REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: CA3573

Product names: Carnadine/Kestrel

Chemical active substance:

Acetamiprid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Re-authorisation acc. to Art. 43)

Applicant: Nufarm Europe GmbH

Submission date: July 2020, updated: December 2020

MS Finalisation date: May 2021 (initial Core Assessment)

November 2021, January 2022 (final Core Assessment)

Version history

When	What
July 2020	Initial dRR – Nufarm Europe GmbH – Version 1
December 2020	Update of the results of storage stability study on honey KCP 8.1/03, Müller S., 2020 Report No 20N08133-01-SSHN (interim report) – Version 2
May 2021	Initial zRMS assessment (re-authorization). 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 2021	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow.
January 2022	Final report (Core Assessment after additional round of the commenting period) No additional information or assessments after the commenting period.

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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 CA3573 / Carnadina / Kestrel are presented in Table 7.1-1. They have been selected from the individual GAPs in the zone for all crops included in GAP. A list of all intended uses within the zone is given in Part B, Section 0.

Justification for the selection of the critical GAP

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.4 mg/kg (oilseed rape); 0.4 mg/kg (apples) 0.01 mg/kg (potatoes), 0.01 mg/kg (maize/corn) for Acetamiprid as laid down in Commission Regulation (EU) 2019/88 is not expected.
Based on available feeding data, the in force MRLs are not expected to be exceeded, for animal origin food commodities.
The chronic and the short-term intakes of acetamiprid residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended use(s).
According to available data, 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/ Member state(s)**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg or L product / ha min max**	**water L/ha min max**	**g as/ha min max**		
1	Apple (MABSD)	PL	CA3573	F	*Aphis* sp. (APHISP)	SL	200 g/L	Foliar spraying overall	May-Oct/ BBCH 62-PHI	a) 1 b) 1	--	a) 0.125 b) 0.125	500-900	a) 25 b) 25	14	A
2	Apple (MABSD)	PL	CA3573	F	*Cydia pomonella* (CARPPO)	SL	200 g/L	Foliar spraying overall	May-Oct/ BBCH 62-PHI	a) 1 b) 1	--	a) 0.25 b) 0.25	500-900	a) 50 b) 50	14	A
3	Potato (SOLTU)	PL	CA3573	F	*Leptinotarsa decemlineata* (LPTNDE)	SL	200 g/L	foliar spraying, overall	Jun-Sep/ BBCH 12-79	a) 1 b) 1	--	a) 0.18 b) 0.18	200-400	a) 36 b) 36	7	A
4	Winter oilseed rape (BRSNN)	PL	CA3573	F	*Meligethes aeneus* (MELIAE)	SL	200 g/L	foliar spraying, overall	May-Jun/ BBCH 50-60	a) 1 b) 1	--	a) 0.3 b) 0.3	200-400	a) 60 b) 60	28	A
5	Winter oilseed rape (BRSNN)	PL	CA3573	F	*Dasineura brassicae* (DASYBR) *Ceutorhynchus obstrictus* (syn assimilis) (CEUTAS)	SL	200 g/L	foliar spraying, overall	May-Jun/ BBCH 61-71	a) 1 b) 1	--	a) 0.3 b) 0.3	200-400	a) 60 b) 60	28	A
6	Winter oilseed rape (BRSNN)	PL	CA3573	F	*Ceutorhynchus napi* (CEUTNA)	SL	200 g/L	foliar spraying, overall	Mar-Jun/ BBCH 31-39	a) 1 b) 1	--	a) 0.3 b) 0.3	200-400	a) 60 b) 60	28	A
7	Winter oilseed rape (BRSNN)	PL	CA3573	F	*Ceutorhynchus quadridens* (CEUTQU)	SL	200 g/L	foliar spraying, overall	Mar-Jun/ BBCH 31-59	a) 1 b) 1	--	a) 0.3 b) 0.3	200-400	a) 60 b) 60	28	A
8	Spring oilseed rape (BRSNN)	PL	CA3573	F	*Ceutorhynchus quadridens* (CEUTQU)	SL	200 g/L	foliar spraying, overall	Mar-Jun/ BBCH 31-59	a) 1 b) 1	--	a) 0.3 b) 0.3	200-400	a) 60 b) 60	28	A

9	Spring oilseed rape (BRSNN)	PL	CA3573	F	*Meligethes aeneus* (MELIAE)	SL	200 g/L	foliar spraying, overall	Apr-Jun/ BBCH 50.-60	a) 1 b) 1	--	a) 0.3 b) 0.3	200-400	a) 60 b) 60	28	A
10	Spring oilseed rape (BRSNN)	PL	CA3573	F	*Ceutorhynchus assimilis* (CEUTAS) *Dasineura brassicae* (DASYBR)	SL	200 g/L	foliar spraying, overall	BBCH 61-71	a) 1 b) 1	--	a) 0,3 b) 0,3	200-400	a) 60 b) 60	28	A
11	Apple (MABSD)	SK	CA3573	F	*Aphis* sp. (APHISP)	SL	200 g/L	foliar spraying, overall	May-Sep/ BBCH 69-PHI	a) 1 b) 1	--	a) 0.125 b) 0.125	500-1000	a) 25 b) 25	14	A
12	Apple (MABSD)	SK	CA3573	F	*Cydia pomonella* (CARPPO)	SL	200 g/L	Foliar spraying overall	May-Oct/ BBCH 69-PHI	a) 1 b) 1	--	a) 0.25 b) 0.25	500-1000	a) 50 b) 50	14	A
13	Potato (SOLTU)	SK	CA3573	F	*Leptinotarsa decemlineata* (LPTNDE)	SL	200 g/L	foliar spraying, overall	Apr-Sep/ BBCH 12-79	a) 1 b) 1	--	a) 0.18 b) 0.18	200-400	a) 36 b) 36	7	A
14	Winter oilseed rape (BRSNN)	SK	CA3573	F	*Ceutorhynchus napi* (CEUTNA) *Ceutorhynchus quadridens* (CEUTQU)	SL	200 g/L	foliar spraying, overall	Mar-Jun/ BBCH 31-69	a) 1 b) 1	--	a) 0.3 b) 0.3	200-400	a) 60 b) 60	28	A
15	Winter oilseed rape (BRSNN)	SK	CA3573	F	*Meligethes aeneus* (MELIAE) *Dasineura brassicae* (DASYBR)	SL	200 g/L	foliar spraying, overall	Mar-Jun/ BBCH 31-71	a) 1 b) 1	--	a) 0.3 b) 0.3	200-400	a) 60 b) 60	28	A
16	Winter oilseed rape (BRSNN)	SK	CA3573	F	*Ceutorhynchus obstrictus* (syn. assimilis) (CEUTAS) *Ceutorhynchus napi* (CEUTNA) *Ceutorhynchus quadridens* (CEUTQU)	SL	200 g/L	foliar spraying, overall	May-Jun/ BBCH 31-71	a) 1 b) 1	--	a) 0.3 b) 0.3	200-400	a) 60 b) 60	28	A
17	Spring oilseed rape (BRSNN)	SK	CA3573	F	*Ceutorhynchus napi* (CEUTNA) *Ceutorhynchus obstrictus* (syn assimilis) (CEUTAS) *Ceutorhynchus*	SL	200 g/L	foliar spraying, overall	Mar-Jun/ BBCH 31-71	a) 1 b) 1	--	a) 0.3 b) 0.3	200-400	a) 60 b) 60	28	A

					quadridens (CEUTQU)										
18	Spring oilseed rape (BRSNN)	SK	CA3573	F	*Meligethes aeneus* (MELIAE) *Dasineura brassicae* (DASYBR)	SL	200 g/L	foliar spraying, overall	Apr-Jun/ BBCH 31-71	a) 1 b) 1	--	a) 0.3 b) 0.3	200-400	a) 60 b) 60	28	A
19	Corn (ZEAMX)	SK	CA3573	F	*Diabrotica virgifera virgifera* (DIABVI)	SL	200 g/L	foliar spraying, overall	Apr-Aug/ BBCH 51-75	a) 1 b) 1	--	a) 0.3 b) 0.3	300-500	a) 60 b) 60	56	A
20	Corn (ZEAMX)	SK	CA3573	F	*Ostrinia nubilalis* (PYRUNU)	SL	200 g/L	foliar spraying, overall	Apr-Aug/ BBCH 51-75	a) 1 b) 1	--	a) 0.3 b) 0.3	300-500	a) 60 b) 60	56	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 CA3573 is composed of acetamiprid.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Acetamiprid					
ADI	EFSA	2016	0.025 mg/kg bw/day	rat developmental neurotoxicity study	100
ARfD	EFSA	2016	0.025 mg/kg bw	rat developmental neurotoxicity study	100

7.1.2.1 Summary for acetamiprid

Table 7.1-3: Summary for acetamiprid

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1, 2, 11, 12	Apple	Yes	Yes	Yes	Yes	Yes	No	No
4 – 10, 14 – 18	Oilseed rape	Yes	Yes	Yes	Yes	Yes		No
3, 13	Potatoes	Yes	Yes	Yes	Yes	Yes		No
19, 20	Corn/maize	Yes	Yes	Yes	Yes	Yes		No

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

The effects of processing on the nature of acetamiprid 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 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.

An acute and chronic risk has not been identified. The uses of CA3573 is therefore acceptable.

7.1.2.2 Summary for CA3573 / Carnadina / Kestrel

Table 7.1-4: Information on CA3573 / Carnadina / Kestrel (KCA 6.8)

Crop	PHI for CA3573 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CA3573 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Acetamiprid		
Apple	14 days	Yes	14 days	-
Oilseed rape	28 days	Yes	28 days	-
Potatoes	7 days	Yes	7 days	-

Crop	PHI for CA3573 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CA3573 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Acetamiprid		
Corn/maize	56 days	Yes	56 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 CA3573
Crop group	Led by acetamiprid	
Leafy vegetables	NR	-
Root vegetables	NR	-

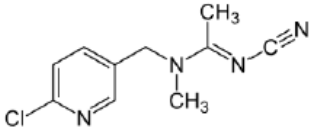
NR: not relevant

Assessment

7.2 Acetamiprid

General data on acetamiprid are summarized in the table below (last updated 2020/02/27)

Table 7.2-1: General information on acetamiprid

Active substance (ISO Common Name)	Acetamiprid
IUPAC	(E)-N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine
Chemical structure	
Molecular formula	$C_{10}H_{11}ClN_4$
Molar mass	222.68
Chemical group	Neonicotinoid
Mode of action (if available)	Systemic with translaminar activity having both contact and stomach action. Acetylcholine receptor (nAChR) agonist.
Systemic	Yes
Company	Nippon Soda Co. Ltd.
Rapporteur Member State (RMS)	Netherlands
Approval status	Approved 01/03/2018 Regulation (EU) 2018/113.
Restriction	Ban or usage restriction may be in place for use on flowering crops in some Member States
Review Report	~~SANCO/10054/2013 rev. 3, 11/07/2013~~ SANTE/10502/2017 Rev 4, 13 December 2017
Current MRL regulation	Regulation (EU) No 2019/88
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes (EFSA Journal 2016;14(11):4610 – see list of references)
EFSA Journal: conclusion on article 12	Yes (EFSA Journal 2011;9(7):2328 – see list of references)
Current MRL applications on intended uses	None

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

New stability studies have been submitted by the applicant in the framework of this application. Results are summarized in the Table below. The detailed assessment of these studies are presented in Appendix 2.
A new storage stability study investigating the stability of acetamiprid in honey for a period of 12 months is being conducted and the interim result is that Acetamiprid can be regarded as stable over 9 months storage at deep frozen storage (≤ -18 °C) in honey (KCP 8.1/03).

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	High water content	≤13 months	The Netherlands, 2015 Greece, 2001 Goller G., 1999 Report No RPA/NI-25/97051 EFSA, 2016a
Potato (tuber)	High starch content	8 months	The Netherlands, 2015, 2016 Netzband D.J., 2003 Report No RD-00243 EFSA, 2016a
Fodder peas	High protein content	12 months	The Netherlands, 2015, 2016 Jean-Baptiste C., 2009 Report No A7125 EFSA, 2016a
Cabbage, cucumber	High water content	12 months	The Netherlands, 2015, 2016 Gieseke L.D., 1999 Report No 10201 EFSA, 2016a
Lettuce (head)	High water content	15 months	
Cotton (seed)	High oil content	12 months	
Orange	High acid content	12 months	
Apple juice/wet pomace, cotton gin trash/hulls/meal/ oil, orange juice/dried pulp/oil	Processed commodities	12 months	
Animal Products			
Samples of the livestock feeding studies were stored for less than 1 month under freezer conditions, therefore, storage stability studies are not required.			

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
New data			
Plant products			
Dry bean (seed)	High protein content	12 months	KCP 8.1/01 Lefresne S., 2014 Report No B13-M1-A-02
Dry bean (straw)	Dry commodity		
Apple (fruit)	High water content		
Olive (whole fruit)	High oil content		
Orange (peel, pulp)	High acid content		
Wheat (grain)	High starch content	15 months	KCP 8.1/02 Barbier G., 2018 Report No B17G-A4-A-02
Honey	High water content	12 months	KCP 8.1/03 Müller S., 2020 Report No 20N08133-01-SSHN (interim report)

Conclusion on stability of residues during storage

EFSA (2016a) concluded: "Residue data are supported by storage stability studies where acetamiprid residues were concluded to be stable up to 1 year in high water-, high oil- and high acid-content commodities and up to 8 months in high starch-content matrices (potato tuber). Acetamiprid was stable under standard hydrolysis conditions."

The Netherlands (2015, 2016) concluded: "In all commodities, the storage was evaluated during a period of 12 months and acetamiprid was found to be stable with acceptable recoveries in all matrices studied. For head lettuce the storage stability was demonstrated over 15 months."

The new study of Barbier (2018) concluded that "at up and including 15 months of freezing storage, the loss of acetamiprid was less than 30%, in line with Guideline 7032/VI/95 rev. 5, appendix H. Thus the study demonstrated that acetamiprid residues are stable in wheat grains at/below -18°C for a storage period of 15 months."

The new study of Müller S. (2020) The storage stability results of acetamiprid in honey will be tested for a period of 12 months. This interim report shows the results of the stability over 9 months. No significant degradation of the test item during storage at ≤ -18 °C was observed for over 9 months for matrix honey.

Therefore, residues in the analysed stored commodities, which were used to support the intended uses of acetamiprid in the product CA 3573 (200 g/L acetamiprid) on apples (high water content commodities), potatoes (high starch content commodities), oilseed rape (high oil content commodities) and corn (high starch commodity) are considered stable during the respective time of storage.

Evaluator comments:
In accordance with OECD Guideline for Stability of Pesticide Residues in Stored Commodities (OECD 506, 2007) corn and potatoes belong to high starch content commodity category, oilseed rape belongs to high oil content commodity category and apples belong to high water content commodity category.

In EFSA Journal 2016;14(11):4610 it is stated that in storage stability studies acetamiprid residues were concluded to be stable up to 1 year in high water-, high oil- and high acid-content commodities and up to 8 months in high starch-content matrices (potato tuber). However study of residues in potatoes of Netzband D.J., 2003 (Report No RD-00243) is protected (Acetamiprid, List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the renewal of the active substance, October 2016, RMS: The Netherlands), so zRMS does not accept the reference to this study (to cover uses on potatoes and corn).
Applicant has submitted additional study of Lefresne, S. (2014): "*Freezing storage stability of acetamiprid in 4 plant matrices: dry (dry bean seed and straw), water (apple), fat (olive whole fruit) and acid (orange peel and pulp)*

at/below -18°C during 1 year (0, 3, 6 and 12 months)". The study has been evaluated and accepted in Registration Report, Section 4 for MCW-2222, Adama Makhteshim Ltd. (10.05.2018). The results obtained in this storage stability study demonstrate that acetamiprid is stable in plant matrices (in commodities with high water, fat, acid and in dry matter content) when stored frozen for up to 12 months. This study did not include high content starch commodities therefore it is not applicable for potatoes and corn (see proposed uses – Table GAP). Consequently, additional studies are required. Applicant has submitted an additional study of the acetamiprid storage stability in wheat grain (high content starch matrices: Gwénaëlle Barbier (2018) – "*Freezing storage stability of acetamiprid in wheat (grain) at/below -18°C during 15 months (0 and 15 months)".* The study has been evaluated and accepted in Registration Report, Section 4 for MCW-2222, Adama Makhteshim Ltd. (10.05.2018). The results obtained in this storage stability study demonstrate that acetamiprid is stable in wheat grain when stored frozen for up to 15 months.

The RMS - The Netherlands has assessed the data matching study for acetamiprid necessary for the renewal of the approval of acetamiprid in product of Nufarm Europe GmbH (2020). According to the RMS - The Netherlands opinion (December 2020): „*The storage stability is covered, in high water, high oil, high acid and dry commodities, by studies presented in the DAR and new study owned by Adama (Lefresne, 2014; Document/ Report No. B13-M1-A-02, R-33766) and Study available R-38589. Even though the applicant has access to the studies R-33766 (Lefresne, 2014) and R-38589 (Barbier, 2018) (Letter of Access dated 15 March 2018), they do not address the storage stability of residues in high starch content matrices, i.e. the matrix potatoes belong to according to OECD guideline 506. (…) It is agreed with the applicant that grains belong to the same matrix group as potatoes. However, it is noted that, according to OECD Guideline 506, the storage stability should be addressed in at least 2 diverse commodities in the high starch content group to extrapolate to all crops within that group. Member States are advised to pay attention to this requirement during evaluation of the product renewals."*

The RMS - The Netherlands took into account point 26 of OECD 506 in their opinion:
„26. If uses are sought in just one of the five commodity categories, then residue freezer storage stability data beyond one representative commodity in that category will be needed (with the exception of the high protein category, which has only one commodity type with respect to this guideline). A study on commodities in the corresponding category is conducted in accordance with the following:

High water content category:
If the stability of test substance in three diverse commodities in this category is confirmed, further examination with other crops that belong to this category is unnecessary.

High oil content category:
If the stability of test substance in two diverse commodities in this category is confirmed, further examination with other crops that belong to this category is unnecessary.

High protein content category:
If the stability of test substance in dry legume / pulses is confirmed, further examination with other commodities that belong to this category is unnecessary.

High starch content category:
If the stability of test substance in two diverse commodities in this category is confirmed, further examination with other commodities that belong to this category is unnecessary.

High acid content category:
If the stability of test substance in two diverse commodities in this category is confirmed, further examination with other commodities that belong to this category is unnecessary."

zRMS-PL position:
In two study submitted by Applicant storage stability has been covered in one commodity from each of the five commodity categories: in dry (dry bean seed and straw), water (apple), fat (olive whole fruit), acid (orange peel and pulp) and starch (wheat) at/below -18°C during 1 year.
It should be highlighted that according to the OECD 506, point 25:
"25. If residues are shown to be stable in all commodities studied, a study on one commodity from each of the five commodity categories is acceptable. In such cases, residues in all other commodities (see Annex 1) would be assumed to be stable for the same duration of time under the same storage conditions."

In our opinion, taking the above into account (point 25 of OECD 506), these two studies (which were accepted) are sufficient to demonstrate the storage stability of acetamiprid in all commodities, including potatoes and corn.

zRMS-PL sent an inquiry regarding this approach and received a reply from Ctgb experts (the Netherlands) on 26 April 2021:
"Ctgb agrees with the conclusion drawn by Poland. In case acceptable studies are available that address storage stability in one commodity from each of the five commodity categories, an extrapolation to all other crops is possible (in line with paragraph 25 of OECD Guideline 506). The data matching table will be updated accordingly."
Taking into account available studies are sufficient to demonstrate the storage stability of acetamiprid in all commodities, including oilseed rape, apples, potatoes and corn.
The studies on the magnitude of residues are valid with regard to storage stability.

Honey
The applicant submitted new study on honey of Müller S. (2020): "Determination of the Storage Stability of Acetamiprid in Honey for a period of 12 months at ≤ -18 °C", 2020, Study No. 20N08133-01-SSHN (interim report). No significant degradation of acetamiprid during storage at ≤ -18 °C was observed within 9 months for matrix honey. Therefore, acetamiprid in honey can be regarded as stable within 9 months storage at deep frozen storage (≤ -18 °C) (see Appendix 2).
Max. storage interval between sampling and analysis is 172 days so the studies Semi-field study for determining the magnitude of residues of Carnadine (CA3573) (a.s. acetamiprid) in honey is valid with regard to storage stability.

Additional studies are not required.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data
Specific studies to determine the stability of residues in stored sample extracts have not been con-ducted because the stability of the analytes through the analytical procedures is adequately demonstrated by the procedural recovery efficiencies obtained during routine analysis of residue samples.

Conclusion on stability of residues in sample extracts
Residues in the analysed sample extracts, which were used to support the intended uses of acetamiprid in the product CA 3573 SL on apples, potatoes, oilseed rape and corn are considered stable during the respective time of storage.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

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

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Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Eggplant	Pyridine-2,6-^{14}C	dotting to the leaf surface (foliar + fruit), G	0.0095 kg a.s/ha	1	7 and 14 days	0.5 ml (47.5 µg)/leaf x 3 leaves, of 3000 fold aqueous solution (95 mg/kg) of 30% SP	The Netherlands, 2015, Greece, 2001 Saito H., 1997a Report No EC-391-3 EFSA, 2016a, 2016b

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	**Rate (kg a.s./ha)**	**No**	**Sampling (DAT)**	**Remarks**	
	Apple	Pyridine-2,6-^{14}C	dotting to surface (foliar), G	0.208 kg a.s.//ha	1	0, 7, 14, 28, 62 and 90 days	0.8 ml/(4 leaves of one branch) of 2000 fold aqueous solution (103.8 mg/kg) of 20% SP, i.e. 20.8 microg a.i. /leaf	The Netherlands, 2015, Greece, 2001 Saito H., 1997b Report No EC-742-1 EFSA, 2016a, 2016b
				0.104 kg a.s./ha	1	0, 14, 28 and 62 days	0.7 ml/fruit of 2000 fold aqueous solution (104.7 mg/kg) of 20% SP, i.e. 73.3 microg a.i./fruit	
Leafy vegetables	Cabbage	Pyridine-2,6-^{14}C	foliar treatment, G	0.302 kg a.s./ha	1	0, 7, 14, 21, 28 and 63 days	10 ml/pot (one plant) of 1000 fold aqueous solution (201 mg/kg) of 20% SP	The Netherlands, 2015, Greece, 2001 Saito H., 1997c Report No EC-743-1 EFSA, 2016a, 2016b
		Pyridine-2,6-^{14}C	soil application, G	5.94 kg a.s./ha	1	7, 14, and 28 days	2 g/pot (one plant) of 2.1% granular	
		Cyano-^{14}C	foliar treatment, G	0.299 kg a.s./ha	1	0, 7, 14, 28 and 63	10 ml/pot (one plant) of 1000 fold aqueous solution (199 mg/kg) of 20% SP	The Netherlands, 2015, Greece, 2001 Kawai T., 1995 Report No EC-617-1 EFSA, 2016a, 2016b
Root and tuber vegetables	Carrot	Pyridine-2,6-^{14}C	foliar treatment, G	0.1 kg a.s./ha	2	14 days	11.12 mL (5.03 mg/vessel/ application) in acetonitrile	The Netherlands, 2015, Greece, 2001 McMillan-Staff S.L. et al., 1997 Report No 11253 EFSA, 2016a, 2016b
Pulses and oilseeds	Cotton	Pyridine-2,6-^{14}C	foliar treatment, G	0.1266 kg a.s./ha	4	14 and 28 days	--	The Netherlands, 2015 Miller N., 1999 Report No EC-97-367 EFSA, 2016a, 2016b
				1.127 kg a.s./ha	4	28 days	--	

Summary of plant metabolism studies reported in the EU
EFSA (2016a) concluded: "Metabolism in primary crops was investigated in the fruit, leafy, root and oilseeds/pulses crop groups, using ^{14}C-acetamiprid applied by dotting to the surface of the leaves and fruits (aubergine, apple), by spraying (cabbage, carrot, cotton) or using soil application (cabbage). In all plant parts, acetamiprid was identified as the major component of the radioactive residues (total radioactive residue (TRR)) accounting for ca. 30–90% TRR 14–90 days after the last application, except in head cabbage where the 6-chloronicotinic acid metabolite (IC-0) was the sole component identified, representing 46% TRR (0.023 mg eq/kg) and in cotton seeds (24% TRR at harvest, 0.27 mg/kg). IC-0 was also detected in carrot roots (26% TRR, 0.02 mg/kg). Other identified metabolites were observed at low levels, accounting mostly for less than 5% TRR, except metabolites IM-1-4 in immature carrot leaves (43% TRR)."

Regarding the residue definition, EFSA (2016a) stated: "Since acetamiprid was identified by far, as the major component of the residues in almost all plant matrices and since the toxicity of the IC-0 metabolite was concluded to be covered by the toxicity of the parent acetamiprid, the plant residue definitions for monitoring and risk assessment were limited to acetamiprid."

The Netherlands (2015, 2016) concluded: "Acetamiprid main component of residues (almost 50 to 99% TRR), except in cabbage head and cotton seeds after foliar application where metabolite IC-0 (6-chloronicotinic acid) was detected as major (ca. 46 and 24% TRR respectively). IC-0 was also present in carrot root at 26% TRR but in this case parent was the major residue."

Conclusion on metabolism in primary crops
No new studies were conducted since the metabolism of acetamiprid was sufficiently investigated in the studies presented in the RAR (The Netherlands, 2015). Since the metabolic pathway in the three different crop groups is generally similar, the residue definition for primary crops for enforcement and risk assessment is also applicable for the intended uses of acetamiprid in the product CA 3573 SL on apples, potatoes, oilseed rape and corn.

Evaluator comments:
The metabolism in plants for acetamiprid was reviewed during the Annex I inclusion and renewal process. No new data submitted in the framework of this application.
Metabolism in primary crops was investigated in the fruit, leafy, root and oilseeds/pulses crop groups.

The plant residue definitions for monitoring and risk assessment: acetamiprid.
The current residue definition set in Regulation (EC) No 396/2005 (Commission Regulation (EU) 2019/88 of 18 January 2019) is identical to the residue definition for enforcement derived by the peer review (EFSA Journal 2016;14(11):4610).
Additional studies are not required.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

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

Table 7.2-4: 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	Spinach	[Pyridyl-	soil	0.266 kg	0	BBCH 49	Since	The

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**	
		^{14}C]-IM-1-5	application, G	a.s./ha			acetamiprid DT_{50} values in soil range between 0.8-7.9 days, study was conducted with metabolite IM-1-5 the most persistent soil metabolite (DT_{50} 319 to 663 days).	Netherlands, 2015, 2016 Hobbs G., Inns L., 2012 Report No RD-02391 ** EFSA, 2016a
Root and tuber vegetables	Turnip	[Pyridyl-^{14}C]-IM-1-5	soil application, G	0.266 kg a.s./ha	0	BBCH 49		
Cereals	Wheat	[Pyridyl-^{14}C]-IM-1-5	soil application, G	0.266 kg a.s./ha	0	BBCH 30 (forage), BBCH 69/89 (hay)		
New data								
Leafy vegetables	Spinach	[^{14}C]-IM-1-5	soil application, G	0.1687 kg a.s./ha	0	BBCH 33/49	-	KCP 8.6.1/01 Hobbs G., 2017, Report No 38356
Root and tuber vegetables	Turnip	[^{14}C]-IM-1-5	soil application, G	0.1687 kg a.s./ha	0	BBCH 49	-	
Cereals	Wheat	[^{14}C]-IM-1-5	soil application, G	0.1687 kg a.s./ha	0	BBCH 30 (forage), BBCH 65 (hay), BBCH 89 (straw, grain)	-	

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

** The presented data is from protected study of Hobbs, G., Inns, L., 2012. A reference to protected data cannot be accepted (see evaluator comments).

