2016/0 19.08.2016/14	69	seed	85	<0.01	<0.01	<0.01	<0.03	25	(g) 16-2145 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 16- 2145 (m) Storage: Analyte 1, 2, 3 seed: 344 days Analyte 1, 2, 3 kernel: 329 days
			7.5	300	2.5				87	<0.01	<0.01	<0.01	<0.03	32	
									89	<0.01	<0.01	<0.01	<0.03	40	
									92	<0.01	<0.01	<0.01	<0.03	47	
								kernel	89	<0.01	<0.01	<0.01	<0.03	40	

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated

- (e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and
information which metabolites are included

- (h) Formulation type
(i) Application method
(j) Method information

- (l) Method validation
(m) Storage (max)
! based on date of analysis

(d)	Either growth stage description or BBCH Code	(g)	Study reference	(k)	LOQ		P based on production date
G	greenhouse F field	*	prior to last treatment	**	residue in control	#	no data available

A 2.2.3.3 Barley

The critical GAP (cGAP) for the proposed use of Sivanto Energy (DLT+FPF EC 85) in barley is summarized in [Table A 50](#).

Table A 50: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2015)	3	7.5	14	-	30
cGAP EU (Art. 12, EFSA, 2015)	1	1 g/ton	-	Post-harvest treatment	n.a.
Intended cGAP* (number 107, 109, 204, 206, 337, 339, 356, 358, 375, 377)	2	7.5	14	BBCH 41-83	30 stage

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

A 2.2.3.3.1 Study report 15-2131

Comments of zRMS:	<p>Four field residue trials were conducted in northern Europe in 2015 to determine the magnitude of the residues of deltamethrin and BYI 02960 (common name flupyradifurone) in/on winter and spring barley (grain, straw and whole plant without root) after two spray applications with Deltamethrin & Flupyradifurone EC 085, an EC formulation containing 10 g/L deltamethrin and 75 g/L BYI 02960 each at a rate of 0.75 L/ha, corresponding to 56.25 g BYI 02960/ha and 7.5 g/ha of deltamethrin with an interval of 13-14 days. The last application was done at a crop growth stage BBCH 73-85. The PHI was 30 days.</p> <p>Residues of BYI 02960 and difluoroacetic acid were determined by HPLC-MS/MS according to method 01212.</p> <p>The individual LOQs for BYI 02960 and difluoroacetic acid are 0.01 and 0.02 mg/kg, respectively in the sample materials barley (grain) and barley (whole plant without root). For the sample material barley (straw) the individual LOQs are 0.05 mg/kg for each analyte.</p> <p>The average recoveries per fortification level were within the range of 70 – 110%. The RSD values were below 20%.</p> <p>Residue results (mg/kg) for grain (PHI: 29-33 days): E (FPF): 0.034; 0.053*; 0.082*; 0.16 E (DFA): 0.011; 0.031*; 0.039; 0.080 RA (sum): 0.12*; 0.15*; 2 x 0.27 * Peak residues detected after PHI.</p> <p>The storage period of deep-frozen samples intended for the analysis of BYI 02960 and its metabolites in the treated samples ranged between 247 and 316 days and the storage period of the corresponding control samples ranged between 252 and 314 days.</p> <p>Residues of deltamethrin and its isomers AE 0035073 and AE F108569 were determined by HPLC-MS/MS according to method 00855/M004 with LOQ of 0.01 mg/kg for grain and for each compound and 0.05 mg/kg for straw and whole plant without root for each compound.</p> <p>For deltamethrin and its two isomers average recoveries were at each fortification level within the acceptable range of 70 – 110% and the RSD values were below 20%.</p> <p>Residue results (mg/kg) in grain: E (deltamethrin): 0.013, 0.030, 0.042, 0.044* RA (sum): 0.033, 0.051, 0.070, 0.070* * Peak residues detected after PHI.</p>
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	The storage period of deep-frozen samples intended for the analysis of deltamethrin and its isomers in the treated samples ranged between 230 and 313 days and the storage period of the corresponding control samples ranged between 235 and 306 days.
	The study is acceptable.

Reference:	KCA 6.3.3.2/01
Title:	Amendment no. 3 to final report - Determination of the residues of BYI 02960 and deltamethrin in/on winter and spring barley after spray application of deltamethrin & flupyradifurone EC 085 in Germany, Belgium and United Kingdom
Report:	Schulte, G.; 2017; 15-2131; M-580973-04-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial
Deviations:	none
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Validity of the study: yes

Materials and methods

In 2015, 4 field trials were conducted in northern Europe (United Kingdom, Germany [2] and Belgium) to support the use of Sivanto Energy EC 085 in spring and winter barley. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960). Two applications were made at an interval of 13-14 days, each at a rate of 0.75 L/ha, corresponding to 7.5 g /ha of deltamethrin. The last application was done at a crop growth stage of BBCH 73-85 (fruit development stages, BBCH 73: early milk; BBCH 85 soft dough). The envisaged PHI was 30 days.

Samples of barley, whole plant without root were collected immediately before and after the last treatment, as well as 6-7 and 13-14 days after the last treatment. Mature grain samples and barley straw were collected 21-22, 29-33 and 34-37 days after the last treatment. All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 313 days). The maximum storage period of 313 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 36 months ([Czarnecki, J. J.; 1996; M-139715-01-1](#)).

The samples were analyzed according to method 00855/M004 ([Lakaschus, S.; Winter; O.; 2009; M 356934-01-1](#)) by LC-MS/MS using stable isotopically labelled internal standards. The LOQ in whole plant without root and straw was 0.05 mg/kg and 0.01 mg/kg in grain for deltamethrin (cis-deltamethrin), AE F108569 (α -(R)-deltamethrin) and AE 0035073 (*trans*-deltamethrin). The LOQ of the isomers is not expressed as deltamethrin. The calculated LOQ for the total residue (sum of deltamethrin and its isomers AE F108569 and AE 0035073) was 0.03 mg/kg in grain and 0.15 mg/kg in whole plant without root and straw.

Results

During the course of the present study, the method performance was checked/validated by concurrent recoveries. The average recoveries per fortification level and analyte were within the range of 70 – 110%. If applicable, the RSD values were always below 20%. Full validation data is documented with the method 00855/M004 itself for matrices representing 5 major crop groups, including strawberry (fruit), tomato (fruit), lambs lettuce, green peas, wheat (grain), wheat (straw), barley (whole plant) and oilseed rape (seed). For barley (grain, whole plant without root and straw) a limited set (1 control, 3 repetitions each at two fortification levels) of additional validation recoveries was done within the course of the study 15-2031. The average recoveries per fortification level and analyte were within the acceptable range of 70 – 110% and the RSD values were always below 20%.

Details of the application and residue information are summarized in [Table A 51](#).

No residues of deltamethrin (cis-deltamethrin) and its isomers AE F108569 (α -(R)-deltamethrin) and AE 0035073 (*trans*-deltamethrin) at or above the limit of quantification of the method were found in any of the untreated samples.

Table A 51: Summary of the trials of study 15-2131

Analyte 1: deltamethrin (determined as deltamethrin, calculated as deltamethrin), Analyte 2: AE F108569 (determined as AE F108569, calculated as AE F108569), Analyte 3: AE 0035073 (determined as AE 0035073, calculated as AE 0035073)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum		
15-2131-01 Germany 04824 Beucha OT Wolfshain Europe, North F 2015	Barley, winter Meridian	1) 29.09.2014 2) 13.05.2015 - 21.05.2015 3) 08.07.2015 - 15.10.2015	7.50	300	2.5	27.05.2015/0 10.06.2015/14	73	whole	73	<0.05	<0.05	<0.05	<0.15	0*	(g) 15-2131 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 grain: 0.01 mg/kg Analyte 1,2,3 whole plant without roots, straw: 0.05 mg/kg (l) Method Validation Data: 00855/M004, 15-2130 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 295 days Analyte 1, 2, 3 straw: 278 days Analyte 1, 2, 3 grain: 272 days
			7.50	300	2.5			plant	73	0.14	<0.05	<0.05	0.24	0	
								without	75	0.11	<0.05	<0.05	0.21	7	
								root	77	0.090	<0.05	<0.05	0.19	14	
								grain	83	0.056	<0.01	0.020	0.086	21	
									89	<u>0.042</u>	<u><0.01</u>	<u>0.018</u>	<u>0.070</u>	<u>30</u>	
									89	0.039	<0.01	0.015	0.064	35	
								straw	83	0.14	<0.05	<0.05	0.24	21	
									89	0.17	<0.05	<0.05	0.27	<u>30</u>	
									89	<u>0.17</u>	<u><0.05</u>	<u>0.057</u>	<u>0.28</u>	35	
15-2131-02 Belgium 1450 Cortil- Noirmont Europe, North F 2015	Barley, winter Meridian	1) 30.09.2014 2) 15.05.2015 - 26.05.2015 3) 10.07.2015 - 24.07.2015	7.50	300	2.5	05.06.2015/0 19.06.2015/14	85	whole	85	0.054	<0.05	<0.05	0.15	0*	(g) 15-2131 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 grain: 0.01 mg/kg Analyte 1,2,3 whole plant without roots, straw: 0.05 mg/kg (l) Method Validation Data: 00855/M004, 15-2130 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 286 days Analyte 1, 2, 3 straw: 269 days Analyte 1, 2, 3 grain: 263 days
			7.50	300	2.5			plant	85	0.23	<0.05	<0.05	0.33	0	
								without	87	0.15	<0.05	<0.05	0.25	7	
								root	87	0.23	<0.05	0.057	0.34	14	
								grain	89	0.055	<0.01	0.021	0.086	21	
									89	0.018	<0.01	<0.01	0.038	<u>33</u>	
									89	<u>0.044</u>	<u><0.01</u>	<u>0.016</u>	<u>0.070</u>	35	
								straw	89	0.24	<0.05	0.050	0.34	21	
									89	0.19	<0.05	0.055	0.30	<u>33</u>	
									89	<u>0.22</u>	<u><0.05</u>	<u>0.059</u>	<u>0.33</u>	35	

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

- (e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

- (h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

- (l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum		
15-2131-03 United Kingdom CB22 5EU Little Shelford, Cambridge Europe, North F 2015	Barley, spring Tipple	1) 12.03.2015 2) 08.06.2015 - 26.06.2015 3) 31.07.2015 - 20.08.2015	7.50	200	3.75	26.06.2015/0 09.07.2015/13	77	whole	77	0.081	<0.05	<0.05	0.18	0*	(g) 15-2131 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 grain: 0.01 mg/kg Analyte 1,2,3 whole plant without roots, straw: 0.05 mg/kg (l) Method Validation Data: 00855/M004, 15-2130 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 272 days Analyte 1, 2, 3 straw: 313 days Analyte 1, 2, 3 grain: 242 days
			7.50	200	3.75			plant	77	0.30	<0.05	<0.05	0.40	0	
								without	77	0.31	<0.05	0.053	0.41	6	
								root	87	0.32	<0.05	0.077	0.45	13	
								grain	89	0.025	<0.01	<0.01	0.045	22	
									89	<u>0.030</u>	<u><0.01</u>	<u>0.011</u>	<u>0.051</u>	29	
									89	0.023	<0.01	0.010	0.043	34	
								straw	89	0.83	<0.05	0.22	1.1	22	
									89	<u>0.70</u>	<u><0.05</u>	<u>0.20</u>	<u>0.95</u>	29	
									89	0.67	<0.05	<u>0.21</u>	0.93	34	
15-2131-04 Germany 49838 Gersten Europe, North F 2015	Barley, spring Vespa	1) 05.03.2015 2) 07.06.2015 - 18.06.2015 3) 10.07.2015 - 28.07.2015	7.50	300	2.5	10.06.2015/0 24.06.2015/14	75	whole	75	0.084	<0.05	<0.05	0.18	0*	(g) 15-2131 (h) EC (deltamethrin 10 g/L, flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 grain: 0.01 mg/kg Analyte 1,2,3 whole plant without roots, straw: 0.05 mg/kg (l) Method Validation Data: 00855/M004, 15-2130 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 287 days Analyte 1, 2, 3 straw: 264 days Analyte 1, 2, 3 grain: 258 days
			7.50	300	2.5			plant	75	0.27	<0.05	<0.05	0.37	0	
								without	77	0.15	<0.05	<0.05	0.25	7	
								root	85	0.11	<0.05	<0.05	0.21	14	
								grain	87	0.018	<0.01	<0.01	0.038	21	
									89	<u>0.013</u>	<u><0.01</u>	<u><0.01</u>	<u>0.033</u>	30	
									89	0.013	<0.01	<0.01	0.033	37	
								straw	87	0.30	<0.05	0.068	0.42	21	
									89	0.16	<0.05	<0.05	0.26	30	
									89	<u>0.21</u>	<u><0.05</u>	<u>0.052</u>	<u>0.31</u>	37	

