

# FINAL REGISTRATION REPORT

## Part B

### Section 7

#### Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA5500A

Product name(s): ASSET (~~ZUXION~~)

Chemical active substance:

Acetamiprid, 200 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

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## Version history

When	What
October 2020	Applicant update
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## 7 Metabolism and residue data (KCA section 6)

### 7.1 Summary and zRMS Conclusion

February 2023 Assessment of updated Section B7

#### Storage stability

Acetamiprid is stable in crops containing high water content, and high oil content matrices when stored under freezer conditions not exceeding 12 months;

The stability tests (on high water content, and high oil content matrices) described in the EFSA document (EFSA Journal 2016;14(11):4610) were accepted during reevaluation of active substance and they are not protected.

New stability study of acetamiprid residues in apple during 2 years of storage have been submitted by the applicant in the framework of this application (see Appendix 2). The results of this study showed that Acetamiprid is stable in apple (fruits) when stored at  $\leq -18^{\circ}\text{C}$  for a period of up to 24 months.

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

The metabolism in plants and livestock for the active substance Acetamiprid was reviewed during the Annex I inclusion and renewal process. No additional studies are available in the framework of this application.

Metabolism in primary crops was investigated in the fruit, leafy, root and oilseeds/pulses crop groups.

Metabolism in rotational crops was investigated in the root/tuber crops, leafy crops and cereal (small grain)

Plant residue definition for monitoring and risk assessment: acetamiprid

Animal residue definition for monitoring: acetamiprid except honey: the sum of acetamiprid and IM-2-1, expressed as acetamiprid (Reg (EU) 219/88)

Based on animal metabolism studies, the residue definition was proposed by EFSA as 'IM-2-1 expressed as acetamiprid' for monitoring and as 'the sum of acetamiprid and IM-2-1, expressed as acetamiprid' for risk assessment (EFSA Journal 2016;14(11):4610).

#### Note:

Study Hobbs, G., Inns, L., 2012 (metabolism in rotational crops) is protected. Equivalent study should be provided (see Data matching, The Netherlands, 2018). Reference to protected data cannot be accepted.

However, data gap indicated in the data matching cannot be a reason for refusal to renew the PPP in Poland.

This study is important for the evaluation of acetamiprid as an active substance, taking into account the possible presence of the metabolite IM-1-5 in succeeding crops grown on calcareous soils. Metabolism in rotational crops is not required for uses of plant protection products in permanent crops (e.g. orchards and nuts) or semi-permanent crops. Given this we find that for ~~ZUXION~~ ASSET, this requirement only applies to the cultivation of oilseed rape.

In addition, it should be noted that the residue definition covers only active substances and does not include any metabolites. It is the same for main and rotational crops. The results obtained from the Hobbs, G., Inns, L. (2012) study did not change the end points in this area. The evaluator wants to emphasize that in Poland only 9% of soils are alkaline and the registration applies only to Poland. Despite this from a formal point of view this study is required for rape seed uses.

Consequently, the evaluator disagreed with the use of this PPP in oilseed rape. Registration will be possible after completing the equivalent study to the protected study (Hobbs, G., Inns, L., 2012 (metabolism in rotational crops)).

New metabolism study has been submitted by the Applicant in the framework of this application. The study was accepted by The Netherlands (2021) as an alternative study in the Matching Active Substance Data check document.

NL conclusion: "The applicant provided an alternative metabolism study in rotational crops (Report no. S19-02432). The study is GLP- and guideline-compliant, and results in approximately the same endpoints at the study by Hobbs, G. and Inns, L. (2012). Acceptable"

A detailed assessment of the study should be carried out at the EU level.

The Applicant has fulfilled the requirements.

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

#### **Oilseed rape**

Proposed GAP:

BBCH: before-69, 1 application, Application rate per treatment: 0.04 kg as/ha, PHI: 28 days;

Critical GAP in NEU (EFSA Journal 2010; 8(11):1898, EFSA Journal 2011;9(7):2328):

BBCH 75-81 (PHI: 28 days); 1 application, Application rate per treatment: 0.05 kg as/ha.

2 applications were made in some of trials used for the active substance assessment instead of one.

New acceptable studies on the magnitude of residue have been submitted by the applicant in the framework of this application (see Appendix 2).

New acceptable studies GAP: 1 application, BBCH: 69, 0.04 kg as/ha, PHI: 28 days

Results: 2 x <0.01; 0.014, 2 x 0.016, 0.018, 2 x 0.022 mg/kg

Sufficient trials on oilseed rape are available to support the proposed uses. The residue data are valid with regard to storage stability data. Samples were stored to 195 days until analyses.

The validated analytical methods used for determination of acetamiprid in oil seed rape fulfil criteria of acceptance. described in SANCO/825/00 rev.8.1 document.

LOQ = 0.01 mg/kg

The residues arising from the proposed uses will not exceed the MRLs for acetamiprid established for oilseed rape (0.4 mg/kg ; Reg. (EU) 2019/88).

#### **Pome fruits**

Proposed GAP:

Apple: before BBCH 59 and from BBCH 69; 2 applications, Application rate per treatment: 0.05 kg as/ha, Interval between applications: 14 days, PHI: 14 days

EU GAP: 2 x 0.075 kg as/ha, BBCH 77-87 (List of Endpoints, Acetamiprid, The Netherlands, 2016)

The residue trials in pome fruit were already evaluated in the original DAR and in renewal process.

Below is the conclusion from the re-evaluation (Acetamiprid, Volume 3, B7 Residue, The Netherlands, 2016):

*The GAP for pome fruit includes an interval of at least 14 days between the two applications. When evaluating the trials in more detail after the peer review within the renewal, it appears that the trials (which have already been used for the initial inclusion of acetamiprid) are performed with at least a 1-month*

*interval up to an interval of 49 days between the two applications. From the trials it can be concluded that at a PHI of 14 days still residues are present on pome fruit. Higher residues might be present when an interval of 14 days is applied in the trials instead of at least 1 month. Therefore, the trials are not conducted according to the cGAP, and are not acceptable.*

According to EU data GAP with 30 – 40 days interval between the two applications is acceptable for pome fruits.

New studies on the magnitude of residue have been submitted by the applicant with interval between treatments of 14 days in the framework of this application.

Trials GAP: 2x0.05 kg as/ha, interval between treatments 14 days, PHI: 14 days, outdoor.

Results: 0.016, 0.017, 0.019, 0.022, 0.026, 0.026, 0.029 mg/kg

The studies were performed according to proposed GAP with 14 days of interval.

The package of EU and the new trials allows to accept the use in pome fruits with 14 days interval between the two applications.

The residues from field trials are below MRL of 0.4 mg/kg (Reg (EU) 219/88).

According to the SANCO 7525/VI/95 rev.10.3 of 13 June 2017 extrapolation from apple to the whole group of pome fruit is possible.

### **Feeding studies**

Data/information on livestock feeding studies were reviewed during the Annex I inclusion process and was considered to be acceptable and no further data have been generated.

The requested uses (and the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded after application of product according to the intended GAP uses.

### **Supplementary Studies on Industrial Processing and/or Household Preparation**

Data on processing studies were evaluated at EU level.

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

### **Residues in Succeeding Crops**

Acetamiprid, IM-1-4 and IM-1-5 residues are not expected to be present in rotational crops.

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

Note:

Studies Raufer, B., 2013, 2014 are protected. Equivalent study should be provided (see Data matching, The Netherlands, 2018). Reference to protected data cannot be accepted.

See note for metabolism.

Evaluator disagreed with the use of this PPP in oilseed rape. Registration will be possible after completing the equivalent study to the protected studies.

New studies for residues in succeeding crops have been submitted by the Applicant in the framework of this application. Studies are acceptable.

New data:

Representative succeeding crops of carrots, spinach and barley were planted at plant back intervals of 30,

63, 130 and 348 days. No residues of Acetamiprid or metabolite IM-1-5 above the LOQ (0.01 mg/kg) were found in any of the samples taken from all the PBIs.

#### **Consumer risk assessment**

The accepted uses of acetamiprid in the formulation SHA5500A do not represent unacceptable acute and chronic risks for the consumer.

#### **Conclusion:**

**Registration in the protection of oil seed rape will be possible after completing the equivalent studies to the following protected studies (see Data matching, The Netherlands, 2018):**

**Study Hobbs, G., Inns, L., 2012 (metabolism in rotational crops).**

**Raufer, B., 2013, 2014 studies (field rotational crop studies).**

**Reference to protected data cannot be accepted.**

Alternative studies have been provided.

According to the current requirements (SANTE/11956/2016 rev. 9), information on residues in honey is required. Such information can be provided after authorization is obtained.

### **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 SHA5500A are presented in Table 7.1-1. They have been selected from the individual GAPs in the central zone for oilseed rape and pome fruits. A list of all intended uses within the central is given in Part B, Section 0.

#### **Overall conclusion**

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.4 - 0.8 mg/kg (pome fruits) and 0.4 mg/kg (oilseed rape) for acetamiprid as laid down in Reg. (EU) 396/2005 is not expected.

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, ~~authority, zRMS~~ agrees with the authorization of the intended use ~~on pome fruits~~ and Oilseed rape.

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

#### **Data gaps**

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

Noticed data gaps are:

- ~~Study Hobbs, G., Inns, L., 2012 (metabolism in rotational crops) is protected. Equivalent study should be provided (see Data matching, The Netherlands, 2018).~~
- ~~Applicant refers to Raufer, B., 2013, 2014 studies (field rotational crop studies). These studies are protected. Equivalent study should be provided (see Data matching, The Netherlands, 2018). ref~~



erence to protected data cannot be accepted

- According to the current requirements (SANTE/11956/2016 rev. 9), information on residues in honey is required. Such information can be provided after registration is obtained.

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

1	2	3	4	5	6	7	8				9			10	11	
GAP number (see part B.0)*	Crop and/ or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
1	Oilseed rape	CEU	SHA5500A	F	Pollen beetle ( <i>Meligethes aeneus</i> )	SG	200 g/kg	Foliar spray	At pest presence. Before BBCH 69	1	NA	0.0067 - 0.02	200 - 600	0.04	28	R***** A
2	Pome fruits	CEU	SHA5500A	F	Aphids	SG	200 g/kg	Foliar spray	At pest presence, before BBCH 59 and from BBCH 69	2	14	0.005 - 0.0056	900 - 1000	0.05	14	A

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

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

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

\*\*\*\* Registration in the protection of oil seed rape will be possible after completing the equivalent studies to the following protected studies (see Data matching, The Netherlands, 2018):  
Raufer, B., 2013, 2014 and Hobbs, G., Inns, L., 2012

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 SHA5500A 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	2016	0.025 mg/kg bw/day	rat developmental neurotoxicity study	100
ARfD	EFSA 2016	2016	0.025 mg/kg bw/day	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	Oilseed rape	Yes	Yes	Yes	Yes	Yes	No	No
2	Pome fruits	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 very unlikely that residues will be present in succeeding crops.

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

An acute risk has not been identified. The use of SHA5500A is therefore acceptable.

### 7.1.2.2 Summary for SHA5500A

**Table 7.1-4: Information on SHA5500A (KCA 6.8)**

Crop	PHI for SHA5500A proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for SHA5500A proposed by zRMS	zRMS Comments (if different PHI proposed)
		Acetamiprid		
Oilseed rape	28 days	Yes		
Pome fruit	14 days	Yes		

NR: not relevant

\* Purpose of withholding period to be specified

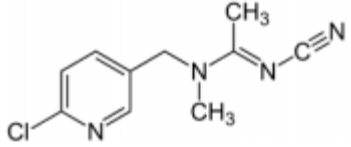
\*\* F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

## Assessment

### 7.2 Acetamiprid

General data on Acetamiprid are summarized in the table below

**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 <sub>10</sub> H <sub>11</sub> ClN <sub>4</sub>
Molar mass	222.68
Chemical group	Neonicotinoid
Mode of action (if available)	Insecticides (pyridylmethylamine neonicotinoid insecticides)
Systemic	Yes
Company (ies)	Nisso Chemical Europe GmbH*
Rapporteur Member State (RMS)	GR (initial) (NL: for renewal)
Approval status	Approved Date of 01/01/2005 and reference to decision Commission Directive 2004/99/EC (Regulation (EU) No 540/2011). Renewal: Commission Implementing Regulation (EU) 2018/113 of 24 January 2018 • date of approval 01/03/2018
Restriction	Only uses as insecticide may be authorised
Review Report	<ul style="list-style-type: none"> <li>• SANCO/1392/2001 – Final 16/06/2004</li> <li>• Renewal: Final Renewal report for the active substance acetamiprid. - SANTE/10502/2017 Rev 4; 13 December 2017</li> </ul>
Current MRL regulation	Reg. (EU) 2019/88
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes (EFSA-Q-2008-485; EFSA Journal 2011;9(7):2328)
EFSA Journal : Conclusion on the peer review	Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610, 26 pp.
EFSA Journal: conclusion on article 12	Review of the existing maximum residue levels (MRLs) for acetamiprid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011;9(7):2328.
Current MRL applications on intended uses	EFSA-Q-2008-485 (EMS)

	Commodities Status: Reasoned opinion available (EFSA Journal 2011;9(7):2328)
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\* Notifier in the EU process to whom the a.s. belong(s)

\*\* If yes: EFSA, YYYY - see list of references

## 7.2.1 Stability of Residues (KCA 6.1)

### 7.2.1.1 Stability of residues during storage of samples

#### Available data

No new data submitted in the framework of this application.