Summary of plant metabolism studies reported in the EU

EFSA (2016a) concluded: "Having regard to the low persistence of acetamiprid in soil (highest field period required for 90% dissipation (DT_{90}) 43 days and 20°C lab DT_{90} 54 days), confined rotational crop studies were not conducted with the active substance and the metabolism in rotational crops was investigated using the more persistent soil metabolite IM-1-5 (period required for 50% dissipation (DT_{50}) 319–663 days) at a single plant back interval of 0 days. In the different rotational crops investigated (wheat, turnip, spinach), IM-1-5 was shown to remain the main component of the radioactive residues accounting in mature plant at harvest for 77–94% TRR. Additional field rotational crop studies conducted in northern and southern EU with acetamiprid applied onto the bare soil at ca. 300 g/ha, confirmed that acetamiprid, IM-1-4 and IM-1-5 residues are not expected to be present in rotational crops.

Since acetamiprid was identified by far, as the major component of the residues in almost all plant matrices and since the toxicity of the IC-0 metabolite was concluded to be covered by the toxicity of the parent acetamiprid, the plant residue definitions for monitoring and risk assessment were limited to acetamiprid. These residue definitions are identical to the definitions proposed in the framework of the review of the existing maximum residue levels (MRLs) under Article 12 of Regulation (EU) No 396/2005 (EFSA, 2011b) and implemented in the EU legislation."

Summary of new plant metabolism studies

Having regard to the low persistence of acetamiprid in soil, confined rotational crop studies were not conducted with the active substance. Metabolism in succeeding crops was investigated with the soil persistent metabolite [^{14}C]-IM-1-5. [^{14}C]-IM-1-5 was applied to the soil as a single spray application at a nominal rate of 160 g/ha; the actual application rate achieved was 168.7 g/ha. Seeds of representative cereal (spring wheat), leafy vegetable (spinach) and root vegetable (turnip) crops were sown into treated soil

within 2 hours of application. Crops were harvested at appropriate immature and mature growth stages and separated into commodities representative of food and feed items (wheat: forage, hay, straw and grain; spinach: immature and mature foliage; turnip: foliage and roots).
Total radioactive residues in the human food commodities such as wheat grain, spinach and turnip tubers were between 0.025 and 0.131 mg/kg.
IM-1-5 was the only extractable residue identified in human food commodities. Total radioactive residues in the human food commodities such as wheat grain, spinach and turnip tubers, were reasonably low (0.025 – 0.131 mg/kg). IM-1-5 accounted for 6.3 – 86.6% TRR.
Animal feed commodities such as wheat forage, hay, straw and turnip foliage showed TRRs of 0.050-0.450 mg/kg. IM-1-5 accounted for all the identified residue present in animal feed commodities and accounted for 64.6 – 81.9% TRR.

The results of the study show that IM-1-5 is taken up from calcareous soil into the crops where it is distributed throughout the crop matrices. Only limited metabolism of IM-1-5 is observed in the crops and therefore no metabolic pathway is proposed.

Conclusion on metabolism in rotational crops
One new study was conducted to investigate the metabolism of the persistent soil metabolite IM-1-5 in rotational crops. IM-1-5 was found to be the main residue in the rotational crops.

Evaluator comments:
In EFSA Journal 2016;14(11):4610 it is stated that "*Having regard to the low persistence of acetamiprid in soil (highest field period required for 90% dissipation (DT_{90}) 43 days and 20°C lab DT_{90} 54 days), confined rotational crop studies were not conducted with the active substance and the metabolism in rotational crops was investigated using the more persistent soil metabolite IM-1-5 (period required for 50% dissipation (DT_{50}) 319–663 days) at a single plant back interval of 0 days. In the different rotational crops investigated (wheat, turnip, spinach), IM-1-5 was shown to remain the main component of the radioactive residues accounting in mature plant at harvest for 77–94% TRR. Additional field rotational crop studies conducted in northern and southern EU with acetamiprid applied onto the bare soil at ca. 300 g/ha, confirmed that acetamiprid, IM-1-4 and IM-1-5 residues are not expected to be present in rotational crops."*
The presented data is from the protected study of Hobbs, G., Inns, L., 2012 (Report No RD-02391; "[^{14}C]-IM-1-5: Uptake and Metabolism of Soil Residues in Confined Rotational Crops") (see Acetamiprid, List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the renewal of the active substance, October 2016, RMS: The Netherlands), so zRMS-PL does not accept the reference to this study and new data was required to identify the plant uptake of a metabolite unique for calcareous soils. Equivalent study should be provided by the Applicant.

The Applicant provided a new metabolism study in rotational crops (Hobbs, 2017; R-37756,) to which access is granted *via* a Letter of Access from 15 March 2018.
According to the evaluation presented in "Matching active substance data necessary for the renewal of the approval of acetamiprid" (RMS: The Netherlands, December 2020) the endpoints seem to be equivalent to study RD-02391 (Hobbs & Inns, 2012). Additionally RMS - The Netherlands concluded that Member States should evaluate the study in more detail during product renewal and confirm that the study R-37756 (Hobbs, 2017) is acceptable to support the intended GAPs of the Applicant. The zRMS evaluation is presented in Appendix 2 in point A 2.1.2.1.2.1.
The study was designed to quantify the total radioactive residue levels in appropriate crop parts (i.e. immature and mature spinach; turnip leaves and tuberous roots; wheat forage, hay, straw and grain) and to determine the extractability and nature of the residues. A single application of [^{14}C]-IM-1-5 made to bare soil, at a nominal application rate of 160 g /ha. The crops used in this study were spring wheat, spinach and turnip to represent cereal, leafy vegetable and root vegetable crops, respectively. Total radioactive residues in the human food commodities (wheat grain, spinach and turnip tubers) were reasonably low (0.025 – 0.131 mg/kg).
Animal feed commodities (wheat forage, hay, straw and turnip foliage) showed higher TRRs (0.050 – 0.450 mg/kg).

zRMS confirms that the study R-37756 (Hobbs, 2017) is acceptable to support the intended GAP of the CA3573 / Carnadine / Kestrel.
Additional studies are not required.

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		
Pasteurisation (20 minutes, 90°C, pH 4)	**Test system 0.1 mg/kg** Acetamiprid only (95.6%) **Test system 1.0 mg/kg** Acetamiprid only (93.3%)	The Netherlands, 2015, 2016 McMillan-Staff S.L. and Austin D.J., 1997 Report No RPAL Study 13442 EFSA, 2016a
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	**Test system 0.1 mg/kg** Acetamiprid only (95.1%) **Test system 1.0 mg/kg** Acetamiprid only (95.59%)	
Sterilisation (20 minutes, 120°C, pH 6)	**Test system 0.1 mg/kg** Acetamiprid only (98.08%) **Test system 1.0 mg/kg** Acetamiprid only (97.57%)	

EFSA (2016b) concluded: "The effect of processing on the nature of acetamiprid residues was investigated and the results indicated that acetamiprid is hydrolytically stable under standard hydrolysis conditions (Greece, 2001; EFSA, 2011). Thus, residue definitions proposed for primary crops are also applicable for processed commodities."
The Netherlands (2015, 2016) concluded: "Acetamiprid was the main component present in all the extracts, ranging between 92.52% and 101.09% of applied radioactivity. [...] All metabolites were at concentrations lower than the trigger value of 0.05 mg/kg. Metabolite IM-1-3 was found in the maximum concentration of 0.0128 mg/kg or 1.33% of applied radioactivity. No significant degradation to carbon dioxide was observed (<0.05% of applied radioactivity). Therefore we can conclude that processing by pasteurisation, baking, brewing, boiling and sterilisation of plant materials and particularly citrus, containing acetamiprid residues, is unlikely to result in the production of any significant metabolites."

Conclusion on nature of residues in processed commodities
No new studies were conducted because the stability of acetamiprid during pasteurisation, baking, boiling, brewing and sterilisation was sufficiently investigated in the studies presented in the RAR (The Netherlands, 2015, 2016). Since the residue pattern in processed commodities is similar to the residue pattern in raw commodities, a different residue definition for processed commodities is not required.

Evaluator comments:
Data on processing studies were evaluated at the EU level. Information given by the Applicant is sufficient.
No further data are required.

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

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

Endpoints	
Plant groups covered	Fruits and fruiting vegetable (Eggplant, Apple) Leafy vegetables (Cabbage) Root and tuber vegetables (Carrot) Pulses and oilseeds (Cotton)

Rotational crops covered	Leafy vegetables (Spinach) Root and tuber vegetables (Turnip) Cereals (Wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	The only [^{14}C]-residue found in the crop commodities was IM-1-5 accounting for the entire extractable radioactive residue (≥76.8% TRR). No other metabolites or unidentified residues were observed in any crop commodity.
Processed commodities	Acetamiprid is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes Acetamiprid is stable under standard hydrolysis conditions. Pasteurisation, boiling and sterilisation are unlikely to result in any significant metabolites.
Plant residue definition for monitoring	Acetamiprid (Regulation (EU) 2019/88)
Plant residue definition for risk assessment	Acetamiprid (EFSA 2016a, EFSA 2018a)
Conversion factor from enforcement to RA	Not applicable

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

Available data

No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[pyridine-2,6-^{14}C]-acetamiprid	1 1	1 10	7	Milk	twice daily	The Netherlands, 2015, 2016 Greece, 2001 xxx xxx, 1997a Report No 628132 EFSA, 2016a
						Urine and faeces	daily	
						Tissues	at sacrifice (22 hour after final administra-tion)	
Laying poultry	Hens	[pyridine-2,6-^{14}C]-acetamiprid	5 5	1 10	14	Eggs	daily	The Netherlands, 2015, 2016 Greece, 2001 xxx xxx., 1997b Report No 628143 EFSA, 2016a
						Excreta	daily	
						Tissues	at sacrifice (24 hour after final administra-tion)	
						Excreta	24h following the first of the daily administrations and at 24h intervals thereafter	
						Tissues	at sacrifice (24 hour after final administra-tion)	

Summary of livestock metabolism studies reported in the EU
EFSA (2016a) concluded: "Metabolism studies on livestock conducted on animals dosed with ^{14}C-acetamiprid at 10 mg/kg dry matter (DM) over 7 (goat) or 17 (poultry) consecutive days were submitted. Most of the radioactivity was excreted in urine and faeces and only 2% of the administrated radioactivity was recovered in organs, tissues, blood and milk or eggs. Acetamiprid was extensively metabolised and not detected in any animal matrices except in milk. The major component was identified as the N-desmethyl metabolite (IM-2-1) representing 50–89% TRR in all animal matrices, except goat muscle (10% TRR) where residues were mainly composed of the metabolite IM-2-2 accounting for 50% TRR (0.03 mg eq/kg). The metabolic profile was confirmed by the feeding studies on cow and poultry where IM-2-1 was detected as the most abundant component in all animal matrices. Acetamiprid was not present in poultry and only detected in significant levels in milk at all feeding levels and at the highest feeding level in the other matrices."

EFSA (2012) concluded: "The metabolic patterns identified for goats and hens were consistent with the rat metabolism and acetamiprid and N-desmethyl-acetamiprid (IM-2-1) are considered as the major indicator compounds in commodities of animal origin."

Conclusion on metabolism in livestock
According to the dietary burden calculation, presented in chapter 7.2.4.1, the trigger of 0.004 mg/kg bw/day is exceeded for ruminants, poultry and pigs. Hence, investigation on the fate of residues in these animals is necessary.

Regarding fish neither metabolism nor feeding studies are required according to SANCO/11187/2013, since acetamiprid is not fat soluble (log P_{ow} of 0.8 for acetamiprid is ≤ 3) and no residues occurred in the fish feed items corn and potato.

No new studies were conducted since the metabolism of acetamiprid in livestock was sufficiently investigated in the studies presented in the RAR (The Netherlands, 2015, 2016). Therefore the residue definition for animals (ruminants, poultry and pigs) for enforcement and risk assessment, which is defined as sum of acetamiprid and metabolite IM-2-1 (N-desmethyl-acetamiprid), expressed as acetamiprid, is also applicable for the intended uses of acetamiprid in the product CA 3573 SL.

Evaluator comments:
The metabolism in livestock for acetamiprid was reviewed during the Annex I inclusion and renewal process. No new data submitted in the framework of this application.
For animal products, EFSA (EFSA Journal 2016;14(11):4610) proposes to limit the enforcement residue definition to the N-desmethyl metabolite (IM-2-1), expressed as acetamiprid since acetamiprid is extensively metabolised by animals and not detected in any animal matrices, except in milk.
The current residue definition set in Regulation (EC) No 396/2005 (Commission Regulation (EU) 2019/88 of 18 January 2019) the animal residue definition for monitoring (except honey): the sum of acetamiprid and IM-2-1, expressed as acetamiprid.

Based on animal metabolism studies, the residue definition for risk assessment was proposed by EFSA as 'the sum of acetamiprid and IM-2-1, expressed as acetamiprid' (EFSA Journal 2016;14(11):4610).
Additional studies are not required.

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

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

	Endpoints
Animals covered	Lactating goats

	Laying hens
Time needed to reach a plateau concentration	1-3 days to reach a steady state in milk
	4-8 days to reach a steady state in eggs
Animal residue definition for monitoring	Sum of acetamiprid and metabolite IM-2-1 (N-desmethyl-acetamiprid), expressed as acetamiprid (Regulation (EU) 2019/88)
Animal residue definition for risk assessment	Sum of acetamiprid and metabolite IM-2-1 (N-desmethyl-acetamiprid), expressed as acetamiprid (EFSA 2016a)
Conversion factor	Not necessary
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of CA 3573 and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [1)]	MRL compliance
Apple	EFSA, 2018a	N-EU [2)]	(Fall-back) GAP on which MRL assessment is based: 2x 0.10 kg a.s./ha, BBCH 69-81, PHI 14d, outdoor E/RA: 2x 0.03, 0.032, 2x 0.034, 0.04, 3x 0.05, 0.058, 0.068, 3x 0.07, 0.071, 0.08, 0.09, 0.12, 0.13, 0.14, 3x 0.21	N/A				
	The Netherlands, 2015, 2016 EFSA, 2016	N-EU	GAP on which EU a.s. assessment is based: 2x 0.075 kg a.s./ha, BBCH 77-87, PHI 14d, outdoor E/RA: 0.010, 2x 0.020, 0.025, 0.026, 2x 0.030, 2x 0.031, 0.034, 0.040, 2x 0.056, 0.071					
	New trials (KCP 8.3/01, KCP 8.3/02)	N-EU	Trials GAP: 2x 0.1 kg a.s./ha, BBCH 81-87, PHI 14d, outdoor E/RA: 2x 0.07, 0.08, 0.09, 0.12, 3x 0.21					
	Overall supporting data for cGAP	N-EU	cGAP on which this submission is based: 0.025-0.05 kg a.s./ha, BBCH 62-PHI, PHI 14d, outdoor E/RA: 2x 0.07, 0.08, 0.09, 0.12, 3x 0.21	E/RA: 0.11	E/RA: 0.21	0.398	0.4	Yes
Potato	EFSA, 2012	N-EU	GAP on which MRL assessment is based: 2x 0.05 kg as/ha, BBCH 60-69, PHI 7d, outdoor E/RA: 4x <0.01	N/A				
	The Netherlands, 2015, 2016 EFSA, 2016	N-EU	GAP on which EU a.s. assessment is based: 3x 0.05 kg a.s./ha, BBCH 45-93, PHI 7d, outdoor E/RA: 4x <0.01					
	New trials (KCP 8.3/03)	N-EU	Trials GAP: 2x 0.06 kg as/ha, BBCH 43-49 [3)], PHI 7d, outdoor E/RA: 4x <0.01					
	Overall supporting data for cGAP	N-EU	cGAP on which this submission is based: 0.036 kg a.s./ha, BBCH 12-79 [4)], PHI 7d, outdoor	E/RA: 0.01	E/RA: 0.01	0.010	0.01	Yes

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [1)]	MRL compliance
			E/RA: 4x <0.01					
OSR	EFSA, 2016b	N-EU	GAP on which MRL assessment is based: 2x 0.042 kg as/ha, BBCH 59 and BBCH 80, PHI not reported, outdoor E/RA: <0.01, 2x 0.02, 0.021, 0.036, 0.05, 0.11, 0.20	N/A				
	New trials (KCP 8.3/04, KCP 8.3/05)	N-EU	Trials GAP: 2x 0.06 kg as/ha, BBCH 73-80, PHI 28-31, outdoor E/RA: 2x <0.01, 0.017, 0.022, 0.028, 0.031, 0.032, 0.052					
	Overall supporting data for cGAP	N-EU	cGAP on which this submission is based: 0.06 kg as/ha, BBCH 31-71, PHI 28, outdoor E/RA: 2x <0.01, 0.017, 0.022, 0.028, 0.031, 0.032, 0.052	E/RA: 0.03	E/RA: 0.05	0.081	0.4	Yes
Maize/corn grain	New trials (KCP 8.3/06)	N-EU	Trials GAP: 0.06 kg a.s./ha, BBCH 71-75, PHI 53-58d, outdoor E/RA: 8x <0.01	N/A				
	Overall supporting data for cGAP	N-EU	cGAP on which this submission is based: 0.06 kg a.s./ha, BBCH 51-75, PHI 56., outdoor E/RA: 8x <0.01	E/RA: 0.01	E/RA: 0.01	0.010	0.01	Yes
Maize/corn whole plant	New trials (KCP 8.3/06)	N-EU	Trials GAP: 0.06 kg a.s./ha, BBCH 71-75, PHI 53-58d, outdoor E/RA: 2x 0.02, 0.04, 0.05, 0.11, 0.18, 0.24, 0.40	N/A				
	Overall supporting data for cGAP	N-EU	cGAP on which this submission is based: 0.06 kg a.s./ha, BBCH 51-75, PHI 56, outdoor E/RA: 2x 0.02, 0.04, 0.05, 0.11, 0.18, 0.24, 0.40	E/RA: 0.08	E/RA: 0.40	N/A	N/A	N/A
Honey	New trials (KCP 8.10.1/01)	N-EU	Trials GAP: 2x 80 g a.s./ha, BBCH 63-65, PHI n.a., indoor E/RA: 0.03, 0.09, 0.16, 0.85	0.13	0.85	2.00	0.05*	No [5)]

1) Source of EU MRL: Reg. (EU) 2019/88
2) Combined data set of trials on apples (21) and pears (2) compliant with GAP or with dose rate within the 25% deviation
3) BBCH 43-49 correspond to growth stages for tuber fromation (consumable part)
4) BBCH 12-79 correspond to growth stages for leaf development and development of fruit
5) Please reref to the Expert Statement on the “Possibility to Estimate Residue Levels for Acetamiprid in Honey” (Appendix 4, KCP 8.10.1/02) providing an argumentation, why the currently valid EU MRL is reliable to reflect residue levels originating from approved uses of acetamiprid

7.2.3.2 Conclusion on the magnitude of residues in plants

Apple

According to the available data, the intended GAP uses of acetamiprid in the product CA 3573 SL on apple are considered acceptable for outdoor uses.

A total of eight residue trials in Northern Europe were performed in apple. All trials are highly overdosed, but as the established EU MRL will not be exceeded, the submitted trials represent the worst case.
According to SANCO/7525/VI/95-rev.10.3 (Table 1), apple is a major crop in Northern Europe. For major crops, usually eight trials have to be submitted to estimate the residues which will be found after application of the product. Therefore, sufficient residue trials are available to support the intended GAP uses on apple.

If residues at a later sampling point were higher than at the intended PHI, these values were used for MRL calculation instead. The data submitted show that no exceedance of the EU MRL of 0.4 mg/kg for apple will occur. The uses are considered acceptable.

Potato

According to the available data, the intended GAP uses of acetamiprid in the product CA 3573 SL on potato are considered acceptable for outdoor uses.

A total of four residue trials in Northern Europe were performed in potato. All trials are overdosed but represents the worst case, since even with a higher application no residues above the LOQ occur.
According to SANCO/7525/VI/95-rev.10.3 (Table 1), potato is a major crop in Northern Europe. For major crops, usually eight trials have to be submitted to estimate the residues which will be found after application of the product. If residue trials show that the residue levels are lower than the LOQ, only a minimum of four trials per zone is required for major crops. Therefore, sufficient residue trials are available to support the intended GAP uses on potato.

The data submitted show that no exceedance of the EU MRL of 0.01 mg/kg for potato will occur.
The uses are considered acceptable.

Oilseed rape

According to the available data, the intended GAP uses of acetamiprid in the product CA 3573 SL on oilseed rape are considered acceptable for outdoor uses.

A total of eight residue trials in Northern Europe were performed on oilseed rape. All trials are overdosed with applications at later growth stages. Since residues are comparable and the calculated MRL based on these trials are well below the established EU MRL, the submitted trials represent the worst case.
According to SANCO/7525/VI/95-rev.10.3 (Table 1), oilseed rape is a major crop in Northern Europe. For major crops, usually eight trials have to be submitted to estimate the residues which will be found after application of the product. Therefore, sufficient residue trials are available to support the intended GAP uses on oilseed rape.

The data submitted show that no exceedance of the EU MRL of 0.4 mg/kg for oilseed rape will occur.
The uses are considered acceptable.

Maize/corn

According to the available data, the intended GAP uses of acetamiprid in the product CA 3573 SL on maize are considered acceptable for outdoor uses.

A total of eight residue trials in Northern Europe were performed in accordance with the intended GAP uses for maize. All trials show residue levels lower than the LOQ.

According to SANCO/7525/VI/95-rev.10.3 (Table 1), maize is a major crop in Northern Europe. For major crops, usually eight trials have to be submitted to estimate the residues which will be found after application of the product. If residue trials show that the residue levels are lower than the LOQ, only a minimum of four trials per zone is required for major crops. Therefore, sufficient residue trials are available to support the intended GAP uses on maize.

The data submitted show that no exceedance of the EU MRL of 0.01 mg/kg for maize will occur.
The uses are considered acceptable.

Evaluator comments:

Apple

Apple is a major crop in northern Europe. A minimum of eight trials representative of the proposed growing area are required (EU guideline Document SANCO 7525/VI/95 rev.10.3 of 13 June 2017).

Applicant submitted sufficient number of residue trials (8 outdoor apples trials conducted in northern EU 2222 in the growing seasons 2013 and 2014) to support the proposed use of CA3573 on apple in Central Europe. The studies have been evaluated and accepted in Registration Report, Section 4 for MCW-2222, Adama Makhteshim Ltd. (10.05.2018).

All trials are overdosed and the trials are not within the ± 25% (in accordance with the SANCO 7525/VI/95 rev. 10.3 June 2017) but represents the worst case.

After two treatments with MCW-2222 (200 g a.i./ha) the residues of acetamiprid in apples ranged from 0.06 mg/kg to 0.21 mg/kg at 14 DALA.

After one treatment with MCW-2222 (100 g a.i./ha), the residues of acetamiprid in apples ranged from 0.03 to 0.12 mg/kg at 14 DALA (normal commercial harvest).

The value of EU MRL for acetamiprid in apple equals 0.4 mg/kg (Commission Regulation (EU) 2019/88 of 18 January 2019). The residues arising from the proposed use will not exceed the MRL for acetamiprid established for apple.

Proposed use of CA3573 / Carnadine/ Kestrel on apple is accepted according to the proposed GAP.

Potatoes

Potatoes are the major crops in northern Europe. A minimum of eight trials representative of the proposed growing area are required (EU guideline Document SANCO 7525/VI/95 rev.10.3 of 13 June 2017).

Applicant submitted 4 outdoor potatoes trials conducted in northern EU in 2013 to support the proposed use of CA3573 on potatoes in Central Europe.

The residue trials have been conducted at a significantly higher application rate (2x 60 g a.s./ha) than proposed application rate (1x 36 g a.s./ha; see table GAP) and the trials are not within the ± 25% (in accordance with the SANCO 7525/VI/95 rev. 10.3 June 2017) but represent the "worst scenario".

Residues of acetamiprid in untreated and treated specimens (after two treatments with MCW-2222; 200 g a.i./ha) were below the limit of detection (<30% of limit of quantification, i.e. 0.003 mg/kg).

The reduced number of residue trials is considered acceptable in this case, because all results were below the LOQ and a no residues situation is expected. Further residue trials are therefore not required.

The value of EU MRL for acetamiprid in potatoes equals 0.01* mg/kg (Commission Regulation (EU) 2019/88 of 18 January 2019). The residues arising from the proposed use will not exceed the MRL for acetamiprid established for potatoes.

Proposed use of CA3573 / Carnadine/ Kestrel on potatoes is accepted according to the proposed GAP.

Oilseed rape

Oilseed rape is a major crop in northern Europe. A minimum of eight trials representative of the proposed growing area are required (EU guideline Document SANCO 7525/VI/95 rev.10.3 of 13 June 2017).

Applicant submitted 8 outdoor oilseed rape trials conducted in northern EU in 2013 and 2014 to support the proposed use of CA3573 on oilseed rape in Central Europe.

The plots were treated once or twice with MCW-2222 at the rate of 0.3 L/ha (60 g a.i./ha of acetamiprid).

Residues of acetamiprid in untreated specimens were below the limit of detection (<30% of limit of quantification, i.e. 0.003 mg/kg).

After one treatment with MCW-2222, the residues of acetamiprid in seeds specimens were from <0.01 mg/kg to 0.037 mg/kg at DALA 28-31.

After two treatments with MCW-2222, the residues of acetamiprid in seeds specimens were from <0.01 mg/kg to 0.052 mg/kg at DALA 28-31.

The value of EU MRL for acetamiprid in oilseed rape equals 0.4 mg/kg (Commission Regulation (EU) 2019/88 of 18 January 2019). The residues arising from the proposed use will not exceed the MRL for acetamiprid established for oilseed rape.
Proposed use of CA3573 / Carnadine/ Kestrel on oilseed rape is accepted according to the proposed GAP.

Maize/corn
Maize is a major crop in northern Europe. A minimum of eight trials representative of the proposed growing area are required (SANCO 7525/VI/95 rev.10.3 of 13 June 2017).
Applicant has submitted eight residue trials which were conducted in compliance with the intended GAP use.
Residues of acetamiprid in untreated specimens were below the limit of detection (<30% of limit of quantification, i.e. 0.003 mg/kg).
After one treatment with MCW-2222, the residues of acetamiprid in grain and cobs were below the LOQ of 0.01 mg/kg.
The value of EU MRL for acetamiprid in maize equals 0.01* mg/kg (Commission Regulation (EU) 2019/88 of 18 January 2019). The residues arising from the proposed use will not exceed the MRL for acetamiprid established for maize.
Proposed use of CA3573 / Carnadine/ Kestrel on maize is accepted according to the proposed GAP.

