

REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: 102000012886

Product name: Fluopyram + trifloxystrobin SC 500
(250 + 250 g/L)

Chemical active substance(s):

Fluopyram, 250 g/L

Trifloxystrobin, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Re-Authorisation)

Applicant: Bayer Crop Science Division

Submission date: 30/06/2020

updated 29/01/2021, June 2021

Finalisation date: September 2021 (initial Core Assessment)

February 2022 (final Core Assessment)

Version history

When	What
June 2020	Original Bayer submission
January 2021	Deletion of GAPs, residue trials and assessment related to southern zone and interzone. Update of acute risk assessment (deletion of crops not relevant for central zone use). Chronic risk remained identical.
June 2021	Summary of trials on currents from which the Conversion factor 1.3 is calculate.
September 2021	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 .
February 2022	Final report (Core Assessment after the commenting period) Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow, while not agreed use pattern is struck through and shaded .

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The product fluopyram + trifloxystrobin SC 500 (250 + 250 g/L) (FLU + TFS SC 500 / Product Code 102000012886) was not the representative formulation during the renewal of approval of trifloxystrobin. All data and information assessed during the EU re-evaluation of trifloxystrobin is considered EU peer-reviewed data. New data relied on by the applicant but not previously evaluated at EU peer review are summarised in Appendix 2.

Non renewed substance fluopyram: according to the guidance SANCO/2010/13170 rev. 14, 7 October 2016, for products containing two or more substances, there is no need to evaluate data related to the « non-renewed » substance(s). It is therefore our understanding that only data pertaining to combined tox assessment will be taken into consideration.

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Note:

This zonal evaluation was performed in line with Article 43 of Regulation (EC) No 1107/2009 due to renewal of trifloxystrobin at the EU level. Fluopyram was not yet renewed and only data for trifloxystrobin were subject of the re-evaluation at the zonal level.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation fluopyram + trifloxystrobin SC 500 (250 + 250 g/L) are presented in In the **below table uses referred as “ $F_{(G)}$ ” are for uses under walk-in tunnel and/or low tunnel/shelter**. In addition use numbers which are not mentioned below are considered less critical and covered by the cited use number i.e use 1 Asparagus /AUT covers uses n° 2 and 3 Asparagus in NLD and SVK cited in B0.

Non edible crops such as Bulbs, Ornamentals, Nurseries, Tree nurseries are not listed in the below GAP table as they are not relevant for the consumer risk assessment.

Table 7.1-1. They have been selected from the individual GAPs. A list of all intended uses is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment.

An exceedance of the current MRLs as laid down in EU Regulations is not expected.

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

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended use(s).

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

Data gaps

Noticed data gaps are: **none**.

~~Minor data gap for Asparagus: lack of determination of trifloxystrobin isomers in residue studies.~~

In the bellow table uses refered as “ $F_{(G)}$ ” are for uses under walk-in tunnel and/or low tunnel/shelter. In addition use numbers wich are not mentioned below are considered less critical and covered by the cited use number i.e use 1 Asparagus /AUT covers uses n° 2 and 3 Asparagus in NLD and SVK cited in B0.

Non edible crops such as Bulbs, Ornamentals, Nurseries, Tree nurseries are not listed in the below GAP table as they are not relevant for the consumer risk assessment.

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)



1	2	3	4	5	6	7		8				9			10		11
GAP number (see part B.0)*	Crop and/ or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests Controlled ****	Formulation		Application				Application rate per treatment			PHI (days)	Comment	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applic. (min)	kg as/hL min max	water L/ha min max	kg as/ha min max			
3	Asparagus (0270010)	north	FLU + TFS SC 500	F	BOTRCI, PLEOHE, PUCCAS	SC	FLU 250 TFS 250	Spray, foliar	40-95 30-35	1-2	10	0.033-0.067	300-600	FLU 0.200 TFS 0.200	Not applicable		RA
10, 13	Bean with pod (0260010)	north	FLU + TFS SC 500	F	BOTRCI, SCLESC	SC	FLU 250 TFS 250	Spray, foliar	59- 79-89	2	7	0.025-0.100	200-800	FLU 0.200 TFS 0.200	14		A
16	Bean without pod (0260020)	north	FLU + TFS SC 500	F	BOTRCI, SCLESC	SC	FLU 250 TFS 250	Spray, foliar	59- 79-89	2	7	0.025-0.100	200-800	FLU 0.200 TFS 0.200	14		A
22, 23, 28, 31	Blackberry (0153010) (covered by raspberry trials)	north	FLU + TFS SC 500	F _(G)	BOTRCI, DIDYAP	SC	FLU 250 TFS 250	Spray, foliar	15-89 13-89	2	7	0.017-0.100 0.013-0.067	200-1200 300-1500	FLU 0.200 TFS 0.200	3	Walk-in tunnel, low tunnel /shelter covered by field use	A
21	Blackberry (0153010) (covered by raspberry trials)	north	FLU + TFS SC 500	F	BOTRCI, SPHRMA, SPHRMU	SC	FLU 250 TFS 250	Spray, foliar	15-89	2	7	0.020	1000	FLU 0.200 TFS 0.200	3		A
33, 34, 39,45	Blueberry (0154010) (covered by currant trials)	north	FLU + TFS SC 500	F _(G)	BOTRCI, CRONRI, DREPRI, SPHRMU	SC	FLU 250 TFS 250	Spray, foliar	15-89 13-89	2	7	0.017-0.100 0.013-0.067	200-1200 300-1500	FLU 0.200 TFS 0.200	7	Walk-in tunnel, low tunnel /shelter covered by field use	A

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)	Comment	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applic. (min)	kg as/hL min max	water L/ha min max	kg as/ha min max			
32 604	Blueberry (0154010) (covered by currant trials)	north	FLU + TFS SC 500	F	(BOTRCI,) SPHRMU, (COLLSP)	SC	FLU 250 TFS 250	Spray, foliar	15-89	2	7	0.020	1000	FLU 0.200 TFS 0.200	7		A
471	Brassica sp. 0251080, 0251070) (covered by lettuce trials)	north	FLU + TFS SC 500	F	BOTRCI, SCLESC, SCLEMI, RHIZSO	SC	FLU 250 TFS 250	Spray, foliar	40-49	1	-	0.025-0.100	200-800	FLU 0.200 TFS 0.200	7		A
46	Buckthorn (0154010-018) (covered by currant trials)	north	FLU + TFS SC 500	F	CRONRI, DREPRI, SPHRMU, BOTRCI, COLLAC	SC	FLU 250 TFS 250	Spray, foliar	57-87	2	14	0.027-0.040	500-750	FLU 0.200 TFS 0.200	7		A
47, 48	Celeriac (0213030)	north	FLU + TFS SC 500	F	SCLESP, SEPTAP	SC	FLU 250 TFS 250	Spray, foliar	40/41-49	2	14	0.016-0.063	200-800	FLU 0.125 TFS 0.125	14		A
471	Chickpea (0260030-003) (covered by bean and pea trials)	north	FLU + TFS SC 500	F	BOTRCI, SCLESC, ASCOSP, ERYSPI	SC	FLU 250 TFS 250	Spray, foliar	55-89/79	1	-	0.050	400	FLU 0.200 TFS 0.200	21		A
276	Chicory, sugar loaf (0251030-005) (covered by lettuce trials)	north	FLU + TFS SC 500	F _(G)	BOTRCI, SCLESC	SC	FLU 250 TFS 250	Spray, foliar	13-49	2		0.025-0.100	200-800	FLU 0.200 TFS 0.200	7	Walk-in tunnel, low tunnel /shelter covered by field use	A
49	Chicory, sugar loaf (0251030-005)	north	FLU + TFS SC 500	F	BOTRCI, SCLESC	SC	FLU 250 TFS 250	Spray, foliar	13-49	1		0.025-0.100	200-800	FLU 0.200 TFS 0.200	7		A

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)	Comment	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applic. (min)	kg as/hL min max	water L/ha min max	kg as/ha min max			
	(covered by lettuce trials)																
51	Chicory, witloof (0255000)	north	FLU + TFS SC 500	F	BOTRCI, SCLESC	SC	FLU 250 TFS 250	Spray, foliar	13-49	1		0.019-0.075	200-800	FLU 0.150 TFS 0.150	21		A
57, 59, 578, 384	Cranberry (0154020) (covered by currant trials)	north	FLU + TFS SC 500	F _(G)	BOTRCI, CRONRI, DREPRI, SPHRMU	SC	FLU 250 TFS 250	Spray, foliar	15-89	2	7	0.017-0.100	200-1200	FLU 0.200 TFS 0.200	7	Walk-in tunnel, low tunnel /shelter covered by field use	A
56, 58	Cranberry (0154020) (covered by currant trials)	north	FLU + TFS SC 500	F	BOTRCI, SPHRMU, COLLSP	SC	FLU 250 TFS 250	Spray, foliar	15-89	2	14	0.013-0.075	200-1200	FLU 0.150 TFS 0.150	7		A
60, 333, 287	Cress, garden (0251040) (covered by lettuce trials)	north	FLU + TFS SC 500	F _(G)	BOTRCI, SCLESC	SC	FLU 250 TFS 250	Spray, foliar	12-49	2	7	0.020-0.040	500-1000	FLU 0.200 TFS 0.200	7	Walk-in tunnel, low tunnel /shelter covered by field use	A
61, 62, 472	Cress, garden (0251040) (covered by lettuce trials)	north	FLU + TFS SC 500	F	BOTRCI, SCLESC, SCLEMI, RHIZSO	SC	FLU 250 TFS 250	Spray, foliar	40-49	1	-	0.025-0.100	200-800	FLU 0.200 TFS 0.200	7		A
63	Currant (0154030)	north	FLU + TFS SC 500	F	BOTRCI, CRONRI, DREPRN, SPHRM	SC	FLU 250 TFS 250	Spray, foliar	15-89 39-87	2	7	0.020 0.027-0.040	1000 500-750	FLU 0.200 TFS 0.200	7		A
65	Currant (0154030)	north	FLU + TFS SC 500	F _(G)	BOTRCI, CRONRI, DREPRN, SPHRM	SC	FLU 250 TFS 250	Spray, foliar	15-89	2	7	0.020 0.027-0.040	1000 500-750	FLU 0.200 TFS 0.200	7	Walk-in tunnel, low tunnel /shelter covered by field use	A
496	Dewberry (0153020)	north	FLU + TFS SC 500	F	BOTRCI, SPHRMA, SPHRMU	SC	FLU 250 TFS 250	Spray, foliar	13-89	1	-	0.013-0.067	300-1500	FLU 0.200 TFS 0.200	3		A

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)	Comment	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applic. (min)	kg as/hL min max	water L/ha min max	kg as/ha min max			
	(covered by raspberry trials)																
105, 106	Dewberry (0153020) (covered by raspberry trials)	north	FLU + TFS SC 500	F	BOTRCI, SPHRMA, SPHRMU	SC	FLU 250 TFS 250	Spray, foliar	40-69	2	21	0.013-0.075	200-1200	FLU 0.150 TFS 0.150	3		A
103-104	Dewberry (0153020) (covered by raspberry trials)	north	FLU + TFS SC 500	$F_{(G)}$	BOTRCI, DIDYAP	SC	FLU 250 TFS 250	Spray, foliar	15-89 13-89	2	7	0.017-0.100 0.013-0.067	200-1200 300-1500	FLU 0.200 TFS 0.200	3	Walk-in tunnel, low tunnel /shelter covered by field use Removed from B0 as it is not registered in AUT	A
109,	Elderberry (covered by currant trials)	north	FLU + TFS SC 500	$F_{(G)}$	BOTRCI, CRONRI, DREPRI, SPHRMU	SC	FLU 250 TFS 250	Spray, foliar	15-89	2	7	0.017-0.100	200-1200	FLU 0.200 TFS 0.200	7	Walk-in tunnel, low tunnel /shelter covered by field use	A
108, 110	Elderberry (0154080) (covered by currant trials)	north	FLU + TFS SC 500	F	BOTRCI, CRONRI, DREPRI, SPHRMU	SC	FLU 250 TFS 250	Spray, foliar	15-89	2	14	0.013-0.075	200-1200	FLU 0.150 TFS 0.150	7		A
112, 113, 115, 116	Endive, winter (0251030) (covered by lettuce trials)	north	FLU + TFS SC 500	F	BOTRCI, SCLESC	SC	FLU 250 TFS 250	Spray, foliar	13-19 13- 40/49	1	-	0.025-0.100	200-800	FLU 0.200 TFS 0.200	7		A
126, 127,	Gooseberry (0154040)	north	FLU + TFS SC 500	$F_{(G)}$	BOTRCI, CRONRI,	SC	FLU 250 TFS 250	Spray, foliar	15-89	2	7	0.017-0.100	200-1200	FLU 0.200 TFS 0.200	7	Walk-in tunnel, low tunnel	A

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)	Comment	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applic. (min)	kg as/hL min max	water L/ha min max	kg as/ha min max			
	(covered by currant trials)				DREPRI, SPHRMU										/shelter covered by field use		
125, 605	Gooseberry (0154040) (covered by currant trials)	north	FLU + TFS SC 500	F	BOTRCI, CRONRI, DREPRI, SPHRMU	SC	FLU 250 TFS 250	Spray, foliar	15-89	2	7	0.020	1000	FLU 0.200 TFS 0.200	7		A
503, 506 138-140	Grape (0151000)	north	FLU + TFS SC 500	F	UNCINE, GUIGBI	SC	FLU 250 TFS 250	Spray, foliar	15-85 15-73/75	2	14	0.003-0.010 0.004-0.013	500-1500 400-1200	FLU 0.050 TFS 0.050	14		A
141	Hop (0700000)	north	FLU + TFS SC 500	F	SPHRFU	SC	FLU 250 TFS 250	Spray, foliar	37-79	2	14	0.005-0.0075	2000-3000	FLU 0.150 TFS 0.150	21		A
142,	Lamb’s lettuce (0251010) (covered by lettuce trials)	north	FLU + TFS SC 500	F _(G)	BOTRCI, SCLESC	SC	FLU 250 TFS 250	Spray, foliar	12-49	2	7	0.020-0.040	500-1000	FLU 0.200 TFS 0.200	7	Walk-in tunnel, low tunnel /shelter covered by field use	A
143, 145, 146, 508	Lamb’s lettuce (0251010) (covered by lettuce trials)	north	FLU + TFS SC 500	F	BOTRCI, SCLESC, SCLEMI, RHIZSO	SC	FLU 250 TFS 250	Spray, foliar	40-49	1	-	0.025-0.100	200-800	FLU 0.200 TFS 0.200	7		A
508, 509	Lamb’s lettuce (0251010) (covered by lettuce trials)	south	FLU + TFS SC 500	F	BOTRCI, SCLESC, SCLEMI, RHIZSO	SC	FLU 250 TFS 250	Spray, foliar	40-49	1	-	0.025-0.100	200-800	FLU 0.200 TFS 0.200	7		-
510	Lentil (0300020) (covered by bean & pea data)	north	FLU + TFS SC 500	F	BOTRCI, SCLESC	SC	FLU 250 TFS 250	Spray, foliar	55-89/79	1	-	0.050	400	FLU 0.200 TFS 0.200	7-14	Use for France removed	A

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)	Comment	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applic. (min)	kg as/hL min max	water L/ha min max	kg as/ha min max			
148, 153, 154,	Lettuce (0251020)	north	FLU + TFS SC 500	$F_{(G)}$	BOTRCI, SCLESC (SCLEMI)	SC	FLU 250 TFS 250	Spray, foliar	12-49 41-49	2	7	0,020-0,040 0,020-0.067	500-1000 300-1000	FLU 0.200 TFS 0.200	7	Walk-in tunnel, low tunnel /shelter covered by field use	A
161	Lettuce (0251020)	north	FLU + TFS SC 500	F	BOTRCI, SCLESC	SC	FLU 250 TFS 250	Spray, foliar	41-49	2	7	0.020-0.067	300-1000	FLU 0.200 TFS 0.200	7		A
165	Mulberries (0154060) (covered by currant trials)	north	FLU + TFS SC 500	$F_{(G)}$	BOTRCI, CRONRI, DREPRI, SPHRMU	SC	FLU 250 TFS 250	Spray, foliar	15-89	2	7	0.017-0.100	200-1200	FLU 0.200 TFS 0.200	7		A
167, 168	Mulberries (0154060) (covered by currant trials)	north	FLU + TFS SC 500	F	BOTRCI, CRONRI, DREPRI, SPHRMU	SC	FLU 250 TFS 250	Spray, foliar	15-89	2	14	0.013-0.075	200-1200	FLU 0.150 TFS 0.150	7		A
176	Pea with pod (0260030)	north	FLU + TFS SC 500	F	BOTRCI, SCLESC	SC	FLU 250 TFS 250	Spray, foliar	59- 79-89	2	7	0.025-0.100	200-800	FLU 0.200 TFS 0.200	14		A
180	Pea without pod (0260040)	north	FLU + TFS SC 500	F	BOTRCI, SCLESC	SC	FLU 250 TFS 250	Spray, foliar	59- 79-89	2	7	0.025-0.100	200-800	FLU 0.200 TFS 0.200	14		A
374	Rad.  chio (0251030- 004) (covered by lettuce trials)	north	FLU + TFS SC 500	$F_{(G)}$	BOTRCI, SCLESC	SC	FLU 250 TFS 250	Spray, foliar	13-49	2	7	0.025-0.100	200-800	FLU 0.200 TFS 0.200	7	Walk-in tunnel, low tunnel /shelter covered by field use	A
189	Rad.  chio (0251030- 004) (covered by lettuce trials)	north	FLU + TFS SC 500	F	BOTRCI, SCLESC	SC	FLU 250 TFS 250	Spray, foliar	13-49	1	-	0.025-0.100	200-800	FLU 0.200 TFS 0.200	7		A

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)	Comment	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applic. (min)	kg as/hL min max	water L/ha min max	kg as/ha min max			
192, 193	Raspberry (0153030)	north	FLU + TFS SC 500	F _(G)	BOTRCI, DIDYAP	SC	FLU 250 TFS 250	Spray, foliar	15-89 13-89	2	7	0.017-0.100 0.013-0.067	200-1200 300-1500	FLU 0.200 TFS 0.200	3	Walk-in tunnel, low tunnel /shelter covered by field use	A
191, 607	Raspberry (0153030)	north	FLU + TFS SC 500	F	BOTRCI, DIDYAP	SC	FLU 250 TFS 250	Spray, foliar	15-89	2	7	0.020	1000	FLU 0.200 TFS 0.200	3		A
205	Rocket salad (0251060) (covered by lettuce trials)	north	FLU + TFS SC 500	F _(G)	BOTRCI, SCLESC	SC	FLU 250 TFS 250	Spray, foliar	12-49	2	7	0.025-0.100	200-800	FLU 0.200 TFS 0.200	7	Walk-in tunnel, low tunnel /shelter covered by field use	A
206, 208, 209, 553	Rocket salad (0251060) (covered by lettuce trials)	north	FLU + TFS SC 500	F	BOTRCI, SCLESC, SCLEMI, RHIZSO	SC	FLU 250 TFS 250	Spray, foliar	13-40 13-19 40-49	1	-	0.025-0.100	200-800	FLU 0.200 TFS 0.200	7		A
211	Rosehip (0154050) (covered by currant trials)	north	FLU + TFS SC 500	F _(G)	BOTRCI, CRONRI, DREPRI, SPHRMU	SC	FLU 250 TFS 250	Spray, foliar	15-89	2	7	0.017-0.100	200-1200	FLU 0.200 TFS 0.200	7	Walk-in tunnel, low tunnel /shelter covered by field use	A
210, 212	Rosehip (0154050) (covered by currant trials)	north	FLU + TFS SC 500	F	BOTRCI, CRONRI, DREPRI, SPHRMU	SC	FLU 250 TFS 250	Spray, foliar	15-89	2	14	0.017-0.100	200-1200	FLU 0.200 TFS 0.200	7		A
555	Sea aster (0252020- 004) (covered by lettuce trials)	north	FLU + TFS SC 500	F	BOTRCI, SCLESC, SCLEMI, RHIZSO	SC	FLU 250 TFS 250	Spray, foliar	40-49	1	-	0.025-0.100	200-800	FLU 0.200 TFS 0.200	7		A
555, 556	Sea aster (0252020- 004)	south	FLU + TFS SC 500	F	BOTRCI, SCLESC, SCLEMI, RHIZSO	SC	FLU 250 TFS 250	Spray, foliar	40-49	1	-	0.025-0.100	200-800	FLU 0.200 TFS 0.200	7		-

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)	Comment	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applic. (min)	kg as/hL min max	water L/ha min max	kg as/ha min max			
	(covered by lettuce trials)																
397	Sea lavender (0252020-005) (covered by lettuce trials)	north	FLU + TFS SC 500	$F_{(G)}$	BOTRCI, SCLESC	SC	FLU 250 TFS 250	Spray, foliar	12-19	2	7	0.025-0.100	200-800	FLU 0.200 TFS 0.200	7	Walk-in tunnel, low tunnel /shelter covered by field use	A
214, 215, 557	Sea lavender (0252020-005) (covered by lettuce trials)	north	FLU + TFS SC 500	F	BOTRCI, SCLESC, (SCLEMI, RHIZSO)	SC	FLU 250 TFS 250	Spray, foliar	13-19 40-49	1	-	0.025-0.100	200-800	FLU 0.200 TFS 0.200	7		A
557, 558	Sea lavender (0252020-005) (covered by lettuce trials)	south	FLU + TFS SC 500	F	BOTRCI, SCLESC, SCLEMI, RHIZSO	SC	FLU 250 TFS 250	Spray, foliar	40-49	1	-	0.025-0.100	200-800	FLU 0.200 TFS 0.200	7		-
228,230	Strawberry (0152000)	north	FLU + TFS SC 500	$F_{(G)}$	variuos	SC	FLU 250 TFS 250	Spray, foliar	up to 89	2	7	0.020-0.067 0.025-0.100	300-1000 200-800	FLU 0.200 TFS 0.200	1	Walk-in tunnel, low tunnel /shelter covered by field use	A
227, 232, 236, 237, 239	Strawberry (0152000)	north	FLU + TFS SC 500	F	various	SC	FLU 250 TFS 250	Spray, foliar	60-89	2	7	0.040/0.033- 0.067	300- 500/600	FLU 0.200 TFS 0.200	1		A

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

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

**** 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

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 plant protection product fluopyram + trifloxystrobin SC 500 (250 + 250 g/L) is composed of fluopyram and trifloxystrobin.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Trifloxystrobin - Parent compound					
ADI	EFSA Journal 2017;15(10):4989	2017	0.1 mg/kg bw/day	2-year chronic tox rat ¹	100
ARfD			0.5 mg/kg bw/day	rabbit, developmental ²	100

¹ Gerspach R., 1997 - Doc [M-040512-02-1](#) (KCA 5.5/01)

² Khalil S., 1994 - Doc [M-039377-03-1](#) (KCA 5.6.2/02)

Table 7.1-3: Toxicological reference values for the dietary risk assessment of fluopyram

Reference value	Source	Year	Value	Study relied upon	Safety factor
Fluopyram - Parent compound					
ADI	EFSA Journal 2013;11(4):3052	2013	0.012 mg/kg bw/day	2-year rat study ¹	100
ARfD			0.5 mg/kg bw/day	Acute neurotoxicity study ²	100

¹ Kennel, P., 2008 – Doc [M-298339-01-1](#) (KIIA 5.5.2/02)

² Gilmore, R. G. and Hoss, H. E. (2007) – Doc [M-289073-01-1](#) (KIIA 5.7.1/01)

7.1.2.1 Summary for Trifloxystrobin

Trifloxystrobin was re-evaluated by the EU in the course of the AIR 3 procedures. The RMS, United Kingdom, published the DRAR in 2015⁶. EFSA published its Conclusion on pesticides peer review in 2017 (EFSA Journal 2017;15(10):4989) and the approval was renewed by the European Commission in 2018.

Within the course of these evaluations, it was documented that sufficient data have been presented to describe the nature of trifloxystrobin residues in relevant plant (primary, rotational, and processed) and animal species. Residue definitions were elucidated for both risk assessment and monitoring purposes.

In EFSA Journal 2017;15(10):4989 it is stated that “In the residue section, several data gaps were identified and the consumer risk assessment for the representative uses has to be regarded as provisional pending upon the toxicological assessment of all relevant compounds to be included in the residue definition for risk assessment for plants and animals.

A data gap was also identified on the level of residues, parent and its relevant metabolites, in bee products. In a screening assessment with the new acute reference dose (ARfD) and the highest residue levels of trifloxystrobin related to the uses evaluated under the Article 12 MRL review an exceedance of the ARfD was identified for one food commodity.”

Strawberry and grape uses were part of the re-evaluation renewal of trifloxystrobin by the EU. The other crops were not part of the re-evaluation renewal of the approval of the active substance. Nevertheless, an Article 12 review of MRLs was done in 2014 (EFSA Journal 2014;12(2):3592).

Table 7.1-4: Summary for Trifloxystrobin

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1-4	Asparagus	Yes	Yes (4 trials N-EU – determination of	Yes /post harvest treatment	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?
			trifloxystrobin and CGA 321113 metabolite; lack of determination of trifloxystrobin isomers)					
138- 140,	Grape	Yes	Yes (bridging trials 2 N-EU. Full sets for cGAP)	Yes	Yes	Yes		No
226 to 239	Strawberry	Yes	Yes (9 trials N-EU)	Yes	Yes	Yes		No
21-31, 52, 107- 111, 167, 168, 191- 204, 608,609	Canefruit	Yes	Yes (10 trials N-EU)	Yes	Yes	Yes		No
32, 46, 56, 58, 63-102, 125- 137 606	Other small fruits and berries	Yes	Yes (6 trials N-EU)	Yes	Yes	Yes		No
47, 48	Celeriac	Yes	Yes (8 trials N-EU)	Yes	Yes	Yes		No
49, 61, 62, 112 -116, 143- 164, 607, 508, 161, 189, 190, 205- 209,	Lettuce and other salad plants	Yes	Yes (9 trials N-EU)	Yes	Yes	Yes		No
51	Chicory witloof	Yes	Yes (4 trials N-EU)	Yes	Yes	Yes		No
9-14	Bean with pod	Yes	Yes (9 trials N-EU)	Yes	Yes	Yes		No
175- 178	Pea with pod	Yes	Yes (9 trials N-EU)	Yes	Yes	Yes		No
15-20	Bean without pod	Yes	Yes (10 trials N-EU)	Yes	Yes	Yes		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?
179- 182	Pea without pod	Yes	Yes (10 trials N-EU)	Yes	Yes	Yes		No
141	Hops	Yes	Yes (10 trials N-EU)	Yes	Yes	Yes		No

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

For the crops listed above (except asparagus) complete sets of residue data are reported for the formulation Fluopyram + Trifloxystrobin SC 500 ~~in post registration to confirm that~~
The available residue trials are in accordance with the existing plant residue definition for monitoring (Reg. (EU) 2019/1791) and confirm that the Maximum residue levels (MRLs) for trifloxystrobin for proposed uses ~~is are not exceeded. and to provide data according to the new residue definition for risk assessment.~~

The effects of processing on the nature of Trifloxystrobin residues have been investigated. Data on effects of processing on the amount of residue have been submitted.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

No long-term or acute risk has been identified for the supported crops. The use of Fluopyram + Trifloxystrobin SC 500 on the supported uses is therefore acceptable.

7.1.2.2 Summary for FLU + TFS SC 500

Table 7.1-5: Information on FLU + TFS SC 500 (KCA 6.8)

Crop	PHI for FLU + TFS SC 500 proposed by applicant	PHI sufficiently supported for			PHI for FLU + TFS SC 500 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Trifloxystrobin				
Asparagus	NR / F	NR / F Yes			F	-
Grape	14 days	Yes			14 days	
Strawberry	1 or 3 days	Yes			1 or 3 days	
Canefruit	3 days	Yes			3 days	
Other berries	7 days	Yes			7 days	
Celeriac	14 days	Yes			14 days	
Lettuce and salad plants	7 days	Yes			7 days	
Chicory witloof	21 days (field)	Yes			21 days	
Bean with pods	7 or 14 days	Yes			7 or 14 days	
Peas with pods	7 or 14 days	Yes			7 or 14 days	
Bean without pods Pea without pods	7 or 14 days	Yes			7 or 14 days	
Chickpea	21 days	Yes			21 days	
Lentil	7	No			14 days	PHI=14 days is proposed in accordance with presented by Applicant residue trials
Hops	21 days	Yes			21 days	

NR: not relevant

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

Table 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for FLU + TFS SC 500
Crop group	Led by Trifloxystrobin	Led by Fluopyram	
Stem vegetables other than leek	NR	120 days Cardoons, celeries, Florence fennels and crops belonging to the category “other stem vegetables” cannot be allowed as succeeding crops	Cardoons, celeries, Florence fennels and crops belonging to the category “other stem vegetables” cannot be allowed as succeeding crops (see zRMS comments below)
All other crops	NR	NR	NR

NR: not relevant

zRMS comments:

Fluopyram

Assessment is not required according to Article 43 of Regulation (EC) No 1107/2009.

However, the assessment prepared by the United Kingdom as Zonal Rapporteur Member State regarding succeeding crops and presented in Registration Report, Part B, Section 7 - Metabolism and Residues for Fluopyram + Trifloxystrobin SC 500 (250 + 250 g/L) (October 2018) was included in this evaluation.

“Rotational crops data has been considered previously in the EU DARs for Trifloxystrobin and are sufficient to cover the proposed GAPs. No further consideration is required for trifloxystrobin with regards to rotation crops. The occurrence of fluopyram residues in rotational crops was investigated in the framework of the peer review. Fluopyram is a highly persistent compound and residues of fluopyram are expected to be present in rotational crops. A default MRL of 0.1 mg/kg was proposed for root/tuber and leafy crops and of 0.01 mg/kg for cereals and oilseed and per annual crops, grown in rotation with crops treated with fluopyram. These proposals were derived from the rotational field studies conducted at the exaggerated dose rate of 500 g a.s./ha, since this dose level was considered to be more representative of the predicted concentration plateau reached in soil after 10 years of consecutive uses (0.08 mg/kg soil, 20 cm depth). However, since these MRLs were set as a result of this rotational crop consideration, the MRLs for cardoons, celeries, Florence fennels and “other stem vegetables” MRLs have been reduced to 0.01 mg/kg. Consequently, cardoons, celeries, Florence fennels and crops belonging to the category “other stem vegetables” cannot be allowed as succeeding crops as the possible residue levels in these crops as a result of being grown in rotation may exceed the current MRL (0.01 mg/kg) which is lower than the MRL originally proposed to accommodate residues in rotational crops.*

According to available data, specific mitigation measures should apply. The label restrictions should therefore read as follows:

‘Cardoons, celeries, Florence fennels and crops belonging to the category “other stem vegetables” cannot be allowed as succeeding crops’.

Remark:

In meantime, the values of MRL for celeries has been changed, from 0.01 mg/kg (Reg. (EU) 2017/978) to 20 mg/kg (Reg. (EU) 2021/618). Celeries are covered by an MRL of 20 mg/kg (reg EU 2021/1807) base on US critical GAP of 2 x 250 g/ha, PHI 0 d. The GAP supported with this label expansion on celeries is 2 x 125 g/ha, with interval 14 days , PHI =14days.

No exceedance of the MRL of 20 g/ha is therefore expected for celeries even if grown as succeeding crop. The label restrictions should therefore read as follows:

‘Cardoons, Florence fennels and crops belonging to the category “other stem vegetables” cannot be allowed as succeeding crops’.

Assessment

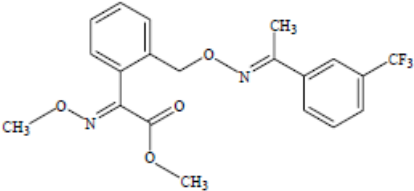
Data covering northern European residue region are submitted in this document. For the the MRLs also the summaries of evaluated data for the southern and indoor zone may be given in Table 7.2-9 for the sake of completeness.

7.2 Trifloxystrobin

General data on Trifloxystrobin are summarized in the table below. All information to be reported in this table can be found in/on:

- DAR, UK, 2000 [DAR, 2000]
- RAR, UK, 2017 [RAR, 2017]
- EFSA Journal 2017;15(10):4989 [EFSA, 2017]

Table 7.2-1: General information on trifloxystrobin

Active substance (ISO Common Name)	Trifloxystrobin
IUPAC	methyl (E)-methoxyimino-{(E)- α -[1- α -(α,α,α -trifluoro- <i>m</i> -tolyl)ethylidene-aminooxy]- <i>o</i> -tolyl] acetate methyl (2 <i>E</i>)-(methoxyimino)[2-({[(1 <i>E</i>)-{1-[3-(trifluoromethyl) phenyl]ethylidene} amino]oxy} methyl)phenyl]acetate (according to ACD Name Batch ver. 12.02 software)
Chemical structure	
Molecular formula	C ₂₀ H ₁₉ F ₃ N ₂ O ₄
Molar mass	408.4 g/mol
Chemical group	Strobilurins
Mode of action (if available)	Inhibition of the mitochondrial complex III o-site in fungal respiration (QoI)
Systemic	No
Company (ies)	Bayer AG, Division CropScience
Rapporteur Member State (RMS)	United Kingdom
Approval status	Approved COMMISSION REGULATION (EU) 2018/1060 of 26 July 2018
Restriction (e.g. is restricted to use as "...")	see Approval Directive / Regulation
Review Report	SANTE/10107/2018 - 25/05/2018
Current MRL regulation	Regulation (EC) No 2019/1791
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 2017 (EFSA Journal 2017;15(10):4989)
EFSA Journal: conclusion on article 12	Yes, EFSA 2014 (EFSA Journal 2014;12(2):3592)
Current MRL applications <i>on intended uses</i>	Sweet pepper (submission 2019, ongoing)

Technical trifloxystrobin consists of a mixture of four diastereomers with the parent substance (*EE* configuration of the two C=N double bonds) being the dominant isomer. The four isomers in the technical product have a typical composition of parent-*E/E* : *E/Z* : *Z/E* : *Z/Z* = 95.8 : 1.3 : 1.2 : 0.7.

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

The storage stability of trifloxystrobin in plant matrices for up to 24 months and in animal matrices for up to 12 months was addressed as sufficiently covered (EFSA, 2017), with some discrepancies for trifloxystrobin in wheat and for CGA 321113 in apple and peanut matrices.

New data

A new additional study (apple fruit, olive fruit, wheat grain) is submitted in the framework of this application. ~~Since the study is ongoing for in total 2 years, an interim report is submitted.~~
The final report with the 2 years results is submitted with this updated version.

In addition a short-term storage stability study on honey is submitted in the framework of this application.

The results of the evaluated data and the new studies are summarized below.

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			
Cucumber (fruit)	High water content	24 months (TFS + CGA 321113)	Kissling, 1999 M-038193-02-1 , report no. 154/96 SANCO/4339/2000 -Appendix III, 2003 KCA 6.1/01 , RAR & EFSA, 2017
Wheat (whole plant) ¹⁾		24 months (TFS + CGA 321113)	Kissling, 1999 M-038193-02-1 , report no. 154/96 SANCO/4339/2000 -Appendix III, 2003 KCA 6.1/01 , RAR & EFSA, 2017
Apple (fruit) ²⁾		18.5 months (TFS + CGA 321113)	Grunenwald, 1999a M-038204-02-1 , report no. 160-97 SANCO/4339/2000 -Appendix III, 2003 KCA 6.1/02 , RAR & EFSA, 2017
Corn (green material)		24 months (TFS + CGA 321113 + CGA 357261 + CGA 357262 + CGA 331409 + CGA 373466)	Schulte & Diehl, 2013 (Stuke, 2019) M-468560-01-1 , report no. MR-11/075 * KCA 6.1 / 01 , RAR & EFSA, 2017
Peanut (nutmeat) ²⁾	High oil content	18.5 months (TFS + CGA 321113)	Grunenwald, 1999a M-038204-02-1 , report no. 160-97 SANCO/4339/2000 -Appendix III, 2003 KCA 6.1/02 , RAR & EFSA, 2017
Oilseed rape (seed)		24 months (TFS + CGA 321113 + CGA 357261 + CGA 357262 + CGA 331409 + CGA 373466)	Schulte & Diehl, 2013 (Stuke, 2019) M-468560-01-1 , report no. MR-11/075 * KCA 6.1 / 01 , RAR & EFSA, 2017
Bean (dry seed)	High protein content	24 months (TFS + CGA 321113 + CGA 357261 + CGA 357262 + CGA 331409 + CGA 373466)	Schulte & Diehl, 2013 (Stuke, 2019) M-468560-01-1 , report no. MR-11/075 * KCA 6.1 / 01 , RAR & EFSA, 2017
Potato (tuber)	High starch content	24 months (TFS + CGA 321113)	Kissling, 1999 M-038193-02-1 , report no. 154/96 SANCO/4339/2000 -Appendix III, 2003 KCA 6.1/01 , RAR & EFSA, 2017
Wheat (grain) ¹⁾		24 months (TFS + CGA 321113)	Kissling, 1999 M-038193-02-1 , report no. 154/96 SANCO/4339/2000 -Appendix III, 2003 KCA 6.1/01 , RAR & EFSA, 2017
Rye (grain)		24 months	Schulte & Diehl, 2013 (Stuke, 2019) M-468560-01-1 , report no. MR-11/075 * KCA 6.1 / 01 , RAR & EFSA, 2017

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
		(TFS + CGA 321113 + CGA 357261 + CGA 357262 + CGA 331409 + CGA 373466)	
Orange (fruit)	High acid content	24 months (TFS + CGA 321113 + CGA 357261 + CGA 357262 + CGA 331409 + CGA 373466)	Schulte & Diehl, 2013 (Stuke, 2019) M-468560-01-1 , report no. MR-11/075 * KCA 6.1 / 07 01 , RAR & EFSA, 2017
Grape (berry)		24 months (TFS + CGA 321113)	Kissling, 1999 M-038193-02-1 , report no. 154/96 SANCO/4339/2000 -Appendix III, 2003 KCA 6.1/01 , RAR & EFSA, 2017
Apple (pomace) ²⁾	Processed products	18.5 months (TFS + CGA 321113)	Grunenwald, 1999a M-038204-02-1 , report no. 160-97 SANCO/4339/2000 -Appendix III, 2003 KCA 6.1/02 , RAR & EFSA, 2017
Peanut (oil) ²⁾		18.5 months (TFS + CGA 321113)	Grunenwald, 1999a M-038204-02-1 , report no. 160-97 SANCO/4339/2000 -Appendix III, 2003 KCA 6.1/02 , RAR & EFSA, 2017
Potato (granules/flakes)		18.5 months (TFS + CGA 321113)	Grunenwald, 1999a M-038204-02-1 , report no. 160-97 SANCO/4339/2000 -Appendix III, 2003 KCA 6.1/02 , RAR & EFSA, 2017
Grape (juice)		18.5 months (TFS + CGA 321113)	Grunenwald, 1999a M-038204-02-1 , report no. 160-97 SANCO/4339/2000 -Appendix III, 2003 KCA 6.1/02 , RAR & EFSA, 2017
Wheat (straw) ¹⁾	Others	24 months (TFS + CGA 321113)	Kissling, 1999 M-038193-02-1 , report no. 154/96 SANCO/4339/2000 -Appendix III, 2003 KCA 6.1/01 , RAR & EFSA, 2017
Peanut (hay) ²⁾		18.5 months (TFS + CGA 321113)	Grunenwald, 1999a M-038204-02-1 , report no. 160-97 SANCO/4339/2000 -Appendix III, 2003 KCA 6.1/02 , RAR & EFSA, 2017
Animal Products			
Ruminant	Muscle (Meat)	12 months (TFS + CGA 321113)	xxx, 1999b M-038213-02-2 , report no. 301-97 SANCO/4339/2000 -Appendix III, 2003 KCA 6.1/03 , RAR & EFSA, 2017
Ruminant	Liver	3-12 months (TFS + CGA 321113)	
Ruminant	Milk	7-12 months (TFS + CGA 321113)	
Poultry	Egg	6-12 months (TFS + CGA 321113)	
New data			
Bee products			
Bee	Honey	6 months (TFS + CGA 321113 + CGA 357261 + CGA 357262 + CGA 331409 + CGA 373466)	Roth, 2020 M-677808-01-1 , report no. S19-01123 KCA 6.1 / 03 See Appendix 2
Plant products			

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Wheat (grain)	High starch content	18 months (ongoing) 24 months (TFS + CGA 321113 + CGA 357261 + CGA 357262 + CGA 331409 + CGA 373466) at ≤ - 20°C	Schmiedt, 2020 M-684506-01-1 M-684506-02-1 , report no. P 642 18 7852 KCA 6.1 / 02 See Appendix 2
Apple (fruit)	High water content	18 months (ongoing) 24 months (TFS + CGA 321113 + CGA 357261 + CGA 357262 + CGA 331409 + CGA 373466) at ≤ - 20°C	
Olive (fruit)	High oil content	18 months (ongoing) 24 months (TFS + CGA 321113 + CGA 357261 + CGA 357262 + CGA 331409 + CGA 373466) at ≤ - 20°C	

TFS = Trifloxystrobin (CGA 279202)

* An amended version of the storage stability study MR-11/075 is available (Stuke, 2019) and is submitted with this dossier.

¹⁾ Recoveries of Trifloxystrobin residues were found to be below 70 % in wheat whole plant (at 118 days), in wheat straw (at 357 days) and in wheat grain (at 357 days). It was agreed at the Pesticides Peer Review TC 146 that the degradation of residues in wheat at these time points was mainly related to analytical performance deficiencies instead of an actual degradation of the residues of trifloxystrobin in wheat. Recoveries were acceptable at later time intervals, including at the 24 month storage period (EFSA Conclusion, 2017)

²⁾ Recoveries of CGA 321113 were reported below 70% at several timepoints in apple fruit and apple wet pomace and in peanut nutmeat and peanut hay. It was agreed at the Pesticides Peer Review TC 146 that these studies were not acceptable and since significant variations in the concentrations in these matrices over various timepoints was observed then it was not possible to conclude on the stability of this metabolite in these commodities. (EFSA Conclusion, 2017)

Conclusion on stability of residues during storage

All residue data referred to and/or reported within the present submission are covered by the storage period evaluated in the course of the EU peer review and submitted within this dRR.

zRMS comments:

In the EFSA Journal 2017;15(10):4989 it is stated that “Storage stability data demonstrated that trifloxystrobin is stable up to 24 months in high water, high oil, high protein, high starch, high acid content commodities, while in processed commodities it was stable up to 18.5 months. Although small deficiencies of trifloxystrobin residues stability in wheat (whole plant, grain and straw) were highlighted during the expert meeting, low recoveries (< 70%) for some time intervals were linked to the performance of the analytical method and not to the degradation of the compound. Stability of trifloxystrobin isomers and CGA 321113 was also investigated and found to be stable up to 24 months in high water (except pome fruits), high oil (except peanut nutmeat), high protein, high starch and high acid commodities. Since the stability of CGA 321113 on apples was not demonstrated, and considering that CGA 321113 is proposed to be included in the risk assessment residue definition as well as pome fruits are representative crops for the renewal, additional data to prove the stability of this metabolite in pome fruits are required (data gap)”.

Additional storage stability studies were submitted in the framework of this application.

1. Stuke, S.; 2019; P642110501; M-468560-04-1: „Amendment no. 3: Storage stability of CGA 279202, CGA 357262, CGA 357261, CGA331409, CGA 321113 and CGA 373466 in plant matrices for 24 months”

The study results demonstrate that the residues of trifloxystrobin (CGA 279202), its three isomers (CGA 357262, CGA 357261 and CGA 331409) and of the metabolite CGA 321113 (M5) and its isomer CGA 373466 are stable under freezer storage conditions at -18° C or below in bean dry seed (high-protein content commodity), corn green material (high-water content commodity), rye grain (high-starch content commodity), rape seed (high-oil content commodity) and orange fruit (high-acid content commodity), for at least 24 months.

2. Schmiedt, S.; 2020; P 642 18 7852; M-684506-01-1 - final report of the study “*Storage stability of CGA 279202 (trifloxystrobin), CGA 357262, CGA 357261, CGA331409, CGA 321113 and CGA 373466 in olive (fruit), apple (fruit) and wheat (grain) for 24 months*”.

It is concluded that all analytes: trifloxystrobin (CGA 279202), CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 can be considered stable in the investigated matrices: wheat grain, olive fruit and apple fruit under deep-freezer storage conditions ($\leq -20^{\circ}\text{C}$) for at least 24 months.

3. Roth, A.; 2020; S19-01123; M-677808-01-1: “Residue analytical method 01598 and short term storage stability of trifloxystrobin (CGA 279202) and its isomers / metabolites CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 in/on honey by HPLC-MS/MS”.

It is concluded that all method validation data are in compliance with the guideline SANCO/825/00, rev. 8.1.

All analytes (trifloxystrobin (CGA 279202), its three isomers CGA 357262, CGA 357261 and CGA 331409, metabolite CGA 321113 and its isomer CGA 373466) can be considered stable in the honey under deep-freezer storage conditions ($\leq -18^{\circ}\text{C}$) for at least 6 months.

The new studies are acceptable.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

The storage stability of pesticide residues in sample extracts is generally checked during the development of the applicable analytical residue methods.

In analytical method 01313 ([M-411496-02-1](#), [Stuke, S. 2011, amended 2013](#)), all analytes were found to be stable in tested extracts of corn (green material), kidney bean (seed), wheat (grain), rape (seed), orange (fruit) and hop (cone, kiln dried) for at least 27 days at $4^{\circ}\text{C} \pm 3^{\circ}\text{C}$.

In analytical method 01300/M005 ([M-453914-02-1](#), [Winter, O., Amann, S. 2013, amended 2013](#)), trifloxystrobin and CGA 321113 were found to be stable in tested extracts of bovine kidney, milk and poultry's eggs for at least seven days. In addition trifloxystrobin was found to be stable in bovine fat and meat for at least 4 days and in bovine liver for at least 13 days. CGA 321113 was found to be stable in bovine liver and fat for at least 4 days, while it declined about 40% in bovine meat within four days.

Additionally, during residue analyses on regular sample sets, the analytical performance of the methods must be checked with concurrent recoveries on each sample set. Therefore, the relevant information on the stability in the final or any intermediate step can be derived from the fortification experiments performed during method validation. Every analytical batch does contain at least one concurrent recovery which is handled and stored in parallel to the residue samples. If the recoveries in the fortified samples are within acceptable ranges, stability is considered to be sufficient.

Conclusion on stability of residues in sample extracts

It can be concluded, that trifloxystrobin, its isomers and CGA 321113 and its isomer were found to be stable in final plant extracts at $4^{\circ}\text{C} \pm 3^{\circ}\text{C}$ in the dark for at least 27 days (corn green material, kidney bean seed, rape seed, orange fruit, hop kiln-dried cone). Therefore, in all final extracts the analytes are stable for at least 3 weeks.

Moreover, in all studies recovery experiments were performed concurrently with the analysis of samples. In all trials presented in this dossier, the recovery rates were within acceptable ranges (70-110%), meaning that residues were stable in sample extracts.

Available data are considered acceptable to support of the intended uses for the product in small cereals.

zRMS comments:

Information given by the Applicant is sufficient.
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 trifloxystrobin (CGA 279202) has been investigated in wheat, apple, cucumber, sugar beet and peanut. The studies were considered in the framework of the peer review under Directive 91/414/EEC (DAR UK, 2000) and for renewal of approval (EFSA Journal 2017;15(10):4989).

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G ^(a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruit crops	Apple	[CF ₃ -phenyl-(U)- ¹⁴ C] trifloxystrobin	foliar treatment, G	100 g as/ha	4	Foliage: day 0 after 1 st and 4 th appl., day 14 after last appl. fruit: day 0 after 4 th appl. and, day 14 (maturity)	400 g as/ha in total, 4-week interval	Kiffe, 1998 M-034389-04-1 , KCA 6.2.1/05 RAR & EFSA, 2017
Fruit crops	Apple	[glyoxyl-phenyl-(U)- ¹⁴ C] trifloxystrobin	foliar treatment, G	100 g as/ha	4	Foliage: day 0 after 1 st and 4 th appl., day 14 after last appl. fruit: day 0 after 4 th appl. and, day 14 (maturity)	400 g as/ha in total, 4-week interval	Kiffe, 1997 M-034423-01-1 , KCA 6.2.1/06 RAR & EFSA, 2017
Fruit crops	Cucumber	[CF ₃ -phenyl-(U)- ¹⁴ C] trifloxystrobin	foliar treatment, G	276-302 g as/ha	3	Foliage, fruits: Day 0, 1 (fruit only) and 7 after last appl.	880 g as/ha in total, 7 day interval	Stingelin, 1997 M-034442-01-1 , KCA 6.2.1/07 RAR & EFSA, 2017
Fruit crops	Cucumber	[glyoxyl-phenyl-(U)- ¹⁴ C] trifloxystrobin	foliar treatment, G	220-326 g as/ha	3	Foliage, fruits: Day 0, 1 (fruit only) and 7 after last appl.	772 g as/ha in total, 7 day interval	Stingelin, 1997 M-034445-01-1 , KCA 6.2.1/08 RAR & EFSA, 2017
Cereals	Wheat	[CF ₃ -phenyl-(U)- ¹⁴ C] trifloxystrobin	foliar treatment, F	250 g as/ha or 500 g as/ha	2	Shoots: day 0 after 1 st and 2 nd appl. Ears and stalks: day 24 after 2 nd appl. Grain, husks, straw: day 52 after 2 nd appl., day 49 after appl. for 2N rate	500 g as/ha in total (BBCH 30/31 and BBCH 49-51)	Gross, 1999 M-034018-04-1 , Gross, 1997 M-034053-01-1 , KCA 6.2.1/01-02 RAR & EFSA, 2017
Cereals	Wheat	[glyoxyl-phenyl-(U)- ¹⁴ C] trifloxystrobin	foliar treatment, F	250 g as/ha	2	Shoots: day 0 after 1 st and 2 nd appl. Ears and stalks: day 24 after 2 nd appl. Grain, husks, straw: day 52 after 2 nd appl.	500 g as/ha in total (BBCH 30/31 and BBCH 49-51)	Stingelin, 1997 M-034352-02-1 Stingelin, 1997 M-034368-01-1 , KCA 6.2.1/03-04 RAR & EFSA, 2017

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G ^(a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
Cereals	Wheat	[CF ₃ -phenyl-(U)- ¹⁴ C] trifloxystrobin	foliar treatment, F	250 g as/ha	2	Immature wheat (hay fraction): day 3 Grain and straw: day 35	500 g as/ha in total (BBCH 33 and BBCH 69)	Reiner and Bongartz, 2002, M-070885-01-1 KCA 6.2.1/09 RAR & EFSA, 2017
Cereals	Wheat	[glyoxyl-phenyl-(U)- ¹⁴ C] trifloxystrobin	foliar treatment, F	250 g as/ha	2	Immature wheat (hay fraction): day 3 Grain and straw: day 35	500 g as/ha in total (BBCH 33 and BBCH 69)	Reiner and Bongartz, 2002, M-072024-01-1 , KCA 6.2.1/10 RAR & EFSA, 2017
Root crops	Sugar beet	CF ₃ -phenyl-(U)- ¹⁴ C] trifloxystrobin	foliar treatment, F	130 g as/ha and overdose exp. 692-768 g as/ha	3	Tops and roots: Day 0 after each appl, day 21 and 45 after last appl.	395 g as/ha in total (starting BBCH 39, 3-w intervals) Overdose experiment: 2153 g as/ha in total	Kiffe, 2000 M-069117-01-1 KCA 6.2.1/11 RAR & EFSA, 2017
Root crops	Sugar beet	[glyoxyl-phenyl-(U)- ¹⁴ C] trifloxystrobin	foliar treatment, F	130 g as/ha	3	Tops and roots: Day 0 after each appl., day 21 and 45 after last appl.	395 g as/ha in total (starting BBCH 39, 3-w intervals) Overdose experiment: 2153 g as/ha in total	Kiffe, 2000 M-069125-01-1 KCA 6.2.1/12 RAR & EFSA, 2017
Pulses / Oilseeds	Peanut	[CF ₃ -phenyl-(U)- ¹⁴ C] and [glyoxyl-phenyl-(U)- ¹⁴ C]	foliar treatment, F	505 g as/ha [14C-GP] and 533 g as/ha [14C-TP]	4	Immature vines: day 0 and day 14 after 1 st appl. hay, mature pods (separated into nutmeat and shell): day 14 after last appl.	2020 g as/ha in total for [glyoxyl-phenyl-(U)- ¹⁴ C] and 2130 g as/ha for [CF ₃ -phenyl-(U)- ¹⁴ C]	Rezaaiyan, 1997, M-038413-01-1 Rezaaiyan, 1997, M-137152-01-1 KCA 6.2.1/13-14 RAR & EFSA, 2017

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

Summary of plant metabolism studies reported in the EU

EFSA Journal 2017;15(10):4989 summarises and concludes on the plant metabolism studies.

Conclusion on metabolism in primary crops

Excerpt from EFSA Journal 2017;15(10):4989:

Metabolism of trifloxystrobin in primary crops was investigated upon foliar spray application on cereals (wheat), fruits (apple, cucumber) , in root (sugar beet), and pulses / oilseeds (peanuts) using trifluoro-phenyl-¹⁴C-labelled trifloxystrobin and glyoxyl-phenyl-¹⁴C-labelled trifloxystrobin.

The peer review (EFSA Journal 2017;15(10):4989) assessed these data and concluded that the parent compound was the major component of the total radioactive residues (TRR) in all crops accounting for maximum 83% TRRs in apple, 87% TRRs in cucumbers, 58% TRRs in sugar beet roots and 65% TRRs in

sugar beet tops, while in peanut hay 47% of TRRs. In wheat, the metabolism pattern was more extensive with the parent trifloxystrobin accounting for max. 20% of TRRs in grain and 19% TRRs in straw. On the contrary, in peanut meat, the parent was recovered together with its metabolites (CGA 357262, CGA 357261 and CGA 331409) and the metabolite CGA 321113, accounting up to 6% of TRRs. In addition, in all investigated crops, besides parent trifloxystrobin, the three isomers (CGA 357262, CGA 357261 and CGA 331409) and the metabolite CGA 321113 were also present.

Although recovered at < 10% of TRRs, the absolute amount was significant (0.05 mg/kg in apple, cucumbers and > 0.1 mg/kg in peanut hay and wheat straw). No major quantitative differences in the metabolic pattern were observed between the ¹⁴C-GP and ¹⁴C-TP labelled trifloxystrobin. The results from field trials on pome fruits, grapes and strawberries confirmed the metabolic pattern with the three isomers CGA 357262, GA 357261, CGA 331409 and CGA 321113, found up to 0.07 mg/kg. Although not fully compliant with the GAP in terms of preharvest interval (PHI), the metabolism studies were considered reliable and sufficient to elucidate the metabolic pathway of trifloxystrobin.

Based on these metabolism studies, a general residue definition for monitoring was proposed as trifloxystrobin while for risk assessment the residue definition is proposed as: trifloxystrobin, its three isomers (CGA 357262, CGA 357261, CGA 331409) and CGA 321113.

zRMS comments:

Information given by the Applicant is sufficient.

In EFSA Journal 2018;16(1):5154 it is stated that “*In the framework of the Article 12 MRL review and the renewal of the approval (EFSA, 2014, 2017), the metabolism of trifloxystrobin following foliar treatment was investigated in primary crops belonging to the groups of fruits and fruiting vegetables (apple, cucumber), root and tuber vegetables (sugar beet), cereals (wheat) and pulses and oilseeds (peanut). In the metabolism studies, the parent compound was the major component of the total radioactive residues (TRR) in all crops. Besides trifloxystrobin, its three isomers CGA 357262, GA 357261, CGA 331409 and its metabolite CGA321113 were also present, all individually accounting for less than 10% of TRRs, but in absolute amounts up to 0.05 mg/kg in apple and cucumbers and > 0.1 mg/kg in peanut hay and wheat straw.*”

Residue definition:

The residue definition for enforcement: trifloxystrobin.

The residue definition for risk assessment: trifloxystrobin, its three isomers (CGA 357262, CGA 357261, CGA 331409) and CGA 321113.

According to the EFSA Journal 2017;15(10):4989 it should be noted, however, that the toxicity of the three isomers and CGA 321113 needs still to be addressed.

The current residue definition for plants set in Regulation (EC) No 396/2005 (Reg. (EU) 2019/1791) is identical to the residue definition for enforcement derived in the peer review (trifloxystrobin). For products of animal origin - terrestrial animals (code 1000000 except 1040000) the definition is: the sum of trifloxystrobin and its metabolite (E, E)-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino-oxymethyl]-phenyl}-acetic acid (CGA 321113).

No further data are required.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

The metabolism of trifloxystrobin in leafy crops (lettuce), root crops (radish) and cereals (wheat) grown in rotation has been considered in the framework of the peer review under Directive 91/414/EEC (UK, 2000) and for renewal of approval (EFSA Journal 2017;15(10):4989).

The characteristics of the available studies are summarised in Table below.

No new data submitted in the framework of this application.

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

Table 7.2-4. Summary of metabolism studies in rotational crops								
Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT/PBI)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy crops	Lettuce	TP- ¹⁴ C (a)	Bare soil, F	0.5	31 120 365	69 181 419	Harvest at maturity of the crops, for small grain cereals additional immature “whole tops” as representative for forage and fodder	Gross, 1998 M-038288-02-1 KCA 6.6.1/01
		GP- ¹⁴ C (a)						Stingelin, 1997 M-038296-01-1 , KCA 6.6.1/02 RAR & EFSA, 2017
Root / tuber crops	Radish	TP- ¹⁴ C (a)	Bare soil, F	0.5	31 120 365	69 ^(d) 181 ^(d) 419 ^(d)		Gross, 1998 M-038288-02-1 KCA 6.6.1/01
		GP- ¹⁴ C (a)						Stingelin, 1997 M-038296-01-1 , KCA 6.6.1/02 RAR & EFSA, 2017
Cereals (small grain)	Wheat	TP- ¹⁴ C (a)	Bare soil, F	0.5	Spring wheat: 31 365	76 (b) 440 (b) 120 (c) 468 (c)		Gross, 1998 M-038288-02-1 KCA 6.6.1/01
		GP- ¹⁴ C (a)			Winter wheat: 174	223 (b) 419 (b) 454 (c)		Stingelin, 1997 M-038296-01-1 , KCA 6.6.1/02 RAR & EFSA, 2017

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

PBI = plant back interval

^(a) TP = [trifluorophenyl-(U)-¹⁴C]; GP = [glyoxyl-phenyl-(U)-¹⁴C] trifloxystrobin

^(b) sampling of forage

^(c) sampling of grain, husk and straw

^(d) sampling of radish tops and roots

Summary of plant metabolism studies reported in the EU

EFSA Journal 2017;15(10):4989 summarises and concludes on the plant metabolism studies.

Conclusion on metabolism in rotational crops

Excerpt from EFSA Journal 2017;15(10):4989:

Confined rotational crops metabolism studies were conducted on leafy crops (lettuce), root crops (radish) and cereals (wheat) using ¹⁴C-labelled TP [Trifluoro-phenyl-¹⁴C-labelled] and GP [glyoxyl-phenyl-¹⁴C-labelled] trifloxystrobin applied to the bare soil at the rate of 0.5 kg/ha (1.7N) at 31, 120/174 and 365 days plant back intervals (PBIs). The TRRs declined significantly from the first to the third rotation from 0.037 to 0.004 mg/kg for wheat grains, and from 0.025 to 0.005 mg/kg in lettuce. Trifloxystrobin and its isomers accounted for max. 15% of TRRs in radish, while trifluoroacetic acid (TFA) was the main metabolite, representing 12%, 23% and 13% of the TRRs in radish root, top and wheat straw, respectively. Due to the

low level of the total TRRs, it is not expected to find significant levels of TFA in food and feed succeeding crops; thus, the experts considered no need to include the TFA in the risk assessment residue definition and the same residue definitions as for primary crops are applicable. [...] Three rotational field trials in lettuce, turnip and wheat conducted with 1,128 g/ha (7.5N) at 30-day PBI were available. They were analysed for trifloxystrobin and CGA 321113 and the results were all below the LOQ (0.02 mg/kg).

Based on the rotational confined crop studies it was concluded that the same residue definitions as for primary crops are applicable. and that relevant residue levels are unlikely to occur in rotational crops.

zRMS comments:

Information given by the Applicant is sufficient. The metabolism of trifloxystrobin in rotational crops was sufficiently investigated during the renewal of approval of the active substance. The metabolism of trifloxystrobin was assessed in lettuce, radish and wheat grown in rotation after application to bare soil at a rate of 500 g a.s./ha. Based on these studies, it was concluded that metabolism in primary and rotational crops is similar (EFSA, 2014). All crops under consideration, except small fruits and berries may be grown in rotation. No further data are required.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

The nature of residues in processed commodities was considered in the framework of the peer review under Directive 91/414/EEC (DAR UK, 2000). Additional information on the nature of residues was presented for renewal. In the DAR (UK, 2000), a study was evaluated which was conducted with [¹⁴C-TP]- and [¹⁴C-GP]- trifloxystrobin in aqueous solution at pH ranging between 1 and 13 and at temperatures ranging between 25-60°C (United Kingdom, 2000). Trifloxystrobin was stable at pH 5 under the range of temperatures and no isomerisation of the parent compound occurred. In neutral and alkaline conditions, CGA 321113 was the major metabolite.

For the purpose of renewal of approval in the DRAR (UK 2017), a hydrolysis study performed at three test conditions (20 minutes at 90°C, pH 4; 60 minutes at 100°C pH 5; 20 minutes at 120°C, pH 6) was evaluated. Trifloxystrobin was hydrolytically stable under conditions simulating pasteurisation, showed minor degradation under baking/brewing/boiling conditions (2.6 % of TRR) and significant degradation under sterilisation (22.5 % of TRR). The main degradation product observed was the metabolite CGA 321113 (2 % at pH 5; 21 % at pH 6).

Summary of EFSA Journal 2017;15(10):4989

Under the standard hydrolysis conditions, trifloxystrobin remained stable under pasteurisation and baking/brewing/boiling but degraded significantly under sterilisation into CGA 321113 (up to 21.5% degradation); therefore, the residue definition for risk assessment in processed commodities is proposed as trifloxystrobin and CGA 321113.

No new data submitted in the framework of this application.

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

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	stable under these conditions Trifloxystrobin (100%)	Morgenroth, 2000 M-047519-01-1 KCA 6.5/01 RAR & EFSA 2017
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	2.6% degradation (Trifloxystrobin 97.4%), mainly (2%) to CGA 321113	
Sterilisation (20 minutes, 120°C, pH 6)	21.5% degradation, mainly (ca. 20%) to CGA 321113	

Conclusion on nature of residues in processed commodities

In the DAR (UK, 2000), and in the Conclusion on Pesticides Peer Review (EFSA Journal 2017;15(10):4989) it was concluded that for risk assessment the residue definition for processed

commodities is the sum of trifloxystrobin and CGA 321113 (M5), expressed as trifloxystrobin and thus remains unchanged (while it differs for primary crops in the 2017 evaluation).

zRMS comments:

Information given by the Applicant is sufficient.

In EFSA Journal 2018;16(1):5154 it is stated that “*Studies investigating the effect of processing on the nature of trifloxystrobin (hydrolysis studies) showed that under conditions simulating pasteurisation trifloxystrobin remained stable, whereas under baking/brewing/boiling conditions minor and under sterilisation significant degradation to CGA 321113 (approximately 20%) occurred. It was concluded that the metabolic pattern of trifloxystrobin in raw commodities is similar to that as in processed commodities (EFSA, 2014).*”

The residue definition for enforcement for processed commodities is parent trifloxystrobin.

For risk assessment the residue definition for processed commodities is the sum of trifloxystrobin and CGA 321113 (M5), expressed as trifloxystrobin.

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 vegetables (apple, cucumber), Cereals (wheat), Root and tuber vegetables (sugar beet), Pulses and oilseeds (peanut)
Rotational crops covered	Leafy vegetables (lettuce), Root and tuber vegetables (radish), Cereals (wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Under the standard hydrolysis conditions, trifloxystrobin remained stable under pasteurisation and baking/brewing/boiling but degraded significantly into M5 (CGA 321113) under sterilisation (up to 20%).
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Trifloxystrobin (UK, 2000) Trifloxystrobin (EFSA Reasoned Opinion 2009-2015) Trifloxystrobin (Peer review, EFSA Conclusion 2017) <u>Trifloxystrobin (Reg. (EU) 2019/1791)</u>
Plant residue definition for risk assessment	<u>Trifloxystrobin (UK, 2000)</u> Sum of trifloxystrobin and its metabolite CGA 321113, expressed as trifloxystrobin (EFSA Reasoned Opinion 2009-2015) <u>EFSA Conclusion 2017;15(10):4989:</u> Primary crops: Sum of trifloxystrobin, its 3 isomers (CGA 357262, CGA 357261 and CGA 331409) and CGA 321113 (M5), expressed as trifloxystrobin Processed commodities: Sum of trifloxystrobin and CGA 321113 (M5), expressed as trifloxystrobin
Conversion factor from enforcement to RA	Residue definition Sum of trifloxystrobin and its metabolite CGA 321113 (EFSA Journal 2014; 12(2):3592): 2.0 root and tuber vegetables 1.2 fruits and fruiting vegetables 1.0 leafy and stem vegetables Residue definition Sum of trifloxystrobin, its 3 isomers (CGA 357262, CGA 357261 and CGA 331409) and CGA 321113 (M5) (EFSA Journal 2017;15(10):4989):

	1.8 pome fruit 1.3 grape 1.4 strawberry
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7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

Livestock metabolism studies in lactating goats and in laying hens using ^{14}C -labelled trifloxystrobin were considered in the framework of the peer review under Directive 91/414/EEC (DAR UK, 2000) and for renewal of approval (EFSA Journal 2017;15(10):4989).

Summary of EFSA Journal 2017;15(10):4989

Livestock metabolism studies were investigated for 4 consecutive days by using [^{14}C -GP] or [^{14}C -TP] labels at maximum dose of 7.7 mg/kg bw per day for laying hens and 4.24 mg/kg bw per day for lactating goats. Although the dosing period is not compliant with the current recommendations, the studies were found to be acceptable to elucidate the metabolic pattern. In goats, parent trifloxystrobin was predominant accounting from 51% to 79% for the ^{14}C -TP labelled and from 74 to 82% for the ^{14}C -GP labelled form in milk, muscle and fat while CGA 321113 was the main compound of the total residues in liver and kidney (39% and 73% TRR, respectively for the ^{14}C -GP labelled and 13% to 54%, respectively for the ^{14}C -TP labelled form). Conjugates of CGA 321113 were also at significant levels in liver (up to 39% TRR) but at a lower proportion in milk and kidney (13% and 18% TRR, respectively). In poultry, parent compound was predominant in fat and muscle, while CGA 321113 was predominant in egg white. In both metabolism studies, the plateau concentration was not reached in eggs and milk and the total radioactive residues cannot be considered as fully reliable.

No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference	
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling		
EU data									
Lactating ruminants	Goat	TP- ¹⁴ C ^(a)	2	4.2	4	Milk	twice daily	xxx, 1997 M-034501-01-1 , KCA 6.2.3/01 RAR & EFSA, 2017	
				Urine and faeces		daily			
				Tissues		at sacrifice			
		GP- ¹⁴ C ^(a)		4.1		Milk	twice daily	xxx, 1997 M-034517-01-1 , KCA 6.2.3/02 RAR & EFSA, 2017	
				Urine and faeces		daily			
				Tissues		at sacrifice			
Laying poultry	Hens	TP- ¹⁴ C ^(a)	5	7.7	4	Eggs	twice daily	xxx, 1997 M-034526-01-1 , KCA 6.2.2/01 RAR & EFSA, 2017	
							Excreta		daily
							Tissues		at sacrifice
Laying poultry	Hens	GP- ¹⁴ C ^(a)		6.7		Eggs	twice daily	xxx, 1998 M-034534-01-1 , KCA 6.2.2/02 RAR & EFSA, 2017	
							Excreta		daily
							Tissues		at sacrifice

^(a) TP = [trifluorophenyl-(U)-¹⁴] trifloxystrobin ; GP = [glyoxyl-phenyl-(U)-¹⁴C] trifloxystrobin

Summary of new animal metabolism studies

No new studies are submitted.

Conclusion on metabolism in livestock

Based on the available metabolism studies, the residue definition for risk assessment for ruminants was derived as: trifloxystrobin and CGA 321113 (free and conjugated) for all the matrices while for poultry matrices, was derived as: trifloxystrobin and CGA 321113 only under its free form. The residue definition for monitoring in animal matrices is parent and CGA 321113. (EFSA Journal 2017;15(10):4989).

zRMS comments:

Information given by the Applicant is sufficient. The metabolism of trifloxystrobin in livestock (goat, laying hen) was sufficiently investigated during the renewal of approval of the active substance.

In EFSA Journal 2017;15(10):4989 EFSA concluded that based on the available metabolism studies, the residue definition for risk assessment for ruminants was derived as: trifloxystrobin and CGA 321113 (free and conjugated) for all the matrices while for poultry matrices, was derived as: trifloxystrobin and CGA 321113 only under its free form. The residue definition for monitoring in animal matrices is parent and CGA 321113.

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
	Laying hens
Time needed to reach a plateau concentration	not reached in milk (a 28-day feeding study is available) not reached in eggs
Animal residue definition for monitoring	DAR (UK, 2000); EFSA Journal 2014;12(2): 3592), (EFSA Journal 2017;15(10):4989): all livestock species: sum of trifloxystrobin and CGA321113 (M5), expressed as trifloxystrobin Reg. (EU) 2019/1791: Sum of trifloxystrobin and CGA321113 (code 1000000 except 1040000)
Animal residue definition for risk assessment	EFSA Journal 2014;12(2): 3592) EFSA Journal 2017;15(10):4989: <u>Ruminants:</u> Sum of trifloxystrobin and CGA 321113 (M5) (free and conjugated), expressed as trifloxystrobin for liver and kidney other commodities: Sum of trifloxystrobin and CGA 321113 (M5) (only free), expressed as trifloxystrobin <u>Poultry</u> Sum of trifloxystrobin and CGA 321113 (M5) (only free), expressed as trifloxystrobin
Conversion factor	EFSA Journal 2014;12(2): 3592: CF for risk assessment: 1.0 – 3-3 EFSA Journal 2017;15(10):4989: Ruminants: Calculation not possible from the feeding study since the content of CGA 321113 (M5) conjugates in ruminant matrices was not determined. Poultry: 1 (RD-Mo = RD-RA)
Metabolism in rat & ruminant similar	Yes
Fat soluble residue	Yes

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

The following table gives an overview of the supervised residue trials selected for the assessment of trifloxystrobin for the uses supported in this dossier.

Data has been previously evaluated at EU level and is described in detail in the DAR and EFSA's Reasoned Opinion on the review of the existing maximum residue levels (MRLs) for trifloxystrobin according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2014;12(2):3592), or in more recent MRL reviews on specific crops.

Additional residue studies have been submitted in the framework of this application. Detailed assessment of these studies is presented in Appendix 2 and summarised in the Table below. The additional studies were performed to support the formulation Fluopyram + Trifloxystrobin SC 500 in the relevant crops.

