REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: ADM.00900.I.1.C

Product name: COSAYR

Chemical active substance:

Chlorantraniliprole, 200 g/L SC

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New authorization)

Applicant: Adama Country organisation / representative as specified in Part A

Submission date: October 2022, updated May 2023, June 2023

MS Finalisation date: June 2023 (initial Core Assessment) November 2023 (final Core Assessment)

Version history

When	What
October 2022	Part B - Section 7 - Core Assessment – Central Zone, Initial version
May 2023	Update: Consumer risk assessment considering the MRL regulation for Chlorantraniliprole, Reg. (EU) 2022/1343 Minor typographical revision: -Current EU MRL regulation -Use on sweetcorn not supported in the framework of this registration
June 2023	Update: Storage stability of Chlorantraniliprole in bee matrices under deep frozen conditions
June 2023	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
November 2023	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.

DATA PROTECTION CLAIM

Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for these studies. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A

STATEMENT FOR OWNERSHIP

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification
The critical GAPs with respect to consumer intake and risk assessment for the preparation ADM.00900.I.1.C are presented in Table 7.1-1. They have been selected from the individual GAPs in the N-EU. A list of all intended uses within the N-EU is given in Part B, Section 0.

Overall conclusion
The data available are considered sufficient for risk assessment. An exceedance of the current MRLs on apple, pear, quince, wine grape, table grape, potato, head cabbage, cauliflower, broccoli and corn for chlorantraniliprole as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of chlorantraniliprole residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, zRMS-PL agrees with the authorization of the intended use(s).

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

Data gaps

Noticed data gaps are: none.

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**g as/hL min max**	**water L/ha min max**	**g as/ha min max**		
5, 6	Apple, Pear, Quince	CEU	ADM.0900.I.1.C	F	*Cydia pomonella*	SC	200 g/L	foliar, air-assisted, overall, HCTM	70-87	1	-	2.07-6.20	500-1500	31	14	A
2	Wine grape, Table grape	CEU	ADM.0900.I.1.C	F	*Lobesia botrana*	SC	200 g/L	foliar, air-assisted, overall, HCTM	57 - 83	1	-	2.25-9	400-1600	36	wine: 30 table: 3	A
7, 8	Potato	CEU	ADM.0900.I.1.C	F	*Leptinotarsa decemlineata*	SC	200 g/L	foliar, spraying, overall, LCTM	31 - 60	2	7	2-3	400-600	12	14	A
1	Head cabbage, Cauliflower, Broccoli	CEU	ADM.0900.I.1.C	F	*Caterpillars (Plutella xylostella, Mamestra brassicae Pieris brassicae)*	SC	200 g/L	foliar, spraying, overall, LCTM	15 - 49	1	-	4.67-7	400-600	28	3	A
3, 4	Corn (grain and silage)	CEU	ADM.0900.I.1.C	F	*Ostrinia nubilalis, Helicoverpa armigera*	SC	200 g/L	foliar, spraying, overall, LCTM	20 – 87	1	-	5.60-7	400-500	28	14	A

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

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

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

Explanation for Column 11 “Conclusion”

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation ADM.00900.I.1.C is composed of chlorantraniliprole.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Chlorantraniliprole					
ADI	EFSA	2013	1.56 mg/kg bw per day	Rat, 2-year study, supported by the mouse, 18-month study	100
ARfD	Not required				

7.1.2.1 Summary for chlorantraniliprole

Table 7.1-3: Summary for chlorantraniliprole

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?
5, 6	Apple, Pear, Quince	Yes	Yes (8 trials)	Yes	Yes	Yes	No	No
2	Wine grape, Table grape	Yes	Yes (8 trials)	Yes	Yes	Yes	No	No
7, 8	Potato	Yes	Yes (4 trials, <LOQ)	Yes	Yes	Yes	No	No
1	Head cabbage	Yes	Yes (8 trials)	Yes	Yes	Yes	No	No
1	Cauliflower, Broccoli	Yes	Yes (8 trials)	Yes	Yes	Yes	No	No
3, 4	Corn	Yes	Yes (8 trials)	Yes	Yes	Yes	No	No

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

The effects of processing on the nature of chlorantraniliprole residues have been investigated. Data on effects of processing on the amount of residue have been submitted.
These data were considered for risk assessment.

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.

7.1.2.2 Summary for ADM.00900.I.1.C

Table 7.1-4: Information on ADM.00900.I.1.C (KCA 6.8)

Crop	PHI for product code proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for product code proposed by zRMS	zRMS Comments (if different PHI proposed)
		chlorantraniliprole		
Apple, Pear,	14 days	Yes	14 days	-

Crop	PHI for product code proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for product code proposed by zRMS	zRMS Comments (if different PHI proposed)
		chlorantraniliprole		
Quince				
Wine grape, Table grape	wine: 30 days table: 3 days	Yes	wine: 30 days table: 3 days	-
Potato	14 days	Yes	14 days	-
Head cabbage	3 days	Yes	3 days	-
Cauliflower, Broccoli	3 days	Yes	3 days	-
Corn	14 days	Yes	14 days	-

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

Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for ADM.00900.I.1.C
Crop group	Chlorantraniliprole	
All crops	NR	NR

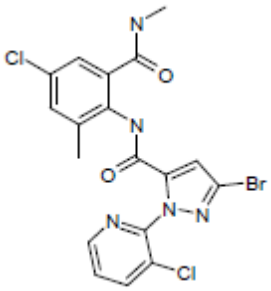
NR: not relevant

Assessment

7.2 Chlorantraniliprole

General data on chlorantraniliprole are summarized in the table below (last updated 2022/08/26)

Table 7.2-1: General information on chlorantraniliprole

Active substance (ISO Common Name)	Chlorantraniliprole
IUPAC	3-bromo-4'-chloro-1-(3-chloro-2-pyridyl)-2'-methyl-6'-(methylcarbamoyl) pyrazole-5-carboxanilide
Chemical structure	
Molecular formula	$C_{18}H_{14}BrCl_2N_5O_2$
Molar mass	483.15 g/mole
Chemical group	Anthranilic diamide
Mode of action (if available)	Exhibits larvicidal activity as an orally ingested toxicant by targeting and disrupting the Ca2+ balance
Systemic	No
Company (ies)	DuPont de Nemours*
Rapporteur Member State (RMS)	Ireland
Approval status	Approved 01.05.2014 (1199/2013)
Restriction	N/A
Review Report	SANCO/12081/2013 rev 2 26/01/2018
Current MRL regulation	~~Regulation (EU) No 2021/1884~~ Regulation (EU) No 2022/1343
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, 2013a)**
EFSA Journal: conclusion on article 12	EFSA, 2020**
Current MRL applications on intended uses	No

* Notifier in the EU process to whom the a.s. belong(s)
** See list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

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

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Apple, tomato, lettuce, cauliflower	High water content	Chlorantraniliprole: 24 months	Ireland, 2008 EFSA, 2013a
Grape	High acid content	Chlorantraniliprole: 24 months	
Potato tuber, wheat grain	High starch content	Chlorantraniliprole: 24 months	
Cottonseed	High oil content	Chlorantraniliprole: 24 months	
Wheat straw, Alfalfa hay	No group (dry)	Chlorantraniliprole: 24 months	
Apple Juice	High water/acid content	Chlorantraniliprole, IN-EQW78, INECD73, IN-F6L99: 12 months	
~~Tomato ketchup, raisin, cotton seed meal, cotton seed oil~~	~~No group (processed)~~	~~Chlorantraniliprole, IN-EQW78, INECD73, IN-F6L99: 12 months~~	
Tomato ketchup	High water/acid content	Chlorantraniliprole, IN-EQW78, INECD73,	
Raisin	Dry commodity	IN-F6L99: 12 months	
Cottonseed meal	High protein content	Chlorantraniliprole, IN-EQW78, INECD73,	
Cottonseed oil	High oil content	IN-F6L99: 12 months	
Honey, pollen nectar	-	Chlorantraniliprole, IN-F9N04: 24 months	Kiemle, A.. (2021); Report No.: FMC-51284
Animal Products			
Ruminant (Cow)	Fat, muscle, liver, kidney milk	Chlorantraniliprole, IN-HXH44, IN-K9T00, INEQW78, IN-GAZ70: 12 months	Ireland, 2008 EFSA, 2013a

Conclusion on stability of residues during storage

The stability of residues for the active substance chlorantraniliprole was already addressed during the EU Review process. Regarding uses intended with this submission, chlorantraniliprole residues are stable for at least 12 to 24 months in the different matrix types. Chlorantraniliprole residues are stable in animal products up to 12 months. No further data is required.

zRMS comment:

Information given by the Applicant is acceptable and sufficient.
In EFSA Journal 2020;18(9):6235 it is stated that *The storage stability of parent chlorantraniliprole was investigated in the framework of the peer review (EFSA, 2013a) in high water content (apple, tomato, lettuce, cauliflower), high acid content (grape), high oil content (cotton seed), high protein (wheat grain) and high starch contain (potato) commodities. Storage stability was also investigated in wheat straw and alfalfa hay (no group). These studies demonstrated storage stability of parent compound for a period of 24 months when stored at -20°C in all investigated matrices (Ireland, 2010; EFSA, 2013a).*
Moreover, the storage stability of metabolites IN-EQW78, IN-ECD73 and IN-F6L99 was investigated in processed commodities (apple juice, tomato ketchup, cottonseed oil, cotton seed meal, raisins; see Section 1.1.2), and found to be stable for at least 12 months when stored at -20°C (Ireland, 2010; EFSA, 2013a).

At the request of zRMS-PL, the Applicant provided the study on the storage stability of chlorantraniliprole in honey under deep frozen conditions has been.
Stability was demonstrated for analytes chlorantraniliprole and its metabolite IN-F9N04 in homogenates of matrices pollen, nectar and honey upon storage at ≤-18 °C for 24 months.

Sufficient stability data are available to support the residue data presented in this dossier.
No further data are required.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

No study on the stability of residues in sample extracts was conducted.
Extracts of residue samples for the intended crops were generally analysed within 24 hours after extraction and therefore, data on the stability of sample extracts are not required in these cases.

Where sample extracts were not analysed within 24 hours after extraction, the stability of analyte residues in the sample extracts was verified within the study by the acceptable fortification recovery data achieved by quantification with freshly prepared standard calibration solutions. At least one or two fortifications were run with each set of analytical samples. These fortifications were run with the specimens in each analysis set and were stored and treated in every way as the treated and control specimens in that set.

zRMS comment:
Data on stability of residues in sample extracts are sufficient and no further studies are necessary to support ADM.00900.I.1.C.

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
Studies on metabolism of chlorantraniliprole in plants were already addressed during the EU Review process and were considered acceptable (EFSA, 2013a). Information on crops tested, application and sampling details are given in **Table 7.2-3** below.
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) (b)	Remarks	
EU data								
Fruits and fruiting vegetable	Apple	[pyrazole carbonyl-^{14}C]-chlorantraniliprole / [benzamide carbonyl- ^{14}C]-chlorantraniliprole	Foliar (G)	0.1	3	0 DAT1, 0 DBT2, 0 DAT2, 0 DBT3, 0 DAT3, 15 DAT3, 30 DAT3	Macdonald, A.M.G. (2005) GLP	Ireland, 2008 EFSA, 2013a
	Tomato	[pyrazole carbonyl-^{14}C]-chlorantraniliprole / [benzamide carbonyl- ^{14}C]-chlorantraniliprole	Foliar (G)	0.1	3	0 DAT1, 0 DBT2, 0 DAT2, 0 DBT3, 0 DAT3, 7 DAT3, 15 DAT3	Macdonald, A.M.G. (2005) GLP	

Leafy vegetables	Lettuce	[pyrazole carbonyl-^{14}C]-chlorantraniliprole / [benzamide carbonyl- ^{14}C]-chlorantraniliprole	Foliar (F)	0.1	3	0 DAT1, 0 DBT2, 0 DAT2, 0 DBT3, 0 DAT3, 7 DAT3, 15 DAT3	Macdonald, A.M.G. (2005) GLP	
Pulses and oilseeds	Cotton	[pyrazole carbonyl-^{14}C]-chlorantraniliprole / [benzamide carbonyl- ^{14}C]-chlorantraniliprole	Foliar (F/G)	0.15	1	8 - 126	Brown, A.M. (2004) Non-GLP	
		[pyrazole carbonyl-^{14}C]-chlorantraniliprole / [benzamide carbonyl- ^{14}C]-chlorantraniliprole	Solution	50 mg/kg		4		
Cereals	Rice	[pyrazole carbonyl-^{14}C]-chlorantraniliprole / [benzamide carbonyl- ^{14}C]-chlorantraniliprole	Soil (F)	0.3	1	0 - 132	Chapleo, S. (2006) GLP	

(a) Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b) DAT1 = days after treatment 1, DBT2 = Days before treatment 2 etc

Summary of plant metabolism studies reported in the EU

From the data evaluated during the EU Review it was concluded that, following foliar applications, chlorantraniliprole was metabolised to a very limited extent, accounting for more than 80% TRR in all plant samples collected up to 30 days after the last application and 57% TRR in the mature cotton seeds harvested 126 days after the last treatment. The metabolism was more extensive in rice after soil application with a total of 14 metabolites identified, each accounting for less than 6% TRR, but chlorantraniliprole still remained the major component of the residues, representing more than 50% TRR in all rice matrices at harvest (0.08 mg/kg in grain) (EFSA, 2013a).

The use of acetonitrile as the extraction solvent was considered in the draft assessment report (DAR, 2008) and found to be as efficient for the extraction of chlorantraniliprole as the extraction techniques used in the metabolism studies (which are in any case acetonitrile or acetonitrile/water, 1:1, v/v). Furthermore, a new 2021 extraction efficiency study has been performed to which the applicant has access. Study FMC-51880 (submitted in the renewal dossier Document M-CA, Section 4, Annex Point 4.2/01) compares a number of methods, including the QuEChERS method used in the magnitude of residues studies in this submission, and demonstrates acceptable extraction efficiency in all standard crop matrix types.

Summary of new plant metabolism studies

No new data submitted in the framework of this application.

Conclusion on metabolism in primary crops

Based on the available information, the plant residue definition for monitoring and risk assessment was proposed as chlorantraniliprole in the EU Review (EFSA, 2013a) and confirmed during the MRL Review (EFSA, 2020).

Evaluator comments:
Information given by the Applicant is sufficient.
The metabolism of chlorantraniliprole was investigated after foliar treatment in fruits (apples and tomatoes), leafy vegetables (lettuces) and pulses and oilseeds (cotton), and after soil drench in cereals (rice) (Ireland, 2008). All studies were assessed in the framework of the peer-review (EFSA, 2013). The metabolism of chlorantraniliprole

was sufficiently addressed in the four crop categories.

The agreed plant residue definition for monitoring and risk assessment is: 'Chlorantraniliprole' (EFSA, 2013, 2020; Reg. (EU) 2022/1343).

The metabolism of chlorantraniliprole in plants following foliar treatment applications is sufficiently addressed to support the proposed uses of the product ADM.00900.I.1.C. No additional study is required.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

Studies on residues in succeeding crops were evaluated during the EU Review process of chlorantraniliprole and were considered to be acceptable. Studies are summarised in **Table 7.2-4** below.

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate [kg a.s./ha]	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	[pyrazole carbonyl-^{14}C]-chlorantraniliprole / [benzamide carbonyl-^{14}C]-chlorantraniliprole	Bare soil, spraying, G	0.3	0, 30, 120 and 365	At crop maturity		Ireland, 2010; EFSA, 2013a
Root and tuber vegetables	Red beet							
Cereals	Spring wheat			0.3	0, 30, 120 and 365	early forage, hay and at crop maturity		
				0.9	0 and 365			

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

Summary of plant metabolism studies reported in the EU

In the studies evaluated during the EU Review (Ireland, 2010; EFSA, 2013a), seeds of spring wheat (cereals), lettuce (leafy crops) and red beet (root and tuber vegetables) were sown into bare soil at nominal plant back intervals (PBI) of 0, 30, 120 and 365 days after treatment (DAT) with 300 g a.s/ha (2.4 N compared to the most critical European GAP under assessment for crops that can be rotated) of [pyrazole carbonyl- ^{14}C]-chlorantraniliprole and at 30 days after treatment with 300 g a.s/ha of [benzamide carbonyl-^{14}C]-chlorantraniliprole. Spring wheat was also sown at 0 and 365 DAT after treatment with [pyrazole carbonyl- ^{14}C]-chlorantraniliprole at 900 g a.s/ha (7 N).

Residues in lettuce increased over time, while residues in spring wheat increased until 120 DAT and decreased afterwards. Residues in red beet did not show a consistent pattern over time. The TRR in food commodities (wheat grain, lettuce, red beet roots) ranged from < 0.01 to 0.046 mg eq/kg, while in animal feed items (wheat forage, hay and straw, red beet forage), TRR was higher, ranging from 0.045 to 2.085 mg eq/kg.

In lettuce and spring wheat, chlorantraniliprole was the major residue in food items, in lettuce from 0 to 365 DAT, it ranged from 85 to 64% TRR; in wheat grain chlorantraniliprole represented 48% TRR at 120 DAT. Minor components were present at a maximum of 5% TRR, individually. Chlorantraniliprole was the main component in animal feed items as well (up to 84% TRR). In red beet, the metabolism was quite extensive. In tops no more than 4.8% (or 0.005 mg eq/kg) of TRR was detected as parent compound together with several metabolites, individually accounting for less than 10% TRR, with the exception of metabolite IN-F6L99 (11% TRR, 0.01 mg eq/kg). No characterisation was accomplished in roots as TRR was below 0.01 mg eq/kg. Following the application of either labelled compound or the exaggerated dose, no relevant differences in the metabolic profile were observed.

The metabolism and distribution of chlorantraniliprole in rotational crops are similar to the metabolic pathway observed in primary crops.

Conclusion on metabolism in rotational crops
Crops under evaluation can be grown in rotation. A nature of the residues in rotational crop study is available and was evaluated during the EU Review (Ireland, 2010; EFSA, 2013a) and considered acceptable. Further investigation of the nature of residues in rotational crops is therefore not required.

Evaluator comments:
Information given by the Applicant is sufficient.
A similar residue pattern as in the primary crops was observed in the edible parts of the rotated crops. Therefore, a specific residue definition for rotational crops is not deemed necessary.
No further data are required to support the proposed uses.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

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

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

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
[benzamide carbonyl-^{14}C]-chlorantraniliprole		
Pasteurisation (20 minutes, 90°C, pH 4)	Chlorantraniliprole (98.35%) IN-EQW78 (0.58%) IN-F6L99 (1.20%) Un-identified components (< 1%)	Ireland, 2008 EFSA, 2013a
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Chlorantraniliprole (87.00%) IN-EQW78 (3.54%) IN-F6L99 (10.93%) Un-identified components (< 1%)	
Sterilisation (20 minutes, 120°C, pH 6)	Chlorantraniliprole (96.40%) IN-EQW78 (0.76%) IN-F6L99 (1.61%) Un-identified components (< 1%)	
[pyrazole carbonyl-^{14}C]-chlorantraniliprole		
Pasteurisation (20 minutes, 90°C, pH 4)	Chlorantraniliprole (99.13%) IN-EQW78 (0.50%) IN-F6L99 (1.26%) Un-identified components (< 1%)	Ireland, 2008 EFSA, 2013a
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Chlorantraniliprole (85.88%) IN-EQW78 (2.85%) IN-F6L99 (13.59%) Un-identified components (< 1%)	
Sterilisation (20 minutes, 120°C, pH 6)	Chlorantraniliprole (96.17%) IN-EQW78 (0.42%) IN-F6L99 (2.88%) Un-identified components (1.48%)	

Conclusion on nature of residues in processed commodities
Based on the available data, it was demonstrated that chlorantraniliprole is hydrolytically stable under conditions representative of pasteurisation (90°C for 20 minutes in pH 4 solution) and sterilisation (120°C for 20 minutes in pH 6 solution). During conditions representative of baking/brewing/boiling (100°C for 60 minutes in pH 5 solution), chlorantraniliprole was slightly degraded to the metabolites IN-ECD73, IN-EQW78 and IN-F6L99 (11%-14% TRR). However, it was concluded that chlorantraniliprole alone remains a sufficient marker for the residues in processed commodities.

Evaluator comments:
The nature of residues of chlorantraniliprole in processed products has been investigated. In EFSA Journal 2020;18(9):6235 it is stated that *Chlorantraniliprole is stable under pasteurisation and sterilisation conditions, but it is slightly degraded to IN-F6L99, IN-ECD73 and IN-EQW78 under baking/brewing/boiling conditions (11-14% TRR). Processing studies indicate the presence of low residues of these metabolites in only few processed commodities, being the magnitude of parent chlorantraniliprole always significantly higher than the magnitude of degradates.*
Therefore, the same residue definitions as for raw agricultural commodities apply.
No further data are required to support the proposed uses.

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, tomato) Leafy vegetables (lettuce) Pulses and oilseeds (cotton) — Foliar applications Cereals (rice) — Soil application
Rotational crops covered	Cereals (wheat), leafy crops (lettuce) and root/tuber crops (red beet)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Standard hydrolytic conditions representative of: - pasteurisation (90ºC; 20 min; pH 4) - baking/brewing/ boiling (100ºC; 60 min; pH 5) - sterilisation (120ºC; 20 min; pH 6)
Residue pattern in processed commodities similar to pattern in raw commodities?	Chlorantraniliprole stable under pasteurisation and sterilisation conditions but slightly degraded to IN-F6L99, IN-ECD73 and IN-EQW78 under baking/ brewing/boiling conditions (10.9% to 13.6% TRR). However, processing data on apple, grape, tomato, plum and cotton indicate low residues of IN-EQW78, IN-ECD73, and IN-F6L99 (≤0.016 mg/kg) in only few end processed tomato fractions (paste, puree and ketchup), the magnitude of chlorantraniliprole residues being always significantly higher than the magnitude of the degradates.
Plant residue definition for monitoring	chlorantraniliprole (~~Regulation n° 2019/50~~ Reg. (EU) 2022/1343)
Plant residue definition for risk assessment	chlorantraniliprole (EFSA 2013; 2020)
Conversion factor from enforcement to RA	Not applicable

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

Available data
Studies on metabolism of chlorantraniliprole in livestock were already addressed during the EU Review process and were considered acceptable (EFSA, 2013a). Studies are summarised in **Table 7.2-7** below.
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	[pyrazole carbonyl-^{14}C]-chlorantraniliprole / [benzamide carbonyl-^{14}C]-chlorantraniliprole	1	0.36	7	Milk	twice daily	Ireland, 2008 EFSA, 2013a
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	[pyrazole carbonyl-^{14}C]-chlorantraniliprole / [benzamide carbonyl-^{14}C]-chlorantraniliprole	5	0.81	14	Eggs	daily	
						Excreta	daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

The metabolic fate of chlorantraniliprole in livestock was investigated in hen and goat. Animals were dosed at 10 mg/kg DM with a mixture (1:1) of ^{14}C-pyrazole-carbonyl and ^{14}C-benzamide-carbonylchlorantraniliprole over 7 (goat) and 14 (poultry) consecutive days. Chlorantraniliprole was extensively eliminated and less than 4% (poultry) and 1% (goat) of the administered radioactivity was recovered eggs, milk and animals products. Contrary to plants, the metabolism was more extensive, chlorantraniliprole accounting for less than 40% TRR in all animal matrices with the exception of the goat fat where it represented up to 75% TRR. In addition to the parent, metabolites IN-HXH44 and IN-K9T00 were identified in significant proportions and levels in milk (26% TRR, 0.02 mg/kg) and metabolites IN-H2H20 and IN-K7H29 in egg yolk and egg white (11-24% TRR, 0.05-0.08 mg/kg).

Summary of new animal metabolism studies

No new data submitted in the framework of this application.

Conclusion on metabolism in livestock

Based on these studies the residue definition for monitoring was limited to chlorantraniliprole. For risk assessment, the residue definition was proposed as "sum of chlorantraniliprole, IN-HXH44, IN-K9T00 expressed as chlorantraniliprole".

Evaluator comments:

The metabolism of chlorantraniliprole residues in livestock was investigated in lactating goats and laying hens. These studies were assessed in the framework of the peer review (EFSA, 2013a). EFSA concludes that the metabolism of chlorantraniliprole in livestock is adequately elucidated. The metabolism exhibited a different pattern in ruminants and poultry, with parent and metabolites IN-GAZ70, IN-H2H20 as the most relevant components of the residue in hen, while parent and metabolites IN-HXH44 and IN-K9T00 were the most relevant components in goat.

As the parent compound was found to be a sufficient marker in all livestock commodities, the residue definition for enforcement is proposed as chlorantraniliprole, and considered to be fat soluble.

EFSA in EFSA Journal 2020;18(9):6235 concluded that

For risk assessment in ruminants, metabolites IN-HXH44 and IN-K9T00 represent a significant part of the residue in milk, they were found in the rat metabolism and considered to be covered by the toxicological profile of the parent (EFSA, 2013a). Hence, the peer review defined the residue for risk assessment as the sum of chlorantraniliprole, IN-HXH44 and IN-K9T00, expressed as chlorantraniliprole. EFSA considers this residue definition as still valid for ruminants and swine.

For poultry, however, the dietary burden was not triggered at the time of the peer review, but it is triggered in this assessment. As indicated above, the metabolic pattern in ruminants and poultry was found to be different. In poultry tissues, no metabolites were found at significant levels of the applied radioactivity, and therefore, the risk

assessment residue definition for poultry tissues is expressed as chlorantraniliprole.
In eggs, metabolite IN-GAZ70 was encountered in the white at significant level, even when scaled down to the calculated dietary burden. Metabolite IN-H2H20 was also found at significant level in egg yolk in the overdosed metabolism study. Both metabolites were found in the rat metabolism and their toxicity can be considered as covered by that of the parent (EFSA, 2013c). In view of the results of the feeding studies conducted with poultry (see Section 2.2), where at the closest feeding level, residues of metabolites IN-GAZ70 and IN-H2H20 remained at or below the LOQ and were twice lower than those of chlorantraniliprole, and the large margin of safety in the exposure calculations (see Section 3), the residue definition for risk assessment for eggs is proposed as chlorantraniliprole only. EFSA emphasises that if new authorisations on crops significantly contributing to the poultry diets are granted in the future, the inclusion of these metabolites should be reconsidered.

No further data are required to support the proposed uses.

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	2 days in milk
	5-8 days in eggs
Animal residue definition for monitoring	Chlorantraniliprole (~~Regulation n° 2019/50~~ Reg. (EU) 2022/1343)
Animal residue definition for risk assessment	Sum chlorantraniliprole and metabolites IN-HXH44 and IN-K9T00 expressed as chlorantraniliprole (EFSA 2013) Ruminants and swine: sum of chlorantraniliprole, IN-HXH44 and IN-K9T00, expressed as chlorantraniliprole Poultry tissues and eggs: chlorantraniliprole (EFSA, 2020)
Conversion factor	(EFSA 2013): Ruminants/pigs: Liver, kidney, muscle: 1.5 Fat: 1 Milk: 3 Poultry: not necessary EFSA (2020): Ruminants/pigs: Liver: 1.8 Kidney: 1.9 Fat, muscle: 1 Milk: 1 Poultry: 1
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the **Table 7.2-9** below. The detailed assessment of these studies is presented in **Appendix 2.**

Table 7.2-9: Summary of EU reported data supporting the intended uses of ADM.00900.I.1.C and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg) *	Current EU MRL (mg/kg) **	MRL compliance
Apple, pear, quince	Ireland, 2008 EFSA, 2013a	NEU + SEU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.06 kg as/ha, PHI 14d, outdoor Trials are at a more critical GAP – evaluation will therefore not rely on this data	N/A			0.5 0.4	Yes Overall supporting data for cGAP
	New trials	NEU	Trials GAP: 1 x 31 g a.s./ha, PHI 14 E=RA: <0.01, 0.013, 0.015, 0.024, 0.024, 0.029, 0.031, 0.032 (trials on apple underlined)					
	Overall supporting data for cGAP	NEU	cGAP: 1 x 31 g a.s./ha, PHI 14 E=RA: <0.01, 0.013, 0.015, 0.024, 0.024, 0.029, 0.031, 0.032 (trials on apple underlined)	0.02	0.03	0.061 (0.07)		
Grape (table)	Ireland, 2008 EFSA, 2013a	SEU	GAP on which MRL/EU a.s. assessment is based: 2 x 43.2 g as/ha, PHI 3d Trials are at a more critical GAP – evaluation will therefore not rely on this data	N/A			1.0	Yes Overall supporting data for cGAP
	New trials	NEU	Trials GAP: 1 x 36 g a.s./ha, PHI 3 E=RA: 0.014, 0.019, 0.020, 0.039, 0.040, 0.050, 0.059, 0.095					
	Overall supporting data for cGAP	NEU	cGAP: 1 x 36 g a.s./ha, PHI 3 E=RA: 0.014, 0.019, 0.020, 0.039, 0.040, 0.050, 0.059, 0.095	0.04	0.10	0.149 (0.15)		

Grape (wine)	Ireland, 2008 EFSA, 2013a	NEU + SEU	GAP on which MRL/EU a.s. assessment is based: 1 x 54 g as/ha, PHI 30d Trials are at a more critical GAP – evaluation will therefore not rely on this data	N/A			1.0	Yes Overall supporting data for cGAP
	New trials	NEU	Trials GAP: 1 x 36 g a.s./ha, PHI 30 E=RA: 3x<0.01, 0.012, 0.020, 0.022, 0.023, 0.034					
	Overall supporting data for cGAP	NEU	cGAP: 1 x 36 g a.s./ha, PHI 30 E=RA: 3x<0.01, 0.012, 0.020, 0.022, 0.023, 0.034	0.02	0.03	0.052 (0.06)		
Potato	Ireland, 2008 EFSA, 2013a	NEU	GAP on which MRL/EU a.s. assessment is based: 2 x 12 g as/ha (interval 10-14d), PHI 14d Trials do not support the intended cGAP – evaluation will therefore not rely on this data	N/A			~~0.02~~ 0.03	Yes Overall supporting data for cGAP
	New trials	NEU	Trials GAP: 2 x 12 g a.s./ha, 7d interval, PHI 14 E=RA: 4x <0.01					
	Overall supporting data for cGAP	NEU	cGAP: 2 x 12 g a.s./ha, 7d interval, PHI 14 E=RA: 4x <0.01	0.01	0.01	0.010 (0.01)		
Cauliflower and broccoli (flowering brassica)	Ireland, 2008 EFSA, 2013a	-	Use not assessed	N/A			~~1~~ 1.5 (broccoli) ~~0.6~~ 0.5 (cauliflowers)	Yes Overall supporting data for cGAP
	New trials	NEU	Trials GAP: 1 x 30 g a.s./ha, PHI 3 E=RA: 3x<0.01, 0.012, 0.024, 0.042, 0.044, 0.063 (trials on broccoli underlined)					
	Overall supporting data for cGAP	NEU	cGAP: 1 x 28 g a.s./ha, PHI 3 E=RA: 3x<0.01, 0.012, 0.024, 0.042, 0.044, 0.063 (trials on broccoli underlined)	0.02	0.06	0.108 (0.15)		
Head cabbage	Ireland, 2008 EFSA, 2013a	-	Use not assessed	N/A			2	Yes Overall supporting data for cGAP
	New trials	NEU	Trials GAP: 1 x 30 g a.s./ha, PHI 3 E=RA: 6x <0.01, 0.037, 0.074					

	Overall supporting data for cGAP	NEU	cGAP: 1 x 28 g a.s./ha, PHI 3 E=RA 6x <0.01, 0.037, 0.074	0.01	0.07	0.114 (0.15)		
Maize (corn) – grain	Ireland, 2008 EFSA, 2013a	-	Use not assessed	N/A			0.02	Yes Overall supporting data for cGAP
	New trials	NEU	Trials GAP: 1 x 30 g a.s./ha, PHI 14 E=RA: 8x <0.01					
	Overall supporting data for cGAP	NEU	cGAP: 1 x 28 g a.s./ha, PHI 14 E=RA: 8x <0.01	0.01	0.01	0.010 (0.01)		
Maize (corn) – forage	Ireland, 2008 EFSA, 2013a	-	Use not assessed	N/A			No MRL on maize forage	N/A Overall supporting data for cGAP
	New trials	NEU	Trials GAP: 1 x 30 g a.s./ha, PHI 14 E=RA: 0.058, 0.085, 0.086, 0.11, 0.16, 0.17, 0.19, 0.34					
	Overall supporting data for cGAP	NEU	cGAP: 1 x 28 g a.s./ha, PHI 14 E=RA: 0.058, 0.085, 0.086, 0.11, 0.16, 0.17, 0.19, 0.34	0.14	0.34	0.510 (0.5)		
Maize (corn) – stover	Ireland, 2008 EFSA, 2013a	-	Use not assessed	N/A			No MRL on maize stover	N/A Overall supporting data for cGAP
	New trials	NEU	Trials GAP: 1 x 30 g a.s./ha, PHI 14 E=RA: 0.16, 0.24, 0.28, 0.31, 0.32, 0.33, 0.49, 0.64					
	Overall supporting data for cGAP	NEU	cGAP: 1 x 28 g a.s./ha, PHI 14 E=RA: 0.16, 0.24, 0.28, 0.31, 0.32, 0.33, 0.49, 0.64	0.32	0.64	1.039 (1)		

* Rounded MRL_{OECD} presented in brackets

~~** Source of EU MRL: (Regulation n°2021/1884)~~

** Source of EU MRL: (Regulation n°2022/1343)

7.2.3.2 Conclusion on the magnitude of residues in plants

Apple, pear, quince: According to SANTE/2019/12752, apples and pears are major crops in the Northern zone of Europe. Quince are minor crops in the Northern zone of Europe. According to SANTE/2019/12752, extrapolation from apples (0130010) (minimum 4 apples trials) + pears (0130020) to Whole group Pome fruits (130000) is possible. 8 NEU trials (minimum 4 apples trials) are therefore required.

A sufficient number of trials are available and the data submitted show that no exceedance of the MRL will occur.

According to the available data, the intended uses on apples, pears and quince considered acceptable.

Grapes: According to SANTE/2019/12752, wine grapes are a major crop in Northern Europe. 8 NEU trials are therefore required. Table grapes are a minor crop in the Northern zone of Europe. 4 NEU trials are therefore required. According to SANTE/2019/12752, extrapolation from table grapes (0151010) and/or wine grapes (0151020) to table grapes and/or wine grapes is possible.

A sufficient number of trials are available and the data submitted show that no exceedance of the MRL will occur.

According to the available data, the intended uses on wine and table grapes are considered acceptable.

Potato: According to SANTE/2019/12752, potato is a major crop in the Northern zone of Europe. 8 NEU trials are therefore required.

The available residue trials indicate a '<LOQ residue' situation, in which case a minimum of 4 trials per zone is sufficient and the data submitted show that no exceedance of the MRL will occur.

According to the available data, the intended uses on potato are considered acceptable.

Cauliflower and broccoli: According to SANTE/2019/12752, cauliflower is a major crop in Northern Europe. Broccoli is a minor crop in Northern Europe. According to document SANTE/2019/12752, extrapolation from cauliflower (0241020) and broccoli (0241010) (4 trials on each crop) to whole subgroup of flowering brassica is possible. Therefore, 4 NEU trials are required for each crop.

A sufficient number of trials are available and the data submitted show that no exceedance of the MRL will occur.

According to the available data, the intended uses on flowering brassica are considered acceptable.

Head cabbage: According to SANTE/2019/12752, head cabbage is a major crop in the Northern zone of Europe. 8 NEU trials are therefore required.

A sufficient number of trials are available and the data submitted show that no exceedance of the MRL will occur.

According to the available data, the intended uses on head cabbage are considered acceptable.

Maize (grain and silage): According to SANTE/2019/12752, maize is a major crop in the Northern Europe. 8 NEU trials are therefore required.