* Indicates lower limit of analytical determination

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-10: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure, the uses under consideration and in EFSA 2018a)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: acetamiprid				
Alfalfa, forage (green)	0.09	STMR (EFSA, 2018a)	0.41	HR (EFSA, 2018a)
Alfalfa, hay (fodder)	0.23	STMR x 2.5[a)] (EFSA, 2018a)	1.03	STMR x 2.5[a)] (EFSA, 2018a)
Alfalfa, meal	0.23	STMR x 2.5[a)] (EFSA, 2018a)	1.03	STMR x 2.5[a)] (EFSA, 2018a)
Alfalfa, silage	0.10	STMR x 1.1[a)] (EFSA, 2018a)	0.45	STMR x 1.1[a)] (EFSA, 2018a)
Barley, straw Oat, straw	0.18	STMR (EFSA, 2018a)	0.32	HR (EFSA, 2018a)
Cabbage, heads leaves	0.10	STMR (EFSA, 2018a)	0.50	HR (EFSA, 2018a)
Corn, field (forage/silage, stover) Corn, pop (stover)	0.08	STMR (see Table 7.2-9)	0.40	HR (see Table 7.2-9)
Corn, grain	0.01	STMR (see Table 7.2-9)	0.01	HR (see Table 7.2-9)
Kale, leaves (forage)	0.10	STMR (EFSA, 2018a)	0.73	HR (EFSA, 2018a)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Triticale, straw Wheat, straw	0.27	STMR (EFSA, 2018a)	1.6	HR (EFSA, 2018a)
Potato, culls	0.01*	STMR (EFSA, 2018a)	0.01*	STMR (EFSA, 2018a)
Barley, grain Oat, grain	0.01	STMR (EFSA, 2018a)	0.01	STMR (EFSA, 2018a)
Bean, seed (dry) Cowpea, seed Lupin, seed Pea (Field pea), seed (dry)	0.02	STMR (EFSA, 2018a)	0.02	STMR (EFSA, 2018a)
Cotton, undelinted seed	0.09	STMR (EFSA, 2018a)	0.09	STMR (EFSA, 2018a)
Triticale, grain Wheat, grain	0.01	STMR (EFSA, 2018a)	0.01	STMR (EFSA, 2018a)
Apple, pomace, wet	0.30	STMR x PF (1.3) (EFSA, 2018a)	0.30	STMR x PF (1.3) (EFSA, 2018a)
Brewer's grain, dried Wheat, distiller's grain (dry)	0.03	STMR x 3.3[a)] (EFSA, 2018a)	0.03	STMR x 3.3[a)] (EFSA, 2018a)
Canola (Rape seed), meal	0.06	STMR x 2[a)] (EFSA; 2018a)	0.06	STMR x 2[a)] (EFSA; 2018a)
Citrus fruits, dried pulp	1.90	STMR x 10[a)] (EFSA, 2018a)	1.90	STMR x 10[a)] (EFSA, 2018a)
Coconut, meal	0.02	STMR x 1.5[a)] (EFSA; 2018a)	0.02	STMR x 1.5[a)] (EFSA; 2018a)
Cotton, meal	0.04	STMR x PF (0.4) (EFSA, 2018a)	0.04	STMR x PF (0.4) (EFSA, 2018a)
Lupin seed, meal	0.02	STMR x 1.1[a)] (EFSA, 2018a)	0.02	STMR x 1.1[a)] (EFSA, 2018a)
Potato, process waste	0.01*	STMR[b)] (EFSA, 2018a)	0.01*	STMR[b)] (EFSA, 2018a)
Potato, dried pulp	0.01*	STMR[b)] (EFSA, 2018a)	0.01*	STMR[b)] (EFSA, 2018a)
Rape, meal	0.06	STMR x 2[a)] (EFSA, 2018a)	0.06	STMR x 2[a)] (EFSA, 2018a)
Wheat gluten, meal	0.02	STMR x 1.8[a)] (EFSA, 2018a)	0.02	STMR x 1.8[a)] (EFSA, 2018a)
Wheat, milled by-pdts	0.07	STMR x 7[a)] (EFSA; 2018a)	0.07	STMR x 7[a)] (EFSA; 2018a)

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

a) For alfalfa hay forage and silage, for distiller's grains, for meals of oilseeds, coconuts, wheat gluten and lupin seeds and for wheat milled by-products, in the absence of processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in these commodities.

b) For potatoes process waste and dried pulp, no default processing factor was applied because residues in the raw commodities were below the LOQ. Concentration of residues in these commodities is therefore not expected.

Table 7.2-11: Results of the dietary burden calculation[a)]

Relevant groups	Dietary burden expressed in				Most critical diet[b)]	Most critical commodity[c)]	Trigger (0.004 mg/kg bw) exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Risk assessment residue definition: acetamiprid							
Cattle (all diets)	**0.167**	**0.199**	**4.33**	**5.17**	**Dairy cattle**	**Citrus, dried pulp**	**Yes**
Cattle (dairy only)	0.167	0.199	4.33	5.17	Dairy cattle	Citrus, dried pulp	Yes
Sheep (all diets)	0.027	0.047	0.80	1.40	Lamb	Wheat, straw	Yes
Sheep (ewe only)	0.027	0.047	0.80	1.40	Ram/Ewe	Wheat, straw	Yes
Swine (all diets)	**0.074**	**0.084**	**3.23**	**3.65**	**Swine (breeding)**	**Citrus, dried pulp**	**Yes**
Poultry (all diets)	**0.008**	**0.018**	**0.11**	**0.26**	**Poultry layer**	**Wheat, straw**	**Yes**
Poultry (layer only)	0.008	0.018	0.11	0.26	Poultry layer	Wheat, straw	Yes

a) Performed according to "OECD Guidance Document, series on testing and assessment number 64, series on pesticides 32" and "OECD Guidance 73 on Residue in livestock", calculated with Animal model 2017.xls.
b) 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".
c) The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

Values in bold were considered for the calculation of the overdosing factor and therefore for the comparison with livestock feeding results

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

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

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	Calculated MRL (mg/kg)	CF for RA[d]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[a]	No	Result for enforcement[f]		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (The Netherlands, 2016[R], EFSA, 2012)												
Enforcement residue definition: sum of acetamiprid and metabolite IM-2-1, expressed as acetamiprid												
Pig meat	0.074	0.084	0.21	3	0.05	0.05	See results for enforcement residue definition		0.02	0.02	0.02	1
			0.63	3	0.18	0.29						
			2.13	3	0.97	1.11						
Pig fat			0.21	3	0.03	0.06			0.01	0.03	0.04	1
			0.63	3	0.07	0.15						
			2.13	3	0.36	0.71						
Pig liver			0.21	3	0.15	0.15			0.06	0.06	0.07	1
			0.63	3	0.45	0.64						
			2.13	3	2.29	2.65						
Pig kidney			0.21	3	0.24	0.25			0.09	0.10	0.1	1
			0.63	3	0.70	0.86						
			2.13	3	2.39	2.54						
Ruminant meat	0.1667	0.199	0.21	3	0.05	0.05			0.04	0.05	0.05	1
			0.63	3	0.19	0.31						
			2.13	3	1.03	1.18						
Ruminant fat			0.21	3	0.04	0.08			0.03	0.08	0.08	1
			0.63	3	0.08	0.16						
			2.13	3	0.39	0.76						
Ruminant liver			0.21	3	0.16	0.16			0.13	0.15	0.15	1
			0.63	3	0.47	0.68						
			2.13	3	2.43	2.81						

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	Calculated MRL (mg/kg)	CF for RA[d]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[a]	No	Result for enforcement[f]		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Ruminant kidney			0.21	3	0.25	0.26			0.19	0.30	0.3	1
			0.63	3	0.75	0.91						
			2.13	3	2.55	2.70						
Milk	0.1667	0.199	0.21	3	0.07[e]	N/A			0.06	0.07	0.07	1
			0.63	3	0.24[e]	N/A						
			2.13	3	1.09[e]	N/A						
Poultry[g] meat	0.008	0.018	1.16	10	<0.02	<0.02			0.003	0.007	0.007	1
			3.51	10	0.034	0.039						
			12.0	10	0.084	0.090						
Poultry[g] fat			1.16	10	<0.02	<0.02			0.003	0.007	0.007	1
			3.51	10	<0.02	<0.02						
			12.0	10	0.022	0.023						
Poultry[g] liver			1.16	10	0.12	0.15			0.018	0.05	0.05	1
			3.51	10	0.24	0.27						
			12.0	10	0.55	0.58						
Eggs[g]	0.008	0.018	1.16	10	0.039	0.041			0.023	0.137	0.15	1
			3.51	10	0.10	0.11						
			12.0	10	0.33	0.36						

(R): Reference: author sanitized, 1999; Report No RD-9989 & author sanitized, 1999; Report No RD-9988
N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.
n.r.: Not reported
(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): Based on nine 562-688 kg lactating cows consuming 6, 18 and 60 mg acetamiprid per kg DM per day (mg/kg DM/day).
(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(d): The median conversion factor for enforcement to risk assessment.
(e): Mean residue level from day 1 until day 28 (3 cows, 11 sampling days).

(f): Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as acetamiprid [mg/kg], calculated while considering a molar mass of 222.68 for acetamiprid and 208.65 for N-desmethyl-acetamiprid

(g): The dietary burden calculation was done by considering a body weight of 1.9 kg for layer according to "OECD Guidance Document, Series on testing and assessment No 64 and Series on pesticides No 32" and "OECD Guidance Document on Residues in livestock, Series on Pesticides No 73".

Summary of feeding studies reported in the EU
EFSA (2018a) concluded: "The calculated dietary burdens exceed the trigger value of 0.1 mg/kg dry matter (DM) for all livestock species and the main contributors are kale leaves (cattle and swine diet) and wheat straw (sheep and poultry diet). Nevertheless, the existing EU MRLs for cattle, sheep and swine tissues and milk, reflect the existing CXLs which are based on a livestock dietary exposure significantly higher than the intake calculated in this framework. […] Therefore, it is concluded that the withdrawal of the most critical uses on kale and apples and the new intended use on barley and oats is not expected to have an impact on the dietary burden calculated for livestock, and thus, there is no need to modify the existing EU MRLs for commodities of animal origin."

The Netherlands (2016) concluded: "However, considering the metabolism study, no residues exceeding the LOQ are expected in any poultry tissues or eggs. Since the representative uses of acetamiprid do neither lead to a significant intake for poultry, this study was not evaluated. The same was concluded in the original DAR: the feeding poultry study was submitted, but not evaluated. However, during the peer review process for the renewal of acetamiprid, it has been requested to evaluate this study."

Conclusion on feeding studies
With the results of the feeding study in ruminants and the results of the dietary burden calculation (see Table 7.2-11), MRLs for pigs and ruminants have been generated. The intended uses of acetamiprid in the product CA 3573 SL do not lead to an exceedance of the existing EU MRL for animal commodities.

A poultry feeding study was conducted and evaluated in the RAR but based on the metabolism study, "no residues exceeding the LOQ are expected in any poultry tissues or eggs" (The Netherlands, 2016). Therefore, the poultry study is presented in Table 7.2-12 as supplemental information. However, the calculated MRL in eggs of 0.15 mg/kg exceeds the current EU MRL of 0.02 mg/kg. Considering the lowest dose level of 1.16 mg/kg bw/d and therefore an 80x higher expected feed burden for poultry, the recalculated MRL would be 0.002 mg/kg. Therefore, there is no risk for animal MRL to be exceeded.

Evaluator comments:
Magnitude of residues in livestock were evaluated at the EU level. Information given by the Applicant is sufficient.
No residues above the MRLs of acetamiprid in tissues, milk and eggs have to be expected after application of CA3573 / Carnadine / Kestrel according to the intended GAP uses.
No further data are required.

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

7.2.5.1 Available data for all crops under consideration

New processing studies have been submitted by the applicant in the framework of this application. These studies are summarized in the table below. The detailed results are presented in Appendix 2.

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: Acetamiprid					
Apple, juice	2	0.80	1	-	The Netherlands, 2015, 2016 Kowite, W.J., 1999 Report No 97512650 Venet, C., Barriere, I., 2000 Report No R&D/CRLD/AN/mba/0015360 EFSA, 2016a
Apple, wet pomace	2	1.30	1	-	

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
New data					
Enforcement residue definition: Acetamiprid					
Apple, juice	2	0.48	1	-	KCP 8.5.3/01 Roussel Ch. H., 2014 Report No ChR-14-17311
Apple, wet pomace	2	1.08	1	-	
Apple, dry pomace	2	3.73	1	-	
Apple, puree	2	0.60	1	-	
Apple, washed	2	0.68	1	-	
Washing water	2	0.05	1	-	
Apple, dried	2	3.15	1	-	

* 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

Processing studies investigating the magnitude of residues in processed commodities are presented in the AIR-DAR (Greece, 2011) and RAR (The Netherlands, 2015, 2016). A new processing study have been performed in apple.

EFSA (2016a) concluded: "Processing studies on apple were submitted and processing factors were derived for juice and wet pomace."

New processing factors were derived for apple juice, wet pomace, dry pomace, puree, washed fruit, washing water and dried apple.

Further processing studies are not considered necessary to support the intended uses of acetamiprid in the product CA 3573, since the magnitude of residues in processed commodities was sufficiently investigated in the studies presented above.

Evaluator comments:
Information given by the Applicant is sufficient. Applicant has submitted processing study on apples (Roussel, Ch. H. 2014; Study number: ChR-14-17311, see Appendix 2, point A 2.1.5.2.1).
Residues of acetamiprid were analysed in processed samples / processing fractions (dry apples, washing water, apple juice, apple puree, wet apple pomaces and dry apple pomaces).
Acetamiprid residues in washed fruits, washing water, wet pomaces, dry pomaces, juice, puree and dried apples ranged between 0.24 – 0.26 mg/kg, < 0.01 – 0.03 mg/kg, 0.33 – 0.47 mg/kg, 1.36 – 1.4 mg/kg, 0.17 – 0.18 mg/kg, 0.21 – 0.23 mg/kg and 1.15 – 1.18 mg/kg, respectively.
The average transfer factor is 3.73 for dry pomace and 3.15 for dried fruits which show a concentration of acetamiprid during drying.
The residues in other processed products are likely stable.

No further data are required.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Data dealing with magnitude of residues in succeeding crops are available and summarized hereafter.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

New studies for residues in succeeding crops have been submitted by the applicant in the framework of this application. These studies are summarized in the table below. The detailed results are presented in Appendix 2.

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

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops				
		Succeeding crop group	Succeeding crop[1)]	Sowing intervals (DAT)	Residues[2)] (mg/kg)	Reference / Remarks
EU data						
n.a.*	0.2817-0.3217 (bare soil)	Leafy vegetables	Spinach (leaves)	31-32 72-73 122 367	<0.01 <0.01 <0.01 <0.01	The Netherlands, 2015 Raufer B., 2013 Report No RD-02495N2 ** EFSA, 2016a
		Root and tuber vegetables	Turnip (plant, top and roots)	29 69 119 410	<0.01 <0.01-0.01[3)] <0.01 0.03-0.15[4)]	
		Cereals	Wheat (forage, hay, grain and straw)	30-32 63-70 119-132 364-377	<0.01 <0.01 <0.01 <0.01	
n.a.*	0.2908-0.3133 (bare soil)	Root and tuber vegetables	Turnip (plant, top and roots)	30 69 120 363	<0.01 <0.01 <0.01 <0.01	The Netherlands, 2015 Raufer, B., 2014 Report No RD-02930 ** EFSA, 2016a
New data						
n.a.*	0.1949-0.2165 (bare soil)	Root and tuber vegetables	Radish (roots and leaves)	30 120 270	<0.01 <0.01-0.01[5)] <0.01	KCP 8.6.2/01 Semrau J., 2017 Report No S15-02364
	0.1949-0.2165 (bare soil)	Leafy vegetable	Spinach (leaves)	30 120 270	<0.01 <0.01 <0.01	
	0.1949-0.2165 (bare soil)	Cereals	Wheat (grain and straw)	30 120 270	<0.01 <0.01 <0.01	

* Application to bare soil

1) Residue soil samples were also taken (at 0 DBA / 0 DAA, 0 DAS, at the time of earliest crop stage to be sampled and at harvest date of the crop)

2) Residues were analysed for acetamiprid, IM-1-4 and IM-1-5

3) Residues were <0.01 mg/kg for acetamiprid and IM-1-4; 0.01 mg/kg for IM-1-5 in turnip whole plant at DAA 128

4) Residues were 0.04 mg/kg for acetamiprid, 0.15 mg/kg for IM-1-4 and 0.03 for IM-1-5 in turnip whole plant at DAA 445

5) Residues were not detectable for acetamiprid (<0.003 mg/kg), <0.01 mg/kg for IM-1-4 and 0.01 mg/kg for IM-1-5 in radish leaves at 160 DAA

** The presented data is from protected studies of Raufer B., 2013 and 2014. A reference to protected data cannot be accepted (see evaluator comments).

EFSA (2018a) concluded: "Field rotational crop studies conducted in northern and southern EU with acetamiprid applied onto the bare soil at ca 300 g/ha were evaluated during the peer review for the renewal. On the basis of these studies, it was concluded that acetamiprid and metabolite IM-1-5 are not expected to

be present in rotational crops following treatment according to the representative uses (EFSA, 2016b). Considering that the conditions of application of the representative uses assessed during the renewal cover the new intended use, this conclusion is still relevant in the framework of the present assessment."

One new field rotational study was conducted. Acetamiprid was applied to the raw agricultural commodities radish, spinach and wheat to bare soil at a target rate of 200 g ai/ha and at different plant-back intervals. Specimens of radish, spinach, wheat and soil were analysed for residues of acetamiprid and its metabolites IM-1-4 and IM-1-5. Residue levels for acetamiprid were not detectable (<0.003 mg/kg) and residues for its metabolites were at (IM-1-5, radish leaves, 160 DAA) or below the LOQ (<0.01 mg/kg) or also not detectable.

Conclusion on rotational crops studies
Field rotational crop studies are presented in the RAR and Addendum (The Netherlands, 2015 and 2016). Additionally, one new study is submitted within this submission. For the intended uses of acetamiprid in the product CA 3573, no residues are expected in rotational crops. No further studies are required.

Evaluator comments:
The presented data in EFSA (2016) is from the protected study of Raufer B., 2013 and 2014 (Report No RD-02495N2 and Report No RD-02930) (see Acetamiprid, List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the renewal of the active substance, October 2016, RMS: The Netherlands), so zRMS-PL does not accept the reference to this study and new data was required to identify the plant uptake of a metabolite unique for calcareous soils. Equivalent study should be provided by the Applicant.

The Applicant provided a confined field rotational study (Semrau J., 2017, Report No S15-02364, R-35750) to which access is granted *via* a Letter of Access from 15 March 2018.
According to the evaluation presented in "Matching active substance data necessary for the renewal of the approval of acetamiprid" (RMS: The Netherlands, December 2020) the endpoints seem to be equivalent to study S10-02822 (Raufer, 2013).
Additionally RMS - The Netherlands concluded that Member States should evaluate the study in more detail during product renewal and confirm that the study R-35750 (Semrau J., 2017) is acceptable to support the intended GAPs of the Applicant. The zRMS evaluation is presented in Appendix 2 in point A 2.1.6.1.

Two rotational crop trials were conducted during 2015 and 2016 in Germany and in France to determine residue levels of acetamiprid and its metabolites IM-1-4 and IM-1-5 in soil and in the raw agricultural commodities: root and tuber vegetables (radish), leafy vegetables (spinach) and cereals (wheat) grown as rotational crops at harvest after one application of MCW-2222 to bare soil. Each trial comprised three plant back intervals of nominal 30, 120 and 270 days.
Residue levels for acetamiprid were not detectable (<0.003 mg/kg) and residues for its metabolites were at (IM-1-5, radish leaves, 160 DAA) or below the LOQ (<0.01 mg/kg) or also not detectable.
For the intended uses of acetamiprid in the product CA 3573 / Carnadine / Kestrel, no residues are expected in rotational crops.

zRMS confirms that the study R-35750 (Semrau J., 2017) is acceptable to support the intended GAPs of the CA3573 / Carnadine / Kestrel.

Taking into account the above information zRMS does not propose a restriction with regard to the succeeding crops. No waiting periods beyond normal agricultural practice are proposed for succeeding crops to be planted.

Additional studies are not required.

7.2.7 Other / special studies (KCA 6.10, 6.10.1)

The data requirement objective of these studies is to determine the residue in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at flowering. According to SANTE/11956/2016 rev. 9, of the intended uses, apples and oilseed rape are considered to possess

melliferous capacity.
Therefore, a study determining the residue levels of acetamiprid in honey (KCP 8.10.1/01) was performed in accordance with SANTE/11956/2016 rev. 9. The study was conducted using *Phacelia tanacetifolia* as surrogate crop with high melliferous capacity under semi-field conditions and at four different locations in Germany and France. At each test location one control and one test item tunnel was used. One colony was setup per tunnel. The treatment included two applications at an application rate of 80 g a.s./ha.

The analysed residues of acetamiprid in honey samples after the applications in the treated tunnels are given in the table below:

Table 7.2-15: Overview of the values derived from the magnitude of residues in honey study

Type of sample	Study site	Acetamiprid [mg/kg]
Honey	Study 1 (Heddesheim, Germany)	0.03
	Study 2 (Drusenheim, France)	0.85, 0.53
	Study 3 (Limburgerhof, Germany)	0.09
	Study 4 (Brensbach, Germany)	0.16

The samples were stored deep-frozen and storage in this study exceeds 30 days. Therefore, a new storage stability study investigating the stability of acetamiprid in honey for a period of 12 months, is being conducted and the interim result is that Acetamiprid can be regarded as stable over 9 months storage at deep frozen storage (≤ -18 °C) in honey (KCP 8.1/03).

The analytical method used for sample extraction and determination of residues was fully validated within this study. Quantification was performed by use of HPLC with MS/MS detection.
The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg and with a limit of detection (LOD) was set at 0.003 mg/kg (30% of the LOQ).

Conclusion on the honey study
The application of the test item on two different consecutive dates resulted in residues in honey of 0.03 mg/kg acetamiprid (study field 1), 0.85 mg/kg acetamiprid in the A-sample and 0.53 mg/kg in the B-sample (study field 2), 0.09 mg/kg acetamiprid (study field 3) and 0.16 mg/kg acetamiprid (study field 4).

Residues in honey would lead to a calculated MRL of 2.0 mg/kg by using the new EU MRL calculator of 2015. But the experimental setup proposed in the technical guidance on residues in pollen and bee products using highly bee-attractive crops to reflect intended uses of acetamiprid in apple and oilseed rape result in unrealistic high residue levels and leads to a massive over-estimation of MRL's in honey. As indicated by monitoring data (EFSA 2014, 2015, 2016c, 2017, 2018b, 2019 and 2020; please also refer to KCP 8.10.1/03 to KCP 8.10.1/09) residues from approved uses as well as unintentional drift to non-target crops will be well below any artificial "worst-case" scenario. Only 0.26% of the total number of analysed honey samples for acetamiprid during 2012 and 2018 exceeded the EU MRL in honey above the level of quantification (0.05 mg/kg). It can be concluded, that the results of the EU monitoring programmes show that no residues of acetamiprid are present in the vast majority of samples. Therefore, no risk for the consumers is expected.

Please refer to the Expert Statement on the "Possibility to Estimate Residue Levels for Acetamiprid in Honey" (Appendix 4, KCP 8.10.1/02) providing an argumentation, why the currently valid EU MRL is reliable to reflect residue levels originating from approved uses of acetamiprid.

Evaluator comments:
The study objective was the determination of residues of acetamiprid in samples of honey, derived from field trials performed by RIFCON GmbH.
Residue levels of the active substance acetamiprid in honey were determined after two consecutive applications at nominal application rates of 80 g/ha acetamiprid per application of the test item Carnadine (CA3573 SL, 200 g/L acetamiprid). The test was conducted under tunnel conditions in summer 2019 at four different study fields. All trials are highly overdosed in comparison with the proposed GAP for Carnadine/ Kestrel. According to the proposed GAP max application rate per treatment is at 60 g as/ ha and one application in season.
No residues above the limit of detection (0.003 mg/kg) of acetamiprid in untreated honey field trial samples were

found. In treated honey field trial samples, the residues of acetamiprid range from 0.03 mg/kg to 0.85 mg/kg. The study is acceptable (more details – see Appendix 2).

The analytical method was fully validated in the current study according to guideline SANCO/3029/99 rev.4 at a limit of quantification of 0.01 mg/kg for matrix honey. Final determination was performed using HPLC-MS/MS.

Evaluator agrees with presented argumentation of Applicant, that the experimental setup proposed in the technical guidance on residues in pollen and bee products using highly bee-attractive crops to reflect intended uses of acetamiprid in apple and oilseed rape result in unrealistic high residue levels and leads to a massive over-estimation of MRL's in honey.
Taking into account the results of the EU monitoring programs it can be concluded, that no residues of acetamiprid are present in the vast majority of samples. Therefore, no risk for consumers is expected.

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

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

After the commenting period the RMS for acetamiprid (NL) informed Polish authorities that although in the data matching table for acetamiprid of June 2021 (and also of December 2020) it was concluded that the data matching was shown sufficiently by Nufarm GmbH & Co. KG, there was a mistake made by the RMS and the conclusion has to be amended since Nufarm needs to show the access to the study on oral developmental toxicity by Nemec (2008), which was used to derive the toxicological reference values and for this reason should have been considered necessary for the active substance renewal.
According to indications of SANTE/2016/11449 (rev 1.5 of October 2021), submission of evidence on ongoing negotiations and steps taken to get access to the vertebrate study are sufficient to conclude matching of the vertebrate data. In support of the zonal evaluation of CA3573, Nufarm submitted copies of the correspondence with the acetamiprid authorisation holder showing that negotiations on the access to the study by Nemec (2008) are ongoing. In addition to that it has to be noted that in line with Article 62 of Regulation (EC) No 1107/2009, the MS authority may use the vertebrate study in evaluation of the application of the prospective Applicant (here: Nufarm) also in case when no agreement with the authorisation holder is reached. Taking this into account, the endpoint from the study may be conditionally used in evaluation performed in area of the residue section, even before the agreement between the two companies is reached.

7.2.8.1 Input values for the consumer risk assessment

Please note, only EU evaluated data were considered for the consumer risk assessment (no Codex MRLs or Codex STMRs).