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of the product 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 ¹ = according to risk assessment residue definition Codex and former EU definition (sum of trifloxystrobin and CGA 321113) RA ² = according to new EU risk assessment residue definition (sum of trifloxystrobin, its isomers and metabolite CGA 321113 [5 analytes])	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Asparagus	(¹) EFSA, 2014a Based on Codex/JMPR 2012	JMPR (USA)	GAP on which Codex a.s. assessment (adopted by EFSA/EU) is based: USA 3 x 0.11-0.14 kg as/ha, PHI 180 days (California 90 days) E: 7 x <0.05 RA ¹ : 7 x <0.07 (trifloxystrobin and CGA 321113 below LOQ)	E: 0.05 RA: 0.07	E: <0.05 RA: <0.07	0.05	0.05	yes
Asparagus	New trials N-EU (08-2209) (09-2073)	N-EU (4)	GAP: 2 x 0.2 kg as/ha, interval 10 days, post harvest application at BBCH 92-95 (PHI 202-238 days) E: 4 x <0.01 RA ¹ : 4 x <0.02 (trifloxystrobin and CGA 321113 below LOQ) RA ² : 4 x <0.05 (expected total residue calc., 5 analytes)	E: 0.01 RA ¹ : 0.02 RA ² : 0.05	E: <0.01 RA ¹ : <0.02 RA ² : <0.05	0.01	0.05	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 ¹ = according to risk assessment residue definition Codex and former EU definition (sum of trifloxystrobin and CGA 321113) RA ² = according to new EU risk assessment residue definition (sum of trifloxystrobin, its isomers and metabolite CGA 321113 [5 analytes])	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Grape	⁽²⁾ EFSA, 2014a Based on Codex/JMPR 2004	JMPR	Different GAPs from USA, Canada, Europe, South Africa, Australia: (worst case USA 4 x 0.14 kg as/ha, PHI 14 days) E: < 0.02; 0.03; 5 x 0.04; 0.05; 3 x 0.06; 2 x 0.08; 3 x 0.09; 2 x 0.11; 2 x 0.13; 2 x 0.14; 0.16; 0.17; 0.18; 0.21; 0.24; 0.26; 0.2; 2 x 0.28, 2 x 0.29; 0.33; 0.36; 0.61; 0.62; 1.1; 2.2 RA ¹ : < 0.02; 4 x 0.04; 3 x 0.05; 2 x 0.06; 0.07; 0.08; 3 x 0.09; 2 x 0.11; 0.13; 0.14; 0.15; 3 x 0.16; 0.17; 0.21; 0.22; 0.26; 2 x 0.28; 0.29; 0.30; 0.33; 0.36; 2 x 0.38; 0.63; 0.64; 1.2; 2.2 (sum of trifloxystrobin and CGA 321113)	E: 0.15 RA ¹ : 0.15	E: 2.2 RA ¹ : 2.2	2.200	3	yes
Grape	⁽³⁾ EFSA, 2017 (AIR)	N-EU (8)	AIR GAP: 3 x 0.125 kg as/ha, PHI 14 days E: 0.14; 0.18; 0.19; 0.29; 0.38; 0.42; 0.42; 0.49 RA ² : 0.15 (0.18); 0.22; 0.25; 0.37; 0.45; 0.49; 0.60; 0.67	E: 0.34 RA: 0.41	E: 0.49 RA: 0.67	0.941	3	yes
Grape	⁽⁴⁾ EFSA, 2017 (AIR)	S-EU (8)	AIR GAP: 3 x 0.125 kg as/ha, PHI 14 days E: 0.12; 0.12; 0.14; 0.18; 0.20; 0.22; 0.39; 0.51 RA ² : 0.16; 0.17; 0.19; 0.22; 0.25; 0.31; 0.46; 0.60	E: 0.19 RA: 0.24	E: 0.51 RA: 0.60	0.800	3	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 ¹ = according to risk assessment residue definition Codex and former EU definition (sum of trifloxystrobin and CGA 321113) RA ² = according to new EU risk assessment residue definition (sum of trifloxystrobin, its iosmers and metabolite CGA 321113 [5 analytes])	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Grape	New bridging trials FLU + TFS N-EU (09-2077)	N-EU (2)	GAP: 2 x 0.05 kg as/ha, interval 14 days, PHI 14 days E: 0.03, 0.06 RA ² : 0.07, 0.10	E: - RA: -	E: 0.06 RA: 0.10	-	3	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 ¹ = according to risk assessment residue definition Codex and former EU definition (sum of trifloxystrobin and CGA 321113) RA ² = according to new EU risk assessment residue definition (sum of trifloxystrobin, its isomers and metabolite CGA 321113 [5 analytes])	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Strawberry	⁽⁵⁾ EFSA, 2014a Based on Codex/JMPR 2012	JMPR (USA)	GAP on which Codex a.s. assessment (adopted by EFSA/EU) is based: USA 6 x 0.07-0.11 kg as/ha, PHI 0 days E: 0.10; 0.19; 0.20; 0.28; 0.30; 0.44; 0.47; 0.50 RA ¹ : 2 x 0.23; 0.27; 0.31; 0.36; 0.47; 0.51; 0.56	E: 0.290 RA ¹ : 0.335	E: 0.50 RA ¹ : 0.56	0.930	1	yes
Strawberry	⁽⁶⁾ EFSA, 2017 (AIR)	N-EU (9)	AIR GAP: 2 x 0.150 kg as/ha, PHI 1 day E: 0.04; 0.07; 0.08; 0.09; 0.10; 0.13; 0.14; 2 x 0.15 RA ² : 0.08; 0.12; 0.13; 0.14; 2 x 0.18; 0.19; 2 x 0.20	E: 0.096 RA ² : 0.18	E: 0.15 RA ² : 0.20	0.317	1	yes
Strawberry	⁽⁷⁾ EFSA, 2017 (AIR)	S-EU (9)	AIR GAP: 2 x 0.150 kg as/ha, PHI 1 day E: 0.06; 0.08; 0.11; 0.13; 0.15; 0.17; 2 x 0.20; 0.23 RA ² : 0.11; 0.13; 0.16; 0.18; 0.20; 3 x 0.26; 0.29	E: 0.15 RA ² : 0.20	E: 0.23 RA ² : 0.29	0.443	1	yes
Strawberry	⁽⁸⁾ EFSA, 2017 (AIR)	EU Indoor (8)	AIR GAP: 2 x 0.150 kg as/ha, PHI 1 day E: 0.08; 0.09; 0.10; 0.12; 0.13; 0.16; 0.27; 0.41 RA ² : 2 x 0.13; 0.14; 0.17; 0.18; 0.20; 0.31; 0.46	E: 0.13 RA ² : 0.18	E: 0.41 RA ² : 0.46	0.627	1	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 ¹ = according to risk assessment residue definition Codex and former EU definition (sum of trifloxystrobin and CGA 321113) RA ² = according to new EU risk assessment residue definition (sum of trifloxystrobin, its iosmers and metabolite CGA 321113 [5 analytes])	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Strawberry	New trials FLU + TFS N-EU (14-2026) (15-2031) (18-2050)	N-EU (9)	GAP: 2 x 0.2 kg as/ha, interval 7 days, PHI 1 day E: 0.055; 2 x 0.10; 2 x 0.12; 0.21; 0.24; 0.36; 0.41 RA ² : 0.12; 0.15; 0.16; 0.18; 0.19; 2 x 0.33; 0.43; 0.51	E: 0.120 RA ² : 0.190	E: 0.41 RA ² : 0.51	0.689	1	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 ¹ = according to risk assessment residue definition Codex and former EU definition (sum of trifloxystrobin and CGA 321113) RA ² = according to new EU risk assessment residue definition (sum of trifloxystrobin, its isomers and metabolite CGA 321113 [5 analytes])	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Raspberry (Canefruit)	⁽⁹⁾ EFSA, 2014b	N-EU (6)	GAP on which EU MRL is based: 2 x 0.2 kg as/ha, interval 7 days, PHI 3 days E: 0.33; 0.51; 0.52; 0.57; 0.98; 1.4 RA ¹ : 0.38, 0.59, 0.60, 0.62, 1.15, 1.44 RA ² : 0.41; 0.62; 0.63; 0.68; 1.2; 1.7 (RA ² calculated with CF of 1.2 or by summing up trifloxystrobin, CGA 321113 and 0.01 mg/kg for CGA 357261, CGA 357261, CGA 331409, each, whatever higher)	E: 0.545 RA ¹ : 0.610 RA ² : 0.655	E: 1.4 RA ¹ : 1.44 RA ² : 1.7	2.307	3	yes
Raspberry (Canefruit)	New trials FLU + TFS N-EU (18-2051)	N-EU (4)	GAP: 2 x 0.2 kg as/ha, interval 7 days, PHI 3 days E: 0.098; 0.36; 1.0; 1.5 RA ² : 0.15; 0.42; 1.1; 1.6	E: 0.680 RA ² : 0.760	E: 1.5 RA ² : 1.6			
Raspberry (Canefruit)	All trials (EFSA, 2014 b and 18-2051)	N-EU (10)	GAP: 2 x 0.2 kg as/ha, interval 7 days, PHI 3 days E: 0.098; 0.33; 0.36; 0.51; 0.52; 0.57; 0.98; 1.0; 1.4; 1.5 RA ² : 0.15; 0.41; 0.42; 0.62; 0.63; 0.68; 1.1; 1.2; 1.6; 1.7	E: 0.545 RA ² : 0.655	E: 1.5 RA ² : 1.7	2.608	3	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 ¹ = according to risk assessment residue definition Codex and former EU definition (sum of trifloxystrobin and CGA 321113) RA ² = according to new EU risk assessment residue definition (sum of trifloxystrobin, its isomers and metabolite CGA 321113 [5 analytes])	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Currant (Berries and other small fruit)	⁽¹⁰⁾ EFSA, 2018 For N-EU some values in EFSA, 2018 were not reproducible and were replaced here with the relevant values	N-EU (6)	GAP on which EU MRL is based: 2 x 0.2 kg as/ha, interval 7 days, PHI 7 days. Also cGAP for FLU + TFS SC 500 in this dRR. E: 0.13; 0.22; 0.25; 0.27 ; 0.31; 0.64 ; 0.77; 0.92 ; 1.2 RA ¹ : 0.14; 0.23; 0.27; 0.29 ; 0.32; 0.65 ; 0.78; 0.93 ; 1.2 RA ² : 0.17; 0.29; 0.40; 0.83; 1.0; 1.6 (RA ² calculated with CF of 1.3)	E: 0.300 RA ¹ : 0.310 RA ² : 0.615	E: 2.1 RA ¹ : 2.11 RA ² : 2.3	2.746	3	yes
		S-EU (8)	GAP on which EU MRL is based: 2 x 0.2 kg as/ha, interval 7 days, PHI 7 days. Also cGAP for FLU + TFS SC 500 in this dRR. E: 0.04 (grape); 0.1 (grape); 0.14; 0.26 (grape); 0.29; 0.46; 0.66 (grape); 2.1 RA ¹ : 0.05 (grape); 0.12 (grape); 0.15; 0.27 (grape); 0.3; 0.47; 0.68 (grape); 2.11 RA ² : 0.08 (grape); 0.14 (grape); 0.18; 0.34 (grape); 0.35; 0.62; 0.86 (grape); 2.3 (RA ² for grape trials calculated with CF of 1.3 or by summing up trifloxystrobin, CGA 321113 and 0.01 mg/kg for CGA 357261, CGA 357261, CGA 331409, each, whatever higher)					
		Indoor (6)	GAP on which EU MRL is based: 2 x 0.2 kg as/ha, interval 7 days, PHI 7 days E: 0.15; 0.27; 0.31; 0.35; 0.36; 0.51 RA ¹ : 0.16; 0.28; 0.32; 0.36; 0.37; 0.52 RA ² : 0.19; 0.31; 0.35; 2 x 0.40; 0.56 (RA ² by summing up trifloxystrobin, its isomers and CGA 321113)	E: 0.330 RA ¹ : 0.340 RA ² : 0.375	E: 0.51 RA ¹ : 0.52 RA ² : 0.56	0.975	3	yes
Celeriac	⁽¹¹⁾ EFSA, 2016	N-EU (4)	GAP on which EU MRL is based: 3 x 0.13 kg as/ha, PHI 14 days E: 3 x <0.02; 0.02 RA ¹ : 3 x <0.04; 0.04	E: 0.02 RA ¹ : 0.04	E: 0.02 RA ¹ : 0.04	0.03	0.03	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 ¹ = according to risk assessment residue definition Codex and former EU definition (sum of trifloxystrobin and CGA 321113) RA ² = according to new EU risk assessment residue definition (sum of trifloxystrobin, its isomers and metabolite CGA 321113 [5 analytes])	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
			RA ² : isomers of TFS not determined, but are expected to be below LOQ, which would result in RA ² of 3 x <0.1; 0.1	(RA ² : 0.1)	(RA ² : 0.1)			
Celeriac (extrapolation from carrot)	New trials FLU + TFS N-EU carrot (16-2155) (18-2044)	N-EU (8)	GAP: 2 x 0.100 - 0.125 kg as/ha, interval 14 days, PHI 14 days E: 6 x <0.01; 2 x 0.016 RA ² : 6 x <0.05; 0.056; 0.057	E: 0.010 RA ² : 0.050	E: 0.016 RA ² : 0.057	0.023	0.03	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 ¹ = according to risk assessment residue definition Codex and former EU definition (sum of trifloxystrobin and CGA 321113) RA ² = according to new EU risk assessment residue definition (sum of trifloxystrobin, its isomers and metabolite CGA 321113 [5 analytes])	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Lettuce	⁽¹⁵⁾ EFSA, 2014a	EU indoor (8)	GAP on which MRL/EU a.s. assessment is based: 3 x 0.2 kg as/ha, PHI 7 days E: 2.4; 2.5; 2.7; 5.4; 5.6; 5.7; 6.6; 7.2 RA ¹ : 2.4; 2 x 2.7; 5.4; 5.65; 5.8; 6.7; 7.2	STMR 5.50 mg/kg; HR 7.20 mg/kg			15	yes
Extrapolation from lettuce: Lamb's lettuce Cress and other sprouts and shoots Land cress Roman rocket Red mustard Others	⁽¹⁶⁾ EFSA, 2018	EU indoor (7)	GAP: 2 x 0.2 kg as/ha, interval 7 days, PHI 7 days E: 0.85; 1.20; 2.60; 3.10; 3.80; 4.50; 9.90 RA ¹ : 0.90; 1.30; 2.84; 3.24; 3.83; 4.69; 10.00	STMR 2.85 mg/kg; HR 10 mg/kg			15	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 ¹ = according to risk assessment residue definition Codex and former EU definition (sum of trifloxystrobin and CGA 321113) RA ² = according to new EU risk assessment residue definition (sum of trifloxystrobin, its isomers and metabolite CGA 321113 [5 analytes])	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Lettuce (and other salad plants)	New trials FLU + TFS lettuce N-EU (14-2029) (14-2184)	N-EU (9)	GAP: 2 x 0.2 kg as/ha, interval 7 days, PHI 7 days E: 0.036; 0.16; 0.24; 0.28; 2 x 0.77; 1.0; 1.2; 1.5 RA ² : 0.076; 0.20; 0.34; 0.35; 0.88; 0.90; 1.2; 1.3; 1.8	E: 0.770 RA ² : 0.880	E: 1.5 RA ² : 1.8	2.710	15	yes
Chicory witloof	EFSA, 2014a	N-EU	GAP: 3 x 125 g as/ha, PHI field 21 days Trials as below (11-2140, GAP 2 x 200 g as/ha) were submitted with evaluation report to close data gap identified in Article 12 review; not yet evaluated.				0.01*	
Chicory witloof	New trials FLU + TFS chicory N-EU (11-2140)	N-EU	GAP: 2 x 0.16-0.2 kg as/ha, interval 7 days, PHI field 21 days (GAP FLU + TFS in this dRR is less critical with 1 x 0.2 kg as/ha, but no residue situation in leaf after forcing, therefore assumed acceptable) E: 4 x <0.01 RA ² : 4 x <0.05	E: 0.01 RA ² : 0.015	E: <0.01 RA ² : <0.05	0.01	0.01*	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 ¹ = according to risk assessment residue definition Codex and former EU definition (sum of trifloxystrobin and CGA 321113) RA ² = according to new EU risk assessment residue definition (sum of trifloxystrobin, its isomers and metabolite CGA 321113 [5 analytes])	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Bean (fresh) with pod	⁽¹⁷⁾ EFSA, 2014a	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.2 kg as/ha, PHI 7 d E: 0.06; 0.07; 0.08; 0.16; 0.23; 0.29; 0.50; 0.51 RA ¹ : 0.08; 0.10	STMR 0.20 mg/kg; HR 0.51 mg/kg; calculated MRL 1			1	yes
Bean (fresh) with pod	⁽¹⁸⁾ EFSA, 2014a	indoor	GAP on which MRL/EU a.s. assessment is based: 3 x 0.125 kg as/ha, PHI 7 d E: 0.10; 0.15; 2 x 0.16; 0.17; 0.18; 0.22; 0.35 RA ¹ : - (not given in EFSA, 2014, although CGA 321113 results available)	STMR 0.17 mg/kg; HR 0.35 mg/kg; calculated MRL 0.6			1	yes
Bean (fresh) with pod	Trials as used for pea in ⁽¹⁹⁾ EFSA, 2018	N-EU (9)	GAP: 2 x 0.2 kg as/ha, interval 7 days, PHI 14 days E: 0.01; 2 x 0.02; 2 x 0.03; 0.05; 0.06; 0.08; 0.23 RA ¹ : 0.02; 2 x 0.03; 2 x 0.05; 0.07; 0.08, 0.09; 0.24 RA²: 0.052; 2 x 0.06; 2 x 0.11; 0.12; 0.13; 0.14; 0.28 (For study RA-2044/02, the RA ² values are calculated with CF of 2.1 or by summing up trifloxystrobin, CGA 321113 and 0.01 mg/kg for CGA 357261, CGA 357261, CGA 331409, each, whatever higher)	STMR 0.05 mg/kg; HR 0.24 mg/kg; calculated MRL 0.40 STMR for R²: 0.11 HR for R²: 0.28			1	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 ¹ = according to risk assessment residue definition Codex and former EU definition (sum of trifloxystrobin and CGA 321113) RA ² = according to new EU risk assessment residue definition (sum of trifloxystrobin, its isomers and metabolite CGA 321113 [5 analytes])	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Pea (fresh) with pod	⁽¹⁹⁾ EFSA, 2018 In bold: values for new risk assessment residue definition	N-EU (9)	GAP on which MRL/EU a.s. assessment is based: 2 x 0.2 kg as/ha, interval 7 days, PHI 14 d (trials on beans and peas) This GAP is also relevant to this dRR. E: 0.01; 2 x 0.02; 2 x 0.03; 0.05; 0.06; 0.08; 0.23 RA ¹ : 0.02; 2 x 0.03; 2 x 0.05; 0.07; 0.08, 0.09; 0.24 RA²: 0.052; 2 x 0.06; 2 x 0.11; 0.12; 0.13; 0.14; 0.28 (For study RA-2044/02, the RA ² values are calculated with CF of 2.1 or by summing up trifloxystrobin, CGA 321113 and 0.01 mg/kg for CGA 357261, CGA 357261, CGA 331409, each, whatever higher)	STMR 0.05 mg/kg; HR 0.24 mg/kg; calculated MRL 0.40 STMR for R²: 0.11 HR for R²: 0.28			1.5	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 ¹ = according to risk assessment residue definition Codex and former EU definition (sum of trifloxystrobin and CGA 321113) RA ² = according to new EU risk assessment residue definition (sum of trifloxystrobin, its isomers and metabolite CGA 321113 [5 analytes])	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Bean and pea without pods	⁽²¹⁾ EFSA, 2018 In bold: values for new risk assessment residue definition	N-EU (10)	GAP on which MRL/EU a.s. assessment is based: 2 x 0.2 kg as/ha, interval 7 days, PHI 14 d (trials on beans and peas) This GAP is also relevant to this dRR. E: 6 x <0.01; 2 x 0.01 (0.012, 0.010); 0.02; 0.04 RA ¹ : 8 x <0.02; 0.04; 0.05 RA²: 6 x <0.05; 0.050; 0.052; 0.06; 0.09	STMR 0.02* mg/kg; HR 0.05 mg/kg; calculated MRL 0.06 STMR for R²: 0.05 HR for R²: 0.09			0.09	yes
Hops (dried)	⁽²⁴⁾ EFSA, 2014a	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.63 kg as/ha, PHI 14 d E: 4.7; 5.4; 8.8; 9.5; 10.8; 11.4; 15.7; 26.1 RA ¹ : 6.2; 6.7; 9.2; 12.1; 12.5; 12.8; 17.7; 28.6	STMR 10.15 mg/kg; HR 26.1 mg/kg			40	yes
Hops (dried)	New trials FLU + TFS N-EU (18-2047) (10-2127) (09-2076 + MR-11/044) (08-2086)	N-EU (14)	GAP: 2 x 0.15 kg as/ha, interval 14 days, PHI 21 days E: 0.056; 0.07; 0.24; 0.39; 0.42; 0.44; 0.61; 0.62; 0.63; 0.74; 0.89; 1.1; 1.2; 1.3 RA ² : 0.16; 0.43; 0.47; 0.63; 0.78; 0.98; 2 x 1.1; 1.5; 1.6	E: 0.615 RA ² : 0.880	E: 1.3 RA ² : 1.6	2.194	40	yes

* Source of EU MRL: Commission Regulation (EU) No 2019/1791

Source of EU MRL: EU MRL data base: <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN>

¹ Asparagus: Trials see JMPR report and evaluation 2012, submitted by USA IR-4 to Codex: Study IR-4 PR No. 08212 ([M-275119-01-1](#))

² Grape: Trials see JMPR report and evaluation 2004

³ Grape: Trials as in AIR dossier: studies 11-2115 ([M-456337-01-1](#)), 12-2010 ([M-453336-02-1](#))

⁴ Grape: Trials as in AIR dossier: studies 11-2114 ([M-454927-01-1](#)), 12-2011 ([M-455561-02-1](#))

- ⁵ Strawberry: Trials see JMPR report and evaluation 2012. Study RATFY012 ([M-281857-01-1](#))
- ⁶ Strawberry: Trials as in AIR dossier: studies 11-2128 ([M-457953-01-1](#)), 12-2012 ([M-452140-01-1](#))
- ⁷ Strawberry: Trials as in AIR dossier: studies 11-2129 ([M-457958-02-1](#)), 12-2013 ([M-460009-01-1](#))
- ⁸ Strawberry: Trials as in AIR dossier: studies 11-2120 ([M-456769-02-1](#)), 12-2014 ([M-453332-02-1](#))
- ⁹ Canefruit: Trials as in EFSA Journal 2014;12(7):3751: studies PTZ-NLI-11797 ([M-434309-02-1](#)), BCS-G401-11 ([M-433737-01-1](#)), RAFR00810 ([M-434815-01-2](#)), RAFR03509 ([M-434818-01-2](#))
- ¹⁰ Berries and other small fruit: Trials as in EFSA Journal 2018;16(1):5154: studies B5111 ([M-565907-02-1](#)), PTZ-NLI-11796 ([M-434301-02-1](#)), BCS-G402-11 ([M-433738-01-1](#)), 15-2033 ([M-553894-01-1](#)), RA-2584/07 ([M-308377-01-1](#)), 14-2025 ([M-535114-03-1](#)), 15-2032 ([M-557440-01-2](#))
- ¹¹ celeriac: Trials as in EFSA Journal 2016;14(1):4383 and EFSA Journal 2014;12(2):3592: studies RA-2025/03 ([M-060493-01-1](#)), RA-2011/04 ([M-262298-01-1](#))
- Footnotes 12, 13, 14 deleted, we related to tomato, aubergine and sweet pepper indoor uses, which are not relevant to this central zone dRR
- ¹⁵ Lettuce indoor, Trials as in EFSA Journal 2014;12(2):3592: study RA-2036/02 ([M-085240-01-1](#))
- ¹⁶ Lettuce indoor: Trials as in EFSA Journal 2018;16(1):5154: studies 14-2028 ([M-534623-01-1](#)), RA-2620/07 ([M-308622-01-1](#))
- ¹⁷ Bean, NEU, Trials as in EFSA Journal 2014;12(2):3592: B 1725-3G ([M-398362-01-1](#)), RA-2044/02 ([M-106401-01-1](#))
- ¹⁸ Bean, indoor, Trials as in EFSA Journal 2014;12(2):3592: RA-2037/02 ([M-104915-01-1](#))
- ¹⁹ Bean and pea with pod, N-EU: Trials as in EFSA Journal 2018;16(1):5154: bean, studies RA-2044/02 ([M-106401-01-1](#)), 10-2125 ([M-425357-01-1](#)), 12-2030 ([M-467728-01-1](#)); pea, study: 15-2030 ([M-566823-03-1](#))
- ²⁰ Bean and pea with pod, S-EU: Trials as in EFSA Journal 2018;16(1):5154: bean, studies 10-2125 ([M-425357-01-1](#)), 11-2001 ([M-445803-01-1](#)), 15-2036 ([M-553880-02-1](#)); pea, studies: 12-2032 ([M-474877-01-1](#)), 12-2155 ([M-477297-01-1](#)), 15-2030 ([M-566823-03-1](#))
- ²¹ Bean and pea without pod, N-EU: Trials as in EFSA Journal 2018;16(1):5154: bean and pea studies 10-2128 ([M-425362-02-1](#)), 12-2031 ([M-475814-01-1](#)), 15-2030 ([M-566823-03-1](#))
- ²² Bean and pea without pod, S-EU: Trials as in EFSA Journal 2018;16(1):5154: bean and pea studies 15-2036 ([M-553880-02-1](#)), 12-2032 ([M-474877-01-1](#)), 12-2155 ([M-477297-01-1](#))
- ²³ Pulses: Trials as in EFSA Journal 2018;16(1):5154: dry pea, studies 15-2030 ([M-566823-03-1](#)), 12-2032 ([M-474877-01-1](#)), 12-2155 ([M-477297-01-1](#))
- ²⁴ Hops: Trials as in EFSA Journal 2014;12(2):3592: studies 2162/97 ([M-021917-01-1](#)), 2163/97 ([M-021928-01-1](#)), 2164/97 ([M-136383-01-1](#)), 2165/97 ([M-021957-01-1](#)), gr01796 ([M-052604-02-1](#)), RF0296 ([M-030563-01-3](#)), RF0396 ([M-030558-01-3](#)), RF0496 ([M-030553-01-3](#))

7.2.3.2 Conclusion on the magnitude of residues in plants

The intended GAPs supported in this dossier are similar or less critical than the GAPs evaluated during the EU reviews of trifloxystrobin to derive the established MRLs.

The data submitted show that no exceedance of the MRLs set for trifloxystrobin will occur for the intended uses of Fluopyram + Trifloxystrobin SC 500 and it is not necessary to revise any MRLs.

As a conclusion, the intended uses of fluopyram + trifloxystrobin SC 500 can be considered as sufficiently supported.

zRMS comments:

Residue Definitions (EFSA Journal 2017;15(10):4989):

Monitoring (Mo): Trifloxystrobin

Risk Assessment (RA): Trifloxystrobin, its 3 isomers and M5 (CGA 321113), expressed as trifloxystrobin

1. Asparagus

Intended EU GAP for asparagus:

Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
2	0.2 kg as/ha	10 days	BBCH 23-95 (green plants)	- (as per growth stage; from studies: 202-238 days)

Asparagus is the minor crop in northern Europe (EU guideline Document SANCO 7525/VI/95-rev.10.3 of 13 June 2017). A minimum of four trials are required.

Four supervised residue trials conducted in North Europe were submitted on/in asparagus according to the intended GAP. Only the residues of trifloxystrobin and the CGA 321113 metabolite were determined. The residue levels of trifloxystrobin and CGA 321113 are below LOQ (0.01 mg/kg) for each analyte. The 3 isomers of trifloxystrobin (CGA 357262, CGA 357261 and CGA 331409) were not analysed in the studies. So the magnitude of residues in line with the residue definition for enforcement only were determined in asparagus. Consequently, this creates a following data gap:

- 4 additional trials which determine residues according to the accepted risk assessment residue definition to support the proposed use on asparagus in the NEU.

However it is noted that the applications were done to the crop at BBCH 93-95 with the last application 202-238 days before the harvest of the asparagus sticks in the next season. It is expected that the isomers residues will be all <0.01 mg/kg, since in general lower than residues of trifloxystrobin and CGA 321113.

~~In our opinion, this is a minor data gap and it should be filled in (post registration), e.g. bridging study with determination of isomers of trifloxystrobin.~~

Remark after the commenting period:

zRMS-PL accepts the arguments presented by Applicant:

"For asparagus the application of Luna Sensation is done to the green plants in summer and growth and harvest of the sticks for consumption only occur in the year after the application. Trifloxystrobin is a mesostemic, but not a systemic compound.

Although according to SANCO 7525/VI/95, rev. 10.3 no trials would be necessary, 4 trials are available, showing trifloxystrobin and CGA 321113 residues below LOQ, which confirm the expected non-residue situation. Although only trifloxystrobin and GA 321113 were analysed, it is assumed that the other isomers would also have residues below the LOQ of 0.01 mg/kg, since they show generally lower residues than trifloxystrobin and CGA 321113 themselves.

In addition, the isomers of trifloxystrobin are photoisomers, which would not be relevant for the asparagus sticks at harvest, which are growing below the soil surface. i.e. in the dark.

Therefore the applicant considers it is not necessary to conduct additional residue trials."

Available results show that the in force MRL of trifloxystrobin on asparagus of 0.05 mg/kg (Reg. (EU) 2019/1791) will not be exceeded. The current EU MRL for f trifloxystrobin is sufficient to support the proposed use. The trials are supported by valid storage stability data and validated analytical method. Therefore, the proposed use on **asparagus** is considered acceptable ~~(data-gap—post-registration)~~.

2. Grape

Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
2	0.05 kg as/ha	14	BBCH 15-75	14

Table grape is the minor crop in northern Europe (EU guideline Document SANCO 7525/VI/95-rev.10.3 of 13 June 2017). A minimum of four trials are required.

Wine grape is the major crop in northern Europe (EU guideline Document SANCO 7525/VI/95-rev.10.3 of 13 June 2017). A minimum of eight trials are required.

Trifloxystrobin RAR, 2017: Eight residue trials were conducted between 2011 and 2012 in the field in northern Europe in/on grapes with Trifloxystrobin WG. The product was applied three times to grapes at application rates of 0.125 kg trifloxystrobin/ha. The spray concentration used in the residue trials is in line with the intended GAP. The treatments were performed with intervals of 10 days. Berry samples were taken, 14 days and 21 days after the last application in all trials, bunch samples were taken at day 0, 14 and 21 days after last application in all trials and at day 7/8 and 10 in some of the trials. Residues of trifloxystrobin (CGA 279202), its isomers CGA 331409, CGA 357261, CGA 357262, as well as the metabolite CGA 321113 and its isomer CGA 373466 were determined according to method 01313 or 01313/M001. The analytical methods were validated by recovery experiments prior to and during analysis of the samples by spiking control samples. the limit of quantification was 0.01 mg/kg for all analytes.

RD-Mo: 0.14; 0.18; 0.19; 0.29; 0.38; 0.42; 0.42; 0.49 mg/kg,

RD-RA: 0.15 (0.18); 0.22; 0.25; 0.37; 0.45; 0.49; 0.60; 0.67 mg/kg.

Applicant submitted bridging study on grapes. Two trials were conducted in N-EU to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409, its metabolite CGA 321113 and its stereo-isomer CGA 373466 in/on grapes after two spraying applications with 50 g/ha trifloxystrobin with 14 days between applications at BBCH 85-89 and with PHI of 14 days.

RD-Mo: 0.03, 0.06 mg/kg,

RD-RA: 0.07, 0.10 mg/kg.

Available results show that the in force MRL of trifloxystrobin on grapes of 3 mg/kg (Reg. (EU) 2019/1791) will not be exceeded. The current EU MRL for trifloxystrobin is sufficient to support the proposed use.

The trials are supported by valid storage stability data and validated analytical methods.

The proposed use on **grapes is considered acceptable.**

3. Strawberry

Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
2	0.2 kg as/ha	7 days	BBCH 40-89	1 day

Strawberry is the major crop in northern Europe (EU guideline Document SANCO 7525/VI/95-rev.10.3 of 13 June 2017). A minimum of eight trials are required.

Field trials

Trifloxystrobin RAR, 2017: Nine residue trials were performed between 2011 and 2012 in the field in northern Europe in/on strawberries with Trifloxystrobin WG 50 according to the intended use pattern. The product was applied two times to strawberries at application rates of 0.15 kg trifloxystrobin/ha. The treatments were performed with intervals of 7 days. Fruit samples were taken on day 1 and 3 after the last application in all trials. Additional samples of fruit were taken at later time points in some trials. Residues of trifloxystrobin (CGA 279202), its isomers CGA 331409, CGA 357261, CGA 357262, as well as the metabolite CGA 321113 and its isomer CGA 373466 were determined according to method 01313 or 01313/M001. The analytical methods were validated by recovery

experiments prior to and during the analysis of the samples by spiking control samples. The limit of quantification was 0.01 mg/kg for all analytes.

RD-Mo: 0.06; 0.08; 0.11; 0.13; 0.15; 0.17; 2 x 0.20; 0.23 mg/kg,

RD-RA: 0.11; 0.13; 0.16; 0.18; 0.20; 3 x 0.26; 0.29 mg/kg.

Applicant submitted additional studies on strawberry. Nine trials were conducted in N-EU to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409, its metabolite CGA 321113 and its stereo-isomer CGA 373466 in/on strawberry after two spraying applications with 200 g/ha trifloxystrobin with 7-8 days between applications at BBCH 85-89 and with PHI of 1 day.

RD-Mo: 0.055; 2 x 0.10; 2 x 0.12; 0.21; 0.24; 0.36; 0.41 mg/kg,

RD-RA: 0.12; 0.15; 0.16; 0.18; 0.19; 2 x 0.33; 0.43; 0.51 mg/kg.

Available results show that the in force MRL of trifloxystrobin on strawberry of 1 mg/kg (Reg. (EU) 2019/1791) will not be exceeded. The current EU MRL for trifloxystrobin is sufficient to support the proposed use.

The trials are supported by valid storage stability data and validated analytical methods.

The proposed use on strawberry (F) is considered acceptable.

4. Raspberry

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP N-EU, field (Blackberry, Raspberry, Dewberry)	2	0.2 kg as/ha	7 days	(up to BBCH 89)	3

Raspberry, Blackberry and Dewberry are the minor crops in northern Europe (EU guideline Document SANCO 7525/VI/95-rev.10.3 of 13 June 2017). A minimum of four trials are required.

Field trials

EFSA Journal 2014;12(7):3751: GAP on which EU MRL is based: 2 x 0.2 kg as/ha, interval 7 days, BBCH 31-89, PHI 3 days.

In support of the MRL application, six trials performed on raspberries in north Europe during 2009-2011 were submitted. These trials were used for the extrapolation from raspberries to cane fruits according to SANCO/7525/VI/95-rev.9. Trials were conducted outdoor under a plastic shelter. Samples were harvested 3 days after the last application and analysed for parent trifloxystrobin and the metabolite CGA 321113. Residue levels were in the range of 0.33-1.4 mg/kg for trifloxystrobin and 0.04-0.17 mg/kg for the metabolite CGA 321113.

(...)The storage stability of trifloxystrobin in primary crops was investigated during the peer review and trifloxystrobin and CGA 321113 were found to be stable for 18 months at -20 °C in high water content, acidic and dry commodities (EFSA 2014). As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

According to the EMS, the analytical method used to analyse the supervised residue trial samples has been sufficiently validated and was proven to be fit for the purpose (Germany 2014).

E: 0.33; 0.51; 0.52; 0.57; 0.98; 1.4

RA₁: 0.38, 0.59, 0.60, 0.62, 1.15, 1.44

RA₂: 0.41; 0.62; 0.63; 0.68; 1.2; 1.7 (RA₂ calculated with CF of 1.2 or by summing up trifloxystrobin, CGA 321113 and 0.01 mg/kg for CGA 357261, CGA 357261, CGA 331409, each, whatever higher)

Applicant submitted additional studies on raspberry. Four trials were conducted in N-EU to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409, its metabolite CGA 321113 and its stereo-isomer CGA 373466 in/on raspberry after two spraying applications with 200 g/ha trifloxystrobin with 7 days between applications at BBCH 85-87 and with PHI of 3 day.

RD-Mo: 0.098, 0.36, 1.0, 1.5 mg/kg,

RD-RA: 0.15, 0.42, 1.1 and 1.6 mg/kg.

Available results show that the in force MRL of trifloxystrobin on raspberry of 3 mg/kg (Reg. (EU) 2019/1791) will not be exceeded. The current EU MRL for trifloxystrobin is sufficient to support the proposed use.

The trials are supported by valid storage stability data and validated analytical methods.

The proposed use on raspberry (F) is considered acceptable.

Based on the Guidance Document SANCO 7525/VI/95, rev. 10.3, at least 6 residue trials on raspberries (red and yellow) (0153030) can be used for extrapolation to the Whole subgroup (c) cane fruits (0153000) (group with only minor crops). Applicant presented sufficient available studies on raspberry.

Available results show that the in force MRL of trifloxystrobin on whole subgroup of cane fruits (blackberries, dewberries, raspberries (red and yellow)) of 3 mg/kg (Reg. (EU) 2019/1791) will not be exceeded.

Therefore, the proposed uses on raspberry, blackberry and dewberry (F) are considered acceptable.

5. Other small fruits and berries

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP EU-N, field Blueberry, Chokeberry, Buckthorn, Cranberry, Currant, Elderberry, Gooseberry, Mulberry, Rosehip	2	0.15 – 0.2 kg as/ha	7 / 14 days	(up to BBCH 89)	7

Blueberry, Buckthorn, Cranberry, Currant, Elderberry, Gooseberry, Mulberry, Rosehip are the minor crops in northern Europe (EU guideline Document SANCO 7525/VI/95-rev.10.3 of 13 June 2017). A minimum of four trials are required.

Currant - field trials

Applicant submitted 6 trials on currant conducted in N-EU to determine the magnitude of trifloxystrobin (CGA 279202) and its metabolite CGA 321113 in/on black and red currants (fruit) after two spraying applications with 0.2 kg/ha trifloxystrobin with 7 days between applications at BBCH 87 and with PHI of 7 days. In these studies only the residues of trifloxystrobin and the CGA 321113 metabolite were determined. The 3 isomers of trifloxystrobin (CGA 357262, CGA 357261 and CGA 331409) were not analysed in this study. However taking into the results of studies 15-2033, 14-2025 and 15-2032 the conversion factor (from monitoring to risk assessment) of 1.3 for currant, based on currant trials including isomer analysis, has been calculated by iRMS Greece (DRR – Part B7 for 102000012886 / fluopyram + trifloxystrobin SC 500 (250 + 250 g/L), 12.02.2021).

RD-Mo: 0.13, 0.22, 0.31, 0.64, 0.77, 1.2 mg/kg.

RD-RA: 0.17, 0.29, 0.40, 0.83, 1.0, 1.6 mg/kg.

Total residue has been calculated with conversion factor (from monitoring to risk assessment) of 1.3 for currant, which is based on currant trials including isomer analysis.

Available results show that the in force MRL of trifloxystrobin on currant ((d) other small fruits and berries) of 3 mg/kg (Reg. (EU) 2019/1791) will not be exceeded. The current EU MRL for trifloxystrobin is sufficient to support the proposed use.

The trials are supported by valid storage stability data and validated analytical methods.

The proposed use on currant (F) is considered acceptable.

Based on the Guidance Document SANCO 7525/VI/95, rev. 10.3, at least 6 residue trials on (black, red, white) currants can be used for extrapolation to the whole subgroup of other small fruits and berries (group with only minor crops).

Therefore, the proposed uses on blueberries, chokeberries, buckthorn, cranberries, (black, red, white), currants, elderberries, gooseberries, rose hips and mulberries (F) are considered acceptable.

6. Celeriac

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP	2	0.125 kg as/ha	14 days	(up to BBCH 49)	14

Celeriac is the minor crop in northern Europe (EU guideline Document SANCO 7525/VI/95-rev.10.3 of 13 June 2017). A minimum of four trials are required.

There are not available residue trials on celeriac. Based on the Guidance Document SANCO 7525/VI/95, rev. 10.3, 8 residue trials on carrot can be used for extrapolation to the Whole subgroup (c) other root and tuber vegetables except sugar beets (0213000), including celeriac, before and after forming of the edible part.

Applicant submitted 8 trials on carrot conducted in N-EU to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 as well as its metabolite CGA 321113 and CGA 373466 in/on carrot after two spraying applications with 0.1-0.125 kg/ha trifloxystrobin with 14-20 days between applications at BBCH 43-49 and with PHI of 14 days.

RD-Mo: $6x < 0.01$ and $2x 0.016$ mg/kg.

RD-RA: $6x < 0.05$, 0.056 and 0.057 mg/kg.

Available results show that the in force MRL of trifloxystrobin on celeriac of 0.03 mg/kg (Reg. (EU) 2019/1791) will not be exceeded. The current EU MRL for trifloxystrobin is sufficient to support the proposed use.

The trials are supported by valid storage stability data and validated analytical methods.

The proposed use on celeriac (F) is considered acceptable.

7. Lettuce and other salad plants and

8. Sea aster (0252020-004) and Sea lavender (0252020-005)

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP, N-EU (Lettuce)	2	0.2 kg as/ha	7 days	(up to BBCH 49)	7
Intended cGAP, N-EU (Cress, garden, Endive, winter, Lamb's lettuce, Lettuce, Radicchio, Rocket, salad, Sea lavender)	1	0.2 kg as/ha	-	(up to BBCH 49)	7

Lettuce

Lettuce is the major crop in northern Europe (EU guideline Document SANCO 7525/VI/95-rev.10.3 of 13 June 2017). A minimum of eight trials are required.

Applicant submitted 9 trials on lettuce (open leaf variety) conducted in N-EU to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 as well as its metabolite CGA 321113 and CGA 373466 in/on lettuce after two spraying applications with 0.2 kg/ha trifloxystrobin with 7-8 days between applications at BBCH 42-49 and with PHI of 7-8 days.

RD-Mo: 0.036, 0.16, 0.24, 0.28, $2x 0.77$, 1.0, 1.2 and 1.5 mg/kg.

RD-RA: 0.076, 0.2, 0.34, 0.35, 0.88, 0.9, 1.2, 1.3 and 1.8 mg/kg.

Available results show that the in force MRL of trifloxystrobin on lettuce of 15 mg/kg (Reg. (EU) 2019/1791) will not be exceeded. The current EU MRL for trifloxystrobin is sufficient to support the proposed use.

The trials are supported by valid storage stability data and validated analytical methods.

The proposed use on lettuce (F) is considered acceptable.

Whole subgroup (a) lettuces and salad plants (0251000)

Based on the Guidance Document SANCO 7525/VI/95, rev. 10.3, 8 residue trials on lettuce (trials from open leaf varieties) can be used for extrapolation to the Whole subgroup (a) lettuces and salad plants (0251000), before and after forming of the edible part.

Available results show that the in force MRL of trifloxystrobin on lettuce of 15 mg/kg (Reg. (EU) 2019/1791) will not be exceeded for uses from whole subgroup (a) lettuces and salad plants (0251000). The current EU MRL for trifloxystrobin is sufficient to support the proposed uses: Brassica sp. (0251080, 0251070), Chicory, sugar loaf (0251030-005), Cress, garden (0251040), Endive, winter (0251030), Lamb's lettuce (0251010), Raddichio (0251030-004), Rocket salad (0251060).

The trials are supported by valid storage stability data and validated analytical methods.

The proposed uses on Brassica sp. (0251080, 0251070), Chicory, sugar loaf (0251030-005), Cress, garden (0251040), Endive, winter (0251030), Lamb's lettuce (0251010), Raddichio (0251030-004), Rocket salad (0251060) are considered acceptable.

Whole subgroup (b) spinaches and similar leaves (0252000)

Based on the Guidance Document SANCO 7525/VI/95, rev. 10.3, 8 residue trials on lettuce (trials from open leaf varieties) can be used for extrapolation to the Whole subgroup (b) spinaches and similar leaves (0252000) before and after forming of the edible part.

Available results show that the in force MRL of trifloxystrobin on lettuce of 15 mg/kg (Reg. (EU) 2019/1791) will not be exceeded for uses from whole subgroup (b) spinaches and similar leaves (0252000). The current EU MRL for trifloxystrobin is sufficient to support the proposed uses: Sea aster (0252020-004), Sea lavender (0252020-005). The trials are supported by valid storage stability data and validated analytical methods.

The proposed uses on Sea aster (0252020-004) and Sea lavender (0252020-005) are considered acceptable.

9. Chicory witloof

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP, N-EU (Chicory witloof)	1	0.150 - 0.200 kg as/ha	-	(up to BBCH 49)	21 (field)

Chicory witloof is the minor crop in northern Europe (EU guideline Document SANCO 7525/VI/95-rev.10.3 of 13 June 2017). A minimum of four trials are required.

Four trials were conducted in N-EU (Germany, Belgium, France and Netherlands) during the 2011 season to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 and its metabolite CGA 321113 and CGA 373466 in/on chicory, witloof (leaf and root) after two spraying applications in the field with 0.16 - 0.2 kg/ha trifloxystrobin with 7-8 days between applications at BBCH 49 and with PHI of 21 days.

Root:

RD-Mo: 0.012, 0.025, 0.028, 0.056 mg/kg.

RD-RA: 0.052, 0.065, 0.069 and 0.098 mg/kg.

Leaf:

RD-Mo: 4x<0.01 mg/kg.

RD-RA: 4x<0.05 mg/kg.

Available results show that the in force MRL of trifloxystrobin on chicory witloof of 0.01 mg/kg (Reg. (EU) 2019/1791) will not be exceeded. The current EU MRL for trifloxystrobin is sufficient to support the proposed use. The trials are supported by valid storage stability data and validated analytical methods.

The proposed use on chicory witloof (F) is considered acceptable.

10. Beans and peas with pod and without pod (0260000 - fresh)

11. Pulses (0300000 - dry)

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP, N-EU (bean with pod and without pod)	2	0.200 kg as/ha	7	59-79/89	14
Intended cGAP, N-EU	1	0.200 kg as/ha	-	55-79/89	21

(Chickpea)					
Intended cGAP, N-EU (lentil (0300020), covered by bean & pea data)	1	0.200 kg as/ha	-	55-79/89	7 14

Bean with pods and peas without pods are the major crops in N-EU (EU guideline Document SANCO 7525/VI/95-rev.10.3 of 13 June 2017). A minimum of eight trials are required.

Based on the Guidance Document SANCO 7525/VI/95, rev. 10.3, at least 8 residue trials on beans (with pods) can be used for extrapolation to peas (with pods) and vice versa, at least 8 residue trials on beans (without pods) can be used for extrapolation to peas (without pods) and vice versa after and before forming the edible part, at least 8 residue trials on beans or peas (dry) can be used for extrapolation to whole category PULSES (0300000).

Applicant submitted sufficient trials conducted in N-EU to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 as well as its metabolite CGA 321113 and CGA 373466 in/on beans or peas after two spraying applications with 0.2 kg/ha trifloxystrobin with 7-8 days between applications at up to BBCH 80 and with PHI of 7-14 days.

Summary:

Study 10-2128 – bean without pod, PHI=14 days, seed green:

RD-Mo: 0.02, 0.04 mg/kg,

RD-RA: 0.06, 0.09 mg/kg.

pod – PHI=7 days:

RD-Mo: 0.16, 0.21 mg/kg,

RD-RA: 0.22, 0.26 mg/kg.

Study 11-2000 – Pea,

dry seed – PHI=14 days:

RD-Mo: 2x0.01 mg/kg,

RD-RA: 2x0.05 mg/kg.

Pod – PHI=7 days:

RD-Mo: 0.15, 0.22 mg/kg,

RD-RA: 0.20, 0.30 mg/kg.

Study 12-2031 – Pea without pod, PHI=14 days (green seed and dry seed):

RD-Mo: 6x0.01 mg/kg,

RD-RA: 6x0.05 mg/kg.

Study 10-2125 – Bean and pea with pod, PHI=14 days:

RD-Mo: 2x0.02 mg/kg,

RD-RA: 2x0.06 mg/kg.

Study 12-2030 - Bean with pod, PHI=14 days,

RD-Mo: 0.012, 0.076 mg/kg

RD-RA: 0.052, 0.12 mg/kg.

Study 15-2030 - Pea with pod, PHI = 6-13 days

RD-Mo: 0.23, 0.49 mg/kg,

RD-RA: 0.28, 0.58 mg/kg.

Study 15-2030 - Pea without pod, seed, green, PHI=6-19 days

RD-Mo: 0.010, 0.012 mg/kg,

RD-RA: 0.050, 0.052 mg/kg.

Study 15-2030 - pea seed, dry, PHI=14-36 days

RD-Mo: 2x<0.01 mg/kg,

RD-RA: 0.051, 0.052 mg/kg.

Study RA-2044/02 - Bean with pod, PHI=14 days,

RD-Mo: 2x0.03, 0.05, 0.06 mg/kg
RD-RA: 2x0.11, 0.13, 0.14 mg/kg.

Available results show that the in force MRL of trifloxystrobin on bean with pods (0260010) of 1 mg/kg, bean without pods (0260020) and pea without pods (0260040) of 0.09 mg/kg, pea with pods (0260030) and chickpea (0260030-003) of 1.5 mg/kg (Reg. (EU) 2019/1791) and lentil (0300020) of 0.2 mg/kg will not be exceeded. The current EU MRLs for trifloxystrobin are sufficient to support the proposed uses.

The trials are supported by valid storage stability data and validated analytical methods.

The proposed uses on bean with pods (0260010), bean without pods (0260020), pea without pods (0260040), pea with pods (0260030), chickpea (0260030-003) and lentil (0300020) (F) are considered acceptable.

12. Hops

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP, N-EU (Hop)	2	0.150 kg as/ha	14	BBCH 37-79	21

Hop is the minor crop in northern Europe (EU guideline Document SANCO 7525/VI/95-rev.10.3 of 13 June 2017). A minimum of four trials are required.

Sufficient trials were conducted in N-EU to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 and its metabolite CGA 321113 and CGA 373466 in/on hop (cone, green and cone, kiln-dried) after two spraying applications in the field with 0.15 kg/ha trifloxystrobin with 14 days between applications at BBCH up to 79 and with PHI of 21 days.

The residue levels of trifloxystrobin in/on cone, kiln-dried were:

RD-Mo: 0.056, 0.07, 0.24, 0.42, 0.44, 0.61, 0.62, 0.63, 0.74, 1.3 mg/kg,

RD-RA: 0.16, 0.43, 0.47, 0.63, 0.78, 0.98, 2x1.1, 1.5, 1.6 mg/kg.

Available results show that the in force MRL of trifloxystrobin on hop of 40 mg/kg (Reg. (EU) 2019/1791) will not be exceeded. The current EU MRL for trifloxystrobin is sufficient to support the proposed use.

The trials are supported by valid storage stability data and validated analytical methods.

The proposed use on hop (F) is considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Trifloxystrobin is authorised for use on vegetables and fruits and several other crops in the EU. The crops relevant to this dRR do not provide commodities which might be fed to livestock. Therefore a dietary burden calculation was not conducted.

zRMS comments:

Information given by the Applicant is sufficient. As the proposed uses are not relevant for animal feeding the dietary burden calculation does not need to be conducted.

No further data are required.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

Data/information on livestock feeding studies were reviewed during the MRL review (EFSA, 2014) and later in the EU peer review (EFSA, 2017) [Reports KCA 6.4.1/01-02]

No new data were submitted in the framework of this application. An overview of the ruminant feeding studies is presented below. No specific feeding study has been conducted with pigs as the metabolic pattern in ruminants does not differ significantly from that in the rat. This point is therefore adequately covered by

the cattle feeding study.

Poultry feeding studies were submitted, but not evaluated, since based on the metabolism studies it was concluded that no residue above LOQ is expected in poultry commodities and therefore no poultry feeding study is required.

Conclusion on feeding studies

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

Table 7.2-10: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) ^(b)	Highest residue (mg/kg) ^(c)	Calculated MRL (mg/kg)	CF for RA ^(d)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) ^(a)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (EFSA Journal 2014 ; 12(2) : 3592) [Reports KCA 6.4.1/01-02]												
Enforcement residue definition: sum of trifloxystrobin and CGA321113, expressed as trifloxystrobin												
Pig muscle	0.07	0.12	0.06	3	n.a.	n.a.	n.a.	n.a.	0.04	0.04	0.04	1.00
			0.19	3	n.a.	n.a.	n.a.	n.a.				
			0.64	3	<0.04	<0.04	<0.04	<0.04				
Pig fat	0.07	0.12	0.06	3	<0.04	<0.04	<0.04	<0.04	0.04	0.04	0.04	1.00
			0.19	3	<0.04	<0.04	<0.04	<0.04				
			0.64	3	0.06	0.08	0.06	0.08				
Pig liver	0.07	0.12	0.06	3	<0.04	<0.04	<0.04	<0.04	0.04	0.04	0.04	1.00
			0.19	3	<0.04	<0.04	<0.04	<0.04				
			0.64	3	0.08	0.11	0.08	0.11				
Pig kidney	0.07	0.12	0.06	3	<0.04	<0.04	<0.04	<0.04	0.04	0.04	0.04	1.00
			0.19	3	<0.04	<0.04	<0.04	<0.04				
			0.64	3	0.04	0.04	0.04	0.04				
Ruminant muscle	0.19	0.38	0.06	3	n.a.	n.a.	n.a.	n.a.	0.04	0.04	0.04	1.00
			0.19	3	n.a.	n.a.	n.a.	n.a.				
			0.64	3	<0.04	<0.04	<0.04	<0.04				
Ruminant fat	0.19	0.38	0.06	3	<0.04	<0.04	<0.04	<0.04	0.04	0.06	0.06	1.00
			0.19	3	<0.04	<0.04	<0.04	<0.04				
			0.64	3	0.06	0.08	0.06	0.08				
Ruminant liver	0.19	0.38	0.06	3	<0.04	<0.04	<0.04	<0.04	0.04	0.07	0.07	3.30
			0.19	3	<0.04	<0.04	<0.04	<0.04				
			0.64	3	0.08	0.11	0.08	0.11				
Ruminant kidney	0.19	0.38	0.06	3	<0.04	<0.04	<0.04	<0.04	0.04	0.04	0.04	1.30
			0.19	3	<0.04	<0.04	<0.04	<0.04				
			0.64	3	0.04	0.04	0.04	0.04				
Milk	0.14	0.27	0.64	3	<0.02 ^(d)	- (e)	<0.02 ^(d)	- (e)	0.02	0.02	0.02	1.00

n.a.: Not analysed

(a): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

(b): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

- (c): The median conversion factor for enforcement to risk assessment.
(d): Mean residue level from day 1 until day 28 (3 cows, 28 sampling days).
(e): Only the mean values are considered for calculating MRLs in milk

zRMS comments:

Information given by the Applicant is sufficient. The livestock feeding studies was sufficiently investigated during the renewal of approval of the active substance. Animal matrices were analysed for trifloxystrobin and CGA 321113, and no residue above the LOQ (0.02 mg/kg) were found.

As the proposed uses are not relevant for animal feeding, the magnitude of trifloxystrobin residues in livestock does not need to be assessed. No further data are required.

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

General data / information on processing were evaluated in the EU peer review for trifloxystrobin under Regulation 91/414.

7.2.5.1 Available data for all crops under consideration

Under the standard hydrolysis conditions, trifloxystrobin remained stable under pasteurisation and baking/brewing/boiling but degraded significantly under sterilisation into CGA 321113 (up to 21.5% degradation); therefore, the residue definition for risk assessment in processed commodities is proposed as trifloxystrobin and CGA 321113 (EFSA Journal 2017;15(10):4989).

In the peer review 2017, data on grape and strawberry were already evaluated.

Additional processing studies have been submitted by the applicant in the framework of this application. These studies, as well as the grape and strawberry studies already evaluated, are summarized in the table below. The detailed results (tomato, bean, hops) are presented in Appendix 2.

Table 7.2-11: Overview of the available processing studies

Table 7.2-11: Overview of the available processing studies					
Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
Available data					
Enforcement residue definition: Trifloxystrobin Risk assessment residue definition (processing): sum of trifloxystrobin and CGA 321113, expressed as trifloxystrobin					
Grapes, must	17	0.4	N/A	-	EFSA Journal 2017;15(10):4989
Grapes, wine	18	0.02	N/A	-	
Grapes, juice	6	0.14	N/A	-	Detailed references see below table
Grapes, pomace	2	5.5	N/A	-	
Grapes, raisins	2	1.45	N/A	-	
strawberry, washed fruit	4	0.58	N/A	-	EFSA Journal 2017;15(10):4989
strawberry, preserve	4	0.3	N/A	-	
strawberry, jam	4	0.43	N/A	-	Detailed references see below table
Additional data					
Cooked bean	2	0.55 (mean PF)	N/A	-	Nuesslein, Eberhardt, 2003, M-104911-01-1 , report Nr. RA-3037/02, Appendix 2
Hops	4	<0.1	-	-	Beinhauer, 1996, M-052604-02-1 , report Nr. GR01796 Nossn, Krusell, 2010,

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
					M-389146-01-1 , report Nr. 08-3086 Noss, Diehl, 2013, M-444838-01-1 , report Nr. 10-3174 Appendix 2

* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study. Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)

** When the residue definition for risk assessment differs from the residue definition for monitoring; N/A because calculation of CF not possible, or not meaningful since residues of CGA 321113 were either not determined or were <LOQ, or close to it in the RAC prior to processing.

References

Grape:

Ipach and Kissling, 1997, [M-037633-01-1](#), report no. gr01296. KCA 6.5.3/15
Ipach and Kissling, 1997, [M-037640-01-1](#), report no. gr01496. KCA 6.5.3/11
Ipach, 1996, [M-037644-01-1](#), report no. CGD03. KCA 6.5.3/23
Ipach and Kissling, 1997, [M-037647-01-1](#), report no. gr01196. KCA 6.5.3/16
Ipach and Kissling, 1997, [M-037676-01-1](#), report no. gr01396. KCA 6.5.3/12
Beinhauer and Kissling, 1996, [M-037690-01-1](#), report no. 951047008. KCA 6.5.3/24
Kissling, 1997, [M-037715-01-1](#), report no. 2085/96. KCA 6.5.3/13
Kissling, 1997, [M-037753-01-1](#), report no. 2086/96. KCA 6.5.3/17
Kissling, 1997, [M-037760-01-1](#), report no. 2084/96. KCA 6.5.3/14
Kissling, 1997, [M-037798-01-1](#), report no. 2087/96. KCA 6.5.3/18
Kissling, 1997, [M-037802-01-1](#), report no. 2117/95. KCA 6.5.3/25
Kissling, 1997, [M-037896-01-1](#), report no. 2055/96. KCA 6.5.3/19
Kissling, 1997, [M-037908-01-1](#), report no. 2056/96. KCA 6.5.3/20
Kissling, 1997, [M-037921-01-1](#), report no. 2028/96. KCA 6.5.3/21
Kissling, 1997, [M-037928-01-1](#), report no. 2029/96. KCA 6.5.3/22
Kissling, 1997, [M-037970-01-1](#), report no. 2035/95. KCA 6.5.3/26
Kissling, 1997, [M-038067-01-1](#), report no. 2036/95. KCA 6.5.3/20
Schmeer and Kuppels, 2009, [M-357708-02-1](#), report no. 08-2204. KCA 6.5.3/04
Schmeer and Hoffmann, 2010, [M-384844-01-1](#), report no. 08-3204. KCA 6.5.3/05
Vincent, 1998, [M-104033-01-1](#), report no. 110440. KCA 6.5.3/06

Strawberry:

Nuesslein, 2003, [M-086063-01-1](#), report no. RA-3038/02. KCA 6.5.3/07
Freitag, 2013, [M-464835-02-1](#), report no. 12-3012. KCA 6.5.3/08

7.2.5.2 Conclusion on processing studies

For the crops of interest in this dossier, adequate processing studies are available on bean and hops and provided with this dossier. Processing data on grapes and strawberry were already evaluated and are therefore not submitted again.

Based on the available processing studies, the transfer factors were calculated for processed products. A concentration of trifloxystrobin residues was observed in in grape raisin (= dried fruit) and grape pomace.

zRMS comments:

Information given by the Applicant is sufficient.

In the current submission, significant residues (>0.1 mg/kg) were found in the submitted residue trials conducted in NEU. Therefore, processing studies are required for grapes, strawberry, beans and hops that can be consumed processed. Processing data on grapes and strawberry were already evaluated in peer review (2017).

Applicant submitted four studies on processed commodities.

According to the EFSA Journal 2017;15(10):4989 the plant residue definitions for processed commodities are:

- for monitoring – trifloxystrobin,
- for risk assessment – sum of trifloxystrobin and CGA 321113 (M5), expressed as trifloxystrobin.

Available studies:

1. Nuesslein, F.; 2003; RA-3037/02; M-104911-01-1 – “*Determination of residues of trifloxystrobin and CGA 321113 in/on climbing French bean and processing products (...) following spray application of Flint 50 WG in the greenhouse in Germany and Italy*”:

All calculated transfer factors for trifloxystrobin were < 1.0. It is concluded that reduction of residues was seen in washed bean with pod, washing water, cooked bean with pod and cooking water.

No transfer factors could be calculated for CGA 321113, because the residues both in the raw agricultural commodity and in the processed products were below the LOQ.

2. Beinhauer, K.; 1996; GR01796; M-052604-02-1 – “*Trial for determination of residue levels in hops according to BBA Guideline IV, 3-3 and 3-4 (1990)*”:

All calculated transfer factors for trifloxystrobin and CGA 321113 were < 1.0 for all hops processed matrices. It is concluded that reduction of residues was seen in processed commodities of hops. No residues above LOQ were found in beer.

3. Noss, G.; Diehl, P.; 2013; 10-3174; M-444838-01-1 – “*Determination of the residues of trifloxystrobin in/on hop and the processed fractions (hops draff, brewer’s yeast and beer) after spraying of trifloxystrobin WG 50 in the field in Germany*”:

All calculated transfer factors for trifloxystrobin, CGA 321113, CGA 331409 and CGA 357261 were < 1.0 for all hops processed matrices.

The calculated transfer factor for sum of trifloxystrobin and CGA 321113 was 1.036 for hops draff and 0.02 for brewer’s yeast. No residues above LOQ were found in beer.

No processing factors for CGA 357262 and CGA 373466 were calculated, because the residues were below LOQ in all processed fractions and in the RAC samples.

4. Noss, G.; Krusell, L.; 2010; 08-3086; M-389146-01-1 – “*Determination of the residues of AE C656948 and trifloxystrobin in/on hops and processed fractions after spraying of AE C656948 & CGA 279202 SC 500 in the field in France (North) and Germany*”:

In the RAC samples of dry cone of hops the residues of trifloxystrobin were 0.39-0.89 mg/kg and the residues of CGA 321113 were 0.23-0.31.

After processing, the trifloxystrobin and CGA 321113 residues were below LOQ.

All calculated transfer factors for sum of trifloxystrobin and CGA 321113 were < 0.3 for all hops processed matrices. It is concluded that reduction of residues was seen in processed commodities of hops.

More information is presented in Appendix 2.

No further data are required.

7.2.6 Magnitude of residues in representative succeeding crops

Crops under evaluation are not expected to be grown in rotation. Further investigation of residues in rotational crops is therefore not required.

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.

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

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

Since the results of the metabolism in rotational crop studies did not indicate that significant accumulation of residues occurs through soil uptake into food or feed commodities, field studies in rotational crops are not required.

EFSA stated in their review done in 2014 (EFSA Journal 2014;12(2):3592):

“Based on the rotational confined crop study, considering that the application rate of trifloxystrobin within the EU ranges between 0.1-1.3 kg a.s./ha and that trifloxystrobin was applied to a bare soil (interception of trifloxystrobin by the plants is expected in practice), it can be concluded that trifloxystrobin residue levels

in rotational commodities are not expected to exceed 0.01 mg/kg, provided that trifloxystrobin is applied in compliance with the GAPs reported in Appendix A.”

Nevertheless, a field study is available and EFSA stated in their review done in 2017 (EFSA Journal 2017;15(10):4989:

“Three rotational field trials in lettuce, turnip and wheat conducted with 1128 g/ha (7.5N) at 30-day PBI were available. They were analysed for trifloxystrobin and CGA 321113 and the results were all below the LOQ (0.02 mg/kg).” (Reference: xxx, 1999. [M-073777-01-1](#), report no. 109-97).

No new data submitted in the framework of this application.

Conclusion on rotational crops studies

It can be concluded that no significant residue levels occur in rotational crops provided that the active substance is used according to the proposed GAP.

Table 7.2-12: Summary of available studies in field rotational crops

Table 7/2-12: Summary of available studies in next rotational crops					
Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals / plant back interval (DAT)	Reference / Remarks
EU data					
Squash	4 x 0.282 (1.128 total)	Leafy crop	Lettuce leaf	30/31	Hayworth, 1999 M-073777-01-1 , report no. 109-97 EFSA, 2017
		Root vegetables	Turnip top/leaf Turnip root	30/31	
Cucumber or squash	4 x 0.282 (1.128 total)	Cereals	Wheat forage Wheat hay Wheat straw Wheat grain	30/31	

zRMS comments:

Information given by the Applicant is sufficient.

In EFSA Journal 2018;16(1):5154 it is stated that the possible transfer of trifloxystrobin residues to crops that are grown in crop rotation has been assessed in the MRL review (EFSA, 2014). Three rotational field trials in lettuce, turnip and wheat conducted with 1.13 kg/ha (2.8N) at 30 days plant back interval were available. They were analysed for trifloxystrobin and CGA 321113 and the results were all below the LOQ of 0.02 mg/kg.

Since the maximum annual application rate for the crops under consideration is lower than the application rate tested in the rotational crop studies, it is concluded that no residues are expected, provided that the active substance is applied according to the proposed GAP.

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

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

A study on residues of trifloxystrobin in honey is available and summarised in Appendix 2.

zRMS comments:

According to the EFSA Journal 2017;15(10):4989: “Two ecotoxicology studies providing concentration data of trifloxystrobin and CGA 321113 in pollen and nectar of almond and phacelia were provided. However, the data requirement for the determination of the residues in bee products for human consumption resulting from residues taken up by honeybees from crops at blossom is not addressed with regard to trifloxystrobin and relevant metabolites for risk assessment (data gap).”

The study on residues of trifloxystrobin in honey has been submitted by the applicant in the framework of this application.

Appeltaufer, A.; 2020; S19-01068; M-678866-01-1 – “Determination of residues of trifloxystrobin and its isomers and metabolites in honey after three applications of TFS WG 50 in Phacelia tanacetifolia at 4 Sites in northern and southern Europe in 2019”

The study included four supervised semi-field residue trials conducted in Northern (2 trials) and Southern (2 trials) Europe during the 2019 season to determine the residues of trifloxystrobin and its isomers and metabolites in bee honey after three applications of TFS WG 50 in Phacelia tanacetifolia during flowering (BBCH 62 – 69). The application rate per treatment was 0.250 kg trifloxystrobin/ha. The product was applied to plots with Phacelia tanacetifolia three times with spray intervals of 6-7 days. Bee honey samples were collected 2-7 days after the last application.

The LOQ for the analytes was 0.01 mg/kg (expressed as parent equivalent for CGA 321113 and CGA 373466).

Residues of trifloxystrobin were <0.01 mg/kg – 0.037 mg/kg.

Residues of CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 were below LOQ (<0.01 mg/kg; parent equivalent for CGA 321113 and CGA 373466).

According to the the Reg. (EU) 2019/1791 residue definition for monitoring for honey is trifloxystrobin. The current value of MRL for honey and other apiculture products is 0.05* mg/kg (Reg. (EU) 2019/1791). Available results show that the in force MRL of trifloxystrobin on honey of 0.05 mg/kg (Reg. (EU) 2019/1791) will not be exceeded. ~~The European Food Safety Authority identified some information on residue trials as unavailable. It should be noted that the residue definition for monitoring and risk assessment for honey is not defined, so in our opinion this issue should be set at the active substance level.~~

No further data are required at this moment.

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).

As ArfD was not deemed necessary, acute risk assessment is not relevant.

Remark after the commenting period:

The following residue definition for risk assessment applies: **Trifloxystrobin, its three isomers (CGA 357261, CGA 357262, CGA 331409) and CGA 321113** (Peer review of the pesticide risk assessment of the active substance trifloxystrobin, September 2017)

In the conclusion on pesticides peer review for trifloxystrobin (September 2017) is following stated:

For the metabolites CGA 357261, CGA 357262 and CGA 331409 their toxicity profile after acute and repeated exposure cannot be concluded on the basis of the available data. Considering the representative uses and final assessment by residues, data gaps are identified for metabolites CGA 357261 (data gap for toxicological profile after repeated dose exposure), CGA 357262 (data gap for toxicological profile after acute and repeated dose exposure), CGA 331409 (toxicological profile after repeated dose exposure) and CGA 321113 (toxicological profile after repeated dose exposure since it cannot be considered covered by the parent).

As for the consumer risk assessment it is noted, that photoisomers were included into the residue definition for risk assessment. For those metabolites, no toxicological reference values are derived due to lack of data. Since the residue definition for monitoring remains the same (trifloxystrobin only), MRL compliance is still given. As internationally discussed, the risk assessment may not be finalised. Since the MRL in force considers the “old” residue definition for risk assessment (i.e. without those photometabolites), the uses intended may be registered until the open point as regards the toxicological properties of the metabolites is addressed and considered in terms of MRL setting.

7.2.8.1 Input values for the consumer risk assessment

The consumer risk assessments were performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMO). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population (EFSA, 2018. Update 2019).

For the calculation of chronic exposure, **all crops and animal matrices are considered**, since MRLs are

available for all and the chronic risk should cover all crops or matrices, not only the ones relevant in this dossier. The existing MRLs as established in Annexes IIIA of Regulation (EC) No 396/2005 were used as input values for trifloxystrobin (Commission Regulation 2019/1791, 2019). Although in case of the MRLs, the other 3 isomers of trifloxystrobin and metabolite CGA 321113 are not included, the calculation using the MRL still represents a worst case, since the MRL values are generally higher than the median residue of the sum of trifloxystrobin, its isomers and CGA 321113 expressed as trifloxystrobin. Exception: chicory witloof, chicory root, sugar beet and beetroots: For these crops the STMRs for the total residue as submitted with the Post AR dRR (Trifloxystrobin WG 50) are used as input values for the chronic risk assessment, since the MRLs are low and the STMRs for risk assessment are higher than the MRLs.

