REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: ASA-01

Product name(s): **VIARES**

Chemical active substance:

Acetamiprid, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: XXXX

Submission date: March 2024

Updating date: September 2025

PL Evaluation date: December 2025

Version history

When	What
March 2024	Submission of the dRR
May 2025	Initial RR
September 2025	The Applicant update
December 2025	RR amendment driven by MRL changing and due to omission of 2 crop codes in assessment.

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

The dRR was not rewritten. New comments and changes from zRMS are on yellow background..

The current acetamiprid enforcement definition “acetamiprid” remains the same. EFSA established (EU 2025/158) a lower acceptable daily intake and a lower acute reference dose for acetamiprid and included the metabolite IM-2-1 in the residue definition for the risk assessment of acetamiprid in fruit and leafy crops. The PRIMo was recalculated. The current MRLs are as follows:

Code number	Groups and examples of individual products to which the MRLs apply	Acetamiprid Reg. (EU) 2025/158 2025/1212 Current
130010	Apples	0,07
130020	Pears	0,07
130030	Quinces	0,15
130040	Medlars	0,3
130050	Loquats/Japanese medlars	0,8
130990	Others (pome)	0,8
401060	Rapeseeds/canola seeds	0,4
1040000	Honey and other apiculture products	0.3

Since MRL in honey was raised to 0,3 and results of the tunnel honey trials conducted according to the GAP consistent with the intended OSR GAP are all definitely below the MRL, the intended OSR GAP can be approved. Also pome fruits intended GAP including BBCH before flowering can be approved except for apples, wild apples, pears and Chinese pears (MRL exceedance).

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, PL agrees with the authorization of the intended uses consistently with the intended GAP in the table 7.1-1. According to available data, no specific mitigation measures should apply.

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 ASA-01 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 (last update Reg. (EU) 2019/88) is not expected.
Acetamiprid is a systemic substance. The residue data for rapeseed and apples are currently sufficient (see the table of MRLs below) to grant approval for the proposed GAP for these uses. However, because the presented in Appendix 2 tunnel studies indicate clearly the possibility of exceeding the MRL in honey (0.05), the product may only be used after the flowering period until the MRL for acetamiprid in honey is appropriately raised. This, in turn, completely excludes the proposed use in rapeseed, as the treatments are

intended to be carried out until the flowering period. In the case of pome fruits, acceptable applications must commence from BBCH 70.

Code number	Groups and examples of individual products to which the MRLs apply	Acetamiprid Reg. (EU) 2019/88 Previous	Acetamiprid Reg. (EU) 2017/626 Previous
130010	Apples	0,4	0,8
130020	Pears	0,4	0,8
130030	Quinces	0,8	0,8
130040	Medlars	0,8	0,8
130050	Loquats/Japanese medlars	0,8	0,8
130990	Others (pome)	0,8	0,8
401060	Rapeseeds/canola seeds	0,4	0,4
1040000	Honey and other apiculture products (7)	0.05*	0.05*

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, PL agrees with the authorization of the intended uses after the flowering period with the complete exclusion of rapeseed.
According to available data, no specific mitigation measures should apply.

Data gaps

None

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 (last update Reg. (EU) 2025/1212) is not expected.
Acetamiprid is a systemic substance. The residue data for rapeseed and apples are currently sufficient to grant approval for the proposed GAP for these uses. The presented in Appendix 2 tunnel studies indicate residue results below existing MRL in honey (0.3 mg/kg). The product can be used before and after the flowering period.
Regarding above, also proposed use in rapeseed can be accepted.

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

1	2	3	4	5	6	7		8				9			10	11	12
GAP number (see part B.0)*	Crop and/ or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate			PHI (days)	Remarks	Conclusion
						Type	Conc. of as	method kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (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			
1	Winter rape (BRSNW) 0401060	PL	ASA-01	F	pollen beetle *Brassicogethes aeneus* (MELIAE)	SC	300 g/L	spraying	BBCH 50-60	a) 1 b) 1	-	a) 0.08-0.1 L/ha b) 0.08-0.1 L/ha	a) 24 - 30 g a.s./ha b) 24- 30 g a.s./ha	200-400 L/ha	NR	-	
2	Apple (MABSD) 0130010	PL	ASA-01	F	Aphids *Aphdidae* (APXXSP)	SC	300 g/L	spraying	BBCH 56-75 70-75	a) 1 b) 1	-	a) 0.03-0.05 L/10000 m^2 LWA b) 0.03-0.05 L/10000 m^2 LWA	a) 9-15 g a.s./10000 m^2 LWA b) 9-15 g a.s. /10000 m^2 LWA	500-900 L/ha	14 days	max. 0.075 L/ha (max. 22.5 g as/ha)	MRL exceedance
3	Apple (MABSD) 0130010	PL	ASA-01	F	codling moth *Cydia pomonella* (CARPPO)	SC	300 g/L	spraying	BBCH 57-75 70-75	a) 1 b) 2	7-10 days	a) 0.07-0.09 L/10000 m^2 LWA b) 0.14-0.18 L/ 10000 m^2 LWA	a) 21-27 g a.s./10000 m^2 LWA b) 42-54 g a.s. /10000 m^2 LWA	500-750 L/ha	14 days	max. 0.09 L/ha (max. 27 g as/ha)	
Minor																	
4	~~Wild apple (MABSY) 0130010~~ ~~Pear~~ (PYUCO) 0130020 ~~Chinese pear (PYULI) 0130020~~ Quince (CYDOB) 0130030 Medlar (MSPGE) 0130040	PL	ASA-01	F	Aphids *Aphdidae* (APXXSP)	SC	300 g/L	spraying	BBCH 56-75 70-75	a) 1 b) 1	-	a) 0.03-0.05 L/10000 m^2 LWA b) 0.03-0.05 L/10000 m^2 LWA	a) 9-15 g a.s./10000 m^2 LWA b) 9-15 g a.s. /10000 m^2 LWA	500-900 L/ha	14 days	max. 0.075 L/ha (max. 22.5 g as/ha)	
5	~~Wild apple (MABSY) 0130010~~ ~~Pear~~ (PYUCO) 0130020 ~~ChinesePear (PYULI) 0130020~~ Quince (CYDOB) 0130030 Medlar (MSPGE) 0130040	PL	ASA-01	F	codling moth *Cydia pomonella* (CARPPO)	SC	300 g/L	spraying	BBCH 57-75 70-75	a) 1 b) 2	7-10 days	a) 0.07-0.09 L/10000 m^2 LWA b) 0.14-0.18 L/ 10000 m^2 LWA	a) 21-27 g a.s./10000 m^2 LWA b) 42-54 g a.s. /10000 m^2 LWA	500-750 L/ha	14 days	max. 0.09 L/ha (max. 27 g as/ha)	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005
*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 "Conclusion"

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

7.1.2 Summary of the evaluation

The preparation ASA-01 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 Revison 8 of the Renewal Report in September 2024	-
ARfD	SANTE/10502/2017 Rev. 8	2024	0.005 mg/kg bw	Reduced 5-fold with Revison 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	Oilseed rape	Yes	Yes	Yes	Yes	Yes	No	No
2, 3	Apple	Yes	Yes	Yes	Yes	Yes		No
4, 5	Wild apple, Pear, Chinese pear, Quince, Medlar	Yes	Yes (extrapolation from apple)	Yes	Yes	Yes		No

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

The effects of processing on the nature of acetamiprid residues have been investigated. Data on effects of processing on the amount of residue have been submitted 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 ASA-01

Table 7.1-4: Information on ASA-01 (KCA 6.8)

Crop	PHI for ASA-01 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for ASA-01 proposed by zRMS	zRMS Comments (if different PHI proposed)
		ASA-01		
Oilseed rape	28 days	Yes	none	
Apple	14 days	Yes		
Wild apple Pear Chinese pear Quince Medlar	14 days	Yes		

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

Table 7.1-5: Waiting periods before planting succeeding crops

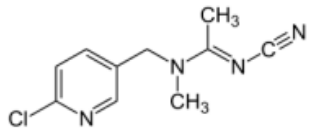
Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for ASA-01
Crop group	Led by acetamiprid	
Leafy vegetables	Regarding waiting periods please refer to dRR Part B Section 3.	none
Root vegetables		
Cereals		

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^1 -[(6-Chloro-3-pyridyl)methyl]-N^2 -cyano-N^1 -methylacetamidine
Chemical structure	
Molecular formula	$C_{10}H_{11}ClN_4$
Molar mass	22.68 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 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011R0540-20230901 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 https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1520336385887&uri=CELEX:32018R0113
Restriction	None
Review Report	SANTE/10502/2017 Rev 4, 13 December 2017
Current MRL regulation	~~Reg. (EU) 2019/88~~ Reg. (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 ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Apple, tomato	High water content	≤13 months	RAR, 2015 EFSA, 2016
Potato (tuber)	High starch content	8 months	
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	
Animal Products			
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
New studies			
Plant products			
Oilseed rape (green plant)	High water content	60 days	Niewelt-Stasiak S. / Study No: DPL/85/2023

New studies on oilseed rape (green plant)

Stability was demonstrated for acetamiprid-N-desmethyl in oilseed rape (green plant) upon storage at ≤ -18°C for a period of 60 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 oilseed rape (green plant). There were no interfering signals at retention time of analysed compound in examined control matrix.

Conclusion on stability of residues during storage

According to EFSA Journal 2016;14(11):4610:
Residue data are supported by storage stability studies where acetamiprid residues were concluded to be stable up to 1 year in high water-, high oil- and high acid-content commodities and up to 8 months in high starch-content matrices (potato tuber). Acetamiprid was stable under standard hydrolysis conditions."

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

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

Residue study number: 23SGS26, 23SGS27, 23SGS28
Testing of final extract stability is not required since the ILIS will compensate for losses during extract storage. As there was used IL-IS in these studies, in addition total analytical procedure was performed and completed within 24h, and recoveries in the fortified samples are within the acceptable range of 70-120 %, stability is sufficiently proven.
Working standards that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis take place (then extract stability should not be considered to be an issue). However, additional injection of calibration standard was performed in the end of sequence. Recoveries in the fortified samples are within the acceptable range.

Residue study number: JBL-20-45212, SDO-20-45215
Extract stability is not considered to be an issue since all samples were analysed within 1 day from preparation.

Conclusion on stability of residues in sample extracts

Stability of residues in sample extracts is sufficiently proven.

zRMS: acceptable

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Eggplant	Pyridine-2,6-^{14}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 solution (95 mg/kg) of 30% SP	RAR, 2015 EFSA, 2016
	Apple	Pyridine-2,6-^{14}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 aqueous solution (103.8 mg/kg) of 20% SP, i.e. 20.8 microg 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 aqueous solution (104.7 mg/kg) of 20% SP, i.e. 73.3 microg a.i./fruit	RAR, 2015 EFSA, 2016
Leafy vegetables	Cabbage	Pyridine-2,6-^{14}C	foliar treatment, G	0.302 kg a.s./ha	1	0, 7, 14, 21, 28, 63	10 ml/pot (one plant) of 1000 fold aqueous solution (201 mg/kg) of 20% SP	RAR, 2015 EFSA, 2016
		Pyridine-2,6-^{14}C	soil application, G	5.94 kg a.s./ha	1	7, 14, 28	2 g/pot (one plant) of 2.1% granular	RAR, 2015 EFSA, 2016
		Cyano-^{14}C	foliar treatment, G	0.299 kg a.s./ha	1	0, 7, 14, 28, 63	10 ml/pot (one plant) of 1000 fold aqueous solution	RAR, 2015 EFSA, 2016

							(199 mg/kg) of 20% SP	
Root and tuber vegetables	Carrot	Pyridine-2,6-^{14}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
Pulses and oilseeds	Cotton	Pyridine-2,6-^{14}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 ^{14}C-acetamiprid applied by dotting to the surface of the leaves and fruits (aubergine, apple), by spraying (cabbage, carrot, cotton) or using soil application (cabbage). In all plant parts, acetamiprid was identified as the major component of the radioactive residues (total radioactive residue (TRR)) accounting for ca. 30–90% TRR 14–90 days after the last application, except in head cabbage where the 6-chloronicotinic acid metabolite (IC-0) was the sole component identified, representing 46% TRR (0.023 mg eq/kg) and in cotton seeds (24% TRR at harvest, 0.27 mg/kg). IC-0 was also detected in carrot roots (26% TRR, 0.02 mg/kg). Other identified metabolites were observed at low levels, accounting mostly for less than 5% TRR, except metabolites IM-1-4 in immature carrot leaves (43% TRR).
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 ASA-01.

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.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Inter-vals (DAT)	Remarks	
EU data								
Leafy vegetables	Spinach	[Pyridyl-^{14}C]-IM-1-5	soil application, G	0.266 kg a.s./ha	0	BBCH 49	Since acetamiprid DT_{50} values in soil range between 0.8-7.9 days, study was conducted with metabolite IM-1-5 the most persistent soil metabolite (DT_{50} 319 to 663 days).	RAR, 2015 EFSA, 2016
Root and tuber vegetables	Turnip	[Pyridyl-^{14}C]-IM-1-5	soil application, G	0.266 kg a.s./ha	0	BBCH 49		RAR, 2015 EFSA, 2016
Cereals	Wheat	[Pyridyl-^{14}C]-IM-1-5	soil application, G	0.266 kg a.s./ha	0	BBCH 30 (forage), BBCH 69/89 (hay)		RAR, 2015 EFSA, 2016

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

Summary of plant metabolism studies reported in the EU

According to EFSA Journal 2016;14(11):4610:
Having regard to the low persistence of acetamiprid in soil (highest field period required for 90% dissipation (DT_{90}) 43 days and 20°C lab DT_{90} 54 days), confined rotational crop studies were not conducted with the active substance and the metabolism in rotational crops was investigated using the more persistent soil metabolite IM-1-5 (period required for 50% dissipation (DT_{50}) 319–663 days) at a single plant back interval of 0 days. In the different rotational crops investigated (wheat, turnip, spinach), IM-1-5 was shown to remain the main component of the radioactive residues accounting in mature plant at harvest for 77–94% TRR. Additional field rotational crop studies conducted in northern and southern EU with acetamiprid applied onto the bare soil at ca. 300 g/ha, confirmed that acetamiprid, IM-1-4 and IM-1-5 residues are not expected to be present in rotational crops.

Summary of new plant metabolism studies

Not relevant.

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 7.2-5: 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
EU data			
Pasteurisation (20 minutes, 90°C, pH 4)	Acetamiprid only (95.6%)	Acetamiprid only (93.3%)	RAR, 2015 EFSA, 2016
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Acetamiprid only (95.1%)	Acetamiprid only (95.59%)	RAR, 2015 EFSA, 2016
Sterilisation (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 7.2-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
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 [^{14}C]-residue found in the crop commodities was IM-1-5 accounting for the entire extractable radioactive residue (≥ 76.8% TRR). No other metabolites or unidentified residues were observed in any crop commodity.
Processed commodities	Acetamiprid 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) 2025/1212)

	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

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

Available data

No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[pyridine-2,6-^{14}C]-acetamiprid	1 1	1 10	7	Milk	twice daily	RAR, 2015 EFSA, 2016
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	[pyridine-2,6-^{14}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 ^{14}C-acetamiprid at 10 mg/kg dry matter

(DM) over 7 (goat) or 17 (poultry) consecutive days were submitted. Most of the radioactivity was excreted in urine and faeces and only 2% of the administrated radioactivity was recovered in organs, tissues, blood and milk or eggs. Acetamiprid was extensively metabolised and not detected in any animal matrices except in milk. The major component was identified as the N-desmethyl metabolite (IM-2-1) representing 50–89% TRR in all animal matrices, except goat muscle (10% TRR) where residues were mainly composed of the metabolite IM-2-2 accounting for 50% TRR (0.03 mg eq/kg).
The metabolic profile was confirmed by the feeding studies on cow and poultry where IM-2-1 was detected as the most abundant component in all animal matrices. Acetamiprid was not present in poultry and only detected in significant levels in milk at all feeding levels and at the highest feeding level in the other matrices.

