

# FINAL REGISTRATION REPORT

## **Part B**

### **Section 7**

#### **Metabolism and Residues**

Detailed summary of the risk assessment

Product code: Acetamipryd 200 SL

Product name(s): -

Chemical active substance:

acetamiprid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### **CORE ASSESSMENT**

(authorization)

Applicant: Pestila Sp. z o.o. / ProAgri International Sp. z o.o.

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## Version history

When	What
March 2025	ZRMS assessment
August 2025	The final Registration Report after the reporting period.
October 2025	update in relation to the new Regulation (EU) 2025/1212

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## 7 Metabolism and residue data (KCA section 6)

### 7.1 Summary and zRMS Conclusion

#### Stability of Residues

Based on storage stability studies evaluated in the EU review of acetamiprid it can be concluded that acetamiprid residues are stable for at least one year in different plant products from high water, protein, oil, acid and processed matrices and for 8 months in high starch content matrices.

New studies for acetamiprid-*N*-desmethyl (IM-2-1) have been submitted by the applicant in the framework of this application.

For acetamiprid-*N*-desmethyl (IM-2-1) stability was demonstrated upon storage at  $\leq -18^{\circ}\text{C}$ :

- in potato for a period of 99 days,
- in rape seed for a period of 406 days,
- in apple for a period of 354 days.

In the field studies, the time from sample collection to extraction was:

Winter rapeseed trials – max. 30 days

Apple trials – max. 49 days

Potato trials – max. 67 days.

The trials are valid with regard to storage stability data.

#### 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.

Plant residue definition for monitoring: Acetamiprid (Reg. (EU) 2019/88, Reg. (EU) 2025/158, New MRL values for Acetamiprid (R) will apply from 19/08/2025 Regulation (EU) 2025/1212)

Plant residue definition for risk assessment:

- Fruit and leafy crops: sum of acetamiprid and *N*-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid
- Pulses/oilseeds: acetamiprid
- Root crops: acetamiprid
- Cereals: acetamiprid

Conversion factor from enforcement to RA:

Leafy crops: 1.44

Fruit crops: 1.21

(EFSA Statement, 2024 (EFSA Journal. 2024;22:e8759))

Animal residue definition for monitoring: Acetamiprid except honey (the sum of acetamiprid and IM-2-1, expressed as acetamiprid) (Reg (EU) 2019/88, Reg. (EU) 2025/158, New MRL values for Acetamiprid (R) will apply from 19/08/2025 Regulation (EU) 2025/1212)

Animal residue definition for risk assessment: Sum of acetamiprid and metabolite IM-2-1 (*N*-desmethyl-acetamiprid), expressed as acetamiprid (EFSA, 2016)

Conversion factor      Milk: 1.3

Other mammalian products: 1.1

Poultry matrices: not required

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

Winter oilseed rape, turnip rape

Proposed GAPs:

1 application, BBCH 30-50 (spring, post emergence), 50 g a.s./ha,

1 application, BBCH 50-65 (spring, post emergence), 20 – 24 g a.s./ha,

1 application, BBCH 60-69 (spring, post emergence), 20 – 24 g a.s./ha,

Spring oilseed rape, turnip rape

1 application, BBCH 30-50 (spring, post emergence), 50 g a.s./ha, PHI: 14 days

1 application, BBCH 50-65 (spring, post emergence), 20 – 24 g a.s./ha, PHI: 14 days

1 application, BBCH 59-71 (spring, post emergence), 60 g a.s./ha, PHI: 14 days

Flax- fiber production, common hemp - fiber production

1 application, 60 g a.s./ha - residue data are not required.

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP: 1x 50 g as/ha, BBCH 69, PHI 42-59d, outdoor

Residues: 4 x < 0.01, 0.012, 0.014, 0.017, 0.021 mg/kg

PHI of 14 days is not accepted. Taking into account the PHI of field studies, 50 days is proposed.

The dose from the field tests is lower than the maximum proposed. However, it is within 25 percent of the difference.

The data submitted show that no exceedance of the EU MRL (0.4 mg/kg - rape seed, turnip rape) for oilseed rape will occur.

According to SANTE/2019/12752 Rev.01 extrapolation from oilseed rape to turnip rape is possible.

Uses are accepted

Potato

Proposed GAP:

1 application, BBCH 35-75 (spring, post emergence), 16-24 g a.s./ha, PHI: 3 days

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP: 1x 24 g as/ha, BBCH 89, PHI 30d, outdoor

Residues: 4x< 0.001 mg/kg (LOD)

The data submitted show that no exceedance of the EU MRL (0.01 mg/kg) for potato will occur.

Use is accepted. PHI of 30 days is proposed according to the PHI of trials.

### Apple

#### Proposed GAPs:

2 applications (interval: 7 days), BBCH 71-84 (spring, post emergence), 25 g a.s./ha, PHI: 14 days

1 application, BBCH 56-84 (spring, post emergence), 22 g a.s./ha or 36 g a.s./ha, PHI: 14 days

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

#### Trials GAP:

Trials GAP: 2 x 40 g as/ha, BBCH 81-85, PHI 14d, indoor

Residues: 0.012, 0.013, 0.017, 0.032, 0.033, 0.037, 0.046, 0.055 mg/kg

The data submitted show that no exceedance of the EU MRL (0.07 mg/kg, ~~Reg. (EU) 2025/158~~ **Regulation (EU) 2025/1212**) for apple will occur.

Use is accepted.

### Wild apple, pears, Chinese pears, quinces, medlars

#### Proposed GAPs:

Wild apple, quinces, medlars: 1 application, BBCH 56-84, 22 g a.s./ha, PHI: 14 days

Wild apple, quinces, medlars: 2 applications (interval: 7 days), BBCH 59-84, 25 g a.s./ha, PHI: 14 days

Pears: 2 applications (interval: 7 days), BBCH 51-84, 25 g a.s./ha, PHI: 14 days

Pears: 1 application, BBCH 51-84, 27 g a.s./ha, PHI: 14 days

According to SANTE/2019/12752 Rev.01 extrapolation from apple to whole group Pome fruits is possible.

The data submitted show that no exceedance of the EU MRL (apple, pears: 0.07 mg/kg; quinces: 0.15 mg/kg, medlar: 0.3 mg/kg; ~~Reg. (EU) 2025/158~~ **Regulation (EU) 2025/1212**) will occur.

Uses are accepted.

### Plum, peach, nectarine, apricot, cherry

#### Proposed GAPs:

1 application, BBCH 51-84, 25 g a.s./ha, PHI: 14 days

2 applications (interval: 7 days), BBCH 51-87, 22 g a.s./ha, PHI: 14 days

Residue trials on plums are available from DAR Acetamiprid Addendum March 2001.

GAP on which EU a.s. assessment is based: 2x 50 g as/ha, PHI 14d

Residues (plums): 5x < 0.01, 0.011, 0.017 mg/kg

Plum is a major crop in the N-EU zone and therefore requires a minimum of eight trials. There is no sufficient number of trials to support the proposed use on plums. One additional trial is required. Use is not accepted.

There is no sufficient data to do extrapolation from plum and apples to peach, apricot, nectarine and cherry.

Uses are not accepted.

#### Walnuts, hazelnuts

Proposed GAP:

2 applications (interval: 10 days), BBCH 51-65, 22 g a.s./ha, PHI: 14 days

There is no sufficient data to do extrapolation from apples and plums to walnuts and hazelnuts.

Uses are not accepted in Poland.

According to SANTE/2019/12752 minimum 4 trials on apples + trials on stone fruit is required to extrapolate the trials to nuts.

PL considers this provision in meaning that a full set of studies on plums is required to extrapolate to nuts. Since plums are a major crop, eight trials are required.

zRMS agrees with the MS comment that the interpretation of this provision may be different, therefore zRMS states that in this case the decision on acceptance of these uses may be made at the member state level (in Poland not accepted).

#### Tomato, aubergine, pepper (indoor)

Proposed GAP:

1 application, BBCH 20-89, 60 g a.s./ha, PHI: 3 days

Applicant refers to DAR, Greece, Addendum 2001.

Tomato:

GAP on which EU a.s. assessment is based: 2x 90 g as/ha, PHI 3d, indoor

Residues (tomato): 0.01, 0.011, 0.016, 2x 0.022, 0.041, 0.049, 0.081 mg/kg

MRLs:

For tomato - 0.06 mg/kg; for aubergine - 0.2 mg/kg (Reg. (EU) 2025/158). New MRL values for Acetamipryd will apply from 19/08/2025 Regulation (EU) 2025/1212).

Exceeding the new MRLs is possible for tomato. Use is not accepted.

According to SANTE/2019/12752 Rev.01 extrapolation from tomato to aubergine is possible.

Since the MRL for eggplant is 0.2, the results indicate that there will be no exceedance of the MRL for this crop after the proposed application. Use is accepted.

EFSA identified some information on residue trials on pepper as unavailable.

GAP on which EU a.s. assessment is based: 2x 90 g as/ha, PHI 3d, indoor

Residues (pepper): 0.024, 0.079, 0.12, 0.15, 0.19 mg/kg

The results indicate the possibility of exceeding the MRL (0.09 mg/kg). Therefore, use on peppers is not acceptable.

Common osier, Purple willow, forest and ornamental nurseries plants, Restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations

Residue data are not required.



**Residues in livestock**

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 GAPs 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**

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

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.

**Other / special studies**

New semi-field/tunnel studies in N-EU zone (Poland and N-France) and S-EU zone (S-France and Italy) have been performed on winter oilseed rape to investigate the magnitude of acetamiprid residues in honey.

Sufficient residue trials (4) are available for honey. All samples were analysed within 30 days from sampling, therefore there is no need to perform studies on the stability of residues during storage. All trials resulted in residues below the actual and planned MRL for honey. Therefore, no risk for consumers is expected.

**Estimation of exposure through diet and other means**

The accepted uses of acetamiprid in the formulation Acetamipryd 200 SL do not represent unacceptable acute and chronic risks for the consumer.

**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 Acetamipryd 200 SL are presented in Table 7.1-1. A list of all intended uses is given in Part B, Section 0.

**Overall conclusion**

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for

acetamiprid as laid down in Reg. (EU) 396/2005 is not expected for accepted uses.

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 agrees with the authorization of the intended use(s) except plum, peach, apricot, nectarine, cherry, tomato, pepper and nuts.

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

### Data gaps

- One additional trial on plums is required to accept extrapolation to whole group stone fruits before forming of the edible part (taking into account also apples). In case of situation after forming of the edible part additional data for peach and apricot is required additionally.
- One additional trial on plums is required to accept extrapolation to walnuts, hazelnuts (taking into account also apples).

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**Table 7.1-1: GAP table - intended uses**

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Mem- ber state(s)	Crop and/or situ- ation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syn- ergist per ha	Conclusions
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val between applica- tions (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
Zonal uses														
1	PL	Winter oilseed rape 0401060	F	Rape stem weevil ( <i>Ceutorhyn- chus napi</i> ) CEUTNA Cabbage stem weevil ( <i>Ceu- torhynchus pallidactylus</i> ) CEUTQU	Foliar spray	BBCH 30-50 Spring, post emergence	1 a) 1 b) 1	N/A	0.25 L/ha a) 0.25 L/ha b) 0.25 L/ha	50 g/ha a) 50 g/ha b) 50 g/ha	200-400 L/ha	N/A 50 days	not relevant	A
2	PL	Winter oilseed rape 0401060	F	Pollen beetle ( <i>Brassicogethes aeneus</i> ) MELIAE	Foliar spray	BBCH 50-65 Spring, post emergence	1 a) 1 b) 1	N/A	0.1-0.12 L/ha a) 0.12 L/ha b) 0.12 L/ha	20-24 g /ha a) 24 g /ha b) 24 g /ha	200-400 L/ha	N/A 50 days	not relevant	A
3	PL	Winter oilseed rape 0401060	F	Cabbage seed weevil ( <i>Ceu- torhynchus obstrictus</i> ) CEU- TAS Brassica pod midge ( <i>Dasi- neura brassicae</i> ) DASYBR	Foliar spray	BBCH 60-69 Spring, post emergence	1 a) 1 b) 1	N/A	0.1-0.12 L/ha a) 0.12 L/ha b) 0.12 L/ha	20-24 g /ha a) 24 g /ha b) 24 g /ha	200-400 L/ha	N/A 50 days	not relevant	A
4	PL	Potato 0211000	F	Colorado beetle ( <i>Leptinotarsa decemlineata</i> ) LPTNDE	Foliar spray	BBCH 35-75 Spring, post emergence	1 a) 1 b) 1	N/A	0.08-0.12 L/ha a) 0.12 L/ha b) 0.12 L/ha	16-24 g /ha a) 24 g /ha b) 24 g /ha	200-400 L/ha	3 days 30 days	not relevant	A
5	PL	Apple 0130010	F	Tortix moths ( <i>Tortricidae sp</i> ) TORTSP	Foliar spray	BBCH 71-84 Spring, post emergence	2 a) 1 b) 2	7 days	0.118 L/10000m² LWA a) 0.118 L/10000m² LWA b) 0.236 L/10000m² LWA	23.6 g/10000m² LWA a) 23.6 g/10000m² LWA b) 47.2 g/10000m² LWA	500-900 L/ha	14 days	Max. 2 x 0.125 L/ha (2 x 25 g as/ha) 10600 LWA	A
6	PL	Apple 0130010	F	Codling moth ( <i>Cydia poma- nella</i> ) CARPPO	Foliar spray	BBCH 71-84 Spring, post emergence	2 a) 1 b) 2	7 days	0.118 L/10000m² LWA	23.6 g/10000m² LWA	500-900 L/ha	14 days	Max. 2 x 0.125 L/ha (2 x 25 g	A

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									a) 0.118 L/10000m <sup>2</sup> LWA b) 0.236 L/10000m <sup>2</sup> LWA	a) 23.6 g/10000m <sup>2</sup> LWA b) 47.2 g/10000m <sup>2</sup> LWA			as/ha) 10600 LWA	
7	PL	Apple 0130010	F	Apple sawfly ( <i>Hoplocampa testudinea</i> ) HOPLTE	Foliar spray	BBCH 65-69 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m <sup>2</sup> LWA a) 0.073 L/10000m <sup>2</sup> LWA b) 0.073 L/10000m <sup>2</sup> LWA	14.6 g/10000m <sup>2</sup> LWA a) 14.6 g/10000m <sup>2</sup> LWA b) 14.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 0.11 L/ha (22 g as/ha) 15000 LWA	A
8	PL	Apple 0130010	F	Aphids ( <i>Aphididae</i> ) – APXXSP	Foliar spray	BBCH 56-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m <sup>2</sup> LWA a) 0.073 L/10000m <sup>2</sup> LWA b) 0.073 L/10000m <sup>2</sup> LWA	14.6 g/10000m <sup>2</sup> LWA a) 14.6 g/10000m <sup>2</sup> LWA b) 14.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 0.11 L/ha (22 g as/ha) 15000 LWA	A
9	PL	Apple 0130010	F	Apple woolly aphid ( <i>Eriosoma lanigerum</i> ) ERISLA	Foliar spray	BBCH 56-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.118 L/10000m <sup>2</sup> LWA a) 0.118 L/10000m <sup>2</sup> LWA b) 0.118 L/10000m <sup>2</sup> LWA	23.6 g/10000m <sup>2</sup> LWA a) 23.6 g/10000m <sup>2</sup> LWA b) 23.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 0.18 L/ha (36 g as/ha) 15000 LWA	A
<b>Minor uses art. 51</b>														
10	PL	Spring oilseed rape 0401060  Turnip rape 0401060	F	Pollen beetle ( <i>Meligethes aeneus</i> ) MELIAE	Foliar spray	BBCH 50-65 Spring, post emergence	1 a) 1 b) 1	N/A	0.1-0.12 L/ha a) 0.12 L/ha b) 0.12 L/ha	20-24 g /ha a) 24 g /ha b) 24 g /ha	200-400 L/ha	14 days 50 days	not relevant	A
11	PL	Spring oilseed rape 0401060  Turnip rape 0401060	F	Rape stem weevil ( <i>Ceutorhynchus napi</i> ) –CEUTNA Cabbage stem weevils( <i>Ceutorhynchus palli-dactylus</i> ) – CEUTQU	Foliar spray	BBCH 30-50 Spring, post emergence	1 a) 1 b) 1	N/A	0.25 L/ha a) 0.25 L/ha b) 0.25 L/ha	50 g/ha a) 50 g/ha b) 50 g/ha	200-400 L/ha	14 days 50 days	not relevant	A
12	PL	Spring oilseed rape 0401060  Turnip rape 0401060	F	Brassica pod midge ( <i>Dasyneura brassicae</i> )- DASYBR Cabbage seed weevil( <i>Ceutorhynchus ob-strictus</i> ) – CE-UTAS	Foliar spray	BBCH 59-71 Spring, post emergence	1 a) 1 b) 1	N/A	0.3 /ha a) 0.3 l/ha b) 0.3 l/ha	60 g/ha a) 60 g/ha b) 60 g/ha	200-400 L/ha	14 day 50 dayss	not relevant	A

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13	PL	Flax- fiber production	F	Cabbage thrips ( <i>Thripsan-gusticeps</i> ) - THRIAN; Flax thrips ( <i>Thrips lini</i> ) - THRILI	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-61	1 a) 1 b) 1	N/A	0.3 l/ha a) 0.3 l/ha b) 0.3 l/ha	60 g/ha a) 60 g/ha b) 60 g/ha	200-400 L/ha	N/A	not relevant	A
14	PL	Common hemp - fiber production	F	Aphids ( <i>Aphididae</i> ) – APXXSP; Thrips ( <i>Thysanoptera</i> ) - ITHYSO	Foliar spray	After reaching thresholds or after warning service appeal BBCH 39-59	1 a) 1 b) 1	N/A	0.3 l/ha a) 0.3 l/ha b) 0.3 l/ha	60 g/ha a) 60 g/ha b) 60 g/ha	200-400 L/ha	N/A	not relevant	A
15	PL	Wild apple 0130010	F	Aphids ( <i>Aphididae</i> ) – APXXSP	Foliar spray	BBCH 56-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m <sup>2</sup> LWA a) 0.073 L/10000m <sup>2</sup> LWA b) 0.073 L/10000m <sup>2</sup> LWA	14.6 g/10000m <sup>2</sup> LWA a) 14.6 g/10000m <sup>2</sup> LWA b) 14.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 0.11 L/ha (22 g as/ha) 15000 LWA	A
16	PL	Wild apple 0130010	F	Codling moth ( <i>Cydia pomonella</i> ) - CARPPO	Foliar spray	BBCH 71-84 Spring, post emergence	2 a) 1 b) 2	7 days	0.118 L/10000m <sup>2</sup> LWA a) 0.118 L/10000m <sup>2</sup> LWA b) 0.236 L/10000m <sup>2</sup> LWA	23.6 g/10000m <sup>2</sup> LWA a) 23.6 g/10000m <sup>2</sup> LWA b) 47.2 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 2 x 0.125 L/ha (2 x 25 g as/ha) 10600 LWA	A
17	PL	Wild apple 0130010	F	Pear leaf blister moth ( <i>Leucoptera scitella</i> ) -LEUCSC	Foliar spray	BBCH 57-69 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m <sup>2</sup> LWA a) 0.073 L/10000m <sup>2</sup> LWA b) 0.073 L/10000m <sup>2</sup> LWA	14.6 g/10000m <sup>2</sup> LWA a) 14.6 g/10000m <sup>2</sup> LWA b) 14.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 0.11 L/ha (22 g as/ha) 15000 LWA	A
18	PL	Wild apple 0130010	F	Apple fruit sawfly ( <i>Hoplocampa testudi-neae</i> ) - HOPLTE	Foliar spray	BBCH 65-69 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m <sup>2</sup> LWA a) 0.073 L/10000m <sup>2</sup> LWA b) 0.073 L/10000m <sup>2</sup> LWA	14.6 g/10000m <sup>2</sup> LWA a) 14.6 g/10000m <sup>2</sup> LWA b) 14.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 0.11 L/ha (22 g as/ha) 15000 LWA	A
19	PL	Wild apple 0130010	F	Apple leaf midge ( <i>Dasineura mali</i> ) -DASYMA	Foliar spray	BBCH 59-73 Spring, post emergence	2 a) 1 b) 2	7 days	0.083 L/10000m <sup>2</sup> LWA a) 0.083 L/10000m <sup>2</sup> LWA	16.6 g/10000m <sup>2</sup> LWA a) 16.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 2 x 0.11 L/ha (2 x 22 g as/ha) 13000 LWA	A

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									b) 1.66 L/10000m <sup>2</sup> LWA	b) 33.2 g/10000m <sup>2</sup> LWA				
20	PL	Wild apple 0130010	F	Bracken clock ( <i>Phyllopertha horticola</i> ) - PHPHHO	Foliar spray	BBCH 59-73 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m <sup>2</sup> LWA a) 0.073 L/10000m <sup>2</sup> LWA b) 0.073 L/10000m <sup>2</sup> LWA	14.6 g/10000m <sup>2</sup> LWA a) 14.6 g/10000m <sup>2</sup> LWA b) 14.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 0.11 L/ha (22 g as/ha) 15000 LWA	A
21	PL	Pear 0130020  Chinese pear 0130020	F	Aphids ( <i>Aphididae</i> ) – APXXSP	Foliar spray	BBCH 56-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m <sup>2</sup> LWA a) 0.073 L/10000m <sup>2</sup> LWA b) 0.073 L/10000m <sup>2</sup> LWA	14.6 g/10000m <sup>2</sup> LWA a) 14.6 g/10000m <sup>2</sup> LWA b) 14.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 0.11 L/ha (22 g as/ha) 15000 LWA	A
22	PL	Pear 0130020  Chinese pear 0130020	F	Tortrix moths ( <i>Tortricidae sp</i> ) TORTSP	Foliar spray	BBCH 71-84 Spring, post emergence	2 a) 1 b) 2	7 days	0.118 L/10000m <sup>2</sup> LWA a) 0.118 L/10000m <sup>2</sup> LWA b) 0.236 L/10000m <sup>2</sup> LWA	23.6 g/10000m <sup>2</sup> LWA a) 23.6 g/10000m <sup>2</sup> LWA b) 47.2 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 2 x 0.125 L/ha (2 x 25 g as/ha) 10600 LWA	A
23	PL	Pear 0130020  Chinese pear 0130020	F	Codling moth ( <i>Cydia pomonella</i> ) CARPPO	Foliar spray	BBCH 71-84 Spring, post emergence	2 a) 1 b) 2	7 days	0.118 L/10000m <sup>2</sup> LWA a) 0.118 L/10000m <sup>2</sup> LWA b) 0.236 L/10000m <sup>2</sup> LWA	23.6 g/10000m <sup>2</sup> LWA a) 23.6 g/10000m <sup>2</sup> LWA b) 47.2 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 2 x 0.125 L/ha (2 x 25 g as/ha) 10600 LWA	A
24	PL	Pear 0130020  Chinese pear 0130020	F	Cherry slug saw- fly ( <i>Caliroa limacina</i> ) -ERICLI	Foliar spray	BBCH 71-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.118 L/10000m <sup>2</sup> LWA a) 0.118 L/10000m <sup>2</sup> LWA b) 0.118 L/10000m <sup>2</sup> LWA	23.6 g/10000m <sup>2</sup> LWA a) 23.6 g/10000m <sup>2</sup> LWA b) 23.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 1 x 0.135 L/ha (1x 27 g as/ha) 11500LWA	A
25	PL	Pear 0130020  Chinese pear 0130020	F	Pear leaf midge ( <i>Dasineura pyri</i> ) - DASYPY	Foliar spray	BBCH 71-84 Spring, post emergence	2 a) 1 b) 2	7 days	0.118 L/10000m <sup>2</sup> LWA a) 0.118 L/10000m <sup>2</sup> LWA b) 0.236 L/10000m <sup>2</sup> LWA	23.6 g/10000m <sup>2</sup> LWA a) 23.6 g/10000m <sup>2</sup> LWA b) 47.2 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 2 x 0.125 L/ha (2 x 25 g as/ha) 10600 LWA	A
26	PL	Pear 0130020	F	Apple bud weevil ( <i>Anthonomus piri</i> ) -ANTHPY	Foliar spray	BBCH 51-59 Spring, post	1 a) 1	N/A	0.083 L/10000m <sup>2</sup> LWA	16.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 0.125 L/ha (1 x 25	A

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		Chinese pear 0130020				emergence	b) 1		a) 0.083 L/10000m <sup>2</sup> LWA b) 1.66 L/10000m <sup>2</sup> LWA	a) 16.6 g/10000m <sup>2</sup> LWA b) 33.2 g/10000m <sup>2</sup> LWA			g as/ha) 15000LWA	
27	PL	Pear 0130020  Chinese pear 0130020		Pear psylla ( <i>Cacopsylla pyri</i> ) - PSYLPY; Pear sucker ( <i>Cacopsylla pyri- suga</i> ) - PSYLPY; Pear psyllid ( <i>Cacopsylla pyricola</i> ) - PSYLPY	Foliar spray	BBCH 51-71 Spring, post emergence	2 a) 1 b) 2	7 days	0.083 L/10000m <sup>2</sup> LWA a) 0.083 L/10000m <sup>2</sup> LWA b) 1.66 L/10000m <sup>2</sup> LWA	16.6 g/10000m <sup>2</sup> LWA a) 16.6 g/10000m <sup>2</sup> LWA b) 33.2 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 2 x 0.11 L/ha (2 x 22 g as/ha) 13000 LWA	A
28	PL	Quinces 0130030  Medlars 0130040	F	Aphids ( <i>Aphididae</i> ) – APXXSP	Foliar spray	BBCH 56-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m <sup>2</sup> LWA a) 0.073 L/10000m <sup>2</sup> LWA b) 0.073 L/10000m <sup>2</sup> LWA	14.6 g/10000m <sup>2</sup> LWA a) 14.6 g/10000m <sup>2</sup> LWA b) 14.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 0.11 L/ha (22 g as/ha) 15000LWA	A
29	PL	Quinces 0130030  Medlars 0130040	F	Codling moth ( <i>Cydia pom- onella</i> ) CARPPO	Foliar spray	BBCH 71-84 Spring, post emergence	2 a) 1 b) 2	7 days	0.118 L/10000m <sup>2</sup> LWA a) 0.118 L/10000m <sup>2</sup> LWA b) 0.236 L/10000m <sup>2</sup> LWA	23.6 g/10000m <sup>2</sup> LWA a) 23.6 g/10000m <sup>2</sup> LWA b) 47.2 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 2 x 0.125 L/ha (2 x 25 g as/ha) 10600 LWA	A
30	PL	Plum 0140040	F	Aphids ( <i>Aphididae</i> ) – APXXSP	Foliar spray	BBCH 56-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m <sup>2</sup> LWA a) 0.073 L/10000m <sup>2</sup> LWA b) 0.073 L/10000m <sup>2</sup> LWA	14.6 g/10000m <sup>2</sup> LWA a) 14.6 g/10000m <sup>2</sup> LWA b) 14.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 0.11 L/ha (22 g as/ha) 15000LWA	N
31	PL	Plum 0140040	F	Plum fruit sawfly ( <i>Hop- locampa minuta</i> ) -HOPLMI; Plum sawfly( <i>Hoplocampa flava</i> ) - HOPLFL	Foliar spray	BBCH 69-84	1 a) 1 b) 1	N/A	0.073 L/10000m <sup>2</sup> LWA a) 0.073 L/10000m <sup>2</sup> LWA b) 0.073 L/10000m <sup>2</sup> LWA	14.6 g/10000m <sup>2</sup> LWA a) 14.6 g/10000m <sup>2</sup> LWA b) 14.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 0.11 L/ha (22 g as/ha) 15000LWA	N
32	PL	Plum 0140040	F	Plum fruit moth ( <i>Laspeyresia funeraria</i> ) - LASPFU	Foliar spray	BBCH 71-81 Spring, post emergence	2 a) 1 b) 2	7 days	0.118 L/10000m <sup>2</sup> LWA a) 0.118 L/10000m <sup>2</sup> LWA b) 0.236 L/10000m <sup>2</sup> LWA	23.6 g/10000m <sup>2</sup> LWA a) 23.6 g/10000m <sup>2</sup> LWA b) 47.2 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 2 x 0.125 L/ha (2 x 25 g as/ha) 10600 LWA	N

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33	PL	Plum 0140040	F	European brown scale( <i>Parthenolecanium corni</i> ) - LECACO	Foliar spray	BBCH 56-59	1 a) 1 b) 1	N/A	0.073 L/10000m <sup>2</sup> LWA a) 0.073 L/10000m <sup>2</sup> LWA b) 0.073 L/10000m <sup>2</sup> LWA	14.6 g/10000m <sup>2</sup> LWA a) 14.6 g/10000m <sup>2</sup> LWA b) 14.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 0.11 L/ha (22 g as/ha) 15000LWA	N
34	PL	Plum 0140040	F	Apple brown tortrix ( <i>Pan-demis heparana</i> ) -PANDHE; Reticulated tortrix ( <i>Adox-ophyes orana</i> ) - CAPURE; European leaf roller ( <i>Archips rosana</i> ) - CACORO; Whelk ( <i>Tortricidae</i> ) - 1TORTF; and other leaf caterpillars	Foliar spray	BBCH 51-87	2 a) 1 b) 2	7 days	0.083 L/10000m <sup>2</sup> LWA a) 0.083 L/10000m <sup>2</sup> LWA b) 1.66 L/10000m <sup>2</sup> LWA	16.6 g/10000m <sup>2</sup> LWA a) 16.6 g/10000m <sup>2</sup> LWA b) 33.2 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 2 x 0.11 L/ha (2 x 22 g as/ha) 13000 LWA	N
35	PL	Peach 0140030  Nectarine 0140030  Apricot 0140010	F	Aphids ( <i>Aphididae</i> ) – APXXSP	Foliar spray	BBCH 56-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m <sup>2</sup> LWA a) 0.073 L/10000m <sup>2</sup> LWA b) 0.073 L/10000m <sup>2</sup> LWA	14.6 g/10000m <sup>2</sup> LWA a) 14.6 g/10000m <sup>2</sup> LWA b) 14.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 0.11 L/ha (22 g as/ha) 15000LWA	N
36	PL	Peach 0140030  Nectarine 0140030  Apricot 0140010	F	Apple brown tortrix ( <i>Pan-demis heparana</i> ) -PANDHE; Reticulated tortrix ( <i>Adox-ophyes orana</i> ) - CAPURE; European leaf roller ( <i>Archips rosana</i> ) - CACORO; Whelk ( <i>Tortricidae</i> ) - 1TORTF; and other leafcaterpillars	Foliar spray	BBCH 51-65	2 a) 1 b) 2	7 days	0.083 L/10000m <sup>2</sup> LWA a) 0.083 L/10000m <sup>2</sup> LWA b) 1.66 L/10000m <sup>2</sup> LWA	16.6 g/10000m <sup>2</sup> LWA a) 16.6 g/10000m <sup>2</sup> LWA b) 33.2 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 2 x 0.11 L/ha (2 x 22 g as/ha) 13000 LWA	N
37	PL	Sour cherry Sweet cherry 0140020	F	Aphids ( <i>Aphididae</i> ) – APXXSP	Foliar spray	BBCH 56-84 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m <sup>2</sup> LWA a) 0.073 L/10000m <sup>2</sup> LWA b) 0.073 L/10000m <sup>2</sup> LWA	14.6 g/10000m <sup>2</sup> LWA a) 14.6 g/10000m <sup>2</sup> LWA b) 14.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 0.11 L/ha (22 g as/ha) 15000LWA	N