A sufficient number of trials are available and the data submitted show that no exceedance of the MRL will occur.

According to the available data, the intended uses on maize are considered acceptable.

zRMS comments:
Residue Definitions (EFSA 2020; Reg EU 2022/1343):
Monitoring (Mo) and Risk Assessment (RA): chlorantraniliprole

Apple, pear, quince
Apple and pear are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Quince is the minor crop in N-EU, a minimum of four trials are required.
Based on the SANTE/2019/12752, minimum 4 apples trials (0130010) + pears (0130020) can be used for extrapolation to Whole group Pome fruits (130000) before and after forming of the edible part.

Two new residue studies conducted according to the plant residue definitions for enforcement and for risk assessment were submitted by Applicant in the framework of this application. The trials on apple and pear were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 31 g a.s. /ha, application at BBCH 81-85, PHI of 13-14 days, outdoor. The trials are supported by valid storage stability data and validated analytical method.

Residues of chlorantraniliprole in apple or pear at harvest are ranging from <LOD to 0.032 mg/kg at 13 or 14 DAA (commercial harvest). More details of the residue studies on pome fruits are provided in Appendix 2.

Available results show that the in force MRL of chlorantraniliprole on pome fruits of 0.4 mg/kg (Reg. (EU) 2022/1343) will not be exceeded. The current EU MRLs for chlorantraniliprole are sufficient to support the proposed uses.
The proposed uses on apple, pear and quince are considered acceptable.

Grapes
Wine grapes are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Table grapes are the minor crops in N-EU, a minimum of four trials are required.
According to SANTE/2019/12752, extrapolation from table grapes (0151010) and/or wine grapes (0151020) to table grapes and/or wine grapes is possible.

Two new residue studies conducted according to the plant residue definitions for enforcement and for risk assessment were submitted by Applicant in the framework of this application. The trials on table and wine grapes were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 36 g a.s. /ha, the application was performed 30 (±2) days before harvest (Plot T1) and to support the use on table grapes, the application was performed 3 days before harvest (Plot T2), outdoor. The trials are supported by valid storage stability data and validated analytical method.

After one application in grape 30 (±2) days before harvest with ADM.00900.I.1.C at the rate of 0.180 L/ha, (representing 36 g/ha of chlorantraniliprole), the residues found in treated specimens (plot T1) are ranging from < LOQ to 0.034 mg/kg at 28 - 31 DAA (commercial harvest)
After one application in grape 3 days before harvest with ADM.00900.I.1.C at the rate of 0.180 L/ha, (representing 36 g/ha of chlorantraniliprole), the residues found in treated specimens (plot T2) are ranging from 0.014 to 0.095 mg/kg at 3 DAA (commercial harvest).
More details of the residue studies on grapes are provided in Appendix 2.

Available results show that the in force MRL of chlorantraniliprole on grapes of 1 mg/kg (Reg. (EU) 2022/1343) will not be exceeded. The current EU MRLs for chlorantraniliprole are sufficient to support the proposed uses.
The proposed uses on table and wine grapes are considered acceptable.

Potato
Potato is the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required.

One new residue study conducted according to the plant residue definitions for enforcement and for risk assessment was submitted by Applicant in the framework of this application. Four trials on potatoes were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 2 x 12 g a.s. /ha, the interval between the 2 applications was 7 days and the last application was done 14 (± 1) days before commercial harvest, outdoor. The trials are supported by valid storage stability data and validated analytical method.

Residues of chlorantraniliprole in potatoes at harvest were all below LOQ.
According to SANTE/2019/12752, in the <LOQ situation the number of independent trials may be reduced. The number of trials shall not be below the minimum of four per zone for major crops.

More details of the residue study on potatoes is provided in Appendix 2.

Available results show that the in force MRL of chlorantraniliprole on potatoes of 0.03 mg/kg (Reg. (EU) 2022/1343) will not be exceeded. The current EU MRL for chlorantraniliprole is sufficient to support the proposed use.
The proposed use on potatoes is considered acceptable.

Cauliflower and broccoli
Cauliflower is the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required.
Broccoli is the minor crop in N-EU, a minimum of four trials are required.
Based on the SANTE/2019/12752, 4 trials on cauliflower (0241020) + 4 trials broccoli (0241010) can be used for extrapolation to Whole subgroup (a) flowering brassica (0241000) before and after forming of the edible part.

Four new residue studies (four trials on broccoli and four trials on cauliflower) conducted according to the plant residue definitions for enforcement and for risk assessment were submitted by Applicant in the framework of this application. The trials on cauliflower and broccoli were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 30 g a.s. /ha, application at BBCH 46-49, PHI of 3 days, outdoor. The trials are supported by valid storage stability data and validated analytical method.

Residues of chlorantraniliprole in broccoli at harvest are ranging from 0.024 to 0.063 mg/kg at 3 DAA (commercial harvest).
Residues of chlorantraniliprole in cauliflower at harvest are ranging from below LOQ and 0.012 mg/kg at 3 DAA (commercial harvest).
More details of the residue studies on cauliflower and broccoli are provided in Appendix 2.

Available results show that the in force MRL of chlorantraniliprole on broccoli of 1.5 mg/kg and on califlower of 0.5 mg/kg (Reg. (EU) 2022/1343) will not be exceeded. The current EU MRLs for chlorantraniliprole are sufficient to support the proposed uses.
The proposed uses on cauliflower and broccoli are considered acceptable.

Head cabbage
Head cabbage is the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required.

Two new residue studies (eight trials) conducted according to the plant residue definitions for enforcement and for risk assessment were submitted by Applicant in the framework of this application. The trials on head cabbage were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 30 g a.s. /ha, application at BBCH 47-49, PHI of 3 days, outdoor. The trials are supported by valid storage stability data and validated analytical method.

Residues of chlorantraniliprole in head cabbage at harvest are ranging from below LOD to 0.074 mg/kg at 3 DAA (commercial harvest).
More details of the residue studies on head cabbage are provided in Appendix 2.

Available results show that the in force MRL of chlorantraniliprole on head cabbage of 2 mg/kg (Reg. (EU) 2022/1343) will not be exceeded. The current EU MRL for chlorantraniliprole is sufficient to support the proposed use.
The proposed use on head cabbage is considered acceptable.

Maize
Maize is the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required.

Two new residue studies (eight trials) conducted according to the plant residue definitions for enforcement and for risk assessment were submitted by Applicant in the framework of this application. The trials on maize were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 30 g a.s. /ha, application at BBCH 71-87, PHI of 14 days, outdoor. The trials are supported by valid storage stability data and validated analytical method.

Residues of chlorantraniliprole in maize grain at harvest are below LOD at 14 DAA (commercial harvest).
More details of the residue studies on maize are provided in Appendix 2.

Available results show that the in force MRL of chlorantraniliprole on maize of 0.02 mg/kg (Reg. (EU) 2022/1343)

will not be exceeded. The current EU MRL for chlorantraniliprole is sufficient to support the proposed use.
The proposed use on maize is considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

According to OECD guidance document on residues in livestock ENV/JM/MONO(2013)8, several of the intended crops are fed to livestock in the EU. Therefore, a dietary burden calculation is presented. In addition to the intended uses, all uses which were evaluated as part of the MRL review (EFSA, 2020) were used as input parameters. Input values are summarised in
Table 7.2-10, results are presented in **Table 7.2-11**.

The excel calculator (Animal model 2017.xls) developed by EFSA was used to perform the animal dietary burden. The default value of processing factor was used for the relevant commodities unless stated otherwise.

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

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Chlorantraniliprole				
Cabbage, heads leaves	0.52	STMR (EFSA, 2020)	1.2	HR (EFSA, 2020)
Corn, field (maize) forage	0.14	STMR	0.34	HR
Corn, field (maize) stover	0.32	STMR	0.64	HR
Rice straw	0.01	STMR (EFSA, 2020)	0.21	HR (EFSA, 2020)
Carrot culls	0.01	STMR (EFSA, 2020)	0.04	HR (EFSA, 2020)
Potato culls	0.01*	STMR (EFSA, 2020)	0.01*	HR (EFSA, 2020)
Swede roots	0.01	STMR (EFSA, 2020)	0.04	HR (EFSA, 2020)
Turnip roots	0.01	STMR (EFSA, 2020)	0.04	HR (EFSA, 2020)
Corn, field (maize) grain	0.01*	STMR (EFSA, 2020)	0.01*	STMR (EFSA, 2020)
Corn, pop grain	0.01*	STMR (EFSA, 2020)	0.01*	STMR (EFSA, 2020)
Cotton undelinted seed	0.05	STMR (EFSA, 2020)	0.05	STMR (EFSA, 2020)
Millet grain	0.01*	STMR (EFSA, 2020)	0.01*	STMR (EFSA, 2020)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sorghum grain	0.01*	STMR (EFSA, 2020)	0.01*	STMR (EFSA, 2020)
Apple pomace, wet	0.21 (0.08 x 2.6)	STMR x PF (2.6) (EFSA, 2020)	0.21 (0.08 x 2.6)	STMR x PF (2.6) (EFSA, 2020)
Canola (Rape seed) meal	0.6 (0.3 x 2)	STMR x PF (2)[(a)] (EFSA, 2020)	0.6 (0.3 x 2)	STMR x PF (2)[(a)] (EFSA, 2020)
Citrus dried pulp	2.1 (0.21 x 10)	STMR x PF (10)[(a)] (EFSA, 2020)	2.1 (0.21 x 10)	STMR x PF (10)[(a)] (EFSA, 2020)
Coconut meal	0.01 (0.01 x 1)	STMR x PF (1)[(b)] (EFSA, 2020)	0.01 (0.01 x 1)	STMR x PF (1)[(b)] (EFSA, 2020)
Corn, field milled by-products	0.01* (0.01 x 1)	STMR x PF (1)[(b)] (EFSA, 2020)	0.01* (0.01 x 1)	STMR x PF (1)[(b)] (EFSA, 2020)
Corn, field hominy meal	0.01* (0.01 x 1)	STMR x PF (1)[(b)] (EFSA, 2020)	0.01* (0.01 x 1)	STMR x PF (1)[(b)] (EFSA, 2020)
Corn, field gluten feed	0.01* (0.01 x 1)	STMR x PF (1)[(b)] (EFSA, 2020)	0.01* (0.01 x 1)	STMR x PF (1)[(b)] (EFSA, 2020)
Corn, field gluten, meal	0.01* (0.01 x 1)	STMR x PF (1)[(b)] (EFSA, 2020)	0.01* (0.01 x 1)	STMR x PF (1)[(b)] (EFSA, 2020)
Cotton meal	0.04 (0.05 x 0.8)	STMR x PF (0.8)[(c)] (EFSA, 2020)	0.04 (0.05 x 0.8)	STMR x PF (0.8)[(c)] (EFSA, 2020)
Distiller's grain dried	0.01* (0.01 x 1)	STMR x PF (1)[(b)] (EFSA, 2020)	0.01* (0.01 x 1)	STMR x PF (1)[(b)] (EFSA, 2020)
Flaxseed/Linseed meal	0.49 (0.245 x 2)	STMR x PF (2)[(a)] (EFSA, 2020)	0.49 (0.245 x 2)	STMR x PF (2)[(a)] (EFSA, 2020)
Palm (hearts) kernel meal	0.01* (0.01 x 1)	STMR x PF (1)[(b)] (EFSA, 2020)	0.01* (0.01 x 1)	STMR x PF (1)[(b)] (EFSA, 2020)
Peanut meal	0.02 (0.01 x 2)	STMR x PF (2)[(a)] (EFSA, 2020)	0.02 (0.01 x 2)	STMR x PF (2)[(a)] (EFSA, 2020)
Potato process waste	0.01 (0.01 x 1)	STMR x PF (1)[(b)] (EFSA, 2020)	0.01 (0.01 x 1)	STMR x PF (1)(b) (EFSA, 2020)
Potato dried pulp	0.01 (0.01 x 1)	STMR x PF (1)[(b)] (EFSA, 2020)	0.01 (0.01 x 1)	STMR x PF (1)(b) (EFSA, 2020)
Rape meal	0.6 (0.3 x 2)	STMR x PF (2)[(a)] (EFSA, 2020)	0.6 (0.3 x 2)	STMR x PF (2)[(a)] (EFSA, 2020)
Rice bran/pollard	1.15 (0.115 x 10)	STMR x PF (10)[(a)] (EFSA, 2020)	1.15 (0.115 x 10)	STMR x PF (10)[(a)] (EFSA, 2020)
Safflower meal	0.49 (0.245 x 2)	STMR x PF (2)[(a)] (EFSA, 2020)	0.49 (0.245 x 2)	STMR x PF (2)[(a)] (EFSA, 2020)
Sugarcane molasses	4.64 (0.145 x 32)	STMR x PF (32)[(a)] (EFSA, 2020)	4.64 (0.145 x 32)	STMR x PF (32)[(a)] (EFSA, 2020)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sunflower meal	0.37 (0.185 x 2)	STMR x PF (2)[(a)] (EFSA, 2020)	0.37 (0.185 x 2)	STMR x PF (2)[(a)] (EFSA, 2020)

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
*: Indicates that the input value is proposed at the limit of quantification.
a): In the absence of processing factors supported by data, default processing factor was included in the calculation to consider the potential concentration of residues in these commodities.
(b): No default processing factor was applied because residues are below the LOQ in the RAC.
(c): The tentative derived processing factors (EFSA, 2020) were included in the calculation to consider the potential concentration of residues in these commodities.

Table 7.2-11: Results of the dietary burden calculation

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Y/N)	Comments
	mg/kg bw per day		mg/kg DM						
	Median	Maximum	Median	Maximum					
Cattle (all diets)	0.051	0.089	1.36	2.38	Dairy cattle	Cabbage, heads	leaves	Yes	-
Cattle (dairy only)	0.051	0.089	1.34	2.30	Dairy cattle	Cabbage, heads	leaves	Yes	-
Sheep (all diets)	0.032	0.056	0.76	1.31	Lamb	Cabbage, heads	leaves	Yes	-
Sheep (ewe only)	0.025	0.044	0.76	1.31	Ram/Ewe	Cabbage, heads	leaves	Yes	-
Swine (all diets)	0.017	0.030	0.74	1.31	Swine (breeding)	Cabbage, heads	leaves	Yes	-
Poultry (all diets)	0.018	0.035	0.26	0.52	Poultry layer	Cabbage, heads	leaves	Yes	-
Poultry (layer only)	0.018	0.035	0.26	0.52	Poultry layer	Cabbage, heads	leaves	Yes	-
Fish	-	-	-	-	-	-	-	-	-

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

zRMS comments:
Information given by the Applicant is acceptable and sufficient.
The median and maximum dietary burdens for livestock were estimated for chlorantraniliprole and were calculated using the animal model calculator developed by EFSA (Animal model 2017).
The calculated dietary burdens for chlorantraniliprole were found to exceed the trigger value of 0.1 mg/kg DM (or 0.004 mg/kg bw/d, respectively) for all livestock groups. Further investigation of residues is therefore required.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

As demonstrated in **Section 7.2.4.1**, dietary burden is expected to be above the trigger value (0.004 mg/kg bw/day) in all livestock.

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

A ruminant feeding study was already evaluated in the EU Review of chlorantraniliprole (Ireland, 2008 and EFSA, 2013a).
Four groups of lactating cows, each consisting of three animals, were dosed for 28 consecutive days with chlorantraniliprole at levels of 1, 3, 10 and 50 ppm in the feed, on a dry weight basis. Two additional cows were included in the 50 ppm group to obtain depuration data. Milk was collected twice daily and samples from days 1, 3, 5, 7, 10, 14, 21 and 28 were analysed. Cows were sacrificed 23 − 24 hours after the last morning dose, except for the animals in the depuration group, which were sacrificed on days 9 and 23 after cessation of dosing. Residues of chlorantraniliprole and metabolites IN-HXH44, IN-K9T00, IN-EQW78, and IN-GAZ70 were determined in all samples.
There were no average residues greater than 0.01 mg/kg of any analyte in any sample at the 1 and 3 ppm feed levels, with the exception of chlorantraniliprole residues at 0.015 mg/kg in day 21 cream from the 3 ppm feed group. Residues of chlorantraniliprole, IN-HXH44, and IN-K9T00 were not detected (<0.003 mg/kg) in whole milk from the lowest dose group (1 ppm feed) but were dose dependent, increasing at higher doses. Residues in milk reached a plateau within 7 to 10 days of dosing. Chlorantraniliprole residues concentrate by a factor of 5.4× in cream compared to whole milk.
Residues of chlorantraniliprole, IN-HXH44, and IN-K9T00 were detected in fat, kidney, liver, and muscle. Residues were dose dependent, increasing with higher doses. Residues of IN-GAZ70 or IN-EQW78 were not detected (<0.003 mg/kg) in any sample from any dose group with the exception of a residue of 0.003 mg/kg for IN-EQW78 in fat from the 50 mg/kg feed group. Chlorantraniliprole residues in fat are a factor of 4.7× higher than in muscle. The designation of chlorantraniliprole residues as being “fat-soluble”, is confirmed by these results, in addition to the results for whole milk and cream.
Following cessation of dosing, residues in milk and tissues rapidly declined to non-detectable levels (<0.003 mg/kg) in the milk samples from 3 days post last dose and in tissue samples collected from the earliest sacrifice time at 9 days after cessation of dosing.
Conversion factors derived from the feeding study were proposed for ruminant products.
For poultry, the metabolism study, performed at 23 N rate compared to the maximum dietary burden, is sufficient to conclude that residue levels would remain below the enforcement LOQ of 0.01 mg/kg in muscle, fat and liver tissues. In addition to this, a feeding study with laying hens was made available during the EFSA MRL review (EFSA, 2020) wherein chlorantraniliprole was administered to laying hens at three different dosing levels, namely 0.230 mg/kg, 0.746 mg/kg and 2.419 mg/kg bw per day. The results of the available feeding studies performed with laying hens at 6.6, 21.3 and 69.1 N rate compared to the maximum dietary burden confirmed this conclusion. However, the occurrence of residues in eggs cannot be excluded from the metabolism study, and thus, the feeding study with laying hens was used to derive MRL and risk assessment values in eggs.

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

Animal commodity	Residues at the closet feeding level (mg/kg)		Estimated value at 1N level		MRL proposal (mg/kg)	CF (c)
	Mean	Highest	$STMR_{Mo}$ (a) (mg/kg)	HR_{Mo} (b) (mg/kg)		
Cattle (all diets)						
Closest feeding level:	0.083	mg/kg bw	0.9	N Dairy cattle (highest diet)		
Muscle	0.003	0.004	<0.01	<0.01	**0.01***	1.0
Fat	0.008	0.015	<0.01	0.016	**0.02**	1.0
Liver	0.009	0.014	<0.01	0.015	**0.015**	1.8
Kidney	0.006	0.009	<0.01	0.012	**0.015**	1.9
Cattle (dairy only)						
Closest feeding level:	0.083	mg/kg bw	0.9	N Dairy cattle		
Milk(d)	0.003	n.a.	<0.01	<0.01	**0.01***	1.0
Sheep (all diets)						
Closest feeding level:	0.029	mg/kg bw	0.52	N Lamb (highest diet)		
Muscle	0.003	0.003	<0.01	<0.01	**0.01***	1.0
Fat	0.003	0.004	<0.01	<0.01	**0.01***	1.0
Liver	0.004	0.005	<0.01	0.01	**0.01**	1.8
Kidney	0.003	0.003	<0.01	0.01	**0.015**	1.9
Sheep (dairy only)						
Closest feeding level:	0.029	mg/kg bw	0.7	N Ewe		
Milk(d)	0.003	n.a	<0.01	<0.01	**0.01***	1.0
Swine						
Closest feeding level:	0.029	mg/kg bw	1.0	N Breeding (highest diet)		
Muscle	0.003	0.003	<0.01	<0.01	**0.01***	1.0
Fat	0.003	0.004	<0.01	<0.01	**0.01***	1.0
Liver	0.004	0.005	<0.01	<0.01	**0.01***	1.0
Kidney	0.003	0.003	<0.01	<0.01	**0.01***	1.0
Poultry (all diets)(e)						
Closest feeding level:	0.23	mg/kg bw	6.6	N Layer (highest diet)		
Muscle	0.011	0.016	<0.01	<0.01	**0.01***	1.0
Fat	0.043	0.066	<0.01	0.01	**0.01***	1.0
Liver	0.038	0.054	<0.01	<0.01	**0.01***	1.0
Poultry (layer only)(e)						
Closest feeding level:	0.23	mg/kg bw	6.6	N Layer		
Eggs(f)	0.146	0.162	0.011	0.025	**0.03**	1.0

* Indicates that the MRL is proposed at the limit of quantification.
n.a.: not applicable
(a): Median residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.
(b): Highest residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.
(c): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment (EFSA, 2020).
(d): For milk, mean was derived from samplings performed from day 7 to day 10 (daily mean of 3 cows).
(e): For poultry, results are derived from the available feeding studies as per the EFSA review of the existing MRLs, (EFSA, 2020)
(f): For eggs, mean and highest residue levels were derived from samplings performed from day 10 to day 14 (daily mean or daily highest of 3 laying hens).

Conclusion on feeding studies

The presented data were sufficient to derive MRLs in animal matrices and therefore no further studies are submitted within this dossier.

The requested uses did not significantly modify the theoretical maximum daily intake for animals compared to calculation in the EFSA Reasoned Opinion and regarding available feeding data, there is no risk for animal MRLs to be exceeded.

Evaluator comments:
Information presented by Applicant is sufficient. The zRMS agrees with the assessment prepared by Applicant in relation to magnitude of residues in livestock. The residues in animal commodities will not exceed MRLs (Reg. (EU) 2022/1343).
No further data are required to support the intended uses of ADM.00900.I.1.C.

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

The intended crops cabbage, cauliflower, broccoli, maize (grain ~~, sweetcorn~~), grape, apple, pear, quince and potato may be processed. However, residue levels are expected to be < 0.1 mg/kg (see **Section 7.2.3** above). Furthermore, the contribution of each of these commodities to the theoretical maximum daily intake (TMDI) is < 10% of the ADI.

7.2.5.1 Available data for all crops under consideration

Processing studies were already evaluated during the EU Review of chlorantraniliprole and were considered acceptable. Additional studies were submitted in the framework of this application. They are summarised in **Table 7.2-13** below.

Table 7.2-13: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Enforcement residue definition: Chlorantraniliprole					
Apple/Wet pomace	4	See 'New data' (1.8, 2.2, 2.2, 4.2)	-		EFSA, 2013a
Apple/Dry pomace	4	11.6 (9.3, 11,12, 13)	-		
Apple/Juice (Pasteurised)	4	See 'New data' (0.12, 0.18, 0.37, 0.38)	-		
Apple/Puree	4	0.23 (0.086, 0.091, 0.37, 0.38)	-		
Apple/Sauce	4	See 'New data' (0.18, 0.27, 0.37, 0.38)	-		
Apple/Preserves (Pasteurised)	4	0.28 (0.12, 0.18, 0.37, 0.38)	-		
Apple/canned (Sterilized)	4	See 'New data' (0.12, 0.18, 0.37, 0.38)	-		
Grape/Raisin	4	3.5 (2.7, 2.9, 4.0, 7.1)	-		EFSA, 2013a
Grape/juice (Pasteurised)	4	See 'New data' (0.43, 0.46, 1.0, 1.7)	-		
Grape/Red wine	2	See 'New data' (0.76, 1.6)	-		
Grape/White wine	2	See 'New data' (0.3, 0.59)	-		

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
New data					
Enforcement residue definition: Chlorantraniliprole					
Apple/Sauce	6 (2 new)	0.27 (0.17, 0.18, 0.26, 0.27, 0.37, 0.38) EU data underlined	-		Meric, D., 2022, Report No. DMC-20-43056 Roussel, Ch.H., 2022, Report No. ChR-20-43058
Apple/Wet pomace	6 (2 new)	2.60 (1.8, 1.84, 2.2, 2.2, 3.33, 4.2) EU data underlined	-		
Apple/Juice (Pasteurised)	6 (2 new)	0.25 (0.12, 0.17, 0.18, 0.26, 0.37, 0.38) EU data underlined	-		
Apple/Canned	6 (2 new)	0.25 (0.12, 0.17, 0.18, 0.26, 0.37, 0.38) EU data underlined	-		
Apple/Jelly	2	0.21 (0.17, 0.26)	-		
Grape/Wet pomace	2	2.15 (1.08, 3.22)	-		Meric, D., 2022, Report No. DMC-20-43062 Roussel, Ch.H., 2022, Report No. ChR-20-43063
Grape/Juice (Pasteurised)	6 (2 new)	0.72 (0.36, 0.4, 0.43, 0.46, 1.0, 1.7 EU data underlined	-		
Grape/Must	2	0.75 (0.4, 1.10)	-		
Grape/White wine	4 (2 new)	0.36 (0.16, 0.3, 0.4, 0.59 EU data underlined	-		
Grape/Red wine	4 (2 new)	0.81 (0.31, 0.56, 0.76, 1.6 EU data underlined	-		

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

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

7.2.5.2 Conclusion on processing studies

The intended crops cabbage, cauliflower, broccoli, maize (grain), grape, apple, pear, quince and potato may be processed. However, residue levels are expected to be < 0.1 mg/kg (see **Section 7.2.3** above). Furthermore, the contribution of each of these commodities to the theoretical maximum daily intake (TMDI) is < 10% of the ADI.

Processing studies are available for apple, grape and tomato. Robust processing factors were obtained for these crops as given in **Table 7.2-13** above. No further studies are deemed necessary.

zRMS comments:
Information given by the Applicant is acceptable and sufficient. Data dealing with magnitude of residues in processed commodities crops are available to support the intended uses.

Additional studies were submitted in the framework of this application.
1. Meric, D., 2022, Report No. DMC-20-43056 and Roussel, Ch.H., 2022, Report No. ChR-20-43058
The field trials were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in apple processed fractions (apples prior processing, sauce, wet pomace, juice, canned apples and apple jelly) after one application of ADM.00900.I.1.C at 0.388 L/ha (representing 77.5 g/ha of chlorantraniliprole).
For apple sauce, juice, canned fruit and jelly, the transfer factor (TF) is lower than 1 thus demonstrating a loss of active substance during the processing. On the contrary, for the wet pomace the transfer factor is higher than 1 (TF = 2.60) showing a concentration of the active substance in this fraction (which is not use for human consumption).

2. Meric, D., 2022, Report No. DMC-20-43062 and Roussel, Ch.H., 2022, Report No. ChR-20-43063
The field trials were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in grape processed fractions (berries prior processing, red wine, wet pomace, juice, must and white wine) after one application performed 30 (±2) days before harvest of ADM.00900.I.1.C at 0.450 L/ha representing 90 g/ha of chlorantraniliprole.
For juice, red and white wines, must the transfer factor is lower than 1, thus demonstrating a loss of active substance during the processing.
The transfer factor is higher than 1 for wet pomaces (TF = 2.15) showing a concentration of the active substance in this processed fraction (which is not use for human consumption).

Further processing studies are not required as chronic consumer exposure is below the trigger value of 10% of ADI.

7.2.6 Magnitude of residues in representative succeeding crops

Crops under evaluation can be grown in rotation.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

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

Rotational crop studies were already evaluated in the EU review of chlorantraniliprole. In the US rotational field studies conducted at a dose rate of 200–225 or 600 g a.s./ha (ca. 0.8–1.7N plateau level in soil), residues of chlorantraniliprole in succeeding crops were < 0.01 mg/kg in leafy vegetables, roots of roots vegetables, cereal grains and soyabean seeds, and mostly ≤ 0.05 mg/kg in tops of root vegetables, cereal forage, hay and straw for rotational crops grown under realistic field conditions. Significant residue levels of chlorantraniliprole are therefore not expected in succeeding crops resulting from the intended uses of ADM.00900.I.1.C.

Evaluator comments:
Information presented by Applicant is sufficient.
Since grapes and pome fruits are permanent crops that cannot be rotated, residues in rotational crops are not required for these uses. The remaining crops under consideration can be grown in crop rotation (potatoes, head cabbage, cauliflower, broccoli, corn).
Based on the available information, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the compound is used according to the proposed good agricultural practice (GAP).

EFSA in EFSA Journal 2020;18(9):6235 concluded that *The peer review stated that the US field trials conducted at ca. 0.8–1.7 N plateau level were sufficient to conclude that no chlorantraniliprole residues are expected to occur in rotational crops when the active substance was used according to the EU GAPs. Since the most critical EU GAP for crops that can be rotated evaluated under the peer review is the same as the one under this assessment, this conclusion is also applicable to this MRL review, and therefore, significant residue levels of chlorantraniliprole are not expected in succeeding crops, provided that the active substance is applied in compliance with the European GAPs reported in Appendix A.*

There is no potential for residues occurring in succeeding crops.

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

No data estimating the residues in honey is submitted in the framework of this application. In the renewal dossier a new 2021 honey field study was submitted, to which the applicant has access (see FMC-52200, Revision number 1, submitted in Document MCA, Section 6.10 and MCP, Section 10.3.1.6, Reference KCP 10.3.1.6/01). Trials, performed with phacelia were overdosed compared to the intended GAPs (bare soil application of 265 g/ha pre-planting/soil incorporation, followed by 2 applications of 60 g/ha at BBCH 59-60 and 63-65) in this submission but show that residues above the 0.05 mg/kg trigger and would not be expected, thus demonstrating compliance with the EU MRL.

Evaluator comments:
ADM.00900.I.1.C may be used on crops which can be considered to be melliferous. Therefore, the possible transfer of residues to honey from the relevant uses should be considered, since chlorantraniliprole may be applied during flowering stage (BBCH60-69) of table grape and wine grape (SANTE/11956/2016 rev. 9).
According to the SANTE/11956/2016 rev. 9 *Field and tunnel trials aim to determine the likely residues in honey based on the tested GAP, via direct foraging of bees on a treated crop. At least four trials are considered necessary.*

In the renewal dossier a new honey field study was submitted, to which the applicant has access (Gonsior, G., 2021; FMC-52200, Revision No. 1; S19-02573). This study is briefly summarised; the detailed assessment is presented in Appendix 2.
The objective of this study was to determine the effects of Chlorantraniliprole 200 g/L SC on the honey bee (*Apis mellifera L.*) in Norther and Southern Germany. Additionally, samples of plants, as well as nectar, pollen and honey from combs, and nectar and pollen collected by forager bees were taken for determination of residues of Chlorantraniliprole and the metabolite IN-F9N04.

The following overview gives the maximum, minimum and mean values of residues detected in the single matrices:

Residues of Chlorantraniliprole							
Trial	**Field T**	**Matrix**	**Residues (mg a.s./kg)**				
			n	**Maximum**	**Min**	**Mean**	**SD**
-01 and -05	all	Soil (dry weight)	6	0.1900	0.0721	0.1211	0.0431
	all	Soil (wet weight)	6	0.162	0.0609	0.1038	0.0370
	all	Spray solution A2*[x)]	6	109 %	81 %	99 %	11.41
	all	Spray solution A3*	6	109 %	91 %	101 %	7.33
	all	**Honey**	**8**	**0.0267**	**0.00156**	**0.00824**	**0.00862**
	all	Nectar from Combs	18	0.0190	0.000873	0.004501	0.004936
	all	Nectar from Forager Bees	24	0.0578	<LOQ	0.00722[1)]	0.0120[1)]
	all	Pollen from Combs	18	4.02	0.253	1.3038	0.8949
	all	Pollen from Forager Bees	23	1.16	0.0153	0.2862	0.2913
	all	Whole Plant	6	4.95	4.38	4.64	0.24

[1)] For calculation of mean and SD values <LOQ were set to LOQ (0.0005 mg/kg).
*% of target rate, [x)] see deviation 1, trial-05 (chapter 3.6.2)

Residues of IN-F9N04							
Trial	Field T	Matrix	Residues (mg a.s./kg)				
			n	Maximum	Min	Mean	SD
-01 and -05	all	Soil (dry weight)	6	n.d.	n.d.	n.d.	n.d.
	all	**Honey**	**8**	**n.d.**	**n.d.**	**n.d.**	**n.d.**
	all	Nectar from Combs	18	n.d.	n.d.	n.d.	n.d.
	all	Nectar from Forager Bees	24	n.d.	n.d.	n.d.	n.d.
	all	Pollen from Combs	18	0.00138	n.d.	0.000690[1)]	0.000267[1)]
	all	Pollen from Forager Bees	23	0.00108	n.d.	0.000473[1)]	0.000239[1)]
	all	Whole Plant	6	0.00833	0.00552	0.00683	0.00129

(LOQ = 0.0005 mg/kg)
n.d.≤0.00015; [1)] or calculation of mean and SD values <LOQ were set to LOQ (0.0005 mg/kg) and values n.d. were set to LOQ (0.00015 mg/kg)

The chlorantraniliprole residues found in honey were from 0.00156 to 0.0267 mg/kg. The IN-F9N04 residues were always below LOD.
The residues arising from the proposed uses will not exceed the MRLs established for chlorantraniliprole for honey of 0.05 mg/kg in Reg. (EU) 2022/1343.
The storage stability was assessed in separate studies FMC-51284 (honey, nectar, pollen). Data generated indicate that chlorantraniliprole and IN-F9N04 residues are stable in the tested matrices for at least 24 months.

No additional data are required.

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 **Section 7.1.2**).

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

7.2.8.1 Input values for the consumer risk assessment

~~For the chronic risk assessment all uses listed in MRL Regulation (EU) No 2021/1884 were considered.~~

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

~~Commodity~~	~~Chronic risk assessment~~	
	~~Input value (mg/kg)~~	~~Comment*~~
~~Risk assessment residue definition: Chlorantraniliprole~~		
~~Apples~~	~~0.5~~	~~EU MRL~~
~~Pears~~	~~0.5~~	~~EU MRL~~
~~Quinces~~	~~0.5~~	~~EU MRL~~
~~Table grapes~~	~~1~~	~~EU MRL~~
~~Wine grapes~~	~~1~~	~~EU MRL~~
~~Potatoes~~	~~0.02~~	~~EU MRL~~
~~Sweet corn~~	~~0.2~~	~~EU MRL~~
~~Broccoli~~	~~1~~	~~EU MRL~~
~~Cauliflowers~~	~~0.6~~	~~EU MRL~~

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment*
Head cabbages	2	EU MRL
Maize/corn	0.02	EU MRL
Other commodities of plant origin	MRL	EU MRL
Risk assessment residue definition: Sum chlorantraniliprole and metabolites IN-HXH44 and IN-K9T00 expressed as chlorantraniliprole		
Commodities of animal origin	MRL	EU MRL x CF** (In force MRL according to Reg. (EU) No 2021/1884)

* In force MRL according to Reg. (EU) No 2021/1884
**CF_{risk} for residue definition, 1.8 and 1.9 for ruminants' liver and kidney, respectively and 1 for swine tissues and ruminants' milk, muscle and fat. Source: EFSA, 2020.

For the chronic risk assessment all uses listed in MRL Regulation (EU) No 2022/1343 were considered.

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

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment*
Risk assessment residue definition: Chlorantraniliprole		
Apples	0.4	EU MRL
Pears	0.4	EU MRL
Quinces	0.4	EU MRL
Table grapes	1	EU MRL
Wine grapes	1	EU MRL
Potatoes	0.03	EU MRL
Broccoli	1.5	EU MRL
Cauliflowers	0.5	EU MRL
Head cabbages	2	EU MRL
Maize/corn	0.02	EU MRL
Other commodities of plant origin	MRL	EU MRL
Risk assessment residue definition: Sum chlorantraniliprole and metabolites IN-HXH44 and IN-K9T00 expressed as chlorantraniliprole		
Commodities of animal origin	MRL	EU MRL x CF** (In force MRL according to Reg. (EU) No 2022/1343)

* In force MRL according to Reg. (EU) No 2022/1343
**CF_{risk} for residue definition, 1.8 and 1.9 for ruminants' liver and kidney, respectively and 1 for swine tissues and ruminants' milk, muscle and fat. Source: EFSA, 2020.