~~For sweet pepper, olive, leek, flax/linseed, artichoke, celery, seed spices, herbal infusions from flowers and herbal infusions from leaves and herbs, the MRLs as recently applied for or applied for in parallel to this dRR and other Post AR dRR or label extension submissions, are used as input values for the chronic risk assessment.~~

~~For the calculation of the acute exposure the same values were used as for the chronic risk, except for lettuce and endive/scarole, for which the highest residues (HR) for risk assessment (5 analytes) were used, as provided in this dossier, since the MRLs lead to ArfD-exhaustions. For lettuce the HR is 10 mg/kg (based on indoor use), for endive/scarole the HR is 2.3 mg/kg (based on the field use; indoor use not supported).~~

Table 7.2-13: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Citrus fruit	0.5	MRL (Commission Regulation 2019/1791)
Tree nuts	0.02	MRL (Commission Regulation 2019/1791)
Pome fruits	0.7	MRL (Commission Regulation 2019/1791)
Stone fruits	3	MRL (Commission Regulation 2019/1791)
Grapes	3 0.41	MRL (Commission Regulation 2019/1791) STMR (Table 7.2-9)
Strawberries	1 0.19	MRL (Commission Regulation 2019/1791) STMR (Table 7.2-9)
Cane fruits	3 0.76	MRL (Commission Regulation 2019/1791) STMR (Table 7.2-9)
Other small fruits and berries	3 0.615	MRL (Commission Regulation 2019/1791) STMR (Table 7.2-9)
Dates, Figs, Kumquats, Carambolas, Kaki, Jambuks, other misc. fruits with edible peel	0.01 *	MRL (Commission Regulation 2019/1791)
Table olives	0.5 P 0.3	New MRL proposal (2020) MRL (Commission Regulation 2019/1791)
Kiwi, Litchis, Prickly pears, Star apple, American persimmon, other misc. fruits with inedible peel, small	0.01 *	MRL (Commission Regulation 2019/1791)
Passionfruits	4	MRL (Commission Regulation 2019/1791)
Avocados, Mangoes, Granate apples, Cherimoyas, Guavas, Pineapples, Breadfruits, Durians, Soursops, other misc. fruits with inedible peel, large	0.01 *	MRL (Commission Regulation 2019/1791)
Bananas	0.05	MRL (Commission Regulation 2019/1791)
Papayas	0.6	MRL (Commission Regulation 2019/1791)
Potatoes	0.02	MRL (Commission Regulation 2019/1791)
Tropical root and tuber vegetables	0.01 *	MRL (Commission Regulation 2019/1791)
Beetroots	0.05	STMR risk assessment
Carrots	0.1	MRL (Commission Regulation 2019/1791)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Celeriac	0.03 0.05	MRL (Commission Regulation 2019/1791) STMR (Table 7.2-9)
Horseradishes, Parsley roots, Radishes	0.08	MRL (Commission Regulation 2019/1791)
Jerusalem artichokes, Others root and tuber vegetables	0.01 *	MRL (Commission Regulation 2019/1791)
Parsnips, Salsifies, Swedes, Turnips	0.04	MRL (Commission Regulation 2019/1791)
Garlic, Onions, Shallots, Others bulb vegetables	0.01 *	MRL (Commission Regulation 2019/1791)
Spring onions	0.1	MRL (Commission Regulation 2019/1791)
Tomatoes	0.7	MRL (Commission Regulation 2019/1791)
Sweet peppers	0.9 P 0.4	New MRL proposal (2019) MRL (Commission Regulation 2019/1791)
Aubergines	0.7	MRL (Commission Regulation 2019/1791)
Okra, Others Solanacea	0.01 *	MRL (Commission Regulation 2019/1791)
Cucurbits with edible peel	0.3	MRL (Commission Regulation 2019/1791)
Cucurbits with inedible peel	0.3	MRL (Commission Regulation 2019/1791)
Sweet corn and other fruiting vegetables	0.01 *	MRL (Commission Regulation 2019/1791)
Broccoli	0.6	MRL (Commission Regulation 2019/1791)
Cauliflower and Other flowering brassica	0.5	MRL (Commission Regulation 2019/1791)
Brussels sprouts	0.6	MRL (Commission Regulation 2019/1791)
Head cabbages	0.5	MRL (Commission Regulation 2019/1791)
Others, head brassica	0.01 *	MRL (Commission Regulation 2019/1791)
Leafy brassica	3	MRL (Commission Regulation 2019/1791)
Kohlrabies	0.01 *	MRL (Commission Regulation 2019/1791)
Lettuces and salad plants	15 0.88	MRL (Commission Regulation 2019/1791) STMR (Table 7.2-9)
Spinaches	20	MRL (Commission Regulation 2019/1791)
Purslanes (Sea aster, Sea lavender)	15 0.88	MRL (Commission Regulation 2019/1791) STMR (Table 7.2-9)
Chards / beet leaves	0.01 *	MRL (Commission Regulation 2019/1791)
Other spinaches and similar leaves	0.01 *	MRL (Commission Regulation 2019/1791)
Grape leaves and similar species	0.01 *	MRL (Commission Regulation 2019/1791)
Watercress	0.01 *	MRL (Commission Regulation 2019/1791)
Witloofs/Belgian endive	0.05 0.05	STMR risk assessment STMR (Table 7.2-9)
Herbs and edible flowers	15	MRL (Commission Regulation 2019/1791)
Beans with pods	1 0.11	MRL (Commission Regulation 2019/1791) STMR (Table 7.2-9)
Beans without pods, Peas without pods	0.09 0.05	MRL (Commission Regulation 2019/1791) STMR (Table 7.2-9)
Peas (with pods)	1.5 0.11	MRL (Commission Regulation 2019/1791) STMR (Table 7.2-9)
Lentils and other legume vegetables	0.01 *	MRL (Commission Regulation 2019/1791)
Asparagus	0.05	MRL (Commission Regulation 2019/1791)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Cardoons, Florence fennels, Rhubarbs, Bamboo shoots, Palm hearts, Others stem vegetables	0.01 *	MRL (Commission Regulation 2019/1791)
Celeries	7 P 1	New MRL proposal (2020) MRL (Commission Regulation 2019/1791)
Globe artichokes	0.5 P 0.3	New MRL proposal (2020) MRL (Commission Regulation 2019/1791)
Leeks	0.9 P 0.7	New MRL proposal (2020) MRL (Commission Regulation 2019/1791)
Fungi, mosses and lichens	0.01 *	MRL (Commission Regulation 2019/1791)
Algae and prokaryotes organisms	0.01 *	MRL (Commission Regulation 2019/1791)
Pulses	0.2	MRL (Commission Regulation 2019/1791)
Lentils (dry)	0.05	STMR (dry seed of pea and bean – new studies)
Oilseeds – except peanuts and soyabeans and cotton seed	0.01 *	MRL (Commission Regulation 2019/1791)
Peanuts	0.02	MRL (Commission Regulation 2019/1791)
Soyabeans	0.05	MRL (Commission Regulation 2019/1791)
Cotton seed	0.4	MRL (Commission Regulation 2019/1791)
Oilfruits – except olives	0.01 *	MRL (Commission Regulation 2019/1791)
Olives for oil production	0.5 P 0.3	New MRL proposal (2020) MRL (Commission Regulation 2019/1791)
Barley	0.5	MRL (Commission Regulation 2019/1791)
Buckwheat, Millet, Sorghum, Others cereals	0.01 *	MRL (Commission Regulation 2019/1791)
Maize	0.02	MRL (Commission Regulation 2019/1791)
Oat	0.4	MRL (Commission Regulation 2019/1791)
Rice	5	MRL (Commission Regulation 2019/1791)
Rye, Wheat	0.3	MRL (Commission Regulation 2019/1791)
Teas, Coffee, Herbal infusions from roots and other parts of the plant, Cocoa, Carobs	0.05 *	MRL (Commission Regulation 2019/1791)
Herbal infusions from flowers	35 P 0.05*	New MRL proposal (2020) MRL (Commission Regulation 2019/1791)
Herbal infusions from leaves and herbs	35 P 0.05*	New MRL proposal (2020) MRL (Commission Regulation 2019/1791)
Hops	40 0.88	MRL (Commission Regulation 2019/1791) STMR (Table 7.2-9)
Seed spices	50 P 0.05*	New MRL proposal (2020) MRL (Commission Regulation 2019/1791)
Fruit spices, Bark spices, Root and rhizome spices, Bud spices, Flower pistil spices, Aril spices	0.05 *	MRL (Commission Regulation 2019/1791)
Sugar beet roots	0.05	STMR risk assessment
Sugar canes, Others sugar plants	0.01 *	MRL (Commission Regulation 2019/1791)
Chicory roots	0.05	STMR risk assessment
Swine, all tissues	0.04	MRL (Commission Regulation 2019/1791)
Bovine, goat, equine, sheep and other farmed terrestrial animals: muscle, kidney	0.04	MRL (Commission Regulation 2019/1791)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Bovine, goat, equine sheep and other farmed terrestrial animals, fat tissue	0.06	MRL (Commission Regulation 2019/1791)
Bovine, goat, equine sheep and other farmed terrestrial animals: liver	0.07	MRL (Commission Regulation 2019/1791)
Bovine, goat, equine sheep and other farmed terrestrial animals: edible offals (other than liver and kidney)	0.07	MRL (Commission Regulation 2019/1791)
Others bovine, goat, equine sheep and other farmed terrestrial animals tissues	0.02*	MRL (Commission Regulation 2019/1791)
Poultry, tissues	0.04	MRL (Commission Regulation 2019/1791)
Milk	0.02 *	MRL (Commission Regulation 2019/1791)
Eggs	0.04	MRL (Commission Regulation 2019/1791)
Honey and other apiculture products	0.05 *	MRL (Commission Regulation 2019/1791)
Amphibians and Reptiles	0.02 *	MRL (Commission Regulation 2019/1791)
Terrestrial invertebrate animals	0.02 *	MRL (Commission Regulation 2019/1791)
Wild terrestrial vertebrate animals	0.02 *	MRL (Commission Regulation 2019/1791)

* Indicates lower limit of analytical determination

Table 7.2-14: ~~Alternative~~ Input values for the acute consumer risk assessment

Commodity	Chronic Acute risk assessment	
	Input value (mg/kg)	Comment
Grapes	0.67	HR for risk assessment, field and indoor use
Strawberries	0.51	
Cane fruits	1.6	
Other small fruits and berries	2.3	
Celeriac	0.057	
Lettuce and salad plants	1.0 1.8	
Purslanes (Sea aster, Sea lavender)	1.8	
Witloofs/Belgian endive	2.3 0.05	
Beans with pods	0.28	
Beans without pods, Peas without pods	0.09	
Peas (with pods)	0.28	
Lentils (dry)	0.052	
Hops	1.6	

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

No long-term or short-term intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo.

The total calculated intake values accounted to up to 50% of the ADI (NL toddler).

Intakes of raw commodities accounted for maximum 76% of the ARfD (Lettuces for children);
Processed commodities do not exceed 30% of the ARfD (max. 30% for boiled escarole and children)

The uses of trifloxystrobin in the formulation Fluopyram + Trifloxystrobin SC 500 do not represent unacceptable acute and chronic risks for the consumer.

Table 7.2-15: Consumer risk assessment


Chronic risk assessment	
TMDI (% ADI) according to EFSA PRIMo	50% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	39%
NTMDI (% ADI) ^{2,3}	39%
NEDI (% ADI) ^{2,3}	39%
ADI	0.1 mg/kg bw per day
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	49% (based on NL toddler Diet)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	39% (based on NL toddler Diet)
ARfD	0.5 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1	14% (escaroles; children) 7% (escaroles; adults)

zRMS comments:

The consumer risk assessments were performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRiMo). The calculation of the TMDI using EFSA model (version 3.1) and MRLs according to Reg. (EU) 2019/1791 led to a utilisation of the ADI of 49% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is spinaches with 14% of the ADI.

If the median residue (STMR) values derived from the available supervised residue trials for proposed uses and current MRLs (Reg. (EU) 2019/1791) for other crops and animals matrices are used as input values, the TMDI using EFSA model (version 3.1) lead to a utilisation of the ADI of 39% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is spinaches with 14% of the ADI.

The results are presented in the Table below:

 <p>European Food Safety Authority EFSA PRiMo revision 3.1; 2019/03/19</p>		Trifloxystrobin LOGs (mg/kg) range from: to:		Input values	
		Toxicological reference values		Details - chronic risk assessment	Supplementary results - chronic risk assessment
ADI (mg/kg bw/day):		0.1	ARID (mg/kg bw):	0.5	
Source of ADI:		EFSA	Source of ARID:	EFSA	
Year of evaluation:		2017	Year of evaluation:	2017	
Details - acute risk assessment/children					
Details - acute risk assessment/adults					
Normal mode					
Chronic risk assessment: JMPR methodology (EDVTMDI)					
No of diets exceeding the ADI :					

TMDI (NED)/EDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	2nd contributor to MS diet (in % of ADI)	3rd contributor to MS diet (in % of ADI)
	MS Diet	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities
	49% NL toddler	49.43 14% Spinaches	4% Apples	5% Table grapes	4% Spinaches
	34% DE child	34.11 8% Apples	4% Table grapes	3% Spinaches	3% Tomatoes
	26% GEMS/Food G06	25.66 8% Rice	3% Table grapes	3% Table grapes	3% Table grapes
	25% NL child	25.37 5% Spinaches	4% Apples	3% Table grapes	3% Table grapes
	24% GEMS/Food G10	23.93 6% Rice	5% Lettuces	1% Lettuces	1% Wine grapes
	20% GEMS/Food G07	20.09 4% Wine grapes	4% Lettuces	2% Rice	2% Rice
	20% IE adult	19.59 4% Wine grapes	3% Spinaches	1% Lettuces	1% Lettuces
	20% PT general	19.52 7% Wine grapes	4% Rice	2% Lettuces	2% Lettuces
	19% GEMS/Food G08	18.54 3% Wine grapes	3% Lettuces	1% Rice	1% Rice
	18% IT adult	17.74 6% Lettuces	2% Other lettuce and other salad plants	2% Spinaches	2% Spinaches
	18% GEMS/Food G11	17.74 3% Wine grapes	2% Spinaches	1% Rice	1% Rice
	17% ES child	17.34 6% Lettuces	2% Rice	2% Spinaches	2% Spinaches
	17% FR child 3-15 yr	17.25 2% Rice	2% Spinaches	2% Changes	2% Changes
	17% ES adult	17.19 8% Lettuces	1% Spinaches	1% Wine grapes	1% Wine grapes
	17% SE general	16.81 6% Lettuces	2% Rice	1% Spinaches	1% Spinaches
	16% GEMS/Food G15	16.44 3% Wine grapes	2% Lettuces	2% Rice	2% Rice
	16% FR adult	15.75 7% Wine grapes	2% Other lettuce and other salad plants	1% Spinaches	1% Spinaches
	16% IT toddler	15.75 4% Lettuces	2% Wheat	2% Other lettuce and other salad plant	2% Other lettuce and other salad plant
	15% FR toddler 2-3 yr	15.49 3% Spinaches	3% Rice	2% Apples	2% Apples
	15% RO general	14.51 5% Wine grapes	2% Wheat	1% Tomatoes	1% Tomatoes
	14% NL general	14.47 3% Spinaches	2% Wine grapes	1% Escaroles/broad-leaved endives	1% Escaroles/broad-leaved endives
	14% DE women 14-50 yr	14.39 3% Wine grapes	2% Apples	2% Lettuces	2% Lettuces
	14% DE general	13.52 2% Wine grapes	2% Apples	1% Lettuces	1% Lettuces
	12% DK child	12.20 2% Lettuces	2% Rice	2% Apples	2% Apples
	11% UK toddler	11.33 3% Rice	1% Apples	1% Wheat	1% Wheat
	11% UK vegetarian	10.79 2% Wine grapes	2% Lettuces	2% Rice	2% Rice
	11% FI 3 yr	10.55 3% Rice	1% Spinaches	0.7% Table grapes	0.7% Table grapes
	10% UK adult	10.00 3% Wine grapes	2% Rice	2% Lettuces	2% Lettuces
	10% FR infant	9.92 5% Spinaches	1% Apples	0.5% Beans (with pods)	0.5% Beans (with pods)
	10% UK infant	9.67 3% Rice	1% Apples	0.8% Wheat	0.8% Wheat
	9% FI 6 yr	8.80 2% Rice	1% Lettuces	1% Spinaches	1% Spinaches
	8% DK adult	8.40 3% Wine grapes	1% Lettuces	0.7% Apples	0.7% Apples
	7% FI adult	6.91 2% Lettuces	0.9% Wine grapes	0.6% Rice	0.6% Rice
	6% LT adult	5.57 1% Apples	1% Rice	1.0% Lettuces	1.0% Lettuces
	5% PL general	5.45 1% Apples	1.0% Table grapes	0.6% Tomatoes	0.6% Tomatoes
	3% IE child	3.01 1% Rice	0.3% Wheat	0.2% Apples	0.2% Apples
Conclusion: The estimated long-term dietary intake (TMDI(NED)/EDI) was below the ADI. The long-term intake of residues of Trifloxystrobin is unlikely to present a public health concern.					

The intended uses will not result in a consumer chronic exposure exceeding the ADI.

Acute risk assessment

IESTI (% ARfD) according to EFSA PRiMo*

Children

76% Lettuces
 44% Table grapes
 18% Escaroles/endive
 11% Sweet peppers
 8% Lamb's lettuce
 8% Tomatoes
 8% Roman rocket
 6% Blackberries
 6% Wine grapes
 6% Raspberries
 5% Currants
 4% Blueberries
 4% Gooseberries
 4% Aubergines
 3% Strawberries
 3% Cranberries
 2% Peas (with pods)
 2% Beans (with pods)
 1% Dewberries
 <1% each for all other relevant crops and animal matrices

Adults

24% Lettuces
 20% Table grapes
 16% Red-mustards
 14% Wine grapes
 9% Escaroles/endive
 6% Lamb's lettuce
 5% Blueberries
 5% Blackberries
 4% Currants
 4% Aubergines
 4% Roman rocket
 3% Raspberries
 3% Sweet peppers
 3% Gooseberries
 2% Tomatoes
 2% Strawberries
 2% Beans (with pods)
 1% Hops (dried)
 1% Rose hips
 1% Cress and others
 1% Peas (with pods)
 <1% each for all other relevant

<p>zRMS comments:</p> <p>For the calculation of the acute exposure the highest residues (HR) levels derived from the available supervised residue trials were used (see Table 7.2-16), based on the uses under consideration. The results are presented in the Table below:</p>
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Acute risk assessment /children				Acute risk assessment /adults / general population				Acute risk assessment /children				Acute risk assessment / adults / general population				
Details - acute risk assessment /children				Details - acute risk assessment /adults				Hide IESTI new calculations				Show IESTI new calculations				
The acute risk assessment is based on the ARID.				The acute risk assessment is based on the ARID.				The acute risk assessment is based on the ARID.				The acute risk assessment is based on the ARID.				
The calculation is based on the large portion of the most critical consumer group.				The calculation is based on the large portion of the most critical consumer group.				The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.				The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.				
Show results for all crops				Show results for all crops				Show results for all crops				Show results for all crops				
Unprocessed commodities	Results for children No. of commodities for which ARID/ADI is exceeded (IESTI)				Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI)				IESTI new Results for children No. of commodities for which ARID/ADI is exceeded (IESTI new)				IESTI new Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI new)			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)
	24%	Escaroles/broad-leaved	1/8/1,8	72	7%	Escaroles/broad-leaved	1/8/1,8	36	14%	Escaroles/broad-leaved	1/8/1,8	43	5%	Escaroles/broad-leaved endives	1/8/1,8	26
	14%	Lettuces	1/8/1,8	69	5%	Table grapes	0/67/0,67	23	8%	Lettuces	1/8/1,8	41	4%	Blueberries	2/3/2,3	21
	10%	Table grapes	0/67/0,67	49	4%	Lettuces	1/8/1,8	22	6%	Table grapes	0/67/0,67	29	3%	Wine grapes	0/67/0,67	16
	4%	Currents (red, black and white)	2/3/2,3	18	4%	Blueberries	2/3/2,3	18	4%	Currents (red, black and white)	2/3/2,3	18	3%	Currents (red, black and white)	2/3/2,3	15
	3%	Blackberries	1/6/1,6	17	3%	Wine grapes	0/67/0,67	16	3%	Blackberries	1/6/1,6	17	3%	Table grapes	0/67/0,67	14
	3%	Raspberries (red and white)	1/6/1,6	15	3%	Currents (red, black and white)	2/3/2,3	15	3%	Raspberries (red and white)	1/6/1,6	15	3%	Blackberries	1/6/1,6	13
	3%	Blueberries	2/3/2,3	14	3%	Blackberries	1/6/1,8	13	3%	Blueberries	2/3/2,3	14	3%	Lettuces	1/8/1,8	13
Expanded/tape list	Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)				Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)				Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI new calculation)				Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI new calculation)			
	0.6%				0.6%				0.6%				0.5%			
	0.6%				0.6%				0.6%				0.5%			
	0.6%				0.6%				0.6%				0.5%			
	0.6%				0.6%				0.6%				0.5%			
	0.6%				0.6%				0.6%				0.5%			
	0.6%															

Processed commodities	Results for children No. of processed commodities for which ARID/ADI is exceeded (IESTI):				Results for adults No. of processed commodities for which ARID/ADI is exceeded (IESTI):				Results for children No. of processed commodities for which ARID/ADI is exceeded (IESTI new):				Results for adults No. of processed commodities for which ARID/ADI is exceeded (IESTI new):			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)
	24%	Escaroles/broad-leaved	1/8/1,8	72	7%	Escaroles/broad-leaved	1/8/1,8	36	14%	Escaroles/broad-leaved	1/8/1,8	43	5%	Escaroles/broad-leaved endives	1/8/1,8	26
	13%	Currents (red, black and w	2/3/2,3	66	6%	Currents (red, black and w	2/3/2,3	29	13%	Currents (red, black and w	2/3/2,3	66	6%	Escaroles/broad-leaved endives	1/8/1,8	28
	7%	Elderberries /juice	2/3/2,3	37	4%	Elderberries /juice	2/3/2,3	21	7%	Elderberries /juice	2/3/2,3	37	4%	Elderberries /juice	2/3/2,3	21
	6%	Wine grapes /juice	0/67/0,67	29	3%	Wine grapes /juice	0/67/0,67	14	6%	Wine grapes /juice	0/67/0,67	29	3%	Wine grapes /juice	0/67/0,67	14
	1%	Raspberries /juice	1/6/1,6	19	1%	Punslanes /boiled	1/8/1,8	19	1%	Raspberries /boiled	1/6/1,6	19	1%	Punslanes /boiled	1/8/1,8	19
	3%	Cranberries /juice	2/3/2,3	13	1%	Wine grapes /wine	0/67/0,67	6,3	3%	Cranberries /juice	2/3/2,3	13	1%	Wine grapes /wine	0/67/0,67	6,3
	3%	Azoreale (mediterranean me	2/3/2,3	13	0,8%	Table grapes /raisins	0/67/31,5	3,9	0,5%	Azoreale (mediterranean me	2/3/2,3	13	0,8%	Table grapes /raisins	0/67/31,5	3,9
Expanded/tape list	Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)				Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)				Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI new calculation)				Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI new calculation)			
	0.6%				0.6%				0.6%				0.5%			
	0.6%				0.6%				0.6%				0.5%			
	0.6%				0.6%				0.6%				0.5%			
	0.6%				0.6%				0.6%				0.5%			
	0.6%				0.6%				0.6%				0.5%			
	0.6%															

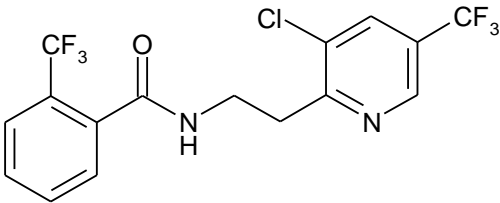
Conclusion:															
No exceedance of the toxicological reference value was identified for any unprocessed commodity.															
A short-term intake of residues of Telivendrasin is unlikely to represent a public health risk															

The highest International Estimated Short-Term Intake (IESTI) is at 14% and 7% of the ARfD for the consumption of escaroles by children and by adults respectively.
The proposed uses of trifloxystrobin in the formulation FLU + TFS SC 500 do not represent unacceptable acute and chronic risks for the consumer.

7.3 Fluopyram

General data on fluopyram are summarized in the table below.

Table 7.3-1: General information on fluopyram

Active substance (ISO Common Name)	Fluopyram
IUPAC	N-{2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]ethyl}- α,α,α -trifluoro-o-toluamide
Chemical structure	
Molecular formula	C ₁₆ H ₁₁ ClF ₆ N ₂ O
Molar mass	396.72 g/mol
Chemical group	Pyridinyl-ethyl-benzamides
Mode of action (if available)	Respiration (SDHi)
Systemic	Yes
Company (ies)	Bayer Division Crop Science*
Rapporteur Member State (RMS)	Germany
Approval status	Approved Date of (01/02/2014) and reference to decision (Regulation (EU) No 802/2013)
Restriction	see Approval Regulation (EU) No. 802/2013, dated 22 August 2013
Review Report	SANCO/11456/2013 – rev. 2 16/07/2013
Current MRL regulation	Commission Regulation (EU) N° 2019/1791 of 17. October 2019
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes ongoing
EFSA Journal : Conclusion on the peer review	Yes, EFSA Journal 2013;11(4):3052
EFSA Journal : conclusion on article 12	Yes, EFSA Journal 2020;18(4):6059
Current MRL applications on intended uses	-

Note:

This zonal evaluation was performed in line with Article 43 of Regulation (EC) No 1107/2009 due to renewal of trifloxystrobin at the EU level. Fluopyram was not yet renewed and only data for trifloxystrobin were subject of the re-evaluation at the zonal level.

7.4 Combined exposure and risk assessment

The product is a mixture of two active substances. Therefore, combined acute exposure could be considered.

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 definition “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.

Combined risk assessment is currently not required by the zRMS and cMS concerned by this application, except for United Kingdom, for which a National Addendum will be provided.

7.5 References

Trifloxystrobin

EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for trifloxystrobin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(2):3592.

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EFSA (European Food Safety Authority), 2016. Reasoned opinion. Modification of the existing maximum residue level (MRL) for trifloxystrobin in celeriacs. EFSA Journal 2016;14(1):4383.

EFSA (European Food Safety Authority), 2017. Peer review of the pesticide risk assessment of the active substance trifloxystrobin. EFSA Journal 2017;15(10):4989.

EFSA (European Food Safety Authority), 2018. Reasoned opinion. Modification of the existing maximum residue levels for trifloxystrobin in various crops. EFSA Journal 2018;16(1):5154.

JMPR, 2004. Pesticide residues in food 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Rome, Italy, 20–29 September 2004.

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EFSA (European Food Safety Authority), 2018. Use of EFSA pesticide intake model (EFSA PRIMo revision 3). EFSA Journal 2018;16(1):5147. Adopted 19 December 2017.

EFSA (European Food Safety Authority), 2019. Pesticide Residue Intake Model – EFSA PRIMo revision 3.1 (update of EFSA PRIMo revision 3). EFSA Supporting publication 2019. Approved 22 March 2019.

DAR, 2000 & RAR, 2017 – Draft (Renewal) Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009 for trifloxystrobin – July 2017.

SANTE/10107/2018 of 25 May 2018 – Final Renewal report for the active substance trifloxystrobin finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 25 May 2018 in view of the renewal of the approval of trifloxystrobin as active substance in accordance with Regulation (EC) No 1107/2009.

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
KCA 6.1 / 01	Stuke, S.	2019	Amendment no. 3: Storage stability of CGA 279202, CGA 357262, CGA 357261, CGA331409, CGA 321113 and CGA 373466 in plant matrices for 24 months Report No.: P642110501, Edition Number: M-468560-04-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2019-09-19 GLP/GEP: Yes unpublished	No	Bayer
KCA 6.1 / 02	Schmiedt, S.	2020	Storage stability of CGA 279202 (trifloxystrobin), CGA 357262, CGA 357261, CGA331409, CGA 321113 and CGA 373466 in olive (fruit), apple (fruit) and wheat (grain) for 24 months – Final report Report No.: P 642 18 7852, Edition Number: M-684506-02-1 EAG Laboratories GmbH, Ulm, Germany ... amended: 2020-12-15 GLP/GEP: Yes unpublished	No	Bayer
KCA 6.1 / 03	Roth, A.	2020	Residue analytical method 01598 and short term storage stability of trifloxystrobin (CGA 279202) and its isomers / metabolites CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 in/on honey by HPLC-MS/MS Report No.: S19-01123, Edition Number: M-677808-01-1 Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Niefern-Oeschelbronn, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.1.1 / 01 ... also filed: KCP 5.1.2.5 / 01	Billian, P.	2010	Determination of the residues of AE C656948 and trifloxystrobin in/on asparagus after spraying of AE C656948 & CGA279202 SC 500 in the field in France (North) and Germany Report No.: 08-2209, Edition Number: M-359460-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2010-07-12 GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.1.1 / 02 ... also filed: KCP 5.1.2.5 / 02	Uceda, L.; Ratajczak, M.	2011	Determination of the residues of AE C656948 and trifloxystrobin in/on asparagus after spraying of AE C656948 & CGA279202 SC 500 in the field in France (north) and Netherlands Report No.: 09-2073, Edition Number: M-415549-01-1 Bayer S.A.S., Bayer CropScience, Lyon, France GLP/GEP: Yes unpublished	No	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCA 6.3.2.1 / 02 ... also filed: KCP 5.1.2.5 / 41	Cavaillé, C.; Uceda, L.	2011	Determination of the residues of AE C656948 and trifloxystrobin in/on grape after spraying and spraying, low-volume of AE C656948 CGA279202 SC 500 in the field in France (north), France (south), Germany and Italy Report No.: 09-2077, Edition Number: M-415381-01-1 Bayer S.A.S., Bayer CropScience, Lyon, France GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.2.1 / 03 ... also filed: KCA 6.3.12.1 / 04 KCA 6.3.3.1 / 07 KCP 5.1.2.5 / 43	Stuke, S.	2013	Amendment no. 1 to report no: P 652 11 5503 – Determination of the residues of trifloxystrobin, CGA 357261, CGA 357262, CGA 331409, CGA 321113, and CGA 373466 in/on materials of plant origin by HPLCMS/MS Report No.: MR-11/044, Edition Number: M-421645-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2013-07-24 GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.3.1 / 01 ... also filed: KCP 5.1.2.5 / 13	Schulte, G.; Sosniak, A.	2015	Determination of the residues of fluopyram and trifloxystrobin in/on strawberry after spray application of fluopyram & trifloxystrobin SC 500 in Germany, northern France, the Netherlands and Belgium Report No.: 14-2026, Edition Number: M-534577-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.3.1 / 02	Szeley, C. M.; Sadler, C.	2016	Determination of the residues of fluopyram and trifloxystrobin in/on strawberry after spray application of AE C656948 & CGA 279202 SC 500 in Germany, Denmark, Spain, southern France and Italy Report No.: 15-2031, Edition Number: M-553855-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.3.1 / 03 ... also filed: KCP 5.1.2.5 / 16	Braune, M.; Eremeeva, T.	2020	Determination of the residues of trifloxystrobin and AE C656948 in/on strawberry after spray application of AE C656948 & CGA279202 SC 500 in Germany and Belgium Report No.: 18-2050, Edition Number: M-684200-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.4.1 / 01 ... also filed: KCP 5.1.2.5 / 26	Buchmueller, K.; Holbein, J.	2019	Determination of the residues of trifloxystrobin and AE C656948 in/on raspberry after spray application of AE C656948 & CGA279202 SC 500 in Hungary, Poland, Germany and northern France Report No.: 18-2051, Edition Number: M-675722-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCA 6.3.5.1 / 01	Perny, A.	2017	Determination of fluopyram and its metabolite fluopyram-benzamide and trifloxystrobin and its metabolite CGA321113 residues in blackcurrant following applications with F413BCS under field conditions in northern Europe in 2015 Report No.: B5111, Edition Number: M-565907-02-1 Anadiag S.A., Haguenau, France ... amended: 2017-11-22 GLP/GEP: Yes unpublished	No	DGAL M. Agriculture France
KCA 6.3.5.1 / 02	Oostingh, C.	2013	Amendment no. 1 to report no: PTZ-NLI-11796 – Residues of fluopyram + trifloxystrobin in red currant under plastic umbrella at intervals following two foliar applications of fluopyram & trifloxystrobin SC 500 Report No.: PTZ-NLI-11796, Edition Number: M-434301-02-1 Proeftuin Zwaagdijk, Zwaagdijk, Netherlands ... amended: 2013-03-06 GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.5.1 / 03	Loriau, P.	2012	Residues of fluopyram and trifloxystrobin in red currant under plastic umbrella at intervals following two foliar applications of FLU+TFS 500 SC – Belgium, season 2011 Report No.: BCS-G402-11, Edition Number: M-433738-01-1 Redebel S.A., Saint Amand, Belgium GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.6.1 / 01 ... also filed: KCP 5.1.2.5 / 39	Semrau, J.	2017	Determination of residues of fluopyram and trifloxystrobin in/on carrots after spray application of fluopyram & trifloxystrobin SC 500 in Northern France, Austria and Germany Report No.: 16-2155, Edition Number: M-598289-01-1 Eurofins Agrosience Services GmbH, Stade, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.6.1 / 02 ... also filed: KCP 5.1.2.5 / 40	Braune, M. ; Cuesta-Pérez, J.	2020	Determination of the residues of trifloxystrobin and AE C656948 in/on carrot after spray application of AE C656948 & CGA279202 SC 500 in Germany, the United Kingdom and northern France Report No.: 18-2044, Edition Number: M-682016-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.9.1 / 05 ... also filed: KCP 5.1.2.5 / 05	Schulte, G. ; Sosniak, A.	2015	Determination of the residues of fluopyram and trifloxystrobin in/on lettuce after spray application of fluopyram & trifloxystrobin SC 500 in Belgium, Germany, the Netherlands and northern France Report No.: 14-2029, Edition Number: M-534202-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCA 6.3.9.1 / 06 ... also filed: KCP 5.1.2.5 / 07	Bellof, S.; Kuester, S.	2015	Determination of the residues of fluopyram and trifloxystrobin in/on lettuce after spray application of fluopyram & trifloxystrobin SC 500 in Germany, the Netherlands, Hungary and the United Kingdom Report No.: 14-2184, Edition Number: M-536965-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.10.1 / 01 ... also filed: KCP 5.1.2.5 / 28	Fargeix, G.	2013	Amendment No.1 – Determination of the residues of AE C656948 and trifloxystrobin in/on chicory, witloof after dip and spraying of fluopyram SC 500 and AE C656948 & CGA279202 SC 500 in the field and room, hall, store, etc. in Germany, Belgium, northern France and the Netherlands Report No.: 11-2140, Edition Number: M-448916-02-1 Bayer S.A.S., Bayer CropScience, Lyon, France ... amended: 2013-10-18 GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.11.1 / 01 ... also filed: KCP 5.1.2.5 / 30	Noss, G.; Guerleyen, N.; Ballmann, C.	2012	Determination of the residues of AE C656948 and trifloxystrobin in/on bean, kidney after spraying of AE C656948 & CGA279202 SC 500 in the field in France (north) Report No.: 10-2128, Edition Number: M-425362-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2012-03-12 GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.11.1 / 02 ... also filed: KCP 5.1.2.5 / 31	Fargeix, G.	2013	Determination of the residues of fluopyram and trifloxystrobin in/on field pea after spray application of AE C656948 & CGA279202 SC 500 in northern France and Germany Report No.: 11-2000, Edition Number: M-444960-01-1 Bayer S.A.S., Bayer CropScience, Lyon, France GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.11.1 / 03 ... also filed: KCP 5.1.2.5 / 33	Glaubitz, J.; Ballmann, C.	2014	Determination of the residues of fluopyram and trifloxystrobin in/on field pea after spray application of AE C656948 & CGA279202 SC 500 in the field in Germany, Northern France, Belgium and United Kingdom Report No.: 12-2031, Edition Number: M-475814-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.11.1 / 04 ... also filed: KCP 5.1.2.5 / 29	Noss, G.; Ballmann, C.	2012	Determination of the residues of AE C656948 and trifloxystrobin in/on bean, kidney after spraying of AE C656948 & CGA279202 SC 500 in the field in Germany, Belgium, Spain, Italy, France (south) and Portugal Report No.: 10-2125, Edition Number: M-425357-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCA 6.3.11.1 / 05 ... also filed: KCP 5.1.2.5 / 32	Glaubitz, J.	2013	Determination of the residues of AE C656948 and trifloxystrobin in/on French bean after spray application of AE C656948 & CGA279202 SC 500 in the field in Germany and northern France Report No.: 12-2030, Edition Number: M-467728-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.11.1 / 06 ... also filed: KCP 5.1.2.5 / 36	Noss, G.; Czaja, C.	2017	Determination of the residues of fluopyram and trifloxystrobin in/on field pea, after spray application of AE C656948 & CGA 279202 SC 500 in Denmark, Germany, Spain and Italy Report No.: 15-2030, Edition Number: M-566823-03-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2017-09-25 GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.11.1 / 07	Nuesslein, F.; Eberhardt, R.	2003	Determination of residues of trifloxystrobin and CGA 321113 in/on kidney bean following spray application of Flint 50 WG in the field in Northern France, Germany and Great Britain Report No.: RA-2044/02, Edition Number: M-106401-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.12.1 / 01 ... also filed: KCP 5.1.2.5 / 49	Buchmueller, K.; van Berkum, S.	2020	Determination of the residues of trifloxystrobin and AE C656948 in/on hop after spray application of AE C656948 & CGA279202 SC 500 in northern France, Germany and Czech Republic – Final report – Report No.: 18-2047, Edition Number: M-681429-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.12.1 / 02 ... also filed: KCP 5.1.2.5 / 47	Noss, G.; Ballmann, C.	2012	Determination of the residues of AE C656948 and trifloxystrobin in/on hop after spraying of AE C656948 & CGA279202 SC 500 in the field in France (North) Report No.: 10-2127, Edition Number: M-432715-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.12.1 / 03 ... also filed: KCP 5.1.2.5 / 48	Noss, G.; Ballmann, C.	2012	Amendment No. 1 to report no: 09-2076 – Determination of the residues of AE C656948 and trifloxystrobin in/on hop after spraying of AE C656948 & CGA279202 SC 500 in the field in France (North) and Germany Report No.: 09-2076, Edition Number: M-423507-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2012-11-23 GLP/GEP: Yes unpublished	No	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCA 6.3.12.1 / 04 ... also filed: KCA 6.3.2.1 / 03 KCA 6.3.3.1 / 07 KCP 5.1.2.5 / 43	Stuke, S.	2013	Amendment no. 1 to report no: P 652 11 5503 – Determination of the residues of trifloxystrobin, CGA 357261, CGA 357262, CGA 331409, CGA 321113, and CGA 373466 in/on materials of plant origin by HPLCMS/MS Report No.: MR-11/044, Edition Number: M-421645-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2013-07-24 GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.12.1 / 05 ... also filed: KCP 5.1.2.5 / 46	Noss, G.	2010	Determination of the residues of AE C656948 and trifloxystrobin in/on hop after spraying of AE C656948 & CGA 279202 SC 500 in the field in France (North) and Germany Report No.: 08-2086, Edition Number: M-389144-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.5.3 / 03	Nuesslein, F.	2003	Determination of residues of trifloxystrobin and CGA 321113 in/on climbing French bean and processing products (...) following spray application of Flint 50 WG in the greenhouse in Germany and Italy Report No.: RA-3037/02, Edition Number: M-104911-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.5.3 / 04	Beinhauer, K.	1996	Trial for determination of residue levels in hops according to BBA Guideline IV, 3-3 and 3-4 (1990) Report No.: GR01796, Edition Number: M-052604-02-1 BioChem GmbH Karlsruhe, Cunnernsdorf, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.5.3 / 05	Noss, G.; Diehl, P.	2013	Determination of the residues of trifloxystrobin in/on hop and the processed fractions (hops draff, brewer's yeast and beer)after spraying of trifloxystrobin WG 50 in the field in Germany Report No.: 10-3174, Edition Number: M-444838-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.5.3 / 06	Noss, G.; Krusell, L.	2010	Determination of the residues of AE C656948 and trifloxystrobin in/on hops and processed fractions after spraying of AE C656948 & CGA 279202 SC 500 in the field in France (North) and Germany Report No.: 08-3086, Edition Number: M-389146-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCA 6.10 / 01 ... also filed: KCP 5.1.2.4 / 02	Stuke, S.; Daniela, M.; van Berkum, S.	2016	Determination of the dislodgeable foliar residues (DFR) of trifloxystrobin and AE C656948 in/on grape after spraying of AE C656948 & CGA279202 SC 500 in the field in the North of France Report No.: 15-2924, Edition Number: M-569303-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.10 / 02 ... also filed: KCP 5.1.2.4 / 04	Daniels, M.; van Berkum, S.	2020	Determination of the dislodgeable foliar residues (DFR) of trifloxystrobin and AE C656948 in/on raspberry after spray application of AE C656948 & CGA279202 SC 500 in the field in Italy Report No.: 18-2905, Edition Number: M-677729-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.10 / 03 ... also filed: KCP 5.1.2.4 / 03	Stuke, S.; van Berkum, S.	2016	Determination of the dislodgeable foliar residues (DFR) of trifloxystrobin and AE C656948 in/on lily after spraying of AE C656948 & CGA279202 SC 500 in the field in the Netherlands Report No.: 15-2925, Edition Number: M-558518-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.10 / 04	Appeltauer, A.	2020	Determination of residues of trifloxystrobin and its isomers and metabolites in honey after three applications of TFS WG 50 in Phacelia tanacetifolia at 4 Sites in northern and southern Europe in 2019 Report No.: S19-01068, Edition Number: M-678866-01-1 Eurofins Agrosience Services EcoChem GmbH / Eurofins Agrosience Services Ecotox GmbH, Niefern-Oeschelbronn, Germany GLP/GEP: Yes unpublished	No	Bayer