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38	PL	Sour cherry Sweet cherry 0140020	F	Cherry fruit moth ( <i>Argyresthia ephippiella</i> ) - ARGYEP	Foliar spray	BBCH 51-59	1 a) 1 b) 1	N/A	0.083 L/10000m <sup>2</sup> LWA a) 0.083 L/10000m <sup>2</sup> LWA b) 0.083 L/10000m <sup>2</sup> LWA	16.6 g/10000m <sup>2</sup> LWA a) 16.6 g/10000m <sup>2</sup> LWA b) 16.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 0.125 L/ha (1 x 25 g as/ha) 15000LWA	N
39	PL	Sour cherry Sweet cherry 0140020	F	Cherry-stone weevil ( <i>Anthonomus rectirostris</i> ) - AN-THRE	Foliar spray	BBCH 57-65 Spring, post emergence	1 a) 1 b) 1	N/A	0.073 L/10000m <sup>2</sup> LWA a) 0.073 L/10000m <sup>2</sup> LWA b) 0.073 L/10000m <sup>2</sup> LWA	14.6 g/10000m <sup>2</sup> LWA a) 14.6 g/10000m <sup>2</sup> LWA b) 14.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 0.11 L/ha (22 g as/ha) 15000LWA	N
40	PL	Sour cherry Sweet cherry 0140020	F	Apple brown tortrix ( <i>Pandemis heparana</i> ) - PANDHE; Reticulated tortrix ( <i>Adoxophyes orana</i> ) - CAPURE; European leaf roller ( <i>Archips rosana</i> ) - CACORO; Whelk ( <i>Tortricidae</i> ) - 1TORTF; and other leafcaterpillars	Foliar spray	BBCH 51-65	2 a) 1 b) 2	7 days	0.083 L/10000m <sup>2</sup> LWA a) 0.083 L/10000m <sup>2</sup> LWA b) 1.66 L/10000m <sup>2</sup> LWA	16.6 g/10000m <sup>2</sup> LWA a) 16.6 g/10000m <sup>2</sup> LWA b) 33.2 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 2 x 0.11 L/ha (2 x 22 g as/ha) 13000 LWA	N
41	PL	Tomato 0231010	G	Glasshouse white- fly ( <i>Trialeurodes va-porariorum</i> ) – TRIAVA; Common cotton thrips ( <i>Thrips tabaci</i> ) – THRITB; Western grass thrips ( <i>Frankliniella occidentalis</i> ) - FRANOC;	Foliar spray	BBCH 20-89	1	N/A	0.30 L/ha	60g/ha	300-750 L/ha	3 days	not relevant	N Exceeding the new MRLs is possible
42	PL	Aubergine/egg-plant 0231010	G	Leaf miner ( <i>Phytomyza sp.</i> ) - PHYYS;P; Aphids ( <i>Aphididae</i> ) – APXXSP; Lygus bug ( <i>Lygus sp.</i> ) - LYGUSP;	Foliar spray	BBCH 20-89	1	N/A	0.30 L/ha	60g/ha	300-750 L/ha	3 days	not relevant	A
43	PL	Pepper 0231020	G	Flea beetle ( <i>Psylliodes</i> ) - 1PSYIG	Foliar spray	BBCH 20-89	1	N/A	0.30 L/ha	60g/ha	300-750 L/ha	3 days	not relevant	N Exceeding the new MRLs is possible
44	PL	Walnuts 0120110	F	Aphids ( <i>Aphididae</i> ) – APXXSP	Foliar spray	BBCH 51-65	2 a) 1 b) 2	10 days	0.083 L/10000m <sup>2</sup> LWA	16.6 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 2 x 0.11 L/ha (2 x 22 g as/ha)	R decision on acceptance of the

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									a) 0.083 L/10000m <sup>2</sup> LWA b) 1.66 L/10000m <sup>2</sup> LWA	a) 16.6 g/10000m <sup>2</sup> LWA b) 33.2 g/10000m <sup>2</sup> LWA			13000 LWA	use may be made at the member state level
45	PL	Hazelnuts 0120060	F	Aphids ( <i>Aphididae</i> ) – APXXSP; , Hazelnut weevil ( <i>Curculio nucum</i> ) - CURCNU; ( <i>Ooberea linearis</i> ) - OBERLI; European brown scale ( <i>Parthenolecanium corni</i> ) - LECACO; , Reticulated tortrix ( <i>Adoxophyes orana</i> ) - CAPURE; European leaf roller ( <i>Archips rosana</i> ) - CACORO; other tortrix and other leaf caterpillars	Foliar spray	BBCH 51-65	2 a) 1 b) 2	7 days	0.083 L/10000m <sup>2</sup> LWA a) 0.083 L/10000m <sup>2</sup> LWA b) 1.66 L/10000m <sup>2</sup> LWA	16.6 g/10000m <sup>2</sup> LWA a) 16.6 g/10000m <sup>2</sup> LWA b) 33.2 g/10000m <sup>2</sup> LWA	500-900 L/ha	14 days	Max. 2 x 0.11 L/ha (2 x 22 g as/ha) 13000 LWA	R decision on acceptance of the use may be made at the member state level
46	PL	Common osier Purple willow	F	Aphids ( <i>Aphididae</i> ) – APXXSP, Balsam poplar leaf beetle ( <i>Chrysomela populi</i> ) - CHRSP; ( <i>Chrysomelasaliceti</i> ) - CHRSSA, Blue willow beetle ( <i>Phratora vulgatissima</i> ) - PHRRVU; Brassy willow leaf beetle ( <i>Phratora vitellinae</i> ) - PHRRVI; Cream-bordered green pea moth ( <i>Earias clorana</i> ) -EARICH; , Gall midge ( <i>Dasineura marginemtorquens</i> ) - RHABMA	Foliar spray	BBCH 51-69	2 a) 1 b) 2	7 days	0.083 L/10000m <sup>2</sup> LWA a) 0.083 L/10000m <sup>2</sup> LWA b) 1.66 L/10000m <sup>2</sup> LWA	16.6 g/10000m <sup>2</sup> LWA a) 16.6 g/10000m <sup>2</sup> LWA b) 33.2 g/10000m <sup>2</sup> LWA	200-750 L/ha	N/A	Max. 2 x 0.11 L/ha (2 x 22 g as/ha) 13000 LWA	A
47	PL	Forest and ornamental nurseries plants Restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations	F	Aphids ( <i>Aphididae</i> ) – APXXSP, Springtails ( <i>Collembola</i> ) - 1COLLO; Larch case-bearer ( <i>Coleophora laricella</i> ) - COLELA	Foliar spray	BBCH 11-69	1 a) 1 b) 1	N/A	0.133 L/10000m <sup>2</sup> LWA a) 0.133 L/10000m <sup>2</sup> LWA b) 0.133 L/10000m <sup>2</sup> LWA	26.6 g/10000m <sup>2</sup> LWA a) 26.6 g/10000m <sup>2</sup> LWA b) 26.6 g/10000m <sup>2</sup> LWA	200-400 L/ha	N/A	Max. 0.19 L/ha (1 x 38 g as/ha)	A

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<b>Remarks table heading:</b>	(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d) Select relevant
	(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c) g/kg or g/l	(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
<b>Remarks columns:</b>	1 Numeration necessary to allow references	7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2 Use official codes/nomenclatures of EU Member States	8 The maximum number of application possible under practical conditions of use must be provided.
	3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9 Minimum interval (in days) between applications of the same product
	4 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	10 For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		13 PHI - minimum pre-harvest interval
		14 Remarks may include: Extent of use/economic importance/restrictions
*	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1	
**	Use also code numbers according to Annex I of Regulation (EU) No 396/2005	
***	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	

Explanation for Column 11 "Conclusion"

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

## 7.1.2 Summary of the evaluation

The preparation Acetamipryd 200 SL 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 Journal 2016;14(11):4610	2016	0.025 mg/kg bw (per day)	rat, developmental neurotoxicity study	100
ARfD	EFSA Journal 2016;14(11):4610	2016	0.025 mg/kg bw (per day)	rat, developmental neurotoxicity study	100
ADI	SANTE/10502/2017 Rev. 8	2024	0.005 mg/kg bw/day	Reduced 5-fold with Revision 8 of the Renewal Report in September 2024	-
ARfD	SANTE/10502/2017 Rev. 8	2024	0.005 mg/kg bw	Reduced 5-fold with Revision 8 of the Renewal Report in September 2024	-

### 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?
1-3	Winter oilseed rape	Yes	Yes	Yes	Yes	Yes	No	No
4	Potato	Yes	Yes	Yes	Yes	Yes	No	No
5-9	Apple	Yes	Yes	Yes	Yes	Yes	No	No
10-12	Spring oilseed rape, Turnip rape	Yes	Yes	Yes	Yes	Yes	No	No
13	Flax- fiber production	NR	NR	NR	NR	NR	NR	NR
14	Common hemp - fiber production	NR	NR	NR	NR	NR	NR	NR
15-20	Wild apple	Yes	Yes	Yes	Yes	Yes	No	No
21-27	Pear Chinese pear	Yes	Yes	Yes	Yes	Yes	No	No
28-	Quinces	Yes	Yes	Yes	Yes	Yes	No	No

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Use- No.*	Crop	Plant me- tabolism covered?	Sufficient residue trials?	PHI suffi- ciently sup- ported?	Sample storage covered by sta- bility data?	MRL compli- ance	Chronic risk for consum- ers identi- fied?	Acute risk for consum- ers identi- fied?
29	Medlars							
30- 34	Plums	Yes	<del>Yes</del> No	<del>Yes</del> No	Yes	Yes	<del>No</del>	<del>No</del>
35- 36	Peach Nectarine Apricot	Yes	<del>Yes</del> No	<del>Yes</del> No	Yes	Yes	<del>No</del>	<del>No</del>
37- 40	Sweet Cherry Sour Cherry	Yes	<del>Yes</del> No	<del>Yes</del> No	Yes	Yes	<del>No</del>	<del>No</del>
41	Tomato	Yes	Yes	Yes	Yes	<del>Yes</del> No	<del>No</del>	<del>No</del>
42	Aubergines/eggplants	Yes	Yes	Yes	Yes	Yes	No	No
43	Pepper	Yes	<del>Yes</del> No	<del>Yes</del> No	Yes	<del>Yes</del> No	<del>No</del>	<del>No</del>
44	Walnuts	Yes	<del>Yes</del> No decision on ac- ceptance of the use may be made at the mem- ber state level	<del>Yes</del> No decision on acceptance of the use may be made at the member state level	Yes	Yes	No	No
45	Hazelnuts	Yes	<del>Yes</del> No decision on ac- ceptance of the use may be made at the mem- ber state level	<del>Yes</del> No decision on acceptance of the use may be made at the member state level	Yes	Yes	No	No
46	Common osier Purple willow	NR	NR	NR	NR	NR	NR	NR
47	Forest and ornamental nurseries plants Restockings, afforestations and forest trees' seed	NR	NR	NR	NR	NR	NR	NR

Use- No.*	Crop	Plant me- tabolism covered?	Sufficient residue trials?	PHI suffi- ciently sup- ported?	Sample storage covered by sta- bility data?	MRL compli- ance	Chronic risk for consum- ers identi- fied?	Acute risk for consum- ers identi- fied?
	plantations; Christmas trees grown on plantations							

\* 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 in RAR 2015 and summarized in EFSA 2016. These data were not considered for risk assessment.

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

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

### 7.1.2.2 Summary for Acetamipryd 200 SL

**Table 7.1-4: Information on Acetamipryd 200 SL (KCA 6.8)**

Crop	PHI for Acetamipryd 200 SL proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for Acetamipryd 200 SL proposed by zRMS	zRMS Comments (if different PHI proposed)
		Acetamipryd 200 SL		
Winter oilseed rape	NR	NR	50 days	
Potato	3 days	Yes	30 days	
Apple	14 days	Yes		
Spring oilseed rape Turnip rape	14 days	Yes	50 days	
Flax- fiber production	NR	NR		
Common hemp - fiber production	NR	NR		
Wild apple	14 days	Yes		
Pear Chinese pear	14 days	Yes		
Quinces Medlars	14 days	Yes		

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Crop	PHI for Acetamipryd 200 SL proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for Acetamipryd 200 SL proposed by zRMS	zRMS Comments (if different PHI proposed)
		Acetamipryd 200 SL		
Plums	14 days	Yes		
Peach Nectarine Apricot	14 days	Yes		
Sweet Cherry Sour Cherry	14 days	Yes		
Tomato	3 days	Yes		
Aubergines/eggplants	3 days	Yes		
Pepper	3 days	Yes		
Walnuts	14 days decision on acceptance of the use may be made at the member state level	Yes decision on acceptance of the use may be made at the member state level		
Hazelnuts	14 days decision on acceptance of the use may be made at the member state level	Yes decision on acceptance of the use may be made at the member state level		
Common osier Purple willow	NR	NR		
Forest and ornamental nurseries plants Restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations	NR	NR		

NR: not relevant

\* Purpose of withholding period to be specified

**Table 7.1-5: Waiting periods before planting succeeding crops**

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for Acetamipryd 200 SL
Crop group	Led by acetamiprid	
All	NR	

NR: not relevant

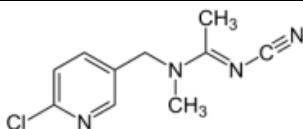
For more information regarding waiting periods please refer to dRR Part B Section 3.

## Assessment

### 7.2 Acetamiprid

General data on acetamiprid are summarized in the table below (last updated 2023/10/03).

**Table 7.2-1: General information on acetamiprid**

Active substance (ISO Common Name)	Acetamiprid
IUPAC	(E)-N <sup>1</sup> -[(6-Chloro-3-pyridyl)methyl]-N <sup>2</sup> -cyano-N <sup>1</sup> -methylacetamidine
Chemical structure	
Molecular formula	C <sub>10</sub> H <sub>11</sub> ClN <sub>4</sub>
Molar mass	222.68 g/mol
Chemical group	Neonicotinoid compounds
Mode of action (if available)	IRAC mode of action classification 4 (Nicotinic acetylcholine receptor (nAChR) competitive modulators) Bind to the acetylcholine site of nAChRS, causing a range of symptoms from hyper-excitation to lethargy and paralysis. Acetylcholine is the major excitatory neurotransmitter in the insect central nervous system.
Systemic	Yes
Company (ies)	Nippon Soda Co. Ltd.*
Rapporteur Member State (RMS)	The Netherlands Co-RMS: Spain
Approval status	Approved Date of approval: 01/01/2005 Date of renewal: 01/03/2018  Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011R0540-20230901">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011R0540-20230901</a>  Commission Implementing Regulation (EU) 2018/113 of 24 January 2018 renewing the approval of the active substance acetamiprid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1520336385887&amp;uri=CELEX:32018R0113">https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1520336385887&amp;uri=CELEX:32018R0113</a>



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Restriction	None
Review Report	SANTE/10502/2017 Rev 8 of 24 September 2024
Current MRL regulation	Reg. (EU) 2019/88, <del>Reg. (EU) 2025/158, New MRL values for Acetamiprid (R) will apply from 19/08/2025</del> Regulation (EU) 2025/1212
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal: Conclusion on the peer review	Yes (EFSA Journal 2016;14(11):4610)
EFSA Journal: conclusion on article 12	Yes (EFSA Journal 2011;9(7):2328)
Current MRL applications on intended uses	NR

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

## 7.2.1 Stability of Residues (KCA 6.1)

### 7.2.1.1 Stability of residues during storage of samples

#### Available data

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>			
Apple, tomato	High water content	$\leq 13$ months	RAR, 2015 EFSA, 2016
Fodder peas	High protein content	12 months	
Cabbage, cucumber	High water content	12 months	
Lettuce (head)	High water content	15 months	
Cotton (seed)	High oil content	12 months	
Orange	High acid content	12 months	
Apple juice/wet pomace, cotton gin trash/hulls/meal/ oil, orange juice/ dried pulp/oil	Processed commodities	12 months	
Cereals	High starch content	8 months	EFSA Journal 2021;19(9):6830
<b>Animal Products</b>			
Samples of the livestock feeding studies were stored for less than 1 month under freezer conditions. Storage stability studies are therefore not required.			EFSA, 2016
<b>New Data</b>			
<b>Plant products</b>			

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Potato	High starch content	99 days (acetamiprid-N-desmethyl)	Niewelt-Stasiak S., 2024 / Study No: DPL/68/2023
Rape (seed)	High oil content	406 days (acetamiprid-N-desmethyl)	Niewelt-Stasiak S., 2024 / Study No: DPL/83/2023
Apple	High water content	354 days (acetamiprid-N-desmethyl)	Niewelt-Stasiak S., 2024 / Study No: DPL/84/2023

### Conclusion on stability of residues during storage

All data on the stability of residues are active substance data and were evaluated in the EU review of acetamiprid. Based on storage stability studies it can be concluded that acetamiprid residues are stable for at least one year in different matrices tested.

Storage stability has been covered in one commodity from each of the five commodity categories. It should be highlighted that according to the OECD 506, point 25: “25. *If residues are shown to be stable in all commodities studied, a study on one commodity from each of the five commodity categories is acceptable. In such cases, residues in all other commodities (see Annex 1) would be assumed to be stable for the same duration of time under the same storage conditions.*”

No further data are required.

### Summary of new stability studies

For acetamiprid-N-desmethyl (IM-2-1) stability was demonstrated upon storage at  $\leq -18^{\circ}\text{C}$ :

- in potato for a period of 99 days,
- in rape seed for a period of 406 days,
- in apple for a period of 354 days.

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

### Available data

Studies to determine the stability of residues in stored sample extracts have not been performed. The stability of the analytes through the analytical procedures is adequately demonstrated by the acceptable procedural recovery efficiencies obtained during analysis of residue samples.

### Conclusion on stability of residues in sample extracts

Stability of residues in sample extracts is sufficiently proven during the respective time of storage.

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

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

### Available data

No new data submitted in the framework of this application.

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

Crop Group	Crop	Label po- sition	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	Eggplant	Pyridine- 2,6- <sup>14</sup> C	dotting to the leaf surface (foliar + fruit), G	0.0095 kg a.s./ha	1	7, 14	0.5 ml (47.5 µg)/leaf x 3 leaves of 3000 fold aqueous so- lution (95 mg/kg) of 30% SP	RAR, 2015 EFSA, 2016
	Apple	Pyridine- 2,6- <sup>14</sup> C	dotting to surface (foliar), G	0.208 kg a.s./ha	1	0, 7, 14, 28, 62, 90	0.8 ml/(4 leaves of one branch) of 2000 fold aque- ous solution (103.8 mg/kg) of 20% SP, i.e. 20.8 mi- crog a.i. /leaf	RAR, 2015 EFSA, 2016
				0.104 kg a.s./ha	1	0, 14, 28, 62	0.7 ml/fruit of 2000 fold aque- ous solution (104.7 mg/kg) of 20% SP, i.e. 73.3 mi- crog a.i./fruit	RAR, 2015 EFSA, 2016
Leafy vegetables	Cabbage	Pyridine- 2,6- <sup>14</sup> C	foliar treat- ment, G	0.302 kg a.s./ha	1	0, 7, 14, 21, 28, 63	10 ml/pot (one plant) of 1000 fold aque- ous solution (201 mg/kg) of 20% SP	RAR, 2015 EFSA, 2016
		Pyridine- 2,6- <sup>14</sup> C	soil appli- cation, G	5.94 kg a.s./ha	1	7, 14, 28	2 g/pot (one plant) of 2.1% gran- ular	RAR, 2015 EFSA, 2016
		Cyano- <sup>14</sup> C	foliar treat- ment, G	0.299 kg a.s./ha	1	0, 7, 14, 28, 63	10 ml/pot (one plant)	RAR, 2015 EFSA, 2016

							of 1000 fold aqueous solution (199 mg/kg) of 20% SP	
<b>Root and tuber vegetables</b>	Carrot	Pyridine-2,6- <sup>14</sup> C	foliar treatment, G	0.1 kg a.s./ha	2	14	11.12 mL (5.03 mg/vessel/application) in acetonitrile	RAR, 2015 EFSA, 2016
<b>Pulses and oilseeds</b>	Cotton	Pyridine-2,6- <sup>14</sup> C	foliar treatment, G	0.123 kg a.s./ha	4	14, 28	-	RAR, 2015 EFSA, 2016
				1.230 kg a.s./ha	4	28	-	RAR, 2015 EFSA, 2016

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

According to EFSA Journal 2016;14(11):4610:

*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).*

*Since acetamiprid was identified by far, as the major component of the residues in almost all plant matrices and since the toxicity of the IC-0 metabolite was concluded to be covered by the toxicity of the parent acetamiprid, the plant residue definitions for monitoring and risk assessment were limited to acetamiprid.*

### Summary of new plant metabolism studies

Not relevant.

### Conclusion on metabolism in primary crops

The metabolism of acetamiprid was sufficiently investigated in the studies presented in the RAR (The Netherlands, 2015). The metabolic pathway in the three different crop groups is generally similar and the residue definition for primary crops for enforcement and risk assessment is also applicable for the intended uses of acetamiprid in the product Acetamipryd 200 SL.

#### 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.

Please refer to point 7.2.6.1 Field rotational crop studies (KCA 6.6.2)

### Conclusion on metabolism in rotational crops

According to EFSA Journal 2016;14(11):4610:

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

### 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 7.2-4: Nature of the residues in processed commodities**

Conditions (Duration, Temperature, pH)	Acetamiprid (0.1 mg/kg) (% Applied Radioactivity)	Acetamiprid (1.0 mg/kg) (% Applied Radioactivity)	Reference
<b>EU data</b>			
<b>Pasteurisation</b> (20 minutes, 90°C, pH 4)	Acetamiprid only (95.6%)	Acetamiprid only (93.3%)	RAR, 2015 EFSA, 2016
<b>Baking, boiling, brewing</b> (60 minutes, 100°C, pH 5)	Acetamiprid only (95.1%)	Acetamiprid only (95.59%)	RAR, 2015 EFSA, 2016
<b>Sterilisation</b> (20 minutes, 120°C, pH 6)	Acetamiprid only (98.08%)	Acetamiprid only (97.57%)	RAR, 2015 EFSA, 2016

### Conclusion on nature of residues in processed commodities

According to EFSA Journal 2016;14(11):4610:

*The effect of processing on the nature of acetamiprid residues was investigated and the results indicated that acetamiprid is hydrolytically stable under standard hydrolysis conditions (Greece, 2001; EFSA, 2011). Thus, residue definitions proposed for primary crops are also applicable for processed commodities. Acetamiprid stable under standard hydrolysis conditions. Pasteurisation, boiling and sterilisation are unlikely to result in any significant metabolites.*

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

**Table 7.2-5: Summary of the nature of residues in commodities of plant origin**

<b>Endpoints</b>	
Plant groups covered	Fruits and fruiting vegetable (Eggplant, Apple) Root and tuber vegetables (Carrot) Leafy vegetables (Cabbage) Pulses and oilseeds (Cotton)
Rotational crops covered	Root and tuber vegetables (Turnip) Leafy vegetables (Spinach)

	Cereals (Wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	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.
Processed commodities	Acetamiprid stable under standard hydrolysis conditions. Pasteurisation, boiling and sterilisation are unlikely to result in any significant metabolites.
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Acetamiprid (Reg. (EU) 2019/88, Reg. (EU) 2025/158, New MRL values for Acetamiprid (R) will apply from 19/08/2025 Regulation (EU) 2025/1212)  Acetamiprid (all metabolism groups) (EFSA Statement, 2024 (EFSA Journal. 2024;22:e8759))
Plant residue definition for risk assessment	Acetamiprid (EFSA, 2016; EFSA, 2021)  – Fruit crops: sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid – Leafy crops: sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid – Pulses/oilseeds: acetamiprid – Root crops: acetamiprid – Cereals: acetamiprid (EFSA Statement, 2024 (EFSA Journal. 2024;22:e8759))
Conversion factor from enforcement to RA	NA (EFSA, 2016; EFSA, 2021)  Leafy crops: 1.44 Fruit crops: 1.21 (EFSA Statement, 2024 (EFSA Journal. 2024;22:e8759))

#### 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 7.2-6: 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]-acetamiprid	1 1	1 10	7	Milk	twice daily	RAR, 2015 EFSA, 2016
						Urine and faeces	daily	

						Tissues	at sacrifice	
<b>Laying poultry</b>	Hens	[pyridine-2,6- <sup>14</sup> C]-acetamiprid	5 5	1 10	14	Eggs	daily	RAR, 2015 EFSA, 2016
						Excreta	daily	
						Tissues	at sacrifice	
						Excreta	24h following the first of the daily administrations and at 24h intervals thereafter	
						Tissues	at sacrifice	

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

According to EFSA Journal 2016;14(11):4610:

*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 administrated radioactivity was recovered in organs, tissues, blood and milk or eggs. Acetamiprid was extensively metabolised and not detected in any animal matrices except in milk. The major component was identified as the N-desmethyl metabolite (IM-2-1) representing 50–89% TRR in all animal matrices, except goat muscle (10% TRR) where residues were mainly composed of the metabolite IM-2-2 accounting for 50% TRR (0.03 mg eq/kg).*

*The metabolic profile was confirmed by the feeding studies on cow and poultry where IM-2-1 was detected as the most abundant component in all animal matrices. Acetamiprid was not present in poultry and only detected in significant levels in milk at all feeding levels and at the highest feeding level in the other matrices.*

### Summary of new animal metabolism studies

Not relevant.

### Conclusion on metabolism in livestock

The current residue definition set in Reg. (EU) 2019/88 of 18 January 2019 the animal residue definition for monitoring (except honey): the sum of acetamiprid and IM-2-1, expressed as acetamiprid. Based on animal metabolism studies, the residue definition for risk assessment was proposed by EFSA as ‘the sum of acetamiprid and IM-2-1, expressed as acetamiprid’ (EFSA Journal 2016;14(11):4610). Additional studies are not required.