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

Endpoints	
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	1-3 days to reach a steady state in milk
	4-8 days to reach a steady state in eggs
Animal residue definition for monitoring	Acetamiprid except honey: the sum of acetamiprid and IM-2-1, expressed as acetamiprid (~~Reg (EU) 2019/88~~ Reg. (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

zRMS: acceptable

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of ASA-01 and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Oilseed rape (0401060)	New trials	N-EU	Trials GAP: 1 x 36 g as/ha, BBCH 77-80, PHI 28d, outdoor E/RA: 3x N.D. (<LOD (0.00252 mg/kg)), 0.0132	N/A				
			Trials GAP: 1 x 36 g as/ha, BBCH 77-80, PHI 28d, outdoor E/RA: < LOD (<0.001 mg/kg), 0.025, 0.028, 0.050					
	Overall supporting data for cGAP	N-EU	E/RA: < 0.001, 3x < 0.00252, 0.0132, 0.025, 0.028, 0.050	E/RA: 0.008	E/RA: 0.05	-	0.4 0.4* 0.4***	Yes
Apple (0130010)	New trials	N-EU	Trials GAP: 2 x 40.5 g as/ha, BBCH 79-81, PHI 14d, indoor E: 0.0104, 0.0131, 0.0342, 0.0363, 0.102 RA[1)]: 0.013, 0.016, 0.041, 0.044, 0.123	N/A				
			Trials GAP: 2 x 40.5 g as/ha, BBCH 79-81, PHI 14d, indoor E: 0.024, 0.043, 0.061 RA: 0.024, 0.043, 0.061					
	Overall supporting data for cGAP	N-EU	E: 0.0104, 0.0131, 0.024, 0.0342, 0.0363, 0.043, 0.061, 0.102 RA: 0.013, 0.016, 0.024, 0.041, 0.043, 0.044, 0.061, 0.123	E: 0.035 RA: 0.042	E: 0.102 RA: 0.123	-	0.4 0.07** 0.07***	Yes

Wild apple (0130010) Pear (0130020) Chinese pear (0130020) (extrapolation from apple)	New trials	N-EU	*Apple:* Trials GAP: 2 x 40.5 g as/ha, BBCH 79-81, PHI 14d, indoor E: 0.0104, 0.0131, 0.0342, 0.0363, 0.102 RA[1)]: 0.013, 0.016, 0.041, 0.044, 0.123 *Apple:* Trials GAP: 2 x 40.5 g as/ha, BBCH 79-81, PHI 14d, indoor E: 0.024, 0.043, 0.061 RA: 0.024, 0.043, 0.061	N/A				
	Overall supporting data for cGAP	N-EU	E: 0.0104, 0.0131, 0.024, 0.0342, 0.0363, 0.043, 0.061, 0.102 RA: 0.013, 0.016, 0.024, 0.041, 0.043, 0.044, 0.061, 0.123	E: 0.035 RA: 0.042	E: 0.102 RA: 0.123	-	0.4 0.07** 0.07***	Yes
Quince (0130030) Medlar (0130040) (extrapolation from apple)	New trials	N-EU	*Apple:* Trials GAP: 2 x 40.5 g as/ha, BBCH 79-81, PHI 14d, indoor E: 0.0104, 0.0131, 0.0342, 0.0363, 0.102 RA[1)]: 0.013, 0.016, 0.041, 0.044, 0.123 *Apple:* Trials GAP: 2 x 40.5 g as/ha, BBCH 79-81, PHI 14d, indoor E: 0.024, 0.043, 0.061 RA: 0.024, 0.043, 0.061	N/A				
	Overall supporting data for cGAP	N-EU	E: 0.0104, 0.0131, 0.024, 0.0342, 0.0363, 0.043, 0.061, 0.102 RA: 0.013, 0.016, 0.024, 0.041, 0.043, 0.044, 0.061, 0.123	E: 0.035 RA: 0.042	E: 0.102 RA: 0.123	-	0.8 0.15** 0.15*** (quince) 0.3** 0.3*** (medlar)	Yes

* Source of EU MRL: Reg. (EU) 2019/88
** Newly planned MRLs (PLAN/2024/1403) – not yet applicable.
*** Reg. (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
New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. A total of eight residue trials in Northern Europe were performed on oilseed rape. All trials were performed in compliance with the intended GAP.
According to SANTE/2019/12752 – rev. 1 - 10 May 2023, oilseed rape is a major crop in Northern Europe. For major crops, usually eight trials have to be submitted to estimate the residues which will be found after application of the product. Therefore, sufficient residue trials are available to support the intended GAP uses on oilseed rape.
All trials are valid regarding storage stability data.
The data submitted show that no exceedance of the EU MRL for oilseed rape will occur.
According to the available data, the intended GAP uses of acetamiprid in the product ASA-01 on oilseed rape are considered acceptable for outdoor uses.
Apple
New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. A total of eight residue trials in Northern Europe were performed on apple. All trials were performed in compliance with the intended GAP.
According to SANTE/2019/12752 – rev. 1 - 10 May 2023 apple is a major crop in Northern Europe. For major crops, usually eight trials have to be submitted to estimate the residues which will be found after application of the product. Therefore, sufficient residue trials are available to support the intended GAP uses on apple.
All trials are valid regarding storage stability data.
The data submitted show that no exceedance of the EU MRL for apple will occur.
According to the available data, the intended GAP uses of acetamiprid in the product ASA-01 on apple are considered acceptable for outdoor uses.
Wild apple, pear, Chinese pear
According to SANTE/2019/12752 Rev.01 extrapolation from apple to wild apple, pear and Chinese pear is possible (before and after forming of the edible part).
New studies on the magnitude of residue in apple have been submitted by the applicant in the framework of this application. A total of eight residue trials in Northern Europe were performed on apple. All trials were performed in compliance with the intended GAP. These trials are sufficient to support uses on wild apple, pear and Chinese pear.
All trials are valid regarding storage stability data.
The data submitted show that no exceedance of the EU MRL for wild apple, pear and Chinese pear will occur.
According to the available data, the intended GAP uses of acetamiprid in the product ASA-01 on wild apple, pear and Chinese pear are considered acceptable for outdoor uses.
Quince, medlar
According to SANTE/2019/12752 Rev.01 extrapolation from apple to quince and medlar is possible (before and after forming of the edible part).
New studies on the magnitude of residue in apple have been submitted by the applicant in the framework of this application. A total of eight residue trials in Northern Europe were performed on apple. All trials were performed in compliance with the intended GAP. These trials are sufficient to support uses on quince and medlar.
All trials are valid regarding storage stability data.
The data submitted show that no exceedance of the EU MRL for quince and medlar will occur.
According to the available data, the intended GAP uses of acetamiprid in the product ASA-01 on quince and medlar are considered acceptable for outdoor uses.

zRMS: see concluding comment in 7.1

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 all crops from GAP table are relevant as food item: oilseed rape (rape forage, meal) and apple (pomace, wet).

Table 7.2-10: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure, the uses under consideration and in EFSA 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[a)] (EFSA, 2016a, EFSA, 2018)	0.06	STMR x 2[a)] (EFSA, 2016a, EFSA, 2018)
Rape, meal	0.06	STMR x 2[a)] (EFSA, 2016a, EFSA, 2018)	0.06	STMR x 2[a)] (EFSA, 2016a, EFSA, 2018)

* Indicates that the input value is proposed at the limit of quantification.
a) default processing factors

Table 7.2-11: Results of the dietary burden calculation

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,018	0,018	0,75	0,75	Beef cattle	Apple	pomace, wet	Yes
Cattle (dairy only)	0,014	0,014	0,38	0,38	Dairy cattle	Apple	pomace, wet	Yes
Sheep (all diets)	0,016	0,016	0,38	0,38	Lamb	Apple	pomace, wet	Yes
Sheep (ewe only)	0,013	0,013	0,38	0,38	Ram/Ewe	Apple	pomace, wet	Yes
Swine (all diets)	0,001	0,001	0,03	0,03	Swine (finishing)	Canola	meal	No
Poultry (all diets)	0,002	0,002	0,03	0,03	Turkey	Canola	meal	No
Poultry (layer only)	0,001	0,001	0,01	0,01	Poultry layer	Canola	meal	No

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

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

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

Commodity	Dietary burden values based on intended GAP		Results of the livestock feeding study						Median residue (mg/kg)(b)	Highest residue (mg/kg)(c)	Calculated MRL (mg/kg)	CF for RA(d)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (The Netherlands, 2016, 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			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* (tentative)	1.00
			0.63	3	0.45	0.64						
			2.13	3	2.29	2.65						
Ruminant kidney			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						

Milk	0.016	0.075	0.21	n.p.	0.08[(a)]	n.a.		0.02	0.03	0.05 (tentative)	1.00
			0.63	n.p.	0.37[(a)]	n.a.					
			2.13	n.p.	1.30[(a)]	n.a.					
New data											
No new data were submitted in the framework of this application.											

Conclusion on feeding studies

According to RAR (The Netherlands, 2015):
A study on determination of the magnitude of acetamiprid residues in poultry was submitted (XXXX 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.

zRMS: acceptable

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 7.2-13: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Enforcement residue definition: acetamiprid					
Apple, juice	2	0.80 (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.

zRMS: acceptable

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)

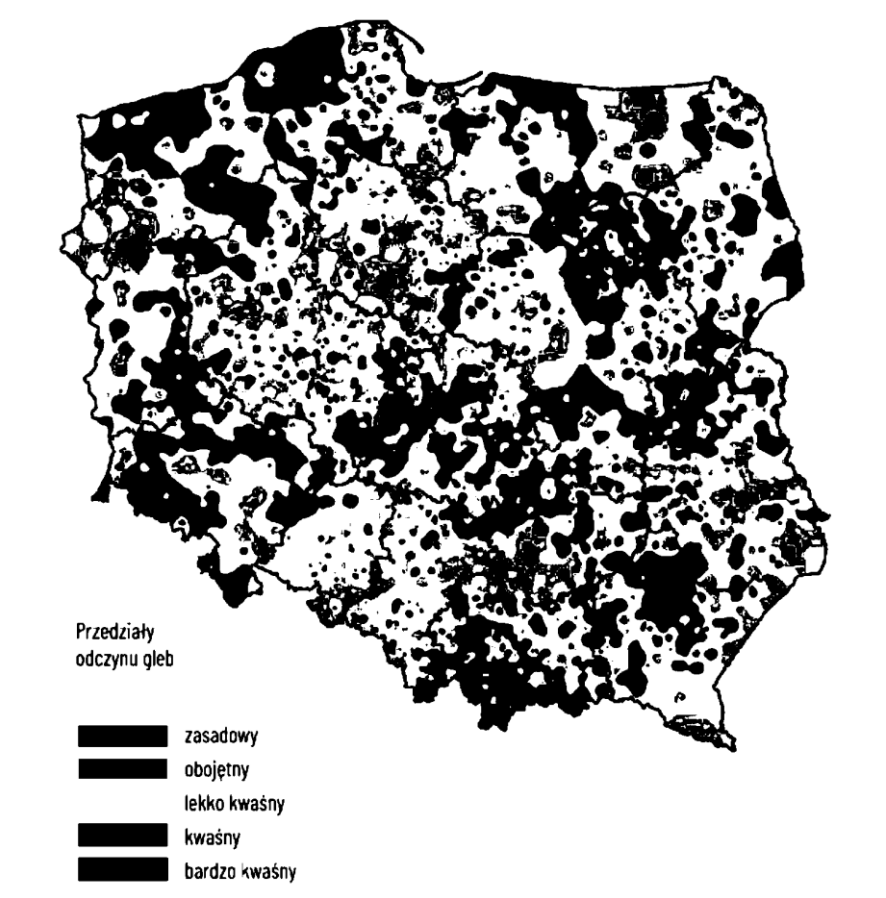
Available data

Based on metabolism studies in rotational crops (see point 7.2.2.2) it was concluded that *the only [^{14}C]-residue found in the crop commodities was IM-1-5 accounting for the entire extractable radioactive residue (≥ 76.8% TRR). No other metabolites or unidentified residues were observed in any crop commodity*.

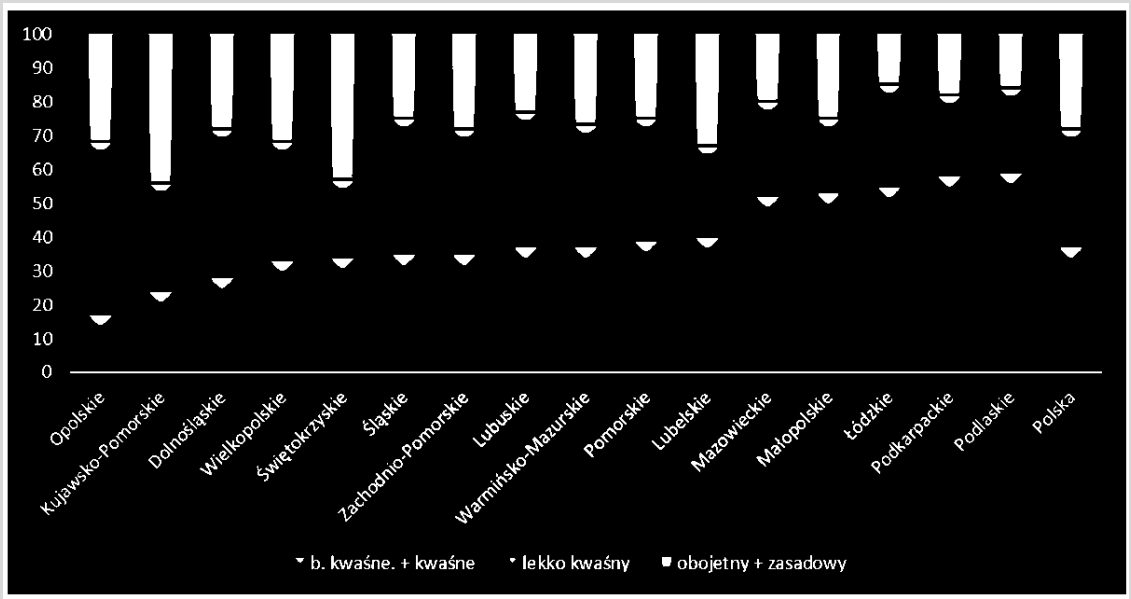
In DAR Addendum 2003, based on study results (Simmonds M.B., 2002, Doc No. RD-00168 (re-evaluation in RAR 2015)) it was concluded that metabolite IM-1-5 is formed only in the soil, of a pH higher than 8.