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-16: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	3% (based on NL toddler consumer group)
IESTI (% ARfD) according to EFSA PRIMo	As ARfD is not necessary, no acute risk assessment was performed

The proposed uses of chlorantraniliprole in the formulation ADM.00900.I.1.C do not represent unacceptable chronic risks for the consumer.

Evaluator comment:
Calculations presented by the Applicant are acceptable.
The data available are considered sufficient for risk assessment. The chronic intakes of chlorantraniliprole residues are unlikely to present a public health concern.
The intended uses of ADM.00900.I.1.C are accepted.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

Evaluator comment:
Information is acceptable.

7.4 References

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the modification of the existing MRLs for chlorantraniliprole in various crops. EFSA Journal 2012;10(1):2548, 38 pp.

European Food Safety Authority, 2013a; Conclusion on the peer review of the pesticide risk assessment of the active substance [chlorantraniliprole]. EFSA Journal 2013;11(6):3143. [107 pp.] doi:10.2903/j.efsa.2013.3143.

EFSA (European Food Safety Authority), 2020. Reasoned opinion on the review of the existing maximum residue levels for chlorantraniliprole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18 (9):6235, 143 pp.

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

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Vertebrate study Y/N	Owner*
KCP 8.1/01	Kiemle, A.	2021	Storage Stability of Chlorantraniliprole and its metabolite IN-F9N04 in bee matrices (pollen, nectar and honey) under deep frozen conditions; FMC Report No.: FMC-51284 Eurofins Agroscience Services EcoChem GmbH GLP: yes Published: no	N	FMC
KCP 8.3/01	MERIC, D.	2022	Magnitude of the residues of chlorantraniliprole in orchard (apple or pear, RAC fruits) and processed fractions, following one application of ADM.00900.I.1.C in 2 trials on apples (1 DCS and 1 HS with process) and 2 trials on pears (1 DCS + 1 HS). Northern Europe (Poland, Hungary and France) – 2020. ADAMA MAKHTESHIM Ltd. Report No. DMC-20-43056 (Sponsor report No. 000105697) STAPHYT, France GLP: yes Published: no	N	ADM
KCP 8.3/02	MERIC, D.	2022	Magnitude of the residues of chlorantraniliprole, after application of ADM.00900.I.1.C in apple or pear in Northern Europe – 2021. ADAMA MAKHTESHIM Ltd. Report No. DMC-21-48212 (Sponsor report No. 000107719) STAPHYT, France GLP: yes Published: no	N	ADM
KCP 8.3/03	MERIC, D.	2022	Magnitude of the residues of chlorantraniliprole in table or wine grapes (RAC berries) and processed fractions, following one application of ADM.00900.I.1.C in 4 trials (2 DCS and 2 HS with process). Northern Europe (France and Hungary) – 2020. ADAMA MAKHTESHIM Ltd. Report No. DMC-20-43062 (Sponsor report No. 000105700) STAPHYT, France GLP: yes Published: no	N	ADM

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Vertebrate study Y/N	Owner*
KCP 8.3/04	MERIC, D.	2022	Magnitude of the residues of chlorantraniliprole after application of ADM.00900.I.1.C in grapevine in Northern Europe – 2021. ADAMA MAKHTESHIM Ltd. Report No. DMC-21-48215 (Sponsor report No. 000107722) STAPHYT, France GLP: yes Published: no	N	ADM
KCP 8.3/05	MERIC, D	2021	Magnitude of the residues of chlorantraniliprole in potatoes (RAC tubers) following two applications of ADM.00900.I.1.C in 4 trials (2 DCS + 2 HS). Northern Europe (Northern France, Poland and Hungary) – 2020 ADAMA MAKHTESHIM Ltd. Report No. DMC-20-43066 (Sponsor report No. 000105704) STAPHYT, France GLP: yes Published: no	N	ADM
KCP 8.3/06	MERIC, D	2021	Magnitude of the residues of chlorantraniliprole in broccoli (RAC flower heads and stems) following one application of ADM.00900.I.1.C in 2 trials (1 DCS + 1 HS). Northern Europe (Poland and Northern France) – 2020 ADAMA MAKHTESHIM Ltd. Report No. DMC-20-43078 (Sponsor report No. 000105715) STAPHYT, France GLP: yes Published: no	N	ADM
KCP 8.3/07	MERIC, D	2022	Magnitude of the residues of chlorantraniliprole after application of ADM.00900.I.1.C in broccoli in Northern Europe – 2021 ADAMA MAKHTESHIM Ltd. Report No. DMC-21-48554 (Sponsor report No. 000107736) STAPHYT, France GLP: yes Published: no	N	ADM
KCP 8.3/08	Delmotte, R	2021	Magnitude of the residues of chlorantraniliprole in cauliflowers (RAC inflorescences) following one application of ADM.00900.I.1.C in 2 trials (1 DCS + 1 HS). ADAMA MAKHTESHIM Ltd. Report No. RDE-20-43076 (Sponsor report No. 000105713) STAPHYT, France GLP: yes Published: no	N	ADM

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Vertebrate study Y/N	Owner*
KCP 8.3/09	Domingo, S	2022	Magnitude of the residues of chlorantraniliprole after application of ADM.00900.I.1.C in cauliflower in Northern Europe – 2021 ADAMA MAKHTESHIM Ltd. Report No. SDO-21-48552 (Sponsor report No. 000107733) STAPHYT, Spain GLP: yes Published: no	N	ADM
KCP 8.3/10	MERIC, D	2021	Magnitude of the residues of chlorantraniliprole in head cabbages (RAC heads) following one application of ADM.00900.I.1.C in 4 trials (2 DCS + 2 HS). Northern Europe (Poland, Hungary, Northern France) – 2020 ADAMA MAKHTESHIM Ltd. Report No DMC-20-43074 (Sponsor report No. 000105711) STAPHYT, France GLP: yes Published: no	N	ADM
KCP 8.3/11	MERIC, D	2022	Magnitude of the residues of chlorantraniliprole after application of ADM.00900.I.1.C in head cabbages in Northern Europe – 2021 ADAMA MAKHTESHIM Ltd. Report No DMC-21-48550 (Sponsor report No. 000107731) STAPHYT, France GLP: yes Published: no	N	ADM
KCP 8.3/12	Delmotte, R	2021	Magnitude of the residues of chlorantraniliprole in Maize (RAC sweet corns (cob), whole plants (silage), stover and grain) following one application of ADM.00900.I.1.C in 4 trials (4 RDCS) Northern Europe (France, Poland and Hungary) – 2020. ADAMA MAKHTESHIM Ltd. Report No. RDE-20-43068 (Sponsor report No. 000105706) STAPHYT, France GLP: yes Published: no	N	ADM
KCP 8.3/13	Roussel, Ch.H.	2022	Magnitude of the residues of chlorantraniliprole after application of ADM.00900.I.1.C in maize in Northern Europe – 2021 ADAMA MAKHTESHIM Ltd. Report No. ChR-21-48545 (Sponsor report No. 000107726) STAPHYT, France GLP: yes Published: no	N	ADM

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Vertebrate study Y/N	Owner*
KCP 8.5.3/01 (KCP 8.3/01)	MERIC, D.	2022	Magnitude of the residues of chlorantraniliprole in orchard (apple or pear, RAC fruits) and processed fractions, following one application of ADM.00900.I.1.C in 2 trials on apples (1 DCS and 1 HS with process) and 2 trials on pears (1 DCS + 1 HS). Northern Europe (Poland, Hungary and France) – 2020. ADAMA MAKHTESHIM Ltd. Report No. DMC-20-43056 (Sponsor report No. 000105697) STAPHYT, France GLP: yes Published: no	N	ADM
KCP 8.5.3/02	Roussel, Ch.H.	2022	Magnitude of the residues of chlorantraniliprole in orchard (apple or pear, RAC fruits) and processed fractions, following one application of ADM.00900.I.1.C in 2 trials on apples (1 DCS and 1 HS with process) and 2 trials on pears (1 DCS + 1 HS). Southern Europe (Italy and France) – 2020 ADAMA MAKHTESHIM Ltd. Report No. ChR-20-43058 (Sponsor report No. 000105698) STAPHYT, France GLP: yes Published: no	N	ADM
KCP 8.5.3/03 (KCP 8.3/03)	MERIC, D.	2022	Magnitude of the residues of chlorantraniliprole in table or wine grapes (RAC berries) and processed fractions, following one application of ADM.00900.I.1.C in 4 trials (2 DCS and 2 HS with process). Northern Europe (France and Hungary) – 2020. ADAMA MAKHTESHIM Ltd. Report No. DMC-20-43062 (Sponsor report No. 000105700) STAPHYT, France GLP: yes Published: no	N	ADM
KCP 8.5.3/04	Roussel, Ch.H.	2022	Magnitude of the residues of chlorantraniliprole in table or wine grapes (RAC berries) and processed fractions, following one application of ADM.00900.I.1.C in 4 trials (2 DCS and 2 HS with process) Southern Europe (Italy and France) – 2020. ADAMA MAKHTESHIM Ltd. Report No. ChR-20-43063 (Sponsor report No. 000105701) STAPHYT, France GLP: yes Published: no	N	ADM
KCP 10.3.1.6/01	Gonsior, G.	2021	Chlorantraniliprole 20 SC: A field study to evaluate effects on the honeybee (*Apis mellifera* L.) in *Phacelia tanacetifolia* in Germany in 2019 Report No.FMC-52200, Revision No. 1 FMC Corporation GLP: yes Published: no	N	FMC

*ADM = proprietary of ADAMA Agricultural Solutions and all affiliates

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
DAR 2008 IIA, 6.5.3./01	Foster, A.C., Cairns, S.D.	2005	Magnitude of DPX-E2Y45, IN-EQW78, IN-ECD73, and IN-F6L99 residues in processed fractions of wine grapes (berries and small fruits) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - Europe, 2004 Inveresk Research DuPont-14572 GLP: Yes Published: No	N	DuPont (out of protection)
DAR 2008 IIA, 6.5.3./02	Foster, A.C., Cairns, S.D., Davidson, J., Hunter, T.M.	2006	Magnitude of DPX-E2Y45, IN-EQW78, IN-ECD73, and IN-F6L99 residues in processed fractions of apples (pome fruits) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - Europe, 2005 Charles River Laboratories DuPont-16587 GLP: Yes Published: No	N	DuPont (out of protection)
DAR 2008 IIA, 6.5.3./04	Foster, A.C., Cairns, S.D., Hunter, T.M.	2006	Magnitude of DPX-E2Y45, IN-EQW78, IN-ECD73, and IN-F6L99 residues in processed fractions of grapes (berries and small fruits) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - Europe, 2005 Charles River Laboratories DuPont-16590 GLP: Yes Published: No	N	DuPont (out of protection)

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 Chlorantraniliprole

A 2.1.1 Stability of residues

~~No n~~New/additional studies submitted within this dossier.

Comments of zRMS:	The storage stability of chlorantraniliprole and its metabolite IN-F9N04 has been checked in bee matrices (pollen, honey and nectar) at ≤ -18 °C in the dark over a storage period up to 24 months. Sample extraction and determination of residues was performed according to an analytical procedure that was validated within EAS study S18-05672 (FMC-51418) and S20-01444 (FMC-54228). Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.0005 mg/kg for each analyte and matrix. Stability was demonstrated for analytes chlorantraniliprole and its metabolite IN-F9N04 in homogenates of matrices pollen, nectar and honey upon storage at ≤-18 °C for 24 months. The study is acceptable.

Reference:	KCP 8.1/01
Report	Kiemle, A. (2021); Storage Stability of Chlorantraniliprole and its metabolite IN-F9N04 in bee matrices (pollen, nectar and honey) under deep frozen conditions; FMC Report No.: FMC-51284
Guideline(s):	Yes Regulation (EC) No 1107/2009; OECD 506 (2007); OPPTS 860.1380 (1996); 7032/VI/95 (Appendix H, rev.5), dated 22/7/97; SANCO/3029/99, rev. 4
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

Executive summary:
Samples of nectar, honey and pollen, fortified with chlorantraniliprole and IN-F9N04 at 0.005 mg/kg were stored at ≤ -18 °C for a duration of 24 months. Stored fortified and stored control samples were analysed after 0, 3, 6, 12, 18 and 24 months for residues of chlorantraniliprole and IN-F9N04. Samples were analyzed following the procedures that was validated in FMC-51418 and FMC-54228.
The data indicate the residues of chlorantraniliprole and IN-F9N04 are stable at ≤ -18 °C for at least 24 months in nectar, honey and pollen.

B. STUDY DESIGN

The study was conducted during the period between Nov 16, 2018 and Feb 24, 2021 at Eurofins Agroscience Services EcoChem GmbH, Germany.

1. Test procedure

Control samples fortified with chlorantraniliprole or IN-F9N04 at 0.005 mg/kg were stored over a period up to 24 months during which they were kept in a frozen condition (≤ -18 °C) pending analysis. At intervals during the storage period, 2 stored fortified and 3 control samples were removed from storage for analysis. Two of the control samples were freshly fortified with chlorantraniliprole

and IN-F9N04 at 0.005 mg/kg and the five samples were analysed for chlorantraniliprole and IN-F9N04 residues using the same analytical procedures as those employed for honey residue studies.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material 1: Chlorantraniliprole technical
   Lot/Batch #: E2Y45-665
   Purity: 99.4%
   Description: Crystalline Powder/off-white
   CAS#: 500008-45-7

   Test material 2: IN-F9N04
   Lot/Batch #: IN-F9N04-001
   Purity: 95.6%
   Description: Solid, Powder/beige
   CAS#: Not available
   Stability of test compound: Ambient
2. Test commodity: Bee matrices
3. Matrix: Nectar, honey, pollen
   Origin: Nectar: Honey-water mixture (1:3) was prepared with organic honey obtained from the local store
   Honey: Organic honey obtained from the local store
   Pollen: Yellow mix pollen, mainly oil seed rape.
   Sample size: 0.2 g

2. Description of analytical procedures

Test Method: Chlorantraniliprole and its metabolite IN-F9N04 in pollen, honey and nectar.	
Method Reference(s)	Method was developed in the EAS study S18-05672 (FMC-51418) and S20-01444 (FMC-54228)
Validation Status	All combinations of analytes and matrices occurring in this study were validated in the EAS study S18-05672 and S20-01444 according to SANCO/825/00, rev. 8.1.
Storage	Final specimen extracts were stored at 1 °C to 10 °C in the dark until analysis.
Detection	Liquid chromatography with tandem mass spectrometry (LC-MS/MS).
Limit of Quantification (LOQ)	0.0005 mg/kg for all analytes.
Limit of Detection (LOD)	30 % of the LOQ.

II. RESULTS AND DISCUSSION

For all combinations of analytes and matrices the average amount of analyte recovered relative to the initial recovery at day 0 was ≥ 70% at any testing interval, which can be seen as criterion for sufficient storage stability. Thus, stability was demonstrated for analytes Chlorantraniliprole and IN-F9N04 in matrices honey, nectar and pollen upon storage at ≤ -18 °C in the dark for 24 months.
All concurrent recoveries fell within the range of 70–120%. These recovery results show the method was well controlled throughout the sample analyses.
The results are presented in Table 1.

Table 1. Stability of chlorantraniliprole and IN-F9N04 residues in honey, nectar and pollen following storage at ≤ -18 °C

Storage Period	Procedural Recoveries		Storage Samples				
	Single Values (%)	Mean (%) [a]	Percentage of analyte found relative to the nominal fortification level (%)				Residue Level in Freezer Storage Stability Sample (mg/kg)
			Single Values (%) [b]	Mean	% of initial day 0 normalized [$P_{remaining}$]	Average Corrected % Recovery [$P_{corrected}$]	
Analyte: Chlorantraniliprole (484 -> 286 m/z) Test System: Honey Nominal Fortification Level: 0.005 mg/kg (10x LOQ)							

Storage Period	Procedural Recoveries		Storage Samples				
	Single Values (%)	Mean (%) [a]"	Percentage of analyte found relative to the nominal fortification level (%)				Residue Level in Freezer Storage Stability Sample (mg/kg)
			Single Values (%) [b]	Mean	% of initial day 0 normalized [$P_{remaining}$]	Average Corrected % Recovery [$P_{corrected}$]	
0 days	-	-	73, 72	73	100	-	0.00365 0.00358
3 months	77, 79	78	86, 82	84	116	108	0.00432 0.00409
6 months	87, 84	86	85, 85	85	117	99	0.00423 0.00423
12 months	70, 77	74	90, 85	88	121	118	0.00451 0.00427
18 months	105, 90	98	88, 92	90	124	92	0.00441 0.00459
24 months	88, 90	89	71, 77	74	102	83	0.00357 0.00383
Analyte: IN-F9N04 (470 -> 286 m/z) Test System: Honey Nominal Fortification Level: 0.005 mg/kg (10x LOQ)							
0 days	-	-	75, 74	75	100	-	0.00376 0.00371
3 months	76, 77	77	86, 77	82	109	106	0.00431 0.00383
6 months	90, 88	89	87, 91	89	119	100	0.00436 0.00457
12 months	70, 75	73	107, 104	106	142	145	0.00534 0.00521
18 months	104, 89	97	109, 109	109	146	112	0.00545 0.00544
24 months	88, 91	90	87, 86	87	96	96	0.00436 0.00432
Analyte: Chlorantraniliprole (484 -> 286 m/z) Test System: Nectar Nominal Fortification Level: 0.005 mg/kg (10x LOQ)							
0 days	--	--	82, 86	84	100	-	0.00411 0.00430
3 months	101, 103	102	102, 100	101	120	99	0.00509 0.00502
6 months	112, 105	109	102, 104	103	123	94	0.00509 0.00519
12 months	89, 89	89	107, 105	106	126	119	0.00536 0.00524
18 months	103, 99	101	86, 92	89	106	88	0.00431 0.00462
24 months	91, 92	92	81, 81	81	96	88	0.00406 0.00404
Analyte: IN-F9N04 (470 -> 286 m/z) Test System: Nectar Nominal Fortification Level: 0.005 mg/kg (10x LOQ)							
0 days	-	-	82, 84	83	100	-	0.00412 0.00418
3 months	98, 96	97	91, 92	92	110	94	0.00454 0.00462
6 months	111, 105	108	95, 96	96	115	88	0.00473 0.00479
12 months	88, 91	90	110, 110	110	133	122	0.00551 0.00552
18 months	102, 99	101	92, 94	93	112	92	0.00460 0.00468
24 months	97, 96	97	78, 83	81	97	83	0.00391 0.00413
Analyte: Chlorantraniliprole (484 -> 286 m/z) Test System: Pollen Nominal Fortification Level: 0.005 mg/kg (10x LOQ)							
0 days	-	-	98, 92	95	100	-	0.00492 0.00459
13 months	112, 107	110	80, 78	79	83	72	0.00402 0.00392

Storage Period	Procedural Recoveries		Storage Samples				
	Single Values (%)	Mean (%) [a]	Percentage of analyte found relative to the nominal fortification level (%)				Residue Level in Freezer Storage Stability Sample (mg/kg)
			Single Values (%) [b]	Mean	% of initial day 0 normalized [$P_{remaining}$]	Average Corrected % Recovery [$P_{corrected}$]	
19 months	89 *	89	85, 80	83	87	93	0.00424 0.00400
24 months	80, 75	78	68, 71	70	73	89	0.00338 0.00356
Analyte: IN-F9N04 (470 -> 286 m/z) Test System: Pollen Nominal Fortification Level: 0.005 mg/kg (10x LOQ)							
0 days	-	-	91, 90	91	100	-	0.00455 0.00452
13 months	111, 108	110	70, 72	71	78	65	0.00349 0.00358
19 months	91*	91	74, 82	78	86	86	0.00372 0.00412
24 months	70, 72	71	67, 64	66	72	92	0.00334 0.00322

[a] calculated from rounded values; [b] not corrected for procedural recoveries, * second recovery was excluded due to an extraction error

III. CONCLUSION

The data indicate the residues of chlorantraniliprole and IN-F9N04 are stable at ≤ -18°C for 24 months in honey, nectar and pollen.
Samples were properly generated and stored at frozen temperatures. With regard to selectivity, accuracy and precision, the analytical method was applied successfully for each analytical set when analysing the storage samples.

(Kiemle, A. 2021)

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

No new/additional studies submitted within this dossier.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Apple / Pear

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 (Ireland, 2008 EFSA, 2013a) – apples and pears	1-2	60 g a.s./ha	14	BBCH 87	14
cGAP EU (Art. 12, EFSA, 2020)	1-2	60 g a.s./ha	14	-	14
Intended cGAP (number* 5, 6)	1	31 g a.s./ha	-	BBCH 87	14

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

A total of 2 new studies, consisting of 8 new trials for apple and pear are summarised in the following.

Study 1

Comments of zRMS:	Four independent field trials (two decline trials and two harvest trials) were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in raw agricultural commodity specimens of apple or pear (RAC fruits) after one application of ADM.00900.I.1.C at 0.155 L/ha representing 31 g/ha of chlorantraniliprole (plot T or T1). Five samplings were done in the two decline trials. On treated plot, fruits were collected at 0, 3, 7, 10 days after application (DAA) and finally at 14 (+/-1) DAA (commercial harvest). For untreated plot, fruits were collected just before application, at 7 DAA and at 14 (+/-1) DAA. In the two harvest trials, fruit specimens were taken only at commercial harvest at 14 (+/-1) DAA. The analytical method for chlorantraniliprole was fully validated in another study on peach (whole fruits without stones) which is a commodity with high water content as pear (fruit), apple (fruit) (POLLENIZ/GIRPA study B20G-A4-C-01 –Sponsor reference 000105719), according to SANTE/2020/12830, Rev.1 of 24/02/2021. The analytical method for chlorantraniliprole was based on the QuEChERS multi-residue method. The analytical method consisted in an extraction by maceration with acetonitrile / 1% formic acid mixture. Then extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Reduced validation of the analytical method on pear (fruit), apple (fruit) was done within this study. Limit of quantification (LOQ) achieved was 0.010 mg/kg. The mean recovery was between 70% and 110% at each level of fortification. **Results:** After one application in apple or pear with ADM.00900.I.1.C at the rate of 0.155 L/ha, (representing 31 g/ha of chlorantraniliprole), the residues found in treated specimens (plot T or T1) are ranging: - from 0.024 to 0.044 mg/kg at 0 DAA - from 0.028 to 0.037 mg/kg at 3 DAA - from 0.025 to 0.032 mg/kg at 7 DAA - from < LOQ to 0.030 mg/kg at 10 DAA - from < LOD to 0.032 mg/kg at 13 or 14 DAA (commercial harvest). The storage duration (interval between sampling and analysis date) was 234 days for the determination of chlorantraniliprole. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCP 8.3/01
Report	Magnitude of the residues of chlorantraniliprole in orchard (apple or pear, RAC fruits) and processed fractions, following one application of ADM.00900.I.1.C in 2 trials on apples (1 DCS and 1 HS with process) and 2 trials on pears (1 DCS + 1 HS). Northern Europe (Poland, Hungary and France) – 2020, Meric, D., 2022, Report No. DMC-20-43056 (Sponsor report No. 000105697)
Guideline(s):	Yes SANCO/7029/VI/95 rev.5 OECD 509 (2009) ENV/JM/MONO(2011)50/REV1 OECD 508 SANTE/2020/12830, Rev.1 ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

Summary of the study 1 trials

Reference:	Magnitude of the residues of chlorantraniliprole in orchard (apple or pear, RAC fruits) and processed fractions, following one application of ADM.00900.I.1.C in 2 trials on apples (1 DCS and 1 HS with process) and 2 trials on pears (1 DCS + 1 HS). Northern Europe (Poland, Hungary and France) – 2020., Meric, D., 2022, Report No. DMC-20-43056 (Sponsor report No. 000105697)		
GLP:	Yes	**Sample storage conditions:**	Maximum of 234 days between sampling and analysis Maximum of 7 days between extraction and analysis
Crop/crop group:	Apple / Pear	**Analytical method:**	Validated method - POLLENIZ/GIRPA study code: B20G-A4-C-01 - Sponsor reference: 000105719 POLLENIZ/GIRPA analytical phase code B20G-S2-C-08 (within this study) Multi-residue Method QuEChERS for the Determination of chlorantraniliprole
Indoor/Outdoor:	Outdoor	**Limit of Quantification (mg/kg):**	0.01 mg/kg
Formulation:	SC	**Limit of Detection (mg/kg):**	0.003 mg/kg
Content of active substance (g/kg or g/l):	200 g/L chlorantraniliprole	**Residues calculated as:**	chlorantraniliprole

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues [mg/kg]	PHI [days] (d)	Details on trial (e)
			[g a.s./ ha]	Water [L/ha]	[g a.s./hl				Chlorantraniliprole		
DMC-20-43056 PL01 / 87-500 Stawiska, Kujawsko-Pomorskie, Poland / N-EU / 2020	Apple / Idared	1- 15/10/2000 2- 04/05/2020 to 27/05/2020 3- 12/10/2020	33	1031	3	29/09/2020	BBCH 85	Fruit	0.044 0.037 0.032 0.030 0.024	0 3 7 10 13(NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 218 days -extraction to analysis: 1 day
DMC-20-43056 HU02 / 4731 Tunyogmatolcs, Szabolcs-Szatmár-Bereg county, Hungary / N-EU / 2020	Apple / Jonatán	1- 1988 2- 30/04/2020 to 20/05/2020 3- 18/09/2020 to 20/09/2020	32	1008	3	04/09/2020	BBCH 85	Fruit	0.032	14(NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 228 days (RAC) -extraction to analysis: 7 days
DMC-20-43056 PL03 / 62-310 Rataje, Wielkopolskie, Poland / N-EU / 2020	Pear / Lukasówka	1- 15/03/2005 2- 24/04/2020 to 16/05/2020 3- 21/09/2020	33	1020	3	07/09/2020	BBCH 81	Fruit	0.024 0.028 0.025 <0.01 <0.01 (<LOD)	0 3 7 10 14(NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 234 days -extraction to analysis: 0 day
DMC-20-43056 FR04/ 37130 Lignières de Touraine, Centre – Val de Loire, N. France / N-EU / 2020	Pear / Conférence	1- 1990 2- 30/03/2020 to 12/04/2020 3-28/08/2020 to 25/09/2020	32	806	4	31/08/2020	BBCH 85	Fruit	0.024	14(NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 227 days -extraction to analysis: 0 day

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Study 2

Comments of zRMS:	Four independent field trials (two decline trials and two harvest trials) were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in raw agricultural commodity specimens of apple or pear (RAC fruits) after one application of ADM.00900.I.1.C at 0.155 L/ha representing 31 g/ha of chlorantraniliprole (plot T or T1). Five samplings were done in the two DCS trials. On treated plot, fruits were collected at 0, 3, 7, 9 or 10 days after application (DAA) and finally at 14 DAA (commercial harvest). For untreated plot, fruits were collected just before application, at 7 DAA and at 14 DAA (commercial harvest). In the 2 HS trials, fruit specimens were taken only at commercial harvest at 13 or 14 DAA. The analytical method for chlorantraniliprole was described and fully validated for apple and pear (fruit) matrices within one previous study and a reduced validation was done during this study. The analytical method consisted in an extraction from laboratory samples of pear, apple and processed fractions by maceration in acetonitrile with 1% formic acid and addition of ultra-pure water for apple wet pomace and apple jelly. Then extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Limit of quantification (LOQ) achieved was 0.01 mg/kg. No residue of chlorantraniliprole was found above LOQ (0.01 mg/kg) in untreated specimens. The mean recovery was between 70% and 110% at each level of fortification. **Results:** After one application in apple or pear with ADM.00900.I.1.C at the rate of 0.155 L/ha, (representing 31 g/ha of chlorantraniliprole), the residues found in treated specimens are ranging: - from 0.018 to 0.043 mg/kg at 0 DAA - from 0.023 to 0.032 mg/kg at 3 DAA - from 0.027 to 0.031 mg/kg at 7 DAA - from 0.014 to 0.034 mg/kg at 9 or 10 DAA - from 0.013 to 0.031 mg/kg at 13 or 14 DAA (commercial harvest). The storage duration (interval between sampling and analysis date) was 102 days for the determination of chlorantraniliprole. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCP 8.3/02
Report	Magnitude of the residues of chlorantraniliprole, after application of ADM.00900.I.1.C in apple or pear in Northern Europe – 2021, Meric, D., 2022, DMC-21-48212 (Sponsor report No. 000107719)
Guideline(s):	SANCO/7029/VI/95 rev.5 OECD 509 (2009) SANTE/2020/12830, Rev.1 ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

Summary of the study 2 trials

Reference:	Magnitude of the residues of chlorantraniliprole, after application of ADM.00900.I.1.C in apple or pear in Northern Europe – 2021, Meric, D., 2022, DMC-21-48212 (Sponsor report No. 000107719)		
GLP:	Yes	**Sample storage conditions:**	Maximum of 102 days between sampling and analysis Maximum of 1 days between extraction and analysis
Crop/crop group:	Apple / Pear	**Analytical method:**	Validated method - POLLENIZ/GIRPA study code: B20G-A4-C-01 - Sponsor reference: 000105719 POLLENIZ/GIRPA analytical phase code B21G-S2-C-02 (within this study) Multi-residue Method QuEChERS for the Determination of chlorantraniliprole
Indoor/Outdoor:	Outdoor	**Limit of Quantification (mg/kg):**	0.01 mg/kg
Formulation:	SC	**Limit of Detection (mg/kg):**	0.003 mg/kg
Content of active substance (g/kg or g/l):	200 g/L chlorantraniliprole	**Residues calculated as:**	chlorantraniliprole

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues [mg/kg]	PHI [days] (d)	Details on trial (e)
			[g a.s./ ha]	Water [L/ha]	[g a.s./hl				Chlorantraniliprole		
DMC-21-48212 PL01 / 89-240 Hiastowice, Kujawsko-Pomorskie, Poland / N-EU / 2021	Apple / Cortland	1- 1995 2- 10/04/2021 to 25/04/2021 3- 22/09/2021 to 27/09/2021	31	990	3	08/09/2021	BBCH 85	Fruit	0.018 0.023 0.027 0.014 0.013	0 3 7 9 14(NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 97 days -extraction to analysis: 1 day
DMC-21-48212 AT02 / 4062 Kirchberg-Thening, Upper Austria, Austria / N-EU / 2021	Apple / Jonagold	1- 2012 2- 30/04/2021 to 10/05/2021 3- 29/09/2021	32	600	5	14/09/2021	BBCH 85	Fruit	0.015	14(NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 77 days -extraction to analysis: 1 day
DMC-21-48212 HU03 / 6795 Bordány, Csongrád-Csanád county, Hungary / N-EU / 2021	Pear / Bosc Cobac	1- Before 2006 2- 10/04/2021 to 01/05/2021 3- 15/09/2021 to 20/09/2021	32	793	4	03/09/2021	BBCH 85	Fruit	0.043 0.032 0.031 0.034 0.029	0 3 7 10 14(NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 102 days -extraction to analysis: 1 day
DMC-21-48212 FR04 / 67170 Rottelsheim, Grand-Est, N. France / N-EU / 2021	Pear / Packham's	1- 2015 2- 20/04/2021 to 28/04/2021 3- 22/09/2021	30	566	5	01/09/2021	BBCH 85	Fruit	0.031	13(NCH)	Untreated specimens <LOQ Max. Storage: -sampling to analysis: 92 days -extraction to analysis: 1 day

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.3.2 Grape

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 (Ireland, 2008 EFSA, 2013a) – Grapes (wine)	1	54 g a.s./ha	-	BBCH 83	30
cGAP EU (Ireland, 2008 EFSA, 2013a) – Grapes (table)	1-2	43.2 g a.s./ha	10-14	BBCH 85	3
SEU cGAP EU (Art. 12, EFSA, 2020) – Grapes (table)	1-2	43 g a.s./ha	10	BBCH 85	3
cGAP EU (Art. 12, EFSA, 2020) – Grapes (wine)	1	54 g a.s./ha	-	BBCH 83	30
Intended cGAP (number* 2)	1	36 g a.s./ha	-	BBCH 83	Wine: 30 Table: 3

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

A total of 2 new studies, consisting of 8 new trials for grape are summarised in the following.