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

All data referred to in this dossier as part of DAR, RAR or EFSA Conclusions have been peer-reviewed for the EU (re-)approval of the active substances fluopyram, trifloxystrobin. Bayer is the owner of the data packages peer-reviewed for the EU (re-)approval of the active substances fluopyram, trifloxystrobin and data protection will be requested when relevant at MS level in the Part A.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1 /01	Kissling, M.	1999	Stability of residues of CGA 279202 and its metabolite CGA 321113 in deep freeze stored analytical specimens of grapes, cucumbers, potatoes and wheat (whole plant, grains and straw) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 154/96, Edition Number: <u>M-038193-02-1</u> EPA MRID No.: 44757212 Date: 1999-01-06 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.1 /02	Grunenwald, M. C.	1999	Stability of CGA-279202 and CGA-321113 in crops and processed fractions under freezer storage conditions Novartis Crop Protection, Inc., Greensboro, NC, USA Bayer CropScience, Report No.: 160-97, Edition Number: <u>M-038204-02-1</u> EPA MRID No.: 44757214 Date: 1999-01-21 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.1 /03	xxx	1999	Stability of CGA-279202 and CGA-321113 in meat, milk, and eggs under freezer storage conditions xxx, Report No.: 110432, Edition Number: <u>M-038213-02-2</u> EPA MRID No.: 44757213 Date: 1999-01-21 GLP/GEP: yes, unpublished	Y	Bayer
KCA 6.1 /04 KCA 4.1.2 /02 KCA 4.2 /03	Kissling, M.	1996	CGA 279202: Determination of parent compound and of metabolite CGA 321113 by GC – cereals, bananas Ciba-Geigy Limited, Basel, Switzerland Bayer CropScience, Report No.: REM 177.03, Edition Number: <u>M-038798-01-1</u>	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
			GLP/GEP: no, unpublished		
KCA 6.1 /05	Kissling, M.	1999	Short time stability of residues of CGA 279202 on deep freeze stored air sorbent tubes Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 206/99, Edition Number: <u>M-024784-01-1</u> Date: 1999-07-01 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.1 /06 KCA 6.3.1 /26 KCA 6.3.4 /10 KCA 6.3.5 /22 KCA 6.5 /02	Ohs, P.	2001	Trifloxystrobin – Comment regarding the topic: point 7: residues Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MO-02-006621, Edition Number: <u>M-061069-01-1</u> GLP/GEP: n.a., unpublished	N	Bayer
KCA 6.1 /07	Schulte, G.; Diehl, P.	2013	Storage stability of CGA 279202, CGA 357262, CGA 357261, CGA331409, CGA 321113 and CGA 373466 in plant matrices for 24 months Bayer CropScience, Report No.: P642110501, Edition Number: <u>M-468560-01-1</u> Date: 2013-11-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.2 /01 KCA 5.1.1 /03	xxx	1997	The metabolism of [glyoxyl-phenyl-(U)-14C] and [trifluormethyl-phenyl-(U)-14C] CGA 279202 in the rat xxx, Report No.: 12/97, Edition Number: <u>M-136745-01-1</u> EPA MRID No.: 44496722, 44636001 Date: 1997-11-14 GLP/GEP: yes, unpublished	Y	Bayer
KCA 6.2.1 /01	Gross, D.	1997	Distribution and degradation of CGA 279202 in field grown spring wheat after treatment with (CF3-phenyl-(U)-) CGA 279202 labelled material Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: CMR15/97, Edition Number: <u>M-034018-04-1</u> Date: 1997-10-01	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
			...Amended: 1999-03-04 GLP/GEP: yes, unpublished		
KCA 6.2.1 /02	Gross, D.	1997	Metabolism of [CF3-phenyl-(U)-14C]CGA 279202 in field grown spring wheat Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: CMR18/97, Edition Number: <u>M-034053-01-1</u> EPA MRID No.: 44496824 Date: 1997-10-23 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.2.1 /03	Stingelin, J.	1997	Behaviour and metabolism of CGA 279202 in field grown spring wheat after treatment with [Glyoxyl-Phenyl-(U)-14C] labelled material Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: CMR04/97, Edition Number: <u>M-034352-02-1</u> Date: 1997-07-16 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.2.1 /04	Stingelin, J.	1997	Metabolism of [glyoxyl-phenyl-(U)-14C] CGA 279202 in field grown spring wheat Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: CMR25/97, Edition Number: <u>M-034368-01-1</u> EPA MRID No.: 44496828 Date: 1997-12-15 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.2.1 /05	Kiffe, M.	1997	Metabolism of CGA 279202 in greenhouse grown apple trees after application of [trifluoromethyl-phenyl-(U)-14C]labelled material Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: CMR12/97, Edition Number: <u>M-034389-04-1</u> Date: 1997-07-01 ...Amended: 1997-11-24 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
KCA 6.2.1 /06	Kiffe, M.	1997	Metabolism of CGA 279202 in greenhouse grown apple trees after application of [glyoxyl-phenyl-(U)-14C] labelled material Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: CMR13/97, Edition Number: <u>M-034423-01-1</u> EPA MRID No.: 44496822 Date: 1997-09-21 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.2.1 /07	Stingelin, J.	1997	Behaviour and metabolism of CGA 279202 in greenhouse grown cucumbers after treatment with [CF3-phenyl-(U)-14C]labelled material Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: CMR23/97, Edition Number: <u>M-034442-01-1</u> EPA MRID No.: 44496827 Date: 1997-10-17 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.2.1 /08	Stingelin, J.	1997	Behaviour and metabolism of CGA 279202 in greenhouse grown cucumbers after treatment with [glyoxyl-phenyl-(U)-14C]labelled material Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: CMR22/97, Edition Number: <u>M-034445-01-1</u> EPA MRID No.: 44496826 Date: 1997-10-14 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.2.1 /09	Reiner, H.; Bongartz, R.	2002	Metabolism of [trifluoromethyl-phenyl-UL-14C]trifloxystrobin in spring wheat Bayer AG, Bayer CropScience, Monheim, Germany Bayer CropScience, Report No.: MR-027/02, Edition Number: <u>M-070885-01-1</u> EPA MRID No.: 45721803 Date: 2002-07-05 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
KCA 6.2.1 /10	Reiner, H.; Bongartz, R.	2002	Metabolism of [glyoxyl-phenyl-UL-14C]trifloxystrobin in spring wheat Bayer AG, Bayer CropScience, Monheim, Germany Bayer CropScience, Report No.: MR-028/02, Edition Number: <u>M-072024-01-1</u> EPA MRID No.: 45721804 Date: 2002-07-16 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.2.1 /11	Kiffe, M.	2000	Behaviour and metabolism of [trifluoromethyl-phenyl-(U)-14C] CGA 279202 in field grown sugar beets Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 99MK09, Edition Number: <u>M-069117-01-1</u> EPA MRID No.: 45269402 Date: 2000-09-21 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.2.1 /12	Kiffe, M.	2000	Behaviour and metabolism of [glyoxyl-phenyl-(U)-14C] CGA 279202 in field grown sugar beets Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 99MK10, Edition Number: <u>M-069125-01-1</u> EPA MRID No.: 45269401 Date: 2000-09-21 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.2.1 /13	Rezaaiyan, R.	1997	Uptake and metabolism of CGA-279202 in field grown peanuts after spray treatment with phenyl (A)-14C-CGA-279202 and phenyl (B)-14C-CGA-279202 Novartis Crop Protection, Inc., Greensboro, NC, USA Bayer CropScience, Report No.: ABR-97084, Edition Number: <u>M-137152-01-1</u> EPA MRID No.: 44496817 Date: 1997-12-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.2.1 /14	Rezaaiyan, R.	1997	Biological phase report uptake and metabolism of CGA-279202 in field grown peanuts after spray treatment with phenyl(A)-14C-CGA-2789202 and phenyl(B)-14C-CGA-279202 Novartis Crop Protection, Inc., Greensboro, NC, USA	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
			Bayer CropScience, Report No.: BIOL-96024, Edition Number: <u>M-038413-01-1</u> Date: 1997-12-02 GLP/GEP: yes, unpublished		
KCA 6.2.2 /01 KCA 5.1.1 /06	xxx.	1997	The metabolism of [trifluormethyl-phenyl-(U)-14C] CGA 279202 after multiple oral administration to laying hens xxx, Report No.: 10/97, Edition Number: <u>M-034526-01-1</u> EPA MRID No.: 44496820 Date: 1997-12-08 GLP/GEP: yes, unpublished	Y	Bayer
KCA 6.2.2 /02 KCA 5.1.1 /07	xxx	1998	The metabolism of [glyoxyl-phenyl-(U)-14C] CGA 279202 after multiple oral administration to laying hens xxx Report No.: 22/97, Edition Number: <u>M-034534-01-1</u> EPA MRID No.: 44496825 Date: 1998-01-19 GLP/GEP: yes, unpublished	Y	Bayer
KCA 6.2.3 /01 KCA 5.1.1 /04	xxx	1997	The metabolism of [trifluormethyl-phenyl(U)-14C] CGA 279202 after multiple oral administration to lactating goats xxx Report No.: 09/97, Edition Number: <u>M-034501-01-1</u> EPA MRID No.: 44496818 Date: 1997-08-27 GLP/GEP: yes, unpublished	Y	Bayer
KCA 6.2.3 /02 KCA 5.1.1 /05	xxx	1997	The metabolism of [glyoxyl-phenyl-(U)-14C] CGA 279202 after multiple oral administration to lactating goats xxx, Report No.: 14/97, Edition Number: <u>M-034517-01-1</u> EPA MRID No.: 44496823 Date: 1997-12-09 GLP/GEP: yes, unpublished	Y	Bayer
KCA 6.3 /01	Ohs, P.	1999	Factor influencing the residue behaviour of pesticides in greenhouses Bayer AG, Leverkusen, Germany	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
			Bayer CropScience, Report No.: MR-140/99, Edition Number: <u>M-008470-01-1</u> Date: 1999-03-10 GLP/GEP: no, unpublished		
KCA 6.3 /02	Sonder, K.	2013	Tier 1 Summary of the residues data and processing studies for trifloxystrobin Bayer CropScience Bayer CropScience, Report No.: <u>M-467298-01-1</u> , Edition Number: <u>M-467298-01-1</u> GLP/GEP: n.a., unpublished	N	Bayer
KCA 6.3.1 /01	Pointurier, R.	1997	Magnitude of residues of CGA 279202 and CGA 321113 in apples after application of formulation A9360B WG 50 (France, South) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF96122/LD69, Edition Number: <u>M-034545-01-1</u> Date: 1997-12-02 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /02	Pointurier, R.	1997	Magnitude of residues of CGA 279202 and CGA 321113 in apples after application of formulation A9360B WG 50 (France, North) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF96122/SJ26, Edition Number: <u>M-034552-01-1</u> Date: 1997-12-02 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /03	Pointurier, R.	1997	Magnitude of residues of CGA 279202 and CGA 321113 in apples after application of formulation A9360B WG 50 (France, South) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF96122/FP13, Edition Number: <u>M-034560-01-1</u> Date: 1997-12-02 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
KCA 6.3.1 /04	Pointurier, R.	1997	Magnitude of residues of CGA 279202 and CGA 321113 in apples after application of formulation A9360B WG 50 – dissipation study (France, North) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF95134/KJ11, Edition Number: <u>M-034569-01-1</u> Date: 1997-12-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /05	Pointurier, R.	1997	Magnitude of residues of CGA 279202 and CGA 321113 in apples after application of formulation A9360B WG 50 – dissipation study (France, South) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF95134/FP97, Edition Number: <u>M-034572-01-1</u> Date: 1997-12-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /06	Pointurier, R.	1997	Magnitude of residues of CGA 279202 and CGA 321113 in apples after application of formulation A9360B WG 50 (France, North) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF96122/KJ72, Edition Number: <u>M-034650-01-1</u> Date: 1997-12-02 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /07	Pointurier, R.	1997	Magnitude of residues of CGA 279202 and CGA 321113 in apples after application of formulation A9360B WG 50 (France, South) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF95152/FP92, Edition Number: <u>M-034762-01-1</u> Date: 1997-12-02 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /08	Pointurier, R.	1997	Magnitude of residues of CGA 279202 and CGA 321113 in apples after application of formulation A9360B WG 50 – dissipation study (France, South) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience,	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
			Report No.: OF95135/LD05, Edition Number: <u>M-034779-01-1</u> Date: 1997-12-02 GLP/GEP: yes, unpublished		
KCA 6.3.1 /09	Beinhauer, K.; Kissling, M.	1995	Field trial for determination of residue levels in apple according to BBA Guideline IV, 3-3 (1990) BioChem GmbH Karlsruhe, Cunnersdorf, Germany Bayer CropScience, Report No.: FR10/95/31, Edition Number: <u>M-034785-01-1</u> Date: 1995-11-28 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /10	Beinhauer, K.	1997	Trial for determination of residue levels in apples according to BBA Guideline IV, 3-3 and 3-4 (1990) BioChem GmbH Karlsruhe, Cunnersdorf, Germany Bayer CropScience, Report No.: gr00996, Report includes Trial Nos.: FR06/96/42 Edition Number: <u>M-034808-01-1</u> Date: 1997-01-31 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /11	Beinhauer, K.; Kissling, M.	1995	Field trial for determination of residue levels in apple according to BBA Guideline IV, 3-3 (1990) BioChem GmbH Karlsruhe, Cunnersdorf, Germany Bayer CropScience, Report No.: FR10/95/42, Edition Number: <u>M-034848-01-1</u> Date: 1995-11-28 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /12	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in apples (Italy) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2083/96, Edition Number: <u>M-034853-01-1</u> Date: 1997-09-10 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /13	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation 50 WG (A-9360 B) in apples (Italy)	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
			Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2115/95, Edition Number: <u>M-034858-01-1</u> Date: 1997-02-14 GLP/GEP: yes, unpublished		
KCA 6.3.1 /14	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in apples (Italy) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2082/96, Edition Number: <u>M-034866-01-1</u> Date: 1997-09-10 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /15	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation 50 WG (A-9360 B) in apples (Italy) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2116/95, Edition Number: <u>M-034882-01-1</u> Date: 1997-02-14 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /16	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in apples Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2215/95, Edition Number: <u>M-034885-01-1</u> Date: 1997-04-04 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /17	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in apples Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2216/95, Edition Number: <u>M-034890-01-1</u> Date: 1997-04-04 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
KCA 6.3.1 /18	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in apples Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2217/95, Edition Number: <u>M-034893-01-1</u> Date: 1997-04-04 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /19	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in apples (Switzerland) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2015/96, Edition Number: <u>M-034897-01-1</u> Date: 1997-09-10 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /20	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in apples (Switzerland) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2017/96, Edition Number: <u>M-034901-01-1</u> Date: 1997-09-10 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /21	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in apples (Switzerland) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2014/96, Edition Number: <u>M-034907-01-1</u> Date: 1997-09-10 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /22	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in apples (Switzerland) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2016/96, Edition Number: <u>M-034910-01-1</u> Date: 1997-09-10 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
KCA 6.3.1 /23	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation 50 WG (A-9360 B) in apples (Switzerland) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2034/95, Edition Number: <u>M-034963-01-1</u> Date: 1997-02-14 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /24	Beinhauer, K.	1996	CGA 279202, WG 50, A-9360 B, pears, Germany BioChem GmbH Karlsruhe, Cunnersdorf, Germany Bayer CropScience, Report No.: GR01096, Edition Number: <u>M-034967-01-1</u> Date: 1996-12-11 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /25	Kissling, M.	1998	Residue study with CGA 279202 in or on apples in Switzerland Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 511/98, Edition Number: <u>M-024717-01-1</u> Date: 1998-12-28 GLP/GEP: no, unpublished	N	Bayer
KCA 6.3.1 /26 KCA 6.1 /06 KCA 6.3.4 /10 KCA 6.3.5 /22 KCA 6.5 /02	Ohs, P.	2001	Trifloxystrobin – Comment regarding the topic: point 7: residues Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MO-02-006621, Edition Number: <u>M-061069-01-1</u> GLP/GEP: n.a., unpublished	N	Bayer
KCA 6.3.1 /27	Maffezzoni, M.	1999	Residue study with CGA 279202 in or on apples in France (North) ADME Bioanalyses S.A., Aigues-Vives, France Bayer CropScience, Report No.: 9811001, Edition Number: <u>M-057644-01-1</u> Date: 1999-02-23 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /28	Kissling, M.	1999	Residue study with CGA 279202 in or on apples in the Netherlands	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
			Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2158/98, Edition Number: <u>M-024752-01-1</u> Date: 1999-06-02 GLP/GEP: yes, unpublished		
KCA 6.3.1 /29	Kissling, M.	1999	Residue study with CGA 279202 in or on apples in the Netherlands Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2159/98, Edition Number: <u>M-024764-01-1</u> Date: 1999-06-02 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /30	Kissling, M.	1999	Residue study with CGA 279202 in or on apples in the Netherlands Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2160/98, Edition Number: <u>M-024777-01-1</u> Date: 1999-06-02 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /31 KCA 6.5.3 /02	Kissling, M.	2000	Residue study with CGA 279202 in or on apples in France (north) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2007/99, Edition Number: <u>M-024932-01-1</u> Date: 2000-04-25 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /32	Kissling, M.	2000	Residue study with CGA 279202 in or on apples in Netherlands Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2109/99, Edition Number: <u>M-030455-01-1</u> Date: 2000-04-25 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /33	Kissling, M.	2000	Residue study with CGA 279202 in or on apples in Switzerland	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
			Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2124/99, Edition Number: <u>M-030187-01-1</u> Date: 2000-04-25 GLP/GEP: yes, unpublished		
KCA 6.3.1 /34 KCA 6.5.3 /03	Kissling, M.	2000	Residue study with CGA 279202 in or on apples in Switzerland Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2125/99, Edition Number: <u>M-136411-01-1</u> Date: 2000-08-17 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /35	Billian, P.	2007	Determination of the residues of trifloxystrobin and tebuconazole in/on apple after spraying of CGA 279202 & HWG 1608 (75 WG) in the field in Germany Bayer CropScience, Report No.: RA-2006/06, Report includes Trial Nos.: R 2006 0120/4 = 0120 – 06 R 2006 0124/7 = 0124 – 06 Edition Number: <u>M-292645-01-1</u> Date: 2007-09-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /36	Nuesslein, F.; Behn, U.	2004	Determination of residues of trifloxystrobin and captan in/on apple after spraying and low-volume spraying of trifloxystrobin & Captan (64 WG) in Germany, Belgium and Great Britain Bayer CropScience, Report No.: RA-2170/03, Report includes Trial Nos.: 0077 – 03 0078 – 03 0079 – 03 0080 – 03 R 2003 0077/8 R 2003 0078/6 R 2003 0079/4 R 2003 0080/8	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
			Edition Number: <u>M-061865-01-1</u> Date: 2004-03-31 GLP/GEP: yes, unpublished		
KCA 6.3.1 /37	Zimmer, D.	2005	Determination of the residues of trifloxystrobin and tolylfluanid in/on apple after spraying of CGA279202 & KUE 13183B (68.8 WG) in the field in Belgium and the Netherlands Bayer CropScience, Report No.: RA-2044/04, Report includes Trial Nos.: 0181 – 04 0182 – 04 R 2004 0181/7 R 2004 0182/5 Edition Number: <u>M-256712-01-1</u> Date: 2005-08-10 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /38	Zimmer, D.	2005	Determination of the residues of trifloxystrobin and tolylfluanid in/on pear after spraying of CGA279202 & KUE13183B (68.8 WG) in the field in United Kingdom and Germany Bayer CropScience, Report No.: RA-2046/04, Report includes Trial Nos.: 0183-04 0184-04 R 2004 0183/3 R 2004 0184/1 Edition Number: <u>M-257107-01-1</u> Date: 2005-09-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /39	Meilland-Berthier, I.	2013	Determination of the residues of trifloxystrobin in/on apple and pear after spray application of trifloxystrobin WG 50 in the field in Germany, northern France and United Kingdom Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 11-2117, Report includes Trial Nos.: 11-2117-01 11-2117-02 11-2117-03	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
			11-2117-04 Edition Number: <u>M-457963-01-1</u> Date: 2013-06-28 GLP/GEP: yes, unpublished		
KCA 6.3.1 /40	Nuesslein, F.; Eberhardt, R.	2004	Determination of the residues of trifloxystrobin and captan in/on apple following spray application and low-volume spray application of Trifloxystrobin & Captan (64 WG) in Spain, Southern France, Portugal and Italy Bayer CropScience, Report No.: RA-2171/03, Report includes Trial Nos.: 0081 – 03 0082 – 03 0083 – 03 0084 – 03 R 2003 0082/4 R 2003 0083/2 R 2003 0084/0 Edition Number: <u>M-061855-01-1</u> Date: 2004-03-26 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /41	Zimmer, D.	2005	Determination of the residues of trifloxystrobin and tolylfluanid in/on apple after spraying of CGA279202 & KUE13183B (68.8 WG) in the field in Italy and Spain Bayer CropScience, Report No.: RA-2045/04, Report includes Trial Nos.: 0186-04 0187-04 R 2004 0186/8 R 2004 0187/6 Edition Number: <u>M-255883-01-1</u> Date: 2005-08-08 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.1 /42	Zimmer, D.	2005	Determination of the residues of trifloxystrobin and tolylfluanid in/on pear after spraying of CGA279202 & KUE13183B (68.8 WG) in the field in Italy and Spain Bayer CropScience, Report No.: RA-2047/04, Report includes Trial Nos.:	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
			0188-04 0189-04 R 2004 0188/4 R 2004 0189/2 Edition Number: <u>M-257391-01-1</u> Date: 2005-09-15 GLP/GEP: yes, unpublished		
KCA 6.3.1 /43	Meilland-Berthier, I.	2013	Determination of the residues of trifloxystrobin in/on apple and pear after spray application of trifloxystrobin WG 50 in the field in southern France, Portugal, Italy and Spain Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 11-2116, Report includes Trial Nos.: 11-2116-01 11-2116-02 11-2116-03 11-2116-04 Edition Number: <u>M-457957-01-1</u> Date: 2013-06-21 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.2 /01	Kissling, M.	1997	Magnitude of residues of CGA 279202 applied as EC 075 to banana plants in Colombia Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 130/96, Report includes Trial Nos.: 2152/96 2153/96 2154/96 Edition Number: <u>M-034972-01-1</u> EPA MRID No.: 44496840 Date: 1997-11-28 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.2 /02	Kissling, M.	1997	Magnitude of residues of CGA 279202 applied as EC 075 to banana plants in Costa Rica Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 128/96,	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
			Report includes Trial Nos.: 2144/96 2145/96 2146/96 2147/96 Edition Number: <u>M-034988-01-1</u> EPA MRID No.: 44496839 Date: 1997-11-28 GLP/GEP: yes, unpublished		
KCA 6.3.2 /03	Kissling, M.	1997	Magnitude of residues of CGA 279202 applied as EC 075 to banana plants in Ecuador Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 129/96, Report includes Trial Nos.: 2148/96 2149/96 2150/96 2151/96 Edition Number: <u>M-035003-01-1</u> Date: 1997-12-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.2 /04	Kissling, M.	1997	Magnitude of residues of CGA 279202 applied as EC 075 to banana plants in Guatemala Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 131/96, Report includes Trial Nos.: 2155/96 2156/96 2157/96 Edition Number: <u>M-035007-02-1</u> Date: 1997-11-28 ...Amended: 2002-07-23 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.2 /05	Kissling, M.	1997	Magnitude of residues of CGA 279202 applied as EC 075 to banana plants in Honduras Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience,	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
			Report No.: 133/96, Report includes Trial Nos.: 2159/96 Edition Number: <u>M-035016-01-1</u> EPA MRID No.: 44496843 Date: 1997-11-28 GLP/GEP: yes, unpublished		
KCA 6.3.2 /06	Kissling, M.	1997	Magnitude of residues of CGA 279202 applied as EC 075 to banana plants in Mexico Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 132/96, Report includes Trial Nos.: 2158/96 Edition Number: <u>M-035086-01-1</u> EPA MRID No.: 44496842 Date: 1997-11-28 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.2 /07	Kissling, M.	1997	Magnitude of residues of CGA 279202 applied as EC 075 to banana plants in USA (Puerto Rico) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 134/96, Report includes Trial Nos.: 2160/96 Edition Number: <u>M-035092-01-1</u> Date: 1997-12-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /01	Tack, T. J.	1997	Winter barley: Generation of crop samples for subsequent residue analyses following foliar treatment with CGA 279202 (A-9604 A) in Denmark Novartis Crop Protection UK Ltd., Whittlesford, United Kingdom Bayer CropScience, Report No.: FR0796, Edition Number: <u>M-035113-01-1</u> Date: 1997-11-22 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /02	Maffezzoni, M.	1997	Magnitude of residues after application of CGA 279202 as formulation EC 125 (A9604A) in winter barley (France, South)	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
			Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF96119, Edition Number: <u>M-035232-01-1</u> Date: 1997-10-14 GLP/GEP: yes, unpublished		
KCA 6.3.3 /03	Maffezzoni, M.	1997	Magnitude of residues after application of CGA 279202 and CGA 64250 as formulation EC 250 (A9525B) in winter barley (France, South) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF96121/BY01, Edition Number: <u>M-035240-01-1</u> Date: 1997-11-10 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /04	Maffezzoni, M.	1997	Magnitude of residues after application of CGA 279202 and CGA 64250 as formulation EC 250 (A9525B) in winter barley (France, North) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF96121/SJ12, Edition Number: <u>M-035246-01-1</u> Date: 1997-11-10 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /05	Maffezzoni, M.	1997	Magnitude of residues after application of CGA 279202 as formulation EC 125 (A9604A) in winter barley (France, South) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF96118/LD88, Edition Number: <u>M-035255-01-1</u> Date: 1997-10-24 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /06	Maffezzoni, M.	1997	Magnitude of residues after application of CGA 279202 and CGA 64250 as formulation EC 250 (A9525B) in winter barley (France, South) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF96121/LD90,	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
			Edition Number: <u>M-035260-01-1</u> Date: 1997-11-10 GLP/GEP: yes, unpublished		
KCA 6.3.3 /07	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation EC 125 (A-9604 A) in barley (France, South) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2167/97, Edition Number: <u>M-035267-01-1</u> Date: 1997-11-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /08	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation EC 125 (A-9604 A) in barley (France, South) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2166/97, Edition Number: <u>M-035271-01-1</u> Date: 1997-11-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /09	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation EC 125 (A-9604 A) in barley (France, South) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2168/97, Edition Number: <u>M-035277-01-1</u> Date: 1997-11-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /10	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation EC 125 (A-9604 A) in barley (France, South) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2169/97, Edition Number: <u>M-035284-01-1</u> Date: 1997-11-05 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
KCA 6.3.3 /11	Maffezzoni, M.	1997	Magnitude of residues after application of CGA 279202 as formulation EC 125 (A9604A) in winter barley (France, North) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF96118/KJ86, Edition Number: <u>M-035361-01-1</u> Date: 1997-10-24 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /12	Maffezzoni, M.	1997	Magnitude of residues after application of CGA 279202 and CGA 64250 as formulation EC 250 (A9525B) in winter barley (France, North) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF96121/KJ88, Edition Number: <u>M-035375-01-1</u> Date: 1997-11-10 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /13	Smith, J. A.	1997	Residues of CGA 279202 + propiconazole in winter barley (test product: CGD 20610 F – A9524B) Novartis Agro GmbH, Frankfurt/Main, Germany Bayer CropScience, Report No.: GR33696, Edition Number: <u>M-035384-01-1</u> Date: 1997-10-07 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /14	Smith, J. A.	1997	Field trial for the determination of residues of CGA 279202 + propiconazole in winter barley (test product: CGD 20610 F – A9524A) Novartis Agro GmbH, Frankfurt/Main, Germany Bayer CropScience, Report No.: GR3295, Edition Number: <u>M-035410-02-1</u> Date: 1997-09-25 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /15	Smith, J. A.	1997	Determination of residues of CGA 279202, CGA 321113 (metabolite of CGA 279202) in barley (whole plants, ears, remainder, grain and straw) – field trial (Germany) Novartis Agro GmbH, Frankfurt/Main, Germany Bayer CropScience, Report No.: GR37296,	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
			Edition Number: <u>M-035500-01-1</u> Date: 1997-09-25 GLP/GEP: yes, unpublished		
KCA 6.3.3 /16	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 and propiconazole (CGA 64250) as formulation EC 250 (A-9525 B) in barley (Switzerland) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2022/96, Edition Number: <u>M-035607-01-1</u> Date: 1997-08-13 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /17	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation EC 125 (A-9604 A) in winter barley (Switzerland) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2273/97, Edition Number: <u>M-035622-01-1</u> Date: 1997-11-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /18	Adams, S. P.	1997	To determine CGA 279202 and CGA 321113 residues in winter barley grain and straw after two applications of A-9604A applied as a foliar application (United Kingdom) Novartis Crop Protection UK Ltd., Whittlesford, United Kingdom Bayer CropScience, Report No.: FR0797, Edition Number: <u>M-035641-01-1</u> Date: 1997-12-09 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /19	Adams, S. P.	1997	To determine CGA 279202 and CGA 321113 residues in winter barley grain and straw after two applications of A-9604A applied as a foliar application (United Kingdom) Novartis Crop Protection UK Ltd., Whittlesford, United Kingdom Bayer CropScience, Report No.: FR0897, Edition Number: <u>M-035657-01-1</u> Date: 1997-12-09 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
KCA 6.3.3 /20	Adams, S. P.	1997	Winter barley: Generation of crop samples for subsequent residue analyses following foliar treatment with CGA 279202 (A-9604 A) in the UK Novartis Crop Protection UK Ltd., Whittlesford, United Kingdom Bayer CropScience, Report No.: FR0396, Edition Number: <u>M-035668-01-1</u> Date: 1997-11-10 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /21	Adams, S. P.	1997	Winter barley: Generation of crop samples for subsequent residue analyses following foliar treatment with CGA 279202 (A-9604 A) in the UK Novartis Crop Protection UK Ltd., Whittlesford, United Kingdom Bayer CropScience, Report No.: FR0296, Edition Number: <u>M-035685-01-1</u> Date: 1997-11-10 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /22	Smith, J. A.	1997	Residues of CGA 279202 + propiconazole in winter rye (test product: CGD 20610 F – A9425B) Novartis Agro GmbH, Frankfurt/Main, Germany Bayer CropScience, Report No.: GR34296, Edition Number: <u>M-035690-02-1</u> Date: 1997-10-09 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /23	Smith, J. A.	1997	Residues of CGA 279202 + propiconazole in winter rye (test product: CGA 20610 F – A9524A) Novartis Agro GmbH, Frankfurt/Main, Germany Bayer CropScience, Report No.: GR3395, Edition Number: <u>M-035702-02-1</u> Date: 1997-09-17 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /24	Tack, T. J.	1997	Winter wheat: Generation of crop samples for subsequent residue analyses following foliar treatment with CGA 279202 (A-9604 A) in Denmark Novartis Crop Protection UK Ltd., Whittlesford, United Kingdom Bayer CropScience, Report No.: FR0896, Edition Number: <u>M-035710-01-1</u>	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
			Date: 1997-11-22 GLP/GEP: yes, unpublished		
KCA 6.3.3 /25	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation EC 125 (A-9604 A) in wheat (France, South) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2171/97, Edition Number: <u>M-035719-01-1</u> Date: 1997-11-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /26	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation EC 125 (A-9604 A) in wheat (France, South) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2172/97, Edition Number: <u>M-035728-01-1</u> Date: 1997-11-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /27	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation EC 125 (A-9604 A) in wheat (France, South) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2170/97, Edition Number: <u>M-035734-01-1</u> Date: 1997-11-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /28	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation EC 125 (A-9604 A) in wheat (France, South) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2173/97, Edition Number: <u>M-035745-01-1</u> Date: 1997-11-05 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
KCA 6.3.3 /29	Maffezzoni, M.	1997	Magnitude of residues after application of CGA 279202 and CGA 64250 as formulation EC 250 (A9525B) in winter wheat (France, North) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF96120/KJ87, Edition Number: <u>M-035756-01-1</u> Date: 1997-10-30 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /30	Maffezzoni, M.	1997	Magnitude of residues after application of CGA 279202 as formulation EC 125 (A9604A) in winter wheat (France, South) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF96117, Edition Number: <u>M-035771-01-1</u> Date: 1997-10-23 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /31	Maffezzoni, M.	1997	Magnitude of residues after application of CGA 279202 and CGA 64250 as formulation EC 250 (A9525B) in winter wheat (France, South) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF96120/AC12, Edition Number: <u>M-035785-01-1</u> Date: 1997-10-30 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /32	Maffezzoni, M.	1997	Magnitude of residues after application of CGA 279202 and CGA 64250 as formulation EC 250 (A9525B) in winter wheat (France, South) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF96120/LD89, Edition Number: <u>M-035794-01-1</u> Date: 1997-10-30 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /33	Maffezzoni, M.	1997	Magnitude of residues after application of CGA 279202 and CGA 64250 as formulation EC 250 (A9525B) in winter wheat (France, North) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience,	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
			Report No.: OF96120/SJ13, Edition Number: <u>M-035798-01-1</u> Date: 1997-10-30 GLP/GEP: yes, unpublished		
KCA 6.3.3 /34	Maffezzoni, M.	1997	Magnitude of residues at harvest after application of CGA 279202 as formulation EC 125 in winter wheat (France, North) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF96116/SJ14, Edition Number: <u>M-035802-01-1</u> Date: 1997-07-10 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /35	Maffezzoni, M.	1997	Magnitude of residues at harvest after application of CGA 279202 as formulation EC 125 in winter wheat (France, South) Novartis Agro S.A., Aigues-Vives, France Bayer CropScience, Report No.: OF96116/LD87, Edition Number: <u>M-037177-01-1</u> Date: 1997-07-10 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /36	Smith, J. A.	1997	Residues of CGA 279202 + propiconazole in winter wheat (test product: CGD 20610 F – A9524B) Novartis Agro GmbH, Frankfurt/Main, Germany Bayer CropScience, Report No.: GR31196, Edition Number: <u>M-037187-01-1</u> Date: 1997-10-07 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /37	Smith, J. A.	1997	Residues of CGA 279202 + propiconazole in winter wheat (test product: CGD 20610 F – A9524B) Novartis Agro GmbH, Frankfurt/Main, Germany Bayer CropScience, Report No.: GR32296, Edition Number: <u>M-037190-01-1</u> Date: 1997-10-07 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
KCA 6.3.3 /38	Smith, J. A.	1997	Residues of CGA 279202 in winter wheat Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: GR36296, Edition Number: <u>M-037210-02-1</u> Date: 1997-06-23 ...Amended: 1997-09-25 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /39	Smith, J. A.	1997	Field trial for the determination of residues of CGA 279202 + propiconazole in winter wheat (test product: CGD 20610 F – A9524A) Novartis Agro GmbH, Frankfurt/Main, Germany Bayer CropScience, Report No.: GR3195, Edition Number: <u>M-037237-02-1</u> Date: 1997-09-25 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /40	Smith, J. A.	1997	Residues of CGA 279202 in winter wheat (test product: CGD 20620 F – A9604A) Novartis Agro GmbH, Frankfurt/Main, Germany Bayer CropScience, Report No.: GR35196, Edition Number: <u>M-037252-02-1</u> Date: 1997-09-25 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /41	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation EC 125 (A-9604 A) in wheat (Switzerland) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2013/96, Edition Number: <u>M-037274-01-1</u> Date: 1997-07-31 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /42	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation EC 125 (A-9604 A) in winter wheat (Switzerland) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2272/97, Edition Number: <u>M-037278-01-1</u>	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
			Date: 1997-11-05 GLP/GEP: yes, unpublished		
KCA 6.3.3 /43	Adams, S. P.	1997	Winter wheat: Generation of crop samples for subsequent residue analysis following foliar treatment with CGA 279202 (A-9604 A) in the UK Novartis Crop Protection UK Ltd., Whittlesford, United Kingdom Bayer CropScience, Report No.: FR0196, Edition Number: <u>M-037456-01-1</u> Date: 1997-11-10 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /44	Kissling, M.	1998	Residue study with CGA 279202, cyproconazole (SAN 619) in or on barley in France (south) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2228/97, Edition Number: <u>M-046472-01-1</u> Date: 1998-06-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /45	Kissling, M.	1998	Residue study with CGA 279202, cyproconazole (SAN 619) in or on barley in France (south) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2229/97, Edition Number: <u>M-046529-01-1</u> Date: 1998-06-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /46	Kissling, M.	1998	Residue study with CGA 279202, cyproconazole (SAN 619) in or on barley in France (south) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2230/97, Edition Number: <u>M-046551-01-1</u> Date: 1998-06-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /47	Kissling, M.	1998	Residue study with CGA 279202, cyproconazole (SAN 619) in or on barley in France (south) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2231/97,	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
			Edition Number: <u>M-046553-01-1</u> Date: 1998-06-12 GLP/GEP: yes, unpublished		
KCA 6.3.3 /48	Kissling, M.	1998	Residue study with CGA 279202, cyproconazole (SAN 619) in or on wheat in France (south) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2244/97, Edition Number: <u>M-046563-01-1</u> Date: 1998-06-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /49	Kissling, M.	1998	Residue study with CGA 279202, cyproconazole (SAN 619) in or on wheat in France (south) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2245/97, Edition Number: <u>M-046566-01-1</u> Date: 1998-06-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /50	Kissling, M.	1998	Residue study with CGA 279202, cyproconazole (SAN 619) in or on wheat in France (south) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2246/97, Edition Number: <u>M-048746-01-1</u> Date: 1998-06-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /51	Kissling, M.	1998	Residue study with CGA 279202, cyproconazole (SAN 619) in or on wheat in France (south) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2247/97, Edition Number: <u>M-048748-01-1</u> Date: 1998-06-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /52	Maffezzoni, M.	1998	Residue study with CGA 279202 and CGA 64250 in or on malting spring barley in France (North) ADME Bioanalyses S.A., Aigues-Vives, France Bayer CropScience, Report No.: 9715102,	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
			Edition Number: <u>M-057849-01-1</u> Date: 1998-09-12 GLP/GEP: yes, unpublished		
KCA 6.3.3 /53	Maffezzoni, M.	1998	Residue study with CGA 279202 and CGA 64250 in or on malting spring barley in France (North) ADME Bioanalyses S.A., Aigues-Vives, France Bayer CropScience, Report No.: 9715101, Edition Number: <u>M-057916-01-1</u> Date: 1998-09-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.3 /54	Maffezzoni, M.	1998	Residue study with CGA 279202 and CGA 64250 in or on malting winter barley in France (North) ADME Bioanalyses S.A., Aigues-Vives, France Bayer CropScience, Report No.: 9711601, Edition Number: <u>M-057994-01-1</u> Date: 1998-09-01 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.4 /01	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in cucumbers (Italy) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2079/96, Edition Number: <u>M-037464-01-1</u> Date: 1997-05-27 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.4 /02	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in cucumbers (Netherlands) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2103/96, Edition Number: <u>M-037478-01-1</u> Date: 1997-09-10 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.4 /03	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in cucumbers (Netherlands) Novartis Crop Protection AG, Basel, Switzerland	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
			Bayer CropScience, Report No.: 2102/96, Edition Number: <u>M-037492-01-1</u> Date: 1997-09-10 GLP/GEP: yes, unpublished		
KCA 6.3.4 /04	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in cucumbers (Spain) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2164/96, Edition Number: <u>M-037511-01-1</u> Date: 1997-08-13 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.4 /05	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in cucumbers (Spain) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2165/96, Edition Number: <u>M-037514-01-1</u> Date: 1997-08-13 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.4 /06	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in cucumbers (Spain) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2053/96, Edition Number: <u>M-037523-01-1</u> Date: 1997-08-13 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.4 /07	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in cucumbers (Spain) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2054/96, Edition Number: <u>M-037570-01-1</u> Date: 1997-08-13 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.4 /08	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in cucumbers (Switzerland)	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
			Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2020/96, Edition Number: <u>M-037578-01-1</u> Date: 1997-08-13 GLP/GEP: yes, unpublished		
KCA 6.3.4 /09	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in cucumbers (Switzerland) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2021/96, Edition Number: <u>M-037592-01-1</u> Date: 1997-08-13 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.4 /10 KCA 6.1 /06 KCA 6.3.1 /26 KCA 6.3.5 /22 KCA 6.5 /02	Ohs, P.	2001	Trifloxystrobin – Comment regarding the topic: point 7: residues Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MO-02-006621, Edition Number: <u>M-061069-01-1</u> GLP/GEP: n.a., unpublished	N	Bayer
KCA 6.3.5 /01	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation EC 125 (A-9604 A) in grapes Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2211/95, Edition Number: <u>M-037604-01-1</u> Date: 1997-04-04 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /02	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation EC 125 (A-9604 A) in grapes Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2213/95, Edition Number: <u>M-037617-01-1</u> Date: 1997-04-04 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
KCA 6.3.5 /03	Ipach, R.; Kissling, M.	1997	Determination of CGA 279202, CGA 321113 (metabolite of CGA 279202) and cymoxanil in grapes (berries, must, young wine and wine), Germany Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: GR01296, Edition Number: <u>M-037633-01-1</u> Date: 1997-11-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /04	Ipach, R.; Kissling, M.	1997	Determination of CGA 279202 and CGA 321113 (metabolite of CGA 279202) in grapes (berries, must, young wine and wine), Germany Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: GR01496, Edition Number: <u>M-037640-01-1</u> Date: 1997-11-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /05	Ipach, R.	1996	CGA 279202 + cymoxanil (and metabolite CGA 321113), grapes, Germany Staatl. Lehr- u. Forschungsanstalt fuer Landwirtschaft, Neustadt/Weinstr., Germany Bayer CropScience, Report No.: CGD03, Edition Number: <u>M-037644-01-1</u> Date: 1996-10-31 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /06	Ipach, R.; Kissling, M.	1997	Field and processing study for determination of CGD 20530 F in white grapes, must, and white wine Staatl. Lehr- u. Forschungsanstalt fuer Landwirtschaft, Neustadt/Weinstr., Germany Bayer CropScience, Report No.: GR01196, Edition Number: <u>M-037647-01-1</u> Date: 1997-11-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /07	Ipach, R.; Kissling, M.	1997	Determination of CGA 279202 and CGA 321113 (metabolite of CGA 279202) in grapes (berries, must, young wine and wine), Germany Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: GR01396, Edition Number: <u>M-037676-01-1</u>	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
			Date: 1997-10-10 GLP/GEP: yes, unpublished		
KCA 6.3.5 /08	Beinhauer, K.; Kissling, M.	1996	Trial for determination of residue levels in bunches of grapes and wine according to BBA Guideline IV, 3-3 and 3-4 (1990) BioChem GmbH Karlsruhe, Cunnersdorf, Germany Bayer CropScience, Report No.: 951047008, Report includes Trial Nos.: FR08/95/43 Edition Number: <u>M-037690-01-1</u> Date: 1996-10-30 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /09	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in grapes (Italy) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2085/96, Edition Number: <u>M-037715-01-1</u> Date: 1997-10-07 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /10	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 and cymoxanil as formulation 49 WG (A-9529 A) in grapes (Italy) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2086/96, Edition Number: <u>M-037753-01-1</u> Date: 1997-10-07 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /11	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in grapes (Italy) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2084/96, Edition Number: <u>M-037760-01-1</u> Date: 1997-10-07 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
KCA 6.3.5 /12	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 and cymoxanil as formulation 49 WG (A-9529 A) in grapes (Italy) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2087/96, Edition Number: <u>M-037798-01-1</u> Date: 1997-10-07 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /13	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 and cymoxanil as formulation 49 WG (A-9529 A) in grapes (Italy) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2117/95, Edition Number: <u>M-037802-01-1</u> Date: 1997-02-14 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /14	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in grapes Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2214/95, Edition Number: <u>M-037872-01-1</u> Date: 1997-04-04 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /15	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 and cymoxanil as formulation 49 WG (A-9529 A) in grapes (Spain) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2055/96, Edition Number: <u>M-037896-01-1</u> Date: 1997-10-07 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /16	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 and cymoxanil as formulation 49 WG (A-9529 A) in grapes (Spain) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience,	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
			Report No.: 2056/96, Edition Number: <u>M-037908-01-1</u> Date: 1997-10-07 GLP/GEP: yes, unpublished		
KCA 6.3.5 /17	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 and cymoxanil as formulation 49 WG (A-9529 A) in grapes (Switzerland) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2028/96, Edition Number: <u>M-037921-01-1</u> Date: 1997-10-07 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /18	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 and cymoxanil as formulation 49 WG A-9529 A) in grapes (Switzerland) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2029/96, Edition Number: <u>M-037928-01-1</u> Date: 1997-10-07 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /19	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 and cymoxanil as formulation 49 WG (A-9529 A) in grapes (Switzerland) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2035/95, Edition Number: <u>M-037970-01-1</u> Date: 1997-04-01 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /20	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 and cymoxanil as formulation 49 WG (A-9529 A) in grapes (Switzerland) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2036/95, Edition Number: <u>M-038067-01-1</u> Date: 1997-04-01 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
KCA 6.3.5 /21	Clarke, C.	2000	Residues of trifloxystrobin (CGA 279202) and its major metabolite (CGA 321113) in grapes and dried fruit following three applications of Flint to grapevines, Australia Novartis Crop Protection Australasia Pty. Ltd, Pendle Hill, NSW, Australia Bayer CropScience, Report No.: P99/49, Edition Number: <u>M-051928-01-1</u> Date: 2000-11-07 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /22 KCA 6.1 /06 KCA 6.3.1 /26 KCA 6.3.4 /10 KCA 6.5 /02	Ohs, P.	2001	Trifloxystrobin – Comment regarding the topic: point 7: residues Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MO-02-006621, Edition Number: <u>M-061069-01-1</u> GLP/GEP: n.a., unpublished	N	Bayer
KCA 6.3.5 /23	Pointurier, R.	2000	Residue study with CGA 279202 in or on grapes in France (North) ADME Bioanalyses S.A., Vergeze, France Bayer CropScience, Report No.: 2114/99, Edition Number: <u>M-055049-01-1</u> Date: 2000-08-29 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /24	Pointurier, R.	2000	Residue study with CGA 279202 in or on grapes in France (North) ADME Bioanalyses S.A., Vergeze, France Bayer CropScience, Report No.: 2115/99, Edition Number: <u>M-055059-01-1</u> Date: 2000-08-29 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /25	Simon, P.	2001	Determination of residues of CGA 279202 and the metabolite CGA 321113 in grapes (white), Germany Syngenta Agro GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: gr 45800, Edition Number: <u>M-071592-02-1</u> Date: 2001-08-21 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
KCA 6.3.5 /26	Simon, P.	2001	Determination of residues of CGA 279202 and the metabolite CGA 321113 in grapes (red), Germany Syngenta Agro GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: gr 44500, Edition Number: <u>M-071601-01-1</u> Date: 2001-08-21 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /27	Simon, P.	2001	Determination of residues of CGA 279202 and the metabolite CGA 321113 in grapes (white), Germany Syngenta Agro GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: gr 43500, Edition Number: <u>M-071607-01-1</u> Date: 2001-08-21 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /28	Simon, P.	2001	Determination of residues of CGA 279202 and the metabolite CGA 321113 in grapes (red), Germany Syngenta Agro GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: gr 46900, Edition Number: <u>M-071610-01-1</u> Date: 2001-08-21 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /29	Kissling, M.	2001	Residue study with CGA 279202 in or on grapes in Switzerland Syngenta Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2008/00, Edition Number: <u>M-136443-01-1</u> Date: 2001-04-10 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /30	Kuehne-Thu, H.	2001	Residue study with CGA 279202 in or on grapes in Switzerland Syngenta Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2147/00, Edition Number: <u>M-071614-01-1</u> Date: 2001-07-06 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
KCA 6.3.5 /31 KCA 6.5.3 /06	Vincent, T. P.	1998	CGA-279202 – Magnitude of the residue in or on grapes Novartis Crop Protection, Inc., Greensboro, NC, USA Bayer CropScience, Report No.: 110440, Report includes Trial Nos.: 02-FR-025-96 NE-FR-825-96 NE-FR-826-96 OW-FR-415-96 OW-FR-416-96 OW-FR-417-96 OW-FR-418-96 OW-FR-419-96 OW-FR-531-96 OW-FR-532-96 OW-FR-647-96 OW-FR-648-96 Edition Number: <u>M-104033-01-1</u> EPA MRID No.: 44496838 Date: 1998-01-20 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /32	Meilland-Berthier, I.	2013	Determination of the residues of trifloxystrobin in/on grape after high or low volume spray application of trifloxystrobin WG 50 in the field in northern France and Germany Bayer S.A.S., Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 11-2115, Report includes Trial Nos.: 11-2115-01 11-2115-02 11-2115-03 11-2115-04 Edition Number: <u>M-456337-01-1</u> Date: 2013-06-03 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /33	Stuke, S.	2013	Determination of the residues of trifloxystrobin in/on grape after spray application and low-volume spray application of trifloxystrobin WG 50 in the field in France (North) and Germany Bayer CropScience,	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
			Report No.: 12-2010, Report includes Trial Nos.: 12-2010-01 12-2010-02 12-2010-03 12-2010-04 Edition Number: <u>M-453336-02-1</u> Date: 2013-05-02 ...Amended: 2013-06-21 GLP/GEP: yes, unpublished		
KCA 6.3.5 /34	Meilland-Berthier, I.	2013	Determination of the residues of trifloxystrobin in/on grape after high or low-volume spray application of trifloxystrobin WG 50 in the field in southern France, Spain, Italy and Portugal Bayer S.A.S., Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 11-2114, Report includes Trial Nos.: 11-2114-01 11-2114-02 11-2114-03 11-2114-04 Edition Number: <u>M-454927-01-1</u> Date: 2013-05-21 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.5 /35	Stuke, S.	2013	Determination of the residues of trifloxystrobin in/on grape after spray of trifloxystrobin WG 50 in the field in Italy, Greece and Spain Bayer CropScience, Report No.: 12-2011, Report includes Trial Nos.: 12-2011-01 12-2011-02 12-2011-03 12-2011-04 12-2011-05 Edition Number: <u>M-455561-02-1</u> Date: 2013-06-05 ...Amended: 2013-06-21 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
KCA 6.3.5.1 / 04	Szeley, C. M.; Sadler, C.	2016	Determination of the residues of fluopyram and trifloxystrobin in/on red and black currant after spray application of AE C656948 & CGA 279202 SC 500 in southern France and Spain Report No.: 15-2033, Edition Number: M-553894-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.5.1 / 06	Bellof, S.	2015	Determination of the residues of fluopyram and trifloxystrobin in/on red and black currant after spray application of fluopyram & trifloxystrobin SC 500 in the greenhouse in Italy Report No.: 14-2025, Edition Number: M-535114-03-1 Bayer CropScience AG, Monheim, Germany ... amended: 2015-12-02 GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.5.1 / 07	Szeley, C. M.; Effertz, C.	2016	Determination of the residues of fluopyram and trifloxystrobin in/on red and black currant after spray application of AE C656948 & CGA 279202 SC 500 in the greenhouse in Northern France and Spain Report No.: 15-2032, Edition Number: M-557440-01-2 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3.6 /01	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in melons (Italy) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2080/96, Edition Number: M-038083-01-1 Date: 1997-08-13 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.6 /02	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in melons (Italy) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2389/97, Edition Number: M-038123-01-1 Date: 1997-12-11 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.6 /03	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in melons (Italy) Novartis Crop Protection AG, Basel, Switzerland	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
			Bayer CropScience, Report No.: 2388/97, Edition Number: <u>M-038132-01-1</u> Date: 1997-12-11 GLP/GEP: yes, unpublished		
KCA 6.3.6 /04	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in melons (Italy) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2081/96, Edition Number: <u>M-038138-01-1</u> Date: 1997-08-13 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.6 /05	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in melons (Spain) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2051/96, Edition Number: <u>M-038142-01-1</u> Date: 1997-08-13 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.6 /06	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in melons (Spain) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2053/97, Edition Number: <u>M-038153-01-1</u> Date: 1997-12-11 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.6 /07	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in melons (Spain) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2052/97, Edition Number: <u>M-038177-01-1</u> Date: 1997-12-11 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.6 /08	Kissling, M.	1997	Magnitude of residues after application of CGA 279202 as formulation WG 50 (A-9360 B) in melons (Spain) Novartis Crop Protection AG, Basel, Switzerland	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
			Bayer CropScience, Report No.: 2052/96, Edition Number: <u>M-038184-01-1</u> Date: 1997-08-13 GLP/GEP: yes, unpublished		
KCA 6.3.7 /01	Beinhauer, K.	1996	Trial for determination of residue levels in hops according to BBA Guideline IV, 3-3 and 3-4 (1990) BioChem GmbH Karlsruhe, Cunnersdorf, Germany Bayer CropScience, Report No.: GR01796, Report includes Trial Nos.: FR11/96/72 Edition Number: <u>M-052604-02-1</u> Date: 1996-12-20 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.7 /02	Steck, U.	1997	Determination of CGA 279202 and CGA 321113 (metabolite of CGA 279202) in hops (green cones and dried cones) Bayerische Landesanstalt fuer Bodenkultur und Pflanzenbau, Muenchen, Germany Bayer CropScience, Report No.: RF0296, Edition Number: <u>M-030563-01-2</u> Date: 1997-02-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.7 /03	Steck, U.	1997	Determination of CGA 279202 and CGA 321113 (metabolite of CGA 279202) in hops (green cones and dried cones) Bayerische Landesanstalt fuer Bodenkultur und Pflanzenbau, Muenchen, Germany Bayer CropScience, Report No.: RF0396, Edition Number: <u>M-030558-01-2</u> Date: 1997-02-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.7 /04	Steck, U.	1997	Determination of CGA 279202 and CGA 321113 (metabolite of CGA 279202) in hops (green cones and dried cones) Bayerische Landesanstalt fuer Bodenkultur und Pflanzenbau, Muenchen, Germany Bayer CropScience, Report No.: RF0496, Edition Number: <u>M-030553-01-2</u>	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
			Date: 1997-02-12 GLP/GEP: yes, unpublished		
KCA 6.3.7 /05	Kissling, M.	1998	Residue study with CGA 279202 and Cymoxanil (ASF 331) in or on hops in Germany Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2162/97, Edition Number: <u>M-021917-01-1</u> Date: 1998-06-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.7 /06	Kissling, M.	1998	Residue study with CGA 279202 and Cymoxanil (ASF 331) in or on hops in Germany Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2163/97, Edition Number: <u>M-021928-01-1</u> Date: 1998-06-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.7 /07	Kissling, M.	1998	Residue study with CGA 279202 and Cymoxanil (ASF 331) in or on hops in Germany Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2164/97, Edition Number: <u>M-136383-01-1</u> Date: 1998-06-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.7 /08	Kissling, M.	1998	Residue study with CGA 279202 and Cymoxanil (ASF 331) in or on hops in Germany Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2165/97, Edition Number: <u>M-021957-01-1</u> Date: 1998-06-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.8 /01	Meilland-Berthier, I.	2013	Determination of the residues of trifloxystrobin in/on strawberry after spray application of trifloxystrobin WG 50 in the field in Germany, northern France and Belgium Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 11-2128,	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
			Report includes Trial Nos.: 11-2128-01 11-2128-02 11-2128-03 11-2128-04 Edition Number: <u>M-457953-01-1</u> Date: 2013-06-21 GLP/GEP: yes, unpublished		
KCA 6.3.8 /02	Stuke, S.; Diehl, P.	2013	Determination of the residues of trifloxystrobin in/on strawberry after spraying of trifloxystrobin WG 50 in the field in Germany, the Netherlands, France (north) and Belgium Bayer CropScience, Report No.: 12-2012, Report includes Trial Nos.: 12-2012-01 12-2012-02 12-2012-03 12-2012-04 12-2012-05 Edition Number: <u>M-452140-01-1</u> Date: 2013-04-19 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.8 /03	Meilland-Berthier, I.	2013	Amendment no. 1 to final report no: 11-2129 – Determination of the residues of trifloxystrobin in/on strawberry after spray application of trifloxystrobin WG 50 in the field in southern France, Spain and Italy Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 11-2129, Report includes Trial Nos.: 11-2129-01 11-2129-02 11-2129-03 11-2129-04 Edition Number: <u>M-457958-02-1</u> Date: 2013-06-28 ...Amended: 2013-09-10 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
KCA 6.3.8 /04	Noss, G.; Czaja, C.; Diehl, P.	2013	Determination of the residues of trifloxystrobin in/on strawberry after spray application of trifloxystrobin WG 50 in Spain, Italy and Greece Bayer CropScience, Report No.: 12-2013, Report includes Trial Nos.: 12-2013-01 12-2013-02 12-2013-03 12-2013-04 12-2013-05 Edition Number: <u>M-460009-01-1</u> Date: 2013-07-16 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.8 /05	Meilland-Berthier, I.	2013	Amendment no. 1 to final report no: 11-2120 – Determination of the residues of trifloxystrobin in/on strawberry after spray application of trifloxystrobin WG 50 in the greenhouse in Spain, Italy, Portugal and Greece Bayer CropScience, Lyon, France Bayer CropScience, Report No.: 11-2120, Report includes Trial Nos.: 11-2120-01 11-2120-02 11-2120-03 11-2120-04 Edition Number: <u>M-456769-02-1</u> Date: 2013-06-14 ...Amended: 2013-07-16 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.3.8 /06	Stuke, S..	2013	Determination of the residues of trifloxystrobin in/on strawberry after spraying of trifloxystrobin WG 50 in the greenhouse in Belgium, France (North) and Germany Bayer CropScience, Report No.: 12-2014, Report includes Trial Nos.: 12-2014-01 12-2014-02 12-2014-03 12-2014-04 Edition Number: <u>M-453332-02-1</u>	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
			Date: 2013-05-02 ...Amended: 2013-06-20 GLP/GEP: yes, unpublished		
KCA 6.4.1 /01	xxx	1999	CGA-279202 – Magnitude of the residues in poultry meat and eggs xxx Report No.: 243-98, Edition Number: <u>M-036568-01-1</u> EPA MRID No.: 44757217 Date: 1999-02-02 GLP/GEP: yes, unpublished	Y	Bayer
KCA 6.4.2 /01	xxx	1997	CGA 279202 – Magnitude of the residues in meat and milk resulting from the feeding of three levels to dairy cattle xxx Report No.: ABR-97075, Edition Number: <u>M-038221-01-1</u> EPA MRID No.: 44496834 Date: 1997-12-05 GLP/GEP: yes, unpublished	Y	Bayer
KCA 6.5 /01	Morgenroth, U.	2000	Hydrolysis of [Glyoxyl-phenyl-U-14C]-CGA 279202 under processing conditions Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 00MO02, Edition Number: <u>M-047519-01-1</u> Date: 2000-11-06 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.5 /02 KCA 6.1 /06 KCA 6.3.1 /26 KCA 6.3.4 /10 KCA 6.3.5 /22	Ohs, P.	2001	Trifloxystrobin – Comment regarding the topic: point 7: residues Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MO-02-006621, Edition Number: <u>M-061069-01-1</u> GLP/GEP: n.a., unpublished	N	Bayer
KCA 6.5.3 /01	Campbell, D. D.	1997	CGA 279202 – Magnitude of the residue in or on crop group 11: pome fruits Novartis Crop Protection, Inc., Greensboro, NC, USA Bayer CropScience, Report No.: ABR-97074, Edition Number: <u>M-038275-01-1</u>	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
			Date: 1997-05-12 GLP/GEP: yes, unpublished		
KCA 6.5.3 /02 KCA 6.3.1 /31	Kissling, M.	2000	Residue study with CGA 279202 in or on apples in France (north) Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2007/99, Edition Number: M-024932-01-1 Date: 2000-04-25 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.5.3 /03 KCA 6.3.1 /34	Kissling, M.	2000	Residue study with CGA 279202 in or on apples in Switzerland Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2125/99, Edition Number: M-136411-01-1 Date: 2000-08-17 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.5.3 /04	Schmeer, K.; Kuppels, U.	2009	Determination of the residues of AE C656948 and trifloxystrobin in/on grape after spraying and spraying, low-volume of AEC656948 & CGA279202 SC 500 in the field in France (South) and Italy Bayer CropScience, Report No.: 08-2204, Report includes Trial Nos.: 08-2204-02 08-2204-03 Edition Number: M-357708-02-1 Date: 2009-10-14 ...Amended: 2012-06-11 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.5.3 /05	Schmeer, K.; Hoffmann, M.	2010	Determination of the residues of AE C656948 and trifloxystrobin in/on grape and the processed fractions (must; pomace, grape; wine at bottling and wine at first taste test) after spraying of AE C656948 & CGA279202 SC 500 in the field in France (South) and Italy Bayer CropScience, Report No.: 08-3204, Report includes Trial Nos.: 08-3204-01 08-3204-02 Edition Number: M-384844-01-1	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
			Date: 2010-06-02 GLP/GEP: yes, unpublished		
KCA 6.5.3 /06 KCA 6.3.5 /31	Vincent, T. P.	1998	CGA-279202 – Magnitude of the residue in or on grapes Novartis Crop Protection, Inc., Greensboro, NC, USA Bayer CropScience, Report No.: 110440, Report includes Trial Nos.: 02-FR-025-96 NE-FR-825-96 NE-FR-826-96 OW-FR-415-96 OW-FR-416-96 OW-FR-417-96 OW-FR-418-96 OW-FR-419-96 OW-FR-531-96 OW-FR-532-96 OW-FR-647-96 OW-FR-648-96 Edition Number: M-104033-01-1 EPA MRID No.: 44496838 Date: 1998-01-20 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.5.3 /07	Nuesslein, F.	2003	Determination of residues of trifloxystrobin and CGA 321113 in/on strawberry (fruit washed, preserve, washings, jam) following spray application of Flint 50 WG in the field in Northern France and Germany Bayer CropScience, Report No.: RA-3038/02, Report includes Trial Nos.: 0188-02 0191-02 R 2002 0188/5 R 2002 0191/5 Edition Number: M-086063-01-1 Date: 2003-03-06 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
KCA 6.5.3 /08	Freitag, T.	2013	Amendment No. 0001 to Report No.: 12-3012 – Determination of the residues of trifloxystrobin in/on strawberry and the processed fractions (fruit, washed; washings; preserve and jam) after spray application of trifloxystrobin WG 50 in the field in the Netherlands and Germany Bayer CropScience, Report No.: 12-3012, Report includes Trial Nos.: 12-3012-01 12-3012-02 Edition Number: M-464835-02-1 Date: 2013-09-02 ...Amended: 2013-10-10 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.5.3 /09	Beinhauer, K. Kissling, M.	1997	CGA 279202 (and metabolite CGA 321113), A 9360 B, Apples (fruit, fruit washed, juice, pomace, purée and fruit dried), Germany. Novartis Agro GmbH, Frankfurt, Germany. Study Report No. gr 00996, Analytical Report No. 2179/96 Novartis File N° 279202 /304 Edition Number: M-034808-01-1 Date: 29.09.1997 GLP, Unpublished	N	Bayer
KCA 6.5.3 /10	Beinhauer, K. Kissling, M.	1997	CGA 279202 (and metabolite CGA 321113), A 9360 B, Pears (fruit, fruit washed, purée and fruit dried), Germany. Novartis Agro GmbH, Frankfurt, Germany. Study Rep. No. GR 01096, Analytical Report No. 2154/95, 29.09.1997 Novartis File N° 279202 / 181 Edition Number: M-034967-01-1 Date: 14.03.1996 GLP, Unpublished	N	Bayer
KCA 6.5.3 /11	Ipach, R., Kissling, M.	1997	CGA 279202 (and metabolite CGA 321113), A-9360 B, Grapes (berries, must, young wine and wine), Germany. Novartis Agro GmbH, Frankfurt, Germany. Study Report No. GR01496, Analytical Report No. 2178/96 Novartis File N° 279202 / 387 Edition Number: M-037640-01-1 Date: 05.11.1997 GLP, 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
KCA 6.5.3 /12	Ipach, R., Kissling, M.	1997	CGA 279202 (and metabolite CGA 321113), A-9360 B, Grapes (berries, must, young wine and wine), Germany. Novartis Agro GmbH, Frankfurt, Germany. Study Report No. GR01396, Analytical Report No. 2177/96 Novartis File N° 279202 / 389 Edition Number: M-037676-01-1 Date: 10.10.1997 GLP, Unpublished	N	Bayer
KCA 6.5.3 /13	Kissling, M.	1997	CGA 279202 (and metabolite CGA 321113), WG 50, A- 9360 B, Grapes, Italy. Novartis Crop Protection AG, Basel, Switzerland. Study Report No. 2085/96, Novartis File N° 279202 / 331 Edition Number: M-037715-01-1 Date: 07.10.1997 GLP, Unpublished	N	Bayer
KCA 6.5.3 /14	Kissling, M.	1997	CGA 279202 (and metabolite CGA 321113), WG 50, A-9360 B, Grapes, Italy. Novartis Crop Protection AG, Basel, Switzerland. Study Report No. 2084/96, Novartis File N° 279202 / 330 Edition Number: M-037760-01-1 Date: 07.10.1997 GLP, Unpublished	N	Bayer
KCA 6.5.3 /15	Ipach, R., Kissling, M.	1997	CGA 279202 (and metabolite CGA 321113) & Cymoxanil, A-9529 A, Grapes (berries, must, young wine and wine), Germany Novartis Agro GmbH, Frankfurt, Germany. Study Report No. GR01296, Analytical Report No. 2176/96 Novartis File N° 279202 / 390 Edition Number: M-037633-01-1 Date: 05.11.1997 GLP, Unpublished	N	Bayer
KCA 6.5.3 /16	Ipach, R., Kissling, M.	1997	CGA 279202 (and metabolite CGA 321113) & Cymoxanil, A-9529 A, Grapes (berries, must, young wine and wine), Germany Novartis Agro GmbH, Frankfurt, Germany. Study Report No. GR01196,	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
			Analytical Report No. 2175/96 Novartis File N° 279202 / 388 Edition Number: M-037647-01-1 Date: 05.11.1997 GLP, Unpublished		
KCA 6.5.3 /17	Kissling, M.	1997	CGA 279202 & Cymoxanil (and metabolite CGA 321113), WG 49, A-9529 A, Grapes, Italy. Novartis Crop Protection AG, Basel, Switzerland. Study Report No. 2086/96, Novartis File N° 279202 / 332 Edition Number: M-037753-01-1 Date: 07.10.1997 GLP, Unpublished	N	Bayer
KCA 6.5.3 /18	Kissling, M.	1997	CGA 279202 & Cymoxanil (and metabolite CGA 321113), WG 49, A-9529 A, Grapes, Italy. Novartis Crop Protection AG, Basel, Switzerland. Study Report No. 2087/96, Novartis File N° 279202 / 333 Edition Number: M-037798-01-1 Date: 07.10.1997 GLP, Unpublished	N	Bayer
KCA 6.5.3 /19	Kissling, M.	1997	CGA 279202 & Cymoxanil (and metabolite CGA 321113), WG 49, A- 9529 A, Grapes, Spain. Novartis Crop Protection AG, Basel, Switzerland. Study Report No. 2055/96, Novartis File N° 279202 / 328 Edition Number: M-037896-01-1 Date: 07.10.1997 GLP, Unpublished	N	Bayer
KCA 6.5.3 /20	Kissling, M.	1997	CGA 279202 & Cymoxanil (and metabolite CGA 321113), WG 49, A-9529 A, Grapes, Spain. Novartis Crop Protection AG, Basel, Switzerland. Study Report No. 2056/96, Novartis File N° 279202 / 329 Edition Number: M-037908-01-1 Date: 07.10.1997 GLP, 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
KCA 6.5.3 /21	Kissling, M.	1997	CGA 279202 & Cymoxanil (and metabolite CGA 321113), WG 49, AS- 9529 A, Grapes, Switzerland. Novartis Crop Protection AG, Basel, Switzerland. Study Report No. 2028/96, Novartis File N° 279202 / 326 Edition Number: M-037921-01-1 Date: 07.10.1997 GLP, Unpublished	N	Bayer
KCA 6.5.3 /22	Kissling, M.	1997	CGA 279202 & Cymoxanil (and metabolite CGA 321113), WG 49, A- 9529 A, Grapes, Switzerland. Novartis Crop Protection AG, Basel, Switzerland. Study Report No. 2029/96, Novartis File N° 279202 / 327 Edition Number: M-037928-01-1 Date: 07.10.1997 GLP, Unpublished	N	Bayer
KCA 6.5.3 /23	Ipach, R. Kissling, M.	1997	CGA 279202 & Cymoxanil (and metabolite CGA 321113), A-9529A, Grapes, Germany. Novartis Crop Protection AG, Basel, Switzerland. Rep. No. CGD03, Analytical Report No. 2173/95 Novartis File N° 279202 / 193 Edition Number: M-037644-01-1 Date: 27.05.1997 GLP, Unpublished	N	Bayer
KCA 6.5.3 /24	Beinhauer, K. Kissling, M.	1997	CGA 279202 & Cymoxanil (and metabolite CGA 321113), A, 9529 A, WG, Grapes, Germany. Novartis Agro GmbH, Frankfurt, Germany. Rep. No. FR 08/95/43, Final Report No. 95 10 47 008, Analytical Report No. 2174/95 Novartis File N° 279202 / 194 Edition Number: M-037690-01-1 Date: 27.05.1997 GLP, Unpublished	N	Bayer
KCA 6.5.3 /25	Kissling, M.	1997	CGA 279202 & Cymoxanil, and metabolite CGA 321113, 49 WG, A-9529 A, Grapes (berries, must, young wine and wine), Italy. Novartis Crop Protection AG, Basel, Switzerland. Rep. No. 2117/95, Novartis File N° 279202 / 140 Edition Number: M-037802-01-1 Date: 14.02.1997 GLP, 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
KCA 6.5.3 /26	Kissling, M.	1997	CGA 279202 & Cymoxanil (and metabolite CGA 321113), 49 WG, A-9529 A, Grapes, Switzerland. Novartis Crop Protection AG, Basel, Switzerland. Rep. No. 2035/95, Novartis File N° 279202 / 175 Edition Number: M-037970-01-1 Date: 01.04.1997 GLP, Unpublished	N	Bayer
KCA 6.5.3 /27	Maffezzoni, M.	1998	Residue Study with CGA 279202 and CGA 64250 in or on Malting Winter Barley in France (North). Final Report No. 9711601, Novartis File No. 64250/3413 Edition Number: M-057994-01-1 Date: 16/09/1998 GLP, not published	N	Bayer
KCA 6.5.3 /28	Maffezzoni, M	1998	Residue Study with CGA 279202 and CGA 64250 in or on Malting Spring Barley in France (North). Final Report No. 9715101, Novartis File No. 64250/3414 Edition Number: M-057916-01-1 Date: 24/09/1998 GLP, not published	N	Bayer
KCA 6.5.3 /29	Maffezzoni, M	1998	Residue Study with CGA 279202 and CGA 64250 in or on Malting Spring Barley in France (North). Final Report No. 9715102, Novartis File No. 64250/3415 Edition Number: M-057849-01-1 Date: 24/09/1998 GLP, not published	N	Bayer
KCA 6.5.3 /30	Maffezzoni, M.	1998	Residue Study with CGA 279202 and CGA 64250 in or on Malting Winter Barley in France (North). Final Report No. 9711602, Novartis File No. 64250/3416 Edition Number: M-057927-01-1 Date: 16/09/1998 GLP, not published	N	Bayer
KCA 6.6.1 /01 KCA 6.6.2 /01	Gross, D.	1997	Outdoor confined accumulation study on rotational crops after bareground application of (CF3-Phenyl-U-14C) labelled CGA 279202 Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: CMR26/97,	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
			Edition Number: M-038288-02-1 Date: 1997-11-17 ...Amended: 1998-01-23 GLP/GEP: yes, unpublished		
KCA 6.6.1 /02 KCA 6.6.2 /02	Stingelin, J.	1997	Outdoor confined accumulation study on rotational crops after bareground application of [glyoxyl-phenyl-(U)-14C]-CGA 279202 Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: CMR24/97, Edition Number: M-038296-01-1 Date: 1997-11-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.9 /01	Schenk, H.	2001	TMDI calculation Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MO-02-006630, Edition Number: M-061104-01-1 GLP/GEP: n.a., unpublished	N	Bayer
KCA 6.10 /01	Stuke, S.	2012	Amendment no. 1 to report no: P 652 11 5503 – Determination of the residues of trifloxystrobin, CGA 357261, CGA 357262, CGA 331409, CGA 321113, and CGA 373466 in/on materials of plant origin by HPLCMS/MS Bayer CropScience, Report No.: MR-11/044, Report includes Trial Nos.: 09-2015-01 – 04 09-2076-01 – 05 09-2077-01 – 04 09-2127-01 – 04 09-2135-01 – 02 09-2136-01 – 02 Edition Number: M-421645-02-1 Date: 2012-01-04 ...Amended: 2013-07-24 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.10 /02	Noss, G.; Diehl, P.	2012	Amendment no. 1 to report no.: 10-2174 – Determination of the residues of trifloxystrobin in/on hop after spraying of trifloxystrobin WG 50 in the field in Germany Bayer CropScience,	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
			Report No.: 10-2174, Report includes Trial Nos.: 10-2174-02 Edition Number: M-443126-02-1 Date: 2012-10-24 ...Amended: 2013-01-07 GLP/GEP: yes, unpublished		
KCA 6.10 /03	Noss, G.; Diehl, P.; Ruhl, S.	2012	Determination of the residues of trifloxystrobin in/on cucumber after spraying of trifloxystrobin WG 50 in the field in France (North), Germany and Belgium Bayer CropScience, Report No.: 10-2179, Report includes Trial Nos.: 10-2179-01 10-2179-02 10-2179-03 10-2179-04 Edition Number: M-441575-01-1 Date: 2012-11-07 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.10 /04	Noss, G.; Diehl, P.	2012	Amendment no. 1 to report no: 10-2180 – Determination of the residues of trifloxystrobin in/on cucumber after spraying of trifloxystrobin WG 50 in the field in France (South), Spain and Italy Bayer CropScience, Report No.: 10-2180, Report includes Trial Nos.: 10-2180-01 10-2180-02 10-2180-03 10-2180-04 Edition Number: M-438321-02-1 Date: 2012-09-10 ...Amended: 2013-02-21 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.10 /05	Noss, G.; Diehl, P.	2012	Amendment no. 1 to report no: 10-2181 – Determination of the residues of trifloxystrobin in/on cucumber after spraying of trifloxystrobin WG 50 in the greenhouse in Spain, Italy, France (South) and the Netherlands Bayer CropScience, Report No.: 10-2181,	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
			Report includes Trial Nos.: 10-2181-01 10-2181-02 10-2181-03 10-2181-04 Edition Number: M-438698-02-1 Date: 2012-09-10 ...Amended: 2013-02-21 GLP/GEP: yes, unpublished		
KCA 6.10 /06	Stuke, S.; Ballmann, C.	2013	Determination of the residues of tebuconazole and trifloxystrobin in/on broccoli and cauliflower after spray application of tebuconazole & trifloxystrobin WG 75 in the field in Germany, France (North) and Belgium Bayer CropScience, Report No.: 12-2068, Report includes Trial Nos.: 12-2068-01 12-2068-02 12-2068-03 12-2068-04 Edition Number: M-457379-01-1 Date: 2013-06-19 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.10 /07	Stuke, S.; Ballmann, C.	2013	Determination of the residues of tebuconazole and trifloxystrobin in/on broccoli and cauliflower after spray application of tebuconazole & trifloxystrobin WG 75 in the field in France (South) Bayer CropScience, Report No.: 12-2069, Report includes Trial Nos.: 12-2069-01 12-2069-02 12-2069-03 12-2069-04 Edition Number: M-457394-01-1 Date: 2013-06-19 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.10 /08	Smith, J. A.	1998	Residues of CGA 279202 + CGA 321113 in winter wheat (test product: NAD 21180 F – A9604A, EC 125) Novartis Agro GmbH, Frankfurt/Main, Germany Bayer CropScience,	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
			Report No.: GR49197, Edition Number: M-069205-01-1 Date: 1998-01-29 GLP/GEP: yes, unpublished		
KCA 6.10 /09	Smith, J. A.	2000	Determination of CGA 279202 and the metabolite CGA 321113 in spring wheat Novartis Agro GmbH, Frankfurt/Main, Germany Bayer CropScience, Report No.: GR38499, Edition Number: M-054730-02-1 Date: 2000-05-09 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.10 /10	Simon, P.	2001	Determination of residues of CGA 279202 and the metabolite CGA 321113 in winter wheat Syngenta Agro GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: gr 57100, Edition Number: M-030968-01-1 Date: 2001-04-20 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.10 /11	Simon, P.	2001	Determination of residues of CGA 279202 and the metabolite CGA 321113 in winter wheat Syngenta Agro GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: gr 58200, Edition Number: M-030971-01-1 Date: 2001-04-20 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.10 /12	Kissling, M.	2001	Residue study with CGA 279202 in or on spring barley in France (North) Syngenta Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 2022/99, Edition Number: M-022006-01-1 Date: 2001-01-24 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.10 /13	Maffezzoni, M.	1999	Residue study with CGA 279202 + cyproconazole in or on barley in North of France ADME Bioanalyses S.A., Aigues-Vives, France Bayer CropScience,	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
			Report No.: 9813201, Edition Number: M-057584-01-1 Date: 1999-11-09 GLP/GEP: yes, unpublished		
KCA 6.10 /14	Smith, J. A.	2000	Determination of residues of CGA 279202 and the metabolite CGA 321113 in spring barley Novartis Agro GmbH, Frankfurt/Main, Germany Bayer CropScience, Report No.: GR35199, Edition Number: M-055021-02-1 Date: 2000-05-09 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.10 /15	Smith, J. A.	2000	Determination of residues of CGA 279202 and the metabolite CGA 321113 in winter barley Novartis Agro GmbH, Frankfurt/Main, Germany Bayer CropScience, Report No.: GR37399, Edition Number: M-054967-02-1 Date: 2000-05-09 GLP/GEP: yes, unpublished	N	Bayer
KCA 6.10 /16	Simon, P.	2001	Determination of residues of CGA 279202 and the metabolite CGA 321113 in winter barley Syngenta Agro GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: gr 59100, Edition Number: M-030958-01-1 Date: 2001-04-20 GLP/GEP: yes, unpublished	N	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
-	-	-	-	-	-

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 Trifloxystrobin

A 2.1.1 7.2.1 Stability of residues – Trifloxystrobin

A 2.1.1.1 7.2.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products (KCA 6.1)

New/additional studies are submitted.

A 2.1.1.1.1.1 Study 1: MR-11/075

Comments of zRMS:	<p>The Applicant submitted amendment no. 3 to final raport of study: "Storage stability of CGA 279202, CGA 357262, CGA 357261, CGA331409, CGA 321113 and CGA 373466 in plant matrices for 24 months", Stuke S., 2019.</p> <p>The Limit of Quantitation (LOQ) 0.01 mg/kg for all analytes.</p> <p>After a deep-freezer storage period of about 24 months, the mean recovery rates from the stored samples of dry bean, corn green material, rye grain, rape seed and orange fruit ranged between 73% and 113% for trifloxystrobin, between 59% and 115% for CGA 331409, between 68% and 114% for CGA 357262, between 74% and 109% for CGA 357261, between 71% and 108% for CGA 321113 and between 78% and 116% for CGA 373466.</p> <p>Furthermore the mean concurrent recoveries determined from freshly fortified samples were in a range of 87% to 117% for trifloxystrobin, in a range of 87% to 116% for CGA 331409, in a range of 90% to 115% for CGA 357262, in a range of 88% to 112% for CGA 357261, in a range of 78% to 109% for CGA 321113 and in a range of 77% to 110% for CGA 373466.</p> <p>Altogether, the study results demonstrate that the residues are stable in the tested plant commodities for at least 24 months under deep-freezer storage conditions.</p> <p>The study is acceptable.</p> <p>Remark: The average recoveries have been added to the tables.</p>
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Reference:	KCA 6.1/01
Title:	Amendment no. 3: Storage stability of CGA 279202, CGA 357262, CGA 357261, CGA331409, CGA 321113 and CGA 373466 in plant matrices for 24 months
Report:	Stuke, S.; 2019; P642110501; M-468560-04-1
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 and repealing Council Directives 79/117/EEC and 91/414/EEC, OECD Guidelines for the Testing of Chemicals. Stability of Pesticide Residues in Stored Commodities. 506. 2007-10-16, US EPA OCSPP 860.1380, Storage Stability Data
Deviations:	Not specified
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The study was already submitted and evaluated, but an amended version is available and is therefore included in this submission.

Materials and methods

The stability of CGA 279202 (trifloxystrobin), CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 for 2 years in deep frozen storage was investigated in plant matrices covering the five

relevant commodity groups (high water content, high oil content, high protein content, high starch content, high acid content).

Samples of corn green material, rape seed, bean dry seed, rye grain and orange fruit were fortified with CGA 279202 (trifloxystrobin), CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 at 0.10 mg/kg. Immediately after fortification, a sample was taken to determine the initial residues. The remaining fortified samples were stored deep frozen at -18°C or below until analysis after nominal storage intervals of 1, 3, 6, 12, 18, and 24 months.

For analysis the residue analytical method 01313 was used with a limit of quantitation of 0.01 mg/kg.

Results and discussions

No significant decrease of residues was observed after the tested period of 24 months. Thus the residues of trifloxystrobin (CGA 279202), CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 are stable under freezer storage conditions for at least 24 months. Hence, the results of the presented storage stability study validate the results from the residue trials with respect to the stability of trifloxystrobin (CGA 279202), CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 in frozen samples.

Conclusion

No significant decrease of residues was observed after the tested period of 24 months in bean dry seed, corn green material, rye grain, rape seed and orange fruit. Thus, the residues of trifloxystrobin (CGA 279202), CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 are stable under freezer storage conditions at -18° C or below for at least 24 months.

Table A 1: **Summary of concurrent recoveries of trifloxystrobin from bean (dry seed)**

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
Trifloxystrobin (CGA 279202)					
Bean (dry seed)	0.01	0	2	91, 90	91
	0.10	0	2	82, 91	87
	0.10	30	2	96, 104	100
	0.10	89	2	94, 98	96
	0.10	181	2	105, 107	106
	0.10	359	2	93, 102	98
	0.10	531	2	103, 105	104
	0.10	733	2	107, 110	109
	Overall Mean and RSD				
CGA 321113					
Bean (dry seed)	0.01	0	2	95, 98	97
	0.10	0	2	85, 93	89
	0.10	30	2	97, 98	98
	0.10	89	2	102, 100	101
	0.10	181	2	108, 105	107
	0.10	359	2	95, 119	107
	0.10	531	2	108, 107	108
	0.10	733	2	111, 107	109
	Overall Mean and RSD				
CGA 331409					
Bean (dry seed)	0.01	0	2	86, 90	88
	0.10	0	2	82, 91	87
	0.10	30	2	93, 96	95
	0.10	89	2	102, 97	100
	0.10	181	2	102, 102	102
	0.10	359	2	93, 87	90
	0.10	531	2	105, 106	106
	0.10	733	2	109, 110	110
	Overall Mean and RSD				
CGA 357261					
Bean (dry seed)	0.01	0	2	91, 93	92
	0.10	0	2	84, 92	88
	0.10	30	2	94, 97	96
	0.10	89	2	92, 89	91
	0.10	181	2	113, 111	112
	0.10	359	2	92, 99	96
	0.10	531	2	101, 102	102
	0.10	733	2	108, 110	109
	Overall Mean and RSD				

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
CGA 357262					
Bean (dry seed)	0.01	0	2	86, 92	89
	0.10	0	2	86, 94	90
	0.10	30	2	96, 106	101
	0.10	89	2	110, 107	109
	0.10	181	2	99, 98	99
	0.10	359	2	93, 92	93
	0.10	531	2	104, 106	105
	0.10	733	2	107, 109	108
	Overall Mean and RSD				
CGA 373466					
Bean (dry seed)	0.01	0	2	87, 95	91
	0.10	0	2	81, 92	87
	0.10	30	2	94, 99	97
	0.10	89	2	87, 77	82
	0.10	181	2	111, 108	110
	0.10	359	2	79, 75	77
	0.10	531	2	101, 99	100
	0.10	733	2	98, 100	99
	Overall Mean and RSD				

Table A 2: Summary of concurrent recoveries of trifloxystrobin from corn (green material)

Table A 2. Summary of concurrent recoveries of trifloxystrobin from corn (green material)					
Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
Trifloxystrobin (CGA 279202)					
Corn (green material)	0.01	0	2	89, 95	92
	0.10	0	2	99, 98	99
	0.10	31	2	90, 91	91
	0.10	89	2	89, 89	89
	0.10	180	2	99, 101	100
	0.10	356	2	89, 92	91
	0.10	537	2	109, 102	106
	0.10	738	2	94, 99	97
	Overall Mean and RSD				
CGA 321113					
Corn (green material)	0.01	0	2	89, 101	95
	0.10	0	2	106, 99	103
	0.10	31	2	110, 103	107
	0.10	89	2	85, 85	85
	0.10	180	2	98, 103	101
	0.10	356	2	89, 105	97
	0.10	537	2	109, 103	106
	0.10	738	2	94, 104	99
	Overall Mean and RSD				
CGA 331409					
Corn (green material)	0.01	0	2	103, 105	104
	0.10	0	2	109, 111	110
	0.10	31	2	88, 89	89
	0.10	89	2	88, 90	89
	0.10	180	2	97, 106	102
	0.10	356	2	91, 92	92
	0.10	537	2	108, 103	106
	0.10	738	2	95, 102	99
	Overall Mean and RSD				
CGA 357261					
Corn (green material)	0.01	0	2	90, 94	92
	0.10	0	2	94, 96	95
	0.10	31	2	87, 92	90
	0.10	89	2	88, 87	88
	0.10	180	2	97, 94	96
	0.10	356	2	87, 90	89
	0.10	537	2	106, 102	104
	0.10	738	2	94, 97	96

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
	Overall Mean and RSD				93 ± 5.8
CGA 357262					
Corn (green material)	0.01	0	2	95, 98	97
	0.10	0	2	103, 106	105
	0.10	31	2	91, 94	93
	0.10	89	2	93, 94	94
	0.10	180	2	107, 108	108
	0.10	356	2	89, 93	91
	0.10	537	2	107, 103	105
	0.10	738	2	94, 99	97
	Overall Mean and RSD				98 ± 6.5
CGA 373466					
Corn (green material)	0.01	0	2	94, 99	97
	0.10	0	2	103, 102	103
	0.10	31	2	108, 104	106
	0.10	89	2	82, 75	79
	0.10	180	2	101, 100	101
	0.10	356	2	88, 101	95
	0.10	537	2	106, 102	104
	0.10	738	2	94, 103	99
	Overall Mean and RSD				98 ± 9.2

Table A 3: Summary of concurrent recoveries of trifloxystrobin from rye (grain)

Table A 3. Summary of concurrent recoveries of trifloxystrobin from rye (grain)					
Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
Trifloxystrobin (CGA 279202)					
Rye (grain)	0.01	0	2	93, 114	104
	0.10	0	2	104, 100	102
	0.10	28	2	104, 103	104
	0.10	85	2	92, 97	95
	0.10	176	2	108, 111	110
	0.10	355	2	99, 96	98
	0.10	533	2	111, 110	111
	0.10	733	2	103, 99	101
	Overall Mean and RSD				
CGA 321113					
Rye (grain)	0.01	0	2	84, 110	97
	0.10	0	2	97, 92	95
	0.10	28	2	106, 100	103
	0.10	85	2	80, 86	83
	0.10	176	2	101, 99	100
	0.10	355	2	100, 95	98
	0.10	533	2	100, 100	100
	0.10	733	2	101, 97	99
	Overall Mean and RSD				
CGA 331409					
Rye (grain)	0.01	0	2	99, 116	108
	0.10	0	2	111, 108	110
	0.10	28	2	113, 109	111
	0.10	85	2	100, 101	101
	0.10	176	2	101, 102	102
	0.10	355	2	99, 98	99
	0.10	533	2	112, 112	112
	0.10	733	2	105, 100	103
	Overall Mean and RSD				
CGA 357261					
Rye (grain)	0.01	0	2	92, 117	105
	0.10	0	2	106, 104	105
	0.10	28	2	99, 100	100
	0.10	85	2	96, 100	98
	0.10	176	2	104, 107	106
	0.10	355	2	97, 95	96
	0.10	533	2	110, 108	109
	0.10	733	2	102, 99	101

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
	Overall Mean and RSD				102 ± 6.2
CGA 357262					
Rye (grain)	0.01	0	2	98, 111	105
	0.10	0	2	108, 105	107
	0.10	28	2	111, 97	104
	0.10	85	2	97, 97	97
	0.10	176	2	105, 110	108
	0.10	355	2	98, 96	97
	0.10	533	2	115, 115	115
	0.10	733	2	100, 104	102
	Overall Mean and RSD				104 ± 6.5
CGA 373466					
Rye (grain)	0.01	0	2	79, 113	96
	0.10	0	2	97, 93	95
	0.10	28	2	103, 100	102
	0.10	85	2	82, 82	82
	0.10	176	2	101, 94	98
	0.10	355	2	98, 95	97
	0.10	533	2	100, 101	101
	0.10	733	2	101, 97	99
	Overall Mean and RSD				96 ± 9.1

Table A 4: Summary of concurrent recoveries of trifloxystrobin from rape (seed)

Table A 4. Summary of concurrent recoveries of trifloxystrobin from rape (seed)						
Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD	
Trifloxystrobin (CGA 279202)						
Rape (seed)	0.01	0	2	94, 90	92	
	0.10	0	2	98, 94	96	
	0.10	28	2	95, 89	92	
	0.10	84	2	98, 101	100	
	0.10	177	2	95, 98	97	
	0.10	353	2	98, 100	99	
	0.10	532	2	117, 116	117	
	0.10	735	2	92, 96	94	
	Overall Mean and RSD					98 ± 8.0
CGA 321113						
Rape (seed)	0.01	0	2	75, 81	78	
	0.10	0	2	80, 76	78	
	0.10	28	2	103, 96	100	
	0.10	84	2	87, 87	87	
	0.10	177	2	92, 94	93	
	0.10	353	2	97, 99	98	
	0.10	532	2	93, 92	93	
	0.10	735	2	91, 94	93	
	Overall Mean and RSD					90 ± 9.1
CGA 331409						
Rape (seed)	0.01	0	2	94, 97	96	
	0.10	0	2	101, 97	99	
	0.10	28	2	96, 86	91	
	0.10	84	2	97, 102	100	
	0.10	177	2	93, 98	96	
	0.10	353	2	95, 95	95	
	0.10	532	2	115, 117	116	
	0.10	735	2	101, 106	104	
	Overall Mean and RSD					99 ± 7.9
CGA 357261						
Rape (seed)	0.01	0	2	95, 90	93	
	0.10	0	2	98, 96	97	
	0.10	28	2	90, 89	90	
	0.10	84	2	96, 101	99	
	0.10	177	2	92, 97	95	
	0.10	353	2	100, 101	101	
	0.10	532	2	106, 107	107	
	0.10	735	2	91, 95	93	

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
	Overall Mean and RSD				97 ± 5.7
CGA 357262					
Rape (seed)	0.01	0	2	91, 95	93
	0.10	0	2	97, 97	97
	0.10	28	2	94, 88	91
	0.10	84	2	97, 101	99
	0.10	177	2	94, 97	96
	0.10	353	2	97, 99	98
	0.10	532	2	111, 112	112
	0.10	735	2	95, 99	97
	Overall Mean and RSD				98 ± 6.4
CGA 373466					
Rape (seed)	0.01	0	2	79; 76	78
	0.10	0	2	86, 80	83
	0.10	28	2	99, 89	94
	0.10	84	2	82, 87	85
	0.10	177	2	90, 92	91
	0.10	353	2	98, 100	99
	0.10	532	2	94, 91	93
	0.10	735	2	92, 98	95
	Overall Mean and RSD				90 ± 8.3

Table A 5: Summary of concurrent recoveries of trifloxystrobin from orange (fruit)

Table A 3: Summary of concurrent recoveries of trifloxystrobin from orange (fruit)					
Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
Trifloxystrobin (CGA 279202)					
Orange (fruit)	0.01	0	2	115, 99	107
	0.10	0	2	111, 106	109
	0.10	28	2	111, 104	108
	0.10	82	2	94, 95	95
	0.10	173	2	97, 89	93
	0.10	351	2	102, 96	99
	0.10	531	2	102, 108	105
	0.10	732	2	94, 95	95
	Overall Mean and RSD				
CGA 321113					
Orange (fruit)	0.01	0	2	104, 92	98
	0.10	0	2	104, 98	101
	0.10	28 / 33	2	103, 100, 98	100
	0.10	82	2	85, 87	86
	0.10	173	2	92, 85	89
	0.10	351	2	100, 96	98
	0.10	531	2	94, 98	96
	0.10	732	2	93, 94	94
	Overall Mean and RSD				
CGA 331409					
Orange (fruit)	0.01	0	2	114, 108	111
	0.10	0	2	114, 107	111
	0.10	28	2	106, 102	104
	0.10	82	2	99, 97	98
	0.10	173	2	103, 91	97
	0.10	351	2	109, 104	107
	0.10	531	2	100, 108	104
	0.10	732	2	95, 96	96
	Overall Mean and RSD				
CGA 357261					
Orange (fruit)	0.01	0	2	111, 103	107
	0.10	0	2	109, 102	106
	0.10	28	2	107, 101	104
	0.10	82	2	91, 93	92
	0.10	173	2	99, 88	94
	0.10	351	2	100, 95	98
	0.10	531	2	104, 109	107
	0.10	732	2	93, 94	94

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
	Overall Mean and RSD				100 ± 7.1
CGA 357262					
Orange (fruit)	0.01	0	2	110, 104	107
	0.10	0	2	110, 107	109
	0.10	28	2	109, 106	108
	0.10	82	2	91, 94	93
	0.10	173	2	99, 90	95
	0.10	351	2	103, 100	102
	0.10	531	2	103, 108	106
	0.10	732	2	94, 96	95
	Overall Mean and RSD				102 ± 6.7
CGA 373466					
Orange (fruit)	0.01	0	2	99, 101	100
	0.10	0	2	97, 95	96
	0.10	28	2	103, 96	100
	0.10	82	2	89, 88	89
	0.10	173	2	94, 88	91
	0.10	351	2	100, 95	98
	0.10	531	2	95, 94	95
	0.10	732	2	95, 96	96
	Overall Mean and RSD				95 ± 4.5

Table A 6: Stability of trifloxystrobin residues in bean (dry seed) following storage at -18°C

Table A 6: Stability of trifloxystrobin residues in bean (dry seed) following storage at -18 °C					
Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)	Average recoveries (%)
Trifloxystrobin (CGA 279202)					
Bean (dry seed)	0.1	0	0.08715, 0.08805, 0.08643, 0.08320, 0.08309	87, 88, 86, 83, 83	85
		30	0.11219, 0.11217, 0.11358	112, 112, 114	113
		89	0.08213, 0.08371, 0.08271	82, 84, 83	83
		181	0.10038, 0.09879, 0.09878	100, 99, 99	99
		359	0.08245, 0.10910, 0.10810	82, 109, 108	100
		531	0.09500, 0.09465, 0.09650	95, 95, 97	96
		733	0.10965, 0.10590, 0.10420	110, 106, 104	107
CGA 321113					
Bean (dry seed)	0.1	0	0.08905, 0.08752, 0.08731, 0.09101, 0.09285	89, 88, 87, 91, 93	90
		30	0.09345, 0.10559, 0.09467	93, 106, 95	98
		89	0.08988, 0.09575, 0.08722	90, 96, 87	81
		181	0.10255, 0.10750, 0.10343	103, 107, 103	104
		359	0.09115, 0.10385, 0.10605	91, 104, 106	100
		531	0.09825, 0.09870, 0.10550	98, 99, 106	101
		733	0.09970, 0.09845, 0.09600	100, 98, 96	98
CGA 331409					
Bean (dry seed)	0.1	0	0.08873, 0.08901, 0.09079, 0.09029, 0.08756	89, 89, 91, 90, 88	89
		30	0.08649, 0.09091, 0.09808	86, 91, 98	92
		89	0.09413, 0.10085, 0.10191	94, 101, 102	99
		181	0.06808, 0.08255, 0.07694	68, 83, 77	76
		359	0.06625, 0.08600, 0.06440	66, 86, 64	72
		531	0.08895, 0.09250, 0.09395	89, 93, 94	92
		733	0.09670, 0.09940, 0.10055	97, 99, 101	99
CGA 357261					
Bean (dry seed)	0.1	0	0.09030, 0.09142, 0.09419, 0.08775, 0.09222	90, 91, 94, 88, 92	91
		30	0.07859, 0.09344, 0.09384	79, 93, 94	89
		89	0.08995, 0.09926, 0.10019	90, 99, 100	96
		181	0.09575, 0.10650, 0.10021	96, 106, 100	101
		359	0.09685, 0.10630, 0.10625	97, 106, 106	103
		531	0.09150, 0.09235, 0.09520	92, 92, 95	93
		733	0.10540, 0.10925, 0.10985	105, 109, 110	108
CGA 357262					
Bean (dry seed)	0.1	0	0.08237, 0.08487, 0.08746, 0.08525, 0.08666	82, 85, 87, 85, 87	85
		30	0.09474, 0.10280, 0.09568	95, 103, 96	98
		89	0.08707, 0.09135, 0.08991	87, 91, 90	89

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)	Average recoveries (%)
		181	0.07990, 0.07794, 0.07904	80, 78, 79	79
		359	0.07260, 0.10035, 0.09230	73, 100, 92	88
		531	0.09120, 0.09865, 0.09965	91, 99, 100	97
		733	0.10030, 0.09515, 0.1059	100, 95, 106	100
CGA 373466					
Bean (dry seed)	0.1	0	0.09238, 0.09302, 0.09486, 0.09028, 0.08240	92, 93, 95, 90, 82	90
		30	0.11419, 0.10297, 0.10070	114, 103, 101	106
		89	0.10655, 0.11140, 0.11511	107, 111, 115	111
		181	0.10769, 0.11091, 0.10989	108, 111, 110	110
		359	0.07535, 0.07885, 0.08050	75, 79, 81	78
		531	0.10505, 0.10840, 0.10180	105, 108, 102	105
		733	0.09690, 0.09975, 0.10655	97, 100, 107	101

Table A 7: Stability of trifloxystrobin residues in corn (green material) following storage at -18°C

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)	Average recoveries (%)
Trifloxystrobin (CGA 279202)					
Corn (green material)	0.1	0	0.10240, 0.10180, 0.09805, 0.09660, 0.09185	102, 102, 98, 97, 92	98
		31	0.09350, 0.09325, 0.09360	94, 93, 94	94
		89	0.08373, 0.08546, 0.08570	84, 85, 86	85
		180	0.09918, 0.09203, 0.09249	99, 92, 92	94
		356	0.09185, 0.09685, 0.09120	92, 97, 91	93
		537	0.10300, 0.10485, 0.10575	103, 105, 106	105
		738	0.09730, 0.10415, 0.10615	97, 104, 106	102
CGA 321113					
Corn (green material)	0.1	0	0.08415, 0.08450, 0.08135, 0.08045, 0.08250	84, 85, 81, 80, 83	83
		31	0.08240, 0.07220, 0.08075	82, 72, 81	78
		89	0.07653, 0.07797, 0.08144	77, 78, 81	79
		180	0.08080, 0.08150, 0.08620	81, 82, 86	83
		356	0.07035, 0.07340, 0.07020	70, 73, 70	71
		537	0.08085, 0.06980, 0.08425	81, 70, 84	78
		738	0.09580, 0.10290, 0.09645	96, 103, 96	98
CGA 331409					
Corn (green material)	0.1	0	0.10445, 0.11385, 0.10875, 0.10075, 0.11135	104, 114, 109, 101, 111	108
		31	0.08950, 0.09675, 0.08920	90, 97, 89	92
		89	0.08099, 0.08386, 0.08280	81, 84, 83	83
		180	0.09479, 0.10034, 0.09521	95, 100, 95	97
		356	0.08790, 0.09190, 0.09570	88, 92, 96	92
		537	0.11355, 0.11550, 0.11385	114, 116, 114	115
		738	0.10155, 0.10195, 0.09455	102, 102, 95	100
CGA 357261					
Corn (green material)	0.1	0	0.09270, 0.10140, 0.09620, 0.09490, 0.09500	93, 101, 96, 95, 95	96
		31	0.08695, 0.08385, 0.08760	87, 84, 88	86
		89	0.08220, 0.08362, 0.08583	82, 84, 86	84
		180	0.08285, 0.08836, 0.08414	83, 88, 84	85
		356	0.08885, 0.09115, 0.09350	89, 91, 94	91
		537	0.10445, 0.10500, 0.11060	104, 105, 111	107
		738	0.09435, 0.08900, 0.09875	94, 89, 99	94
CGA 357262					
Corn (green material)	0.1	0	0.10670, 0.10830, 0.10900, 0.10335, 0.10695	107, 108, 109, 103, 107	107
		31	0.09815, 0.09305, 0.09620	92, 93, 96	94
		89	0.08339, 0.08346, 0.08263	83, 83, 83	83

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)	Average recoveries (%)
		180	0.08359, 0.08607, 0.08599	84, 86, 86	85
		356	0.08925, 0.09150, 0.09265	89, 92, 93	91
		537	0.10630, 0.11245, 0.11315	106, 112, 113	110
		738	0.09610, 0.09390, 0.09835	96, 94, 98	96
CGA 373466					
Corn (green material)	0.1	0	0.09200, 0.09695, 0.09725, 0.08960, 0.08885	92, 97, 97, 90, 89	93
		31	0.07890, 0.09375, 0.08700	79, 94, 87	87
		89	0.07917, 0.08809, 0.08224	79, 88, 82	83
		180	0.08936, 0.08785, 0.08958	89, 88, 90	89
		356	0.07680, 0.07595, 0.09320	77, 76, 93	82
		537	0.07565, 0.09005, 0.09100	76, 90, 91	86
		738	0.09710, 0.08320, 0.10420	97, 83, 104	95

Table A 8: Stability of trifloxystrobin residues in rye (grain) following storage at -18°C