~~Accorging 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 Krysztoforski, Główny Specjalista, Dział Rolnictwa Ekologicznego i Działań 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~~)



With regard to apple (pome fruit) rotational crop studies are not required as pome fruits are not intended into rotation: *Rotational crop studies shall not be required for uses of plant protection products in permanent crops (such as citrus and pome fruits crop group), semi-permanent crops (such as asparagus, pineapples) or fungi, where rotations on the same substrate are not part of the normal agricultural* practices (Reg (EU) 283/2013).

~~With regard to 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).~~

Conclusion on rotational crops studies

Based on metabolism studies in rotational crops (see point 7.2.2.2) it was concluded that the only [14C]-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.
~~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 ASA-01 for apple and oilseed rape.~~
Not relevant because OSR is excluded but 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.

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.
Both of the proposed uses (oilseed rape and apple) 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.

Four new tunnel studies in N-EU zone (Poland) have been performed on phacelia crop (*Phacelia tanacetifolia* Benth) to investigate the magnitude of acetamiprid residues in honey. These studies consider a "worst case" situation (the most critical scenario was used on a crop (phacelia) representing a worst case in terms of residues in honey). The results of these studies are summarized in the table below. The details are presented in Appendix 2.

Table 7.2-14: Summary of new data on honey supporting the intended uses of ASA-01

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
Phacelia (worst case) -	New trials (report no. 23SGS26)	N-EU	Trial GAP: 1 x 81 g as/ha, BBCH 65, semi-field (tunnel) trial	N/A				

residues in honey			E: 0.098, 0.099, 2x 0.1 RA: 0.098, 0.099, 2x 0.1					
	Overall supporting data for honey	N-EU	E: 0.098, 0.099, 2x 0.1 RA: 0.098, 0.099, 2x 0.1	E: 0.1 RA: 0.1	E: 0.1 RA: 0.1	-	0.05* 0.3** 0.3***	Yes

*Source of EU MRL: Reg. (EU) 2019/88 / PLAN/2024/1403
** SANTE/11278/2021
*** Source of MRL: Reg. (EU) 2025/1212

A tunnel study (containing four trials) for determining the magnitude of residues of ASA-01 in honey was conducted in compliance with current guidelines. In four honey trials ASA-01 was applied at a rate 81 g as/ha at a flowering phase (BBCH 65), representing worst case scenario. Results are summarised in table above.
All samples were analysed within 30 days from sampling, therefore there is no need to perform studies on the stability of residues during storage.
This study resulted in residues above the LOQ. However, the applicant wishes to draw attention that the experimental study setup proposed in the technical guidance on residues in pollen and bee products (SANTE/11956/2016 rev. 9) using highly bee-attractive crops to reflect intended uses of acetamiprid e.g. phacelia, most likely results in unrealistic high residue levels.
Additionally, EFSA, 2021 proposed EU MRL for honey as 0.3 mg/kg. According to EFSA Journal 2021;19(9):6830: *The MRL proposal reflects residues in honey from the critical authorised use and intended EU uses of acetamiprid on melliferous crops. MRL in honey is derived from semi-field/tunnel trials performed on Phacelia tanacetifolia. In addition, monitoring data from official EU National control programmes conducted by several Member States during 2012–2018 indicated that in the vast majority of honey samples of acetamiprid residues were below the LOQ of 0.05 mg/kg (0.26 % exceedance of all analysed samples in 2018). Therefore, risk for consumers unlikely.*

EFSA Statement, 2024 (EFSA Journal. 2024;22:e8759)):
Furthermore, for (…) honey (0.3 mg/kg), it was concluded that risk for consumers was still unlikely for the new MRLs proposed in SANTE/11278/2021. For these crops, risk managers can therefore implement the MRLs proposed in SANTE/11278/2021.

Actual MRL for honey is established as 0.3 mg/kg (Regulation (EU) 2025/1212, applicable from 20/08/2025). All four results from residue trials are below actual MRL for honey and cam support proposed uses on melliferous crops. No further trials are required.

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

Present data on honey MRL situation (EFSA Journal 2022;20(8):7535)

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
1040000	Honey and other apiculture products	0.05*	Further risk management considerations required (2 or 0.3)	Risk Managers are given the options to either set an MRL for honey of 2 mg/kg based on the four residue trials provided with the current application (despite the deviation of not having control samples for two trials) or merge two data sets to derive an MRL of 0.3 mg/kg based on six residue trials performed in accordance with the requirements of the honey guidelines. Risk for consumers unlikely for both MRLs proposed.
			Further risk management considerations required	For the NEU use a MRL proposal of 1 mg/kg was calculated.
			No MRL proposal	

zRMS: see concluding comment in 7.1

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 subgroups 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 7.2-15: 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**
Risk assessment residue definitions in plant commodities: - **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)** - **Any other crops: acetamiprid**				
Apple (incl. wild apple)	0.4 * CF	EU MRL[1)]	0.4 * CF	EU MRL[1)]
Pears (incl. Chinese pear)	0.4 * CF	EU MRL[1)]	0.4 * CF	EU MRL[1)]
Quinces	0.8 * CF	EU MRL[1)]	0.8 * CF	EU MRL[1)]
Medlars	0.8 * CF	EU MRL[1)]	0.8 * CF	EU MRL[1)]
Rapeseed	0.4	EU MRL[1)]	0.4	EU MRL[1)]
All other commodities of plant origin	various (* CF if relevant)	EU MRL[1)]	Not relevant. Acute risk assessment performed only for intended uses.	
Risk assessment residue definition: Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid				
Honey and other apiculture	0.05	EU MRL[1)]	0.05	EU MRL[1)]
All other commodities of animal origin	various	EU MRL[1)]	Not relevant. Acute risk assessment performed only for intended uses.	

1) Reg. (EU) 2019/88

Table 7.2-16: 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
Risk assessment residue definitions in plant commodities: - **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)** - **Any other crops: acetamiprid**				
Apple (incl. wild apple)	0.07 * CF 0.07 * CF	PLAN EU MRL[2)] Existing EU MRL[3)]	0.07 * CF 0.07 * CF	PLAN EU MRL[2)] Existing EU MRL[3)]
Pears (incl. Chinese pear)	0.07 * CF 0.07 * CF	PLAN EU MRL[2)] Existing EU MRL[3)]	0.07 * CF 0.07 * CF	PLAN EU MRL[2)] Existing EU MRL[3)]
Quinces	0.15 * CF 0.15 * CF	PLAN EU MRL[2)] Existing EU MRL[3)]	0.15 * CF 0.15 * CF	PLAN EU MRL[2)] Existing EU MRL[3)]
Medlars	0.15 * CF 0.3 * CF	PLAN EU MRL[2)] Existing EU MRL[3)]	0.15 * CF 0.3 * CF	PLAN EU MRL[2)] Existing EU MRL[3)]
Rapeseed	0.4 0.4	PLAN EU MRL[2)] Existing EU MRL[3)]	0.4 0.4	PLAN EU MRL[2)] Existing EU MRL[3)]
All others commodities of plant origin	various (* CF if relevant)	PLAN EU MRL[2)] Existing EU MRL[3)]	Not relevant. Acute risk assessment performed only for intended uses.	
Risk assessment residue definition: Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid				
Honey and other apiculture	0.05 0.3	PLAN EU MRL[2)] Existing EU MRL[3)]	0.05 0.3	PLAN EU MRL[2)] Existing EU MRL[3)]
All other commodities of animal origin	various	PLAN EU MRL[2)] Existing EU MRL[3)]	Not relevant. Acute risk assessment performed only for intended uses.	

2) PLAN/2024/1403 (planned MRLs)
3) Regulation (EU) 2025/1212 applicable from 20/08/2025

Table 7.2-17: 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
Risk assessment residue definitions in plant commodities: - **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)** - **Any other crops: acetamiprid**				
Citrus fruits	0.006	STMR-RAC CF*PeF (EFSA, 2024)	-	-
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	0.086	HR-RAC*CF

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		(EFSA, 2024)		(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)	-	-
Peaches	0.030	STMR-RAC*CF (EFSA, 2024)	-	-
Plums	0.012	STMR-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 (EFSA, 2024)	-	-
Blueberries, Cranberries, Currants (red, black and white), Gooseberries (green, red and yellow) Elderberries	0.247	STMR-RAC*CF (EFSA, 2024)	-	-
Rose hips, Mulberries (black and white)	0.774	STMR-RAC*CF (EFSA, 2024)	-	-
Figs	0.012	STMR-RAC*CF (EFSA, 2024)	-	-
Table olives	0.290	STMR-RAC*CF (EFSA, 2024)	-	-
Granate apples/pomegranate	0.012	STMR-RAC*CF (EFSA, 2024)	-	-
Potatoes	0.01 0.01	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Garlic	0.01	STMR-RAC (EFSA, 2024)	-	-
Onions	0.01	STMR-RAC (EFSA, 2024)	-	-

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Tomatoes	0.013	STMR-RAC*CF (EFSA, 2024)	-	-
Sweet peppers/bell peppers	0.041	STMR-RAC*CF (EFSA, 2024)	-	-
Aubergines/egg plants	0.079	STMR-RAC*CF (EFSA, 2024)	-	-
Okra/lady's fingers	0.048	STMR-RAC*CF (EFSA, 2024)	-	-
Other solanacea	0.242	EU-MRL[2)] *CF (EFSA, 2024)	-	-
Cucumbers, Courgettes	0.024	STMR-RAC*CF (EFSA, 2024)	-	-
Gherkins	0.169	STMR-RAC*CF (EFSA, 2024)	-	-
Other cucurbits - edible peel	0.073	STMR-RAC*CF (EFSA, 2024)	-	-
Melons, Pumpkins Watermelons	0.012	STMR-RAC*CF (EFSA, 2024)	-	-
Other cucurbits - inedible peel	0.061	STMR-RAC*CF (EFSA, 2024)	-	-
Sweet corn	0.012 0.01	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
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)	-	-

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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 0.01	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Globe artichokes	0.11	STMR-RAC*CF (EFSA, 2024)	-	-
Dry Pulses	0.02	STMR-RAC (EFSA, 2024)	-	-
Linseeds, Gold of pleasure seeds	0.01 0.06	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Poppy seeds	0.01 0.3	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Rapeseeds/canola seeds	0.03	STMR-RAC (EFSA, 2024)	0.03	STMR-RAC (EFSA, 2024)
Mustard seeds	0.01 0.15	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
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 0.05	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Cardamom, Peppercorn (black, green and white)	0.1 0.1	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Horseradish, root spices	0.07 0.05	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
All others commodities of plant origin	various (* CF if relevant) various (* CF if relevant)	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Risk assessment residue definition: Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid				

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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 1	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
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)	-	-
Sheep: Liver	0.11	STMR-RAC (EFSA, 2024)	-	-
Sheep: Kidney	0.11	STMR-RAC (EFSA, 2024)	-	-
Sheep: Edible offals (other than liver and kidney)	1 1	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Goat: Muscle/meat	0.02	STMR-RAC (EFSA, 2024)	-	-
Goat: Fat tissue	0.02	STMR-RAC (EFSA, 2024)	-	-
Goat: Liver	0.11	STMR-RAC (EFSA, 2024)	-	-
Goat: Kidney	0.11	STMR-RAC (EFSA, 2024)	-	-
Goat: Edible offals (other tha liver and kindey)	1 1	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Equine: Muscle/meat	0.02	STMR-RAC (EFSA, 2024)	-	-
Equine: Fat tissue	0.02	STMR-RAC (EFSA, 2024)	-	-

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Equine: Liver	0.11	STMR-RAC (EFSA, 2024)	-	-
Equine: Kidney	0.11	STMR-RAC (EFSA, 2024)	-	-
Equine: Edible offals (other than liver and kidney)	1 1	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Poultry: Muscle/meat	0.02 0.02	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Poultry: Fat tissue	0.02 0.02	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Poultry: Liver	0.1 0.1	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Other farmed animals: Muscle/meat	0.5 0.5	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Other farmed animals: Fat tissue	0.3 0.3	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Other farmed animals: Liver	1 1	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Other farmed animals: Kidney	1 1	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Other farmed animals: Edible offals (other than liver and kidney)	1 1	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Milk	0.02	STMR-RAC (EFSA, 2024)	-	-
Eggs	0.02 0.02	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-
Honey and other apiculture products	0.13 0.1	STMR-RAC (EFSA, 2024) Table 7.2-15	0.85 0.1	HR-RAC (EFSA, 2024) Table 7.2-15
All other products of animal origin	various various	PLAN EU MRL[2)] Existing EU MRL[3)]	-	-

2) PLAN/2024/1403 (planned MRLs)
3) Regulation (EU) 2025/1212 applicable from 20/08/2025

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-18: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	**SCENARIO 1** **679** % (based on NL toddler diet) *Highest contributors:* 239% Milk: cattle 104% Apples

	52% Bananas
TMDI (% ADI) according to EFSA PRIMo 3.1	**SCENARIO 2** **417** % (based on NL toddler diet) *Highest contributors:* 239% Milk: cattle 49% Oranges 18% Apples **SCENARIO 2** **417** % (based on NL toddler diet) *Highest contributors:* 239% Milk: cattle 49% Oranges 18% Apples
IEDI (% ADI) according to EFSA PRIMo rev.3.1	52 % (based on NL toddler diet) *Highest contributors:* 24% Milk: cattle 6% Apples 3% Rose hips **SCENARIO 3** 53 % (based on NL toddler diet) *Highest contributors:* 24% Milk: cattle 6% Apples 3% Rose hips
IESTI (% ARfD) according to EFSA PRIMo rev.3.1*	**SCENARIO 1** Unprocessed commodities (children): **1341**% Pears (based on diet: NL toddler) **1043**% Apples (based on diet: NL toddler) **476**% Quinces (based on diet: ES child) **268**% Medlar (based on diet: ES child) 11% Rapeseeds/canola seeds (based on diet: DE child) 4% Honey and other apiculture products (based on diet: NL toddler) Unprocessed commodities (adults): **296**% Pears (based on diet: NL general population) **294**% Quinces (based on diet: ES adult) **272**% Apples (based on diet: FR adult) **133**% Medlar (based on diet: ES adult) 4% Rapeseeds/canola seeds (based on diet: DE women 14-50) 1% Honey and other apiculture products (based on diet: CZ males 15-17 years) Processed commodities (children): **524**% Apples / juice (based on diet: DE child) **315**% Pears / juice (based on diet: NL child) 59% Quinces / jam (based on diet: NL child) 5% Rapeseeds / oils (based on diet: NL toddler) Processed commodities (adults): **323**% Apples / juice (based on diet: NL general population) 24% Quinces / jam (based on diet: NL general population)
IESTI (% ARfD) according to EFSA PRIMo	**SCENARIO 2**

rev.3.1*	Unprocessed commodities (children): **298**% Quinces (based on diet: ES child) **235**% Pears (based on diet: NL toddler) **183**% Apples (based on diet: NL toddler) 100% Medlar (based on diet: ES child) 11% Rapeseeds/canola seeds (based on diet: DE child) 4% Honey and other apiculture products (based on diet: NL toddler) Unprocessed commodities (adults): **184**% Quinces (based on diet: ES adult) 52% Pears (based on diet: NL general population) 50% Medlar (based on diet: ES adult) 48% Apples (based on diet: FR adult) 4% Rapeseeds/canola seeds (based on diet: DE women 14-50) 1% Honey and other apiculture products (based on diet: CZ males 15-17 years) Processed commodities (children): 92% Apples / juice (based on diet: DE child) 55% Pears / juice (based on diet: NL child) 37% Quinces / jam (based on diet: NL child) 5% Rapeseeds / oils (based on diet: NL toddler) Processed commodities (adults): 56% Apples / juice (based on diet: NL general population) 15% Quinces / jam (based on diet: NL general population) **SCENARIO 2** Unprocessed commodities (children): **235**% Pears (based on diet: NL toddler) **183**% Apples (based on diet: NL toddler) **100**% Medlar (based on diet: ES child) 89% Quinces (based on diet: ES child) 21% Honey and other apiculture products (based on diet: NL toddler) 11% Rapeseeds/canola seeds (based on diet: DE child) Unprocessed commodities (adults): 55% Quinces (based on diet: ES adult) 52% Pears (based on diet: NL general population) 50% Medlar (based on diet: ES adult) 48% Apples (based on diet: FR adult) 8% Honey and other apiculture products (based on diet: CZ males 15-17 years) 4% Rapeseeds/canola seeds (based on diet: DE women 14-50) Processed commodities (children): 92% Apples / juice (based on diet: DE child) 55% Pears / juice (based on diet: NL child) 11% Quinces / jam (based on diet: NL child) 5% Rapeseeds / oils (based on diet: NL toddler) Processed commodities (adults): 56% Apples / juice (based on diet: NL general population) 5% Quinces / jam (based on diet: NL general population)
IESTI (% ARfD) according to EFSA PRIMo rev.3.1*	**SCENARIO 3** Unprocessed commodities (children): 97% Pears (based on diet: NL toddler) 76% Apples (based on diet: NL toddler) 67% Medlar (based on diet: ES child)