Study 1

Comments of zRMS:	Four independent field trials (two decline trials and two harvest trials) were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in raw agricultural commodity specimens of table or wine grapes (RAC berries) after one application of ADM.00900.I.1.C at 0.180 L/ha representing 36 g/ha of chlorantraniliprole. In order to support the use on wine grapes, the application was performed 30 (±2) days before harvest (Plot T1) and to support the use on table grapes, the application was performed 3 days before harvest (Plot T2). The analytical method for chlorantraniliprole was described and fully validated for grape (bunches, commodity with high acid content as berries) in another study (POLLENIZ/GIRPA study B20G-A4-C-01 – Sponsor reference 000105719) and a reduced validation was done during this study. The analytical method consisted in an extraction from homogenised laboratory samples of grape (berries) by maceration with acetonitrile / 1% formic acid mixture. Then extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Limit of quantification (LOQ) achieved was 0.010 mg/kg. No residue of chlorantraniliprole was found above LOQ (0.01 mg/kg) in untreated specimens. The mean recovery was between 70% and 110% at each level of fortification. **Results:** After one application in grape 30 (±2) days before harvest with ADM.00900.I.1.C at the rate of 0.180 L/ha, (representing 36 g/ha of chlorantraniliprole), the residues found in treated specimens (plot T1) are ranging: - from 0.038 to 0.069 mg/kg at 0 DAA - from 0.019 to 0.046 mg/kg at 7 DAA - from 0.015 to 0.029 mg/kg at 14 DAA - from 0.018 to 0.022 mg/kg at 21 DAA - from < LOQ to 0.034 mg/kg at 28 - 31 DAA (commercial harvest) After one application in grape 3 days before harvest with ADM.00900.I.1.C at the rate of 0.180 L/ha, (representing 36 g/ha of chlorantraniliprole), the residues found in treated specimens (plot T2) are ranging: - from 0.044 to 0.048 mg/kg at 0 DAA - 0.055 mg/kg at 1 DAA - from 0.014 to 0.095 mg/kg at 3 DAA (commercial harvest) - from 0.042 to 0.050 mg/kg at 5 DAA The storage duration (interval between sampling and analysis date) was 259 days for the determination of chlorantraniliprole. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCP 8.3/03
Report	Magnitude of the residues of chlorantraniliprole in table or wine grapes (RAC berries) and processed fractions, fol-lowing one application of ADM.00900.I.1.C in 4 trials (2 DCS and 2 HS with process). Northern Europe (France and Hungary) – 2020, Meric, D., 2022, Report No. DMC-20-43062 (Sponsor report No. 000105700)
Guideline(s):	SANCO/7029/VI/95 rev.5 OECD 509 (2009) ENV/JM/MONO(2011)50/REV1 OECD 508 SANTE/2020/12830, Rev.1

	ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

Summary of the study 1 trials

Reference:	Magnitude of the residues of chlorantraniliprole in table or wine grapes (RAC berries) and processed fractions, following one application of ADM.00900.I.1.C in 4 trials (2 DCS and 2 HS with process). Northern Europe (France and Hungary) – 2020, Meric, D., 2022, Report No. DMC-20-43062 (Sponsor report No. 000105700)		
GLP:	Yes	**Sample storage conditions:**	Maximum of 259 days between sampling and analysis Maximum of <1 day between extraction and analysis
Crop/crop group:	Grape	**Analytical method:**	Validated method - POLLENIZ/GIRPA study code: B20G-A4-C-01 - Sponsor reference: 000105719 POLLENIZ/GIRPA analytical phase code B20S-S2-C-13 (within this study) Multi-residue Method QuEChERS for the Determination of chlorantraniliprole
Indoor/Outdoor:	Outdoor	**Limit of Quantification (mg/kg):**	0.01 mg/kg
Formulation:	SC	**Limit of Detection (mg/kg):**	0.003 mg/kg
Content of active substance (g/kg or g/l):	200 g/L chlorantraniliprole	**Residues calculated as:**	chlorantraniliprole

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues [mg/kg]	PHI [days] (d)	Details on trial (e)
			[g a.s./ ha]	Water [L/ha]	[g a.s./hl				Chlorantraniliprole		
DMC-20-43062 FR01/ 41150 Onzain, Centre Val de Loire, N. France / N-EU / 2020	Wine grape / Gamay (red)	1- 1985 2- 01/06/2020 to 15/06/2020 3- 15/09/2020 to 16/09/2020	38	616	6	11/08/2020	BBCH 83	Berries	0.038 0.019 0.029 0.018 0.023	0 7 14 21 30(NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 177 days -extraction to analysis: <1 day
			38	614	6	07/09/2020	BBCH 85-89	Berries	0.048 0.055 0.036 0.050	0 1 3(NCH) 5	
DMC-20-43062 HU02 / 8691 Szölöskislak, Somogy county, Hungary / N-EU / 2020	Table grape / Moldova (red)	1- 2005 2- 02/06/2020 to 16/06/2020 3- 22/09/2020 to 01/10/2020	34	643	5	19/08/2020	BBCH 79	Berries	0.069 0.046 0.015 0.022 0.020	0 7 14 21 30(NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 169 days -extraction to analysis: <1 day
			40	747	5	15/09/2020	BBCH 85	Berries	0.044 0.055 0.059 0.042	0 1 3(NCH) 5	
DMC-20-43062 HU03 / 5465 Cserkeszőlő, Jász-Nagykun-Szolnok county, Hungary / N-EU / 2020	Wine grape / Kék Frankos (red)	1- 2008 2- 19/06/2020 to 03/07/2020 3- 15/09/2020	39	416	9	18/08/2020	BBCH 81	Berries	0.034	28(NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 245 days -extraction to analysis: <1 day
			38	409	9	12/09/2020	BBCH 89	Berries	0.095	3(NCH)	
DMC-20-43062 FR04 / 49700 Brossay, Centre Val de Loire, N. France / N-EU / 2020	Wine grape / Chenin (white)	1- 1980 2- 21/05/2020 to 02/06/2020 3- 04/09/2020	35	561	6	31/07/2020	BBCH 81	Berries	<0.01	31(NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 259 days -extraction to analysis: <1 day
			36	583	6	28/08/2020	BBCH 89	Berries	0.014	3(NCH)	

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Study 2

Comments of zRMS:	Four independent field trials (two decline trials and two harvest trials) were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in raw agricultural commodity specimens of table or wine grapes (RAC berries) after one application of ADM.00900.I.1.C at 0.180 L/ha representing 36 g/ha of chlorantraniliprole. In order to support the use on wine grapes, the application was performed 30 (±1) days before harvest (Plot T1) and to support the use on table grapes, the application was performed 3 days before harvest (Plot T2). The analytical method for chlorantraniliprole was fully validated on grape (bunches) (commodity with high acid content) in another study (GIRPA study B20G-A4-C-01 – Sponsor reference 000105719), according to SANTE/2020/12830, Rev.1 of 24/02/2021 and a reduced validation was done during this study. The analytical method consisted in an extraction from homogenised laboratory samples of grape (berries) by maceration with acetonitrile / 1% formic acid mixture. Then extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Limit of quantification (LOQ) achieved was 0.010 mg/kg. No residue of chlorantraniliprole was found above LOQ (0.01 mg/kg) in untreated specimens. The mean recovery was between 70% and 110% at each level of fortification. **Results:** After one application in grape 30 (±2) days before harvest with ADM.00900.I.1.C at the rate of 0.180 L/ha, (representing 36 g/ha of chlorantraniliprole), the residues found in treated specimens (plot T1) are ranging: - from 0.023 to 0.028 mg/kg at 0 DAA - from < LOQ to 0.017 mg/kg at 7 DAA - from < LOQ to 0.017 mg/kg at 14 DAA - < LOQ at 21 or 27 DAA - from < LOQ to 0.022 at 30 or 31 DAA (commercial harvest). After one application in grape 3 days before harvest with ADM.00900.I.1.C at the rate of 0.180 L/ha, (representing 36 g/ha of chlorantraniliprole), the residues found in treated specimens (plot T2) are ranging: - from 0.022 to 0.031 mg/kg at 0 DAA - from 0.021 to 0.028 mg/kg at 1 DAA - from 0.018 to 0.040 mg/kg at 3 DAA (commercial harvest) - from < LOQ to 0.019 mg/kg at 5 DAA. The storage duration (interval between sampling and analysis date) was 127 days for the determination of chlorantraniliprole. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCP 8.3/04
Report	Magnitude of the residues of chlorantraniliprole after application of ADM.00900.I.1.C in grapevine in Northern Europe – 2021, Meric, D., 2022, Report No. DMC-21-48215 (Sponsor report No. 000107722)
Guideline(s):	SANCO/7029/VI/95 rev.5 OECD 509 (2009) SANTE/2020/12830, Rev.1 ENV/JM/MONO(2007)17

Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

Summary of the study 2 trials

Reference:	Magnitude of the residues of chlorantraniliprole after application of ADM.00900.I.1.C in grapevine in Northern Europe – 2021, Meric, D., 2022, Re-port No. DMC-21-48215 (Sponsor report No. 000107722)		
GLP:	Yes	**Sample storage conditions:**	Maximum of 127 days between sampling and analysis Maximum of 1 day between extraction and analysis
Crop/crop group:	Grape	**Analytical method:**	Validated method - POLLENIZ/GIRPA study code: B20G-A4-C-01 - Sponsor reference: 000105719 POLLENIZ/GIRPA analytical phase code B21S-S2-C-05 (within this study) Multi-residue Method QuEChERS for the Determination of chlorantraniliprole
Indoor/Outdoor:	Outdoor	**Limit of Quantification (mg/kg):**	0.01 mg/kg
Formulation:	SC	**Limit of Detection (mg/kg):**	0.003 mg/kg
Content of active substance (g/kg or g/l):	200 g/L chlorantraniliprole	**Residues calculated as:**	chlorantraniliprole

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues [mg/kg]	PHI [days] (d)	Details on trial (e)
			[g a.s./ ha]	Water [L/ha]	[g a.s./hl				Chlorantraniliprole		
DMC-21-48215 HU02 / 8692 Szőlősgyörök, Somogy county, Hungary/ N-EU / 2021	Wine grape / Merlot (red)	1- 1990 2- 08/07/2021 to 22/07/2021 3- 17/09/2021 to 25/09/2021	35	460	8	17/08/2021	BBCH 81	Berries	0.023 <0.01 <0.01 <0.01 <u><0.01</u>	0 7 14 27 30(NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 127 days -extraction to analysis: 1 day
			38	490	8	13/09/2021	BBCH 87	Berries	0.031 0.021 <u>0.020</u> <0.01	0 1 3(NCH) 5	
DMC-21-48215 FR03 / 21700 Chaux, Bourgogne, N. France / N-EU / 2021	Wine grape / Pinot noir (red)	1- 1962 2- 16/06/2021 to 30/06/2021 3- 20/09/2021	38	517	7	18/08/2021	BBCH 83	Berries	<u>0.012</u>	30(NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 97 days -extraction to analysis: 1 day
			39	533	7	14/09/2021	BBCH 89	Berries	<u>0.039</u>	3(NCH)	
DMC-21-48215 AT04 / 3452 Atzenbrugg, Niederöstereich, Austria / N-EU / 2021	Wine grape / Grüner Veltliner (white)	1- 2000 2- 17/06/2021 to 27/06/2021 3- 25/09/2021	37	596	6	20/08/2021	BBCH 83	Berries	<u>0.022</u>	31(NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 94 days -extraction to analysis: 1 day
			36	588	6	17/09/2021	BBCH 89	Berries	<u>0.040</u>	3(NCH)	
DMC-21-48215 FR05 / 37380 Reugny, Centre Val de Loire, N. France / N-EU / 2021	Wine grape / Chenin (white)	1- 2006 2- 20/06/2021 to 30/06/2021 3- 28/09/2021 to 09/10/2021	37	498	7	07/09/2021	BBCH 83	Berries	0.028 0.017 0.017 <0.01 <u><0.01</u>	0 7 14 21 30(NCH)	Untreated specimens <LOQ Max. Storage: -sampling to analysis: 107 days -extraction to analysis: 1 day
			37	507	7	04/10/2021	BBCH 89	Berries	0.022 0.028 0.018 <u>0.019</u>	0 1 3(NCH) 5	

(a) According to CODEX Classification / Guide
(b) Only if relevant

(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.3.3 Potato

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 (Ireland, 2008 EFSA, 2013a)	1-2	12 g a.s./ha	10-14	BBCH 60	14
cGAP EU (Art. 12, EFSA, 2020)	2	12 g a.s./ha	14 (SEU)	BBCH 69 (NEU) BBCH 89 (SEU)	14
Intended cGAP (number* 7, 8)	2	12 g a.s./ha	7	BBCH 60	14

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

A total of 1 new study, consisting of 4 NEU new trials for potato are summarised in the following.

Study 1

Comments of zRMS:	Four independent field trials (two decline trials and two harvest trials) were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in raw agricultural commodity specimens of potatoes (RAC tubers) after two applications of ADM.00900.I.1.C at 0.06 L/ha representing 12 g/ha of chlorantraniliprole per application. Two plots were established in the trial site: U plot was left untreated while T plot was treated twice at 0.06 L/ha (12 g/ha of chlorantraniliprole per application) of ADM.00900.I.1.C. The interval between the 2 applications was 7 days and the last application was done 14 (± 1) days before commercial harvest. Tubers were collected at the commercial harvest (13 or 14 days after the last application) on the harvest trials. On the decline curve trials, specimens of tubers were collected just before the application, at 0, 3, 7, 13 or 14 (harvest) and 20 or 21 days after the last application. The analytical method for chlorantraniliprole was fully validated in another study on peach (whole fruits without stones) which is a commodity with high water content as potato (POLLENIZ/GIRPA study B20G-A4-C-01 – Sponsor reference 000105719), according to SANTE/2020/12830, Rev.1 of 24/02/2021 and a reduced validation was done during this study. The analytical method consisted in an extraction from homogenised laboratory samples of potatoes (tubers) by maceration with acetonitrile / 1% formic acid mixture. Then extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Limit of quantification (LOQ) achieved was 0.010 mg/kg. No residue of chlorantraniliprole was found above LOQ (0.01 mg/kg) in untreated specimens. The mean recovery was between 70% and 110% at each level of fortification. **Results:** After two applications, with a 7 day interval, with ADM.00900.I.1.C at the rate of 0.06 L/ha, (representing 12 g/ha of chlorantraniliprole at each application), the residues found in treated potatoes tubers were all below LOQ from 0 day to 21 days after the last application. The storage duration (interval between sampling and analysis date) was 209 days for the determination of chlorantraniliprole. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCP 8.3/05
Report	Magnitude of the residues of chlorantraniliprole in potatoes (RAC tubers) following two applications of ADM.00900.I.1.C in 4 trials (2 DCS + 2 HS). Northern Europe (Northern France, Poland and Hungary) – 2020, MERIC, D., 2021, Report No. DMC-20-43066 (Sponsor report No. 000105704)
Guideline(s):	Yes SANCO/7029/VI/95 rev.5 OECD 509 (2009) SANTE/2020/12830, Rev.1 ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

Summary of the study 1 trials

Reference:	Magnitude of the residues of chlorantraniliprole in potatoes (RAC tubers) follow-ing two applications of ADM.00900.I.1.C in 4 trials (2 DCS + 2 HS). Northern Europe (Northern France, Poland and Hungary) – 2020, MERIC, D., 2021, Re-port No. DMC-20-43066 (Sponsor report No. 000105704)		
GLP:	Yes	**Sample storage conditions:**	Maximum of 208 days between sampling and analysis Maximum of 24h between extraction and analysis
Crop/crop group:	potato	**Analytical method:**	Validated method - POLLENIZ/GIRPA study code: B20G-A4-C-01 - Sponsor reference: 000105719 POLLENIZ/GIRPA analytical phase code B20G-S2-C-26 (within this study) – Sponsor reference: 000104713 Reduced validation done within this study Multi-residue Method QuEChERS for the Determination of chlorantraniliprole
Indoor/Outdoor:	Outdoor	**Limit of Quantification (mg/kg):**	0.01 mg/kg
Formulation:	SC	**Limit of Detection (mg/kg):**	0.003 mg/kg
Content of active substance (g/kg or g/l):	200 g/L chlorantraniliprole	**Residues calculated as:**	chlorantraniliprole

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues [mg/kg]	PHI [days] (d)	Details on trial (e)
			[g a.s./ ha]	Water [L/ha]	[g a.s./hl				Chlorantraniliprole		
DMC-20-43066 FR01 / France (N. France) Hauts de France 62860 Inchy en Artois / N-EU / 2020	Potato Fontane	1- 23/04/2020 2- 01/07/2020 to 20/07/2020 3- 31/08/2020	12 12	493 467	2 3	11/08/2020 18/08/2020	47-48/93 48/95	Tubers Tubers Tubers Tubers Tubers	<0.01 <0.01 <0.01 <0.01 <0.01	0 3 7 13 (NCH) 20	Untreated specimens <LOD Max. Storage: -sampling to analysis: 191 days -extraction to analysis: <1 day
DMC-20-43066 PL02 / Poland Mazowiekie 96-317 Nowy Oryszew / N-EU / 2020	Potato Irga	1- 26/04/2020 2- 30/05/2020 to 15/06/2020 3- 10/09/2020	12 12	503 500	2 2	24/07/2020 31/07/2020	47 48	Tubers Tubers Tubers Tubers Tubers	<0.01 <0.01 <0.01 <0.01 <0.01	0 3 7 14 (NCH) 21	Untreated specimens <LOD Max. Storage: -sampling to analysis: 208 days -extraction to analysis: <1 day
DMC-20-43066 PL03 / Poland Wielkopolska 63-220 Slawoszew / N-EU / 2020	Potato Lilly	1- 14/04 /2020 2- 27/06/2020 to 08/07/2020 3- 19/08/2020	13 12	513 507	3 2	30/07/2020 06/08/2020	47 48	Tubers	<u><0.01</u>	13 (NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 190 days -extraction to analysis: <1 day
DMC-20-43066 HU04 / Hungary Veszprém 8317 Lesencefalu / N-EU / 2020	Potato White Lady	1- 26/04/2020 2- 13/05/2020 to 17/06/2020 3-30/07/2020	13 13	417 423	3 3	09/07/2020 16/07/2020	41 43	Tubers	<u><0.01</u>	14 (NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 209 days -extraction to analysis: <1 day

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.3.4 Broccoli and cauliflower

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 (Ireland, 2008 EFSA, 2013a)	Use not assessed				
cGAP EU (Art. 12, EFSA, 2020)	1-2	35 g a.s./ha	7	BBCH 89	1
Intended cGAP (number* 1)	1	28 g a.s./ha	-	BBCH 49	3

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

A total of 2 new studies, consisting of 4 new trials for broccoli are summarised in the following. A total of 2 new studies, consisting of 4 new trials for cauliflower are summarised in the following

Broccoli

Study 1

Comments of zRMS:	Two independent field trials (one decline trial and one harvest trial) were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in raw agricultural commodity specimens of broccoli (RAC flower heads and stems) after one application of ADM.00900.I.1.C at 0.150 L/ha representing 30 g/ha of chlorantraniliprole. Broccoli flower heads and stems were collected at the commercial harvest (3 days after the application) on the harvest trial. On the decline curve trial, specimens of flower heads and stems were collected just before the application, at 0, 1, 3 (harvest) and 5 days after the application. The analytical method for chlorantraniliprole was described and fully validated in another study on peach, commodity with high water content as broccoli (flower heads and stems) (POLLENIZ/GIRPA study B20G-A4-C-01 – Sponsor reference 000105719), according to SANTE/2020/12830, Rev.1 of 24/02/2021 and a reduced validation was done during this study. The analytical method consisted in an extraction from homogenised laboratory samples of broccoli (flower heads and stems) by maceration with acetonitrile / 1% formic acid mixture. Then extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Limit of quantification (LOQ) achieved was 0.010 mg/kg. No residue of chlorantraniliprole was found above LOQ (0.01 mg/kg) in untreated specimens. The mean recovery was between 70% and 110% at each level of fortification. **Results:** After one application with ADM.00900.I.1.C (plot T) at the rate of 0.150 L/ha, representing 30 g/ha of chlorantraniliprole at application, residues of chlorantraniliprole in flower heads and stems were or ranged as follows: - 0.073 mg/kg at 0 day after the application, - 0.055 mg/kg at 1 day after the application, - between 0.024 and 0.042 mg/kg at 3 days after the application - 0.027 mg/kg at 5 days after the application. The storage duration (interval between sampling and analysis date) was 157 days for the determination of chlorantraniliprole. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCP 8.3/06
Report	Magnitude of the residues of chlorantraniliprole in broccoli (RAC flower heads and stems) following one application of ADM.00900.I.1.C in 2 trials (1 DCS + 1 HS). Northern Europe (Poland and Northern France) – 2020, MERIC, D., 2021, Report No. DMC-20-43078 (Sponsor report No. 000105715)
Guideline(s):	Yes SANCO/7029/VI/95 rev.5 OECD 509 (2009) SANTE/2020/12830, Rev.1 ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

Summary of the study 1 trials

Reference: Magnitude of the residues of chlorantraniliprole in broccoli (RAC flower heads and stems) following one application of ADM.00900.I.1.C in 2 trials (1 DCS + 1 HS). Northern Europe (Poland and Northern France) – 2020, MERIC, D., 2021, Report No. DMC-20-43078 (Sponsor report No. 000105715)

GLP: Yes

Crop/crop group: Broccoli

Indoor/Outdoor: Outdoor

Formulation: SC

Content of active substance (g/kg or g/l): 200 g/L chlorantraniliprole

Sample storage conditions: Maximum of 157 days between sampling and analysis
Maximum of 24h between extraction and analysis

Analytical method: Validated method - POLLENIZ/GIRPA study code: B20G-A4-C-01 - Sponsor reference: 000105719
POLLENIZ/GIRPA analytical phase code B20G-S2-C-26 (within this study) – Sponsor reference: 000104713
Reduced validation done within this study (flower heads and stems).
Multi-residue Method QuEChERS for the Determination of chlorantraniliprole

Limit of Quantification (mg/kg): 0.01 mg/kg

Limit of Detection (mg/kg): 0.003 mg/kg

Residues calculated as: chlorantraniliprole

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues [mg/kg]	PHI [days] (d)	Details on trial (e)
			[g a.s./ ha]	Water [L/ha]	[g a.s./hl				Chlorantraniliprole		
DMC-20-43078 PL01 / Poland Lubelskie 21-210 Kostry / N-EU / 2020	Broccoli Parthenon	1- 10/07/2020 2- NAP 3- 26/09/2020	31	500	6	22/09/2020	49	Flower heads and stems Flower heads and stems Flower heads and stems Flower heads and stems	0.073 0.055 0.042 0.027	0 1 3 (NCH) 5	Untreated specimens <LOD Max. Storage: -sampling to analysis: 157 days -extraction to analysis: 0 day
DMC-20-43078 FR02 / France (N. France) Hauts de France 62860 Inchy en Artois / N-EU / 2020	Broccoli Besty	1- 16/072020 2- NAP 3- 24/09/2020	31	500	6	21/09/2020	46	Flower heads and stems	0.024	3 (NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 157 days -extraction to analysis: 0 day

(a) According to CODEX Classification / Guide
(b) Only if relevant

(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Study 2

Comments of zRMS:	Two independent field trials (one decline trial and one harvest trial) were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in raw agricultural commodity specimens of broccoli (RAC flower heads and stems) after one application of ADM.00900.I.1.C at 0.150 L/ha representing 30 g/ha of chlorantraniliprole. Flower heads and stems specimens were collected 3 days after the application on the harvest trial and at 0, 1, 3 (commercial harvest) and 5 days after the application on the decline curve trial. The analytical method for chlorantraniliprole was described and fully validated in another study on peach, commodity with high water content as broccoli (flower heads and stems) (POLLENIZ/GIRPA study B20G-A4-C-01 – Sponsor reference 000105719), according to SANTE/2020/12830, Rev.1 of 24/02/2021 and a reduced validation was done during this study. The analytical method consisted in an extraction from homogenised laboratory samples of broccoli (flower heads and stems) by maceration with acetonitrile / 1% formic acid mixture. Then extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Limit of quantification (LOQ) achieved was 0.010 mg/kg. No residue of chlorantraniliprole was found above LOQ (0.01 mg/kg) in untreated specimens. The mean recovery was between 70% and 110% at each level of fortification. **Results:** After one application with ADM.00900.I.1.C (plot T) at the rate of 0.150 L/ha, representing 30 g/ha of chlorantraniliprole at application, residues of chlorantraniliprole in flower heads and stems were or ranged as follows: - 0.071 mg/kg at 0 day after the application, - 0.99 mg/kg at 1 day after the application, - between 0.044 and 0.063 mg/kg at 3 days after the application - 0.058 mg/kg at 5 days after the application. The storage duration (interval between sampling and analysis date) was 133 days for the determination of chlorantraniliprole. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCP 8.3/07
Report	Magnitude of the residues of chlorantraniliprole after application of ADM.00900.I.1.C in broccoli in Northern Europe – 2021, MERIC, D., 2022, Report No. DMC-21-48554 (Sponsor report No. 000107736)
Guideline(s):	Yes SANCO/7029/VI/95 rev.5 OECD 509 (2009) SANTE/2020/12830, Rev.1 ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

Summary of the study 2 trials

Reference: Magnitude of the residues of chlorantraniliprole after application of ADM.00900.I.1.C in broccoli in Northern Europe – 2021, MERIC, D., 2022, Re-port No. DMC-21-48554 (Sponsor report No. 000107736)

GLP: Yes

Sample storage conditions: Maximum of 133 days between sampling and analysis
Maximum of 3 days between extraction and analysis

Crop/crop group: Broccoli

Analytical method: Validated method - POLLENIZ/GIRPA study code: B20G-A4-C-01 - Sponsor reference: 000105719
POLLENIZ/GIRPA analytical phase code B21S-S2-C-18 (within this study)
Reduced validation done within this study (flower heads and stems).
Multi-residue Method QuEChERS for the Determination of chlorantraniliprole

Indoor/Outdoor: Outdoor

Limit of Quantification (mg/kg): 0.01 mg/kg

Formulation: SC

Limit of Detection (mg/kg): 0.003 mg/kg

Content of active substance (g/kg or g/l): 200 g/L chlorantraniliprole

Residues calculated as: chlorantraniliprole

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues [mg/kg]	PHI [days] (d)	Details on trial (e)
			[g a.s./ ha]	Water [L/ha]	[g a.s./hl				Chlorantraniliprole		
DMC-21-48554 HU01 / Hungary Békés county 5900 Orosháza / N-EU / 2021	Broccoli Fiesta F1	1- 21/07/2021 2- NAP 3-16/12/2021	30	393	8	10/12/2021	49	Flower heads and stems Flower heads and stems Flower heads and stems Flower heads and stems	0.071 0.099 0.063 0.058	0 1 3 (NCH) 5	Untreated specimens <LOD Max. Storage: -sampling to analysis: 67 days -extraction to analysis: 1 day
DMC-21-48554 FR02 / France (N. France) Hauts de France 62232 Hinges N-EU / 2021	Broccoli Ironman	1-08/07/2021 2- NAP 3-27/09/2021	31	510	6	24/09/2021	48	Flower heads and stems	0.044	3 (NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 133 days -extraction to analysis: 3 days

(a) According to CODEX Classification / Guide
(b) Only if relevant

(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Cauliflower

Study 3

Comments of zRMS:	Two independent field trials (one decline trial and one harvest trial) were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in raw agricultural commodity specimens of cauliflower (RAC inflorescences) after one application of ADM.00900.I.1.C at 0.15 L/ha representing 30 g/ha of chlorantraniliprole. Inflorescences of cauliflower were collected 3 days after the application on the harvest trial and at 0, 1, 3 (commercial harvest) and 5 days after the application on the decline curve trial. The analytical method for chlorantraniliprole was described and fully validated in another study on peach, commodity with high water content as cauliflower (POLLENIZ/GIRPA study B20G-A4-C-01 – Sponsor reference 000105719), according to SANTE/2020/12830, Rev.1 of 24/02/2021 and a reduced validation was done during this study. The analytical method consisted in an extraction by maceration with acetonitrile/1% formic acid mixture. Then extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Limit of quantification (LOQ) achieved was 0.010 mg/kg. No residue of chlorantraniliprole was found above LOQ (0.01 mg/kg) in untreated specimens. The mean recovery was between 70% and 110% at each level of fortification. **Results:** After a single application of ADM.00900.I.1.C at the rate of 0.150 L/ha, representing 30 g/ha of chlorantraniliprole, the residues found in treated Cauliflower at commercial harvest, 3 days after application, were found to be below LOQ and 0.012 mg/kg. In the decline curve study trial, residues decreased from 0.032 mg/kg (at 0 DALA) to below LOQ. The storage duration (interval between sampling and analysis date) was 304 days for the determination of chlorantraniliprole. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCP 8.3/08
Report	Magnitude of the residues of chlorantraniliprole in cauliflowers (RAC inflorescences) following one application of ADM.00900.I.1.C in 2 trials (1 DCS + 1 HS). Northern Europe (Poland and Hungary)– 2020., Delmotte, R., 2021, Report No. RDE-20-43076 (Sponsor report No. 000105713)
Guideline(s):	Yes SANCO/7029/VI/95 rev.5 OECD 509 (2009) SANTE/2020/12830, Rev.1 ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

Summary of the study 3 trials

Reference: Magnitude of the residues of chlorantraniliprole in cauliflowers (RAC inflorescences) following one application of ADM.00900.I.1.C in 2 trials (1 DCS + 1 HS). Northern Europe (Poland and Hungary)– 2020., Delmotte, R., 2021, Report No. RDE-20-43076 (Sponsor report No. 000105713)

GLP: Yes

Crop/crop group: Cauliflower

Indoor/Outdoor: Outdoor

Formulation: SC

Content of active substance (g/kg or g/l): 200 g/L chlorantraniliprole

Sample storage conditions: Maximum of 304 days between sampling and analysis
Maximum of 4 days between extraction and analysis

Analytical method: Validated method - POLLENIZ/GIRPA study code: B20G-A4-C-01 - Sponsor reference: 000105719
POLLENIZ/GIRPA analytical phase code B20G-S2-C-26 (within this study) – Sponsor reference: 000104713
Multi-residue Method QuEChERS for the Determination of chlorantraniliprole

Limit of Quantification (mg/kg): 0.01 mg/kg

Limit of Detection (mg/kg): 0.003 mg/kg

Residues calculated as: chlorantraniliprole

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues [mg/kg]	PHI [days] (d)	Details on trial (e)
			[g a.s./ ha]	Water [L/ha]	[g a.s./hl				Chlorantraniliprole		
RDE-20-43076 PL01 / 21-200 Parczew, Lubelskie, Poland / N-EU / 2020	Cauliflower / Fargo	1- 22/05/2020 2- N/A 3- 22/08/2020	31	497	6	17/08/2020	BBCH 48	Inflorescence Inflorescence Inflorescence Inflorescence	0.032 0.018 <u>0.012</u> <0.01	0 1 3(NCH) 5	Untreated specimens <LOD Max. Storage: -sampling to analysis: 249 days -extraction to analysis: 4 days
RDE-20-43076 HU02 / 6135 Csólyospálos, Bács-Kiskun, Hungary / N-EU / 2020	Cauliflower / Chambord	1- 04/04/2020 2- N/A 3- 23/06/2020	30	384	8	20/06/2020	BBCH 48	Inflorescence	<u><0.01</u>	3(NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 304 days -extraction to analysis: 4 days

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Study 4

Comments of zRMS:	Two independent field trials (one decline trial and one harvest trial) were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in raw agricultural commodity specimens of cauliflower (RAC inflorescences) after one application of ADM.00900.I.1.C at 0.15 L/ha representing 30 g/ha of chlorantraniliprole. Inflorescences of cauliflower were collected 3 days after the application on the harvest trial and at 0, 1, 3 (commercial harvest) and 5 days after the application on the decline curve trial. The analytical method for chlorantraniliprole was described and fully validated in another study on peach, commodity with high water content as cauliflower (POLLENIZ/GIRPA study B20G-A4-C-01 – Sponsor reference 000105719), according to SANTE/2020/12830, Rev.1 of 24/02/2021 and a reduced validation was done during this study. The analytical method consisted in an extraction by maceration with acetonitrile/1% formic acid mixture. Then extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Limit of quantification (LOQ) achieved was 0.010 mg/kg. No residue of chlorantraniliprole was found above LOQ (0.01 mg/kg) in untreated specimens. The mean recovery was between 70% and 110% at each level of fortification. **Results:** After a single application of ADM.00900.I.1.C at the rate of 0.150 L/ha, representing 30 g/ha of chlorantraniliprole, the residues found in treated Cauliflower at commercial harvest, 3 days after application, were found to be below LOQ. In the decline curve study trial, residues decreased from 0.025 mg/kg (at 0 DALA) to below LOQ. The storage duration (interval between sampling and analysis date) was 114 days for the determination of chlorantraniliprole. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCP 8.3/09
Report	Magnitude of the residues of chlorantraniliprole after application of ADM.00900.I.1.C in cauliflower in Northern Europe – 2021., Domingo, S., 2022, Report No. SDO-21-48552 (Sponsor report No. 000107733)
Guideline(s):	SANCO/7029/VI/95 rev.5 OECD 509 (2009) SANTE/2020/12830, Rev.1 ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

Summary of the study 4 trials

Reference: Magnitude of the residues of chlorantraniliprole after application of ADM.00900.I.1.C in cauliflower in Northern Europe – 2021., Domingo, S., 2022, Report No. SDO-21-48552 (Sponsor report No. 000107733)

GLP: Yes

Crop/crop group: Cauliflower

Indoor/Outdoor: Outdoor

Formulation: SC

Content of active substance (g/kg or g/l): 200 g/L chlorantraniliprole

Sample storage conditions: Maximum of 122 days between sampling and analysis
Maximum of 8 days between extraction and analysis

Analytical method: Validated method - POLLENIZ/GIRPA study code: B20G-A4-C-01 - Sponsor reference: 000105719
POLLENIZ/GIRPA analytical phase code B20G-S2-C-26 (STPAHYT study number: RDE-20-43076 – Sponsor reference: 000104713
Multi-residue Method QuEChERS for the Determination of chlorantraniliprole

Limit of Quantification (mg/kg): 0.01 mg/kg

Limit of Detection (mg/kg): 0.003 mg/kg

Residues calculated as: chlorantraniliprole

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues [mg/kg]	PHI [days] (d)	Details on trial (e)
			[g a.s./ ha]	Water [L/ha]	[g a.s./hl				Chlorantraniliprole		
SDO-21-48552 PL01 / 89-200 Szubin, Kujawskopomorskie, Poland / N-EU / 2021	Cauliflower / Adelanto RZ F1	1- 10/07/2021 2- NAP 3- 02/10/2021	30	580	5	27/09/2021	BBCH 48	Inflorescence	0.025 <0.01 <u><0.01</u> <0.01	0 1 3(NCH) 5	Untreated specimens <LOD Max. Storage: -sampling to analysis: 108 days -extraction to analysis: 8 days
SDO-21-48552 FR02 / 62232 Hinges, Hauts de France, N. France / N-EU / 2020	Cauliflower / Guideline	1- 03/06/2021 2- NAP 3- 08/09/2021	30	486	6	10/09/2021	BBCH 47	Inflorescence	<u><0.01</u> (<LOD)	3(NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 122 days -extraction to analysis: 8 days

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.3.5 Head cabbage

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 (Ireland, 2008 EFSA, 2013a)	Use not assessed				
cGAP EU (Art. 12, EFSA, 2020)	1-2	35 g a.s./ha	7	BBCH 89	1
Intended cGAP (number* 1)	1	28 g a.s./ha	-	BBCH 49	3

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

A total of 2 new studies, consisting of 8 new trials for head cabbage are summarised in the following.