**Table 7.2-2: Summary of stability data achieved at  $\leq -18^{\circ}\text{C}$  (unless stated otherwise)**

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
<b>Data relied on in EU</b>			
<b>Plant products</b>			
Tomato	High water content	12 months	DAR acetamiprid, 2001, Netherlands, 2015, 2016
Apple	High water content	12 months	DAR acetamiprid, 2001 Netherlands, 2015, 2016
Apple	High water content	12 months	EMS, 2010 Netherlands, 2015, 2016
Cabbage	High water content	12 months	EMS, 2010 Netherlands, 2015, 2016
Cotton	High oil content	12 months	EMS, 2010 Netherlands, 2015, 2016
Foldder peas	High protein content	12 months	EMS, 2010 Netherlands, 2015, 2016
Lettuce	High water content	15 months	EMS, 2010 Netherlands, 2015, 2016
Apples	High water content	24 months	KCP 8.2

#### Conclusion on stability of residues during storage

Acetamiprid is stable in crops containing high water content, high acid content, high starch content, high oil content and high protein content matrices when stored under freezer conditions not exceeding 12 months (leafy vegetables up to 15 months, potato up to 239 days).

Acetamiprid is stable in watery matrix for at least 24 months.

### 7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Not relevant.

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

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

#### Available data

No new data submitted in the framework of this application.

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

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruit- ing vegetable	Aubergine	Pyridine-2,6- <sup>14</sup> C	foliar treatment, G	9.5 g as/100 L	-	7, 14	-	DAR acetamiprid, 2001 Netherlands 2015,2016
	Apple	Pyridine-2,6- <sup>14</sup> C	foliar treatment, G	208 g as/ha (foliar) 104 g a.i./ha (fruit)	-	0, 7, 14, 28, 62, 90	-	DAR acetamiprid, 2001 Netherlands 2015,2016
Leafy vegetables	Cabbage	Pyridine-2,6- <sup>14</sup> C	foliar treatment, G	301.5 g as/ha	-	0, 7, 14, 21, 28, 62	-	DAR acetamiprid, 2001 Netherlands 2015,2016
		Pyridine-2,6- <sup>14</sup> C	soil treat-ment, G	5.94 kg as/ha	-	7, 14, 28	-	
	Cabbage	Cyano- <sup>14</sup> C	foliar treatment, G	298.5 g as/ha	-	0, 7, 14, 28, 63	-	DAR acetamiprid, 2001 Netherlands 2015,2016
Root and tuber vegetables	Carrot	Pyridine-2,6- <sup>14</sup> C	foliar treatment, F	100 g as/ha	2	0, 14	-	DAR acetamiprid, 2001 Netherlands 2015,2016
Pulses and oilseeds	Cotton	Pyridine-2,6- <sup>14</sup> C	foliar treatment, F	123g a.s./ha 1.23 kg a.s./ha	4	14 and 28 DAT		Netherlands 2015,2016
Cereals	-	-	-	-	-	-	-	-

## Summary of plant metabolism studies reported in the EU

Metabolism in primary crops was investigated in the fruit, leafy, root and oilseeds/pulses crop groups, using <sup>14</sup>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).

## Conclusion on metabolism in primary crops

Residue definition for risk assessment and monitoring purposes is stated as parent.

### 7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

#### Available data

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

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- <sup>14</sup> C]-IM-5	Bare soil appl., F	0.266	0	Sampled mature	-	Netherlands, 2015, 2016
Root and tuber vegetables	Turnip	[Pyridyl- <sup>14</sup> C]-IM-5	Bare soil appl., F	0.266	0	Sampled mature	-	Netherlands, 2015, 2016
Cereals	Spring wheat	[Pyridyl- <sup>14</sup> C]-IM-5	Bare soil appl., F	0.266	0	Sampled mature	-	Netherlands, 2015, 2016
New data								
Leafy vegetables	Spinach	[Pyridyl- <sup>14</sup> C]-IM-5	Bare soil appl., F	0.266	0	Leaves – BBCH 49 (57 DAT)	-	KCP 8.2.1, S. Tobias, Report No.: S19-02432
Root and tuber vegetables	Turnip	[Pyridyl- <sup>14</sup> C]-IM-5	Bare soil appl., F	0.266	0	Foliage, tuber – BBCH 49 (57 DAT)	-	KCP 8.2.1, S. Tobias, Report No.: S19-02432



<b>Cereals</b>	<b>Wheat</b>	[Pyridyl- <sup>14</sup> C]-IM-5	Bare soil appl., F	0.266	0	Forage – BBCH 30 (30 DAT); Hay – BBCH 69 (60 DAT); Straw, grain – BBCH 89 (91 DAT)	-	KCP 8.2.1, S. Tobias, Report No.: S19-02432
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\* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

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

Since acetamiprid DT<sub>50</sub> values in soil range between 0.8-7.9 days, study was conducted with metabolite IM-1-5 the most persistent soil metabolite (DT<sub>50</sub> 319 to 663 days) at a single plant back interval of 0 days.

Total radioactive residues ranged from 0.096-0.531 mg eq./kg in animal feed commodities and 0.004-0.100 mg eq./kg in human food commodities. Between 76.8% - 93.9% of the residue is extractable (acetonitrile : water), with IM-1-5 as the sole metabolite (0.087-0.407 mg/kg in animal feed commodities and 0.012-0.094 mg eq./kg in human food commodities).

Only in wheat straw with a TRR of 0.531 mg eq./kg an attempt was made to further extraction by ammonium hydroxide, hydrochloric acid, sodium hypochlorite and potassium hydroxide, releasing an additional 8.1 %TRR (0.043 mg eq./kg), 3.0 % TRR (0.016 mg eq./kg), 1.0% TRR (0.005 mg eq./kg) and 1.8% (0.010 mg eq./kg).

The only [<sup>14</sup>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. In all RACs the PES fraction was less than 8.3% TRR.

### Summary of new plant metabolism studies

TRR values of individual RACs accounted for 0.042 mg eq/kg for wheat forage, 0.102 mg eq/kg for wheat hay, 0.143 mg eq/kg for wheat straw, 0.024 mg eq/kg for wheat grains, 0.159 mg eq/kg for turnip foliage, 0.117 mg eq/kg for turnip tubers and 0.009 mg eq/kg for spinach leaves.

The total recoveries following solvent extraction were 88.7% TRR (0.037 mg eq/kg), 94.5% TRR (0.096 mg eq/kg), 95.5% of TRR (0.137 mg eq/kg), 99.5% of TRR (0.024 mg eq/kg), 98.9% of TRR (0.157 mg eq/kg), 97.8% of TRR (0.114 mg eq/kg) and 84.3% TRR (0.007 mg eq/kg) for wheat forage, wheat hay, wheat straw, wheat grains, turnip foliage, turnip tubers and spinach leaves respectively.

Identification rates were 88.7% TRR (0.037 mg eq/kg), 72.1% TRR (0.073 mg eq/kg), 77.2% of TRR (0.111 mg eq/kg), 98.9% of TRR (0.157 mg eq/kg), 95.7% of TRR (0.112 mg eq/kg) and 84.3% TRR (0.007 mg eq/kg) for wheat forage, wheat hay, wheat straw, turnip foliage, turnip tubers and spinach leaves respectively. No peak above target LOQ of 0.005 mg eq/kg was found for wheat grains.

### Conclusion on metabolism in rotational crops

IM-1-5 was the only compound that was detected in conventional extracts of wheat forage, wheat hay, wheat straw, turnip foliage, turnip tubers and spinach leaves, the test item IM-1-5, [Pyridil<sup>14</sup>C] was not further metabolised in wheat, turnip and spinach after application to bare sandy loam soil.

New metabolism study has been submitted by the applicant in the framework of this application. The study was accepted by The Netherlands (2021) as an alternative study in the Matching Active Substance Data check document.

NL conclusion: “The applicant provided an alternative metabolism study in rotational crops (Report no. S19-02432). The study is GLP- and guideline-compliant, and results in approximately the same endpoints at the study by Hobbs, G. and Inns, L. (2012). Acceptable”

A detailed assessment of the study should be carried out at the EU level.

The applicant has fulfilled the requirements.

#### **Conclusion on metabolism in rotational crops**

The DT90 value for acetamiprid is less than 100 days (trigger value), however, soil metabolite IM-1-5 was found to be more persistent in calcareous soil. Applicant wish to highlight that IM-5 metabolite is only present in calcareous soils. In applicant view this study is not triggered when application is intended in soil types other than calcareous, moreover this study is not triggered on permanent crops like stone and pome fruits.

#### **7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)**

##### **Available data**

No new data submitted in the framework of this application.

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

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
<b>EU data</b>		
<b>Pasteurisation</b> (20 minutes, 90°C, pH 4)	Parent (97.01-99.98)	DAR acetamiprid, 2001 Netherlands 2015,2016
<b>Baking, boiling, brewing</b> (60 minutes, 100°C, pH 5)	Parent (98.73-99.58)	DAR acetamiprid, 2001 Netherlands 2015,2016
<b>Sterilisation</b> (20 minutes, 120°C, pH 6)	Parent (101.70-102.19)	DAR acetamiprid, 2001 Netherlands 2015,2016

Acetamiprid was the main component present in all the extracts, ranging between 92.52% and 101.09% of applied radioactivity. All the 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).

#### **Conclusion on nature of residues in processed commodities**

Processing by pasteurization, baking/brewing/boiling and sterilization of plant material containing Acetamiprid residues is unlikely to result in the production of significant metabolites. The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops.

#### **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**

<b>Endpoints</b>
------------------

Plant groups covered	Root crops: Carrot Fruit crops: Apple, aubergine (eggplant) Leafy crops: Cabbage
Rotational crops covered	NR
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	a.s. is stable
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Acetamiprid (EFSA 2010; EFSA Journal 2010;8(1):1494) ** EFSA Journal 2018;16(5):5262
Plant residue definition for risk assessment	Acetamiprid (EFSA 2011, AFSA Journal 2011;9(7):2328)*** EFSA Journal 2018;16(5):5262
Conversion factor from enforcement to RA	Not required

\* If residue pattern in processed commodities is not similar to that in raw commodities

\*\* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).

\*\*\* If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

#### 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- <sup>14</sup> C	2	1-10 mg/kg feed	7	Milk	twice daily	DAR acetamiprid 2001 Netherlands 2015,2016
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	pyridine-2,6- <sup>14</sup> C	10	1-10 mg/kg feed	14	Eggs	daily	DAR acetamiprid 2001 Netherlands 2015,2016
						Excreta	daily	
						Tissues	at sacrifice	

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

Metabolism studies on livestock conducted on animals dosed with <sup>14</sup>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 administered 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 me-

tabolite(IM-2-1) representing 50–89% TRR in all animal matrices, except goat muscle (10% TRR) whereresidues were mainly composed of the metabolite IM-2-2 accounting for 50% TRR (0.03 mg eq/kg).

#### Conclusion on metabolism in livestock

The residue definition was proposed as ‘IM-2-1 expressed as acetamiprid’ for monitoring and as ‘the sum of acetamiprid and IM-2-1, expressed as acetamiprid’ for risk assessment. Conversion factors (CF) of 1.3 and 1.1 were derived for milk and other mammalian products, respectively. CF values were concluded to be unnecessary for poultry products.

### 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 in milk
	4-8 days in eggs
Animal residue definition for monitoring	IM-2-1 expressed as acetamiprid (EFSA Journal 2016;14(11):4610)
Animal residue definition for risk assessment	Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid (EFSA Journal 2016;14(11):4610)
Conversion factor	Conversion factors (CF) of 1.3 and 1.1 were derived for milk and other mammalian products, respectively. CF values were concluded to be unnecessary for poultry products.
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

\* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)

\*\* If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

\*\*\* If metabolism in rat and ruminant are not similar

## 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 Acetamiprid 20% SG and conformity to existing MRL**

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Apples → extrapolated to the whole group of pome fruits	New trials	N-EU	GAP: 2x0.05 kg as/ha, interval between treatments 14 days, PHI: 14 days, outdoor. 0.016, 0.017, 0.019, 0.022, 0.026, 0.026, 0.029	N/A				
	RMS, 2001	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.075 kg as/ha, PHI 14d, outdoor 0.01, 2x0.02, 0.025, 0.026, 2x0.03, 2x0.031, 0.034, 0.04, 2x0.056, 0.071					
	Overall supporting data for cGAP	N-EU	0.01, 0.016, 0.017, 0.019, 2x0.02, 0.022, 0.025, 3x0.026, 0.029, 2x0.03, 2x0.031, 0.034, 0.04, 2x0.056, 0.071	0.026	0.071	0.09	0.4	Yes
Oilseed rape	New trials	N-EU	GAP on which MRL/EU a.s. assessment is based 1 x 0.04 kg as/ha, PHI 28 d, outdoor 2 x <0.01; 0.014, 2 x 0.016, 0.018, 2 x 0.022					
	Overall supporting data for cGAP	N-EU	GAP on which MRL/EU a.s. assessment is based 1 x 0.04 kg as/ha, PHI 28 d, outdoor 2 x <0.01; 0.014, 2 x 0.016, 0.018, 2 x 0.022	0.016	0.022	0.04	0.4	Yes

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

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

According to the available data, the intended uses are considered acceptable, for outdoor uses.