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)	Average recoveries (%)
Trifloxystrobin (CGA 279202)					
Rye (grain)	0.1	0	0.10265, 0.11145, 0.10095, 0.10455, 0.10345	103, 111, 101, 105, 103	105
		28	0.10160, 0.09865, 0.09560	102, 99, 96	99
		85	0.08996, 0.09402, 0.09470	90, 94, 95	93
		176	0.09552, 0.09916, 0.10196	96, 99, 102	99
		355	0.09675, 0.09675, 0.09825	97, 97, 98	97
		533	0.10515, 0.10685, 0.10800	105, 107, 108	107
		733	0.09760, 0.10400, 0.09255	98, 104, 93	98
CGA 321113					
Rye (grain)	0.1	0	0.08360, 0.07860, 0.08310, 0.08490, 0.08210	84, 79, 83, 85, 82	83
		28	0.09650, 0.09710, 0.08625	96, 97, 86	93
		85	0.09294, 0.09176, 0.09216	93, 92, 92	92
		176	0.10479, 0.11783, 0.10195	105, 118, 102	108
		355	0.09025, 0.09780, 0.10105	90, 98, 101	96
		533	0.10065, 0.10525, 0.10680	101, 105, 107	104
		733	0.10065, 0.09985, 0.10345	101, 100, 103	101
CGA 331409					
Rye (grain)	0.1	0	0.11010, 0.10550, 0.10235, 0.10715, 0.10410	110, 106, 102, 107, 104	106
		28	0.08365, 0.08085, 0.08685	84, 81, 87	84
		85	0.08945, 0.09234, 0.09131	89, 92, 91	91
		176	0.09094, 0.09455, 0.09541	91, 95, 95	94
		355	0.08865, 0.09200, 0.09180	89, 92, 92	91
		533	0.09915, 0.09960, 0.10080	99, 100, 101	100
		733	0.08835, 0.09330, 0.09310	88, 93, 93	91
CGA 357261					
Rye (grain)	0.1	0	0.10165, 0.10740, 0.10320, 0.10135, 0.09845	102, 107, 103, 101, 98	102
		28	0.09090, 0.08725, 0.08825	91, 87, 88	89
		85	0.09081, 0.09228, 0.09470	91, 92, 95	93
		176	0.09173, 0.08914, 0.09855	92, 89, 99	93
		355	0.08725, 0.09055, 0.09125	87, 91, 91	90
		533	0.09675, 0.10160, 0.10760	97, 102, 108	102
		733	0.08065, 0.09105, 0.08345	81, 91, 83	85
CGA 357262					
Rye (grain)	0.1	0	0.10550, 0.10215, 0.09960, 0.10465, 0.10290	106, 102, 100, 105, 103	103
		28	0.09205, 0.09410, 0.09395	92, 94, 94	93
		85	0.08561, 0.09026, 0.09026	86, 90, 90	89

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)	Average recoveries (%)
		176	0.08573, 0.09172, 0.08633	86, 92, 86	88
		355	0.09325, 0.09445, 0.08930	93, 94, 89	92
		533	0.10260, 0.09970, 0.10035	103, 100, 100	101
		733	0.09740, 0.09465, 0.09620	97, 95, 96	96
CGA 373466					
Rye (grain)	0.1	0	0.09225, 0.08885, 0.09320, 0.08935, 0.08845	92, 89, 93, 89, 88	90
		28	0.09680, 0.10790, 0.09950	97, 108, 100	102
		85	0.09938, 0.10793, 0.10671	99, 108, 107	105
		176	0.11388, 0.11725, 0.11819	114, 117, 118	116
		355	0.10145, 0.10140, 0.10335	101, 101, 103	102
		533	0.10190, 0.11480, 0.11420	102, 115, 114	110
		733	0.10270, 0.10450, 0.10080	103, 105, 101	103

Table A 9: Stability of trifloxystrobin residues in rape (seed) following storage at -18°C

Table A-9: Stability of trifloxystrobin residues in rape (seed) following storage at -16 °C					
Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)	Average recoveries (%)
Trifloxystrobin (CGA 279202)					
Rape (seed)	0.1	0	0.09860, 0.10020, 0.09740, 0.09855, 0.09805	99, 100, 97, 99, 98	99
		28	0.07500, 0.07445, 0.07135	75, 74, 71	73
		85	0.08561, 0.08106, 0.08451	86, 81, 85	84
		177	0.07361, 0.07540, 0.07496	74, 75, 75	75
		353	0.09640, 0.09655, 0.10395	96, 97, 104	99
		532	0.09535, 0.10335, 0.10170	95, 103, 102	100
		735	0.09680, 0.09790, 0.09775	97, 98, 98	98
CGA 321113					
Rape (seed)	0.1	0	0.09595, 0.08955, 0.09335, 0.08910, 0.09175	96, 90, 93, 89, 92	92
		28	0.07915, 0.07485, 0.08470	79, 75, 85	80
		85	0.08224, 0.08512, 0.08615	82, 85, 86	84
		177	0.09981, 0.09927, 0.09696	100, 99, 97	99
		353	0.08910, 0.09135, 0.09295	89, 91, 93	91
		532	0.08555, 0.07755, 0.08540	86, 78, 85	83
		735	0.09930, 0.10800, 0.10735	99, 108, 107	105
CGA 331409					
Rape (seed)	0.1	0	0.10595, 0.09745, 0.10480, 0.10650, 0.10505	106, 97, 105, 107, 105	104
		28	0.05755, 0.05870, 0.06125	58, 59, 61	59
		85	0.06575, 0.07330, 0.07024	66, 73, 70	70
		177	0.07735, 0.08023, 0.08083	77, 80, 81	79
		353	0.06820, 0.07590, 0.07335	68, 76, 73	72
		532	0.07435, 0.07270, 0.07260	74, 73, 73	73
		735	0.07895, 0.08085, 0.08295	79, 81, 83	81
CGA 357261					
Rape (seed)	0.1	0	0.09600, 0.09495, 0.09615, 0.09565, 0.09275	96, 95, 96, 96, 93	95
		28	0.07635, 0.06975, 0.07555	76, 70, 76	74
		85	0.08282, 0.08922, 0.08592	83, 89, 86	86
		177	0.07910, 0.07932, 0.07386	79, 79, 74	77
		353	0.09915, 0.09305, 0.09290	99, 93, 93	95
		532	0.09615, 0.09845, 0.10005	96, 98, 100	98
		735	0.08830, 0.09035, 0.09265	88, 90, 93	90
CGA 357262					
Rape (seed)	0.1	0	0.10355, 0.09880, 0.09795, 0.09810, 0.09240	104, 99, 98, 98, 92	98
		28	0.07055, 0.06380, 0.06820	71, 64, 68	68
		85	0.08090, 0.07326, 0.08183	81, 73, 82	79

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)	Average recoveries (%)
		177	0.07671, 0.07789, 0.07733	77, 78, 77	77
		353	0.09185, 0.08455, 0.08350	92, 85, 84	87
		532	0.08345, 0.08645, 0.08865	83, 86, 89	86
		735	0.08450, 0.08700, 0.08880	85, 87, 89	87
CGA 373466					
Rape (seed)	0.1	0	0.09520, 0.09100, 0.09245, 0.09175, 0.09200	95, 91, 92, 92, 92	92
		28	0.08935, 0.08565, 0.08370	89, 86, 84	86
		84	0.08806, 0.08826, 0.09213	88, 88, 92	89
		177	0.10571, 0.09878, 0.09981	106, 99, 100	102
		353	0.09890, 0.10005, 0.09225	99, 100, 92	97
		532	0.07660, 0.08350, 0.08085	77, 84, 81	81
		735	0.10785, 0.11510, 0.11425	108, 115, 114	112

Table A 10: Stability of trifloxystrobin residues in orange (fruit) following storage at -18°C

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)	Average recoveries (%)
Trifloxystrobin (CGA 279202)					
Orange (fruit)	0.1	0	0.10965, 0.10630, 0.10270, 0.10540, 0.10380	110, 106, 103, 105, 104	106
		28	0.09970, 0.10225, 0.09490	100, 102, 95	99
		83	0.09440, 0.09759, 0.09722	94, 98, 97	96
		173	0.09599, 0.09801, 0.09671	96, 98, 97	97
		351	0.10665, 0.09225, 0.10910	107, 92, 109	103
		531	0.10860, 0.11200, 0.11415	109, 112, 114	112
		732	0.09560, 0.09890, 0.09855	96, 99, 99	98
CGA 321113					
Orange (fruit)	0.1	0	0.08200, 0.08055, 0.07935, 0.07910, 0.08560	82, 81, 79, 79, 86	81
		33	0.08875, 0.09095, 0.08275	89, 91, 83	88
		83	0.08699, 0.09117, 0.07266	87, 91, 73	84
		173	0.09663, 0.08436, 0.08774	97, 84, 88	90
		351	0.09015, 0.09005, 0.09055	90, 90, 91	90
		531	0.09330, 0.10080, 0.09580	93, 101, 96	97
		732	0.10145, 0.09480, 0.10885	101, 95, 109	102
CGA 331409					
Orange (fruit)	0.1	0	0.10890, 0.10905, 0.10820, 0.10810, 0.10660	109, 109, 108, 108, 107	108
		28	0.09630, 0.09990, 0.10145	96, 100, 101	99
		83	0.09041, 0.10066, 0.10229	90, 101, 102	98
		173	0.09966, 0.10616, 0.10231	100, 106, 102	103
		351	0.10780, 0.10670, 0.11155	108, 107, 112	109
		531	0.11340, 0.11585, 0.11380	113, 116, 114	114
		732	0.09570, 0.10180, 0.09935	96, 102, 99	99
CGA 357261					
Orange (fruit)	0.1	0	0.09620, 0.09750, 0.09595, 0.09075, 0.09635	96, 98, 96, 91, 96	95
		28	0.09375, 0.09080, 0.09440	94, 91, 94	93
		83	0.09637, 0.09775, 0.09294	96, 98, 93	96
		173	0.10110, 0.09671, 0.10272	101, 97, 103	100
		351	0.10015, 0.10485, 0.10760	100, 105, 108	104
		531	0.10800, 0.10870, 0.11145	108, 109, 111	109
		732	0.09215, 0.10025, 0.09285	92, 100, 93	95
CGA 357262					
Orange (fruit)	0.1	0	0.10375, 0.10620, 0.10535, 0.10340, 0.10015	104, 106, 105, 103, 100	104
		28	0.10425, 0.08860, 0.09770	104, 89, 98	97
		83	0.09526, 0.09433, 0.09812	95, 94, 98	96

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)	Average recoveries (%)
		173	0.09721, 0.09920, 0.10144	97, 99, 101	99
		351	0.10715, 0.10635, 0.11095	107, 106, 111	108
		531	0.10800, 0.11730, 0.11625	108, 117, 116	114
		732	0.09800, 0.10030, 0.10250	98, 100, 103	100
CGA 373466					
Orange (fruit)	0.1	0	0.08390, 0.08835, 0.09000, 0.08 830, 0.08560	84, 88, 90, 88, 86	87
		28	0.07335, 0.09165, 0.08740	73, 92, 87	84
		82	0.10214, 0.11110, 0.10910	102, 111, 109	107
		173	0.10929, 0.11307, 0.10699	109, 113, 107	110
		351	0.09555, 0.09260, 0.0972	96, 93, 97	95
		531	0.09465, 0.09720, 0.07730	95, 97, 77	90
		732	0.11160, 0.11395, 0.10550	112, 114, 106	111

A 2.1.1.1.1.2 Study 2: P 642 18 7852

Comments of zRMS:	<p>Applicant submitted final report of the Schmiedt study “<i>Storage stability of CGA 279202 (trifloxystrobin), CGA 357262, CGA 357261, CGA331409, CGA 321113 and CGA 373466 in olive (fruit), apple (fruit) and wheat (grain) for 24 months</i>”.</p> <p>A storage stability study was conducted with CGA 279202 (trifloxystrobin), CGA 357262, CGA 357261, CGA331409, CGA 321113 and CGA 373466 in olive (fruit), apple (fruit) and wheat (grain) to determine the stability of the residues while stored frozen for up to approximately 24 months using BCS Method 01313/M001.</p> <p>The fortified samples were stored frozen and analyzed for each analyte at nominal intervals of 1, 3, 6, 12, 18, and 24 months.</p> <p>All method validation data (pre-validation and concurrent) are within the acceptable criteria: mean recovery range of 70-120% and relative standard deviation $\leq 20\%$.</p> <p>The limit of quantification (LOQ) for each analyte was established at 0.01 mg/kg. The limit of detection (LOD) was estimated to be $\leq 30\%$ of the LOQ.</p> <p>After a deep-freezer storage ($\leq -20^{\circ}\text{C}$) period of about 24 months, the mean recovery rates from the stored samples fortified at 0.10 mg/kg were within a $\pm 20\%$ range compared to day-0 results. The results of the additional storage experiment of CGA 331409 at a fortification level of 1.0 mg/kg lead to a similar conclusion and confirm the storage stability of CGA 331409 in all three matrices.</p> <p>For each analyte two MRM transitions were successfully validated, therefore an additional confirmatory method is not necessary.</p> <p>All analytes: trifloxystrobin (CGA 279202), CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 can be considered stable in the investigated matrices: wheat grain, olive fruit and apple fruit under deep-freezer storage conditions ($\leq -20^{\circ}\text{C}$) for at least 24 months.</p> <p>The study is acceptable.</p> <p>Remark: The average recoveries have been added to the tables. The low values of 69% and 68% should be seen in context with the values at day 0, which were also low (84% and 70%, respectively). Taking into account the day 0 normalized values, the values are all above 70% and therefore considered stable up to 700 days for all analytes and matrices.</p>
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Reference:	KCA 6.1/02
Title:	Storage stability of CGA 279202 (trifloxystrobin), CGA 357262, CGA 357261, CGA331409, CGA 321113 and CGA 373466 in olive (fruit), apple (fruit) and wheat (grain) for 24 months – Interim report
Report:	Schmiedt, S.; 2020; P 642 18 7852; M-684506-01-1
Authority registration No:	
Guideline(s):	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 OECD 506, 2007; OECD Guideline for the Testing of Chemicals – Stability of Pesticide Residues in Stored Commodities Guideline US EPA OCSPP 860.1380, Storage Stability Data
Deviations:	None
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Reference:	KCA 6.1/02
Title:	Storage stability of CGA 279202 (trifloxystrobin), CGA 357262, CGA 357261, CGA331409, CGA 321113 and CGA 373466 in olive (fruit), apple (fruit) and wheat (grain) for 24 months – Final report
Report:	Schmiedt, S.; 2020; P 642 18 7852; M-684506-02-1
Authority registration No:	
Guideline(s):	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 OECD 506, 2007; OECD Guideline for the Testing of Chemicals – Stability of Pesticide Residues in Stored Commodities Guideline US EPA OCSP 860.1380, Storage Stability Data
Deviations:	None
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Materials and methods

The stability of CGA 279202 (trifloxystrobin), CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 for ~~18 months (interim report, study is ongoing for 2 years in total)~~ 24 months in deep frozen storage was investigated in the plant matrices wheat grain (high starch content), olive fruit (high oil content) and apple fruit (high water content).

Samples of wheat grain, apple fruit and olive fruit were fortified with CGA 279202 (trifloxystrobin), CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 at 0.10 mg/kg. Immediately after fortification, a sample was taken to determine the initial residues. The remaining fortified samples were stored deep frozen at -20°C or below until analysis after nominal storage intervals of 1, 3, 6, 12, ~~and 18 and~~ 24 months. The study is ongoing and analysis of the 24 months storage interval will be reported in a final report at a later time point.

For CGA 331409 an additional storage stability experiment was set up at 1.0 mg/kg. This second storage experiment at a higher fortification level was conducted after obtaining relatively low recoveries for the analyte (~ 70%) in the first experiment. The experiment was started 3 months later to confirm the obtained results and to detect possible degradation at confident observable fortification level.

For analysis the residue analytical method 01313/M001 was used with a limit of quantitation of 0.01 mg/kg.

Results and discussions

No significant decrease of residues was observed after the tested period of ~~18~~ 24 months. Thus, the residues of trifloxystrobin (CGA 279202), CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 are stable under freezer storage conditions for at least ~~18~~ 24 months.

Conclusion

No significant decrease of residues was observed after the tested period of ~~18~~ 24 months in wheat grain, apple fruit and olive fruit. Thus, the residues of trifloxystrobin (CGA 279202), CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 are stable under freezer storage conditions at -20° C or below for at least ~~18~~ 24 months.

Table A 11: Summary of concurrent recoveries of trifloxystrobin from wheat (grain)

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
Trifloxystrobin (CGA 279202)					
Wheat (grain)	0.01	0	2	86, 84	85
	0.10	0	2	84, 82	83
	0.10	34	3	85, 83, 81	83 ± 2.4

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
	0.10	92	3	90, 87, 86	88 ± 2.4
	0.10	181	3	85, 86, 82	84 ± 2.5
	0.10	366	3	86, 85, 84	85 ± 1.2
	0.10	548	3	85, 84, 84	84 ± 0.7
	0.10	700	3	85, 79, 79	81 ± 4.3
CGA 331409					
Wheat (grain)	0.01	0	2	71, 69	70
	0.10	0	2	73, 75	74
	0.10	34	3	75, 74, 74	74 ± 0.8
	0.10	92	3	75, 74, 73	74 ± 1.4
	0.10	181	3	71, 72, 72	72 ± 0.8
	0.10	366	3	77, 77, 72	75 ± 3.8
	0.10	548	3	70, 70, 70	70 ± 0.0
	0.10	700	3	76, 69, 69	71 ± 5.7
Wheat (grain)	1.0	0	2	77, 76	77
	1.0	34	3	80, 73, 77	77 ± 4.6
	1.0	98	3	77, 74, 75	75 ± 2.0
	1.0	182	3	71, 73, 75	73 ± 2.7
	1.0	365	3	70, 74, 68	71 ± 4.3
	1.0	549	3	76, 69, 73	73 ± 4.8
	1.0	734	3	76, 72, 70	73 ± 4.2
CGA 357261					
Wheat (grain)	0.01	0	2	89, 86	88
	0.10	0	2	90, 86	88
	0.10	34	3	92, 81, 87	87 ± 6.4
	0.10	92	3	88, 92, 87	89 ± 3.0
	0.10	181	3	91, 87, 85	88 ± 3.5
	0.10	366	3	97, 94, 95	92 ± 6.8
	0.10	548	3	92, 94, 91	92 ± 1.7
	0.10	700	3	85, 81, 82	83 ± 2.5
CGA 357262					
Wheat (grain)	0.01	0	2	81, 84	83
	0.10	0	2	81, 79	80
	0.10	34	3	83, 78, 81	81 ± 3.1
	0.10	92	3	83, 82, 82	82 ± 0.7
	0.10	181	3	79, 76, 80	78 ± 2.7
	0.10	366	3	83, 76, 75	78 ± 5.6
	0.10	548	3	83, 75, 83	80 ± 5.7
	0.10	700	3	80, 79, 73	77 ± 4.9
CGA 321113					

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
Wheat (grain)	0.01	0	2	87, 84	86
	0.10	0	2	88, 84	86
	0.10	34	3	85, 85, 83	84 ± 1.4
	0.10	92	3	91, 92, 89	91 ± 1.7
	0.10	181	3	88, 87, 83	86 ± 3.1
	0.10	366	3	86, 83, 81	83 ± 3.0
	0.10	548	3	73, 73, 78	75 ± 3.9
	0.10	700	3	77, 64, 68	70 ± 9.6
CGA 373466					
Wheat (grain)	0.01	0	2	87, 86	87
	0.10	0	2	89, 89	89
	0.10	34	3	85, 85, 85	85 ± 0.0
	0.10	92	3	91, 93, 91	92 ± 1.3
	0.10	181	3	90, 88, 87	88 ± 1.7
	0.10	366	3	83, 85, 84	84 ± 1.2
	0.10	548	3	76, 76, 73	75 ± 2.3
	0.10	700	3	75, 68, 66	70 ± 6.8

Table A 12: Summary of concurrent recoveries of trifloxystrobin from olive (fruit)

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
Trifloxystrobin (CGA 279202)					
Olive (fruit)	0.01	0	2	85, 80	83
	0.10	0	2	80, 80	80
	0.10	33	3	87, 79, 79	82 ± 5.7
	0.10	91	3	85, 83, 83	84 ± 1.4
	0.10	180	3	81, 81, 85	82 ± 2.8
	0.10	365	3	88, 86, 84	86 ± 2.3
	0.10	547	3	83, 84, 85	84 ± 1.2
	0.10	700	3	83, 86, 83	84 ± 2.1
CGA 331409					
Olive (fruit)	0.01	0	2	71, 68	70
	0.10	0	2	71, 73	72
	0.10	33	3	79, 73, 70	74 ± 6.2
	0.10	91	3	74, 74, 70	73 ± 3.2
	0.10	180	3	69, 71, 73	71 ± 2.8
	0.10	365	3	77, 79, 75	77 ± 2.6
	0.10	547	3	70, 73, 70	71 ± 2.4
	0.10	700	3	76, 74, 71	74 ± 3.4
Olive (fruit)	1.0	0	2	78, 78	78
	1.0	34	3	78, 81, 81	80 ± 2.2
	1.0	98	3	73, 76, 74	74 ± 2.1
	1.0	182	3	74, 72, 72	73 ± 1.6
	1.0	365	3	81, 75, 72	76 ± 6.0
	1.0	549	3	73, 73, 73	73 ± 0.0
	1.0	734	3	77, 78, 75	77 ± 2.0
CGA 357261					
Olive (fruit)	0.01	0	2	90, 87	89
	0.10	0	2	85, 87	86
	0.10	33	3	86, 86, 81	84 ± 3.4
	0.10	91	3	90, 85, 82	86 ± 4.7
	0.10	180	3	83, 81, 87	84 ± 3.7
	0.10	365	3	89, 92, 91	91 ± 1.7
	0.10	547	3	89, 85, 94	89 ± 5.0
	0.10	700	3	96, 93, 89	93 ± 3.8
CGA 357262					
Olive (fruit)	0.01	0	2	80, 73	77
	0.10	0	2	78, 80	79
	0.10	33	3	85, 81, 73	80 ± 7.7
	0.10	91	3	84, 78, 81	81 ± 3.7

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean \pm RSD
	0.10	180	3	78, 80, 86	81 \pm 5.1
	0.10	365	3	78, 76, 77	77 \pm 1.3
	0.10	547	3	78, 72, 75	75 \pm 40
	0.10	700	3	84, 81, 82	82 \pm 1.9
CGA 321113					
Olive (fruit)	0.01	0	2	88, 90	89
	0.10	0	2	85, 87	86
	0.10	33	3	94, 88, 83	88 \pm 6.2
	0.10	91	3	92, 93, 89	91 \pm 2.3
	0.10	180	3	82, 85, 86	84 \pm 2.5
	0.10	365	3	83, 83, 80	82 \pm 2.1
	0.10	547	3	76, 71, 70	72 \pm 4.4
	0.10	700	3	73, 74, 71	73 \pm 2.1
CGA 373466					
Olive (fruit)	0.01	0	2	87, 83	85
	0.10	0	2	86, 89	88
	0.10	33	3	93, 87, 85	88 \pm 4.7
	0.10	91	3	93, 93, 90	92 \pm 1.9
	0.10	180	3	86, 88, 92	89 \pm 3.4
	0.10	365	3	83, 84, 84	84 \pm 0.7
	0.10	547	3	77, 73, 71	74 \pm 4.1
	0.10	700	3	74, 75, 70	73 \pm 3.6

Table A 13: Summary of concurrent recoveries of trifloxystrobin from apple (fruit)

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
Trifloxystrobin (CGA 279202)					
Apple (fruit)	0.01	0	2	82, 82	82
	0.10	0	2	82, 84	83
	0.10	33	3	80, 85, 81	82 ± 3.2
	0.10	91	3	84, 83, 84	84 ± 0.7
	0.10	180	3	83, 81, 75	80 ± 5.2
	0.10	365	3	85, 85, 86	85 ± 0.7
	0.10	547	3	83, 84, 82	83 ± 1.2
	0.10	700	3	86, 87, 85	86 ± 1.2
CGA 331409					
Apple (fruit)	0.01	0	2	74, 69	72
	0.10	0	2	74, 77	76
	0.10	33	3	74, 75, 73	74 ± 1.4
	0.10	91	3	75, 77, 75	76 ± 1.5
	0.10	180	3	73, 73, 67	71 ± 4.9
	0.10	365	3	68, 71, 73	71 ± 3.6
	0.10	547	3	70, 70, 69	70 ± 0.8
	0.10	700	3	79, 76, 77	77 ± 2.0
Apple (fruit)	1.0	0	2	76, 76	76
	1.0	34	3	80, 85, 79	81 ± 4.0
	1.0	98	3	68, 68, 74	70 ± 4.9
	1.0	182	3	72, 74, 73	73 ± 1.4
	1.0	365	3	69, 71, 77	72 ± 5.8
	1.0	549	3	73, 73, 72	73 ± 0.8
	1.0	734	3	72, 72, 70	71 ± 1.6
CGA 357261					
Apple (fruit)	0.01	0	2	91, 90	91
	0.10	0	2	85, 87	86
	0.10	33	3	88, 90, 86	88 ± 2.3
	0.10	91	3	90, 88, 93	90 ± 2.8
	0.10	180	3	88, 90, 79	86 ± 6.8
	0.10	365	3	94, 94, 93	94 ± 0.6
	0.10	547	3	92, 90, 91	91 ± 1.1
	0.10	700	3	90, 89, 89	89 ± 0.6
CGA 357262					
Apple (fruit)	0.01	0	2	79, 73	76
	0.10	0	2	80, 82	81
	0.10	33	3	81, 82, 76	80 ± 4.0
	0.10	91	3	77, 79, 74	77 ± 3.3

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
	181 0.10	180	3	80, 76, 73	76 ± 4.6
	0.10	365	3	75, 77, 74	75 ± 2.0
	0.10	547	3	74, 76, 71	74 ± 3.4
	0.10	700	3	84, 77, 84	82 ± 4.9
CGA 321113					
Apple (fruit)	0.01	0	2	84, 80	82
	0.10	0	2	90, 89	90
	0.10	33	3	89, 91, 85	88 ± 3.5
	0.10	91	3	94, 89, 92	92 ± 2.7
	181 0.10	180	3	84, 83, 82	83 ± 1.2
	0.10	365	3	80, 82, 81	81 ± 1.2
	0.10	547	3	72, 70, 73	72 ± 2.1
	0.10	700	3	70, 75, 70	72 ± 4.0
CGA 373466					
Apple (fruit)	0.01	0	2	86, 82	84
	0.10	0	2	88, 87	88
	0.10	33	3	88, 88, 86	87 ± 1.3
	0.10	91	3	91, 91, 91	91 ± 0.0
	181 0.10	180	3	88, 85, 82	85 ± 3.5
	0.10	365	3	81, 82, 82	82 ± 0.7
	0.10	547	3	71, 71, 70	71 ± 0.8
	0.10	700	3	72, 74, 64	70 ± 7.6

Table A 14: Stability of trifloxystrobin residues in wheat (grain) following storage at -20°C

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)	Average recoveries (%)
Trifloxystrobin (CGA 279202)					
Wheat (grain)	0.1	0	0.078, 0.082, 0.081, 0.082, 0.080	78, 82, 81, 82, 80	81
		34	0.081, 0.082, 0.080	81, 82, 80	81
		92	0.092, 0.092, 0.087	92, 92, 87	90
		181	0.083, 0.087, 0.088	83, 87, 88	86
		366	0.082, 0.084, 0.084	82, 84, 84	83
		548	0.085, 0.087, 0.088	85, 87, 88	87
		700	0.083, 0.082, 0.086	83, 82, 86	84
CGA 331409					
Wheat (grain)	0.1	0	0.072, 0.071, 0.073, 0.073, 0.073	72, 71, 73, 73, 73	72
		34	0.069, 0.070, 0.069	69, 70, 69	69
		92	0.075, 0.074, 0.075	75, 74, 75	75
		181	0.062, 0.069, 0.072	62, 69, 72	68
		366	0.069, 0.072, 0.072	69, 72, 72	71
		548	0.070, 0.071, 0.070	70, 71, 70	70
		700	0.076, 0.078, 0.074	76, 78, 74	76
Wheat (grain)	1.0	0	0.754, 0.708, 0.794, 0.758, 0.784	75, 71, 79, 76, 78	76
		34	0.770, 0.732, 0.740	77, 73, 74	75
		98	0.697, 0.684, 0.714	70, 68, 71	70
		182	0.771, 0.764, 0.724	77, 76, 72	75
		365	0.696, 0.788, 0.627	70, 79, 63	71
		549	0.634, 0.737, 0.748	63, 74, 75	71
		734	0.623, 0.826, 0.644	62, 83, 64	70
CGA 357261					
Wheat (grain)	0.1	0	0.088, 0.083, 0.089, 0.084, 0.081	88, 83, 89, 84, 81	85
		34	0.086, 0.084, 0.086	86, 84, 86	85
		92	0.097, 0.095, 0.090	97, 95, 90	94
		181	0.086, 0.088, 0.094	86, 88, 94	89
		366	0.095, 0.085, 0.084	95, 85, 84	88
		548	0.090, 0.099, 0.089	90, 99, 89	93
		700	0.090, 0.091, 0.087	90, 91, 87	89
CGA 357262					
Wheat (grain)	0.1	0	0.081, 0.077, 0.076, 0.077, 0.078	81, 77, 76, 77, 78	78
		34	0.079, 0.079, 0.082	79, 79, 82	80
		92	0.086, 0.084, 0.084	86, 84, 84	85
		181	0.083, 0.079, 0.086	83, 79, 86	83

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)	Average recoveries (%)
		366	0.083, 0.077, 0.076	83, 77, 76	79
		548	0.081, 0.087, 0.080	81, 87, 80	83
		700	0.082, 0.082, 0.080	82, 82, 80	81
CGA 321113					
Wheat (grain)	0.1	0	0.086, 0.085, 0.087, 0.088, 0.084	86, 85, 87, 88, 84	86
		34	0.081, 0.080, 0.081	81, 80, 81	81
		92	0.090, 0.090, 0.088	90, 90, 88	89
		181	0.085, 0.091, 0.090	85, 91, 90	89
		366	0.079, 0.082, 0.084	79, 82, 84	82
		548	0.075, 0.074, 0.072	75, 74, 72	74
		700	0.074, 0.074, 0.068	74, 74, 68	72
CGA 373466					
Wheat (grain)	0.1	0	0.085, 0.084, 0.082, 0.083, 0.086	85, 84, 82, 83, 86	84
		34	0.083, 0.082, 0.075	83, 82, 75	80
		92	0.095, 0.097, 0.098	95, 97, 98	97
		181	0.090, 0.091, 0.088	90, 91, 88	90
		366	0.085, 0.085, 0.084	85, 85, 84	85
		548	0.074, 0.070, 0.074	74, 70, 74	73
		700	0.070, 0.069, 0.069	70, 69, 69	69

Table A 15: Stability of trifloxystrobin residues in olive (fruit) following storage at -20°C

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)	Average recoveries (%)
Trifloxystrobin (CGA 279202)					
Olive (fruit)	0.1	0	0.081, 0.080, 0.080, 0.074, 0.080	81, 80, 80, 74, 80	79
		33 34	0.082, 0.078, 0.081	82, 78, 81	80
		91 92	0.084, 0.082, 0.084	84, 82, 84	83
		181	0.083, 0.084, 0.083	83, 84, 83	83
		366	0.084, 0.085, 0.084	84, 85, 84	84
		548	0.080, 0.082, 0.086	80, 82, 86	83
		700	0.082, 0.082, 0.083	82, 82, 83	82
CGA 331409					
Olive (fruit)	0.1	0	0.072, 0.070, 0.070, 0.070, 0.070	72, 70, 70, 70, 70	70
		33 34	0.069, 0.070, 0.071	69, 70, 71	70
		91 92	0.070, 0.075, 0.070	70, 75, 70	72
		181	0.070, 0.072, 0.068	70, 72, 68	70
		366	0.073, 0.075, 0.072	73, 75, 72	73
		548	0.067, 0.067, 0.070	67, 67, 70	68
		700	0.063, 0.059, 0.065	63, 59, 65	62
Olive (fruit)	1.0	0	0.750, 0.731, 0.734, 0.741, 0.761	75, 73, 73, 74, 76	74
		34	0.808, 0.759, 0.723	81, 76, 72	76
		98	0.678, 0.638, 0.739	68, 64, 74	69
		182	0.729, 0.725, 0.763	73, 73, 76	74
		365	0.724, 0.671, 0.614	72, 67, 61	67
		549	0.725, 0.716, 0.734	73, 72, 73	73
		734	0.709, 0.701, 0.732	71, 70, 73	71
CGA 357261					
Olive (fruit)	0.1	0	0.082, 0.085, 0.088, 0.086, 0.086	82, 85, 88, 86, 86	85
		33 34	0.080, 0.077, 0.076	80, 77, 76	78
		91 92	0.088, 0.084, 0.087	88, 84, 87	86
		181	0.088, 0.092, 0.090	88, 92, 90	90
		366	0.089, 0.084, 0.086	89, 84, 86	86
		548	0.093, 0.096, 0.084	93, 96, 84	91
		700	0.098, 0.093, 0.092	98, 93, 92	94
CGA 357262					
Olive (fruit)	0.1	0	0.083, 0.084, 0.079, 0.081, 0.078	83, 84, 79, 81, 78	81
		33 34	0.079, 0.079, 0.075	79, 79, 75	78
		91 92	0.078, 0.071, 0.085	78, 71, 85	78
		181	0.078, 0.073, 0.077	78, 73, 77	76

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)	Average recoveries (%)
		366	0.083, 0.073, 0.077	83, 73, 77	78
		548	0.070, 0.082, 0.075	70, 82, 75	76
		700	0.083, 0.074, 0.082	83, 74, 82	80
CGA 321113					
Olive (fruit)	0.1	0	0.087, 0.088, 0.085, 0.087, 0.086	87, 88, 85, 87, 86	87
		33 34	0.088, 0.083, 0.083	88, 83, 83	85
		91 92	0.092, 0.087, 0.093	92, 87, 93	91
		181	0.091, 0.090, 0.089	91, 90, 89	90
		366	0.082, 0.085, 0.084	82, 85, 84	84
		548	0.072, 0.073, 0.077	72, 73, 77	74
		700	0.072, 0.073, 0.073	72, 73, 73	73
CGA 373466					
Olive (fruit)	0.1	0	0.086, 0.089, 0.085, 0.087, 0.088	86, 89, 85, 87, 88	87
		33 34	0.085, 0.085, 0.085	85, 85, 85	85
		91 92	0.093, 0.094, 0.096	93, 94, 96	94
		181	0.094, 0.092, 0.094	94, 92, 94	93
		366	0.084, 0.082, 0.086	84, 82, 86	84
		548	0.073, 0.074, 0.075	73, 74, 75	74
		700	0.073, 0.080, 0.076	73, 80, 76	76

Table A 16: Stability of trifloxystrobin residues in apple (fruit) following storage at -20°C

Table A 10. Stability of trifloxystrobin residues in apple (fruit) following storage at -20 °C					
Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)	Average recoveries (%)
Trifloxystrobin (CGA 279202)					
Apple (fruit)	0.10	0	0.081, 0.083, 0.081, 0.081, 0.081	81, 83, 81, 81, 81	81
		34	0.075, 0.076, 0.082	75, 76, 82	78
		92	0.084, 0.086, 0.085	84, 86, 85	85
		181	0.085, 0.088, 0.083	85, 88, 83	85
		366	0.086, 0.087, 0.083	86, 87, 83	85
		548	0.086, 0.084, 0.082	86, 84, 82	84
		700	0.085, 0.085, 0.085	85, 85, 85	85
CGA 331409					
Apple (fruit)	0.10	0	0.076, 0.074, 0.076, 0.074, 0.073	76, 74, 76, 74, 73	75
		34	0.069, 0.070, 0.069	69, 70, 69	69
		92	0.078, 0.072, 0.076	78, 72, 76	75
		181	0.071, 0.074, 0.073	71, 74, 73	73
		366	0.064, 0.073, 0.072	64, 73, 72	70
		548	0.069, 0.072, 0.071	69, 72, 71	71
		700	0.080, 0.078, 0.078	80, 78, 78	79
Apple (fruit)	1.0	0	0.760, 0.763, 0.777, 0.714, 0.804	76, 76, 78, 71, 80	76
		34	0.751, 0.738, 0.719	75, 74, 72	74
		98	0.711, 0.701, 0.706	71, 70, 71	71
		182	0.792, 0.745, 0.730	79, 75, 73	76
		365	0.697, 0.734, 0.679	70, 73, 68	70
		549	0.755, 0.794, 0.765	76, 79, 77	77
		734	0.702, 0.700, 0.697	70, 70, 70	70
CGA 357261					
Apple (fruit)	0.10	0	0.078, 0.080, 0.083, 0.084, 0.087	78, 80, 83, 84, 87	82
		34	0.088, 0.086, 0.087	88, 86, 87	87
		92	0.093, 0.093, 0.092	93, 93, 92	93
		181	0.092, 0.089, 0.085	92, 89, 85	89
		366	0.102, 0.093, 0.104	102, 93, 104	100
		548	0.081, 0.090, 0.096	81, 90, 96	89
		700	0.094, 0.085, 0.092	94, 85, 92	90
CGA 357262					
Apple (fruit)	0.10	0	0.081, 0.078, 0.081, 0.082, 0.082	81, 78, 81, 82, 82	81
		34	0.077, 0.082, 0.082	77, 82, 82	80
		92	0.083, 0.082, 0.078	83, 82, 78	81
		181	0.081, 0.085, 0.078	81, 85, 78	81

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)	Average recoveries (%)
		366	0.082, 0.084, 0.077	82, 84, 77	81
		548	0.079, 0.086, 0.082	79, 86, 82	82
		700	0.079, 0.081, 0.080	79, 81, 80	80
CGA 321113					
Apple (fruit)	0.10	0	0.085, 0.084, 0.086, 0.083, 0.085	85, 84, 86, 83, 85	85
		34	0.087, 0.085, 0.083	87, 85, 83	85
		92	0.094, 0.090, 0.093	94, 90, 93	92
		181	0.085, 0.087, 0.082	85, 87, 82	85
		366	0.083, 0.082, 0.079	83, 82, 79	81
		548	0.072, 0.071, 0.071	72, 71, 71	71
		700	0.075, 0.077, 0.068	75, 77, 68	73
CGA 373466					
Apple (fruit)	0.10	0	0.088, 0.087, 0.086, 0.085, 0.090	88, 87, 86, 85, 90	87
		34	0.084, 0.084, 0.084	84, 84, 84	84
		92	0.095, 0.095, 0.096	95, 95, 96	95
		181	0.081, 0.087, 0.092	81, 87, 92	87
		366	0.084, 0.083, 0.081	84, 83, 81	83
		548	0.070, 0.073, 0.074	70, 73, 74	72
		700	0.072, 0.071, 0.068	72, 71, 68	70

A 2.1.1.1.2 Storage stability of residues in animal products

Comments of zRMS:	<p>The objective of the study was to validate the analytical method 01598 for the determination of trifloxystrobin (CGA 279202), its three isomers CGA 357262, CGA 357261 and CGA 331409, metabolite CGA 321113 and its isomer CGA 373466 in honey in accordance to the guidance document SANCO/825/00, rev. 8.1. In the study the stability of the residues of trifloxystrobin (CGA 279202) and its isomers / metabolites CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 was investigated in honey for about 6 months under frozen storage conditions.</p> <p>The limit of quantification was 0.01 mg/kg.</p> <p>Two transitions (quantification and confirmation) were determined.</p> <p>All method validation data are in compliance with the guideline SANCO/825/00, rev. 8.1.</p> <p>All analytes can be considered stable in the honey under deep-freezer storage conditions ($\leq -18^{\circ}\text{C}$) for at least 6 months.</p> <p>The study is acceptable.</p> <p>Remark: The average recoveries have been added to the table.</p>
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Reference:	KCA 6.1/03
Title:	Residue analytical method 01598 and short term storage stability of trifloxystrobin (CGA 279202) and its isomers / metabolites CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 in/on honey by HPLC-MS/MS
Report:	Roth, A.; 2020; S19-01123; M-677808-01-1
Authority registration No:	
Guideline(s):	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 Guidance document on residue analytical methods, SANCO/825/00/rev. 8.1, European Commission, Directorate General Health and Consumer Protection 16/11/2010 OECD 506, 2007; OECD Guideline for the Testing of Chemicals – Stability of Pesticide Residues in Stored Commodities SANTE/11956/2016 rev.9
Deviations:	None
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

A short-term storage stability study is available on honey, which is reported in the analytical method report 01598.

Materials and methods

The stability of CGA 279202 (trifloxystrobin), CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 for about 6 months in deep frozen storage was investigated in honey.

Samples of honey were spiked with the single analytes and stored in a deep-freezer at $\leq -18^{\circ}$. The temperature in the deep-freezer was recorded during the entire storage period. Slight temperature deviations ($\leq -17^{\circ}\text{C}$ for less than an hour) occurred 84 and 97 days after day 0, which had no negative impact on the samples.

After 1 month (30 days), 3 months (90 days) and 6 months (182 days), three fortified samples per analyte and one control sample were removed from the deep-freezer. Subsequently, two samples of honey were fortified with a mix of the analytes to determine the concurrent recoveries (fortification levels were at the same magnitude as the spiked storage samples). These samples were extracted and analyzed concurrently with the remaining (unfortified) control samples and the spiked storage samples.

For analysis the residue analytical method 01598 was used with limits of quantitation of 0.01 mg/kg.

Results and discussions

After a deep-freezer storage ($\leq -18^{\circ}\text{C}$) period of about 6 months, the mean recovery rates were 109% for trifloxystrobin (CGA 279202) in honey, 108% for CGA 357262 in honey, 112% for CGA 357261 in honey, 105% for CGA 331409 in honey, 101% for CGA 321113 in honey and 107% for CGA 373466 in honey.

Furthermore, the mean concurrent recoveries of all investigated days of storage determined from freshly fortified samples were in a range of 101-110% for trifloxystrobin (CGA 279202) in honey, in a range of 103-109% for CGA 357262 in honey, in a range of 104-110% for CGA 357261 in honey, in a range of 103-110% for CGA 331409 in honey, in a range of 101-104% for CGA 321113 in honey and in a range of 95-105% for CGA 373466 in honey.

Conclusion

No significant decrease of residues was observed after the tested period of 6 months in honey. Thus, the residues of trifloxystrobin (CGA 279202), CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 are considered stable under freezer storage conditions at -18°C or below for at least 6 months.

Table A 17: Summary of concurrent recoveries of trifloxystrobin from honey

Matrix	Spike level * (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± RSD
Trifloxystrobin (CGA 279202)					
Honey	0.10	0		#	#
	0.10	30	2	104, 102	103
	0.10	90	2	103, 99	101
	0.10	182	2	109, 111	110
CGA 321113					
Honey	0.10	0		#	#
	0.10	30	2	105, 98	102
	0.10	90	2	99, 103	101
	0.10	182	2	101, 106	104
CGA 331409					
Honey	0.10	0		#	#
	0.10	30	2	104, 106	105
	0.10	89	2	102, 100	101
	0.10	182	2	109, 111	110
CGA 357261					
Honey	0.10	0		#	#
	0.10	30	2	105, 103	104
	0.10	90	2	106, 102	104
	0.10	182	2	110, 110	110
CGA 357262					
Honey	0.10	0		#	#
	0.10	30	2	102, 103	103
	0.10	89	2	105, 105	105
	0.10	182	2	105, 113	109
CGA 373466					
Honey	0.10	0	2	#	#
	0.10	30	2	98, 100	99
	0.10	90	2	98, 92	95
	0.10	182	2	103, 107	105

* trifloxystrobin parent equivalents for CGA 321113 and CGA 373466

see table X below

Table A 18: Stability of trifloxystrobin residues in honey following storage at -18°C

Table A 10: Stability of trifloxystrobin Residues in honey following storage at -18 °C					
Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)	Average recoveries (%)
Trifloxystrobin (CGA 279202)					
Honey	0.10	0	0.103, 0.104, 0.106, 0.106, 0.120	103, 104, 106, 106, 120	108
		30	0.104, 0.107, 0.106	104, 107, 106	106
		90	0.104, 0.109, 0.111	104, 109, 111	108
		182	0.113, 0.108, 0.106	113, 108, 106	109
CGA 321113					
Honey	0.10	0	0.103, 0.111, 0.109, 0.109, 0.105	103, 111, 109, 109, 105	107
		28	0.0991, 0.0986, 0.104	99, 99, 104	101
		90	0.0992, 0.107, 0.104	99, 107, 104	103
		182	0.111, 0.0947, 0.0974	111, 95, 97	101
CGA 331409					
Honey	0.10	0	0.107, 0.105, 0.104, 0.108, 0.103	107, 105, 104, 108, 103	105
		30	0.102, 0.108, 0.104	102, 108, 104	105
		90	0.0941, 0.105, 0.0964	94, 105, 96	98
		182	0.0975, 0.112, 0.104	98, 112, 104	105
CGA 357261					
Honey	0.10	0	0.106, 0.111, 0.112, 0.108, 0.107	106, 111, 112, 108, 107	109
		30	0.112, 0.112, 0.111	112, 112, 111	112
		90	0.107, 0.0993, 0.103	107, 99, 103	103
		182	0.126, 0.104, 0.106	126, 104, 106	112
CGA 357262					
Honey	0.10	0	0.128 *, 0.103, 0.105, 0.103, 0.108	128 *, 103, 105, 103, 108	105
		30	0.114, 0.106, 0.110	114, 106, 110	110
		90	0.117, 0.123, 0.121	117, 123, 121	120
		182	0.106, 0.108, 0.110	106, 108, 110	108
CGA 373466					
Honey	0.10	0	0.105, 0.105, 0.114, 0.107, 0.111	105, 105, 114, 107, 111	108
		28	0.108, 0.111, 0.119	108, 111, 119	113
		90	0.107, 0.107, 0.106	107, 107, 106	107
		183	0.110, 0.108, 0.104	110, 108, 104	107

* Excluded as outlier

A 2.1.1.2 7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

A 2.1.1.2.1 Study method 1 (Method 01598)

Comments of zRMS:	The study is acceptable.
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Reference:	KCA 6.1/03
Title:	Residue analytical method 01598 and short term storage stability of trifloxystrobin (CGA 279202) and its isomers / metabolites CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 in/on honey by HPLC-MS/MS
Report:	Roth, A.; 2020; S19-01123; M-677808-01-1
Authority registration No:	
Guideline(s):	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 Guidance document on residue analytical methods, SANCO/825/00/rev. 8.1, European Commission, Directorate General Health and Consumer Protection 16/11/2010 OECD 506, 2007; OECD Guideline for the Testing of Chemicals – Stability of Pesticide Residues in Stored Commodities SANTE/11956/2016 rev.9
Deviations:	None
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The stability of residue in sample extracts of honey was tested within residue analytical method 01598.

Materials and methods

The analytical method 01598 is a method for the determination of the residues of trifloxystrobin and its isomers/metabolites in honey. Details on the method are reported in Section B5.

During method development the stability of the analytes in the final extracts was checked for the sample material honey at the 0.10 mg/kg level.

Results and conclusion

The table below shows the measured recoveries comparing initial analysis and analysis after storage of the final sample extracts.

Residues of all analytes were stable over a time period of 8 days after storage of the final extracts at 1 °C to 10 °C under dark conditions.

Table A 19: Stability in final extracts of honey

Sample Material	Fortification Level [mg/kg]	Analyte	1 st MRM	Recovery Rates [%]					Mean [%]
Honey	0.10	Trifloxy-strobin (CGA 279202)	initial analysis	109	110	110	111	109	110
			8 days reanalysis	101	102	100	105	109	103
			deviation*						-5.8
	0.10	CGA 357262	initial analysis	108	106	108	111	107	108
			8 days reanalysis	105	102	100	104	106	103
			deviation*						-4.3
	0.10	CGA 357261	initial analysis	110	109	111	108	108	109
			8 days reanalysis	103	105	106	105	107	105
			deviation*						-3.7
	0.10	CGA 331409	initial analysis	106	114	109	109	114	110
			8 days reanalysis	93	103	99	105	104	101
			deviation*						-8.7
	0.10	CGA 321113	initial analysis	104	102	100	103	104	103
			8 days reanalysis	105	104	101	105	106	104
			deviation*						+1.6
	0.10	CGA 373466	initial analysis	104	104	99	104	102	103
			8 days reanalysis	99	98	98	101	99	99
			deviation*						-3.5

LOQ = 0.01 mg/kg (parent equivalent for CGA 321113 and CGA 373466)

Calculation of Deviation: Absolute value (100 x (mean_{reanalysis} – mean_{initial})/ mean_{initial analysis})

* For the calculation of deviations between initial analysis and reanalysis, unrounded mean values were used. Therefore, minor deviations may occur by calculating the deviations between the initial analysis and the reanalysis with the above-shown rounded mean values.

A 2.1.2 7.2.2 Nature of residues in plants, livestock and processed commodities (KCA 6.2) – Trifloxystrobin

A 2.1.2.1 7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

No additional submitted within this dossier.

A 2.1.2.2 7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

No additional submitted within this dossier.

A 2.1.2.3 7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

No additional submitted within this dossier.

A 2.1.2.4 7.2.2.4 Nature of residues in livestock (poultry KCA 6.2.2, lactating ruminants KCA 6.2.3, pigs KCA 6.2.4, fish KCA 6.2.5)

No additional submitted within this dossier.

A 2.1.3 7.2.3 Magnitude of residues in plants (KCA 6.3) – Trifloxystrobin

A 2.1.3.1 Asparagus

Table A 20: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP USA (EFSA, 2014, via Codex/JMPR 2012 and USA GAP)	3	0.14 kg as/ha	14 days	-	180 / 90 days
Intended cGAP (Asparagus: 1*)	2	0.2 kg as/ha	10 days	BBCH 23-95 (green plants)	- (as per growth stage)

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

A 2.1.3.1.1 Study 08-2209 (Asparagus, northern Europe)

Comments of zRMS:	<p>This study has been evaluated in 2011. However the residue definition for risk assessment has been changed (EFSA Journal 2017;15(10):4989), so the study is reevaluated.</p> <p>The study included two supervised residue trials conducted in North Europe, in Germany and in France during the 2008 season to determine the magnitude of CGA 321113 and trifloxystrobin in/on asparagus (sticks) after two spraying applications with 200 g/ha trifloxystrobin with 10-11 days between applications at BBCH 92-93.</p> <p>The analyses were conducted according to the analytical method 01013 (Dr. B. Brumhard, S. Stuke, 2007) with LOQ 0.01 mg/kg for CGA 321113 and trifloxystrobin in/on asparagus (stick). The average recoveries were within the acceptable range of 70 – 110% and the relative standard deviations were below 20% for all the substances analysed.</p> <p>The storage period of deep-frozen samples for trifloxystrobin and its metabolite ranged between 167 and 175 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>Only the residues of trifloxystrobin and the CGA 321113 metabolite were determined. The residue levels of trifloxystrobin and CGA 321113 are below LOQ (0.01 mg/kg) for each analyte.</p> <p>The 3 isomers of trifloxystrobin (CGA 357262, CGA 357261 and CGA 331409) were not analysed in this study, so only the existing plant residue definition for monitoring can be followed (Reg. (EU) 2019/1791).</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.1.1/01
Title:	Determination of the residues of AE C656948 and trifloxystrobin in/on asparagus after spraying of AE C656948 & CGA279202 SC 500 in the field in France (North) and Germany
Report:	Billian, P.; 2010; 08-2209; M-359460-02-1
Authority registration No:	
Guideline(s):	91/414/EEC of July 15, 1991, 7029/VI/95 rev. 5 (1997-07-22)
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on asparagus with application rates of 200 g/ha trifloxystrobin and 300-600 L water per ha. The applications were done to the crop at BBCH 91-93, spray interval about 10 days, with the last application 209-238 days before the harvest of the asparagus sticks in the next season.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Although only trifloxystrobin and GA 321113 were analysed, it is assumed that the other isomers would also have residues below the LOQ of 0.01 mg/kg, since they show generally lower residues than trifloxystrobin and CGA 321113 themselves.

Table A 21: Summary of the study 08-2209 trials – GAP summary

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)
08-2209-01 Germany 76316 Malsch Europe, North F 2008	Asparagus Rapsody	1) 12.04.2005 2) 16.07.2008 - 05.08.2008 3) 01.05.2009 - 15.06.2009	200 200	600 600	33 33	07.10.2008/0 18.10.2008/11	93	(g) 08-2209 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
08-2209-02 France, north 80750 Fienvillers Europe, North F 2008	Asparagus Andreas	1) 20.04.2000 3) 20.04.2009 - 30.06.2009	200 200	300 300	67 67	01.09.2008/0 11.09.2008/10	92	(g) 08-2209 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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
- (m) Storage (max)
- G greenhouse F field
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ
- (l) Method validation

Analytical part of study 08-2209

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 321113 (determined as CGA 321113, calculated as CGA 321113)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 321113 as CGA 321113	CGA 357261 as CGA 357261	CGA 357262 as CGA 357262	CGA 331409 as CGA 331409	CGA 373466 as CGA 373466	Total residue (5 first compound)		
08-2209-01 Germany 76316 Malsch Europe, North F 2008	Asparagus Rapsody	sticks	49	<0.01	<0.01	Not analysed, but it is assumed that residues will be all <0.01, since in general lower than residues of trifloxystrobin and CGA 321113				<0.05	209	(g) 08-2209 (j) Analytical method: 01013 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01013 and residue study 08-2209 (m) Storage: Analyte 1, 2 sticks: 167 days
08-2209-02 France, north 80750 Fienvillers Europe, North F 2008	Asparagus Andreas	sticks	49	<0.01	<0.01	Not analysed, but it is assumed that residues will be all <0.01, since in general lower than residues of trifloxystrobin and CGA 321113				<0.05	238	(g) 08-2209 (j) Analytical method: 01013 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01013 and residue study 08-2209 (m) Storage: Analyte 1, 2 sticks: 175 days

A 2.1.3.1.2 Study 09-2073 (Asparagus, northern Europe)

Comments of zRMS:	<p>The study included two supervised residue trials conducted in Europe, North (France and Netherlands) during the 2009 season to determine the magnitude of CGA 321113 and trifloxystrobin in/on asparagus (sticks) after two spraying applications with 200 g/ha trifloxystrobin with 10 days between applications at BBCH 93-95.</p> <p>The analyses were conducted according to the analytical method 01013 (Dr. B. Brumhard, S. Stuke, 2007) with LOQ 0.01 mg/kg for CGA 321113 and trifloxystrobin in/on asparagus (stick). The average recoveries were within the acceptable range of 70 – 110% and the relative standard deviations were below 20% for all the substances analysed.</p> <p>The storage period of deep-frozen samples for trifloxystrobin and its metabolite ranged between 63 and 91 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>Only the residues of trifloxystrobin and the CGA 321113 metabolite were determined. The residue levels of trifloxystrobin and CGA 321113 are below LOQ (0.01 mg/kg) for each analyte.</p> <p>The 3 isomers of trifloxystrobin (CGA 357262, CGA 357261 and CGA 331409) were not analysed in this study, so only the existing plant residue definition for monitoring can be followed (Reg. (EU) 2019/1791).</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.1.1/02
Title:	Determination of the residues of AE C656948 and trifloxystrobin in/on asparagus after spraying of AE C656948 & CGA279202 SC 500 in the field in France (north) and Netherlands
Report:	Uceda, L.; Ratajczak, M.; 2011; 09-2073; M-415549-01-1
Authority registration No:	
Guideline(s):	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8; Residues in or on Treated Products, Food and Feed; EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on asparagus with application rates of 200 g/ha trifloxystrobin and 300-800 L water per ha. The applications were done to the crop at BBCH 93-95, spray interval 10 days, with the last application 202-205 days before the harvest of the asparagus sticks in the next season.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Although only trifloxystrobin and GA 321113 were analysed, it is assumed that the other isomers would also have residues below the LOQ of 0.01 mg/kg, since they show generally lower residues than trifloxystrobin and CGA 321113 themselves.

Table A 22: Summary of the study 09-2073 trials – GAP summary

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)
09-2073-01 France, north 37320 Truyes Centre Europe, North F 2009	Asparagus Andréas; white variety	1) 01.01.1999 2) 08.07.2009 - 24.07.2009 3) 15.04.2010 - 10.06.2010	200 200	300 300	66.7 66.7	18.09.2009/0 28.09.2009/10	95	(g) 09-2073 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
09-2073-02 Netherlands 4631 nr Hoogerheide Zeeland Europe, North F 2009	Asparagus Grolim; white variety	1) 2002 3) 18.05.2010 - 15.06.2010	200 200	800 800	25.0 25.0	19.10.2009/0 29.10.2009/10	95	(g) 09-2073 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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
- (m) Storage (max)
- G greenhouse F field
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ
- (l) Method validation

Analytical part of study 09-2073

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 321113 (determined as CGA 321113, calculated as CGA 321113)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 321113 as CGA 321113	CGA 357261 as CGA 357261	CGA 357262 as CGA 357262	CGA 331409 as CGA 331409	CGA 373466 as CGA 373466	Total residue (5 first compound)		
09-2073-01 France, north 37320 Truyes Centre Europe, North F 2009	Asparagus Andréas; white variety	sticks	49	<0.01	<0.01	Not analysed, but it is assumed that residues will be all <0.01, since in general lower than residues of trifloxystrobin and CGA 321113				<0.05	205	(g) 09-2073 (j) Analytical method: 01013 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01013 and residue study 09-2073 (m) Storage: Analyte 1, 2 sticks: 91 days
09-2073-02 Netherlands 4631 nr Hoogerheide Zeeland Europe, North F 2009	Asparagus Grolim; white variety	sticks	49	<0.01	<0.01	Not analysed, but it is assumed that residues will be all <0.01, since in general lower than residues of trifloxystrobin and CGA 321113				<0.05	202	(g) 09-2073 (j) Analytical method: 01013 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01013 and residue study 09-2073 (m) Storage: Analyte 1, 2 sticks: 63 days

A 2.1.3.2 Grape

Table A 23: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP JMPR (EFSA, 2014, via Codex/JMPR 2012 and USA (+others) GAP)	4	0.14 kg as/ha	14	-	14
EU AIR GAP, S-EU, N-EU EFSA 2017	3	0.125 kg as/ha	10	-	14
Intended cGAP N-EU (Grape : 138-140*)	2	0.05 kg as/ha	14	BBCH 15-75	14

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

A 2.1.3.2.1 Study 09-2077 and MR-11/044 (Grape, northern Europe)

Comments of zRMS:	<p>The purpose of the study P 652 11 5503 was to determine the magnitude of the relevant residues of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 as well as its metabolite CGA 321113 and its stereo-isomer CGA 373466 in/on samples from plant origin after spraying applications with Trifloxystrobin containing formulations. Samples from field residue studies of the 2009 residue program were reanalysed for the above mentioned compounds.</p> <p>Two trials were conducted in N-EU (France and Germany) to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 as well as its metabolite CGA 321113 and its stereo-isomer CGA 373466 in/on grapes after two spraying applications with 50 g/ha trifloxystrobin with 14 days between applications at BBCH 85-89 and with PHI of 14 days.</p> <p>Residues of trifloxystrobin and its isomers/metabolites were determined by HPLCMS/MS according to method 01313. The analytical method 01313 was validated for the determination of residues of trifloxystrobin (CGA 279202) and its stereo-isomers (E/Z-isomers) CGA 357261, 357262, 331409 as well as its metabolite CGA 321113 and its stereoisomer CGA 373466 in/on plant materials.</p> <p>The LOQ for all compounds was 0.01 mg/kg for grapes samples.</p> <p>The residue levels of trifloxystrobin were 0.03 and 0.06 mg/kg mg/kg.</p> <p>The residue levels of sum of trifloxystrobin, its isomers and metabolite CGA 321113 (5 analytes) were 0.07 and 0.10 mg/kg.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.2.1/02
Title:	Determination of the residues of AE C656948 and trifloxystrobin in/on grape after spraying and spraying, low-volume of AE C656948 CGA279202 SC 500 in the field in France (north), France (south), Germany and Italy
Report:	Cavaillé, C. ; Uceda, L. ; 2011 ; 09-2077 ; M-415381-01-1
Authority registration No:	
Guideline(s):	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Reference:	KCA 6.3.2.1/03
Title:	Amendment no. 1 to report no: P 652 11 5503 – Determination of the residues of trifloxystrobin, CGA 357261, CGA 357262, CGA 331409, CGA 321113, and CGA 373466 in/on materials of plant origin by HPLCMS/MS
Report:	Stuke, S.; 2013; MR-11/044; M-421645-02-1
Authority registration No:	
Guideline(s):	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times to grape with application rates of 50 g/ha trifloxystrobin and 200-1000 L water per ha. The applications were done with a spray interval of about 14 days, with the last application 14 days before the harvest.

Analysis of all six analytes as reported below was done in study MR-11/044.

Concurrent recoveries obtained during the conduct of this study were acceptable with overall mean values in the range 70-110%. All RSD values were below 20%.

Table A 24: Summary of the study 09-2077 trials – GAP summary

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)
09-2077-01 09-2077-01-MR- 11/044 France, north 37270 Athée sur Cher Centre Europe, North F 2009	Grape Chardonnay	1) 01.01.1994 2) 04.06.2009 - 12.06.2009 3) 10.09.2009 - 21.09.2009	50 50	200 200	25 25	18.08.2009/0 31.08.2009/13	85	(g) 09-2077 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying, low-volume
09-2077-02 09-2077-02-MR- 11/044 Germany 67487 Maikammer Rheinland-Pfalz Europe, North F 2009	Grape Dornfelder	1) 01.04.1992 2) 29.05.2009 - 13.06.2009 3) 05.09.2009 - 15.10.2009	50 50	800 800	6.3 6.3	24.08.2009/0 07.09.2009/14	89	(g) 09-2077 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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
- (m) Storage (max)
- G greenhouse F field
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ
- (l) Method validation

Analytical part of study 09-2077

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1-5)		
09-2077-01 09-2077-01- MR-11/044 France, north 37270 Athée sur Cher Centre Europe, North F 2009	Grape Chardonnay	bunch of grapes	85	0.02	<0.01	<0.01	<0.01	<0.01	<0.01	0.06	0*	(g) 09-2077 and MR-11/044 (j) Analytical method: 01313 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313 and residue study MR-11/044 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 bunch of grapes: 590 days * prior to last application
			85	0.08	<0.01	<0.01	<0.01	<0.01	<0.01	0.12	0	
			85	0.09	0.01	<0.01	<0.01	<0.01	<0.01	0.13	3	
			85	0.06	<0.01	<0.01	<0.01	<0.01	<0.01	0.10	7	
			89	0.03	<0.01	<0.01	<0.01	<0.01	<0.01	0.07	14	
			89	0.02	<0.01	<0.01	<0.01	<0.01	<0.01	0.06	21	
09-2077-02 09-2077-02- MR-11/044 Germany 67487 Maikammer Rheinland-Pfalz Europe, North F 2009	Grape Dornfelder	bunch of grapes	89	0.03	<0.01	<0.01	<0.01	<0.01	<0.01	0.07	0*	(g) 09-2077 and MR-11/044 (j) Analytical method: 01313 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313 and residue study MR-11/044 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 bunch of grapes: 704 days * prior to last application
			89	0.10	<0.01	<0.01	<0.01	<0.01	<0.01	0.14	0	
			89	0.09	<0.01	<0.01	<0.01	<0.01	<0.01	0.13	3	
			89	0.08	<0.01	<0.01	<0.01	<0.01	<0.01	0.12	7	
			89	0.05	<0.01	<0.01	<0.01	<0.01	<0.01	0.09	14	
			89	0.04	<0.01	<0.01	<0.01	<0.01	<0.01	0.08	21	
			89	0.06	0.01	0.01	<0.01	<0.01	<0.01	0.10	28	

A 2.1.3.3 Strawberry

Table A 25: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP USA (EFSA, 2014, via Codex/JMPR 2012 and USA GAP)	6	0.07 – 0.11 kg as/ha	7 days	-	0 day
EU AIR GAP, EU-S, EU-N, indoor EFSA 2017	2	0.15 kg as/ha	7 days	-	1 day
Intended cGAP EU-N, field (Strawberry: 227, 232, 236, 237, 239*)	2	0.2 kg as/ha	7 days	(BBCH 40-89)	1 day

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

A 2.1.3.3.1 Study 14-2026 (Strawberry, northern Europe, field)

Comments of zRMS:	<p>Four trials were conducted in N-EU (Germany, France, the Netherlands and Belgium) during the 2014 season to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 as well as its metabolite CGA 321113 and its stereo-isomer CGA 373466 in/on strawberry (fruit) after two spraying applications with 0.2 kg/ha trifloxystrobin with 7-8 days between applications at BBCH 81-87 and with PHI of 1 day.</p> <p>Residues of trifloxystrobin and its isomers/metabolites were determined by HPLCMS/MS according to method 01313/M001.</p> <p>The LOQ for all compounds was 0.01 mg/kg for strawberry fruits.</p> <p>The residue levels of trifloxystrobin were: 2x0.1, 0.12 and 0.36 mg/kg.</p> <p>The residue levels of sum of trifloxystrobin, its isomers and metabolite CGA 321113 (5 analytes) were 0.15, 0.16, 0.18 and 0.43 mg/kg.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.3.1/01
Title:	Determination of the residues of fluopyram and trifloxystrobin in/on strawberry after spray application of fluopyram & trifloxystrobin SC 500 in Germany, northern France, the Netherlands and Belgium
Report:	Schulte, G.; Sosniak, A.; 2015; 14-2026; M-534577-01-1
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):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on strawberry with application rates of 200 g/ha trifloxystrobin and 500-1000 L water per ha. The applications were done with a spray interval of about 7 days, with the last application 1 day before the harvest.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Table A 26: Summary of the study 14-2026 trials – GAP summary

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)
14-2026-01 14-2026-01-T Germany 49685 Bühren Europe, North F 2014	Strawberry Elsanta	1) 01.05.2012 2) 01.05.2014 - 22.05.2014 3) 30.05.2014 - 30.06.2014	200 228	500 570	40 40	03.06.2014/0 11.06.2014/8	87	(g) 14-2026 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
14-2026-02 14-2026-02-T France, north 41230 Soings en Sologne Europe, North F 2014	Strawberry Mathis	1) 15.07.2013 2) 15.04.2014 - 07.05.2014 3) 25.05.2014 - 15.06.2014	200 200	600 600	33 33	27.05.2014/0 03.06.2014/7	87	(g) 14-2026 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
14-2026-03 14-2026-03-T Netherlands 1682 NS Zwaagdijk Europe, North F 2014	Strawberry Elsanta	1) 01.05.2014 2) 05.06.2014 - 05.07.2014 3) 01.07.2014 - 01.08.2014	200 200	1000 1000	20 20	30.06.2014/0 07.07.2014/7	85	(g) 14-2026 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
14-2026-04 14-2026-04-T Belgium 1460 Ittre Europe, North F 2014	Strawberry Lambada	1) 27.07.2013 2) 15.04.2014 - 25.04.2014 3) 29.05.2014 - 15.06.2014	200 200	900 900	22 22	19.05.2014/0 26.05.2014/7	85	(g) 14-2026 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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
- (m) Storage (max)
- G greenhouse
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ
- (l) Method validation
- F field

Analytical part of study 14-2026

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 3: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 4: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 5: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

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 Trifloxy- strobin as trifloxy-strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
14-2026-01 14-2026-01-T Germany 49685 Bühren Europe, North F 2014	Strawberry Elsanta	fruit	87 87 87 87 89	0.029 0.12 0.10 0.085 0.079	<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 <0.01	0.040 0.039 0.031 0.047 0.045	<0.01 <0.01 <0.01 <0.01 <0.01	0.10 0.19 0.16 0.16 0.16	0* 0 <u>1</u> 3 7	(g) 14-2026 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue reports 12-2012, 12-2013, 12-2014 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 357 days * prior to last application
14-2026-02 14-2026-02-T France, north 41230 Soings en Sologne Europe, North F 2014	Strawberry Mathis	fruit	87 87 87 87 89	0.046 0.098 0.10 0.099 0.066	<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 <0.01	<0.01 <0.01 <0.01 0.020 0.056	<0.01 <0.01 <0.01 <0.01 <0.01	0.086 0.14 0.14 0.15 0.15	0* 0 <u>1</u> 3 7	(g) 14-2026 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue reports 12-2012, 12-2013, 12-2014 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 365 days * prior to last application
14-2026-03 14-2026-03-T Netherlands 1682 NS Zwaagdijk Europe, North F 2014	Strawberry Elsanta	fruit	85 87 87 87 87	0.16 0.33 0.36 0.19 0.12	<0.01 <0.01 0.011 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.032 0.039 0.039 0.063 0.11	<0.01 0.011 0.010 0.011 0.014	0.22 0.40 0.43 0.29 0.26	0* 0 <u>1</u> 3 7	(g) 14-2026 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue reports 12-2012, 12-2013, 12-2014 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 331 days * prior to last application

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 Trifloxy- strobin as trifloxy-strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
14-2026-04	Strawberry Lambada	fruit	85	0.078/0.028**	<0.01	<0.01	<0.01	0.026	<0.01	0.14	0*	(g) 14-2026 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue reports 12-2012, 12-2013, 12-2014 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 373 days * prior to last application ** residues in control
14-2026-04-T			85	0.14	<0.01	<0.01	<0.01	0.024	<0.01	0.20	0	
Belgium			85	0.12/0.034**	<0.01	<0.01	<0.01	0.024/0.010**	<0.01	0.18	<u>1</u>	
1460 Ittre			87	0.091/0.020**	<0.01	<0.01	<0.01	0.037/0.010**	0.010	0.16	3	
Europe, North F 2014			87	0.062	<0.01	<0.01	<0.01	0.028	<0.01	0.12	7	

A 2.1.3.3.2 Study 15-2031 (Strawberry, northern Europe, field)

Comments of zRMS:	<p>Two trials were conducted in N-EU (Germany and Denmark) during the 2015 season to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 as well as its metabolite CGA 321113 and its stereo-isomer CGA 373466 in/on strawberry (fruit) after two spraying applications with 0.2 kg/ha trifloxystrobin with 7 days between applications at BBCH 85-87 and with PHI of 1 day.</p> <p>Residues of trifloxystrobin and its isomers/metabolites were determined by HPLCMS/MS according to method 01313/M001.</p> <p>The LOQ for all compounds was 0.01 mg/kg for strawberry fruits.</p> <p>The residue levels of trifloxystrobin were: 0.12 and 0.24 mg/kg.</p> <p>The residue levels of sum of trifloxystrobin, its isomers and metabolite CGA 321113 (5 analytes) were 0.19 and 0.33 mg/kg.</p> <p>The storage period of deep-frozen samples for trifloxystrobin and its isomers and metabolite ranged between 185 and 199 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.3.1/02
Title:	Determination of the residues of fluopyram and trifloxystrobin in/on strawberry after spray application of AE C656948 & CGA 279202 SC 500 in Germany, Denmark, Spain, southern France and Italy
Report:	Szeley, C. M.; Sadler, C.; 2016; 15-2031; M-553855-01-1
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:	Yes, No impact on the study.
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on strawberry with application rates of 200 g/ha trifloxystrobin and 300-400 L water per ha. The applications were done with a spray interval of 7 days, with the last application 1 day before the harvest.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Table A 27: Summary of the study 15-2031 trials – GAP summary

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)
15-2031-01 15-2031-01-T Germany 49685 Emstek Europe, North F 2015	Strawberry Elsanta	1) 26.05.2015 2) 15.06.2015 - 13.07.2015 3) 17.07.2015 - 28.07.2015	200 200	400 400	50 50	14.07.2015/0 21.07.2015/7	87	(g) 15-2031 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
15-2031-02 15-2031-02-T Denmark 6200 Aabenraa Europe, North F 2015	Strawberry Honeoye	1) 16.05.2013 2) 09.06.2015 - 25.06.2015 3) 04.07.2015 - 11.07.2015	200 200	300 300	67 67	30.06.2015/0 07.07.2015/7	85	(g) 15-2031 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying

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|---|--------------------------|
| - (a) According to CODEX Classification / Guide | - (g) Study reference |
| - (b) Only if relevant | - (h) Formulation type |
| - (c) Year must be indicated | - (i) Application method |
| - (d) Either growth stage description or BBCH Code | - (j) Method information |
| - (e) Days after last application (Label pre-harvest interval, PHI, underline) | - (k) LOQ |
| - (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included | - (l) Method validation |
| - (m) Storage (max) | |
| - G greenhouse F field | |