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

**Table 7.2-7: Summary on the nature of residues in commodities of animal origin**

Endpoints	
Animals covered	Lactating goats

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	Laying hens
Time needed to reach a plateau concentration	1-3 days to reach a steady state in milk
	4-8 days to reach a steady state in eggs
Animal residue definition for monitoring	Acetamiprid except honey: the sum of acetamiprid and IM-2-1, expressed as acetamiprid ( <del>Reg (EU) 2019/88, Reg. (EU) 2025/158, New MRL values for Acetamiprid (R) will apply from 19/08/2025</del> Regulation (EU) 2025/1212)  IM-2-1 expressed as acetamiprid EFSA Journal 2016;14(11):4610
Animal residue definition for risk assessment	Sum of acetamiprid and metabolite IM-2-1 (N-desmethyl-acetamiprid), expressed as acetamiprid (EFSA, 2016)
Conversion factor	Milk: 1.3 Other mammalian products: 1.1 Poultry matrices: not required
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No



### 7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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

**Table 7.2-8: Summary of EU reported and new data supporting the intended uses of Acetamipryd 200 SL 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)	Un-rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Oilseed rape (winter and spring)	New trials	N-EU	Trials GAP: 1x 50 g as/ha, BBCH 69, PHI 14d, outdoor  E/RA: < 0.005, 0.0069, 0.0078, 0.0084, 0.012, 0.014, 0.017, 0.021	E/RA: 0.01	E/RA: 0.02	-	0.4 0.4*	Yes
Turnip rape (extrapolation from oilseed rape)	New trials	N-EU	<i>Oilseed rape:</i> Trials GAP: 1x 50 g as/ha, BBCH 69, PHI 14d, outdoor  E/RA: < 0.005, 0.0069, 0.0078, 0.0084, 0.012, 0.014, 0.017, 0.021	E/RA: 0.01	E/RA: 0.02	-	0.4 0.4*	Yes
Potato	New trials	N-EU	Trials GAP: 1x 24 g as/ha, BBCH 89, PHI 3d, outdoor	E/RA: 0.001	E/RA: 0.001	-	0.01 0.01*	Yes

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			E/RA: 4x< 0.001 (LOD)					
Apple	New trials	N-EU	Trials GAP: 2 x 40 g as/ha, BBCH 81-85, PHI 14d, indoor  E: 0.012, 0.013, 0.017, 0.032, 0.033, 0.037, 0.046, 0.055 RA: 0.012, 0.013, 0.017, 0.032, 0.033, 0.037, 0.046, 0.055	E: 0.033 RA: 0.033	E: 0.055 RA: 0.055	-	0.4 0.07**	Yes
Wild apple (extrapolation from apple)	New trials	N-EU	<i>Apple:</i> Trials GAP: 2 x 40 g as/ha, BBCH 81-85, PHI 14d, indoor  E: 0.012, 0.013, 0.017, 0.032, 0.033, 0.037, 0.046, 0.055 RA: 0.012, 0.013, 0.017, 0.032, 0.033, 0.037, 0.046, 0.055	E: 0.033 RA: 0.033	E: 0.055 RA: 0.055	-	0.4 0.07**	Yes
Pear, Chinese pear (extrapolation from apple)	New trials	N-EU	<i>Apple:</i> Trials GAP: 2 x 40 g as/ha, BBCH 81-85, PHI 14d, indoor  E: 0.012, 0.013, 0.017, 0.032, 0.033, 0.037, 0.046, 0.055 RA: 0.012, 0.013, 0.017, 0.032, 0.033, 0.037, 0.046, 0.055	E: 0.033 RA: 0.033	E: 0.055 RA: 0.055	-	0.4 0.07**	Yes
Quince, Medlar (extrapolation from apple)	New trials	N-EU	<i>Apple:</i> Trials GAP: 2 x 40 g as/ha, BBCH 81-85, PHI 14d, indoor  E: 0.012, 0.013, 0.017, 0.032, 0.033, 0.037, 0.046, 0.055 RA: 0.012, 0.013, 0.017, 0.032, 0.033, 0.037, 0.046, 0.055	E: 0.033 RA: 0.033	E: 0.055 RA: 0.055	-	0.8 0.15** (quince) 0.3** (medlar)	Yes
Plum	DAR, Greece, Addendum 2001	N-EU	GAP on which EU a.s. assessment is based: 2x 50 g as/ha, PHI 14d, outdoor  E: 5x< 0.01, 0.011, 0.017 RA <sup>1)</sup> : 5x< 0.012, 0.013, 0.021	E: 0.01 RA <sup>1)</sup> : 0.01	E: 0.02 RA <sup>1)</sup> : 0.02	-	<del>0.03</del> 0.03** 0.04	Yes
Peach, nectarine, apricot (extrapolation from apples and	DAR, Greece, Addendum 2001	N-EU	<i>Plums:</i> GAP on which EU a.s. assessment is based: 2x 50 g as/ha, PHI 14d, outdoor  E: 5x< 0.01, 0.011, 0.017 RA <sup>1)</sup> : 5x< 0.012, 0.013, 0.021	E: 0.01 RA <sup>1)</sup> : 0.01	E: 0.02 RA <sup>1)</sup> : 0.02	-	0.2 (peach, nectarine) 0.8 (apricot) 0.08** (peach, apricot)	Yes

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plums)	New trials	N-EU	<i>Apple:</i> Trials GAP: 2 x 40 g as/ha, BBCH 81-85, PHI 14d, indoor  E: 0.012, 0.013, 0.017, 0.032, 0.033, 0.037, 0.046, 0.055 RA: 0.012, 0.013, 0.017, 0.032, 0.033, 0.037, 0.046, 0.055	E: 0.033 RA: 0.033	E: 0.055 RA: 0.055	-	0.2 (peach, nectarine) 0.8 (apricot) 0.08** (peach, apricot)	Yes
Cherries (sweet and sour)  (extrapolation from cherries and apples)	DAR, Greece, Addendum 2001	N-EU	<i>Cherries:</i> GAP on which EU a.s. assessment is based: 1x 75 g as/ha, PHI 14d, outdoor  E: 0.038, 0.050, 0.055, 0.067 RA <sup>1)</sup> : 0.046, 0.061, 0.067, 0.081	E: 0.05 RA <sup>1)</sup> : 0.06	E: 0.07 RA <sup>1)</sup> : 0.08	-	1.5 0.8**	Yes
	New trials	N-EU	<i>Apple:</i> Trials GAP: 2 x 40 g as/ha, BBCH 81-85, PHI 14d, indoor  E: 0.012, 0.013, 0.017, 0.032, 0.033, 0.037, 0.046, 0.055 RA: 0.012, 0.013, 0.017, 0.032, 0.033, 0.037, 0.046, 0.055	E: 0.033 RA: 0.033	E: 0.055 RA: 0.055	-	1.5 0.8**	Yes
Tomato (I)	DAR, Greece, Addendum 2001	Indoor S-EU	GAP on which EU a.s. assessment is based: 2x 90 g as/ha, PHI 3d, indoor  E: 0.01, 0.011, 0.016, 2x 0.022, 0.041, 0.049, 0.081 RA <sup>1)</sup> : 0.012, 0.013, 0.019, 2x 0.027, 0.05, 0.06, 0.098	E: 0.02 RA <sup>1)</sup> : 0.03	E: 0.08 RA <sup>1)</sup> : 0.1	-	0.5 0.06**	Yes
Aubergines/ Eggplants (I)  (extrapolation from tomato)	DAR, Greece, Addendum 2001	Indoor S-EU	<i>Tomato:</i> GAP on which EU a.s. assessment is based: 2x 90 g as/ha, PHI 3d, indoor  E: 0.01, 0.011, 0.016, 2x 0.022, 0.041, 0.049, 0.081 RA <sup>1)</sup> : 0.012, 0.013, 0.019, 2x 0.027, 0.05, 0.06, 0.098	E: 0.02 RA <sup>1)</sup> : 0.03	E: 0.08 RA <sup>1)</sup> : 0.1	-	0.2 0.2**	Yes
Pepper (I)	DAR, Greece, Addendum 2001	Indoor S-EU	GAP on which EU a.s. assessment is based: 2x 90 g as/ha, PHI 3d, indoor  E: 0.024, 0.079, 0.12, 0.15, 0.19 RA <sup>1)</sup> : 0.029, 0.096, 0.15, 0.18, 0.23	E: 0.1 RA <sup>1)</sup> : 0.15	E: 0.2 RA <sup>1)</sup> : 0.23	-	0.3 0.09**	Yes

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Walnut, hazelnut  (extrapolation from apples and plums)	DAR, Greece, Addendum 2001	N-EU	<i>Plums:</i> GAP on which EU a.s. assessment is based: 2x 50 g as/ha, PHI 14d, outdoor  E: 5x< 0.01, 0.011, 0.017 RA <sup>1)</sup> : 5x< 0.012, 0.013, 0.021	E: 0.01 RA <sup>1)</sup> : 0.01	E: 0.02 RA <sup>1)</sup> : 0.02	-	0.07 0.07**	Yes
	New trials	N-EU	<i>Apple:</i> Trials GAP: 2 x 40 g as/ha, BBCH 81-85, PHI 14d, indoor  E: 0.012, 0.013, 0.017, 0.032, 0.033, 0.037, 0.046, 0.055 RA: 0.012, 0.013, 0.017, 0.032, 0.033, 0.037, 0.046, 0.055	E: 0.033 RA: 0.033	E: 0.055 RA: 0.055	-	0.07 0.07**	Yes

\* ~~Source of EU MRL: Reg. (EU) 2019/88~~ Regulation (EU) 2025/1212

\*\* ~~Newly planned MRLs (PLAN/2024/1403) – not yet applicable. Reg. (EU) 2025/158, New MRL values for Acetamiprid (R) will apply from 19/08/2025~~ Regulation (EU) 2025/1212

1) Residue for risk assessment recalculated using conversion factor (CF): CF for fruit crops (1.21) (EFSA Statement, 2024 (EFSA Journal. 2024;22:e8759))

E: (enforcement residue definition) - Acetamiprid (all metabolism groups) (EFSA Statement, 2024 (EFSA Journal. 2024;22:e8759))

RA: (risk assessment residue definition) - Fruit crops: sum of acetamiprid and N-desmethyl-Acetamiprid (IM-2-1), expressed as acetamiprid; - Leafy crops: sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid; - Pulses/oilseeds: acetamiprid; – Root crops: acetamiprid; – Cereals: acetamiprid (EFSA Statement, 2024 (EFSA Journal. 2024;22:e8759))

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

#### Oilseed rape (winter and spring)

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. Sufficient trials are available to support the proposed use on oilseed rape. The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL for oilseed rape will occur.

#### PHI of 50 days is proposed by zRMS

#### Turnip rape (winter and spring)

According to SANTE/2019/12752 Rev.01 extrapolation from oilseed rape to turnip rape is possible.

Sufficient trials are available to support the proposed use on turnip rape. The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL for turnip rape will occur.

#### Potato

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. Sufficient trials are available to support the proposed use on potato. The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL for potato will occur.

#### Apple

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. Sufficient trials are available to support the proposed use on apple. The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL for apple will occur.

#### Wild apple (extrapolation from apple)

According to SANTE/2019/12752 Rev.01 extrapolation from apple to wild apple is possible.

Sufficient trials are available to support the proposed use on wild apple. The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL for wild apple will occur.

#### Pear, Chinese pear (extrapolation from apple)

According to SANTE/2019/12752 Rev.01 extrapolation from apple to pear and Chinese pear is possible.

Sufficient trials are available to support the proposed use on pear and Chinese pear. The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL for pear and Chinese pear will occur.

#### Quince, medlar (extrapolation from apple)

According to SANTE/2019/12752 Rev.01 extrapolation from apple to whole group pome fruits (130000) is possible. Sufficient trials are available to support the proposed use on quince and medlar. The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL for quince and medlar will occur.

#### Plum

Residue trials on plums are available from DAR Acetamiprid Addendum March 2001. Since the residue concentrations detected are at about LOQ, 7 trials was accepted as a sufficient number in 'no residue situation'. Sufficient trials on plum are available to support the proposed use.

The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL for plum will occur.

See zRMS conclusion (point 7.1)

Peach, nectarine, apricot (extrapolation from apple and plums)

According to SANTE/2019/12752 Rev.01 extrapolation from apple and plums to whole group stone fruits (140000) is possible. Sufficient trials are available to support the proposed use on peaches, nectarines and apricots. The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL for peaches, nectarines and apricots will occur.

See zRMS conclusion (point 7.1)

Cherries (sweet and sour) (extrapolation from cherries and apples)

According to SANTE/2019/12752 Rev.01 extrapolation from cherries and apples to whole group stone fruits (140000) is possible. Sufficient trials are available to support the proposed use on cherries. The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL for cherries will occur.

See zRMS conclusion (point 7.1)

Tomato (indoor)

Residue trials on tomatoes are available from DAR Acetamiprid Addendum March 2001. Sufficient trials are available to support the proposed use on tomatoes. The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL for tomatoes will occur.

See zRMS conclusion (point 7.1)

Aubergines/Eggplants (indoor)

According to SANTE/2019/12752 Rev.01 extrapolation from tomatoes to aubergines/eggplants (0211030) is possible. Sufficient trials on tomatoes are available to support the proposed use on aubergines.

The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL aubergines/eggplants will occur.

Pepper (indoor)

Residue trials on pepper are available from DAR Acetamiprid Addendum March 2001. Sufficient trials are available to support the proposed use on pepper. Pepper is a minor crop in Poland and number of available trials fulfils the requirements for pepper in N EU. Studies presented in DAR are sufficient to support registration of product for indoor use. The application rates for pepper in DAR are higher than the application rate of Acetamipryd 200 SL. Thus, it should be considered as a worst case. The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL for pepper will occur.

See zRMS conclusion (point 7.1)

Walnut, hazelnut (extrapolation from apples and plums)

According to SANTE/2019/12752 Rev.01 extrapolation from apple and plums to whole group tree nuts (120000) is possible. Sufficient trials are available to support the proposed use on walnut and hazelnut. The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL for walnut and hazelnut will occur.

See zRMS conclusion (point 7.1)

**Decision on acceptance of these uses may be made at the member state level**

Flax- fiber production, Common hemp - fiber production, Common osier, purple willow, forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations, Christmas trees grown on plantations

The intended uses are not relevant in terms of consumer health protection. The submission of supervised residue trials is not necessary.

## 7.2.4 Magnitude of residues in livestock

### 7.2.4.1 Dietary burden calculation

The active substance acetamiprid is authorised in EU for use on crops that might be fed to livestock, so dietary burden calculation was performed in EFSA (European Food Safety Authority), 2018: Focussed assessment of certain existing MRLs of concern for acetamiprid and modification of the existing MRLs for table olives, olives for oil production, barley and oats. EFSA Journal 2018;16(5):5262, 1-39.

Regarding the intended uses not all crops from GAP table are relevant as food item.

**Table 7.2-9: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure, the uses under consideration and in EFSA 2018)**

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: acetamiprid				
Apple, pomace, wet	0.30	STMR x PF (1.3) (EFSA, 2011; EFSA 2018)	0.30	STMR x PF (1.3) (EFSA, 2011; EFSA 2018)
Canola (Rape seed), meal	0.06	STMR x 2 <sup>a)</sup> (EFSA, 2016a, EFSA, 2018)	0.06	STMR x 2 <sup>a)</sup> (EFSA, 2016a, EFSA, 2018)
Potato, culls	0.01*	STMR (EFSA, 2011; EFSA 2018)	0.01*	STMR (EFSA, 2011; EFSA 2018)
Potato, process waste	0.01*	STMR (EFSA, 2011; EFSA 2018)	0.01*	STMR (EFSA, 2011; EFSA 2018)
Potato, dried pulp	0.01*	STMR (EFSA, 2011; EFSA 2018)	0.01*	STMR (EFSA, 2011; EFSA 2018)
Rape, meal	0.06	STMR x 2 <sup>a)</sup> (EFSA, 2016a, EFSA, 2018)	0.06	STMR x 2 <sup>a)</sup> (EFSA, 2016a, EFSA, 2018)

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

a) default processing factors

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

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,020	0,020	0,77	0,77	Dairy cattle	Potato	process waste	Yes
Cattle (dairy only)	0,020	0,020	0,52	0,52	Dairy cattle	Potato	process waste	Yes
Sheep (all diets)	0,023	0,023	0,68	0,68	Ram/Ewe	Potato	process waste	Yes
Sheep (ewe only)	0,023	0,023	0,68	0,68	Ram/Ewe	Potato	process waste	Yes
Swine (all diets)	0,008	0,008	0,36	0,36	Swine (breeding)	Potato	process waste	Yes
Poultry (all diets)	0,006	0,006	0,09	0,09	Poultry broiler	Potato	dried pulp	Yes
Poultry (layer only)	0,005	0,005	0,07	0,07	Poultry layer	Potato	dried pulp	Yes

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

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

### zRMS calculation

Input values: proposed uses

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: acetamiprid				
Apple	0.03 x 1.21	STMR x CF New trials	-	-
Rape seed	0.01*	STMR New trials	-	-
Potato	0.01*	STMR New trials	0.01*	HR

### Animal model 2017

Animal Model 2017

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)			Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM						
	Median	Maximum	Median	Maximum					
	mg/kg bw								
Cattle (all diets)	0,020	0,020	0,68	0,68	Dairy cattle	Potato	process waste	Yes	
Cattle (dairy only)	0,020	0,020	0,52	0,52	Dairy cattle	Potato	process waste	Yes	
Sheep (all diets)	0,023	0,023	0,68	0,68	Ram/Ewe	Potato	process waste	Yes	
Sheep (ewe only)	0,023	0,023	0,68	0,68	Ram/Ewe	Potato	process waste	Yes	
Swine (all diets)	0,008	0,008	0,36	0,36	Swine (breeding)	Potato	process waste	Yes	
Poultry (all diets)	0,006	0,006	0,09	0,09	Poultry broiler	Potato	dried pulp	Yes	
Poultry (layer only)	0,005	0,005	0,07	0,07	Poultry layer	Potato	dried pulp	Yes	

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

#### Available data

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



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

Commodity	Dietary burden values based on intended GAP		Results of the livestock feeding study						Median residue (mg/kg)	Highest residue (mg/kg)	Calculated MRL (mg/kg)	CF for RA			
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforcement		Result for RA								
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)							
EU data (The Netherlands, 2015, EFSA, 2011)															
Enforcement residue definition: sum of acetamiprid and metabolite IM-2-1, expressed as acetamiprid															
Pig meat	0.007	0.024	0.21	3	0.05	0.05	See results for enforcement residue definition	0.02	0.02	0.02* (tentative)	1.00				
			0.63	3	0.18	0.29									
			2.13	3	0.97	1.11									
Pig fat			0.21	3	0.03	0.06						0.02	0.02	0.02* (tentative)	1.00
			0.63	3	0.07	0.15									
			2.13	3	0.36	0.71									
Pig liver			0.21	3	0.15	0.15						0.10	0.10	0.1* (tentative)	1.00
			0.63	3	0.45	0.64									
			2.13	3	2.29	2.65									
Pig kidney			0.21	3	0.24	0.25						0.10	0.10	0.1* (tentative)	1.00
			0.63	3	0.70	0.86									
			2.13	3	2.39	2.54									
Ruminant meat	0.034	0.088	0.21	3	0.05	0.05	See results for enforcement residue definition	0.02	0.02	0.05 (tentative)	1.00				
			0.63	3	0.18	0.29									
			2.13	3	0.97	1.11									
Ruminant fat			0.21	3	0.03	0.06						0.02	0.03	0.05 (tentative)	1.00
			0.63	3	0.07	0.15									
			2.13	3	0.036	0.071									
Ruminant liver			0.21	3	0.15	0.15						0.10	0.10	0.1*	1.00

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			0.63	3	0.45	0.64				(tentative)	
			2.13	3	2.29	2.65					
<b>Ruminant kidney</b>			0.21	3	0.24	0.25		0.10	0.11	0.2 (tentative)	1.00
			0.63	3	0.70	0.86					
			2.13	3	2.39	2.54					
<b>Milk</b>	0.016	0.075	0.21	n.p.	0.08 <sup>(a)</sup>	n.a.		0.02	0.03	0.05 (tentative)	1.00
			0.63	n.p.	0.37 <sup>(a)</sup>	n.a.					
			2.13	n.p.	1.30 <sup>(a)</sup>	n.a.					
<b>New data</b>											
No new data were submitted in the framework of this application.											

n.a.: not applicable – only the mean values are considered for calculating MRLs in milk  
 n.p.: not precised  
 (\*): 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

According to RAR (The Netherlands, 2015):

*A study on determination of the magnitude of acetamiprid residues in poultry was submitted (■■■■ 1999). However, considering the metabolism study, no residues exceeding the LOQ are expected in any poultry tissues or eggs. Since the representative uses of acetamiprid do neither lead to a significant intake for poultry, this study was not evaluated by the rapporteur. The same was concluded in the original DAR: the feeding poultry study was submitted, but not evaluated.*

According to EFSA Journal 2016;14(11):4610:

*The metabolic profile was confirmed by the feeding studies on cow and poultry where IM-2-1 was detected as the most abundant component in all animal matrices. Acetamiprid was not present in poultry and only detected in significant levels in milk at all feeding levels and at the highest feeding level in the other matrices. Based on these studies, 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. It is highlighted that RMS expressed its disagreement on the livestock residue definition for risk assessment and proposes to include IM-2-1 compound only.*

According to EFSA Journal 2018;16(5):5262:

*Nevertheless, the existing EU MRLs for cattle, sheep and swine tissues and milk, reflect the existing CXLs which are based on a livestock dietary exposure significantly higher than the intake calculated in this framework.*

*For poultry, the new intended uses had no impact on the dietary burdens calculated in the framework of the Article 12 MRL review, (EFSA, 2011) when the MRLs for poultry tissues and eggs were derived.*

*It is noted that during the peer review for the renewal, (EFSA, 2016b) it was proposed to limit the residue definition for enforcement in animal commodities to metabolite N-desmethyl-acetamiprid only, while in the framework of this assessment the residue definition currently implemented in the EU legislation and by the JMPR (sum of acetamiprid and N-desmethyl-acetamiprid, expressed as acetamiprid) was considered. Moreover, the Article 12 review concluded that acetamiprid and N-desmethyl-acetamiprid (IM-2-1) could be enforced in food of animal origin with a LOQ of 0.01 mg/kg in milk, muscle, fat and eggs, and a LOQ of 0.05 mg/kg in liver and kidney but that a confirmatory method was still required (EFSA, 2011). In the framework of the renewal for the approval, the QuEChERS multiresidue method with HPLC–MS/MS was considered sufficiently validated to enforce both acetamiprid and N-desmethylacetamiprid at the LOQ of 0.01 mg/kg for each compound (EFSA, 2016b). Therefore, it is concluded that the data gap identified during the MRL review is covered by the additional method evaluated during the renewal.*

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

### **7.2.5.1 Available data for all crops under consideration**

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>					
Enforcement residue definition: acetamiprid					
Apple, juice	2	0.80 (0.73; 0.87)	1		RAR, 2015 EFSA, 2016
Apple, wet pomace	2	1.30 (1.23; 1.39)	1		

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

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

### 7.2.5.2 Conclusion on processing studies

Processing studies investigating the magnitude of residues in processed commodities are presented in the DAR, 2001 and RAR, 2015.

According to EFSA Journal 2016;14(11):4610:

*Processing studies on apple were submitted and processing factors were derived for juice and wet pomace.*

### 7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

#### 7.2.6.1 Field rotational crop studies (KCA 6.6.2)

##### Available data

No new studies submitted in the framework of this application.

##### Conclusion on rotational crops studies

In EFSA Journal 2016;14(11):4610 it was concluded:

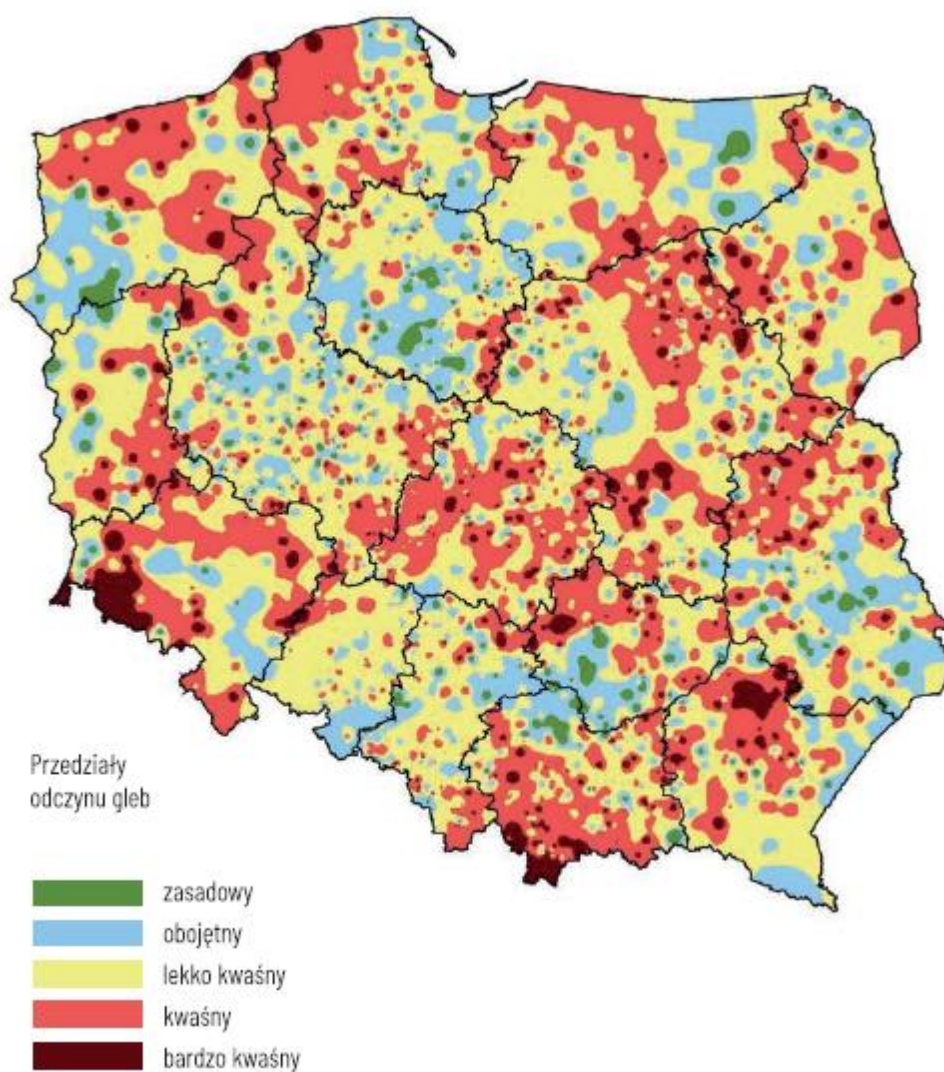
*The only [<sup>14</sup>C]-residue found in the crop commodities was IM-1-5 accounting for the entire extractable radioactive residue (≥ 76.8% TRR). No other metabolites or unidentified residues were observed in any crop commodity.*

In DAR Addendum 2003, based on study results (Simmonds M.B., 2002, Doc No. RD-00168 (re-evaluation in RAR 2015)) it was concluded that metabolite IM-1-5 is formed only in the soil, of a pH higher than 8.

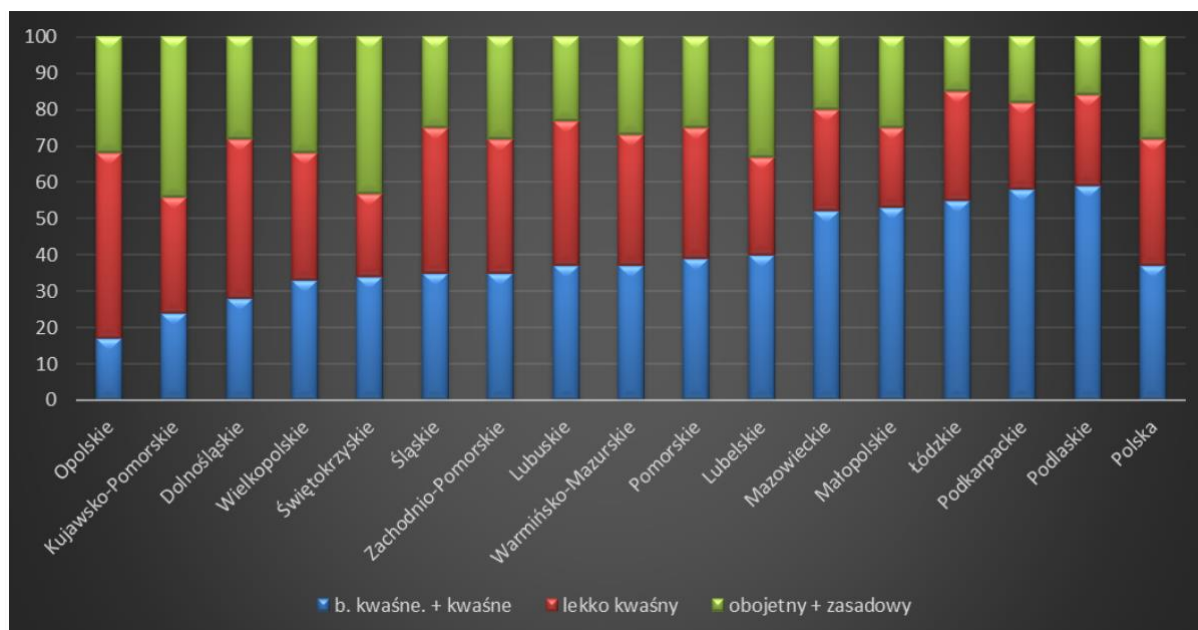
According to the on-line published report (*Krajowy raport o stanie gruntów rolnych w Polsce: zakwaszenie gleb oraz ich regeneracja poprzez wapnowanie – stan obecny i propozycje systemowych rozwiązań*, Wydanie II – Kraków 2022, Redakcja naukowa: prof. dr hab. inż. Stanisław J. Pietr, Katedra Ochrony Roślin,

*Uniwersytet Przyrodniczy we Wrocławiu; mgr inż. Marek Krysztoforowski, Główny Specjalista, Dział Rolnictwa Ekologicznego i Działów Rolno-Środowiskowo-Klimatycznych, Centrum Doradztwa Rolniczego w Brwinowie, Oddział w Radomiu; zespół ekspertów Stowarzyszenia Przemysłu Wapienniczego) in Poland prevail acidic soils (sse Picture 1 and Picture 2).*

Picture 1. Krajowy raport o stanie gruntów rolnych w Polsce: zakwaszenie gleb oraz ich regeneracja poprzez wapnowanie – stan obecny i propozycje systemowych rozwiązań, Wydanie II – Kraków 2022 - Map prepared by Łysiak i Smreczek, opracowanie własne, 2017, IUNG-PIB Puławy)



Picture 2. Aktualny stan zakwaszenia gleb w Polsce - <https://nawozy.eu/wiedza/porady-ekspertow/z-kraju/aktualny-stan-zakwaszenia-gleb-w-polsce>)



**Rys 1. Struktura odczynu gleb wg. województw  
(opracowanie własne na podstawie danych GUS 2020).**

With regard to pome and stone fruit, walnut and hazelnut rotational crop studies are not required as these fruits are not intended to grow into rotation.

#### Oilseed rape

According to the public available Integrated Methodology for Rapeseed Protection, this crop requires a neutral soil reaction with a pH of 6.6–7.2; However, it tolerates slightly acidic reactions quite well (*Metodyka integrowanej ochrony rzepaku ozimego I jarego dla producentów, Poznań 2013, Instytut Ochrony Roślin – Państwowy Instytut Badawczy, opracowanie zbiorowe pod redakcją: Dr Ewy Jajor i Prof. dr. hab. Marka Mrówczyńskiego*).

#### Potato

According to the public available Integrated Methodology of Integrated Potato Production, potato is a plant tolerant to soil reaction (pH 4.5-6.5). The alkaline reaction is unfavorable and often causes the tubers to be infected with common scab (*Metodyka INTEGROWANEJ PRODUKCJI ZIEMNIAKÓW (wydanie czwarte zmienione, Luty 2020, Instytutu Hodowli i Aklimatyzacji Roślin - Państwowy Instytut Badawczy Oddział w Jadwisinie pod kierunkiem dr. Wojciecha Nowackiego*).

#### Common hemp

According to the public available Methodology of integrated hemp protection, hemp is a nitrogen-loving plant and grows best in soil rich in this element. Due to the fact that hemp requires neutral or slightly alkaline soil (optimal pH 7.0–7.6), liming the soil is especially important when growing it for seeds. Soil liming is recommended when the pH is less than 6.0 (*Metodyka integrowanej ochrony konopi dla doradców, Poznań 2018, INSTYTUT OCHRONY ROŚLIN – PAŃSTWOWY INSTYTUT BADAWCZY Opracowanie zbiorowe pod redakcją: dr. hab. Andrzeja Wójtowicza, dr. inż. Przemysław Strażyńskiego, prof. dr. hab. Marka Mrówczyńskiego*).

#### Flax

According to the public available Methodology of integrated flax protection, in case of flax cultivation the soil should have appropriate acidity (soil reaction close to neutral pH 6.5–6.9 (*Metodyka integrowanej ochrony lnu dla doradców, Poznań 2017, INSTYTUT OCHRONY ROŚLIN – PAŃSTWOWY INSTYTUT BADAWCZY Opracowanie zbiorowe pod redakcją: dr. inż. Przemysława Strażyńskiego i prof. dr. hab. Marka Mrówczyńskiego*))

Taking into account above it is highly unlikely that a metabolite IM-1-5 will appear in soil, therefore rotational crops studies are not required for registration of Acetamipryd 200 SL for intended uses.

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

If residues in honey are expected considering the proposed uses and the properties of the active substance, then further data on crop or field/tunnel trials are required.

Some of the proposed uses are classified as a melliferous crops according to SANTE/11956/2016 rev. 9 (14 September 2018). Also, acetamiprid is an active substance with systemic properties and is applied during the flowering stage. Regarding above is highly possible that residues in honey can occur.

New semi-field/tunnel studies in N-EU zone (Poland and N-France) and S-EU zone (S-France and Italy) have been performed on winter oilseed rape to investigate the magnitude of acetamiprid residues in honey. The results of these studies are summarized in the table below. The details are presented in Appendix 2.