Study 1

Comments of zRMS:	Four independent field trials (two decline trials and two harvest trials) were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in head cabbages after one application of ADM.00900.I.1.C at 0.15 L/ha representing 30 g/ha of chlorantraniliprole. Heads were collected 3 days after the application on the harvest trial and at 0, 1, 3 (commercial harvest) and 5 days after the application on the decline curve trial. The analytical method for chlorantraniliprole was described and fully validated in another study on peach, commodity with high water content as head cabbages (POLLENIZ/GIRPA study B20G-A4-C-01 – Sponsor reference 000105719), according to SANTE/2020/12830, Rev.1 of 24/02/2021 and a reduced validation was done during this study. The analytical method consisted in an extraction by maceration with acetonitrile/1% formic acid mixture. Then extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Limit of quantification (LOQ) achieved was 0.010 mg/kg. No residue of chlorantraniliprole was found above LOQ (0.01 mg/kg) in untreated specimens. The mean recovery was between 70% and 110% at each level of fortification. **Results:** After one application, 3 days before harvest, with ADM.00900.I.1.C at the rate of 0.150 L/ha, (representing 30 g/ha of chlorantraniliprole), the residues found in treated head cabbages were: - below LOD to below LOQ at 0 day after the application, - below LOD to below LOQ at 1 day after the application, - below LOD to below LOQ at 3 days after the application (commercial harvest) - below LOD 5 days after the application. The storage duration (interval between sampling and analysis date) was 291 days for the determination of chlorantraniliprole. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCP 8.3/10
Report	Magnitude of the residues of chlorantraniliprole in head cabbages (RAC heads) following one application of ADM.00900.I.1.C in 4 trials (2 DCS + 2 HS). Northern Europe (Poland, Hungary, Northern France) – 2020, MERIC, D, 2021, study report n° DMC-20-43074 (Sponsor report No. 000105711)

Guideline(s):	SANCO/7029/VI/95 rev.5 OECD 509 (2009) SANTE/2020/12830, Rev.1 ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

Summary of the study 1 trials

Reference: Magnitude of the residues of chlorantraniliprole in head cabbages (RAC heads) following one application of ADM.00900.I.1.C in 4 trials (2 DCS + 2 HS). Northern Europe (Poland, Hungary, Northern France) – 2020, MERIC, D, 2021, study report n° DMC-20-43074 (Sponsor report No. 000105711)

GLP: Yes

Crop/crop group: Head cabbage

Indoor/Outdoor: Outdoor

Formulation: SC

Content of active substance (g/kg or g/l): 200 g/L chlorantraniliprole

Sample storage conditions: Maximum of 291 days between sampling and analysis
Maximum of 24h between extraction and analysis

Analytical method: Validated method - POLLENIZ/GIRPA study code: B20G-A4-C-01 - Sponsor reference: 000105719
Reduced validation done within this study.
Multi-residue Method QuEChERS for the Determination of chlorantraniliprole

Limit of Quantification (mg/kg): 0.01 mg/kg

Limit of Detection (mg/kg): 0.003 mg/kg

Residues calculated as: chlorantraniliprole

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues [mg/kg]	PHI [days] (d)	Details on trial (e)
			[g a.s./ ha]	Water [L/ha]	[g a.s./hl				Chlorantraniliprole		
DMC-20-43074 PL01 / Poland, Wielkopolska, 62-100 Rgielsko / N-EU / 2020	White head cabbage Kamienna glowa	1- 04/05/2020 2- NAP 3- 22/10/2020 to 30/10/2020	30	489	6	19/10/2020	49	Heads Heads Heads Heads	<0.01 <0.01 <u><0.01</u> <0.01	0 1 3 (NCH) 5	Untreated specimens <LOD Max. Storage: -sampling to analysis: 179 days -extraction to analysis: 0 day
DMC-20-43074 HU02 / Hungary, Csongrád, Csanád county, 6135 Csolyóspálos / N-EU / 2020	White head cabbage Bronco	1- 04/04/2020 2- NAP 3- 02/07/2020	31	394	8	29/06/2020	47	Heads Heads Heads Heads	<0.01 <0.01 <u><0.01</u> <0.01	0 1 3 (NCH) 5	Untreated specimens <LOD Max. Storage: -sampling to analysis: 291 days -extraction to analysis: 0 day
DMC-20-43074 FR03 / France (N. France) Grand-Est 08190 Sault Saint Rémy / N-EU / 2020	White head cabbage Casitor	1- 28/05/2020 2- NAP 3- 16/11/2020	32	520	6	13/11/2020	49	Heads	<u><0.01</u>	3 (NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 151 days -extraction to analysis: 0 day

DMC-20-43074 PL04 / Poland Łódźkie 99-440 Łaźniki / N-EU / 2020	White head cabbage Kamienna głowa	1- 10/07/2020 2- NAP 3-24/10/2020	32	510	6	20/10/2020	49	Heads	<u><0.01</u>	3 (NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 175 days -extraction to analysis: 0 day

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Study 2

Comments of zRMS:	Four independent field trials (two decline trials and two harvest trials) were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in head cabbages after one application of ADM.00900.I.1.C at 0.15 L/ha representing 30 g/ha of chlorantraniliprole. Heads were collected 3 days after the application on the harvest trial and at 0, 1, 3 (commercial harvest) and 5 days after the application on the decline curve trial. The analytical method for chlorantraniliprole was described and fully validated in another study on peach, commodity with high water content as head cabbages (POLLENIZ/GIRPA study B20G-A4-C-01 – Sponsor reference 000105719), according to SANTE/2020/12830, Rev.1 of 24/02/2021 and a reduced validation was done during this study. The analytical method consisted in an extraction by maceration with acetonitrile/1% formic acid mixture. Then extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Limit of quantification (LOQ) achieved was 0.010 mg/kg. No residue of chlorantraniliprole was found above LOQ (0.01 mg/kg) in untreated specimens. The mean recovery was between 70% and 110% at each level of fortification. **Results:** After one application, 3 days before harvest, with ADM.00900.I.1.C at the rate of 0.150 L/ha, (representing 30 g/ha of chlorantraniliprole), the residues found in treated head cabbages were: - below LOQ at 0 day after the application, - below LOD at 1 day after the application, - below LOD to 0.074 mg/kg at 3 days after the application (commercial harvest) - below LOD 5 days after the application. The storage duration (interval between sampling and analysis date) was 104 days for the determination of chlorantraniliprole. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCP 8.3/11
Report	Magnitude of the residues of chlorantraniliprole after application of ADM.00900.I.1.C in head cabbages in Northern Europe – 2021, MERIC, D, 2022, study report n° DMC-21-48550 (Sponsor report No. 000107731)
Guideline(s):	SANCO/7029/VI/95 rev.5 OECD 509 (2009) SANTE/2020/12830, Rev.1 ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

Summary of the study 2 trials

Reference: Magnitude of the residues of chlorantraniliprole after application of ADM.00900.I.1.C in head cabbag-es in Northern Europe – 2021, MERIC, D, 2022, study report n° DMC-21-48550 (Sponsor report No. 000107731)

GLP: Yes

Crop/crop group: Head cabbage

Indoor/Outdoor: Outdoor

Formulation: SC

Content of active substance (g/kg or g/l): 200 g/L chlorantraniliprole

Sample storage conditions: Maximum of 104 days between sampling and analysis
Maximum of 7 days between extraction and analysis

Analytical method: Validated method - POLLENIZ/GIRPA study code: B20G-A4-C-01 - Sponsor reference: 000105719
Reduced validation within this study (Analytical phase B21S-S2-C-14).
Multi-residue Method QuEChERS for the Determination of chlorantraniliprole

Limit of Quantification (mg/kg): 0.01 mg/kg

Limit of Detection (mg/kg): 0.003 mg/kg

Residues calculated as: chlorantraniliprole

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues [mg/kg]	PHI [days] (d)	Details on trial (e)
			[g a.s./ ha]	Water [L/ha]	[g a.s./hl				Chlorantraniliprole		
DMC-21-48550 PL01 / 99-335 Gozdków, Łódzkie, Poland / N-EU / 2021	White head Cabbage / Galaxy	1-26/06/2021 2- NAP 3-20/10/2021	29	475	6	15/10/2021	49	Head	<0.01 <0.01 (<LOD) <u>≤0.01</u> (<LOD) <0.01 (<LOD)	0 1 3 (NCH) 5	Untreated specimens <LOD Max. Storage: -sampling to analysis: 90 days -extraction to analysis: 7 days
DMC-21-48550 HU02 / 6060 Tiszakécske, Bács-Kiskun county, Hungary / N-EU / 2021	White head Cabbage / Busoni	1-10/07/2021 2- NAP 3-08/11/2021	32	417	8	03/11/2021	49	Heads	<0.01 <0.01 (<LOD) <u>≤0.01</u> (<LOD) <0.01 (<LOD)	0 1 3 (NCH) 5	Untreated specimens <LOD Max. Storage: -sampling to analysis: 71 days -extraction to analysis: 7 days
DMC-21-48550 FR03 / 62232 Hinges, Hauts de France, N.France / N-EU / 2021	Savoy Cabbage / Nebraska	1-13/06/2021 2- NAP 3-28/10/2021	30	493	6	25/10/2021	48	Heads	<u>0.037</u>	3 (NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 77 days -extraction to analysis: 7 days

DMC-21-48550 DE04 / 97990 Weikersheim-Elpersheim, Baden-Württemberg, Germany / N-EU / 2021	White head Cabbage / Toughma	1-22/06/2021 2- NAP 3-01/10/2021	31	513	6	28/09/2021	49	Heads	0.074	3 (NCH)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 104 days -extraction to analysis: 7 days

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.3.6 Maize

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 (Ireland, 2008 EFSA, 2013a)	Use not assessed				
cGAP EU (Art. 12, EFSA, 2020) – Maize (grain)	1-2	30 g a.s./ha	10	BBCH 87	7
cGAP EU (Art. 12, EFSA, 2020) – Maize (for forage)	2	25 g a.s./ha	10	BBCH 77	n.a.
Intended cGAP maize (grain and silage) (number* 3, 4)	1	28 g a.s./ha	-	BBCH 87	14

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

A total of 2 new studies, consisting of 8 new trials for maize are summarized in the following.

Study 1

Comments of zRMS:	Four independent field trials (two decline trials and two harvest trials) were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in raw agricultural commodity specimens of maize (RAC sweet corn (cob), whole plant (silage), stover and grain) after one application of ADM.00900.I.1.C at 0.15 L/ha representing 30 g/ha of chlorantraniliprole. Four plots were established in the trial site: U plot was left untreated while T1, T2 and T3 plot were treated once at 0.15 L/ha (30 g/ha of chlorantraniliprole) of ADM.00900.I.1.C. T1 plot was treated 7 days before BBCH 73, T2 14 (±1) days before BBCH 83 and plot T3 was treated 14 (±1) days before BBCH 89, except on trial FR01, where application on plot T2 was done at BBCH 85. On plots T1 and U, sweet corns cobs were collected 6-7 days after application on plot T1. On plots T2 and U, whole plants were collected 13-14 days after application on plot T2. On plots T3 and U, grain and stover were collected 13-15 days after the application on plot T3. The analytical method for chlorantraniliprole was fully validated in another study (POLLENIZ/GIRPA study B20G-A4-C-01 – Sponsor reference 000105719) for the dry commodity with high starch content matrix, wheat (grain) according to SANTE/2020/12830, Rev.1 of 24/02/2021. A reduced validation in maize grain was carried out in this study. The analytical method for the maize (sweet corn, whole plant and stover) was fully validated within this study. The analytical method consisted in an extraction by maceration with acetonitrile/1% formic acid mixture and addition of water according to natural water content. Then extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Limit of quantification (LOQ) achieved was 0.01 mg/kg. No residue of chlorantraniliprole was found above LOQ (0.01 mg/kg) in untreated specimens. The mean recovery was between 70% and 110% at each level of fortification. **Results:** After a single application with ADM.00900.I.1.C at the rate of 0.150 L/ha, representing 30 g/ha of chlorantraniliprole, the residues found in treated maize were: . - Sweet corn (cob) (6-7 days after application): <LOD to 0.023 mg/kg - Whole plants (13 – 14 days after application): 0.058 to 0.34 mg/kg - Grain (13-15 days after application): <LOD - Stover (13–15 days after application): 0.32 to 0.64 mg/kg The storage duration (interval between sampling and analysis date) was 169 days for the determination of chlorantraniliprole. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCP 8.3/12
Report	Magnitude of the residues of chlorantraniliprole in Maize (RAC sweet corns (cob), whole plants (silage), stover and grain) following one application of ADM.00900.I.1.C in 4 trials (4 RDCS) Northern Europe (France, Poland and Hungary) – 2020., Delmotte, R., 2021, Report No. RDE-20-43068 (Sponsor report No. 000105706)
Guideline(s):	SANCO/7029/VI/95 rev.5 OECD 509 (2009) SANTE/2020/12830, Rev.1 ENV/JM/MONO(2007)17

Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

Summary of the study 1 trials

Reference:	Magnitude of the residues of chlorantraniliprole in Maize (RAC sweet corns (cob), whole plants (silage), stover and grain) following one application of ADM.00900.I.1.C in 4 trials (4 RDCS) Northern Europe (France, Poland and Hungary) – 2020., Delmotte, R., 2021, Report No. RDE-20-43068 (Sponsor report No. 000105706)		
GLP:	Yes	**Sample storage conditions:**	Maximum of 169 days between sampling and analysis Maximum of 4 days between extraction and analysis
Crop/crop group:	Maize	**Analytical method:**	Validated method - POLLENIZ/GIRPA study code: B20G-A4-C-01 - Sponsor reference: 000105719 POLLENIZ/GIRPA analytical phase code: B20S-S2-C-19 (within this study) Multi-residue Method QuEChERS for the Determination of chlorantraniliprole
Indoor/Outdoor:	Outdoor	**Limit of Quantification (mg/kg):**	0.01 mg/kg
Formulation:	SC	**Limit of Detection (mg/kg):**	0.003 mg/kg
Content of active substance (g/kg or g/l):	200 g/L chlorantraniliprole	**Residues calculated as:**	chlorantraniliprole

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues [mg/kg]	PHI [days] (d)	Details on trial (e)
			[g a.s./ ha]	Water [L/ha]	[g a.s./hl				Chlorantraniliprole		
RDE-20-43068 FR01 / 71150 Demigny, Bourgogne – Franche Comté, N. France / N-EU / 2020	Maize / RGT Hexxagone	1- 24/04/2020 2- 07/07 to 20/07/2020 3- 01/10/2020	29	427	7	04/08/2020	BBCH 71	Sweetcorn (cob)	<0.01 (<LOD)	7* (BBCH 73)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 165 days -extraction to analysis: 4 days
			29	420	7	25/08/2020	BBCH 85	Whole plant	0.16	14 (BBCH 85)	
			29	422	7	18/09/2020	BBCH 87	Grain Stover	<0.01 (<LOD) 0.49	13(NCH)	
RDE-20-43068 PL02 / 63-040 Michałów, Wielkopolska, Poland / N-EU / 2020	Maize / Pioneer P9175	1- 08/04/2020 2- 20/07 to 25/07/2020 3- 23/10/2020	30	387	8	10/08/2020	BBCH 71	Sweetcorn (cob)	<0.01 (<LOD)	6* (BBCH 73)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 160 days -extraction to analysis: 4 days
			30	383	8	28/08/2020	BBCH 79	Whole plant	0.058	14 (BBCH 83)	
			30	390	8	07/10/2020	BBCH 87	Grain Stover	<0.01 (<LOD) 0.33	14(NCH)	
RDE-20-43068 PL03 / 96-124 Słomków, Łódzkie, Poland / N-EU / 2020	Maize / Lokata	1- 21/04/2020 2- 28/07 to 07/08/2020 3- 20/10/2020	30	430	7	10/08/2020	BBCH 71	Sweetcorn (cob)	<0.01 (<LOD)	7* (BBCH 73)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 159 days -extraction to analysis: 4 days
			31	453	7	28/08/2020	BBCH 79	Whole plant	0.086	14 (BBCH 83)	
			30	443	7	29/09/2020	BBCH 87	Grain Stover	<0.01 (<LOD) 0.32	15(NCH)	
RDE-20-43068 HU04 / 5054 Jászalsószentgy örgy, Jász-Nagykun-Szolnok county, Hungary / N-EU / 2020	Maize / DKC4717	1- 10/04/2020 2- 10/07 to 27/07/2020 3- 01/10/2020	31	400	8	27/07/2020	BBCH 71	Sweetcorn (cob)	0.023	7* (BBCH 73)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 169 days -extraction to analysis: 4 days
			31	396	8	03/08/2020	BBCH 73	Whole plant	0.34	14 (BBCH 81)	
			32	411	8	08/09/2020	BBCH 87	Grain Stover	<0.01 (<LOD) 0.64	13(NCH)	

*Normal commercial harvest (NCH) for sweetcorn varieties

(a) According to CODEX Classification / Guide
(b) Only if relevant; Harvest = normal commercial harvest (NCH) i.e. maize for grain
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Study 2

Comments of zRMS:	Four independent field trials (two decline trials and two harvest trials) were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in raw agricultural commodity specimens of maize (RAC cobs, whole plant (silage), stover and grain) after one application of ADM.00900.I.1.C at 0.15 L/ha representing 30 g/ha of chlorantraniliprole, either 7 (+/-1) days before harvest at sweet corn stage (plot T1), 14 (+/-1) days before harvest at silage stage (plot T2) or 14 (+/-1) days before grain harvest (plot T3). Sweet corn sampling at BBCH 73 consisted in cobs without husks. At harvest (BBCH 89), the specimens taken were and grain stover separately. The analytical method for chlorantraniliprole was fully validated according to SANTE/2020/12830, Rev.1 of 24/02/2021: on wheat grain (commodity with high starch content) in another study (GIRPA study B20G-A4-C-01 – Sponsor reference 000105719), on sweet corn, whole plant and stover in another study (RDE-20-43068 – Sponsor reference 000105706). A reduced validation on sweet corn, whole plant, grain and stover was performed within this study. The analytical method consisted in an extraction by maceration with acetonitrile/1% formic acid mixture and addition of water according to natural water content. Then extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Limit of quantification (LOQ) achieved was 0.01 mg/kg. No residue of chlorantraniliprole was found above LOQ (0.01 mg/kg) in untreated specimens. The mean recovery was between 70% and 110% at each level of fortification. Results: After a single application with ADM.00900.I.1.C at the rate of 0.150 L/ha, representing 30 g/ha of chlorantraniliprole, the residues found in treated maize were: . - Sweet corn (cob) (7 days after application): <LOD - Whole plants (14 days after application): 0.085 to 0.19 mg/kg - Grain (14 days after application): <LOD - Stover (14 days after application): 0.16 to 0.31 mg/kg The storage duration (interval between sampling and analysis date) was 184 days for the determination of chlorantraniliprole. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCP 8.3/13
Report	Magnitude of the residues of chlorantraniliprole after application of ADM.00900.I.1.C in maize in Northern Europe –2021, Report No. ChR-21-48545 (Sponsor report No. 000107726)
Guideline(s):	SANCO/7029/VI/95 rev.5 OECD 509 (2009) SANTE/2020/12830, Rev.1 ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

Summary of the study 2 trials

Reference:	Magnitude of the residues of chlorantraniliprole after application of ADM.00900.I.1.C in maize in Northern Europe –2021, Report No. ChR-21-48545 (Sponsor report No. 000107726)		
GLP:	Yes	**Sample storage conditions:**	Maximum of 184 days between sampling and analysis Maximum of 1 day (9 days for stover) between extraction and analysis
Crop/crop group:	Maize	**Analytical method:**	Validated method - POLLENIZ/GIRPA study code: B20G-A4-C-01 - Sponsor reference: 000105719 POLLENIZ/GIRPA analytical phase code: B20S-S2-C-19 (STAPHYT Study number: RDE-20-43068 - Sponsor reference: 000105706) Multi-residue Method QuEChERS for the Determination of chlorantraniliprole
Indoor/Outdoor:	Outdoor	**Limit of Quantification (mg/kg):**	0.01 mg/kg
Formulation:	SC	**Limit of Detection (mg/kg):**	0.003 mg/kg
Content of active substance (g/kg or g/l):	200 g/L chlorantraniliprole	**Residues calculated as:**	chlorantraniliprole

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues [mg/kg]	PHI [days] (d)	Details on trial (e)
			[g a.s./ ha]	Water [L/ha]	[g a.s./hl				Chlorantraniliprole		
ChR-21-48545 FR01 / 71350 St Gervais en Valliere, Bourgogne – Franche Comté, N. France / N-EU / 2021	Maize / Milady	1- 04/05/2021 2- From 23/07 to 06/08/2021 3- 11/10/2021	31	450	7	12/08/2021	BBCH 71	Sweetcorn (cob)	<0.01 (<LOD)	7* (BBCH 73)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 182 days -extraction to analysis: <1 days
			32	477	7	26/08/2021	BBCH 75	Whole plant	0.19	14 (BBCH 83)	
			31	460	7	28/09/2021	BBCH 87	Grain Stover	<0.01 (<LOD) 0.16	13(NCH)	
ChR-21-48545 DE02 / 04600 Greipzig, Thuringia, Germany / N-EU / 2021	Maize / LG 30.222	1- 25/04/2021 2- From 14/06 to 26/08/2021 3- 08/11/2021	33	433	8	01/09/2021	BBCH 71	Sweetcorn (cob)	<0.01 (<LOD)	7* (BBCH 73)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 162 days -extraction to analysis: < 1 day (5 days for stover)
			31	410	8	22/09/2021	BBCH 79	Whole plant	0.085	15 (BBCH 83)	
			31	407	8	28/10/2021	BBCH 87	Grain Stover	<0.01 (<LOD) 0.28	15(NCH)	
ChR-21-48545 PL03 / 62-100 Werkowo, Wielkopolska, Poland / N-EU / 2021	Maize / LG 31.277	1- 12/05/2021 2- From 10/07 to 25/07/2021 3- 12/10/2021	32	413	8	10/08/2021	BBCH 71	Sweetcorn (cob)	<0.01 (<LOD)	7* (BBCH 73)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 184 days -extraction to analysis: < 1 day (9 days for stover)
			31	410	8	24/08/2021	BBCH 79	Whole plant	0.17	15 (BBCH 83)	
			30	390	8	27/09/2021	BBCH 85	Grain Stover	<0.01 (<LOD) 0.31	14(NCH)	
ChR-21-48545 HU04 / 6750 Algyo, Csongrád-Csanad county, Hungary / N-EU / 2021	Maize / KWS Hypolito	1- 05/05/2021 2- From 21/07 to 08/08/2021 3- 20/09/2021	30	392	8	10/08/2021	BBCH 71	Sweetcorn (cob)	<0.01 (<LOD)	8* (BBCH 73)	Untreated specimens <LOD Max. Storage: -sampling to analysis: 183 days -extraction to analysis: < 1 day (9 days for stover
			30	387	8	25/08/2021	BBCH 77	Whole plant	0.11	14 (BBCH 83)	
			30	387	8	04/09/2021	BBCH 83-85	Grain Stover	<0.01 (<LOD) 0.24	15(NCH)	

*Normal commercial harvest (NCH) for sweetcorn varieties
(a) According to CODEX Classification / Guide

(b) Only if relevant; Harvest = normal commercial harvest (NCH) i.e. maize for grain
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.4 Magnitude of residues in livestock

No new/additional studies submitted within this dossier.

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

A 2.1.5.1 Processing studies on a core set of representative processes

Apple

A 2.1.5.1.2 Study 1

Comments of zRMS:	The field trials were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in apple processed fractions (apples prior processing, sauce, wet pomace, juice, canned apples and apple jelly) after one application of ADM.00900.I.1.C at 0.388 L/ha. Processing phase was performed with the apples from trial HU02 by Staphyt (France). The following sub-specimens were obtained during the processing phase: apples prior processing, sauce, wet pomace, juice, canned apples and apple jelly. The analytical method for chlorantraniliprole was validated for all matrices. Limit of quantification (LOQ) achieved was 0.01 mg/kg. For trial HU02, after one application in apple with ADM.00900.I.1.C at the rate of 0.388 L/ha, (representing 77.6 g/ha of chlorantraniliprole), the residues found in the processing treated specimens (plot T2) at 14 DAA (commercial harvest) are: - 0.060 mg/kg in apple before processing - < LOD in apple sauce - 0.20 mg/kg in apple wet pomace - < LOD in apple juice - < LOD in apple canned fruit - < LOQ in apple jelly For apple sauce, juice, canned fruit and jelly, the transfer factor is lower than 1 (TF = 0.17) thus demonstrating a loss of active substance during the processing. On the contrary, for the wet pomace the transfer factor is higher than 1 (TF = 3.3) showing a concentration of the active substance in this fraction (which is not use for human consumption). The study is acceptable.

Reference:	KCP 8.5.3/01 (KCP 8.3/01)
Report	Magnitude of the residues of chlorantraniliprole in orchard (apple or pear, RAC fruits) and processed fractions, following one application of ADM.00900.I.1.C in 2 trials on apples (1 DCS and 1 HS with process) and 2 trials on pears (1 DCS + 1 HS). Northern Europe (Poland, Hungary and France) – 2020., Meric, D., 2022, Report No. DMC-20-43056 (Sponsor report No. 000105697)
Guideline(s):	Yes SANCO/7029/VI/95 rev.5 OECD 509 (2009) ENV/JM/MONO(2011)50/REV1 SANTE/2020/12830, Rev.1 ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

MATERIALS AND METHODS

A study was performed on the processing of apples to wet pomace, juice, sauce, canned apples and apple jelly. Additional plots were included in the magnitude of the residue in apple study. The plots for the processing study were treated once at 77.6 g a.s./ha (2.5N) with ADM.00900.I.1.C.

Samples of apple from the untreated and treated plots were taken 14 days after application at commercial harvest and immediately shipped to the processing lab at ambient temperature.

Samples were processed to sauce, wet pomace, juice, canned apples and apple jelly as shown in **Figure A 2.1.5.1.2**. Processing of the RAC samples was initiated within 2 days of receipt as follows:

- Apple sauce: apples were blanched to avoid enzymatic browning. The blanched apples were crushed and sieved to be processed into sauce. The Brix degree of the sauce was measured and white sugar was added. The mix after homogenisation was heated up to in a double jacketed saucepan. The reduction was stopped when the Brix degree reaches 25.2% for untreated specimen and 24.7 % for treated specimen. No citric acid was added to lower down the pH of sauce because it was lower than 3.5. Two sauce sub-specimens were taken in metallic cans and sterilized for at least 10 minutes at minimum 118°C.
- Apple juice: apples were crushed and pressed. Two wet pomace sub-specimens were taken in plastic bags and deep-frozen (below -18°C). The juice was collected and transferred to a stainless steel container with addition of pectolytic enzymes for depectinisation. The juice was left to stand for at least 12 hours. It was then racked. The clear juice was filtered. No citric acid was added to lower the pH of sauce because it was low at 3.5. The juice was pasteurised at 85 - 90°C for 1 minute.
- Canned apple: apples were peeled and blanched in boiling water for two minutes approximately. The blanched apples were cored and cut in several parts. A syrup at 20% of sugar and pH at approximately 3.5, was added to the cored fruits during canning. The proportions of canned apples were two thirds (≈500 g) of apple and one third (≈250 g) of syrup. Two cans were sealed with a cover. Two canned apple sub-specimens were pasteurized at approximately 90°C for one minute.
- Apple jelly: apples were cooked in boiled water (1L of water per kg of apple) for 45 minutes. Cooked apples were pressed with the cooking water. Pressed apples (= wet pomace) was discarded. The mix of cooking water and apple juice obtained after pressing was put in a double jacketed saucepan. White sugar was added. The mix after homogenisation was heated up. The Brix degree of the mix was measured regularly to follow the reduction. Reduction was stopped when the Brix degree reaches 63.2% for untreated specimen and 65.2 % for treated specimen. No citric acid was added to lower down the pH of the jelly because it was lower than 3.5. Two jelly sub-specimens were taken in metallic cans and sterilized for at least 10 minutes at minimum 118°C.

Specimens of the processed fractions were taken and frozen (≤-18°C) as soon as the corresponding processing step was finished. All processing specimens were stored for a maximum period of 248 days from sampling to extraction. For apple (fruit), apple sauce, apple juice, apple canned fruit and apple jelly, final sample extracts were analysed within 24 hours after initial extraction, thus no stability study was performed. For apple wet pomace, as final sample extracts were injected 7 days after the extraction, a stability assessment of chlorantraniliprole in final sample extracts was performed during this analytical

phase which confirmed that final sample extracts of apple wet pomace were considered stable for at least 7 days.
The analytical method for chlorantraniliprole was based on the QuEChERS multi-residue method and validated on peach (high water content commodity) in POLLENIZ/GIRPA study B20G-A4-C-01 (Sponsor reference 000105719) according to SANTE/2020/12830, Rev.1 of 24/02/2021 (part risk assessment). A full validation on apple wet pomace and reduced validation on pear (fruit), apple (fruit), apple sauce, apple juice, apple canned fruit and apple jelly (commodities with high water content) was carried out in this study according to SANTE/2020/12830, Rev.1 of 24/02/2021 (part risk assessment).
The analytical method consisted in an extraction by shaking with acetonitrile/1% formic acid mixture and addition of water according to natural water content. Then extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Limit of quantification (LOQ) achieved was 0.01 mg/kg. Limit of determination (LOD) was defined as 30% of the LOQ (0.003 mg/kg).
Processing factors were calculated by dividing the residue level in the processed commodity by the residue level found in the raw agricultural commodity prior to processing.

RESULTS AND DISCUSSIONS
The analytical method has been demonstrated to be a reliable and accurate procedure for the determination of chlorantraniliprole in high water content commodities: peach, pear and apple (fruit, wet pomace, sauce, juice, canned fruit and jelly) in accordance with the guidance SANTE/2020/12830, Rev.1. The Mean procedural recoveries prepared at 0.01 mg/kg for each matrix type ranged between 60 and 120 % with a relative standard deviation of less than 30 %. The mean procedural recoveries prepared at 0.1 mg/kg for each matrix type ranged between 70 and 120 % with a relative standard deviation of less than 20 %. No residues of chlorantraniliprole were detected at or above the LOQ in any of the untreated samples.
A summary of the residues found in the processed samples is given in **Table 2.1.5.1.2-1.**

Table A 2.1.5.1.2-1 Residue data from apple processing study with chlorantraniliprole

RAC (prior to processing)	Residues in RAC (unwashed sample, mg/kg)	Processed commodity	Residue [mg/kg]	PF*	Comments/ Reference
Apple (fruit)	0.060	Sauce	<0.01 (<LOD)	0.17	Trial number DMC-20-43056 HU02
		Wet pomace	0.20	3.33	
		Juice	<0.01 (<LOD)	0.17	
		Canned	<0.01 (<LOD)	0.17	
		Jelly	<0.01	0.17	

* processing factor

Figure A 2.1.5.1.2-1 Processing flowchart for apple sauce

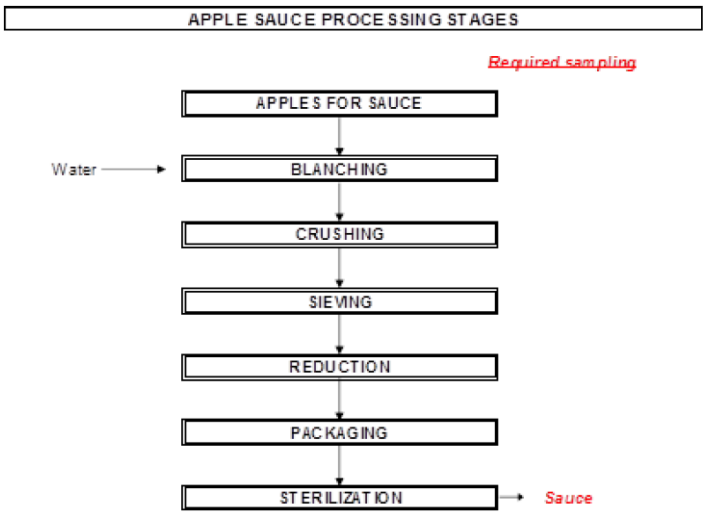


Figure A 2.1.5.1.2-2 Processing flowchart for apple juice

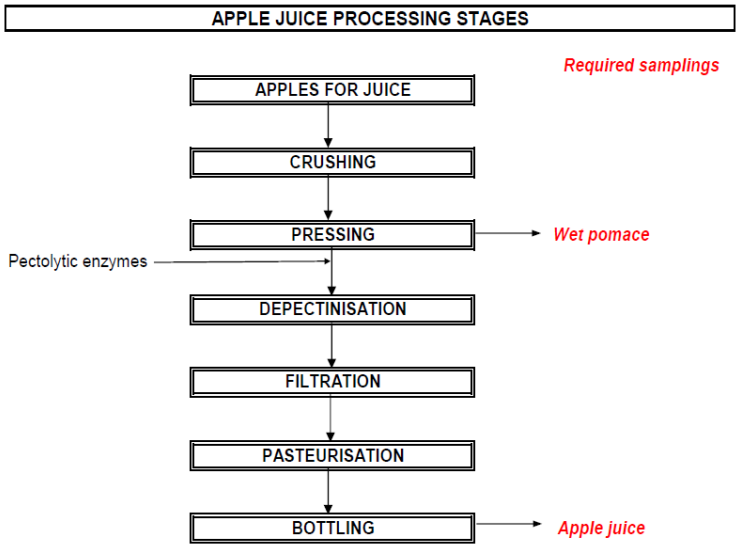


Figure A 2.1.5.1.2-3 Processing flowchart for canned apple

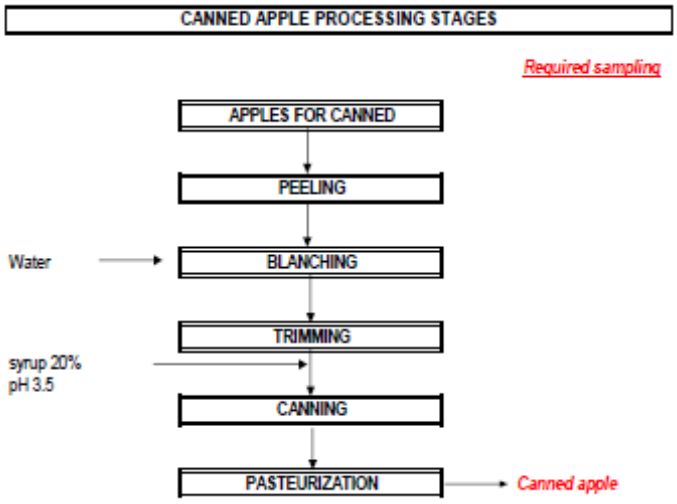
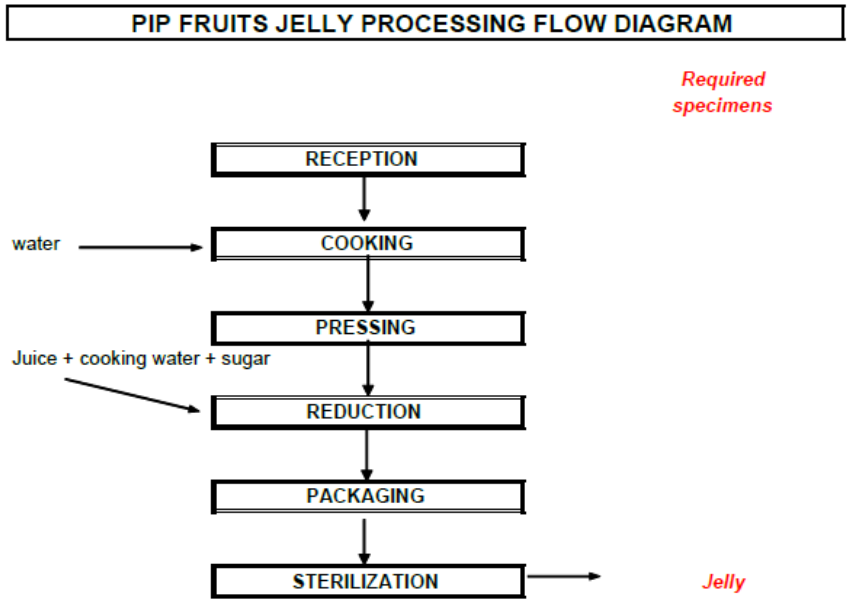


Figure A 2.1.5.1.2-4 Processing flowchart for apple jelly



CONCLUSION

A residue trial on apple is available to investigate residue levels of chlorantraniliprole in wet pomace, juice, sauce, canned apples and apple jelly and to determine a processing factor between raw agricultural commodities and the processed commodities. Based on the results from this study, the processing of apple to apple juice, sauce, canned apples and apple jelly is expected to reduce the residue of chlorantraniliprole, whereas in apple wet pomace, the residue is expected to concentrate.

A 2.1.5.1.3 Study 2

Comments of zRMS:	The field trials were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in apple processed fractions (apples prior processing, sauce, wet pomace, juice, canned apples and apple jelly) after one application of ADM.00900.I.1.C at 0.388 L/ha. Processing phase was performed with the apples from trial FR02. The following sub-specimens were obtained during the processing phase: apples prior processing, sauce, wet pomace, juice, canned apples and apple jelly. The analytical method for chlorantraniliprole was validated for all matrices. Limit of quantification (LOQ) achieved was 0.01 mg/kg. For processing phase (trial FR02), after one application in apple with ADM.00900.I.1.C at the rate of 0.388 L/ha, (representing 77.5 g/ha of chlorantraniliprole), the residues found in the treated specimens (plot T2) at 14 DAA (commercial harvest) are 0.038 mg/kg. For apple sauce, juice, canned fruit and jelly, the transfer factor (TF) is lower than 1 (TF = 0.26) thus demonstrating a loss of active substance during the processing. On the contrary, for the wet pomace the transfer factor is higher than 1 (TF = 1.84) showing a concentration of the active substance in this fraction (which is not use for human consumption). The study is acceptable.

Reference:	KCP 8.5.3/02
Report	Magnitude of the residues of chlorantraniliprole in orchard (apple or pear, RAC fruits) and processed fractions, following one application of ADM.00900.I.1.C in 2 trials on apples (1 DCS and 1 HS with process) and 2 trials on pears (1 DCS + 1 HS). Southern Europe (Italy and France) – 2020, Roussel, Ch.H., 2022, Report No. ChR-20-43058 (Sponsor report No. 000105698)
Guideline(s):	SANCO/7029/VI/95 rev.5 OECD 509 (2009) ENV/JM/MONO(2011)50/REV1 OECD 508 SANTE/2020/12830, Rev.1 ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

MATERIALS AND METHODS

A study was performed on the processing of apples to wet pomace, juice, sauce, canned apples and apple jelly. Additional plots were included in the magnitude of the residue in apple study. The plots for the processing study were treated once at 77.5 g a.s./ha (2.5N) with ADM.00900.I.1.C.

Samples of apple from the untreated and treated plots were taken 14 days after application at commercial harvest and immediately shipped to the processing lab at ambient temperature.