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

(h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

(l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.2.3.3.2 Study report 16-2035

Comments of zRMS:	<p>Four field residue trials were conducted in northern Europe in 2016 to determine the magnitude of the residues of deltamethrin and BYI 02960 (common name flupyradifurone) in/on winter and spring barley (grain, straw and whole plant without root) after two spray applications with Deltamethrin & Flupyradifurone EC 085, an EC formulation containing 10 g/L deltamethrin and 75 g/L BYI 02960 each at a rate of 0.75 L/ha, corresponding to 56.25 g BYI 02960/ha and 7.5 g/ha of deltamethrin with an interval of 14-15 days. The last application was done at a crop growth stage BBCH 73-89. The PHI was 30 days.</p> <p>Residues of BYI 02960 and difluoroacetic acid were determined by HPLC-MS/MS according to method 01304.</p> <p>The individual LOQs for BYI 02960 and difluoroacetic acid are 0.01 and 0.02 mg/kg, respectively in the sample materials whole plant without root, grain and straw.</p> <p>The average recoveries per fortification level were within the range of 70 – 110%. The RSD values were below 20%.</p> <p>Residue results (mg/kg) for grain (PHI: 29-33 days): E (FPF): <0.01; 0.022; 0.081*; 0.099* E (DFA): 0.036*; 0.052; 0.059*; 0.064 RA (sum): 0.18; 0.20; 0.21*; 0.26* * Peak residues detected after PHI.</p> <p>The storage period of deep frozen samples used for the analysis of BYI 02960 and its metabolites was between 476 and 541 days.</p> <p>Residues of deltamethrin and its isomers AE 0035073 and AE F108569 were determined by HPLC-MS/MS according to method 00855/M004 with LOQ of 0.01 mg/kg for grain and for each compound and 0.05 mg/kg for straw and whole plant without root for each compound.</p> <p>For deltamethrin and its two isomers average recoveries were at each fortification level within the acceptable range of 70 – 110% and the RSD values were below 20%.</p> <p>Residue results (mg/kg) in grain: E (deltamethrin): <0.01, 0.014*, 0.019*, 0.048 RA (sum): <0.03, 0.034*, 0.039*, 0.073 * Peak residues detected after PHI.</p> <p>The storage period of deep frozen samples used for the analysis of deltamethrin and its isomers was between 365 and 431 days.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.3.2/02
Title:	Determination of the residues of BYI 02960 and deltamethrin in/on winter and spring barley after spray application of deltamethrin & flupyradifurone EC 085 in the Netherlands, Germany and Belgium
Report:	Kaussmann, M.; 2018; 16-2035; M-634410-01-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP 860.1500, Crop Field Trial
Deviations:	None
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Validity of the study: yes

Materials and methods

In 2016, 4 field trials were conducted in northern Europe (the Netherlands, Germany [2] and Belgium) to support the use of Sivanto Energy EC 085 in winter and spring barley. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960). Two applications were made at an interval of 14-15 days, each at a rate of 0.75 L/ha, corresponding to 7.5 g/ha of deltamethrin. The last application was done at a crop growth stage of BBCH 73-83 (fruit development stages, BBCH 73: early milk; BBCH 83 early dough). The envisaged PHI was 30 days.

Samples of barley, whole plant without root were collected immediately before and after the last treatment. Mature grain samples and barley straw were collected 27-33 and 31-35 days after the last treatment. All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 431 days). The maximum storage period of 431 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 36 months ([Czarnecki, J. J.; 1996; M-139715-01-1](#)).

The samples were analyzed according to method 00855/M004 ([Lakaschus, S.; Winter; O.; 2009; M 356934-01-1](#)) by LC-MS/MS using stable isotopically labelled internal standards. The LOQ in whole plant without root and straw was 0.05 mg/kg and 0.01 mg/kg in grain for deltamethrin (cis-deltamethrin), AE F108569 (α -(R)-deltamethrin) and AE 0035073 (*trans*-deltamethrin). The LOQ of the isomers is not expressed as deltamethrin. The calculated LOQ for the total residue (sum of deltamethrin and its isomers AE F108569 and AE 0035073) was 0.03 mg/kg in grain and 0.15 mg/kg in whole plant without root and straw.

Results

During the course of the present study, the method performance was checked/validated by concurrent recoveries. Full validation data is documented with the method 00855/M004 itself for matrices representing 5 major crop groups, including strawberry (fruit), tomato (fruit), lambs lettuce, green peas, wheat (grain), wheat (straw), barley (whole plant) and oilseed rape (seed). For barley (grain, whole plant without root and straw) a limited set (1 control, 3 repetitions each at two fortification levels) of additional validation recoveries was done within the course of this study. The average recoveries per fortification level and analyte were within the acceptable range of 70 – 110% and the RSD values were always below 20%.

Details of the application and residue information are summarized in [Table A 52](#).

No residues of deltamethrin (cis-deltamethrin) and its isomers AE F108569 (α -(R)-deltamethrin) and AE 0035073 (*trans*-deltamethrin) at or above the limit of quantification of the method were found in any of the untreated samples.

Table A 52: Summary of the trials of study 16-2035

Analyte 1: deltamethrin (determined as deltamethrin, calculated as deltamethrin), Analyte 2: AE F108569 (determined as AE F108569, calculated as AE F108569), Analyte 3: AE 0035073 (determined as AE 0035073, calculated as AE 0035073)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum		
16-2035-01 Netherlands 1437 EG Rozenburg Europe, North F 2016	Barley, winter Cassiopée	1) 15.10.2015 2) 06.06.2016 - 13.06.2016 3) 18.07.2016 - 23.07.2016	7.5	400	1.9	06.06.2016/0 21.06.2016/15	83	whole plant without root grain straw	83	0.050	<0.05	<0.05	0.15	0*	(g) 16-2035 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 grain: 0.01 mg/kg Analyte 1,2,3 whole plant without roots, straw: 0.05 mg/kg (l) Method Validation Data: 00855/M004, 16-2034, 16-2035 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 423 days Analyte 1, 2, 3 straw: 395 days Analyte 1, 2, 3 grain: 396 days
			7.5	400	1.9				83	0.18	<0.05	<0.05	0.28		
									89	<0.01	<0.01	<0.01	<0.03		
									89	<0.01	<0.01	<0.01	<0.03		
									89	0.18	<0.05	<0.05	0.28		
									89	<u>0.21</u>	<u><0.05</u>	<u>0.052</u>	<u>0.31</u>		
16-2035-02 Germany 59609 Anröchte- Berge Europe, North F 2016	Barley, winter Keeper	1) 29.09.2015 2) 22.05.2016 - 30.05.2016 3) 05.07.2016 - 25.07.2016	7.5	300	2.5	30.05.2016/0 13.06.2016/14	73	whole plant without root grain straw	73	<0.05	<0.05	<0.05	<0.15	0*	(g) 16-2035 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 grain: 0.01 mg/kg Analyte 1,2,3 whole plant without roots, straw: 0.05 mg/kg (l) Method Validation Data: 00855/M004, 16-2034, 16-2035 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 431 days Analyte 1, 2, 3 straw: 402 days Analyte 1, 2, 3 grain: 403 days
			7.5	300	2.5				73	0.18	<0.05	<0.05	0.28		
									89	<u>0.048</u>	<u><0.01</u>	<u>0.015</u>	<u>0.073</u>		
									89	0.029	<0.01	<0.01	0.049		
									89	<u>0.25</u>	<u><0.05</u>	<u>0.072</u>	<u>0.37</u>		
									89	0.20	<0.05	0.064	0.31		

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

(a) According to CODEX Classification / Guide
(b) Only if relevant

(e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and

(h) Formulation type
(i) Application method

(l) Method validation
(m) Storage (max)

(c)	Year must be indicated			information which metabolites are included	(j)	Method information		! based on date of analysis
(d)	Either growth stage description or BBCH Code	(g)		Study reference	(k)	LOQ		P based on production date
G	greenhouse F field	*		prior to last treatment	**	residue in control	#	no data available

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum		
16-2035-03 Belgium 6211 Mellet Europe, North F 2016	Barley, spring Hilford	1) 18.03.2016 2) 16.06.2016 - 19.06.2016 3) 26.07.2016 - 01.08.2016	7.5	300	2.5	14.06.2016/0 28.06.2016/14	83	whole plant without root	83	<0.05	<0.05	<0.05	<0.15	0*	(g) 16-2035 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 grain: 0.01 mg/kg Analyte 1,2,3 whole plant without roots, straw: 0.05 mg/kg (l) Method Validation Data: 00855/M004, 16-2034, 16-2035 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 416 days Analyte 1, 2, 3 straw: 386 days Analyte 1, 2, 3 grain: 387 days
			7.5	300	2.5				83	0.22	<0.05	<0.05	0.32		
								grain	89	0.011	<0.01	<0.01	0.031		
									89	0.014	<0.01	<0.01	0.034		
								straw	89	0.27	<0.05	0.12	0.44		
									89	0.25	<0.05	0.12	0.42		
16-2035-04 Germany 51399 Burscheid Europe, North F 2016	Barley, spring Vespa	1) 04.04.2016 2) 16.06.2016 - 21.06.2016 3) 01.08.2016 - 31.08.2016	7.5	300	2.5	29.06.2016/0 13.07.2016/14	83	whole plant without root	83	0.062	<0.05	<0.05	0.16	0*	(g) 16-2035 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 grain: 0.01 mg/kg Analyte 1,2,3 whole plant without roots, straw: 0.05 mg/kg (l) Method Validation Data: 00855/M004, 16-2034, 16-2035 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 401 days Analyte 1, 2, 3 straw: 367 days Analyte 1, 2, 3 grain: 368 days
			7.5	300	2.5				83	0.28	<0.05	<0.05	0.38		
								grain	89	0.012	<0.01	<0.01	0.032		
									89	0.019	<0.01	<0.01	0.039		
								straw	89	0.49	<0.05	0.14	0.68		
									89	0.40	<0.05	0.11	0.56		

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

- (e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and
information which metabolites are included
(g) Study reference
* prior to last treatment

- (h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

- (l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.2.3.4 Wheat

The critical GAP (cGAP) for the proposed use of Sivanto Energy (DLT+FPF EC 85) in ~~barley~~ wheat is summarized in Table A 53.