**Table 7.2-13: Summary of new data on honey supporting the intended uses of Acetamipryd 200 SL**

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
Winter oilseed rape - residues in honey	New trials (report no. R C2051)	N-EU & S-EU	Trial GAP: 1x 50 g as/ha, BBCH 65, semi-field (tunnel) trial  E: < 0.0015 (LOD), 2x < 0.005 (LOQ) RA: < 0.0015 (LOD), 2x < 0.005 (LOQ)	N/A				
	New trials (report no. R C4055)	N-EU	Trial GAP: 1x 50 g as/ha, BBCH 65, semi-field (tunnel) trial  E: 0.02 RA: 0.02	N/A				
	Overall supporting data for honey	N-EU & S-EU	E: < 0.0015 (LOD), 2x < 0.005 (LOQ), 0.02 RA: < 0.0015 (LOD), 2x < 0.005 (LOQ), 0.02	0.005	0.02	0.033	0.05* 0.05** 0.3 0.05***	Yes

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

\*\* PLAN/2024/1403

\*\*\* Reg. (EU) 2025/158 not applicable

New semi-field/tunnel studies (study no. C2051 and study no. R C4055) for determining the magnitude of residues of Acetamipryd 200 SL in honey was conducted in compliance with current guidelines. In all trials Acetamipryd 200 SL was applied at a rate 50 g as/ha at a flowering phase (BBCH 65) on rape. Results are summarised in table above. Sufficient residue trials (4) are available for honey.

All samples were analysed within 30 days from sampling, therefore there is no need to perform studies on the stability of residues during storage. All trials resulted in residues below the actual and planned MRL for honey. Therefore, no risk for consumers is expected.

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

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

Chronic and acute exposure calculations were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev. 3.1) provided on the internet homepage of EFSA (<https://www.efsa.europa.eu/>). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population. The model was developed to calculate simultaneously the short-term (acute) and long-term (chronic) dietary exposure to pesticide residue in food according to internationally agreed methodologies. The exposure is compared to the toxicological reference values (i.e., the ADI and the ARfD).

EFSA, 2024 evaluated acute and chronic risk for consumers by performing risk assessment with the latest PRIMo rev. 3.1 and using three scenarios:

1. *A first consumer risk assessment (CRA) was performed using PRIMo rev. 3.1. In this scenario, EFSA applied the newly derived HBGVs for acetamiprid and N-desmethyl-acetamiprid (IM-2-1) and the existing residue definitions for risk assessment, as derived in the framework of the renewal of the approval of acetamiprid under Regulation (EU) No 844/2012. EFSA assessed not only the existing MRLs but also considered those MRLs that were considered safe in the most recent EFSA outcomes (see scenario 1 in Section 3.4.1).*
2. *A second consumer risk assessment (CRA) was performed using PRIMo rev. 3.1. In this scenario, EFSA applied the newly derived HBGVs for acetamiprid and N-desmethyl-acetamiprid (IM-2-1) and the newly derived residue definitions for risk assessment (including conversion factors), as proposed in the framework of the present mandate. EFSA assessed not only the existing MRLs but also considered those MRLs that were considered safe in the most recent EFSA outcomes (see scenario 2 in Section 3.4.2).*
3. *EFSA launched a call for data for possible fall-back GAPs and supporting valid residue trials that could lead to safe MRL options for the plant commodities for which a risk for consumer has been identified under scenario 2. The data call was addressed to the EU Member States. Specific templates for submitting authorised good agricultural practices (GAPs) and supporting data were made available by EFSA (see Section 3.5.1).*
4. *EFSA screened and assessed the GAPs and supporting data received from Members States applying a stepwise approach to identify potential fall-back MRL option that would be safe for consumers (see Section 3.5.2).*
5. *A detailed assessment of the robustness of the identified fall-back MRL options for plant commodities was performed (see Sections 3.5.3 and 3.5.4). Further considerations were also made on the risk characterisation for those plant commodities for which no fall-back MRL could be identified (see Section 3.5.5).*
6. *For those commodities of animal origin for which a risk for consumer has been identified under scenario 2, further assessment was performed by EFSA to also identify fall-back MRL options.*
7. *A third consumer risk assessment (CRA) was performed using PRIMo rev. 3.1. EFSA applied the*



*newly derived HBGVs for acetamiprid and N-desmethyl-acetamiprid (IM-2-1) and the newly derived residue definitions for risk assessment (including conversion factors), as proposed in the framework of the present mandate. In this scenario, EFSA used the fall-back MRLs (and risk assessment values) identified under points 4, 5 and 6 (see scenario 3 in Section 3.5.7).*

8. *Based on scenario 3, EFSA recommended alternative MRLs for which risk to consumer is unlikely and provided further advice to risk managers where more than one option was identified.*

Similar approach was used by the applicant, with the difference that acute exposure was carried out only for the crops concerned:

- Scenario 1: Calculations were performed using input values from Reg. (EU) 2019/88 (actual MRLs), considering new residue definition and new toxicological reference values (TRVs).
- Scenario 2: Calculations were performed using input values from PLAN/2024/1403 (planned MRLs), considering new residue definition and new toxicological reference values (TRVs).
- Scenario 3: Calculations were performed using input values from EFSA, 2024, considering new residue definition and new toxicological reference values (TRVs).

### 7.2.8.1 Input values for the consumer risk assessment

**Table 7.2-14: Input values for the consumer risk assessment – SCENARIO 1**

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definitions in plant commodities:</b> <ul style="list-style-type: none"> <li>- <b>Fruit and leafy crops:</b> sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid (CF of 1.21 is used for fruit crops; CF of 1.44 is used for leafy crops)</li> <li>- <b>Any other crops:</b> acetamiprid</li> </ul>				
Apple	0.4 * CF	EU MRL <sup>1)</sup>	0.4 * CF	EU MRL <sup>1)</sup>
Pears	0.4 * CF	EU MRL <sup>1)</sup>	0.4 * CF	EU MRL <sup>1)</sup>
Quinces	0.8 * CF	EU MRL <sup>1)</sup>	0.8 * CF	EU MRL <sup>1)</sup>
Medlars	0.8 * CF	EU MRL <sup>1)</sup>	0.8 * CF	EU MRL <sup>1)</sup>
Plum	0.03 * CF	EU MRL <sup>1)</sup>	0.03 * CF	EU MRL <sup>1)</sup>
Cherry	1.5 * CF	EU MRL <sup>1)</sup>	1.5 * CF	EU MRL <sup>1)</sup>
Rapeseed	0.4	EU MRL <sup>1)</sup>	0.4	EU MRL <sup>1)</sup>
Potato	0.01	EU MRL <sup>1)</sup>	0.01	EU MRL <sup>1)</sup>
Tomato	0.5 * CF	EU MRL <sup>1)</sup>	0.5 * CF	EU MRL <sup>1)</sup>
Aubergines/eggplants	0.2 * CF	EU MRL <sup>1)</sup>	0.2 * CF	EU MRL <sup>1)</sup>
Pepper	0.3 * CF	EU MRL <sup>1)</sup>	0.3 * CF	EU MRL <sup>1)</sup>
Walnuts	0.07 * CF	EU MRL <sup>1)</sup>	0.07 * CF	EU MRL <sup>1)</sup>
Hazelnuts	0.07 * CF	EU MRL <sup>1)</sup>	0.07 * CF	EU MRL <sup>1)</sup>
All other commodities of plant origin	various (* CF if relevant)	EU MRL <sup>1)</sup>	Not relevant. Acute risk assessment performed only for intended uses.	

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Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definition: Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid</b>				
Honey and other apiculture	0.05	EU MRL <sup>1)</sup>	0.05	EU MRL <sup>1)</sup>
All other commodities of animal origin	various	EU MRL <sup>1)</sup>	Not relevant. Acute risk assessment performed only for intended uses.	

1) Reg. (EU) 2019/88

**Table 7.2-15: Input values for the consumer risk assessment – SCENARIO 2**

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definitions in plant commodities:</b> <ul style="list-style-type: none"> <li><b>Fruit and leafy crops: sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid (CF of 1.21 is used for fruit crops; CF of 1.44 is used for leafy crops)</b></li> <li><b>Any other crops: acetamiprid</b></li> </ul>				
Apple	0.07 * CF	PLAN EU MRL <sup>2)</sup>	0.07 * CF	PLAN EU MRL <sup>2)</sup>
Pears	0.07 * CF	PLAN EU MRL <sup>2)</sup>	0.07 * CF	PLAN EU MRL <sup>2)</sup>
Quinces	0.15 * CF	PLAN EU MRL <sup>2)</sup>	0.15 * CF	PLAN EU MRL <sup>2)</sup>
Medlars	0.15 * CF	PLAN EU MRL <sup>2)</sup>	0.15 * CF	PLAN EU MRL <sup>2)</sup>
Plum	0.03 * CF	PLAN EU MRL <sup>2)</sup>	0.03 * CF	PLAN EU MRL <sup>2)</sup>
Cherry	0.8 * CF	PLAN EU MRL <sup>2)</sup>	0.8 * CF	PLAN EU MRL <sup>2)</sup>
Rapeseed	0.4	PLAN EU MRL <sup>2)</sup>	0.4	PLAN EU MRL <sup>2)</sup>
Potato	0.01	PLAN EU MRL <sup>2)</sup>	0.01	PLAN EU MRL <sup>2)</sup>
Tomato	0.06 * CF	PLAN EU MRL <sup>2)</sup>	0.06 * CF	PLAN EU MRL <sup>2)</sup>
Aubergines/eggplants	0.2 * CF	PLAN EU MRL <sup>2)</sup>	0.2 * CF	PLAN EU MRL <sup>2)</sup>
Pepper	0.09 * CF	PLAN EU MRL <sup>2)</sup>	0.09 * CF	PLAN EU MRL <sup>2)</sup>
Walnuts	0.07 * CF	PLAN EU MRL <sup>2)</sup>	0.07 * CF	PLAN EU MRL <sup>2)</sup>
Hazelnuts	0.07 * CF	PLAN EU MRL <sup>2)</sup>	0.07 * CF	PLAN EU MRL <sup>2)</sup>
All others commodities of plant origin	various (* CF if relevant)	PLAN EU MRL <sup>2)</sup>	-	-
<b>Risk assessment residue definition: Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid</b>				
Honey and other apiculture	0.05	PLAN EU MRL <sup>2)</sup>	0.05	PLAN EU MRL <sup>2)</sup>
All other commodities of animal origin	various	PLAN EU MRL <sup>2)</sup>	Not relevant. Acute risk assessment performed only for intended uses.	

2) PLAN/2024/1403 (planned MRLs)

**Table 7.2-16: Input values for the consumer risk assessment – SCENARIO 3**

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definitions in plant commodities:</b> <ul style="list-style-type: none"> <li><b>Fruit and leafy crops:</b> sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid (CF of 1.21 is used for fruit crops; CF of 1.44 is used for leafy crops)</li> <li><b>Any other crops:</b> acetamiprid</li> </ul>				
Citrus fruits	0.006	STMR-RAC CF*PeF (EFSA, 2024)	-	-
Walnut	0.012	STMR-RAC*CF (EFSA, 2024)	0.061	HR-RAC*CF (EFSA, 2024)
Hazelnut	0.012	STMR-RAC*CF (EFSA, 2024)	0.061	HR-RAC*CF (EFSA, 2024)
Other tree nuts, except pistachios	0.012	STMR-RAC*CF (EFSA, 2024)	-	-
Pistachios	0.399	STMR-RAC*CF (EFSA, 2024)	-	-
Apples, Pears	0.027	STMR-RAC*CF (EFSA, 2024)	0.035	HR-RAC*CF (EFSA, 2024)
Quinces	0.036	STMR-RAC*CF (EFSA, 2024)	0.086	HR-RAC*CF (EFSA, 2024)
Medlar	0.079	STMR-RAC*CF (EFSA, 2024)	0.242	HR-RAC*CF (EFSA, 2024)
Loquats/Japanese medlars	0.278	STMR-RAC*CF (EFSA, 2024)	-	-
Other pome fruit	0.278	STMR-RAC*CF (EFSA, 2024)	-	-
Apricots	0.030	STMR-RAC*CF (EFSA, 2024)	-	-
Cherries (sweet)	0.260	STMR-RAC*CF (EFSA, 2024)	0.399	HR-RAC*CF (EFSA, 2024)
Peaches	0.030	STMR-RAC*CF (EFSA, 2024)	-	-
Plums	0.012	STMR-RAC*CF (EFSA, 2024)	0.036	HR-RAC*CF (EFSA, 2024)
Table grapes, Wine grapes	0.024	STMR-RAC*CF (EFSA, 2024)	-	-
Strawberries	0.121	STMR-RAC*CF (EFSA, 2024)	-	-
Blackberries, Raspberries (red and yellow)	0.212	STMR-RAC*CF (EFSA, 2024)	-	-
Dewberries	0.774	STMR-RAC*CF (EFSA, 2024)	-	-
Other cane fruit	0.774	STMR-RAC*CF	-	-

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Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		(EFSA, 2024)		
Blueberries, Cranberries, Currants (red, black and white), Gooseberries (green, red and yellow) Elderberries	0.247	STM-RAC*CF (EFSA, 2024)	-	-
Rose hips, Mulberries (black and white)	0.774	STM-RAC*CF (EFSA, 2024)	-	-
Figs	0.012	STM-RAC*CF (EFSA, 2024)	-	-
Table olives	0.290	STM-RAC*CF (EFSA, 2024)	-	-
Granate apples/pomegranate	0.012	STM-RAC*CF (EFSA, 2024)	-	-
Potatoes	0.01	PLAN EU MRL <sup>2)</sup>	0.01	PLAN EU MRL <sup>2)</sup>
Garlic	0.01	STM-RAC (EFSA, 2024)	-	-
Onions	0.01	STM-RAC (EFSA, 2024)	-	-
Tomatoes	0.013	STM-RAC*CF (EFSA, 2024)	0.048	HR-RAC*CF (EFSA, 2024)
Sweet peppers/bell peppers	0.041	STM-RAC*CF (EFSA, 2024)	0.062	HR-RAC*CF (EFSA, 2024)
Aubergines/egg plants	0.079	STM-RAC*CF (EFSA, 2024)	0.109	HR-RAC*CF (EFSA, 2024)
Okra/lady's fingers	0.048	STM-RAC*CF (EFSA, 2024)	-	-
Other solanacea	0.242	EU-MRL <sup>2)</sup> *CF (EFSA, 2024)	-	-
Cucumbers, Courgettes	0.024	STM-RAC*CF (EFSA, 2024)	-	-
Gherkins	0.169	STM-RAC*CF (EFSA, 2024)	-	-
Other cucurbits - edible peel	0.073	STM-RAC*CF (EFSA, 2024)	-	-
Melons, Pumpkins Watermelons	0.012	STM-RAC*CF (EFSA, 2024)	-	-
Other cucurbits - inedible peel	0.061	STM-RAC*CF (EFSA, 2024)	-	-
Sweet corn	0.012	PLAN EU MRL <sup>2)</sup>	-	-

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Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Broccoli, Cauliflowers	0.022	STMR-RAC*CF (EFSA, 2024)	-	-
Other flowering brassica	0.043	STMR-RAC*CF (EFSA, 2024)	-	-
Brussels sprouts	0.029	STMR-RAC*CF (EFSA, 2024)	-	-
Head cabbages	0.014	STMR-RAC*CF (EFSA, 2024)	-	-
Lamb's lettuce/corn salads	0.706	STMR-RAC*CF (EFSA, 2024)	-	-
Cress and other sprouts and shoots, Baby leaf crops (including brassica species)	1.16	STMR-RAC*CF (EFSA, 2024)	-	-
Land cress	1.17	STMR-RAC*CF (EFSA, 2024)	-	-
Roman rocket/rucola	0.706	STMR-RAC*CF (EFSA, 2024)	-	-
Red mustards	0.216	STMR-RAC*CF (EFSA, 2024)	-	-
Purslanes	0.288	STMR-RAC*CF (EFSA, 2024)	-	-
Other spinach and similar	0.288	STMR-RAC*CF (EFSA, 2024)	-	-
Herbs and edible flowers	1.20	STMR-RAC*CF (EFSA, 2024)	-	-
Beans (with pods), Peas (with pods)	0.06	STMR-RAC (EFSA, 2024)	-	-
Beans (without pods), Peas (without pods)	0.03	STMR-RAC (EFSA, 2024)	-	-
Asparagus	0.01	PLAN EU MRL <sup>2)</sup>	-	-
Globe artichokes	0.11	STMR-RAC*CF (EFSA, 2024)	-	-
Dry Pulses	0.02	STMR-RAC (EFSA, 2024)	-	-
Linseeds, Gold of pleasure seeds	0.01	PLAN EU MRL <sup>2)</sup>	-	-
Poppy seeds	0.01	PLAN EU MRL <sup>2)</sup>	-	-
Rapeseeds/canola seeds	0.03	STMR-RAC (EFSA, 2024)	0.03	STMR-RAC (EFSA, 2024)
Mustard seeds	0.01	EU-MRL <sup>2)</sup>	-	-

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Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cotton seeds	0.09	STMR-RAC (EFSA, 2024)	-	-
Olives for oil production	0.968	STMR-RAC*CF (EFSA, 2024)	-	-
Barley, Oat	0.01	STMR-RAC (EFSA, 2024)	-	-
Wheat	0.01	STMR-RAC (EFSA, 2024)	-	-
Spices (seeds)	0.05	PLAN EU MRL <sup>2)</sup>	-	-
Cardamom, Peppercorn (black, green and white)	0.1	PLAN EU MRL <sup>2)</sup>	-	-
Horseradish, root spices	0.07	PLAN EU MRL <sup>2)</sup>	-	-
All others commodities of plant origin	various (* CF if relevant)	PLAN EU MRL <sup>2)</sup>	-	-
<b>Risk assessment residue definition: Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid</b>				
Swine: Muscle/meat	0.02	STMR-RAC (EFSA, 2024)	-	-
Swine: Fat tissue	0.02	STMR-RAC (EFSA, 2024)	-	-
Swine: Liver	0.11	STMR-RAC (EFSA, 2024)	-	-
Swine: Kidney	0.11	STMR-RAC (EFSA, 2024)	-	-
Swine: Edible offals (other than liver and kidney)	1	PLAN EU MRL <sup>2)</sup>	-	-
Bovine: Muscle/meat	0.02	STMR-RAC (EFSA, 2024)	-	-
Bovine: Fat tissue	0.02	STMR-RAC (EFSA, 2024)	-	-
Bovine: Liver	0.02	STMR-RAC (EFSA, 2024)	-	-
Bovine: Kidney	0.11	STMR-RAC (EFSA, 2024)	-	-
Bovine: Edible offals (other than liver and kidney)	0.02	STMR-RAC (EFSA, 2024)	-	-
Sheep: Muscle/meat	0.02	STMR-RAC (EFSA, 2024)	-	-
Sheep: Fat tissue	0.02	STMR-RAC (EFSA, 2024)	-	-

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Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sheep: Liver	0.11	STM-RAC (EFSA, 2024)	-	-
Sheep: Kidney	0.11	STM-RAC (EFSA, 2024)	-	-
Sheep: Edible offals (other than liver and kidney)	1	PLAN EU MRL <sup>2)</sup>	-	-
Goat: Muscle/meat	0.02	STM-RAC (EFSA, 2024)	-	-
Goat: Fat tissue	0.02	STM-RAC (EFSA, 2024)	-	-
Goat: Liver	0.11	STM-RAC (EFSA, 2024)	-	-
Goat: Kidney	0.11	STM-RAC (EFSA, 2024)	-	-
Goat: Edible offals (other than liver and kidney)	1	PLAN EU MRL <sup>2)</sup>	-	-
Equine: Muscle/meat	0.02	STM-RAC (EFSA, 2024)	-	-
Equine: Fat tissue	0.02	STM-RAC (EFSA, 2024)	-	-
Equine: Liver	0.11	STM-RAC (EFSA, 2024)	-	-
Equine: Kidney	0.11	STM-RAC (EFSA, 2024)	-	-
Equine: Edible offals (other than liver and kidney)	1	PLAN EU MRL <sup>2)</sup>	-	-
Poultry: Muscle/meat	0.02	PLAN EU MRL <sup>2)</sup>	-	-
Poultry: Fat tissue	0.02	PLAN EU MRL <sup>2)</sup>	-	-
Poultry: Liver	0.1	PLAN EU MRL <sup>2)</sup>	-	-
Other farmed animals: Muscle/meat	0.5	PLAN EU MRL <sup>2)</sup>	-	-
Other farmed animals: Fat tissue	0.3	PLAN EU MRL <sup>2)</sup>	-	-
Other farmed animals: Liver	1	PLAN EU MRL <sup>2)</sup>	-	-
Other farmed animals: Kidney	1	PLAN EU MRL <sup>2)</sup>	-	-
Other farmed animals: Edible offals (other than liver and kidney)	1	PLAN EU MRL <sup>2)</sup>	-	-
Milk	0.02	STM-RAC (EFSA, 2024)	-	-

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Eggs	0.02	PLAN EU MRL <sup>2)</sup>	-	-
Honey and other apiculture products	0.13	STMR-RAC (EFSA, 2024)	0.02	HR-RAC (EFSA, 2024)
All other products of animal origin	various	PLAN EU MRL <sup>2)</sup>	-	-

2) PLAN/2024/1403 (planned MRLs)

## 7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in A 2.1.7.1.2.

**Table 7.2-17: Consumer risk assessment**

TMDI (% ADI) according to EFSA PRIMo 3.1	<b>SCENARIO 1</b> <b>679 %</b> (based on NL toddler diet)  <i>Highest contributors:</i> <b>239%</b> Milk: cattle <b>104%</b> Apples 52% Bananas
IEDI (% ADI) according to EFSA PRIMo 3.1	<b>SCENARIO 2</b> <b>417 %</b> (based on NL toddler diet)  <i>Highest contributors:</i> <b>239%</b> Milk: cattle 49% Oranges 18% Apples
IEDI (% ADI) according to EFSA PRIMo rev.3.1	<b>SCENARIO 3</b> <b>64 %</b> (based on NL toddler diet)  <i>Highest contributors:</i> 24% Milk: cattle 10% Beans (with pods) 6% Apples
IESTI (% ARfD) according to EFSA PRIMo rev.3.1*	<b>SCENARIO 1</b> <u>Unprocessed commodities (children):</u> <b>1341%</b> Pears (based on diet: NL toddler) <b>1043%</b> Apples (based on diet: NL toddler) <b>704%</b> Tomatoes (based on diet: BE toddlers) <b>476%</b> Quinces (based on diet: ES child) <b>444%</b> Cherries (sweet) (based on diet: DK child) <b>432%</b> Sweet peppers/bell peppers (based on diet: DE child) <b>268%</b> Medlar (based on diet: ES child) <b>121%</b> Aubergines/egg plants (based on diet: UK 4-6 years) 31% Potatoes (based on diet: UK infant) 31% Plums (based on diet: NL toddler) 11% Rapeseeds/canola seeds (based on diet: DE child) 6% Walnuts (based on diet: BE toddlers)



	<p>6% Hazelnuts/cobnuts (based on diet: IE child) 4% Honey and other apiculture products (based on diet: NL toddler)</p> <p><u>Unprocessed commodities (adults):</u>  <b>363%</b> Cherries (sweet) (based on diet: DE women 14-50)  <b>296%</b> Pears (based on diet: NL general population)  <b>294%</b> Quinces (based on diet: ES adult)  <b>272%</b> Apples (based on diet: FR adult)  <b>192%</b> Tomatoes (based on diet: LT adult)  <b>133%</b> Medlar (based on diet: ES adult)  <b>131%</b> Aubergines/egg plants (based on diet: NL general population)  <b>118%</b> Sweet peppers/bell peppers (based on diet: UK vegetarian)  13% Plums (based on diet: DE women 14-50)  6% Potatoes (based on diet: UK vegetarian)  4% Rapeseeds/canola seeds (based on diet: DE women 14-50)  4% Walnuts (based on diet: DE women 14-50)  2% Hazelnuts/cobnuts (based on diet: DE general population)  1% Honey and other apiculture products (based on diet: CZ males 15-17 years)</p> <p><u>Processed commodities (children):</u>  <b>524%</b> Apples / juice (based on diet: DE child)  <b>315%</b> Pears / juice (based on diet: NL child)  <b>230%</b> Tomatoes / juice (based on diet: DE child)  <b>115%</b> Tomatoes / sauce/puree (based on diet: NL child)  59% Quinces / jam (based on diet: NL child)  19% Potatoes / fried (based on diet: NL toddler)  12% Potatoes / dried (flakes) (based on diet: DE child)  7% Plums / juice (based on diet: DE child)  5% Rapeseeds / oils (based on diet: NL toddler)</p> <p><u>Processed commodities (adults):</u>  <b>323%</b> Apples / juice (based on diet: NL general population)  99% Tomatoes / sauce/puree (based on diet: NL general population)  24% Quinces / jam (based on diet: NL general population)  2% Potatoes / chips (based on diet: NL general population)  1% Potatoes / dried (flakes) (based on diet: NL general population)</p>
<p>IENTI (% ARfD) according to EFSA PRIMo rev.3.1*</p>	<p><b>SCENARIO 2</b>  <u>Unprocessed commodities (children):</u>  <b>298%</b> Quinces (based on diet: ES child)  <b>237%</b> Cherries (sweet) (based on diet: DK child)  <b>235%</b> Pears (based on diet: NL toddler)  <b>183%</b> Apples (based on diet: NL toddler)  <b>130%</b> Sweet peppers/bell peppers (based on diet: DE child)  <b>121%</b> Aubergines/egg plants (based on diet: UK 4-6 years)  100% Medlar (based on diet: ES child)  84% Tomatoes (based on diet: BE toddlers)  31% Potatoes (based on diet: UK infant)  31% Plums (based on diet: NL toddler)  11% Rapeseeds/canola seeds (based on diet: DE child)  6% Walnuts (based on diet: BE toddlers)</p>

	<p>6% Hazelnuts/cobnuts (based on diet: IE child) 4% Honey and other apiculture products (based on diet: NL toddler) <u>Unprocessed commodities (adults):</u> <b>194%</b> Cherries (sweet) (based on diet: DE women 14-50) <b>184%</b> Quinces (based on diet: ES adult) <b>131%</b> Aubergines/egg plants (based on diet: NL general population) 52% Pears (based on diet: NL general population) 50% Medlar (based on diet: ES adult) 48% Apples (based on diet: FR adult) 36% Sweet peppers/bell peppers (based on diet: UK vegetarian) 23% Tomatoes (based on diet: LT adult) 13% Plums (based on diet: DE women 14-50) 6% Potatoes (based on diet: UK vegetarian) 4% Rapeseeds/canola seeds (based on diet: DE women 14-50) 4% Walnuts (based on diet: DE women 14-50) 2% Hazelnuts/cobnuts (based on diet: DE general population) 1% Honey and other apiculture products (based on diet: CZ males 15-17 years)</p> <p><u>Processed commodities (children):</u> 92% Apples / juice (based on diet: DE child) 55% Pears / juice (based on diet: NL child) 37% Quinces / jam (based on diet: NL child) 28% Tomatoes / juice (based on diet: DE child) 19% Potatoes / fried (based on diet: NL toddler) 14% Tomatoes / sauce/puree (based on diet: NL child) 12% Potatoes / dried (flakes) (based on diet: DE child) 7% Plums / juice (based on diet: DE child) 5% Rapeseeds / oils (based on diet: NL toddler) <u>Processed commodities (adults):</u> 56% Apples / juice (based on diet: NL general population) 15% Quinces / jam (based on diet: NL general population) 12% Tomatoes / sauce/puree (based on diet: NL general population) 2% Potatoes / chips (based on diet: NL general population) 1% Potatoes / dried (flakes) (based on diet: NL general population)</p>
<p>IESTI (% ARfD) according to EFSA PRIMo rev.3.1*</p>	<p><b>SCENARIO 3</b> <u>Unprocessed commodities (children):</u> 98 % Cherries (sweet) (based on diet: DK child) 97 % Pears (based on diet: NL toddler) 75 % Apples (based on diet: NL toddler) 74% Sweet peppers/bell peppers (based on diet: UK vegetarian) 67 % Medlar (based on diet: ES child) 56 % Tomatoes (based on diet: BE toddlers) 55% Aubergines/egg plants (based on diet: UK 4-6 years) 42% Quinces (based on diet: ES child) 31% Potatoes (based on diet: UK vegetarian) 30 % Plums (based on diet: NL toddler) 4 % Walnuts (based on diet: BE toddlers)</p>

	<p>4 % Hazelnuts/cobnuts (based on diet: IE child)  4 % Honey and other apiculture products (based on diet: NL toddler)  0.8 % Rapeseeds/canola seeds (based on diet: DE child)  <u>Unprocessed commodities (adults):</u>  80 % Cherries (sweet) (based on diet: DE women 14-50)  59 % Aubergines/egg plants (based on diet: NL general population)  33 % Medlar (based on diet: ES adult)  26 % Quinces (based on diet: ES adult)  21 % Pears (based on diet: NL general population)  20 % Sweet peppers/bell peppers (based on diet: UK vegetarian)  20 % Apples (based on diet: FR adult)  15 % Tomatoes (based on diet: LT adult)  13 % Plums (based on diet: DE women 14-50)  6 % Potatoes (based on diet: UK vegetarian)  3 % Walnuts (based on diet: DE women 14-50)  1 % Hazelnuts/cobnuts (based on diet: DE general population)  1 % Honey and other apiculture products (based on diet: CZ males 15-17 years)  0.3 % Rapeseeds/canola seeds (based on diet: DE women 14-50)  <u>Processed commodities (children):</u>  29 % Apples / juice (based on diet: DE child)  19 % Potatoes / fried (based on diet: NL toddler)  18 % Pears / juice (based on diet: NL child)  12 % Potatoes / dried (flakes) (based on diet: DE child)  5 % Tomatoes / juice (based on diet: DE child)  2 % Tomatoes / sauce/puree (based on diet: NL child)  2 % Plums / juice (based on diet: DE child)  20% Quinces / jam (based on diet: NL child)  0.4 % Rapeseeds / oils (based on diet: NL toddler)  <u>Processed commodities (adults):</u>  18 % Apples / juice (based on diet: NL general population)  2 % Tomatoes / sauce/puree (based on diet: NL general population)  2 % Potatoes / chips (based on diet: NL general population)  1 % Potatoes / dried (flakes) (based on diet: NL general population)  0.9 % Quinces / jam (based on diet: NL general population)</p>
NTMDI (% ADI) **	not relevant
NEDI (% ADI)**	not relevant
NESTI (% ARfD) **	not relevant

\* include raw and processed commodities if both values are required for PRIMo rev.3.1

\*\* if national model is available

The proposed uses of acetamiprid in the formulation Acetamipryd 200 SL do not represent unacceptable acute and chronic risks for the consumer.

**zRMS: changing the MRL for honey (Regulation (EU) 2025/1212) will not change the positive consumer assessment in relation to approved crops**

### **7.3 Combined exposure and risk assessment**

Not relevant. The product contains only one active substance.

## 7.4 References

France 2001. Draft assessment report prepared in the context of the possible inclusion of the possible inclusion of the following active substance in Annex I of council Directive 91/414/EEC. Acetamiprid. RMS: Ellas, Co-rapporteur: France, March 2001

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

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, 1-59. doi:10.2903/j.efsa.2011.2328.