The data submitted show that no exceedance of the MRL will occur.  
The uses are considered acceptable.

### Magnitude of residues in livestock

#### 7.2.3.3 Dietary burden calculation

**Table 7.2-09: Input values for the dietary burden calculation (considering the intended uses)**

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Apple, pomace, wet	0.03	STMR (0.026) x PF (1.3)	0.03	STMR (0.026) x PF (1.3)
Canola (Rape seed), meal	0.03	STMR x PF (2)	0.03	STMR x PF (2)
Rape, meal	0.03	STMR x PF (2)	0.03	STMR x PF (2)

**Table 7.2-10: Results of the dietary burden calculation**

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Cattle (all diets)	0.000	0.000	Apple pomace (wet)	0.02	No
Cattle (dairy only)	0.000	0.000	Apple pomace (wet)	0.01	No
Sheep (all diets)	0.000	0.000	Apple pomace (wet)	0.01	No
Sheep (ewe only)	0.000	0.000	Apple pomace (wet)	0.01	No
Swine (all diets)	0.000	0.000	Canola meal	0.01	No
Poultry (all diets)	0.001	0.001	Canola meal	0.01	No
Poultry (layer only)	0.000	0.000	Canola meal	0.00	No

#### 7.2.3.4 Livestock feeding studies (KCA 6.4.1-6.4.3)

##### Available data

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

**Table 7.2-11: Overview of the values derived from livestock feeding studies**

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) <sup>(b)</sup>	Highest residue (mg/kg) <sup>(c)</sup>	Calculated MRL (mg/kg)	CF for RA <sup>(d)</sup>
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) <sup>(a)</sup>	No	Result for enforce-ment		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (Netherlands, 2015, 2016)												
IM-2-1 expressed as acetamiprid												
Pig meat	0.000	0.000	0.21	3	0.04	0.04	0.05	0.05				
			0.63	3	0.17	0.28	0.19	0.31				
			2.13	3	0.96	1.07	1.03	1.18				
Pig fat	0.000	0.000	0.21	3	0.03	0.06	0.04	0.08				
			0.63	3	0.17	0.28	0.08	0.16				
			2.13	3	0.35	0.69	0.39	0.76				
Pig liver	0.000	0.000	0.21	3	0.11	0.11	0.16	0.16				
			0.63	3	0.42	0.62	0.47	0.68				
			2.13	3	2.27	2.56	2.43	2.81				
Pig kidney	0.000	0.000	0.21	3	0.2	0.21	0.25	0.26				
			0.63	3	0.69	0.86	0.75	0.91				
			2.13	3	2.45	2.56	2.55	2.70				
Ruminant meat	0.000	0.000	0.21	3	0.04	0.04	0.05	0.05				
			0.63	3	0.17	0.28	0.19	0.31				
			2.13	3	0.96	1.07	1.03	1.18				
Ruminant fat	0.000	0.000	0.21	3	0.03	0.06	0.04	0.08				



			0.63	3	0.17	0.28	0.08	0.16				
			2.13	3	0.35	0.69	0.39	0.76				
<b>Ruminant liver</b>	0.000	0.000	0.21	3	0.11	0.11	0.16	0.16				
			0.63	3	0.42	0.62	0.47	0.68				
			2.13	3	2.27	2.56	2.43	2.81				
<b>Ruminant kidney</b>	0.000	0.000	0.21	3	0.2	0.21	0.25	0.26				
			0.63	3	0.69	0.86	0.75	0.91				
			2.13	3	2.45	2.56	2.55	2.70				
<b>Milk</b>	0.000	0.000	0.21	3	0.05	N/A	0.07	N/A				
			0.63	3	0.19	N/A	0.24	N/A				
			2.13	3	0.90	N/A	1.09	N/A				

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

n.p.: not precise

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

(a): Mean residue level from day -1 until day 27 (3 cows, 11 sampling days).

## Conclusion on feeding studies

Based on available feeding data, the in force MRLs are not expected to be exceeded, for animal origin food commodities.

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

### 7.2.4.1 Available data for all crops under consideration

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

**Table 7.2-12: Overview of the available processing studies**

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
<b>EU data</b>					
Citrus fruits, peeled	2	0.03	1.00		EFSA, 2011
Citrus fruits, juice	1	0.13	1.00	-	EFSA, 2011
Apple, juice	2	0.80	1.00	-	EFSA, 2011
Apple, wet pomace	2	1.30	1.00		EFSA, 2011
Apple, sauce	1	0.73	1.00		EFSA, 2011
Cotton seed, refined oil	1	0.04	1.00		EFSA, 2011
Cotton seed, meal/press cake	1	0.40	1.00		EFSA, 2011

\* 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 Magnitude of residues in representative succeeding crops

~~The crops under consideration can be grown in rotation.~~

~~Considering available data dealing with nature of residues (see 0), no study dealing with magnitude of residues in succeeding crops is needed.~~

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

### 7.2.5.1 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 7.2-13: Summary of available studies in field rotational crops**

Primary crop	Rate (kg a.s./ha)	Residue levels in succeeding crops			
	(GS at application or PHI)	Succeeding crop group	Succeeding crop	Plant Back intervals (DAT)	Reference / Remarks
EU data					
Application on bare soil	0.3 kg a.s./ha	Leafy vegetables	Spinach	31 72 122 367	Netherlands, 2015, 2016
		Root and tuber vegetables	Turnip	30 70 120 365	Netherlands, 2015, 2016
		Small grains	Wheat	32 63 132 377	Netherlands, 2015, 2016
New data					
Application on bare soil	0.3 kg a.s./ha	Root and tuber vegetables	Carrot	30 63 130 348	KCP 8.3.3-01, G. Wagner, Report No.: SRHU19-154-034IR; KCP 8.3.3-02, C. Marteau Report No.: S-2201946
		Leafy vegetables	Spinach	30 63 130 348	
		Small grains	Barley	30 63 130 348	

### Conclusion on rotational crops studies

#### EU data (EFSA, 2016):

Field studies in NEU conducted at ca. 300 g/ha on bare soil. Acetamiprid, IM-1-4 and IM-1-5 residues:  
<0.01 mg/kg in spinach (all PBIs and growth stages).  
<0.01 mg/kg in turnip (all PBIs and growth stages when harvested at maturity).  
-0.04/0.15/0.03 mg/kg for acetamiprid/IM-1-4/IM-1-5 in immature whole plant at 360 day PBI.  
<0.01 mg/kg in wheat, except forage at 30 d PBI in NEU with IM-1-4 at 0.013 mg/kg.

#### New data:

Representative succeeding crops of carrots, spinach and barley were planted at plant back intervals of 30, 63, 130 and 348 days. No residues of Acetamiprid or metabolite IM-1-5 above the LOQ (0.01 mg/kg) were found in any of the samples taken from all the PBIs.

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of Acetamiprid 20% SG. Therefore, other special studies are not needed.

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

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

### 7.2.7.1 Input values for the consumer risk assessment

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Pome fruit	0.026	STMR	0.071	Highest residue
Oilseed rape	0.015	STMR	0.022	Highest residue
Other commodities	EU MRL (Commission Regulation (EU) No Reg. (EU) 2019/88)		-	

### 7.2.7.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

**Table 7.2-15: Consumer risk assessment**

TMDI (% ADI) according to EFSA PRIMo	122.3% NL toddler
IEDI (% ADI) according to EFSA PRIMo	98.2% NL toddler
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities Results for children 221.58% Pears 172.45% Apples 78.70% Quinces 44.27% Medlar 2.21% Rapeseeds/canola seeds Results for adults 48.87% Pears 48.67% Quinces 44.92% Apples 21.91% Medlar 0.84% Rapeseeds/canola seeds Processed commodities Results for children 86.6% Apples / juice 52.1% Pears / juice 9.7% Quinces / jam 0.9% Rapeseeds / oils Results for adults 53.3% Apples / juice 4.00% Quinces / jam
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities

Refined calculation	Results for children 39.33% Pears 30.61% Apples 6.98% Quinces 3.93% Medlar 0.08% Rapeseeds/canola seeds Results for adults 8.67% Pears 7.97% Apples 4.32% Quinces 1.94% Medlar 0.03% Rapeseeds/canola seeds Processed commodities Results for children 5.6% Apples / juice 3.4% Pears / juice 0.3% Quinces / jam 0.0% Rapeseeds / oils Results for adults 3.5% Apples / juice 0.13% Quinces / jam
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\* include raw and processed commodities if both values are required for PRIMo

The proposed uses of Acetamiprid in the formulation Acetamiprid 20% SG do not represent unacceptable acute and chronic risks for the consumer.

### 7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

### 7.4 References

EFSA (European Food Safety Authority), 2010. Reasoned opinion of EFSA: Modification of the existing MRL(s) for Acetamiprid in various commodities. EFSA Scientific Report (2010);8(11):1898. [60 pp.] doi:10.2903/j.efsa.2010.1898. Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

EFSA (European Food Safety Authority), 2011. Review of the existing maximum residue levels (MRLs) for acetamiprid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011;9(7):2328. [59 pp.] doi:10.2903/j.efsa.2011.2328. Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

EFSA (European Food Safety Authority), 2016. Reasoned opinion of EFSA: Modification of the existing maximum residue levels for acetamiprid in various crops. EFSA Journal 2016;14(2):4385. doi: 10.2903/j.efsa.2016.4385. Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

EFSA (European Food Safety Authority), 2016. Reasoned opinion of EFSA: Peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610. doi: 10.2903/j.efsa.2016.4610. Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

RAR 2015, 2016  
DAR 2001

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

Tables considered not relevant can be deleted as appropriate.

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

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.2	A. Markowicz	2020	Stability study of acetamiprid residues in apple during 2 years of storage. A. Markowicz, 2020. Report No. ZBBZ-2018/06/DPL/1 Food Safety Laboratory Report No. ZBBZ-2018/06/DPL/1 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.2.1	S. Tobias	2021	Metabolism of [Pyridil <sup>14</sup> C]-IM-1-5 metabolite in Rotational Crops Eurofins Agroscience Services EcoChem GmbH Report No.: S19-02432 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.1-01	Rump, K.	2017	Determination of residues at harvest of Acetamiprid in oilseed rape, following one broadcast application of Acetamiprid 20% SG, under open field conditions, Central Europe – Season 2017. Field Research Support Report no. FRS 003/17 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.1-02	Sikorski, P.	2018	Determination of acetamiprid residues in oilseed rape after application of “Acetamiprid 20% SG” in one trial (IHS), Germany – 2017.	N	Sharda Cropchem Ltd.

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
			Food Safety Laboratory Report no. ZBBZ-2016/14/DPL/1DE GLP Unpublished		
KCP 8.3.1-03	Rump, K.	2017	Determination of residues at harvest and decline of Acetamprid in oilseed rape, following one broadcast application of Acetamprid 20% SG, under open field conditions, Central Europe – Season 2016. Field Research Support Report no. FRS 058/16-V2 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.1-04	Sikorski, P.	2017	Determination of acetamprid residues in oilseed rape after application of “Acetamprid 20% SG”. Food Safety Laboratory Report no. ZBBZ-2016/14/DPL/1DE GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.1-05	Kull, S.	2018	Residue study (Harvest and Decline) in oilseed rape following one application with Acetamprid 20% SG in Germany 2017 – field part. CropTrials GmbH Report no. CT17-1-35 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.1-06	Sikorski, P.	2018	Magnitude of residues of acetamprid in oilseed rape raw agricultural commodity after one application of acetamprid 20% SG under field conditions – 1 harvest trial and 1 decline trial – Germany – 2017 Food Safety Laboratory Report no. ZBBZ-2017/25/DPL/1DE GLP Unpublished	N	Sharda Cropchem Ltd.
KCP	Romero, S.	2018	Magnitude of residue of Acetamprid in oilseed rape Raw Agricultural Commodity after	N	Sharda Cropchem

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
8.3.1-07			one application of Acetamiprid 20% SG under field conditions – 1 harevesttrial and 1 decline trial – Poland – 2017. BIOTEK Agriculture España SL Report no. BPL17-013 GLP Unpublished		Ltd.
KCP 8.3.1-08	Gábor Wágner	2020	Determination of the residues of acetamiprid in/on oilseed rape after one application of acetamiprid 20% SG in Northern Europe – Hungary in 2019. SynTech Research Hungary Study number 034SRHU19R32 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.1-09	A. Markowicz	2019	Determination of the residues of acetamiprid in/on oilseed rape after one application of acetamiprid 20% SG in Northern Europe – Hungary in 2019. Food Safety Laboratory Study number ZBBZ-2017/25/DPL/1HU GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.2-01	H. Zoellner	2019	Determination of residues at harvest of acetamiprid in apple, following two applications of acetamiprid 20% SG, under open field conditions. Germany - season 2018. Field Research Support. Study number FRS 055/18 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.2-02	Z. Hordyjewicz-Baran	2019	Determination of residues at harvest of acetamiprid in apple, following two applications of acetamiprid 20% SG, under open field conditions Germany – Season 2018 Analytical part. Łukasiewicz Research Network – Institute of Heavy Organic Synthesis “Blachownia” Study number 206/2019 GLP	N	Sharda Cropchem Ltd.