Samples were processed to sauce, wet pomace, juice, canned apples and apple jelly as shown in **Figure A 2.1.5.1.3**. The processing of the RAC samples was initiated within 1 day of receipt as follows:

- Apple sauce: apples were blanched to avoid enzymatic browning. The blanched apples were crushed and sieved to be processed into sauce. The Brix degree of the sauce was measured and white sugar was added. The mix after homogenisation was heated up to in a double jacketed saucepan. The reduction was stopped when the Brix degree reaches 25.2% for untreated specimen and 24.7 % for treated specimen.. No citric acid was added to lower down the pH of sauce because it was lower than 3.5. Two sauce sub-specimens were taken in metallic cans and sterilized for at least 10 minutes at minimum 118°C.
- Apple juice: apples were crushed and pressed. Two wet pomace sub-specimens were taken in plastic bags and deep-frozen (below -18°C). The juice was collected and transferred to a stainless steel container with addition of pectolytic enzymes for depectinisation. The juice was left to stand for at least 12 hours. It was then racked. The clear juice was filtered. No citric acid was added to lower the pH of sauce because it was low at 3.5. The juice was pasteurised at 85 - 90°C for 1 minute.
- Canned apple: apples were peeled and blanched in boiling water for two minutes approximately. The blanched apples were cored and cut in several parts. A syrup at 20% of sugar and pH at approximately 3.5, was added to the cored fruits during canning. The proportions of canned apples were two thirds (≈500 g) of apple and one third (≈250 g) of syrup. Two cans were sealed with a cover. Two canned apple sub-specimens were pasteurized at approximately 90°C for one minute.
- Apple jelly: apples were cooked in boiled water (1L of water per kg of apple) for 45 minutes. Cooked apples were pressed with the cooking water. Pressed apples (= wet pomace) was discarded. The mix of cooking water and apple juice obtained after pressing was put in a double jacketed saucepan. White sugar was added. The mix after homogenisation was heated up. The Brix degree of the mix was measured regularly to follow the reduction. Reduction was stopped when the Brix degree reaches 63.2% for untreated specimen and 65.2 % for treated specimen. No citric acid was added to lower down the pH of the jelly because it was lower than 3.5. Two jelly sub-specimens were taken in metallic cans and sterilized for at least 10 minutes at minimum 118°C.

Specimens of the processed fractions were taken and frozen (≤-18°C) as soon as the corresponding processing step was finished. All processing specimens were stored for a maximum period of 235 days from sampling to extraction. Final sample extracts were analysed within 24 hours after initial extraction, thus no stability study was performed.

The analytical method for chlorantraniliprole was based on the QuEChERS multi-residue method and validated on peach (high water content commodity) in POLLENIZ/GIRPA study B20G-A4-C-01 (Sponsor

reference 000105719) according to SANTE/2020/12830, Rev.1 of 24/02/2021 (part risk assessment). A full validation on apple wet pomace and reduced validation on pear (fruit), apple (fruit), apple sauce, apple juice, apple canned fruit and apple jelly (commodities with high water content) was carried out in POLLENIZ/GIRPA study B20G-S2-C-08 (Study No. DMC-20-43056 - Sponsor reference 000105697) according to SANTE/2020/12830, Rev.1 of 24/02/2021 (part risk assessment).
The analytical method consisted in an extraction by shaking with acetonitrile/1% formic acid mixture and addition of water according to natural water content. Then extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Limit of quantification (LOQ) achieved was 0.01 mg/kg. Limit of determination (LOD) was defined as 30% of the LOQ (0.003 mg/kg).
Processing factors were calculated by dividing the residue level in the processed commodity by the residue level found in the raw agricultural commodity prior to processing.

RESULTS AND DISCUSSIONS

The analytical method has been demonstrated to be a reliable and accurate procedure for the determination of chlorantraniliprole in high water content commodities: peach, pear and apple (fruit, wet pomace, sauce, juice, canned fruit and jelly) in accordance with the guidance SANTE/2020/12830, Rev.1. The Mean procedural recoveries prepared at 0.01 mg/kg for each matrix type ranged between 60 and 120 % with a relative standard deviation of less than 30 %. No residues of chlorantraniliprole were detected at or above the LOQ in any of the untreated samples.
A summary of the residues found in the processed samples is given in **Table 2.1.5.1.3-1.**

Table A 2.1.5.1.3-1 Residue data from apple processing study with chlorantraniliprole

RAC (prior to processing)	Residues in RAC (unwashed sample, mg/kg)	Processed commodity	Residue [mg/kg]	PF*	Comments/ Reference
Apple (fruit)	0.038	Sauce	<0.01 (<LOD)	0.26	Trial number ChR-20-43058 FR02
		Wet pomace	0.070	1.84	
		Juice	<0.01 (<LOD)	0.26	
		Canned	<0.01 (<LOD)	0.26	
		Jelly	<0.01 (<LOD)	0.26	

* processing factor

Figure A 2.1.5.1.3-1 Processing flowchart for apple sauce

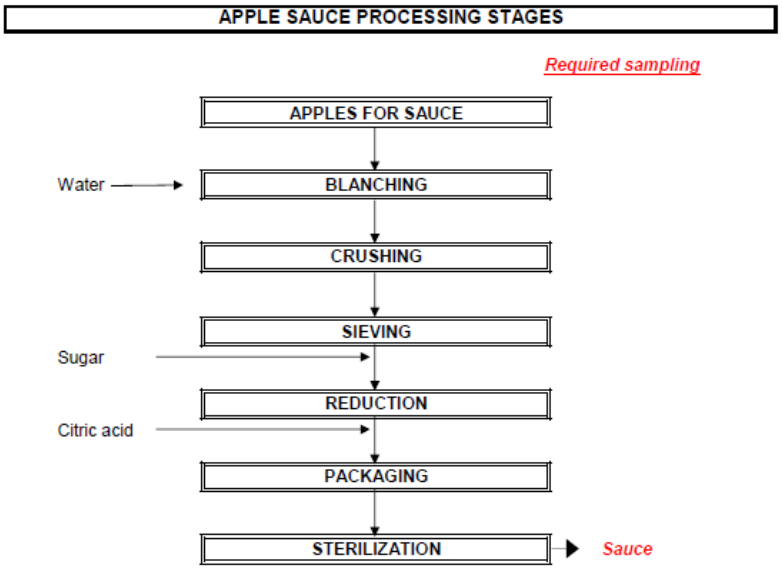


Figure A 2.1.5.1.3-2 Processing flowchart for apple juice

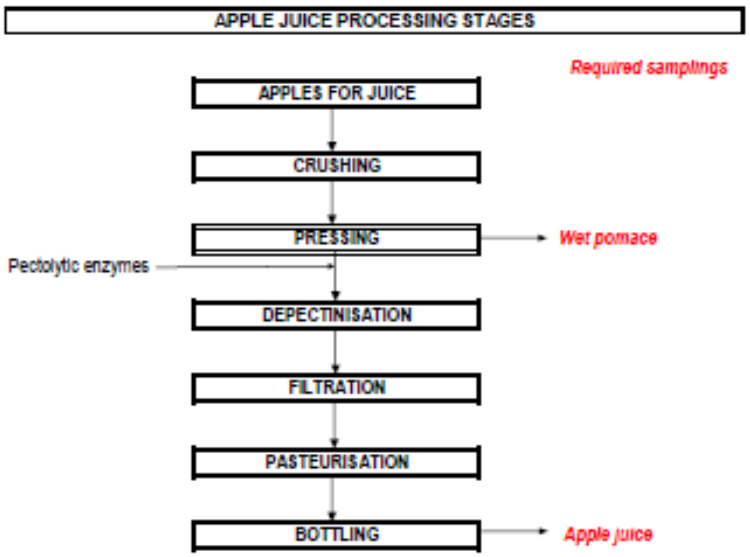


Figure A 2.1.5.1.3-3 Processing flowchart for canned apple

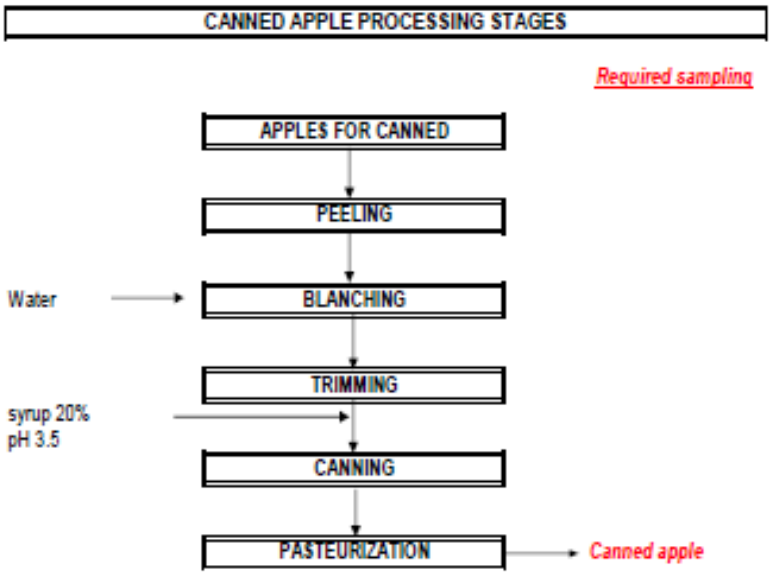
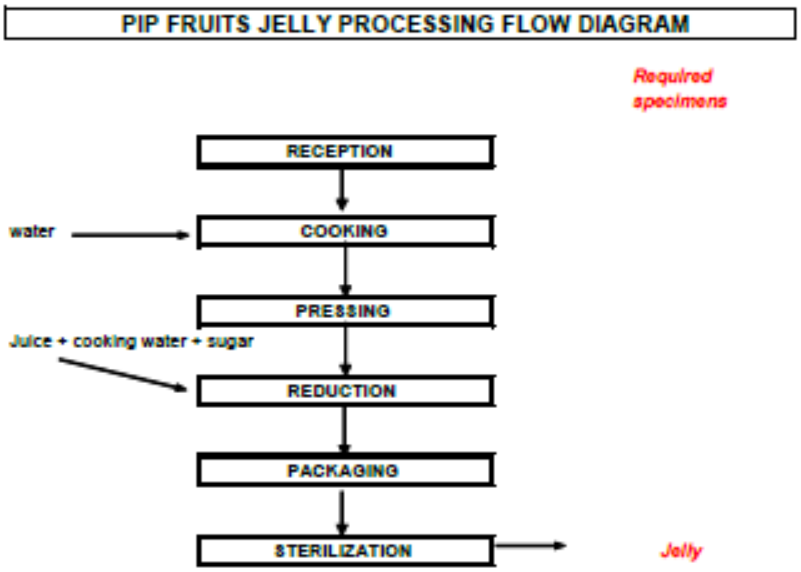


Figure A 2.1.5.1.3-4 Processing flowchart for apple jelly



CONCLUSION

A residue trial on apple is available to investigate residue levels of chlorantraniliprole in wet pomace, juice, sauce, canned apples and apple jelly and to determine a processing factor between raw agricultural commodities and the processed commodities. Based on the results from this study, the processing of apple to apple juice, sauce, canned apples and apple jelly is expected to reduce the residue of chlorantraniliprole, whereas in apple wet pomace, the residue is expected to concentrate.

Grape

A 2.1.5.1.4 Study 1

Comments of zRMS:	The field trials were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in grape processed fractions (berries prior processing, red wine, wet pomace, juice, must and white wine) after one application performed 30 (±2) days before harvest of ADM.00900.I.1.C at 0.450 L/ha representing 90 g/ha of chlorantraniliprole (plot T3). The analytical method for chlorantraniliprole was validated for all matrices. Limit of quantification (LOQ) achieved was 0.01 mg/kg. After one application in grape 30 (±2) days before harvest with ADM.00900.I.1.C at the rate of 0.450 L/ha, (representing 90 g/ha of chlorantraniliprole), the residues found in the processing treated specimens (plot T3) at 30 (±2) DAA (commercial harvest) are: - from 0.024 to 0.095 mg/kg in berries before processing, - 0.029 mg/kg in red wine, - 0.027 mg/kg in wet pomace, - < LOD in juice, - < LOQ in must, - < LOQ in white wine. For red and white wine, juice and must, the transfer factor is lower than 1 (TF = 0.31 to 0.40) thus demonstrating a loss of active substance during the processing. On the contrary, for the wet pomace the transfer factor is just higher than 1 (TF = 1.08) showing a slight concentration of the active substance in this fraction (which is not use for human consumption). The study is acceptable.

Reference:	KCP 8.5.3/03 (KCP 8.3/03)
Report	Magnitude of the residues of chlorantraniliprole in table or wine grapes (RAC berries) and processed fractions, fol-lowing one application of ADM.00900.I.1.C in 4 trials (2 DCS and 2 HS with process). Northern Europe (France and Hungary) – 2020, Meric, D., 2022, Report No. DMC-20-43062 (Sponsor report No. 000105700)
Guideline(s):	SANCO/7029/VI/95 rev.5 OECD 509 (2009) ENV/JM/MONO(2011)50/REV1 SANTE/2020/12830, Rev.1 ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

MATERIALS AND METHODS

A study was performed on the processing of grapes to red wine, wet pomace, juice, must and white wine. Additional plots were included in the magnitude of the residue in grape study. The plots for the processing study were treated once at 90 g a.s./ha (2.5N) with ADM.00900.I.1.C.

Samples of grape from the untreated and treated plots were taken 30 days after application at commercial harvest and immediately shipped to the processing lab at ambient temperature.

Samples were processed to red wine, wet pomace, juice, must and white wine as shown in **Figure A 2.1.5.1.4**. The Processing of the RAC samples was initiated on the same day of receipt as follows:

- Red wine: the bunches were crushed and stemmed using an electric crusher. The stems were discarded. Potassium metabisulphite and yeasts were added to the crushed grapes (must) in order to induce the alcoholic fermentation which was monitored every working day by measuring the density and temperature of the must. The alcoholic fermentation was considered complete when the wine density was stabilized

below the 1000 value. The liquid wine was collected and the solid part was pressed with a water press to recover the maximum of wine. The wet pomace was discarded. Then, the malolactic fermentation was carried out in absence of air into demijohns, at ambient temperature by addition of lactic bacteria to accelerate this process. The progress of the malolactic fermentation was followed-up each week by chromatography on paper. After the malolactic fermentation, potassium metabisulphite was added to wine for natural clarification which lasted at least four days. After racking, wine was separated from lees which were discarded. The same day dry gelatine and potassium metabisulphite were added to wine, to improve the clarification. The wine was kept in demijohns and stored in a cold room to be stabilized with regard to tartaric deposits and so that clarification could be achieved. To remove impurities (solid material), the wine was racked. Sediments were discarded. Finally, the wine was filtered and potassium metabisulphite was added to protect the wine from oxidation.
- Juice and wet pomace: the bunches were stemmed and crushed manually. The stems were discarded. Crushed bunches were pressed to separate juice (liquid phase) from wet pomace (solid phase). Two sub-specimens of wet pomace were taken. Pectolytic enzymes used for the clarification and gelatine were added to the juice. The clarification of juice was carried out under a cold storage (<+10°C) during at least 12 hours. At the end of the clarification, a deposit was formed. After racking, the deposit was discarded and the clarified juice was filtered and then pasteurised (1 minute, at 85°C).
- White wine: the bunches specimens were directly pressed with a water press. The must (crushed bunches) was recovered and the wet pomace (including stems) was discarded. Two must sub-specimens were transferred into plastic bags and deep-frozen. Pectolytic enzymes and potassium metabisulphite were added to the must. After more than 12 hours of settling, the must was racked and the deposit was discarded. Dry active yeast was added to the must to induce the alcoholic fermentation. The progress of the alcoholic fermentation was followed each working day by measuring the density and temperature of the must. The alcoholic degree of the specimens (estimated by refractometric degree) was considered insufficient, sugar was added in order to respect the oenological practices in force. The alcoholic fermentation was considered complete when the wine density was stabilized below the 1000 value. After at least four days, the wine was racked and lees were discarded. The racked wine was clarified with gelatine, potassium metabisulphite was added and the wine was placed into demijohns. The clarification was carried out in a cold room (temperature <+ 10 ° C) for at least 14 days to avoid any possibility of additional precipitation in the bottle. After racking, the wine was filtered and the sediments were discarded. Potassium metabisulphite was added to the filtered wine.
Specimens of the processed fractions were taken and frozen (≤-18°C) as soon as the corresponding processing step was finished. All processing specimens were stored for a maximum period of 259 days from sampling to extraction. All final sample extracts were analysed within 24 hours after initial extraction, thus no stability study was performed.
The analytical method for chlorantraniliprole was based on the QuEChERS multi-residue method and validated on grape (high acid content commodity) in POLLENIZ/GIRPA study B20G-A4-C-01 (Sponsor reference 000105719) according to SANTE/2020/12830, Rev.1 of 24/02/2021 (part risk assessment). A reduced validation on grape berries, wine, juice, must and wet pomace (commodities with high acid content) was carried in this study according to SANTE/2020/12830, Rev.1 of 24/02/2021 (part risk assessment).
The analytical method consisted in an extraction by shaking with acetonitrile/1% formic acid mixture and addition of water according to natural water content. Then extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Limit of quantification (LOQ) achieved was 0.01 mg/kg. Limit of determination (LOD) was defined as 30% of the LOQ (0.003 mg/kg).
Processing factors were calculated by dividing the residue level in the processed commodity by the residue level found in the raw agricultural commodity prior to processing.

RESULTS AND DISCUSSIONS
The analytical method has been demonstrated to be a reliable and accurate procedure for the determination of chlorantraniliprole in high acid content commodities: grape (berries, wine, juice, must and wet pomace) in accordance with the guidance SANTE/2020/12830, Rev.1. The Mean procedural recoveries prepared at 0.01 mg/kg for each matrix type ranged between 60 and 120 % with a relative standard deviation of less than 30 %. The Mean procedural recoveries prepared at 0.1 mg/kg for each matrix type ranged between 70 and 120 % with a relative standard deviation of less than 20 %. No residues of chlorantraniliprole were detected at or above the LOQ in any of the untreated samples.

A summary of the residues found in the processed samples is given in **Table 2.1.5.1.4-1.**

Table A 2.1.5.1.4-1 Residue data from grape processing study with chlorantraniliprole

RAC (prior to processing)	Residues in RAC (unwashed sample, mg/kg)	Processed commodity	Residue [mg/kg]	PF*	Comments/ Reference
Grape (berries)	0.025**	Wet pomace	0.027	1.08	Trial number DMC-20-43062 FR04
		Juice	<0.01 (<LOD)	0.4	
		Must	<0.01	0.4	
		White wine	<0.01	0.4	
Grape (berries)	0.095	Red wine	0.029	0.31	Trial number DMC-20-43062 HU03

* processing factor
** A mean of the results from analysing the retain specimen was used for the calculation of the processing factor

Figure A 2.1.5.1.4-1 Processing flowchart for red wine

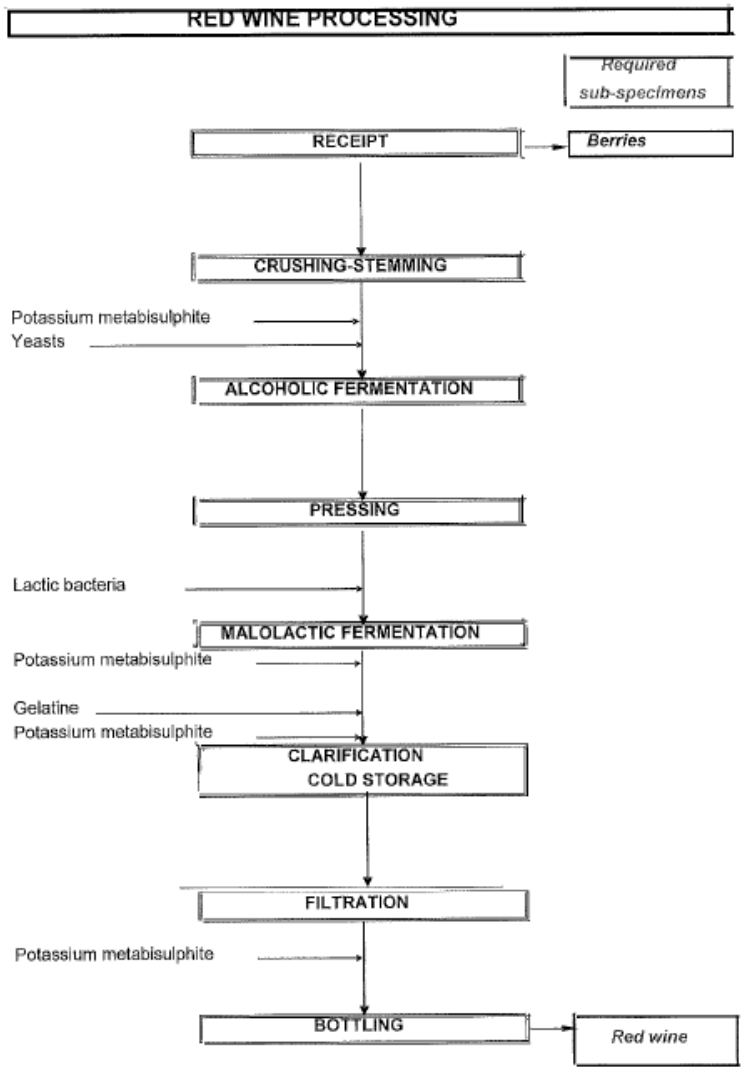


Figure A 2.1.5.1.4-2 Processing flowchart for grape juice

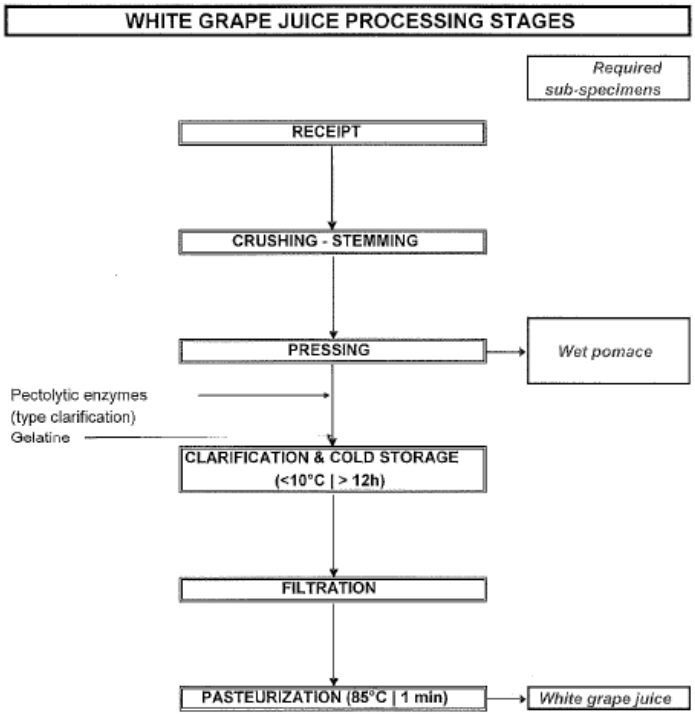
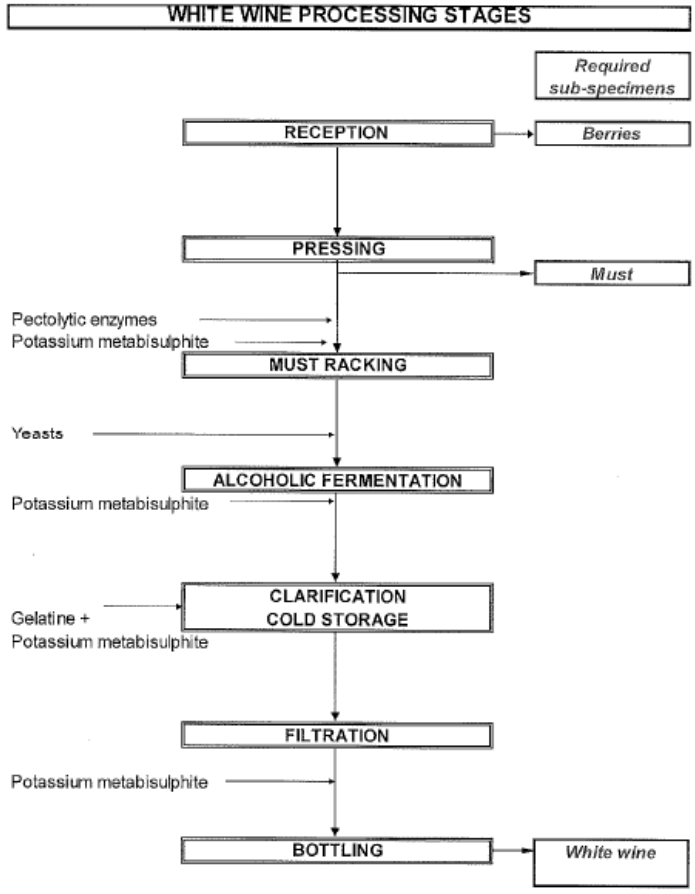


Figure A 2.1.5.1.4-3 Processing flowchart for white wine



CONCLUSION

A residue trial on grape is available to investigate residue levels of chlorantraniliprole in wet pomace, juice, must, white wine and red wine and to determine a processing factor between raw agricultural commodities and the processed commodities. Based on the results from this study, the processing of grape to grape juice, white wine and red wine is expected to reduce the residue of chlorantraniliprole, whereas in grape wet pomace, the residue is expected to concentrate.

A 2.1.5.1.5 Study 2

Comments of zRMS:	The field trials were conducted in Northern Europe to determine the magnitude of residues of chlorantraniliprole in grape processed fractions (berries prior processing, red wine, wet pomace, juice, must and white wine) after one application performed 30 (±2) days before harvest of ADM.00900.I.1.C at 0.450 L/ha representing 90 g/ha of chlorantraniliprole (plot T3). The analytical method for chlorantraniliprole was validated for all matrices. Limit of quantification (LOQ) achieved was 0.01 mg/kg. For processing phase (trials FR03 and FR04), after one application in grapevine with ADM.00900.I.1.C at the rate of 0.450 L/ha, (representing 90 g/ha of chlorantraniliprole), the residues found in the treated specimens (plot T3) at 30 (+/-2) DAA (commercial harvest) are 0.069 mg/kg in average. For juice, red and white wines, the transfer factor is lower than 1, thus demonstrating a loss of active substance during the processing. For the must specimen, the transfer factor is close to 1 (TF = 1.10) showing a conservation of theresidues in this fraction. The transfer factor is higher than 1 for wet pomaces (TF = 3.22) showing a concentration of the active substance in this processed fraction (which is not use for human consumption). The study is acceptable.

Reference:	KCP 8.5.3/04
Report	Magnitude of the residues of chlorantraniliprole in table or wine grapes (RAC berries) and processed fractions, following one application of ADM.00900.I.1.C in 4 trials (2 DCS and 2 HS with process) Southern Europe (Italy and France) – 2020., Roussel, Ch.H., 2022, Report No. ChR-20-43063 (Sponsor report No. 000105701)
Guideline(s):	SANCO/7029/VI/95 rev.5 OECD 509 (2009) ENV/JM/MONO(2011)50/REV1 SANCO 7035/VI/95 rev.5 OECD 508 SANTE/2020/12830, Rev.1 ENV/JM/MONO(2007)17
Deviations:	No deviation with impact on quality and integrity of the study.
GLP:	Yes
Acceptability:	Yes

MATERIALS AND METHODS

A study was performed on the processing of grapes to red wine, wet pomace, juice, must and white wine. Additional plots were included in the magnitude of the residue in grape study. The plots for the processing study were treated once at 90 g a.s./ha (2.5N) with ADM.00900.I.1.C.

Samples of grape from the untreated and treated plots were taken 30 days after application at commercial harvest and immediately shipped to the processing lab at ambient temperature.

Samples were processed to red wine, wet pomace, juice, must and white wine as shown in **Figure A 2.1.5.1.5**. The Processing of the RAC samples was initiated within 2 days of receipt as follows:

- Red wine: The grapes were crushed and stemmed using an electric crusher. The crushed grapes (= must) were collected in a stainless steel tank and weighed. Potassium metabisulfite was added to the crushed grapes at a rate of 0.06 g/L, depending on the health status of the crop.

Two must sub specimen were taken and placed in plastic bottles and then frozen (below - 18 ° C). Yeasts were added to the crushed grapes (must) in order to induce the alcoholic fermentation which was monitored every working day by measuring the density and temperature of the must. The alcoholic fermentation was considered complete when the wine density was stabilized below the 1000 value. The liquid wine was

collected, and the solid part was pressed with a water press to recover the maximum of wine. The wet pomace was discarded. Then, the malolactic fermentation was carried out in absence of air into demijohns, at ambient temperature by addition of lactic bacteria to accelerate this process. 0.10 g/L of potassium metabisulphite was added to wine on the same day. The natural clarification lasted four days.
After racking, wine after malolactic fermentation was separated from lees. Lees were weighed and discarded. Dry gelatine and potassium metabisulphite were added to the wine, to improve the clarification. The wine was kept in demijohns and stored in a cold room to be stabilized with regard to tartaric deposits. The wine was racked. Sediments were weighed and discarded. The wine was filtered and bottled.
- Juice and wet pomace: Bunches were stemmed and crushed manually. Stems and crushed grapes were weighed. Stems were discarded. Crushed grapes were weighed, placed into a saucepan and, after the addition of pectolytic enzymes, heated on a hot-plate up to 50-55°C for 45 minutes. The grapes were then pressed (water press) to separate juice (= must, liquid phase) from pomace (solid phase). Pomace was weighed.
Two sub specimen of wet pomace were taken and placed in plastic bags and then frozen (below -18 ° C).
After weighing, pectolytic enzymes (clarification) and gelatine were added to the juice. The clarification of juice was carried out under a cold storage (<+10°C) during at least 12 hours. After racking, clarified juice and deposit were weighed. Deposit was discarded. Clarified juice was filtered.
The filtered juice was weighed. The filtered juice was then pasteurized for 1 minute at + 85°C.
- White wine: The grapes were directly pressed with a water press. The must was recovered in a stainless steel tank. Wet pomace was weighed and discarded. Pectolytic enzymes and potassium metabisulphite were added to the must. After more than 12 hours of settling, the must was racked. Must deposit was weighed and discarded. Yeasts were added to the crushed grapes (must) in order to induce the alcoholic fermentation which was monitored every working day by measuring the density and temperature of the must.
The alcoholic fermentation was considered complete when the wine density was stabilized below the 1000 value. After at least four days, the stainless steel tank was weighed, and the wine was racked. Lees were weighed and discarded.
The racked wine was clarified with gelatine, added with potassium metabisulphite, and filled into topped-up demijohns. The clarification was carried out in a cold room (temperature <+ 10 ° C) for at least 14 days. After racking, the wine was filtered. The sediments were weighed and discarded. Potassium metabisulphite (0.10 g/L) was added to the filtered wine.
Specimens of the processed fractions were taken and frozen (≤-18°C) as soon as the corresponding processing step was finished. All processing specimens were stored for a maximum period of 169 days from sampling to extraction. All final sample extracts were analysed within 5 days (RAC) and <1 day (processed fractions) after initial extraction. Therefore, a stability assessment of chlorantraniliprole in final sample extracts was performed during this analytical phase which confirmed that final sample extracts of grape berries were considered stable for at least 6 days.
The analytical method for chlorantraniliprole was based on the QuEChERS multi-residue method and validated on grape (high acid content commodity) in POLLENIZ/GIRPA study B20G-A4-C-01 (Sponsor reference 000105719) according to SANTE/2020/12830, Rev.1 of 24/02/2021 (part risk assessment). A reduced validation on grape berries, wine, juice, must and wet pomace (commodities with high acid content) was carried within study POLLENIZ/GIRPA analytical phase code B20S-S2-C-13 according to SANTE/2020/12830, Rev.1 of 24/02/2021 (part risk assessment).
The analytical method consisted in an extraction by shaking with acetonitrile/1% formic acid mixture and addition of water according to natural water content. Then extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Limit of quantification (LOQ) achieved was 0.01 mg/kg. Limit of determination (LOD) was defined as 30% of the LOQ (0.003 mg/kg).
Processing factors were calculated by dividing the residue level in the processed commodity by the residue level found in the raw agricultural commodity prior to processing.

RESULTS AND DISCUSSIONS

The analytical method has been demonstrated to be a reliable and accurate procedure for the determination of chlorantraniliprole in high acid content commodities: grape (berries, wine, juice, must and wet pomace) in accordance with the guidance SANTE/2020/12830, Rev.1. The Mean procedural recoveries prepared at 0.01 mg/kg for each matrix type ranged between 60 and 120 % with a relative standard deviation of less than 30 %. The mean procedural recoveries prepared at 0.1 mg/kg for each matrix type ranged between 70

and 120 % with a relative standard deviation of less than 20 %. No residues of chlorantraniliprole were detected at or above the LOQ in any of the untreated samples. Within this study, the individual recoveries fulfilled the requirements for residue analytical methods.
A summary of the residues found in the processed samples is given in **Table 2.1.5.1.5-1.**

Table A 2.1.5.1.5-1 Residue data from grape processing study with chlorantraniliprole

RAC (prior to processing)	Residues in RAC (unwashed sample, mg/kg)	Processed commodity	Residue [mg/kg]	PF*	Comments/ Reference
Grape (berries)	0.059	Wet pomace	0.19	3.22	Trial number ChR-20-43063 FR03
		Juice	0.021	0.36	
		Must	0.065	1.10	
		Red wine	0.033	0.56	
Grape (berries)	0.079	White wine	0.013	0.16	Trial number ChR-20-43063 FR04

* processing factor

Figure A 2.1.5.1.5-1 Processing flowchart for red wine

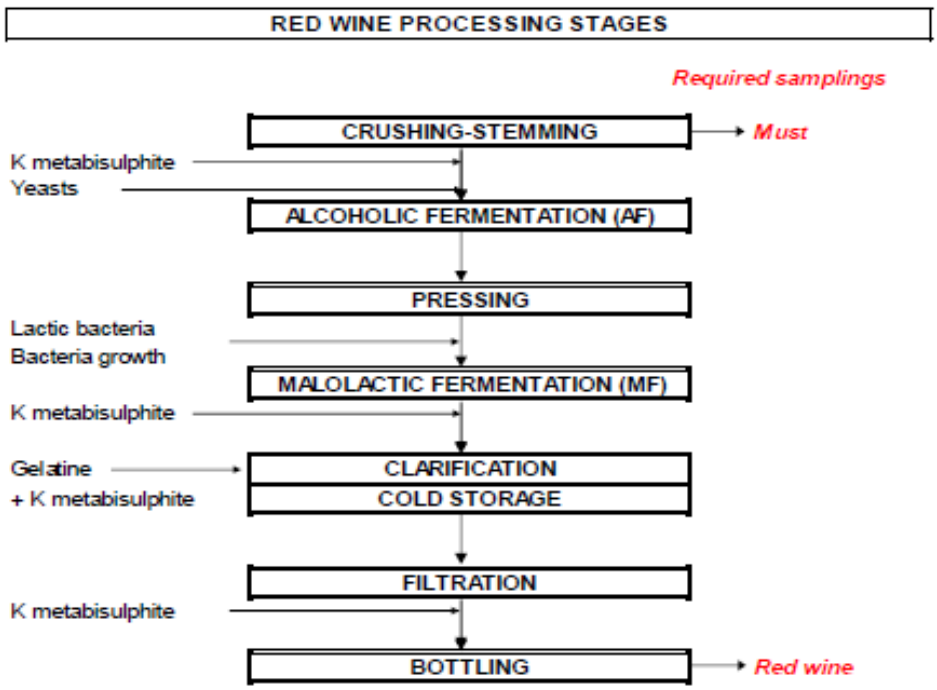


Figure A 2.1.5.1.5-2 Processing flowchart for grape juice

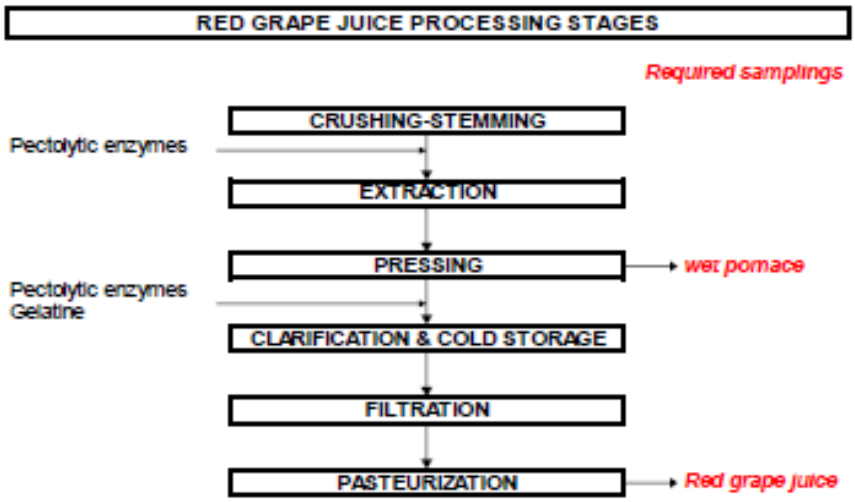
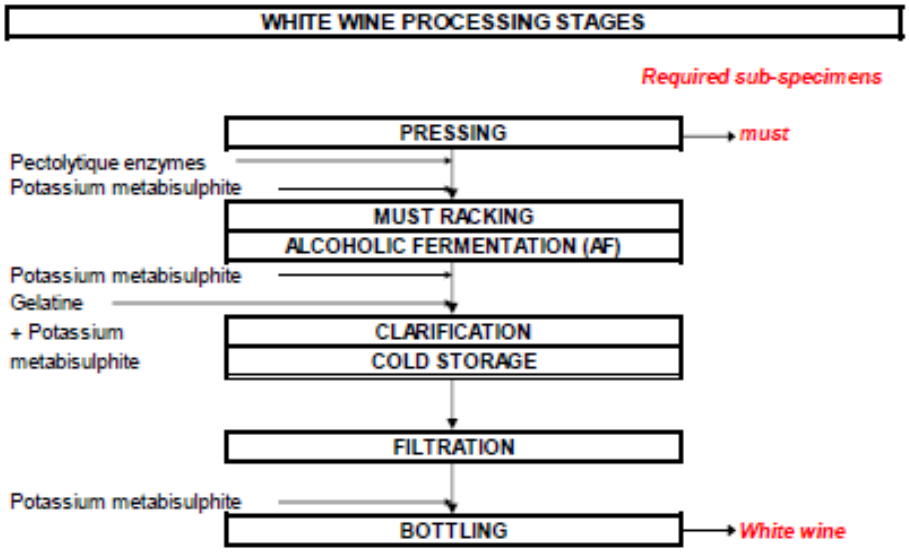


Figure A 2.1.5.1.5-3 Processing flowchart for white wine



CONCLUSION

A residue trial on grape is available to investigate residue levels of chlorantraniliprole in wet pomace, juice, must, white wine and red wine and to determine a processing factor between raw agricultural commodities and the processed commodities. Based on the results from this study, the processing of grape to grape juice, white wine and red wine is expected to reduce the residue of chlorantraniliprole, whereas in grape wet pomace, the residue is expected to concentrate.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new/additional studies submitted within this dossier.