	61% Honey and other apiculture products (based on diet: NL toddler) 42% Quinces (based on diet: ES child) 0.8% Rapeseeds/canola seeds (based on diet: DE child) Unprocessed commodities (adults): 33% Medlar (based on diet: ES adult) 26% Quinces (based on diet: ES adult) 23% Honey and other apiculture products (based on diet: CZ males 15-17 years) 21% Pears (based on diet: NL general population) 20% Apples (based on diet: FR adult) 0.3% Rapeseeds/canola seeds (based on diet: DE women 14-50) Processed commodities (children): 29% Apples / juice (based on diet: DE child) 17% Pears / juice (based on diet: NL child) 2% Quinces / jam (based on diet: NL child) 0.4% Rapeseeds / oils (based on diet: NL toddler) Processed commodities (adults): 18% Apples / juice (based on diet: NL general population) 0.9% Quinces / jam (based on diet: NL general population) **SCENARIO 3** Unprocessed commodities (children): 97% Pears (based on diet: NL toddler) 76% Apples (based on diet: NL toddler) 67% Medlar (based on diet: ES child) 42% Quinces (based on diet: ES child) 7% Honey and other apiculture products (based on diet: NL toddler) 0.8% Rapeseeds/canola seeds (based on diet: DE child) Unprocessed commodities (adults): 33% Medlar (based on diet: ES adult) 26% Quinces (based on diet: ES adult) 21% Pears (based on diet: NL general population) 20% Apples (based on diet: FR adult) 3% 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) Processed commodities (children): 29% Apples / juice (based on diet: DE child) 17% Pears / juice (based on diet: NL child) 2% Quinces / jam (based on diet: NL child) 0.4% Rapeseeds / oils (based on diet: NL toddler) Processed commodities (adults): 18% Apples / juice (based on diet: NL general population) 0.9% Quinces / jam (based on diet: NL general population)
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 ASA-01 do not represent unacceptable acute and chronic risks for the consumer.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

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 396/20051. 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.

Commission Regulation (EU) 2025/1212 of 24 June 2025 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 or on certain products

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1/01	Author	2024	Acetamiprid-N-desmethyl in oilseed rape (green plant) - stability study Report No. SGS POLSKA Sp. z o.o. GLP Unpublished	N	XXXX
KCA 6.3/01	Bagnall J.	2022	Acetamiprid – Residue Study on Apples in Northern Europe – 2020 Report No. JBL-20-45212 STAPHYT Ltd. GLP Unpublished	N	XXXX
KCA 6.3/02	Wańczyk K.	2023	Magnitude of residue of Acetamiprid (Sum of Acetamiprid and N-desmethylacetamiprid (IM-2-1) expressed as Acetamiprid) in apple (Raw Agricultural Commodity) after two applications of ASA-01 – three trials in Hungary, Czech Republic and Poland - 2023 Report No. 23SGS28 SGS Polska Sp. z o. o. GLP Unpublished	N	XXXX
KCA 6.3/03	Domingo S.	2023	Acetamiprid – Residue Study on winter oilseed rape in Northern Eu-rope – 2020 Report No. SDO-20-45215 STAPHYT Ltd. GLP Unpublished	N	XXXX
KCA 6.3/04	Wańczyk K.	2023	Magnitude of residue of Acetamiprid (Sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid) in oilseed rape (Raw Agricultural Commodity) after one application of ASA-01 – four trials in Hungary, Czech Republic and Poland - 2023	N	XXXX

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report No. 23SGS27 SGS Polska Sp. z o. o. GLP Unpublished		
KCA 6.10, 6.10.1/01	Wańczyk K.	2023	Magnitude of residue of Acetamiprid (Sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid) in honey after one application of ASA-01 on phacelia (Raw agricultural Commodity) – four harvest study trials in Poland Report No. 23SGS26 SGS Polska Sp. z o. o. GLP Unpublished	N	XXXX

* XXXX

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
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	XXXX
KCA 6.1	Maestracci, M.	1998	Acetamiprid/Storage Stabillity Study RPA/NI-25/97051 ADME-Bioanalyses GLP Unpublished	N	XXXX

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCA 6.1	Netzband D.J.	2003	Stability study of Acetamiprid in potatoes during frozen storage, USA, 2002 in freezer at or below -18°C Report No RD-00243 Bayer CropScience GLP Unpublished	N	XXXX
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	XXXX
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	XXXX
KCA 6.2.1	Saito H.	1997a	NI-25 [Pyridine-2,6-14C] - Nature of the Residue in Eggplants Report No EC-391-3 Nisso Chemical Analysis Service Co, Ltd GLP, GEP Unpublished	N	XXXX
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	XXXX
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	N	XXXX

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			GLP, GEP Unpublished		
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	XXXX
KCA 6.2.1	McMillan-Staff S.L., Austin D.J., Lingwood A.	1997	[^{14}C]-NI-25: Metabolism in Carrots. Report No 11253 Rhône-Poulenc Agriculture Ltd GLP, GEP Unpublished	N	XXXX
KCA 6.2.1	Miller N.	1999	Foliarly applied 14C-acetamiprid: Metabolic fate and distribution in cotton (Gossypium hirsutum) Report No EC-97-367 Rhone-Poulenc Ag Company GLP Unpublished	N	XXXX
KCA 6.2.2-6.2.5	xxxx	1997b	^{14}C-NI-25 (Acetamiprid): Absorption, Distribution, Metabolism and Excretion after Repeated Oral Administration to Laying Hens. Report No 628143 xxxxx GLP, GEP Unpublished	N	XXXX
KCA 6.2.2-6.2.5	xxxx	1997a	^{14}C-NI-25 (Acetamiprid): Absorption, Distribution, Metabolism and Excretion after Repeated Oral Administration to Lactating Goats Report No 628132 xxx GLP, GEP Unpublished	N	XXXX
KCA 6.3	D'AccriscioM.,	1997	Aetamiprid (NI-25) – Formulation EXP60707A (SP) – Trial United Kingdom – residues in Apple decline	N	XXXX

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
	Maestracci M.		study Rhone-Poulenc Agro Report/file: R&D/CRLD/AN/dbe 9716245 GLP, GEP : yes Not published		
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	XXXX
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/dbe 9716246 GLP, GEP : yes Not published	N	XXXX
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	XXXX
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/dbe 9716757 GLP, GEP : yes Not published	N	XXXX
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	N	XXXX

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			GLP, GEP : yes Not published		
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	XXXX
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	XXXX
KCA 6.5.1 KCA 6.5.2-6.5.3	McMillan-Staff S.L., Austin D.J.,	1997	[^{14}C]-NI-25 Investigation of the Nature of the Potential Residue in the Products of Industrial Processing or Household Preparation. Report No RPAL Study 13442 Rhone-Poulenc Ag Company GLP Unpublished	N	XXXX
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	XXXX
KCA 6.5.2-6.5.3	Venet C., Barriere I.,	2000	Acetamiprid (NI-25) – Formulation EXP60707A (SP) - Trials France 1999 - Residues in Apple + Processed products Report No R&D/CRLD/AN/mba/0015360 Aventis CropScience GLP, GEP	N	XXXX

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			Unpublished		
KCA 6.6.1	Hobbs G., Inns L.	2012	[^{14}C]-IM-1-5: Uptake and Metabolism of Soil Residues in Confined Rotational Crops Report No RD-02391 GLP Unpublished	N	XXXX
KCA 6.6.2	Raufer B.	2013	Residue study on rotational crops after one application of Acetamiprid on bare soil at 2 sites in Europe in 2010 to 2012. Report No RD-02495N2 GLP Unpublished	N	XXXX
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	XXXX

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.6.2/01	Pietr S.J, Krysztoforski M., *et al.*	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	Not relevant. Public available
KCA	Ochal P.	2020	Aktualny stan zakwaszenia gleb w Polsce	N	Not relevant.

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
6.6.2/02			https://nawozy.eu/wiedza/porady-ekspertow/z-kraju/aktualny-stan-zakwaszenia-gleb-w-polsce 28.06.2020 Published on-line article		Public available
KCA 6.6.2/03	Jajor E., Mrówczyński M.	2013	Metodyka integrowanej ochrony rzepaku ozimego i jarego dla producentów – Poznań 2013 Instytut Ochrony Roślin – Państwowy Instytut Badawczy Published	N	Not relevant. Public available

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 Evaluator:	The study has been accepted.

Reference:	KCA 6.1/01
Report	Acetamiprid-N-desmethyl in oilseed rape (green plant) - stability study; Niewelt-Stasiak S., 2024, Study No: DPL/85/2023
Guideline(s):	Yes, SANTE/2020/12830 Rev.2
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of the study was to evaluate the stability of stability of acetamiprid-N-desmethyl (IM-2-1) in oilseed rape (green plant) for a period of 60 days.
Specimen extraction of residues of acetamiprid-N-desmethyl (IM-2-1) was performed according to the QuEChERS method.
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 in oilseed rape (green plant) was validated according to SANTE/2020/12830 Rev.2. 14. February 2023. Validation criteria and results were summarized in Part B Section 5 (study VAL/14/2023).

Results and discussions

Stability was demonstrated for acetamiprid-N-desmethyl in oilseed rape (green plant) upon storage at ≤ -18°C for a period of 60 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 oilseed rape (green plant).
There were no interfering signals at retention time of analysed compound in examined control matrix.

Table A 1: Reporting for a spike level of 0.050 mg/kg – oilseed rape (green plant)

Commodity	Analyte	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 (%)
oilseed rape (plant)	(IM-2-1)*	0	-	-	99.7 98.8
oilseed rape (plant)	(IM-2-1)*	60	0.054 0.055 0.058	108.0 111.0 115.1	105.2 96.6

* acetamiprid-N-desmethyl

Conclusion

Stability was demonstrated for acetamiprid-N-desmethyl in oilseed rape (green plant) upon storage at ≤ -18°C for a period of 60 days.

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 2: 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)	2	75 g a.s/ha	-	BBCH 77-87	14
cGAP EU (Art. 12, EFSA, 2018)	2	100 g a.s./ha	-	BBCH 69-81	14
Intended cGAP (number 2*)	1	max. 22.5 g as/ha	-	BBCH 56-75	14
Intended cGAP (number 3*)	2	max. 27 g as/ha	7 days	BBCH 57-75	14

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

A 2.1.3.1.1 Study 1

Comments of Evaluator:	The study has been accepted.

Reference:	KCA 6.3/01
Report	Acetamiprid – Residue Study on Apples in Northern Europe – 2020; BAGNALL J.; 2022; report no. JBL-20-45212
Guideline(s):	Yes - The national GLP guideline in UK: The UK Good Laboratory Practice Regulations – UK Statutory Instrument 1999 No. 3106, The Good Laboratory Practice Regulations 1999; UK Statutory Instrument 2004 No. 994, The Good Laboratory Practice (Codification Amendment Etc.) Regulations 2004." - The OECD Principles of Good Laboratory Practice (as Revised in 1997), OECD Series on Principles of GLP and Compliance Monitoring Number 1, ENV/MC/CHEM(98)17. - General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95 rev.5, 22 July 1997). - OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published on 7 September 2009).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Field Phase of the study:
Three decline curve study trials and two harvest study trials were located in Northern Europe (three in

Poland, one in Hungary and one in Germany) in 2020. Two plots were established in all trials: U plot was left untreated, the T plot was treated twice at BBCH 81 and then 7 DAA 1 with ASA-01 at the target rate of 0.135 L/ha, representing 40.5 g/ha of acetamiprid.
Applications were carried out using mist blower (PL01, 02, 05 & DE04) or air blast (HU03) sprayers in order to reproduce a normal agricultural application technique on a small scale size. The amounts of spray mixture applied of ASA-01 were between 617 (lower limit) and 919 (upper limit) L/ha.
In decline trials (PL01, PL02 and HU03), fruit was taken at 0 DBLA/DALA, 3, 7 (±1),14 (±1) and 21 (±2) DALA. In harvest trials (DE04 and PL05) fruit was taken at 14 DALA (± 1 DALA).
Specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen (<-18°C) within 4 hours after sampling and shipped by freezer truck. Shipments to the analytical laboratory were done in frozen conditions (<-18°C) with short peaks up to -16.4°C (PL01, PL02 & HU03) and -16.6°C (DE04 & PL05).

Analytical Phase of the study:
The analytical method was validated under GLP compliance according to the SANCO/825/00 rev.8.1 and SANCO/3029/99 rev.4 guidelines on Apple samples. Residues of acetamiprid were extracted from apple fruit samples with acetonitrile and addition of water, then the samples were shaken. Sodium chloride was added following further shaking and centrifugation of samples. An aliquot of the final extract was quantified by HPLC-MS/MS.
For the fruit samples, procedural recovery tests at two levels were carried out to confirm method performance.
The limit of quantification (LOQ) of the analytical method is 0.01 mg/kg for acetamiprid.
Limit of detection corresponds to 30% of the target LOQ (0.01 mg/kg).
The accuracy and precision of the method during specimen analysis were considered to be acceptable since single and mean recoveries were in the range of 70 - 110 % with relative standard deviations below 20 % for all analytes. Details are described in dRR Part B Section 5.

Conclusion

No residue of acetamiprid was detected in any untreated apple specimens.
After two applications with ASA-01 at the rate of 0.135 L/ha, the residues of acetamiprid were:
From 0.0429 to 0.105 mg/kg at 0 DALA, from 0.0132 to 0.0835 mg/kg at 3 DALA, from 0.0164 to 0.0740 mg/kg at 7 (±1) DALA, from 0.0104 to 0.102 mg/kg at 14 (±1) DALA and from <LOQ to 0.0355 at 21 (±2) DALA.