Table A 53: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2015)	3	7.5	14	-	30
cGAP EU (Art. 12, EFSA, 2015)	1	0.5 g/ton	-	Post harvest treatment	n.a.
Intended cGAP* (number 115, 117, 212, 214, 259, 261, 345, 347, 364, 366, 383, 385)	2	7.5	14	BBCH 41-83	30 stage

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

A 2.2.3.4.1 Study report 15-2129

Comments of zRMS:	<p>Four field residue trials were conducted in northern Europe in 2015 to determine the magnitude of the residues of deltamethrin and BYI 02960 (common name flupyradifurone) in/on winter and spring wheat (grain, straw and whole plant without root, ear and rest of plant) after two spray applications with Deltamethrin & Flupyradifurone EC 085, an EC formulation containing 10 g/L deltamethrin and 75 g/L BYI 02960 each at a rate of 0.75 L/ha, corresponding to 56.25 g BYI 02960/ha and 7.5 g/ha of deltamethrin with an interval of 13-14 days. The last application was done at a crop growth stage BBCH 73-85. The PHI was 30 days.</p> <p>Residues of BYI 02960 and difluoroacetic acid were determined by HPLC-MS/MS according to method 01212.</p> <p>The individual LOQs for BYI 02960 and difluoroacetic acid are 0.01 and 0.02 mg/kg respectively in the sample materials wheat (grain), wheat (ear), wheat (rest of plant) and wheat (whole plant without root). For the sample material wheat (straw) the individual LOQs are 0.05 mg/kg for each analyte.</p> <p>The average recoveries per fortification level were within the range of 70 – 110%. The RSD values were below 20%.</p> <p>Residue results (mg/kg) for grain (PHI: 30 days): E (FPF): 2 x <0.01; 0.011; 0.015* E (DFA): 0.10; 0.16; 0.20; 0.34 RA (sum): 0.32; 0.48; 0.62; 1.0 * Peak residues detected after PHI.</p> <p>The storage period of deep-frozen samples intended for the analysis of BYI 02960 and its metabolites in the treated samples ranged between 123 and 239 days and the storage period of the corresponding control samples ranged between 128 and 230 days.</p> <p>Residues of deltamethrin and its isomers AE 0035073 and AE F108569 were determined by HPLC-MS/MS according to method 00855/M004 with LOQ of 0.01 mg/kg for grain and ear for each compound and 0.05 mg/kg for straw, rest of plant and whole plant without root for each compound.</p> <p>For deltamethrin and its two isomers average recoveries were at each fortification level within the acceptable range of 70 – 110% and the RSD values were below 20%.</p> <p>Residue results (mg/kg) in grain: E (deltamethrin): 4 x <0.01 RA (sum): 4 x <0.03</p>
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	The storage period of deep-frozen samples intended for the analysis of deltamethrin and its isomers in the treated samples ranged between 112 and 177 days and the storage period of the corresponding control samples ranged between 117 and 177 days.
	The study is acceptable.

Reference:	KCA 6.3.4.2/01
Title:	Amendment no. 2 to final report - Determination of the residues of BYI 02960 and deltamethrin in/on spring wheat and winter wheat after spray application of deltamethrin & flupyradifurone EC 085 in Germany, the Netherlands and Belgium
Report:	Schulte, G.; 2017; 15-2129; M-580528-03-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial
Deviations:	none
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Validity of the study: yes

Materials and methods

In 2015, 4 field trials were conducted in northern Europe (Germany [2], the Netherlands and Belgium) to support the use of Sivanto Energy EC 085 in wheat. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960). Two applications were made at an interval of 14-16 days, each at a rate of 0.75 L/ha, corresponding to 7.5 g/ha of deltamethrin. The last application was done at a crop growth stage of BBCH 71-75 (BBCH 71: watery ripe, first grains have reached half their final size; BBCH 75: medium milk, grain content milky, grains reached final size, still green). The envisaged PHI was 30 days.

Samples of whole plant without root were collected before and after the last treatment and 7 and 14 days after last treatment. Samples of grain and straw were collected 21, 30 and 35-36 days after the last treatment, except in trial 15-2129-01 where the sampling at 21 days after last treatment was changed from grain and straw to ear and rest of plant due to an unexpected slow development of the crop (amendment to the study plan). All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 177 days). The maximum storage period of 177 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 36 months ([Czarnecki, J. J.; 1996; M-139715-01-1](#)).

The samples were analyzed according to method 00855/M004 ([Lakaschus, S.; Winter, O.; 2009; M 356934-01-1](#)) by LC-MS/MS using stable isotopically labelled internal standards. The LOQ in whole plant without root and straw was 0.05 mg/kg and 0.01 mg/kg in grain for deltamethrin (cis-deltamethrin), AE F108569 (α -(R)-deltamethrin) and AE 0035073 (*trans*-deltamethrin). The LOQ of the isomers is not expressed as deltamethrin. The calculated LOQ for the total residue (sum of deltamethrin and its isomers AE F108569 and AE 0035073) was 0.03 mg/kg in grain and 0.15 mg/kg in whole plant without root and straw.

Results

During the course of the present study, the method performance was checked/validated by concurrent recoveries. The average recoveries per fortification level and analyte were within the acceptable range of 70 – 110%. If applicable, the RSD values were always below 20%. Full validation data is documented with the method 00855/M004 itself for matrices representing 5 major crop groups, including strawberry (fruit), tomato (fruit), lambs lettuce, green peas, wheat (grain), wheat (straw), barley (whole plant) and oilseed rape (seed). For wheat (whole plant without root and straw), a limited set (1 control, 3 repetitions each at two fortification levels) of additional validation recoveries and for wheat (grain) a full validation (2 controls and 5 repetitions each at two fortification levels) were done within the course of the study 15-2127. The

average recoveries per fortification level and analyte were within the acceptable range of 70–110%. The RSD values were always below 20%.

Details of the application and residue information are summarized in [Table A 54](#).

No residues of deltamethrin (cis-deltamethrin) and its isomers AE F108569 (α -(R)-deltamethrin) and AE 0035073 (*trans*-deltamethrin) at or above the limit of quantification of the method were found in any of the untreated samples.

Analyte 1: deltamethrin (determined as deltamethrin, calculated as deltamethrin), Analyte 2: AE F108569 (determined as AE F108569, calculated as AE F108569), Analyte 3: AE 0035073 (determined as AE 0035073, calculated as AE 0035073)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)								
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum										
15-2129-01 Germany 49377 Vechta, OT Deindrup Europe, North F 2015	Wheat, spring Granus	1) 11.04.2015 2) 08.07.2015 - 17.07.2015 3) 10.08.2015 - 20.08.2015	7.50	300	2.5	29.06.2015/0 15.07.2015/16	71	whole plant without root	71	<0.05	<0.05	<0.05	<0.15	0* 0 7 14 21 21 <u>30</u> 35 <u>30</u> 35	(g) 15-2129 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 ear, grain: 0.01 mg/kg Analyte 1,2,3 whole plant without roots, rest of plant, straw: 0.05 mg/kg (l) Method Validation Data: 00855/M004, 15-2127 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 155 days Analyte 1, 2, 3 straw: 118 days Analyte 1, 2, 3 rest of plant: 134 days Analyte 1, 2, 3 grain: 123 days Analyte 1, 2, 3 ear: 132 days								
			7.50	300	2.5				77	0.23	<0.05	<0.05	0.33										
									77	0.079	<0.05	<0.05	0.18										
									83	0.066	<0.05	<0.05	0.17										
									ear	85	0.12	0.010	0.041			0.17							
									rest of plant	85	0.061	<0.05	<0.05			0.16							
									grain	89	<u><0.01</u>	<u><0.01</u>	<u><0.01</u>			<u><0.03</u>							
										89	<0.01	<0.01	<0.01			<0.03							
									straw	89	0.11	<0.05	0.050			0.21							
										89	<u>0.12</u>	<u><0.05</u>	<u>0.053</u>			<u>0.22</u>							
			15-2129-02 Netherlands 1775 PN Middenmeer Europe, North F 2015	Wheat, spring Tybalt	1) 18.03.2015 2) 20.06.2015 - 30.06.2015 3) 20.08.2015 - 27.08.2015				7.500	400	1.875	30.06.2015/0 14.07.2015/14	75			whole plant without root	75	<0.05	<0.05	<0.05	<0.15	0* 0 7 14 21 30 36 21 30 36	(g) 15-2129 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 grain: 0.01 mg/kg Analyte 1,2,3 whole plant without roots, straw: 0.05 mg/kg (l) Method Validation Data: 00855/M004, 15-2127 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 156 days Analyte 1, 2, 3 straw: 128 days Analyte 1, 2, 3 grain: 133 days
									7.500	400	1.875						77	0.16	<0.05	<0.05	0.26		
						77	0.11	<0.05	<0.05	0.21													
						77	0.070	<0.05	<0.05	0.17													
						grain	83	<0.01	<0.01	<0.01	<0.03												
							87	<u><0.01</u>	<u><0.01</u>	<u><0.01</u>	<u><0.03</u>												
							89	<0.01	<0.01	<0.01	<0.03												
						straw	83	0.096	<0.05	<0.05	0.20												
							87	<u>0.12</u>	<u><0.05</u>	<u>0.050</u>	<u>0.22</u>												
							89	0.13	<0.05	<0.05	0.23												

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

(a)	According to CODEX Classification / Guide	(e)	Days after last application (Label pre-harvest interval, PHI, underline)			(h)	Formulation type		(l)	Method validation					
(b)	Only if relevant	(f)	Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included			(i)	Application method		(m)	Storage (max)					
(c)	Year must be indicated					(j)	Method information			! based on date of analysis					
(d)	Either growth stage description or BBCH Code	(g)	Study reference			(k)	LOQ			P based on production date					
G	greenhouse	F	field	*	prior to last treatment			**	residue in control		#	no data available			
Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum		
15-2129-03 Germany 04720 Lüttewitz Europe, North F 2015	Wheat, winter Kerubino	1) 09.10.2014 2) 03.06.2015 - 07.06.2015 3) 20.07.2015 - 12.08.2015	7.50	300	2.5	09.06.2015/0 23.06.2015/14	73	whole plant without root grain straw	73	<0.05	<0.05	<0.05	<0.15	0*	(g) 15-2129 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 grain: 0.01 mg/kg Analyte 1,2,3 whole plant without roots, straw: 0.05 mg/kg (l) Method Validation Data: 00855/M004, 15-2127 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 177 days Analyte 1, 2, 3 straw: 149 days Analyte 1, 2, 3 grain: 154 days
			7.50	300	2.5				73	0.18	<0.05	<0.05	0.28	0	
									73	0.097	<0.05	<0.05	0.20	7	
									75	0.079	<0.05	<0.05	0.18	14	
									83	0.011	<0.01	<0.01	0.031	21	
									89	<0.01	<0.01	<0.01	<0.03	30	
									89	<0.01	<0.01	<0.01	<0.03	35	
									83	0.12	<0.05	<0.05	0.22	21	
									89	0.17	<0.05	0.072	0.29	30	
									89	0.17	<0.05	0.069	0.29	35	
			15-2129-04 Belgium 6210 Villers-Perwin Europe, North F 2015	Wheat, winter Edgar	1) 20.10.2014 2) 01.06.2015 - 16.06.2015 3) 24.07.2015 - 03.08.2015				7.50	300	2.5	10.06.2015/0 24.06.2015/14	73	whole plant without root grain straw	
7.50	300	2.5				73	0.16	<0.05	<0.05	0.26	0				
						73	0.085	<0.05	<0.05	0.19	7				
						83	0.051	<0.05	<0.05	0.15	14				
						85	<0.01	<0.01	<0.01	<0.03	21				
						89	<0.01	<0.01	<0.01	<0.03	30				
						89	<0.01	<0.01	<0.01	<0.03	35				
						85	0.068	<0.05	<0.05	0.17	21				
						89	0.13	<0.05	0.055	0.24	30				
						89	0.17	<0.05	0.078	0.30	35				