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
			Unpublished		
KCP 8.3.2-03	R. Figurski	2019	Magnitude of the residue of acetamiprid in pome fruits (raw agricultural commodity - rac) grown in open field conditions after two applications of formulated product acetamiprid 20% SG - two decline curve trials in Poland – 2018. Fertico Sp. z o.o. Study number PB-2018-02 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.2-04	M. Zarębska	2019	Magnitude of the residue of acetamiprid in pome fruits (raw agricultural commodity - rac) grown in open field conditions after two applications of formulated product acetamiprid 20% SG - two decline curve trials in Poland – 2018. Łukasiewicz Research Network – Institute of Heavy Organic Synthesis “Blachownia” Study number 197/2019 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.2-05	Gábor Szilágyi	2019	Determination of the residues of acetamiprid in/on apple after two applications of acetamiprid 20% SG in Northern Europe - Hungary in 2019. SynTech Research Hungary Study number 034SRHU19R22 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.2-06	M. Zarębska	2019	Determination of the residues of acetamiprid in/on apple after two applications of acetamiprid 20% SG in Northern Europe - Hungary in 2019. Łukasiewicz Research Network – Institute of Heavy Organic Synthesis “Blachownia” Study number 205/2019 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.2-07	Z. Hordyjewicz-Baran	2020	Magnitude of the residue of acetamiprid in pome fruits (Raw Agricultural Commodity) after two applications of Acetamiprid 20% SG – one harvest and two decline curve trials in Poland – 2018.	N	Sharda Cropchem Ltd.

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
			Lukasiewicz Research Network – Institute of Heavy Organic Synthesis “Blachownia” Study number 18SGS01. GLP Unpublished		
KCP 8.3.3-01	Gábor Wágner	2022	Determination of the residues of acetamiprid in/on crop rotation crops after one application of Acetamiprid 20% SG in Northern Europe - Hungary in 2019, CPR Europe Kft. Report No.: 034SRHU19R21 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.3-02	Charlotte Marteau	2022	Determination of the residues of Acetamiprid in/on crop rotation crops after one application of Acetamiprid 20% SG in Hungary in 2019, Eurofins Agrosience Services Chem SAS Report No.: S22-01946 GLP Unpublished	N	Sharda Cropchem Ltd.

**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
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP	Y/N	Owner

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
			Published/Unpublished		

The following tables are to be completed by MS.

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

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

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	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

No additional study.

##### A 2.1.1.1.1 Study 1

Comments of zRMS:	Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information
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Reference:	KCP 8.2
Report	Stability study of acetamiprid residues in apple during 2 years of storage. A. Markowicz, 2020. Report No. ZBBZ-2018/06/DPL/1
Guideline(s):	Yes Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1 EC Guide No. 7032/VI/95 rev. 5 OECD Test Guidance No. 506
Deviations:	No
GLP:	Yes
Acceptability:	Yes

#### Materials and methods

The 1000 g of apple (fruits) without Acetamiprid residues was used for the storage stability study. The sample was supplied on August 31, 2018 by the Test Facility from its own resources and then the same day was prepared for further activities. This sample was divided into two parts and assigned unique identification numbers:

- ZBBZ-2018/06/DPL/1/1 – untreated for calibration and recovery study - the 500 g of homogenized apple sample was divided on 6 subsamples (5 analytical and 1 archival) and stored at  $\leq -18^{\circ}\text{C}$  in polyethylene bags until analyses;
- ZBBZ-2018/06/DPL/1/2 – treated with Acetamiprid (Reference Items) for stability study - the 500 g of apple sample was cut, spiked with Acetamiprid at 0.1 mg/kg (0.5 mL of 100  $\mu\text{g/mL}$  Acetamiprid was

added), homogenized with dry ice, well mixed, divided into 6 subsamples (5 analytical and 1 archival) and stored at  $\leq -18^{\circ}\text{C}$  in polyethylene bags until analyses.

At time “0” one control sample, three samples spiked at 0.1 mg/kg with Acetamiprid, and three samples fortified before extraction at 0.01 mg/kg with Acetamiprid were analyzed. At each time point subsequent to time “0”, the analysis consisted of one control sample, three samples stored with spiked at 0.1 mg/kg with Acetamiprid and three samples fortified before extraction at 0.01 mg/kg with Acetamiprid. The temperature during storage of the samples was  $\leq 18^{\circ}\text{C}$  (in the range:  $-18.0^{\circ}\text{C} \div -29.5^{\circ}\text{C}$ ).

Validation data were presented in the Final Report No. ZBBZ-2016/62/DPL/1ES (Please refer to the Section B5 - KCP 5.2.1)

## Results and discussions

**Table A 1: Summary of concurrent recoveries of acetamiprid from watery matrix.**

Matrix	Spike level (mg/kg)	Storage Interval (months)	Individual procedural recoveries (%)	Mean $\pm$ std dev (%)
Apples	0.100	0	89, 90, 92 Quantification Ion Mass Transition m/z 223.1 $\rightarrow$ 126.1 87, 92, 93 Confirmation Ion Mass Transition m/z 223.1 $\rightarrow$ 90.1 86, 91, 96	90 $\pm$ 1.7  91 $\pm$ 3.1  91 $\pm$ 5.3
Apples	0.100	6	110, 109, 110 Quantification Ion Mass Transition m/z 223.1 $\rightarrow$ 126.1 99, 80, 100 Confirmation Ion Mass Transition m/z 223.1 $\rightarrow$ 90.1 101, 84, 103	110 $\pm$ 0.5  93 $\pm$ 12.1  96 $\pm$ 11.1
Apples	0.100	12	105, 104, 102 Quantification Ion Mass Transition m/z 223.1 $\rightarrow$ 126.1 97, 105, 102 Confirmation Ion Mass Transition m/z 223.1 $\rightarrow$ 90.1 100, 109, 101	104 $\pm$ 1.5  102 $\pm$ 3.9  103 $\pm$ 4.7
Apples	0.100	18	98, 102, 101 Quantification Ion Mass Transition m/z 223.1 $\rightarrow$ 126.1 98, 98, 100 Confirmation Ion Mass Transition m/z 223.1 $\rightarrow$ 90.1 96, 104, 103	100 $\pm$ 2.1  99 $\pm$ 1.2  101 $\pm$ 4.0
Apples	0.100	24	94, 97, 100 Quantification Ion Mass Transition m/z 223.1 $\rightarrow$ 126.1	97 $\pm$ 3.1

Matrix	Spike level (mg/kg)	Storage Interval (months)	Individual procedural recoveries (%)	Mean ± std dev (%)
			99, 100, 101 Confirmation Ion Mass Transition m/z 223.1→90.1 96, 104, 103	100 ± 1.3  101 ± 1.8

**Table A 2: Stability of acetamiprid residues in watery matrix following storage at -18 °C**

Matrix	Spike level (mg/kg)	Storage Interval (months)	Individual recovered residues (mg/kg)	Individual recoveries (%)
acetamiprid				
Apples	0.100	0	0.089	89
Apples	0.100	0	0.090	90
Apples	0.100	0	0.092	92
Apples	0.100	6	0.110	110
Apples	0.100	6	0.109	109
Apples	0.100	6	0.110	110
Apples	0.100	12	0.105	105
Apples	0.100	12	0.104	104
Apples	0.100	12	0.102	102
Apples	0.100	18	0.098	98
Apples	0.100	18	0.102	102
Apples	0.100	18	0.101	101
Apples	0.100	24	0.094	94
Apples	0.100	24	0.097	97
Apples	0.100	24	0.100	100

## Conclusion

The results of this study showed that Acetamiprid is stable in apple (fruits) when stored at ≤ -18°C for a period of up to 24 months.

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

No additional study.

### 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 additional study.

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

~~No additional study.~~

##### A 2.1.2.1.2.1 Study 1

Comments of zRMS:	<p>The study was accepted by The Netherlands (2021) as an alternative study in the Matching Active Substance Data check document.</p> <p>NL conclusion: “The applicant provided an alternative metabolism study in rotational crops (Report no. S19-02432). The study is GLP- and guideline-compliant, and results in approximately the same endpoints at the study by Hobbs, G. and Inns, L. (2012). Acceptable”</p> <p>A detailed assessment of the study should be carried out at the EU level.</p> <p>The Applicant has fulfilled the requirements.</p>
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Reference: KCP 8.2.1

Report Metabolism of [Pyridyl-<sup>14</sup>C]-IM-1-5 metabolite in Rotational Crops, S. Tobias, 2021, Report No.: S19-02432

Guideline(s): Yes  
 OECD Test Guideline No. 502  
 EPA guideline OPPTS 860.1300

Deviations: No

GLP: Yes

Acceptability: Yes

#### Materials and methods

The metabolism of acetamiprid metabolite IM-1-5, [pyridyl-2,6-<sup>14</sup>C]\*HCl was investigated in wheat, turnip and spinach as a result of an application to bare soil approx. one hour before the planting interval. IM-1-5, [pyridyl-2,6-<sup>14</sup>C]\*HCl was applied at a nominal application rate of 266 g a.s./ha, which represents the proposed GAP application rate. The actual application rate corresponded to 287 g a.s./ha which was slightly above the intended rate.

Cereals are represented by wheat, root crops by turnip and leafy crops by spinach. They were sown on the same day but approx. 1 hour after soil treatment. Wheat forage, hay, straw and grain as well as turnip foliage and tubers and spinach leaves were harvested at BBCH 30, 69, 89, 89, 49, 49, 49, respectively. This corresponds to 30, 60, 91, 91, 57, 57, 57 days after treatment. The total radioactive residues (TRR) in all raw agricultural commodities (RACs) were determined by summing up the extractable and unextractable radioactivity.

#### Test item

Test item name: IM-1-5, [pyridyl-2,6-<sup>14</sup>C]\*HCl

Batch number: XXIII/60/C/3

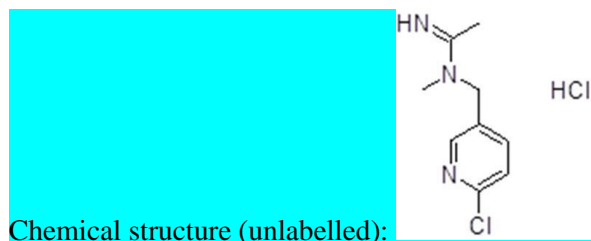
EAS Test item code: M-00024612

Appearance / colour: solid / white-yellowish

CAS number: not available

Specific activity: 9.378 MBq/mg  
 2214 MBq/mmol





Molecular weight (unlabelled): 234.1 g/mol

Density: not applicable

Signal word(s): radioactive

Issue date of certificate: 05 Aug 2019

Expiry date: 08 Aug 2020

Date of manufacture: not available

Storage conditions: deep frozen ( $\leq -18\text{ }^{\circ}\text{C}$ ), dark, dry

### Sample Handling and Preparation

Plant samples were collected by using clean secateurs or dug out from soil. Wheat straw and grains were separated by hand. Any diseased plant material that was not typical of commercial practice for a specific sample type (RAC) was not collected as part of that sample and was discarded. The total weight of each sample was determined. Wheat forage, hay, straw and grains were harvested at BBCH 30, 69, 89 and 89 corresponding to 30, 60, 91 and 91 days after the application.

Turnip foliage and tubers were both harvested at BBCH 49 corresponding to 57 days after the application.

Spinach leaves were harvested at BBCH 49 corresponding to 57 days after the application.

The complete samples were homogenised with liquid nitrogen using a high speed blender (ULTR TUR-RAX ®). Aliquots of each homogenised sample were combusted and radioassayed by LSC to estimate the initial total radioactive residue (ITRR) of the sample. The samples were stored in a freezer ( $\leq -18\text{ }^{\circ}\text{C}$ ) until analysis.

Aliquots of the homogenates were extracted. The actual TRR values of the samples were determined by summing up the radioactivity measured in the extracts and in the remaining solids.