Table A 3: Summary of the study JBL-20-45212 (5 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 (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				Acetamiprid		
	(a)	(b)				(c)				(d)	(e)
Trial number JBL-20-45212 / PL-01 / Poland, Lodzkie 96-124 Makow / N-EU / 2020	Apple/ Idared	1. 20/10/1998 2. From 06/05/2020 To 21/05/2020 3. 05/10/2020 to 22/10/2020	0.0396 0.0405	686 701	0.0058 0.0058	11/09/2020 18/09/2020	81 85	Fruit Fruit Fruit Fruit Fruit	0.0938 0.0636 0.0641 0.0363 0.0355	0 3 7 14 21	The analytical method was validated in apple fruit in the study GLP Study -20-40-1, full validation according to SANCO/3029/99, rev. 4. LOQ: 0.01 mg/kg Max. Storage Interval between sampling and analysis: 67 days
Trial number JBL-20-45212 / PL-02 / Poland Warminsko-Mazurskie, 11-010 Bark / N-EU / 2020	Apple/ Antonowka	1. 15/09/2004 2. From 04/05/2020 To 27/05/2020 3. 15/09/2020	0.0417 0.0414	721 716	0.0058 0.0058	19/08/2020 25/08/2020	81 81	Fruit Fruit Fruit Fruit Fruit	0.0429 0.0132 0.0164 0.0104 < LOQ	0 3 7 14 21	The analytical method was validated in apple fruit in the study GLP Study -20-40-1, full validation according to SANCO/3029/99, rev. 4. LOQ: 0.01 mg/kg Max. Storage Interval between sampling and analysis: 91 days
Trial number JBL-20-45212 / HU-03 / Hungary Csongradcsanad 6763 Szatymaz / N-EU / 2020	Apple/ Golden Delicious	1. Autumn 1999 2- From 20/04/2020 To 20/05/2020 3. 27/09/2020 To 10/10/2020	0.0423 0.0417	627 617	0.0067 0.0068	04/09/2020 12/09/2020	81 81	Fruit Fruit Fruit Fruit Fruit	0.105 0.0835 0.0740 0.0342 0.0237	0 3 8 15 22	The analytical method was validated in apple fruit in the study GLP Study -20-40-1, full validation according to SANCO/3029/99, rev. 4. LOQ: 0.01 mg/kg Max. Storage Interval between sampling and analysis: 73 days
Trial number JBL-20-45212 / DE-04 / Germany Baden-Wurtemberg 77855 Achern / N-EU / 2020	Apple/ Elstar	1. 2005 2. From 18/04/2020 To 01/05/2020 3. 05/09/2020	0.0396 0.0414	879 919	0.0045 0.0045	12/08/2020 19/08/2020	81 85	Fruit	0.0131	14	The analytical method was validated in apple fruit in the study GLP Study -20-40-1, full validation according to SANCO/3029/99, rev. 4. LOQ: 0.01 mg/kg

											Max. Storage Interval between sampling and analysis: 83 days
Trial number JBL-20-45212 / PL-05 / Poland Wielkopolskie 62-310 Pyzdry / N-EU /2020	Apple/ Red Gala	1. 04/03/2019 2. From 20/04/2020 To 09/05/2020 3. 26/08/2020	0.0390 0.0417	674 719	0.0058 0.0058	05/08/2020 12/08/2020	81 85	Fruit	0.102	14	The analytical method was validated in apple fruit in the study GLP Study -20-40-1, full validation according to SANCO/3029/99, rev. 4. LOQ: 0.01 mg/kg Max. Storage Interval between sampling and analysis: 90 days

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

A 2.1.3.1.2 Study 2

Comments of Evaluator:	The study has been accepted.

Reference:	KCA 6.3/02
Report	Magnitude of residue of Acetamiprid (Sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid) in apple (Raw Agricultural Commodity) after two applications of ASA-01 – three trials in Hungary, Czech Republic and Poland - 2023; Wańczyk K.; 2023; report no. 23SGS28
Guideline(s):	Yes - Regulation (EC) N°1107/2009 of 21 October 2009 (Repealing the Council Directive 91/414/EEC) concerning the placing of plant protection products on the market. - Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, 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. - General recommendations for the design, preparation and realization of residue trials, 7029/VI/95-rev 5, 22.07.97 and amendments - OECD (2021),Test No. 509: Crop Field Trial, OECD Guidelines for the Testing of Chemicals, Section 5, OECD Publishing. - EU pesticide residue legislation: Guidance document on pesticide analytical methods for risk assessment and post-approval control and monitoring purposes-SANTE/2020/12830 rev.2, 14 February 2023. - Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Field Phase of the study:
Three trials were established in 3 countries Poland, Czech Republic and Hungry. Trials consisted of one untreated plot U and one treated plot T with minimum plots size 6 trees for HS and 8 trees for DCS.

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 0,135 L/ha (ASA-01). The target spray volume was 500-900 litres per hectare according to Good Agricultural Practices.
For the test item ASA-01 the reported dose rate was at:

- Trial 23SGS28-01 – 0.140 L/ha and 0.137 (779.5 L/ha water and 760.7)
- Trial 23SGS28-02 – 0.130 L/ha and 0.136 (575.7 L/ha water and 604.2)
- Trial 23SGS28-03 – 0.134 L/ha and 0.138 (796.7 L/ha water and 816.7)

Applications were performed: first at 7 days before application A2 or 21 days before harvest (if possible BBCH 79- 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. The calculations and the delivery rates were verified by the Study Director.

Deviations to the target rates were all between ± 5% as requested in the study plan, actually it was:
- Trial 23SGS28-01 – + 3.7% and + 1.5
- Trial 23SGS28-02 – - 4.0% and + 0.8
- Trial 23SGS28-03 – - 0.74 % and + 2.2

In DCS trial RAC specimens for analyses were collected at:
S1: - 0/+ DALA - Fruit without stem
S2: 3 DALA - Fruit without stem
S3: 7 DALA - Fruit without stem
S4: 14±1 DALA - Fruit without stem
S5: 21±1 DALA- Fruit without stem

In HS trials RAC specimens for analyses were collected at:
S1: CH/14±1 DALA - 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 ≤ -18° 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 for analysis.

Analytical Phase of the study:
Specimen extraction and determination of residues of acetamiprid and acetamiprid-N-desmethyl were performed according to the multi-residue QuEChERS method. The method was validated according to SANTE/2020/12830 Rev.2, 14 February 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), and for "sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid" limit of quantification was 0.01 mg/kg.
The performance of the method during the analytical study complies with SANTE/2020/12830 Rev.2 criteria (accuracy in the range 70 120%). Details are described in dRR Part B Section 5 (VAL/15/23).

Conclusion

This study was fully performed as anticipated, in accordance with the study plan and the amendment issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s).

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 in apple samples after two applications of ASA-01.

Table A 4: Summary of the study 23SGS28 (3 trials)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				Acetamiprid	N-desmethyl-acetamiprid (IM-2-1)	Sum of acetamiprid and N-desmethyl-acetamiprid		
Trial number 23SGS28-01 / Poland (Goszczyn) / N-EU / 2023	Apple/ Gloster	1. 19.03.2017 2. 03.05.2023-10.05.2023 3. 05.10.2023-10.10.2023	0.042 0.041	779.5 760.7	0.0054 0.0054	08/09/2023 15/09/2023	85 85	Fruit Fruit Fruit Fruit Fruit	0.074 0.081 0.059 0.043 0.023	<LOQ <LOQ <LOQ <LOQ <LOD	0.074 0.081 0.059 <u>0.043</u> 0.023	0 3 7 14 20	Analytical Method: LC-MS/MS LOQ: 0.005 mg/kg (for acetamiprid and IM-2-1) LOQ: 0.01 mg/kg (for sum of acetamiprid and IM-2-1) Max. Storage Interval between sampling and analysis: 29 days
Trial number 23SGS28-02 / Hungary (Újfehértó) / N-EU / 2023	Apple/ Jonagold	1. 2012 2. 20.04.2023-10.05.2023 3. 20.09.2023-25.09.2023	0.039 0.041	575.7 604.3	0.0068 0.0068	30/08/2023 06/09/2023	81 85	Fruit	0.061	<LOD	<u>0.061</u>	14	Analytical Method: LC-MS/MS LOQ: 0.005 mg/kg (for acetamiprid and IM-2-1) LOQ: 0.01 mg/kg (for sum of acetamiprid and IM-2-1) Max. Storage Interval between sampling and analysis: 24 days
Trial number 23SGS28-03 / Czech Republic (Doudleby and Orlici)/ N-EU / 2023	Apple/ Vanda	1. 2002 2. 28.04.2023-11.05.2023 3. 22.09.2023-25.09.2023	0.040 0.041	796.7 816.7	0.0050 0.0050	31/08/2023 07/09/2023	85-87 87	Fruit	0.024	<LOQ	<u>0.024</u>	13	Analytical Method: LC-MS/MS LOQ: 0.005 mg/kg (for acetamiprid and IM-2-1) LOQ: 0.01 mg/kg (for sum of acetamiprid and IM-2-1) Max. Storage Interval between sampling and analysis: 24 days

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

A 2.1.3.2 Oilseed rape

Table A 5: 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	24 - 30 g as/ha	NR	BBCH 50-60	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:	The study has been accepted.

Reference: KCA 6.3/03

Report: Acetamiprid – Residue Study on winter oilseed rape in Northern Europe – 2020; DOMINGO S.; 2023; report no. SDO-20-45215

Guideline(s): Yes
- The national GLP guideline in UK: The UK Good Laboratory Practice Regulations – UK Statutory Instrument 1999 No. 3106, The Good Laboratory Practice Regulations 1999; UK Statutory Instrument 2004 No. 994, The Good Laboratory Practice (Codification Amendment Etc.) Regulations 2004."
- The OECD Principles of Good Laboratory Practice (as Revised in 1997), OECD Series on Principles of GLP and Compliance Monitoring Number 1, ENV/MC/CHEM(98)17.
- General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95 rev.5, 22 July 1997).
- OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published on 7 September 2009).

Deviations: Yes

Trial PL01 and PL03

Maximum temperatures at shipment times at freezer truck were reached: for the first shipment on 06-07-2020: -16.9ºC and for the second shipment on 17/18-08-2020: -16.4ºC, instead required at study plan “temperatures must be kept at or below -18ºC. No impact on the study results.

Trial DE02 and DE04

During the shipments of the specimens to the analytical laboratory some peaks above -18ºC were observed. The max. temperatures were the following. Trial DE02: 10.07.2020 to 13.07.2020: -16.7ºC; 17.08.2022/21.08.2020 to 26.08.2020: -16.8ºC. Trial DE04:17.08.2020 to 20.08.2020: -16.4ºC. The samples remained frozen. No impact on the study results.

Trial PL03

Freezer 1220U was broken, ship and retain samples were removed to different freezer, from 17/01/2021 (23h36) to 18/01/2021 (09h00) temperature was higher than -18°C (Maximum temperature observed -15.9°C and period of

	time 9 hours and 24 minutes). Samples were removed on 18.01.2021 at 08h55 from freezer 1220U to 1394U. Samples affected were: sample no. 53 (ship sample not send to be analysed), 57 (ship sample not send to be analysed), 50 (retain sample), 62 (retain sample) and 70 (retain sample). No impact on the study results. Specimens remained frozen.
GLP:	Yes
Acceptability:	Yes

Materials and methods

Field Phase of the study:
Three decline curve study trials and one harvest study trial were located in Northern Europe (two in Poland and two in Germany) in 2020. Two plots were established in every trials: U plot was left untreated, plot T was treated once at BBCH 77-80 (28 Days before harvest) with ASA-01 at the rate of 0.12 L/ha, representing 36 g/ha of acetamiprid.
Applications were carried out using boom sprayers in order to reproduce a normal agricultural application technique on a small scale size. The amounts of spray mixture applied of ASA-01 were between 213 (lower limit) and 303 (upper limit) L/ha.
In decline trials (PL01, DE02 and PL03), whole plants of winter oilseed rape crop were taken at 0 DBA/DAA, 7 (±1) and 14 (±1) DAA, pods and whole plants without pods of winter oilseed rape crop were taken at 21 (±2) DAA and seeds were taken at commercial Harvest (28 ± 2 DAA). In harvest trial (DE04) seeds were taken at commercial Harvest (28 ± 2 DAA).
Specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen (<-18°C) within 11 hours after sampling and shipped by freezer truck or on dry ice. Shipment to the analytical laboratory was done in frozen conditions (<-18°C).

Analytical Phase of the study:
The analytical method was validated under GLP compliance according to the SANCO/825/00 rev.8.1 and SANCO/3029/99 rev.4 for oilseed rape whole plant and seeds.
Residues of acetamiprid were extracted from oilseed rape whole plant and seeds samples with acetonitrile and addition of water, then the samples were shaken. Sodium chloride was added following further shaking and centrifugation of samples. An aliquot of the final extract was quantified by HPLC-MS/MS.
For pod samples and whole plant without pod samples, procedural recovery tests at two levels were carried out to confirm method performance.
The limit of quantification (LOQ) of the analytical method is 0.01 mg/kg for acetamiprid.
Limit of detection corresponds to 30% of the target LOQ (0.01 mg/kg).
The accuracy and precision of the method during specimen analysis were considered to be acceptable since single and mean recoveries were in the range of 70 - 110 % with relative standard deviations below 20 % for all analytes. Details are described in dRR Part B Section 5.

Conclusion

No residue of acetamiprid was detected in any untreated oilseed rape specimens.
After one application with ASA-01 at the rate of 0.12 L/ha, the residues of acetamiprid were:
- in oilseed rape whole plant: From 0.2676 to 0.5625 mg/kg just after application, from <LOD to 0.1697 mg/kg at 7 (±1) DAA and from 0.0851 to 0.3207mg/kg at 14 (±1) DAA.
- in pods: from 0.1305 to 0.3800 mg/kg at 21 (±2) DAA.
- in whole plants without pods: from 0.0439 to 0.2468 mg/kg at 21 (±2) DAA.
- in seeds: from <LOD to 0.0132 mg/kg at Commercial Harvest 28 (±2) DAA.

