REGISTRATION REPORT
Part A
Risk Management

Product code: ASA-01

Product name(s): **VIARES**

Chemical active substance:

Acetamiprid, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorization)

Applicant: XXXX

Submission date: March 2024, update 2025-03-24

Evaluation date: May 2025

PL Evaluation date: October 2025

Version history

When	What
2025-03-03	Update on evaluator request
May 2025	Version evaluated by zRMS PL
October 2025	RR amendment driven by MRL changing
December 2025	Version revised by zRMS PL
January 2026	Update on Ministry request
February 2026	Update due to change in PUF value for metabolite IM-I-5 by zRMS PL

Table of Contents

PART A
RISK MANAGEMENT

1 Details of the application

This document describes the acceptable used conditions required for the registration of ASA-01, containing active substance acetamiprid (300 g/L), in Poland. This evaluation is required since the product is a new formulation and has not yet been authorised in Poland.

The risk assessment conclusions are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C. The information, data and assessments provided in the Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to ASA-01 where that data has not been considered in the EU review. Otherwise, assessments for the safe use of ASA-01 have been made using endpoints agreed in the EU review of acetamiprid.

This document describes the specific conditions of use and labelling required for Poland for the registration of ASA-01.

1.1 Application background

This application was submitted by XXXX.

This is the application for registration plant protection product under working name of ASA-01 according to Article 33 of Regulation 1107/2009. ASA-01 is a suspension concentrate formulation (SC), containing 300 g/L of acetamiprid to be used as insecticide for protection of oilseed rape and apple trees.

1.2 Letters of Access

Letters of Access are submitted as a separate document to this application.

1.3 Justification for submission of tests and studies

In accordance with Art. 33 (3), the submitted studies and presented in Appendix 4, are relevant and necessary to obtain the authorisation of the product ASA-01 in Poland.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	ASA-01
Product name in MS	Please refer to application form
Authorization number	Not relevant
Function	insecticide
Applicant	XXX
Active substance(s) (incl. content)	acetamiprid, 300 g/L
Formulation type	Suspension concentrate [SC]
Packaging	0.1 L, 0.5 L, 1 L HDPE professional user
Coformulants of concern for national authorizations	None
Restrictions related to identiy	None
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

2.2 Conclusion

Residues:
The evaluation of the application for VIARES resulted in the decision to grant the authorization. All uses applied for were authorised except apples, wild apples, pears and Chinese pears due to the MRLs exceedance (see 2.6).

Fate and behaviour: The submitted exposure assessment in soil, groundwater and surface water was sufficient. The evaluation of the application for VIARES resulted in the decision to grant the authorization for all intended uses.

Based on submitted assessment it can be concluded that the safe use for annual application of Viares in winter OSR and single application in orchards was confirmed.

For orchards at multiple application 2 x 27 g a.s./ha – every other year application of Viares is required.

Ecotoxicology:
All relevant data and risk assessment are considered as adequate and sufficient.
The evaluation of the application for VIARES resulted in the decision to grant the authorization for all intended uses.

MS-PL conclusion on assessment of co-formulants according to Article 3 of Regulation (EU)2023/574:
Based on the currently available MSDSs and other information provided by applicant or manufacturers/suppliers of co-formulants, the product ASA-01 does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009 at content above 0.1% w/w (- the limit for the acceptable presence of the substances listed in Annex III as unintentional impurity in the finished product).
According to the current knowledge and available information, none of the co-formulants in the plant protection product ASA-01 meets criteria in the Annex to Regulation (EU) 2023/574 for identification of co-formulants that are unacceptable for inclusion in a plant protection products.

2.3 Substances of concern for national monitoring

Not applicable. ASA-01 does not contain any substances of concern.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Skin Sens. 1; H317 Acute Tox. 4, H302 Repr. 2, H361d Aquatic Chronic 1, H410