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

(a)	According to CODEX Classification / Guide	(e)	Days after last application (Label pre-harvest interval, PHI, underline)	(h)	Formulation type	(l)	Method validation
(b)	Only if relevant	(f)	Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included	(i)	Application method	(m)	Storage (max)
(c)	Year must be indicated			(j)	Method information		! based on date of analysis

(d) G	Either growth stage description or BBCH Code greenhouse F field	(g) *	Study reference prior to last treatment	(k) **	LOQ residue in control	#	P based on production date no data available
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A 2.2.3.4.2 Study report 16-2033

Comments of zRMS:	<p>Four field residue trials were conducted in northern Europe in 2016 to determine the magnitude of the residues of deltamethrin and BYI 02960 (common name flupyradifurone) in/on winter and spring wheat (grain, straw and whole plant without root) after two spray applications with Deltamethrin & Flupyradifurone EC 085, an EC formulation containing 10 g/L deltamethrin and 75 g/L BYI 02960 each at a rate of 0.75 L/ha, corresponding to 56.25 g BYI 02960/ha and 7.5 g/ha of deltamethrin with an interval of 13-14 days. The last application was done at a crop growth stage BBCH 77-87. The PHI was 30 days.</p> <p>Residues of BYI 02960 and difluoroacetic acid were determined by HPLC-MS/MS according to method 01304.</p> <p>The individual LOQs for BYI 02960 and difluoroacetic acid are 0.01 and 0.02 mg/kg, respectively in the sample materials whole plant without root, grain and straw.</p> <p>The average recoveries per fortification level were within the range of 70 – 110%. The RSD values were below 20%.</p> <p>Residue results (mg/kg) for grain (PHI: 30 days): E (FPF): 0.010; 0.012*; 0.032*; 0.061 E (DFA): 0.018; 0.067; 0.074; 0.14* RA (sum): 0.12; 2 x 0.23; 0.42* * Peak residues detected after PHI.</p> <p>The storage period of deep-frozen samples intended for the analysis of BYI 02960 and its metabolites in the treated samples ranged between 455 and 512 days.</p> <p>Residues of deltamethrin and its isomers AE 0035073 and AE F108569 were determined by HPLC-MS/MS according to method 00855/M004 with LOQ of 0.01 mg/kg for grain for each compound and 0.05 mg/kg for straw and whole plant without root for each compound. For deltamethrin and its two isomers average recoveries were at each fortification level within the acceptable range of 70 – 110% and the RSD values were below 20%.</p> <p>Residue results (mg/kg) in grain: E (deltamethrin): 4 x <0.01 RA (sum): 4 x <0.03</p> <p>The storage period of deep-frozen samples intended for the analysis of deltamethrin and its isomers in the treated samples ranged between 391 and 450 days.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.4.2/02
Title:	Determination of the residues of BYI 02960 and deltamethrin in/on winter and spring wheat after spray application of deltamethrin & flupyradifurone EC 085 in Belgium, Germany and the Netherlands
Report:	Kaussmann, M.; Kerkerling, S.; 2018; 16-2033; M-634190-01-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP 860.1500, Crop Field Trial
Deviations:	None
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Validity of the study: yes

Materials and methods

In 2016, 4 field trials were conducted in northern Europe (Belgium, Germany [2] and the Netherlands) to support the use of Sivanto Energy EC 085 in wheat. Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960). Two applications were made at an interval of 13-14 days, each at a rate of 0.75 L/ha, corresponding to 7.5 g/ha of deltamethrin. The last application was done at a crop growth stage of BBCH 77-87 (BBCH 77: late milk; BBCH 87: hard dough, grain content solid. Fingernail impression held). The envisaged PHI was 30 days.

Samples of whole plant without root were collected before and after the last treatment. Samples of mature grain and wheat straw were collected 30-31 and 35-36 days after the last treatment. All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 450 days). The maximum storage period of 450 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 36 months ([Czarnecki, J. J.; 1996; M-139715-01-1](#)).

The samples were analyzed according to method 00855/M004 ([Lakaschus, S.; Winter; O.; 2009; M 356934-01-1](#)) by LC-MS/MS using stable isotopically labelled internal standards. The LOQ in whole plant without root and straw was 0.05 mg/kg and 0.01 mg/kg in grain for deltamethrin (cis-deltamethrin), AE F108569 (α -(R)-deltamethrin) and AE 0035073 (*trans*-deltamethrin). The LOQ of the isomers is not expressed as deltamethrin. The calculated LOQ for the total residue (sum of deltamethrin and its isomers AE F108569 and AE 0035073) was 0.03 mg/kg in grain and 0.15 mg/kg in whole plant without root and straw.

Results

During the course of the present study, the method performance was checked/validated by concurrent recoveries. The individual and the average recoveries per fortification level and analyte were within the acceptable range of 70 – 110%, the overall RSD values were always below 20%. Full validation data is documented with the method 00855/M004 itself for matrices representing 5 major crop groups, including strawberry (fruit), tomato (fruit), lambs lettuce, green peas, wheat (grain), wheat (straw), barley (whole plant) and oilseed rape (seed). For wheat (whole plant without root and straw), a limited set (1 control, 3 repetitions each at two fortification levels) of additional validation recoveries and for wheat (grain) a full validation (2 controls and 5 repetitions each at two fortification levels) were done within the course of the study 15-2127. The average recoveries per fortification level and analyte were within the acceptable range of 70–110%. The RSD values were always below 20%.

Details of the application and residue information are summarized in [Table A 55](#).

No residues of deltamethrin (cis-deltamethrin) and its isomers AE F108569 (α -(R)-deltamethrin) and AE 0035073 (*trans*-deltamethrin) at or above the limit of quantification of the method were found in any of the untreated samples.

Table A 55: Summary of the trials of study 16-2033

Analyte 1: deltamethrin (determined as deltamethrin, calculated as deltamethrin), Analyte 2: AE F108569 (determined as AE F108569, calculated as AE F108569), Analyte 3: AE 0035073 (determined as AE 0035073, calculated as AE 0035073)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum		
16-2033-01 Belgium 6211 Mellet Europe, North F 2016	Wheat, spring Triso	1) 18.03.2016 2) 15.06.2016 - 24.06.2016 3) 10.08.2016 - 17.08.2016	7.5	250	3.0	22.06.2016/0 06.07.2016/14	83	whole plant	83	0.083	<0.05	<0.05	0.18	0*	(g) 16-2033 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 grain: 0.01 mg/kg Analyte 1,2,3 whole plant without roots, straw: 0.05 mg/kg (l) Method Validation Data: 00855/M004, 15-2127 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 442 days Analyte 1, 2, 3 straw: 413 days Analyte 1, 2, 3 grain: 410 days
			7.5	250	3.0			without root	83	0.24	<0.05	<0.05	0.34		
								grain	87	<0.01	<0.01	<0.01	<0.03		
									89	<0.01	<0.01	<0.01	<0.03		
								straw	87	0.41	<0.05	0.13	0.59		
									89	0.44	<0.05	0.14	0.63		
16-2033-02 Germany 42799 Leichlingen Europe, North F 2016	Wheat, spring Tybalt	1) 15.03.2016 2) 10.06.2016 - 16.06.2016 3) 15.08.2016 - 31.08.2016	7.5	300	2.5	06.07.2016/0 20.07.2016/14	85	whole plant	85	0.093	<0.05	<0.05	0.19	0*	(g) 16-2033 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 grain: 0.01 mg/kg Analyte 1,2,3 whole plant without roots, straw: 0.05 mg/kg (l) Method Validation Data: 00855/M004, 15-2127 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 428 days Analyte 1, 2, 3 straw: 399 days Analyte 1, 2, 3 grain: 396 days
			7.5	300	2.5			without root	85	0.23	<0.05	<0.05	0.33		
								grain	89	<0.01	<0.01	<0.01	<0.03		
									89	<0.01	<0.01	<0.01	<0.03		
								straw	89	0.13	<0.05	<0.05	0.23		
									89	0.091	<0.05	<0.05	0.19		

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated

- (e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

- (h) Formulation type
(i) Application method
(j) Method information

- (l) Method validation
(m) Storage (max)
! based on date of analysis

(d) G	Either growth stage description or BBCH Code greenhouse F field	(g) *	Study reference prior to last treatment	(k) **	LOQ residue in control	#	P based on production date no data available
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Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum		
16-2033-03 Netherlands 1606 MG Venhuizen Europe, North F 2016	Wheat, winter Mediator	1) 19.10.2015 3) 15.08.2016 - 25.08.2016	7.5	400	1.9	06.07.2016/0 20.07.2016/14	87	whole plant without root	87	0.095	<0.05	<0.05	0.20	0* 0	(g) 16-2033 (h) EC (deltamethrin 10 g/L .flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 grain: 0.01 mg/kg Analyte 1,2,3 whole plant without roots, straw: 0.05 mg/kg (l) Method Validation Data: 00855/M004, 15-2127 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 428 days Analyte 1, 2, 3 straw: 399 days Analyte 1, 2, 3 grain: 396 days
			7.5	400	1.9				87	0.24	<0.05	<0.05	0.34		
									89	<0.01	<0.01	<0.01	<0.03		
									92	<0.01	<0.01	<0.01	<0.03		
									89	0.21	<0.05	0.061	0.32		
									92	0.19	<0.05	0.059	0.30		
16-2033-04 Germany 59457 Werl- Niederbergstraße Europe, North F 2016	Wheat, winter Winnetou	1) 25.10.2015 2) 30.05.2016 - 08.06.2016 3) 27.07.2016 - 24.08.2016	7.5	300	2.5	15.06.2016/0 28.06.2016/13	77	whole plant without root	77	<0.05	<0.05	<0.05	<0.15	0* 0	(g) 16-2033 (h) EC (deltamethrin 10 g/L .flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 grain: 0.01 mg/kg Analyte 1,2,3 whole plant without roots, straw: 0.05 mg/kg (l) Method Validation Data: 00855/M004, 15-2127 (m) Storage: Analyte 1, 2, 3 whole plant without roots: 450 days Analyte 1, 2, 3 straw: 420 days Analyte 1, 2, 3 grain: 417 days
			7.5	300	2.5				77	0.16	<0.05	<0.05	0.26		
									89	<0.01	<0.01	<0.01	<0.03		
									89	<0.01	<0.01	<0.01	<0.03		
									89	0.20	<0.05	0.056	0.31		
									89	0.14	<0.05	<0.05	0.24		

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

- (e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference
* prior to last treatment

- (h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

- (l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.2.3.5 Maize/Corn

The critical GAPs (cGAP) for the proposed use of Sivanto Energy (DLT+FPF EC 85) in maize/corn (field/sweet) are summarized in [Table A 56](#).