### Conventional Extraction Procedures and Clean-Up

Aliquots of the homogenised plant samples were extracted two times with a mixture of acetonitrile/water (1/1; v/v) followed by one extraction with acetonitrile using a high speed blender (ULTRA-TURRAX®). All extractions were performed with a solvent to solid ratio of approx. 10:1. Wheat hay, straw and grains were soaked with a sufficient amount of water, beforehand. After each extraction step, the extracts were filtered with technical filter paper (30 s Herzberg) by suction and the solids were rinsed with a small amount of the solvent mixture used for extraction. The volume of each extract was measured and the radioactivity determined by LSC. The remaining solids were dried, aliquots subjected to combustion and the radioactivity determined by LSC. The actual TRR value of the sample was determined by summing up the radioactivity (RA) measured in the extracts and in the remaining solids.

### Exhaustive Extraction Procedures and Clean-Up

Aliquots of solids from the conventional extraction of hay, straw and grains were exhaustively extracted with an approx. tenfold volume of sample weight of 10% ammonium hydroxide (approx. two hours, ambient temperature) twice, then refluxed with hydrochloric acid (1.0M, approx. three hours) followed by sodium hypochlorite (2%, approx. three hours), then extracted with potassium hydroxide (24%, approx. 16 hours, ambient temperature). After each step, the solids were centrifuged at 3500 rpm. The volume of each extract was measured and the radioactivity determined by LSC. The remaining solids were dried at room temperature in a hood, aliquots subjected to combustion and the radioactivity determined by LSC. The actual TRR value of the sample was determined by summing up the radioactivity (RA) measured in the extracts and in the remaining solids.

### Isolation and clean-up of test item for identification

For confirmation of metabolite identity, single peaks from wheat straw and turnip foliage (IM-1-5

## Quantification of test item

- Comparison of the HPLC retention times of reference item with the one of the respective components in the sample extracts.
- Comparison of metabolic profiles of all RACs, as analysed by HPLC among themselves.
- NP-TLC analysis for confirmation of test item prior to application.
- Identification of isolated metabolite peak using LC-MS.

## Results and discussion

Matrix	Timing and application	TRR (ppm)
		IM-1-5
Wheat forage	Spray application to bare soil (1 h prior to sowing) 287.4 g a.s./ha  PBI: 0 days	0.042
Wheat hay		0.102
Wheat straw		0.143
Wheat grains		0.024
Turnip foliage		0.159
Turnip tubers		0.117
Spinach leaves		0.009

[illegible]

Compound	Wheat forage TRR = 0.042 ppm		Wheat hay TRR = 0.102 ppm		Wheat straw TRR = 0.143 ppm		Wheat grain TRR = 0.024 ppm	
	% TRR	ppm	% TRR	ppm	% TRR	ppm	% TRR	ppm
(mg a.s. equivalents / kg)	After planting interval: 0.391							

\* Residues remaining after exhaustive extractions.

\*\* Accountability = (Total extractable + Total unextractable)/(TRRs from combustion analysis) \* 100.

\*\*\* no peak above target LOQ of 0.005 mg eq/kg

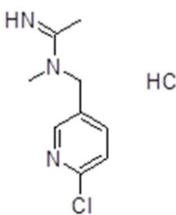
Compound	Turnip Foliage TRR = 0.159 ppm		Turnip Tubers TRR = 0.117 ppm		Spinach Leaves TRR = 0.009 ppm	
	% TRR	ppm	% TRR	ppm	% TRR	ppm
Conventional Extraction	98.9	0.157	97.8	0.114	84.3	0.007
IM-1-5, [pyridyl-2,6- <sup>14</sup> C]*HCl	98.9	0.157	95.7	0.112	84.3	0.007
Total identified	98.9	0.157	95.7	0.112	84.3	0.007
Total characterized	<0.1	<0.001	<0.1	0.112	84.3	0.007
Total extractable	98.9	0.157	97.8	0.114	84.3	0.007
Unextractable (PES)*	1.1	0.002	2.2	0.003	15.7	0.001
Accountability**	100.0	0.159	100.0	0.117	100.0	0.009
Total Radioactive Residues (TRRs*) in soil samples (mg a.s. equivalents / kg)	<b>Turnip soil</b> Before planting interval: 0.310 After planting interval: 0.431 <sup>A</sup>				<b>Spinach soil</b> Before planting interval: 1.078 After planting interval: 0.464	

\* Residues remaining after exhaustive extractions.

\*\* Accountability = (Total extractable + Total unextractable)/(TRRs from combustion analysis) \* 100.

A value is higher than before the planting interval, may result from inhomogeneity of soil.

**Table A 5: Identification of compounds from metabolism study**

Common name/code Figure B.3.1.-1. ID No.	Chemical name	Chemical structure
Acetamiprid metabolit IM-1-5	N-[(6-chloropyridin-3-yl)methyl]-N-methylethanimidamide hydrochloride	

**Figure A 1: Proposed Metabolic Profile of IM-1-5 in wheat, turnip and spinach**

The only residue found in the crop commodities was IM-1-5, [pyridyl-2,6-<sup>14</sup>C]\*HCl. No other metabolites or unidentified residues were detected in any conventional extract of the crop commodities. Therefore, no metabolic pathway was described.

## Conclusions

IM-1-5 was the only compound that was detected in conventional extracts of wheat forage, wheat hay, wheat straw, turnip foliage, turnip tubers and spinach leaves. The test item IM-1-5, [Pyridil<sup>14</sup>C] was not further metabolised in wheat, turnip and spinach after application to bare sandy loam soil.

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

No additional study.

**A 2.1.2.2      Nature of residues in livestock**

No additional study.

### A 2.1.3 Magnitude of residues in plants

#### A 2.1.3.1 Oilseed rape

##### Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, RMS, year)	NA				
cGAP EU (Art. 12, EFSA, 2011)	1	0.05	NR	BBCH 65-81	28
Intended cGAP (number 1)	1	0.04	NR	At pest presence. Before BBCH 69	28

#### A 2.1.3.1.1 Study 1

Comments of zRMS:	<p>Study is accepted.</p> <p>The objective of this study was to determine the magnitude of residues of Acetamiprid in Oilseed rape (seeds) samples taken from the field trial, after applications of Acetamiprid 20% SG. To achieve the objective appropriate analytical method for determination of Acetamiprid was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1 and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2016/14/DPL/1DE. The validated limit of quantification is 0.01 mg/kg.</p> <p>Sampling date : 10.08.2017; arrival at laboratory: 21.09.2017; samples were stored in freezer at <math>\leq -20</math> °C ; date of analyses: 12.02.2018</p>
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Reference:	KCP 8.3.1-01
Report	Determination of residues at harvest of Acetamiprid in oilseed rape, following one broadcast application of Acetamiprid 20% SG, under open field conditions, Central Europe – Season 2017, Rump, K., 2017, Report no. FRS 003/17
Guideline(s):	Yes ENV/JM/MONO(99)22 ENV/JM/MONO(99)17 EC Commission Directive 2004/10/EC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Reference: KCP 8.3.1-02

Report Determination of acetamiprid residues in oilseed rape after application of “Acetamiprid 20% SG” in one trial (1HS), Germany - 2017, Sikorski, P., 2018, Report no. ZBBZ-2016/14/DPL/1DE

Guideline(s): Yes  
Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC  
EU Directive 96/46/EC Amending Directive 91/414/EEC, Annex II, section 4 of Part A  
EU Guidance Document SANCO/3029/99 rev. 4  
EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No

GLP: Yes

Acceptability: Yes

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

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)	(b)				(c)				(d)	(e)
FRS 003/17/SH- 002/ Germany/ NEU/ 2017	Oilseed rape	30.08.2016. May 2017. 10.08.2017.	0.04	400	0.02	17.05.2017.	BBCH69	seeds	<LOQ	85	

#### A 2.1.3.1.2 Study 2

Comments of zRMS:	<p>Study is accepted.</p> <p>Sampling date : 22.07.2016; arrival at laboratory: 02.09.2016; samples were stored in freezer at <math>\leq -20</math> °C; date of analyses: 28.07.2017</p> <p>The objective of this study was to determine the magnitude of residues of Acetamiprid in Oilseed rape (seeds) samples taken from the field trial, after applications of Acetamiprid 20% SG. To achieve the objective appropriate analytical method for determination of Acetamiprid was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1 and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2016/14/DPL/1DE. The validated limit of quantification is 0.01 mg/kg.</p>
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Reference: KCP 8.3.1-03

Report	Determination of residues at harvest and decline of Acetamiprid in oilseed rape, following one broadcast application of Acetamiprid 20% SG, under open field conditions, Central Europe – Season 2016, Rump, K., 2017, Report no. FRS 058/16-V2
Guideline(s):	ENV/JM/MONO(99)22 ENV/JM/MONO(99)17 EC Commission Directive 2004/10/EC
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Reference:	KCP 8.3.1-04
Report	Determination of acetamiprid residues in oilseed rape after application of “Acetamiprid 20% SG”, Sikorski, P., 2017, Report no. ZBBZ-2016/14/DPL/1DE
Guideline(s):	Yes Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC EU Directive 96/46/EC Amending Directive 91/414/EEC, Annex II, section 4 of Part A EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

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

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)
FRS 058/16/ Germany/ NEU/ 2016	Oilseed rape/ Sherpa	01.09.2015 04.2016 22.07.2016	0.04	200	0.02	12.05.2016	BBCH 69	seeds	0.413 0.076 0.016 <LOQ <LOQ	1 5 11 20 71	

### A 2.1.3.1.3 Study 3

Comments of zRMS:	Study is accepted The purpose of the study was to generate specimens for the determination of resi-
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	<p>dues after one application with Acetamiprid 20% SG in oilseed rape in Germany 2017. The specimens to be analysed were the raw agricultural commodity whole plants without roots and seeds for the decline trial and seeds for the harvest trial. The specimens were stored frozen (targeting -18°C). After receiving and registering in the Lab the samples were stored in freezer at <math>\leq -20</math> °C until future preparation. Date of Reception to the laboratory: 05.12.2017; date of Extraction and analysis: 23.03.2018.</p>
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Reference:	KCP 8.3.1-05
Report	Residue study (Harvest and Decline) in oilseed rape following one application with Acetamiprid 20% SG in Germany 2017 – field part, Kull, S., 2018, Report no. CT17-1-35
Guideline(s):	<p>Yes</p> <ul style="list-style-type: none"> <li>- OECD Guidelines for the testing of chemicals, No 509: Crop Field Trials (2009)</li> <li>- EEC document 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97, rev. 2, 1999: General recommendation for the design, preparation and realisation of residue trials</li> <li>- The Principles of Good Laboratory Practice, ChemG 25.07.1994, §19, Annex 1 (BGBL 21, I, 2001, p. 843-855)</li> <li>- OECD-Principles of Good Laboratory Practice, No. 4: Quality Assurance and GLP (as revised in 1999), ENV/JM/MONO (1999) 20, Paris 2002</li> <li>- The Application of the GLP Principles to Field Studies, OECD Consensus Document, 6, revised, ENV/JM/MONO (1999) 22, Paris 2002</li> <li>- The Application of the OECD Principles of GLP to the Organisation and Management of Multi-site Studies, OECD Consensus Document, 13, ENV/JM/MONO (2002) 9</li> <li>- Rückstandsversuche, Teil 1 Prüfungen an Pflanzen, A: Allgemeiner Teil, B: Spezieller Teil, IVA-Guideline, Industrieverband Agrar e. V. 1992</li> <li>- The national requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (EPA and FDA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements.</li> </ul>

Deviations:	No
GLP:	Yes
Acceptability:	Yes

Reference:	KCP 8.3.1-06
Report	<p>Magnitude of residues of acetamiprid in oilseed rape raw agricultural commodity after one application of acetamiprid 20% SG under field conditions – 1 harvest trial and 1 decline trial – Germany – 2017</p> <p>Food Safety Laboratory, Sikorski, P., 2018, Report no. ZBBZ-2017/25/DPL/1DE</p>
Guideline(s):	<p>Yes</p> <p>Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EEC</p> <p>EU Directive 96/46/EC Amending Directive 91/414/EEC, Annex II, section 4 of Part A</p>



EU Guidance Document SANCO/3029/99 rev. 4  
 EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No  
 GLP: Yes  
 Acceptability: Yes

**Table A 3: Summary of the study 3**

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		
CT17-1- 35DE1/ Germany/ 2017	Oilseed rape	03.09.2016. May 2017 25.07.2017.	41.7	400		31.05.2017.	BBCH69	seed	0.016	51	
CT17-1- 35DE2/ Germany/ 2017	Oilseed rape	01.09.2016. April-May 2017 21.07.2017.	38.7	400		25.05.2017.	BBCH69	Whole plants  seeds	0.784 0.259 0.136 0.056 0.018	0 5 10 20 60	

#### A 2.1.3.1.4 Study 4

Comments of zRMS:	Two field trials were conducted in Poland (Northern Europe). Study is accepted. LOQ = 0.01 mg/kg for Acetamiprid Results in all untreated specimens were below LOQ. The maximum storage duration between sampling and extraction was 295 days.
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Reference: KCP 8.3.1-07

Report Magnitude of residue of Acetamiprid in oilseed rape Raw Agricultural Commodity after one application of Acetamiprid 20% SG under field conditions – 1 harevestrial and 1 decline trial – Poland - 2017, Romero, S. 2018, Report no. BPL17-013

Guideline(s): Yes  
 - The EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997).  
 - OECD/OCDE 509 Adopted: 7 September 2009, OECD guidelines for the testing of chemicals, Crop Field Trial.  
 - Guidance document SANCO/3029/99 rev. 4 of 11/07/00 of the European Commission.