Table A 6: Summary of the study SDO-20-45215 (4 trials)

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: kg a.s./ ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: kg a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): Acetamiprid	PHI (days) (d)	Details on trial (e)
Trial number SDO-20-45215 / PL-01 / Poland Wielkopolska 63-040 Michałów/ N-EU / 2020	Winter oilseed rape/ Valegro	1. 29/08/2019 2. From 24/04/2020 To 15/05/2020 3. 15/07/2020	0.0363	303	0.0120	25/06/2020	80	Whole plant Whole plant Whole plant Pods Whole plant without pods Seeds	0.4179 0.1697 0.2000 0.2117 0.0737 <u>0.0132</u>	0 7 13 21 21 26	The analytical method was validated in apple fruit in the study GLP Study -20-26, full validation according to SANCO 825/00 rev. 8.1 and SANCO/3029/99, rev. 4. LOQ: 0.01 mg/kg LOD: 0.002 mg/kg Max. Storage Interval between sampling and analysis: 77 days
Trial number SDO-20-45215 / DE-02 / Germany Bayern 91622 Lindach-Rügland / N-EU / 2020	Winter oilseed rape/ DK Expansion	1. 29/08/2019 2. From 23/04/2020 To 05/05/2020 3. 01/08/2020	0.0366	303	0.0121	24/06/2020	80	Whole plant Whole plant Whole plant Pods Whole plant without pods Seeds	0.2676 <LOD 0.3207 0.3800 0.2468 <u><LOD</u>	0 7 14 23 23 28	The analytical method was validated in apple fruit in the study GLP Study -20-26, full validation according to SANCO 825/00 rev. 8.1 and SANCO/3029/99, rev. 4. LOQ: 0.01 mg/kg LOD: 0.002 mg/kg Max. Storage Interval between sampling and analysis: 76 days
Trial number SDO-20-45215 / PL-03 / Poland Wielkopolska 64-610 Pruśce/ N-EU / 2020	Winter oilseed rape/ Chrobry	1. 28/08/2019 2. 23/04/2020 to 21/05/2020 3. 16/07/2020	0.0354	295	0.0120	16/06/2020	79	Whole plant Whole plant Whole plant Pods Whole plant without pods Seeds	0.5625 0.1591 0.0851 0.1305 0.0439 <u><LOD</u>	0 7 15 21 21 30	The analytical method was validated in apple fruit in the study GLP Study -20-40-1, full validation according to SANCO/3029/99, rev. 4. LOQ: 0.01 mg/kg LOD: 0.002 mg/kg Max. Storage Interval between sampling and analysis: 86 days
Trial number	Winter oilseed rape/	1. 21/08/2019	0.0384	213	0.0180	18/06/2020	80	Seeds	<u><LOD</u>	29	The analytical method was validated in apple fruit in the

SDO-20-45215 / DE-04 / Germany Schles-wig-Holstein 23919 Rondeshagen/ N-EU / 2020	Sy Alibaba	2. 15/04/2020 to 10/05/2020 3. 29/07/2020									study GLP Study -20-40-1, full validation according to SANCO/3029/99, rev. 4. LOQ: 0.01 mg/kg LOD: 0.002 mg/kg Max. Storage Interval between sampling and analysis: 41 days

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

A 2.1.3.2.2 Study 2

Comments of Evaluator:	The study has been accepted.

Reference:	KCA 6.3/04
Report	Magnitude of residue of Acetamiprid (Sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid) in oilseed rape (Raw Agricultural Commodity) after one application of ASA-01 – four trials in Hungary, Czech Republic and Poland - 2023; Wańczyk K.; 2023; report no. 23SGS27
Guideline(s):	Yes - Regulation (EC) N°1107/2009 of 21 October 2009 (Repealing the Council Directive 91/414/EEC) concerning the placing of plant protection products on the market. - Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, 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. - General recommendations for the design, preparation and realization of residue trials, 7029/VI/95-rev 5, 22.07.97 and amendments - OECD (2021),Test No. 509: Crop Field Trial, OECD Guidelines for the Testing of Chemicals, Section 5, OECD Publishing. - EU pesticide residue legislation: Guidance document on pesticide analytical methods for risk assessment and post-approval control and monitoring purposes-SANTE/2020/12830 rev.2, 14 February 2023. - Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Field Phase of the study:
Four trials were established in 3 countries Poland, Czech Republic and Hungry. Trials consisted of one untreated plot U and one treated plot T with minimum plots size 30 m^2 for HS and 45 m^2 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 (ASA-01). The target spray volume was 200-400 litres per hectare according to Good Agricultural Practices.

For the test item ASA-01 the reported dose rate was at:
- Trial 23SGS27-01 - 0.123 L/ha (306.7 L/ha water)
- Trial 23SGS27-02 - 0.121 L/ha (302.0 L/ha water)
- Trial 23SGS27-03 - 0.118 L/ha (293.8 L/ha water)
- Trial 23SGS27-04 – 0.123 L/ha (306.7 L/ha water)

Applications were performed at BBCH 77-80 (28 ±2 DBCH).

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

Deviations to the target rates were all between ± 5% as requested in the study plan, actually it was:
- Trial 23SGS27-01 – +2.1%
- Trial 23SGS27-02 – +0.8%
- Trial 23SGS27-03 – -1.7%
- Trial 23SGS27-04 – +2.5 %

In DCS trial RAC specimens for analyses were collected at:
S1: - 0/+ DAA - whole plant without root
S2: 7 ±1 DAA - whole plant without root
S3: 14 ±1 DAA - whole plant without root
S4: 21 ±1 DAA - pods, rest of plant without pods
S5: CH/28 ±2 DAA - seeds

In HS trial RAC specimens for analyses were collected at:
S1: CH/28 ±2 DAA - seeds

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 ≤ -18°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 for analysis.

Analytical Phase of the study:
Specimen extraction and determination of residues of acetamiprid and acetamiprid-N-desmethyl were performed according to the multi-residue QuEChERS method. The method was validated according to SANTE/2020/12830 Rev.2, 14 February 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), and for "sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid" limit of quantification was 0.01 mg/kg.
The performance of the method during the analytical study complies with SANTE/2020/12830 Rev.2 criteria (accuracy in the range 70 120%). Details are described in dRR Part B Section 5 (VAL/14/23).

Conclusion

This study was fully performed as anticipated, in accordance with the study plan and the amendment issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s).

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 in winter oilseed rape after one application of ASA-01.

Table A 7: Summary of the study 23SGS27 (4 trials)

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: kg a.s./ ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: kg a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): Acetamiprid	Residues (mg/kg): N-desmethyl-acetamiprid (IM-2-1)	Residues (mg/kg): Sum of acetamiprid and N-desmethyl-acetamiprid	PHI (days) (d)	Details on trial (e)
Trial number 23SGS27-01 / Hungary (Monok) / N-EU / 2023	Winter Oilseed Rape/ DK Excited	1. 02.09.2022 2. 02.05.2023-02.05.2023 3. 12.07.2023	0.0368	306.7	0.012	12/06/2023	80	whole plant w/o root	0.19	<LOQ	0.19	0	Analytical Method: LC-MS/MS LOQ: 0.005 mg/kg (for acetamiprid and IM-2-1) LOQ: 0.01 mg/kg (for sum of acetamiprid and IM-2-1) Max. Storage Interval between sampling and analysis: 60 days
								whole plant w/o root	0.18	0.037	0.22	7	
								whole plant w/o root	0.053	0.021	0.075	14	
								Pods	0.20	0.076	0.28	21	
								Rest of plant w/o pods	<LOQ	<LOD	<LOQ	21	
								Seeds	0.028	0.0080	0.037	30	
Trial number 23SGS27-02 / Poland (Białożewin) / N-EU / 2023	Winter Oilseed Rape/ Glorietta	1. 25.08.2022 2. 01.05.2023-21.05.2023 3. 18.07.2023	0.0363	302.0	0.0120	20/06/2023	79	Seeds	<LOD	<LOD	<LOD	28	Analytical Method: LC-MS/MS LOQ: 0.005 mg/kg (for acetamiprid and IM-2-1) LOQ: 0.01 mg/kg (for sum of acetamiprid and IM-2-1) Max. Storage Interval between sampling and analysis: 24 days
Trial number 23SGS27-03 / Poland (Ostrowo) / N-EU / 2023	Winter Oilseed Rape/ Kadore	1. 26.08.2022 2. 03.05.2023-25.05.2023 3. 19.07.2023	0.0354	293.8	0.0120	19/06/2023	77	Seeds	0.025	<LOQ	0.025	30	Analytical Method: LC-MS/MS LOQ: 0.005 mg/kg (for acetamiprid and IM-2-1)

													LOQ: 0.01 mg/kg (for sum of acetamiprid and IM-2-1) Max. Storage Interval between sampling and analysis: 23 days
Trial number 23SGS27-04 / Czech Republic (Chvojenec) / N-EU / 2023	Winter Oilseed Rape/ Architect LG	1. 20.08.2022 2. 30.04.2023-25.05.2023 3. 17.07.2023-18.07.2023	0.0369	306.7	0.0120	19/06/2023	77-80	Seeds	0.050	0.0067	0.057	28	Analytical Method: LC-MS/MS LOQ: 0.005 mg/kg (for acetamiprid and IM-2-1) LOQ: 0.01 mg/kg (for sum of acetamiprid and IM-2-1) Max. Storage Interval between sampling and analysis: 25 days

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

A 2.1.4 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 Study 1

Comments of Evaluator:	The study has been accepted. MRL in honey can be exceeded.

Reference:	KCA 6.10, 6.10.1/01
Report	Magnitude of residue of Acetamiprid (Sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid) in honey after one application of ASA-01 on phacelia (Raw agricultural Commodity) – four harvest study trials in Poland; Wańczyk K., 2023; report no. 23SGS26
Guideline(s):	Yes - Regulation (EC) N°1107/2009 of 21 October 2009 (Repealing the Council Directive 91/414/EEC) concerning the placing of plant protection products on the market. - Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, 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. - Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No

	1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (Text with EEA relevance). - General recommendations for the design, preparation and realization of residue trials, 7029/VI/95-rev 5, 22.07.97 and amendments. - OECD (14.06.2021),Test Guideline No. 509: Crop Field Trial, OECD Guidelines for the Testing of Chemicals, Section 5, OECD Publishing. - EU pesticide residue legislation: Guidance document on pesticide analytical methods for risk assessment and post-approval control and monitoring purposes-SANTE/2020/12830 rev.2, 14 February 2023. - Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17. - Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residues Levels in honey, SANTE/11956/2016 rev. 9, 14 September 2018.
Deviations:	Yes There were analysed retain samples from untreated plots from trial 23SGS26-01 and 23SGS26-02 for the request of Sponsor and Study Director decision.
GLP:	Yes
Acceptability:	Yes

Materials and methods

Field Phase of the study:
Four trials were established in Poland. Each trial consists of one control tunnel and one treated tunnel with phacelia protected with an insect-proof net without possibility to foraging on another nectar source. Also covered tunnel area was empty of melliferous plants but with regular access to the water. Each tunnel consists at least 120 m^2 required in the study plan.

Beehives were placed in tunnels (one colony per tunnel) one day before application to give the bees possibility to acclimatise to the new place. During application hives were covered and closed.

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 0.270 L/ha (ASA-01).
For the test item ASA-01 the reported dose rate was at: 0.273; 0.267; 0.272; 0.271 L/ha.
The target spray volume was 200-400 litres per hectare according to Good Agricultural Practices. The reported spray volume was actually: 303.3; 296.7; 301.7; 300.7 L/ha.
Foliar application was performed in BBCH 65.

The spray mixture volumes remaining after applications were measured and the volumes applied to the treated plot were calculated to verify delivery rates. The calculations and the delivery rates were verified by the Study Director.
Deviations to the target rates were all between ± 5% as requested in the study plan, actually it was: +1.1 %; -1.1%; +0.7%; +0.4%
After application, the beehives were opened and bees working until the honey was ripe, or honey cell-closured.
In four trials RAC specimens for analyses (honey) were collected at:
S1 - Honeycomb closure or at the end of flowering.

Maturity of Honey was measured by refractometer, all samples were collected after water content reach below 20%.

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site.
Honey was taken at 3 different spots on one pooled sample per colony with a tool such as a spoon.

RAC specimens were put in deep freezing conditions at a target temperature of ≤ -18° 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 for analysis.

Analytical Phase of the study:
Specimen extraction and determination of residues of acetamiprid and acetamiprid-N-desmethyl were performed according to the multi-residue QuEChERS method. The method was validated according to SANTE/2020/12830 Rev.2, 14 February 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), and for "sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid" limit of quantification was 0.01 mg/kg.
The performance of the method during the analytical study complies with SANTE/2020/12830 Rev.2 criteria (accuracy in the range 70 120%).
After comparing the results of all the samples in this study, it was found that the result for samples DPL/69/2023/01U (from trial 23SGS26-01) and DPL/69/2023/03U (from trial 23SGS26-02) is questionable. Therefore, on the request of Client and Study Director, an analysis of retain samples of trials 23SGS26-01 and 23SGS26-02 were carried out to eliminate possibility of mistake on any step.
After analysis it is confirmed that minor contamination occurred in the main samples and the results obtained from retain samples are considered as definitive results. Details are described in dRR Part B Section 5 (VAL/13/23).

Conclusion

This study was fully performed as anticipated, in accordance with the study plan and the amendment issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s).

The health of the colonies was assessed prior to introduction to the tunnels and at the end of the trial just before the honey collection. The following parameters was assessed:

- strength of the colony (number of frames covered with bees)
- presence of healthy queen (i.e. presence of eggs or presence of queen cells)
- visual assessment - percentage of frames containing pollen, nectar and brood.

During trials periods there were no bee mortality (e.g. dead bees, health problems) and applications did not show any impact to the bees' colony.

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 in honey after one application of ASA-01.

Table A 8: Summary of the study 23SGS26 (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 treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				Acetamiprid	N-desmethyl-acetamiprid (IM-2-1)	Sum of acetamiprid and N-desmethyl-acetamiprid		
	(a)	(b)				(c)						(d)	(e)
Trial number 23SGS26-01 / Poland (Krzelków) / N-EU / 2023	Phacelia/ Stala	1. 18.03.2023 2. 24.05.2023-24.06.2023 3. 19.06.2023	0.082	303.3	0.027	02/06/2023	65	Honey	0.1	<LOQ	0.1	17	Analytical Method: LC-MS/MS LOQ: 0.005 mg/kg (for acetamiprid and IM-2-1) LOQ: 0.01 mg/kg (for sum of acetamiprid and IM-2-1) Max. Storage Interval between sampling and analysis: 30 days
Trial number 23SGS26-02 / Poland (Piskorzówek) / N-EU / 2023	Phacelia/ Stala	1. 04.04.2023 2. 21.05.2023-19.06.2023 3. 19.06.2023	0.080	296.7	0.027	25/05/2023	65	Honey	0.1	<LOQ	0.1	25	Analytical Method: LC-MS/MS LOQ: 0.005 mg/kg (for acetamiprid and IM-2-1) LOQ: 0.01 mg/kg (for sum of acetamiprid and IM-2-1) Max. Storage Interval between sampling and analysis: 30 days
Trial number 23SGS26-03 / Poland (Zamarte) / N-EU / 2023	Phacelia/ Stala	1. 10.04.2023 2. 01.06.2023-18.06.2023 3. 22.06.2023	0.081	301.7	0.027	05/06/2023	65	Honey	0.098	<LOQ	0.098	17	Analytical Method: LC-MS/MS LOQ: 0.005 mg/kg (for acetamiprid and IM-2-1) LOQ: 0.01 mg/kg (for sum of acetamiprid and IM-2-1) Max. Storage Interval between sampling and analysis: 27 days
Trial number	Phacelia/	1. 18.04.2023	0.081	300.7	0.027	02/06/2023	65	Honey	0.099	<LOQ	0.099	21	Analytical Method:

23SGS26-04 / Poland (Wenecja) / N-EU / 2023	Stala	2. 26.05.2023-25.06.2023 3. 23.06.2023											LC-MS/MS LOQ: 0.005 mg/kg (for acetamiprid and IM-2-1) LOQ: 0.01 mg/kg (for sum of acetamiprid and IM-2-1) Max. Storage Interval between sampling and analysis: 26 days

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

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations – SCENARIO 1

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

acetamiprid

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

Toxicological reference values

ADI (mg/kg bw/day):	0,005	ARfD (mg/kg bw):	0,005
Source of ADI:	RR	Source of ARfD:	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 : 25