Table A 56: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2015)	2 + 1	2 x 12.5 + 1 x 17.5	14	-	30
cGAP EU (Art. 12, EFSA, 2015)	1	1 g/ton	-	Post-harvest treatment	n.a.
Intended cGAP* (field corn) (number 118, 215, 262, 348, 367, 386)	1	7.5	-	BBCH 51-75	As per growth stage
Intended cGAP* (sweet corn) (number 121, 217, 265, 351, 370, 389)	1	7.5	-	BBCH 51-75	7

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

A 2.2.3.5.1 Study report 15-2134

Comments of zRMS:	<p>Four field residue trials were conducted in northern Europe in 2015 to determine the magnitude of the residues of deltamethrin and BYI 02960 (common name flupyradifurone) in/on maize/corn (green material, kernel (immature), kernel and rest of plant) after one spray application with Deltamethrin & Flupyradifurone EC 085, an EC formulation containing 10 g/L deltamethrin and 75 g/L BYI 02960 at a rate of 1.25 L/ha, corresponding to 93.75 g BYI 02960/ha and 12.5 g/ha of deltamethrin. The last application was done at a crop growth stage BBCH 75. The PHI for immature kernel samples was 7-8 days.</p> <p>Residues of BYI 02960 and difluoroacetic acid were determined by HPLC-MS/MS according to method 01212.</p> <p>The individual LOQs for BYI 02960 and difluoroacetic acid are 0.01 and 0.02 mg/kg, respectively in the sample materials green material, kernel (immature), kernel and rest of plant.</p> <p>The average recoveries per fortification level were within the range of 70 – 110%. The RSD values were below 20%.</p> <p>Residue results (mg/kg) for kernel: E (FPF): 4 x <0.01 E (DFA): 0.013; 0.016; 0.021; 0.026 RA (sum): 0.050; 0.057; 0.072; 0.088</p> <p>Residue results (mg/kg) for kernel, immature: E (FPF): 4 x <0.01 E (DFA): <0.007; 0.007; 0.009; 0.015 RA (sum): <0.03; 0.032; 0.038; 0.056</p> <p>The storage period of deep-frozen samples intended for the analysis of BYI 02960 and its metabolites in the treated samples ranged between 152 and 239 days.</p> <p>Residues of deltamethrin and its isomers AE 0035073 and AE F108569 were determined by HPLC-MS/MS according to method 00855/M004 with LOQ of 0.01 mg/kg for kernel for each compound and 0.05 mg/kg for green material and rest of plant for each compound. For deltamethrin and its two isomers average recoveries were at each fortification level within the acceptable range of 70 – 110% and the RSD values were below 20%.</p>
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	Residue results (mg/kg) in kernel: E (deltamethrin): 4 x <0.01 RA (sum): 4 x <0.03 Residue results (mg/kg) in kernel, immature: E (deltamethrin): 4 x <0.01 RA (sum): 4 x <0.03 The storage period of deep-frozen samples intended for the analysis of deltamethrin and its isomers in the treated samples ranged between 132 and 218 days. The study is acceptable.
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Reference:	KCA 6.3.5.2/01
Title:	Amendment no. 1: Determination of the residues of BYI 02960 and deltamethrin in/on maize/corn after spray application of deltamethrin & flupyradifurone EC 085 in Germany, Belgium and the Netherlands
Report:	Schulte, G.; 2017; 15-2134; M-574350-02-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial
Deviations:	yes, see report
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Validity of the study: yes

Materials and methods

In 2015, 4 field trials were conducted in northern Europe (Germany [2], Belgium and the Netherlands) to support the use of Sivanto Energy EC 085 in field and sweet corn (kernels). Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960).

One application was made at a rate of 1.25 L/ha, corresponding to 12.5 g/ha of deltamethrin. The application was done at a crop growth stage of BBCH 75 (BBCH 75: kernels in middle of cob yellowish-white (variety-dependent), content milky, about 40% dry matter).

Samples of green material were collected immediately after treatment and 7-8 and 17-24 days after application. Immature kernel samples were collected 7-8 days after the treatment in order to represent sweet corn. Mature samples (BBCH 89) of kernel and rest of plant were sampled on day 27-73. All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 218 days). The maximum storage period of 218 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 36 months ([Czarnecki, J. J.; 1996; M-139715-01-1](#)).

The samples were analyzed according to method 00855/M004 ([Lakaschus, S.; Winter; O.; 2009; M 356934-01-1](#)) by LC-MS/MS using stable isotopically labelled internal standards. The LOQ in green material and rest of plant was 0.05 mg/kg and 0.01 mg/kg in kernel for deltamethrin (cis-deltamethrin), AE F108569 (α -(R)-deltamethrin) and AE 0035073 (*trans*-deltamethrin). The LOQ of the isomers is not expressed as deltamethrin. The calculated LOQ for the total residue (sum of deltamethrin and its isomers AE F108569 and AE 0035073) was 0.03 mg/kg in kernel and 0.15 mg/kg in green material and rest of plant.

Results

During the course of this study, the method performance was checked/validated by concurrent recoveries. The individual and the average recoveries per fortification level and analyte were within the acceptable

range of 70 – 110%, the overall RSD values were always below 20%. Full validation data is documented with the method 00855/M004 itself for matrices representing 5 major crop groups, including strawberry (fruit), tomato (fruit), lambs lettuce, green peas, wheat (grain), wheat (straw), barley (whole plant) and oilseed rape (seed). For maize/corn (green material and kernel), a limited set (1 control, 3 repetitions each at two fortification levels) and a full validation (2 controls and 5 repetitions each at two fortification levels) for maize/corn (rest of plant) of additional validation recoveries were done within the course of the study 15-2133. The average recoveries per fortification level and analyte were within the acceptable range of 70 – 110% and the RSD values were always below 20%.

Details of the application and residue information are summarized in [Table A 57](#).

No residues of deltamethrin (cis-deltamethrin) and its isomers AE F108569 (α -(R)-deltamethrin) and AE 0035073 (*trans*-deltamethrin) at or above the limit of quantification of the method were found in any of the untreated samples.

Table A 57: Summary of the trials of study 15-2134

Analyte 1: deltamethrin (determined as deltamethrin, calculated as deltamethrin), Analyte 2: AE F108569 (determined as AE F108569, calculated as AE F108569), Analyte 3: AE 0035073 (determined as AE 0035073, calculated as AE 0035073)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum		
15-2134-01 Germany 49377 Vechta, OT Deindrup Europe, North F 2015	Maize / Corn, field Galbi CS Hybrid	1) 04.05.2015 2) 31.07.2015 - 14.08.2015 3) 15.10.2015 - 30.11.2015	12.5	400	3.13	31.08.2015/0	75	green material	75	0.062	<0.05	<0.05	0.16	0	(g) 15-2134 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 green material, rest of plant: 0.05 mg/kg Analyte 1,2,3 kernel, immature, kernel: 0.01 mg/kg (l) Method Validation Data: 15- 2133 (m) Storage: Analyte 1, 2, 3 rest of plant: 132 days Analyte 1, 2, 3 kernel, immature: 199 days Analyte 1, 2, 3 kernel: 134 days Analyte 1, 2, 3 green material: 206 days
									79	<0.05	<0.05	<0.05	<0.15	8	
									85	<0.05	<0.05	<0.05	<0.15	24	
								kernel, immature	79	<0.01	<0.01	<0.01	<0.03	8	
									89	<0.01	<0.01	<0.01	<0.03	73	
									89	<0.05	<0.05	<0.05	<0.15	73	

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum		
15-2134-02 Germany 51399 Burscheid Europe, North F 2015	Maize / Corn, field LG30.222	1) 12.05.2015 2) 28.07.2015 - 05.08.2015 3) 30.09.2015 - 30.10.2015	12.5	300	4.17	19.08.2015/0	75	green material	75	0.081	<0.05	<0.05	0.18	0	(g) 15-2134 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 green material, rest of plant: 0.05 mg/kg Analyte 1,2,3 kernel, immature, kernel: 0.01 mg/kg (l) Method Validation Data: 15- 2133 (m) Storage: Analyte 1, 2, 3 rest of plant: 175 days Analyte 1, 2, 3 kernel, immature: 212 days Analyte 1, 2, 3 kernel: 177 days Analyte 1, 2, 3 green material: 218 days
									79	0.050	<0.05	<0.05	0.15	7	
									85	<0.05	<0.05	<0.05	<0.15	21	
								kernel, immature	79	<0.01	<0.01	<0.01	<0.03	7	
								kernel	89	<0.01	<0.01	<0.01	<0.03	42	
								rest of plant	89	<0.05	<0.05	<0.05	<0.15	42	

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

- | | | | |
|--|---|-------------------------|-----------------------------|
| (a) According to CODEX Classification / Guide | (e) Days after last application (Label pre-harvest interval, PHI, underline) | (h) Formulation type | (l) Method validation |
| (b) Only if relevant | (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included | (i) Application method | (m) Storage (max) |
| (c) Year must be indicated | (g) Study reference | (j) Method information | ! based on date of analysis |
| (d) Either growth stage description or BBCH Code | (*) prior to last treatment | (k) LOQ | P based on production date |
| G greenhouse | | (**) residue in control | # no data available |
| F field | | | |

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum		
15-2134-03 Belgium 6221 Saint- Amand Europe, North F 2015	Maize / Corn, field Tokala Classic	1) 12.05.2015 2) 23.07.2015 - 05.08.2015 3) 22.10.2015 - 10.11.2015	12.5	350	3.57	19.08.2015/0	75	green material	75	0.11	<0.05	<0.05	0.21	0	(g) 15-2134 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 green material, rest of plant: 0.05 mg/kg Analyte 1,2,3 kernel, immature, kernel: 0.01 mg/kg (l) Method Validation Data : 15-2133 (m) Storage: Analyte 1, 2, 3 rest of plant: 153 days Analyte 1, 2, 3 kernel, immature: 212 days Analyte 1, 2, 3 kernel: 155 days Analyte 1, 2, 3 green material: 218 days
									79	0.051	<0.05	<0.05	0.15	7	
									85	<0.05	<0.05	<0.05	<0.15	23	
								kernel, immature	79	<0.01	<0.01	<0.01	<0.03	7	
								kernel	89	<0.01	<0.01	<0.01	<0.03	64	
								rest of plant	89	<0.05	<0.05	<0.05	<0.15	64	
15-2134-04 Netherlands 1771 SC Wieringerwerf Europe, North F 2015	Maize / Corn, field Ricardinio	1) 20.05.2015 2) 01.07.2015 - 01.08.2015 3) 01.10.2015 - 01.11.2015	12.5	600	2.08	11.09.2015/0	75	green material	75	0.13	<0.05	<0.05	0.23	0	(g) 15-2134 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 green material, rest of plant: 0.05 mg/kg Analyte 1,2,3 kernel, immature, kernel: 0.01 mg/kg (l) Method Validation Data : 15-2133 (m) Storage: Analyte 1, 2, 3 rest of plant: 167 days Analyte 1, 2, 3 kernel, immature: 189 days Analyte 1, 2, 3 kernel: 169 days Analyte 1, 2, 3 green material: 195 days
									79	0.080	<0.05	<0.05	0.18	7	
									85	0.070	<0.05	<0.05	0.17	17	
								kernel, immature	79	<0.01	<0.01	<0.01	<0.03	7	
								kernel	89	<0.01	<0.01	<0.01	<0.03	27	
								rest of plant	89	0.086	<0.05	<0.05	0.19	27	

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code

- (e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(g) Study reference

- (h) Formulation type
(i) Application method
(j) Method information
(k) LOQ

- (l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date

G	greenhouse	F	field	*	prior to last treatment	**	residue in control	#	no data available
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A 2.2.3.5.2 Study report 16-2192