Deviations: No  
 GLP: Yes

Acceptability: Yes

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

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		
BPL17- 013-01/ Poland/ NEU/ 2017	Oilseed rape/ DK Exalte	22.08.2016. 08- 29.05.2017. 20.07.2017.	40.31	403	10.00	25.05.2017.	BBCH69	seeds	0.016	56	
BPL17- 013-02	Oilseed rape/ Monolit	24.08.2016. 04.05. – 01.06.2017. 24.07.2017.	39.58	396	9.99	25.05.2017.	BBCH69	Whole plant Whole plant Whole plant Whole plants Seed	0.994 0.251 0.174 0.066 0.014	0 5 11 20 60	

#### A 2.1.3.1.5 Study 5

Comments of zRMS:	Study is accepted. Two trials were conducted in Hungary in 2019.
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Reference: KCP 8.3.1-08

Report Determination of the residues of acetamiprid in/on oilseed rape after one application of acetamiprid 20% SG in Northern Europe – Hungary in 2019. Gábor Wágner, 2020. Study number 034SRHU19R32

Guideline(s): Yes  
- Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC) No. 1107/2009 of the European Parliament.  
- "Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997.  
- OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009).

Deviations: No

GLP: Yes

Acceptability: Yes

Reference: KCP 8.3.1-09

Report Determination of the residues of acetamiprid in/on oilseed rape after one application of acetamiprid 20% SG in Northern Europe – Hungary in 2019.

A. Markowicz, 2019. Study number ZBBZ-2017/25/DPL/1HU

Guideline(s):

Yes

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC  
Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009  
EU Guidance Document SANCO/3029/99 rev. 4  
EU Guidance Document SANCO/825/00 rev. 8.1

Deviations:

No

GLP:

Yes

Acceptability:

Yes

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

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)	(a)	(b)				(c)				(d)	(e)
034SRH U19R32// Hungary/ NEU/ 2019	Oilseed rape/ DK Excep-tion	1) 30/08/2018 2) Late April – mid May 2019 3) 05/07/2019	42.29 3	528.6 7	8.45 9	16/05/2019	BBCH 69	Seed	0.022	50	Analytical phase report: ZBBZ-2017/25/DPL/1HU  LOD = 0.002 mg/kg LOQ = 0.01 mg/kg Time between harvest and extrac-tion: 139 d
034SRH U19R32// Hungary/ NEU/ 2019	Oilseed rape/ DK Expres-sion	1) 28/08/2018 2) Late April – mid May 2019 3) 05/07/2019	42.98 7	537.3 3	8.59 7	20/05/2019	BBCH 69	Whole plant Whole plant Whole plant Whole plant Seed	1.377 0.750 0.118 0.104 0.022	0 5 10 22 46	Analytical phase report: ZBBZ-2017/25/DPL/1HU  LOD = 0.002 mg/kg LOQ = 0.01 mg/kg Time between harvest and extrac-tion: 139 d

### A 2.1.3.1

### Pome fruits

**Table A 6: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between applica-tion	Growth stage at last application	PHI (days)
Intended cGAP (1)	2	0.25 kg fp/ha	14 days	From BBCH 69	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:	Study is accepted Sampling date : 03.09.2018; arrival at laboratory: 15.11.2019; samples were stored in freezer at $\leq -20$ °C; date of analyses: 03.12.2019
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Reference: KCP 8.3.2-01

Report Determination of residues at harvest of acetamiprid in apple, following two applications of acetamiprid 20% SG, under open field conditions. Germany - season 2018. H. Zoellner, 2019. Study number FRS 055/18, Field Research Support

Guideline(s): Yes  
EC Commission Directive 2004/10/EC of 11 February 2004 (Official Journal No L 50/44).  
OECD Principles of Good Laboratory Practice (as revised in 1997) and Compliance Monitoring No 1, ENV/MC/CHEM(98)17.  
The application of the GLP Principles to Field Studies, Compliance Monitoring No. 6, ENV/JM/MONO(99)22.  
National GLP reference guideline: Chemikaliengesetz, § 19a-d (Germany)  
Council Regulation (EC) No 440/2008, LUKASIEWICZ Research Network – ISCO Procedure BA-AB/SPO-1 and validated research method No BA-AB/MS/MB-11  
Directive 2004/10/EC  
Minister of Health Regulations of 22<sup>nd</sup> May 2013 on Good Laboratory Practice  
Act of 25<sup>th</sup> February 2011 on the chemical substances and their mixtures  
OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No 1, OECD Principles of Good Laboratory Practice, 1998

Deviations: No

GLP: Yes

Acceptability: Yes

Reference: KCP 8.3.2-02

Report Determination of residues at harvest of acetamiprid in apple, following two applications of acetamiprid 20% SG, under open field conditions Germany – Season 2018 Analytical part. Z. Hordyjewicz-Baran, 2019. Study number 206/2019

Guideline(s): Yes  
Directive 2004/10/EC  
Minister of Health Regulations of 22<sup>nd</sup> May 2013 on Good Laboratory Practice  
Act of 25<sup>th</sup> February 2011 on the chemical substances and their mixtures  
OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No 1, OECD Principles of Good Laboratory Practice, 1998

Deviations: No

GLP: Yes

Acceptability: Yes

### Materials and methods:

During the growing season of 2018, a total of one trial was conducted in pome fruit in Northern Europe (Germany) to determine the magnitude of harvest residues of Acetamiprid in or on raw agricultural commodities (RAC).

Sample was extracted by acetonitrile, after liquid-liquid partition by using buffer salt mixture and purification by dispersive SPE and Quechers. Final extract in acetonitrile was analyzed via LC-MS/MS method, validated according to SANCO/8028/00 and SANCO/3029/99.

### Results:

No residue above the LOQ were detected in the control samples. The analytical results in mg per kg are summarized in Table A.7:

**Table A 7: Summary of the study 1**

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)
FRS055 /18 / Germany / NEU / 2018	Apple/Elstar	1) May 2002 2) 24/04/2018 3) 03/09/2018	50 50	1000 1000	5.00 5.00	07/08/2018 21/08/2018	BBCH 81 BBCH 85	Fruit	0.017	13	Analytical phase report: 206/2019 Time between harvest and extraction: 217 d Sampling date : 03.09.2018; arrival at laboratory: 15.11.2019; samples were stored in freezer at ≤ -20 °C; date of analyses: 03.12.2019

### **A 2.1.3.1.2 Study 2**

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.2-03

Report Magnitude of the residue of acetamiprid in pome fruits (raw agricultural commodity - rac) grown in open field conditions after two applications of formulated product acetamiprid 20% SG - two decline curve trials in Poland – 2018. Rafał Figurski, 2019. Study number PB-2018-02, Fertico Sp. z o.o.

Guideline(s): Yes  
Regulation (EC) No 1107/2009  
7029/VI/95-rev 5.  
ENV/MC/CHEM(98)17

ENV/JM/MONO(99)22

Deviations: No

GLP: Yes

Acceptability: Yes

Reference: KCP 8.3.2-04

Report Magnitude of the residue of acetamiprid in pome fruits (raw agricultural commodity - rac) grown in open field conditions after two applications of formulated product acetamiprid 20% SG - two decline curve trials in Poland – 2018. M. Zarębska, 2019. Study number 197/2019

Guideline(s): Yes  
Regulation (EC) No 1107/2009  
7029/VI/95-rev 5.  
ENV/MC/CHEM(98)17  
ENV/JM/MONO(99)22

Deviations: No

GLP: Yes

Acceptability: Yes

#### Materials and methods:

During the growing season of 2019, a total of two trials were conducted in pome fruit in Northern Europe (Poland) to determine the decline residues of Acetamiprid in or on raw agricultural commodities (RAC).

Sample was extracted by acetonitrile, after liquid-liquid partition by using buffer salt mixture and purification by dispersive SPE and Quechers. Final extract in acetonitrile was analyzed via LC-MS/MS method, validated according to SANCO/8028/00 and SANCO/3029/99.

#### Results:

No residue above the LOQ were detected in the control samples. The analytical results in mg per kg are summarized in Table A.8:

**Table A 8: Summary of the study 2**

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)

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)
D-2018-02-F01 / Poland / NEU / 2019	Pome fruit/Malus domestica L.	1) 10/1994 2) 17/04/2018 – 04/05/2018 3) 10/09/2018	50.6 49.0	1010.7 981.4	5.01 4.99	27/08/2018 10/09/2018	BBCH 75 BBCH 78	Fruit Fruit Fruit Fruit	0.040 0.060 0.059 0.016	0 2 7 14	Analytical phase report: 197/2019 LOD = 0.003 mg/kg Time between harvest and extraction: 426 d
D-2018-02-F02 / Poland / NEU / 2019	Pome fruit/Malus domestica L.	1) 1993 2) 28/04/2018 – 14/05/2018 3) 16/08/2018	47.8 50.0	956.0 1001.6	5.00 4.99	02/08/2018 16/08/2018	BBCH 75 BBCH 78	Fruit Fruit Fruit Fruit	0.046 0.048 0.034 0.019	0 2 7 14	Analytical phase report: 197/2019 LOD = 0.003 mg/kg Time between harvest and extraction: 460 d

### A 2.1.3.1.3 Study 3

Comments of zRMS:	Study is accepted.
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Reference: KCP 8.3.2-05

Report Determination of the residues of acetamiprid in/on apple after two applications of acetamiprid 20% SG in Northern Europe - Hungary in 2019. Gábor Szilágyi, 2019. Study number 034SRHU19R22; Trial number SRHU19-182-034IR, SynTech Research Hungary

Guideline(s): Yes

- Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC) No. 1107/2009 of the European Parliament.
- "Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997.
- OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
- European Community Guidelines SANCO 7525/VI/95 – Rev 10.3, 13 June 2017: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs.

Deviations: No

GLP: Yes

Acceptability: Yes

Reference: KCP 8.3.2-06

Report Determination of the residues of acetamiprid in/on apple after two applications of acetamiprid 20% SG in Northern Europe - Hungary in 2019. M. Zarębska, 2019. Study number 205/2019

Guideline(s): Yes  
Regulation (EC) No 1107/2009  
7029/VI/95-rev 5.  
ENV/MC/CHEM(98)17  
ENV/JM/MONO(99)22

Deviations: No

GLP: Yes

Acceptability: Yes

#### Materials and methods:

During the growing season of 2019, a total of one trial was conducted in apple in Northern Europe (Hungary) to determine the magnitude of harvest residues of Acetamiprid in or on raw agricultural commodities (RAC).

Sample was extracted by acetonitrile, after liquid-liquid partition by using buffer salt mixture and purification by dispersive SPE and Quechers. Final extract in acetonitrile was analyzed via LC-MS/MS method, validated according to SANCO/8028/00 and SANCO/3029/99.

#### Results:

No residue above the LOQ were detected in the control samples. The analytical results in mg per kg are summarized in Table A.9:

**Table A 9: Summary of the study 3**

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)
034SRH U19R22 / Hungary / NEU / 2019	Apple/Téli arany	1) 20/05/2010 2) NA 3) 27/08/2019	49.00 48.67	980.00 973.3	5.00 5.00	30/07/2019 13/08/2019	BBCH 82 BBCH 85	Fruit	0.026	14	Analytical phase report: 205/2019  LOD = 0.003 mg/kg (for apple) LOQ = 0.01 mg/kg (for apple) Time between harvest and extraction: 112 d



#### A 2.1.3.1.4 Study 4

Comments of zRMS: Study is accepted

Reference: KCP 8.3.2-07

Report Magnitude of the residue of acetamiprid in pome fruits (Raw Agricultural Commodity) after two applications of Acetamiprid 20% SG – one harvest and two decline curbe trials in Poland – 2018. Z. Hordyjewicz-Baran, 2020. Study number 18SGS01.