Analytical part of study 15-2031

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
15-2031-01	Strawberry	fruit	87	0.056	<0.01	<0.01	<0.01	0.032	<0.01	0.12	0*	(g) 15-2031 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 15-2031 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 185 days * prior to last application
15-2031-01-T	Elsanta		87	0.31	<0.01	<0.01	<0.01	0.033	<0.01	0.37	0	
Germany			87	0.24	0.015	<0.01	<0.01	0.041	<0.01	0.32	1	
49685 Emstek			87	0.24	0.015	<0.01	<0.01	0.049	0.010	0.33	3	
Europe, North F 2015			87	0.086	<0.01	<0.01	<0.01	0.046	<0.01	0.16	7	
15-2031-02	Strawberry	fruit	85	0.040	<0.01	<0.01	<0.01	0.029	<0.01	0.10	0*	(g) 15-2031 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 15-2031 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 199 days * prior to last application
15-2031-02-T	Honeoye		85	0.15	<0.01	<0.01	<0.01	0.027	<0.01	0.21	0	
Denmark			85	0.12	<0.01	<0.01	<0.01	0.038	<0.01	0.19	1	
6200 Aabenraa			85	0.11	<0.01	<0.01	<0.01	0.044	<0.01	0.19	3	
Europe, North F 2015			87	0.085	<0.01	<0.01	<0.01	0.049	<0.01	0.17	7	

A 2.1.3.3.3 Study 18-2050 (Strawberry, northern Europe, field)

Comments of zRMS:	<p>Three trials were conducted in N-EU (Germany and Belgium) during the 2018 season to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 as well as its metabolite CGA 321113 and its stereo-isomer CGA 373466 in/on strawberry (fruit) after two spraying applications with 0.2 kg/ha trifloxystrobin with 7 days between applications at BBCH 85-87 and with PHI of 1 day.</p> <p>Residues of trifloxystrobin and its isomers/metabolites were determined by HPLCMS/MS according to method 01313/M001.</p> <p>The LOQ for all compounds was 0.01 mg/kg for strawberry fruits.</p> <p>The residue levels of trifloxystrobin were: 0.055, 0.21 and 0.41 mg/kg.</p> <p>The residue levels of sum of trifloxystrobin, its isomers and metabolite CGA 321113 (5 analytes) were 0.12, 0.33 and 0.51 mg/kg.</p> <p>The storage period of deep-frozen samples for trifloxystrobin and its isomers and metabolite ranged between 168 and 230 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.3.1/03
Title:	Determination of the residues of trifloxystrobin and AE C656948 in/on strawberry after spray application of AE C656948 & CGA279202 SC 500 in Germany and Belgium
Report:	Braune, M.; Ereemeeva, T.; 2020; 18-2050; M-684200-01-1
Authority registration No:	
Guideline(s):	<p>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</p> <p>OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)</p> <p>US EPA OCSPP 860.1500, Crop Field Trial</p>
Deviations:	None
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on strawberry with application rates of about 200 g/ha trifloxystrobin and 301-606 L water per ha. The applications were done with a spray interval of 7 days, with the last application 1 day before the harvest.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Table A 28: Summary of the study 18-2050 trials – GAP summary

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)
18-2050-01 18-2050-01-T Germany 42799 Leichlingen Europe, North F 2018	Strawberry Elsanta	1) 10.05.2016 2) 08.05.2018 - 01.06.2018 3) 04.06.2018 - 25.06.2018	204 207	511 518	39.9 39.9	30.05.2018/0 06.06.2018/7	87	(g) 18-2050 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
18-2050-02 18-2050-02-T Germany 49377 Vechta OT Calveslage Europe, North F 2018	Strawberry Elsanta	1) 11.05.2018 2) 10.06.2018 - 30.06.2018 3) 20.06.2018 - 10.07.2018	201 206	301 413	66.7 50.0	20.06.2018/0 27.06.2018/7	87	(g) 18-2050 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
18-2050-03 18-2050-03-T Belgium 6221 Saint- Amand Europe, North F 2018	Strawberry Tenira	1) 20.06.2018 2) 15.07.2018 - 23.07.2018 3) 07.08.2018 - 14.08.2018	194 202	581 606	33.3 33.3	31.07.2018/0 07.08.2018/7	87	(g) 18-2050 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying

- | | |
|---|--------------------------|
| - (a) According to CODEX Classification / Guide | - (g) Study reference |
| - (b) Only if relevant | - (h) Formulation type |
| - (c) Year must be indicated | - (i) Application method |
| - (d) Either growth stage description or BBCH Code | - (j) Method information |
| - (e) Days after last application (Label pre-harvest interval, PHI, underline) | - (k) LOQ |
| - (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included | - (l) Method validation |
| - (m) Storage (max) | |
| - G greenhouse F field | |

Analytical part of study 18-2050

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1-5)		
18-2050-01 18-2050-01-T Germany 42799 Leichlingen Europe, North F 2018	Strawberry Elsanta	fruit	87 87 87 89 89	0.021 0.070 0.055 0.053 0.033	<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 <0.01	0.019 0.019 0.024 0.032 0.039	<0.01 <0.01 <0.01 <0.01 <0.01	0.071 0.12 0.11 0.12 0.10	0* 0 <u>1</u> <u>3</u> 7	(g) 18-2050 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 18-2050 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 230 days * prior to last treatment
18-2050-02 18-2050-02-T Germany 49377 Vechta OT Calveslage Europe, North F 2018	Strawberry Elsanta	fruit	87 87 87 87 89	0.12 0.59 0.41 0.26 0.19	<0.01 <0.01 0.016 0.011 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.020 0.022 0.059 0.090 0.098	<0.01 <0.01 0.014 0.023 0.015	0.17 0.64 0.51 0.38 0.32	0* 0 <u>1</u> 3 8	(g) 18-2050 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 18-2050 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 209 days * prior to last treatment
18-2050-03 18-2050-03-T Belgium 6221 Saint- Amand Europe, North F 2018	Strawberry Tenira	fruit	87 87 87 89 89	0.14 0.25 0.21 0.17 0.14	<0.01 0.013 0.016 0.015 0.011	<0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0.086 0.073 0.085 0.098 0.089	0.021 0.016 0.020 0.021 0.016	0.26 0.36 0.33 0.31 0.26	0* 0 <u>1</u> 3 7	(g) 18-2050 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 18-2050 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 168 days * prior to last treatment

A 2.1.3.4 Canefruit (Blackberry, Dewberry, Raspberry)

Table A 29: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA, 2014b)	2	0.2 kg as/ha	7 days	BBCH 31-89	3
Intended cGAP N-EU, field (Blackberry: 21*) (Raspberry: 191, 194*)	2	0.2 kg as/ha	7 days	(up to BBCH 89)	3
Intended cGAP N-EU, field (Dewberry: 105, 106*)	2	0.15 kg as/ha	21 days	(up to BBCH 89)	3

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

EFSA Journal 2014;12(7):3751 (canefruit)

Blackberry N-EU, field: there are further GAPs, which are less critical (24, 27, 29, 30*)

Raspberry N-EU, field: there are further GAPs, which are less critical (197, 199, 203*)

A 2.1.3.4.1 Study 18-2051 (Raspberry, northern Europe)

Comments of zRMS:	<p>Four trials were conducted in N-EU (Hungary, Poland, Germany and northern France) during the 2018 season to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 as well as its metabolite CGA 321113 and CGA 373466 in/on raspberry (fruit) after two spraying applications with 0.2 kg/ha trifloxystrobin with 7 days between applications at BBCH 85-87 and with PHI of 3 days.</p> <p>Residues of trifloxystrobin and its isomers/metabolites were determined by HPLCMS/MS according to method 01313/M001.</p> <p>The LOQ for all compounds was 0.01 mg/kg for raspberry fruits.</p> <p>The residue levels of trifloxystrobin were: 0.098, 0.36, 1.0, 1.5 mg/kg.</p> <p>The residue levels of sum of trifloxystrobin, its isomers and metabolite CGA 321113 (5 analytes) were 0.15, 0.42, 1.1 and 1.6 mg/kg.</p> <p>The storage period of deep-frozen samples for trifloxystrobin and its isomers and metabolite ranged between 152 and 232 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.4.1/01
Title:	Determination of the residues of trifloxystrobin and AE C656948 in/on raspberry after spray application of AE C656948 & CGA279202 SC 500 in Hungary, Poland, Germany and northern France
Report:	Buchmueller, K.; Holbein, J.; 2019; 18-2051; M-675722-01-1
Authority registration No:	
Guideline(s):	<p>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</p> <p>US EPA OCSPP 860.1500, Crop Field Trial</p> <p>OECD Guideline for the Testing of Chemicals on Crop Field Trial</p> <p>(TG 509 published in September 2009)</p>
Deviations:	None
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on raspberry with application rates of about 200 g/ha trifloxystrobin and 382-803 L water per ha. The applications were done with a spray interval of 7 days, with the last application 3 days before the harvest.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Table A 30: Summary of the study 18-2051 trials – GAP summary

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)
18-2051-01 18-2051-01-T Hungary 9725 Cak Europe, North F 2018	Raspberry Fertodi zamoto	1) 2012 2) 05.05.2018 - 20.05.2018 3) 30.06.2018 - 31.07.2018	195 193	778 770	25.00 25.0	18.06.2018/0 25.06.2018/7	85	(g) 18-2051 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
18-2051-02 18-2051-02-T Poland 27-320 Dziurków Europe, North F 2018	Raspberry Polana; Autumn variety	1) 2012 2) 03.08.2018 - 24.08.2018 3) 05.09.2018 - 19.09.2018	209 209	731 732	28.6 28.6	28.08.2018/0 04.09.2018/7	87	(g) 18-2051 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
18-2051-03 18-2051-03-T Germany 74199 Untergruppen- bach Europe, North F 2018	Raspberry Green Ample	2) 15.06.2018 - 15.07.2018 3) 30.07.2018 - 01.09.2018	201 194	803 777	25.0 25.0	20.07.2018/0 27.07.2018/7	87	(g) 18-2051 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
18-2051-04 18-2051-04-T France, north 71570 La Chapelle de Guinchay Europe, North F 2018	Raspberry Zeva; Fruit production twice/year	1) 2016 2) 02.08.2018 - 24.08.2018 3) 20.08.2018 - 14.09.2018	191 192	382 384	49.9 50.0	31.08.2018/0 07.09.2018/7	87	(g) 18-2051 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ
- (l) Method validation

- information which metabolites are included
- (m) Storage (max)
 - G greenhouse F field

Analytical part of study 18-2051

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466),

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1-5)		
18-2051-01 18-2051-01-T Hungary 9725 Cak Europe, North F 2018	Raspberry Fertodi zamos	fruit	87 87 87 87 89 89	0.21 0.48 0.22 0.36 0.31 0.064	<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 <0.01 <0.01 0.010 <0.01	0.028 0.023 0.018 0.025 0.025 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.27 0.53 0.27 0.42 0.37 0.10	0* 0 1 3 7 15	(g) 18-2051 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: in method 01313/M001 and residue study 18-2051 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 232 days * prior to last treatment
18-2051-02 18-2051-02-T Poland 27-320 Dziurków Europe, North F 2018	Raspberry Polana; Autumn variety	fruit	87 87 87 87 87 87	0.30 1.1 1.0 1.0 0.52 0.35	<0.01 <0.01 0.010 0.014 0.014 0.016	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 0.012 0.015 0.014 0.017	0.023 0.025 0.048 0.056 0.045 0.041	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.35 1.2 1.1 1.1 0.61 0.44	0* 0 1 3 7 14	(g) 18-2051 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: in method 01313/M001 and residue study 18-2051 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 164 days * prior to last treatment

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1-5)		
18-2051-03 18-2051-03-T Germany 74199 Untergruppen- bach Europe, North F 2018	Raspberry Green Ample	fruit	89 89 89 89 89 89	0.17 0.19 0.15 0.098 0.054 0.028	<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 <0.01 <0.01 <0.01 <0.01	0.037 0.015 0.026 0.019 0.019 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.24 0.24 0.21 0.15 0.10 0.058	0* 0 1 <u>3</u> 7 14	(g) 18-2051 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: in method 01313/M001 and residue study 18-2051 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 200 days * prior to last treatment
18-2051-04 18-2051-04-T France, north 71570 La Chapelle de Guinchay Europe, North F 2018	Raspberry Zeva; Fruit production twice/year	fruit	89 89 89 89 89 89	0.99 2.8 1.4 1.5 0.66 0.26	0.028 0.050 0.024 0.032 0.019 0.011	0.012 0.019 0.011 0.017 0.012 <0.01	0.021 0.029 0.018 0.029 0.020 0.013	0.032 0.028 0.023 0.038 0.048 0.035	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	1.1 2.9 1.5 1.6 0.76 0.33	0* 0 1 <u>3</u> 7 13	(g) 18-2051 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: in method 01313/M001 and residue study 18-2051 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 152 days * prior to last treatment

A 2.1.3.5 Other berries and small fruit (blueberry, buckthorn, chokeberry, cranberry, currant, elderberry, gooseberry, mulberry, rosehips)

Table A 31: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA, 2018)	2	0.2 kg as/ha	7 days	(up to BBCH 89)	7
Intended cGAP EU-N, field (Blueberry: 32*) (Buckthorn: 46*) (Chokeberry: 52*) (Currant: 63, 66, 71, 84, 97*) (Elderberry: 107*) (Gooseberry: 125*)	2	0.2 kg as/ha	7 / 14days	(up to BBCH 89)	7
Intended cGAP EU-N, field (Cranberry: 56, 58*) (Mulberry: 167, 168*) (Gooseberry: *) (Rosehip: 210, 212*)	2	0.15 kg as/ha	7 / 14days	(up to BBCH 89)	7

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
Further less critical GAPs are available and not listed here

The studies summarised below were already evaluated in EFSA Journal 2018;16(1):5154, but are submitted again, including the total residue for risk assessment, since this was not taken into account in this EFSA evaluation of 2018.

A 2.1.3.5.1 Study B5111 (Currant, northern Europe)

Comments of zRMS:	<p>The study summarised below in black currant was already evaluated in EFSA Journal 2018;16(1):5154 but is submitted again because of that the total residue for risk assessment was not taken into account in the evaluation by EFSA (EFSA, 2018). <u>In this study only the residues of trifloxystrobin and the CGA 321113 metabolite were determined.</u></p> <p>Four trials were conducted in N-EU (France) during the 2015 season to determine the magnitude of trifloxystrobin (CGA 279202) and its metabolite CGA 321113 in/on blackcurrant (fruit) after two spraying applications with 0.2 kg/ha trifloxystrobin with 7 days between applications at BBCH 87 and with PHI of 7 days. Residues of trifloxystrobin and its metabolites were determined by LCMS/MS according to method GIR/MET/TRIFLOXY/01 based on BAYER Method No. 01013 (validated). The method had been validated previously on raspberries. An additional validation for the method has been conducted on blackcurrant during the analytical phase (3 recovery experiments fortified at the LOQ level, 3 recovery experiments fortified at ten times the LOQ level and 1 control sample). The limit of quantification of trifloxystrobin and its metabolite CGA 321113 expressed as trifloxystrobin was 0.005 mg/kg for each reference item. The residue levels of trifloxystrobin were: 0.13, 0.22, 0.64, 1.2 mg/kg at the intended PHI of 7-8 days in fruit samples. The storage period of deep-frozen samples for trifloxystrobin and its metabolite ranged between 139 and 149 days. The studies on the magnitude of residues are valid with regard to storage stability. The study is acceptable.</p> <p><u>Remarks:</u></p>
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0. Trials B5111 MA1 and B5111 MA2 are at less than 10 km distance from each other (213efinit. 8 km). This deviation has a weak impact on the study since they are grown in different conditions and on different soil types.

1.2.2 Crop and soil Information

Trial No.	Crop	Variety	Crop density (plants/ha)	Sowing / Planting date	Soil type	pH	Organic matter (%)
B5111 BM1	Blackcurrant	Blackdown	5714	2007	Silty clay	6.4	2.5
B5111 BM2	Blackcurrant	Andorine	6250	2009	Sand	6.8	1.27
B5111 MA1	Blackcurrant	Noir de Bourgogne	7692	2013	Loam	7	1.72
B5111 MA2	Blackcurrant	Noir de Bourgogne	7812	2011	Sandy clay	7	6.9

Trials B5111 BM1 and B5111 BM2 are 213efinit. 45 km distance from each other.

2. The 3 isomers of trifloxystrobin (CGA 357262, CGA 357261 and CGA 331409) were not analysed in this study, so only the existing plant residue 213efinitione for monitoring can be followed (Reg. (EU) 2019/1791).
However taking into the results of studies 15-2033, 14-2025 and 15-2032 (submitted by Applicant) the conversion factor (from monitoring to risk assessment) of 1.3 for currant, based on currant trials including isomer analysis, has been calculated by iRMS Greece (DRR – Part B7 for 102000012886 / fluopyram + trifloxystrobin SC 500 (250 + 250 g/L), 12.02.2021).
The study is acceptable.

Reference:	KCA 6.3.5.1/01
Title:	Determination of fluopyram and its metabolite fluopyram-benzamide and trifloxystrobin and its metabolite CGA321113 residues in blackcurrant following applications with F413BCS under field conditions in northern Europe in 2015
Report:	Perny, A.; 2017; B5111; M-565907-02-1
Authority registration No:	
Guideline(s):	Regulation (EC) No 1107/2009 US EPA OCSPP Guideline Number: 860.1500
Deviations:	Yes, but acceptable
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on currants with application rates of about 200 g/ha trifloxystrobin and 461-513 L water per ha. The applications were done with a spray interval of 7 days, covering the PHI of 7 days.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Although only trifloxystrobin and GA 321113 were analysed, total residue (sum of trifloxystrobin, its isomers, and metabolite CGA 321113) was calculated with conversion factor (from monitoring to risk assessment) of 1.3 for currant, which is based on currant trials including isomer analysis (indoor and southern European trials summarized further below).

Table A 32: Summary of the study B5111 trials – GAP summary

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)
B5111 BM2 B5111 BM2-T France, north 72800 Thoree- les-pins Europe, North F 2015	Currant, black Andorine	1) 20.01.2009 2) 15.04.2015 - 20.04.2015 3) 06.07.2015	205.2 194.8	513 487	40.0 40.0	23.06.2015/0 30.06.2015/7	87	(g) B5111 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
B5111 MA1 B5111 MA1-T France, north 21190 Merceuil Europe, North F 2015	Currant, black Noir de Bourgogne	1) 11.2013 2) 20.04.2015 - 27.04.2015 3) 08.07.2015 - 10.07.2015	200.0 204.0	500 510	40.0 40.0	23.06.2015/0 30.06.2015/7	87	(g) B5111 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
B5111 BM1 B5111 BM1-T France, north 37360 Neuille- Pont-Pierre Europe, North F 2015	Currant, black Blackdown	1) 2007 2) 17.04.2015 - 23.04.2015 3) 13.07.2015	184.4 191.2	461 478	40.0 40.0	01.07.2015/0 08.07.2015/7	87	(g) B5111 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
B5111 MA2 B5111 MA2-T France, north 21200 Beaune Europe, North F 2015	Currant, black Noir de Bourgogne	1) 11.2011 2) 20.04.2015 - 28.04.2015 3) 08.07.2015 - 11.07.2015	202.4 198.8	506 497	40.0 40.0	23.06.2015/0 30.06.2015/7	87	(g) B5111 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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
- (m) Storage (max)
- G greenhouse F field
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ
- (l) Method validation

Analytical part of study B5111

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 321113 (determined as CGA 321113, calculated as trifloxystrobin)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 321113 as trifloxy- strobin		Total residue calc. (CF 1.3)		
B5111 MA1 B5111 MA1-T France, north 21190 Merceuil Europe, North F 2015	Currant, black Noir de Bourgogne	fruit	87 87 87 87	2.0 2.0 1.5 1.2	<0.005 0.007 0.009 0.009	Not analysed for CGA 357261, CGA 357262, CGA 331409. Total residue calculated with conversion factor (from monitoring to risk assessment) of 1.3 for currant, which is based on currant trials including isomer analysis	2.6 2.6 2.0 1.6	0 1 3 7	(g) B5111 (j) Analytical method: GIR/MET/TRIFLOXY/01 (k) LOQ: 0.005 mg/kg (l) Method Validation Data in B5111 (m) Storage: Analyte 1, 2 fruit: 147 days
B5111 MA2 B5111 MA2-T France, north 21200 Beaune Europe, North F 2015	Currant, black Noir de Bourgogne	fruit	87 87 87 87	1.7 1.1 0.92 0.64	0.015 0.026 0.018 0.011	Not analysed for CGA 357261, CGA 357262, CGA 331409. Total residue calculated with conversion factor (from monitoring to risk assessment) of 1.3 for currant, which is based on currant trials including isomer analysis	2.2 1.4 1.2 0.83	0 1 3 7	(g) B5111 (j) Analytical method: GIR/MET/TRIFLOXY/01 (k) LOQ: 0.005 mg/kg (l) Method Validation Data in B5111 (m) Storage: Analyte 1, 2 fruit: 147 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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 321113 as trifloxy- strobin		Total residue calc. (CF 1.3)		
B5111 BM2 B5111 BM2-T France, north 72800 Thoree- les-pins Europe, North F 2015	Currant, black Andorine	fruit	89 BBCH: 87-89 89 89	0.52 0.40 0.35 0.22	<0.005 <0.005 <0.005 <0.005	Not analysed for CGA 357261, CGA 357262, CGA 331409. Total residue calculated with conversion factor (from monitoring to risk assessment) of 1.3 for currant, which is based on currant trials including isomer analysis	0.68 0.52 0.46 0.29	0 1 3 <u>6</u>	(g) B5111 (j) Analytical method: GIR/MET/TRIFLOXY/01 (k) LOQ: 0.005 mg/kg (l) Method Validation Data in B5111 (m) Storage: Analyte 1 fruit: 149 days Analyte 2 fruit: 147 days
B5111 BM1 B5111 BM1-T France, north 37360 Neuille- Pont-Pierre Europe, North F 2015	Currant, black Blackdown	fruit	87 BBCH: 87-89 89 89	0.40 0.40 0.28 0.13	<0.005 <0.005 <0.005 <0.005	Not analysed for CGA 357261, CGA 357262, CGA 331409. Total residue calculated with conversion factor (from monitoring to risk assessment) of 1.3 for currant, which is based on currant trials including isomer analysis	0.52 0.52 0.36 0.17	0 1 3 <u>7</u>	(g) B5111 (j) Analytical method: GIR/MET/TRIFLOXY/01 (k) LOQ: 0.005 mg/kg (l) Method Validation Data in B5111 (m) Storage: Analyte 1 fruit: 141 days Analyte 2 fruit: 139 days

A 2.1.3.5.2 Study PTZ-NLI-11796 (Currant, northern Europe)

Comments of zRMS:	<p>The study summarised below in currant was already evaluated in EFSA Journal 2018;16(1):5154 but is submitted again because of that the total residue for risk assessment was not taken into account in the evaluation by EFSA (EFSA, 2018). <u>In this study only the residues of trifloxystrobin and the CGA 321113 metabolite were determined.</u></p> <p>One trial was conducted in N-EU (the Netherlands) during the 2011 season to determine the magnitude of trifloxystrobin (CGA 279202) and its metabolite CGA 321113 in/on red currant (fruit) under plastic umbrella after two spraying applications with 0.2 kg/ha trifloxystrobin with 7 days between applications at BBCH 87 and with PHI of 7 days. Residues of trifloxystrobin and its metabolites were determined by HPLCMS/MS according to method 01207.</p> <p>The LOQ for all compounds was 0.01 mg/kg mg/kg for red currant fruits.</p> <p>The residue level of trifloxystrobin was 0.26 mg/kg at the intended PHI of 7 days in fruit samples.</p> <p>The storage period of deep-frozen samples for trifloxystrobin and its metabolite ranged between 102 and 123 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p> <p><u>Remarks:</u></p> <p>The 3 isomers of trifloxystrobin (CGA 357262, CGA 357261 and CGA 331409) were not analysed in this study, so only the existing plant residue 217efinitione for monitoring can be followed (Reg. (EU) 2019/1791).</p> <p>However taking into the results of studies 15-2033, 14-2025 and 15-2032 (submitted by Applicant) the conversion factor (from monitoring to risk assessment) of 1.3 for currant, based on currant trials including isomer analysis, has been calculated by iRMS Greece (DRR – Part B7 for 102000012886 / fluopyram + trifloxystrobin SC 500 (250 + 250 g/L), 12.02.2021).</p>
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Reference:	KCA 6.3.5.1/02
Title:	Amendment no. 1 to report no: PTZ-NLI-11796 – Residues of fluopyram + trifloxystrobin in red currant under plastic umbrella at intervals following two foliar applications of fluopyram & trifloxystrobin SC 500
Report:	Oostingh, C.; 2013; PTZ-NLI-11796; M-434301-02-1
Authority registration No:	
Guideline(s):	<p>EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8;</p> <p>Residues in or on Treated Products, Food and Feed; EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)</p> <p>OECD Guideline for testing of Chemicals; Residues in rotational crops (limited field studies), No. 504, 8 Jan. 2007</p> <p>US EPA OCSPP Guideline No. 860.1500</p>
Deviations:	Not specified
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on currants with application rates of 200 g/ha trifloxystrobin and 1000 L water per ha. The applications were done with a spray interval of 7 days, covering the PHI of 7 days.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Although only trifloxystrobin and GA 321113 were analysed, total residue (sum of trifloxystrobin, its isomers, and metabolite CGA 321113) was calculated with conversion factor (from monitoring to risk assessment) of 1.3 for currant, which is based on currant trials including isomer analysis (indoor and southern European trials summarized further below).

Table A 33: Summary of the study PTZ-NLI-11796 trials – GAP summary

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)
11796-1 Netherlands NL-1617 KZ Westwoud Europe, North F 2011	Currant, red Rovada	1) 2005 2) 05.2011 3) 20.07.2011 - 10.08.2011	200 200	1000 1000	20.0 20.0	18.07.2011/0 25.07.2011/7	87	(g) PTZ-NLI-11796 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying grown under plastic umbrella

- | | |
|---|--------------------------|
| - (a) According to CODEX Classification / Guide | - (g) Study reference |
| - (b) Only if relevant | - (h) Formulation type |
| - (c) Year must be indicated | - (i) Application method |
| - (d) Either growth stage description or BBCH Code | - (j) Method information |
| - (e) Days after last application (Label pre-harvest interval, PHI, underline) | - (k) LOQ |
| - (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included | - (l) Method validation |
| - (m) Storage (max) | |
| - G greenhouse F field | |

Analytical part of study PTZ-NLI-11796

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 321113 (determined as CGA 321113, calculated as CGA 321113)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 321113 as CGA 321113		Total residue calc. (CF 1.3)		
11796-1	Currant, red Rovada	fruit	87	0.46	<0.01	Not analysed for CGA 357261, CGA 357262, CGA 331409. Total residue calculated with conversion factor (from monitoring to risk assessment) of 1.3 for currant, which is based on currant trials including isomer analysis	0.60	0*	(g) PTZ-NLI-11796 (j) Analytical method: 01207 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01207 and residue study PTZ-NLI-11796 (m) Storage: Analyte 1, 2 fruit: 123! Days *prior to last treatment
Netherlands			87	0.56	<0.01		0.73	0	
NL-1617 KZ			87	0.45	<0.01		0.59	1	
Westwoud			87	0.36	<0.01		0.47	3	
Europe, North			87	0.26	<0.01		0.34	7	
F			87	0.27	<0.01		0.35	14	
2011			89	0.31	<0.01		0.40	21	

A 2.1.3.5.3 Study BCS-G402-11 (Currant, northern Europe)

Comments of zRMS:	<p>The study summarised below in currant was already evaluated in EFSA Journal 2018;16(1):5154 but is submitted again because of that the total residue for risk assessment was not taken into account in the evaluation by EFSA (EFSA, 2018). <u>In this study only the residues of trifloxystrobin and the CGA 321113 metabolite were determined.</u></p> <p>One trial was conducted in N-EU (Belgium) during the 2011 season to determine the magnitude of trifloxystrobin (CGA 279202) and its metabolite CGA 321113 in/on red currant (fruit) under plastic umbrella after two spraying applications with 0.2 kg/ha trifloxystrobin with 7 days between applications at BBCH 81-87 and with PHI of 7 days. Residues of trifloxystrobin and its metabolites were determined by HPLCMS/MS according to method BCS 01207.</p> <p>The LOQ for all compounds was 0.01 mg/kg mg/kg for red currant fruits.</p> <p>The residue level of trifloxystrobin was 0.77 mg/kg at the intended PHI of 7 days in fruit samples. The residue level of metabolite CGA 321113 was below LOQ in all fruit samples.</p> <p>The storage period of deep-frozen samples for trifloxystrobin and its metabolite ranged between 160 and 186 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p> <p><u>Remarks:</u></p> <p>The 3 isomers of trifloxystrobin (CGA 357262, CGA 357261 and CGA 331409) were not analysed in this study, so only the existing plant residue 221efinitione for monitoring can be followed (Reg. (EU) 2019/1791).</p> <p>However taking into the results of studies 15-2033, 14-2025 and 15-2032 (submitted by Applicant) the conversion factor (from monitoring to risk assessment) of 1.3 for currant, based on currant trials including isomer analysis, has been calculated by iRMS Greece (DRR – Part B7 for 102000012886 / fluopyram + trifloxystrobin SC 500 (250 + 250 g/L), 12.02.2021).</p>
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Reference:	KCA 6.3.5.1/03
Title:	Residues of fluopyram and trifloxystrobin in red currant under plastic umbrella at intervals following two foliar applications of FLU+TFS 500 SC – Belgium, season 2011
Report:	Loriau, P. ; 2012 ; BCS-G402-11 ; M-433738-01-1
Authority registration No:	
Guideline(s):	<p>EC Guideline SANCO 1607NI/97 rev.2, 10.06.99: 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 and Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market – Appendix B: EC Guideline SANCO 7029NI/95 rev.5, 22/07/97 General recommendations for the design, preparation and realization of residue trial – Appendix D: EC Guideline SANCO 7525NI/95 rev.9, March 2011 Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs.</p> <p>FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials, Rome 1990</p> <p>other appropriate SOP's or OECD Guidelines</p> <p>US EPA OCSPP Guideline Number 860.1500</p>
Deviations:	Not specified
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on currant with application rates of

about 200 g/ha trifloxystrobin and 927-953 L water per ha. The applications were done with a spray interval of 7 days, covering the PHI of 7 days.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Although only trifloxystrobin and GA 321113 were analysed, total residue (sum of trifloxystrobin, its isomers, and metabolite CGA 321113) was calculated with conversion factor (from monitoring to risk assessment) of 1.3 for currant, which is based on currant trials including isomer analysis (indoor and southern European trials summarized further below).

Table A 34: Summary of the study BCS-G402-11 trials – GAP summary

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)
G402-11F-1 Belgium 1360 Perwez Europe, North F 2011	Currant, red Rosetta	3) - 06.2011	206 212	927 953	22.2 22.3	03.06.2011/0 10.06.2011/7	81 – 85	(g) BCS-G402-11 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying Date of planting: before 2008, grown under plastic umbrella

- | | |
|---|--------------------------|
| - (a) According to CODEX Classification / Guide | - (g) Study reference |
| - (b) Only if relevant | - (h) Formulation type |
| - (c) Year must be indicated | - (i) Application method |
| - (d) Either growth stage description or BBCH Code | - (j) Method information |
| - (e) Days after last application (Label pre-harvest interval, PHI, underline) | - (k) LOQ |
| - (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included | - (l) Method validation |
| - (m) Storage (max) | |
| - G greenhouse F field | |

Analytical part of study BCS-G402-11

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 321113 (determined as CGA 321113, calculated as CGA 321113)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 321113 as CGA 321113		Total residue calc. (CF 1.3)		
G402-11F-1 Belgium 1360 Perwez Europe, North F 2011	Currant, red Rosetta	fruit	BBCH:81-85 BBCH:81-85 85 85 BBCH:85-87 87 87	0.71 1.5 1.3 1.1 0.77 0.58 0.51	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	Not analysed for CGA 357261, CGA 357262, CGA 331409. Total residue calculated with conversion factor (from monitoring to risk assessment) of 1.3 for currant, which is based on currant trials including isomer analysis	0.92 1.9 1.7 1.4 1.0 0.75 0.66	0* 0 1 3 7 14 21	(g) BCS-G402-11 (j) Analytical method: 01207 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01207 and residue study BCS-G402-11 (m) Storage: Analyte 1, 2 fruit: 181! Days * prior to last treatment.

A 2.1.3.5.4 Study 15-2033 (Currant, southern Europe)

Comments of zRMS:	The study summarised below was already evaluated in EFSA Journal 2018;16(1):5154, but is submitted again, including the total residue for risk assessment, since this was not taken into account in this EFSA evaluation of 2018. This study has not been reevaluated by zRMS – Poland because this study was conducted in southern France and Spain. However, taking into the results of studies 15-2033, 14-2025 and 15-2032 the conversion factor (from monitoring to risk assessment) of 1.3 for currant, based on currant trials including isomer analysis, has been calculated by iRMS Greece.
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Reference:	KCA 6.3.5.1/04
Title:	Determination of the residues of fluopyram and trifloxystrobin in/on red and black currant after spray application of AE C656948 & CGA 279202 SC 500 in southern France and Spain
Report:	Szeley, C. M.; Sadler, C.; 2016; 15-2033; M-553894-01-1
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:	yes, see report
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on currant with application rates of 200 g/ha trifloxystrobin and 500-800 L water per ha. The applications were done with a spray interval of about 7 days (6-7), covering the PHI of 7 days.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Table A 35: Summary of the study 15-2033 trials – GAP summary

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)
15-2033-01 15-2033-01-T France, south 34590 Marsillargues Europe, South F 2015	Currant, red Junifer	1) 04.2012 2) 06.04.2015 - 17.04.2015 3) 04.06.2015	200 200	800 800	25 25	25.05.2015/0 01.06.2015/7	85	(g) 15-2033 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
15-2033-02 15-2033-02-T France, south 69220 Lancia Europe, South F 2015	Currant, black Noir de Bourgogne	1) 2006 2) 17.04.2015 - 24.04.2015 3) 30.06.2015	200 200	500 500	40 40	19.06.2015/0 26.06.2015/7	87	(g) 15-2033 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
15-2033-03 15-2033-03-T Spain 33430 Carreño Europe, South F 2015	Currant, black Negra	1) 01.2012 2) 04.2015 3) 09.07.2015	200 200	700 700	29 29	30.06.2015/0 06.07.2015/6	87	(g) 15-2033 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
15-2033-04 15-2033-04-T Spain 10549 Guijo de Santa Barbara Europe, South F 2015	Currant, red Rovada	1) 02.2012 2) 04.2015 3) 25.06.2015	200 200	700 700	29 29	16.06.2015/0 22.06.2015/6	87	(g) 15-2033 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying

- ### Analytical part of study 15-2033

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)							PHI (days)	Details on trial
				Analyte 1 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
	(a)		(d)								(e)	(f)
15-2033-01 15-2033-01-T France, south 34590 Marsillargues Europe, South F 2015	Currant, red Junifer	fruit	85 85 85 87 87 87	2.2 2.9 3.7 2.3 2.1 1.0	0.076 0.085 0.10 0.078 0.12 0.077	0.020 0.025 0.031 0.021 0.035 0.027	0.039 0.044 0.050 0.041 0.064 0.047	<0.01 <0.01 <0.01 <0.01 <0.01 0.012	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	2.3 3.1 3.9 2.5 2.3 1.2	0* 0 1 3 3 14	(g) 15-2033 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 14-2025 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 231 days * prior to last treatment
15-2033-02 15-2033-02-T France, south 69220 Lancia Europe, South F 2015	Currant, black Noir de Bourgogne	fruit	87 87 87 89 89 89	0.38 1.2 0.98 0.87 0.46 0.46	0.034 0.044 0.053 0.065 0.062 0.079	0.010 0.013 0.015 0.018 0.018 0.025	0.016 0.023 0.027 0.034 0.033 0.042	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.45 1.3 1.1 1.0 0.58 0.62	0* 0 1 3 3 14	(g) 15-2033 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 14-2025 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 206 days * prior to last treatment

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
15-2033-03 15-2033-03-T Spain 33430 Carreño Europe, South F 2015	Currant, black Negra	fruit	87 87 87 89 89 89	0.23 0.56 0.48 0.30 0.29 0.24	0.025 0.022 0.023 0.018 0.024 0.030	<0.01 <0.01 <0.01 <0.01 <0.01 0.010	0.012 0.011 0.011 <0.01 0.014 0.017	<0.01 <0.01 <0.01 <0.01 <0.01 0.010	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.29 0.61 0.53 0.35 0.35 0.31	0* 0 1 3 7 14	(g) 15-2033 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 14-2025 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 196 days * prior to last treatment
15-2033-04 15-2033-04-T Spain 10549 Guijo de Santa Barbara Europe, South F 2015	Currant, red Rovada	fruit	87 87 87 87 89	0.13 0.30 0.23 0.15 0.14 0.060	<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 <0.01 <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 <0.01 <0.01	0.17 0.34 0.27 0.19 0.18 0.10	0* 0 1 3 7 16	(g) 15-2033 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 14-2025 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 210 days * prior to last treatment start of flowering. End of April

A 2.1.3.5.5 Study 14-2025 (Currant, indoor)

Comments of zRMS:	<p>The study in red and black currant after spray application of fluopyram & trifloxystrobin SC 500 in the greenhouse in Italy has been already evaluated in the EFSA Journal 2018;16(1):5154 but has been reevaluated by iRMS Greece on 12.02.2021 (DRR – Part B7 for 102000012886 / fluopyram + trifloxystrobin SC 500 (250 + 250 g/L)), including the total residue for risk assessment not included in EFSA assessment (EFSA, 2018). Residues of trifloxystrobin were between 0.31 and 0.35 mg/kg at the intended PHI of 7-8 days in fruit samples.</p> <p>Taking into the results of studies 15-2033, 14-2025 and 15-2032 the conversion factor (from monitoring to risk assessment) of 1.3 for currant, based on currant trials including isomer analysis, has been calculated by iRMS Greece.</p>
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Reference:	KCA 6.3.5.1/06
Title:	Determination of the residues of fluopyram and trifloxystrobin in/on red and black currant after spray application of fluopyram & trifloxystrobin SC 500 in the greenhouse in Italy
Report:	Bellof, S.; 2015; 14-2025; M-535114-03-1
Authority registration No:	
Guideline(s):	<p>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</p> <p>OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)</p> <p>US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial</p>
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on currant with application rates of 200 g/ha trifloxystrobin and 700 L water per ha. The applications were done with a spray interval of about 7 days, and with samplings covering a PHI of 7 days.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Table A 36: Summary of the study 14-2025 trials – GAP summary

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)
14-2025-01 14-2025-01-T Italy 38057 Azienda Agricola Petra Oss / Pergine Val Sugana Europe, South G 2014	Currant, red Rovada	1) 2008 2) 10.04.2014 - 28.04.2014 3) 04.07.2014 - 16.07.2014	200 200	700 700	28.6 28.6	24.06.2014/0 01.07.2014/7	87	(g) 14-2025 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
14-2025-02 14-2025-02-T Italy 37134 Berry plant / Verona Europe, South G 2014	Currant, black Titania	1) 2010 2) 02.04.2014 - 18.04.2014 3) 09.06.2014 - 21.06.2014	200 200	700 700	28.6 28.6	31.05.2014/0 06.06.2014/6	85	(g) 14-2025 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying

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|---|--------------------------|
| - (a) According to CODEX Classification / Guide | - (g) Study reference |
| - (b) Only if relevant | - (h) Formulation type |
| - (c) Year must be indicated | - (i) Application method |
| - (d) Either growth stage description or BBCH Code | - (j) Method information |
| - (e) Days after last application (Label pre-harvest interval, PHI, underline) | - (k) LOQ |
| - (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included | - (l) Method validation |
| - (m) Storage (max) | |
| - G greenhouse F field | |

Analytical part of study 14-2025

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)							PHI (days)	Details on trial
				Analyte 1 trifloxystrobin as trifloxystrobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
14-2025-01 14-2025-01-T Italy 38057 Azienda Agricola Petra Oss / Pergine Val Sugana Europe, South G 2014	Currant, red Rovada	fruit	87 87 87 87 89 89	0.33 0.57 0.31 0.20 0.31 0.25	0.012 0.016 0.010 <0.01 0.014 0.018	<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 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.37 0.62 0.35 0.24 0.35 0.30	0* 0 1 3 8 15	(g) 14-2025 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 14-2025 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 373 days * prior to last treatment
14-2025-02 14-2025-02-T Italy 37134 Berry plant / Verona Europe, South G 2014	Currant, black Titania	fruit	85 85 85 87 87 87	0.36 1.5 1.2 0.49 0.35 0.29	0.022 0.028 0.027 0.021 0.022 0.029	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.013 0.015 0.015 0.012 0.012 0.019	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.42 1.6 1.3 0.54 0.40 0.36	0* 0 1 3 7 15	(g) 14-2025 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 14-2025 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 398 days * prior to last treatment

A 2.1.3.5.6 Study 15-2032 (Currant, indoor)

Comments of zRMS:	<p>The study in/on red and black currant after spray application of AE C656948 & CGA 279202 SC 500 in the greenhouse in Northern France and Spain has been already evaluated in the EFSA Journal 2018;16(1):5154 but has been reevaluated by iRMS Greece on 12.02.2021 (DRR – Part B7 for 102000012886 / fluopyram + trifloxystrobin SC 500 (250 + 250 g/L)), including the total residue for risk assessment not included in EFSA assessment (EFSA, 2018).</p> <p>Residues of trifloxystrobin were between 0.15 and 0.51 mg/kg at the intended PHI of 7-14 days in fruit samples.</p> <p>Taking into the results of studies 15-2033, 14-2025 and 15-2032 the conversion factor (from monitoring to risk assessment) of 1.3 for currant, based on currant trials including isomer analysis, has been calculated by iRMS Greece.</p>
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Reference:	KCA 6.3.5.1/07
Title:	Determination of the residues of fluopyram and trifloxystrobin in/on red and black currant after spray application of AE C656948 & CGA 279202 SC 500 in the greenhouse in Northern France and Spain
Report:	Szeley, C. M.; Effertz, C.; 2016; 15-2032; M-557440-01-2
Authority registration No:	
Guideline(s):	<p>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</p> <p>OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)</p> <p>US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial</p>
Deviations:	Yes, (see report)
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on currant with application rates of 200 g/ha trifloxystrobin and 500-1000 L water per ha. The applications were done with a spray interval of about 7 days (6-8), and with samplings covering a PHI of 7 days.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Table A 37: Summary of the study 15-2032 trials – GAP summary

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)
15-2032-01 15-2032-01-T France, north 60400 Mondescourt Europe, North G 2015	Currant, red Rovada	1) 2006 2) 01.05.2015 - 25.05.2015 3) 10.07.2015	200 200	500 500	40.0 40.0	29.06.2015/0 06.07.2015/7	85	(g) 15-2032 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
15-2032-02 15-2032-02-T France, north 02300 Ugné le Gay Europe, North G 2015	Currant, red Rovada	1) 2003 2) 28.04.2015 - 20.05.2015 3) 10.07.2015 - 20.07.2015	200 200	500 500	40.0 40.0	06.07.2015/0 13.07.2015/7	85	(g) 15-2032 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
15-2032-03 15-2032-03-T Spain 33430 Carreño Europe, South G 2015	Currant, black Negra	1) 01.2012 2) 15.04.2015 3) 09.07.2015	200 200	700 700	28.6 28.6	30.06.2015/0 06.07.2015/6	87	(g) 15-2032 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
15-2032-04 15-2032-04-T Spain 10549 Guijo de Santa Barbara Europe, South G 2015	Currant, red Rovada	1) 02.2012 2) 30.04.2015 3) 30.07.2015	200 200	1000 1000	20.0 20.0	20.07.2015/0 28.07.2015/8	87	(g) 15-2032 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying

- | | |
|--|--------------------------|
| - (a) According to CODEX Classification / Guide | - (g) Study reference |
| - (b) Only if relevant | - (h) Formulation type |
| - (c) Year must be indicated | - (i) Application method |
| - (d) Either growth stage description or BBCH Code | - (j) Method information |
| - (e) Days after last application (Label pre-harvest interval, PHI, underline) | - (k) LOQ |
| - (f) Remarks may include: Climatic conditions; Reference to analytical method and | - (l) Method validation |

- information which metabolites are included
- (m) Storage (max)
 - G greenhouse F field

Analytical part of study 15-2032

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

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 trifloxystrobin as trifloxystrobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
15-2032-01	Currant, red Rovada	fruit	85	0.28	<0.01	<0.01	<0.01	<0.01	<0.01	0.32	0*	(g) 15-2032 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 14-2025 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 189 days * prior to last treatment
15-2032-01-T			85	0.58	<0.01	<0.01	<0.01	<0.01	<0.01	0.62	0	
France, north			85	0.57	0.011	<0.01	<0.01	<0.01	<0.01	0.61	1	
60400			87	0.19	<0.01	<0.01	<0.01	<0.01	<0.01	0.23	3	
Mondescourt			87	0.34	<0.01	<0.01	<0.01	<0.01	<0.01	0.38	7	
Europe, North G 2015			89	0.51	0.016	<0.01	0.011	<0.01	<0.01	0.56	14	
15-2032-02	Currant, red Rovada	fruit	85	0.26	<0.01	<0.01	<0.01	<0.01	<0.01	0.30	0*	(g) 15-2032 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 14-2025 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 182 days * prior to last treatment
15-2032-02-T			85	0.55	<0.01	<0.01	<0.01	<0.01	<0.01	0.59	0	
France, north			85	0.39	<0.01	<0.01	<0.01	<0.01	<0.01	0.43	1	
02300 Ugny le			87	0.35	<0.01	<0.01	<0.01	<0.01	<0.01	0.39	3	
Gay			87	0.27	<0.01	<0.01	<0.01	<0.01	<0.01	0.31	7	
Europe, North G 2015			89	0.23	<0.01	<0.01	<0.01	<0.01	<0.01	0.27	14	

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 trifloxystrobin as trifloxystrobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
15-2032-03 15-2032-03-T Spain 33430 Carreño Europe, South G 2015	Currant, black Negra	fruit	87 87 87 89 89 89	0.45 0.86 0.68 0.34 0.36 0.022	<0.01 0.015 <0.01 <0.01 0.011 <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 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.49 0.94 0.72 0.38 0.40 0.062	0* 0 1 3 7 14	(g) 15-2032 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 14-2025 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 189 days * prior to last treatment
15-2032-04 15-2032-04-T Spain 10549 Guijo de Santa Barbara Europe, South G 2015	Currant, red Rovada	fruit	87 87 87 87 87	0.035 0.27 0.20 0.11 0.15 0.091	<0.01 <0.01 <0.01 <0.01 0.011 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 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.075 0.31 0.24 0.15 0.19 0.13	0* 0 1 3 7 14	(g) 15-2032 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 14-2025 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 fruit: 167 days * prior to last treatment

A 2.1.3.6 Celeriac

Table A 38: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA, 2014a, and EFSA 2016)	3	0.13 kg as/ha	-	-	14
Intended cGAP (Celeriac: 47, 48*)	2	0.125 kg as/ha	14 days	(up to BBCH 49)	14

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

According to SANCO 7525/VI/95, Rev. 10.3, extrapolation is possible for the other root and tuber vegetables group (including celeriac) via residue trials of carrot.

Therefore, carrot trials covering the critical GAP of celeriac are submitted and summarised below.

A 2.1.3.6.1 Study 16-2155 (Carrot [extrapolation to celeriac], northern Europe)

Comments of zRMS:	<p>Four trials were conducted in N-EU (France, Austria and Germany) during the 2016 season to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 as well as its metabolite CGA 321113 and CGA 373466 in/on carrot after two spraying applications with 0.1 kg/ha trifloxystrobin with 14 days between applications at BBCH 43-47 and with PHI of 14 days.</p> <p>Residues of trifloxystrobin and its isomers/metabolites were determined by HPLCMS/MS according to method 01313/M001.</p> <p>The LOQ for all compounds was 0.01 mg/kg for carrot.</p> <p>The residue levels of trifloxystrobin were: $3 \times < 0.01$ and 0.016 mg/kg.</p> <p>The residue levels of sum of trifloxystrobin, its isomers and metabolite CGA 321113 (5 analytes) were $3 \times < 0.05$ and 0.057 mg/kg.</p> <p>The storage period of deep-frozen samples for trifloxystrobin and its isomers and metabolite ranged between 116 and 175 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.6.1/01
Title:	Determination of residues of fluopyram and trifloxystrobin in/on carrots after spray application of fluopyram & trifloxystrobin SC 500 in Northern France, Austria and Germany
Report:	Semrau, J.; 2017; 16-2155; M-598289-01-1
Authority registration No:	
Guideline(s):	<p>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</p> <p>OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)</p> <p>US EPA OCSPP Guideline No. 860.1500</p>
Deviations:	None
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on carrot with application rates of

about 100 g/ha trifloxystrobin and 400-700 L water per ha. The applications were done with a spray interval of about 14 days, with the last application 14 days before the harvest.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Table A 39: Summary of the study 16-2155 trials – GAP summary

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)
16-2155-01 16-2155-01-T France, north 49650 Allones, / Maine-et-Loire Europe, North F 2016	Carrot Almaro F1	1) 15.06.2016 3) 02.09.2016	100 100	400 400	25.0 25.0	05.08.2016/0 19.08.2016/14	46	(g) 16-2155 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
16-2155-02 16-2155-02-T Austria 8141 Zettling, / Steiermark Europe, North F 2016	Carrot Jubila	1) 27.05.2016 3) 10.10.2016	100 100	700 700	14.3 14.3	12.09.2016/0 26.09.2016/14	48	(g) 16-2155 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
16-2155-03 16-2155-03-T Germany 27449 Kutenholz, / Niedersachsen Europe, North F 2016	Carrot Nautaise	1) 28.03.2016 3) 04.10.2016	100 105	600 633	16.7 16.6	06.09.2016/0 20.09.2016/14	48	(g) 16-2155 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
16-2155-04 16-2155-04-T Germany 68789 St. Leon- Rot, / Baden- Württemberg Europe, North F 2016	Carrot Romance	1) 10.06.2016 3) 28.09.2106	100 100	400 400	25.0 25.0	01.09.2016/0 14.09.2016/13	47	(g) 16-2155 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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)
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ

- (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
- (m) Storage (max)
- G greenhouse F field
- (l) Method validation

Analytical part of study 16-2155

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
16-2155-01 16-2155-01-T France, north 49650 Allones, / Maine-et-Loire Europe, North F 2016	Carrot Almaro F1	root	46 46 46 46 47 48	<0.01 0.014 0.027 <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 <0.01	<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 <0.01 <0.01 <0.01 <0.01 <0.01	<0.05 0.054 0.067 <0.05 <0.05 <0.05	0* 0 3 7 14 21	(g) 16-2155 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 16-2155 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 root: 175 days * prior to last treatment
16-2155-02 16-2155-02-T Austria 8141 Zettling, / Steiermark Europe, North F 2016	Carrot Jubila	root	48 48 48 49 49 49	0.011 0.019 0.011 0.025 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 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 0.011 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.051 0.059 0.051 0.065 0.057 <0.05	0* 0 3 7 14 21	(g) 16-2155 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 16-2155 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 root: 137 days * prior to last treatment
16-2155-03 16-2155-03-T Germany 27449 Kutenholz, / Niedersachsen Europe, North F 2016	Carrot Nautaise	root	48 48 48 49 49	<0.01 0.011 <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 <0.01 <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 <0.01 <0.01	<0.05 0.051 <0.05 <0.05 <0.05 <0.05	0* 0 3 8 14 23	(g) 16-2155 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 16-2155 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 root: 143 days * prior to last treatment

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
16-2155-04	Carrot Romance	root	46	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	0*	(g) 16-2155
16-2155-04-T			46	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	0	(j) Analytical method: 01313/M001
Germany			46	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	3	(k) LOQ: 0.01 mg/kg
68789 St. Leon- Rot, / Baden-			47	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	6	(l) Method Validation Data in method 01313/M001 and
Württemberg			48	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	14	residue study 16-2155
Europe, North F 2016			49	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	23	(m) Storage: Analyte 1, 2, 3, 4, 5, 6 root: 149 days * prior to last treatment

A 2.1.3.6.2 Study 18-2044 (Carrot [extrapolation to celeriac], northern Europe)

Comments of zRMS:	<p>Four trials were conducted in N-EU (Germany, The United Kingdom and Northern France) during the 2018 season to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 and its metabolite CGA 321113 and CGA 373466 in/on carrot after two spraying applications with 0.1 kg/ha or 0.125 kg/ha trifloxystrobin with 14-20 days between applications at BBCH 47-49 and with PHI of 14 days.</p> <p>Residues of trifloxystrobin and its isomers/metabolites were determined by HPLCMS/MS according to method 01313/M001.</p> <p>The LOQ for all compounds was 0.01 mg/kg for carrot.</p> <p>The residue levels of trifloxystrobin were: $3x < 0.01$ and 0.016 mg/kg.</p> <p>The residue levels of sum of trifloxystrobin, its isomers and metabolite CGA 321113 (5 analytes) were $3x < 0.05$ and 0.056 mg/kg.</p> <p>The storage period of deep-frozen samples for trifloxystrobin and its isomers and metabolite ranged between 186 and 312 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.6.1/02
Title:	Determination of the residues of trifloxystrobin and AE C656948 in/on carrot after spray application of AE C656948 & CGA279202 SC 500 in Germany, the United Kingdom and northern France
Report:	Braune, M. ; Cuesta-Pérez, J. ; 2020 ; 18-2044 ; M-682016-01-1
Authority registration No:	
Guideline(s):	<p>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</p> <p>OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)</p> <p>US EPA OCSPP 860.1500, Crop Field Trial</p>
Deviations:	None
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on carrot with application rates of about 100 or 125 g/ha trifloxystrobin and 291-606 L water per ha. The applications were done with a spray interval of about 14 days (20 days in one trial), with the last application 14 days before the harvest.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Table A 40: Summary of the study 18-2044 trials – GAP summary

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)
18-2044-01 18-2044-01-T Germany 51399 Burscheid Europe, North F 2018	Carrot Merida	1) 09.04.2018 3) 15.07.2018 - 31.07.2018	101 102	303 307	33.3 33.3	26.06.2018/0 10.07.2018/14	48	(g) 18-2044 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
18-2044-02 18-2044-02-T Germany 49456 Bakum OT Vestrup Europe, North F 2018	Carrot Elegance F1	1) 26.04.2018 3) 01.09.2018 - 30.11.2018	127 121	304 291	41.7 41.7	18.09.2018/0 03.10.2018/15	48	(g) 18-2044 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
18-2044-03 18-2044-03-T United Kingdom CB22 5EU Little Shelford, near Cambridge Europe, North F 2018	Carrot Nairobi	1) 23.05.2018 3) 03.09.2018 - 03.12.2018	125 128	300 307	41.7 41.7	04.09.2018/0 24.09.2018/20	49	(g) 18-2044 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
18-2044-04 18-2044-04-T France, north 37510 Saint Genouph Europe, North F 2018	Carrot Bolero F1	1) 02.04.2018 3) 15.06.2018 - 15.07.2018	101 101	606 606	16.6 16.6	08.06.2018/0 22.06.2018/14	47	(g) 18-2044 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ
- (l) Method validation

- information which metabolites are included
- (m) Storage (max)
 - G greenhouse F field

Analytical part of study 18-2044

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1-5)		
18-2044-01 18-2044-01-T Germany 51399 Burscheid Europe, North F 2018	Carrot Merida	root	48 48 49 49 49 49	<0.01 <0.01 0.015 <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 <0.01	<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 <0.01 <0.01 <0.01 <0.01 <0.01	<0.05 <0.05 0.055 <0.05 <0.05 <0.05	0* 0 3 7 14 21	(g) 18-2044 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 18-2044 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 root: 293 days * prior to last treatment
18-2044-02 18-2044-02-T Germany 49456 Bakum OT Vestrup Europe, North F 2018	Carrot Elegance F1	root	48 48 48 49 49 49	<0.01 0.011 0.010 0.017 0.016 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 <0.01 <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 <0.01 <0.01	<0.05 0.051 0.050 0.057 0.056 0.052	0* 0 3 7 14 22	(g) 18-2044 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 18-2044 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 root: 208 days * prior to last treatment
18-2044-03 18-2044-03-T United Kingdom CB22 5EU Little Shelford, near Cambridge Europe, North F 2018	Carrot Nairobi	root	49 49 49 49 49 49	<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 <0.01 <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 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.05 <0.05 <0.05 <0.05 <0.05 <0.05	0* 0 3 7 14 22	(g) 18-2044 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 18-2044 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 root: 218 days * prior to last treatment

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1-5)		
18-2044-04	Carrot Bolero F1	root	47	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	0*	(g) 18-2044 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 18-2044 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 root: 312 days * prior to last treatment
18-2044-04-T			47	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	0	
France, north			47	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	3	
37510 Saint			47	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	7	
Genouph			49	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	14	
Europe, North F 2018			49	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	21	

A 2.1.3.7 Lettuce and other salad plants

Table A 41: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP (EFSA, 2014) indoor	3	0.2 kg as/ha			7
cGAP (EFSA, 2018) indoor	2	0.2 kg as/ha	7 days		7
Intended cGAP, N-EU (Lettuce : 161*)	2	0.2 kg as/ha	7 days	(up to BBCH 49)	7
Intended cGAP, N-EU (Cress, garden: 61, 62*, Endive, winter: 112, 113, 115, 116*, Lamb's lettuce: 143, 145, 146*, Lettuce: 147, 149, 151, 155-157, 160, 164*, Radicchio: 189*, Rocket, salad: 206, 208, 209*, Sea lavender: 214, 215)	1	0.2 kg as/ha	-	(up to BBCH 49)	7

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

A 2.1.3.7.1 Study 14-2029 (Lettuce, northern Europe)

Comments of zRMS:	<p>Five trials were conducted in N-EU (Belgium, The Netherlands, France and Germany) during the 2014 season to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 and its metabolite CGA 321113 and CGA 373466 in/on lettuce (open leaf variety) after two spraying applications with 0.2 kg/ha trifloxystrobin with 7 days between applications at BBCH 47-49 and with PHI of 7 days.</p> <p>Residues of trifloxystrobin and its isomers/metabolites were determined by HPLCMS/MS according to method 01313/M001.</p> <p>The LOQ for all compounds was 0.01 mg/kg for lettuce.</p> <p>The residue levels of trifloxystrobin were: 0.16, 2x0.77, 1.0 and 1.5 mg/kg.</p> <p>The residue levels of sum of trifloxystrobin, its isomers and metabolite CGA 321113 (5 analytes) were 0.2, 0.88, 0.9, 1.2 and 1.8 mg/kg.</p> <p>The storage period of deep-frozen samples for trifloxystrobin and its isomers and metabolite ranged between 331 and 371 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.9.1/05
Title:	Determination of the residues of fluopyram and trifloxystrobin in/on lettuce after spray application of fluopyram & trifloxystrobin SC 500 in Belgium, Germany, the Netherlands and northern France
Report:	Schulte, G.; Sosniak, A.; 2015; 14-2029; M-534202-01-1
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:	not specified
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on lettuce (loose leaf varieties) with application rates of 200 g/ha trifloxystrobin and 300-900 L water per ha. The applications were done with a spray interval of 7 days, with the last application 7 days before the harvest.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Table A 42: **Summary of the study 14-2029 trials – GAP summary**

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			
14-2029-01 14-2029-01-T Belgium 6210 Villers- Perwin Europe, North F 2014	Lettuce Sansula; Oakleaf variety	1) 20.05.2014 3) 05.07.2014 - 14.07.2014	200 200	900 900	22 22	23.06.2014/0 30.06.2014/7	48	(g) 14-2029 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
14-2029-02 14-2029-02-T Germany 67125 Dannstadt- Schauernheim Europe, North F 2014	Lettuce Cavernet; Lollo Rosso	1) 13.05.2014 3) 20.06.2014 - 04.07.2014	200 200	600 600	33 33	10.06.2014/0 17.06.2014/7	47	(g) 14-2029 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
14-2029-03 14-2029-03-T Netherlands 1681 ND Zwaagdijk Europe, North F 2014	Lettuce Loka; Lollo Rossa	1) 22.05.2014 3) 29.06.2014 - 06.07.2014	200 200	500 500	40 40	17.06.2014/0 24.06.2014/7	46	(g) 14-2029 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
14-2029-04 14-2029-04-T France, north 37130 Lignières de Touraine Europe, North F 2014	Lettuce Kiribati; Loose leaf variety (oak leaf)	1) 15.05.2014 3) 20.06.2014 - 10.07.2014	200 200	600 600	33 33	13.06.2014/0 20.06.2014/7	48	(g) 14-2029 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying

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)
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)
14-2029-05 14-2029-05-T Germany 42799 Leichlingen Europe, North F 2014	Lettuce Aleppo; Lollo bionda	1) 28.04.2014 3) 10.06.2014 - 20.06.2014	200 200	300 300	68 68	28.05.2014/0 04.06.2014/7	47	(g) 14-2029 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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
- (m) Storage (max)
- G greenhouse F field
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ
- (l) Method validation

Analytical part of study 14-2029

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

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 trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1-5)		
14-2029-01 14-2029-01-T Belgium 6210 Villers- Perwin Europe, North F 2014	Lettuce Sansula; Oakleaf variety	head	48 48 48 49 49	0.56 2.0 1.7 0.77 0.10	<0.01 0.015 0.019 0.011 <0.01	<0.01 <0.01 0.012 <0.01 <0.01	0.018 0.025 0.028 0.022 <0.01	0.058 0.15 0.099 0.066 0.018	<0.01 <0.01 <0.01 <0.01 <0.01	0.66 2.2 1.9 0.88 0.15	0* 0 3 7 14	(g) 14-2029 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2144 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 head: 345 days
14-2029-02 14-2029-02-T Germany 67125 Dannstadt- Schauernheim Europe, North F 2014	Lettuce Cavernet; Lollo Roso	head	47 47 47 48 49	0.54 2.4 1.6 1.0 0.18	0.026 0.042 0.048 0.048 <0.01	0.012 0.018 0.020 0.021 <0.01	0.026 0.036 0.041 0.041 0.014	0.079 0.099 0.099 0.12 0.044	0.016 0.018 0.023 0.024 <0.01	0.69 2.6 1.8 1.2 0.26	0* 0 3 7 14	(g) 14-2029 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2144 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 head: 358 days * prior to last treatment
14-2029-03 14-2029-03-T Netherlands 1681 ND Zwaagdijk Europe, North F 2014	Lettuce Loka; Lollo Rossa	head	46 46 48 49 49	2.6 8.6 3.5 1.5 0.18	0.050 0.066 0.056 0.025 <0.01	0.016 0.023 0.016 <0.01 <0.01	0.036 0.048 0.049 0.032 <0.01	0.17 0.17 0.33 0.23 0.063	0.024 0.024 0.036 0.021 <0.01	2.9 8.9 4.0 1.8 0.28	0* 0 3 7 14	(g) 14-2029 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2144 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 head: 351 days * prior to last treatment

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 trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1-5)		
14-2029-04 14-2029-04-T France, north 37130 Lignières de Touraine Europe, North F 2014	Lettuce Kiribati; Loose leaf variety (oak leaf)	head	48 48 49 49 49	1.2 5.8 2.6 0.16 <0.01	0.019 0.042 0.038 <0.01 <0.01	0.010 0.019 0.017 <0.01 <0.01	0.023 0.041 0.036 <0.01 <0.01	0.034 0.069 0.029 0.010 <0.01	<0.01 0.016 <0.01 <0.01 <0.01	1.3 6.0 2.7 0.20 <0.05	0* 0 3 7 14	(g) 14-2029 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2144 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 head: 355 days * prior to last treatment
14-2029-05 14-2029-05-T Germany 42799 Leichlingen Europe, North F 2014	Lettuce Aleppo; Lollo bionda	head	47 47 48 49 49	1.7 5.3 3.1 0.77 0.12	0.042 0.049 0.055 0.023 <0.01	0.014 0.017 0.019 <0.01 <0.01	0.025 0.035 0.042 0.021 <0.01	0.079 0.10 0.099 0.072 0.015	0.014 0.019 0.021 <0.01 <0.01	1.9 5.5 3.3 0.90 0.17	0* 0 3 7 14	(g) 14-2029 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2144 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 head: 371 days * prior to last treatment

A 2.1.3.7.2 Study 14-2184 (Lettuce, northern Europe)

Comments of zRMS:	<p>Four trials were conducted in N-EU (Germany, the Netherlands, Hungary and the United Kingdom) during the 2014 season to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 and its metabolite CGA 321113 and CGA 373466 in/on lettuce (open leaf variety) after two spraying applications with 0.2 kg/ha trifloxystrobin with 7-9 days between applications at BBCH 42-49 and with PHI of 7-8 days.</p> <p>Residues of trifloxystrobin and its isomers/metabolites were determined by HPLCMS/MS according to method 01313/M001.</p> <p>The LOQ for all compounds was 0.01 mg/kg for lettuce.</p> <p>The residue levels of trifloxystrobin were: 0.036, 0.24, 0.28, 1.2 mg/kg.</p> <p>The residue levels of sum of trifloxystrobin, its isomers and metabolite CGA 321113 (5 analytes) were 0.076, 0.34, 0.35 and 1.3 mg/kg.</p> <p>The storage period of deep-frozen samples for trifloxystrobin and its isomers and metabolite ranged between 234 and 348 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.9.1/06
Title:	Determination of the residues of fluopyram and trifloxystrobin in/on lettuce after spray application of fluopyram & trifloxystrobin SC 500 in Germany, the Netherlands, Hungary and the United Kingdom
Report:	Bellof, S.; Kuester, S.; 2015; 14-2184; M-536965-01-1
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):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on lettuce (loose leaf varieties) with application rates of 200 g/ha trifloxystrobin and 350-500 L water per ha. The applications were done with a spray interval of about 7 days, with the last application 7 day before the harvest.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean values in the range 70-110%. All RSD values were below 20%.

Table A 43: Summary of the study 14-2184 trials – GAP summary

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)
14-2184-01 14-2184-01-T Germany 16816 Neuruppin Europe, North F 2014	Lettuce Lollo Rosso; open leaf variety	1) 30.08.2014 3) 10.10.2014 - 25.10.2014	200 200	500 500	40 40	01.10.2014/0 10.10.2014/9	41	(g) 14-2184 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
14-2184-02 14-2184-02-T Netherlands 9414 VL Hooghalen Europe, North F 2014	Lettuce Smile; open leaf variety	1) 10.07.2014 3) 25.08.2014 - 08.09.2014	200 200	400 400	50 50	18.08.2014/0 25.08.2014/7	49	(g) 14-2184 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
14-2184-03 14-2184-03-T Hungary 4400 Nyiregyhaza Europe, North F 2014	Lettuce Linaro RZ; open leaf variety	1) 25.06.2014 3) 22.07.2014 - 29.07.2014	200 200	500 500	40 40	08.07.2014/0 15.07.2014/7	47	(g) 14-2184 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
14-2184-04 14-2184-04-T United Kingdom OX15 6EP Banbury Europe, North F 2014	Lettuce Anaconda; open leaf variety	1) 29.04.2014 3) 10.07.2014 - 20.07.2014	200 200	350 350	58 58	25.06.2014/0 03.07.2014/8	46	(g) 14-2184 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying

- | | |
|--|--------------------------|
| - (a) According to CODEX Classification / Guide | - (g) Study reference |
| - (b) Only if relevant | - (h) Formulation type |
| - (c) Year must be indicated | - (i) Application method |
| - (d) Either growth stage description or BBCH Code | - (j) Method information |
| - (e) Days after last application (Label pre-harvest interval, PHI, underline) | - (k) LOQ |
| - (f) Remarks may include: Climatic conditions; Reference to analytical method and | - (l) Method validation |

information which metabolites are included

- (m) Storage (max)
- G greenhouse F field

Analytical part of study 14-2184

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)							PHI (days)	Details on trial
				Analyte 1 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1-5)		
14-2184-01 14-2184-01-T Germany 16816 Neuruppin Europe, North F 2014	Lettuce Lollo Rosso; open leaf variety	head	42 42 42 42 43	1.2 0.56 0.21 0.036 0.028	<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 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	1.2 0.60 0.25 0.076 0.068	0* 0 3 8 15	(g) 14-2184 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2144 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 head: 249 days
14-2184-02 14-2184-02-T Netherlands 9414 VL Hooghalen Europe, North F 2014	Lettuce Smile; open leaf variety	head	49 49 49 49 49	0.54 3.0 2.9 1.2 0.51	0.011 0.020 0.039 0.021 0.010	<0.01 0.012 0.015 <0.01 <0.01	0.013 0.017 0.038 0.023 0.014	0.063 0.10 0.13 0.075 0.043	<0.01 <0.01 0.018 <0.01 <0.01	0.64 3.2 3.1 1.3 0.59	0* 0 3 7 14	(g) 14-2184 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2144 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 head: 295 days
14-2184-03 14-2184-03-T Hungary 4400 Nyiregyhaza Europe, North F 2014	Lettuce Linaro RZ; open leaf variety	head	47 47 47 49 49	0.023 4.6 2.0 0.24 0.037	<0.01 0.036 0.034 <0.01 <0.01	<0.01 0.010 0.011 <0.01 <0.01	<0.01 0.028 0.031 <0.01 <0.01	0.061 0.16 0.13 0.080 0.020	<0.01 0.019 0.033 <0.01 <0.01	0.12 4.8 2.2 0.35 0.088	0* 0 3 7 13	(g) 14-2184 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: 14-2144 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 head: 336 days

[illegible]

A 2.1.3.8 Chicory witloof

Table A 44: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA, 2014a)	3	0.125 kg as/ha			21 (field)
Intended cGAP, N-EU (Chicory witloof: 51*)	1	0.150 – 0.200 kg as/ha	-	(up to BBCH 49)	21 (field)

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

Chicory witloof is treated in the field, the PHI is related to the harvest in the field. After harvest, the roots are stored for some time, before forcing them to produce the leaves for consumption.

A 2.1.3.8.1 Study 11-2140 (Chicory witloof, northern Europe)

Comments of zRMS:	<p>Four trials were conducted in N-EU (Germany, Belgium, France and Netherlands) during the 2011 season to determine the magnitude of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 and its metabolite CGA 321113 and CGA 373466 in/on chicory, witloof (leaf and root) after two spraying applications in the field with 0.16 – 0.2 kg/ha trifloxystrobin with 7-8 days between applications at BBCH 49 and with PHI of 21 days.</p> <p>Residues of trifloxystrobin and its isomers/metabolites were determined by LCMS/MS according to method 01313.</p> <p>The LOQ for all compounds was 0.01 mg/kg for leaf and root of chicory.</p> <p><u>Root:</u></p> <p>The residue levels of trifloxystrobin were: 0.012, 0.025, 0.028, 0.056 mg/kg.</p> <p>The residue levels of sum of trifloxystrobin, its isomers and metabolite CGA 321113 (5 analytes) were 0.052, 0.065, 0.069 and 0.098 mg/kg.</p> <p><u>Leaf:</u></p> <p>The residue levels of trifloxystrobin were: 4x<0.01 mg/kg.</p> <p>The residue levels of sum of trifloxystrobin, its isomers and metabolite CGA 321113 (5 analytes) were 4x<0.05 mg/kg.</p> <p>The storage period of deep-frozen samples for trifloxystrobin and its isomers and metabolite ranged between 319 and 372 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.10.1/01
Title:	Amendment No.1 – Determination of the residues of AE C656948 and trifloxystrobin in/on chicory, witloof after dip and spraying of fluopyram SC 500 and AE C656948 & CGA279202 SC 500 in the field and room, hall, store, etc. in Germany, Belgium, northern France and the Netherlands
Report:	Fargeix, G.; 2013; 11-2140; M-448916-02-1
Authority registration No:	
Guideline(s):	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8; Residues in or on Treated Products, Food and Feed; EC Guidance working document 7029/VI/95 rev.5 (1997-07-22); US EPA OCSPP Guideline No. 860.1500.SUPP
Deviations:	see page 16
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing

250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on chicory plants in the field with application rates of 160-200 g/ha trifloxystrobin and 300-350 L water per ha. The applications were done with a spray interval of about 7 days, with the last application 21 day before the harvest in the field. After harvest the roots were stored under cool conditions and later the roots were forced to produce the leaves for consumption.