EFSA (European Food Safety Authority), 2016: Peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal (2016) 14(11):4610, 1-26. doi: 10.2903/j.efsa.2016.4610.

EFSA (European Food Safety Authority), 2018a: Focussed assessment of certain existing MRLs of concern for acetamiprid and modification of the existing MRLs for table olives, olives for oil production, barley and oats. EFSA Journal 2018;16(5):5262, 1-39. doi: 10.2903/j.efsa.2018.5262

EFSA (European Food Safety Authority), 2021. Reasoned opinion - Modification of the existing maximum residue levels for acetamiprid in various crops. EFSA Journal 2021;19(9):6830. doi: 10.2903/j.efsa.2021.6830

Commission Regulation (EU) 2019/88 of 18 January 2019 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid in certain products.

EFSA (European Food Safety Authority), 2024: Statement on the toxicological properties and maximum residue levels of acetamiprid and its metabolites, EFSA Journal. 2024;22:e8759. <https://doi.org/10.2903/j.efsa.2024.8759>

# 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
KCA 6.1/01	Niewelt-Stasiak S.	2024	Acetamiprid-N-desmethyl in potato - stability study Study No: DPL/68/2023 SGS Polska Sp. z o. o. GLP Unpublished	N	Pestila* ProAgri*
KCA 6.1/02	Niewelt-Stasiak S.	2024	Acetamiprid-N-desmethyl in oilseed rape (seed) - stability study Study No: DPL/83/2023 SGS Polska Sp. z o. o. GLP Unpublished	N	Pestila* ProAgri*
KCA 6.1/03	Niewelt-Stasiak S.	2024	Acetamiprid-N-desmethyl in apple - stability study Study No: DPL/84/2023 SGS Polska Sp. z o. o. GLP Unpublished	N	Pestila* ProAgri*
KCA 6.3/01	Wańczyk K.	2023	Magnitude of the residue of Acetamiprid in Apples (Raw Agricultural Commodity) after two applications of Acetamipryd 200 SL – two har-vest study trials in Poland - 2022	N	Pestila* ProAgri*

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<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			Report No. 22SGS42 SGS Polska Sp. z o. o. GLP Unpublished		
KCA 6.3/02	Wańczyk K.	2023	Magnitude of residue of acetamiprid (sum of acetamiprid and N-desmethyacetamiprid (IM-2-1) expressed as acetamiprid) in Apples (Raw Agricultural Commodity) after two applications of Acetamipryd 200 SL – six study trials in Poland – 2023 Report No. 23SGS29 SGS Polska Sp. z o. o. GLP Unpublished	N	Pestila* ProAgri*
KCA 6.3/03	Wańczyk K.	2022	Magnitude of the residue of Acetamiprid in Oilseed rape (Raw Agricultural Commodity) after one application of Acetamipryd 200 SL – two harvest study trials in Poland - 2022 Report No. 22SGS41 SGS Polska Sp. z o. o. GLP Unpublished	N	Pestila* ProAgri*
KCA 6.3/04	Wańczyk K.	2022	Magnitude of the residue of Acetamiprid in Oilseed rape (Raw Agricultural Commodity) after one application of Acetamipryd 200 SL – two harvest study trials in Poland - 2022 Report No. 22SGS45 SGS Polska Sp. z o. o. GLP Unpublished	N	Pestila* ProAgri*
KCA 6.3/05	Wańczyk K.	2023	Magnitude of residue of acetamiprid (sum of acetamiprid and N-desmethyacetamiprid (IM-2-1) expressed as acetamiprid) in oilseed rape (Raw Agricultural Commodity) after one application of Acetamipryd 200 SL – four decline study trials in Poland – 2023 Report No. 23SGS19	N	Pestila* ProAgri*

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<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			SGS Polska Sp. z o. o. GLP Unpublished		
KCA 6.3/06	Wańczyk K.	2023	Magnitude of residue of acetamiprid (sum of acetamiprid and N-desmethyacetamiprid (IM-2-1) expressed as acetamiprid) in potato (Raw Agricultural Commodity) after one application of Acetamipryd 200 SL – two har-vest and two decline curve study trials in Poland – 2023 Report No. 23SGS20 SGS Polska Sp. z o. o. GLP Unpublished	N	Pestila* ProAgri*
KCA 6.3/07	Grzeczka P.	2024	Magnitude of residue of Acetamiprid (sum acetamiprid and N-desmethyacetamiprid (IM-2-1) expressed as Acetamiprid) in Apples (Raw Agricultural Commodity) after two applications of Acetamipryd 200 SL – one harvest study trial in Poland – 2024 Report No. 24SGS52 SGS Polska Sp. z o. o. GLP Unpublished	N	Pestila* ProAgri*
KCA 6.10, 6.10.1/01	Lefebvre C.	2023	Determination of Acetamiprid residues in Honey Following Application on Winter Oilseed Rape with Piorun 200 SL under semi field Condi-tions in Northern and Southern Europe in 2023 Report No. C2051 ANADIAG GLP Unpublished	N	Pestila* ProAgri*
KCA 6.10, 6.10.1/02	Schneider E.	2024	Determination of Acetamiprid and its metabolite Acetamiprid-N-desmethyl Residues in Honey Following Application on Winter Oilseed Rape with Piorun 200 SL under semi field Condi-tions in Northern Europe in 2024 Report No. R C4055	N	Pestila* ProAgri*



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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
			ANADIAG GLP Unpublished		
KCA 6.6.2/01	Pietr S.J, Krysztoforski M., <i>et al.</i>	2022	Krajowy raport o stanie gruntów rolnych w Polsce: zakwaszenie gleb oraz ich regeneracja poprzez wapnowanie – stan obecny i propozycje systemowych rozwiązań, Wydanie II – Kraków 2022, Published	N	-
KCA 6.6.2/02	Ochal P.	2020	Aktualny stan zakwaszenia gleb w Polsce <a href="https://nawozy.eu/wiedza/porady-ekspertow/z-kraju/aktualny-stan-zakwaszenia-gleb-w-polsce">https://nawozy.eu/wiedza/porady-ekspertow/z-kraju/aktualny-stan-zakwaszenia-gleb-w-polsce</a> 28.06.2020 Published on-line article	N	-
KCA 6.6.2/03	Jajor E., Mrówczyński M. <i>et al.</i>	2013	Metodyka integrowanej ochrony rzepaku ozimego i jarego dla producentów – Poznań 2013 Instytut Ochrony Roślin – Państwowy Instytut Badawczy Published	N	-
KCA 6.6.2/04	Nowacki W. <i>et al.</i>	2020	Metodyka INTEGROWANEJ PRODUKCJI ZIEMNIAKÓW (wydanie czwarte zmienione) - Warszawa, luty 2020 r. Instytutu Hodowli i Aklimatyzacji Roślin - Państwowy Instytut Badawczy Published	N	-
KCA 6.6.2/05	Wójtowicz A., Strażyński P., Mrówczyński M. <i>et al.</i>	2018	Metodyka integrowanej ochrony konopi dla doradców – Poznań 2018 Instytut Ochrony Roślin – Państwowy Instytut Badawczy Published	N	-
KCA 6.6.2/06	Strażyński P., Mrówczyński M. <i>et al.</i>	2017	Metodyka integrowanej ochrony lnu dla doradców – Poznań 2017 Instytut Ochrony Roślin – Państwowy Instytut Badawczy Published	N	-

\*Pestila Spółka z ograniczoną odpowiedzialnością (short name: Pestila Sp. z o.o.)

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\*\*ProAgri Spółka z ograniczoną odpowiedzialnością or ProAgri International Spółka z ograniczoną odpowiedzialnością (short name: ProAgri Sp. z o.o. or ProAgri International Sp. z o.o.)

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 6.1	Goller G.	1999	Stability Study of NI-25 (Acetamiprid) in apple and tomato samples after storage in freezer at or below - 18 °C - Fortification experiments with active ingredient Report No RPA/NI-25/97051 A.D.M.E. - Bioanalyses, France GLP Unpublished	N	Nippon Soda
KCA 6.1	Maestracci, M.	1998	Acetamiprid/Storage Stability Study RPA/NI-25/97051 ADME-Bioanalyses GLP Unpublished	N	Nippon Soda
KCA 6.1	Jean-Baptiste C.	2009	Frozen Storage Stability of Residues of Acetamiprid in Fodder Pea Report No A7125 Anadiag Laboratories GLP Unpublished	N	Nippon Soda
KCA 6.1	Gieseke L.D.	1999	NI-25 (acetamiprid): Freezer storage stability of acetamiprid residues in various raw agricultural commodities and processing fractions (plant matrices) Report No 10201 Horizon Laboratories, Inc. GLP Unpublished	N	Nippon Soda
KCA 6.2.1	Saito H.	1997a	NI-25 [Pyridine-2,6-14C] - Nature of the Residue in Eggplants	N	Nippon Soda

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<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			Report No EC-391-3 Nisso Chemical Analysis Service Co, Ltd GLP, GEP Unpublished		
KCA 6.2.1	Saito H.	1997b	NI-25 [Pyridine-2,6-14C] - Nature of the Residue in Apples Report No EC-742-1 Nisso Chemical Analysis Service Co, Ltd GLP, GEP Unpublished	N	Nippon Soda
KCA 6.2.1	Saito H.	1997c	NI-25 [Pyridine-2,6-14C] - Nature of the Residue in Cabbages Plants Report No EC-743-1 Nisso Chemical Analysis Service Co, Ltd GLP, GEP Unpublished	N	Nippon Soda
KCA 6.2.1	Kawai T.	1995	NI-25 [CN-14C] - Nature of the Residue in Cabbages Plants Report No EC-617-1 Nisso Chemical Analysis Service Co, Ltd GLP, GEP Unpublished	N	Nippon Soda
KCA 6.2.1	McMillan-Staff S.L., Austin D.J., Lingwood A.	1997	[14C]-NI-25: Metabolism in Carrots. Report No 11253 Rhône-Poulenc Agriculture Ltd GLP, GEP Unpublished	N	Nippon Soda
KCA 6.2.1	Miller N.	1999	Foliarly applied 14C-acetamiprid: Metabolic fate and distribution in cotton (Gossypium hirsutum) Report No EC-97-367	N	Nippon Soda

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<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			Rhone-Poulenc Ag Company GLP Unpublished		
KCA 6.2.2-6.2.5	xxxx	1997b	<sup>14</sup> C-NI-25 (Acetamiprid): Absorption, Distribution, Metabolism and Excretion after Repeated Oral Administration to Laying Hens. Report No 628143 xxxxx GLP, GEP Unpublished	N	Nippon Soda
KCA 6.2.2-6.2.5	xxxx	1997a	<sup>14</sup> C-NI-25 (Acetamiprid): Absorption, Distribution, Metabolism and Excretion after Repeated Oral Administration to Lactating Goats Report No 628132 xxx GLP, GEP Unpublished	N	Nippon Soda
KCA 6.3	Sonder K-H	2001	Acetamiprid (AEF124370 Water Soluble Powder (SP) 20% w/w) - Decline of residues in Sweet Pepper European Union (indoor) 2000 Aventis CropScience Report/file: DR 00EUI 606 GLP, GEP : yes Not published	N	ROP
KCA 6.3	Sonder K-H	2002	Acetamiprid (AEF124370 Water Soluble Powder (SP) 20% w/w) – Residue behaviour in Sweet Pepper (indoor) European Union (Southern zone) 2001 Aventis CropScience Report/file: 01 RI 612 GLP, GEP : yes Not published	N	ROP

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<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 6.3	Baudet L., Yslan F.	1999	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – North/France/1998 – 1 harvest trial – residues in Plum (fruit without stone). Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9916082 GLP, GEP : yes Not published	N	ROP
KCA 6.3	D'AccriscioM., Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial United Kingdom – residues in Apple decline study Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/dbe 9716245 GLP, GEP : yes Not published	N	ROP
KCA 6.3	D'AccriscioM., Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial The Netherlands 1996 – residues in Apple Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9715752 GLP, GEP : yes Not published	N	Nippon Soda
KCA 6.3	Freschi, G.	2000	Analysis of Ni-25 (Acetamiprid) Residues in Tomato (Whole fruit) SIP1224 Sipcam Spa GLP Unpublished	N	Sipcam
KCA 6.3	Richard M., Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial Italy 1996 – residues in Tomato (greenhouse) – Decline study Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9715986 GLP, GEP : yes	N	ROP

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<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			Not published		
KCA 6.3	Richard M., Maestracci M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial Spain 1996 – residues in Tomato (greenhouse) – Decline study Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9716021 GLP, GEP : yes Not published	N	ROP
KCA 6.3	Richard, M. Maestracci, M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial The Netherlands 1996 – residues in Apple Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/dbc 9716246 GLP, GEP : yes Not published	N	ROP
KCA 6.3	Maestracci, M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial France 1997 – residues in Plum (quetsche and mirabelle). Decline Study Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/dbc 9716762 GLP, GEP : yes Not published	N	ROP
KCA 6.3	Richard, M. Maestracci, M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial United Kingdom 1996 – residues in Apple Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9716024 GLP, GEP : yes Not published	N	ROP
KCA 6.3	Richard, M. Maestracci, M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trials France 1997 – residues in Apple. Decline study Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/dbc 9716757	N	ROP

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<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			GLP, GEP : yes Not published		
KCA 6.3	Richard, M. Maestracci, M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial France 1997 – residues in tomato (in Greenhouse) Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/dbe 9716514 GLP, GEP : yes Not published	N	ROP
KCA 6.3	Richard, M. Maestracci, M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial France 1997 – residues in tomato (in Greenhouse) Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/dbe 9716513 GLP, GEP : yes Not published	N	ROP
KCA 6.3	Richard, M. Maestracci, M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial Spain 1995 – residues in pepper (in Netting) GRhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9715753 GLP, GEP : yes Not published	N	ROP
KCA 6.3	Richard, M. Maestracci, M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial Italy 1996 – residues in pepper (in greenhouse) – decline study Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9716013 GLP, GEP : yes Not published	N	ROP
KCA 6.3	Richard, M. Maestracci, M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial Spain 1997 – residues in pepper (in greenhouse) – decline study	N	ROP

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<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9716441 GLP, GEP : yes Not published		
KCA 6.3	Richard, M. Maestracci, M.	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial France 1996 – residues in apple – decline study Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9715990 GLP, GEP : yes Not published	N	ROP
KCA 6.3	Richard, M. Maestracci, M.	1999	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial France 1998 – residues in cherry (fruit and stoned fruit) Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9916066 GLP, GEP : yes Not published	N	ROP
KCA 6.3	Venet C., Barriere I.	2000	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trials France 1999 – residues in apples + processed products Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/mba 0015360 GLP, GEP : yes Not published	N	ROP
KCA 6.3	Venet C., Barriere I.	2000	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – North/France/1999 – 1 decline study trial – residues in plum (fruit and fruit without stone) Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/mba 0015275 GLP, GEP : yes	N	ROP



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<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			Not published		
KCA 6.3	Venet C., Barriere I.	2000	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – North/France/1999 – 1 decline study trial – residues in plum (fruit and fruit without stone) Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/mba 0015288 GLP, GEP : yes Not published	N	ROP
KCA 6.3	Venet C., Barriere I.	2000	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – South/Italy/1999 – 1 harvest study trial – residues in tomato (fruit).(in greenhouse) Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/bva 0015356 GLP, GEP : yes Not published	N	ROP
KCA 6.3	Venet C., Barriere I.	2000	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trials France 1999 – decline study trials – residues in cherries (fruit and stoned fruit) Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/mba 0015257 GLP, GEP : yes Not published	N	ROP
KCA 6.3	Venet C., Barriere I.	2000	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trials France 1999 – harvest study trials – residues in cherries (stoned fruit) Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/bva 0015258 GLP, GEP : yes Not published	N	ROP
KCA 6.3	D'AccrisioM., Richard M.,	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial Spain 1996 – residues in Eggplant (greenhouse)	N	ROP

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<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
	Maestracci M.		Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9716020 GLP, GEP : yes Not published		
KCA 6.3	Freschi G.	2000	Analysis of Acetamiprid Residues on Pepper (whole fruit) Sipcam Spa Report/file: SIP1225 GLP, GEP : yes Not published	N	Sipcam
KCA 6.4.1-6.4.3	xxxx	1999	Acetamiprid : Magnitude of Residues in Dairy Cow Milk and Tissues. ABC Laboratories, Inc. Report/file:Study 98514428/File N° 45649 Not published	N	Nippon Soda
KCA 6.5.1 KCA 6.5.2-6.5.3	McMillan-Staff S.L., Austin D.J.,	1997	[ <sup>14</sup> C]-NI-25 Investigation of the Nature of the Potential Residue in the Products of Industrial Processing or Household Preparation. Report No RPAL Study 13442 Rhone-Poulenc Ag Company GLP Unpublished	N	Nippon Soda
KCA 6.5.2-6.5.3	Kowite W.J.	1999	NI-25: Magnitude of Residues in Apple Processed Commodities Resulting from Foliar Applications of EXP 80667A Insecticide Report No 97512650 Rhône- Poulenc Agriculture Ltd GLP, GEP Unpublished	N	Nippon Soda
KCA	Venet C., Barriere I.,	2000	Acetamiprid (NI-25) – Formulation EXP60707A (SP) - Trials France 1999 - Residues in Apple +	N	Nippon Soda

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<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Verte- brate study Y/N</b>	<b>Owner</b>
6.5.2-6.5.3			Processed products Report No R&D/CRLD/AN/mba/0015360 Aventis CropScience GLP, GEP Unpublished		
KCA 6.6.2	Simmonds M.B.	2002	[14C]-Acetamiprid: Rate of Degradation in Three Calcareous Soils at 20°C Aventis CropScience SA., report C019428 Nippon Soda Doc No. RD-00168 GLP not published	N	Nippon Soda

The following tables are to be completed by MS.

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Verte- brate study Y/N</b>	<b>Owner</b>

**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>Verte- brate study Y/N</b>	<b>Owner</b>

## Appendix 2 Detailed evaluation of the additional studies relied upon

### A 2.1 Acetamiprid

#### A 2.1.1 Stability of residues

##### A 2.1.1.1 Stability of residues during storage of samples

##### A 2.1.1.1.1 Storage stability of residues in plant products

##### A 2.1.1.1.1.1 Study 1

Comments of zRMS:	Study is accepted
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Reference:	KCA 6.1/01
Report	Acetamiprid-N-desmethyl in potato - stability study, Niewelt-Stasiak S., 2024, Study No: DPL/68/2023
Guideline(s):	Yes. Regulation (EC) No 1107/2009 SANTE/2020/12830 Rev.2, 14 February 2023
Deviations:	No
GLP:	Yes
Acceptability:	Yes

### Materials and methods

The objective of the study was to evaluate the stability of acetamiprid-N-desmethyl (IM-2-1) in potato for a period of 99 days.

Specimen extraction and determination of residues of acetamiprid-N-desmethyl (IM-2-1) in potato was performed using the QuEChERS technique.

Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.005 mg/kg for acetamiprid-N-desmethyl (IM-2-1).

The method for determination of acetamiprid-N-desmethyl (IM-2-1) in potato was validated according to SANTE/2020/12830 Rev.2, 14 February 2023. Validation criteria and results were summarized in dRR Part B Section 5 (study no. VAL/11/2023 entitled: “Validation of an analytical method for the determination of residues of acetamiprid and acetamiprid-N-desmethyl in potato”).

#### Initial sample preparation and homogenization

Untreated potato samples originated from GLP study – DPL/61/2023/01U. Prior to the stability tests, samples were tested for possible interference and analytical background. Samples were stored in a freezer at  $\leq -18^{\circ}\text{C}$  before analysis. Then prepared a series of spiked samples that were dedicated as storage samples. It

was weighed 10 g (potato) samples into clean 50 mL centrifuge tubes. After adding 50 µL of fortification solution at concentration 10.0 µg/mL, the samples were transferred to the freezer.

#### Extraction

10 g of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile was added together with 100 µL of internal standard solution, and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogencitrate sesquihydrate), the mixture was shaken by hand again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation. Afterwards, 6 mL of the supernatant was transferred to a polypropylene centrifuge tube containing of cleanup mixture (900 mg of anhydrous magnesium sulphate, 150 mg of C18, 150 mg of PSA), next the mixture was shaken again by hand intensively for 0.5 min, then centrifuged at 4700 rpm for 5 min for phase separation. After that, the extract was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

#### Fortification and control samples

For each analytical sequence one untreated sample plus two fresh fortified samples at the level of 0.05 mg/kg were prepared.

10 g of the homogenized untreated sample were weighed into a 50 ml centrifuge tube. To two samples 50 µL of 10 ppm standard solution was added, and the sample was extracted.

12.12.2023 - (time “0”) – it was extraction and analysis of one fresh blank sample, two fresh fortified samples. After extraction the samples were directly employed for LC-MS/MS analysis, that was started on the same day. The extracts were analysed within 24 hours.

20.03.2024 – (time after 99 days) – it was extraction and analysis of one fresh blank sample, two fresh fortified samples and three storage samples (that were spiked at the level of 0.05 mg/kg on 12.12.2023). After extraction the samples were directly employed for LC-MS/MS analysis, that was started on the same day. The extracts were analysed within 24 hours.

#### Analysis

The extracts were analysed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day). Data acquisition was carried out in the MRM mode. The analysis was performed using internal standard addition.

For each analyte, one mass transition was evaluated and used for quantification. Representative chromatograms are shown in this report. A second and third mass transition was monitored for confirmation of peak identity, but was not used for quantification.

### Results and discussions

**Table A 1: Reporting for a spike level of 0.05 mg/kg for acetamiprid-N-desmethyl**

Matrix	Spike level (mg/kg)	Storage Period (days)	Residue Level in Freezer Storage Stability Sample (mg/kg)	Residue Level in Freezer Storage Stability Sample (% of nominal spiking level)	Procedural Recovery for Freshly Spiked Control Sample (%)
<b>acetamiprid-N-desmethyl (IM-2-1)</b>					
potato	0.05 mg/kg	0	-	-	108.4 109.2

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Matrix	Spike level (mg/kg)	Storage Period (days)	Residue Level in Freezer Storage Stability Sample (mg/kg)	Residue Level in Freezer Storage Stability Sample (% of nominal spiking level)	Procedural Recovery for Freshly Spiked Control Sample (%)
potato	0.05 mg/kg	99	0.051 0.051 0.050	102.9 101.7 100.0	101.6 97.6

**Table A 2: Results for analysed samples – acetamiprid-N-desmethyl at  $\leq -18^{\circ}\text{C}$**

Matrix	Treatment	Storage interval (days)	Results (mg/kg)	Individual recoveries (%)
<b>acetamiprid-N-desmethyl (IM-2-1)</b>				
potato	blank sample	0	< LOD	-
potato	fresh fortified	0	0.054	108.4
potato	fresh fortified	0	0.055	109.2
potato	blank sample	99	< LOD	-
potato	fresh fortified	99	0.051	101.6
potato	fresh fortified	99	0.049	97.6
potato	storage sample	99	0.051	-
potato	storage sample	99	0.051	-
potato	storage sample	99	0.050	-

## Conclusion

Stability was demonstrated for acetamiprid-N-desmethyl in potato upon storage at  $\leq -18^{\circ}\text{C}$  for a period of 99 days.

The method was validated according to SANTE/2020/12830, Rev.1 guidelines, which is in line with SANTE/2020/12830 Rev.2, 14 February 2023.

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120%.

The limit of detection of the method was the lowest calibration standard and the limit of quantification of the method was established at 0.005 mg/kg for acetamiprid-N-desmethyl in potato.

### A 2.1.1.1.1.2 Study 2

Comments of zRMS:	Study is accepted
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Reference: KCA 6.1/02

Report Acetamiprid-N-desmethyl in oilseed rape (seed) - stability study, Niewelt-Stasiak S., 2024, Study No: DPL/83/2023

Guideline(s): Yes.  
Regulation (EC) No 1107/2009

SANTE/2020/12830 Rev.2, 14 February 2023

Deviations: No  
GLP: Yes  
Acceptability: Yes

## Materials and methods

The objective of the study was to evaluate the stability of acetamiprid-N-desmethyl (IM-2-1) in oilseed rape (seed) for a period of 406 days.

Specimen extraction and determination of residues of acetamiprid-N-desmethyl (IM-2-1) in oilseed rape (seed) was performed using the QuEChERS technique.

Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.005 mg/kg for acetamiprid-N-desmethyl (IM-2-1).

The method for determination of acetamiprid-N-desmethyl (IM-2-1) in oilseed rape (seed) was validated according to SANTE/2020/12830 Rev.2, 14 February 2023. Validation criteria and results were summarized in dRR Part B Section 5 (study no. VAL/10/2023 entitled: “Validation of an analytical method for the determination of residues of acetamiprid and acetamiprid-N-desmethyl in oilseed rape (seed, plant)”.

### Initial sample preparation and homogenization

Untreated oilseed rape (seed) samples originated from GLP study – DPL/63/2023/01U. Samples were stored in a freezer at  $\leq -18^{\circ}\text{C}$  before analysis. Then, prepared a series of spiked samples that were dedicated as storage samples. It was weighed 5 g (oilseed rape seed) samples into clean 50 mL centrifuge tubes. After adding 25  $\mu\text{L}$  of fortification solution at concentration 10.0  $\mu\text{g/mL}$ , the samples were transferred to the freezer.

### Extraction

5 g of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile and 10 mL of deionized water was added together with 50  $\mu\text{L}$  of internal standard solution, and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogencitrate sesquihydrate), the mixture was shaken by hand again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation. Afterwards, 6 mL of the supernatant was transferred to a polypropylene centrifuge tube containing of cleanup mixture (900 mg of anhydrous magnesium sulphate, 150 mg of C18, 150 mg of PSA), next the mixture was shaken again by hand intensively for 0.5 min, then centrifuged at 4700 rpm for 5 min for phase separation. After that, the extract was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis.

Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

### Fortification and control samples

For each analytical sequence one untreated sample plus two (point “0”) or three (point “406 days”) fresh fortified samples at the level of 10 x LOQ (0.05 mg/kg) were prepared.

*In case of point “406 days” there was prepared three fresh fortified samples instead two (like it is usually practiced), because there was used new equipment in the end point. Usage of three fortified samples was as a minor validation to prove that new LC-MS/MS is also proper for residues analysis.*

5 g of the homogenized untreated sample were weighed into a 50 mL centrifuge tube. To two samples 25  $\mu\text{L}$  of 10 ppm standard solution was added, and the sample was extracted.



14.09.2023 - (point “0”) – it was extraction and analysis of one fresh blank sample and two fresh fortified samples of acetamiprid-N-desmethyl (IM-2-1) in oilseed rape (seed). After extraction the samples were directly employed for LC-MS/MS analysis, that was started on the same day. The extracts were analysed within 24 hours.

24.10.2024 – (point “406 days” – end point) – it was extraction and analysis of one fresh blank sample, three fresh fortified samples and three storage samples, that were spiked with acetamiprid-N-desmethyl (IM-2-1) at the level of 10 x LOQ (0.05 mg/kg) on 14.09.2023. After extraction the samples were directly employed for LC-MS/MS analysis, that was started on the same day. The extracts were analysed within 24 hours.

### Analysis

The extracts were analysed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day). Data acquisition was carried out in the MRM mode. The analysis was performed using internal standard addition.

For each analyte, one mass transition was evaluated and used for quantification. Representative chromatograms are shown in this report. A second and third mass transition was monitored for confirmation of peak identity, but was not used for quantification.

## Results and discussions

**Table A 3: Reporting for a spike level of 0.05 mg/kg for acetamiprid-N-desmethyl**

Matrix	Spike level (mg/kg)	Storage Period (days)	Residue Level in Freezer Storage Stability Sample (mg/kg)	Residue Level in Freezer Storage Stability Sample (% of nominal spiking level)	Procedural Recovery for Freshly Spiked Control Sample (%)
<b>acetamiprid-N-desmethyl (IM-2-1)</b>					
oilseed rape (seed)	0.05 mg/kg	0	-	-	96.1 98.6
oilseed rape (seed)	0.05 mg/kg	406	0.053 0.052 0.050	105.5 103.2 100.6	98.2 101.6 102.0

**Table A 4: Results for analysed samples – acetamiprid-N-desmethyl at ≤ -18°C**

Matrix	Treatment	Storage interval (days)	Results (mg/kg)	Individual recoveries (%)
<b>acetamiprid-N-desmethyl (IM-2-1)</b>				
oilseed rape (seed)	blank sample	0	< LOD	-
oilseed rape (seed)	fresh fortified	0	0.048	96.1
oilseed rape (seed)	fresh fortified	0	0.049	98.6
oilseed rape	blank sample	406	< LOD	-

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Matrix	Treatment	Storage interval (days)	Results (mg/kg)	Individual recoveries (%)
(seed)				
oilseed rape (seed)	fresh fortified	406	0.049	98.2
oilseed rape (seed)	fresh fortified	406	0.051	101.6
oilseed rape (seed)	fresh fortified	406	0.051	102.0
oilseed rape (seed)	storage sample	406	0.053	-
oilseed rape (seed)	storage sample	406	0.052	-
oilseed rape (seed)	storage sample	406	0.050	-

## Conclusion

Stability was demonstrated for acetamiprid-N-desmethyl in oilseed rape (seed) upon storage at  $\leq -18^{\circ}\text{C}$  for a period of 406 days.

The method was validated according to SANTE/2020/12830 Rev.2, 14 February 2023 guideline.

The limit of detection of the method was the lowest calibration standard and the limit of quantification of the method was established at 0.005 mg/kg for acetamiprid-N-desmethyl in oilseed rape (seed).

The performance of the method during the analytical study complies with SANTE/2020/12830 Rev. 2 criteria (accuracy in the range 70 – 120%).

There were no interfering signals at retention time of analysed compound in examined control matrix.

### A 2.1.1.1.1.3 Study 3

Comments of zRMS:	Study is accepted
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Reference:	KCA 6.1/03
Report	Acetamiprid-N-desmethyl in apple - stability study, Niewelt-Stasiak S., 2024, Study No: DPL/84/2023
Guideline(s):	Yes. Regulation (EC) No 1107/2009 SANTE/2020/12830 Rev.2, 14 February 2023
Deviations:	No
GLP:	Yes
Acceptability:	Yes

## Materials and methods

The objective of the study was to evaluate the stability of acetamiprid-N-desmethyl (IM-2-1) in apple for a period of 354 days.

Specimen extraction and determination of residues of acetamiprid-N-desmethyl (IM-2-1) in apple was performed using the QuEChERS technique.

Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.005 mg/kg

The method for determination of acetamiprid-N-desmethyl (IM-2-1) in apple was validated according to SANTE/2020/12830 Rev.2, 14 February 2023. Validation criteria and results were summarized in dRR Part B Section 5 (study no. VAL/12/2023 entitled: “Validation of an analytical method for the determination of residues of acetamiprid and acetamiprid-N-desmethyl in apple”).