Guideline(s): Yes  
 Regulation (EC) No 1107/2009  
 7029/VI/95-rev 5.  
 ENV/MC/CHEM(98)17  
 ENV/JM/MONO(99)22

Deviations: No

GLP: Yes

Acceptability: Yes

**Table A 10: Summary of the study 4**

Trial No./ Location/ EU zone/ Year	Com-modity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Har-vest	Application rate per treatment			Dates of treat-ment or no. of treat-ments and last date	Growth stage at last treat-ment or date	Portion ana-lyzed	Residues (mg/kg)	PHI (days )	Details on trial
			g a.s./ ha	Wa-ter (l/ha)	g a.s./ hl				Acetamiprid		
(a)	(b)					(c)				(d)	(e)
18SHS01PL01	Apple	1. 03.2016 2. 28.08.2018	54.6 48.6	1092.3 972.0		01.08.2018 16.08.2018	BBCH 79 BBCH 81	Fruits	0.026	14	Time between harvest and extraction: 535 d
18SHS01PL02	Apple	1. 10.2006 2. 15.09.2018	49.6 46.8	992.7 934.9		07.08.2018 22.08.2018	BBCH 81 BBCH 87	Fruits Fruits Fruits	0.072 0.047 0.026 0.029	0 3 7 14	Time between harvest and extraction: 517 d
18SHS01PL03	Apple	1. 10.10.2014 2. 24.08.2018	54.6 51.8	1093.0 1037.3		07.08.2018 21.08.2018	BBCH 79 BBCH 87	Fruits Fruits Fruits	0.066 0.047 0.016 0.022	0 3 7 14	Time between harvest and extraction: 539 d

**A 2.1.4            Magnitude of residues in livestock**

**A 2.1.4.1          Livestock feeding studies**

No additional study.

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

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

No additional study.

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

No additional study.

## A 2.1.6 Magnitude of residues in representative succeeding crops

No additional study:

Comments of zRMS:	<p>The studies are accepted as alternative to the Raufer, B., 2013, 2014 studies (field rotational crop studies).</p> <p>The objective of the Study was to provide results from the magnitude of residues of acetamiprid in/on rotational crops (spinach, carrot, spring barley), grown in open field conditions, in order to support the registration of the plant protection product applied according Good Laboratory Practice (GLP).</p> <p>One application (P5: 30 days, P4: 63 days, P3: 130 days and P2: 348 days PBI (plant back interval)) of the formulated product Acetamiprid 20 % SG was applied at a target rate of 1.5 kg/ha to bare soil (0.3 kg a.s./ha).</p> <p>Specimens (whole plant, grain, straw, roots, tops and mature leaves) were collected from spinach at BBCH 13-15, at earliest commercial harvest date (BBCH 45) and at harvest (BBCH 49), from carrot at BBCH 13-15, at earliest commercial harvest date (BBCH 45) and at harvest (BBCH 49), from spring barley at BBCH 13-15, at BBCH 75-85 and at harvest (BBCH 89).</p> <p>Validation of the analytical method used was done according to SANTE/2020/12830, rev.1.</p> <p>No residues of Acetamiprid or metabolite IM-1-5 above the LOQ (0.01 mg/kg) were found in any of the samples taken from all the PBIs.</p> <p>The Applicant has fulfilled the requirements.</p>
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### A 2.1.6.1 Study 1

Reference:

Report

Test Guidelines and data requirements

KCP 8.3.3-01 (field part)

Determination of the residues of acetamiprid in/on crop rotation crops after one application of Acetamiprid 20% SG in Northern Europe - Hungary in 2019, Gábor Wágner, 2022, Report No.: 034SRHU19R21

- Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC) No. 1107/2009 of the European Parliament.
- "Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997.
- OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009).
- OECD Guideline for the testing of chemicals on Crop Field Trial (TG 504 published in January 2007).

Reference:

Report

KCP 8.3.3-02 (analytical part)

Determination of the residues of Acetamiprid in/on crop rotation crops after one application of Acetamiprid 20% SG in Hungary in 2019, Charlotte Marteau, 2022, Report No.: S22-01946

Test Guidelines and data requirements

SANTE/2020/12830, rev.1

GLP:	Yes	Sample storage conditions:	Samples were kept deep frozen [min: -33.5°C, max: -17.4°C], samples were put in the freezer within 8 hours after sampling.
Preceding crop:	Application on bare soil	Analytical method:	KCP 8.3.3-2 Report No.: S22-01946
Succeeding crop:	Carrot/ spinach/ spring barley	Limit of Quantification (mg/kg):	0.01 mg/kg (crops) 0.002 mg/kg (soil)
Indoor/Outdoor:	Outdoor	Limit of Detection (mg/kg):	0.003 mg/kg (crops) 0.0006 mg/kg (soil)
Formulation:	Acetamiprid 20% SG	Residues calculated as:	acetamiprid and IM-1-5
Content of active substance (g/kg or g/L):	200 g/kg		

**Table A 6: Rotational trial summary for carrot**

Trial No./ Location/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)		PBI (days)	Remarks
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid	IM-1-5		
SRHU19-154- 034IR/ / Hungary/ NEU/ 2021	Carrot / Flakker	1. 28.04.2020 2. NA 3. Oct 2020	P2: 300 P3: 300 P4: 300 P5: 300	P2: 400 P3: 400 P4: 400 P5: 400	-	P2: 16.05.2019 P3: 20.12.2019 P4: 25.02.2020 P5: 29.03.2020	NA	Carrot (whole plant)	<0.01	<0.01	30 (P5)	Analytical report No.: S22-01946  LOD: 0.003 mg/kg LOQ: 0.01 mg/kg
								Carrot (root)	<0.01	<0.01	30 (P5)	
								Carrot (top)	<0.01	<0.01	30 (P5)	
								Carrot (root)	<0.01	<0.01	30 (P5)	
								Carrot (top)	<0.01	<0.01	30 (P5)	
								Carrot (whole plant)	<0.01	<0.01	63 (P4)	
								Carrot (root)	<0.01	<0.01	63 (P4)	
								Carrot (top)	<0.01	<0.01	63 (P4)	
								Carrot (root)	<0.01	<0.01	63 (P4)	
								Carrot (top)	<0.01	<0.01	63 (P4)	
								Carrot (whole plant)	<0.01	<0.01	130 (P3)	
								Carrot (root)	<0.01	<0.01	130 (P3)	
								Carrot (top)	<0.01	<0.01	130 (P3)	
								Carrot (root)	<0.01	<0.01	130 (P3)	
								Carrot (top)	<0.01	<0.01	130 (P3)	
								Carrot (whole plant)	<0.01	<0.01	348 (P2)	
								Carrot (root)	<0.01	<0.01	348 (P2)	
								Carrot (top)	<0.01	<0.01	348 (P2)	
								Carrot (root)	<0.01	<0.01	348 (P2)	
								Carrot (top)	<0.01	<0.01	348 (P2)	

**Table A 7: Rotational trial summary for spinach**

Trial No./ Location/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)		PHI (days)	Remarks
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid	IM-1-5		
SRHU19-154- 034IR/ / Hungary/ NEU/ 2021	Spinach / Popey	1. 28.04.2020 2. May 2020 3. Jul 2020	P2: 300	P2: 400	-	P2: 16.05.2019 P3: 20.12.2019 P4: 25.02.2020 P5: 29.03.2020	NA	Spinach	<0.01	<0.01	30 (P5)	Analytical report No.: S22-01946  LOD: 0.003 mg/kg LOQ: 0.01 mg/kg
			P3: 300	P3: 400				(whole plant)				
			P4: 300	P4: 400				Spinach (im- mature leaves)	<0.01	<0.01	30 (P5)	
			P5: 300	P5: 400				Spinach (ma- ture leaves)	<0.01	<0.01	30 (P5)	
								Spinach	<0.01	<0.01	63 (P4)	
								(whole plant)				
								Spinach (im- mature leaves)	<0.01	<0.01	63 (P4)	
								Spinach (ma- ture leaves)	<0.01	<0.01	63 (P4)	
								Spinach	<0.01	<0.01	130 (P3)	
								(whole plant)				
								Spinach (im- mature leaves)	<0.01	<0.01	130 (P3)	
								Spinach (ma- ture leaves)	<0.01	<0.01	130 (P3)	
								Spinach	<0.01	<0.01	348 (P2)	
								(whole plant)				
								Spinach (im- mature leaves)	<0.01	<0.01	348 (P2)	
								Spinach (ma- ture leaves)	<0.01	<0.01	348 (P2)	

**Table A 8: Rotational trial summary for spring barley**

Trial No./ Location/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Remarks
			g a.s./ ha	Water (l/ha)	g a.s./hl				Acetamiprid	IM-1-5		
SRHU19-154- 034IR/ / Hungary/ NEU/ 2021	Barley / GK Toma	1. 28.04.2020 2. May 2020 3. Jul 2020	P2: 300 P3: 300 P4: 300 P5: 300	P2: 400 P3: 400 P4: 400 P5: 400	-	P2: 16.05.2019 P3: 20.12.2019 P4: 25.02.2020 P5: 29.03.2020	NA	Barley (whole plant)	<0.01	<0.01	30 (P5)	Analytical report No.: S22-01946  LOD: 0.003 mg/kg LOQ: 0.01 mg/kg
								Barley (whole plant)	<0.01	<0.01	30 (P5)	
								Barley (grain)	<0.01	<0.01	30 (P5)	
								Barley (straw)	<0.01	<0.01	30 (P5)	
								Barley (whole plant)	<0.01	<0.01	63 (P4)	
								Barley (whole plant)	<0.01	<0.01	63 (P4)	
								Barley (grain)	<0.01	<0.01	63 (P4)	
								Barley (straw)	<0.01	<0.01	63 (P4)	
								Barley (whole plant)	<0.01	<0.01	130 (P3)	
								Barley (whole plant)	<0.01	<0.01	130 (P3)	
								Barley (grain)	<0.01	<0.01	130 (P3)	
								Barley (straw)	<0.01	<0.01	130 (P3)	
								Barley (whole plant)	<0.01	<0.01	348 (P2)	
								Barley (whole plant)	<0.01	<0.01	348 (P2)	
								Barley (grain)	<0.01	<0.01	348 (P2)	
								Barley (straw)	<0.01	<0.01	348 (P2)	

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

No additional study.



## **Appendix 3    Pesticide Residue Intake Model (PRIMo)**

### **A 3.1            TMDI calculations**



EFSA PRIMo revision 3.1; 2019/03/19

<b>Acetamiprid (R)</b>			
LOQs (mg/kg) range from:		to:	
<b>Toxicological reference values</b>			
ADI (mg/kg bw/day):	<b>0.025</b>	ARfD (mg/kg bw):	<b>0.025</b>
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

### Details - chronic risk assessment

## Supplementary results - chronic risk assessment

## Details - acute risk assessment/children

## Details - acute risk assessment/adults

Comments:

### Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

				No of diets exceeding the ADI :		1				Exposure resulting from	
	Calculated exposure (% of ADI)		Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities n under assessment (n % of ADI)
TMDI/NEDI/MEDI calculation (based on average food consumption)	122%	NL toddler	30.58	48%	Milk: Cattle	17%	Apples	9%	Bananas		26%
	78%	DE child	19.56	20%	Apples	16%	Milk: Cattle	14%	Oranges		21%
	64%	NL child	16.04	20%	Milk: Cattle	9%	Apples	5%	Oranges		12%
	54%	FR child 3 15 yr	13.61	18%	Milk: Cattle	12%	Oranges	3%	Bovine: Muscle/meat		3%
	52%	FR toddler 2 3 yr	13.06	23%	Milk: Cattle	5%	Oranges	5%	Apples		6%
	51%	UK infant	12.74	31%	Milk: Cattle	5%	Oranges	3%	Apples		3%
	48%	ES child	12.08	10%	Milk: Cattle	9%	Olives for oil production	8%	Oranges		3%
	42%	GEMS/Food G08	10.58	10%	Olives for oil production	4%	Milk: Cattle	4%	Swine: Muscle/meat		3%
	41%	UK toddler	10.18	17%	Milk: Cattle	7%	Oranges	3%	Apples		3%
	40%	SE general	10.12	10%	Milk: Cattle	9%	Bovine: Muscle/meat	3%	Bananas		2%
	40%	GEMS/Food G07	10.08	5%	Milk: Cattle	5%	Oranges	4%	Olives for oil production		3%
	38%	GEMS/Food G06	9.61	7%	Tomatoes	4%	Olives for oil production	4%	Oranges		2%
	38%	DE women 14-50 yr	9.38	10%	Milk: Cattle	7%	Oranges	4%	Apples		4%
	37%	GEMS/Food G10	9.13	5%	Olives for oil production	4%	Milk: Cattle	4%	Oranges		2%
	36%	DE general	8.88	10%	Milk: Cattle	6%	Oranges	4%	Apples		4%
	35%	GEMS/Food G11	8.72	6%	Milk: Cattle	3%	Olives for oil production	3%	Oranges		3%
	35%	GEMS/Food G15	8.68	6%	Milk: Cattle	3%	Swine: Muscle/meat	2%	Oranges		3%
	34%	DK child	8.40	10%	Milk: Cattle	4%	Swine: Muscle/meat	4%	Apples		5%
	33%	IE adult	8.30	4%	Oranges	3%	Milk: Cattle	3%	Grapefruits		2%
	33%	RO general	8.17	9%	Milk: Cattle	4%	Tomatoes	3%	Wine grapes		3%
	31%	ES adult	7.64	5%	Olives for oil production	5%	Oranges	4%	Milk: Cattle		2%
	27%	NL general	6.79	7%	Milk: Cattle	4%	Oranges	2%	Apples		3%
	25%	FR infant	6.24	13%	Milk: Cattle	3%	Apples	1%	Beans (with pods)		3%
	22%	FR adult	5.48	5%	Wine grapes	4%	Milk: Cattle	2%	Oranges		1%
	21%	PT general	5.25	5%	Wine grapes	3%	Olives for oil production	2%	Oranges		2%
	17%	DK adult	4.34	4%	Milk: Cattle	2%	Wine grapes	2%	Swine: Muscle/meat		2%
	17%	IT toddler	4.13	3%	Tomatoes	3%	Wheat	2%	Lettuces		2%
	15%	UK vegetarian	3.80	3%	Oranges	3%	Milk: Cattle	2%	Wine grapes		1%
	15%	FI 3 yr	3.74	2%	Bananas	2%	Apples	1%	Raspberries (red and yellow)		2%
	14%	IT adult	3.60	2%	Tomatoes	2%	Lettuces	2%	Wheat		2%
14%	UK adult	3.45	2%	Milk: Cattle	2%	Wine grapes	2%	Oranges		0.8%	
14%	LT adult	3.43	3%	Milk: Cattle	3%	Apples	2%	Swine: Muscle/meat		3%	
11%	FI 6 yr	2.75	1%	Bananas	1%	Mandarins	1%	Raspberries (red and yellow)		1%	
10%	FI adult	2.42	1%	Oranges	1%	Coffee beans	1%	Tomatoes		1%	
9%	PL general	2.37	3%	Apples	2%	Tomatoes	0.6%	Table grapes		4%	
6%	IE child	1.58	3%	Milk: Cattle	0.5%	Apples	0.5%	Wheat		0.6%	
<b>Conclusion:</b> The estimated TMDI/NEDI/MEDI was in the range of 0 % to 122.3 % of the ADI. For 1 diet(s) the ADI is exceeded.											