Concurrent recoveries obtained during the conduct of this study were acceptable with overall mean value in the range 70-110%. All RSD values were below 20%.

Table A 45: Summary of the study 11-2140 trials – GAP summary

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)
11-2140-01 11-2140-01-T Germany 04886 Dautzschen Europe, North F 2011	Chicory, Witloof Omblin	0) 20.05.20 11 3) 15.10.2011 - 20.11.2011	160 160	300 300	53.3 53.3	16.09.2011/0 23.09.2011/7	49	(g) 11-2140 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
11-2140-02 11-2140-02-T Belgium 1450 Cortil- Noirmont Europe, North F 2011	Chicory, Witloof Atlas	0) 31.05.20 11 3) 13.10.2011 - 20.10.2011	200 200	350 350	57.1 57.1	15.09.2011/0 22.09.2011/7	46	(g) 11-2140 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
11-2140-03 11-2140-03-T France, north 80700 Goyencourt Europe, North F 2011	Chicory, Witloof Hermes	0) 29.04.20 11 3) 10.10.2011 - 20.10.2011	200 200	300 300	66.7 66.7	14.09.2011/0 21.09.2011/7	46	(g) 11-2140 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
11-2140-04 11-2140-04-T Netherlands 8322 NB, Urk Europe, North F 2011	Chicory, Witloof Topscore	0) 15.05.20 11 3) 01.11.2011 - 15.11.2011	200 200	300 300	66.7 66.7	13.10.2011/0 21.10.2011/8	47	(g) 11-2140 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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)
- G greenhouse F field

Analytical part of study 11-2140

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
11-2140-01 11-2140-01-T Germany 04886 Dautzschen Europe, North F 2011	Chicory, Witloof Omblin	root	49	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	<0.01 <0.01 <0.01	0.052 <0.05 <0.05	21 49 49	(g) 11-2140 (j) Analytical method: 01313 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313 and residue study 11-2140 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 root: 368 days Analyte 1, 2, 3, 4, 5, 6 leaf: 346 days
		leaf		<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.05 <0.05	49 49	leaf after forcing, 49 days after trifloxystrobin treatment in the field
11-2140-02 11-2140-02-T Belgium 1450 Cortil- Noirmont Europe, North F 2011	Chicory, Witloof Atlas	root	49	0.025 0.018 0.012	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 0.044 0.037	<0.01 <0.01 <0.01	0.065 0.094 0.080	21 49 49	(g) 11-2140 (j) Analytical method: 01313 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313 and residue study 11-2140 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 root: 369 days Analyte 1, 2, 3, 4, 5, 6 leaf: 347 days
		leaf		<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.05 <0.05	49 49	leaf after forcing, 49 days after trifloxystrobin treatment in the field

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 Trifloxy- strobins as trifloxy- strobins	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
11-2140-03 11-2140-03-T France, north 80700 Goyencourt Europe, North F 2011	Chicory, Witloof Hermes	root	49	0.056 0.017 0.019	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	0.012 0.017 0.014	<0.01 <0.01 <0.01	0.098 0.065 0.064	21 50 50	(g) 11-2140 (j) Analytical method: 01313 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313 and residue study 11-2140 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 root: 372 days Analyte 1, 2, 3, 4, 5, 6 leaf: 347 days
		leaf		<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.05 <0.05	50 50	leaf after forcing, 50 days after trifloxystrobin treatment in the field
11-2140-04 11-2140-04-T Netherlands 8322 NB, Urk Europe, North F 2011	Chicory, Witloof Topscore	root	49	0.028 0.018 0.020	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	0.011 0.024 0.031	<0.01 <0.01 <0.01	0.069 0.073 0.082	19 48 48	(g) 11-2140 (j) Analytical method: 01313 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313 and residue study 11-2140 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 root: 344 days Analyte 1, 2, 3, 4, 5, 6 leaf: 319 days
		leaf		<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.05 <0.05	48 48	leaf after forcing, 48 days after trifloxystrobin treatment in the field

A 2.1.3.9 Beans and peas (fresh) and pulses (dry)

Table A 46: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP bean with pods (EFSA, 2014)	2	0.2 kg as/ha	7 days		7
cGAP pea with pods N-EU (EFSA, 2018)	2	0.2 kg as/ha	7 days	(up to BBCH 79)	14
cGAP pea with pods S-EU (EFSA, 2018)	2	0.2 kg as/ha	7 days	(up to BBCH 89)	7
cGAP bean without pods and pea without pod N-EU (EFSA, 2018)	2	0.2 kg as/ha	7 days	(up to BBCH 79)	14
cGAP bean without pods and pea without pod S-EU (EFSA, 2018)	2	0.2 kg as/ha	7 days	(up to BBCH 89)	7
cGAP pulses S-EU (EFSA, 2018)	2	0.2 kg as/ha	7 days	(up to BBCH 89)	21

According to SANCO 7525/VI/95, Rev. 10.3, extrapolation is possible from bean to pea and vice versa.

The studies summarised below were already evaluated in EFSA Journal 2018;16(1):5154, but are submitted again, including the total residue for risk assessment, since this was not taken into account in this EFSA evaluation of 2018.

The cGAPs in this dRR are identical or less critical to the cGAPs already evaluated.

A 2.1.3.9.1 Study 10-2128 (Bean, northern Europe)

Comments of zRMS:	<p>The study summarised below in bean was already evaluated in EFSA Journal 2018;16(1):5154 but is submitted again because of that the total residue for risk assessment was not taken into account in the evaluation by EFSA (EFSA, 2018).</p> <p><u>In this study the residues of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 and its metabolite CGA 321113 and CGA 373466 were determined.</u></p> <p>Two trials were conducted in N-EU (France) during the 2010 season to determine the magnitude of trifloxystrobin (comprising trifloxystrobin, CGA 321113, CGA 357261, CGA 357262, CGA 331409 and CGA 373466) in/on a specific variety of kidney bean (pod and green seed) called flageolet, after two spray applications with 0.2 kg/ha trifloxystrobin with 7 days between applications at BBCH 76-77 and with PHI of 7 days for pod and 14 days for green seed.</p> <p>Residues of trifloxystrobin, stereo-isomers and metabolites were determined by HPLC-MS/MS according to method 01313.</p> <p>The Limit of Quantification (LOQ) defined as the lowest validated fortification level, was mg/kg for all analytes in/on the kidney bean matrices. The apparent residues in the control sample were below 30% of the LOQ. The average recoveries were within the acceptable range of 70 – 110%. The RSD values were below 20%.</p> <p>The residue levels of trifloxystrobin were 0.16 and 0.21 mg/kg at the intended PHI of 7 days in pod samples and were 0.02 and 0.04 mg/kg at the intended PHI of 14 days in green seed samples.</p> <p>The storage period of deep-frozen samples for trifloxystrobin (AG02) and its metabolites ranged between 346 and 379 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.11.1/01
Title:	Determination of the residues of AE C656948 and trifloxystrobin in/on bean, kidney after spraying of AE C656948 & CGA279202 SC 500 in the field in France (north)
Report:	Noss, G.; Guerleyen, N.; Ballmann, C.; 2012; 10-2128; M-425362-02-1
Authority registration No:	
Guideline(s):	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)
Deviations:	Not specified
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on beans with application rates of 200 g/ha trifloxystrobin and 300 L water per ha. The applications were done with a spray interval of 7 days. Pod (day 7) and green seed (day 14, 21, 28) were sampled.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%.

Table A 47: Summary of the study 10-2128 trials – GAP summary

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)
10-2128-01 10-2128-01-T France, north 27340 Criquebeuf sur Seine Europe, North F 2010	Bean, Kidney Flagrano, Flageolet	1) 02.06.2010 2) 21.07.2010 - 12.08.2010 3) 10.08.2010 - 20.08.2010	200 200	300 300	67 67	05.08.2010/0 12.08.2010/7	77	(g) 10-2128 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
10-2128-02 10-2128-02-T France, north 80700 Damery Europe, North F 2010	Bean, Kidney Flagrano, Flageolet	1) 02.06.2010 2) 20.07.2010 - 20.08.2010 3) 28.08.2010 - 02.09.2010	200 200	300 300	67 67	10.08.2010/0 17.08.2010/7	76	(g) 10-2128 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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
- (m) Storage (max)
- G greenhouse F field
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ
- (l) Method validation

Analytical part of study 10-2128

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
10-2128-01 10-2128-01-T France, north 27340 Criquebeuf sur Seine Europe, North F 2010	Bean, Kidney Flagrano, Flageolet	pod	77	0.12	<0.01	<0.01	<0.01	0.02	<0.01	0.17	0*	(g) 10-2128 (j) Analytical method: 01313 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01013 and residue study 10-2128 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 seed, green: 365 days Analyte 1, 2, 3, 4, 5, 6 pod: 379 days * prior to last treatment
			77	0.50	<0.01	<0.01	<0.01	0.02	<0.01	0.55	0	
			77	0.21	<0.01	<0.01	0.01	0.02	<0.01	0.26	7	
		seed, green	79	0.02	<0.01	<0.01	<0.01	<0.01	<0.01	0.06	14	
			82	0.01	<0.01	<0.01	<0.01	0.02	<0.01	0.06	21	
			85	<0.01	<0.01	<0.01	<0.01	0.02	<0.01	<0.05	28	
10-2128-02 10-2128-02-T France, north 80700 Damery Europe, North F 2010	Bean, Kidney Flagrano, Flageolet	pod	76	0.01	<0.01	<0.01	<0.01/0.01**	0.01	<0.01	0.05	0*	(g) 10-2128 (j) Analytical method: 01313 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01013 and residue study 10-2128 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 seed, green: 360 days Analyte 1, 2, 3, 4, 5, 6 pod: 374 days * prior to last treatment
			76	0.24	<0.01	<0.01	<0.01	0.01	<0.01	0.28	0	
			77	0.16	<0.01	<0.01	<0.01	0.03	<0.01	0.22	7	
		seed, green	89	0.04	<0.01	<0.01	<0.01/0.01**	0.02	<0.01	0.09	14	
			89	0.03	<0.01	<0.01	<0.01	0.03	<0.01	0.09	21	
			89	0.02	<0.01	<0.01	<0.01	0.03	<0.01	0.08	28	

A 2.1.3.9.2 Study 11-2000 (Pea, northern Europe)

Comments of zRMS:	<p>The study summarised below in bean was already evaluated in EFSA Journal 2018;16(1):5154 but is submitted again because of that the total residue for risk assessment was not taken into account in the evaluation by EFSA (EFSA, 2018). <u>In this study the residues of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 and its metabolite CGA 321113 and CGA 373466 were determined.</u></p> <p>Two trials were conducted in N-EU (northern France and Germany) during the 2011 season to determine the magnitude of trifloxystrobin (comprising trifloxystrobin, CGA 321113, CGA 357261, CGA 357262, CGA 331409 and CGA 373466) in/on in/on field pea (pod and dry seed), after two spray applications with 0.2 kg/ha trifloxystrobin with 7 days between applications at BBCH 81-87 and with PHI of 7 days for pod and 14 days for dry seed. Residues of trifloxystrobin, stereo-isomers and metabolites were determined by HPLC-MS/MS according to method 01313.</p> <p>The Limit of Quantification (LOQ) defined as the lowest validated fortification level, was 0.01 mg/kg for all analytes in/on the peas matrices. No residues above the LOQ were found in the control samples. The average recoveries were within the acceptable range of 70 – 110% except for:</p> <ul style="list-style-type: none"> - Trifloxystrobin at the LOQ level in dry seed (116%) - CGA 331409 at the LOQ level in dry seed (118%) - CGA 357262 at the LOQ level in dry seed (112%) - CGA 321113 at the LOQ level in dry seed (111%). <p>As residues in the study samples were all below the LOQ for dry seed, there is no major impact on the study results: RSD values are below 20%.</p> <p>The residue levels of trifloxystrobin were 0.15 and 0.22 mg/kg at the intended PHI of 7 days in pod samples and were <0.01 mg/kg at the intended PHI of 14 days in dry seed samples. The storage period of deep-frozen samples intended for Trifloxystrobin and its isomers / metabolites ranged between 419 and 464 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.11.1/02
Title:	Determination of the residues of fluopyram and trifloxystrobin in/on field pea after spray application of AE C656948 & CGA279202 SC 500 in northern France and Germany
Report:	Fargeix, G.; 2013; 11-2000; M-444960-01-1
Authority registration No:	
Guideline(s):	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed, EC Guidance working document 7029/VI/95 rev.5 (1997-07-22) US EPA OCSPP Guideline No. 860.1500.SUPP
Deviations:	see page 146
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on peas with application rates of 200 g/ha trifloxystrobin and 300 L water per ha. The applications were done with a spray interval of 7 days. Samples of pod (day 7) and dry seed (day 14, 21, 28) were taken for analysis.

Concurrent recoveries obtained during the conduct of this study were acceptable with overall mean value in the range 70-110% or slightly above (trifloxystrobin 111%, CGA 331409 113%, which is deemed acceptable. All RSD values were below 20%.

Table A 48: Summary of the study 11-2000 trials – GAP summary

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)
11-2000-01 11-2000-01-T France, north F-95710 Ambleville Europe, North F 2011	Pea, field Athos ; pea field	1) 07.03.2011 2) 06.05.2011 - 31.05.2011 3) 04.07.2011 - 15.07.2011	200 200	300 300	68 68	15.06.2011/0 22.06.2011/7	80	(g) 11-2000 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
11-2000-02 11-2000-02-T Germany D-51399 Burscheid Europe, North F 2011	Pea, field Mascara ; Field pea	1) 11.04.2011 2) 06.06.2011 - 20.06.2011 3) 31.07.2011 - 31.08.2011	200 200	300 300	67 67	12.07.2011/0 19.07.2011/7	80	(g) 11-2000 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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
- (m) Storage (max)
- G greenhouse
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ
- (l) Method validation
- F field

Analytical part of study 11-2000

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
11-2000-01 11-2000-01-T France, north F-95710 Ambleville Europe, North F 2011	Pea, field Athos ; pea field	pod	80	0.17	<0.01	<0.01	<0.01	<0.01	<0.01	0.21	0*	(g) 11-2000 (j) Analytical method: 01313 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313 and residue study 11-2000 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 seed, dry: 460 days Analyte 1, 2, 3, 4, 5, 6 pod: 464 days *prior to last treatment
			87	0.22	0.038	0.015	0.020	<0.01	<0.01	0.30	7	
			80	0.52	0.011	<0.01	<0.01	<0.01	<0.01	0.56	0	
			80	0.22	0.011	<0.01	<0.01	<0.01	<0.01	0.26	0	
		seed, dry	89	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	14	
			89	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	21	
			97	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	28	
			80	0.063	<0.01	<0.01	<0.01	<0.01	<0.01	0.10	0*	
			80	0.91	0.015	<0.01	<0.01	<0.01	<0.01	0.96	0	
			81	0.15	0.018	<0.01	0.015	<0.01	<0.01	0.20	7	
			89	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	14	
			89	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	21	
			89	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	28	

A 2.1.3.9.3 Study 12-2031 (Pea, northern Europe)

Comments of zRMS:	<p>The study summarised below in bean was already evaluated in EFSA Journal 2018;16(1):5154 but is submitted again because of that the total residue for risk assessment was not taken into account in the evaluation by EFSA (EFSA, 2018). In this study the residues of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 and its metabolite CGA 321113 and CGA 373466 were determined.</p> <p>Six trials were conducted in N-EU (France, Belgium, the United Kingdom and Germany) during the 2012 season to determine the magnitude of trifloxystrobin (comprising trifloxystrobin, CGA 321113, CGA 357261, CGA 357262, CGA 331409 and CGA 373466) in/on in/on field pea (pod and dry seed), after two spray applications with 0.2 kg/ha trifloxystrobin with 7 days between applications at BBCH 71-76 and with PHI of 7 days for pod and 14 days for green seed.</p> <p>Residues of trifloxystrobin, stereo-isomers and metabolites were determined by HPLC-MS/MS according to method 01313.</p> <p>The Limit of Quantification (LOQ) defined as the lowest validated fortification level, was mg/kg for all analytes in/on the peas matrices. No residues above the LOQ were found in the control samples. The average recoveries were within the acceptable range of 70 – 110% with RSD values below 20%.</p> <p>The residue levels of trifloxystrobin were 0.028, 0.029, 0.063, 0.066, 0.075, 0.24 mg/kg at the intended PHI of 7 days in pod samples and were <0.01 mg/kg at the intended PHI of 14 days in green seed samples and were <0.01 mg/kg in dry seed samples.</p> <p>The storage period of deep-frozen samples intended for trifloxystrobin and its isomers / metabolites ranged between 355 and 458 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.11.1/03
Title:	Determination of the residues of fluopyram and trifloxystrobin in/on field pea after spray application of AE C656948 & CGA279202 SC 500 in the field in Germany, Northern France, Belgium and United Kingdom
Report:	Glaubitz, J.; Ballmann, C.; 2014; 12-2031; M-475814-01-1
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 and repealing Council Directives 79/117/EEC and 91/414/EEC, EC Guidance working document 7029/VI/95 rev.5 (1997-07-22), OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial, US EPA OCSPP Guideline No. 860.1500
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on pea with application rates of 200 g/ha trifloxystrobin and 300-400 L water per ha. The applications were done with a spray interval of about 7 days. Pods (day 7), green seed (day 10 and 14) and dry seeds (day 21-43) were taken for analysis.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%., except for pea rest of plant, CGA 321113 (21.3), which was considered acceptable with reference to the OECD guidance document ENV/JM/MONO(2007)17.

Table A 49: **Summary of the study 12-2031 trials – GAP summary**

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)
12-2031-01 12-2031-01-T Germany 51399 Burscheid Europe, North F 2012	Pea, field Respect	1) 17.04.2012 2) 21.06.2012 - 07.07.2012 3) 01.08.2012 - 31.08.2012	200 200	300 300	67 67	02.07.2012/0 09.07.2012/7	71	(g) 12-2031 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
12-2031-02 12-2031-02-T France, north 95710 Chaussy Europe, North F 2012	Pea, field Genial	1) 14.03.2012 2) 29.05.2012 - 19.06.2012 3) 23.07.2012 - 26.07.2012	200 200	300 300	67 67	13.06.2012/0 20.06.2012/7	75	(g) 12-2031 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
12-2031-03 12-2031-03-T Germany 04824 Beucha- Wolfshain Europe, North F 2012	Pea, field Rocket	1) 29.03.2012 2) 28.05.2012 - 20.06.2012 3) 30.07.2012 - 10.08.2012	200 200	300 300	67 67	11.06.2012/0 18.06.2012/7	75	(g) 12-2031 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
12-2031-04 12-2031-04-T Belgium 6210 Villers- Perwin Europe, North F 2012	Pea, field Ravenna	1) 16.04.2012 2) 15.06.2012 - 05.07.2012 3) 10.07.2012 - 09.08.2012	200 200	400 400	50 50	26.06.2012/0 03.07.2012/7	71	(g) 12-2031 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
12-2031-05 12-2031-05-T United Kingdom CB22 5EU Cambridge Europe, North F 2012	Pea, field Tommy	1) 05.04.2012 2) 11.06.2012 - 10.07.2012 3) 25.07.2012 - 10.08.2012	200 200	300 300	67 67	12.07.2012/0 21.07.2012/9	76	(g) 12-2031 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying

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)
12-2031-06 12-2031-06-T Germany 49377 Langförden Europe, North F 2012	Pea, field Alvesta	1) 18.04.2012 2) 18.06.2012 - 10.07.2012 3) 01.08.2012 - 31.08.2012	200 200	300 300	67 67	05.07.2012/0 12.07.2012/7	76	(g) 12-2031 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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
- (m) Storage (max)
- G greenhouse F field
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ
- (l) Method validation

Analytical part of study 12-2031

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
12-2031-01 12-2031-01-T Germany 51399 Burscheid Europe, North F 2012	Pea, field Respect	pod	71	0.081	<0.01	<0.01	<0.01	<0.01	<0.01	0.12	0*	(g) 12-2031 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 12-2031 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 straw: 411 days Analyte 1, 2, 3, 4, 5, 6 seed, green: 394 days Analyte 1, 2, 3, 4, 5, 6 seed, dry: 355 days Analyte 1, 2, 3, 4, 5, 6 rest of plant: 394 days Analyte 1, 2, 3, 4, 5, 6 pod: 399 days * prior to last treatment
			71	0.26	<0.01	<0.01	<0.01	<0.01	<0.01	0.30	0	
			79	0.063	<0.01	<0.01	<0.01	<0.01	<0.01	0.10	7	
		rest of plant	71	1.3	0.047	0.011	0.036	0.016	<0.01	1.4	0*	
			71	3.9	0.089	<0.01	0.053	0.020	<0.01	4.1	0	
			79	0.44	0.057	0.018	0.041	0.029	<0.01	0.59	7	
			80	0.26	0.034	0.015	0.031	0.022	<0.01	0.36	14	
			82	0.23	0.040	0.019	0.041	0.032	<0.01	0.36	21	
		seed, green	79	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	7	
			79	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	10	
			80	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	14	
			82	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	21	
		seed, dry	89	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	39	
		straw	89	0.40	0.074	0.032	0.043	0.047	0.019	0.60	39	

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
12-2031-02 12-2031-02-T France, north 95710 Chaussy Europe, North F 2012	Pea, field Genial	pod	75	0.046	<0.01	<0.01	<0.01	<0.01	<0.01	0.086	0*	(g) 12-2031 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 12-2031 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 straw: 434 days Analyte 1, 2, 3, 4, 5, 6 seed, green: 413 days Analyte 1, 2, 3, 4, 5, 6 seed, dry: 378 days Analyte 1, 2, 3, 4, 5, 6 rest of plant: 413 days Analyte 1, 2, 3, 4, 5, 6 pod: 418 days * prior to last treatment
			75	0.30	<0.01	<0.01	<0.01	<0.01	<0.01	0.34	0	
			79	0.075	<0.01	<0.01	<0.01	<0.01	<0.01	0.12	7	
		rest of plant	75	0.39	0.021	<0.01	0.018	0.018	<0.01	0.46	0*	
			75	3.5	0.029	<0.01	0.023	0.021	<0.01	3.6	0	
			79	1.4	0.046	<0.01	0.038	0.043	<0.01	1.5	7	
			79	0.99	0.041	0.015	0.037	0.039	<0.01	1.1	14	
			80	0.36	0.041	0.015	0.036	0.033	<0.01	0.49	21	
		seed, green	79	0.010	<0.01	<0.01	<0.01	<0.01	<0.01	0.05	7	
			79	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	10	
			79	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	14	
			80	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	21	
		seed, dry	89	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	35	
		straw	89	0.97	0.11	0.048	0.077	0.15	0.045	1.4	35	

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
12-2031-03 12-2031-03-T Germany 04824 Beucha- Wolfshain Europe, North F 2012	Pea, field Rocket	pod	75	0.19	0.011	<0.01	<0.01	<0.01	<0.01	0.23	0*	(g) 12-2031 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 12-2031 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 straw: 450 days Analyte 1, 2, 3, 4, 5, 6 seed, green: 415 days Analyte 1, 2, 3, 4, 5, 6 seed, dry: 394 days Analyte 1, 2, 3, 4, 5, 6 rest of plant: 415 days Analyte 1, 2, 3, 4, 5, 6 pod: 420 days * prior to last treatment; Storage temperature exceeded, therefore special stability study S13-03307
			75	0.38	0.012	<0.01	<0.01	<0.01	<0.01	0.42	0	
			79	0.066	<0.01	<0.01	<0.01	<0.01	<0.01	0.11	7	
		rest of plant	75	1.4	0.023	<0.01	0.019	0.011	<0.01	1.5	0*	
			75	3.1	0.030	<0.01	0.022	0.011	<0.01	3.2	0	
			79	1.6	0.031	<0.01	0.029	0.022	<0.01	1.7	7	
			79	1.0	0.030	<0.01	0.028	0.021	<0.01	1.1	14	
		seed, green	79	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	7	
			79	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	10	
			79	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	14	
		seed, dry	83	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	21	
			89	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	43	
		straw	83	0.88	0.057	0.018	0.047	0.050	<0.01	1.1	21	
			89	1.2	0.20	0.087	0.11	0.15	0.067	1.8	43	

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
12-2031-04 12-2031-04-T Belgium 6210 Villers- Perwin Europe, North F 2012	Pea, field Ravenna	pod	71	0.037	<0.01	<0.01	<0.01	<0.01	<0.01	0.077	0*	(g) 12-2031 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 12-2031 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 straw: 435 days Analyte 1, 2, 3, 4, 5, 6 seed, green: 400 days Analyte 1, 2, 3, 4, 5, 6 seed, dry: 379 days Analyte 1, 2, 3, 4, 5, 6 rest of plant: 400 days Analyte 1, 2, 3, 4, 5, 6 pod: 405 days * prior to last treatment
			71	0.14	<0.01	<0.01	<0.01	<0.01	<0.01	0.18	0	
			79	0.028	<0.01	<0.01	<0.01	<0.01	<0.01	0.068	7	
		rest of plant	71	1.3	0.030	<0.01	0.022	0.011	<0.01	1.4	0*	
			71	3.9	0.037	<0.01	<0.01	0.013	<0.01	4.0	0	
			79	1.0	0.045	<0.01	0.035	0.037	<0.01	1.1	7	
			80	0.25	0.017	<0.01	0.020	0.020	<0.01	0.32	14	
		seed, green	79	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	7	
			79	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	10	
			80	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	14	
		seed, dry	81	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	21	
			89	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	37	
		straw	81	0.31	0.032	0.016	0.021	0.049	<0.01	0.43	21	
			89	1.3	0.11	0.070	0.11	0.45	0.15	2.1	37	

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
12-2031-05 12-2031-05-T United Kingdom CB22 5EU Cambridge Europe, North F 2012	Pea, field Tommy	pod	79	0.021	<0.01	<0.01	<0.01	<0.01	<0.01	0.061	0*	(g) 12-2031 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 12-2031 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 straw: 418 days Analyte 1, 2, 3, 4, 5, 6 seed, green: 383 days Analyte 1, 2, 3, 4, 5, 6 seed, dry: 362 days Analyte 1, 2, 3, 4, 5, 6 rest of plant: 382 days Analyte 1, 2, 3, 4, 5, 6 pod: 387 days * prior to last treatment
			79	0.27	<0.01	<0.01	<0.01	<0.01	<0.01	0.31	0	
			81	0.24	0.011	<0.01	<0.01	<0.01	<0.01	0.28	6	
		rest of plant	79	0.32	0.042	0.013	0.032	0.056	0.013	0.47	0*	
			79	7.7	0.098	<0.01	<0.01	0.068	0.017	7.9	0	
			81	7.1	0.32	0.13	0.23	0.17	0.075	8.0	6	
			86	5.8	0.44	0.21	0.30	0.30	0.14	7.1	13	
		seed, green	81	0.010	<0.01	<0.01	<0.01	<0.01	<0.01	0.05	6	
			81	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	10	
			86	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	13	
		seed, dry	89	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	20	
			89	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	20	
		straw	89	6.5	1.7	0.48	1.7	1.4	0.66	12	20	

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
12-2031-06 12-2031-06-T Germany 49377 Langförden Europe, North F 2012	Pea, field Alvesta	pod	76	0.054	<0.01	<0.01	<0.01	<0.01	<0.01	0.094	0*	(g) 12-2031 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 12-2031 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 straw: 425 days Analyte 1, 2, 3, 4, 5, 6 seed, green: 391 days Analyte 1, 2, 3, 4, 5, 6 seed, dry: 369 days Analyte 1, 2, 3, 4, 5, 6 rest of plant: 391 days Analyte 1, 2, 3, 4, 5, 6 pod: 396 days * prior to last treatment
			76	0.15	<0.01	<0.01	<0.01	<0.01	<0.01	0.19	0	
			79	0.029	<0.01	<0.01	<0.01	<0.01	<0.01	0.069	7	
		rest of plant	76	1.5	0.031	<0.01	0.023	0.033	<0.01	1.6	0*	
			76	4.8	0.039	<0.01	<0.01	0.048	<0.01	4.9	0	
			79	1.9	0.045	0.013	0.051	0.077	<0.01	2.1	7	
			81	1.5	0.064	<0.01	0.066	0.16	0.017	1.8	13	
		seed, green	79	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	7	
			80	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	10	
			81	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	13	
		seed, dry	84	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	22	
			89	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	32	
		straw	84	2.2	0.12	0.044	0.11	0.29	0.041	2.8	22	
			89	5.1	0.38	0.15	0.30	1.6	0.22	7.6	32	

A 2.1.3.9.4 Study 10-2125 (Bean, northern Europe)

Comments of zRMS:	<p>The study summarised below in bean was already evaluated in EFSA Journal 2018;16(1):5154 but is submitted again because of that the total residue for risk assessment was not taken into account in the evaluation by EFSA (EFSA, 2018). In this study the residues of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 and its metabolite CGA 321113 and CGA 373466 were determined.</p> <p>Six trials were conducted in N-EU (2 trials: Germany, Belgium) and S-EU (4 trials: Spain, Italy, France and Portugal)) during the 2010 season to determine the magnitude of trifloxystrobin (comprising trifloxystrobin, CGA 321113, CGA 357261, CGA 357262, CGA 331409 and CGA 373466) in/on in/on specific variety of kidney beans (green material and pod), after two spray applications with 0.2 kg/ha trifloxystrobin with 7 days between applications at BBCH 63-67 and with PHI of 14-15 days for pod. Residues of trifloxystrobin, stereo-isomers and metabolites were determined by HPLC-MS/MS according to method 01313. The Limit of Quantification (LOQ) defined as the lowest validated fortification level, was mg/kg for all analytes in/on the kidney beans (green material and pod). No residues above the LOQ were found in the control samples. The average recoveries were within the acceptable range of 70 – 110% with RSD values below 20%. The residue levels of trifloxystrobin were 2x0.02 mg/kg at the intended PHI of 14 days in pod samples. The storage period of deep-frozen samples for trifloxystrobin (AG02) and its metabolite and isomers ranged between 250 and 429 days. The studies on the magnitude of residues are valid with regard to storage stability. The study is acceptable.</p>
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Reference:	KCA 6.3.11.1/04
Title:	Determination of the residues of AE C656948 and trifloxystrobin in/on bean, kidney after spraying of AE C656948 & CGA279202 SC 500 in the field in Germany, Belgium, Spain, Italy, France (south) and Portugal
Report:	Noss, G.; Ballmann, C.; 2012; 10-2125; M-425357-01-1
Authority registration No:	
Guideline(s):	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029/VI/95 rev. 5 (1997-07-22) EPA OCSPP Guideline Number 860.1500
Deviations:	Not specified
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on bean with application rates of about 200 g/ha trifloxystrobin and 300-530 L water per ha. The applications were done with a spray interval of 7 days. Pod samples for analysis were taken on days 7, 14/15, 21/22, 28 after the last application.

Concurrent recoveries obtained during the conduct of this study were acceptable with overall mean value in the range 70-110%. All RSD values were below 20%., with exception of the overall RSD for pod for CGA 331409 (21.1%) and CGA 357262 (21.5%), which was nevertheless considered acceptable.

Table A 50: Summary of the study 10-2125 trials – GAP summary

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)				(e)	(d)	(f)
10-2125-01 Germany 53913 Heimerzheim Europe, North F 2010	Bean, Kidney Orinoko, yellow French bean	1) 12.06.2010 2) 21.07.2010 - 31.08.2010 3) 26.08.2010 - 31.08.2010	200 200	300 300	67 67	27.07.2010/0 03.08.2010/7	63	(g) 10-2125 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
10-2125-02 Belgium 6210 Villers- Perwin Europe, North F 2010	Bean, Kidney Beaufort	1) 17.05.2010 2) 06.07.2010 - 15.07.2010 3) 27.07.2010 - 20.08.2010	200 200	400 400	50 50	06.07.2010/0 13.07.2010/7	67	(g) 10-2125 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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
- (m) Storage (max)
- G greenhouse F field
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ
- (l) Method validation

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

[illegible]

A 2.1.3.9.5 Study 12-2030 (Bean, northern Europe)

Comments of zRMS:	<p>The study summarised below in bean was already evaluated in EFSA Journal 2018;16(1):5154 but is submitted again because of that the total residue for risk assessment was not taken into account in the evaluation by EFSA (EFSA, 2018). In this study the residues of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 and its metabolite CGA 321113 and CGA 373466 were determined.</p> <p>Two trials were conducted in N-EU (Germany, France) during the 2012 season to determine the magnitude of trifloxystrobin (comprising trifloxystrobin, CGA 321113, CGA 357261, CGA 357262, CGA 331409 and CGA 373466) in/on French bean (green material and pod), after two spray applications with 0.2 kg/ha trifloxystrobin with 7 days between applications at BBCH 63-75 and with PHI of 14 days for pod.</p> <p>Residues of trifloxystrobin, stereo-isomers and metabolites were determined by HPLC-MS/MS according to method 01313/M003.</p> <p>The Limit of Quantification (LOQ) defined as the lowest validated fortification level, was mg/kg for all analytes in/on the beans (green material and pod). No residues above the LOQ were found in the control samples. The average recoveries were within the acceptable range of 70 – 110% with RSD values below 20%.</p> <p>The residue levels of trifloxystrobin were 0.012 and 0.076 mg/kg at the intended PHI of 14 days in pod samples.</p> <p>The storage period of deep-frozen samples for trifloxystrobin (AG02) and its metabolite and isomers ranged between 349 and 379 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.11.1/05
Title:	Determination of the residues of AE C656948 and trifloxystrobin in/on French bean after spray application of AE C656948 & CGA279202 SC 500 in the field in Germany and northern France
Report:	Glaubitz, J.; 2013; 12-2030; M-467728-01-1
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 and repealing Council Directives 79/117/EEC and 91/414/EEC, EC Guidance working document 7029/VI/95 rev.5 (1997-07-22), OECD 509 Adopted 2009-09-07 OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial, US EPA US EPA OCSPP Guideline No. 860.1500
Deviations:	not specified
GLP/GEP:	No yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on bean with application rates of 200 g/ha trifloxystrobin and 300-500 L water per ha. The applications were done with a spray interval of 7 days. Pod samples were taken for analysis on day 7, 10, 14, 21 after the last application with the last application.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Table A 51: Summary of the study 12-2030 trials – GAP summary

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)
12-2030-01 12-2030-01-T Germany 59457 Werl- Mawicke Europe, North F 2012	Bean, Kidney Primel; French Bean	1) 08.06.2012 2) 01.07.2012 - 02.08.2012 3) 15.07.2012 - 30.09.2012	200 200	300 300	67 67	18.07.2012/0 25.07.2012/7	69	(g) 12-2030 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
12-2030-02 12-2030-02-T France, north 37230 Fondettes Europe, North F 2012	Bean, Kidney Contender; French bean	1) 16.05.2012 2) 25.06.2012 - 09.07.2012 3) 15.07.2012 - 31.07.2012	200 200	500 500	40 40	09.07.2012/0 16.07.2012/7	75	(g) 12-2030 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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
- (m) Storage (max)
- G greenhouse F field
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ
- (l) Method validation

Analytical part of study 12-2030

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
12-2030-01 12-2030-01-T Germany 59457 Werl- Mawicke Europe, North F 2012	Bean, Kidney Primel; French Bean	green material	69	3.3	0.21	0.071	<0.01	0.086	0.036	3.7	0*	(g) 12-2030 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 12-2030 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 pod: 363 days Analyte 1, 2, 3, 4, 5, 6 green material: 371 days * prior to last treatment
			69	9.5	0.21	0.052	<0.01	0.11	0.035	9.9	0	
		pod	72	0.038	<0.01	<0.01	<0.01	0.013	<0.01	0.081	7	
			76	0.028	<0.01	<0.01	<0.01	<0.01	<0.01	0.068	10	
			77	0.012	<0.01	<0.01	<0.01	<0.01	<0.01	0.052	14	
			78	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	21	
12-2030-02 12-2030-02-T France, north 37230 Fondettes Europe, North F 2012	Bean, Kidney Contender; French bean	pod	75	0.035	<0.01	<0.01	<0.01	<0.01	<0.01	0.075	0*	(g) 12-2030 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 12-2030 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 pod: 379 days * prior to last treatment
			75	0.28	<0.01	<0.01	<0.01	<0.01	<0.01	0.32	0	
			79	0.074	<0.01	<0.01	<0.01	0.016	<0.01	0.12	7	
			79	0.079	<0.01	<0.01	<0.01	0.019	<0.01	0.13	10	
			79	0.076	<0.01	<0.01	<0.01	<0.01	<0.01	0.12	14	
			79	0.038	<0.01	<0.01	<0.01	<0.01	<0.01	0.078	21	

A 2.1.3.9.6 Study 15-2030 (Pea, northern Europe)

Comments of zRMS:	<p>The study summarised below in bean was already evaluated in EFSA Journal 2018;16(1):5154 but is submitted again because of that the total residue for risk assessment was not taken into account in the evaluation by EFSA (EFSA, 2018).</p> <p>In this study the residues of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 and its metabolite CGA 321113 and CGA 373466 were determined.</p> <p>Four trials were conducted in N-EU (Germany, Denmark) and in S-EU (Spain and Italy) during the 2015 and 2016 seasons to determine the magnitude of trifloxystrobin (comprising trifloxystrobin, CGA 321113, CGA 357261, CGA 357262, CGA 331409 and CGA 373466) in/on pea, field (green material, pod, seed, dry and seed, green) after two spray applications with 0.2 kg/ha trifloxystrobin with 7 days between applications at BBCH 71-75 and with PHI of 14 days for pods, for seed, green, and 14-36 days for seed, dry.</p> <p>Residues of trifloxystrobin, stereo-isomers and metabolites were determined by HPLC-MS/MS according to method 01313/M003.</p> <p>The Limit of Quantification (LOQ) defined as the lowest validated fortification level, was mg/kg for all analytes in/on the beans (pod, seed, green and dry). No residues above the LOQ were found in the control samples. The average recoveries were within the acceptable range of 70 – 110% with RSD values below 20%.</p> <p>The residue levels of trifloxystrobin were:</p> <p>Pea with pod, PHI = 6-13 days RD-Mo: 0.23, 0.49 mg/kg, RD-RA: 0.28, 0.58 mg/kg.</p> <p>Pea without pod, seed, green, PHI=6-19 days RD-Mo: 0.010, 0.012 mg/kg, RD-RA: 0.050, 0.052 mg/kg.</p> <p>Pea seed, dry, PHI=14-36 days RD-Mo: 2x<0.01 mg/kg, RD-RA: 0.051, 0.052 mg/kg.</p> <p>The storage period of deep-frozen samples for trifloxystrobin (AG02) and its metabolite and isomers ranged between 86 and 439 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.11.1/06
Title:	Determination of the residues of fluopyram and trifloxystrobin in/on field pea, after spray application of AE C656948 & CGA 279202 SC 500 in Denmark, Germany, Spain and Italy
Report:	Noss, G.; Czaja, C.; 2017; 15-2030; M-566823-03-1
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:	yes, see report
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on pea with application rates of 200 g/ha trifloxystrobin and 300-500 L water per ha. The applications were done with a spray interval of about 7 days. Samples of pod were taken on day 6 or 7 after the last application, samples of green seed were taken at day 6 to 21, and samples of dry seed were taken at harvest (day 21 to 48).

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Table A 52: Summary of the study 15-2030 trials – GAP summary

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)
15-2030-01 15-2030-01-T Denmark 6200 Abenraa Europe, North F 2015	Pea, field Maxigold	1) 12.06.2015 2) 03.08.2015 - 31.08.2015 3) 01.10.2015	200 200	300 300	67 67	19.08.2015/0 26.08.2015/7	71	(g) 15-2030 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
15-2030-02 15-2030-02-T Germany 77694 Kehl- Bodersweier Europe, North F 2015	Pea, field Astronaut	1) 21.03.2015 2) 23.05.2015 - 30.05.2015 3) 11.07.2015	200 200	400 400	50 50	19.06.2015/0 26.06.2015/7	75	(g) 15-2030 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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
- (m) Storage (max)
- G greenhouse F field
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ
- (l) Method validation

Analytical part of study 15-2030

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
15-2030-01 15-2030-01-T Denmark 6200 Abenraa Europe, North F 2015	Pea, field Maxigold	green material	71	2.8	0.063	0.018	0.042	0.013	<0.01	2.9	0*	(g) 15-2030 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 15-2030 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 seed, green: 366 days Analyte 1, 2, 3, 4, 5, 6 seed, dry: 343 days Analyte 1, 2, 3, 4, 5, 6 pod: 376 days Analyte 1, 2, 3, 4, 5, 6 green material: 384 days * prior to last treatment
			71	6.3	0.070	0.020	0.051	0.019	<0.01	6.5	0	
			75	4.6	0.15	0.041	0.11	0.081	0.014	5.0	7	
			79	2.8	0.18	0.073	0.12	0.11	0.036	3.3	13	
			79	1.9	0.12	0.059	0.10	0.11	0.033	2.3	19	
		pod	71	0.62	<0.01	<0.01	<0.01	<0.01	<0.01	0.66	0	
			75	0.23	<0.01	<0.01	<0.01	<0.01	<0.01	0.27	7	
			79	0.23	0.018	<0.01	0.012	<0.01	<0.01	0.28	13	
		seed, green	79	0.012	<0.01	<0.01	<0.01	<0.01	<0.01	0.052	13	
			79	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	19	
		seed, dry	89	<0.01	<0.01	<0.01	<0.01	0.011	<0.01	0.051	36	

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1 to 5)		
15-2030-02 15-2030-02-T Germany 77694 Kehl- Bodersweier Europe, North F 2015	Pea, field Astronaut	green material	75	0.49	0.033	0.015	0.028	0.035	<0.01	0.60	0*	(g) 15-2030 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 15-2030 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 seed, green: 434 days Analyte 1, 2, 3, 4, 5, 6 seed, dry: 426 days Analyte 1, 2, 3, 4, 5, 6 pod: 437 days Analyte 1, 2, 3, 4, 5, 6 green material: 439 days * prior to last treatment
			75	3.9	0.073	0.025	0.052	0.053	0.011	4.1	0	
			79	3.2	0.18	0.060	0.11	0.12	0.034	3.7	6	
		pod	75	0.63	0.019	<0.01	0.012	<0.01	<0.01	0.68	0	
			79	0.49	0.035	0.013	0.022	0.023	<0.01	0.58	6	
		seed, dry	89	<0.01	<0.01	<0.01	<0.01	0.012	<0.01	0.052	21	
			89	<0.01	<0.01	<0.01	<0.01	0.012	<0.01	0.052	<u>14</u>	
		seed, green	79	0.010	<0.01	<0.01	<0.01	<0.01	<0.01	0.050	6	

A 2.1.3.9.7 Study RA-2044/02 (Bean, northern Europe)

Comments of zRMS:	<p>Four supervised residue trials were conducted with the formulation Flint 50 WG, containing 50% trifloxystrobin in beans during 2002. Two spray applications with application rates of 200 g trifloxystrobin/ha were done with a spray interval of 7 days, with the last application 14 days prior to be expected date of harvest. In trial R 2002 0201/6, the interval between the applications was 9 days because of the weather conditions.</p> <p>The residues of trifloxystrobin and the CGA 321113 metabolite were determined according to the analytical method 00742/E001 by HPLC-MS/MS after extraction and clean-up by solid-phase-extraction on a ChemElut cartridge.</p> <p>The Limit of Quantitation (LOQ), defined as the lowest validated fortification level, was 0.02 mg/kg for both, trifloxystrobin and CGA 321113 in beans with pods. The obtained recovery values show the validity of the method used.</p> <p>At the proposed harvest date, 14 (13) days after the last application, residues of trifloxystrobin were between 0.03 and 0.06 mg/kg. CGA 321113 residues were below the LOQ of 0.02 mg/kg. In study R 2002 0199/0, the trifloxystrobin residues did not decrease between day 13 and day 21 after the last application.</p> <p>No residues of trifloxystrobin and CGA 321113 above the LOQ were found in any of the control samples.</p> <p>The treated samples analyzed for trifloxystrobin and CGA 321113 for this report were kept deep-frozen for a maximum of 6 months, ranging from July 18, 2002 (date of deepfreezing) to January 15, 2003 (date of extraction). The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>Remark: <u>In this study only the residues of trifloxystrobin and the CGA 321113 metabolite were determined.</u></p> <p>The 3 isomers of trifloxystrobin (CGA 357262, CGA 357261 and CGA 331409) were not analysed in this study, so only the existing plant residue definition for monitoring can be followed (Reg. (EU) 2019/1791).</p> <p>However, taking into the results of another studies, the conversion factor (from monitoring to risk assessment) of 2.1 for bean and pea pod, based on bean and pea trials including isomer analysis, has been calculated.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.11.1/07
Title:	Determination of residues of trifloxystrobin and CGA 321113 in/on kidney bean following spray application of Flint 50 WG in the field in Northern France, Germany and Great Britain
Report:	Nuesslein, F.; Eberhardt, R.; 2003; RA-2044/02; M-106401-01-1
Authority registration No:	
Guideline(s):	--
Deviations:	--
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Trifloxystrobin WG 50, a water dispersible granule formulation containing 500 g/kg trifloxystrobin, was applied two times on pea with application rates of 200 g/ha trifloxystrobin and 600 L water per ha. The applications were done with a spray interval of about 7 days. Samples of pod were taken at the PHI of 14 days.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.

Although only trifloxystrobin and CGA 321113 were analysed, the sum trifloxystrobin, its 3 isomers (CGA 357262, CGA 357261 and CGA 331409) and CGA 321113 (M5), expressed as trifloxystrobin, can be calculated with a conversion factor of 2.1. (Mean Conversion factor based on bean and pea

trials including analysis of all these five analytes; pod PHI 14 days). In case of low residues of trifloxystrobin the sum may be higher, if 0.02 mg/kg (LOQ) is assumed for CGA 357262, CGA 357261 and CGA 331409 and added to the residues of trifloxystrobin and CGA 321113. Whatever results in a higher value, was entered for the total residue (sum of trifloxystrobin, its 3 isomers (CGA 357262, CGA 357261 and CGA 331409) and CGA 321113 (M5), expressed as trifloxystrobin.

Table A 53: Summary of the study RA-2044/02 – GAP summary

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)
R 2002 0081/1 0081-02 France, north F-37150 Luzille Europe, North F 2002	Bean, Kidney Cropper Teepee	1) 31.05.2002 2) 12.07.2002 - 24.07.2002 3) 10.08.2002	200.0 200.0	600 600	33.50 33.50	24.07.2002/0 31.07.2002/7	73	(g) RA-2044/02 (h) WG (trifloxystrobin 50 %) (i) Application method: Spraying
R 2002 0199/0 0199-02 Germany D-51377 Leverkusen Europe, North F 2002	Bean, Kidney Roma II	1) 20.05.2002 2) 15.06.2002 - 15.08.2002 3) 15.07.2002 - 15.08.2002	200.0 200.0	600 600	33.50 33.50	23.07.2002/0 30.07.2002/7	75	(g) RA-2044/02 (h) WG (trifloxystrobin 50 %) (i) Application method: Spraying
R 2002 0200/8 0200-02 Germany D-40789 Monheim Europe, North F 2002	Bean, Kidney Dublette	1) 29.04.2002 2) 15.06.2002 - 15.07.2002 3) 15.07.2002 - 15.08.2002	200.0 200.0	600 600	33.50 33.50	11.07.2002/0 18.07.2002/7	75	(g) RA-2044/02 (h) WG (trifloxystrobin 50 %) (i) Application method: Spraying
R 2002 0201/6 0201-02 United Kingdom GB-CM3 3EJ Boreham, Chelmsford, Essex Europe, North F 2002	Bean, Kidney Laguna	1) 06.06.2002 2) 24.07.2002 - 10.08.2002 3) 21.08.2002	200.0 200.0	600 600	33.50 33.50	29.07.2002/0 07.08.2002/9	68	(g) RA-2044/02 (h) WG (trifloxystrobin 50 %) (i) Application method: Spraying

- (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
- (m) Storage (max)
- G greenhouse F field
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ
- (l) Method validation

Analytical part of study RA-2044/02

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 321113 (determined as CGA 321113, calculated as CGA 321113)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 321113 as CGA 321113		Total residue calc.		
R 2002 0081/1 0081-02 France, north F-37150 Luzille Europe, North F 2002	Bean, Kidney Cropper Teepee	bean with pod	73 73 75 77 79	0.07 0.59 0.06 0.03 <0.02	0.02 0.03 <0.02 <0.02 <0.02	Not analysed for CGA 357261, CGA 357262, CGA 331409. Total residue calculated with conversion factor (from monitoring to risk assessment) of 2.1 for bean and pea pod (which is based on bean and pea trials including isomer analysis), or by adding 0.02 mg/kg per TFS isomer analyte, whatever higher	0.15 1.2 0.14 0.11 <0.1	0* 0 7 <u>14</u> 21	(g) RA-2044/02 (j) Analytical method: 00742/E001 (k) LOQ: 0.02 mg/kg (l) Method Validation Data in method 00742/E001 and residue study RA-2044/02 (m) Storage: Analyte 1, 2 bean with pod: 166 days * prior to last treatment
R 2002 0200/8 0200-02 Germany D-40789 Monheim (Laacherhof) Europe, North F 2002	Bean, Kidney Dublette	bean with pod	75 77-79	0.16 0.03	<0.02 <0.02	Not analysed for CGA 357261, CGA 357262, CGA 331409. Total residue calculated with conversion factor (from monitoring to risk assessment) of 2.1 for bean and pea pod (which is based on bean and pea trials including isomer analysis), or by adding 0.02 mg/kg per TFS isomer analyte, whatever higher	0.34 0.11	0 <u>14</u>	(g) RA-2044/02 (j) Analytical method: 00742/E001 (k) LOQ: 0.02 mg/kg (l) Method Validation Data in method 00742/E001 and residue study RA-2044/02 (m) Storage: Analyte 1, 2 bean with pod: 181 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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 321113 as CGA 321113		Total residue calc.		
R 2002 0201/6 0201-02 United Kingdom GB-CM3 3EJ Boreham, Chelmsford, Essex Europe, North F 2002	Bean, Kidney Laguna	bean with pod	68-70 77	0.47 0.05	0.03 <0.02	Not analysed for CGA 357261, CGA 357262, CGA 331409. Total residue calculated with conversion factor (from monitoring to risk assessment) of 2.1 for bean and pea pod (which is based on bean and pea trials including isomer analysis), or by adding 0.02 mg/kg per TFS isomer analyte, whatever higher	0.99 0.13	0 <u>13</u>	(g) RA-2044/02 (j) Analytical method: 00742/E001 (k) LOQ: 0.02 mg/kg (l) Method Validation Data in method 00742/E001 and residue study RA-2044/02 (m) Storage: Analyte 1, 2 bean with pod: 161 days
R 2002 0199/0 0199-02 Germany D-51377 Leverkusen (F.J. Klein) Europe, North F 2002	Bean, Kidney Roma II	bean with pod	77-79 77-79 77-79 77-79 77-79	0.03 0.14 0.08 0.06 0.06	<0.02 <0.02 <0.02 <0.02 <0.02	Not analysed for CGA 357261, CGA 357262, CGA 331409. Total residue calculated with conversion factor (from monitoring to risk assessment) of 2.1 for bean and pea pod (which is based on bean and pea trials including isomer analysis), or by adding 0.02 mg/kg per TFS isomer analyte, whatever higher	0.11 0.29 0.17 0.14 0.14	0* 0 7 <u>13</u> 21	(g) RA-2044/02 (j) Analytical method: 00742/E001 (k) LOQ: 0.02 mg/kg (l) Method Validation Data in method 00742/E001 and residue study RA-2044/02 (m) Storage: Analyte 1, 2 bean with pod: 168 days * prior to last treatment

A 2.1.3.10 Hops

Table A 54: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA, 2014)	2	0.63 kg as/ha	10-14 days	BBCH 31-55	14
Intended cGAP (Hops: 141*)	2	0.15 kg as/ha	14 days	BBCH 37-79	21

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

A 2.1.3.10.1 Study 18-2047 (Hops, northern Europe)

Comments of zRMS:	<p>In this study the residues of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 and its metabolite CGA 321113 and CGA 373466 were determined.</p> <p>Five trials were conducted in N-EU (Northern France, Czech Republic and Germany) during the 2018 season to determine the magnitude of trifloxystrobin (comprising trifloxystrobin, CGA 321113, CGA 357261, CGA 357262, CGA 331409 and CGA 373466) in/on hop (cone, green and cone, kiln-dried) after two spray applications with 0.15 kg/ha trifloxystrobin with 13-15 days between applications at BBCH 71-82 and with PHI of 20-22 days for cone, green and kiln-dried.</p> <p>Residues of trifloxystrobin, stereo-isomers and metabolites were determined by HPLC-MS/MS according to method 01313/M001.</p> <p>The limit of quantification (LOQ) (expressed as parent equivalents) is 0.01 mg/kg for each analyte. No residues above the LOQ were found in the control samples. The average recoveries were within the acceptable range of 70 – 110% with RSD values below 20%.</p> <p>The residue levels of trifloxystrobin in/on cone, kiln-dried were: RD-Mo: 0.056, 0.42, 0.44, 0.61, 0.62 mg/kg, RD-RA: 0.16, 0.63, 0.78, 0.98, 1.1 mg/kg.</p> <p>The storage period of deep-frozen samples for trifloxystrobin (AG02) and its metabolite and isomers ranged between 260 and 300 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.12.1/01
Title:	Determination of the residues of trifloxystrobin and AE C656948 in/on hop after spray application of AE C656948 & CGA279202 SC 500 in northern France, Germany and Czech Republic - Final report -
Report:	Buchmueller, K.; van Berkum, S.; 2020; 18-2047; M-681429-01-1
Authority registration No:	
Guideline(s):	<p>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</p> <p>OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)</p> <p>US EPA OCSPP Guideline No. 860.1500 on Crop Field Trial</p>
Deviations:	None
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on hops with application rates of about 150 g/ha trifloxystrobin and up to 2029 L water per ha. The applications were done with a spray

interval of about 14 days, with the last application about 21 days before the harvest.

Concurrent recoveries obtained during the conduct of this study were acceptable with mean values in the range 70-110%. All RSD values were below 20%.

Table A 55: Summary of the study 18-2047 trials – GAP summary

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)
18-2047-01 18-2047-01-T France, north 59270 METEREN Europe, North F 2018	Hop Nuggets	1) 26.03.2017 2) 23.07.2018 - 20.08.2018 3) 03.09.2018 - 17.09.2018	145 147	1550 1572	9.38 9.38	07.08.2018/0 22.08.2018/15	71	(g) 18-2047 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
18-2047-02 18-2047-02-T Czech. Republic 751 16 Zelatovice Europe, North F 2018	Hop Sladek	1) 19.03.2002 2) 10.07.2018 - 18.07.2018 3) 04.09.2018 - 10.09.2018	151 148	1606 1578	9.37 9.38	01.08.2018/0 14.08.2018/13	82	(g) 18-2047 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
18-2047-03 18-2047-03-T Germany 84091 Attenhofen Europe, North F 2018	Hop Perle	1) 2003 2) 11.07.2018 - 18.07.2018 3) 29.08.2018 - 11.09.2018	152 152	2027 2025	7.50 7.50	25.07.2018/0 08.08.2018/14	75	(g) 18-2047 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
18-2047-04 18-2047-04-T Germany 88069 Tettnang Europe, North F 2018	Hop Tettnanger	1) 1987 2) 06.07.2018 - 13.07.2018 3) 20.08.2018 - 05.09.2018	141 152	1877 2029	7.50 7.50	20.07.2018/0 02.08.2018/13	75	(g) 18-2047 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying
18-2047-05 18-2047-05-T Czech. Republic 751 24 Prerov - Cekyne Europe, North F 2018	Hop ZPC (Zatecky polorany cervnak)	1) 13.03.1996 2) 29.06.2018 - 06.07.2018 3) 21.08.2018 - 31.08.2018	152 151	1524 1513	10.00 10.00	14.07.2018/0 27.07.2018/13	79	(g) 18-2047 (h) SC (fluopyram 250 g/L ,trifloxystrobin 250 g/L) (i) Application method: Spraying

- | | | | | | |
|---|-----|---|---|-----|--------------------|
| - | (a) | According to CODEX Classification / Guide | - | (g) | Study reference |
| - | (b) | Only if relevant | - | (h) | Formulation type |
| - | (c) | Year must be indicated | - | (i) | Application method |
| - | (d) | Either growth stage description or BBCH Code | - | (j) | Method information |
| - | (e) | Days after last application (Label pre-harvest interval, PHI, underline) | - | (k) | LOQ |
| - | (f) | Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included | - | (l) | Method validation |
| - | (m) | Storage (max) | | | |
| - | G | greenhouse | | | |
| | | F field | | | |

Analytical part of study 18-2047

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)							PHI (days)	Details on trial
				Analyte 1 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1-5)		
	(a)		(d)								(e)	(f)
18-2047-01 18-2047-01-T France, north 59270 METEREN Europe, North F 2018	Hop Nuggets	cone, green	71	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	0*	(g) 18-2047 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 18-2047 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 cone, kiln-dried: 260 days Analyte 1, 2, 3, 4, 5, 6 cone, green: 274 days * prior to last treatment
			71	0.20	<0.01	<0.01	<0.01	0.019	<0.01	0.25	0	
			75	0.090	<0.01	<0.01	<0.01	0.025	<0.01	0.15	6	
			81	0.010	<0.01	<0.01	<0.01	<0.01	<0.01	0.050	14	
			89	0.017	<0.01	<0.01	<0.01	0.013	<0.01	0.060	<u>20</u>	
			89	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.05	27	
		cone, kiln-dried	81	0.027	<0.01	<0.01	<0.01	0.041	<0.01	0.099	14	
			89	0.044	<0.01	<0.01	<0.01	0.084	<0.01	0.16	<u>20</u>	
			89	0.056	<0.01	<0.01	<0.01	0.073	<0.01	0.16	<u>27</u>	
18-2047-02 18-2047-02-T Czech Republic 751 16 Zelatovice Europe, North F 2018	Hop Sladek	cone, green	82	3.0	0.027	0.012	0.020	0.13	0.010	3.2	0	(g) 18-2047 (j) Analytical method: 01313/M001 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01313/M001 and residue study 18-2047 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 cone, kiln-dried: 267 days Analyte 1, 2, 3, 4, 5, 6 cone, green: 282 days
			86	0.87	0.019	<0.01	0.014	0.11	<0.01	1.0	7	
			89	0.39	<0.01	<0.01	<0.01	0.081	<0.01	0.50	15	
			89	0.22	<0.01	<0.01	<0.01	0.048	<0.01	0.30	<u>22</u>	
			89	0.21	<0.01	<0.01	<0.01	0.050	<0.01	0.29	27	
		cone, kiln-dried	89	1.7	0.030	0.013	0.034	0.47	0.037	2.3	15	
			89	0.62	0.014	<0.01	0.020	0.31	0.024	0.98	<u>22</u>	
			89	0.44	0.015	<0.01	0.016	0.26	0.026	0.75	27	

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 Trifloxy- strobilin as trifloxy- strobilin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1-5)		
18-2047-03 18-2047-03-T Germany 84091 Attenhofen Europe, North F 2018	Hop Perle	cone, green	75	0.11	<0.01	<0.01	<0.01	0.062	<0.01	0.20	0*	(g) 18-2047
			75	0.88	<0.01	<0.01	<0.01	0.14	<0.01	1.1	0	(j) Analytical method: 01313/M001
			79	0.61	<0.01	<0.01	<0.01	0.12	<0.01	0.76	6	(k) LOQ: 0.01 mg/kg
			81	0.36	<0.01	<0.01	<0.01	0.11	<0.01	0.50	14	(l) Method Validation Data in method 01313/M001 and
			89	0.30	<0.01	<0.01	<0.01	0.068	<0.01	0.40	20	residue study 18-2047
			89	0.078	<0.01	<0.01	<0.01	0.023	<0.01	0.13	27	(m) Storage:
		cone, kiln- dried	81	0.72	<0.01	<0.01	0.011	0.24	0.011	1.0	14	Analyte 1, 2, 3, 4, 5, 6 cone, kiln-dried: 274 days
			89	0.17	<0.01	<0.01	<0.01	0.060	<0.01	0.26	20	Analyte 1, 2, 3, 4, 5, 6 cone, green: 288 days
			89	0.44	<0.01	<0.01	<0.01	0.15	0.010	0.63	27	* prior to last treatment
18-2047-04 18-2047-04-T Germany 88069 Tett nang Europe, North F 2018	Hop Tett nanger	cone, green	75	0.046	<0.01	<0.01	<0.01	0.047	<0.01	0.13	0*	(g) 18-2047
			75	0.65	<0.01	<0.01	<0.01	0.16	<0.01	0.85	0	(j) Analytical method: 01313/M001
			79	0.22	<0.01	<0.01	<0.01	0.18	0.011	0.44	7	(k) LOQ: 0.01 mg/kg
			81	0.074	<0.01	<0.01	<0.01	0.051	<0.01	0.16	14	(l) Method Validation Data in method 01313/M001 and
			89	0.083	<0.01	<0.01	<0.01	0.068	<0.01	0.18	21	residue study 18-2047
			89	0.083	<0.01	<0.01	<0.01	0.044	<0.01	0.16	28	(m) Storage:
		cone, kiln- dried	81	0.49	0.012	0.012	0.018	0.36	0.024	0.90	14	Analyte 1, 2, 3, 4, 5, 6 cone, kiln-dried: 280 days
			89	0.30	<0.01	<0.01	<0.01	0.24	0.020	0.58	21	Analyte 1, 2, 3, 4, 5, 6 cone, green: 294 days
			89	0.42	<0.01	<0.01	<0.01	0.32	0.026	0.78	28	* prior to last treatment
18-2047-05 18-2047-05-T Czech. Republic 751 24 Prerov - Cekyne Europe, North F 2018	Hop ZPC (Zatecky polorany cervenak)	cone, green	79	0.42	<0.01	<0.01	<0.01	0.12	<0.01	0.57	0*	(g) 18-2047
			79	2.3	0.022	0.012	0.017	0.26	0.013	2.6	0	(j) Analytical method: 01313/M001
			85	1.1	0.028	0.013	0.025	0.26	0.017	1.4	7	(k) LOQ: 0.01 mg/kg
			88	0.42	0.012	<0.01	0.012	0.16	0.011	0.62	13	(l) Method Validation Data in method 01313/M001 and
			89	0.25	<0.01	<0.01	<0.01	0.11	<0.01	0.39	22	residue study 18-2047
			89	0.25	<0.01	<0.01	<0.01	0.11	0.012	0.39	27	(m) Storage:
		cone, kiln- dried	88	0.99	0.019	0.018	0.034	0.74	0.043	1.8	13	Analyte 1, 2, 3, 4, 5, 6 cone, kiln-dried: 287 days
			89	0.61	0.014	<0.01	0.015	0.42	0.034	1.1	22	Analyte 1, 2, 3, 4, 5, 6 cone, green: 300 days
			89	0.47	0.015	<0.01	0.011	0.31	0.026	0.83	27	* prior to last treatment

A 2.1.3.10.2 Study 10-2127 (Hops, northern Europe)

Comments of zRMS:	<p>In this study the residues of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 and its metabolite CGA 321113 and CGA 373466 were determined.</p> <p>One trial was conducted in N-EU (France) during the 2010 season to determine the magnitude of trifloxystrobin (comprising trifloxystrobin, CGA 321113, CGA 357261, CGA 357262, CGA 331409 and CGA 373466) in/on hop (cone, green and cone, kiln-dried) after two spray applications with 0.15 kg/ha trifloxystrobin with 12 days between applications at BBCH 75 and with PHI of 22 days for cone, green and kiln-dried.</p> <p>Residues of trifloxystrobin, stereo-isomers and metabolites were determined by HPLC-MS/MS according to method 01313.</p> <p>The LOQ for all compounds, defined as the lowest validated fortification level, was 0.05 mg/kg for cone, kiln-dried samples.</p> <p>No residues above the LOQ were found in the control samples. The average recoveries were within the acceptable range of 70 – 110% with RSD values below 20%.</p> <p>The residue level of trifloxystrobin in/on cone, kiln-dried was: RD-Mo: 0.07 mg/kg, RD-RA:0.43 mg/kg.</p> <p>The storage period of deep-frozen samples for trifloxystrobin analysis (AG02) and its metabolite / isomers ranged between 356 and 384 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.12.1/02
Title:	Determination of the residues of AE C656948 and trifloxystrobin in/on hop after spraying of AE C656948 & CGA279202 SC 500 in the field in France (North)
Report:	Noss, G.; Ballmann, C.; 2012; 10-2127; M-432715-01-1
Authority registration No:	
Guideline(s):	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)
Deviations:	the soil characterization, the weather data recording, the irrigation recording, the pesticide history, the cultural practices and the applications for maintenance (if relevant) which were not conducted under GLP
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on hops with application rates of about 140 g/ha trifloxystrobin and 2045-2068 L water per ha. The applications were done with a spray interval of 12 days, with the last application 22 day before the harvest.

Concurrent recoveries obtained during the conduct of this study were acceptable with overall mean values in the range 70-110%. All RSD values were below 20%.

Table A 56: Summary of the study 10-2127 trials – GAP summary

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)
10-2127-01 10-2127-01-T France, north 67117 Dossenheim- Kochersberg Europe, North F 2010	Hop Tradition	1) 2006 3) 02.09.2010	141.0 139.5	2068 2045	6.818 6.822	30.07.2010/0 11.08.2010/12	75	(g) 10-2127 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying

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|---|--------------------------|
| - (a) According to CODEX Classification / Guide | - (g) Study reference |
| - (b) Only if relevant | - (h) Formulation type |
| - (c) Year must be indicated | - (i) Application method |
| - (d) Either growth stage description or BBCH Code | - (j) Method information |
| - (e) Days after last application (Label pre-harvest interval, PHI, underline) | - (k) LOQ |
| - (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included | - (l) Method validation |
| - (m) Storage (max) | |
| - G greenhouse F field | |

Analytical part of study 10-2127

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

Trial No. / Location / EU zone / Year	Commodity / Variety	Portion analyzed	Growth stage at sampling	Residues (mg/kg)							PHI (days)	Details on trial
				Analyte 1 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1-5)		
	(a)		(d)								(e)	(f)
10-2127-01 10-2127-01-T France, north 67117 Dossenheim- Kochersberg Europe, North F 2010	Hop Tradition	cone, green	75	0.03	<0.01	<0.01	<0.01	0.05	<0.01	0.11	0*	(g) 10-2127 (j) Analytical method: 01313 (k) LOQ: Analyte 1, 2, 3, 4, 5, 6 cone, kiln-dried: 0.05 mg/kg Analyte 1, 2, 3, 4, 5, 6 cone, green: 0.01 mg/kg (l) Method Validation Data: method 01313 and 10-2127 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 cone, kiln-dried: 369 days Analyte 1, 2, 3, 4, 5, 6 cone, green: 384 days * prior to last treatment
			75	0.48	<0.01	<0.01	<0.01	0.13	<0.01	0.64	0	
			83	0.07	<0.01	<0.01	<0.01	0.06	<0.01	0.16	7	
			87	0.05	<0.01	<0.01	<0.01	0.07	<0.01	0.15	15	
			89	0.03	<0.01	<0.01	<0.01	0.04	<0.01	0.10	<u>22</u>	
			89	0.04	<0.01	<0.01	<0.01	0.04	<0.01	0.11	<u>28</u>	
	cone, kiln- dried		87	0.06	<0.05	<0.05	<0.05	0.19	<0.05	0.41	15	
			89	0.07	<0.05	<0.05	<0.05	0.20	<0.05	0.43	<u>22</u>	
			89	0.07	<0.05	<0.05	<0.05	0.20	<0.05	0.43	<u>28</u>	

A 2.1.3.10.3 Study 09-2076 and MR-11/044 (Hops, northern Europe)

Comments of zRMS:	<p>In the study of Stuke, S.; 2013 (MR-11/044; M-421645-02-1) the residues of trifloxystrobin (CGA 279202) and its stereo-isomers CGA 357261, CGA 357262, CGA 331409 and its metabolite CGA 321113 and CGA 373466 were determined.</p> <p>Four trials were conducted in N-EU (France, Germany) during the 2009 season to determine the magnitude of trifloxystrobin (comprising trifloxystrobin, CGA 321113, CGA 357261, CGA 357262, CGA 331409 and CGA 373466) in/on hop (cone, green and cone, kiln-dried) after two spray applications with 0.15 kg/ha trifloxystrobin with 12 days between applications at BBCH 79-87 and with PHI of 20-21 days for cone, green and kiln-dried. Residues of trifloxystrobin, stereo-isomers and metabolites were determined by HPLC-MS/MS according to method 01313.</p> <p>The LOQ for all compounds, defined as the lowest validated fortification level, was 0.05 mg/kg for cone, kiln-dried samples.</p> <p>The average recoveries were within the acceptable range of 70 – 110% with RSD values below 20%.</p> <p>The residue level of trifloxystrobin in/on cone, kiln-dried was: RD-Mo: 0.24, 0.63, 0.74, 1.3 mg/kg, RD-RA: 0.47, 1.1, 1.5, 1.6 mg/kg.</p> <p>The storage period of deep-frozen samples for trifloxystrobin analysis (AG02) and its metabolite / isomers ranged between 639 and 719 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.12.1/03
Title:	Amendment No. 1 to report no: 09-2076 - Determination of the residues of AE C656948 and trifloxystrobin in/on hop after spraying of AE C656948 & CGA279202 SC 500 in the field in France (North) and Germany
Report:	Noss, G.; Ballmann, C.; 2012; 09-2076; M-423507-02-1
Authority registration No:	
Guideline(s):	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Reference:	KCA 6.3.12.1/04
Title:	Amendment no. 1 to report no: P 652 11 5503 - Determination of the residues of trifloxystrobin, CGA 357261, CGA 357262, CGA 331409, CGA 321113, and CGA 373466 in/on materials of plant origin by HPLCMS/MS
Report:	Stuke, S.; 2013; MR-11/044; M-421645-02-1
Authority registration No:	
Guideline(s):	EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on hops with application rates of

about 150 g/ha trifloxystrobin and up to 2400 L water per ha. The applications were done with a spray interval of about 14 days, with the last application about 21 days before the harvest. A fifth trial is not summarised below, since no sampling was done at the intended PHI of 21 days. Analysis of all six analytes as reported below was done in study MR-11/044.

Concurrent recoveries obtained during the conduct of this study were acceptable with overall mean values in the range 70-110%, and the corresponding RSD values below 20%.