A 2.1.7 Other/Special Studies

~~No n~~New/additional studies submitted within this dossier.

Comments of zRMS:	Two trials were conducted to determine the effects of Chlorantraniliprole 200 g/L SC on the honey bee (Apis mellifera L.). Additionally samples of plants, as well as nectar, pollen and honey from combs, and nectar and pollen collected by forager bees were taken for determination of residues of chlorantraniliprole and the metabolite IN-F9N04. For pollen, nectar, honey and whole plant matrices and for soil matrix the limit of quantification (LOQ) of the analytical method was 0.0005 mg/kg for each analyte. The mean recovery at each fortification level was in the target range of 70-110% with a relative standard deviation of $\leq$ 20% for all analytes and in all tested matrices. No residues of analytes were detected at or above the LOD in any of the untreated samples. The maximum storage interval from sampling until last extraction was 221 days for nectar samples, 364 days for pollen samples, 303 days for honey samples, 420 days for spray solutions, 218 days for whole plant and 290 days for soil samples. The storage temperature was $\leq$ -18 °C. The storage stability was assessed in separate studies DuPont-12985 (plant), DuPont-12955 (soil), FMC-54079 (soil), FMC-51284 (honey, nectar, pollen). Data generated indicate that chlorantraniliprole and IN-F9N04 residues are stable in the tested matrices for at least 24 months. The chlorantraniliprole residues found in honey were from 0.00156 to 0.0267 mg/kg. The IN-F9N04 residues were always below LOD. The study in the area of chlorantraniliprole and the metabolite IN-F9N04 residues determination in honey matrices is acceptable.

Reference:	KCP 10.3.1.6/01
Report author:	Gonsior, G.
Report year	2021
Report title	Chlorantraniliprole 20 SC: A field study to evaluate effects on the honeybee (*Apis mellifera* L.) in *Phacelia tanacetifolia* in Germany in 2019
Report No.:	FMC-52200, Revision No. 1
Test Facility Document No.:	S19-02573
Guidelines followed:	EPPO PP 1/170(4) (2010), Directive 7029/VI/95 rev.5, 91/414/EEC, (EU) No 283/2013, (EU) No 284/2013, (EC) No 1107/2009, SANCO/3029/99 rev.4
Deviations from current guidelines:	None
Previous evaluation:	No, not previously submitted
GLP/Officially recognised testing facilities:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes

Executive Summary:

The objective of this study was to determine the effects of Chlorantraniliprole 200 g/L SC on the honey bee (Apis mellifera L.) in Germany, following the OEPP/EPPO Guideline No. 170 (4) (2010). One field trial (S19-02573-01) was located in Southern Germany and the second field trial was located in Northern Germany (S19-02573-05). Each trial consisted of three pairs of fields (P1, P2, P3) with one treated with Chlorantraniliprole 200 g/L SC (T) and one control field each (C).

The test item was applied to the bare soil at a target application rate of 265.15 g a.s./ha of Chlorantraniliprole 200 g/L SC and mixed into the top 20 cm soil layer before Phacelia seeding to achieve a modelled worst-

case predicted 20-year plateau concentration in 20 cm top soil. Additionally, two applications at a target rate of 60 g a.s./ha were performed. The first application before flowering (BBCH 59-60) and the 2nd application during flowering and honey bee-flight (BBCH 63-65) were done with a seven to 13-day spray interval in Phacelia tanacetifolia (For trial -05: the actual rate absolute was 120 g a.s./ha at the pre-flowering application).
Mortality, colony development and overwintering success were assessed. In addition, sublethal parameters such as flight intensity (number of honey bees that are both foraging on flowering Phacelia and flying over the crop were assessed for 15 seconds per 1 m2) and behavior of the honey bees were evaluated for possible indirect impacts of the test item on honey bees.
Additionally, samples of plants, as well as nectar, pollen and honey from combs, and nectar and pollen collected by forager bees were taken for determination of residues of Chlorantraniliprole and the metabolite IN-F9N04. Pollen from pollen traps was collected for pollen source analysis. Spray solution samples were taken to check the concentration of the application solutions.
Honey bee disease and viruses were analyzed in honey bees and honey samples from colonies once prior to selection of hives, once before overwintering and once after overwintering.
To simulate a modelled worst-case 20-year soil plateau concentration in 20 cm top soil, the test item in treatment group T was applied directly to bare soil at a rate of 1417.91 g Chlorantraniliprole 200 g/L SC/ha (equivalent to 265.15 g a.s./ha based on analyzed concentration of a.s.).
After the application, the test item was incorporated in the 20 cm top soil layer. The sowing of the Phacelia at the test item fields was performed after the incorporation of the test item into the soil and after the sowing of the control fields (C) for each group of field pairs (C1 and T1, C2 and T2, C3 and T3).
Application A2 and A3:
Treatment group T: Two applications - one during pre-flowering and one during flowering, respectively and at a rate of 320.86 g Chlorantraniliprole 200 g/L SC/ha (equivalent to 60 g a.s./ha based on analyzed concentration of a.s.) with a seven to 13-day interval. For Trial -05 the application A2 accidentally was applied with the double amount of spray solution (120 g a.s./ha), now representing worst case scenario.
For trial -01, the honey bee colonies were placed at the fields at early flowering of Phacelia (BBCH 61-63, 4-5DBA3) in June to July 2019. Placement was done on both fields of each pair of fields (C1 and T1, C2 and T2, C3 and T3) on the same day. Placement occurred as soon as the last field of each pair had started flowering so bees could start foraging in the fields.
For trial -05, the honey bee colonies were placed at the fields at early flowering of Phacelia (BBCH 61-62, 8-10DBA3) in July 2019. Placement was done on both fields of each pair of fields (C1 and T1, C2 and T2, C3 and T3) on the same day. Placement occurred as soon as the last field of each pair had started flowering so bees could start foraging in the fields.
The fields were located near Karlsruhe (P1 and P2) and near Pforzheim (P3) in Baden-Württemberg, Southern Germany for trial S19-02573-01.
The fields were located near Celle in Lower Saxony, Northern Germany for trial S19-02573-05.
For both trials colonies were kept at monitoring sites (one monitoring site for each pair of fields) after end of Phacelia flowering.
According to beekeeper practice, honeybee colonies were fed during late summer to bridge periods with poor natural flowering sources and to prepare the colonies for overwintering. Since only low amounts of honey were produced, none was harvested and resources were consumed over winter. Also, Varroa control measures were performed as locally recommended.
The following parameters were observed:
Mortality: Number of dead honey bees on the linen and in the bee traps;
Flight intensity: Number of forager honey bees/m²/15 seconds of flowering P. tanacetifolia;
Behavior of the honey bees on the crop and around the hive;
Condition of the colonies
Overwintering success
The determined level of the residues in the samples of nectar stomach contents and pollen loads from forager bees as well as nectar, pollen and honey from combs, plants, spray solution and soil.

I MATERIALS AND METHODS

Test material:	Chlorantraniliprole 200 g/L SC
Name:	E2Y45-733
Synonyms/Codes:	Coragen

	Chlorantraniliprole 200 g/L SC
Formulation:	SC (suspension concentrate)
Test Item Code:	M-00021192
Active Substance(s):	Chlorantraniliprole
CAS Registry Number(s):	500008-45-7 (for the active substance)
Batch/Lot Number:	DEC17VL801
Molecular Weight:	483.2 g/mol
CAS Name (uninverted):	3-Bromo-N-[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide
IUPAC Name:	3-Bromo-4′-chloro-1-(3-chloro-2-pyridyl)-2′-methyl-6′-(methylcarbamoyl)pyrazole-5-carboxanilide
Concentration of a.s., nominal:	18.4 % (w/w) Chlorantraniliprole
Concentration of a.s., determined by Certificate of Analysis:	18.7 % (w/w) Chlorantraniliprole
Date of Analysis:	04 Apr 2018
Date of Certificate:	10 May 2018
Expiry Date:	04 Apr 2021
Appearance/Color:	liquid/ white
Density:	1.089 g/cm3
Stability:	97.6% of the Chlorantraniliprole remains in the delivery vehicle after one hour under agitation.
Storage Conditions:	Out of direct sunlight at a temperature less than 40 °C
Safety Precautions:	As indicated in the MSDS
Product Use:	Insecticide
Test Design (Trial 01 + 05)	
Trial location:	S19-02573-01 (Southern Germany), S19-02573-05 (Northern Germany),
Treatment Groups:	Control C, treatment T
Replicates:	Three replicates (fields) per treatment (C1, C2, C3; T1, T2, T3) for each trial and 8 hives per field site
Treatment Application (Trial 01+05)	
Application Rate:	Application A1: To simulate a predicted 20-year soil plateau concentration in 20 cm top soil, the test item in treatment group T was applied directly to bare soil at a rate of 1417.91 g Chlorantraniliprole 200 g/L SC/ha (equivalent to 265.15 g a.s./ha based on analyzed concentration of a.s.). After the application, the test item was incorporated in the 20 cm top soil layer. The sowing of the Phacelia at the test item fields was performed after the incorporation of the test item into the soil and after the sowing of the control area (C) for each group of field pairs (C1 and T1, C2 and T2, C3 and T3). Application A2 and A3: Trial -01: Treatment group T: two applications - one during pre-flowering and one during flowering, respectively and at a rate of 320.86 g Chlorantraniliprole 200 g/L SC/ha (equivalent to 60 g a.s./ha based on analyzed concentration of a.s.) with a seven day interval. Trial -05: Treatment group T: two applications - one during pre-flowering and one during flowering, respectively and at a rate of 320.86 g Chlorantraniliprole 200 g/L SC/ha (equivalent to 60 g a.s./ha based on analyzed concentration of a.s.) with a nine to 13-day interval. For Trial -05 the application A2 was applied with the double amount of spray solution.
Target Application Volume:	Application A1 (soil plateau; before sowing): 300 L water/ ha Applications A2, A3: 300 L water/ ha
Spray Dilution Preparation:	Shortly before application
Preparation of Application Solution:	The appropriate amount of test item was weighed in the laboratory and transported to the field site.
Application Timing:	The control fields (C1, C2, C3) remained untreated throughout the course of the study. Trial -01: The application in the treatment group T was performed three times:

	Application Timing A1 in the treated fields: before sowing of Phacelia Application Timing A2: at pre-flowering (BBCH 59-60) Application Timing A3: during full flowering of P. tanacetifolia (BBCH 63-65) and during honey bee flight activity (≥5 forager bees/m²) (seven days after A2) Trial -05: The application in the treatment group T was performed three times: Application Timing A1 in the treated fields: before sowing of Phacelia Application Timing A2: at pre-flowering (BBCH 59) Application Timing A3: during full flowering of P. tanacetifolia (BBCH 63-65) and during honey bee flight activity (≥2.7 forager bees/m²) (nine to 13 days after A2)
Method of Application:	Trial -01: Spray application. A1: spray application to bare soil. A2 and A3: foliar spray application The maximum wind speed was 1.4 m/s (application before sowing), 1.8 m/s (application before flowering), and 1.0 m/s (application during flowering) Trial -05: Spray application. A1: spray application to bare soil. A2 and A3: foliar spray application The maximum wind speed was 2.0 m/s during the applications
Application Equipment:	Large scale boom sprayer.
Distance to Target:	Approx. 50 cm
Calibration Procedure:	Visual check of the nozzles. The sprayer was calibrated according to the respective SOP and the total output was determined. Based on the total output per time the application time per plot were determined and verified before start of application.
Biological System (Trial -01):	
Taxonomic Group:	Hymenoptera, Apidae
Species:	Apis mellifera L.
Bee Colonies:	The honey bee colonies were randomly assigned to treatments and controls and placed at the fields at early flowering of Phacelia (BBCH 61-63, 4-5DBA3) in June to July 2019. Placement was done on both fields of each pair of fields (C1 and T1, C2 and T2, C3 and T3, on the same day. Placement occurred as soon as the last field of each pair had started flowering so bees could start foraging in the fields. The honey bee colonies were setup a few meters away from the edge of the fields. A part of the crop was removed and the bee colonies were placed on the experimental field. The colonies contained from 7735 to 16575 honey bees per colony at the time of the 1st colony assessment. The hives intended for sampling (C1s, C2s, C3s, T1s, T2s, T3s) contained a higher amount of honey bees per hive (19175 to 30615 honey bees/colony). Each colony contained at least 20 frames including at least six to 12 brood frames and at least three fully developed combs with no or only little content for further growth. Additional super(s) were placed on top of the brood chamber (P1 and P2: 05 Jul 2019; P3: 04 Jul 2019) to allow for colony growth and honey storage. Bee traps were fixed in front of the hives to record the number of dead honey bees. The queens, colonies and new queens were from one breeding line in order to guarantee uniform bee material in all treatments

	of the trial (origin: Eurofins apiary). Furthermore, honey bees were free of symptoms of Nosema and varoosis. The queens were marked with color plates so that the presence of the queen could be identified easier during the colony assessments.
Monitoring until start of overwintering of the bee colonies:	The honey bee colonies for each pair were removed from the field site and transported to a monitoring site after flowering of Phacelia has ended for the first field in the respective pair of fields (BBCH 65 - 69). The colonies from one pair of fields were located at the same monitoring site.
Source:	The honey bee colonies used were provided by Eurofins Agroscience Services Ecotox GmbH (Address: Eutinger Str. 24, 75223 Niefern-Öschelbronn, Germany).
Biological System (Trial -05):	
Taxonomic Group:	Hymenoptera, Apidae
Species:	Apis mellifera L.
Bee Colonies:	The honey bee colonies were randomly assigned to treatments and controls and placed at the fields at early flowering of Phacelia (BBCH 61-62, 5-10DBA3) in July 2019. Placement was done on both fields of each pair of fields (C1 and T1, C2 and T2, C3 and T3, on the same day. Placement occurred as soon as the last field of each pair had started flowering so bees could start foraging in the fields. The honey bee colonies were setup a few meters away from the edge of the fields. A part of the crop was removed and the bee colonies were placed on the experimental field. The colonies contained 7722 to 10238 honey bees per colony at the time of the 1st colony assessment. The hives intended for sampling (C1s, C2s, C3s, T1s, T2s, T3s) contained a higher amount of honey bees per hive (9945 to 10589 honey bees/ colony). Each colony contained at least 11 to 12 frames including at least seven to ten brood frames and at least two fully developed combs with no or only little content for further growth. Additional super(s) were placed on top of the brood chamber shortly after application A3 and shortly before the second colony assessment (P1: between 17 Jul 2019 and 23 Jul 2019, P2: between 14 Jul 2019 and 16 Jul 2019, P3: between 15 Jul 2019 and 17 Jul 2019) to allow for colony growth and honey storage. Bee traps were fixed in front of the hives to record the number of dead honey bees. The queens, colonies and new queens were from one breeding line in order to guarantee uniform bee material in all treatments of the trial (origin: LAVES apiary). Furthermore, honey bees were free of symptoms of Nosema and varoosis. The queens were marked with color plates so that the presence of the queen could be identified easier during the colony assessments.
Monitoring until start of overwintering of the bee colonies:	The honey bee colonies were removed from the field site and transported to a monitoring site after flowering of Phacelia has ended for the first field in the respective pair of fields (BBCH 67 - 69). The colonies from one pair of fields were located at the same monitoring site.
Source:	The honey bee colonies used were provided by Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit (LAVES).

1. Study Design and Methods

Experimental dates Trial 01: 07 May 2019 to 16 Mar 2020
Experimental dates Trial 05: 20 May 2019 to 28 Apr 2020
Mortality (Trial -01 and Trial -05)

At the monitoring sites, before the start of exposure, the number of dead honey bees was assessed in dead bee traps. These traps with gauze on bottom and on the top were attached to the entrance of the hives in order to register those dead bees which were carried out of the hives.
Water-permeable linen sheets of 1.5 m width and about 1.5 m length were spread out at the experimental fields in front of each hive to record the number of dead honey bees during the exposure phase.
At each evaluation date during the exposure at the field the dead honey bees were counted on the linen sheets and in the dead-bee traps and removed. Dead honey bees were differentiated as adult worker bees, pupae and larvae in the raw data and this report. For statistical analysis, these were summarized (one value per hive and assessment). Dead male bees and male brood were also recorded in the raw data but were excluded from evaluation of mortality.
The observations of mortality in the control and test item fields of both trials were carried out according to the scheme given in the following table.

Trial -01			
Test period	Field Pair	Timing	Evaluations of number of dead bees
Over at least 4 days before transport and set-up at the experimental fields (at monitoring site)	P1	7DBA3	Once at the same time of day in the morning up to noon
	P2	8DBA3	
	P3	10DBA3	
After start of the exposure phase at the experimental fields	P1	3DBA3 to 1DBA3	Once at the same time of day in the morning up to noon
	P2	4DBA3 to 1DBA3	
	P3	3DBA3 to 1DBA3	
Day of application A3 during bee flight	P11), P2 and P3	0DBA3	Once before application A3
		0DAA3	2 h after application A3 4 h after application A3 6 h after application A3
After application A3 until end of flowering period (at field sites)	P1	1DAA3 to 18DAA3	Once at the same time of day in the morning up to noon
	P2	1DAA3 to 17DAA3	
	P3	1DAA3 to 12DAA3	

DBA3/DAA3 = Days before/after application A3

Trial -05			
Test period	Field Pair	Timing	Evaluations of number of dead bees
Over at least 4 days before transport and set-up at the experimental fields (at monitoring site)	P1	13DBA3	Once at the same time of day in the morning up to noon
	P2	10DBA3	
	P3	11DBA3	
After start of the exposure phase at the experimental fields	P1	9DBA3 to 1DBA3	Once at the same time of day in the morning up to noon
	P2	5DBA3 to 1DBA3	
	P3	7DBA3 to 1DBA3	
Day of application A3 during bee flight	P1, P2 and P3	0DBA3	Once before application A3
		0DAA3	2 h after application A3 4 h after application A3 6 h after application A3
After application A3 until end of flowering period (at field sites)	P1	1DAA3 to 13DAA3	Once at the same time of day in the morning up to noon
	P2	1DAA3 to 16DAA3	
	P3	1DAA3 to 15DAA3	

DBA3/DAA3 = Days before/after application A3

Flight Intensity (Trial -01 and Trial -05)

The observations of the flight intensity in the field took place in ten representative marked squares (1 m²) regularly distributed over each of the test item fields as well as the control fields. At each assessment time the number of honey bees that are both foraging on flowering Phacelia and flying over the crop were assessed for 15 seconds per square (honey bees per 1 m2). At each assessment the cloud cover and the time of evaluation was recorded.
The observations in both trials were carried out according to the scheme given in the following table.

Trial -01			
Test period	Field Pair	Timing	Evaluations of number of forager bees
After start of the exposure phase at the experimental fields	P1	3DBA3 to 1DBA3	Once during flight activity of the honey bees. Assessments were done in parallel on both fields of each pair of fields (C1 and T1, C2 and T2, C3 and T3) to facilitate later comparison.
	P2	4DBA3 to 1DBA3	
	P3	3DBA3 to 1DBA3	
Day of application A3 during bee flight	P1, P2 and P3	0DBA3	Once before application A3 (at least 5 forager bees/m² should be foraging before the application)
		0DAA3	30 min after application A3 1 h after application A3 2 h after application A3 4 h after application A3 6 h after application A3
After application A3 until end of flowering period (at field sites)	P1, P2 and P3	1DAA3	Three times during flight activity of the honey bees (preferably in the morning, midday and afternoon)
	P1	2DAA3 to 18DAA3	Once at the same time of day in the morning up to noon
	P2	2DAA3 to 17DAA3	
	P3	2DAA3 to 12DAA3	

DBA3/DAA3 = Days before/after application A3

Trial -05			
Test period	Field Pair	Timing	Evaluations of number of forager bees
After start of the exposure phase at the experimental fields	P1	9DBA3 to 1DBA3	Once during flight activity of the honey bees. Assessments were done in parallel on both fields of each pair of fields (C1 and T1, C2 and T2, C3 and T3) to facilitate later comparison.
	P2	5DBA3 to 1DBA3	
	P3	7DBA3 to 1DBA3	
Day of application A3 during bee flight	P1, P2 and P3	0DBA3	Once before application A3 (at least 5 forager bees/m² should be foraging before the application)
		0DAA3	30 min after application A3 1 h after application A3 2 h after application A3 4 h after application A3 6 h after application A3
After application A3 until end of flowering period (at field sites)	P1, P2 and P3	1DAA3	Three times during flight activity of the honey bees (preferably in the morning, midday and afternoon)
	P1	2DAA3 to 13DAA3	Once at the same time of day in the morning up to noon
	P2	2DAA3 to 16DAA3	
	P3	2DAA3 to 15DAA3	

Behavior (Trial -01 and Trial -05)
The behavior of the honey bees foraging in the crop and at the entrance of the hives were observed during the evaluation period at the time of assessment of flight intensity and at the hive entrance during assessment of mortality. Special attention was paid to the presence or absence of the following behaviors and symptoms:
Aggressiveness towards the observer

Aggressiveness towards other honey bees/ filtering of returning bees at the hive entrance by guard bees
Intensive cleaning (personal grooming)
Flying without landing on the crop
Clustering at the bee hive entrance (estimated number or size)
Cramping
Locomotion Problems
Trembling
Inactive/motionless bees
Hanging honey bee (bees dangling from flowers)
Numbers of bees displaying other than normal behavior were counted and recorded during the assessments.
Management and Maintenance of Honey Bee Colonies (Trial -01 + 05)
Management of the honey bee colonies were done according to beekeeping practice, treatment against Varroa mites and prevention of swarming.
Number of boxes: During growth of the colonies in spring and early summer, the number of boxes for brood rearing were limited to one brood box but was increased up to three boxes. A queen excluder prevented brood rearing in additional super(s) intended for food storage.
Pest control: Treatments against Varroa mites were done in all hives according to local beekeeping practice (i.e., formic acid and oxalic acid at the appropriate times, and the regular removal of drone brood).
Swarm control: Swarming prevented by providing sufficient space for growth inside the hive (additional super(s)), by regular removal of queen cups.
Feeding: Feeding of all colonies was done during periods of low natural food availability to prevent starvation. In this case, all colonies were fed the same amount of sucrose solution.
Condition of Colonies, Brood Development (Trial -01 + 05)
The condition of the colonies and the development of the honey bee brood were checked once shortly before the set-up of the colonies at the fields and then, seven times afterwards. Furthermore, the conditions of the colonies were assessed once before the start of overwintering and once at the end of overwintering.
In order to record effects of the test item, the following parameters were assessed for each colony:
Colony strength (number of bees, estimation adapted to Imdorf & Gerig, 1999, and Imdorf et al., 1987)
Presence of a healthy queen (e.g. presence of marked queen and presence of eggs)
Pollen storage area and area with nectar or honey (estimation adapted to Imdorf & Gerig, 1999, and Imdorf et al., 1987)
Number of cells with eggs, larvae and capped cells (estimation adapted to Imdorf & Gerig, 1999, and Imdorf et al., 1987)
At each assessment the comb area containing bees and cells with nectar, pollen, eggs, larvae and capped cells were estimated per comb side and the total number of honey bees and cells containing the brood stages, pollen and nectar per hive were calculated. Afterwards the mean values were calculated for each treatment and assessment date.
Trial 01:
The calculation of the area containing brood and food cells was based on a comb size of 800 cm2 (per comb side) and assuming 400 cells per 100 cm2 (800 cm² = 3200 cells per comb side) or 230 male brood cells per 100 cm² (800 cm² = 1840 male brood cells per comb side). For the calculation of colony strength, 130 honey bees per 100 cm² were assumed as full coverage (800 cm² = 1040 honey bees per comb side).
Trial 05:
The calculation of area containing brood and food stages was based on a comb size of 720 cm2 (per comb side) and assuming 360 cells per 90 cm2 (720 cm² = 2880 cells per comb side) or 207 male brood cells per 90 cm² (720 cm² = 1656 male brood cells per comb side). For the calculation of colony strength 117 honey bees per 90 cm² were assumed as full coverage (720 cm² = 936 honey bees per comb side).
At each assessment, colonies were also assessed for bee diseases according to standard beekeeping practice. Accordingly, any unusual occurrence (e.g. presence of dead bees or immobile bees, unusual brood patterns or brood age structure) and clear symptoms of disease (e.g. chalk brood, sac brood, osmosis, American or European foulbrood) or pests (e.g. Varroa sp per 30 bees, Aethina tumida, Tropilaelaps spp.) were recorded.
No samples to monitor Varroa infestation level were taken during the course of the study. Treatments against Varroa were conducted according to the local beekeeper practice.
The assessments were only conducted for the hives used for biological assessments (replicates a – h), except for the 1st colony assessment, which was carried out for all hives (replicates a – h, s).
Assessments of the condition of the colonies were conducted according to the following time schedule:

Trial 01:

Activity Code	Timing	Evaluation of condition of colonies and brood development
EV	7DBA3 (P1), 8DBA3 (P2 and P3)	1st assessment of condition of the colonies (a-h, s)
EV	5DAA3 (P1) and 4DAA3 (P2), 2DAA3 (P3)	2nd assessment of condition of the colonies (a-h)
EV	11DAA3 (P1), 12DAA3 (P2), 10DAA3 (P3)	3rd assessment of condition of the colonies (a-h)
EV	19DAA3 (P1), 18DAA3 (P2), 16DAA3 (P3)	4th assessment of condition of the colonies (a-h)
EV	27DAA3 (P1), 26DAA3 (P2), 24DAA3 (P3)	5th assessment of condition of the colonies (a-h)
EV	34DAA3 (P1 and P3), 33DAA3 (P2)	6th assessment of condition of the colonies (a-h)
EV	45DAA3 (P1), 41DAA3 (P2), 43DAA3 (P3)	7th assessment of condition of the colonies (a-h)
EV	68DAA3 (P1 and P2), 70DAA3 (P3)	8th assessment of condition of the colonies (a-h)
EV	109DAA3 (P1), 110DAA3 (P2), 108DAA3 (P3)	9th assessment of condition of the colonies (a-h), before overwintering
EV	251DAA3 (P1), 255DAA3 (P2), 253DAA3 (P3)	10th assessment of condition of the colonies (a-h), after overwintering

DBA3/DAA3 = Days before/after application A3
EV = Evaluation

Additionally, four simplified beekeeper checks were made until start of overwintering. During each beekeeper check, the following parameters were assessed:
Estimation of colony strength (the number of alleyways between the combs that are filled with honey bees was documented)
Presence of a healthy, egg-laying queen (verified by direct observation or the presence of eggs)
Presence of queen cells
Presence of all brood stages (eggs, larvae, capped cells)
Number of combs containing brood
Indicators of bee diseases

Activity Code	Timing	Evaluation of condition of colonies and brood development
EV	52DAA3 (P1, P2 and P3)	Beekeeper check
EV	61DAA3 (P1 and P2), 63DAA3 (P3)	Beekeeper check
EV	81DAA3 (P1 and P2), 84DAA3 (P3)	Beekeeper check
EV	95DAA3 (P1 and P2), 97DAA3 (P3)	Beekeeper check

DBA3/DAA3 = Days before/after application A3
EV = Evaluation

Trial 05:

Activity Code	Timing	Evaluation of condition of colonies and brood development

EV	13DBA3 (P1), 6DBA3 (P2), 11DBA3 (P3)	1st assessment of condition of the colonies (a-h, s)
EV	6DAA3 (P1), 2DAA3 (P2 and P3)	2nd assessment of condition of the colonies (a-h)
EV	13DAA3 (P1), 10DAA3 (P2 and P3)	3rd assessment of condition of the colonies (a-h)
EV	20DAA3 (P1), 17DAA3 (P2), 16DAA3 (P3)	4th assessment of condition of the colonies (a-h)
EV	27DAA3 (P1), 24DAA3 (P2 and P3)	5th assessment of condition of the colonies (a-h)
EV	33DAA3 (P1), 31DAA3 (P2 and P3)	6th assessment of condition of the colonies (a-h)
EV	40DAA3 (P1), 43DAA3 (P2), 42DAA3 (P3)	7th assessment of condition of the colonies (a-h)
EV	70DAA3 (P1), 72DAA3 (P2 and P3)	8th assessment of condition of the colonies (a-h)
EV	92DAA3 (P1), 93DAA3 (P2), 91DAA3 (P3)	9th assessment of condition of the colonies (a-h), before overwintering

Activity Code	Timing	Evaluation of condition of colonies and brood development
EV	254DAA3 (P1), 257DAA3 (P2), 256DAA3 (P3)	10th assessment of condition of the colonies (a-h), after overwintering

DBA3/DAA3 = Days before/after application A3
EV = Evaluation

Additionally, two to three simplified beekeeper checks were made until start of overwintering. During each beekeeper check, the following parameters were assessed:
Estimation of colony strength (the number of alleyways between the combs that are filled with bees was documented)
Presence of a healthy, egg-laying queen (verified by direct observation or the presence of eggs)
Presence of queen cells
Presence of all brood stages (eggs, larvae, capped cells)
Number of combs containing brood
Indicators of bee diseases

Activity Code	Timing	Evaluation of condition of colonies and brood development
EV	49DAA3 (P1) 52DAA3 (P2), 51DAA3 (P3)	Beekeeper check
EV	61DAA3 (P1 and P2), 60DAA3 (P3)	Beekeeper check
EV	111DAA3 (P1), 115DAA3 (P2)	Beekeeper check

DBA3/DAA3 = Days before/after application A3
EV= Evaluation

Samplings:
For residue analysis spray solution, soil, nectar and pollen collected by forager bees, nectar and pollen from within the hives and honey from combs and in plants from Phacelia were collected.

Results:
Assessment Periods
Mortality, flight intensity and behavior were assessed during the following periods:
For mortality:

"Pre-exposure period": Several days at the initial monitoring site until setup of the hives at the Phacelia field sites (using dead bee trap).
For mortality and flight intensity:
"Exposure period 1": Time period from set up at the Phacelia field sites until the third application (A3) (0DBA3) (using dead bee trap and linen sheet for mortality).
"Exposure period 2": Time period from the third application (A3) (0DAA3) until end of Phacelia flowering and removal of the colonies to the post-exposure monitoring site (using dead bee trap and linen sheet).
"0DAA3": Time period directly after the third application (A3) (0DAA3) until end of the day (Using dead bee trap and linen sheet) - (This period is only summarized here when relevant).
Mortality – Combined Data Assessment of Trial -01 and Trial -05 Including Statistical Analysis
For the analysis mean mortality data of the different observation periods (pre-exposure period, exposure period 1, exposure period 2 and 0DAA3) were analyzed in order to overcome variations in local weather conditions which may have some impact on measured endpoints like mortality.
Mean mortality values for the six control fields and the six test item treated fields of trial -01 and -05 are given in the following overview:

Trial		S-Germany (S19-02573-01)			N-Germany (S19-02573-05)		
Treatment group		Control (C1)	Control (C2)	Control (C3)	Control (C1)	Control (C2)	Control (C3)
Daily mean mortality (dead worker bees/colony) ± STD	Pre-exposure period	19.4 ± 23.8	25.0 ± 13.6	10.7 ± 4.2	61.2 ± 107.7	10.4 ± 6.7	103.0 ± 182.7
	Exposure period 1	24.3 ± 5.2	31.2 ± 15.9	18.5 ± 7.0	17.3 ± 7.1	26.9 ± 21.2	18.4 ± 7.7
	0DAA3	21.0 ± 8.1	5.5 ± 2.1	12.1 ± 7.4	8.4 ± 5.4	8.5 ± 5.1	7.4 ± 5.3
	Exposure period 2	17.0 ± 3.0	12.6 ± 5.2	28.0 ± 11.3	3.5 ± 1.9	15.9 ± 7.7	25.5 ± 22.9
Treatment group		Test item (T1)	Test item (T2)	Test item (T3)	Test item (T1)	Test item (T2)	Test item (T3)
Daily mean mortality (dead worker bees/colony) ± STD	Pre-exposure period	17.7 ± 21.2	27.3 ± 22.7	8.1 ± 3.5	15.6 ± 3.6	6.0 ± 1.2	30.8 ± 32.3
	Exposure period 1	24.7 ± 10.4	40.1 ± 20.8	11.2 ± 4.8	18.9 ± 8.3	10.6 ± 4.2	11.3 ± 6.6
	0DAA3	14.3 ± 4.4	16.6 ± 10.2	8.0 ± 4.8	19.6 ± 15.7	5.8 ± 5.9	4.6 ± 2.6
	Exposure period 2	13.8 ± 3.8	20.3 ± 8.6	16.7 ± 6.8	14.7 ± 14.2	9.3 ± 3.0	22.9 ± 13.2

(Student's t-test, $\alpha = 0.05$)
0DAA3= Day of application A3 until approx. 6 hours after treatment
STD = Standard deviation
Before exposure: Dead honey bees from dead bee traps
During exposure and before application A3: Dead honey bees from linen sheets in the field and dead bee traps

During the pre-exposure period mean values of 10.7 to 103.0 dead worker bees/ colony/ day were determined for the control fields compared to 8.1 to 30.8 dead worker bees/ colony/ day for the test item treated fields.
During exposure period 1 (before the 3rd application A3), mean values of 17.3 to 31.2 dead worker bees/ colony/ day were determined for the control fields compared to 10.6 to 40.1 dead worker bees/ colony/ day for the test item treated fields.
During exposure on the day following the 3rd application A3 (0DAA3) mean values of 5.5 to 21.0 dead worker bees/ colony/ day were determined for the control fields which is comparable to the range of 4.6 to 19.6 dead worker bees/ colony/ day for the test item treated fields.
During exposure period 2 (0DAA3 until the hives were moved to the post-exposure monitoring sites) mean values of 3.5 to 28.0 dead worker bees/ colony/ day were calculated for the control. This is on the same level as the values determined for the test item treated fields with 9.3 to 22.9 dead worker bees/ colony/ day.