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

Hazard pictograms:	 **GHS07 GHS08 GHS09**
Signal word:	**Warning**
Hazard statement(s):	**H302 - Harmful if swallowed** **H317 - May cause an allergic skin reaction** **H361d - Suspected of damaging the unborn child.** **H410 - Very toxic to aquatic life with long lasting effects.**
Precautionary statement(s):	~~P201 - Obtain special instructions before use.~~ P202 - Do not handle until all safety precautions have been read and understood. ~~P260 - Do not breathe dust/fume/gas/mist/vapours/ spray.~~ P261 - Avoid breathing spray. P263 - Avoid contact during pregnancy and while nursing. P264 - Wash hands thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/ protective clothing P301 + P312, P330 - IF SWALLOWED: Rinse mouth. Call a POISON CENTRE or doctor if you feel unwell. P302 + P352 - IF ON SKIN: Wash with plenty of water P308 + P313 - IF exposed or concerned: Get medical advice/ attention. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention P362 + P364 - Take off contaminated clothing and wash it before reuse. P405 - Store locked up P501 - Dispose of contents/ container to … … in accordance with local/ regional/national regulation**e with local regulation.**
Additional labelling phrases:	**EUH401 - To avoid risks to man and the environment, comply with the instructions for use.**

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	

-	-

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	~~Use no. 2, 3, 4, 5~~ ~~To protect aquatic organisms respect an:~~ ~~- unsprayed buffer zone of 20m or~~ ~~- 15m no spray buffer zone + 50% nozzle reduction or~~ ~~- 10m no spray buffer zone + 75% nozzle reduction or~~ ~~- 5m no spray buffer zone + 90% nozzle reduction.~~ Use no. 1 ~~To protect aquatic organisms respect an:~~ ~~- unsprayed buffer zone of 10m + 50% nozzle reduction or~~ ~~- unsprayed vegetated buffer zone of 20m~~ unsprayed vegetated buffer zone of 20m or unsprayed vegetated buffer zone of 10m + 50% nozzle reduction to surface water bodies. Use no. 2, 4 To protect aquatic organisms respect an: -unsprayed vegetated buffer zone of 20m + 90% nozzle reduction or -unsprayed buffer zone of 50m with vegetated buffer zone of 20m + 50% nozzle reduction or -unsprayed buffer zone of 100m with vegetated buffer zone of 20m to surface water bodies. Use no. 3, 5 To protect aquatic organisms respect an: -unsprayed buffer zone of 50m with vegetated buffer zone of 20m + 90% nozzle reduction or -unsprayed buffer zone of 100m with vegetated buffer zone of 20m to surface water bodies.
SPe 2	To protect groundwater, apply formulation every other year in multiple application in orchards

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

-	-

2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
-	Workwear

	Recomended: Gloves during mixing/loading and application.
Worker protection:	
-	Workwear Recomended: Gloves during field activities.
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
SPe 2	To protect groundwater, apply formulation every other year in multiple application in orchards
SPe3	~~Use no. 2, 3, 4, 5~~ ~~To protect aquatic organisms respect an:~~ ~~- unsprayed buffer zone of 20m or~~ ~~- 15m no spray buffer zone + 50% nozzle reduction or~~ ~~- 10m no spray buffer zone + 75% nozzle reduction or~~ ~~- 5m no spray buffer zone + 90% nozzle reduction,~~ ~~to surface water bodies.~~ Use no. 1 To protect aquatic organisms respect an: ~~- To protect aquatic organisms respect an:~~ ~~-unsprayed buffer zone of 10m +50% nozzle reduction or~~ ~~-unsprayed vegetated buffer zone of 20m~~ unsprayed vegetated buffer zone of 20m or unsprayed vegetated buffer zone of 10m + 50% nozzle reduction to surface water bodies. Use no. 2, 4 To protect aquatic organisms respect an: -unsprayed vegetated buffer zone of 20m + 90% nozzle reduction or -unsprayed buffer zone of 50m with vegetated buffer zone of 20m + 50% nozzle reduction or -unsprayed buffer zone of 100m with vegetated buffer zone of 20m to surface water bodies. Use no. 3, 5 To protect aquatic organisms respect an: -unsprayed buffer zone of 50m with vegetated buffer zone of 20m + 90% nozzle reduction or -unsprayed buffer zone of 100m with vegetated buffer zone of 20m to surface water bodies.
Other specific restrictions	
-	-