Table 7.2-16: Input values for the consumer risk assessment

Commodity	Chronic risk assessment				Acute risk assessment			
	TMDI		IEDI		IESTI		IESTI refined	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: acetamiprid								
Citrus fruits	0.9	EU-MRL[1)]	0.01	STMR x PF (0.3) (EFSA, 2018a)	-	-	-	-
Tree nuts	0.07	EU-MRL[1)]	0.01	STMR (EFSA, 2018a)	-	-	-	-
Apples	0.4	EU-MRL[1)]	0.11	Calculated STMR (see Table 7.2-9)	0.4	EU-MRL[1)]	0.21	HR (EFSA, 2018a)

Commodity	Chronic risk assessment				Acute risk assessment			
	TMDI		IEDI		IESTI		IESTI refined	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Pears	0.4	EU-MRL[1)]	0.07	STMR (Fall-back[2)]) (EFSA; 2018a)	-	-	-	-
Quinces	0.8	EU-MRL[1)]	0.23	STMR (EFSA, 2018a)	-	-	-	-
Medlars	0.8	EU-MRL[1)]	0.23	STMR (EFSA, 2018a)	-	-	-	-
Loquats/Japanese medlars	0.8	EU-MRL[1)]	0.23	STMR (EFSA, 2018a)	-	-	-	-
Apricots	0.8	EU-MRL[1)]	0.22	STMR (EFSA, 2018a)	-	-	-	-
Peaches	0.2	EU-MRL[1)]	0.06	STMR (Fall-back[2)]) (EFSA, 2018a)	-	-	-	-
Strawberries	0.5	EU-MRL[1)]	0.10	STMR (EFSA, 2018a)	-	-	-	-
Figs	0.03	EU-MRL[1)]	0.01	STMR (EFSA, 2018a)	-	-	-	-
Table olives Olives for oil production	3.0	EU-MRL[1)]	0.80	STMR (EFSA, 2018a)	-	-	-	-
Bananas	0.4	EU-MRL[1)]	0.05	STMR x PF (0.49) (EFSA, 2018a)	-	-	-	-
Potatoes	0.01*	EU-MRL[1)]	0.01	STMR (EFSA, 2018a)	0.01*	EU-MRL[1)]	0.01	HR (EFSA, 2018a)
Onions	0.02	EU-MRL[1)]	0.01	STMR (EFSA, 2018a)	-	-	-	-
Tomatoes	0.5	EU-MRL[1)]	0.13	STMR (EFSA, 2018a)	-	-	-	-
Sweet peppers/ bell peppers	0.3	EU-MRL[1)]	0.10	STMR (EFSA, 2018a)	-	-	-	-
Aubergines/ eggplants	0.2	EU-MRL[1)]	0.04	STMR (EFSA, 2018a)	-	-	-	-
Cucumbers	0.3	EU-MRL[1)]	0.05	STMR (EFSA, 2018)	-	-	-	-
Gherkins	0.6	EU-MRL[1)]	0.14	STMR (EFSA, 2018a)	-	-	-	-
Courgettes	0.3	EU-MRL[1)]	0.05	STMR (EFSA, 2018a)	-	-	-	-
Broccoli	0.4	EU-MRL[1)]	0.03	STMR (EFSA, 2018a)	-	-	-	-
Brussels sprouts	0.05	EU-MRL[1)]	0.02	STMR (EFSA, 2018a)	-	-	-	-
Head cabbages	0.4	EU-MRL[1)]	0.02	STMR (Fall-	-	-	-	-

Commodity	Chronic risk assessment				Acute risk assessment			
	TMDI		IEDI		IESTI		IESTI refined	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
				back[2]) (EFSA, 2018a)				
Lamb's lettuces/ corn salads	3.0	EU-MRL[1])	0.83	STMR (EFSA, 2018a)	-	-	-	-
Lettuces	1.5	EU-MRL[1])	0.49	STMR (Fall-back[2]) (EFSA, 2018a)	-	-	-	-
Escaroles/broad-leaved endives	0.4	EU-MRL[1])	0.10	STMR (Fall-back[2]), tentative) (EFSA, 2018a)	-	-	-	-
Cresses and other sprouts and shoots Roman rocket/ rucola Baby leaf crops (including brassica species)	3.0	EU-MRL[1])	0.83	STMR (EFSA, 2018a)	-	-	-	-
Land cresses Red mustards	3.0	EU-MRL[1])	0.81	STMR (EFSA, 2018a)	-	-	-	-
Spinaches	0.6	EU-MRL[1])	0.20	STMR (Fall-back[2]) (EFSA, 2018a)	-	-	-	-
Purslanes	0.6	EU-MRL[1])	0.20	STMR (Fall-back[2]) (EFSA, 2018a)	-	-	-	-
Chards/beet leaves	0.6	EU-MRL[1])	0.20	STMR (Fall-back[2]) (EFSA, 2018a)	-	-	-	-
Fresh herbs	3.0	EU-MRL[1])	0.83	STMR (EFSA, 2018a)	-	-	-	-
Beans (with pods) Peas (with pods)	0.6	EU-MRL[1])	0.06	STMR (EFSA, 2018a)	-	-	-	-
Celeries	0.01*	EU-MRL[1])	0.32	STMR (EFSA, 2018a)	-	-	-	-
Globe artichokes	0.7	EU-MRL[1])	0.11	STMR (EFSA, 2018)	-	-	-	-
Pulses	0.15	EU-MRL[1])	0.02	STMR (EFSA, 2018a)	-	-	-	-
Rapeseeds/canola seeds	0.4	EU-MRL[1])	0.03	Calculated STMR (see Table 7.2-9)	0.4	EU-MRL[1])	0.2	HR (EFSA, 2018a)
Maize/corn	0.01*	EU-MRL[1])	0.01	Calculated STMR (see Table 7.2-9)	0.01*	EU-MRL[1])	0.01	Calculated HR (see Table 7.2-9)
Cotton seeds	0.7	EU-MRL[1])	0.09	STMR (EFSA, 2018a)	-	-	-	-
Barley and oat grains	0.05	EU-MRL[1])	0.03	STMR (EFSA, 2018a)	-	-	-	-
Wheat grains	0.1	EU-MRL[1])	0.01	STMR	-	-	-	-

Commodity	Chronic risk assessment				Acute risk assessment			
	TMDI		IEDI		IESTI		IESTI refined	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
				(EFSA, 2018a)				
Honey and other apiculture	2.00	Calculated MRL (see Table 7.2-9)	0.13	Calculated STMR (see Table 7.2-9)	2.00	Calculated MRL (see Table 7.2-9)	0.85	Calculated HR (see Table 7.2-9)
Risk Assessment residue definition: sum of acetamiprid and metabolite IM-2-1, expressed as acetamiprid								
Swine meat	0.5	EU-MRL[1)]	0.02	Calculated STMR (see Table 7.2-12)	0.5	EU-MRL[1)]	0.02	Calculated HR (see Table 7.2-12)
Swine fat	0.3	EU-MRL[1)]	0.01	Calculated STMR (see Table 7.2-12)	0.3	EU-MRL[1)]	0.03	Calculated HR (see Table 7.2-12)
Swine liver	1.0	EU-MRL[1)]	0.06	Calculated STMR (see Table 7.2-12)	1.0	EU-MRL[1)]	0.06	Calculated HR (see Table 7.2-12)
Swine kidney	1.0	EU-MRL[1)]	0.09	Calculated STMR (see Table 7.2-12)	1.0	EU-MRL[1)]	0.1	Calculated HR (see Table 7.2-12)
Bovine, sheep, goat and equine meat	0.5	EU-MRL[1)]	0.04	Calculated STMR (see Table 7.2-12)	0.5	EU-MRL[1)]	0.05	Calculated HR (see Table 7.2-12)
Bovine, sheep, goat and equine fat tissue	0.3	EU-MRL[1)]	0.03	Calculated STMR (see Table 7.2-12)	0.3	EU-MRL[1)]	0.08	Calculated HR (see Table 7.2-12)
Bovine, sheep, goat and equine liver	1.0	EU-MRL[1)]	0.13	Calculated STMR (see Table 7.2-12)	1.0	EU-MRL[1)]	0.15	Calculated HR (see Table 7.2-12)
Bovine, sheep, goat and equine kidney	1.0	EU-MRL[1)]	0.19	Calculated STMR (see Table 7.2-12)	1.0	EU-MRL[1)]	0.30	Calculated HR (see Table 7.2-12)
Cattle, sheep, goat and horse milk	0.2	EU-MRL[1)]	0.06	Calculated STMR (see Table 7.2-12)	0.2	EU-MRL[1)]	0.06	Calculated STMR (see Table 7.2-12)
All other plant and animal commodities	EU-MRL[1)]	EU MRLs[1)]	-	-	-	-	-	-

* Indicates that the input value is proposed at the limit of analytical quantification (LOQ)

1) Source of EU MRL: Reg. (EU) 2019/88

2) Acetamiprid was evaluated for renewal of approval in the framework of Commission Regulation (EC) No 1107/2009 and the toxicological reference values for the substance were lowered. The European Commission requested therefore EFSA to perform a focussed review of the existing MRLs for acetamiprid taking into consideration the new TRV and to derive fall-back MRLs that would not lead to unacceptable risk for consumers.

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-17: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	123 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo 3.1	38 % (based on NL toddler)

IESTI (% ARfD) according to EFSA PRIMo 3.1 Unrefined	Apples: 172% (based on NL toddler) Potato: 6% (based on UK infant) Rapeseed: 2.2% (based on DE child) Maize/corn: 0.3% (based on UK infant)
IESTI (% ARfD) according to EFSA PRIMo 3.1 Refined	Apples: 91% (based on NL toddler) Potato: 6% (based on UK infant) Maize/corn: 0.3% (based on UK infant) Rapeseed: 0.2% (based on DE child)

The proposed uses of acetamiprid in the product CA 3573 (SL) do not represent unacceptable acute and chronic risks for the consumer.

Evaluator comments:
Information given by the Applicant is sufficient.
The proposed uses of acetamiprid in the product CA3573 / Carnadine/ / Kestrel do not represent unacceptable acute and chronic risks for the consumer.
No further studies are required to support the proposed uses.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

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The Netherlands, 2016: Draft Re-Assessment Report and Proposed decision of the Netherlands prepared in the context of the possible renewal of acetamiprid under Regulation (EC) 1107/2009, November 2015, updated June 2016

The Netherlands, 2015: Draft Re-Assessment Report and Proposed decision of the Netherlands prepared in the context of the possible renewal of acetamiprid under Regulation (EC) 1107/2009, November 2015

Greece, 2002: Draft Assessment Report prepared in the context of the possible inclusion of the following active substance in Annex I of Council Directive 91/414/EEC, Acetamiprid Addendum, October 2002

Greece, 2001: Draft Assessment Report prepared in the context of the possible inclusion of the following active substance in Annex I of Council Directive 91/414/EEC, Acetamiprid, March 2001

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	Lefresne S.	2014	Freezing storage stability of acetamiprid in 4 plant matrices: Dry (dry bean seed and straw, water (apple), fat (olive whole fruit) and acid (or-ange peel and pulp) at/below -18°C during 1 year (0, 3, 6 and 12 months) Report No B13-M1-A-02, Sponsor No R-33766 FREDON Pays de la Loire/GIRPA GLP Unpublished	N	Adama
KCP 8.1/02	Barbier G.	2018	Freezing storage stability of acetamiprid in wheat (grain) at/below -18°C during 15 months (0 and 15 months) Report No B17G-A4-A-02 FREDON Pays de la Loire/GIRPA GLP Unpublished	N	Adama
KCP 8.1/03	Müller, S.	2020	Determination of the Storage Stability of Acetamiprid in Honey for a period of 12 months at ≤ -18 °C, Müller, S., 2020, Study No. 20N08133-01-SSHN (interim report) Study No. 20N08133-01-SSHN (interim report) CIP GLP Unpublished	N	Nufarm
KCP 8.3/01 KCP 8.5.3/01	Roussel, Ch. H.	2014	Magnitude of the residues of acetamiprid in apple (RAC fruits and processed fractions), following one or two applications of MCW-2222 in six trials (3 DCS + 3 HS), Northern Europe (Northern France, Germany, Poland and Belgium) – 2014 Report No ChR-14-17311, Sponsor No R-34915 STAPHYT GLP Unpublished	N	Adama
KCP 8.3/02	Méric, D.	2014	Magnitude of the residues of acetamiprid in apples (RAC fruits) follow-ing one or two applications of MCW-2222 in two trials (1 DCS + 1 HS), Northern Europe (Northern France) – 2013 Report No DMC-13-16134, Sponsor No R-33599 STAPHYT GLP Unpublished	N	Adama

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 8.3/03	Bousquet C.	2014	Magnitude of the Residue of acetamiprid in potato Raw Agricultural Commodity after two applications of MCW-2222 in three decline curve trials (Poland, United Kingdom and Northern France) and in one harvest trial (Poland) in Northern Europe – 2013 Report No 13SGS102, Sponsor No R-33600 SGS AGRI MIN GLP Unpublished	N	Adama
KCP 8.3/04	Méric D.	2014	Magnitude of the residues of acetamiprid in oilseed rape (RAC whole plants, pods and seeds) following one or two applications of MCW-2222 in two trials (1 DCS + 1HS), Northern Europe (Germany and Northern France) – 2013 Report No DMC-13-16129, Sponsor No R-33598 STAPHYT GLP Unpublished	N	Adama
KCP 8.3/05	Chevallier E.	2014	Magnitude of the residue of acetamiprid in winter oil seed rape (Raw Agricultural Commodity) after one or two applications of MCW-2222 - three decline curve trials and three harvest trials in Northern Europe (Northern France, Poland, Germany, Czech Republic and Hungary) - 2014 Report No 14SGS035, Sponsor No R-34910 SGS AGRI MIN GLP Unpublished	N	Adama
KCP 8.3/06	Lebrun F.	2014	Magnitude of the residue of acetamiprid in maize (Raw Agricultural Commodity) after one application of MCW-2222 – four semi decline curve trials and four decline curve trials in Northern Europe (Northern France, Poland, Germany, Hungary and Austria) – 2014 Report No 14SGS039, Sponsor No R-34912 SGS AGRI MIN Bâtiment ADAMANTIS GLP Unpublished	N	Adama
KCP 8.5.3/01 KCP 8.3/01	Roussel Ch. H.	2014	Magnitude of the residues of acetamiprid in apple (RAC fruits and processed fractions), following one or two applications of MCW-2222 in six trials (3 DCS + 3 HS), Northern Europe (Northern France, Germany, Poland and Belgium) – 2014 Report No ChR-14-17311, Sponsor No R-34915 STAPHYT GLP Unpublished	N	Adama
KCP 8.6.1/01	Hobbs G.	2017	Uptake and Metabolism in Confined Rotational Crops Using [^{14}C]-IM-1-5	N	Adama

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report No 38356, Sponsor No R-37756 Charles River Laboratories Edinburgh Ltd GLP Unpublished		
KCP 8.6.2/01	Semrau J.	2017	Determination of residues of acetamiprid and its soil metabolites IM-1-4 and IM-1-5 after one application of MCW-2222 to bare soil in rotational crops (radish, spinach and wheat) at 1 site in Northern Europe and 1 site in Southern Europe 2015 / 2016 Report No S15-02364, Sponsor No R-35750 Eurofins Agroscience Services GmbH GLP Unpublished	N	Adama
KCP 8.10.1/01	Hecht-Rost S.	2020	Semi-field study for determining the magnitude of residues of Carnadine (CA3573) (a.s. acetamiprid) in honey GLP Study No. 467, Report No. R1940050 RIFCON GmbH GLP Unpublished	N	Nufarm
KCP 8.10.1/02	Sagner A., Kessler M.	2020	Expert Statement - Possibility to Estimate Residue Levels for Acetamiprid in Honey Report No. R1960175_01 GLP not applicable Unpublished	N	Nufarm
KCP 8.10.1/03	EFSA	2014	Scientific Report of EFSA - The 2012 European Union Report on pesticide residues in food EFSA Journal 2014;12(12):3942 GLP not applicable Published	N	Publicly available
KCP 8.10.1/04	EFSA	2015	Scientific Report of EFSA – The 2013 European Union report on pesticide residues in food EFSA Journal 2015;13(3):4038 GLP not applicable Published	N	Publicly available
KCP 8.10.1/05	EFSA	2016c	Scientific Report of EFSA – The 2014 European Union report on pesticide residues in food EFSA Journal 2016;14(10):4611 GLP not applicable Published	N	Publicly available
KCP 8.10.1/06	EFSA	2017	Scientific Report of EFSA – The 2015 European Union report on pesticide residues in food EFSA Journal 2017;15(4):4791	N	Publicly available

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
			GLP not applicable Published		
KCP 8.10.1/07	EFSA	2018b	Scientific Report of EFSA – The 2016 European Union report on pesticide residues in food EFSA Journal 2018;16(7):5348 GLP not applicable Published	N	Publicly available
KCP 8.10.1/08	EFSA	2019	Scientific report on the 2017 European Union report on pesticide residues in food EFSA Journal 2019;17(6):5743 GLP not applicable Published	N	Publicly available
KCP 8.10.1/09	EFSA	2020	Scientific Report of EFSA – The 2018 European Union report on pesticide residues in food EFSA Journal 2020;18(4):6057 GLP not applicable Published	N	Publicly available

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**
CP 8.1	Goller G.	1999	Stability Study of NI-25 (Acetamiprid) in apple and tomato samples after storage in freezer at or below -18 °C - Fortification experiments with active ingredient Report No RPA/NI-25/97051 A.D.M.E. - Bioanalyses, France GLP Unpublished	N	Nippon Soda
CP 8.1	Netzband D.J.	2003	Stability study of Acetamiprid in potatoes during frozen storage, USA, 2002 in freezer at or below -18°C Report No RD-00243 Bayer CropScience GLP Unpublished	N	Nippon Soda
CP 8.1	Jean-Baptiste C.	2009	Frozen Storage Stability of Residues of Acetamiprid in Fodder Pea	N	Nippon

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
			Report No A7125 Anadiag Laboratories GLP Unpublished		Soda
CP 8.1	Gieseke L.D.	1999	NI-25 (acetamiprid): Freezer storage stability of acetamiprid residues in various raw agricultural commodities and processing fractions (plant matrices) Report No 10201 Horizon Laboratories, Inc. GLP Unpublished	N	Nippon Soda
CP 8.2.1	Saito H.	1997a	NI-25 [Pyridine-2,6-14C] - Nature of the Residue in Eggplants Report No EC-391-3 Nisso Chemical Analysis Service Co, Ltd GLP, GEP Unpublished	N	Nippon Soda
CP 8.2.1	Saito H.	1997b	NI-25 [Pyridine-2,6-^{14}C] - Nature of the Residue in Apples Report No EC-742-1 Nisso Chemical Analysis Service Co, Ltd GLP, GEP Unpublished	N	Nippon Soda
CP 8.2.1	Saito H.	1997c	NI-25 [Pyridine-2,6-14C] - Nature of the Residue in Cabbages Plants Report No EC-743-1 Nisso Chemical Analysis Service Co, Ltd GLP, GEP Unpublished	N	Nippon Soda
CP 8.2.1	Kawai T.	1995	NI-25 [CN-^{14}C] - Nature of the Residue in Cabbages Plants Report No EC-617-1 Nisso Chemical Analysis Service Co, Ltd GLP, GEP Unpublished	N	Nippon Soda
CP 8.2.1	McMillan-Staff S.L., Austin D.J., Lingwood A.	1997	[^{14}C]-NI-25: Metabolism in Carrots. Report No 11253 Rhône-Poulenc Agriculture Ltd	N	Nippon Soda

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
			GLP, GEP Unpublished		
CP 8.2.1	Miller N.	1999	Foliarly applied 14C-acetamiprid: Metabolic fate and distribution in cotton (Gossypium hirsutum) Report No EC-97-367 Rhone-Poulenc Ag Company GLP Unpublished	N	Nippon Soda
CP 8.2.2	xxx xxx.	1997b	^{14}C-NI-25 (Acetamiprid): Absorption, Distribution, Metabolism and Excretion after Repeated Oral Administration to Laying Hens. Report No 628143 xxxxx GLP, GEP Unpublished	Y	Nippon Soda
CP 8.2.3	Xxx xxx.	1997a	^{14}C-NI-25 (Acetamiprid): Absorption, Distribution, Metabolism and Excretion after Repeated Oral Administration to Lactating Goats Report No 628132 xxx GLP, GEP Unpublished	Y	Nippon Soda
CP 8.4	Author sanitized	1999a	Acetamiprid: Magnitude of Residues in Cairy Cow Milk and Tissues Report No RD-9989 Source sanitized Unpublished	Y	Nippom Soda
CP 8.4	Author sanitized	1999b	Acetamiprid (Code No.: NI-25) – Magnitude of Residues in Poultry Tissue and Eggs. Report No RD-9988 Source sanitized Unpublished	Y	Nippon Soda
CP 8.5.1	McMillan-Staff S.L., Austin D.J.,	1997	[^{14}C]-NI-25 Investigation of the Nature of the Potential Residue in the Products of Industrial Processing or Household Preparation. Report No RPAL Study 13442 Rhone-Poulenc Ag Company GLP Unpublished	N	Nippon Soda
CP 8.5.3	Kowite W.J.	1999	NI-25: Magnitude of Residues in Apple Processed Commodities Resulting from Foliar Applications of EXP	N	Nippon

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**
			80667A Insecticide Report No 97512650 Rhône- Poulenc Agriculture Ltd GLP, GEP Unpublished		Soda
CP 8.5.3	Venet C., Barriere I.,	2000	Acetamiprid (NI-25) – Formulation EXP60707A (SP) - Trials France 1999 - Residues in Apple + Processed products Report No R&D/CRLD/AN/mba/0015360 Aventis CropScience GLP, GEP Unpublished	N	Nippon Soda
CP 8.6.1	Hobbs G., Inns L.	2012	[^{14}C]-IM-1-5: Uptake and Metabolism of Soil Residues in Confined Rotational Crops Report No RD-02391 GLP Unpublished	N	Nippon Soda
CP 8.6.2	Raufer B.	2013	Residue study on rotational crops after one application of Acetamiprid on bare soil at 2 sites in Europe in 2010 to 2012. Report No RD-02495N2 GLP Unpublished	N	Nippon Soda
CP 8.6.2	Raufer B.	2014	Residue study on rotational crop (turnip) after one application of Acetamiprid on bare soil at 1 site in Europe in 2012 to 2013. Report No RD-02930 GLP Unpublished	N	Nippon Soda

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 Acetamiprid

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

A 2.1.1.1.1.1 Study 1

Comments of zRMS:	The study has been evaluated and accepted in Registration Report, Section 4 for MCW-2222, Adama Makhteshim Ltd. (10.05.2018). The study demonstrated that actamiprid is stable in 4 plant matrices (dry bean seed and straw (dry), apple (water), olive whole fruit (fat) and orange peel and pulp (acid)) at/below -18 ºC for a storage period up to 12 months.

Reference:	KCP 8.1/01
Report	Freezing storage stability of acetamiprid in 4 plant matrices: Dry (dry bean seed and straw, water (apple), fat (olive whole fruit) and acid (orange peel and pulp) at/below -18°C during 1 year (0, 3, 6 and 12 months); Lefresne S., 2014, Report No B13-M1-A-02, Sponsor No R-33766
Guideline(s):	Yes French GLP requirements ("Annexe 2 à l'article D523-8 du code de l'environnement du 16 octobre 2007 - Principes de l'OCDE de Bonnes Pratiques de Laboratoire (BPL)") Regulation (EC) No 1107/2009 7032/VI/95 rev.5
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods
The storage stability of acetamiprid in fortified dry bean seed and straw (dry), apple (water), olive whole fruit (fat), orange peel and pulp (acid) samples stored under frozen condition (-18°C) was determined over a 12 months period. Untreated samples were fortified with acetamiprid at 0.1 mg/kg and were analyzed after 0, 3, 6 and 12 months of frozen storage. Untreated samples were used as controls and were fortified freshly with a standard solution of acetamiprid at 0.1 mg/kg for procedural recoveries.
Residues of acetamiprid were extracted from specimens by agitation in acetonitrile and ultra-pure water. Then extracts were purified by dispersive solid phase extraction (SPE). The quantification was performed by liquid chromatography with tandem mass spectrometry detection.
The limit of quantification (LOQ) of acetamiprid was 0.01 mg/kg for each specimen.

Results and discussions
The procedural recoveries in control samples analysed concurrently during the storage stability tests were between 81 and 102% at a fortification level of 0.1 mg/kg as shown in Table A 1 below. Results comply with standard acceptance criteria of the Guidance of method validation and quality control procedures for pesticide residues in food and feed, SANCO/2007/3131. The limit of quantification (LOQ) of acetamiprid was 0.01 mg/kg for each specimen.

The recoveries for acetamiprid after freezer storage were within a range of 80 and 109% for dry bean seed

and straw (dry), apple (water), olive whole fruit (fat), orange peel and pulp (acid).
There was no significant reduction of acetamiprid residues following freezer storage for up to 12 months in all plant matrices tested.

Table A 1: Summary of concurrent recoveries of acetamiprid from dry bean, apple, olive and orange

Matrix	Spike level (mg/kg)	Storage Interval (months)	Sample size (n)	Mean procedural recoveries (%)
Acetamiprid				
Dry bean (seed)	0.1	0	3	81
		3	2	84
		6	2	98
		12	2	99
Dry bean (straw)	0.1	0	3	87
		3	2	81
		6	2	100
		12	2	97
Apple (fruit)	0.1	0	3	102
		3	2	87
		6	2	86
		12	2	93
Olive (whole fruit)	0.1	0	3	85
		3	2	94
		6	2	100
		12	2	90
Orange (peel)	0.1	0	3	90
		3	2	82
		6	2	85
		12	2	85
Orange (pulp)	0.1	0	3	94
		3	2	98
		6	2	95
		12	2	87

n.a. = not applicable

Table A 2: Stability of acetamiprid residues in dry bean, apple, olive and orange following storage at -18°C

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Mean recoveries (%)
Acetamiprid				
Dry bean (seed)	0.1	0	0.081, 0.082, 0.078	80
		3	0.089, 0.090	89
		6	0.098, 0.098	98
		12	0.104, 0.105	104
Dry bean (straw)	0.1	0	0.084, 0.091, 0.075	84
		3	0.091, 0.085	88

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Mean recoveries (%)
		6	0.108, 0.106	107
		12	0.106, 0.089	98
Apple (fruit)	0.1	0	0.098, 0.102, 0.099	100
		3	0.096, 0.094	95
		6	0.089, 0.085	87
		12	0.097, 0.098	97
Olive (whole fruit)	0.1	0	0.088, 0.082, 0.081	84
		3	0.109, 0.108	109
		6	0.093, 0.095	94
		12	0.089, 0.090	89
Orange (peel)	0.1	0	0.096, 0.098, 0.093	96
		3	0.088, 0.086	87
		6	0.082, 0.086	84
		12	0.085, 0.087	86
Orange (pulp)	0.1	0	0.094, 0.091, 0.088	91
		3	0.110, 0.095	102
		6	0.091, 0.092	92
		12	0.087, 0.089	88

Conclusion
The results obtained in this storage stability study demonstrate that acetamiprid is stable in plant matrices (dry, water, fat and acid) when stored frozen at -18°C for up to 12 months.

A 2.1.1.1.1.2 Study 2

Comments of zRMS:	The study has been evaluated and accepted in Registration Report, Section 4 for MCW-2222, Adama Makhteshim Ltd. (10.05.2018). The study demonstrated that actamiprid is stable in wheat grain (high content starch matrice) at/below -18 ºC for a storage period up to 15 months.

Reference:	KCP 8.1/02
Report	Freezing storage stability of acetamiprid in wheat (grain) at/below -18°C during 15 months (0 and 15 months); Barbier G., 2018, Report No B17G-A4-A-02
Guideline(s):	Yes 'French GLP requirements ("Annexe 2 à l'article D523-8 du code de l'environnement du 16 octobre 2007 - Principes de l'OCDE de Bonnes Pratiques de Laboratoire (BPL)") OECD series on GLP and compliance monitoring, ENV/MC/CHEM(98)17 2004/10/EC Regulation (EC) No. 1107/2009 Commission regulation (EU) No.283/2013 Commission regulation (EU) No.546/2011 ENV/JM/MONO(2007)17 SANCO/3029/99 rev.4 7032/VI/95 rev.5

	OECD Guideline 506/2007
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods
The storage stability of acetamiprid was determined in high starch content commodities from the chosen crop wheat grains, at/below -18°C during 15 months.
Residues of acetamiprid were extracted from homogenised wheat grains by agitation in acetonitrile and ultra-pure water. Then extracts were purified by dispersive solid phase extraction (SPE). The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS).
In order to ensure unambiguous identification, two mass transition were monitored for acetamiprid.

Results and discussions
The procedural recoveries in control samples analysed concurrently during the storage stability tests were 98 and 100% at a fortification level of 0.1 mg/kg as shown in Table A 3 below. The limit of quantification (LOQ) of acetamiprid was 0.01 mg/kg.

According to the Guideline SANCO/3029/99 rev. 4, the analytical residues in specimens and recovery experiments were quantified with one transition (223 → 126 (m/z)) and confirmed with another one (223 → 90 (m/z)).
The acetamiprid residue results of the three freshly fortified samples were 0.074, 0.073 and 0.081 mg/kg corresponding to recoveries respectively at 74, 73 and 81% (mean 76% ± RSD 6%).

Table A 3: Summary of concurrent recoveries of acetamiprid from wheat

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Mean procedural recoveries (%)
Acetamiprid				
Wheat (grain)	0.1	0	3	100
		15	2	98

n.a. = not applicable

Table A 4: Stability of acetamiprid residues in wheat following storage at -18°C

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Mean recoveries (%)
Acetamiprid				
Wheat (grain)	0.1	0	0.074, 0.073, 0.081	76
		15	0.074, 0.076	75

Conclusion
The results obtained in this storage stability study demonstrate that acetamiprid is stable in high starch matrices (wheat, grain) when stored frozen at -18°C for up to 15 months.

A 2.1.1.1.1.3 Study 3

Comments of zRMS:	The data presented in the study of Müller demonstrate that the method permits the determination of residues of acetamiprid in honey with satisfactory accuracy, precision and repeatability according to guideline SANCO/3029/99 rev.4 and meet the criteria of OECD 506. Additionally, results of procedural recoveries are presented below. **Table 1. Results of procedural recoveries (freshly prepared).**

	Matrix	Fortification level [mg/kg]	Mass fragments [m/z]	No of analyses	Recoveries		
					Single Values [%]	Mean [%]	RSD [%]
	honey	0.01	223→126 Quantifier	8	110, 105, 105, 105, 101, 91, 90, 91	100	7.9
			223→90 Qualifier		111, 112, 106, 108, 101, 94, 93, 88	102	8.9
		0.1	223→126 Quantifier		113, 105, 114, 107, 108, 89, 87, 95	102	10.3
			223→90 Qualifier		112, 100, 108, 104, 105, 88, 87, 94	100	9.2
	No significant degradation of acetamiprid during storage at ≤ -18 °C was observed within 9 months for matrix honey. Therefore, acetamiprid in honey can be regarded as stable within 9 months storage at deep frozen storage (≤ -18 °C). The study is acceptable.						

Reference:	KCP 8.1/03
Report	Determination of the Storage Stability of Acetamiprid in Honey for a period of 12 months at ≤ -18 °C, Müller, S., 2020, Study No. 20N08133-01-SSHN (interim report)
Guideline(s):	Yes, SANCO/7032/VI/95 rev.5 and OECD Test Number 506
Deviations:	According to the study plan, the linearity should have been fully shown at t = 0 months and t = 9 months. In the study, a complete calibration curve with over 5 points was only shown at t = 0 months, whereas a calibration curve with 3 points was shown at t = 9 months. This resulted in no negative impact on the study. The linearity was shown at t = 0 months and was sufficiently proven for the whole study. For t = max, a complete calibration curve will be additionally shown again.
GLP:	Yes
Acceptability:	Yes

The storage stability results of acetamiprid in honey will be tested for a period of 12 months. This interim report shows the results of the stability over 9 months.