#### Initial sample preparation and homogenization

Untreated apple samples originated from private sources. Prior to the stability tests, samples were tested for possible interference and analytical background. Samples were stored in a freezer at  $\leq -18^{\circ}\text{C}$  before analysis. Then prepared a series of spiked samples that were dedicated as storage samples. It was weighed 10 g samples into clean 50 mL centrifuge tubes. After adding 50  $\mu\text{L}$  of fortification solution at concentration 10.0  $\mu\text{g/mL}$ , the samples were transferred to the freezer.

#### Extraction

10 g of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile was added together with 100  $\mu\text{L}$  of internal standard solution, and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogencitrate sesquihydrate), the mixture was shaken by hand again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation. Afterwards, 6 mL of the supernatant was transferred to a polypropylene centrifuge tube containing of cleanup mixture (900 mg of anhydrous magnesium sulphate, 150 mg of C18, 150 mg of PSA), next the mixture was shaken again by hand intensively for 0.5 min, then centrifuged at 4700 rpm for 5 min for phase separation. After that, the extract was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

#### Fortification and control samples

For each analytical sequence one untreated sample plus two fresh fortified samples at the level of 0.05 mg/kg were prepared.

10 g of the homogenized untreated sample were weighed into a 50 ml centrifuge tube. To two samples 50  $\mu\text{L}$  of 10 ppm standard solution was added and the sample was extracted.

14.09.2023 - (time “0”) – it was extraction and analysis of one fresh blank sample, two fresh fortified samples. After extraction the samples were directly employed for LC-MS/MS analysis, that was started on the same day. The extracts were analysed within 24 hours.

02.09.2024 – (time after 354 days) – it was extraction and analysis of one fresh blank sample, two fresh fortified samples and three storage samples (that were spiked at the level of 0.05 mg/kg on 14.09.2023). After extraction the samples were directly employed for LC-MS/MS analysis, that was started on the same day. The extracts were analysed within 24 hours.

#### Analysis

The extracts were analysed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day). Data acquisition was carried out in the MRM mode. The analysis was performed using internal standard addition.

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For each analyte, one mass transition was evaluated and used for quantification. Representative chromatograms are shown in this report. A second and third mass transition was monitored for confirmation of peak identity, but was not used for quantification.

## Results and discussions

**Table A 5: Reporting for a spike level of 0.05 mg/kg for acetamiprid-N-desmethyl**

Matrix	Spike level (mg/kg)	Storage Period (days)	Residue Level in Freezer Storage Stability Sample (mg/kg)	Residue Level in Freezer Storage Stability Sample (% of nominal spiking level)	Procedural Recovery for Freshly Spiked Control Sample (%)
acetamiprid-N-desmethyl (IM-2-1)					
apple	0.05 mg/kg	0	-	-	113.3 112.2
apple	0.05 mg/kg	354	0.047 0.048 0.047	94.9 96.8 93.8	101.5 104.3

**Table A 6: Results for analysed samples – acetamiprid-N-desmethyl at  $\leq -18^{\circ}\text{C}$**

Matrix	Treatment	Storage interval (days)	Results (mg/kg)	Individual recoveries (%)
acetamiprid-N-desmethyl (IM-2-1)				
apple	blank sample	0	< LOD	-
apple	fresh fortified	0	0.057	113.3
apple	fresh fortified	0	0.056	112.2
apple	blank sample	354	< LOD	-
apple	fresh fortified	354	0.051	101.5
apple	fresh fortified	354	0.052	104.3
apple	storage sample	354	0.047	-
apple	storage sample	354	0.048	-
apple	storage sample	354	0.047	-

## Conclusion

Stability was demonstrated for acetamiprid-N-desmethyl in apple upon storage at  $\leq -18^{\circ}\text{C}$  for a period of 354 days.

The method was validated according to SANTE/2020/12830 Rev.2, 14 February 2023.

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120%.

The limit of detection of the method was the lowest calibration standard and the limit of quantification of the method was established at 0.005 mg/kg for acetamiprid-N-desmethyl in apple.

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

### **A 2.1.2.1 Nature of residue in plants**

#### **A 2.1.2.1.1 Nature of residue in primary crops**

No new data submitted in the framework of this application.

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

No new data submitted in the framework of this application.

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

No new data submitted in the framework of this application.

### **A 2.1.2.2 Nature of residues in livestock**

No new data submitted in the framework of this application.

## **A 2.1.3 Magnitude of residues in plants**

### **A 2.1.3.1 Apples**

**Table A 7: Comparison of intended and critical EU GAPs**

<b>Type of GAP</b>	<b>Number of applications</b>	<b>Application rate per treatment</b>	<b>Interval between application</b>	<b>Growth stage at last application</b>	<b>PHI (days)</b>
cGAP EU (RAR, The Netherlands, 2015)	2	75 g a.s./ha	-	BBCH 77-87	14 days
cGAP EU (Art. 12, EFSA, 2018)	2	100 g a.s./ha	-	BBCH 69-81	14 days
Intended cGAP (number 5*)	2	23.6 g a.s./ha	7 days	BBCH 71-84	14 days
Intended cGAP (number 6*)	2	23.6 g a.s./ha	7 days	BBCH 71-84	14 days
Intended cGAP (number 7*)	1	14.6 g a.s./ha	N/A	BBCH 65-69	14 days
Intended cGAP (number 8*)	1	14.6 g a.s./ha	N/A	BBCH 56-84	14 days
Intended cGAP (number 9*)	1	23.6 g a.s./ha	N/A	BBCH 56-84	14 days

\* 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 Evaluator:	Study is accepted
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Reference:	KCA 6.3/01
Report	Magnitude of the residue of Acetamiprid in Apples (Raw Agricultural Commodity) after two applications of Acetamipryd 200 SL – two harvest study trials in Poland - 2022; Wańczyk K.; 2023; report no. 22SGS42
Guideline(s):	Yes Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC 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 Guidelines for the Testing of Chemicals on Crop Field Trial (TG 509 published in June 2021) SANTE/2020/12830 rev.2
Deviations:	No
GLP:	Yes
Acceptability:	Yes

### Materials and methods

#### Field Phase of the study:

Two harvest study trials (HS) were established in Poland. Trial consisted of one untreated plot U and one treated plot T.

Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negative impact on the integrity and validity of this study.

Two typical for insecticide applications were performed in trials with airblast sprayer on the treated plots at the target dose rate of 0.2 L/ha (Acetamipryd 200 SL). For the test item reported dose rate was: 0.204 L/ha; 0.197 L/ha (trial 22SGS42-01) and 0.199 L/ha; 0.199 L/ha (trial 22SGS42-02).

The target spray volume was 900 L/ha according to GAP. The reported spray volume was actually 915.63 L/ha; 887.5 L/ha (trial 22SGS42-01) and 896.9 L/ha, 896.9 L/ha (trial 22SGS42-02).

Foliar applications were performed in BBCH 81 (first application) and BBCH 85 (second application).

The spray mixture volumes remaining after applications were measured and the volumes applied to the treated plot were calculated to verify delivery rates. Deviations to the target rates were all between  $\pm 5\%$ .

In harvest study trial (HS), RAC specimens for analyses (fruit) were collected at S1 - CH (Fruit).

RAC specimens were put in deep freezing conditions at a target temperature of  $\leq -18^{\circ}\text{C}$  on the day of sampling, within 12 hours after sampling.

All specimens remained deep frozen during storage at the test site, during shipment to laboratory.

#### Analytical Phase of the study:

Method of determination by LC-MS/MS fulfils the requirements as defined in EC Guidance document on

residue analytical methods (SANTE/2020/12830 Rev.2) and is applicable as enforcement and data generation method for determination of acetamiprid and acetamiprid-N-desmethyl (IM-2-1) in apple two applications of Acetamipryd 200 SL.

Originally, only the active substance (acetamiprid) was determined. Then a second report from the analytical part was prepared, in which it was acetamiprid and N-desmethyl-acetamiprid (IM-2-1) was determined (DPL/65/2023)

LOD = 0.001 mg/kg for acetamiprid; LOD = 0.001 mg/kg for N-desmethyl-acetamiprid,

LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for N-desmethyl-acetamiprid,

LOQ = 0.01 mg/kg for sum of acetamiprid and N-desmethyl-acetamiprid.

Details are described in dRR Part B Section 5 (VAL/12/2023).

### Conclusion

Residues of acetamiprid and acetamiprid-N-desmethyl (IM-2-1) were not detected in any of the untreated samples.

Residue concentrations of acetamiprid detected in analysed field samples are in the table below.

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**Table A 8: Summary of the study 22SGS42 (1 trial)**

Trial No./ Location/ EU zone/ 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 analyzed	Residues (mg/kg)			PHI or DALA (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	L (f. p./ha)				Acetam- iprid	Acetam- iprid- N- desmethyl (IM-2-1)	Sum of Acet- amiprid and Acetam- iprid- N-desmethyl (IM-2-1)		
(a)	(a)	(b)				(c)						(d)	(e)
Harvest Study Study Trial 22SGS42-01 / Po- land, Piskorzówek (55-216) / N-EU / 2022	Apple/ Gala Royale	1- 25.10.2010 2- 20.04.202- 12.05.2022 3-02.09.2022	0.0408 0.0394	915.63 887.50	0.204 0.197	12.08.2021 19.08.2021	81 85	Fruit	<u>0.017</u>	<LOD	<u>0.017</u>	14	Method: LC-MS/MS  LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl LOD = 0.001 mg/kg

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



### A 2.1.3.1.2 Study 2

Comments of Evaluator:	Study is accepted
Reference:	KCA 6.3/02
Report	Magnitude of residue of acetamiprid (sum of acetamiprid and N-desmethyacetamiprid (IM-2-1) expressed as acetamiprid) in Apples (Raw Agricultural Commodity) after two applications of Acetamipryd 200 SL – six study trials in Poland – 2023; Wańczyk K.; 2023; report no. 23SGS29
Guideline(s):	Yes Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC 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) SANTE/2020/12830 rev.2, 14 February 2023
Deviations:	No
GLP:	Yes
Acceptability:	Yes

### Materials and methods

#### Field Phase of the study:

Six trials were established in Poland, 2 harvest study and four decline curve study. Trials consisted of one untreated plot U and one treated plot T with minimum plots size :6 trees for HS and min. 8 trees for DCS with LWA in the scope 12 000-15 000 m<sup>2</sup>.

Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negative impact on the integrity and validity of this study.

Two insecticide applications were performed in trials with air blast sprayer on the treated plots at the target dose rate of 0.2 L/ha (Acetamipryd 200 SL). The target spray volume was 500-900 L/ha according to GAP. For the test item Acetamipryd 200 SL the reported dose rate was at:

- Trial 23SGS29-01 – 0.201 L/ha and 0.198 L/ha (802.9 L/ha and 793.8 L/ha water)
- Trial 23SGS29-02 – 0.198 L/ha and 0.201 L/ha (792.0 L/ha and 802.9 L/ha water)
- Trial 23SGS29-03 – 0.200 L/ha and 0.199 L/ha (601.2 L/ha and 597.2 L/ha water)
- Trial 23SGS29-04 – 0.207 L/ha and 0.200 L/ha (776.3 L/ha and 750.3 L/ha water)
- Trial 23SGS29-05 – 0.200 L/ha and 0.201 L/ha (669.1 L/ha and 701.9 L/ha water)
- Trial 23SGS29-06 – 0.203 L/ha and 0.195 L/ha (810.1 L/ha and 779.2 L/ha water)

Applications were performed: first at 7 days before application A2 or 21 days before harvest (if possible BBCH 81) and second 14 ±1 days before commercial harvest.

The spray mixture volumes remaining after applications were measured and the volumes applied to the treated plot were calculated to verify delivery rates. Deviations to the target rates were all between ± 5%.

In DCS trial RAC specimens for analyses were collected at:

S1: - 0/+ DALA - Fruit without stem

S2: 3 DALA - Fruit without stem

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S3: 5 DALA - Fruit without stem  
S4: 7±1 DALA - Fruit without stem  
S5: 14±1 DALA/CH- Fruit without stem

In HS trials RAC specimens for analyses were collected at:

S1: 14±1 DALA/CH- Fruit without stem

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site.

RAC specimens were put in deep freezing conditions at a target temperature of  $\leq -18^{\circ}\text{C}$  on the day of sampling, within 12 hours after sampling.

All specimens remained deep frozen during storage at the test site, during shipment to the laboratory.

#### Analytical Phase of the study:

Method of determination by LC-MS/MS fulfils the requirements as defined in EC Guidance document on residue analytical methods (SANTE/2020/12830 Rev.2) and is applicable as enforcement and data generation method for determination of Acetamiprid (Sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid) in apples after two applications of Acetamipryd 200 SL.

LOD = 0.001 mg/kg for acetamiprid; LOD = 0.001 mg/kg for N-desmethyl-acetamiprid,

LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for N-desmethyl-acetamiprid,

LOQ = 0.01 mg/kg for sum of acetamiprid and N-desmethyl-acetamiprid.

Details are described in dRR Part B Section 5 (VAL/12/2023).

#### **Conclusion**

Residues of acetamiprid and acetamiprid-N-desmethyl (IM-2-1) were not detected in any of the untreated samples.

Residue concentrations of acetamiprid detected in analysed field samples are in the table below.

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**Table A 9: Summary of the study 23SGS29 (6 trials)**

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treat- ment or date	Portion ana- lyzed	Residues (mg/kg)			PHI or DALA (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	L (f. p./ha)				Acetam- iprid	N- desmethyl- acetam- iprid (IM-2-1)	Sum of acetam- iprid and N- desmethyl- acetam- iprid		
(a)	(b)	(b)				(c)						(d)	(e)
Harvest Study Study Trial 23SGS29-01 / Po- land, Wysoki Kościół (55-114) / N-EU / 2023	Apple/ Idared	1. 25.10.2008 2. 19.04.2023- 15.05.2023 3. 03.10.2023	0.0402 0.0396	802.9 793.8	0.201 0.198	13/09/2023 20/09/2023	81 85	Fruit	0.013	<LOD	<u>0.013</u>	14	Method: LC-MS/MS  LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N-desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl LOD = 0.001 mg/kg
Harvest Study Study Trial 23SGS29-02 / Po- land, Swarzędz (62-020) / N-EU / 2023	Apple/ Golden Delicious	1. 09.10.2007 221.04.2023- 18.05.2023 3. 03.10.2023	0.0396 0.0402	792.0 802.9	0.198 0.201	13/09/2023 20/09/2023	81 85	Fruit	0.055	<LOD	<u>0.055</u>	14	Method: LC-MS/MS  LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N-desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl LOD = 0.001 mg/kg
Decline Study Study Trial 23SGS29-03 / Po- land, Gębice (88- 330) / N-EU / 2023	Apple/ Alwa	1. 20.09.2018 2. 18.05.2023- 29.05.2023 3. 02.10.2023	0.0400 0.0398	601.2 597.2	0.200 0.199	11/09/2023 07/09/2023	81 85	Fruit Fruit Fruit Fruit Fruit	0.13 0.11 0.14 0.065 0.046	<LOD <LOQ <LOQ <LOQ <LOQ	0.13 0.11 0.14 0.065 <u>0.046</u>	0 3 5 7 14	Method: LC-MS/MS  LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N-desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl

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													LOD = 0.001 mg/kg
Decline Study Study Trial 23SGS29-04 / Po- land, Goszczyn (05-610) / N-EU / 2023	Apple/ Gloster	1. 19.03.2017 2. 03.05.2023- 10.05.2023 3. 05.10.2023- 10.10.2023	0.0414 0.0400	776.3 750.3	0.207 0.200	08/09/2023 15/09/2023	85 85	Fruit Fruit Fruit Fruit Fruit	0.074 0.088 0.052 0.055 0.033	<LOQ 0.0054 <LOQ <LOQ <LOQ	0.074 0.094 0.052 0.055 <u>0.033</u>	0 3 5 7 14	Method: LC-MS/MS  LOQ = 0.005 mg/kg for ac- etamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetam- iprid-N-desmethyl LOD = 0.001 mg/kg
Decline Study Study Trial 23SGS29-06 / Po- land, Miastowice (89-240) / N-EU / 2023	Apple/ Topaz	1. 20.03.2006 2. 28.04.2023- 17.05.2023 3. 29.09.2023	0.0400 0.0402	669.1 701.9	0.200 0.201	08/09/2023 15/09/2023	81 85	Fruit Fruit Fruit Fruit Fruit	0.13 0.14 0.061 0.081 0.032	<LOQ <LOQ <LOQ <LOQ <LOQ	0.13 0.14 0.061 0.081 <u>0.032</u>	0 3 5 7 14	Method: LC-MS/MS  LOQ = 0.005 mg/kg for ac- etamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetam- iprid-N-desmethyl LOD = 0.001 mg/kg
Decline Study Study Trial 23SGS29-06 / Po- land, Gać (55-200) / N-EU / 2023	Apple/ Gloster	1. 25.10.2010 2. 24.04.2023- 18.05.2023 3. 25.09.2023	0.0406 0.0390	810.1 779.2	0.203 0.195	04/09/2023 11/09/2023	81 85	Fruit Fruit Fruit Fruit Fruit	0.033 0.027 0.015 0.018 0.012	<LOQ <LOQ <LOQ <LOQ <LOQ	0.033 0.027 0.015 0.018 <u>0.012</u>	0 3 5 7 14	Method: LC-MS/MS  LOQ = 0.005 mg/kg for ac- etamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetam- iprid-N-desmethyl LOD = 0.001 mg/kg

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

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

### A 2.1.3.1.3 Study 3

Comments of Evaluator:	Study is accepted
Reference:	KCA 6.3/07
Report	Magnitude of residue of Acetamiprid (sum acetamiprid and N-desmethyacetamiprid (IM-2-1) expressed as Acetamiprid) in Apples (Raw Agricultural Commodity) after two applications of Acetamipryd 200 SL – one harvest study trial in Poland – 2024; Grzeczka P.; 2024; report no. 24SGS52
Guideline(s):	Yes Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC 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 Guidelines for the Testing of Chemicals on Crop Field Trial (TG 509 published in June 2021) SANTE/2020/12830 rev.2
Deviations:	No
GLP:	Yes
Acceptability:	Yes

#### Materials and methods

##### Field Phase of the study:

One trial was established in Poland. Trial consisted of one untreated plot U and one treated plot T with a plots size of 8 trees for HS trial.

Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negative impact on the integrity and validity of this study.

Two insecticide applications were performed with air blast sprayer on the treated plot at the target dose rate of 0.2 L/ha (Acetamipryd 200 SL). The target spray volume was 500-900 litres per hectare according to Good Agricultural Practices.

Applications were performed: first at 7 days before application A2 (21 days before harvest at BBCH stage 81) and second 14 days before commercial harvest.

In the trial RAC specimens for analyses were collected at 14 DALA (fruits without stem).

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site.

RAC specimens were put in deep freezing conditions at a target temperature of  $\leq -18^{\circ}\text{C}$  on the day of sampling, within 12 hours after sampling.

All specimens remained deep frozen during storage at the test site, during shipment to laboratory.

##### Analytical Phase of the study:

Method of determination by LC-MS/MS fulfils the requirements as defined in EC Guidance document on residue analytical methods (SANTE/2020/12830 Rev.2) and is applicable as enforcement and data generation method for determination of acetamiprid and acetamiprid-N-desmethyl (IM-2-1) in apple two applications of Acetamipryd 200 SL.

Originally, only the active substance (acetamiprid) was determined. Then a second report from the analytical part was prepared, in which it was acetamiprid and N-desmethyl-acetamiprid (IM-2-1) was determined (DPL/65/2023)

LOD = 0.001 mg/kg for acetamiprid; LOD = 0.001 mg/kg for N-desmethyl-acetamiprid,

LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for N-desmethyl-acetamiprid,

LOQ = 0.01 mg/kg for sum of acetamiprid and N-desmethyl-acetamiprid.

The method for determination of acetamiprid and acetamiprid-N-desmethyl (IM-2-1) in apple was validated according to SANTE/2020/12830 Rev. 2, 14 February 2023. Validation criteria and results were summarized in study VAL/12/2023, entitled Validation of an analytical method for the determination of residues of acetamiprid and acetamiprid-N-desmethyl in apple". Details are described in dRR Part B Section 5.

## Conclusion

Residues of acetamiprid and acetamiprid-N-desmethyl (IM-2-1) were not detected in any of the untreated samples.

Residue concentrations of acetamiprid detected in analysed field samples are in the table below.

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**Table A 10: Summary of the study 24SGS52 (1 trial)**

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 treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI or DALA (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	L (f. p./ha)				Acetam- iprid	Acetam- iprid- N- desmethyl (IM-2-1)	Sum of Acet- amiprid and Acetam- iprid- N-desmethyl (IM-2-1)		
(a)	(a)	(b)				(c)						(d)	(e)
Harvest Study Study Trial 24SGS52-01 / Po- land (Kujawsko- Pomorskie), Mia- stowice (89-240) / N-EU / 2024	Apple/ Szampion	1- 20.09.2011 2- 21.04.2024- 15.05.2024 3-16.09.2024	0.0396 0.0402	495.6 502.7	0.198 0.137	26.09.2024 02.09.2024	81 85	Fruit	0.037	<LOD	<u>0.037</u>	14	Method: LC-MS/MS  LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl LOD = 0.001 mg/kg

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

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

### A 2.1.3.2 Oilseed rape

**Table A 11: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (RAR, The Netherlands, 2015)	-	-	-	-	-
cGAP EU (EFSA Journal 2016;14(2):4385)	2	42 g as/ha	-	1st appl.: BBCH 59 2nd appl.: BBCH 80	NR
Intended cGAP (number 1*)	1	50 g as/ha	NR	BBCH 30-50	NR
Intended cGAP (number 2*)	1	20-24 g as/ha	NR	BBCH 50-56	NR
Intended cGAP (number 3*)	1	20-24 g as/ha	NR	BBCH 60-69	NR

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

#### A 2.1.3.2.1 Study 1

Comments of Evaluator:	Study is accepted
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Reference:	KCA 6.3/03
Report	Magnitude of the residue of Acetamiprid in Oilseed rape (Raw Agricultural Commodity) after one application of Acetamipryd 200 SL – two harvest study trials in Poland - 2022; Wańczyk S.; 2022; report no. 22SGS41
Guideline(s):	Yes Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC 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 Guidelines for the Testing of Chemicals on Crop Field Trial (TG 509 published in June 2021) SANTE/2020/12830 rev.2
Deviations:	No
GLP:	Yes
Acceptability:	Yes



## Materials and methods

### Field Phase of the study:

Two harvest trials (HS) were established in Poland. Trial consisted of one untreated plot U and one treated plot T.

Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negative impact on the integrity and validity of this study.

One typical for insecticide application was performed in trials with boom sprayer on the treated plots at the target dose rate of 0.25 L/ha (Acetamipryd 200 SL). For the test item reported dose rate was: 0.252 L/ha (trial 22SGS41-01) and 0.254 (trial 22SGS41-02).

The target spray volume was 300-400 L/ha to GAP.

Foliar application was performed in BBCH 69.

The spray mixture volumes remaining after application was measured and the volumes applied to the treated plot were calculated to verify delivery rates.

Deviations to the target rates were all between  $\pm 5\%$ .

In harvest study trial (HS), RAC specimens for analyses (seeds) were collected mechanically by mini combine harvester at S1 - CH

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site.

RAC specimens were put in deep freezing conditions at a target temperature of  $\leq -18^{\circ}\text{C}$  on the day of sampling, within 12 hours after sampling.

All specimens remained deep frozen during storage at the test site, during shipment to the laboratory.

### Analytical Phase of the study:

Method of determination by LC-MS/MS fulfils the requirements as defined in EC Guidance document on residue analytical methods (SANTE/2020/12830 Rev.2) and is applicable as enforcement and data generation method for determination of Acetamiprid (Sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid) in oilseed rape after one application of Acetamipryd 200 SL.

Originally, only the active substance (acetamiprid) was determined. Then a second report from the analytical part was prepared, in which it was acetamiprid and N-desmethyl-acetamiprid (IM-2-1) was determined (DPL/63/2023)

LOD = 0.001 mg/kg for acetamiprid; LOD = 0.001 mg/kg for N-desmethyl-acetamiprid,

LOQ = 0.005 mg/kg for acetamiprid; LOQ = 0.005 mg/kg for N-desmethyl-acetamiprid,

LOQ = 0.01 mg/kg for sum of acetamiprid and N-desmethyl-acetamiprid.

Details are described in dRR Part B Section 5 (VAL/10/2023).

## Conclusion

Residues of acetamiprid and acetamiprid-N-desmethyl (IM-2-1) were not detected in any of the untreated samples.

Residue concentrations of acetamiprid detected in analysed field samples are in the table below.

Acetamipryd 200 SL  
Part B – Section 7 - Core Assessment  
Applicant version

**Table A 12: Summary of the study 22SGS41 (2 trials)**

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 or DALA (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	L (f. p./ha)				Acetam- iprid	Acetam- iprid- N- desmethyl (IM-2-1)	Sum of Acet- amiprid and Acetam- iprid- N-desmethyl (IM-2-1)		
(a)	(a)	(b)				(c)						(d)	(e)
Harvest Study Study Trial 22SGS41-01 / Po- land, Piskorzówek (55-216) / N-EU / 2022	Winter rape / LG Angelico	1- 30.08.2021 2- 05.05.202- 22.05.2022 3-11.07.2022	0.0504	302.0	0.252	23.05.2022	69	Seeds	<u>0.0069</u>	<LOQ	0.0069	49 DALA	Method: LC-MS/MS  LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl LOD = 0.001 mg/kg
Harvest Study Study Trial 22SGS41-01 / Po- land Słubowo (88- 400) / N-EU / 2022	Winter rape / Dominador	1- 28.08.2021 2- 29.04.202- 25.05.2022 3-21.07.2022	0.0508	305.1	0.254	23.05.2022	69	Seeds	<u>0.014</u>	<LOQ	0.014	59 DALA	Method: LC-MS/MS  LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl LOD = 0.001 mg/kg

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

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

### A 2.1.3.2.2 Study 2

Comments of Evaluator:	Study is accepted
Reference:	KCA 6.3/04
Report	Magnitude of the residue of Acetamiprid in Oilseed rape (Raw Agricultural Commodity) after one application of Acetamipryd 200 SL – two harvest study trials in Poland - 2022; Wańczyk K.; 2022; report no. 22SGS45
Guideline(s):	Yes Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC 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 Guidelines for the Testing of Chemicals on Crop Field Trial (TG 509 published in June 2021) SANTE/2020/12830 rev.2.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

### Materials and methods

#### Field Phase of the study:

Two harvest trials (HS) were established in Poland. Trial consisted of one untreated plot U and one treated plot T.

Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negative impact on the integrity and validity of this study.

One typical for insecticide application was performed in trials with boom sprayer on the treated plots at the target dose rate of 0.25 L/ha (Acetamipryd 200 SL).

The target spray volume was 300-400 L/ha according to GAP.

Foliar application was performed in BBCH 69.

The spray mixture volumes remaining after application was measured and the volumes applied to the treated plot were calculated to verify delivery rates.

Deviations to the target rates were all between  $\pm 5\%$ .

In harvest study trial (HS), RAC specimens for analyses (seeds) were collected mechanically by mini combine harvester and combine harvester at S1 - CH.

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site.

RAC specimens were put in deep freezing conditions at a target temperature of  $\leq -18^{\circ}\text{C}$  on the day of sampling, within 12 hours after sampling.

All specimens remained deep frozen during storage at the test site, during shipment to the laboratory.

#### Analytical Phase of the study:

Method of determination by LC-MS/MS fulfils the requirements as defined in EC Guidance document on residue analytical methods (SANTE/2020/12830 Rev.2) and is applicable as enforcement and data generation method for determination of Acetamiprid (Sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid) in oilseed rape after one application of Acetamipryd 200 SL.

Originally, only the active substance (acetamiprid) was determined. Then a second report from the analytical part was prepared, in which it was acetamiprid and N-desmethyl-acetamiprid (IM-2-1) was determined (DPL/64/2023)

LOD = 0.001 mg/kg for acetamiprid; LOD = 0.001 mg/kg for N-desmethyl-acetamiprid,

LOQ = 0.005 mg/kg for acetamiprid; LOQ = 0.005 mg/kg for N-desmethyl-acetamiprid,

LOQ = 0.01 mg/kg for sum of acetamiprid and N-desmethyl-acetamiprid.

Details are described in dRR Part B Section 5 (VAL/10/2023).

## Conclusion

Residues of acetamiprid and acetamiprid-N-desmethyl (IM-2-1) were not detected in any of the untreated samples.

Residue concentrations of acetamiprid detected in analysed field samples are in the table below.

Acetamipryd 200 SL  
Part B – Section 7 - Core Assessment  
Applicant version

**Table A 13: Summary of the study 22SGS45 (4 trials)**

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 treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI or DALA (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	L (f. p./ha)				Acetam- iprid	Acetam- iprid- N- desmethyl (IM-2-1)	Sum of Acet- amiprid and Acetam- iprid- N-desmethyl (IM-2-1)		
(a)	(a)	(b)				(c)						(d)	(e)
Harvest Study Study Trial 22SGS45-01 / Po- land, Malczów (55-100) / N-EU / 2022	Winter rape / LG Ambas- sador F1	1- 26.08.2021 2- 02.05.202- 25.05.2022 3-12.07.2022	0.0519	309.6	0.252	31.05.2022	69	Seeds	<u>0.0078</u>	<LOQ	0.0078	42 DALA	Method: LC-MS/MS  LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl LOD = 0.001 mg/kg
Harvest Study Study Trial 22SGS45-01 / Po- land Zamarte (89- 430) / N-EU / 2022	Winter rape / Jurek	1- 31.08.2021 2- 05.05.202- 01.06.2022 3-21.07.2022	0.0492	295.0	0.246	01.06.2022	69	Seeds	<u>0.012</u>	<LOQ	0.012	50 DALA	Method: LC-MS/MS  LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl LOD = 0.001 mg/kg

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

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

**A 2.1.3.2.3      Study 3**

Comments of Evaluator:	Study is accepted
Reference:	KCA 6.3/05
Report	Magnitude of residue of acetamiprid (sum of acetamiprid and N-desmethy-lacetamiprid (IM-2-1) expressed as acetamiprid) in oilseed rape (Raw Agricul-tural Commodity) after one application of Acetamipryd 200 SL – four decline study trials in Poland – 2023; Wańczyk K.; 2023; report no. 23SGS19
Guideline(s):	Yes Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repeal-ing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommenda-tions 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 Guidelines for the Testing of Chemicals on Crop Field Trial (TG 509 published in June 2021) SANTE/2020/12830 rev.2.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

**Materials and methods**

Field Phase of the study:  
Four Decline Curve Study trials (DCS) were established in Poland. Trial consisted of one untreated plot U and one treated plot T.  
Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negative impact on the integrity and validity of this study.  
One typical for insecticide application of Acetamipryd 200 SL was performed in trials with boom sprayer on the treated plots at the target dose rate of 0.25 L/ha (equivalent to 50 g as/ha).  
The target spray volume was 300-400 L/ha according to GAP.  
Foliar application was performed in BBCH 69.  
The spray mixture volumes remaining after application was measured and the volumes applied to the treated plot were calculated to verify delivery rates.  
Deviations to the target rates were all between  $\pm$  5%.  
RAC specimens for analyses (whole plant without root, seeds) were collected at:  
S1 – 0 DALA  
S2 – 7 DALA  
S3 – 14 DALA  
S4 – 21 DALA  
S5 – CH.  
Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site.