Table A 57: Summary of the study 09-2076 (and MR-11/044) trials – GAP summary

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)
09-2076-02 09-2076-02-MR- 11/044 Germany 06408 Weddegast Europe, North F 2009	Hop Magnum	1) 1998 2) 11.07.2009 - 08.08.2009 3) 08.09.2009	150 150	2000 2000	7.5 7.5	05.08.2009/0 19.08.2009/14	79	(g) 09-2076 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
09-2076-03 09-2076-03-MR- 11/044 Germany 84091 Attenhofen Europe, North F 2009	Hop Herkules	1) 2005 2) 20.07.2009 - 20.08.2009 3) 10.09.2009	150 150	2400 2400	6.3 6.3	06.08.2009/0 20.08.2009/14	87	(g) 09-2076 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
09-2076-04 09-2076-04-MR- 11/044 Germany 85283 Wolznach Europe, North F 2009	Hop Perle	1) 1991 2) 10.07.2009 - 05.08.2009 3) 03.09.2009	150 150	2400 2400	6.3 6.3	29.07.2009/0 13.08.2009/15	79	(g) 09-2076 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
09-2076-05 09-2076-05-MR- 11/044 Germany 88069 Tettngang Europe, North F 2009	Hop Hallertauer Mittelfrüh	1) 1984 2) 05.07.2009 - 20.07.2009 3) 07.09.2009	150 150	2100 2100	7.1 7.1	31.07.2009/0 17.08.2009/17	83	(g) 09-2076 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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)
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ

- | | | | |
|---|---|---------|-----------------------|
| - | (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included | - | (l) Method validation |
| - | (m) Storage (max) | | |
| - | G greenhouse | F field | |

Analytical part of study 09-2076 (and MR-11/044)

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA 321113), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as CGA 373466)

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 trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1-5)		
09-2076-02 09-2076-02-MR- 11/044 Germany 06408 Weddegast Europe, North F 2009	Hop Magnum	cone, green	79	0.05	<0.05	<0.05	<0.05	0.08	<0.05	0.28	0*	(g) 09-2076 (j) Analytical method: 01313 (k) LOQ: 0.05 mg/kg (l) Method Validation Data: 01313 and MR-11/044 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 cone, kiln-dried: 719 days Analyte 1, 2, 3, 4, 5, 6 cone, green: 639 days * prior to last treatment
			79	0.93	<0.05	<0.05	<0.05	0.20	<0.05	1.3	0	
			82	0.61	<0.05	<0.05	<0.05	0.33	<0.05	1.1	7	
			87	0.13	<0.05	<0.05	<0.05	0.15	<0.05	0.44	14	
			89	0.37	<0.05	<0.05	<0.05	0.29	<0.05	0.82	<u>20</u>	
			89	0.28	<0.05	<0.05	<0.05	0.31	<0.05	0.75	28	
		cone, kiln- dried	87	n.a.	n.a.	n.a.	n.a.	n.a.	-	14		
			89	0.52	<0.05	<0.05	0.05	0.53	0.05	1.2	<u>20</u>	
			89	0.63	0.05	<0.05	0.06	0.71	0.08	1.5	<u>28</u>	
09-2076-03 09-2076-03-MR- 11/044 Germany 84091 Attenhofen Europe, North F 2009	Hop Herkules	cone, green	87	0.22	<0.05	<0.05	<0.05	0.08	<0.05	0.45	0*	(g) 09-2076 (j) Analytical method: 01313 (k) LOQ: 0.05 mg/kg (l) Method Validation Data: 01313 and MR-11/044 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 cone, kiln-dried: 630 days Analyte 1, 2, 3, 4, 5, 6 cone, green: 644 days * prior to last treatment
			87	1.4	<0.05	<0.05	<0.05	0.21	<0.05	1.8	0	
			87	0.35	<0.05	<0.05	<0.05	0.13	<0.05	0.63	7	
			87	0.14	<0.05	<0.05	<0.05	0.10	<0.05	0.39	14	
			89	0.13	<0.05	<0.05	<0.05	0.08	<0.05	0.36	<u>21</u>	
			90	0.71	<0.05	<0.05	<0.05	0.08	<0.05	0.94	<u>28</u>	
		cone, kiln- dried	87	0.26	<0.05	<0.05	<0.05	0.10	<0.05	0.51	14	
			89	0.21	<0.05	<0.05	<0.05	0.13	<0.05	0.49	<u>21</u>	
			90	1.3	<0.05	<0.05	<0.05	0.13	<0.05	1.6	28	

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 trifloxy- strobins as trifloxy- strobins	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466	Total residue (Analyte 1-5)						
09-2076-04 09-2076-04-MR-11/044 Germany 85283 Wolznach Europe, North F 2009	Hop Perle	cone, green	79	0.10	<0.05	<0.05	<0.05	<0.05	<0.05	0.30	0*	(g) 09-2076 (j) Analytical method: 01313 (k) LOQ: 0.05 mg/kg (l) Method Validation Data: 01313 and MR-11/044 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 cone, kiln-dried: 651 days Analyte 1, 2, 3, 4, 5, 6 cone, green: 665 days * prior to last treatment ** residues in control				
			79	1.8	<0.05	<0.05	<0.05	<0.07	<0.05	2.0	0					
			87	0.95	<0.05	<0.05	<0.05	0.19	<0.05	1.3	7					
			89	0.46	<0.05	<0.05	<0.05	0.15	<0.05	0.77	14					
			89	0.31	<0.05	<0.05	<0.05	0.12	<0.05	0.58	21					
			90	0.17	<0.05	<0.05	<0.05	0.07	<0.05	0.39	28					
		cone, kiln-dried	89	1.2/0.10**	<0.05	<0.05	0.05	0.32	<0.05	1.7	14					
			89	0.74	<0.05	<0.05	<0.05	0.23	<0.05	1.1	21					
			90	0.44	<0.05	<0.05	<0.05	0.13	<0.05	0.72	28					
			09-2076-05 09-2076-05-MR-11/044 Germany 88069 Tettngang Europe, North F 2009	Hop Hallertauer Mittelfrüh	cone, green	83	0.46	<0.05	<0.05	<0.05	0.11		<0.05	0.72	0*	(g) 09-2076 (j) Analytical method: 01313 (k) LOQ: 0.05 mg/kg (l) Method Validation Data: 01313 and MR-11/044 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 cone, kiln-dried: 648 days Analyte 1, 2, 3, 4, 5, 6 cone, green: 662 days * prior to last treatment
						83	0.76	<0.05	<0.05	<0.05	0.21		<0.05	1.1	0	
						89	0.36	<0.05	<0.05	<0.05	0.10		<0.05	0.61	7	
89	0.21	<0.05				<0.05	<0.05	0.07	<0.05	0.43	14					
89	0.09	<0.05				<0.05	<0.05	<0.05	<0.05	0.29	21					
90	0.13	<0.05				<0.05	<0.05	<0.05	<0.05	0.33	28					
cone, kiln-dried	89	0.26			<0.05	<0.05	<0.05	0.14	<0.05	0.56	14					
	89	0.14			<0.05	<0.05	<0.05	0.06	<0.05	0.35	21					
	90	0.24			<0.05	<0.05	<0.05	0.08	<0.05	0.47	28					

A 2.1.3.10.4 Study 08-2086 (Hops, northern Europe)

Comments of zRMS:	<p>Four supervised residue trials were conducted with the formulation AE C656948 & CGA 279202 SC 500 in hop during 2008. Two spray applications with application rates of 150 g trifloxystrobin/ha were done with a spray interval of 14-15 days, with the last application 21 days prior to be expected date of harvest.</p> <p>The residues of trifloxystrobin and the CGA 321113 metabolite were determined according to the analytical method 01013/M002 by HPLC-MS/MS.</p> <p>The Limit of Quantitation (LOQ), defined as the lowest validated fortification level, was 0.1 mg/kg for both, trifloxystrobin and CGA 321113 in hop.</p> <p>In report it is stated that: <i>“For trifloxystrobin residues in control samples of trial 08-2086-01, 08-2086-02 and 08-2086-03 ranged from the < 0.10 mg/kg (LOQ) to 1.5 mg/kg whereas in control samples of trial 08-2086-04 no residues above the LOQ were found. For CGA321113 no residues in control samples above the LOQ = 0.10 mg/kg were found with the exception of trial 08-2086-02 where the residues for cone, kiln-dried at DALT 14 and 21 were 0.12 mg/kg.</i></p> <p><i>Control samples in trials 08-2086-01, 08-2086-02 and 08-2086-03 exhibited considerable residue levels of trifloxystrobin, but none of AE C656948. This is not characteristic of a contamination of the samples with the test item, nor do the maintenance treatments on the plots give any indication of why trifloxystrobin is present (with the exception of trial 08-2086-01 where trifloxystrobin was applied for maintenance on July 06, 2008 and July 14, 2008, 30 and 22 days before the start of trial). Thus it is assumed that the farmers whose land was used for the trials applied Flint or a similar trifloxystrobin-containing product on their adjacent fields and that the product deposited on the test plots via spray drift.”</i></p> <p>The storage period of deep-frozen samples for trifloxystrobin and its metabolite ranged between 656 and 700 days. The studies on the magnitude of residues are valid with regard to storage stability.</p> <p>The residue level of trifloxystrobin in/on cone, kiln-dried was: RD-Mo: 0.39, 0.89, 1.1, 1.2 mg/kg.</p> <p>Remark: <u>In this study only the residues of trifloxystrobin and the CGA 321113 metabolite were determined.</u> The 3 isomers of trifloxystrobin (CGA 357262, CGA 357261 and CGA 331409) were not analysed in this study, so only the existing plant residue definition for monitoring can be followed (Reg. (EU) 2019/1791).</p> <p>The study can be considered as informative.</p>
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Reference:	KCA 6.3.12.1/05
Title:	Determination of the residues of AE C656948 and trifloxystrobin in/on hop after spraying of AE C656948 & CGA 279202 SC 500 in the field in France (North) and Germany
Report:	Noss, G.; 2010; 08-2086; M-389144-01-1
Authority registration No:	
Guideline(s):	EU: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8; EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

The formulation Fluopyram + Trifloxystrobin SC 500, a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin, was applied two times on hops with application rates of 150 g/ha trifloxystrobin and 2000-2500 L water per ha. The applications were done with a spray interval of 14-15 days, with the last application 21 days before the harvest.

Concurrent recoveries obtained during the conduct of this study were acceptable with overall mean values

in the range 70-110%. All RSD values were below 20%.

Although only trifloxystrobin and GA 321113 were analysed, the trials are relevant for MRL setting and are therefore summarised below.

Table A 58: Summary of the study 08-2086 trials – GAP summary

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			
08-2086-01 France, north 67160 Schleithal Europe, North F 2008	Hop Stiesselspalt	1) 1998 2) 15.07.2008	150 150	2000 2000	7.5 7.5	05.08.2008/0 20.08.2008/15	79	(g) 08-2086 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
08-2086-02 France, north 67210 Obernai Europe, North F 2008	Hop Stiesselspalt	1) 1998 2) 15.07.2008	150 150	2000 2000	7.5 7.5	06.08.2008/0 21.08.2008/15	79	(g) 08-2086 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
08-2086-03 Germany 85283 Wolnzach Europe, North F 2008	Hop Perle	1) 1991 2) 07.07.2008 - 25.07.2008	150 150	2500 2500	6.0 6.0	24.07.2008/0 07.08.2008/14	75	(g) 08-2086 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying
08-2086-04 Germany 88069 Tettngang Europe, North F 2008	Hop Spalter	1) 1950 2) 10.07.2008 - 08.08.2008	150 150	2500 2500	6.0 6.0	29.07.2008/0 13.08.2008/15	78	(g) 08-2086 (h) SC (fluopyram 250 g/L, trifloxystrobin 250 g/L) (i) Application method: Spraying

- (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
- (m) Storage (max)
- G greenhouse F field
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ
- (l) Method validation

Analytical part of study 08-2086

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 321113 (determined as CGA 321113, calculated as CGA 321113)

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 321113 as CGA 321113			
08-2086-01 France, north 67160 Schleithal Europe, North F 2008	Hop Stiesselspalt	cone, green	79	0.13	<0.10		0*	(g) 08-2086 (j) Analytical method: 01013/M002 (k) LOQ: 0.10 mg/kg (l) Method Validation Data in method 01013/M002 and residue study 08-2086 (m) Storage: Analyte 1, 2 hops draff: 679 days Analyte 1, 2 cone, kiln-dried: 671 days Analyte 1, 2 cone, green: 686 days Analyte 1, 2 brewer's yeast: 684 days Analyte 1, 2 beer: 679 days * prior to last treatment ** residues in control
			79	1.1	<0.10		0	
			83	0.47	<0.10		7	
			87	0.33	<0.10		14	
			89	0.25	<0.10		21	
			89	0.18	<0.10		28	
		cone, kiln- dried		1.3/0.25**	0.23		14	
				0.89/0.13**	0.23		21	
				0.78	0.17		28	
08-2086-02 France, north 67210 Obernai Europe, North F 2008	Hop Stiesselspalt	cone, green	79	0.18	0.14		0*	(g) 08-2086 (j) Analytical method: 01013/M002 (k) LOQ: 0.10 mg/kg (l) Method Validation Data in method 01013/M002 and residue study 08-2086 (m) Storage: Analyte 1, 2 cone, kiln-dried: 670 days Analyte 1, 2 cone, green: 685 days * prior to last treatment ** residues in control
			79	1.0	<0.10		0	
			83	0.48	<0.10		7	
			87	0.29/0.10**	<0.10		14	
			89	0.29	<0.10		21	
			89	0.22	<0.10		28	
		cone, kiln- dried		1.5/0.59**	0.28/0.12**		14	
				1.2/0.36**	0.30/0.12**		21	
				0.95	0.26		28	

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 Trifloxy- strobin as trifloxy- strobin	Analyte 2 CGA 321113 as CGA 321113			
08-2086-03 Germany 85283 Wolnzach Europe, North F 2008	Hop Perle	cone, green	75	0.19/1.5**	<0.10		0*	(g) 08-2086 (j) Analytical method: 01013/M002 (k) LOQ: 0.10 mg/kg (l) Method Validation Data in method 01013/M002 and residue study 08-2086 (m) Storage: Analyte 1, 2 hops draff: 692 days Analyte 1, 2 cone, kiln-dried: 547 days Analyte 1, 2 cone, green: 700 days Analyte 1, 2 brewer's yeast: 697 days Analyte 1, 2 beer: 692 days * prior to last treatment ** residues in control
			75	2.0	0.21		0	
				0.57	0.18		7	
			87	0.41/0.14**	0.13		14	
			89	0.14	0.12		21	
			89	0.13	0.11		28	
		cone, kiln- dried		0.67/0.23**	0.31		14	
				0.39	0.31		21	
				0.29	0.27		28	
08-2086-04 Germany 88069 Tett nang Europe, North F 2008	Hop Spalter	cone, green	78	0.33	0.13		0*	(g) 08-2086 (j) Analytical method: 01013/M002 (k) LOQ: 0.10 mg/kg (l) Method Validation Data in method 01013/M002 and residue study 08-2086 (m) Storage: Analyte 1, 2 cone, kiln-dried: 678 days Analyte 1, 2 cone, green: 694 days * prior to last treatment
			78	1.2	0.11		0	
			86	0.64	<0.10		7	
			89	0.60	<0.10		14	
			89	0.41	<0.10		21	
			89	0.37	<0.10		28	
		cone, kiln- dried		1.4	0.31		14	
				0.91	0.24		21	
				1.1	0.30		28	

A 2.1.4 7.2.4 Magnitude of residues in livestock – Trifloxystrobin

**A 2.1.4.1 7.2.4.2 Livestock feeding studies (poultry KCA 6.4.1 - ruminants KCA 6.4.2
- pig KCA 6.4.3 – fish 6.4.4)**

No additional study has been submitted.

**A 2.1.5 7.2.5 Magnitude of residues in processed commodities (Industrial
Processing and/or Household Preparation) (KCA 6.5.2-6.5.3) –
Trifloxystrobin**

A 2.1.5.1 Distribution of the residue in peel/pulp (KCA 6.5.2)

No additional submitted within this dossier.

A 2.1.5.2 Processing studies on a core set of representative processes (KCA 6.5.3)

Processing data on grape and strawberry were already submitted and evaluated and are not summarised again.

Studies on bean and hops are summarised below.

A 2.1.5.2.1 Study report RA-3037/02 (Bean - processing)

Comments of zRMS:

After three spray applications of Trifloxystrobin WG 50 to climbing french beans in Germany and Italy (greenhouse) and subsequent processing of beans with pod to washed and cooked beans with pod, washing and cooking water, residues of trifloxystrobin and CGA 321113 in/on the raw agricultural commodity and the processed products were determined.

Residues of the parent compound trifloxystrobin and its metabolite CGA 321113 were determined by HPLC-MS/MS according to method 00742/E001.

The analytical method 00742/E001 was validated prior to analysis by running a set of recoveries at the LOQ. The LOQ was 0.02 mg/kg for both, trifloxystrobin and CGA 321113. The recoveries for trifloxystrobin ranged from 79 to 106% with mean values (per level) between 90 and 96% and relative standard deviations (RSD) between 5.5 and 10.3%. In case of CGA 321113, the recoveries were between 81 and 96% with mean values (per level) between 90 and 94% and relative standard deviations between 1.8 and 9.5%.

Table 7: Recovery data for trifloxystrobin and CGA 321113 in climbing french beans, beans with pod (FL: fortification level, RSD: relative standard deviation, LOQ: practical limit of quantitation)

Sample Material	Analyte	FL [mg/kg]	Single Values [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg]
Bean with pod ^a	Trifloxystrobin ^b	0.02	92 92 94 104	96	6.0	0.02
		0.2	91 91 93 90 92 106 93 94 96 88 94 90 84	92	5.5	
		2.0	79 95 95	90	10.3	
		Overall Recovery a.s. Trifloxystrobin, n=20			93	6.3
Bean with pod ^a	CGA 321113 ^c	0.02	92 94 93 96	94	1.8	0.02
		0.2	88 90 91 90 92 92 95 91 91 86 91 87 82	90	3.7	
		2.0	81 96 96	91	9.5	
		Overall Recovery CGA 321113, n=20			91	4.7

^a The recoveries for the sample material bean with pod also covers the recoveries of the sample materials washing and cooking water.

^b Final determination as : Trifloxystrobin, Residues calculated as : Trifloxystrobin

^c Final determination as : CGA 321113, Residues calculated as : CGA 321113

In the sample of French bean taken at harvest in study R 2002 0072/2, the residue of trifloxystrobin was 0.10 mg/kg. After processing, the trifloxystrobin residues were 0.04 and 0.07 mg/kg for washing water, 0.05 and 0.06 mg/kg for washed beans with pod, 0.03 and 0.04 mg/kg for cooked beans with pod and below the LOQ of 0.02 mg/kg for cooking water. The residue of trifloxystrobin was 0.18 mg/kg in/on the sample of climbing French bean taken at harvest in study R 2002 0181/8. After processing, the trifloxystrobin residues were 0.05 and 0.04 mg/kg for washing water, 0.10 and 0.14 mg/kg for washed beans with pod, 0.15 and 0.13 mg/kg for cooked beans with pod and below the LOQ of 0.02 mg/kg for cooking water.

No residues of trifloxystrobin above the LOQ of 0.02 mg/kg were found in the control samples.

Residues of CGA 321113 were below the LOQ of 0.02 mg/kg in all samples.

All calculated transfer factors for trifloxystrobin were < 1.0. It is concluded that reduction of residues was seen in washed bean with pod, washing water, cooked bean with pod and cooking water.

No transfer factors could be calculated for CGA 321113, because the residues both in the raw agricultural commodity and in the processed products were below the LOQ.

The study is acceptable.

Reference:	KCA 6.5.3/03
Title:	Determination of residues of trifloxystrobin and CGA 321113 in/on climbing French bean and processing products (...) following spray application of Flint 50 WG in the greenhouse in Germany and Italy
Report:	Nuesslein, F.; 2003; RA-3037/02; M-104911-01-1
Authority registration No:	
Guideline(s):	-- EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, point 6 and Annex III, part A, point 8 Residues in or on Treated Products, Food and Feed
Deviations:	--
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Materials and methods

A processing study was conducted on beans. Two greenhouse trials were conducted in 2002 with Trifloxystrobin WG 50. Three spray applications were performed at maximum rates of 0.125 kg trifloxystrobin/ha per application. The applications were done at with spray intervals of 7 days and a PHI of 1 day.

Bean pod samples were taken 1 day after the last treatment. Residues were determined in the raw agricultural commodity (bean with pod), washed bean, washing water, cooked bean and cooking water. The washing and cooking of climbing French beans was done using household practices.

"Washed bean" samples were prepared by washing beans in standing water under slow movement. The washed beans and samples of washing water were stored deep frozen until analysis.

For the preparation of cooked beans, the beans were washed in standing water under slow movement. After washing the beans were cut in small pieces and then cooked for 15 to 20 minutes in salt water. The cooked beans and samples of cooking water were stored deep frozen until analysis.

Residues of trifloxystrobin and CGA 321113 were determined according to method 00742/E001.

Results and discussions

Residues of trifloxystrobin in bean with pod (RAC) were 0.10 and 0.18 mg/kg. Residues of trifloxystrobin ranged from 0.05 to 0.14 mg/kg in washed beans, from 0.04 to 0.07 mg/kg in washing water and from 0.03 to 0.15 mg/kg in cooked beans. No residues of trifloxystrobin were detected in the cooking water, i.e. at least residues below the LOQ of 0.02 mg/kg. No residues of CGA 321113 were detected in all matrices and therefore transfer factors in this study were only calculated for trifloxystrobin itself.

The transfer factors calculated for trifloxystrobin were between 0.5 and 0.8 for washed bean with pod, 0.2 to 0.7 for washing water, 0.3 to 0.8 for cooked bean with pod and 0.1 to 0.2 for cooking water. All transfer factors were < 1.0, trifloxystrobin residues were not concentrated during processing of beans.

The residues values for trifloxystrobin and CGA 321113 and the processing factors for trifloxystrobin are summarised in the tables below.

Table A 59: Residue data from bean processing study – trifloxystrobin and CGA 321113

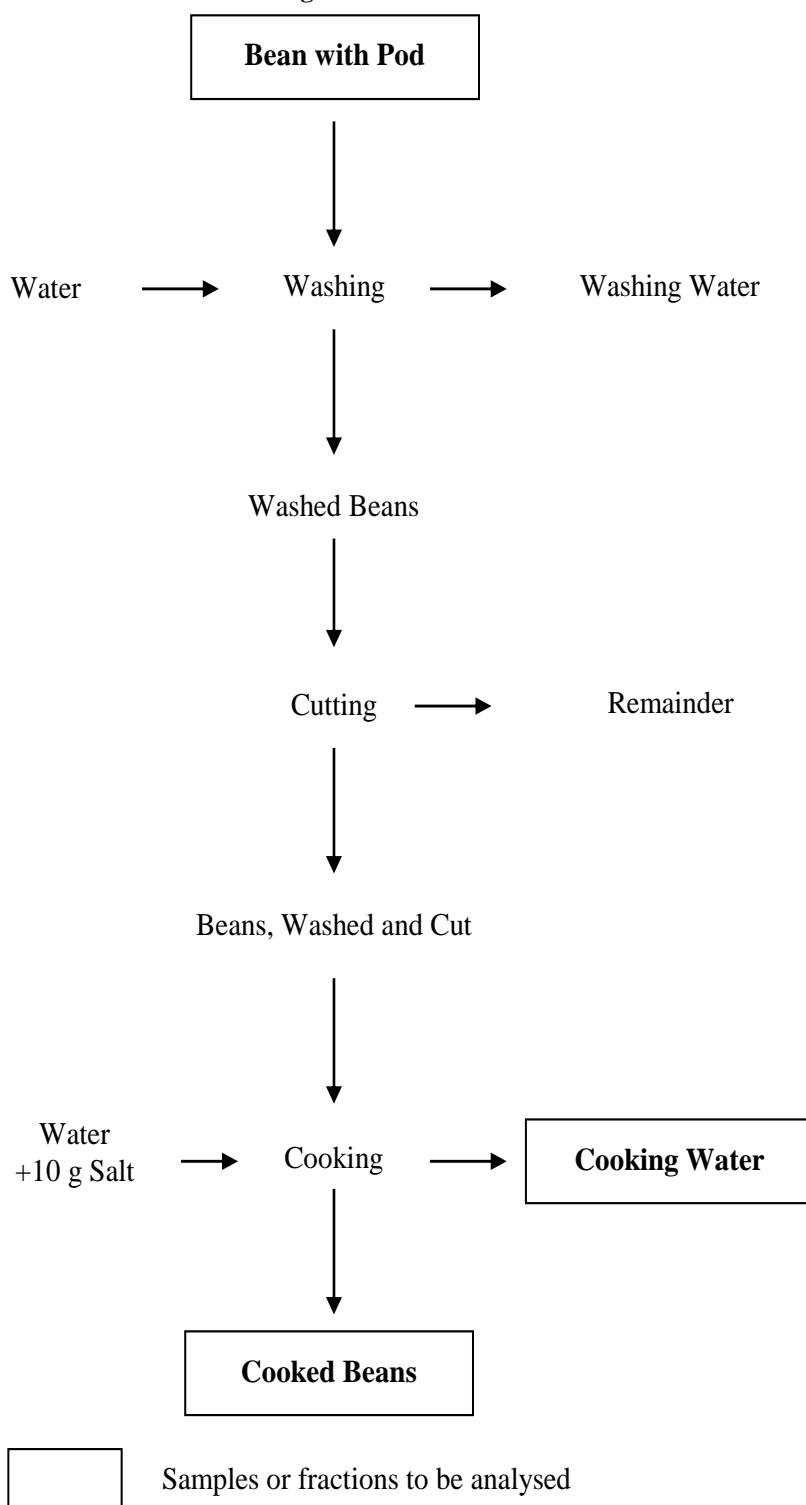
RAC	Residues in RAC (mg/kg)	Processed commodity	Residue trifloxystrobin (mg/kg or mg/L)	Residue CGA 321113 (mg/kg or mg/L)	Comments/ Reference
Bean with pod	Trifloxystrobin: 0.10 CGA 321113: <0.02	Cooked bean	0.03 / 0.04	<0.02 / <0.02	R 2002 0072/2
		Washed bean	0.05 / 0.06	<0.02 / <0.02	
		Washing water	0.04 / 0.07	<0.02 / <0.02	
		Cooking water	<0.02 / <0.02	<0.02 / <0.02	
Bean with pod	Trifloxystrobin:0.18 CGA 321113: <0.02	Cooked bean	0.15 / 0.13	<0.02 / <0.02	R 2002 0181/8
		Washed bean	0.10 / 0.14	<0.02 / <0.02	
		Washing water	0.05 / 0.04	<0.02 / <0.02	
		Cooking water	<0.02 / <0.02	<0.02 / <0.02	

Table A 60: Residue data from bean processing study – trifloxystrobin

RAC	Residues in RAC (mg/kg)	Processed commodity	Residue trifloxystrobin (mg/kg or mg/L)	PF*	Comments/ Reference
Bean with pod	Trifloxystrobin: 0.10	Cooked bean	0.03 / 0.04	0.3 / 0.4	R 2002 0072/2
		Washed bean	0.05 / 0.06	0.5 / 0.6	
		Washing water	0.04 / 0.07	0.4 / 0.7	
		Cooking water	<0.02 / <0.02	0.2 / 0.2	
Bean with pod	Trifloxystrobin:0.18	Cooked bean	0.15 / 0.13	0.8 / 0.7	R 2002 0181/8
		Washed bean	0.10 / 0.14	0.6 / 0.8	
		Washing water	0.05 / 0.04	0.3 / 0.2	
		Cooking water	<0.02 / <0.02	0.1 / 0.1	

* PF = processing factor

Figure A 1: Processing flowchart cooked beans



Conclusion

All transfer factors were < 1.0, therefore, trifloxystrobin residues were not concentrated during processing of beans. No residues of CGA 321113 were detected in any of the matrices.

A 2.1.5.2.2 Study report GR01796 (Hops - processing)

Comments of zRMS:	<p>A study on hops processed commodities was submitted. One processing trial in Germany was conducted during the 1996 season. Hops were sprayed four times at 0.38 to 0.50 kg a.s./ha application rate. Hops samples (green and dried cones) were taken on day 7 after the last application. Residues were determined in the raw agricultural commodity (RAC) and in a processed products. Additionally, (untreated) brewer's malt was analysed.</p> <p>Method REM 177.04 was used to determine residues of trifloxystrobin and CGA 321113 in hops processed matrices. Acceptable recoveries were reported for the method.</p> <p>Recoveries: the lowest fortification level was performed at the limit of quantitation; recovery results:</p> <table><tr><th rowspan="2">Substrate</th><th rowspan="2">fortification level</th><th colspan="2">percent recovery of</th></tr><tr><th>CGA 279202</th><th>CGA 321113</th></tr><tr><td rowspan="2">cones green</td><td>0.10 mg/kg</td><td>90</td><td>86</td></tr><tr><td>1.00 mg/kg</td><td>94</td><td>88</td></tr><tr><td rowspan="2">cones dried</td><td>0.50 mg/kg</td><td>112</td><td>91</td></tr><tr><td>5.00 mg/kg</td><td>90</td><td>79</td></tr><tr><td rowspan="2">malt</td><td>0.02 mg/kg</td><td>93</td><td>113</td></tr><tr><td>0.20 mg/kg</td><td>95</td><td>105</td></tr><tr><td rowspan="2">young beer</td><td>0.02 mg/L</td><td>95</td><td>88</td></tr><tr><td>0.20 mg/L</td><td>92</td><td>110</td></tr><tr><td rowspan="2">beer</td><td>0.02 mg/L</td><td>87</td><td>97</td></tr><tr><td>0.20 mg/L</td><td>98</td><td>113</td></tr><tr><td rowspan="2">yeast</td><td>0.02 mg/L</td><td>87</td><td>85</td></tr><tr><td>0.20 mg/L</td><td>86</td><td>90</td></tr><tr><td rowspan="2">spent/flocs</td><td>0.02 mg/kg</td><td>73</td><td>75</td></tr><tr><td>0.20 mg/kg</td><td>92</td><td>82</td></tr><tr><td rowspan="2">wort</td><td>0.02 mg/L</td><td>85</td><td>86</td></tr><tr><td>0.20 mg/L</td><td>90</td><td>94</td></tr></table> <p>Correction of results: Residue results were neither corrected for control nor for recoveries.</p> <p>All calculated transfer factors for trifloxystrobin and CGA 321113 were < 1.0 for all hops processed matrices. It is concluded that reduction of residues was seen in processed commodities of hops. No residues above LOQ were found in beer.</p> <p>The study is acceptable.</p>	Substrate	fortification level	percent recovery of		CGA 279202	CGA 321113	cones green	0.10 mg/kg	90	86	1.00 mg/kg	94	88	cones dried	0.50 mg/kg	112	91	5.00 mg/kg	90	79	malt	0.02 mg/kg	93	113	0.20 mg/kg	95	105	young beer	0.02 mg/L	95	88	0.20 mg/L	92	110	beer	0.02 mg/L	87	97	0.20 mg/L	98	113	yeast	0.02 mg/L	87	85	0.20 mg/L	86	90	spent/flocs	0.02 mg/kg	73	75	0.20 mg/kg	92	82	wort	0.02 mg/L	85	86	0.20 mg/L	90	94
Substrate	fortification level			percent recovery of																																																											
		CGA 279202	CGA 321113																																																												
cones green	0.10 mg/kg	90	86																																																												
	1.00 mg/kg	94	88																																																												
cones dried	0.50 mg/kg	112	91																																																												
	5.00 mg/kg	90	79																																																												
malt	0.02 mg/kg	93	113																																																												
	0.20 mg/kg	95	105																																																												
young beer	0.02 mg/L	95	88																																																												
	0.20 mg/L	92	110																																																												
beer	0.02 mg/L	87	97																																																												
	0.20 mg/L	98	113																																																												
yeast	0.02 mg/L	87	85																																																												
	0.20 mg/L	86	90																																																												
spent/flocs	0.02 mg/kg	73	75																																																												
	0.20 mg/kg	92	82																																																												
wort	0.02 mg/L	85	86																																																												
	0.20 mg/L	90	94																																																												

Reference:	KCA 6.5.3/04
Title:	Trial for determination of residue levels in hops according to BBA Guideline IV, 3-3 and 3-4 (1990)
Report:	Beinhauer, K.; 1996; GR01796; M-052604-02-1
Authority registration No:	
Guideline(s):	-- BBA Guideline IV, 3-3 and 3-4 (1990) IVA Guideline I-III (1992)
Deviations:	--
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Materials and methods

In 1996 one trial was performed in Germany to investigate the effects of processing on the residue level in processed commodities of hops. Trifloxystrobin 50 WG was applied four times to hop plants at a product rate of 0.75 to 1.0 kg/ha corresponding to 0.38 to 0.50 kg a.s./ha. The spray rate was adjusted to the plant height (max. spray volume 5000 L/ha). Samples of green and dried cones were taken at the recommended PHI of 14 days. Residues were determined in the green cone, dried cone (RAC) and in a variety of processed

products. Additionally, (untreated) brewer's malt was analysed.

Analysis for trifloxystrobin and metabolite CGA 321113 was done with method REM 177.04, AG 659, which was already evaluated during the EU review under directive 91/414/EEC of trifloxystrobin.

Results and discussions

Residues in dried cones sampled 14 days after the last application amounted to 15.7 mg/kg (trifloxystrobin) and 1.98 mg/kg (CGA 321113). Processing of hops to beer showed no residues in wort, young beer and beer. Transfer factors are < 1 for all processed matrices, indicating a reduction of residues. The residues values for trifloxystrobin and CGA 321113 and the processing factors for the total residue are summarised in the tables below.

Table A 61: Residue data from hop processing study - trifloxystrobin

RAC	Residues in RAC (mg/kg)	Processed commodity	Residue (mg/kg or mg/L)	Comments/ Reference
Hop, dried cone	15.7	brewer's malt	<0.02	GR01796
		spent hops	0.68	
		wort	<0.02	
		beer, young	<0.02	
		yeast	0.08	
		beer	<0.02	

Table A 62: Residue data from hop processing study - CGA 321113 (as trifloxystrobin)

RAC	Residues in RAC (mg/kg)	Processed commodity	Residue (mg/kg or mg/L)	Comments/ Reference
Hop, dried cone	1.96	brewer's malt	<0.02	GR01796
		spent hops	0.04	
		wort	<0.02	
		beer, young	<0.02	
		yeast	0.04	
		beer	<0.02	

Table A 63: Residue data from hop processing study – total residue (sum of trifloxystrobin and CGA 321113)

RAC	Residues in RAC (mg/kg) *	Processed commodity	Residue (mg/kg or mg/L) *	PF*	Comments/ Reference
Hop, dried cone	17.66	brewer's malt	<0.04	<0.002	GR01796
		spent hops	0.72	0.04	
		wort	<0.04	<0.002	
		beer, young	<0.04	<0.002	
		yeast	0.12	0.007	
		beer	<0.04	<0.002	

* total trifloxystrobin equivalents = mg/kg trifloxystrobin + mg/kg CGA 321113. A value of =LOQ mg/kg is used for residues determined as < LOQ mg/kg.

PF = processing factor

Conclusion

Transfer factors are < 1 for all processed matrices, indicating a reduction of residues. No residues above LOQ were found in beer.

A 2.1.5.2.3 Study report 10-3174 (Hops - processing)

Comments of zRMS:	<p>A study on hops processed commodities was submitted. One processing trial in Germany was conducted during the 2010 season. Hops were sprayed two times at 1.25 kg a.s./ha application rate. Hops samples (hop green cone samples) were taken on day 13 after the last application.</p> <p>Residues were determined in the raw agricultural commodity (RAC) and in a processed products.</p> <p>Residues of trifloxystrobin and its metabolites / isomers were determined by LC-MS/MS according to method 01313. The limits of quantitation (LOQ) for trifloxystrobin (CGA 279202), its isomers CGA 357262, CGA 331409, CGA 357261 and metabolite CGA 321113 and its isomer CGA 373466 are 0.01 mg/kg, for all sample materials tested.</p> <p>All calculated transfer factors for trifloxystrobin, CGA 321113, CGA 331409 and CGA 357261 were < 1.0 for all hops processed matrices.</p> <p>The calculated transfer factor for sum of trifloxystrobin and CGA 321113 was 1.036 for hops draff and 0.02 for brewer's yeast. No residues above LOQ were found in beer.</p> <p>No processing factors for CGA 357262 and CGA 373466 were calculated, because the residues were below LOQ in all processed fractions and in the RAC samples.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.5.3/05
Title:	Determination of the residues of trifloxystrobin in/on hop and the processed fractions (hops draff, brewer's yeast and beer) after spraying of trifloxystrobin WG 50 in the field in Germany
Report:	Noss, G.; Diehl, P.; 2013; 10-3174; M-444838-01-1
Authority registration No:	
Guideline(s):	<p>Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EC</p> <p>EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, point 6 and Annex III, part A, point 8</p> <p>Residues in or on Treated Products, Food and Feed</p> <p>EC guidance working document 7035/VI/95 rev. 5 (1997-07-22)</p> <p>OECD Guideline for the Testing of Chemicals, Magnitude of the Pesticide Residues in Processed Commodities, 508 (2008-10-03)</p> <p>US EPA Ref: OCSPP860.1520.SUPP</p>
Deviations:	Except for the soil characterization, the weather data recording, the irrigation recording, the pesticide history, the cultural practices and the applications for maintenance (if relevant) which were not conducted under GLP.
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Materials and methods

The samples of hop kiln-dried cone to be processed and reference raw agricultural commodity (RAC) samples originate from one supervised residue trial (10-2174-02) in the conduct of study 10-2174. This trial was conducted in the field in northern Europe (Germany) during the 2010 season. The raw agricultural commodities were obtained after two spray applications with Trifloxystrobin WG 50 a water-dispersible granule formulation containing 50% trifloxystrobin.

Hop green cone samples of treated plot and corresponding control plot were harvested at 13 days after the second treatment (DALT 13), BBCH 83. For the preparation of kiln-dried hop cone samples which are defined as raw agricultural commodity (RAC) for this processing study, freshly harvested green hop cones (at least 2 kg) were taken and dried in a sample drier designed to dry hop similar to the driers which are used by the farmers. In this machine, the hop cones were dried gentle but also quickly with ventilation and heat. The drying temperature was between 18 °C and 53 °C. The drying duration was between 6 and 11

hours. These actions were performed during the conduct of the study 10-2174 and the processing of hop kiln-dried samples into processed fractions (hops draff, brewer's yeast and beer) was performed to simulate common industrial processes under responsibility of the processing test site.

Analysis for trifloxystrobin, its isomers and metabolite CGA 321113 and its isomer was done with method 01313, which was already evaluated during the EU review.

Results and discussions

Residues in kiln dried cones sampled 13 days after the last application amounted to 2.1 mg/kg (trifloxystrobin) and 0.18 mg/kg (CGA 321113). Detectable residues were found in hops' draff 0.25mg/kg for Trifloxystrobin and <0.01mg/kg for CGA 321113, in brewer's yeast 0.03mg/kg for Trifloxystrobin and 0.01mg/kg for CGA 321113, respectively. The residues in beer for both trifloxystrobin and CGA 321113 were <0.01mg/kg.

The residues values for all six analytes and the processing factors for the total residue (sum of trifloxystrobin and CGA 321113) are summarised in the tables below.

Table A 64: Residue data from hop processing study

Study No. Trial No. Country	Sample material	Residues [mg/kg]					
		Trifloxy- strobin	CGA 321113	CGA 331409	CGA 357262	CGA 357261	CGA 373466
10-3174 10-3174-01 Germany	cones, kiln dried (RAC)	2.1	0.18	<0.05	<0.05	<0.05	<0.05
	hops draff	0.25	<0.01	0.03	<0.01	0.01	<0.01
	brewer's yeast	0.03	0.01	<0.01	<0.01	<0.01	<0.01
	beer	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01

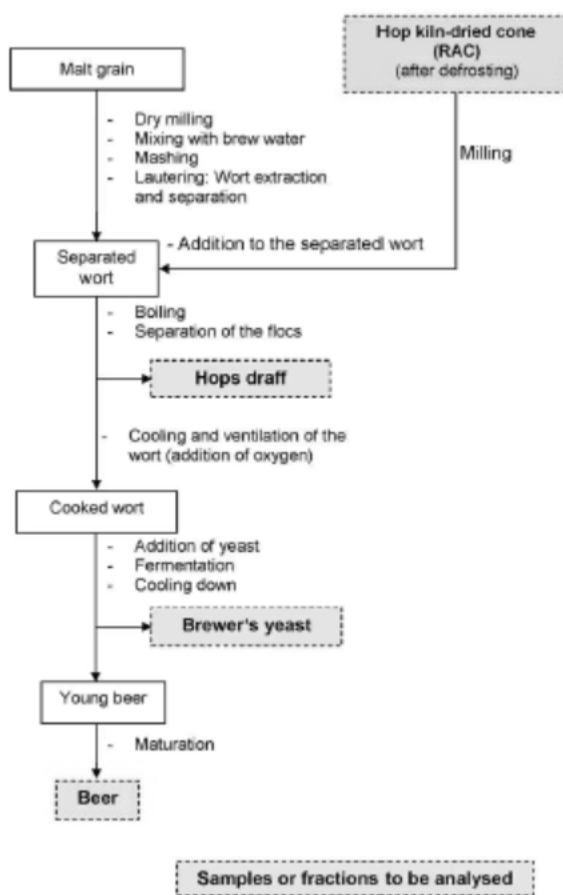
Table A 65: Residue data from hop processing study – total residue (sum of trifloxystrobin and CGA 321113) and processing factors

RAC	Residues in RAC (mg/kg) *	Processed commodity	Residue (mg/kg or mg/L) *	PF*	Comments/Reference
Cones, kiln dried	2.3	hops draff	0.26	0.1	10-3174-01
		brewer's yeast	0.04	0.02	
		beer	<0.02	<0.009	

* total trifloxystrobin equivalents = mg/kg trifloxystrobin + mg/kg CGA 321113 (as parent equivalent [factor 1.036]). A value of =LOQ mg/kg is used for residues determined as < LOQ mg/kg.

PF = processing factor

Figure A 2: Processing flowchart for beer



Conclusion

In beer, residues were below the LOQ for both parent and CGA 321113, indicating a dilution of residues with a processing factor of less than 0.01 for the total residue (sum of trifloxystrobin and CGA 321113).

A 2.1.5.2.4 Study report 08-3086 (Hops - processing)

Comments of zRMS:	<p>A study on hops processed commodities was submitted. Two processing trials in France and Germany were conducted during the 2008 season. Hops were sprayed two times at 0.15 kg a.s./ha application rate. Hops samples (hop green cone samples) were taken on day 21 after the last application.</p> <p>Residues were determined in the raw agricultural commodity (RAC) and in a processed products.</p> <p>Residues of trifloxystrobin and its metabolite were determined by LC-MS/MS according to method 01013/M002.</p> <p>The limits of quantitation (LOQ) for trifloxystrobin (CGA 279202) and for CGA 321113 are 0.1 mg/kg, for all sample materials tested.</p> <p>In the RAC samples of dry cone of hops the residues of trifloxystrobin were 0.39-0.89 mg/kg and the residues of CGA 321113 were 0.23-0.31.</p> <p>After processing, the trifloxystrobin and CGA 321113 residues were below LOQ.</p> <p>All calculated transfer factors for sum of trifloxystrobin and CGA 321113 were < 0.3 for all hops processed matrices. It is concluded that reduction of residues was seen in processed commodities of hops.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.5.3/06
Title:	Determination of the residues of AE C656948 and trifloxystrobin in/on hops and processed fractions after spraying of AE C656948 & CGA 279202 SC 500 in the field in France (North) and Germany
Report:	Noss, G.; Krusell, L.; 2010; 08-3086; M-389146-01-1
Authority registration No:	
Guideline(s):	EU: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8; EC guidance working document 7035/VI/95 rev. 5 (1997-07-22)
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Materials and methods

Balance studies on processing of hops (dry cones) into beer were conducted to determine the transfer of AE C656948 and its metabolites (AE C656948-pyridyl-acetic acid, AE C656948-benzamide, AE C656948-pyridyl-carboxylic acid), trifloxystrobin and CGA 321113.

The hops samples (dry cone) to be processed and reference raw agricultural commodity (RAC) samples originate from 2 supervised residue trials (08-2086-01 and 08-2086-03) in the conduct of study 08-2086. These trials were conducted in northern Europe (northern Germany and Germany) during the 2008 season. Detailed descriptions of the field part are presented in summary of residue study 08-2086. 2 applications were done at 150 g trifloxystrobin/ha and samples to be processed were taken 21 days after the last application.

The processing of the hop samples (dry cone) into the processed fractions (hops draff, brewer's yeast and beer) was performed in processing laboratory of Eurofins-GAB GmbH (Carl-Goerdeler-Weg 5, D-21684 Stade). The processing study simulated industrial practice at a laboratory scale.

For the brewing process following ingredients were used: hops (dry cone) from study 08-2086, commercially bought malt and yeast, drinking water available. After grinding the malt, 5 kg of malt was filled into 23 L of water (at 48°C) in "Speidel Braumeister" to produce mash. After about 10 minutes at 48°C, the mash was heated to 62°C (for 30 minutes), then the mash was heated to 72°C (for 20 minutes). After testing the saccharification with iodine reaction, the mash was heated to 78°C (for 10 minutes). Lautering was carried out by removing the pomace and rinsing it with 5.5 L of water at about 80°C. The remaining wort was cooked for about 80 minutes and the extract concentration was determined by cooking

or filling up with water. During the cooking process the hops was added in two portions (after 10 minutes and after 60 minutes).

For primary fermentation, the wort was cooled down and filled into open fermenting tank. The deposited trub was removed and the yeast was added. About 3 L of wort was frozen for the secondary fermentation. The primary fermentation was done for 1 week at 13.8 – 19.7°C, after which brewer's yeast was collected.

For secondary fermentation the 3 L of wort was induced by placing it beneath the fermenting tank to ensure it had the same temperature. A short time after induction of the wort the beer was filled into bottles which were stored 4 weeks at 14.9 – 18.5°C. After secondary fermentation in bottles, beer was sampled.

Analysis for trifloxystrobin and metabolite CGA 321113 was done with method 01013/M002.

Results and discussions

Residues of trifloxystrobin in the RAC (raw agricultural commodity = hops, dry cone) was 0.89 and 0.39 mg/kg. Residues of CGA 321113 in the RAC was 0.23 and 0.31 mg/kg. In hops draff, brewer's yeast and beer, residues were below the LOQ (<0.1 mg/kg) for both parent and CGA 321113.

The residues values for trifloxystrobin and CGA 321113 and the processing factors for the total residue are summarised in the tables below.

Table A 66: Residue data from hops processing study - trifloxystrobin

RAC	Residues in RAC (mg/kg)	Processed commodity	Residue (mg/kg or mg/L)	Comments/ Reference
Hops, dry cone	0.89	hops draff	<0.10	08-3086-01
		brewer's yeast	<0.10	
		beer	<0.10	
Hops, dry cone	0.39	hops draff	<0.10	08-3086-02
		brewer's yeast	<0.10	
		beer	<0.10	

Table A 67: Residue data from hops processing study - CGA 321113

RAC	Residues in RAC (mg/kg)	Processed commodity	Residue (mg/kg or mg/L)	Comments/ Reference
Hops, dry cone	0.23	hops draff	<0.10	08-3086-01
		brewer's yeast	<0.10	
		beer	<0.10	
Hops, dry cone	0.31	hops draff	<0.10	08-3086-02
		brewer's yeast	<0.10	
		beer	<0.10	

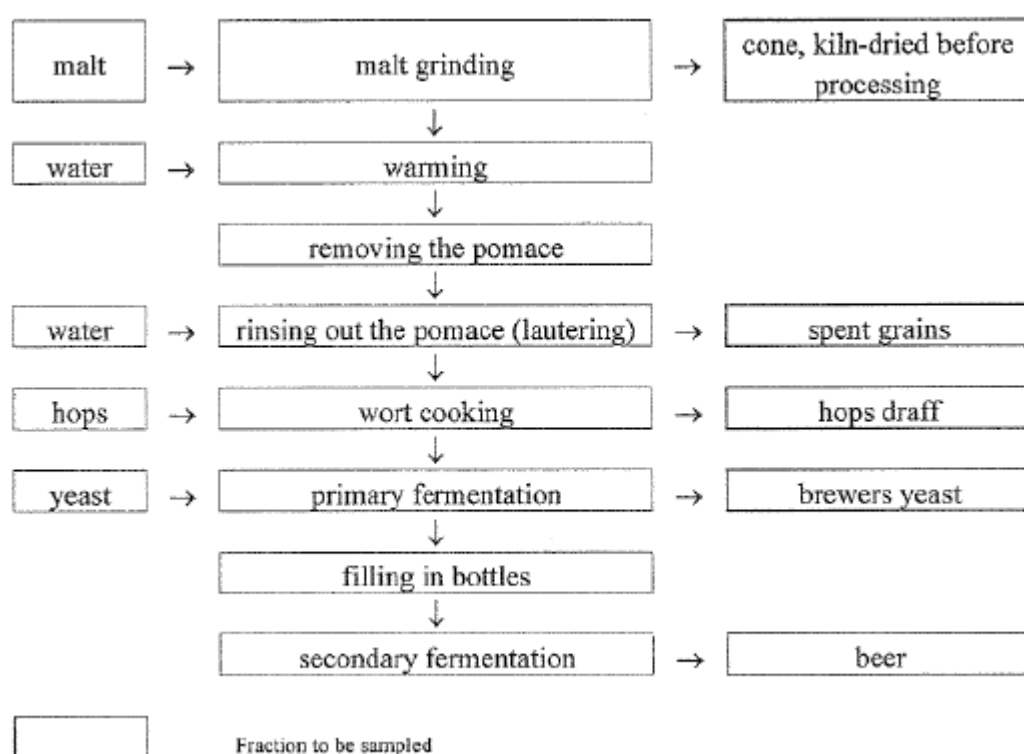
Table A 68: Residue data from hops processing study – total residue (sum of trifloxystrobin and CGA 321113)

RAC	Residues in RAC (mg/kg) *	Processed commodity	Residue (mg/kg or mg/L) *	PF*	Comments/Reference
Hops, dry cone	1.1	hops draff	<0.20	<0.2	08-3086-01
		brewer's yeast	<0.20	<0.2	
		beer	<0.20	<0.2	
Hops, dry cone	0.71	hops draff	<0.20	<0.3	08-3086-02
		brewer's yeast	<0.20	<0.3	
		beer	<0.20	<0.3	

* total trifloxystrobin equivalents = mg/kg trifloxystrobin + mg/kg CGA 321113. A value of =LOQ mg/kg is used for residues determined as < LOQ mg/kg.

PF = processing factor

Figure A 3: Processing flowchart for beer



Conclusion

In beer, residues were below the LOQ for both parent and CGA 321113, indicating a dilution of residues with a processing factor of less than 0.3 for the total residue (sum of trifloxystrobin and CGA 321113).

A 2.1.6 7.2.6 Magnitude of residues in representative succeeding crops (KCA 6.6.2) – Trifloxystrobin

No additional study submitted within this dossier.

A 2.1.7 7.2.7 Other/Special Studies (KCA 6.10)

A study on residues of trifloxystrobin in honey is available and summarised below.

Comments of zRMS:	<p>The study included four supervised semi-field residue trials conducted in Northern (2 trials) and Southern (2 trials) Europe during the 2019 season to determine the residues of trifloxystrobin and its isomers and metabolites in bee honey after three applications of TFS WG 50 in <i>Phacelia tanacetifolia</i> during flowering (BBCH 62 – 69). The application rate per treatment was 0.250 kg trifloxystrobin/ha. The product was applied to plots with <i>Phacelia tanacetifolia</i> three times with spray intervals of 6-7 days. Bee honey samples were collected 2-7 days after the last application.</p> <p>The analytical method 01598 was validated to determine the residues of trifloxystrobin (CGA 279202) and its isomers / metabolites CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 in/on honey by HPLC–MS/MS detection. The LOQ for the analytes was 0.01 mg/kg (expressed as parent equivalent for CGA 321113 and CGA 373466). No residues of the analytes above the LOQ were found in any of the control samples of honey.</p> <p>The storage period of deep-frozen samples intended for the analysis of trifloxystrobin and its isomers/ metabolites was between 26 and 49 days (from sampling to last extraction). The maximum storage period is covered by the storage stability study.</p> <p>Residues of trifloxystrobin were <0.01 mg/kg - 0.037 mg/kg.</p> <p>Residues of CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 were below LOQ (<0.01 mg/kg; parent equivalent for CGA 321113 and CGA 373466).</p> <p>Table 22: Residues in Honey after Application of Trifloxystrobin</p> <table><tr><th>Sample Type</th><th>CGA 279202</th><th>CGA 357262</th><th>CGA 357261</th><th>CGA 331409</th><th>CGA 321113</th><th>CGA 373466</th></tr><tr><td>C</td><td><0.01</td><td><0.01</td><td><0.01</td><td><0.01</td><td><0.01</td><td><0.01</td></tr><tr><td>T</td><td><0.01 - 0.037</td><td><0.01</td><td><0.01</td><td><0.01</td><td><0.01</td><td><0.01</td></tr></table> <p>C = Control, T = Treatment, LOQ = Limit of Quantification = 0.01 mg/kg (= 10 µg/kg = 10 ppb) for all analytes (expressed as parent equivalent for CGA 321113 and CGA 373466), LOD = Limit of Detection = 0.003 mg/kg (= 3 µg/kg = 3 ppb) for all analytes (expressed as parent equivalent for CGA 321113 and CGA 373466)</p> <p>The study is acceptable.</p>	Sample Type	CGA 279202	CGA 357262	CGA 357261	CGA 331409	CGA 321113	CGA 373466	C	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	T	<0.01 - 0.037	<0.01	<0.01	<0.01	<0.01	<0.01
Sample Type	CGA 279202	CGA 357262	CGA 357261	CGA 331409	CGA 321113	CGA 373466																
C	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01																
T	<0.01 - 0.037	<0.01	<0.01	<0.01	<0.01	<0.01																

Reference:	KCA 6.10/04
Title:	Determination of residues of trifloxystrobin and its isomers and metabolites in honey after three applications of TFS WG 50 in <i>Phacelia tanacetifolia</i> at 4 Sites in northern and southern Europe in 2019
Report:	Appeltauer, A.; 2020; S19-01068; M-678866-01-1
Authority registration No:	
Guideline(s):	<p>OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)</p> <p>EC (2018) Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey (SANTE/11956/2016 rev. 9)</p> <p>Commission Regulation (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 (Oct. 2009)</p>
Deviations:	None
GLP/GEP:	yes
Acceptability:	yes
Duplication (if vertebrate study):	

Test system

In 2019 a total of four trials were performed in Germany (2), southern France and Spain under semi-field conditions in order to determine the magnitude of residues of trifloxystrobin in bee honey.

The fungicide Trifloxystrobin WG 50, a water dispersible granule formulation containing 500 g/kg trifloxystrobin, was applied to plots with *Phacelia tanacetifolia* by spraying three times with spray intervals of about 7 days and product rates of about 0.5 kg/ha. The amount of trifloxystrobin was about 0.25 kg/ha per application. In all trials the applications were performed during flowering (BBCH 62 – 69).

On each trial site one tunnel confining the bees was established on the control and the treated plot. One bee hive was set up per tunnel for the control and treated plot, each. Colony assessments were performed before

set-up of the hives in the tunnels and after sampling of the honey.

Honey was collected from initially empty combs which were introduced in the hives the evening before the first application, which took place the following morning. Honey was collected 2 to 7 days after the last application, once it was mature at the end of flowering or if the water content was < 20 % or after comb closure – whatever occurred first.

Residues of trifloxystrobin, its isomers CGA 357262, CGA 357261, CGA 331409 and metabolite CGA 321113 and its isomer CGA 373466 in honey were determined according to method 01598 by HPLC-MS/MS. Residues were quantified using matrix matched standards. Concurrent recovery determinations were included in each set of analyses (at least one recovery for ten study samples). The respective Limit of Quantification (LOQ) for the analytes, defined as the lowest validated fortification level, was 0.01 mg/kg (expressed as parent equivalent for CGA 321113 and CGA 373466). The corresponding respective Limit of Detection (LOD) was 0.003 mg/kg (expressed as parent equivalent for CGA 321113 and CGA 373466).

Findings

- **Method performance:** The analytical method was validated by recovery experiments prior to and concurrent with analysis by spiking control samples with trifloxystrobin and its isomers and metabolites at fortification levels of 0.01 and 0.10 mg/kg for bee honey. The mean recovery values (reduced method validation) of the analytes in honey ranged between 89 and 101% per fortification level with relative standard deviations between 0.6 and 8.7%. The overall mean recoveries of the analytes ranged between 89% and 99% and the corresponding overall relative standard deviation (RSD) ranged between 4.1% and 6.0% (n = 6 for each analyte). The obtained recovery data show the validity of the method used.

Table A 69: Recoveries for trifloxystrobin, CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 in bee honey

Report No.	Analyte	Sample Material	Fortification level [mg/kg]	Single Values [%]	Mean Value [%]	RSD [%]	LOQ [mg/kg]
S19-01068	Trifloxystrobin (Method 01598)	bee honey	0.01	97; 97; 98	98	0.6	0.01
			0.10	97; 99; 108	101	5.8	
			Overall Recovery (n = 6)		99	4.3	
	CGA 357262 (Method 01598)	bee honey	0.01	93; 95; 96	95	1.6	0.01
			0.10	88; 94; 104	95	8.5	
			Overall Recovery (n = 6)		95	5.5	
	CGA 357261 (Method 01598)	bee honey	0.01	96; 96; 99	97	1.8	0.01
			0.10	92; 97; 104	98	6.2	
			Overall Recovery (n = 6)		97	4.1	
	CGA 331409 (Method 01598)	bee honey	0.01	93; 98; 99	97	3.3	0.01
			0.10	92; 97; 106	98	7.2	
			Overall Recovery (n = 6)		98	5.1	
	CGA 321113 (Method 01598)	bee honey	0.01	92; 93; 95	93	1.6	0.01*
			0.10	83; 87; 98	89	8.7	
			Overall Recovery (n = 6)		91	6.0	
	CGA 373466 (Method 01598)	bee honey	0.01	88; 89; 89	89	0.7	0.01*
			0.10	83; 87; 97	89	8.1	
			Overall Recovery (n = 6)		89	5.2	

RSD = relative standard deviation

n = number of tests

* expressed as parent equivalent

- **Storage stability:** The maximum storage period of deep-frozen samples was 49 days for trifloxystrobin and its isomers/metabolites and is therefore covered by the available short-term storage stability study (6 months) which is included in the method report 01598.

- Residue results: After three spray application of Trifloxystrobin WG 50 to *Phacelia tanacetifolia*, the residues of trifloxystrobin and its isomers / metabolites were determined in bee honey sampled 2-7 days after the last application to the flowering *Phacelia* plants.

Residues of trifloxystrobin were either below LOQ (<0.01 mg/kg) or up to 0.037 mg/kg. Residues of CGA 357262, CGA 357261, CGA 331409, CGA 321113 and CGA 373466 were below LOQ (<0.01 mg/kg; parent equivalent for CGA 321113 and CGA 373466).

- No residues of the analytes above the LOQ were found in any of the control samples of honey. The results were not corrected for concurrent recoveries.

Table A 70: Summary of the study S19-01068 trials – GAP summary

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)
S19-01068 S19-01068-01 Germany 75177 Pforzheim, Baden- Württemberg Europe, North F 2019	Phacelia Balo	1) 29.03.2019	251 257 250	402 411 400	62.4 62.5 62.5	14.06.2019/0 21.06.2019/7 27.06.2019/6	68	(g) S19-01068 (h) WG (trifloxystrobin 500 g/kg) (i) Application method: Spraying
S19-01068 S19-01068-02 Germany 76927 Stutensee, Baden- Württemberg Europe, North F 2019	Phacelia Balo	1) 15.04.2019	251 256 253	402 409 405	62.4 62.6 62.5	18.06.2019/0 25.06.2019/7 02.07.2019/7	69	(g) S19-01068 (h) WG (trifloxystrobin 500 g/kg) (i) Application method: Spraying
S19-01068 S19-01068-03 France, south 47460 Monheurt, Lot-et-Garonne Europe, South F 2019	Phacelia Stala	1) 22.02.2019	251 249 249	402 398 399	62.4 62.6 62.4	25.05.2019/0 01.06.2019/7 08.06.2019/7	68-69	(g) S19-01068 (h) WG (trifloxystrobin 500 g/kg) (i) Application method: Spraying

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)
S19-01068 S19-01068-04 Spain 46620 Ayora, Valencia Europe, South F 2019	Phacelia Stala	1) 15.02.2019	283 257 253	452 411 405	62.6 62.5 62.5	22.05.2019/0 28.05.2019/6 04.06.2019/7	65-66	(g) S19-01068 (h) WG (trifloxystrobin 500 g/kg) (i) Application method: Spraying

- (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
- (m) Storage (max)
- G greenhouse F field
- (g) Study reference
- (h) Formulation type
- (i) Application method
- (j) Method information
- (k) LOQ
- (l) Method validation


Analytical part of study S19-01068

Analyte 1: trifloxystrobin (determined as trifloxystrobin, calculated as trifloxystrobin), Analyte 2: CGA 357261 (determined as CGA 357261, calculated as CGA 357261), Analyte 3: CGA 357262 (determined as CGA 357262, calculated as CGA 357262), Analyte 4: CGA 331409 (determined as CGA 331409, calculated as CGA 331409), Analyte 5: CGA 321113 (determined as CGA 321113, calculated as CGA trifloxystrobin), Analyte 6: CGA 373466 (determined as CGA 373466, calculated as trifloxystrobin)

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 Trifloxy- strobilin as trifloxy- strobilin	Analyte 2 CGA 357261 as CGA 357261	Analyte 3 CGA 357262 as CGA 357262	Analyte 4 CGA 331409 as CGA 331409	Analyte 5 CGA 321113 as CGA 321113	Analyte 6 CGA 373466 as CGA 373466			
S19-01068 S19-01068-01 Germany 75177 Pforzheim, Baden- Württemberg Europe, North F 2019	Phacelia Balo	Bee honey	Not relevant	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01		2	(g) S19-01068 (j) Analytical method: 01598 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01598 and residue study S19-01068 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 honey: 31 days
S19-01068 S19-01068-02 Germany 76927 Stutensee, Baden- Württemberg Europe, North F 2019	Phacelia Balo	Bee honey	Not relevant	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01		2	(g) S19-01068 (j) Analytical method: 01598 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01598 and residue study S19-01068 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 honey: 26 days
S19-01068 S19-01068-03 France, south 47460 Monheurt, Lot-et-Garonne Europe, South F 2019	Phacelia Stala	Bee honey	Not relevant	0.013	<0.01	<0.01	<0.01	<0.01	<0.01		3	(g) S19-01068 (j) Analytical method: 01598 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01598 and residue study S19-01068 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 honey: 49 days
S19-01068 S19-01068-04 Spain 46620 Ayora, Valencia Europe, South F 2019	Phacelia Stala	Bee honey	Not relevant	0.037	<0.01	<0.01	<0.01	<0.01	<0.01		7	(g) S19-01068 (j) Analytical method: 01598 (k) LOQ: 0.01 mg/kg (l) Method Validation Data in method 01598 and residue study S19-01068 (m) Storage: Analyte 1, 2, 3, 4, 5, 6 honey: 49 days

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations - Trifloxystrobin



European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Trifloxystrobin

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(NED)/IEDI calculation (based on average food consumption)	49%	NL toddler	49.43	14%	Spinaches	8%	Apples	5%	Table grapes				
	34%	DE child	34.11	9%	Apples	4%	Table grapes	4%	Spinaches				
	26%	GEMS/Food G06	25.66	8%	Rice	3%	Table grapes	3%	Tomatoes				
	25%	NL child	25.37	5%	Spinaches	4%	Apples	3%	Table grapes				
	24%	GEMS/Food G10	23.93	6%	Rice	5%	Lettuces	1%	Wine grapes				
	20%	GEMS/Food G07	20.09	4%	Wine grapes	4%	Lettuces	2%	Rice				
	20%	IE adult	19.59	4%	Wine grapes	3%	Spinaches	1%	Lettuces				
	20%	PT general	19.52	7%	Wine grapes	4%	Rice	2%	Lettuces				
	19%	GEMS/Food G08	18.54	3%	Wine grapes	3%	Lettuces	1%	Rice				
	18%	IT adult	17.74	6%	Lettuces	2%	Other lettuce and other salad plants	2%	Spinaches				
	18%	GEMS/Food G11	17.74	3%	Wine grapes	2%	Spinaches	1%	Rice				
	17%	ES child	17.34	6%	Lettuces	2%	Rice	2%	Spinaches				
	17%	FR child 3 15 yr	17.25	2%	Rice	2%	Spinaches	2%	Oranges				
	17%	ES adult	17.19	8%	Lettuces	1%	Spinaches	1%	Wine grapes				
	17%	SE general	16.81	6%	Lettuces	2%	Rice	1%	Spinaches				
	16%	GEMS/Food G15	16.44	3%	Wine grapes	2%	Lettuces	2%	Rice				
	16%	FR adult	15.75	7%	Wine grapes	2%	Other lettuce and other salad plants	1%	Spinaches				
	16%	IT toddler	15.75	4%	Lettuces	2%	Wheat	2%	Other lettuce and other salad plant				
	15%	FR toddler 2 3 yr	15.49	3%	Spinaches	3%	Rice	2%	Apples				
	15%	RO general	14.51	5%	Wine grapes	2%	Wheat	1%	Tomatoes				
	14%	NL general	14.47	3%	Spinaches	2%	Wine grapes	1%	Escaroles/broad-leaved endives				
	14%	DE women 14-50 yr	14.39	3%	Wine grapes	2%	Apples	2%	Lettuces				
	14%	DE general	13.52	2%	Wine grapes	2%	Apples	1%	Lettuces				
	12%	DK child	12.20	2%	Lettuces	2%	Rye	2%	Apples				
	11%	UK toddler	11.33	3%	Rice	1%	Apples	1%	Wheat				
	11%	UK vegetarian	10.79	2%	Wine grapes	2%	Lettuces	2%	Rice				
	11%	FI 3 yr	10.55	3%	Rice	1%	Spinaches	0.7%	Table grapes				
	10%	UK adult	10.00	3%	Wine grapes	2%	Rice	2%	Lettuces				
	10%	FR infant	9.92	5%	Spinaches	1%	Apples	0.5%	Beans (with pods)				
	10%	UK infant	9.67	3%	Rice	1%	Apples	0.8%	Wheat				
9%	FI 6 yr	8.80	2%	Rice	1%	Lettuces	1%	Spinaches					
8%	DK adult	8.40	3%	Wine grapes	1%	Lettuces	0.7%	Apples					
7%	FI adult	6.91	2%	Lettuces	0.9%	Wine grapes	0.6%	Rice					
6%	LT adult	5.57	1%	Lettuces	1%	Rice	1.0%	Lettuces					
5%	PL general	5.45	1%	Apples	1.0%	Table grapes	0.6%	Tomatoes					
3%	IE child	3.01	1%	Rice	0.3%	Wheat	0.2%	Apples					

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

A 3.2 IEDI calculations - Trifloxystrobin

Since the TMDI calculations demonstrate a margin of safety, it was not deemed necessary to perform IEDI calculations in order to refine the dietary risk assessment.

Acute risk assessment /children				Acute risk assessment /adults / general population				Acute risk assessment /children				Acute risk assessment /adults / general population				
Details - acute risk assessment /children				Details - acute risk assessment /adults				Hide IESTI new calculations				Show IESTI new calculations				
<p>The acute risk assessment is based on the ARID.</p> <p>The calculation is based on the large portion of the most critical consumer group.</p>								<p>IESTI new calculations:</p> <p>The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.</p> <p>Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.</p>								
Show results for all crops																
Unprocessed commodities	Results for children No. of commodities for which ARID/ADI is exceeded (IESTI): ---				Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI): ---				IESTI new Results for children No. of commodities for which ARID/ADI is exceeded (IESTI new): ---				IESTI new Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI new): ---			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)
	14%	Escaroles/broad-leaved	1,8 /1,8	72	7%	Escaroles/broad-leaved	1,8 /1,8	36	9%	Escaroles/broad-leaved	1,8 /1,8	43	5%	Escaroles/broad-leaved endives	1,8 /1,8	26
	14%	Lettuces	1,8 /1,8	69	5%	Table grapes	0,67 /0,67	23	8%	Lettuces	1,8 /1,8	41	4%	Blueberries	2,3 /2,3	21
	10%	Table grapes	0,67 /0,67	49	4%	Lettuces	1,8 /1,8	22	6%	Table grapes	0,67 /0,67	29	3%	Wine grapes	0,67 /0,67	16
	4%	Currants (red, black and white)	2,3 /2,3	18	4%	Blueberries	2,3 /2,3	21	4%	Currants (red, black and white)	2,3 /2,3	18	3%	Currants (red, black and white)	2,3 /2,3	15
	3%	Blackberries	1,6 /1,6	17	3%	Wine grapes	0,67 /0,67	16	3%	Blackberries	1,6 /1,6	17	3%	Table grapes	0,67 /0,67	14
	3%	Raspberries (red and white)	1,6 /1,6	15	3%	Currants (red, black and white)	2,3 /2,3	15	3%	Raspberries (red and white)	1,6 /1,6	15	3%	Blackberries	1,6 /1,6	13
	3%	Blueberries	2,3 /2,3	14	3%	Blackberries	1,6 /1,6	13	3%	Blueberries	2,3 /2,3	14	3%	Lettuces	1,8 /1,8	13
3%	Gooseberries (green, red and white)	2,3 /2,3	14	2%	Gooseberries (green, red and white)	2,3 /2,3	10	3%	Gooseberries (green, red and white)	2,3 /2,3	14	2%	Gooseberries (green, red and white)	2,3 /2,3	10	
2%	Cranberries	2,3 /2,3	10	2%	Red mustards	1,8 /1,8	9,6	2%	Cranberries	2,3 /2,3	10	2%	Raspberries (red and yellow)	1,6 /1,6	8,6	
2%	Strawberries	0,51 /0,51	8,3	2%	Raspberries (red and white)	1,6 /1,6	8,6	2%	Strawberries	0,51 /0,51	8,3	1%	Rose hips	2,3 /2,3	5,1	
1%	Wine grapes	0,67 /0,67	6,2	1%	Rose hips	2,3 /2,3	5,1	1%	Wine grapes	0,67 /0,67	6,2	1,0%	Strawberries	0,51 /0,51	4,8	
1%	Lamb's lettuce/corn	1,8 /1,8	5,1	1,0%	Strawberries	0,51 /0,51	4,8	1%	Lamb's lettuce/corn	1,8 /1,8	5,1	0,8%	Red mustards	1,8 /1,8	4,1	
1,0%	Roman rocket/fruicola	1,8 /1,8	4,8	0,7%	Purslanes	1,8 /1,8	4,8	1,0%	Roman rocket/fruicola	1,8 /1,8	4,8	0,7%	Purslanes	1,8 /1,8	3,4	
0,6%	Beans (with pods)	0,28 /0,28	3,2	0,7%	Lamb's lettuce/corn	1,8 /1,8	3,4	0,6%	Beans (with pods)	0,28 /0,28	3,2	0,7%	Lamb's lettuce/corn salads	1,8 /1,8	3,4	
0,6%	Celeriacs/turnip rooted	0,06 /0,06	3,2	0,5%	Cranberries	2,3 /2,3	2,6	0,6%	Dewberries	1,6 /1,6	2,8	0,5%	Cranberries	2,3 /2,3	2,6	
Expand/collapse list																
Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)								Total number of commodities found exceeding the ARID/ADI in children and adult diets (IESTI new calculation)								
Processed commodities	Results for children No. of processed commodities for which ARID/ADI is exceeded (IESTI): ---				Results for adults No. of processed commodities for which ARID/ADI is exceeded (IESTI): ---				Results for children No. of processed commodities for which ARID/ADI is exceeded (IESTI new): ---				Results for adults No. of processed commodities for which ARID/ADI is exceeded (IESTI new): ---			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)
	24%	Escaroles/broad-leaved endives	1,8 /1,8	119	7%	Escaroles/broad-leaved endives	1,8 /1,8	37	14%	Escaroles/broad-leaved endives	1,8 /1,8	72	6%	Currants (red, black and white) /	2,3 /2,3	29
	13%	Currants (red														

Appendix 4 Additional information provided by the applicant

Nothing submitted.