Comments of zRMS:	<p>Four field residue trials were conducted in northern Europe in 2016 to determine the magnitude of the residues of deltamethrin and BYI 02960 (common name flupyradifurone) in/on maize/corn (green material, kernel (immature), kernel and rest of plant) after one spray application with Deltamethrin & Flupyradifurone EC 085, an EC formulation containing 10 g/L deltamethrin and 75 g/L BYI 02960 at a rate of 1.25 L/ha, corresponding to 93.75 g BYI 02960/ha and 12.5 g/ha of deltamethrin. The last application was done at a crop growth stage BBCH 75. The PHI for immature kernel samples was 7 days.</p> <p>Residues of BYI 02960 and difluoroacetic acid were determined by HPLC-MS/MS according to method 01304.</p> <p>The individual LOQs for BYI 02960 and difluoroacetic acid are 0.01 and 0.02 mg/kg, respectively in the sample materials green material, kernel (immature), kernel and rest of plant.</p> <p>The average recoveries per fortification level were within the range of 70 – 110%. The RSD values were below 20%.</p> <p>Residue results (mg/kg) for kernel: E (FPF): 4 x <0.01 E (DFA): 2x <0.007; 0.008; 0.018; RA (sum): 2 x <0.03; 0.035; 0.064;</p> <p>Residue results (mg/kg) for kernel, immature: E (FPF): 4 x <0.01 E (DFA): 3 x <0.007; 0.009; RA (sum): 3 x <0.03; 0.038.</p> <p>The storage period of deep-frozen samples intended for the analysis of BYI 02960 and its metabolites in the treated samples ranged between 141 and 246 days.</p> <p>Residues of deltamethrin and its isomers AE 0035073 and AE F108569 were determined by HPLC-MS/MS according to method 00855/M004.</p> <p>The individual LOQs for deltamethrin and its isomers are 0.05 mg/kg in green material and rest of plant and 0.01 mg/kg in mature and immature kernel.</p> <p>For deltamethrin and its two isomers average recoveries were at each fortification level within the acceptable range of 70 – 110% and the RSD values were below 20%.</p> <p>Residue results (mg/kg) in kernel: E (deltamethrin): 4 x <0.01 RA (sum): 4 x <0.03</p> <p>Residue results (mg/kg) in kernel, immature: E (deltamethrin): 4 x <0.01 RA (sum): 4 x <0.03</p> <p>The storage period of deep-frozen samples intended for the analysis of deltamethrin and its isomers in the treated samples ranged between 260 and 345 days.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.5.2/02
Title:	Determination of the residues of BYI 02960 and deltamethrin in/on maize/corn after spray application of deltamethrin & flupyradifurone EC 085 in Germany, Belgium and the Netherlands
Report:	Schulte, G.; Kerkerling, S.; 2018; 16-2192; M-628803-01-1
Authority registration No:	
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 OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP 860.1500, Crop Field Trial
Deviations:	None
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Validity of the study: yes

Materials and methods

In 2016, 4 field trials were conducted in northern Europe (Germany [2], Belgium and the Netherlands) to support the use of Sivanto Energy EC 085 in field and sweet corn (kernels). Sivanto Energy is an emulsifiable concentrate formulation containing 10 g/L deltamethrin and 75 g/L flupyradifurone (BYI 02960).

One application was made at a rate of 1.25 L/ha, corresponding to 12.5 g/ha of deltamethrin. In deviation the application rate in trial 16-2192-03 was underdosed by 6.4%, resulting in an actual rate of 1.17 L/ha, corresponding to 11.7 g/ha of deltamethrin. As this deviation is less than 25% and well within the European acceptance criteria for use pattern equality, the trial is considered valid. The application was done at a crop growth stage of BBCH 75 (BBCH 75: kernels in middle of cob yellowish-white (variety-dependent), content milky, about 40% dry matter).

Samples of green material were collected immediately after the treatment and 7 and 17-29 days (BBCH 85) after application. Immature kernel samples were collected 7 days after the treatment in order to represent sweet corn. Mature samples (BBCH 89) of kernel and rest of plant were sampled on day 28-61. All samples were frozen within 24 hours after sampling and stored at a temperature at or below -18°C until analysis (max. 345 days). The maximum storage period of 345 days is covered by the available storage stability study where the analytes have been proven to be stable for a period of at least 36 months ([Czarnecki, J. J.; 1996; M-139715-01-1](#)).

The samples were analyzed according to method 00855/M004 ([Lakaschus, S.; Winter, O.; 2009; M 356934-01-1](#)) by LC-MS/MS using stable isotopically labelled internal standards. The LOQ in green material and rest of plant was 0.05 mg/kg and 0.01 mg/kg in kernel for deltamethrin (cis-deltamethrin), AE F108569 (α -(R)-deltamethrin) and AE 0035073 (*trans*-deltamethrin). The LOQ of the isomers is not expressed as deltamethrin. The calculated LOQ for the total residue (sum of deltamethrin and its isomers AE F108569 and AE 0035073) was 0.03 mg/kg in kernel and 0.15 mg/kg in green material and rest of plant.

Results

During the course of this study, the method performance was checked/validated by concurrent recoveries. The individual and the average recoveries per fortification level and analyte were within the acceptable range of 70 – 110%, the overall RSD values were always below 20%. Full validation data is documented with the method 00855/M004 itself for matrices representing 5 major crop groups, including strawberry (fruit), tomato (fruit), lambs lettuce, green peas, wheat (grain), wheat (straw), barley (whole plant) and oilseed rape (seed). For maize/corn (green material and kernel), a limited set (1 control, 3 repetitions each at two fortification levels) and a full validation (2 controls and 5 repetitions each at two fortification levels) for maize/corn (rest of plant) of additional validation recoveries were done within the course of the study 15-2133. Additionally, within the course of the studies 16-2192 and 16-2100 which were conducted in parallel, additional validation recoveries (1 control and 2 repetitions each at two fortification levels for each study) for maize/corn (kernel and rest of plant) were analyzed. The average recoveries per fortification level and analyte were within the acceptable range of 70 – 110% and the RSD values were always below 20%.

Details of the application and residue information are summarized in [Table A 58](#).

No residues of deltamethrin (cis-deltamethrin) and its isomers AE F108569 (α -(R)-deltamethrin) and AE 0035073 (*trans*-deltamethrin) at or above the limit of quantification of the method were found in any of the untreated samples.

Table A 58: Summary of the trials of study 16-2192

Analyte 1: deltamethrin (determined as deltamethrin, calculated as deltamethrin), Analyte 2: AE F108569 (determined as AE F108569, calculated as AE F108569), Analyte 3: AE 0035073 (determined as AE 0035073, calculated as AE 0035073)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum		
16-2192-01 Germany 49377 Vechta, OT Langförden Europe, North F 2016	Maize / Corn, field Amball	1) 07.05.2016 2) 20.07.2016 - 10.08.2016 3) 15.10.2016 - 30.11.2016	12.5	400	3.13	25.08.2016/0	75	green material	75 79 85	0.093 0.10 0.12	<0.05 <0.05 <0.05	<0.05 <0.05 <0.05	0.19 0.20 0.22	0 7 29	(g) 16-2192 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 green material, rest of plant: 0.05 mg/kg Analyte 1,2,3 kernel, immature, kernel: 0.01 mg/kg (l) Method Validation Data: 15-2133, 16-2100, 16-2192 (m) Storage: Analyte 1, 2, 3 rest of plant: 283 days Analyte 1, 2, 3 kernel, immature: 343 days Analyte 1, 2, 3 kernel: 282 days Analyte 1, 2, 3 green material: 341 days
								kernel, immature	79	<u><0.01</u>	<u><0.01</u>	<u><0.01</u>	<u><0.03</u>	7	
								kernel	89	<u><0.01</u>	<u><0.01</u>	<u><0.01</u>	<u><0.03</u>	60	
								rest of plant	89	<u>0.13</u>	<u><0.05</u>	<u><0.05</u>	<u>0.23</u>	60	

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

- | | | | |
|--|---|-------------------------|-----------------------------|
| (a) According to CODEX Classification / Guide | (e) Days after last application (Label pre-harvest interval, PHI, underline) | (h) Formulation type | (l) Method validation |
| (b) Only if relevant | (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included | (i) Application method | (m) Storage (max) |
| (c) Year must be indicated | (g) Study reference | (j) Method information | ! based on date of analysis |
| (d) Either growth stage description or BBCH Code | (*) prior to last treatment | (k) LOQ | P based on production date |
| G greenhouse | | (**) residue in control | # no data available |
| F field | | | |

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum		
16-2192-02 Germany 51399 Burscheid Europe, North F 2016	Maize / Corn, field LG 30222	1) 09.05.2016 2) 25.07.2016 - 03.08.2016 3) 01.10.2016 - 31.10.2016	12.5	600	2.08	23.08.2016/0	75	green material	75	0.13	<0.05	<0.05	0.23	0	(g) 16-2192 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 green material, rest of plant: 0.05 mg/kg Analyte 1,2,3 kernel, immature, kernel: 0.01 mg/kg (l) Method Validation Data: 15-2133, 16-2100, 16-2192 (m) Storage: Analyte 1, 2, 3 rest of plant: 302 days Analyte 1, 2, 3 kernel, immature: 345 days Analyte 1, 2, 3 kernel: 301 days Analyte 1, 2, 3 green material: 343 days
									79	<0.05	<0.05	<0.05	<0.15	7	
									85	<0.05	<0.05	<0.05	<0.15	17	
								kernel, immature	79	<0.01	<0.01	<0.01	<0.03	7	
								kernel	89	<0.01	<0.01	<0.01	<0.03	43	
								rest of plant	89	<0.05	<0.05	<0.05	<0.15	43	

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

- (e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and
information which metabolites are included
(g) Study reference
* prior to last treatment

- (h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

- (l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum		
16-2192-03 Belgium 6211 Mellet Europe, North F 2016	Maize / Corn, field Avalon	1) 27.05.2016 2) 12.08.2016 - 28.08.2016 3) 15.11.2016	11.7	467	2.50	15.09.2016/0	75	green material	75	0.12	<0.05	<0.05	0.22	0	(g) 16-2192 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 green material, rest of plant: 0.05 mg/kg Analyte 1,2,3 kernel, immature, kernel: 0.01 mg/kg (l) Method Validation Data: 15- 2133, 16-2100, 16-2192 (m) Storage: Analyte 1, 2, 3 rest of plant: 261 days Analyte 1, 2, 3 kernel, immature: 322 days Analyte 1, 2, 3 kernel: 260 days Analyte 1, 2, 3 green material: 320 days
									79	0.059	<0.05	<0.05	0.16	7	
									85	<0.05	<0.05	<0.05	<0.15	18	
								kernel, immature	79	<0.01	<0.01	<0.01	<0.03	7	
								kernel	89	<0.01	<0.01	<0.01	<0.03	61	
								rest of plant	89	0.066	<0.05	<0.05	0.17	61	

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

- (e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and
information which metabolites are included
(g) Study reference
* prior to last treatment

- (h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

- (l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL					Analyte 1 deltamethrin	Analyte 2 AE F108569	Analyte 3 AE 0035073	Sum		
16-2192-04 Netherlands 1771 SC Wieringerwerf Europe, North F 2016	Maize / Corn, field LG 30.224	1) 21.04.2016 2) 20.07.2016 - 10.08.2016 3) 24.09.2016 - 15.10.2016	12.5	600	2.08	31.08.2016/0	75	green material	75	0.13	<0.05	<0.05	0.23	0	(g) 16-2192 (h) EC (deltamethrin 10 g/L ,flupyradifurone 75 g/L) (i) Application method: Spraying (j) Analytical method: 00855/M004 (k) LOQ: Analyte 1,2,3 green material, rest of plant: 0.05 mg/kg Analyte 1,2,3 kernel, immature, kernel: 0.01 mg/kg (l) Method Validation Data: 15- 2133, 16-2100, 16-2192 (m) Storage: Analyte 1, 2, 3 rest of plant: 309 days Analyte 1, 2, 3 kernel, immature: 337 days Analyte 1, 2, 3 kernel: 308 days Analyte 1, 2, 3 green material: 335 days
									79	0.059	<0.05	<0.05	0.16	7	
									85	0.050	<0.05	<0.05	0.15	19	
								kernel, immature	79	<0.01	<0.01	<0.01	<0.03	7	
								kernel	89	<0.01	<0.01	<0.01	<0.03	28	
								rest of plant	89	0.081	<0.05	<0.05	0.18	28	

*Sum of deltamethrin and its isomers AE F108569 and AE 0035073

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Either growth stage description or BBCH Code
G greenhouse F field

- (e) Days after last application (Label pre-harvest interval, PHI, underline)
(f) Remarks may include: Climatic conditions; Reference to analytical method and
information which metabolites are included
(g) Study reference
* prior to last treatment

- (h) Formulation type
(i) Application method
(j) Method information
(k) LOQ
** residue in control

- (l) Method validation
(m) Storage (max)
! based on date of analysis
P based on production date
no data available

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

No new data presented.