Materials and methods
The stability of residues of acetamiprid under freezer storage conditions in honey, were determined by the analysis of fortified samples.

The samples were stored under freezer storage conditions (≤ -18 °C) and analysed for the content of acetamiprid after a storage time of 0 and 9 months (12 months will follow). The recovery values obtained from these stored fortified samples were compared with the recovery values obtained from freshly fortified recovery samples.

Minimum and maximum temperatures were recorded during the entire storage period. The temperature was kept at a level of ≤ -18 °C.

Control matrix honey was purchased from a local food store and checked prior usage for its content of acetamiprid.

Honey specimens were homogenised by shaking and/or stirring. The (homogenised) untreated samples were stored deep frozen (≤ -18 °C) until start of analysis. From the deep frozen specimens material, an aliquot was transferred into centrifugation tubes (50 mL, polyethylene tubes) and fortified at 10 fold LOQ with acetamiprid (0.1 mg/kg for matrix honey).

The test item was dissolved in methanol and applied drop wise to the entire specimen with a solvent volume not exceeding a total of 500 µL per specimen. The solvent was then allowed to evaporate for approx. 5 min, the tubes were closed with screw caps and placed into the deep freezer and were removed only for analysis.

Residues of acetamiprid in samples of honey were extracted based on the QuEChERS multi-residue method (DIN EN 15662:2018) and analysed by high performance liquid chromatography coupled with tandem mass spectrometry.

Results and discussions
The analytical method used for sample extraction and determination of residues was fully validated within this study. Quantification was performed by use of HPLC with MS/MS detection.
The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg and with a limit of detection (LOD) was set at 0.003 mg/kg (30% of the LOQ).
The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 87 – 114% and the mean recoveries at each fortification level were in the range of 70 – 110% with relative standard deviation(s) below 20%.

The summary of the stability results of acetamiprid in honey samples is presented in the table below.

Table A 5: Stability results of acetamiprid

Storage		Residues and recoveries in specimens stored frozen (**not corrected for procedural recoveries**)								Residues and recoveries in specimens stored frozen (**recovery corrected**)		
Matrix	Period	Uncorrected residue results						Procedural recoveries [%]	Corrected results with day 0 as 100% [%]	Procedural recoveries for freshly fortified samples Mean [%]	Corrected results	
	Months	Sample 1 [mg/kg]	Sample 2 [mg/kg]	Sample 3 [mg/kg]	Sample 4 [mg/kg]	Sample 5 [mg/kg]	Mean [mg/kg]				Corr. [mg/kg]	Day -0 as 100 %
Honey	0	0.113	0.105	0.114	0.107	0.108	0.109	109	100	109	0.100	**100**
	9	0.082	0.091	0.086	-	-	0.086	86	79	90	0.096	**96**
	12	Results will be shown in the final report										

Corrected refers in this case to the fact that the values are expressed relative to the value for t = 0 which has been set as 100%.

No significant degradation of the test item during storage at ≤ -18 °C was observed for over 9 months for matrix honey.

Conclusion
Acetamiprid can be regarded as stable over 9 months storage at deep frozen storage (≤ -18 °C) in honey.

A 2.1.1.1.2 Storage stability of residues in animal products
No new studies were conducted.

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops
No new studies were conducted.

A 2.1.2.1.2 Nature of residue in rotational crops

A 2.1.2.1.2.1 Study 1

Comments of zRMS:	One new study was conducted to investigate the metabolism of the persistent soil metabolite IM-1-5 in rotational crops. M-1-5 is a metabolite form in calcareous soil. The study was designed to quantify the total radioactive residue levels in appropriate crop parts (i.e. immature and mature spinach; turnip leaves and tuberous roots; wheat forage, hay, straw and grain) and to determine the extractability and nature of the residues. A single application of [^{14}C]-IM-1-5 made to bare soil, at a nominal application rate of 160 g /ha. The crops used in this study were spring wheat, spinach and turnip to represent cereal, leafy vegetable and root vegetable crops, respectively. IM-1-5 is a metabolite known to form in calcareous soil; the study was designed to only investigate the fate of this metabolite and therefore no aging of the soil was required following application. Total radioactive residues in the human food commodities (wheat grain, spinach and turnip tubers) were reasonably low (0.025 – 0.131 mg/kg). Animal feed commodities (wheat forage, hay, straw and turnip foliage) showed higher TRRs (0.050 – 0.450 mg/kg). IM-1-5 is taken up from calcareous soil into the crops where it is distributed throughout the crop matrices. Limited metabolism of IM-1-5 is observed in the crops. Natural incorporation was indicated at low levels, potentially a result of degradation in the soil and the subsequent absorption of $^{14}CO_2$. The study was conducted to comply with the current data requirements. The study is acceptable.

Reference:	KCP 8.6.1/01
Report	Uptake and Metabolism in Confined Rotational Crops Using [^{14}C]-IM-1-5; Hobbs G., 2017, Report No 38356, Sponsor No R-37756
Guideline(s):	Yes OECD Guideline 502 for the Testing of Chemicals, Metabolism in Rotational Crops, (January 2007). OECD Draft Guidance Document on Residues in Rotational Crops, 1st draft July, 2016 OECD Series on Testing and Assessment No. 64. Series on Pesticides No. 32. ENV/JM/MONO 2009 Residue Test Guideline, OPPTS 860.1850, Confined Accumulation in Rotational Crops, (August 1996).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

IM-1-5 is a persistent metabolite of acetamiprid known to form in calcareous soil. The aim of the present study was to investigate the uptake and metabolism of [^{14}C]-IM-1-5 in representative succeeding crops (wheat, spinach and turnip) in calcareous soil.

[^{14}C]-IM-1-5 was applied at a nominal rate of 160.0 g/ha; the actual application rate was 168.7 g/ha. The study was designed to only investigate the fate of this metabolite and therefore no aging of the soil was required following application.

The study was designed to quantify the total radioactive residue (TRR) levels as well as the nature of any metabolites present in the various crop parts and so define the metabolic pathway and to determine the extractability and nature of the residues.

The radiochemical was combined with non-radiolabelled IM-1-5 to provide a suitable specific activity for the study. The radiodiluted IM-1-5 was dissolved in aqueous acetonitrile and applied to the soil as a single spray application, the test item was incorporated into the soil (top 2-3 cm) within an hour after application. Throughout the application procedure stability of the test item was maintained (>99.3 % radiochemical purity).

Seeds of representative cereal (spring wheat, cv Paragon), leafy vegetable (spinach, cv Renegade F1) and root vegetable (turnip, cv Golden Ball) crops were sown into treated soil within 2 hours from application. Crops were harvested at appropriate immature and mature growth stages and separated into commodities representative of food and feed items (wheat: forage, hay, straw and grain; spinach: immature and mature foliage; turnip: foliage and roots). Homogenised samples of all the commodities were prepared for analysis. The total radioactive residue (TRR), mg IM-1-5 equivalents per kg of commodity, was measured in each commodity sampled.

Plant samples were stored in a freezer set to maintain -20°C within 2 hours of being harvested until they were taken for analysis. Following analysis, all samples were returned to storage at ca. -20°C.

Sub-samples of the crop commodities were taken for initial overall residue determination employing sample oxidation with LSC analysis. Appropriate amounts of sample were combusted to achieve a limit of determination (LOD) of 0.001mg/kg. Commodities with a TRR ≥ 0.01 mg/kg were extracted with aqueous acetonitrile solvent combinations and where possible the extracted residue was analysed by HPLC and TLC to determine the nature of the residues (further extraction with ammonium hydroxide, hydrochloric acid, sodium hyperchloride and potassium hydroxide).

Results and discussion

Results of the TRRs in harvested crop commodities after soil application of [^{14}C]-IM-1-5 are presented in the table below. Total radioactive residues in the human food commodities such as wheat grain, spinach and turnip tubers, were between 0.025 – 0.131 mg/kg and in animal feed commodities

Table A 6: Total Radioactive Residues (TRRs) in Harvested Crop Commodities after soil application of [^{14}C]-IM-1-5

Matrix	By Direct Quantification of Sample (mg/kg)[1]	Extractable Residue		Unextractable Residue		By Summation of Extracts and Debris Radioactivity (mg/kg)[2]
		% TRR	mg/kg	% TRR	mg/kg	
Wheat forage	0.045	85.7	0.043	14.3	0.007	0.050
Wheat hay	0.100	77.9	0.086	22.0	0.024	0.111
Wheat straw	0.448	80.4	0.362	19.6	0.088	0.450
Wheat grain	0.052	31.9	0.016	68.1	0.035	0.049
Immature spinach	0.022	87.4	0.027	12.6	0.004	0.030
Mature spinach	0.018	76.1	0.019	23.9	0.006	0.025
Turnip foliage	0.052	89.4	0.047	10.5	0.006	0.053
Turnip tubers	0.108	93.2	0.122	6.7	0.009	0.131

1 The TRR values of all commodities were initially determined by direct quantification of the radioactivity by combustion/LSC.

2 TRR values of commodities were also determined by the summation of the radioactivity present in the solvent extracts and non-extractable debris after the initial extraction methodology

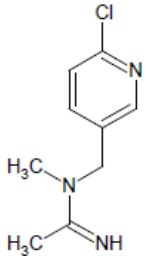
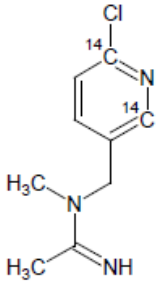
A summary of characterization and identification of radioactive residues in wheat, spinach and turnip following application of radiolabelled IM-1-5 is given in the following table. Total radioactive residues in the human food commodities such as wheat grain, spinach and turnip tubers were between 0.025 and 0.131 mg/kg. Animal feed commodities such as wheat forage, hay, straw and turnip foliage showed TRRs of 0.050-0.450 mg/kg

Table A 7: Summary of characterization and identification of Radioactive Residues in rotational crop matrices following application of radiolabelled IM-1-5 at a nominal rate of 160 g a.s./ha

Compound	Wheat								Spinach				Turnip			
	Forage TRR = 0.05 mg/kg		Hay TRR = 0.111 mg/kg		Straw TRR = 0.450 mg/kg		Grain TRR = 0.049 mg/kg		Immature Leaves TRR = 0.03 mg/kg		Mature Leaves TRR = 0.025 mg/kg		Mature Leaves TRR = 0.053 mg/kg		Tubers TRR = 0.131 mg/kg	
	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR	mg/kg
IM-1-5	64.6	0.033	74.2	0.082	81.3	0.366	6.3	0.003	78.1	0.024	53.3	0.013	81.9	0.043	86.6	0.114
Total identified	64.6	0.033	74.2	0.082	81.3	0.366	6.3	0.003	78.1	0.024	53.3	0.012	81.9	0.043	86.6	0.114
Total characterized	2.7	0.001	-	-	3.7	0.017	15	0.007	-	-	10	0.002	4.5	0.002	4.1	0.005
Total extractable	77.0	0.039	88.7	0.098	89.6	0.404	91.2	0.045	83.4	0.026	67.9	0.016	90.3	0.047	90.7	0.119
Unextractable (PES)*	14.3	0.007	7.5	0.008	3.1	0.014	8.7	0.004	12.6	0.004	23.9	0.006	10.5	0.006	6.7	0.009
Difference during processing	8.7	0.004	3.8	0.005	7.3	0.032	0.1	<0.001	4.0	-0.001	8.2	0.003	-0.8	<0.001	2.6	0.003
Accountability**	100	0.05	100	0.111	100	0.450	100	0.049	100	0.030	100	0.025	100	<0.053	100	0.131

* Residues remaining after exhaustive extractions.
** Accountability = Total extractable + Total unextractable + Difference during processing

Table A 8: Identification of compounds from metabolism study

Common name/code Figure B.3.1.-1. ID No.	Chemical name	Chemical structure
IM-1-5	N-((6-chloropyridin-3-yl)methyl)-N-methylacetimidamide	
[Pyridyl-2,6-^{14}C] IM-1-5	N-((6-chloro-[2,6-14C]pyridin-3-yl)methyl)-N-methylacetimidamide	

Conclusions

Total radioactive residues in the human food commodities such as wheat grain, spinach and turnip tubers, were low (0.025 – 0.131 mg/kg). Animal feed commodities such as wheat forage, hay, straw and turnip foliage showed higher TRRs (0.050 – 0.450 mg/kg).

IM-1-5 is the major component of the total radioactive residue for both human food commodities and animal feed commodities, accounting for 6.3 – 86.6% of the TRR. Only limited metabolism of IM-1-5 is observed in the rotational crops. Therefore, no metabolic pathway is proposed for IM-1-5.

A 2.1.2.1.3 Nature of residues in processed commodities

No new studies were conducted.

A 2.1.2.2 Nature of residues in livestock

No new studies were conducted.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Apple

Table A 9: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (kg a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (RAR, The Netherlands, 2015/2016)	2	0.075	-	BBCH 77-87	14
cGAP EU (EFSA, 2018a)	2	0.10	-	BBCH 69-81	14
Intended cGAP (use No 1, 2, 11 and 12*)	1	0.025-0.05	-	BBCH 62-PHI	14

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

A 2.1.3.1.1 Study 1

Comments of zRMS:	The study has been evaluated and accepted in Registration Report, Section 4 for MCW-2222, Adama Makhteshim Ltd. (10.05.2018). Three decline and three harvest trials have been performed in 2014 in Northern Europe (Northern France (FR01 and FR06), Germany (trial DE02), Poland (PL03) and Belgium (BE04 and BE05). At least two plots were established in each trial site: U plot was left untreated while T plot was treated twice at 0.500 L/ha (equivalent to 2*100 g a.i./ha), 22 and 14 days before harvest. In trials FR01 and FR06, an additional plot (T1) was treated once at the same rate (100 g a.i./ha). In trials FR01 and BE04, another additional plot (T3) was treated at 1.250 L/ha (2*250 g a.i./ha) in order to generate apples for processing. Fruits specimens were collected at 0, 3, 7, 14 and 21 days after last application (DALA) in decline trials and at 14 (+/-1) DALA in harvest trials. Specimens for processing were sampled at 14 (+/-1) DALA. No residue of acetamiprid was found in any untreated specimen. After one treatment with MCW-2222 (plot T- 100 g a.i./ha), the residues of acetamiprid in treated apple specimens ranged from 0.08 mg/kg maximum observed on the day of last application to 0.03 mg/kg in average at 14 DALA. After two treatments with MCW-2222 (plot T- 2*100 g a.i./ha), the residues of acetamiprid in treated apple specimens ranged from 0.20 mg/kg maximum observed on the day of last application to 0.12 mg/kg in average at 14 DALA. At 21 DALA, the average of three trials was 0.11 mg/kg. The acetamiprid LOQ was 0.01 mg/kg and the LOD defined as 0.003 mg/kg. Acceptance criteria for method validation were met, with average recoveries ranging from 70% to 110% and relative standard deviations ≤ 20%. The study has been accepted.

Reference:	KCP 8.3/01
Report	Magnitude of the residues of acetamiprid in apple (RAC fruits and processed fractions), following one or two applications of MCW-2222 in six trials (3

	DCS + 3 HS), Northern Europe (Northern France, Germany, Poland and Belgium) - 2014, Roussel, Ch. H., 2014, Report No ChR-14-17311, Sponsor No R-34915
Guideline(s):	Yes Commission Regulations (EU) n°283/2013 and 284/2013 (GLP) OECD Principles of GLP: ENV/JM/MONO(2002)9, ENV/JM/MONO(99)22, ENV/MC/CHEM(98)17 Directive 2004/10/EC Principes de l'OCDE de Bonnes Pratiques de Laboratoire (BPL) Grundsätze der Guten Laborpraxis des Chemikaliengesetzes; §19a, Anh.1" and Guideline IV/3-2, (1992) 91/414/EEC (1607/VI/97 rev. 2) 7029/VI/95rev.5 SANCO 3029/99, 2000 SANCO 825/00, 2004 SANCO/3029/99 rev.4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 10: Summary of the study 1 trials (apple)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid		
	(a)	(b)				(c)				(d)	(e)
ChR 14 17311 FR01 Nord Pas de Calais 59400 Fontaine Notre Dame, Northern France N-EU 2014	Apple/Idared	1. 2000 2. 03 - 25/04/2014 3. Weeks 40-41	104	1027	10	08/09/2014	85	Fruits Fruits Fruits Fruits Fruits	0.08 0.09 0.07 0.03 0.03	0 3 7 14 21	Analytic: QuEChERS/ HPLC-MS/MS (report CIP 13M06017-01-VMPL) Validation: Mean recovery 70- 110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: Foliar broadcast application Max. Storage Interval between sampling and analysis: 76 days
			104 105	1027 1033	10 10	2 08/09/2014	85	Fruits Fruits Fruits Fruits Fruits	0.11 0.11 0.11 0.06 <u>0.07</u>	0 3 7 14 21	
ChR 14 17311 DE02 Rheinland-Pfalz 67551 Worms Pfeddersheim Germany N-EU 2014	Apple/Braeburn	1. 1999 2. 24/04 - 12/05/2014 3. 10/10/2014	102 103	1005 1013	10 10	2 26/09/2014	87	Fruits Fruits Fruits Fruits Fruits	0.20 0.18 0.16 <u>0.21</u> 0.20	0 3 7 14 21	Analytic: QuEChERS/ HPLC-MS/MS (report CIP 13M06017-01-VMPL) Validation: Mean recovery 70- 110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: Foliar broadcast application Max. Storage Interval between sampling and analysis: 58 days

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid		
	(a)	(b)				(c)				(d)	(e)
ChR 14 17311 PL03 Lodzkie 99307 Strzelce Poland N-EU 2014	Apple/Topaz	1. 2002 2. Week 20 3. 17/10/2014	101 101	994 999	10 10	2 30/09/2014	85	Fruits Fruits Fruits Fruits Fruits	0.09 0.10 0.08 <u>0.08</u> 0.06	0 3 7 14 21	Analytic: QuEChERS/ HPLC-MS/MS (report CIP 13M06017-01-VMPL) Validation: Mean recovery 70- 110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: Foliar broad-cast application Max. Storage Interval between sampling and analysis: 54 days
ChR 14 17311 BE04 Hainaut 6220 Fleurus Belgium N-EU 2014	Apple/Rubinola	1. before 1999 2. April 2014 3. 27/08/2014	106 99	1045 980	10 10	2 07/08/2014	85	Fruits	<u>0.07</u>	14	Analytic: QuEChERS/ HPLC-MS/MS (report CIP 13M06017-01-VMPL) Validation: Mean recovery 70- 110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: Foliar broad-cast application Max. Storage Interval between sampling and analysis: 95 days

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid		
	(a)	(b)				(c)				(d)	(e)
ChR 14 17311 BE05 Brabant wallon 1320 Nodebois Belgium N-EU 2014	Apple/Jonagold	1. 1999 2. 06 - 25/04/2014 3. 27/09 - 08/10/2014	100 103	984 1013	10 10	2 11/09/2014	87	Fruits	<u>0.09</u>	14	Analytic: QuEChERS/ HPLC-MS/MS (report CIP 13M06017-01-VMPL) Validation: Mean recovery 70- 110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: Foliar broad-cast application Max. Storage Interval between sampling and analysis: 59 days
ChR 14 17311 FR06 Centre 37110 Dame Marie les Bois Northern France N-EU 2014	Apple/Antares	1. 2005 2. 11 - 30/04/2014 3. 13 - 20/10/2014	99	979	10	03/10/2014	85	Fruits	0.12	14	Analytic: QuEChERS/ HPLC-MS/MS (report CIP 13M06017-01-VMPL) Validation: Mean recovery 70- 110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: Foliar broad-cast application Max. Storage Interval between sampling and analysis: 37 days
			99 99	976 979	10 10	2 03/10/2014	85	Fruits	<u>0.21</u>	14	

(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 2.1.3.1.2 Study 2

Comments of zRMS:	The study has been evaluated and accepted in Registration Report, Section 4 for MCW-2222, Adama Makhteshim Ltd. (10.05.2018). Two residue trials have been performed in Northern Europe (Northern France): one decline trial (DMC-13-16134 FR01) and one harvest trial (DMC-13-16134 FR02). T1 plot was treated once with MCW-2222 at the rate of 0.5 L/ha (100 g a.i./ha of acetamiprid) 14 days before harvest at BBCH 85; the plot T2 was treated twice at 0.5 L/ha (200 g a.i./ha of acetamiprid), 22 (±1) and 14 days before harvest at BBCH 85. For decline trial, fruits specimens were collected at 0, 3, 7, 14 and 21 days after last application (DALA). For harvest trial, fruits specimens were collected 14 days after last application, at normal commercial harvest. No residue of acetamiprid was found in any untreated specimen. After one treatment with MCW-2222 (plot T1), the residues of acetamiprid in treated specimens were 0.11 mg/kg at 0 DALA and ranged from 0.06 to 0.08 mg/kg at 14 DALA (normal commercial harvest). After two treatments with MCW-2222 (plot T2), the residues of acetamiprid in treated specimens were 0.17 mg/kg at 0 DALA and ranged from 0.11 to 0.21 mg/kg at 14 DALA (normal commercial harvest). The acetamiprid LOQ was 0.01 mg/kg and the LOD defined as 0.003 mg/kg. Acceptance criteria for method validation were met, with average recoveries ranging from 70% to 110% and relative standard deviations ≤ 20%. The study has been accepted.

Reference:	KCP 8.3/02
Report	Magnitude of the residues of acetamiprid in apples (RAC fruits) following one or two applications of MCW-2222 in two trials (1 DCS + 1 HS), Northern Europe (Northern France) - 2013, Méric, D., 2014, Report No DMC-13-16134, Sponsor No R-33599
Guideline(s):	Yes Commission Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC The OECD Principles of Good Laboratory Practice, OECD Series on Principles of GLP and Compliance Monitoring Number 1, ENV/MC/CHEM(98)17 The Application of GLP Principles to Field Studies, OECD Series on Principles of GLP and Compliance Monitoring Number 6 (Revised 1999), ENV/JM/MONO(99)22 ENV/JM/MONO(2002)9 ENV/JM/MONO(2007)17 Principes de l'OCDE de Bonnes Pratiques de Laboratoire (BPL) Grundsätze der Guten Laborpraxis des Chemikaliengesetzes; §19a, Anh.1" and Guideline IV/3-2, (1992)Directive 2004/10/EC 7029/VI/95-rev 5 SANCO/3029/99 rev.4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 11: Summary of the study 2 trials (apple)

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				Acetamiprid		
DMC-13-16134 FR01 Centre 37110 Dame Marie les Bois Northern France N-EU 2014	Apple/Antares	1. 2005 2. 22/04 - 05/05/2013 3. 30/09 - 06/10/2013	98	969	10	24/09/2013	85	Fruits Fruits Fruits Fruits Fruits	0.11 0.09 0.07 0.06 0.06	0 3 7 14 22	Analytic: QuEChERS/ HPLC-MS/MS (report CIP 13M06017-01-VMPL) Validation: Mean recovery 70- 110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: Foliar broadcast application Max. Storage Interval between sampling and analysis: 100 days
			97 102	958 1008	10 10	2 24/09/2013	85	Fruits Fruits Fruits Fruits Fruits	0.17 0.15 0.18 0.11 <u>0.12</u>	0 3 7 14 22	
DMC-13-16134 FR02 Centre 37110 Dame Marie les Bois Northern France N-EU 2014	Apple/ Golden 972	1. 2011 2. 29/04 - 15/05/2013 3. 16/09 - 29/09/2013	100	982	10	04/09/2013	85	Fruits	0.08	14	Analytic: QuEChERS/ HPLC-MS/MS (report CIP 13M06017-01-VMPL) Validation: Mean recovery 70- 110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: Foliar broadcast application Max. Storage Interval between sampling and analysis: 106 days
			98 99	971 981	10 10	2 04/09/2013	85	Fruits	<u>0.21</u>	14	

(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 Potato

Table A 12: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (kg a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (RAR, The Netherlands, 2015, 2016)	3	0.05	-	BBCH 45-93	7
cGAP EU (Art. 12, EFSA, 2012)	2	0.05	-	BBCH 60-69	7
Intended cGAP (use No 3 and 13*)	1	0.036	-	BBCH 12-79	7

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

A 2.1.3.2.1 Study 1

Comments of zRMS:	The study has been evaluated and accepted in Registration Report, Section 4 for MCW-2222, Adama Makhteshim Ltd. (10.05.2018). The study on the magnitude of the residue of acetamiprid in potato Raw Agricultural Commodity (RAC) was conducted in Northern Europe following two foliar applications of MCW-2222 containing 200 g/L of acetamiprid. Four field trials (three decline and one harvest trials) have been performed in 2013 in Poland, United Kingdom and Northern France. Two foliar applications of MCW-2222 were performed with boom sprayers on the treated plots at the target dose rate of 0.3 L/ha (equivalent to 60 g a.s./ha). Applications were performed at the following timing: - 1st foliar application performed 7-8 days before the 2nd application, - 2nd foliar application performed 7 days before commercial harvest. In the decline curve trials (DCS), RAC specimens for analyses (potato tuber) were collected at 0, 1, 3, 7 (at the time of commercial harvest) and 10 DALA (Days After Last Application). In the harvest trial (HS), RAC specimens for analyses (potato tuber) were collected at 7 DALA at the time of commercial harvest. Residues of acetamiprid in untreated and treated specimens were below the limit of detection (<30% of limit of quantification, i.e. 0.003 mg/kg). Max. storage interval between sampling and analysis was 65 days. The acetamiprid LOQ was 0.01 mg/kg and the LOD defined as 0.003 mg/kg. Acceptance criteria for method validation were met, with average recoveries ranging from 70% to 110% and relative standard deviations ≤ 20%. The study has been accepted. * Indicates lower limit of analytical determination

Reference:	KCP 8.3/03
Report	Magnitude of the Residue of acetamiprid in potato Raw Agricultural Commodity after two applications of MCW-2222 in three decline curve trials (Poland, United Kingdom and Northern France) and in one harvest trial (Poland) in Northern Europe – 2013, Bousquet C., 2014, Report No 13SGS102, Sponsor No R-33600
Guideline(s):	Yes Regulation (EC) N°1107/2009 of 21 October 2009 (Repealing the Council Directive 91/414/EEC) concerning the placing of plant protection products on the market General recommendations for the design, preparation and realisation of residue trials, 7029/VI/95-rev 5, 22.07.97 and amendments The OECD Principles of Good Laboratory Practice (as Revised in 1997),

	OECD Series on Principles of GLP and Compliance Monitoring Number 1, ENV/MC/CHEM(98)17 ENV/JM/MONO(99)22 ENV/JM/MONO(2002)9 SANCO/3029/99 rev.4 ENV/JM/MONO(2007)17 DIN EN 15662:2009-02 (D) Article Annexe II à l'article D523-8 du Code de l'Environnement du 16 Oct 2007.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 13: Summary of the study 1 trials (potato)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid		
	(a)	(b)				(c)				(d)	(e)
13SGS102 PL01 Mazowiecki 05-850 Ozarow Poland N-EU 2014	Potato/Irga	1. 07/05/2013 2. 27/06 - 01/07/2013 3. 28/08 - 30/08/2013	61.1 61.3	407 409	15 15	2 22/08/2013	49	Tuber Tuber Tuber Tuber Tuber	<0.003 (LOD) <0.003 (LOD) <0.003 (LOD) <0.003 (LOD) <0.003 (LOD)	0 1 3 7* 10	Analytic: QuEChERS/ HPLC-MS/MS (report: 13M06017-01-VMPL) Validation: Mean recovery 70- 110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 41 days
13SGS102 UK02 Oxfordshire OX15 6EP Alkerton United Kingdom N-EU 2014	Potato/Arran pilot	1. 07/05/2013 2. 20/07 - 04/08/2013 3. 27/08/2013	60.3 59.4	301 297	20 20	2 16/08/2013	46	Tuber Tuber Tuber Tuber Tuber	<0.003 (LOD) <0.003 (LOD) <0.003 (LOD) <0.003 (LOD) <0.003 (LOD)	0 1 3 7* 11	Analytic: QuEChERS/ HPLC-MS/MS (report: 13M06017-01-VMPL) Validation: Mean recovery 70- 110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 47 days

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid		
	(a)	(b)				(c)				(d)	(e)
13SGS102 FR03 Pays de Loire 49650 Allonnes Northern France N-EU 2014	Potato/Spunta	1. 22/04/2013 2. 22/06 - 15/07/2013 3. 31/07 - 15/08/2013	609 601	304 300	20 20	2 29/07/2013	45	Tuber Tuber Tuber Tuber Tuber	<0.003 (LOD) <0.003 (LOD) <0.003 (LOD) <u><0.003 (LOD)</u> <0.003 (LOD)	0 1 3 7* 10	Analytic: QuEChERS/ HPLC-MS/MS (report: 13M06017-01-VMPL) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 47 days
13SGS102 PL04 Mazowieckie 96-323 Piekary Poland N-EU 2014	Potato/Irga	1. 10/05/2013 2. 21/06 - 10/07/2013 3. 28/08 - 30/08/2013	619 606	413 404	15 15	2 21/08/2013	49	Tuber	<u><0.003 (LOD)</u>	7*	Analytic: QuEChERS/ HPLC-MS/MS (report: 13M06017-01-VMPL) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 35 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
* Commercial harvest

A 2.1.3.3 Oilseed rape

Table A 14: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (kg a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA, 2016b)	2	0.042	-	BBCH 59 and 80	n.g.
Intended cGAP (use No 4-10 and 14-18*)	1	0.06	-	BBCH 31-71	28

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
n.g. not given

A 2.1.3.3.1 Study 1

Comments of zRMS:	The study has been evaluated and accepted in Registration Report, Section 4 for MCW-2222, Adama Makhteshim Ltd. (10.05.2018). Two residue trials have been performed in Northern Europe in 2013: one decline trial (trial DE01) and one harvest trial (trial FR02). T1 plot was treated once with MCW-2222 at the rate of 0.3 L/ha (60 g a.i./ha of acetamiprid) 28 (±3) days before harvest. The plot T2 was treated twice at 0.3 L/ha, 35 (±2) and 28 (±3) days before harvest. Whole plants, whole plants without pods and pods separately were sampled at intervals, between 0 and 21 days after last application. Seeds were collected at harvest between 28 to 31 days after last application. No residue of acetamiprid was found in any untreated specimen. After one treatment with MCW-2222, the residues of acetamiprid in seeds specimens were from below LOQ to 0.037 mg/kg at DALA 28-31. After two treatments with MCW-2222, the residues of acetamiprid in seeds specimens were from 0.017 to 0.052 mg/kg at DALA 28-31. The acetamiprid LOQ was 0.01 mg/kg and the LOD defined as 0.003 mg/kg (30% of the LOQ). Recoveries and relative standard deviations at each fortification level were therefore within the accepted ranges of 70 – 110% and ≤ 20%, respectively. The study has been accepted.