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	679%	NL toddler	33,97	239%	Milk: Cattle	104%	Apples	52%	Bananas	5%	154%
	454%	DE child	22,72	121%	Apples	88%	Oranges	79%	Milk: Cattle	3%	127%
	359%	NL child	17,95	98%	Milk: Cattle	56%	Apples	31%	Oranges	4%	71%
	298%	FR child 3 15 yr	14,89	91%	Milk: Cattle	74%	Oranges	16%	Apples	3%	19%
	282%	FR toddler 2 3 yr	14,10	117%	Milk: Cattle	31%	Oranges	31%	Apples	3%	34%
	269%	UK infant	13,46	155%	Milk: Cattle	28%	Oranges	15%	Apples	2%	18%
	266%	ES child	13,30	50%	Milk: Cattle	47%	Oranges	44%	Olives for oil production	2%	16%
	235%	GEMS/Food G08	11,74	49%	Olives for oil production	22%	Milk: Cattle	20%	Swine: Muscle/meat	3%	16%
	227%	GEMS/Food G07	11,33	30%	Oranges	26%	Milk: Cattle	18%	Wine grapes	3%	16%
	226%	SE general	11,30	50%	Milk: Cattle	44%	Bovine: Muscle/meat	17%	Bananas	2%	14%
	223%	UK toddler	11,15	83%	Milk: Cattle	43%	Oranges	17%	Apples	2%	18%
	221%	GEMS/Food G06	11,05	43%	Tomatoes	22%	Olives for oil production	22%	Oranges	3%	11%
	212%	DE women 14-50 yr	10,61	50%	Milk: Cattle	42%	Oranges	25%	Apples	2%	26%
	207%	GEMS/Food G10	10,37	25%	Oranges	23%	Olives for oil production	22%	Milk: Cattle	3%	11%
	199%	DE general	9,96	49%	Milk: Cattle	34%	Oranges	23%	Apples	2%	25%
	196%	GEMS/Food G11	9,79	31%	Milk: Cattle	16%	Oranges	15%	Apples	4%	17%
	194%	GEMS/Food G15	9,71	28%	Milk: Cattle	15%	Oranges	14%	Tomatoes	3%	16%
	191%	IE adult	9,55	23%	Oranges	17%	Milk: Cattle	15%	Grapefruits	3%	11%
	183%	DK child	9,15	51%	Milk: Cattle	22%	Apples	22%	Swine: Muscle/meat	3%	29%
	182%	RO general	9,08	46%	Milk: Cattle	23%	Tomatoes	20%	Wine grapes	2%	16%
	174%	ES adult	8,68	28%	Oranges	25%	Olives for oil production	23%	Lettuces	1,0%	11%
	152%	NL general	7,59	34%	Milk: Cattle	22%	Oranges	14%	Apples	2%	18%
	134%	FR infant	6,71	67%	Milk: Cattle	16%	Apples	6%	Beans (with pods)	1%	18%
	123%	FR adult	6,15	28%	Wine grapes	18%	Milk: Cattle	13%	Oranges	2%	9%
	122%	PT general	6,09	30%	Wine grapes	15%	Olives for oil production	13%	Oranges	2%	14%
	99%	IT toddler	4,97	17%	Tomatoes	13%	Wheat	13%	Lettuces	0,7%	12%
	97%	DK adult	4,83	21%	Milk: Cattle	12%	Wine grapes	9%	Apples	0,8%	12%
	89%	FI 3 yr	4,47	13%	Bananas	9%	Apples	9%	Raspberries (red and yellow)	2%	11%
	89%	UK vegetarian	4,44	19%	Oranges	13%	Milk: Cattle	10%	Wine grapes	0,8%	6%
	88%	IT adult	4,42	16%	Lettuces	14%	Tomatoes	8%	Wheat	0,4%	10%
	79%	UK adult	3,95	13%	Wine grapes	12%	Oranges	12%	Milk: Cattle	0,9%	5%
	76%	LT adult	3,82	18%	Apples	16%	Milk: Cattle	10%	Swine: Muscle/meat	1%	20%
	66%	FI 6 yr	3,30	8%	Bananas	7%	Mandarins	6%	Raspberries (red and yellow)	2%	8%
	58%	FI adult	2,90	9%	Oranges	7%	Tomatoes	6%	Lettuces	6%	6%
	57%	PL general	2,87	20%	Apples	11%	Tomatoes	4%	Table grapes	0,9%	22%
	34%	IE child	1,70	14%	Milk: Cattle	3%	Apples	2%	Wheat	0,4%	3%

Conclusion:
The estimated TMDI/NEDI/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.

A 3.2 TMDI calculations – SCENARIO 2

European Food Safety Authority
EFSA PRIMo revision 3.1; 2021/01/06

acetamiprid

LOQs (mg/kg) range from:	0,01	to:	0,10
Toxicological reference values			
ADI (mg/kg bw/day):	0,005	ARfD (mg/kg bw):	0,005
Source of ADI:	RR	Source of ARfD:	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 : 23

TMDI/NEDI/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	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
417%	NL toddler	20,84	239%	Milk: Cattle	49%	Oranges	18%	Apples	5%	33%
269%	DE child	13,44	88%	Oranges	79%	Milk: Cattle	21%	Apples	3%	23%
248%	FR child 3 15 yr	12,38	91%	Milk: Cattle	74%	Oranges	15%	Bovine: Muscle/meat	3%	3%
230%	FR toddler 2 3 yr	11,52	117%	Milk: Cattle	31%	Oranges	17%	Mandarins	3%	6%
226%	NL child	11,32	98%	Milk: Cattle	31%	Oranges	14%	Mandarins	4%	16%
221%	UK infant	11,06	155%	Milk: Cattle	28%	Oranges	12%	Bovine: Muscle/meat	2%	3%
203%	ES child	10,14	50%	Milk: Cattle	47%	Oranges	44%	Olives for oil production	2%	3%
172%	UK toddler	8,62	83%	Milk: Cattle	43%	Oranges	13%	Bovine: Muscle/meat	2%	3%
162%	GEMS/Food G08	8,11	49%	Olives for oil production	22%	Milk: Cattle	20%	Swine: Muscle/meat	3%	5%
154%	GEMS/Food G07	7,70	30%	Oranges	26%	Milk: Cattle	18%	Olives for oil production	3%	6%
152%	SE general	7,61	50%	Milk: Cattle	44%	Bovine: Muscle/meat	16%	Oranges	2%	3%
146%	DE women 14-50 yr	7,32	50%	Milk: Cattle	42%	Oranges	9%	Swine: Muscle/meat	2%	5%
143%	GEMS/Food G10	7,15	25%	Oranges	23%	Olives for oil production	22%	Milk: Cattle	3%	4%
139%	DE general	6,93	49%	Milk: Cattle	34%	Oranges	11%	Swine: Muscle/meat	2%	4%
137%	GEMS/Food G11	6,86	31%	Milk: Cattle	16%	Oranges	14%	Olives for oil production	4%	3%
131%	GEMS/Food G06	6,54	22%	Olives for oil production	22%	Oranges	14%	Wheat	3%	2%
128%	IE adult	6,41	23%	Oranges	17%	Milk: Cattle	15%	Grapefruits	3%	2%
126%	GEMS/Food G15	6,32	28%	Milk: Cattle	15%	Oranges	14%	Swine: Muscle/meat	3%	4%
120%	DK child	6,00	51%	Milk: Cattle	22%	Swine: Muscle/meat	13%	Bovine: Muscle/meat	3%	5%
115%	ES adult	5,73	28%	Oranges	25%	Olives for oil production	20%	Milk: Cattle	1,0%	2%
104%	NL general	5,22	34%	Milk: Cattle	22%	Oranges	10%	Swine: Muscle/meat	2%	5%
104%	RO general	5,20	46%	Milk: Cattle	12%	Swine: Muscle/meat	10%	Wheat	2%	3%
103%	FR infant	5,17	67%	Milk: Cattle	6%	Beans (with pods)	5%	Oranges	1%	3%
77%	FR adult	3,83	18%	Milk: Cattle	13%	Oranges	7%	Swine: Muscle/meat	2%	2%
59%	PT general	2,94	15%	Olives for oil production	13%	Oranges	8%	Wheat	2%	3%
56%	DK adult	2,81	21%	Milk: Cattle	9%	Swine: Muscle/meat	5%	Bovine: Muscle/meat	0,8%	2%
51%	UK vegetarian	2,54	19%	Oranges	13%	Milk: Cattle	4%	Wheat	0,8%	1%
46%	IT toddler	2,30	13%	Wheat	10%	Oranges	5%	Mandarins	0,7%	2%
46%	UK adult	2,29	12%	Oranges	12%	Milk: Cattle	7%	Bovine: Muscle/meat	0,9%	0,8%
42%	LT adult	2,09	16%	Milk: Cattle	10%	Swine: Muscle/meat	3%	Apples	1%	3%
37%	IT adult	1,85	8%	Wheat	8%	Oranges	4%	Mandarins	0,4%	2%
35%	FI 3 yr	1,77	8%	Mandarins	4%	Strawberries	3%	Oranges	2%	3%
27%	FI 6 yr	1,36	7%	Mandarins	3%	Strawberries	3%	Oranges	2%	2%
26%	FI adult	1,30	9%	Oranges	6%	Coffee beans	3%	Mandarins	6%	1%
25%	IE child	1,24	14%	Milk: Cattle	2%	Wheat	2%	Oranges	0,4%	0,6%
15%	PL general	0,76	3%	Apples	2%	Cherries (sweet)	1%	Lemons	0,9%	4%

Conclusion:
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.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

acetamiprid

LOQs (mg/kg) range from: 0,01 to: 0,30

Toxicological reference values

ADI (mg/kg bw/day):	0,005	ARfD (mg/kg bw):	0,005
Source of ADI:	RR	Source of ARfD:	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 : 23

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	417%	NL toddler	20,85	239%	Milk: Cattle	49%	Oranges	18%	Apples	5%	34%
	269%	DE child	13,47	88%	Oranges	79%	Milk: Cattle	21%	Apples	3%	23%
	248%	FR child 3 15 yr	12,39	91%	Milk: Cattle	74%	Oranges	15%	Bovine: Muscle/meat	3%	4%
	231%	FR toddler 2 3 yr	11,53	117%	Milk: Cattle	31%	Oranges	17%	Mandarins	3%	6%
	226%	NL child	11,32	98%	Milk: Cattle	31%	Oranges	14%	Mandarins	4%	16%
	221%	UK infant	11,07	155%	Milk: Cattle	28%	Oranges	12%	Bovine: Muscle/meat	3%	3%
	203%	ES child	10,14	50%	Milk: Cattle	47%	Oranges	44%	Olives for oil production	2%	3%
	172%	UK toddler	8,62	83%	Milk: Cattle	43%	Oranges	13%	Bovine: Muscle/meat	2%	3%
	162%	GEMS/Food G08	8,11	49%	Olives for oil production	22%	Milk: Cattle	20%	Swine: Muscle/meat	3%	5%
	154%	GEMS/Food G07	7,70	30%	Oranges	26%	Milk: Cattle	18%	Olives for oil production	3%	6%
	152%	SE general	7,61	50%	Milk: Cattle	44%	Bovine: Muscle/meat	16%	Oranges	2%	3%
	147%	DE women 14-50 yr	7,33	50%	Milk: Cattle	42%	Oranges	9%	Swine: Muscle/meat	3%	5%
	143%	GEMS/Food G10	7,15	25%	Oranges	23%	Olives for oil production	22%	Milk: Cattle	3%	4%
	139%	DE general	6,94	49%	Milk: Cattle	34%	Oranges	11%	Swine: Muscle/meat	3%	5%
	137%	GEMS/Food G11	6,86	31%	Milk: Cattle	16%	Oranges	14%	Olives for oil production	4%	3%
	131%	GEMS/Food G06	6,53	22%	Olives for oil production	22%	Oranges	14%	Wheat	3%	2%
	128%	IE adult	6,42	23%	Oranges	17%	Milk: Cattle	15%	Grapefruits	3%	2%
	126%	GEMS/Food G15	6,32	28%	Milk: Cattle	15%	Oranges	14%	Swine: Muscle/meat	3%	4%
	120%	DK child	6,00	51%	Milk: Cattle	22%	Swine: Muscle/meat	13%	Bovine: Muscle/meat	3%	5%
	115%	ES adult	5,73	28%	Oranges	25%	Olives for oil production	20%	Milk: Cattle	1%	2%
	104%	NL general	5,22	34%	Milk: Cattle	22%	Oranges	10%	Swine: Muscle/meat	2%	5%
	104%	RO general	5,20	46%	Milk: Cattle	12%	Swine: Muscle/meat	10%	Wheat	2%	3%
	103%	FR infant	5,17	67%	Milk: Cattle	6%	Beans (with pods)	5%	Oranges	1%	3%
	77%	FR adult	3,83	18%	Milk: Cattle	13%	Oranges	7%	Swine: Muscle/meat	2%	2%
	59%	PT general	2,93	15%	Olives for oil production	13%	Oranges	8%	Wheat	2%	2%
	56%	DK adult	2,81	21%	Milk: Cattle	9%	Swine: Muscle/meat	5%	Bovine: Muscle/meat	0,8%	2%
	51%	UK vegetarian	2,54	19%	Oranges	13%	Milk: Cattle	4%	Wheat	0,8%	1%
	46%	IT toddler	2,30	13%	Wheat	10%	Oranges	5%	Mandarins	0,7%	2%
	46%	UK adult	2,29	12%	Oranges	12%	Milk: Cattle	7%	Bovine: Muscle/meat	1%	0,9%
	42%	LT adult	2,09	16%	Milk: Cattle	10%	Swine: Muscle/meat	3%	Apples	1%	3%
	37%	IT adult	1,85	8%	Wheat	8%	Oranges	4%	Mandarins	0,4%	2%
	35%	FI 3 yr	1,77	8%	Mandarins	4%	Strawberries	3%	Oranges	2%	3%
	27%	FI 6 yr	1,36	7%	Mandarins	3%	Strawberries	3%	Oranges	2%	2%
	26%	FI adult	1,30	9%	Oranges	6%	Coffee beans	3%	Mandarins	6%	1%
	25%	IE child	1,24	14%	Milk: Cattle	2%	Wheat	2%	Oranges	0,4%	0,6%
	15%	PL general	0,76	3%	Apples	2%	Cherries (sweet)	1%	Lemons	0,9%	4%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 417,1 % 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.