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

A 2.2.5.1 Distribution of the residue in peel/pulp

No additional studies are submitted.

A 2.2.5.2 Processing studies on a core set of representative processes

No additional studies are submitted.

A 2.2.6 Magnitude of residues in representative succeeding crops

No additional studies are submitted.

A 2.2.7 Other/Special Studies

No additional studies are required.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Flupyradifurone

Two separate residue definitions for monitoring were proposed in food of plant and animal origin: parent flupyradifurone (expressed as flupyradifurone) and second, its metabolite DFA (expressed as DFA). Since the residue definition for risk assessment comprises the sum of both compounds, a TMDI calculation, based on MRL values, is not reasonable.

Deltamethrin

Since the residue definition for risk assessment and for monitoring are different, a TMDI calculation, based on MRL values, is not reasonable.

A 3.2 IEDI calculations

Flupyradifurone (Scenario 1: Intake of primary crops and commodities of animal origin)



European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Flupyradifurone			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0.064	ARfD (mg/kg bw):	0.15
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2015	Year of evaluation:	2015

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/IEDI calculation (based on average food consumption)	53%	NL toddler	33.81	32%	Milk: Cattle	5%	Apples	4%	Wheat		7%
	30%	UK infant	19.44	21%	Milk: Cattle	3%	Wheat	2%	Bovine: Muscle/meat		3%
	27%	DE child	17.54	10%	Milk: Cattle	5%	Apples	4%	Wheat		6%
	27%	NL child	17.30	13%	Milk: Cattle	4%	Wheat	3%	Apples		5%
	26%	FR toddler 2 3 yr	16.88	16%	Milk: Cattle	3%	Wheat	2%	Bovine: Muscle/meat		3%
	26%	FR child 3 15 yr	16.54	12%	Milk: Cattle	5%	Wheat	3%	Bovine: Muscle/meat		6%
	22%	UK toddler	14.08	11%	Milk: Cattle	4%	Wheat	2%	Bovine: Muscle/meat		4%
	21%	SE general	13.69	8%	Bovine: Muscle/meat	7%	Milk: Cattle	3%	Wheat		3%
	20%	ES child	12.57	7%	Milk: Cattle	5%	Wheat	2%	Bovine: Muscle/meat		5%
	18%	DK child	11.82	7%	Milk: Cattle	4%	Wheat	2%	Bovine: Muscle/meat		5%
	18%	RO general	11.37	6%	Milk: Cattle	5%	Wheat	2%	Wine grapes		7%
	18%	GEMS/Food G07	11.28	4%	Wheat	3%	Milk: Cattle	2%	Bovine: Muscle/meat		7%
	17%	GEMS/Food G11	10.96	4%	Milk: Cattle	4%	Wheat	1%	Bovine: Muscle/meat		6%
	17%	GEMS/Food G15	10.74	5%	Wheat	4%	Milk: Cattle	1.0%	Barley		7%
	16%	GEMS/Food G08	10.39	4%	Wheat	3%	Milk: Cattle	1%	Barley		7%
	16%	GEMS/Food G10	10.27	4%	Wheat	3%	Milk: Cattle	2%	Bovine: Muscle/meat		6%
	16%	GEMS/Food G06	10.26	7%	Wheat	1%	Milk: Cattle	1%	Tomatoes		9%
	15%	DE women 14-50 yr	9.41	7%	Milk: Cattle	2%	Wheat	1%	Apples		4%
	15%	DE general	9.41	7%	Milk: Cattle	2%	Wheat	1%	Apples		4%
	13%	FR infant	8.56	9%	Milk: Cattle	0.8%	Wheat	0.7%	Apples		0.8%
	13%	IE adult	8.15	2%	Wheat	2%	Milk: Cattle	1%	Wine grapes		4%
	12%	NL general	7.99	5%	Milk: Cattle	2%	Wheat	1%	Bovine: Muscle/meat		3%
	12%	ES adult	7.52	3%	Milk: Cattle	2%	Wheat	1%	Bovine: Muscle/meat		3%
	11%	FR adult	7.07	2%	Milk: Cattle	2%	Wheat	2%	Wine grapes		5%
	10%	PT general	6.31	4%	Wheat	2%	Wine grapes	0.5%	Potatoes		7%
	10%	IT toddler	6.25	7%	Wheat	0.5%	Lettuces	0.4%	Tomatoes		7%
	8%	DK adult	5.26	3%	Milk: Cattle	1%	Wheat	0.9%	Bovine: Muscle/meat		2%
	7%	UK adult	4.78	2%	Wheat	2%	Milk: Cattle	1%	Bovine: Muscle/meat		3%
	7%	IT adult	4.69	4%	Wheat	0.7%	Lettuces	0.4%	Tomatoes		4%
	7%	UK vegetarian	4.52	2%	Wheat	2%	Milk: Cattle	0.8%	Wine grapes		3%
	6%	LT adult	4.04	2%	Milk: Cattle	1%	Wheat	0.8%	Apples		1%
	5%	FI 3 yr	3.03	1%	Wheat	0.7%	Oat	0.4%	Potatoes		2%
	4%	FI adult	2.79	2%	Coffee beans	0.3%	Wheat	0.3%	Wine grapes		0.9%
	4%	IE child	2.51	2%	Milk: Cattle	1%	Wheat	0.1%	Apples		1%
	4%	FI 6 yr	2.40	1.0%	Wheat	0.4%	Oat	0.4%	Potatoes		2%
	2%	PL general	1.59	0.9%	Apples	0.3%	Potatoes	0.3%	Table grapes		0.3%

Flupyradifurone (Scenario 2: Exposure to flupyradifurone-related residues from rotational crops):



Flupyradifurone			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0.064	ARfD (mg/kg bw):	0.15
Source of ADI:	EFSA/EC	Source of ARfD:	EFSA/EC
Year of evaluation:	2015	Year of evaluation:	2015

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/IEDI calculation (based on average food consumption)	16%	GEMS/Food G06	10.47	5%	Wheat	4%	Tomatoes	1%	Watermelons		11%
	12%	NL toddler	7.84	3%	Wheat	2%	Maize/corn	1%	Potatoes		7%
	11%	DK child	7.03	4%	Rye	3%	Wheat	2%	Cucumbers		8%
	11%	IE adult	6.85	2%	Wheat	1%	Peas	1%	Sweet potatoes		9%
	10%	RO general	6.46	3%	Wheat	2%	Tomatoes	1%	Potatoes		6%
	10%	GEMS/Food G15	6.40	3%	Wheat	1%	Tomatoes	1%	Potatoes		6%
	10%	UK toddler	6.33	4%	Beans	3%	Wheat	1%	Potatoes		7%
	10%	GEMS/Food G10	6.30	3%	Wheat	1%	Tomatoes	0.9%	Potatoes		7%
	9%	FR child 3 15 yr	5.95	3%	Wheat	0.9%	Lentils	0.9%	Beans		6%
	9%	GEMS/Food G08	5.92	3%	Wheat	1%	Potatoes	1%	Tomatoes		6%
	9%	IT toddler	5.81	4%	Wheat	1%	Tomatoes	1.0%	Other cereals		5%
	9%	ES child	5.45	3%	Wheat	1%	Lentils	1.0%	Tomatoes		6%
	9%	GEMS/Food G07	5.45	3%	Wheat	1%	Potatoes	1%	Tomatoes		5%
	8%	PT general	5.41	3%	Wheat	2%	Potatoes	0.9%	Tomatoes		6%
	8%	UK infant	5.22	2%	Beans	2%	Wheat	1%	Potatoes		6%
	8%	DE child	5.22	3%	Wheat	1.0%	Tomatoes	0.8%	Potatoes		5%
	8%	GEMS/Food G11	5.13	2%	Wheat	1%	Potatoes	0.9%	Tomatoes		5%
	7%	SE general	4.69	2%	Wheat	1%	Potatoes	0.8%	Tomatoes		5%
	7%	FR toddler 2 3 yr	4.47	2%	Wheat	1%	Beans (with pods)	0.6%	Potatoes		5%
	7%	NL child	4.45	3%	Wheat	1%	Potatoes	0.6%	Tomatoes		4%
	7%	FI 3 yr	4.30	1%	Potatoes	1%	Cucumbers	0.8%	Wheat		5%
	6%	IT adult	4.13	3%	Wheat	1%	Tomatoes	0.5%	Other cereals		4%
	6%	UK vegetarian	3.71	2%	Beans	1%	Wheat	0.6%	Tomatoes		4%
	6%	FI 6 yr	3.69	1%	Potatoes	0.7%	Cucumbers	0.6%	Wheat		5%
	6%	ES adult	3.54	2%	Wheat	0.8%	Tomatoes	0.5%	Lentils		4%
	5%	NL general	2.98	1%	Wheat	0.8%	Potatoes	0.4%	Tomatoes		3%
	5%	FR adult	2.97	1%	Wheat	0.6%	Beans	0.5%	Tomatoes		3%
	4%	DE general	2.73	1%	Wheat	0.6%	Tomatoes	0.4%	Potatoes		3%
	4%	DE women 14-50 yr	2.73	1%	Wheat	0.7%	Tomatoes	0.3%	Potatoes		3%
	4%	LT adult	2.70	1.0%	Potatoes	0.7%	Rye	0.7%	Wheat		3%
	4%	UK adult	2.63	1%	Wheat	1%	Beans	0.4%	Potatoes		3%
	4%	FR infant	2.41	0.7%	Beans (with pods)	0.6%	Potatoes	0.5%	Wheat		3%
	3%	DK adult	1.99	0.7%	Wheat	0.5%	Tomatoes	0.4%	Potatoes		2%
	3%	PL general	1.89	1%	Potatoes	0.9%	Tomatoes	0.2%	Head cabbages		3%
	3%	FI adult	1.82	0.5%	Tomatoes	0.5%	Rye	0.4%	Potatoes		3%
	2%	IE child	1.01	0.8%	Wheat	0.2%	Rice	0.2%	Potatoes		0.8%