Reference:	KCP 8.3/04
Report	Magnitude of the residues of acetamiprid in oilseed rape (RAC whole plants, pods and seeds) following one or two applications of MCW-2222 in two trials (1 DCS + 1HS), Northern Europe (Germany and Northern France) - 2013, Méric D., 2014, Report No DMC-13-16129, Sponsor No R-33598
Guideline(s):	Yes Commission Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ENV/JM/MONO(2002)9 ENV/JM/MONO(99)22 Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC 7029/VI/95rev.5 SANCO 3029/99, 2000 SANCO 825/00, 2004
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 15: Summary of the study 1 trials (OSR)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid		
	(a)	(b)				(c)				(d)	(e)
DMC-13-16129 DE01 Lower Saxony 31608 Marklohe Germany N-EU 2014	Oilseed rape/ Visby	1. 23/08/2012 2. 02/05 - 01/06/2013 3. 31/07/2013	66	217	30	27/06/2013	75	Whole plant Whole plant Plant without pod Pods Plant without pod Pods Seeds	1.1 0.55 0.11 0.41 0.03 0.45 <0.01 (LOQ)	0 6 14 14 21 21 28*	Analytic: QuEChERS/ LC-MS/MS (GIRPA study B13-M1-A-01) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar broadcast application Max. Storage Interval between sampling and analysis: 134 days
			65 63	213 207	31 30	2 27/06/2013	75	Whole plant Whole plant Plant without pod Pods Plant without pod Pods Seeds	1.0 0.46 0.16 0.34 0.067 0.35 <u>0.017</u>	0 6 14 14 21 21 28*	
DMC-13-16129 FR02 Champagne-Ardennes 08310 Annelles Northern France N-EU 2014	Oilseed rape/ DK Explicit	1. 26/08/2012 2. 10/05 - 29/05/2013 3. 01/08/2013	64	236	27	02/07/2013	80	Seeds	0.037	31*	Analytic: QuEChERS/ LC-MS/MS (GIRPA study B13-M1-A-01) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar broadcast application Max. Storage Interval between sampling and analysis: 81 days
			58 57	216 209	27 27	2 02/07/2013	80	Seeds	<u>0.052</u>	31*	

(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
* Harvest

A 2.1.3.3.2 Study 2

Comments of zRMS:	The study has been evaluated and accepted in Registration Report, Section 4 for MCW-2222, Adama Makhteshim Ltd. (10.05.2018). Six residue trials have been performed on oilseed rape in Northern Europe in 2014: three decline trials and three harvest trials. The plots were treated once or twice with MCW-2222 at the rate of 0.3 L/ha (60 g a.i./ha of acetamiprid). Applications were performed following the target schedule: - one foliar application performed 28 ± 2 days before the anticipated harvest, or - 1st foliar application performed 7 ± 1 days before the 2nd application, - 2nd foliar application performed 28 days ± 2 days before the anticipated harvest. No residue of acetamiprid was found in any untreated specimen. After one treatment with MCW-2222, the residues of acetamiprid in seeds specimens were from <0.01 mg/kg to 0.01 mg/kg at DALA 28± 2. After two treatments with MCW-2222, the residues of acetamiprid in seeds specimens were from <0.01 mg/kg to 0.032 mg/kg at DALA 28± 2. The acetamiprid LOQ was 0.01 mg/kg and the LOD defined as 0.003 mg/kg (30% of the LOQ). Recoveries and relative standard deviations at each fortification level were therefore within the accepted ranges of 70 – 110% and ≤ 20%, respectively. The study has been accepted.

Reference:	KCP 8.3/05
Report	Magnitude of the residue of acetamiprid in winter oil seed rape (Raw Agricultural Commodity) after one or two applications of MCW-2222 - three decline curve trials and three harvest trials in Northern Europe (Northern France, Poland, Germany, Czech Republic and Hungary) - 2014, Chevallier E., 2014, Report No 14SGS035, Sponsor No R-34910
Guideline(s):	Yes Commission Regulation (EU) no 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) no 1107/2009 7029/VI/95-rev 5 OECD (2009),Test No. 509: Crop Field Trial, OECD Guidelines for the Testing of Chemicals, Section 5, OECD Publishing ENV/MC/CHEM(98)17 ENV/JM/MONO(99)22 ENV/JM/MONO(2002)9 SANCO/3029/99 rev.4, 11 July 2000 ENV/JM/MONO(2007)17
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 16: Summary of the study 2 trials (OSR)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid		
	(a)	(b)				(c)				(d)	(e)
14SGS035 FR01 Champagne Ardenne 08310 La Neuville en Tourne à Fuy Northern France N-EU 2014	Oilseed rape/ DK Explicit	1. 27/08/2013 2. 28/03 - 8/04/2014 3. 15/07/2014	59.2 58.5	246.7 243.3	24 24.1	2 18/06/2014	82	Whole plant Whole plant Plants w/o pods Pods Plants w/o pods Pods Seeds	1.5 1.5 0.089 2.0 0.034 0.39 <u>0.032</u>	0 6 15 15 22 22 27	Analytic: QuEChERS/ LC-MS/MS (GIRPA study B13-M1-A-01) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 76 days
			61.2	255	24	18/06/2014	82	Whole plant Whole plant Plants w/o pods Pods Plants w/o pods Pods Seeds	0.86 0.63 0.073 0.87 0.020 0.19 0.010	0 16 15 15 22 22 27	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid		
	(a)	(b)				(c)				(d)	(e)
14SGS035 GE02 Brandenburg 16818 Wahlendorf Germany N-EU 2014	Oilseed rape/ NK Linus	1. 03/09/2013 2. 10/04 – 21/04/2014 3. 19/07/2014	60.5 61.1	201.7 203.3	30 30	2 16/06/2014	78	Whole plant Whole plant Plants w/o pods Pods Plants w/o pods Pods Seeds	1.2 0.81 0.054 0.69 0.023 0.23 < 0.01	0 7 14 14 23 23 30	Analytic: QuEChERS/ LC-MS/MS (GIRPA study B13-M1-A-01) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 62 days
14SGS035 CZ03 Zlinsky kraj 68724 Uhersky Ostroh Czech republic N-EU 2014	Oilseed rape/ DK Expower	1. 10/09/2013 2. 10/04 – 05/05/2014 3.10/07 – 15/07/2014	57.7 61.6	288.5 308	20 20	2 13/06/2014	79	Whole plant Whole plant Plants w/o pods Pods Plants w/o pods Pods Seeds	1.1 1.1 0.032 1.3 0.047 0.44 0.028	0 7 13 13 20 20 27	Analytic: QuEChERS/ LC-MS/MS (GIRPA study B13-M1-A-01) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 69 days

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid		
	(a)	(b)				(c)				(d)	(e)
14SGS035 PL04 Kujawsko-Pomoroskie 88-400 Murczyn Poland N-EU 2014	Oilseed rape/ Artoga F1	1. 16/08/2013 2. 28/04 –15/05/2014 3. 05 – 10/07//2014	59.5 57.4	297.5 286.7	20 20	2 12/06/2014	80	Seeds	0.031	28	Analytic: QuEChERS/ LC-MS/MS (GIRPA study B13-M1-A-01) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 41 days
			62.8	313.9	20	12/06/2014	80	Seeds	<0.010	28	
14SGS035 GE05 Lower Saxony 49661 Cloppenburg Germany N-EU 2014	Oilseed rape/ Vision	1. 05/09/2013 2. 24/04 – 10/05/2014 3. 14 – 16/07/2014	60 59	200 196.7	30 30	19/06/2014	82	Seeds	0.022	27	Analytic: QuEChERS/ LC-MS/MS (GIRPA study B13-M1-A-01) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 35 days

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid		
	(a)	(b)				(c)				(d)	(e)
14SGS035 HU06 North-East 4482 Kótaj Hungary N-EU 2014	Oilseed rape/ PT200 CL	1. 04/09/2013 2. 20/04 –10/05/2014 3. 28/06 – 30/06/2014	61.5 61.7	306.9 308.3	20 20	02/06/2014	76	Seeds	<u><0.01</u>	26	Analytic: QuEChERS/ LC-MS/MS (GIRPA study B13-M1-A-01) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 53 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
w/o without

A 2.1.3.4 Corn

Table A 17: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (kg a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (use No 19 and 20*)	1	0.06	-	BBCH 51-75	56

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

A 2.1.3.4.1 Study 1

Comments of zRMS:	The study has been evaluated and accepted in Registration Report, Section 4 for MCW-2222, Adama Makhteshim Ltd. (10.05.2018). The study on the magnitude of the residue of acetamiprid in maize Raw Agricultural Commodity (RAC) was conducted in Northern Europe following one foliar application of the formulated product MCW-2222 containing 200 g/L of acetamiprid. Four semi decline curve trials and four decline curve trials were set up on maize in 2014 in Northern France, Poland, Germany, Hungary and Austria. The foliar application of MCW-2222 was performed on the treated plot at the target dose rate of 0.3 L/ha (equivalent to 60 g a.s./ha for acetamiprid) at BBCH stage 71-75. Application was performed at 56±3 days before the grain harvest date. In the decline curve trials (DCS), RAC specimens for analyses (whole plant, whole plant without cobs and without kernel, cobs, and grain) were collected at 0 DAA, 5±2 DAA, at milky stage - BBCH 73/75, at silage stage and grain harvest date – BBCH 89. In the semi decline curve trials (SDCS), RAC specimens for analyses (whole plant, whole plant without cobs and without kernel, cobs, and grain) were collected at milky stage - BBCH 73/75, at silage stage and grain harvest date – BBCH 89. No residues of acetamiprid were detected above the limit detection in the untreated specimens (LOD= 0.003 mg/kg). Residues of acetamiprid in grain and in cobs were below the LOQ of 0.01 mg/kg. The acetamiprid LOQ was 0.01 mg/kg and the LOD defined as 0.003 mg/kg. Acceptance criteria for method validation were met, with average recoveries ranging from 70% to 110% and relative standard deviations ≤ 20%. The study has been accepted.

Reference:	KCP 8.3/06
Report	Magnitude of the residue of acetamiprid in maize (Raw Agricultural Commodity) after one application of MCW-2222 – four semi decline curve trials and four decline curve trials in Northern Europe (Northern France, Poland, Germany, Hungary and Austria) - 2014, Lebrun, F., 2014, Report No 14SGS039, Sponsor No R-34912
Guideline(s):	Yes DIN EN 15662:2009-02 (D) Commission Regulations (EU) n°283/2013 7029/VI/95-rev 5, 22.07.97 and amendments OECD Guidelines for the Testing of Chemicals, Section 5, 2009 ENV/MC/CHEM(98)17 ENV/JM/MONO(99)22 ENV/JM/MONO(2002)9 SANCO/3029/99 rev.4 ENV/JM/MONO(2007)17
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 18: Summary of the study 1 trials (corn)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid		
	(a)	(b)				(c)				(d)	(e)
14SGS039 FR01 Centre 41500 Suèvre Northern France N-EU 2014	Maize/DKC 3930	1. 12/04/14 2. 10/07 - 24/07/14 3. 17/10 - 20/10/14	59.2	445.6	13.3	20/08/14	75	Whole plant Whole plant Whole plants w/o cobs and w/o kernel Cobs w/o husk Whole plant Grain	0.43 0.34 0.35 <0.01 (LOQ) 0.40 <u><0.01 (LOQ)</u>	0 5 9 9 27 58*	Analytic: QuEChERS/ HPLC-MS/MS (report: 13M06017-01-VMPL) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 72 days
14SGS039 PL02 Mazowieckie 05180 Pomiechówek Poland N-EU 2014	Maize/P8057	1. 25/04/14. 2. 09/07 - 23/07/14 3. 26/09 - 03/10/14	57.2	381.9	15	31/07/14	71	Whole plant Whole plant Whole plants w/o cobs and w/o kernel Cobs w/o husk Whole plant Grain	0.63 0.09 0.08 <0.01 (LOQ) 0.02 <u><0.01 (LOQ)</u>	0 6 11 11 33 55*	Analytic: QuEChERS/ HPLC-MS/MS (report: 13M06017-01-VMPL) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 92 days

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid		
	(a)	(b)				(c)				(d)	(e)
14SGS039 GE03 Lower Saxony 49685 Emstek Germany N-EU 2014	Maize/ SY COMANDOR MESUROL	1. 05/05/14 2. 28/07 - 11/08/14 3. 27/10/14	59.4	395.6	15	03/09/14	71	Whole plant Whole plant Whole plants w/o cobs and w/o kernel Cobs w/o husk Whole plant Grain	0.77 0.59 0.65 <0.01 (LOQ) 0.24 <u><0.01 (LOQ)</u>	0 5 9 9 29 54*	Analytic: QuEChERS/ HPLC-MS/MS (report: 13M06017-01-VMPL) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 58 days
14SGS039 HU04 Szabolcs- Szatmar-Bereg County H-4461 Nyirtelek Ferenctanya Hungary N-EU 2014	Maize/P0017	1. 18/04/14 2. 10/07 - 26/07/14 3. 22/09 - 24/09/14	62.2	621.1	10	28/07/14	71	Whole plant Whole plant Whole plants w/o cobs and w/o kernel Cobs w/o husk Whole plant Grain	0.42 0.10 0.16 <0.01 (LOQ) 0.02 <u><0.01 (LOQ)</u>	0 5 8 8 30 56*	Analytic: QuEChERS/ HPLC-MS/MS (report: 13M06017-01-VMPL) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 95 days

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid		
	(a)	(b)				(c)				(d)	(e)
14SGS039 FR05 Centre 37380 Reugny Northern France N-EU 2014	Maize/DKC 4117	1. 10/04/14 2. 18/07 - 26/07/14 3. 12/10 - 15/10/14	59.7	496.7	12	19/08/14	71	Whole plant w/o cobs and w/o kernel Cobs w/o husk Whole plant Grain	0.57 <0.01 (LOQ) 0.18 <u><0.01 (LOQ)</u>	6 6 29 58*	Analytic: QuEChERS/ HPLC-MS/MS (report: 13M06017-01-VMPL) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 67 days
14SGS039 PL06 Lubelskie 21307 Klębów Poland N-EU 2014	Maize/SILIEN	1. 21/04/14 2. 05/07 - 27/07/14 3. 26/09 - 03/10/14	62.6	417	15	01/08/14	71	Whole plant w/o cobs and w/o kernel Cobs w/o husk Whole plant Grain	0.37 <0.01 (LOQ) 0.04 <u><0.01 (LOQ)</u>	9 9 31 53*	Analytic: QuEChERS/ HPLC-MS/MS (report: 13M06017-01-VMPL) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 82 days

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid		
	(a)	(b)				(c)				(d)	(e)
14SGS039 GE07 Brandenburg 16818 Kränzlin Germany N-EU 2014	Maize/LG31.85	1. 25/04/14 2. 10/07 - 27/07/14 3. 21/09 - 26/09/14	60.2	300	20	01/08/14	71	Whole plant w/o cobs and w/o kernel Cobs w/o husk Whole plant Grain	0.28 <0.01 (LOQ) 0.05 <u><0.01 (LOQ)</u>	19 19 42 53*	Analytic: QuEChERS/ HPLC-MS/MS (report: 13M06017-01-VMPL) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 72 days
14SGS039 AU08 Upper Austria 4614 Marchtrenk Austria N-EU 2014	Maize/P 8400	1. 08/04/14 2. 10/07 - 15/07/14 3. end of Sept - early Oct 14	62.9	313.7	20.1	06/08/14	73	Whole plant w/o cobs and w/o kernel Cobs w/o husk Whole plant Grain	0.27 <0.01 (LOQ) 0.11 <u><0.01 (LOQ)</u>	8 8 23 55*	Analytic: QuEChERS/ HPLC-MS/MS (report: 13M06017-01-VMPL) Validation: Mean recovery 70-110 %, RSD ≤20% LOQ: 0.01 mg/kg LOD: 0.003 mg/kg MCW-2222 (SL) Method: foliar application (boom sprayer) Max. Storage Interval between sampling and analysis: 78 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
* BBCH 89 harvest

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new studies were conducted.

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

A 2.1.5.1 Distribution of the residue in peel/pulp

No new studies were conducted.

A 2.1.5.2 Processing studies on a core set of representative processes

A 2.1.5.2.1 Study 1

Comments of zRMS:	The study has been evaluated and accepted in Registration Report, Section 4 for MCW-2222, Adama Makhteshim Ltd. (10.05.2018). Residues of acetamiprid were analysed in processed samples / processing fractions (dry apples, washing water, apple juice, apple puree, wet apple pomaces and dry apple pomaces). Acetamiprid residues in washed fruits, washing water, wet pomaces, dry pomaces, juice, puree and dried apples ranged between 0.24 – 0.26 mg/kg, < 0.01 – 0.03 mg/kg, 0.33 – 0.47 mg/kg, 1.36 – 1.4 mg/kg, 0.17 – 0.18 mg/kg, 0.21 – 0.23 mg/kg and 1.15 – 1.18 mg/kg, respectively. The average transfer factor is 3.73 for dry pomace and 3.15 for dried fruits which show a concentration of acetamiprid during drying. The residues in other processed products are likely stable. The study has been accepted.

Reference:	KCP 8.5.3/01
Report	Magnitude of the residues of acetamiprid in apple (RAC fruits and processed fractions), following one or two applications of MCW-2222 in six trials (3 DCS + 3 HS), Northern Europe (Northern France, Germany, Poland and Belgium) - 2014, Roussel, Ch. H., 2014, Report No ChR-14-17311, Sponsor No R-34915
Guideline(s):	Yes Commission Regulations (EU) n°283/2013 and 284/2013 (GLP) OECD Principles of GLP: ENV/JM/MONO(2002)9, ENV/JM/MONO(99)22, ENV/MC/CHEM(98)17 Directive 2004/10/EC Principes de l'OCDE de Bonnes Pratiques de Laboratoire (BPL) Grundsätze der Guten Laborpraxis des Chemikaliengesetzes; §19a, Anh.1" and Guideline IV/3-2, (1992) 91/414/EEC (1607/VI/97 rev. 2) 7029/VI/95rev.5 SANCO 3029/99, 2000 SANCO 825/00, 2004 SANCO/3029/99 rev.4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

In the growing season 2014, two follow-up trials were established on apple in Northern Europe (Northern

France and Belgium), intended to determine acetamiprid residues in processed fractions. The sites were representative of apple grown in a way typical of the producing region in the test countries. One plot was foliar treated twice with MCW-2222 at the rate of 1.250 L/ha (equivalent to 250 g acetamiprid/ha) 22 and 14 days before harvest. A second plot was left untreated. The specimens for processing were taken 14 ± 1 days after last application and were transported under ambient conditions to the processing site. Samples were stored for max. 96 days in frozen conditions (<-18°C). The acetamiprid LOQ was 0.01 mg/kg and the LOD defined as 0.003 mg/kg (30% of the LOQ).

Two trials were processed into washed fruits, juice, puree, and dried fruits. The specimens for processing were considered in excellent conditions at their arrival at processing site. The apples were processed on the day of their arrival and kept unwashed for each process.
Washed fruits: At reception, the apples were washed thoroughly with water sprayed at the rate of approximately 0.5 L/kg of fruits (BE04) or 0.75 L/kg of fruits (FR01). Apples were then strained. Washing water and fruits were collected separately.
Juice: At reception, unwashed apples were crushed and pressed. Wet pomaces were collected, sampled and the remaining was dried during approximately one day at 60 °C in order to generate dry pomace specimens. The juice was depectinised with enzymes and clarified before being bottled and pasteurized at approximately 85 °C during 1 minute.
Puree: At reception, unwashed apples were blanched 2 minutes in boiling water, then crushed and sieved to separate pips and peel. Waste was discarded. Sugar was added according to their sugar content and the mix was reduced in a saucepan in order to reach 24% Brix. Puree was bottled and sterilized at 115/125 °C for 10 minutes.
Dried fruits: At reception, the fruits were cored and cut in slice about 3 mm thick. Cores were removed and discarded. The slices were placed in an oven at approximately 60 °C and left for drying until the humidity loss was more than 60% of original weight.

Samples were homogenised in a large scale mixer with addition of dry ice, except for processed fractions of washing water, apple juice and apple puree which were homogenised by shaking after defrosting. Samples were stored at -18 °C until required. For analysis, 10.0 g (± 0.1 g) of each sample (5 g ± 0.05 g for dry apples, wet apple pomaces and dry apple pomaces) were weighed into 50 mL centrifugation tubes, fortification samples were fortified at this step and 8.5 mL water were added for matrix dry apples, wet apple pomaces and dry apple pomaces. 10 mL acetonitrile were added and the samples were extracted using a sample homogeniser at high speed for at least 2 min. A buffer salt mixture (1 g sodium citrate, 0.5 g sodium hydrogen citrate sesquihydrate, 4 g magnesium sulphate, 1 g sodium chloride) was then added, shaken and mixed with the samples on a Vortex mixer for at least 1 min. The samples were then centrifuged at 3500 min-1 for at least 10 min. Samples were cleaned up by taking a 1 mL aliquot of the supernatant, transferring this into a 2 mL tube prepared with 25 mg PSA, 150 mg anhydrous magnesium sulphate and 2.5 mg GCB and then shaking on a vortex mixer for 30 s. The extract was filtered through a 0.45 µm disposable syringe filter into an autosampler vial (1.8 mL). The final extracts were diluted 1:10 (100 µL sample + 900 µL ACN) and 1:5 (200 µL sample + 800 µL ACN) for matrix dry apples, wet apple pomaces and dry apple pomaces, respectively. The diluted final extracts were used directly for analysis by HPLC-MS/MS.

Results and discussions
For method validation purposes, suitable fortification experiments were performed with untreated apple fruits, dry apples, washing water, apple juice, apple puree, wet and dry apple pomaces, fortified with acetamiprid to reach concentrations between 0.01 and 5.0 mg a.s./kg. Recoveries and relative standard deviations for each matrix and at each fortification level were within the accepted ranges of 70 – 110% and ≤ 20%, respectively. The acetamiprid LOQ was 0.01 mg/kg and the LOD defined as 0.003 mg/kg (30% of the LOQ). The method was found to be specific for the target analyte with interference less than 30% of the LOQ. The detector response was linear within the range 0.25 µg/L – 100 µg/L for a series of matrix matched samples. The associated correlation coefficients were ≥ 0.999.