A 3.3 IEDI calculations – SCENARIO 3

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

acetamiprid

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

Toxicological reference values

ADI (mg/kg bw/day):	0,005	ARfD (mg/kg bw):	0,005
Source of ADI:	RR	Source of ARfD:	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 : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	52%	NL toddler	2,60	24%	Milk: Cattle	6%	Apples	3%	Rose hips	5%	9%
	32%	DE child	1,58	8%	Milk: Cattle	7%	Apples	2%	Cherries (sweet)	3%	7%
	31%	GEMS/Food G08	1,53	16%	Olives for oil production	2%	Milk: Cattle	1%	Lamb's lettuce/corn salads	3%	0,9%
	28%	ES child	1,39	14%	Olives for oil production	5%	Milk: Cattle	0,9%	Wheat	2%	1,0%
	27%	NL child	1,37	10%	Milk: Cattle	3%	Apples	2%	Sugar beet roots	4%	4%
	23%	UK infant	1,16	15%	Milk: Cattle	0,8%	Apples	0,7%	Potatoes	2%	1%
	23%	FR child 3 15 yr	1,15	9%	Milk: Cattle	2%	Olives for oil production	0,9%	Wheat	3%	1%
	22%	FR toddler 2 3 yr	1,12	12%	Milk: Cattle	2%	Apples	0,9%	Beans (with pods)	2%	2%
	22%	GEMS/Food G10	1,11	7%	Olives for oil production	2%	Milk: Cattle	2%	Cress and other sprouts and shoo	3%	0,6%
	22%	GEMS/Food G06	1,09	7%	Olives for oil production	1%	Wheat	1,0%	Milk: Cattle	3%	0,6%
	20%	GEMS/Food G07	1,02	6%	Olives for oil production	3%	Milk: Cattle	0,8%	Wheat	3%	1,0%
	19%	GEMS/Food G11	0,96	5%	Olives for oil production	3%	Milk: Cattle	1%	Lamb's lettuce/corn salads	4%	0,9%
	19%	GEMS/Food G15	0,94	4%	Olives for oil production	3%	Milk: Cattle	1%	Rose hips	3%	0,9%
	18%	IE adult	0,90	3%	Other farmed animals: Muscle/meat	2%	Sheep: Edible offals (other than liver an	2%	Milk: Cattle	3%	0,6%
	16%	UK toddler	0,82	8%	Milk: Cattle	0,9%	Apples	0,8%	Wheat	2%	1%
	16%	DE women 14-50 yr	0,81	5%	Milk: Cattle	2%	Olives for oil production	1%	Apples	2%	2%
	16%	ES adult	0,81	8%	Olives for oil production	2%	Milk: Cattle	0,7%	Other farmed animals: Muscle/me	1,0%	0,6%
	16%	DE general	0,78	5%	Milk: Cattle	2%	Olives for oil production	1%	Apples	2%	1%
	14%	SE general	0,71	5%	Milk: Cattle	2%	Bovine: Muscle/meat	0,8%	Potatoes	2%	0,8%
	14%	DK child	0,70	5%	Milk: Cattle	1%	Apples	1%	Rye	3%	2%
	14%	RO general	0,68	5%	Milk: Cattle	1%	Wheat	0,8%	Wine grapes	2%	0,9%
	12%	FR infant	0,61	7%	Milk: Cattle	0,9%	Apples	0,6%	Beans (with pods)	1%	1%
	11%	PT general	0,57	5%	Olives for oil production	1%	Wine grapes	1%	Potatoes	2%	0,8%
	11%	NL general	0,56	3%	Milk: Cattle	0,8%	Apples	0,6%	Sugar beet roots	2%	1%
	11%	FR adult	0,53	2%	Milk: Cattle	1%	Olives for oil production	1%	Wine grapes	2%	0,5%
	8%	FI adult	0,41	6%	Coffee beans	0,3%	Strawberries	0,3%	Apples	6%	0,3%
	7%	FI 3 yr	0,36	0,9%	Potatoes	0,9%	Strawberries	0,8%	Raspberries (red and yellow)	2%	0,7%
	6%	DK adult	0,30	2%	Milk: Cattle	0,5%	Apples	0,5%	Wine grapes	0,8%	0,7%
	6%	IT toddler	0,29	1%	Wheat	0,5%	Apples	0,5%	Cherries (sweet)	0,7%	0,7%
	6%	LT adult	0,29	2%	Milk: Cattle	1,0%	Apples	0,6%	Potatoes	1%	1%
	5%	FI 6 yr	0,26	0,8%	Potatoes	0,7%	Strawberries	0,6%	Raspberries (red and yellow)	2%	0,5%
	5%	IT adult	0,25	0,8%	Wheat	0,4%	Apples	0,4%	Other spinach and similar	0,4%	0,5%
	5%	UK vegetarian	0,25	1%	Milk: Cattle	0,4%	Wheat	0,4%	Wine grapes	0,8%	0,4%
	5%	UK adult	0,23	1%	Milk: Cattle	0,5%	Wine grapes	0,3%	Wheat	0,9%	0,3%
	4%	PL general	0,20	1%	Apples	0,7%	Potatoes	0,5%	Cherries (sweet)	0,9%	1%
	3%	IE child	0,15	1%	Milk: Cattle	0,2%	Wheat	0,2%	Apples	0,4%	0,2%

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

EFSA PRIMo revision 3.1; 2021/01/06

acetamiprid

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

Toxicological reference values

ADI (mg/kg bw/day):	0,005	ARfD (mg/kg bw):	0,005
Source of ADI:	RR	Source of ARfD:	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 : ---

TMDI/NEDI/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	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
53%	NL toddler	2,66	24%	Milk: Cattle	6%	Apples	3%	Rose hips	6%	9%
32%	DE child	1,60	8%	Milk: Cattle	7%	Apples	2%	Cherries (sweet)	3%	7%
31%	GEMS/Food G08	1,54	16%	Olives for oil production	2%	Milk: Cattle	1%	Lamb's lettuce/corn salads	3%	0,9%
28%	ES child	1,40	14%	Olives for oil production	5%	Milk: Cattle	0,9%	Wheat	2%	0,9%
28%	NL child	1,39	10%	Milk: Cattle	3%	Apples	2%	Sugar beet roots	4%	4%
23%	UK infant	1,17	15%	Milk: Cattle	0,8%	Apples	0,7%	Potatoes	3%	1%
23%	FR child 3 15 yr	1,16	9%	Milk: Cattle	2%	Olives for oil production	0,9%	Wheat	3%	1%
23%	FR toddler 2 3 yr	1,13	12%	Milk: Cattle	2%	Apples	0,9%	Beans (with pods)	3%	2%
22%	GEMS/Food G10	1,12	7%	Olives for oil production	2%	Milk: Cattle	2%	Cress and other sprouts and shoo	3%	0,6%
22%	GEMS/Food G06	1,10	7%	Olives for oil production	1%	Wheat	1,0%	Milk: Cattle	3%	0,6%
21%	GEMS/Food G07	1,03	6%	Olives for oil production	3%	Milk: Cattle	0,8%	Wheat	3%	1,0%
19%	GEMS/Food G11	0,97	5%	Olives for oil production	3%	Milk: Cattle	1%	Lamb's lettuce/corn salads	4%	0,9%
19%	GEMS/Food G15	0,95	4%	Olives for oil production	3%	Milk: Cattle	1%	Rose hips	3%	0,9%
18%	IE adult	0,92	3%	Other farmed animals: Muscle/meat	2%	Sheep: Edible offals (other than liver an	2%	Milk: Cattle	3%	0,6%
17%	UK toddler	0,83	8%	Milk: Cattle	0,9%	Apples	0,8%	Wheat	2%	1%
16%	ES adult	0,82	8%	Olives for oil production	2%	Milk: Cattle	0,7%	Other farmed animals: Muscle/me	1%	0,6%
16%	DE women 14-50 yr	0,81	5%	Milk: Cattle	2%	Olives for oil production	1%	Apples	2%	2%
16%	DE general	0,79	5%	Milk: Cattle	2%	Olives for oil production	1%	Apples	2%	1%
15%	SE general	0,74	5%	Milk: Cattle	2%	Bovine: Muscle/meat	0,8%	Potatoes	2%	0,8%
14%	DK child	0,71	5%	Milk: Cattle	1%	Apples	1%	Rye	3%	2%
14%	RO general	0,68	5%	Milk: Cattle	1%	Wheat	0,8%	Wine grapes	2%	0,9%
12%	FR infant	0,61	7%	Milk: Cattle	0,9%	Apples	0,6%	Beans (with pods)	1%	1%
12%	PT general	0,58	5%	Olives for oil production	1%	Wine grapes	1%	Potatoes	2%	0,8%
11%	NL general	0,57	3%	Milk: Cattle	0,8%	Apples	0,6%	Sugar beet roots	2%	1%
11%	FR adult	0,53	2%	Milk: Cattle	1%	Olives for oil production	1%	Wine grapes	2%	0,5%
8%	FI adult	0,42	6%	Coffee beans	0,3%	Strawberries	0,3%	Apples	6%	0,3%
8%	FI 3 yr	0,38	0,9%	Potatoes	0,9%	Strawberries	0,8%	Raspberries (red and yellow)	2%	0,7%
6%	DK adult	0,31	2%	Milk: Cattle	0,5%	Apples	0,5%	Wine grapes	0,9%	0,7%
6%	IT toddler	0,30	1%	Wheat	0,5%	Apples	0,5%	Cherries (sweet)	0,8%	0,7%
6%	LT adult	0,29	2%	Milk: Cattle	1,0%	Apples	0,6%	Potatoes	1%	1%
5%	FI 6 yr	0,27	0,8%	Potatoes	0,7%	Strawberries	0,6%	Raspberries (red and yellow)	2%	0,5%
5%	IT adult	0,26	0,8%	Wheat	0,4%	Apples	0,4%	Other spinach and similar	0,5%	0,5%
5%	UK vegetarian	0,25	1%	Milk: Cattle	0,4%	Wheat	0,4%	Wine grapes	0,9%	0,4%
5%	UK adult	0,24	1%	Milk: Cattle	0,5%	Wine grapes	0,3%	Wheat	1,0%	0,3%
4%	PL general	0,20	1%	Apples	0,7%	Potatoes	0,5%	Cherries (sweet)	0,9%	1%
3%	IE child	0,15	1%	Milk: Cattle	0,2%	Wheat	0,2%	Apples	0,4%	0,2%

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

A 3.4 IESTI calculations – SCENARIO 1

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 ARfD. 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 ARfD/ADI is exceeded (IESTI): 4

IESTI

Highest % of ARfD/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
476%	Quinces	0,8 / 0,97	24
268%	Medlar	0,8 / 0,97	13
11%	Rapeseeds/canola	0,4 / 0,4	0,55
4%	Honey and other apiculture products	0,05 / 0,05	0,18

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 4

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): 4

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
296%	Pears	0,4 / 0,48	15
294%	Quinces	0,8 / 0,97	15
272%	Apples	0,4 / 0,48	14
133%	Medlar	0,8 / 0,97	6,6
4%	Rapeseeds/canola seeds	0,4 / 0,4	0,21
1%	Honey and other apiculture products	0,05 / 0,05	0,07

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): 2

IESTI

Highest % of ARfD/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
59%	Quinces / jam	0,8 / 0,97	2,9
5%	Rapeseeds / oils	0,4 / 0,8	0,24

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
323%	Apples / juice	0,4 / 0,48	16
24%	Quinces / jam	0,8 / 0,97	1,2

Conclusion:
The estimated short term intake (IESTI) exceeded the toxicological reference value for 4 commodities.
For processed commodities, the toxicological reference value was exceeded in one or several cases.

A 3.5 IESTI calculations – 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 ARfD. 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 ARfD/ADI is exceeded (IESTI): 4

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
298%	Quinces	0,5 / 0,61	15
235%	Pears	0,07 / 0,08	12
183%	Apples	0,07 / 0,08	9,1
100%	Medlar	0,3 / 0,36	5,0
11%	Rapeseeds/canola seeds	0,4 / 0,4	0,55
4%	Honey and other apiculture products	0,05 / 0,05	0,18

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 4

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
184%	Quinces	0,5 / 0,61	9,2
52%	Pears	0,07 / 0,08	2,6
50%	Medlar	0,3 / 0,36	2,5
48%	Apples	0,07 / 0,08	2,4
4%	Rapeseeds/canola seeds	0,4 / 0,4	0,21
1%	Honey and other apiculture products	0,05 / 0,05	0,07

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
92%	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
5%	Rapeseeds / oils	0,4 / 0,8	0,24

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
56%	Apples / juice	0,07 / 0,08	2,8
15%	Quinces / jam	0,5 / 0,61	0,76

Conclusion:
The estimated short term intake (IESTI) exceeded the toxicological reference value for 4 commodities.
For processed commodities, no exceedance of the ARfD/ADI was identified.

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 ARfD. 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 ARfD/ADI is exceeded (IESTI):			3	**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
235%	Pears	0,07 / 0,08	12	55%	Quinces	0,15 / 0,18	2,8
183%	Apples	0,07 / 0,08	9,1	52%	Pears	0,07 / 0,08	2,6
100%	Medlar	0,3 / 0,36	5,0	50%	Medlar	0,3 / 0,36	2,5
89%	Quinces	0,15 / 0,18	4,5	48%	Apples	0,07 / 0,08	2,4
21%	Honey and other apiculture products	0,3 / 0,3	1,1	8%	Honey and other apiculture products	0,3 / 0,3	0,41
11%	Rapeseeds/canola seeds	0,4 / 0,4	0,55	4%	Rapeseeds/canola seeds	0,4 / 0,4	0,21
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)			3				

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
92%	Apples / juice	0,07 / 0,08	4,6	56%	Apples / juice	0,07 / 0,08	2,8
55%	Pears / juice	0,07 / 0,08	2,8	5%	Quinces / jam	0,15 / 0,18	0,23
11%	Quinces / jam	0,15 / 0,18	0,55				
5%	Rapeseeds / oils	0,4 / 0,8	0,24				
	#LICZBA!	#LICZBA!					
Expand/collapse list							

Conclusion:
The estimated short term intake (IESTI) exceeded the toxicological reference value for 3 commodities.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.6 IESTI calculations – 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 ARfD. 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 ARfD/ADI is exceeded (IESTI):	---			**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):	---		
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
97%	Pears	0,07 / 0,04	4,9	33%	Medlar	0,3 / 0,24	1,7
76%	Apples	0,07 / 0,04	3,8	26%	Quinces	0,15 / 0,09	1,3
67%	Medlar	0,3 / 0,24	3,3	23%	Honey and other	2 / 0,85	1,2
61%	Honey and other	2 / 0,85	3,0	21%	Pears	0,07 / 0,04	1,1
42%	Quinces	0,15 / 0,09	2,1	20%	Apples	0,07 / 0,04	0,99
0,8%	Rapeseeds/canola seeds	0,4 / 0,03	0,04	0,3%	Rapeseeds/canola seeds	0,4 / 0,03	0,02
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):	---			**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):	---		
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
29%	Apples / juice	0,07 / 0,03	1,4	18%	Apples / juice	0,07 / 0,03	0,89
17%	Pears / juice	0,07 / 0,03	0,87	0,9%	Quinces / jam	0,15 / 0,04	0,05
2%	Quinces / jam	0,15 / 0,04	0,11				
0,4%	Rapeseeds / oils	0,4 / 0,06	0,02				
Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
For processed commodities, no exceedance of the ARfD/ADI was identified.

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 ARfD. 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 ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
97%	Pears	0,07 / 0,04	4,9
76%	Apples	0,07 / 0,04	3,8
67%	Medlar	0,3 / 0,24	3,3
42%	Quinces	0,15 / 0,09	2,1
7%	Honey and other apiculture products	0,3 / 0,1	0,36
0,8%	Rapeseeds/canola seeds	0,4 / 0,03	0,04

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
33%	Medlar	0,3 / 0,24	1,7
26%	Quinces	0,15 / 0,09	1,3
21%	Pears	0,07 / 0,04	1,1
20%	Apples	0,07 / 0,04	0,99
3%	Honey and other apiculture products	0,3 / 0,1	0,14
0,3%	Rapeseeds/canola seeds	0,4 / 0,03	0,02

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
29%	Apples / juice	0,07 / 0,03	1,4
17%	Pears / juice	0,07 / 0,03	0,87
2%	Quinces / jam	0,15 / 0,04	0,11
0,4%	Rapeseeds / oils	0,4 / 0,06	0,02
	#LICZBA!	#LICZBA!	

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
18%	Apples / juice	0,07 / 0,03	0,89
0,9%	Quinces / jam	0,15 / 0,04	0,05

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix 4 Additional information provided by the applicant

Not relevant.