RAC specimens were put in deep freezing conditions at a target temperature of  $\leq -18^{\circ}\text{C}$  on the day of sampling, within 12 hours after sampling.

All specimens remained deep frozen during storage at the test site, during shipment to the laboratory.

Analytical Phase of the study:

Method of determination by LC-MS/MS fulfils the requirements as defined in EC Guidance document on residue analytical methods (SANTE/2020/12830 Rev.2) and is applicable as enforcement and data generation method for determination of Acetamiprid (Sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid) in oilseed rape after one application of Acetamipryd 200 SL.

LOD = 0.001 mg/kg for acetamiprid; LOD = 0.001 mg/kg for N-desmethyl-acetamiprid,

LOQ = 0.005 mg/kg for acetamiprid; LOQ = 0.005 mg/kg for N-desmethyl-acetamiprid,

LOQ = 0.01 mg/kg for sum of acetamiprid and N-desmethyl-acetamiprid.

Details are described in dRR Part B Section 5 (VAL/10/2023).

**Conclusion**

Residues of acetamiprid and acetamiprid-N-desmethyl (IM-2-1) were not detected in any of the untreated samples.

Residue concentrations of acetamiprid detected in analysed field samples are in the table below.

Acetamipryd 200 SL  
Part B – Section 7 - Core Assessment  
Applicant version

**Table A 14: Summary of the study 23SGS19 (4 trials)**

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 treat- ments and last date	Growth stage at last treatment or date	Portion ana- lysed	Residues (mg/kg)			PHI or DALA (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	L (f. p./ha)				Acetam- iprid	Acetam- iprid- N- desmethyl (IM-2-1)	Sum of Acet- amiprid and Acetam- iprid- N-desmethyl (IM-2-1)		
(a)	(b)	(b)				(c)						(d)	(e)
Decline Study Study Trial 23SGS19 -01 / Po- land, Ostrowo (88- 320) / N-EU / 2023	Winter rape / Kadore	1- 26.08.2022 2- 03.05.2023- 26.05.2023 3-17.07.2023	0.049	296.7	0.247	26.05.2023	69	Whole plant w/o root	0.36	<LOD	0.36	0 DALA	Method: LC-MS/MS
								Whole plant w/o root	0.24	0.0052	0.25	7 DALA	LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl
								Whole plant w/o root	0.20	0.0095	0.21	14 DALA	LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl
								Whole plant w/o root	0.044	0.0081	0.053	21 DALA	LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl
								Seeds	<u>0.017</u>	0.0053	0.023	harvest	LOD = 0.001 mg/kg
Decline Study Study Trial 23SGS19 -02 / Po- land, Białozewin (88-400) / N-EU / 2023	Winter rape / Absolut	1- 25.08.2022 2- 26.04.2023- 27.05.2023 3-17.07.2022	0.049	294.9	0.246	24.05.2023	69	Whole plant w/o root	0.22	<LOD	0.22	0 DALA	Method: LC-MS/MS
								Whole plant w/o root	0.11	<LOQ	0.22	7 DALA	LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl
								Whole plant w/o root	0.11	0.0099	0.12	14 DALA	LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl
								Whole plant w/o root	0.13	0.015	0.15	21 DALA	LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl
								Seeds	<u>0.0084</u>	<LOQ	0.0084	harvest	LOD = 0.001 mg/kg
Decline Study Study Trial 23SGS19 -03 / Po- land, Stoszowice (57-213) / N-EU / 2023	Winter rape / Sienna	1- 31.08.2022 2- 27.04.2023- 25.05.2023 3-20.07.2023	0.049	294.7	0.246	22.05.2023	69	Whole plant w/o root	0.22	<LOD	0.22	0 DALA	Method: LC-MS/MS
								Whole plant w/o root	0.033	<LOQ	0.033	7 DALA	LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl
								Whole plant w/o root	0.036	<LOQ	0.036	14 DALA	LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl
								Whole plant w/o root	0.0092	<LOQ	0.0092	21 DALA	LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl
								Seeds	<u>&lt;LOQ</u>	<LOQ	<LOQ	harvest	LOD = 0.001 mg/kg



Acetamipryd 200 SL

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Applicant version

Decline Study Study Trial 23SGS19 -04 / Po- land, Chwastnica (55-100) / N-EU / 2023	Winter rape / Sienna	1- 30.08.2022 2- 25.04.2023- 26.05.2023 3-20.07.2022	0.049	295.3	0.246	24.05.2023	69	Whole plant	0.33	<LOD	0.33	0 DALA	Method: LC-MS/MS
								w/o root					
								Whole plant	0.28	0.0083	0.29	7 DALA	LOQ = 0.005 mg/kg for
								w/o root					acetamiprid; LOQ= 0.005
								Whole plant	0.14	0.0083	0.15	14 DALA	mg/kg for acetamiprid-N-
								w/o root					desmethyl
								Whole plant	0.042	0.0068	0.049	21 DALA	LOQ = 0.01 mg/kg for
								w/o root					sum of acetamiprid and
								Seeds	<u>0.021</u>	<LOQ	0.021	harvest	acetamiprid-N-desmethyl
													LOD = 0.001 mg/kg

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

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

### A 2.1.3.3 Potato

**Table A 15: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (RAR, The Netherlands, 2015)	3	50 g as/ha	7 days	BBCH 45-93	7 days
cGAP EU (EFSA Journal 2016;14(2):4385)	3	50 g as/ha	7 days	BBCH 45-93	7 days
Intended cGAP (number 4*)	1	16-24 g as/ha	NR	BBCH 35-75	3 days

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

#### A 2.1.3.3.1 Study 1

Comments of Evaluator:	Study is accepted
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Reference:	KCA 6.3/06
Report	Magnitude of residue of acetamiprid (sum of acetamiprid and N-desmethyacetamiprid (IM-2-1) expressed as acetamiprid) in potato (Raw Agricultural Commodity) after one application of Acetamipryd 200 SL – two harvest and two decline curve study trials in Poland – 2023; Wańczyk K.; 2023; report no. 23SGS20
Guideline(s):	Yes Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC 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 Guidelines for the Testing of Chemicals on Crop Field Trial (TG 509 published in June 2021) SANTE/2020/12830 rev.2.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

### Materials and methods

#### Field Phase of the study:

Four trials were established in Poland (2 decline and 2 harvest). Trials consisted of one untreated plot U

and one treated plot T with minimum plots size 30 m<sup>2</sup> for HS and 45 m<sup>2</sup> for DCS trial.

Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negative impact on the integrity and validity of this study.

One insecticide application was performed in trials with boom sprayer on the treated plots at the target dose rate of 0.120 L/ha (Acetamipryd 200 SL). The target spray volume was 200-400 L/ha according to GAP.

For the test item Acetamipryd 200 SL the reported dose rate was at:

- Trial 23SGS20-01 – 0.123 L/ha (306.7 L/ha water)
- Trial 23SGS20-02 – 0.123 L/ha (307.3 L/ha water)
- Trial 23SGS20-03 – 0.119 L/ha (297.3 L/ha water)
- Trial 23SGS20-04 – 0.117 L/ha (388.9 L/ha water)

Applications were performed at BBCH 75.

The spray mixture volumes remaining after applications were measured and the volumes applied to the treated plot were calculated to verify delivery rates.

Deviations to the target rates were all between  $\pm 5\%$ .

In DCS trial RAC specimens for analyses were collected at:

- S1: - 0/+ DAA - potato tubers
- S2: 7 $\pm$ 1 DAA - potato tubers
- S3: 14 $\pm$ 1 DAA - potato tubers
- S4: 14 $\pm$ 1 DBH - potato tubers
- S5: CH/BBCH 89 - potato tubers

In HS trial RAC specimens for analyses were collected at S1: CH/BBCH 89 - potato tubers.

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site.

RAC specimens were put in deep freezing conditions at a target temperature of  $\leq -18^{\circ}\text{C}$  on the day of sampling, within 12 hours after sampling.

All specimens remained deep frozen during storage at the test site, during shipment to the laboratory.

#### Analytical Phase of the study:

Method of determination by LC-MS/MS fulfils the requirements as defined in EC Guidance document on residue analytical methods (SANTE/2020/12830 Rev.2) and is applicable as enforcement and data generation method for determination of Acetamiprid (Sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid) in oilseed rape after one application of Acetamipryd 200 SL.

LOD = 0.001 mg/kg for acetamiprid; LOD = 0.001 mg/kg for N-desmethyl-acetamiprid,

LOQ = 0.005 mg/kg for acetamiprid; LOQ = 0.005 mg/kg for N-desmethyl-acetamiprid,

LOQ = 0.01 mg/kg for sum of acetamiprid and N-desmethyl-acetamiprid.

Details are described in dRR Part B Section 5 (VAL/11/2023).

#### **Conclusion**

Residues of acetamiprid and acetamiprid-N-desmethyl (IM-2-1) were not detected in any of the untreated samples.

Residue concentrations of acetamiprid detected in analysed field samples are in the table below.

Acetamipryd 200 SL  
Part B – Section 7 - Core Assessment  
Applicant version

**Table A 16: Summary of the study 23SGS20 (4 trials)**

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 treat- ments and last date	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)			PHI or DALA (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	L (f. p./ha)				Acetam- iprid	Acetam- iprid- N- desmethyl (IM-2-1)	Sum of Acet- amiprid and Acetam- iprid- N-desmethyl (IM-2-1)		
(a)	(b)	(b)				(c)						(d)	(e)
Harvest Study Study Trial 23SGS20 -01 / Po- land, Kolonia Bodzanowska (87- 702) / N-EU / 2023	Potato / Eu- rostarch	1- 10.04.2023 2- 20.06.2023 -12.07.2023 3-29.09.2023	0.0246	306.7	0.123	28.08.2023	75	Potato Tubers	<LOD	<LOD	<LOD	harvest	Method: LC-MS/MS  LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl LOD = 0.001 mg/kg
Harvest Study Study Trial 23SGS20 -02 / Po- land, Watkowo (06-420) / N-EU / 2023	Potato / Laskara	1- 12.04.2023 2- 30.06.2023 -15.07.2023 3-11.09.2023	0.0246	307.3	0.123	10.08.2023	75	Potato Tubers	<LOD	<LOD	<LOD	harvest	Method: LC-MS/MS  LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl LOD = 0.001 mg/kg
Decline Study Study Trial 23SGS20 -03 / Po- land, Cerekwica (88-400) / N-EU / 2023	Potato / Skawa	1- 16.04.2023 2- 15.06.2023 - 08.07.2023 3-27.09.2023	0.0238	297.3	0.119	23.08.2023	75	Potato Tubers Potato Tubers Potato Tubers Potato Tubers Potato Tubers	<LOD <LOD <LOD <LOD <LOD	<LOD <LOD <LOD <LOD <LOD	<LOD <LOD <LOD <LOD <LOD	0 DAA 7 DAA 14 DAA 14 DBH harvest	Method: LC-MS/MS  LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl

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													LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl LOD = 0.001 mg/kg
Decline Study Study Trial 23SGS20 -04 / Poland, Piskorzówek (55-216) / N-EU / 2023	Potato / Vineta	1- 26.04.2023 2- 22.06.2023 - 03.07.2023 3-14.09.2023	0.0234	388.9	0.117	10.08.2023	75	Potato Tubers Potato Tubers Potato Tubers Potato Tubers	<LOD <LOD <LOD <LOD <u>&lt;LOD</u>	<LOD <LOD <LOD <LOD <LOD	<LOD <LOD <LOD <LOD <LOD	0 DAA 7 DAA 14 DAA 14 DBH harvest	Method: LC-MS/MS  LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N-desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl LOD = 0.001 mg/kg

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

#### **A 2.1.4 Magnitude of residues in livestock**

##### **A 2.1.4.1 Livestock feeding studies**

No new data submitted in the framework of this application.

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

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

No new data submitted in the framework of this application.

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

No new data submitted in the framework of this application.

#### **A 2.1.6 Magnitude of residues in representative succeeding crops**

No new data submitted in the framework of this application.

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

##### **A 2.1.7.1 Residues in Honey**

##### **A 2.1.7.1.1 Study 1**

Comments of Evaluator:	Study is accepted
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Reference:	KCA 6.10, 6.10.1/01
Report	Determination of Acetamiprid residues in Honey Following Application on Winter Oilseed Rape with Piorun 200 SL under semi field Conditions in Northern and Southern Europe in 2023; Lefebvre C., 2023; report no. C2051
Guideline(s):	<p>Yes</p> <p><i>OECD Series on Principles of GLP and Compliance Monitoring:</i></p> <p>Number 1, OECD Principles on Good Laboratory Practice (as revised in 1997) (ENV/MC/CHEM(98)17)</p> <p>Number 6, The Application of the GLP Principles to Field Studies (ENV/JM/MONO(99)22)</p> <p>Number 13, The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies (ENV/JM/MONO(2002)9)</p>

*National GLP reference guideline(s):*

Article Annexe II à l'Article D523-8 du Code de l'Environnement (France)  
 Rozporządzenie Ministra Zdrowia z dnia 3 sierpnia 2021 r. w sprawie Dobrej Praktyki Laboratoryjnej i wykonywania badań zgodnie z zasadami Dobrej Praktyki Laboratoryjnej - Poz. 1422 (Poland)  
 Decreto legislativo 2 marzo 2007, n°50 (Italy)

*General*

Regulation (EC) No. 1107/2009  
 Regulation (EU) No. 283/2013 and 284/2013  
 2004/10/EC GLP Directive

*Field*

OECD – guideline for the testing of chemicals, 509; Crop field trial, 14/06/2021

SANTE/11956/2016 rev.9 – Technical Guidelines for determining the magnitude of pesticide residue in honey and setting maximum Residue Levels in honey.

Guideline 1607/VI/97 rev.2 to Directive 91/414/EEC and Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009, under consideration of the provisions of the Afssa saisine No 2007-SA-0209 – Document guide de fixation de LMR pour le miel.

*Analytics*

SANTE/2020/12830 Rev.2, 14/02/2023 - Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes

OECD series on testing and assessment No. 72 and series on pesticides No. 39.

Deviations:

Yes

**Deviation No. 27/04/2023**

Trial C2051 EF1:

The weight of spare honey sample for the untreated tunnel was 57.45 g instead of minimum 100 g required by the Study Plan.

The production of honey was lower in the untreated tunnel than the treated tunnel for an unknown reason.

This deviation has no impact as the specimen is still representative of the plot. Moreover, spare specimen was not analysed.

**Deviation No. 12/05/2023-1**

Trial C2051 MA1:

The thermo-hygrometer data logger was started on the day of the first application instead of on the day the hives were installed in the tunnels.

This was due to a mistake of the Principal Investigator.

This deviation has no impact as only one day of temperature and humidity data is missing and it is only weather data.

**Deviation No. 12/05/2023-2**

Trial C2051 IT1:

The weight of specimen C2051 IT1 / TH / R is 79.09 g instead of min. 100 g as required by the Study Plan.

Due to mortality of the bees in treated tunnel the honey production was lower than expected.

This deviation has no impact as the spare specimen is still representative of the plot and was not analysed.

**Deviation No. 22/05/2023-2**

**Trial C2051 MA1:**

The weight of specimen C2051 MA1 / UH / R was 96.68 g instead of minimum 100 g as required by the Study Plan.

The amount of honey on sampled frames was not sufficient.

This deviation has no impact as the specimen still representative of the plot (residue is not impacted) and the spare specimen was not analysed.

**Deviation No. 23/05/2023****Trial C2051 MA1:**

The untreated hive contained 5 food frames (honey and pollen) and treated hive contained 4 food frames instead of 1 to 3 food frames required by the Study Plan. The Principal Investigator adapted the composition of the hives upon the requests from the beekeeper.

This deviation has no impact as it did not affect the honey production and the residue level in honey specimens.

**Deviation No. 27/09/2023****Trial C2051 IT1:**

The thermo-hygrometer data logger was started on the day of the first application instead of on the day the hives were installed in the tunnels.

This was due to a mistake of the Principal Investigator.

This deviation has no impact as only one day of temperature and humidity data is missing and it is only weather data.

**Deviation No. 18/10/2023-1****Trial C2051 IT1:**

For organizational reason, the specimens were shipped within 11 days after sampling, whereas the Study Plan required that specimens be shipped no later than one week after sampling.

This deviation has no impact on the study as the delay of 30 days between sampling and analysis was respected.

GLP: Yes

Acceptability: Yes

**Materials and methods****Field Phase of the study:**

The objective of the study was to determine the residue levels of acetamiprid and its metabolite acetamiprid-N-desmethyl (IM-2-1) in honey from bees foraging on winter oilseed rape following one application of the formulated product Piorun 200 SL (200 g acetamiprid/L), under semi-field conditions in Northern and Southern Europe in 2023.

The study consisted of 2 phases: the field phase, and the analytical phase. The study was conducted under semi-field conditions in Northern Europe and in Southern Europe.

On each site, 2 tunnels covered with anti-insect nets were used. Winter oilseed rape was grown under both tunnels. At flowering stage (BBCH 65) one tunnel was treated with Piorun 200 SL at the rate of 0.25 L product/ha (50 g acetamiprid/ha) in 300-400 L/ha water. The second tunnel remained untreated.

At flowering stage, one honeybee colony was installed under each tunnel and bees foraging was restricted to the tunnels. Honey was sampled (at commercial maturity), and the residue level of acetamiprid and acetamiprid-N-desmethyl (IM-2-1) were analysed in the samples.

Specimens were directly transported after sampling to the laboratory freezers (16 rue Ampère, 67500 Haguenau). No storage at the field station.

**Analytical Phase of the study:**

The objectives of the analytical phase were to validate the analysis of acetamiprid-N-desmethyl (IM-2-1)



in honey and to determine residue levels of acetamiprid and its metabolite acetamiprid-N-desmethyl (IM-2-1) expressed as acetamiprid in honey specimens generated during the field phase.

Samples were analysed within 30 days after sampling.

Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.005 mg/kg for acetamiprid and 0.005 mg/kg for N-desmethyl-acetamiprid (IM-2-1). LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl (IM-2-1).

The stability of the analytes in the final extracts was sufficiently proven according to the SANTE/2020/12830, Rev.2 guideline, as mean recoveries in the fortified samples were within the range 70-120%, measured against freshly prepared standards. Details are described in dRR Part B Section 5.

## Conclusion

Residues in control samples were non-detectable or below the LOQ. The residue results for acetamiprid and its metabolite acetamiprid-N-desmethyl in the treated specimens are summarized below.

One result from trial number C2051 PL1 significantly exceeds the other results (trials: C2051 MA1, C2051 EF1, C2051 IT1).

Regarding above trial C2051 PL1 was repeated in 2024, in the same location and on the same variety of crop plant. The new trial result (C4055 PL1) shows a level consistent with the trials C2051 MA1, C2051 EF1 and C2051 IT1, therefore trial number C2051 PL1 should be treated as a deviation and should not be taken into account. Thus, trial C2051 PL1 was not included.

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**Table A 17: Summary of the study C2051 (3 trials)**

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treat- ment or date	Portion ana- lysed	Residues (mg/kg)			DAA (days)	Details on trial
			g a.s./ ha	Water (l/ha)	kg a.s./hl				Acetam- iprid	N- desmethyl- acetamiprid (IM-2-1)	Sum of acetamiprid and N- desmethyl- acetamiprid		
(a)	(b)	(b)				(c)						(d)	(e)
Trial number C2051 MA1 / France, Donnelay (57810) / N-EU / 2023	Oilseed rape/ Memori CS Protect	1. 20.09.2022 2. 28.04.2023- 25.05.2023 3. n.a.	50.5	404	12.5	06/05/2023	65	Honey	<LOQ	NDR	<LOQ	16	Method: LC-MS/MS  LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl LOD = 0.0015 mg/kg
Trial number C2051 EF1 / France, La- landusse (47330) / S-EU / 2023	Oilseed rape/ Memori CS + ES Alicia	1. 08.09.2022 2. 27.04.2023- 03.05.2023 3. n.a.	47.4	285	16.7	04/04/2023	65	Honey	NDR	NDR	<LOD	23	Method: LC-MS/MS  LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl LOD = 0.0015 mg/kg
Trial number C2051 IT1 / Italy, Tortona (15057) / S-EU / 2023	Oilseed rape/ PX125CL	1. 03.11.2022 2. 10.04.2023- 09.05.2023 3. n.a.	50.4	404	12.5	06/05/2023	65	Honey	<LOQ	NDR	<LOQ	23	Method: LC-MS/MS  LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl LOD = 0.0015 mg/kg

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- (b) Only if relevant
  - (c) Year must be indicated
  - (d) Days after last application (Label pre-harvest interval, PHI, underline)
  - (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
- NDR: No detectable residues (residues below the LOD)

**A 2.1.7.1.2      Study 2**

Comments of Evaluator:	Study is accepted
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Reference:	KCA 6.10, 6.10.1/02
Report	Determination of Acetamiprid and its metabolite Acetamiprid-N-desmethyl Residues in Honey Following Application on Winter Oilseed Rape with Piorun 200 SL under semi field Conditions in Northern Europe in 2024; Schneider E., 2024; report no. R C4055
Guideline(s):	<p>Yes</p> <p><i>OECD Series on Principles of GLP and Compliance Monitoring:</i></p> <p>Number 1, OECD Principles on Good Laboratory Practice (as revised in 1997) (ENV/MC/CHEM(98)17)</p> <p>Number 6, The Application of the GLP Principles to Field Studies (ENV/JM/MONO(99)22)</p> <p>Number 13, The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies (ENV/JM/MONO(2002)9)</p> <p><i>National GLP reference guideline(s):</i></p> <p>Article Annexe II à l'Article D523-8 du Code de l'Environnement (France)</p> <p>Rozporządzenie Ministra Zdrowia z dnia 3 sierpnia 2021 r. w sprawie Dobrej Praktyki Laboratoryjnej i wykonywania badań zgodnie z zasadami Dobrej Praktyki Laboratoryjnej - Poz. 1422 (Poland)</p> <p>Decreto legislativo 2 marzo 2007, n°50 (Italy)</p> <p><i>General</i></p> <p>Regulation (EC) No. 1107/2009</p> <p>Regulation (EU) No. 283/2013 and 284/2013</p> <p>2004/10/EC GLP Directive</p> <p><i>Field</i></p> <p>OECD – guideline for the testing of chemicals, 509; Crop field trial, 14/06/2021</p> <p>SANTE/11956/2016 rev.9 – Technical Guidelines for determining the magnitude of pesticide residue in honey and setting maximum Residue Levels in honey.</p> <p>Guideline 1607/VI/97 rev.2 to Directive 91/414/EEC and Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC)1107/2009, under consideration of the provisions of the Afssa saisine No 2007-SA-0209 – Document guide de fixation de LMR pour le miel.</p> <p><i>Analytics</i></p> <p>SANTE/2020/12830 Rev.2, 14/02/2023 - Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes</p> <p>OECD series on testing and assessment No. 72 and series on pesticides No. 39.</p>
Deviations:	<p>Yes</p> <p><b>Deviation No. 25/04/2024</b></p> <p>1. The honeybee colonies were brought in the tunnels site 2 days before the application instead of bring the honeybee colonies in the tunnels site the day before the application.</p>

2. The application was performed between 12h00 and 12h05 instead of before noon required by the study plan.

1. The weather was very bad the day after that the honeybee colonies were brought in the tunnels site at the crop, consequently the application was postponed.

2. Result of weather conditions, low temperature of about 4 °C and heavy cloud cover around 10 a.m. and minor problems.

1. The deviation has no impact on the study as the bees were not active and there was even a loss of supplies from the food frames, so if anything flew out of the hive, it was just a single bee. Moreover bees need an acclimatization period after they were brought in the tunnels site.

2. The deviation has no impact on the study as due to low temperature no bees were outside of hive and the hive of the treated tunnel were protected during the application.

**Deviation No. 15/05/2024**

The weight of specimen C4055 PL1 / UH / R was 60.13 g instead of minimum 100 g as required by the Study Plan.

The amount of honey on sampled frames was not sufficient.

The deviation has no impact on the study as the specimen is still representative of the plot (residue is not impacted). Moreover the spare specimen was not analysed.

**Deviation No. 25/10/2024**

The analytical samples C4055 PL1 / UH / A and C4055 PL1 / TH / A were sent within 11 days after sampling instead of as soon as possible (maximum 1 week after sampling) mentioned in the study plan.

Error of the field technician.

The deviation has no impact on the study as the samples were analysed within 30 days from sampling as required by the study plan.

GLP: Yes

Acceptability: Yes

## Materials and methods

### Field Phase of the study:

The objective of the study was to determine the residue levels of acetamiprid and its metabolite acetamiprid-N-desmethyl (IM-2-1) in honey from bees foraging on winter oilseed rape following one application of the formulated product Piorun 200 SL (200 g acetamiprid/L), under semi-field conditions in Northern Europe in 2024.

The study consisted of 2 phases: the field phase, and the analytical phase. The study was conducted under semi-field conditions at one site in Northern Europe (Poland).

2 tunnels covered with anti-insect nets were used. Winter oilseed rape was grown under both tunnels. At flowering stage (BBCH 65) one tunnel was treated with Piorun 200 SL at the rate of 0.25 L product/ha (50 g acetamiprid/ha) in 400 L/ha water. The second tunnel remained untreated.

At flowering stage, one honeybee colony was installed under each tunnel and bees foraging was restricted to the tunnels. Honey was sampled (at commercial maturity), and the residue level of acetamiprid and acetamiprid-N-desmethyl (IM-2-1) were analysed in the samples.

### Analytical Phase of the study:

The objective of the analytical phase was to determine residue levels of acetamiprid and its metabolite

acetamiprid-N-desmethyl (IM-2-1) expressed as acetamiprid in honey specimens generated during the field phase. Samples were analysed within 30 days after sampling.

The method was validated by ANADIAG study No C2051 entitled: “Determination of Acetamiprid Residues in Honey Following Application on Winter Oilseed Rape with Piorun 200 SL under semi field Conditions in Northern and Southern Europe in 2023”.

Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.005 mg/kg for acetamiprid and 0.005 mg/kg for N-desmethyl-acetamiprid (IM-2-1). LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl (IM-2-1).

The stability of the analytes in the final extracts was sufficiently proven according to the SANTE/2020/12830, Rev.2 guideline, as mean recoveries in the fortified samples were within the range 70-120%, measured against freshly prepared standards. Details are described in dRR Part B Section 5.

## Conclusion

Residues in control samples were non-detectable or below the LOQ. The residue results for acetamiprid and its metabolite acetamiprid-N-desmethyl in the treated specimens are summarized below.

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**Table A 18: Summary of the study R C4055 (1 trial)**

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treat- ment or date	Portion analysed	Residues (mg/kg)			DAA (days)	Details on trial
			g a.s./ ha	Water (l/ha)	kg a.s./hl				Acetam- iprid	N- desmethyl- acetamiprid (IM-2-1)	Sum of acetamiprid and N- desmethyl- acetamiprid		
(a)	(a)	(b)				(c)						(d)	(e)
Trial number C4055 PL1 / Po- land, Góra Świę- tej Małgorzaty (99-122) / N-EU / 2024	Oilseed rape/ Chrobry	1. 12.09.2023 2. 09.04.2024- 03.05.2024 3. n.a.	51.5	412	12.5	23/05/2024	65	Honey	0.02	NDR	<u>0.02</u>	10	Method: LC-MS/MS  LOQ = 0.005 mg/kg for ac- etamiprid; LOQ= 0.005 mg/kg for acetamiprid-N- desmethyl LOQ = 0.01 mg/kg for sum of acetamiprid and acetam- iprid-N-desmethyl LOD = 0.0015 mg/kg

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)


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

NDR: No detectable residues (residues below the LOD)

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## Appendix 3 Pesticide Residue Intake Model (PRIMo)


### A 3.1 TMDI calculations – SCENARIO 1

 <p>European Food Safety Authority</p> <p>EFSA PRIMo revision 3.1; 2021/01/06</p>		<b>acetamiprid</b>				Input values					
		LOQs (mg/kg) range from: 0,01 to: 0,10				Details - chronic risk assessment Supplementary results - chronic risk assessment					
		<b>Toxicological reference values</b>									
		ADI (mg/kg bw/day): 0,005		ARID (mg/kg bw): 0,005		Details - acute risk assessment/children Details - acute risk assessment/adults					
Source of ADI: RR		Source of ARID: RR									
Year of evaluation: 2024		Year of evaluation: 2024									
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IED/TMDI)											
			No of diets exceeding the ADI : 25								
TMDI/IED/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	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	MRIs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
	679%	NL toddler	33,97	239%	Milk: Cattle	104%	Apples	52%	Bananas	5%	169%
	454%	DE child	22,72	121%	Apples	88%	Oranges	79%	Milk: Cattle	3%	156%
	359%	NL child	17,95	98%	Milk: Cattle	56%	Apples	31%	Oranges	4%	82%
	298%	FR child 3 15 yr	14,89	91%	Milk: Cattle	74%	Oranges	16%	Apples	3%	32%
	282%	FR toddler 2 3 yr	14,10	117%	Milk: Cattle	31%	Oranges	31%	Apples	3%	40%
	269%	UK infant	13,46	155%	Milk: Cattle	28%	Oranges	15%	Apples	2%	25%
	266%	ES child	13,30	50%	Milk: Cattle	47%	Oranges	44%	Olives for oil production	2%	33%
	235%	GEMS/Food G08	11,74	49%	Olives for oil production	22%	Milk: Cattle	20%	Swine: Muscle/meat	3%	35%
	227%	GEMS/Food G07	11,33	30%	Oranges	26%	Milk: Cattle	18%	Wine grapes	3%	31%
	226%	SE general	11,30	50%	Milk: Cattle	44%	Bovine: Muscle/meat	17%	Bananas	2%	26%
	223%	UK toddler	11,15	83%	Milk: Cattle	43%	Oranges	17%	Apples	2%	27%
	221%	GEMS/Food G06	11,05	43%	Tomatoes	22%	Olives for oil production	22%	Oranges	3%	64%
	212%	DE women 14-50 yr	10,61	50%	Milk: Cattle	42%	Oranges	25%	Apples	2%	41%
	207%	GEMS/Food G10	10,37	25%	Oranges	23%	Olives for oil production	22%	Milk: Cattle	3%	32%
	199%	DE general	9,96	49%	Milk: Cattle	34%	Oranges	23%	Apples	2%	38%
	196%	GEMS/Food G11	9,79	31%	Milk: Cattle	16%	Oranges	15%	Apples	4%	31%
	194%	GEMS/Food G15	9,71	28%	Milk: Cattle	15%	Oranges	14%	Tomatoes	3%	39%
	191%	IE adult	9,55	23%	Oranges	17%	Milk: Cattle	15%	Grapefruits	3%	20%
	183%	DK child	9,15	51%	Milk: Cattle	22%	Apples	22%	Swine: Muscle/meat	3%	38%
	182%	RO general	9,08	46%	Milk: Cattle	23%	Tomatoes	20%	Wine grapes	2%	49%
	174%	ES adult	8,68	28%	Oranges	25%	Olives for oil production	23%	Lettuces	1,0%	24%
	152%	NL general	7,59	34%	Milk: Cattle	22%	Oranges	14%	Apples	2%	25%
	134%	FR infant	6,71	67%	Milk: Cattle	16%	Apples	6%	Beans (with pods)	1%	20%
	123%	FR adult	6,15	28%	Wine grapes	18%	Milk: Cattle	13%	Oranges	2%	16%
	122%	PT general	6,09	30%	Wine grapes	15%	Olives for oil production	13%	Oranges	2%	29%
	99%	IT toddler	4,97	17%	Tomatoes	13%	Wheat	13%	Lettuces	0,7%	34%
	97%	DK adult	4,83	21%	Milk: Cattle	12%	Wine grapes	9%	Apples	0,8%	20%
	89%	FI 3 yr	4,47	13%	Bananas	9%	Apples	9%	Raspberries (red and yellow)	2%	20%
	89%	UK vegetarian	4,44	19%	Oranges	13%	Milk: Cattle	10%	Wine grapes	0,8%	15%
	88%	IT adult	4,42	16%	Lettuces	14%	Tomatoes	8%	Wheat	0,4%	28%
	79%	UK adult	3,95	13%	Wine grapes	12%	Oranges	12%	Milk: Cattle	0,9%	11%
	76%	LT adult	3,82	18%	Apples	16%	Milk: Cattle	10%	Swine: Muscle/meat	1%	29%
	66%	FI 6 yr	3,30	8%	Bananas	7%	Mandarins	6%	Raspberries (red and yellow)	2%	15%
	58%	FI adult	2,90	9%	Oranges	7%	Tomatoes	6%	Lettuces	6%	14%
	57%	PL general	2,87	20%	Apples	11%	Tomatoes	4%	Table grapes	0,9%	38%
34%	IE child	1,70	14%	Milk: Cattle	3%	Apples	2%	Wheat	0,4%	5%	
<b>Conclusion:</b> The estimated TMDI/IED/IEDI was in the range of 0 % to 679,4 % of the ADI. For 25 diet(s) the ADI is exceeded. DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.											