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:
-	-

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.
SPe3	~~To protect aquatic organisms respect an:~~ ~~- unsprayed buffer zone of 20m or~~ ~~- 15m no spray buffer zone + 50% nozzle reduction or~~ ~~- 10m no spray buffer zone + 75% nozzle reduction or~~ ~~- 5m no spray buffer zone + 90% nozzle reduction,~~ ~~to surface water bodies.~~ Use no. 1 To protect aquatic organisms respect an: ~~To protect aquatic organisms respect an:~~ ~~- unsprayed buffer zone of 10m + 50% nozzle reduction or~~ ~~- unsprayed vegetated buffer zone of 20m~~ unsprayed vegetated buffer zone of 20m or unsprayed vegetated buffer zone of 10m + 50% nozzle reduction to surface water bodies. Use no. 2, 4 To protect aquatic organisms respect an: -unsprayed vegetated buffer zone of 20m + 90% nozzle reduction or -unsprayed buffer zone of 50m with vegetated buffer zone of 20m + 50% nozzle reduction or -unsprayed buffer zone of 100m with vegetated buffer zone of 20m to surface water bodies. Use no. 3, 5 To protect aquatic organisms respect an: -unsprayed buffer zone of 50m with vegetated buffer zone of 20m + 90% nozzle reduction or -unsprayed buffer zone of 100m with vegetated buffer zone of 20m to surface water bodies.	2, 3, 4, 5
SPe 2	To protect groundwater, apply formulation every other year in multiple application in orchards	Use No 3 and 5 from GAP table in p. 2.6

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 1.0, date: 2023-06-12

PPP (product name/code):	ASA-01	Formulation type:	SC [a, b]
Active substance 1:	acetamiprid	Conc. of as 1:	300 g/L [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	XXXX	Professional use:	☒
Zone(s):	central [d]	Non professional use:	☐
Verified by MS:	yes		
Field of use:	Insecticide		

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 excee-dance	Tier 1
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)		Tier 2
Minor																		

4	~~Wild apple~~ (MABSY) 0130010 ~~Pear~~ (PYUCO) 0130020 ~~Chinese pear~~ (PYULI) 0130020 Quince (CYDOB) 0130030 Medlar (MSPGE) 0130040	PL	ASA-01	F	Aphids *Aphidae* (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)	Tier 1 Tier 2

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m^3 in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of white liquid, with a medium intense, characteristic odour. Flash point was not observed. It is not explosive, has no oxidising properties. It has an auto-ignition temperature of 485°C. In aqueous solution, it has a pH value around 5.28 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 12 weeks at 35±2°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE bottles. Its technical characteristics are acceptable for a suspension concentrate formulation (SC).

3.2 Efficacy (Part B, Section 3)

ASA-01 is a suspension concentrate (SC) containing 300 g/L of acetamiprid. The plant protection product is intended to be registered in apple and winter oilseed rape.

In compliance with the GAP the following dose rates are applied for registration:

- One application in winter oilseed rape to control pollen beetle, recommended rates 0.08-0.1 L/ha. The higher, recommended dose is to be used in conditions of increased risk of infestation.
- One application in apple in control aphids, recommended rates: 0.03-0.05 L/10000 m2 LWA (max.0.075 L/ha). The higher, recommended dose is to be used in conditions of increased risk of infestation.
- Two applications in apple in control codling moth, recommended rates: 0.07-0.09 L/10000 m2 LWA (max. 0.09 L/ha). The higher, recommended dose is to be used in conditions of increased risk of infestation.

Comprehensive field trials were conducted in Poland in years 2019-2023. The overall assessments were performed according to the uniform principles. All trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organizations.

3.3 Efficacy data

Preliminary tests

No results of the preliminary range-finding tests are presented since no screening trials were carried out. However, the active substance of ASA-01- acetamiprid, has been commonly used in agricultural practice for many years.

Minimum effective dose tests

Minimum effective dose tests were not carried out. However, several doses of ASA-01 were tested during efficacy studies and the lowest effective dose was selected. The tests were concluded in line with EPPO standard PP 1/225 (2) '*Minimum effective dose',* which advises on the minimum requirements necessary to ensure consistency of decision making.

Apple and codling moth

7 efficacy trials were conducted in years 2019-2021 in Poland to present the control of codling moth in apple. ASA-01 was tested at rates: 0.03 L/10000m^2 LWA (6 trials), 0.05 L/10000m^2 LWA (7 trials), 0.07 L/10000m^2 LWA (7 trials) and 0.09 L/10000m^2 LWA (7 trials) in order to determine the minimum effective dose in apple for the control of codling moth. The rates reflect the proposed label rates and 43% and 71% of the lowest recommended rate of ASA-01.