### **A 3.2 TMDI calculations– considering STMR/HR values from the intended uses**



Input values	
Details - chronic risk assessment	Supplementary results - chronic risk assessment
Details - acute risk assessment/children	Details - acute risk assessment/adults

Comments:	
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	<b>Normal mode</b>
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Chronic risk assessment: JMPR methodology (IEDI/TMDI)

				No of diets exceeding the ADI : ---						Exposure resulting from	
	Calculated exposure (% of ADI)		Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities under assessment (in % of ADI)
TMD/INWED/EDI calculation (based on average food consumption)	98%	NL toddler	24.56	48%	Milk: Cattle	9%	Bananas	8%	Oranges		2%
	58%	DE child	14.62	16%	Milk: Cattle	14%	Oranges	3%	Table grapes		1%
	53%	NL child	13.25	20%	Milk: Cattle	5%	Oranges	3%	Bananas		0.8%
	51%	FR child 3 15 yr	12.87	18%	Milk: Cattle	12%	Oranges	3%	Bovine: Muscle/meat		0.2%
	48%	UK infant	12.06	31%	Milk: Cattle	5%	Oranges	2%	Bovine: Muscle/meat		0.2%
	47%	FR toddler 2 3 yr	11.75	23%	Milk: Cattle	5%	Oranges	3%	Mandarins		0.4%
	46%	ES child	11.45	10%	Milk: Cattle	9%	Olives for oil production	8%	Oranges		0.2%
	40%	GEMS/Food G08	9.94	10%	Olives for oil production	4%	Milk: Cattle	4%	Swine: Muscle/meat		0.2%
	38%	SE general	9.59	10%	Milk: Cattle	9%	Bovine: Muscle/meat	3%	Bananas		0.1%
	38%	UK toddler	9.47	17%	Milk: Cattle	7%	Oranges	3%	Bovine: Muscle/meat		0.2%
	38%	GEMS/Food G07	9.42	5%	Milk: Cattle	5%	Oranges	4%	Olives for oil production		0.2%
	37%	GEMS/Food G06	9.17	7%	Tomatoes	4%	Olives for oil production	4%	Oranges		0.1%
	35%	GEMS/Food G10	8.63	5%	Olives for oil production	4%	Milk: Cattle	4%	Oranges		0.1%
	33%	DE women 14-50 yr	8.35	10%	Milk: Cattle	7%	Oranges	2%	Swine: Muscle/meat		0.3%
	32%	GEMS/Food G11	8.08	6%	Milk: Cattle	3%	Olives for oil production	3%	Oranges		0.2%
	32%	GEMS/Food G15	8.07	6%	Milk: Cattle	3%	Swine: Muscle/meat	2%	Oranges		0.2%
	32%	DE general	7.92	10%	Milk: Cattle	6%	Oranges	2%	Swine: Muscle/meat		0.3%
	31%	IE adult	7.87	4%	Oranges	3%	Milk: Cattle	3%	Grapefruits		0.1%
	30%	RO general	7.57	9%	Milk: Cattle	4%	Tomatoes	3%	Wine grapes		0.2%
	29%	DK child	7.28	10%	Milk: Cattle	4%	Swine: Muscle/meat	3%	Bovine: Muscle/meat		0.3%
	29%	ES adult	7.21	5%	Olives for oil production	5%	Oranges	4%	Milk: Cattle		0.1%
	24%	NL general	6.07	7%	Milk: Cattle	4%	Oranges	2%	Swine: Muscle/meat		0.2%
	22%	FR infant	5.53	13%	Milk: Cattle	1%	Beans (with pods)	0.9%	Oranges		0.2%
	21%	FR adult	5.14	5%	Wine grapes	4%	Milk: Cattle	2%	Oranges		0.1%
	19%	PT general	4.71	5%	Wine grapes	3%	Olives for oil production	2%	Oranges		0.1%
	15%	DK adult	3.86	4%	Milk: Cattle	2%	Wine grapes	2%	Swine: Muscle/meat		0.1%
	15%	IT toddler	3.67	3%	Tomatoes	3%	Wheat	2%	Lettuces		0.1%
	14%	UK vegetarian	3.55	3%	Oranges	3%	Milk: Cattle	2%	Wine grapes		0.1%
	13%	FI 3 yr	3.29	2%	Bananas	1%	Raspberries (red and yellow)	1%	Mandarins		0.1%
	13%	UK adult	3.27	2%	Milk: Cattle	2%	Wine grapes	2%	Oranges		0.0%
13%	IT adult	3.21	2%	Tomatoes	2%	Lettuces	2%	Wheat		0.1%	
11%	LT adult	2.67	3%	Milk: Cattle	2%	Swine: Muscle/meat	1%	Tomatoes		0.2%	
10%	FI 6 yr	2.44	1%	Bananas	1%	Mandarins	1%	Raspberries (red and yellow)		0.1%	
9%	FI adult	2.19	1%	Oranges	1%	Coffee beans	1%	Tomatoes		0.1%	
6%	PL general	1.50	2%	Tomatoes	0.6%	Table grapes	0.6%	Head cabbages		0.2%	
6%	IE child	1.45	3%	Milk: Cattle	0.5%	Wheat	0.3%	Swine: Muscle/meat		0.0%	

The long-term intake of residues of Acetamiprid (R) 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): 2				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				IESTI				IESTI new				IESTI new			
	Highest % of ARfD/ADI		MRL / input for RA (mg/kg) Exposure (µg/kg bw)		Highest % of ARfD/ADI		MRL / input for RA (mg/kg) Exposure (µg/kg bw)		Highest % of ARfD/ADI		MRL / input for RA (mg/kg) Exposure (µg/kg bw)		Highest % of ARfD/ADI		MRL / input for RA (mg/kg) Exposure (µg/kg bw)	
	222%	Pears	0.4 / 0.4	55	49%	Pears	0.4 / 0.4	12	99%	Apples	0.4 / 0.4	25	57%	Pears	0.4 / 0.4	14
	172%	Apples	0.4 / 0.4	43	49%	Quinces	0.8 / 0.8	12	95%	Pears	0.4 / 0.4	24	48%	Apples	0.4 / 0.4	12
	79%	Quinces	0.8 / 0.8	20	45%	Apples	0.4 / 0.4	11	47%	Quinces	0.8 / 0.8	12	29%	Quinces	0.8 / 0.8	7.3
	44%	Medlar	0.8 / 0.8	11	22%	Medlar	0.8 / 0.8	5.5	33%	Medlar	0.8 / 0.8	8.1	15%	Medlar	0.8 / 0.8	3.8
	2%	Rapeseeds/canola	0.4 / 0.4	0.55	0.8%	Rapeseeds/canola seeds	0.4 / 0.4	0.21	2%	Rapeseeds/canola	0.4 / 0.4	0.55	0.8%	Rapeseeds/canola seeds	0.4 / 0.4	0.21
	Expand/collapse list															
	Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 2								Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)							

### A 3.4 IESTI calculations - Raw commodities – considering STMR/HR values from the intended uses

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.								<b>IESTI new calculations:</b> 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. <b>Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.</b>								
Show results of IESTI calculation only for crops with GAPs under assessment																
Unprocessed commodities	<b>Results for children</b> No. of commodities for which ARfD/ADI is exceeded (IESTI):				---				<b>IESTI new Results for children</b> No. of commodities for which ARfD/ADI is exceeded (IESTI new):				---			
	<b>IESTI</b>								<b>IESTI new</b>							
	Highest % of ARfD/ADI		Commodities		MRL /input for RA (mg/kg)		Exposure (µg/kg bw)		Highest % of ARfD/ADI		Commodities		MRL /input for RA (mg/kg)		Exposure (µg/kg bw)	
	39%		Pears		0.4 / 0.07		9.8		9%		Pears		0.4 / 0.07		2.2	
	31%		Apples		0.4 / 0.07		7.7		8%		Apples		0.4 / 0.07		2.0	
	7%		Quinces		0.8 / 0.07		1.7		4%		Quinces		0.8 / 0.07		1.1	
	4%		Medlar		0.8 / 0.07		0.98		2%		Medlar		0.8 / 0.07		0.49	
	0.08%		Rapeseeds/canola		0.4 / 0.02		0.02		0.03%		Rapeseeds/canola seeds		0.4 / 0.02		0.01	
Expand/collapse list																
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)								

## IESTI calculations - Processed commodities

Processed commodities	Results for children				Results for adults				Results for children				Results for adults			
	No of processed commodities for which ARID/ADI is exceeded (IESTI):				No of processed commodities for which ARID/ADI is exceeded (IESTI):				No of processed commodities for which ARID/ADI is exceeded (IESTI new):				No of processed commodities for which ARID/ADI is exceeded (IESTI new):			
	---				---				---				---			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	87%	Apples / juice	0.4 / 0.4	22	53%	Apples / juice	0.4 / 0.4	13	87%	Apples / juice	0.4 / 0.4	22	53%	Apples / juice	0.4 / 0.4	13
	52%	Pears / juice	0.4 / 0.4	13	4%	Quinces / jam	0.8 / 0.8	1.0	52%	Pears / juice	0.4 / 0.4	13	4%	Quinces / jam	0.8 / 0.8	1.0
	10%	Quinces / jam	0.8 / 0.8	2.4	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	10%	Quinces / jam	0.8 / 0.8	2.4	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	0.9%	Rapeseeds / oils	0.4 / 0.8	0.24	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	0.9%	Rapeseeds / oils	0.4 / 0.8	0.24	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list																
<b>Conclusion:</b> The estimated short term intake (IESTI) exceeded the toxicological reference value for 2 commodities.																
For processed commodities, no exceedance of the ARID/ADI was identified.																

### **IESTI calculations - Processed commodities – considering STMR/HR values from the intended uses**

Processed commodities	Results for children				Results for adults				Results for children				Results for adults			
	No of processed commodities for which ARID/ADI is exceeded (IESTI):				No of processed commodities for which ARID/ADI is exceeded (IESTI):				No of processed commodities for which ARID/ADI is exceeded (IESTI new):				No of processed commodities for which ARID/ADI is exceeded (IESTI new):			
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	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	6%	Apples / juice	0.4 / 0.03	1.4	3%	Apples / juice	0.4 / 0.03	0.87	87%	Apples / juice	0.4 / 0.4	22	53%	Apples / juice	0.4 / 0.4	13
	3%	Pears / juice	0.4 / 0.03	0.85	0.1%	Quinces / jam	0.8 / 0.03	0.03	52%	Pears / juice	0.4 / 0.4	12	4%	Quinces / jam	0.8 / 0.8	1.0
	0.3%	Quinces / jam	0.8 / 0.03	0.08	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	10%	Quinces / jam	0.8 / 0.8	2.4	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	0.0%	Rapeseeds / oils	0.4 / 0.03	0.01	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	0.9%	Rapeseeds / oils	0.4 / 0.8	0.24	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list																
Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Acetaminorid (R) is unlikely to present a public health risk. For processed commodities, no exceedance of the ARID/ADI was identified.																



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

No additional information.