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### A 3.2 IEDI calculations – SCENARIO 2

 European Food Safety Authority EFSA PRIMo revision 3.1; 2021/01/06		acetamiprid				Input values					
		LOQs (mg/kg) range from: 0,01 to: 0,10				Details - chronic risk assessment		Supplementary results - chronic risk assessment			
		Toxicological reference values									
		ADI (mg/kg bw/day): 0,005		ARID (mg/kg bw): 0,005		Details - acute risk assessment/children		Details - acute risk assessment/adults			
Source of ADI: RR		Source of ARID: RR									
Year of evaluation: 2024		Year of evaluation: 2024									
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
No of diets exceeding the ADI : 23											
TMDI/NEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities under assessment (in % of ADI)
	417%	NL toddler	20,84	239%	Milk: Cattle	49%	Oranges	18%	Apples	5%	37%
	269%	DE child	13,44	88%	Oranges	79%	Milk: Cattle	21%	Apples	3%	33%
	248%	FR child 3 15 yr	12,38	91%	Milk: Cattle	74%	Oranges	15%	Bovine: Muscle/meat	3%	6%
	230%	FR toddler 2 3 yr	11,52	117%	Milk: Cattle	31%	Oranges	17%	Mandarins	3%	7%
	226%	NL child	11,32	98%	Milk: Cattle	31%	Oranges	14%	Mandarins	4%	19%
	221%	UK infant	11,06	155%	Milk: Cattle	28%	Oranges	12%	Bovine: Muscle/meat	2%	6%
	203%	ES child	10,14	50%	Milk: Cattle	47%	Oranges	44%	Olives for oil production	2%	7%
	172%	UK toddler	8,62	83%	Milk: Cattle	43%	Oranges	13%	Bovine: Muscle/meat	2%	5%
	162%	GEMS/Food G08	8,11	49%	Olives for oil production	22%	Milk: Cattle	20%	Swine: Muscle/meat	3%	10%
	154%	GEMS/Food G07	7,70	30%	Oranges	26%	Milk: Cattle	18%	Olives for oil production	3%	10%
	152%	SE general	7,61	50%	Milk: Cattle	44%	Bovine: Muscle/meat	16%	Oranges	2%	6%
	146%	DE women 14-50 yr	7,32	50%	Milk: Cattle	42%	Oranges	9%	Swine: Muscle/meat	2%	9%
	143%	GEMS/Food G10	7,15	25%	Oranges	23%	Olives for oil production	22%	Milk: Cattle	3%	8%
	139%	DE general	6,93	49%	Milk: Cattle	34%	Oranges	11%	Swine: Muscle/meat	2%	8%
	137%	GEMS/Food G11	6,86	31%	Milk: Cattle	16%	Oranges	14%	Olives for oil production	4%	6%
	131%	GEMS/Food G06	6,54	22%	Olives for oil production	22%	Oranges	14%	Wheat	3%	13%
	128%	IE adult	6,41	23%	Oranges	17%	Milk: Cattle	15%	Grapefruits	3%	6%
	126%	GEMS/Food G15	6,32	28%	Milk: Cattle	15%	Oranges	14%	Swine: Muscle/meat	3%	11%
	120%	DK child	6,00	51%	Milk: Cattle	22%	Swine: Muscle/meat	13%	Bovine: Muscle/meat	3%	7%
	115%	ES adult	5,73	28%	Oranges	25%	Olives for oil production	20%	Milk: Cattle	1,0%	5%
	104%	NL general	5,22	34%	Milk: Cattle	22%	Oranges	10%	Swine: Muscle/meat	2%	7%
	104%	RO general	5,20	46%	Milk: Cattle	12%	Swine: Muscle/meat	10%	Wheat	2%	11%
	103%	FR infant	5,17	67%	Milk: Cattle	6%	Beans (with pods)	5%	Oranges	1%	4%
	77%	FR adult	3,83	18%	Milk: Cattle	13%	Oranges	7%	Swine: Muscle/meat	2%	3%
	59%	PT general	2,94	15%	Olives for oil production	13%	Oranges	8%	Wheat	2%	6%
	56%	DK adult	2,81	21%	Milk: Cattle	9%	Swine: Muscle/meat	5%	Bovine: Muscle/meat	0,8%	3%
	51%	UK vegetarian	2,54	19%	Oranges	13%	Milk: Cattle	4%	Wheat	0,8%	3%
	46%	IT toddler	2,30	13%	Wheat	10%	Oranges	5%	Mandarins	0,7%	7%
	46%	UK adult	2,29	12%	Oranges	12%	Milk: Cattle	7%	Bovine: Muscle/meat	0,9%	2%
	42%	LT adult	2,09	16%	Milk: Cattle	10%	Swine: Muscle/meat	3%	Apples	1%	6%
	37%	IT adult	1,85	8%	Wheat	8%	Oranges	4%	Mandarins	0,4%	6%
	35%	FI 3 yr	1,77	8%	Mandarins	4%	Strawberries	3%	Oranges	2%	5%
	27%	FI 6 yr	1,36	7%	Mandarins	3%	Strawberries	3%	Oranges	2%	4%
	26%	FI adult	1,30	9%	Oranges	6%	Coffee beans	3%	Mandarins	6%	2%
	25%	IE child	1,24	14%	Milk: Cattle	2%	Wheat	2%	Oranges	0,4%	1,0%
15%	PL general	0,76	3%	Apples	2%	Cherries (sweet)	1%	Lemons	0,9%	8%	
<b>Conclusion:</b> The estimated TMDI/NEDI/IEDI was in the range of 0 % to 416,9 % of the ADI. For 23 diet(s) the ADI is exceeded. DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.											

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### A 3.3 IEDI calculations – SCENARIO 3



acetamiprid			
LOQs (mg/kg) range from:		0,01	to: 0,10
Toxicological reference values			
ADI (mg/kg bw/day):		0,005	ARID (mg/kg bw): 0,005
Source of ADI:		RR	Source of ARID: RR
Year of evaluation:		2024	Year of evaluation: 2024

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

Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
No of diets exceeding the ADI : ---						Exposure resulting from					
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	64%	NL toddler	3,21	24%	Milk: Cattle	10%	Beans (with pods)	6%	Apples	4%	10%
	33%	DE child	1,65	8%	Milk: Cattle	7%	Apples	2%	Cherries (sweet)	2%	10%
	32%	NL child	1,60	10%	Milk: Cattle	4%	Beans (with pods)	3%	Apples	3%	5%
	32%	FR toddler 2 3 yr	1,59	12%	Milk: Cattle	9%	Beans (with pods)	2%	Apples	2%	2%
	32%	GEMS/Food G08	1,58	16%	Olives for oil production	2%	Milk: Cattle	1%	Lamb's lettuce/corn salads	2%	3%
	31%	ES child	1,55	14%	Olives for oil production	5%	Milk: Cattle	3%	Beans (with pods)	2%	2%
	30%	FR child 3 15 yr	1,48	9%	Milk: Cattle	6%	Beans (with pods)	2%	Olives for oil production	3%	2%
	27%	UK infant	1,35	15%	Milk: Cattle	3%	Peas (without pods)	0,8%	Apples	2%	2%
	24%	GEMS/Food G10	1,20	7%	Olives for oil production	2%	Milk: Cattle	2%	Cress and other sprouts and shod	3%	2%
	24%	GEMS/Food G07	1,18	6%	Olives for oil production	3%	Milk: Cattle	2%	Peas (with pods)	2%	2%
	23%	GEMS/Food G06	1,17	7%	Olives for oil production	1%	Wheat	1,0%	Milk: Cattle	2%	3%
	23%	IE adult	1,16	3%	Other farmed animals: Muscle/meat	2%	Sheep: Edible offals (other than liver an	2%	Beans (with pods)	2%	2%
	22%	GEMS/Food G11	1,08	5%	Olives for oil production	3%	Milk: Cattle	2%	Beans (without pods)	3%	2%
	20%	GEMS/Food G15	1,01	4%	Olives for oil production	3%	Milk: Cattle	1%	Rose hips	2%	3%
	19%	ES adult	0,97	8%	Olives for oil production	3%	Beans (with pods)	2%	Milk: Cattle	0,8%	2%
	18%	UK toddler	0,92	8%	Milk: Cattle	2%	Peas (without pods)	0,9%	Apples	2%	2%
	18%	FR infant	0,89	7%	Milk: Cattle	6%	Beans (with pods)	0,9%	Apples	0,9%	1%
	17%	SE general	0,87	5%	Milk: Cattle	2%	Bovine: Muscle/meat	1,0%	Beans (with pods)	1,0%	2%
	17%	DE women 14-50 yr	0,85	5%	Milk: Cattle	2%	Olives for oil production	1%	Apples	2%	3%
	17%	DE general	0,83	5%	Milk: Cattle	2%	Olives for oil production	1%	Apples	2%	3%
	15%	RO general	0,75	5%	Milk: Cattle	1%	Beans (with pods)	1%	Wheat	1%	4%
	15%	NL general	0,73	3%	Milk: Cattle	3%	Beans (with pods)	0,8%	Apples	2%	2%
	14%	DK child	0,71	5%	Milk: Cattle	1%	Apples	1%	Rye	2%	3%
	14%	PT general	0,70	5%	Olives for oil production	2%	Beans (without pods)	1%	Wine grapes	0,6%	2%
	14%	FR adult	0,68	3%	Beans (with pods)	2%	Milk: Cattle	1%	Olives for oil production	1%	1,0%
	8%	FI adult	0,42	6%	Coffee beans	0,3%	Strawberries	0,3%	Apples	6%	0,8%
	8%	FI 3 yr	0,40	0,9%	Potatoes	0,9%	Strawberries	0,8%	Raspberries (red and yellow)	0,8%	2%
	8%	IT toddler	0,38	1%	Wheat	1%	Beans (with pods)	0,6%	Peas (without pods)	0,5%	2%
	7%	IT adult	0,36	2%	Beans (with pods)	0,8%	Wheat	0,4%	Apples	0,3%	2%
	7%	DK adult	0,35	2%	Milk: Cattle	0,7%	Peas (without pods)	0,5%	Apples	0,5%	1%
	6%	UK vegetarian	0,31	1%	Milk: Cattle	0,8%	Peas (without pods)	0,4%	Wheat	0,5%	1,0%
	6%	LT adult	0,30	2%	Milk: Cattle	1%	Apples	0,6%	Potatoes	0,6%	2%
	6%	FI 6 yr	0,29	0,8%	Potatoes	0,7%	Strawberries	0,6%	Raspberries (red and yellow)	0,8%	1%
	6%	UK adult	0,28	1%	Milk: Cattle	0,8%	Peas (without pods)	0,5%	Wine grapes	0,7%	0,7%
	4%	PL general	0,22	1%	Apples	0,7%	Potatoes	0,5%	Cherries (sweet)	0,2%	3%
	4%	IE child	0,18	1%	Milk: Cattle	0,6%	Beans (without pods)	0,2%	Wheat	0,3%	0,4%
<b>Conclusion:</b> The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of acetamiprid is unlikely to present a public health concern. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.											

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## A 3.4 Raw and processed commodities – SCENARIO 1

Acute risk assessment /children				Acute risk assessment / adults / general population																																																																																																																												
Details - acute risk assessment /children				Details - acute risk assessment/adults																																																																																																																												
<p>The acute risk assessment is based on the ARID. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the EU.</p> <p>The calculation is based on the large portion of the most critical consumer group.</p>																																																																																																																																
Show results of IESTI calculation only for crops with GAPs under assessment																																																																																																																																
Unprocessed commodities	<b>Results for children</b> No. of commodities for which ARID/ADI is exceeded (IESTI): 8				<b>Results for adults</b> No. of commodities for which ARID/ADI is exceeded (IESTI): 8																																																																																																																											
	<b>ESTI</b> <table border="1"> <thead> <tr> <th>Highest % of ARID/ADI</th> <th>Commodities</th> <th>MRL / input for RA (mg/kg)</th> <th>Exposure (µg/kg bw)</th> </tr> </thead> <tbody> <tr><td>1341%</td><td>Pears</td><td>0.4 / 0.48</td><td>67</td></tr> <tr><td>1043%</td><td>Apples</td><td>0.4 / 0.48</td><td>52</td></tr> <tr><td>704%</td><td>Tomatoes</td><td>0.5 / 0.61</td><td>35</td></tr> <tr><td>476%</td><td>Quinces</td><td>0.8 / 0.97</td><td>24</td></tr> <tr><td>444%</td><td>Cherries (sweet)</td><td>1.5 / 1.82</td><td>22</td></tr> <tr><td>432%</td><td>Sweet peppers/bell peppers</td><td>0.3 / 0.36</td><td>22</td></tr> <tr><td>268%</td><td>Medlar</td><td>0.8 / 0.97</td><td>13</td></tr> <tr><td>121%</td><td>Aubergines/egg plants</td><td>0.2 / 0.24</td><td>6.1</td></tr> <tr><td>31%</td><td>Potatoes</td><td>0.01 / 0.01</td><td>1.5</td></tr> <tr><td>31%</td><td>Plums</td><td>0.03 / 0.04</td><td>1.5</td></tr> <tr><td>11%</td><td>Rapeseeds/canola seeds</td><td>0.4 / 0.4</td><td>0.55</td></tr> <tr><td>6%</td><td>Walnuts</td><td>0.07 / 0.08</td><td>0.29</td></tr> <tr><td>6%</td><td>Hazelnuts/cobnuts</td><td>0.07 / 0.08</td><td>0.28</td></tr> <tr><td>4%</td><td>Honey and other apiculture products</td><td>0.05 / 0.05</td><td>0.18</td></tr> </tbody> </table>				Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	1341%	Pears	0.4 / 0.48	67	1043%	Apples	0.4 / 0.48	52	704%	Tomatoes	0.5 / 0.61	35	476%	Quinces	0.8 / 0.97	24	444%	Cherries (sweet)	1.5 / 1.82	22	432%	Sweet peppers/bell peppers	0.3 / 0.36	22	268%	Medlar	0.8 / 0.97	13	121%	Aubergines/egg plants	0.2 / 0.24	6.1	31%	Potatoes	0.01 / 0.01	1.5	31%	Plums	0.03 / 0.04	1.5	11%	Rapeseeds/canola seeds	0.4 / 0.4	0.55	6%	Walnuts	0.07 / 0.08	0.29	6%	Hazelnuts/cobnuts	0.07 / 0.08	0.28	4%	Honey and other apiculture products	0.05 / 0.05	0.18	<b>ESTI</b> <table border="1"> <thead> <tr> <th>Highest % of ARID/ADI</th> <th>Commodities</th> <th>MRL / input for RA (mg/kg)</th> <th>Exposure (µg/kg bw)</th> </tr> </thead> <tbody> <tr><td>363%</td><td>Cherries (sweet)</td><td>1.5 / 1.82</td><td>18</td></tr> <tr><td>296%</td><td>Pears</td><td>0.4 / 0.48</td><td>15</td></tr> <tr><td>294%</td><td>Quinces</td><td>0.8 / 0.97</td><td>15</td></tr> <tr><td>272%</td><td>Apples</td><td>0.4 / 0.48</td><td>14</td></tr> <tr><td>192%</td><td>Tomatoes</td><td>0.5 / 0.61</td><td>9.6</td></tr> <tr><td>133%</td><td>Medlar</td><td>0.8 / 0.97</td><td>6.6</td></tr> <tr><td>131%</td><td>Aubergines/egg plants</td><td>0.2 / 0.24</td><td>6.6</td></tr> <tr><td>118%</td><td>Sweet peppers/bell peppers</td><td>0.3 / 0.36</td><td>5.9</td></tr> <tr><td>13%</td><td>Plums</td><td>0.03 / 0.04</td><td>0.65</td></tr> <tr><td>6%</td><td>Potatoes</td><td>0.01 / 0.01</td><td>0.30</td></tr> <tr><td>4%</td><td>Rapeseeds/canola seeds</td><td>0.4 / 0.4</td><td>0.21</td></tr> <tr><td>4%</td><td>Walnuts</td><td>0.07 / 0.08</td><td>0.19</td></tr> <tr><td>2%</td><td>Hazelnuts/cobnuts</td><td>0.07 / 0.08</td><td>0.10</td></tr> <tr><td>1%</td><td>Honey and other apiculture products</td><td>0.05 / 0.05</td><td>0.07</td></tr> </tbody> </table>				Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	363%	Cherries (sweet)	1.5 / 1.82	18	296%	Pears	0.4 / 0.48	15	294%	Quinces	0.8 / 0.97	15	272%	Apples	0.4 / 0.48	14	192%	Tomatoes	0.5 / 0.61	9.6	133%	Medlar	0.8 / 0.97	6.6	131%	Aubergines/egg plants	0.2 / 0.24	6.6	118%	Sweet peppers/bell peppers	0.3 / 0.36	5.9	13%	Plums	0.03 / 0.04	0.65	6%	Potatoes	0.01 / 0.01	0.30	4%	Rapeseeds/canola seeds	0.4 / 0.4	0.21	4%	Walnuts	0.07 / 0.08	0.19	2%	Hazelnuts/cobnuts	0.07 / 0.08	0.10	1%	Honey and other apiculture products	0.05 / 0.05	0.07
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1%	Honey and other apiculture products	0.05 / 0.05	0.07																																																																																																																													
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	<b>ESTI</b> <table border="1"> <thead> <tr> <th>Highest % of ARID/ADI</th> <th>Processed commodities</th> <th>MRL / input for RA (mg/kg)</th> <th>Exposure (µg/kg bw)</th> </tr> </thead> <tbody> <tr><td>524%</td><td>Apples / juice</td><td>0.4 / 0.48</td><td>26</td></tr> <tr><td>315%</td><td>Pears / juice</td><td>0.4 / 0.48</td><td>16</td></tr> <tr><td>230%</td><td>Tomatoes / juice</td><td>0.5 / 0.61</td><td>12</td></tr> <tr><td>115%</td><td>Tomatoes / sauce/puree</td><td>0.5 / 0.61</td><td>5.8</td></tr> <tr><td>59%</td><td>Quinces / jam</td><td>0.8 / 0.97</td><td>2.9</td></tr> <tr><td>19%</td><td>Potatoes / fried</td><td>0.01 / 0.01</td><td>0.93</td></tr> <tr><td>12%</td><td>Potatoes / dried (flakes)</td><td>0.01 / 0.05</td><td>0.59</td></tr> <tr><td>7%</td><td>Plums / juice</td><td>0.03 / 0.04</td><td>0.34</td></tr> <tr><td>5%</td><td>Rapeseeds / oils</td><td>0.4 / 0.8</td><td>0.24</td></tr> </tbody> </table>				Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	524%	Apples / juice	0.4 / 0.48	26	315%	Pears / juice	0.4 / 0.48	16	230%	Tomatoes / juice	0.5 / 0.61	12	115%	Tomatoes / sauce/puree	0.5 / 0.61	5.8	59%	Quinces / jam	0.8 / 0.97	2.9	19%	Potatoes / fried	0.01 / 0.01	0.93	12%	Potatoes / dried (flakes)	0.01 / 0.05	0.59	7%	Plums / juice	0.03 / 0.04	0.34	5%	Rapeseeds / oils	0.4 / 0.8	0.24	<b>ESTI</b> <table border="1"> <thead> <tr> <th>Highest % of ARID/ADI</th> <th>Processed commodities</th> <th>MRL / input for RA (mg/kg)</th> <th>Exposure (µg/kg bw)</th> </tr> </thead> <tbody> <tr><td>323%</td><td>Apples / juice</td><td>0.4 / 0.48</td><td>16</td></tr> <tr><td>99%</td><td>Tomatoes / sauce/puree</td><td>0.5 / 0.61</td><td>5.0</td></tr> <tr><td>24%</td><td>Quinces / jam</td><td>0.8 / 0.97</td><td>1.2</td></tr> <tr><td>2%</td><td>Potatoes / chips</td><td>0.01 / 0.01</td><td>0.08</td></tr> <tr><td>1%</td><td>Potatoes / dried (flakes)</td><td>0.01 / 0.05</td><td>0.06</td></tr> </tbody> </table>				Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	323%	Apples / juice	0.4 / 0.48	16	99%	Tomatoes / sauce/puree	0.5 / 0.61	5.0	24%	Quinces / jam	0.8 / 0.97	1.2	2%	Potatoes / chips	0.01 / 0.01	0.08	1%	Potatoes / dried (flakes)	0.01 / 0.05	0.06																																																								
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Acetamipryd 200 SL  
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## A 3.5 Raw and processed commodities – SCENARIO 2

Acute risk assessment /children

Acute risk assessment / adults / general population

Details - acute risk assessment /children

Details - acute risk assessment/adults

The acute risk assessment is based on the ARID. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the EU. The calculation is based on the large portion of the most critical consumer group.

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

Unprocessed commodities

Results for children

No. of commodities for which ARID/ADI is exceeded (IESTI):

7

Results for adults

No. of commodities for which ARID/ADI is exceeded (IESTI):

3

IESTI

Highest % of ARID/ADI

Commodities

MRL / input for RA (mg/kg)

Exposure (µg/kg bw)

298%

Quinces

0.5 / 0.61

15

237%

Cherries (sweet)

0.8 / 0.97

12

235%

Pears

0.07 / 0.08

12

183%

Apples

0.07 / 0.08

9.1

130%

Sweet peppers/bell peppers

0.09 / 0.11

6.5

121%

Aubergines/egg plants

0.2 / 0.24

6.1

100%

Medlar

0.3 / 0.36

5.0

84%

Tomatoes

0.06 / 0.07

4.2

31%

Potatoes

0.01 / 0.01

1.5

31%

Plums

0.03 / 0.04

1.5

11%

Rapeseeds/canola seeds

0.4 / 0.4

0.55

6%

Walnuts

0.07 / 0.08

0.29

6%

Hazelnuts/cobnuts

0.07 / 0.08

0.28

4%

Honey and other apiculture products

0.05 / 0.05

0.18

IESTI

Highest % of ARID/ADI

Commodities

MRL / input for RA (mg/kg)

Exposure (µg/kg bw)

194%

Cherries (sweet)

0.8 / 0.97

9.7

184%

Quinces

0.5 / 0.61

9.2

131%

Aubergines/egg plants

0.2 / 0.24

6.6

52%

Pears

0.07 / 0.08

2.6

50%

Medlar

0.3 / 0.36

2.5

48%

Apples

0.07 / 0.08

2.4

36%

Sweet peppers/bell peppers

0.09 / 0.11

1.8

23%

Tomatoes

0.06 / 0.07

1.2

13%

Plums

0.03 / 0.04

0.65

6%

Potatoes

0.01 / 0.01

0.30

4%

Rapeseeds/canola seeds

0.4 / 0.4

0.21

4%

Walnuts

0.07 / 0.08

0.19

2%

Hazelnuts/cobnuts

0.07 / 0.08

0.10

1%

Honey and other apiculture products

0.05 / 0.05

0.07

Expand/collapse list

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

7

Processed commodities

Results for children

No. of processed commodities for which ARID/ADI is exceeded (IESTI):

---

Results for adults

No. of processed commodities for which ARID/ADI is exceeded (IESTI):

---

IESTI

Highest % of ARID/ADI

Processed commodities

MRL / input for RA (mg/kg)

Exposure (µg/kg bw)

32%

Apples / juice

0.07 / 0.08

4.6

55%

Pears / juice

0.07 / 0.08

2.8

37%

Quinces / jam

0.5 / 0.61

1.8

28%

Tomatoes / juice

0.06 / 0.07

1.4

19%

Potatoes / fried

0.01 / 0.01

0.93

14%

Tomatoes / sauce/puree

0.06 / 0.07

0.69

12%

Potatoes / dried (flakes)

0.01 / 0.05

0.59

7%

Plums / juice

0.03 / 0.04

0.34

5%

Rapeseeds / oils

0.4 / 0.8

0.24

IESTI

Highest % of ARID/ADI

Processed commodities

MRL / input for RA (mg/kg)

Exposure (µg/kg bw)

56%

Apples / juice

0.07 / 0.08

2.8

15%

Quinces / jam

0.5 / 0.61

0.76

12%

Tomatoes / sauce/puree

0.06 / 0.07

0.60

2%

Potatoes / chips

0.01 / 0.01

0.08

1%

Potatoes / dried (flakes)

0.01 / 0.05

0.06

Expand/collapse list

Conclusion:

The estimated short term intake (IESTI) exceeded the toxicological reference value for 7 commodities.

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

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## A 3.6 Raw and processed commodities – SCENARIO 3

Acute risk assessment /children

Acute risk assessment / adults / general population

Details - acute risk assessment /children

Details - acute risk assessment/adults

The acute risk assessment is based on the ARID. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the EU. The calculation is based on the large portion of the most critical consumer group.

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

Unprocessed commodities

Results for children

No. of commodities for which ARID/ADI is exceeded (IESTI):

---

IESTI

Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
98%	Cherries (sweet)	0.26 / 0.4	4.9
97%	Pears	0.03 / 0.04	4.8
75%	Apples	0.03 / 0.04	3.8
74%	Sweet peppers/bell	0.04 / 0.06	3.7
67%	Medlar	0.08 / 0.24	3.3
56%	Tomatoes	0.01 / 0.05	2.8
55%	Aubergines/egg plants	0.08 / 0.11	2.7
42%	Quinces	0.04 / 0.09	2.1
31%	Potatoes	0.01 / 0.01	1.5
30%	Plums	0.01 / 0.04	1.5
4%	Walnuts	0.01 / 0.06	0.21
4%	Hazelnuts/cobnuts	0.01 / 0.06	0.20
4%	Honey and other	0.05 / 0.05	0.18
0.8%	Rapeseeds/canola	0.03 / 0.03	0.04

Expand/collapse list

Results for adults

No. of commodities for which ARID/ADI is exceeded (IESTI):

---

IESTI

Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
80%	Cherries (sweet)	0.26 / 0.4	4.0
59%	Aubergines/egg plants	0.08 / 0.11	3.0
33%	Medlar	0.08 / 0.24	1.7
26%	Quinces	0.04 / 0.09	1.3
21%	Pears	0.03 / 0.04	1.1
20%	Sweet peppers/bell	0.04 / 0.06	1.0
20%	Apples	0.03 / 0.04	0.98
15%	Tomatoes	0.01 / 0.05	0.76
13%	Plums	0.01 / 0.04	0.64
6%	Potatoes	0.01 / 0.01	0.30
3%	Walnuts	0.01 / 0.06	0.13
1%	Hazelnuts/cobnuts	0.01 / 0.06	0.07
1%	Honey and other	0.05 / 0.05	0.07
0.3%	Rapeseeds/canola seeds	0.03 / 0.03	0.02

Expand/collapse list

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

Processed commodities

Results for children

No of processed commodities for which ARID/ADI is exceeded (IESTI):

---

IESTI

Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
29%	Apples / juice	0.03 / 0.03	1.5
19%	Potatoes / fried	0.01 / 0.01	0.93
18%	Pears / juice	0.03 / 0.03	0.88
12%	Potatoes / dried (flakes)	0.01 / 0.05	0.59
5%	Tomatoes / juice	0.01 / 0.01	0.25
2%	Tomatoes / sauce/puree	0.01 / 0.01	0.12
2%	Plums / juice	0.01 / 0.01	0.11
2%	Quinces / jam	0.04 / 0.04	0.11
0.4%	Rapeseeds / oils	0.03 / 0.06	0.02

Expand/collapse list

Results for adults

No of processed commodities for which ARID/ADI is exceeded (IESTI):

---

IESTI

Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
18%	Apples / juice	0.03 / 0.03	0.90
2%	Tomatoes / sauce/puree	0.01 / 0.01	0.11
2%	Potatoes / chips	0.01 / 0.01	0.08
1%	Potatoes / dried (flakes)	0.01 / 0.05	0.06
0.9%	Quinces / jam	0.04 / 0.04	0.05

Expand/collapse list

Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of acetamiprid is unlikely to present a public health risk.

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

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

Not relevant.