Comparisons of mean mortality values of the test item treatments with controls for the 4 different time periods (Pre-exposure period, exposure period 1, 0DAA3 and exposure period 2) did not show any statistically significant differences (Student's t-test, $\alpha = 0.05$).
Regarding mortality over all field pairs P1 to P3 from trial -01 and trial -05, observed differences cannot be dedicated to the test item treatment.
Overall, there was no adverse effect of the Chlorantraniliprole 200 g/L SC treatment compared to the control on the mortality of honey bees during the pre-exposure period, exposure period 1, 0DAA3 and exposure period 2.
Flight Intensity - Combined Data Assessment of Trial -01 and Trial -05 Including Statistical Analysis
During exposure period 1 (before application A3) mean values between 2.0 to 8.5 bees/m² were recorded for the control compared to 2.8 to 17.6 bees/m² for the test item treatment group. On the day of application A3 shortly before spraying (0DBA3) values for flight intensity were between 2.7 and 9.3 bees/m² for the control and between 4.8 and 21.7 bees/m² for the test item treatment. After application A3 (0DAA3) mean values ranged between 1.6 to 18.7 bees/m² and 3.2 to 14.7 bees/m² were determined for the control and test item treatment groups. On the first day after application A3 (1DAA3), mean values ranged between 1.4 to 14.1 and 3.3 to 14.4 bees/m² for control and test item treatment groups. Over exposure period 2 mean values ranged between 3.6 to 7.1 bees/m² for the control groups and between 4.3 and 9.7 bees/m² for the test item treatment groups. Mean flight intensity values for the six control fields and the six test item treated fields of trial -01 and -05 are given in the following overview:

Trial		S-Germany (S19-02573-01)			N-Germany (S19-02573-05)		
Treatment group		Control (C1)	Control (C2)	Control (C1)	Control (C2)	Control (C1)	Control (C2)
Daily mean flight intensity (bees/m² and 15 sec) ± STD	Exposure period 1	8.5 ± 2.0	5.6 ± 1.0	6.7 ± 0.9	5.3 ± 1.0	2.0 ± 0.7	5.6 ± 1.8
	0DBA3	8.8 ± 2.5	6.4 ± 1.7	5.6 ± 1.3	9.3 ± 1.9	2.7 ± 1.3	5.9 ± 2.8
	0DAA3	18.7 ± 2.4	4.8 ± 1.2	9.1 ± 1.6	11.1 ± 2.1	1.6 ± 0.4	6.1 ± 1.3
	1DAA3	10.7 ± 2.5	5.1 ± 1.2	9.5 ± 2.4	14.1 ± 3.9	1.4 ± 0.6	5.7 ± 1.3
	Exposure period 2	6.5 ± 1.3	3.6 ± 0.4	6.9 ± 1.2	5.8 ± 1.6	4.2 ± 0.6	7.1 ± 0.8
Treatment group		Test item (T1)	Test item (T2)	Test item (T3)	Test item (T1)	Test item (T2)	Test item (T3)
Daily mean flight intensity (bees/m² and 15 sec) ± STD	Exposure period 1	6.3 ± 1.6	17.6 ± 1.9	8.8 ± 1.7	3.2 ± 1.2	4.8 ± 1.0	2.8 ± 0.7
	0DBA3	6.1 ± 1.6	21.7 ± 4.0	7.9 ± 2.9	4.8 ± 2.6	4.8 ± 1.6	5.0 ± 1.6
	0DAA3	9.9 ± 0.8	14.7 ± 3.1	8.9 ± 1.7	6.5 ± 3.7	3.8 ± 1.0	3.2 ± 0.8
	1DAA3	13.0 ± 2.2	14.4 ± 2.0	12.7 ± 3.0	6.2 ± 1.3	5.5 ± 1.4	3.3 ± 0.9
	Exposure period 2	9.6 ± 1.7	5.7 ± 0.8	5.6 ± 0.9	4.3 ± 0.7	9.7 ± 1.5	6.5 ± 0.6

(Student's t-test, $\alpha = 0.05$)
0DAA3 = Day of application A3 until approx. 6 hours after treatment
STD = Standard deviation
Before exposure: Dead honey bees from dead bee traps
During exposure and before application A3: Dead honey bees from linen sheets in the field and dead bee traps

Comparison of means of the 6 test item treatment fields and 6 control fields for the 5 different time periods (exposure period 1, 0DBA3, 0DAA3, 1DAA3 and exposure period 2) did not show any statistically significant differences (Student's t-test, $\alpha = 0.05$).
Overall, there was no adverse effect of the Chlorantraniliprole 200 g/L SC treatment compared to the control on the flight intensity during the whole exposure periods.
Behavior - Combined Data Assessment of Both Trials in Group P1, P2 and P3 (Trial -01 and -05)

Daily numbers of worker bees recorded with unusual behavior for the six control fields and the six test item treated fields of trial -01 and -05 are given in the following overview:

Trial		S-Germany (S19-02573-01)			N-Germany (S19-02573-05)		
Treatment group		Control (C1)	Control (C2)	Control (C3)	Control (C1)	Control (C2)	Control (C3)
Number of bees recorded with unusual behaviour/ day (No. worker bees/day/8 colonies)	Pre-exposure period	1.25	21.25	0.00	8.25	6.40	21.75
	Exposure period 1	3.50	5.40	1.75	7.30	0.17	3.38
	0DBA3	5	12	4	9	0	17
	0DAA3	1	20	6	30	2	63
	Exposure period 2	3.47	3.11	2.92	2.43	1.06	4.31
Treatment group		Test item (T1)	Test item (T2)	Test item (T3)	Test item (T1)	Test item (T2)	Test item (T3)
Number of bees recorded with unusual behaviour/ day (No. worker bees/day/8 colonies)	Pre-exposure period	1.25	4.75	0.14	6.25	2.00	10.25
	Exposure period 1	5.50	6.60	4.00	4.10	7.83	6.50
	0DBA3	8	3	0	6	0	14
	0DAA3	45	9	14	34	25	89
	Exposure period 2	7.95	4.00	7.23	15.43	6.88	11.63

Regarding the number of bees recorded with unusual behavior on a daily basis for the eight hives/ field site, values are on an acceptable level throughout the test period.
Overall, numbers of honey bees showing unusual behavior were generally low during the exposure periods. Punctual differences between control and treatment are regarded as acceptable and within biological variation. There was no biologically relevant adverse effect of the Chlorantraniliprole 200 g/L SC treatment compared to the control on behavior during the whole exposure period
Colony Development – Combined Data Assessment of Both Trials in Group P1, P2 and P3 (Trial-01 and -05)
The following overview shows the mean colony strength determined for the different trial sites in Southern and Northern Germany before exposure, at the end of exposure, and before and after overwintering. Fluctuations were not test item related but show usual development of colonies over the year, reflecting climatic and regional differences.

Trial		S-Germany (S19-02573-01)			N-Germany (S19-02573-05)		
Treatment group		Control (C1)	Control (C2)	Control (C3)	Control (C1)	Control (C2)	Control (C3)
Mean colony strength (bees/ colony ± STD)	Pre exposure period (1st CA)	12383 ±1334	14430 ±1186	13122 ± 980	10040 ±76	9156 ±710	10055 ±58
	End of exposure period 2 (4th CA)	16721 ±3538	17851 ±2629	19979 ±3018	4410 ±1411	3832 ±1979	4176 ±640

	Before overwintering (9th CA)	14333 ±3154	13934 ±4409	11521 ±2979	5682 ± 1363	4234 ±1183	4564 ±647
	After overwintering (10th CA)	6841 ±2826	4778 ±4251	7488 ±2915	3766 ±642	2172 ±1660	2479 ±881
Treatment group		Test item (T1)	Test item (T2)	Test item (T3)	Test item (T1)	Test item (T2)	Test item (T3)
Mean colony strength (bees/ colony± STD)	Pre exposure period (1st CA)	11708 ±1781	14983 ±1126	13114 ±1364	10055 ±91	9156 ±332	10084 ±88
	End of exposure period 2 (4th CA)	19541 ±1955	21938 ±5117	19313 ±3124	6209 ± 617	5755 ±614	6218 ±633
	Before overwintering (9th CA)	9352 ±3793	13967 ±3090	14934 ±2666	5763 ±974	5543 ±1438	4863 ±1156
	After overwintering (10th CA)	5237 ±3075	4518 ±2863	4810 ±4010	3599 ±1187	4176 ±2224	2765 ±1076

STD = Standard deviation
CA = Colony assessment

Also variations in amount of brood and food cells only reflect climatic and regional differences.
Comparison of means of colony strength between the 6 test item treatment fields and 6 control fields for the 4 different time periods (pre-exposure period, end of exposure period 2, before overwintering and after overwintering) did not show any statistically significant differences (Student's or Mann-Whitney t-test, $p>0.05$). Also, for the amount of brood (sum of eggs, larvae and capped brood cells) and food cells (sum of nectar and pollen cells) no negative impact of the test item treatment versus the control was determined (Student's t-test, $p>0.05$).
Overall, there was no adverse effect of the Chlorantraniliprole 200 g/L SC treatment compared to the control on colony strength or amount of brood (sum of eggs, larvae and capped brood cells) and food cells (sum of nectar and pollen cells).
Overwintering success - Trial -01 and Trial -05
For Trial -01 altogether 48 colonies were used for the trial on six fields. From these 48 colonies, 11 did not survive winter, five colonies of the treatment groups and six colonies of the control groups. Except one colony (T3f), all of the failing colonies showed a high Varroa infestation (>7% infested worker bees is regarded as critical (OIE 2019) before overwintering, which might be a reason for colony loss.
For Trial -05 from 48 colonies, three did not survive winter, one colony of the treatment groups and two colonies of the control groups. Except one colony (C2e), all of the failing colonies showed a high Varroa infestation (>7% infested worker bees) is regarded as critical) before overwintering, which might be a reason for colony loss.

Trial		S-Germany (S19-02573-01)			N-Germany (S19-02573-05)		
Treatment group		C1	C2	C3	C1	C2	C3
	Colony						
	Ca	3.6	6.9	3.5	6.2	0.3	2.1

Varroa infestation before overwintering (%)	Cb	5.6	2.1	7.3	2.2	3.1	1.6
	Cc	4.6	25.9	3.8	14.4	9.8	1.2
	Cd	6.8	8.9	15.4	1.4	0.2	2.9
	Ce	10.1	19.8	12.3	0.4	5.5	0.0
	Cf	8.6	14.3	10.5	1.3	3.5	0.5
	Cg	8.0	23.4	10.6	3.2	2.1	2.1
	Ch	7.1	12.2	4.6	1.0	3.5	1.4
Treatment group Colony		T1	T2	T3	T1	T2	T3
Varroa infestation before overwintering (%)	Ta	8.4	3.4	10.5	5.0	2.2	2.6
	Tb	15.8	6.5	3.8	1.7	4.1	0.6
	Tc	5.1	4.2	11.5	0.6	6.0	0.3
	Td	13.3	1.5	26.0	0.3	3.1	1.7
	Te	11.0	18.5	7.3	18.3	3.0	3.4
	Tf	7.0	10.3	4.6	0.8	2.5	5.3
	Tg	11.1	14.5	8.9	5.3	4.7	0.5
	Th	8.5	22.0	7.7	2.2	0.9	3.9

Italic: infestation >7
Bold: colony did not survive winter

In total 40 of 48 control colonies and 42 of 48 test item treatment colonies successfully overwintered. Overall, there was no adverse effect of the Chlorantraniliprole 200 g/L SC treatment compared to the control on honey bee colony overwintering success.

Bee Disease Analysis Trial -01 and Trial -05

Trial -01: Over the three sampling days, Nosema sp. was detected a total of 19 times in group P1, distributed among five control hives (C1a, C1c, C1e, C1g and C1s) and seven treatment hives (T1a, T1b, T1c, T1f, T1g, T1h and T1s) with an infestation level between low and high. In group P2, Nosema sp. was detected a total of six times, distributed among three control hives (C2a, C2c and C2e) and two treatment hives (T2d and T2f, infestation level between low and high). In group P3 Nosema sp. was detected a total of 16 times, distributed among six control hives (C3a, C3c, C3d, C3g, C3h and C3s) and six treatment hives (T3b, T3c, T3d, T3g, T3h, and T3s, infestation level between low and high). If one colony was infested on several sampling days, the infestation level varied between low, medium and high with no tendency.

Trial -05: Over the three sampling days, Nosema sp. was detected a total of one time in group P1 (T1f, infestation level low). In group P2, Nosema sp. was detected a total of four times, distributed among one control hive (C2a) and three treatment hives (T2b, T2d and T2g, infestation level between low and high). In group P3 Nosema sp. was detected a total of two times, distributed among one control hive (C3b) and one treatment hive (T3e, infestation level between medium and high). None of the infested colonies was infested on several sampling days.

Malpighamoeba. mellificae could not be detected before start of exposure and at the time point ‘before start of overwintering’. After end of overwintering M. mellificae could only be detected in one hive (T1c).

Before start of exposure the infestation rate with Varroa destructor was low in all hives. The critical level of >7 % was not reached. In autumn 2019 – before overwintering – in some some control and test item treatment colonies increased levels of Varroa infestation were observed although Varroa control measures according to local recommendations were conducted and may have been a reason for individual colony losses The causative agent of American Foulbrood (AFB), Paenibacillus larvae, could not be detected at any time point.

Bee Virus Analysis Trial -01 and -05

The bee viruses Kashmir bee virus (KBV) and Israeli acute paralysis virus (IAPV) were not detected in any of the samples taken at any time point.

Deformed wing virus (DWV), Sacbrood virus (SBV), Acute bee paralysis virus (ABPV), Chronic bee paralysis virus (CBPV), and Black queen cell virus (BQCV) were detected in single colonies and some time points in trial -01 and in trial -05.
No relevant differences in the bee health status in terms of virus infection between the colonies of the control groups (C1a-C1h and C1s, C2a-C2h and C2s, C3a-C3h and C3s) and the corresponding test item treatment groups (T1a-T1h and T1s, T2a-T2h and T2s, T3a-T3h andT3s) in trial -01 and -05 were observed at any sampling date.
Bee Disease, AFB and Bee Virus Analysis Trial -01 and -05
Regarding disease and virus occurrence in trial -01 and -05, detected levels were within expected range considering location and seasonal yearly development.
No test item related differences were detected in control and test item treatment. It should be pointed out, that 2019 was a difficult year for honeybee colonies with temporary low offer of nectar and pollen and cool spring time regionally resulting in smaller colonies and higher Varroa infestation levels.
No relevant differences in the bee health status in terms of disease infection between the colonies of the control groups and the corresponding test item treatment groups in trial -01 and -05 were observed at any sampling date.
Pollen Source Analysis
Pollen Source Analysis Trial -01
Proportion of Phacelia tanacetifolia pollen collected by the honey bees is presented below:

Sampling Interval	C1	T1	C2	T2	C3	T3
P1:2DBA3 to 1DBA3 P2:2DBA3 to 1DBA3 P3:1DBA3 to 0DBA3	87.4%	92.8%	88.0%	99.8%	62.4%	52.8%
P1:2DAA3 P2:2DAA3 P3:2DAA3	71.2%	99.6%	94.4%	79.6%	95.0%	78.4%
P1:7DAA3 + 8DAA3 P2:7DAA3 to 8DAA3 P3:7DAA3	89.6%	98.6%	42.2%	77.8%	76.2%	32.0%
P1:11DAA3 P2:11DAA3 P3:10DAA3 to 11DAA3	36.2%	97.2%	74.6%	16.4%	99.8%	73.2%

(P1 = C1/T1, P2 = C2/T2 and P3 = C3/T3)

All colonies collected Phacelia pollen on all four sampling dates during the exposure period at the experimental fields. The variability of the proportion of Phacelia pollen between the fields and over time (within groups) is expected and not unusual as it reflects different individual preferences of the honey bee colonies, the condition (flowering stage) of Phacelia as well as the availability of other food sources near the experimental fields.
One additional sampling of honey from combs was conducted to collect honey from at least two colonies of each treatment group on 11-18DAA3. Proportion of Phacelia tanacetifolia pollen in selected honey samples collected by the honey bees is presented below:

Sampling Interval	C2a-h*1	C2a-h*2	T2a-h*1	T2a-h*2
C2a-h*1: 12DAA3 C2a-h*2, T2: 17DAA3	74.4%	83.2%	64.0%	75.4%
	C3a-h*1	C3a-h*2	T3a-h*1	T3a-h*2
P3:11DAA3	17.2%	51.1%	20.1%	55.6%

Pollen Source Analysis Trial -05
Proportion of Phacelia tanacetifolia pollen collected by the honey bees is presented below:

Sampling Interval	C1	T1	C2	T2	C3	T3
P1:6DBA3 to 4DBA3 P2:3DBA3 to 1DBA3 P3:4DBA3 to 2DBA3	95.4 %	86.0%	51.6%	84.3%	98.6%	97.6%
P1:1DAA3 to 6DAA3 P2:3DAA3 to 4DAA3 P3:2DAA3 to 3DAA3	56.4%	96.2%	30.6%	86.6%	97.0%	92.4%
P1:6DAA3 to 7DAA3 P2:8DAA3 to 10DAA3 P3:7DAA3 to 8DAA3	22.2%	94.4%	53.0%	64.6%	97.0%	90.6%

P1:11DAA3 to 12DAA3 P2:14DAA3 to 16DAA3 P3:13DAA3 to 16DAA3	88.0%	52.6%	12.8%	91.4%	89.0%	71.4%

All colonies collected Phacelia pollen on all four sampling dates during the exposure period at the experimental fields. The variability of the proportion of Phacelia pollen between the fields and over time (within groups) is expected and not unusual as it reflects different individual preferences of the honey bee colonies, the condition (flowering stage) of Phacelia as well as the availability of other food sources near the experimental fields.
One additional sampling of honey from combs were collected from at least two colonies of each treatment group on 12-15DAA3. Proportion of Phacelia tanacetifolia pollen in selected honey samples collected by the honey bees is presented below:

Sampling Interval	C1a-h*1	C1a-h*2	T1a-h*1	T1a-h*2
P1:12DAA3	48.4%	70.7%	93.9%	98.0%
	C2a-h*1	C2a-h*2	T2a-h*1	T2a-h*2
P2:15DAA3	65.6%	65.6%	94.9%	92.6%

Overall, all honey bee colonies on all experimental fields were primarily exposed to Phacelia during the observation period at the field sites of both trial sites.

Analytical Results
Analyses of residues of Chlorantraniliprole and its metabolite IN-F9N04 in spray solution, soil, nectar and pollen collected by forager bees, nectar and pollen from within the hives and honey from combs and in plants from Phacelia resulted in the following residue levels.
For pollen, nectar, honey and whole plant matrices the limit of quantification (LOQ) of the analytical method was 0.0005 mg/kg for each analyte with a limit of detection (LOD) set at 0.00015 mg/kg (30 % of the LOQ). For soil matrix the limit of quantification (LOQ) of the analytical method was 0.0005 mg/kg for each analyte based on wet weight basis with a limit of detection (LOD) set at 0.00015 mg/kg (30 % of the LOQ).
No residues of analytes were detected at or above the LOD in any of the untreated control samples.
The following overview gives the maximum, minimum and mean values of residues detected in the single matrices (LOQ = 0.0005 mg a.s./kg):

Residues of Chlorantraniliprole							
Trial	Field T	Matrix	Residues (mg a.s./kg)				
			n	Maximum	Min	Mean	SD
-01 and -05	all	Soil (dry weight)	6	0.1900	0.0721	0.1211	0.0431
	all	Soil (wet weight)	6	0.162	0.0609	0.1038	0.0370
	all	Spray solution A2*x)	6	109 %	81 %	99 %	11.41
	all	Spray solution A3*	6	109 %	91 %	101 %	7.33
	all	Honey	8	0.0267	0.00156	0.00824	0.00862
	all	Nectar from Combs	18	0.0190	0.000873	0.004501	0.004936
	all	Nectar from Forager Bees	24	0.0578	<LOQ	0.007221)	0.01201)
	all	Pollen from Combs	18	4.02	0.253	1.3038	0.8949
	all	Pollen from Forager Bees	23	1.16	0.0153	0.2862	0.2913
	all	Whole Plant	6	4.95	4.38	4.64	0.24

(LOQ = 0.0005 mg a.s./kg); 1) For calculation of mean and SD values <LOQ were set to LOQ (0.0005 mg/kg).
*% of target rate, x) see deviation 1, trial-05 (chapter 3.6.2)

Residues of IN-F9N04							
Trial	Field T	Matrix	Residues (mg a.s./kg)				
			n	Maximum	Min	Mean	SD
-01 and -05	all	Soil (dry weight)	6	n.d.	n.d.	n.d.	n.d.
	all	Honey	8	n.d.	n.d.	n.d.	n.d.
	all	Nectar from Combs	18	n.d.	n.d.	n.d.	n.d.
	all	Nectar from Forager Bees	24	n.d.	n.d.	n.d.	n.d.
	all	Pollen from Combs	18	0.00138	n.d.	0.0006901)	0.0002671)
	all	Pollen from Forager Bees	23	0.00108	n.d.	0.0004731)	0.0002391)
	all	Whole Plant	6	0.00833	0.00552	0.00683	0.00129

(LOQ = 0.0005 mg/kg)
(LOQ = 0.0005 mg/kg)
n.d.≤0.00015; 1) or calculation of mean and SD values <LOQ were set to LOQ (0.0005 mg/kg) and values n.d. were set to LOQ (0.00015 mg/kg)

III. Conclusion

Chlorantraniliprole 200 g/L SC was applied to the bare soil at an application rate of 265.15 g a.s./ha of Chlorantraniliprole 200 g/L SC and mixed into the top 20 cm soil layer before Phacelia seeding to achieve a modelled worst-case 20-year plateau concentration in 20 cm top soil. Additionally, two applications of 60 g a.s./ha were performed, the first application before flowering (BBCH 59-60) and the 2nd application during flowering and honey bee-flight (BBCH 63-65) in Phacelia tanacetifolia with a seven to 13-day spray interval (For trial -05: the actual rate absolute was 120 g a.s./ha at the pre-flowering application).
One trial (S19-02573-01) was located in Southern Germany and the other trial was located in Northern Germany (S19-02573-05). Each trial consisted in three pairs of fields (C and T).
Regarding mortality, over all field pairs P1 to P3 from trial -01 and trial -05, no adverse effect and no statistical differences (Student's t-test, $\alpha = 0.05$) of the test item were observed.

Regarding flight intensity over all field pairs P1 to P3 from trial -01 and trial -05, no adverse effect and no statistical differences (Student's t-test, $\alpha = 0.05$) of the test item were observed.
In both trials (-01 and -05) numbers of honey bees showing unusual behavior were generally low during the exposure periods. Punctual differences between control and treatment are regarded as acceptable within biological variation. There was no biologically relevant adverse effect of the Chlorantraniliprole 200 g/L SC treatment compared to the control on behavior during the whole exposure periods.
There was no effect and no statistical differences of test item treatment on colony strength (Student's or Mann-Whitney t-test, $\alpha = 0.05$), total number of brood cells (Student's or Mann-Whitney t-test, $\alpha = 0.05$)) and total number of food cells (number of cells with nectar/honey or pollen), (Student's or Mann-Whitney t-test, $\alpha = 0.05$) over all replicates from trial -01 and trial -05.
Development of the colonies followed the natural course of honey bee development in summer and autumn, only reflecting regional differences.
Overall, no relevant differences in the bee health status in terms of virus and disease infection between the colonies of the control groups and the test item treatment groups in both trials were observed at any sampling date.
Over both trials, -01 and -05, no treatment related difference in honey bee colony overwintering success can be noticed. From 96 colonies in total six colonies of the test item groups and eight colonies of the control groups were lost.
No residues of Chlorantraniliprole and its metabolite were detected at or above the LOD in any of the untreated samples. The residues detected in the samples taken from treated matrices showed residues (as expected).

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Chlorantraniliprole (F)

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw/day):	1.56	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	
Year of evaluation:	2013	Year of evaluation:	

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
	3%	NL toddler	49.34	0.9%	Spinaches	0.3%	Apples	0.3%	Witloofs/Belgian endives	0.0%	0.7%
	2%	DE child	27.02	0.4%	Apples	0.3%	Spinaches	0.2%	Oranges	0.0%	0.5%
	2%	NL child	24.49	0.3%	Spinaches	0.2%	Apples	0.1%	Escaroles/broad-leaved endives	0.0%	0.3%
	2%	GEMS/Food G10	23.55	0.4%	Lettuces	0.2%	Chinese cabbages/pe-tsai	0.1%	Cress and other sprouts and shoo	0.0%	0.1%
	1%	SE general	22.84	0.5%	Lettuces	0.3%	Chinese cabbages/pe-tsai	0.1%	Spinaches	0.0%	0.1%
	1%	IT adult	20.37	0.5%	Lettuces	0.2%	Other lettuce and other salad plants	0.1%	Spinaches	0.0%	0.0%
	1%	GEMS/Food G07	19.24	0.3%	Lettuces	0.1%	Wine grapes	0.1%	Celeries	0.0%	0.2%
	1%	IE adult	18.88	0.2%	Other leafy brassica	0.2%	Spinaches	0.1%	Lettuces	0.0%	0.2%
	1%	ES adult	18.79	0.7%	Lettuces	0.1%	Chards/beet leaves	0.1%	Spinaches	0.0%	0.1%
	1%	GEMS/Food G08	18.76	0.3%	Lettuces	0.1%	Lamb's lettuce/corn salads	0.1%	Watercress	0.0%	0.2%
	1%	ES child	18.14	0.5%	Lettuces	0.1%	Spinaches	0.1%	Chards/beet leaves	0.0%	0.1%
	1%	GEMS/Food G06	17.95	0.1%	Tomatoes	0.1%	Lettuces	0.1%	Table grapes	0.0%	0.1%
	1%	NL general	17.82	0.2%	Spinaches	0.2%	Witloofs/Belgian endives	0.1%	Escaroles/broad-leaved endives	0.0%	0.1%
	1%	GEMS/Food G11	17.31	0.2%	Celeries	0.1%	Spinaches	0.1%	Lamb's lettuce/corn salads	0.0%	0.2%
	1%	IT toddler	16.44	0.4%	Lettuces	0.1%	Other lettuce and other salad plants	0.1%	Chards/beet leaves	0.0%	0.1%
	1%	FR child 3 15 yr	16.20	0.2%	Oranges	0.1%	Other lettuce and other salad plants	0.1%	Spinaches	0.0%	0.1%
	1.0%	GEMS/Food G15	14.83	0.1%	Lettuces	0.1%	Head cabbages	0.1%	Sunflower seeds	0.0%	0.2%
	0.9%	FR toddler 2 3 yr	14.52	0.2%	Spinaches	0.1%	Apples	0.1%	Milk: Cattle	0.0%	0.1%
	0.8%	FR adult	12.56	0.2%	Other lettuce and other salad plants	0.1%	Wine grapes	0.1%	Witloofs/Belgian endives	0.0%	0.2%
	0.8%	PT general	12.43	0.2%	Kales	0.2%	Wine grapes	0.1%	Lettuces	0.0%	0.2%
	0.8%	DE women 14-50 yr	11.99	0.1%	Lettuces	0.1%	Oranges	0.1%	Apples	0.0%	0.2%
	0.7%	DE general	11.28	0.1%	Lettuces	0.1%	Apples	0.1%	Oranges	0.0%	0.2%
	0.7%	RO general	11.18	0.2%	Head cabbages	0.1%	Wine grapes	0.1%	Sunflower seeds	0.0%	0.4%
	0.7%	FR infant	10.53	0.3%	Spinaches	0.1%	Milk: Cattle	0.1%	Apples	0.0%	0.1%
	0.6%	DK child	8.81	0.2%	Lettuces	0.1%	Apples	0.0%	Milk: Cattle	0.0%	0.1%
	0.5%	UK vegetarian	8.06	0.2%	Lettuces	0.1%	Wine grapes	0.0%	Spinaches	0.0%	0.1%
	0.5%	UK toddler	7.86	0.1%	Oranges	0.1%	Milk: Cattle	0.1%	Apples	0.0%	0.1%
	0.4%	UK infant	6.84	0.1%	Milk: Cattle	0.1%	Oranges	0.1%	Apples	0.0%	0.1%
	0.4%	UK adult	6.52	0.2%	Lettuces	0.1%	Wine grapes	0.0%	Oranges	0.0%	0.1%
	0.4%	FI 6 yr	6.35	0.1%	Lettuces	0.1%	Spinaches	0.0%	Chinese cabbages/pe-tsai	0.0%	0.1%
	0.4%	FI 3 yr	6.32	0.1%	Spinaches	0.0%	Lettuces	0.0%	Apples	0.0%	0.1%
	0.4%	DK adult	6.03	0.1%	Lettuces	0.1%	Wine grapes	0.0%	Apples	0.0%	0.1%
	0.4%	FI adult	5.92	0.2%	Lettuces	0.0%	Chinese cabbages/pe-tsai	0.0%	Tomatoes	0.0%	0.1%
	0.3%	LT adult	4.68	0.1%	Lettuces	0.1%	Apples	0.1%	Head cabbages	0.0%	0.1%
	0.3%	PL general	4.64	0.1%	Apples	0.0%	Head cabbages	0.0%	Tomatoes	0.0%	0.2%
	0.1%	IE child	1.36	0.0%	Milk: Cattle	0.0%	Apples	0.0%	Lettuces	0.0%	0.0%

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Chlorantraniliprole (F)

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

Toxicological reference values

ADI (mg/kg bw/day):	1.56	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	
Year of evaluation:	2013	Year of evaluation:	

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments: EU MRL Reg. (EU) 2022/1343

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	3%	NL toddler	49.11	0.9%	Spinaches	0.3%	Witloofs/Belgian endives	0.3%	Escaroles/broad-leaved endives	0.0%	
	2%	DE child	26.14	0.3%	Apples	0.3%	Spinaches	0.2%	Oranges	0.0%	
	2%	NL child	24.97	0.3%	Spinaches	0.2%	Kales	0.1%	Apples	0.0%	
	1%	SE general	23.37	0.5%	Lettuces	0.3%	Chinese cabbages/pe-tsai	0.1%	Kales	0.0%	
	1%	GEMS/Food G10	23.26	0.4%	Lettuces	0.2%	Chinese cabbages/pe-tsai	0.1%	Cress and other sprouts and shoo	0.0%	
	1%	IT adult	21.03	0.5%	Lettuces	0.2%	Other lettuce and other salad plants	0.1%	Spinaches	0.0%	
	1%	IE adult	20.87	0.2%	Other leafy brassica	0.2%	Spinaches	0.1%	Rhubarbs	0.0%	
	1%	GEMS/Food G08	19.10	0.3%	Lettuces	0.1%	Lamb's lettuce/corn salads	0.1%	Watercress	0.0%	
	1%	GEMS/Food G07	18.92	0.3%	Lettuces	0.1%	Wine grapes	0.1%	Rapeseeds/canola seeds	0.0%	
	1%	NL general	18.73	0.2%	Spinaches	0.2%	Witloofs/Belgian endives	0.2%	Kales	0.0%	
	1%	GEMS/Food G06	18.72	0.1%	Tomatoes	0.1%	Lettuces	0.1%	Kales	0.0%	
	1%	ES adult	18.54	0.7%	Lettuces	0.1%	Chards/beet leaves	0.1%	Spinaches	0.0%	
	1%	GEMS/Food G11	17.61	0.1%	Celeries	0.1%	Spinaches	0.1%	Lamb's lettuce/corn salads	0.0%	
	1%	ES child	17.61	0.5%	Lettuces	0.1%	Spinaches	0.1%	Chards/beet leaves	0.0%	
	1%	IT toddler	16.93	0.4%	Lettuces	0.1%	Other lettuce and other salad plants	0.1%	Chards/beet leaves	0.0%	
	1%	PT general	16.08	0.5%	Kales	0.2%	Wine grapes	0.1%	Lettuces	0.0%	
	1.0%	FR child 3 15 yr	15.56	0.2%	Oranges	0.1%	Other lettuce and other salad plants	0.1%	Spinaches	0.0%	
	0.9%	GEMS/Food G15	14.49	0.1%	Lettuces	0.1%	Head cabbages	0.1%	Sunflower seeds	0.0%	
	0.9%	FR toddler 2 3 yr	14.21	0.2%	Spinaches	0.1%	Milk: Cattle	0.1%	Witloofs/Belgian endives	0.0%	
	0.8%	FR adult	12.31	0.2%	Other lettuce and other salad plants	0.1%	Wine grapes	0.1%	Witloofs/Belgian endives	0.0%	
	0.8%	DE women 14-50 yr	11.78	0.1%	Lettuces	0.1%	Oranges	0.1%	Apples	0.0%	
	0.7%	DE general	11.15	0.1%	Lettuces	0.1%	Oranges	0.1%	Apples	0.0%	
	0.7%	RO general	10.84	0.2%	Head cabbages	0.1%	Wine grapes	0.1%	Sunflower seeds	0.0%	
	0.7%	FR infant	10.68	0.3%	Spinaches	0.1%	Milk: Cattle	0.0%	Apples	0.0%	
	0.5%	DK child	8.08	0.2%	Lettuces	0.1%	Apples	0.0%	Milk: Cattle	0.0%	
	0.5%	UK vegetarian	8.02	0.2%	Lettuces	0.1%	Wine grapes	0.0%	Spinaches	0.0%	
	0.5%	UK toddler	7.55	0.1%	Oranges	0.1%	Milk: Cattle	0.0%	Apples	0.0%	
	0.4%	UK infant	6.54	0.1%	Milk: Cattle	0.1%	Oranges	0.0%	Apples	0.0%	
	0.4%	FI 6 yr	6.54	0.1%	Lettuces	0.1%	Spinaches	0.0%	Chinese cabbages/pe-tsai	0.0%	
	0.4%	FI 3 yr	6.49	0.1%	Spinaches	0.0%	Lettuces	0.0%	Chinese cabbages/pe-tsai	0.0%	
	0.4%	UK adult	6.43	0.2%	Lettuces	0.1%	Wine grapes	0.0%	Oranges	0.0%	
	0.4%	FI adult	5.92	0.2%	Lettuces	0.0%	Chinese cabbages/pe-tsai	0.0%	Tomatoes	0.0%	
	0.4%	DK adult	5.84	0.1%	Lettuces	0.1%	Wine grapes	0.0%	Apples	0.0%	
	0.3%	PL general	4.44	0.1%	Apples	0.0%	Head cabbages	0.0%	Tomatoes	0.0%	
	0.3%	LT adult	4.35	0.1%	Lettuces	0.1%	Head cabbages	0.0%	Apples	0.0%	
	0.1%	IE child	1.41	0.0%	Milk: Cattle	0.0%	Lettuces	0.0%	Apples	0.0%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Chlorantraniliprole (F) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.