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(F)				
LOQs (mg/kg) range from :		to:		
Toxicological reference values				
ADI (mg/kg bw/day):	0,01	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/IEDI calculation (based on average food consumption)	31%	NL toddler	3,12	12%	Milk: Cattle	3%	Apples	3%	Rice		
	18%	GEMS/Food G06	1,79	7%	Rice	2%	Wheat	1%	Tomatoes		
	17%	DE child	1,72	4%	Milk: Cattle	4%	Apples	1%	Wheat		
	17%	UK infant	1,69	8%	Milk: Cattle	3%	Rice	1%	Beans		
	17%	NL child	1,65	5%	Milk: Cattle	3%	Sugar beet roots	2%	Apples		
	15%	GEMS/Food G10	1,54	6%	Rice	1%	Wheat	1%	Milk: Cattle		
	15%	FR toddler 2 3 yr	1,54	6%	Milk: Cattle	3%	Rice	1,0%	Apples		
	15%	FR child 3 15 yr	1,51	5%	Milk: Cattle	2%	Rice	1%	Wheat		
	15%	UK toddler	1,46	4%	Milk: Cattle	3%	Rice	2%	Beans		
	14%	ES child	1,36	2%	Milk: Cattle	2%	Rice	2%	Olives for oil production		
	13%	GEMS/Food G08	1,29	2%	Olives for oil production	1%	Wheat	1%	Rice		
	12%	DK child	1,19	3%	Milk: Cattle	2%	Rye	1%	Wheat		
	12%	GEMS/Food G07	1,17	2%	Rice	1%	Milk: Cattle	1%	Wheat		
	11%	GEMS/Food G15	1,14	1%	Milk: Cattle	1%	Rice	1%	Wheat		
	11%	SE general	1,14	2%	Milk: Cattle	2%	Rice	1%	Bovine: Muscle/meat		
	11%	RO general	1,14	2%	Milk: Cattle	2%	Wheat	1%	Potatoes		
	11%	GEMS/Food G11	1,11	2%	Milk: Cattle	1%	Rice	1%	Potatoes		
	11%	PT general	1,05	3%	Rice	2%	Potatoes	1%	Wheat		
	9%	IE adult	0,92	1%	Rice	0,9%	Milk: Cattle	0,7%	Peas		
	9%	DE women 14-50 yr	0,92	2%	Milk: Cattle	1%	Sugar beet roots	0,8%	Apples		
	9%	DE general	0,89	2%	Milk: Cattle	1%	Sugar beet roots	0,7%	Apples		
	8%	ES adult	0,84	1%	Olives for oil production	1%	Rice	1%	Lettuces		
	8%	NL general	0,78	2%	Milk: Cattle	0,9%	Sugar beet roots	0,7%	Potatoes		
	7%	FR infant	0,72	3%	Milk: Cattle	0,6%	Potatoes	0,5%	Apples		
	7%	FI 3 yr	0,70	2%	Rice	1%	Potatoes	0,4%	Wheat		
	6%	UK vegetarian	0,64	2%	Rice	0,9%	Beans	0,7%	Milk: Cattle		
	6%	FR adult	0,62	0,9%	Milk: Cattle	0,8%	Wine grapes	0,7%	Rice		
	6%	FI 6 yr	0,57	2%	Rice	1%	Potatoes	0,3%	Wheat		
	6%	IT toddler	0,57	2%	Wheat	0,8%	Rice	0,6%	Lettuces		
	6%	UK adult	0,56	2%	Rice	0,6%	Milk: Cattle	0,6%	Beans		
	5%	LT adult	0,53	1,0%	Potatoes	0,9%	Rice	0,8%	Milk: Cattle		
	5%	IT adult	0,47	1%	Wheat	0,8%	Rice	0,7%	Lettuces		
	5%	DK adult	0,47	1%	Milk: Cattle	0,4%	Potatoes	0,4%	Rice		
	3%	IE child	0,32	1%	Rice	0,7%	Milk: Cattle	0,3%	Wheat		
	3%	PL general	0,30	1%	Potatoes	0,6%	Apples	0,3%	Tomatoes		
	3%	FI adult	0,27	0,6%	Rice	0,4%	Potatoes	0,3%	Lettuces		

A 3.3 IESTI calculations - Raw commodities

Flupyradifurone (Scenario 1):

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

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

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	95%	Table grapes	0 / 1.95	142	44%	Table grapes	0 / 1.95	66
	14%	Sweet corn	0 / 0.5	22	31%	Wine grapes	0 / 1.95	46
	12%	Wine grapes	0 / 1.95	18	5%	Sweet corn	0 / 0.5	8.0
	6%	Wheat	0 / 0.65	9.4	4%	Wheat	0 / 0.65	5.5
	3%	Barley	0 / 0.81	4.5	3%	Barley	0 / 0.81	3.9
	1%	Sorghum	0 / 0.64	2.1	0.3%	Oat	0 / 0.81	0.52
	0.6%	Oat	0 / 0.81	0.90	0.1%	Sorghum	0 / 0.64	0.19
	0.3%	Maize/corn	0 / 0.06	0.40	0.09%	Maize/corn	0 / 0.06	0.13
	0.2%	Sunflower seeds	0 / 0.09	0.28	0.06%	Sunflower seeds	0 / 0.09	0.09
	0.06%	Common millet/proso	0 / 0.06	0.08	0.04%	Common millet/proso	0 / 0.06	0.05

Flupyradifurone (Scenario 2):

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

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

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	5%	Sweet corn	0 / 0.17	7.4	2%	Wheat	0 / 0.42	3.5
	4%	Wheat	0 / 0.42	6.1	2%	Sweet corn	0 / 0.17	2.7
	2%	Barley	0 / 0.42	2.4	1%	Barley	0 / 0.42	2.0
	0.8%	Maize/corn	0 / 0.17	1.1	0.2%	Maize/corn	0 / 0.17	0.37
	0.4%	Sorghum	0 / 0.17	0.55	0.2%	Oat	0 / 0.42	0.27
	0.3%	Oat	0 / 0.42	0.47	0.1%	Common millet/proso	0 / 0.17	0.15
	0.2%	Sunflower seeds	0 / 0.09	0.29	0.06%	Sunflower seeds	0 / 0.09	0.09
	0.2%	Common millet/proso	0 / 0.17	0.24	0.03%	Sorghum	0 / 0.17	0.05

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Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

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

Show results for all crops

Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	26%	Table grapes	0 / 0,04	2,6	12%	Table grapes	0 / 0,04	1,2
	25%	Milk: Cattle	0 / 0,02	2,5	8%	Wine grapes	0 / 0,04	0,83
	13%	Sweet corn	0 / 0,03	1,3	8%	Milk: Cattle	0 / 0,02	0,77
	5%	Poultry: Muscle/meat	0 / 0,03	0,51	5%	Sweet corn	0 / 0,03	0,48
	5%	Milk: Goat	0 / 0,02	0,48	4%	Milk: Goat	0 / 0,02	0,37
Expand/collapse list	4%	Wheat	0 / 0,03	0,43	4%	Poultry: Muscle	0 / 0,03	0,35
	4%	Swine: Muscle/meat	0 / 0,03	0,36	3%	Milk: Sheep	0 / 0,02	0,30
	3%	Wine grapes	0 / 0,04	0,32	3%	Wheat	0 / 0,03	0,25
	3%	Barley	0 / 0,05	0,25	2%	Barley	0 / 0,05	0,22
	2%	Eggs: Chicken	0 / 0,02	0,25	2%	Swine: Fat tissue	0 / 0,09	0,18
	2%	Bovine: Muscle/meat	0 / 0,03	0,22	2%	Bovine: Muscle	0 / 0,03	0,17
	2%	Maize/corn	0 / 0,03	0,20	1%	Rye	0 / 0,03	0,15
	2%	Rye	0 / 0,03	0,19	1%	Swine: Muscle/meat	0 / 0,03	0,15
	2%	Bovine: Fat tissue	0 / 0,09	0,19	1%	Equine: Muscle/meat	0 / 0,03	0,14
	2%	Equine: Muscle/meat	0 / 0,03	0,18	1%	Sheep: Muscle/meat	0 / 0,03	0,14

A 3.4 IESTI calculations - Processed commodities

Flupyradifurone (Scenario 1):

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):			
---				---			
IESTI				IESTI			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
18%	Wine grapes / juice	0 / 0.62	27	12%	Wine grapes / wine	0 / 1.95	18
5%	Wheat / milling (flour)	0 / 0.65	7.9	9%	Wine grapes / juice	0 / 0.62	13
2%	Wheat / milling (wholemea	0 / 0.65	3.6	7%	Table grapes / raisins	0 / 9.17	11
2%	Oat / boiled	0 / 0.81	2.9	4%	Barley / beer	0 / 0.16	5.8
2%	Barley / cooked	0 / 0.81	2.9	2%	Wheat / bread/pizza	0 / 0.65	2.9
2%	Oat / milling (flakes)	0 / 0.81	2.4	2%	Wheat / pasta	0 / 0.65	2.5
1.0%	Barley / milling (flour)	0 / 0.81	1.5	2%	Wheat / bread	0 / 0.65	2.3
0.9%	Maize / oil	0 / 1.5	1.4	0.8%	Oat / boiled	0 / 0.81	1.2
0.2%	Millet / boiled	0 / 0.02	0.33	0.5%	Maize / oil	0 / 1.5	0.76
0.1%	Sunflower seeds / oils	0 / 0.18	0.21	0.09%	Millet / boiled	0 / 0.02	0.14
0.1%	Maize / processed (not spe	0 / 0.06	0.13	#Z AHL!	#Z AHL!	#Z AHL!	#Z AHL!

Flupyradifurone (Scenario 2):

Processed commodities	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):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI		MRL / input for RA Exposure		Highest % of ARfD/ADI		MRL / input for RA Exposure	
	Processed commodities		(mg/kg) (µg/kg bw)		Processed commodities		(mg/kg) (µg/kg bw)	
	3%	Wheat / milling (flour)	0 / 0.42	5.1	2%	Barley / beer	0 / 0.08	3.0
	3%	Maize / oil	0 / 4.25	4.0	1%	Maize / oil	0 / 4.25	2.2
	2%	Wheat / milling (wholemea	0 / 0.42	2.3	1%	Wheat / bread/pizza	0 / 0.42	1.8
	1%	Oat / boiled	0 / 0.42	1.5	1%	Wheat / pasta	0 / 0.42	1.6
1%	Barley / cooked	0 / 0.42	1.5	0.5%	Wheat / bread	0 / 0.42	0.71	
0.8%	Oat / milling (flakes)	0 / 0.42	1.3					
0.6%	Millet / boiled	0 / 0.07	0.92					
0.5%	Barley / milling (flour)	0 / 0.42	0.76					
0.1%	Sunflower seeds / oils	0 / 0.18	0.21					
0.1%	Maize / processed (not spe	0 / 0.17	0.20					
Expand/collapse list								
Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Flupyradifurone is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.								

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Processed commodities	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):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	14%	Wine grapes / juice	0 / 0,03	1,4	7%	Wine grapes / juice	0 / 0,03	0,69
	6%	Maize / oil	0 / 0,6	0,56	5%	Barley / beer	0 / 0,01	0,53
	3%	Barley / cooked	0 / 0,07	0,26	3%	Maize / oil	0 / 0,6	0,30
	1%	Barley / milling (flour)	0 / 0,07	0,13	0,5%	Oat / boiled	0 / 0,03	0,05
	1%	Oat / boiled	0 / 0,03	0,11	0,4%	Wheat / bread	0 / 0,01	0,04
	1,0%	Wheat / milling (flour)	0 / 0,01	0,10	0,08%	Wheat / bread/pizza	0 / 0	0,01
	0,9%	Oat / milling (flakes)	0 / 0,03	0,09	0,06%	Wheat / pasta	0 / 0	0,01
	0,7%	Sunflower seeds / oils	0 / 0,06	0,07	#NOMBRE!	#NOMBRE!	#NOMBRE!	#NOMBRE!
	0,7%	Wheat / milling (wholemea	0 / 0,01	0,07	#NOMBRE!	#NOMBRE!	#NOMBRE!	#NOMBRE!
	0,6%	Maize / processed (not spe	0 / 0,03	0,06	#NOMBRE!	#NOMBRE!	#NOMBRE!	#NOMBRE!

Appendix 4 Additional information provided by the applicant

No additional information.