Table A 19: Residue data from apple processing study with acetamiprid

RAC	Residues in RAC(unwashed sample, mg/kg)	PHI (days)	Processed commodity	Residue (mg/kg)	PF*
Apple	0.37	13	Whole fruit	0.37	1.00
	0.37	14		0.37	1.00
	0.37	13	Washed fruits	0.26	0.70
	0.37	14		0.24	0.65
	0.37	13	Washing water	0.03	0.08
	0.37	14		<0.01 (LOQ)	0.03
	0.37	13	Wet pomace	0.47	1.27
	0.37	14		0.33	0.89
	0.37	13	Dry pomace	1.36	3.68
	0.37	14		1.4	3.78
	0.37	13	Juice	0.18	0.49
	0.37	14		0.17	0.46
	0.37	13	Puree	0.21	0.57
	0.37	14		0.23	0.62
	0.37	13	Dried apples	1.18	3.19
	0.37	14		1.15	3.11

* processing factor

Figure A 1: Processing flowchart for apple distribution

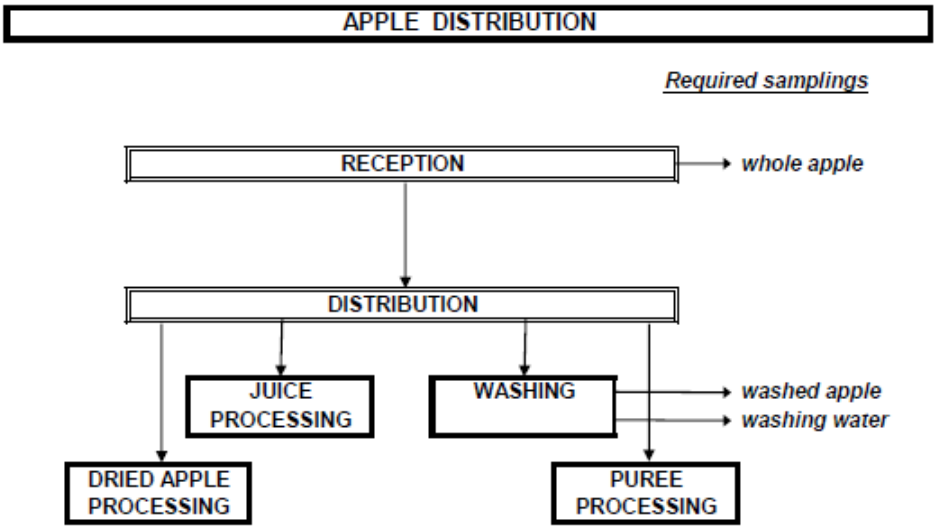


Figure A 2: Processing flowchart for apple juice

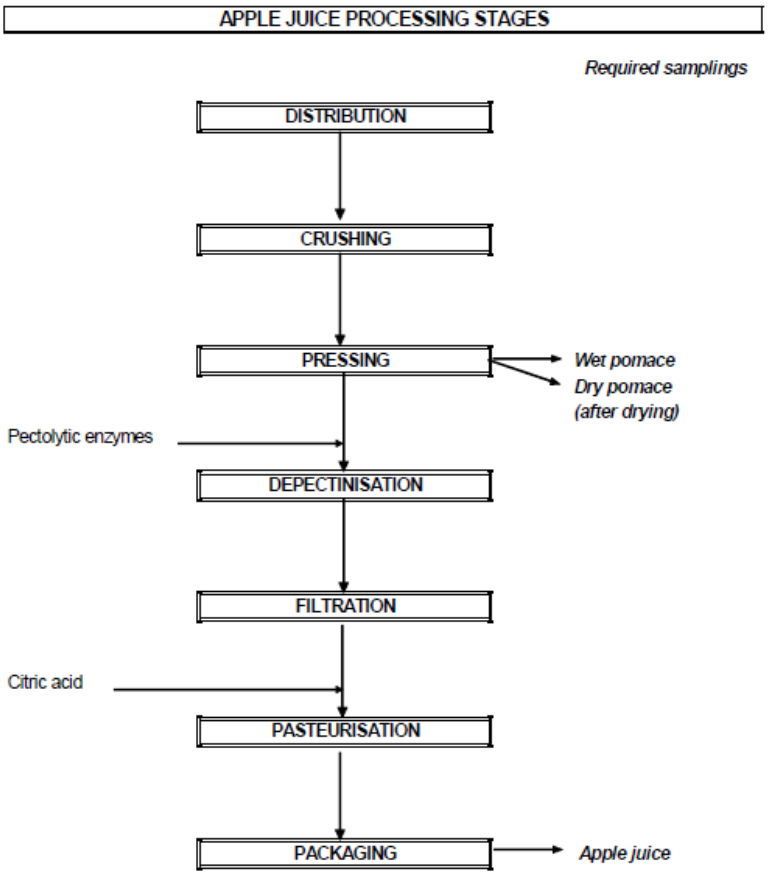


Figure A 3: Processing flowchart for apple puree

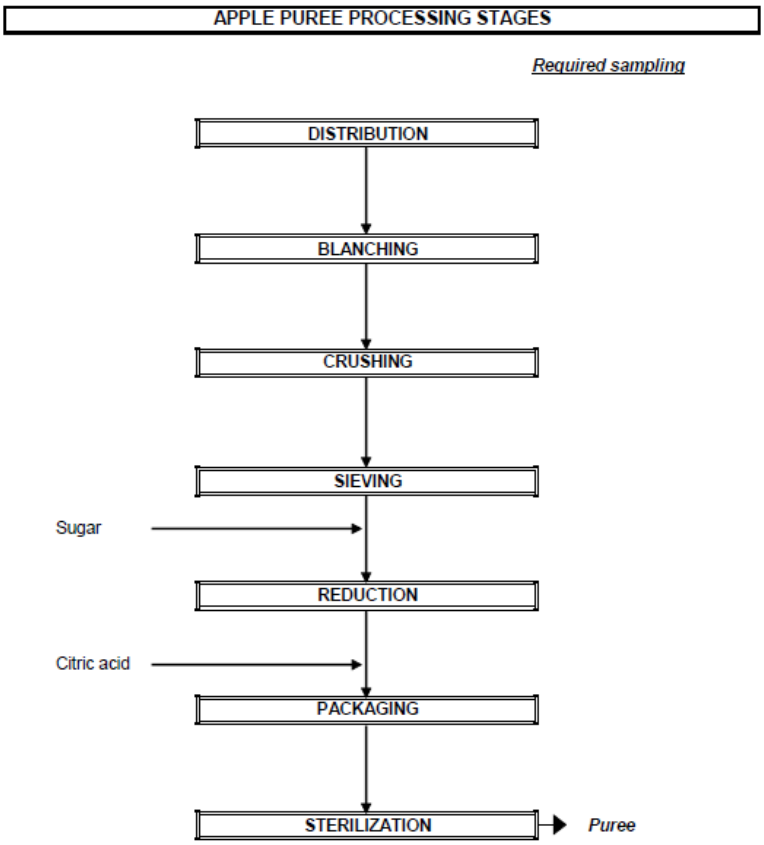
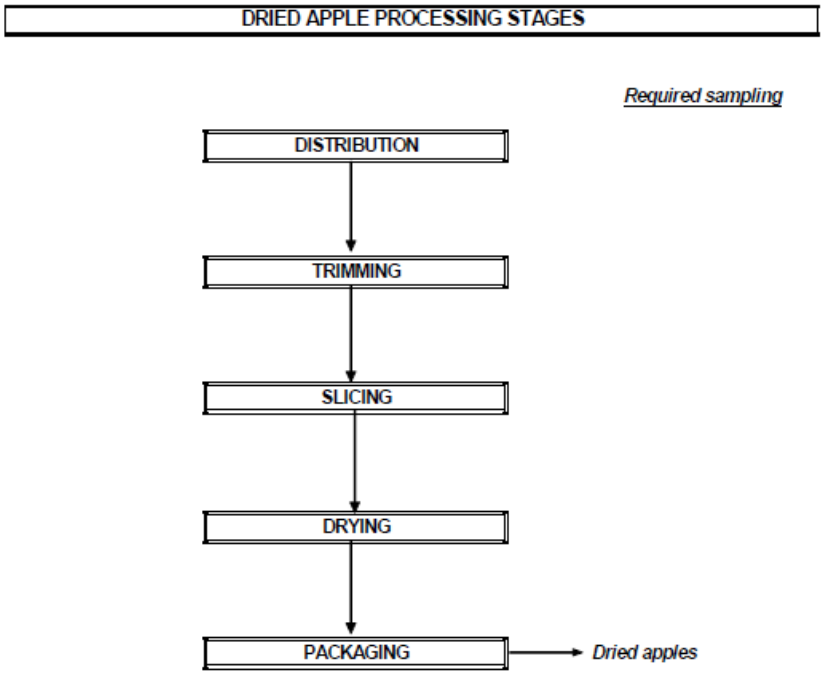


Figure A 4: Processing flowchart for dried apple



Conclusion

The transfer factor was increased in dried apples (3.15) and dry pomaces (3.73). The acetamiprid residue is likely stable in all process except drying that demonstrates an important concentration.

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A 2.1.6 Magnitude of residues in representative succeeding crops

A 2.1.6.1 Study 1

Comments of zRMS:	The objective of the study was to determine residue levels of acetamiprid and its metabolites IM-1-4 and IM-1-5 in soil and in the raw agricultural commodities radish, spinach and wheat grown as rotational crops at harvest after one application of MCW-2222 to bare soil. Two rotational crop trials were conducted during 2015 and 2016 in Germany (S15-02364-01) and in France (S15-02364). Each trial comprised three plant back intervals of nominal 30, 120 and 270 days. For all trials 6 plots were established, three untreated and three treated with MCW-2222 (SL formulation containing nominal 200 g acetamiprid /L). In all trials one application of MCW-2222 per crop and plant back interval was performed to bare soil at a target rate of 200 g ai/ha (nominal), using boom sprayer equipment. The test item was diluted with water immediately prior to application to a spray volume of 100 to 1000 L/ha (nominal). Plot 4, 5, and 6 were divided into three equal sub-plots on which radish, spinach and wheat were planted in 2015 and 2016 after the dedicated plant back intervals. Plots 4 and 5 were dedicated for planting and drilling only in 2015 and plot 6 was dedicated for planting and drilling in spring 2016 (except trial S15-02364-01, plot 4, subplot wheat with drilling in 2016). In the period between application and planting of the rotated crops the plots were maintained mostly in a bare soil condition by lightly cultivating. The soil was cultivated at least one day before application. Samples of radish and wheat were taken at normal commercial harvest time while spinach samples were taken at normal commercial harvest and at earliest commercial harvest time. Specimens of radish (leaves and tops) and spinach (leaves) were taken manually while specimens of wheat (grain and straw) were taken mechanically on the field or were taken manually and threshed mechanically at the test site. Soil cores of 0-20 cm from the untreated and treated plots of the trials were taken 0 to 1 day before application, 0 day after application, 0 to 1 day before planting of the rotated crops as well as immediately after harvest (except S15-02364-01, plot 6, subplot radish and spinach, soil samples were taken before or at harvest). Soil samples were sent in deep frozen conditions to the soil preparation test site. The soil core horizons were homogenised by grinding and sieving with dry ice. One aliquot of at least 400 g frozen homogenised soil was taken and stored deep frozen for analysis (except specimens L16-02364-02 -004, -005 and -006, prepared at the analytical test site). No residues of acetamiprid and its metabolites IM-1-4 and IM-1-5 were detected in soil samples collected before application, confirming the trial sites were free of contamination or carry over from any previous study. Crop specimens were placed in freezer immediately after sampling and transported frozen to the analytical laboratory or to the soil preparation test site. Crop specimens and soil specimens (after preparation) were stored at the laboratory in a freezer set to maintain a sample temperature of ≤ -18°C. The maximum storage interval at ≤ -18 °C from sampling to extraction was 590 days. Quantification was performed by use of highly selective LC-MS/MS detection. A validation according to SANCO/3029/99, rev. 4 for radish (leaves and roots), wheat (grain and straw) and soil was performed by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the recoveries. Five (5) fortifications of untreated control samples were performed. Specimens of radish, spinach, wheat and soil were analysed for residues of acetamiprid and its metabolites with a limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for acetamiprid, IM-1-4 and IM-1-5 in soil and each crop type, with the exception of 0.05 mg/kg as LOQ for IM-1-5 in straw. Quantification was performed by use of highly selective LC-MS/MS detection.

	The limits of detection (LOD) of the analytical method were 0.003 mg/kg for Acetamiprid, IM-1-4 and IM-1-5 in each crop type, with the exception of 0.015 mg/kg for IM-1-5 in straw. For soil, the limit of detection (LOD) of the analytical method was 0.003 mg/kg for all analytes. Results were not corrected for recoveries. No residues above 30% of the LOQ were detected in the control (untreated) test portions used for recovery determinations. Residue levels for acetamiprid were not detectable (<0.003 mg/kg) and residues for its metabolites were at (IM-1-5, radish leaves, 160 DAA) or below the LOQ (<0.01 mg/kg) or also not detectable. For the intended uses of acetamiprid in the product CA 3573 / Carnadine / Kestrel, no residues are expected in rotational crops. The study is acceptable.

Reference:	KCP 8.6.2/01
Report	Determination of residues of acetamiprid and its soil metabolites IM-1-4 and IM-1-5 after one application of MCW-2222 to bare soil in rotational crops (radish, spinach and wheat) at 1 site in Northern Europe and 1 site in Southern Europe 2015 / 2016, Semrau J., 2017, Report No S15-02364, Sponsor No R-35750
Guideline(s):	Yes OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32) OECD Test Guideline 509: Crop field trials OECD (2011) Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66) EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials OECD Test Guideline 504: Residues in rotational crops (limited field studies) EU Guidance Document SANCO/3029/99 rev. 4 for generating and reporting methods of analysis in support of pre-registration data requirements Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

GLP:	Yes	Sample storage conditions:	Max. 590 days at ≤-18°C
Preceeding crop:	Wheat, barley, maize	Analytical method:	S15-02364-L2 (validation report)
Succeeding crop:	Radish, spinach, wheat	Limit of Quantification (mg/kg):	0.01 mg/kg except 0.05 mg/kg for IM-1-5 in straw
Indoor/Outdoor:	Outdoor	Limit of Detection (mg/kg):	0.003 mg/kg except of 0.015 mg/kg for IM-1-5 in straw
Formulation:	MCW-2222 (SL)	Residues calculated as:	mg/kg Acetamiprid, IM-1-4, IM-1-5
Content of active substance (g/kg or g/L):	200 g/L		

Table A 20: Rotational trial summary for radish, spinach and wheat

Trial No./ Location/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI (days)	Remarks
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid	IM-1-4	IM-1-5		
S15-02364-01 Baden Würtemberg 71665 Kleinglattbach Germany N-EU 2017	*Preceeding: Wheat (2012, 2013), barley (2014)[1)]* Succeeding: Radish (Celesta F1)	1. 01/09/2015 2. n.a. 3. 15/10/2015	194.9	292	67	03/08/2015	Bare soil	Leaves Roots	<0.003 (n.d.) <0.003 (n.d.)	<0.01 <0.003	<0.01 <0.01	73 73	Nominal Plant Back Interval: 30 (Plot 4)
		1. 01/09/2015 2. n.a. 3. 15/10/2015	198.6	298	67	08/05/2015	Bare soil	Leaves Roots	<0.003 (n.d.) <0.003 (n.d.)	<0.01 <0.01	0.01 <0.01	160 160	Nominal Plant Back Interval: 120 (Plot 5)
		1. 11/04/2016 2. n.a. 3. 13/06/2016	201.2	302	67	06/07/2015	Bare soil	Leaves Roots	<0.003 (n.d.) <0.003 (n.d.)	<0.003 <0.003	<0.003 <0.003	343 343	Nominal Plant Back Interval: 270 (Plot 6)
	Succeeding: Spinach (Racoon)	1. 01/09/2015 2. n.a. 3. 15/10/2015	194.9	292	67	03/08/2015	Bare soil	Leaves Leaves	<0.003 (n.d.) <0.003 (n.d.)	<0.003 <0.003	<0.003 <0.01	64 73	Nominal Plant Back Interval: 30 (Plot 4)
	Succeeding: Spinach (Racoon)	1. 01/09/2015 2. n.a. 3. 15/10/2015	198.6	298	67	08/05/2015	Bare soil	Leaves Leaves	<0.003 (n.d.) <0.003 (n.d.)	<0.003 <0.003	<0.003 <0.003	151 160	Nominal Plant Back Interval: 120 (Plot 5)
	Succeeding: Spinach (Woodpecker)	1. 11/04/2016 2. n.a. 3. 13/06/2016	201.2	302	67	06/07/2015	Bare soil	Leaves Leaves	<0.003 (n.d.) <0.003 (n.d.)	<0.003 <0.003	<0.003 <0.003	336 343	Nominal Plant Back Interval: 270 (Plot 6)
	Succeeding: Wheat (Vinjett)	1. 04/04/2016 2. 15-30/06/2016 3. 26/07/2016	208.3	313	67	01/03/2016	Bare soil	Grain Straw	<0.003 (n.d.) <0.003 (n.d.)	<0.003 <0.003	<0.003 <0.003	147 147	Nominal Plant Back Interval: 30 (Plot 4)
	Succeeding: Wheat (Pamier)	1. 06/10/2015 2. 29/05-17/06/2016 3. 26/07/2016	211.1	317	67	02/06/2015	Bare soil	Grain Straw	<0.003 (n.d.) <0.003 (n.d.)	<0.003 <0.003	<0.003 <0.003	420 420	Nominal Plant Back Interval: 120 (Plot 5)
	Succeeding: Wheat (Vinjett)	1. 11/04/2016 2. 15-30/06/2016 3. 26/07/2016	201.2	302	67	06/07/2015	Bare soil	Grain Straw	<0.003 (n.d.) <0.003 (n.d.)	<0.003 <0.003	<0.003 <0.003	386 386	Nominal Plant Back Interval: 270 (Plot 6)

Trial No./ Location/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI (days)	Remarks
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid	IM-1-4	IM-1-5		
S15-02364-02 Tarn et Garonne 82290 Baryd'islemade France S-EU195 2017	*Preceeding: Maize*[2)] Succeeding: Radish (Pernot clair)	1. 04/06/2015 2. n.a. 3. 06/08/2015	216.5	217	100	05/05/2015	Bare soil	Leaves Roots	<0.003 (n.d.) <0.003 (n.d.)	<0.003 <0.003	<0.01 <0.01	93 93	Nominal Plant Back Interval: 30 (Plot 4)
		1. 04/09/2015 2. n.a. 3. 12/10/2015	195.3	195	100	05/05/2015	Bare soil	Leaves Roots	<0.003 (n.d.) <0.003 (n.d.)	<0.003 <0.003	<0.01 <0.01	160 160	Nominal Plant Back Interval: 120 (Plot 5)
		1. 23/03/2016 2. n.a. 3. 13/05/2016	202.5	202	100	01/07/2015	Bare soil	Leaves Roots	<0.003 (n.d.) <0.003 (n.d.)	<0.003 <0.003	<0.01 <0.01	317 317	Nominal Plant Back Interval: 270 (Plot 6)
	Succeeding: Spinach (Kauai)	1. 04/06/2015 2. n.a. 3.29/07/2015	216.5	217	100	05/05/2015	Bare soil	Leaves Leaves	<0.003 (n.d.) <0.003 (n.d.)	<0.003 <0.003	<0.003 <0.003	73 85	Nominal Plant Back Interval: 30 (Plot 4)
		1. 04/09/2015 2. n.a. 3.05/11/2015	195.3	195	100	05/05/2015	Bare soil	Leaves Leaves	<0.003 (n.d.) <0.003 (n.d.)	<0.003 <0.003	<0.01 <0.003	168 184	Nominal Plant Back Interval: 120 (Plot 5)
	Succeeding: Spinach (Samos Fi)	1. 23/03/2016 2. n.a. 3. 25/05/2016	202.5	202	100	01/07/2015	Bare soil	Leaves Leaves	<0.003 (n.d.) <0.003 (n.d.)	<0.003 <0.003	<0.003 <0.003	317 329	Nominal Plant Back Interval: 270 (Plot 6)
	Succeeding: Wheat (Sensas)	1. 04/06/2015 2. n.r. 3. 11/09/2015	216.5	217	100	05/05/2015	Bare soil	Grain Straw	<0.003 (n.d.) <0.003 (n.d.)	<0.003 <0.003	<0.003 <0.003	129 129	Nominal Plant Back Interval: 30 (Plot 4)
	Succeeding: Wheat (Galibier)	1. 22/10/2015 2. n.r. 3. 30/06/2016	186.1	186	100	19/06/2015	Bare soil	Grain Straw	<0.003 (n.d.) <0.003 (n.d.)	<0.003 <0.003	<0.003 <0.003	377 377	Nominal Plant Back Interval: 120 (Plot 5)
	Succeeding: Wheat (Triso)	1. 23/03/2016 2. n.r. 3. 27/07/2016	202.5	202	100	01/07/2015	Bare soil	Grain Straw	<0.003 (n.d.) <0.003 (n.d.)	<0.003 <0.003	<0.003 <0.003	392 392	Nominal Plant Back Interval: 270 (Plot 6)

n.a. not applicable
n.d. not detectable
1) preceeding crops belongs to all plots for trial S15-02364-01
2) preceeding crop belongs to all plots for trial S15-02364-02

A 2.1.7 Other/Special Studies

A 2.1.7.1 Study 1

Comments of zRMS:	The study objective was the determination of residues of acetamiprid in samples of honey, derived from field trials performed by RIFCON GmbH. To determine the residue levels of the active substance acetamiprid in honey Carnadine was applied twice on two different consecutive dates resulting in nominal application rates of 80 g/ha acetamiprid per application. The first application was conducted nine days (study field 1), ten days (study field 2 study field 3) and seven days (study field 4) before the second application. The second application took place during full flowering of Phacelia tanacetifolia, i.e. at BBCH growth stage 65 (study field 1, study field 2), BBCH growth stage 64 (study field 3) and BBCH growth stage 63 (study field 4). The test was conducted under tunnel conditions in summer 2019 at four different study fields in Germany and France. No residues above the limit of detection (0.003 mg/kg) of acetamiprid in untreated honey field trial samples were found. In treated honey field trial samples, the residues of acetamiprid range from 0.03 mg/kg to 0.85 mg/kg. The analytical method was fully validated in the current study according to guideline SANCO/3029/99 rev.4 at a limit of quantification (LOQ) of 0.01 mg/kg for matrix honey. Final determination was performed using HPLC-MS/MS. The study is acceptable.

Reference:	KCP 8.10.1/01
Report	Semi-field study for determining the magnitude of residues of Carnadine (CA3573) (a.s. acetamiprid) in honey, Hecht-Rost, S., 2020, GLP Study No. 467, Report No. R1940050
Guideline(s):	Yes (SANTE/11956/2018)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Residue levels of the active substance acetamiprid in honey were determined after two consecutive applications at nominal application rates of 80 g/ha acetamiprid per application.of the test item Carnadine (CA3573 SL, 200 g/L acetamiprid). The test was conducted under tunnel conditions in summer 2019 at four different study fields. Two tunnels were assembled per study field with the crop *Phacelia tanacetifolia*. The first application took place at the BBCH growth stages 62 (study field 1), 63 (study field 22) and 61 (study field 3 and study field 4). The second application was performed during full flowering of the crop (BBCH growth stages 65 (study field 1), 64 (study field 2 and study field 3), and 63 (study field 4)) and during bee-flight activity, nine days (study field 1), seven days (study field 4), and ten days (study field 2 and study field 3) after the first application. The tap water treated control was applied at the same dates as the second test item applications. The applications were carried out with a nominal spray volume of 400 L water/ha per treatment. The study was conducted under semi-field conditions and at four different locations, three in Germany and one in France. At each test location one control and one test item tunnel was used. One colony was setup per tunnel. The colonies were placed in the tunnels in the evening before the second test item application.

Table A 21: Target application rates and timings for phacelia (honey production)

Year	No of trials	No of appl.	F, P or G	Test item	Active substance	Appl. Rate (kg a.s./ha)	Water volume (L/ha)	BBCH
2019	4	2	G	Carnadine (CA3573 SL)	Acetamiprid	0.08	400	65

For residue analysis, honey was sampled. Generally, control samples were taken first or from different personal. All samples were maintained frozen at the testing facility, during shipping to the laboratory, and were stored frozen until analysis.
All shipped honey samples were analysed for acetamiprid by the Test Site CIP Analytical Services GmbH, Germany.

Results and discussions
The analytical method used for sample extraction and determination of residues was fully validated within this study. Quantification was performed by use of HPLC with MS/MS detection.
The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg and with a limit of detection (LOD) was set at 0.003 mg/kg (30% of the LOQ).
The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 92 – 114% and the mean recoveries at each fortification level were in the range of 70 – 110% with relative standard deviation(s) below 20%.

The summary of the analysed residues of acetamiprid in honey samples is presented in the table below.

Table A 22: Residue data of acetamiprid in honey

Study Site	Tunnel	Crop	Type of sample	DALA	Acetamiprid (mg/kg)
Study field 1 (Heddesheim, Germany)	C1	Phacelia	Honey	-	<LOD
	T1	Phacelia	Honey	0 – 19 [2)]	0.03
Study field 2 (Drusenheim, N-France)	C2	Phacelia	Honey	-	[1)]
	T2	Phacelia	Honey	7	0.85, 0.53
Study field 3 (Limburgerhof, Germany)	C3	Phacelia	Honey	-	<LOD
	T3	Phacelia	Honey	5	0.09
Study field 4 (Brensbach, Germany)	C4	Phacelia	Honey	-	[1)]
	T4	Phacelia	Honey	7	0.16

1) no honey samples available
2) The colonies at study field 1 were exposed inside the tunnels for 8 days, until they were brought to the remote location, where the bees foraged for another 12 days on natural occurring flowers. This led in the test item colony T1 to a mixture of the test item treated nectar collected inside the test item treated tunnel (DAT 0 to DAT 7) with the untreated nectar from the surrounding plants and trees collected at the monitoring site (DAT 8 to DAT 19). This reflected a realistic agricultural scenario, as honeybees in agricultural landscapes are also forced to find alternative nectar sources when flowers on which they foraged faded away.

Most likely as a result of the high dryness of the soil during the entire growing season, no honey was available in the control colonies at study field 2 and study field 4. The control honey taken from the colonies at study field 1 and study field 3 showed no acetamiprid residue (analysed values were below the LOD (LOD: defined as 0.003 mg/kg).

Conclusion
The application of the test item on two different consecutive dates resulted in residues in honey of 0.03 mg/kg acetamiprid (study field 1), 0.85 mg/kg acetamiprid in the A-sample and 0.53 mg/kg in the B-sample (study field 2), 0.09 mg/kg acetamiprid (study field 3) and 0.16 mg/kg acetamiprid (study field 4).
Most likely as a result of the high dryness of the soil during the entire growing season, no honey was available in the control colonies at study field 2 and study field 4. The control honey taken from the colonies at study field 1 and study field 3 showed no acetamiprid residue (analysed values were below the LOD

(LOD: defined as 0.003 mg/kg).

Residues in honey would lead to a calculated MRL of 2.0 mg/kg by using the new EU MRL calculator of 2015. But the experimental setup proposed in the technical guidance on residues in pollen and bee products using highly bee-attractive crops to reflect intended uses of acetamiprid in apple and oilseed rape result in unrealistic high residue levels and leads to a massive over-estimation of MRL's in honey. As indicated by monitoring data (EFSA 2014, 2015, 2016c, 2017, 2018b, 2019 and 2020; please also refer to KCP 8.10.1/03 to KCP 8.10.1/09) residues from approved uses as well as unintentional drift to non-target crops will be well below any artificial "worst-case" scenario. Only 0.26% of the total number of analysed honey samples for acetamiprid during 2012 and 2018 exceeded the EU MRL in honey above the level of quantification (0.05 mg/kg). It can be concluded, that the results of the EU monitoring programmes show that no residues of acetamiprid are present in the vast majority of samples. Therefore, no risk for the consumers is expected.

Please refer to the Expert Statement on the "Possibility to Estimate Residue Levels for Acetamiprid in Honey" (Appendix 4, KCP 8.10.1/02) providing an argumentation, why the currently valid EU MRL is reliable to reflect residue levels originating from approved uses of acetamiprid.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Acetamiprid

LOQs (mg/kg) range from: 0,01 to: 0,10

Toxicological reference values

ADI (mg/kg bw/day):	0,025	ARfD (mg/kg bw):	0,025
Source of ADI:	Reg. (EU)	Source of ARfD:	Reg. (EU) 2018/113
Year of evaluation:		Year of evaluation:	

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI: 1

	Calculated exposure (% of ADI)	MS Diet	Exposure (mg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	123%	NL toddler	30,67	48%	Milk: Cattle	17%	Apples	9%	Bananas	1,0%	73%
	79%	DE child	19,75	20%	Apples	16%	Milk: Cattle	14%	Oranges	0,5%	39%
	64%	NL child	16,08	20%	Milk: Cattle	9%	Apples	5%	Oranges	0,8%	35%
	55%	FR child 3 15 yr	13,66	18%	Milk: Cattle	12%	Oranges	3%	Bovine: Muscle/meat	0,6%	28%
	53%	FR toddler 2 3 yr	13,13	23%	Milk: Cattle	5%	Oranges	5%	Apples	0,5%	34%
	51%	UK infant	12,84	31%	Milk: Cattle	5%	Oranges	3%	Apples	0,5%	37%
	48%	ES child	12,12	10%	Milk: Cattle	9%	Olives for oil production	8%	Oranges	0,4%	18%
	42%	GEMS/Food G08	10,58	10%	Olives for oil production	4%	Milk: Cattle	4%	Swine: Muscle/meat	0,6%	13%
	41%	UK toddler	10,23	17%	Milk: Cattle	7%	Oranges	3%	Apples	0,4%	22%
	41%	SE general	10,18	10%	Milk: Cattle	9%	Bovine: Muscle/meat	3%	Bananas	0,4%	21%
	40%	GEMS/Food G07	10,08	5%	Milk: Cattle	5%	Oranges	4%	Olives for oil production	0,6%	14%
	38%	GEMS/Food G06	9,61	7%	Tomatoes	4%	Olives for oil production	4%	Oranges	0,5%	5%
	38%	DE women 14-50 yr	9,45	10%	Milk: Cattle	7%	Oranges	4%	Apples	0,5%	17%
	37%	GEMS/Food G10	9,13	5%	Olives for oil production	4%	Milk: Cattle	4%	Oranges	0,7%	10%
	36%	DE general	8,96	10%	Milk: Cattle	6%	Oranges	4%	Apples	0,5%	18%
	35%	GEMS/Food G11	8,72	6%	Milk: Cattle	3%	Olives for oil production	3%	Oranges	0,8%	13%
	35%	GEMS/Food G15	8,68	6%	Milk: Cattle	3%	Swine: Muscle/meat	2%	Oranges	0,6%	13%
	34%	DK child	8,40	10%	Milk: Cattle	4%	Swine: Muscle/meat	4%	Apples	0,5%	22%
	33%	IE adult	8,30	4%	Oranges	3%	Milk: Cattle	3%	Grapefruits	0,5%	8%
	33%	RO general	8,20	9%	Milk: Cattle	4%	Tomatoes	3%	Wine grapes	0,4%	15%
	31%	ES adult	7,67	5%	Olives for oil production	5%	Oranges	4%	Milk: Cattle	0,2%	9%
	27%	NL general	6,81	7%	Milk: Cattle	4%	Oranges	2%	Apples	0,4%	13%
	25%	FR infant	6,25	13%	Milk: Cattle	3%	Apples	1%	Beans (with pods)	0,2%	18%
	22%	FR adult	5,52	5%	Wine grapes	4%	Milk: Cattle	2%	Oranges	0,3%	8%
	21%	PT general	5,25	5%	Wine grapes	3%	Olives for oil production	2%	Oranges	0,3%	2%
	17%	DK adult	4,34	4%	Milk: Cattle	2%	Wine grapes	2%	Swine: Muscle/meat	0,2%	9%
	17%	IT toddler	4,13	3%	Tomatoes	3%	Wheat	2%	Lettuces	0,1%	1%
	15%	UK vegetarian	3,80	3%	Oranges	3%	Milk: Cattle	2%	Wine grapes	0,2%	4%
	15%	FI 3 yr	3,75	2%	Bananas	2%	Apples	1%	Raspberries (red and yellow)	0,4%	2%
	14%	IT adult	3,60	2%	Tomatoes	2%	Lettuces	2%	Wheat	0,1%	1%
	14%	UK adult	3,47	2%	Milk: Cattle	2%	Wine grapes	2%	Oranges	0,2%	5%
	14%	LT adult	3,43	3%	Milk: Cattle	3%	Apples	2%	Swine: Muscle/meat	0,3%	9%
	11%	FI 6 yr	2,76	1%	Bananas	1%	Mandarins	1%	Raspberries (red and yellow)	0,3%	1%
	10%	FI adult	2,42	1%	Oranges	1%	Coffee beans	1%	Tomatoes	1%	1,0%
	9%	PL general	2,37	3%	Apples	2%	Tomatoes	0,6%	Table grapes	0,2%	3%
	6%	IE child	1,59	3%	Milk: Cattle	0,5%	Apples	0,5%	Wheat	0,1%	4%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 122,7 % of the ADI.
For 1 diet(s) the ADI is exceeded.

A 3.2 IEDI calculations

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

Acetamiprid

LOQs (mg/kg) range from: 0,01 to: 0,10

Toxicological reference values

ADI (mg/kg bw/day):	0,025	ARfD (mg/kg bw):	0,025
Source of ADI:	Reg. (EU)	Source of ARfD:	Reg. (EU) 2018/113
Year of evaluation:		Year of evaluation:	

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI: ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (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)
38%	NL toddler	9,40	14%	Milk: Cattle	5%	Apples	3%	Table grapes	0,5%	20%
22%	DE child	5,60	5%	Apples	5%	Milk: Cattle	3%	Table grapes	0,4%	11%
20%	NL child	4,98	6%	Milk: Cattle	3%	Apples	2%	Table grapes	0,6%	9%
20%	GEMS/Food G08	4,97	10%	Olives for oil production	2%	Wine grapes	1%	Milk: Cattle	0,4%	2%
17%	ES child	4,28	9%	Olives for oil production	3%	Milk: Cattle	0,8%	Lettuces	0,3%	4%
15%	GEMS/Food G06	3,80	4%	Olives for oil production	2%	Table grapes	2%	Tomatoes	0,4%	1%
15%	UK infant	3,73	9%	Milk: Cattle	0,7%	Pears (without peel)	0,7%	Apples	0,3%	10%
15%	GEMS/Food G07	3,68	4%	Olives for oil production	3%	Wine grapes	2%	Milk: Cattle	0,4%	3%
13%	FR child 3 15 yr	3,36	5%	Milk: Cattle	1%	Olives for oil production	0,7%	Apples	0,5%	7%
13%	GEMS/Food G10	3,27	5%	Olives for oil production	1%	Milk: Cattle	0,8%	Wine grapes	0,5%	2%
13%	GEMS/Food G15	3,21	2%	Olives for oil production	2%	Wine grapes	2%	Milk: Cattle	0,4%	3%
13%	GEMS/Food G11	3,17	3%	Olives for oil production	2%	Wine grapes	2%	Milk: Cattle	0,6%	3%
13%	FR toddler 2 3 yr	3,14	7%	Milk: Cattle	1%	Apples	0,5%	Olives for oil production	0,4%	9%
12%	DE women 14-50 yr	2,97	3%	Milk: Cattle	2%	Wine grapes	1%	Apples	0,4%	4%
12%	PT general	2,93	5%	Wine grapes	3%	Olives for oil production	0,6%	Table grapes	0,1%	0,7%
11%	ES adult	2,86	5%	Olives for oil production	1%	Milk: Cattle	1%	Lettuces	0,2%	2%
11%	DE general	2,82	3%	Milk: Cattle	2%	Wine grapes	1%	Apples	0,4%	4%
11%	IE adult	2,79	3%	Wine grapes	1%	Milk: Cattle	0,9%	Blackberries	0,4%	2%
11%	RO general	2,76	3%	Wine grapes	3%	Milk: Cattle	1%	Tomatoes	0,2%	4%
11%	UK toddler	2,75	5%	Milk: Cattle	1%	Currants (red, black and white)	0,8%	Raspberries (red and yellow)	0,3%	6%
10%	FR adult	2,39	5%	Wine grapes	1%	Milk: Cattle	0,8%	Olives for oil production	0,3%	2%
9%	SE general	2,19	3%	Milk: Cattle	0,8%	Lettuces	0,7%	Bovine: Muscle/meat	0,2%	4%
8%	NL general	2,00	2%	Milk: Cattle	1%	Wine grapes	0,6%	Apples	0,3%	3%
8%	DK child	1,90	3%	Milk: Cattle	1%	Apples	0,4%	Table grapes	0,4%	5%
7%	FR infant	1,74	4%	Milk: Cattle	0,7%	Apples	0,4%	Cauliflowers	0,2%	5%
6%	FI 3 yr	1,44	1%	Raspberries (red and yellow)	0,5%	Currants (red, black and white)	0,5%	Table grapes	0,2%	0,6%
6%	DK adult	1,41	2%	Wine grapes	1%	Milk: Cattle	0,4%	Apples	0,1%	2%
5%	UK vegetarian	1,23	2%	Wine grapes	0,8%	Milk: Cattle	0,3%	Tomatoes	0,1%	1%
5%	UK adult	1,22	2%	Wine grapes	0,7%	Milk: Cattle	0,2%	Lettuces	0,1%	1%
4%	IT toddler	1,05	0,7%	Tomatoes	0,6%	Lettuces	0,5%	Cherries (sweet)	0,1%	0,4%
4%	FI 6 yr	1,01	1%	Raspberries (red and yellow)	0,3%	Table grapes	0,3%	Currants (red, black and white)	0,2%	0,4%
4%	FI adult	0,99	1%	Coffee beans	0,6%	Wine grapes	0,3%	Raspberries (red and yellow)	1%	0,3%
4%	IT adult	0,99	0,7%	Lettuces	0,6%	Tomatoes	0,4%	Cherries (sweet)	0,1%	0,4%
4%	PL general	0,93	0,9%	Apples	0,6%	Table grapes	0,5%	Cherries (sweet)	0,0%	1%
3%	LT adult	0,85	1,0%	Milk: Cattle	0,8%	Apples	0,3%	Tomatoes	0,1%	2%
2%	IE child	0,48	0,9%	Milk: Cattle	0,3%	Currants (red, black and white)	0,1%	Apples	0,1%	1%

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

A 3.3 IESTI calculations - Raw commodities

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 1

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

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
172%	Apples	0,4 / 0,4	43
99%	Milk: Cattle	0,2 / 0,2	25
32%	Bovine: Liver	1 / 1	8,1
29%	Honey and other apiculture	2 / 2	7,2
24%	Swine: Muscle/meat	0,5 / 0,5	6,1
19%	Milk: Goat	0,2 / 0,2	4,8
15%	Bovine: Kidney	1 / 1	3,8
14%	Bovine: Muscle/meat	0,5 / 0,5	3,6
12%	Equine: Muscle/meat	0,5 / 0,5	3,0
11%	Sheep: Muscle/meat	0,5 / 0,5	2,7
6%	Potatoes	0,01 / 0,01	1,5
5%	Swine: Kidney	1 / 1	1,3
5%	Swine: Liver	1 / 1	1,2
3%	Milk: Sheep	0,2 / 0,2	0,71
2%	Bovine: Fat tissue	0,3 / 0,3	0,62

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 1

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
45%	Apples	0,4 / 0,4	11
31%	Milk: Cattle	0,2 / 0,2	7,7
16%	Bovine: Liver	1 / 1	4,0
15%	Milk: Goat	0,2 / 0,2	3,7
12%	Milk: Sheep	0,2 / 0,2	3,0
11%	Bovine: Muscle	0,5 / 0,5	2,8
11%	Sheep: Liver	1 / 1	2,8
11%	Honey and other apiculture	2 / 2	2,8
10%	Swine: Muscle/meat	0,5 / 0,5	2,4
10%	Equine: Muscle/meat	0,5 / 0,5	2,4
9%	Sheep: Muscle/meat	0,5 / 0,5	2,4
9%	Swine: Kidney	1 / 1	2,2
8%	Bovine: Kidney	1 / 1	2,1
6%	Swine: Liver	1 / 1	1,4
3%	Goat: Muscle	0,5 / 0,5	0,78

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
99%	Milk: Cattle	0,2 / 0,2	25
99%	Apples	0,4 / 0,4	25
32%	Bovine: Liver	1 / 1	8,1
29%	Honey and other apiculture	2 / 2	7,2
24%	Swine: Muscle/meat	0,5 / 0,5	6,1
19%	Milk: Goat	0,2 / 0,2	4,8
15%	Bovine: Kidney	1 / 1	3,8
14%	Bovine: Muscle/meat	0,5 / 0,5	3,6
12%	Equine: Muscle/meat	0,5 / 0,5	3,0
11%	Sheep: Muscle/meat	0,5 / 0,5	2,7
5%	Swine: Kidney	1 / 1	1,3
5%	Swine: Liver	1 / 1	1,2
3%	Milk: Sheep	0,2 / 0,2	0,71
3%	Potatoes	0,01 / 0,01	0,66
2%	Bovine: Fat tissue	0,3 / 0,3	0,62

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
48%	Apples	0,4 / 0,4	12
31%	Milk: Cattle	0,2 / 0,2	7,7
16%	Bovine: Liver	1 / 1	4,0
15%	Milk: Goat	0,2 / 0,2	3,7
12%	Milk: Sheep	0,2 / 0,2	3,0
11%	Bovine: Muscle	0,5 / 0,5	2,8
11%	Sheep: Liver	1 / 1	2,8
11%	Honey and other apiculture	2 / 2	2,8
10%	Swine: Muscle/meat	0,5 / 0,5	2,4
10%	Equine: Muscle/meat	0,5 / 0,5	2,4
9%	Sheep: Muscle/meat	0,5 / 0,5	2,4
9%	Swine: Kidney	1 / 1	2,2
8%	Bovine: Kidney	1 / 1	2,1
6%	Swine: Liver	1 / 1	1,4
3%	Goat: Muscle	0,5 / 0,5	0,78

A 3.4 IESTI calculations - Raw commodities – refined

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
91%	Apples	0,4 / 0,21	23
30%	Milk: Cattle	0,2 / 0,06	7,5
12%	Honey and other	2 / 0,85	3,0
6%	Potatoes	0,01 / 0,01	1,5
6%	Milk: Goat	0,2 / 0,06	1,5
5%	Bovine: Liver	1 / 0,15	1,2
5%	Bovine: Kidney	1 / 0,3	1,1
1%	Bovine: Muscle/meat	0,5 / 0,05	0,36
1%	Equine: Muscle/meat	0,5 / 0,05	0,30
1%	Sheep: Muscle/meat	0,5 / 0,05	0,27
1,0%	Swine: Muscle/meat	0,5 / 0,02	0,24
0,9%	Milk: Sheep	0,2 / 0,06	0,21
0,7%	Bovine: Fat tissue	0,3 / 0,08	0,17
0,5%	Swine: Kidney	1 / 0,1	0,13
0,3%	Swine: Liver	1 / 0,06	0,07

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
24%	Apples	0,4 / 0,21	5,9
9%	Milk: Cattle	0,2 / 0,06	2,3
5%	Honey and other	2 / 0,85	1,2
4%	Milk: Goat	0,2 / 0,06	1,1
4%	Milk: Sheep	0,2 / 0,06	0,91
3%	Bovine: Kidney	1 / 0,3	0,63
2%	Bovine: Liver	1 / 0,15	0,60
2%	Sheep: Liver	1 / 0,15	0,42
1%	Potatoes	0,01 / 0,01	0,30
1%	Bovine: Muscle	0,5 / 0,05	0,28
1,0%	Equine: Muscle/meat	0,5 / 0,05	0,24
0,9%	Sheep: Muscle/meat	0,5 / 0,05	0,24
0,9%	Swine: Kidney	1 / 0,1	0,22
0,4%	Swine: Muscle/meat	0,5 / 0,02	0,10
0,3%	Swine: Liver	1 / 0,06	0,08

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
99%	Milk: Cattle	0,2 / 0,2	25
99%	Apples	0,4 / 0,4	25
32%	Bovine: Liver	1 / 1	8,1
29%	Honey and other	2 / 2	7,2
24%	Swine: Muscle/meat	0,5 / 0,5	6,1
19%	Milk: Goat	0,2 / 0,2	4,8
15%	Bovine: Kidney	1 / 1	3,8
14%	Bovine: Muscle/meat	0,5 / 0,5	3,6
12%	Equine: Muscle/meat	0,5 / 0,5	3,0
11%	Sheep: Muscle/meat	0,5 / 0,5	2,7
5%	Swine: Kidney	1 / 1	1,3
5%	Swine: Liver	1 / 1	1,2
3%	Milk: Sheep	0,2 / 0,2	0,71
3%	Potatoes	0,01 / 0,01	0,66
2%	Bovine: Fat tissue	0,3 / 0,3	0,62

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
48%	Apples	0,4 / 0,4	12
31%	Milk: Cattle	0,2 / 0,2	7,7
16%	Bovine: Liver	1 / 1	4,0
15%	Milk: Goat	0,2 / 0,2	3,7
12%	Milk: Sheep	0,2 / 0,2	3,0
11%	Bovine: Muscle	0,5 / 0,5	2,8
11%	Sheep: Liver	1 / 1	2,8
11%	Honey and other apiculture	2 / 2	2,8
10%	Swine: Muscle/meat	0,5 / 0,5	2,4
10%	Equine: Muscle/meat	0,5 / 0,5	2,4
9%	Sheep: Muscle/meat	0,5 / 0,5	2,4
9%	Swine: Kidney	1 / 1	2,2
8%	Bovine: Kidney	1 / 1	2,1
6%	Swine: Liver	1 / 1	1,4
3%	Goat: Muscle	0,5 / 0,5	0,78

A 3.5 IESTI calculations - Processed commodities

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
87%	Apples / juice	0,4 / 0,4	22	53%	Apples / juice	0,4 / 0,4	13
4%	Potatoes / fried	0,01 / 0,01	0,93	0,5%	Maize / oil	0,01 / 0,25	0,13
2%	Potatoes / dried (flakes)	0,01 / 0,05	0,59	0,3%	Potatoes / chips	0,01 / 0,01	0,08
0,3%	Rapeseeds / oils	0,4 / 0,8	0,24	0,2%	Potatoes / dried (flakes)	0,01 / 0,05	0,06
0,3%	Maize / oil	0,01 / 0,25	0,23	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0,1%	Maize / processed (not spe	0,01 / 0,01	0,02	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
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Expand/collapse list							

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---
IESTI new				**IESTI new**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
87%	Apples / juice	0,4 / 0,4	22	53%	Apples / juice	0,4 / 0,4	13
2%	Potatoes / dried (flakes)	0,01 / 0,05	0,59	0,5%	Maize / oil	0,01 / 0,25	0,13
2%	Potatoes / fried	0,01 / 0,01	0,44	0,3%	Potatoes / chips	0,01 / 0,01	0,08
0,3%	Rapeseeds / oils	0,4 / 0,8	0,24	0,2%	Potatoes / dried (flakes)	0,01 / 0,05	0,06
0,3%	Maize / oil	0,01 / 0,25	0,23	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0,09%	Maize / processed (not	0,01 / 0,01	0,02	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!

Conclusion:
The estimated short term intake (IESTI) exceeded the toxicological reference value for 1 commodities.

For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.6 IESTI calculations - Processed commodities – refined

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
24%	Apples / juice	0,4 / 0,11	6,0
4%	Potatoes / fried	0,01 / 0,01	0,93
2%	Potatoes / dried (flakes)	0,01 / 0,05	0,59
0,9%	Maize / oil	0,01 / 0,25	0,23
0,1%	Maize / processed (not sp	0,01 / 0,01	0,02
0,1%	Rapeseeds / oils	0,4 / 0,06	0,02
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
15%	Apples / juice	0,4 / 0,11	3,7
0,5%	Maize / oil	0,01 / 0,25	0,13
0,3%	Potatoes / chips	0,01 / 0,01	0,08
0,2%	Potatoes / dried (flakes)	0,01 / 0,05	0,06
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
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#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
87%	Apples / juice	0,4 / 0,4	22
2%	Potatoes / dried (flakes)	0,01 / 0,05	0,59
2%	Potatoes / fried	0,01 / 0,01	0,44
0,9%	Rapeseeds / oils	0,4 / 0,8	0,24
0,9%	Maize / oil	0,01 / 0,25	0,23
0,09%	Maize / processed (not	0,01 / 0,01	0,02
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
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#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
53%	Apples / juice	0,4 / 0,4	13
0,5%	Maize / oil	0,01 / 0,25	0,13
0,3%	Potatoes / chips	0,01 / 0,01	0,08
0,2%	Potatoes / dried (flakes)	0,01 / 0,05	0,06
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
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#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Acetamiprid is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix 4 Additional information provided by the applicant

Comments of zRMS:	The expert statement is acceptable. Taking into account the results of the EU monitoring programs it can be concluded, that no residues of acetamiprid are present in the vast majority of samples. Therefore, no risk for consumers is expected.

Reference:	KCP 8.10.01/02
Report	Expert Statement - Possibility to Estimate Residue Levels for Acetamiprid in Honey; Sagner A. and Kessler M., 2020, Report No R1960175_01
Guideline(s):	Not applicable
Deviations:	No
GLP:	Not applicable
Acceptability:	Yes

1 Background

Within the legislative framework of Regulation (EC) 1107/2009 setting out rules for authorisation of plant protection products in the European Union, specific data requirements for active substances and plant protection products have been defined in Regulations (EU) 283/2013 and 284/2013, respectively.
To address all routes of exposure of pesticide residues and resulting risks to consumers, data on residues of the active substance in plants, livestock, fish and other commodities are required under specific circumstances. In any case, Regulations (EU) 283/2013 requires to address *"residue in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom"*.
Further guidance on residues in pollen and bee products is given in the Technical Guidance Document for determining the magnitude of residues in honey and setting maximum residue levels in honey (SANTE/11956/2016 rev. 9), which has entered into force 01. January 2020. It describes procedures for setting MRLs in honey and serves as experimental and trial guidance for conduction of residue studies under field, tunnel or feeding conditions.

2 Introduction

Acetamiprid is an insecticide belonging to the class of neonicotinoids that is taken up from plant sucking insects. It is approved in the European Union for supported uses in citrus, pome and stone fruits, fruiting vegetables and oil seeds.
Acetamiprid was included in Annex I to Directive 91/414/EEC on 01 January 2005. The active substance was subsequently approved under Regulation (EC) 1107/2009 via Implementing Regulation (EU) 540/2011 and was renewed in 2018.
The insecticide is usually applied at a broad range of growth stages starting from BBCH 20 (formation of side shoots) to BBCH 81-90 (fruit ripening). Earlier applications are also envisaged for apple (BBCH 69-PHI), potato (BBCH 12-79), oilseed rape (BBCH 31-71) and corn (BBCH 51-75).
While some crops such as potatoes and corn are not attractive for bees (non-melliferous), others are considered to exhibit melliferous capacity. For this reason, field trials on residues in honey are usually required.
The technical guidance document was designed to cover all possible entry paths for residues in honey and bee products. A very conservative approach has been developed to cover all possible contaminates which might occur in these matrices. While in the past mainly application on bee attractive crops were considered, now also contamination via non-target plants, succeeding crops and honeydew collected from plant-sucking insects are to be taken into account.
For both melliferous and non-melliferous crops, different trial designs are proposed in the technical guidance to assess the residues expected to be found in bee products (i.e. studies on transfer from syrup, field or tunnel residue trials). For all trial designs, a realistic worst case scenario is to be considered expressed by highest application rates, shortest waiting periods etc. To cover uses on permanent crops with high melliferous capacity (e.g. apple), model crops with high melliferous capacity (e.g. phacelia) are

proposed for tunnel trials.
However, in all of the proposed experimental setups, bees get in contact with unrealistic high amounts of substances. Therefore, the studies are only useful to clarify if a transfer from either plants or syrup to bee products are generally possible, but are rather unsuitable to get a realistic estimation of residue levels in honey to be found under realistic conditions. It has therefore been criticized that the outcome of such studies cannot be used to derive a realistic MRL, needed for consumer risk assessment and for monitoring purposes.
To protect consumers and the environment, MRLs should generally not be higher than needed to cover EU critical GAPs (ALARA principle - level as low as reasonably achievable). According to the technical guidance, monitoring data might be a useful tool, if the residue definition for monitoring covers all substances (parent and respective metabolites) which need to be taken into account for bee products according to technical guidance.
In the absence of specific metabolism studies with honey bees, the residue definitions for risk assessment needs to be derived taking into account other sources of information, such as studies investigating the nature of residues in primary crops (i.e. crops that were treated with the pertinent pesticide), the degradation during pasteurisation and studies investigating the nature of residues in rotational crops (i.e. residues taken up by plants from the soil).
For acetamiprid, residue definition for risk assessment for primary crops, rotational crops and for processing is according EFSA Art. 12: acetamiprid. The residue definition used for monitoring, which needs to be fulfilled during EU monitoring of crops and animal matrices (including honey and bee products) is also defined as acetamiprid. Monitoring data should therefore cover the residue definition and are therefore suitable to derive an MRL according to the technical guideline.
This statement provides an argumentation, why the currently valid EU MRL is reliable to reflect residue levels originating from approved uses of acetamiprid.

3 Theoretical Requirements for Residue Studies in Honey

According to Reg(EU)283/2013 data on residues in pollen and bee products needs to be addressed.
To assess whether or not residue studies are required, the technical guidance document includes a decision-making scheme starting with the question if residues in honey after pesticides application are expected. Besides some clear cases such as application to melliferous crops, also certain conditions of unintentional exposure of bees to residues are considered, e.g. due to unintentional application on non-target plants (in-field weeds, adjacent plants) or due to uptake of soil-persistent residues in rotational crops.
Following the decision making scheme given in the technical guidance, it has to be determined if residues in honey are expected. For the intended uses in apple and oilseed rape, residues in honey could occur:

- from applications during the flowering stage (BBCH 60-69),
- from uses on non-target plants (in-field weeds and adjacent plants) when a substance is applied during the flowering period from April to September,
- from succeeding crops after application of a persistent and systemic active substance,
- via honeydew collected from plant-sucking insects in forestry.

Accordingly, any intended use with applications between April and September and in particular intended uses on oilseed rape require data on residues in honey. In a second and third step, the levels of residues in aerial parts are considered. The highest residues in aerial parts of after application account for up to 1.50 mg/kg and therefore are well above 0.5 mg/kg. In consequence, residue data in honey would be required from either syrup feeding, tunnel or field trials. Based on the results of these trials, a specific MRL would be set.
Following this reasoning, the technical guidance requires residue trials in honey. For intended uses on apple and also rapeseed, it is recommended in the guidance document to conduct residue studies in an artificial model system using highly melliferous crops such as phacelia to consider a worst-case scenario.

4 Realistic Scenarios of Residues in Honey

4.1 General Considerations

The insecticide is applied pre-, inter- and post-emergence in oilseed rape (BBCH 31-71; before, during and after flowering), apple (BBCH 69-PHI; end of flowering to fruit ripening) and other crops at single

application rates of up to 60 g/ha with up to 2 applications per use/season and water volumes of 200-1000 L/ha.
Residues in aerial parts of oilseed rape account for up to 1.50 mg/kg directly after application.

4.2 Monitoring Data

According to the technical guidance, "Monitoring data might be a useful tool to provide additional information if such data are available. Article 16 of Reg(EU)396/2005 allows the setting of temporary MRLs in honey on the basis of monitoring data. [...]
The available monitoring data should:

- reflect the agreed residue definition;
- reflect different production areas."

The residue definition for risk assessment for plants, rotational crop and processing according to EFSA Reasoned Opinion Art. 12 of 2012 is defined as: acetamiprid.
The same residue definition is used for monitoring purposes: acetamiprid.
As the residue definitions for purposes of monitoring and risk assessment are identical, monitoring data can be used to derive residue levels for risk assessment purposes, as proposed by the technical guidance.
Therefore, a literature research has been conducted to retrieve information on actual residue levels of acetamiprid in honey, determined within the frame of annual EU monitoring programmes. The results show that no residues of acetamiprid are present in the vast majority of samples. Only a few number of samples exceeded the EU MRL in honey above the level of quantification of 0.05 mg/kg.

Table 18 Number of honey samples and MRL exceedances for acetamiprid

Annual Programme	2012	2013	2014	2015	2016	2017	2018
Total no. of samples analysed	n.r.	n.r.	881	966	1,131	659	762
MRL exceedances	7	0	2	1	0	1	2
Ratio MRL exceedance/total analyses	-	0.00%	0.23%	0.10%	0.00 %	0.15%	0.26%
max. acetamiprid residues [mg/kg]	0.097*	n.d.	0.22	0.16	n.d.	0.47	0.17

n.d. not detected
n.r. not reported
* one sample from China contained 0.52 mg/kg

For comparison, the overall numbers of analysed food samples and MRL exceedances throughout Europe are summarized in Table 19.

Table 19 Number of animal product samples and MRL exceedances for acetamiprid

Annual Programme	2012	2013	2014	2015	2016	2017	2018
Total no. of samples analysed	7678	8257	9152	7822	8351	9682	11549
MRL exceedance	n.r.	25	70	33	159	102	202
Ratio MRL exceedance/total analyses	0.50%	0.30%	0.76%	0.42%	1.90%	1.05%	1.7 %

n.r. not reported

5 Conclusion

In general, residues in honey were below the level of current EU MRL of 0.05 mg/kg in the vast majority of samples. Only in rare cases, residues were detected or MRLs were exceeded. The fraction of samples with MRL exceedances accounted for a maximum of 0.26 % of the total number of analysed honey samples.
A potential reason for MRL exceedance is given by EFSA:

- "GAP not respected: i.e. different to the ones set as the GAP application rates, preharvest intervals, number or method of applications of the pesticide product (e.g. ethephon in sweet peppers). This may also concern drift-contamination resulting from inappropriate application during adverse weather conditions or unauthorised use of EU-approved pesticides in crops where MRLs have not been set."

In the light of MRL exceedances for all analysed food products, which account for up to 1.90% of all analyses, the fraction of MRL exceedances for honey are well below the average exceedance rate and therefore, the currently valid EU MRL of 0.05 mg/kg is considered robust and reliable to reflect residue levels originating from approved uses of acetamiprid.

An experimental setup proposed in the technical guidance on residues in pollen and bee products using highly bee-attractive crops to reflect intended uses of acetamiprid in apple and oilseed rape results in unrealistic high residue levels and leads to a massive over-estimation of MRL's in honey. As indicated by monitoring data, residues from approved uses as well as unintentional drift to non-target crops will be well below any artificial "worst-case" scenario.
Consequently, an MRL on acetamiprid residues in honey should be derived from monitoring data, as proposed in the technical guidance document. Since acetamiprid residues are in general found below the limit of quantification in EU monitoring programmes, an MRL increase is inappropriate.
Furthermore, any potential residue will not contribute a significant portion to the consumer risk. EFSA PRIMo calculations (EFSA 2018a) with all existing MRLs and fall-back MRL for various crops show a very high safety margin with the highest chronic exposure representing 13% of the ADI for WHO cluster diet B and the highest acute exposure representing 87 % of the ARfD (scarole). Therefore, a risk for consumers from potential residues in honey can be excluded.
In conclusion, an MRL increase for acetamiprid residues in honey is not reasonable and not required to allow for safe intended uses on apple and oilseed rape.

6 References

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