For the assessment conducted at 22-37 DA-T (BBCH 74-76), the recommended doses 0.07 L/10000m^2 LWA and 0.09 L/10000m^2 LWA of ASA-01 provided a superior control codling moth to dose 0.05 L/10000m^2 LWA of tested product in 2 out of 7 conducted trials and provided a superior control codling moth to dose 0.03 L/10000m^2 LWA in 3 out of 6 trials. In remaining trials, doses 0.07 L/10000m^2 LWA and 0.09 L/10000m^2 LWA of ASA-01 provided similar control to doses 0.03 and 0.05 L/10000m^2 LWA.

Apple and green apple aphid

8 efficacy trials were conducted in years 2019-2023 in Poland to present the control of green apple aphids in apple. ASA-01 was tested at rates: 0.01 L/10000m2 (3 trials), 0.02 L/10000m2 LWA (5 trials), 0.03 L/10000m2 LWA (8 trials), 0.05 L/10000m2 LWA (8 trials) and 0.06 L/10000m2 LWA (3 trials) in order to determine the minimum effective dose in apple for the control of aphids. The rates reflect the proposed label rates and 33.3 %, 66.7% and 150% of the lowest recommended rate of ASA-01.

For the assessment conducted at 7-8 DA-T (BBCH 65-76), the recommended doses 0.03 L/10000m^2 LWA and 0.05 L/10000m^2 LWA of ASA-01 provided a superior control green apple aphid to dose 0.01 L/10000m^2 LWA of tested product in 3 out of 3 conducted trials. Dose 0.02 L/10000m^2 LWA of ASA-01 provided an inferior control to the recommended doses 0.03 L/10000m^2 LWA and 0.05 L/10000m^2 LWA in 4 out of 5 conducted trials. In one out of 5 trials, dose 0.02 L/10000m^2 LWA provided similar control green apple aphids to recommended doses: 0.03 L/10000m^2 LWA and 0.05 L/10000m^2 LWA of ASA-01. Dose 0.06 L/10000m^2 LWA of ASA-01 provided similar control green apple aphids to dose 0.05 L/10000m^2 LWA in 5 out of 5 trials. Dose 0.06 L/10000m^2 LWA of ASA-01 provided similar control green apple aphids to dose 0.03 L/10000m^2 LWA in 2 out of 5 trials and provided superior control aphids in 3 out of 5 trials.

Winter oilseed rape and pollen beetle

8 efficacy trials were established in order to present the control of pollen beetle in winter oilseed rape. Trials were conducted in 2020-2023 in Poland. ASA-01 was tested at 0.03 to 0.12 L/ha (18 – 36 g of acetamiprid per hectare) in order to determine the minimum effective dose in winter oilseed rape for control of pollen beetle. The rates reflect the proposed label rates, 37.5 % (0.03 L/ha, 6 trials) and 75% of the lowest recommended rate (0.06 L/ha) of ASA-01 and 0.12 L/ha (150 % of the lowest recommended rate), in accordance with the EPPO standard PP 1/225 (2) '*Minimum effective dose'*.

For the assessment conducted at 7-9 DA-T (BBCH 57-64), the higher recommended dose 0.1 L/ha of ASA-01 provided a superior control to dose 0.03 L/ha in 6 out of 6 trials and superior control to dose 0.06 L/ha in 7 out of 8 trials. In one trial, efficacy after application of dose rate 0.1 L/ha was similar to efficacy after 0.06 L/ha application. The lower recommended rate- 0.08 L/ha provides a superior control to dose 0.03 L/ha in 5 out of 6 trials and provided a superior control to dose 0.06 L/ha in 5 out of 8 trials. In the rest of trials, efficacies were similar.

The dose rate of 0,1 L/ha should be considered the minimum effective dose rate. Lower dose 0,08L/ha performed medium effectively, giving less consistent results (68,2%-76,8%) 1-6 DAA and achieved 80,2% 7-9 DAA. The efficacy at 0,08 l/ha was statistically lower than the efficacy of the reference product in two trials. It may be considered sufficient in case of lower density of the pest.

Summary and conclusions on the minimum effective dose

The dose rates 0.03 L/10000m2 LWA and 0.05 L/10000m2 LWA of ASA-01 applied once provided the optimum overall control and should be considered as effective against green apple aphids in apple. The higher, recommended dose is to be used in conditions of increased risk of infestation.
The dose rates 0.07 L/10000m2 LWA and 0.09 L/10000m2 LWA of ASA-01applied twice provided the optimum overall control and should be considered as effective against codling moth in apple. The higher, recommended dose is to be used in conditions of increased risk of infestation.
The dose rates 0.08 L/ha and 0.1 L/ha of ASA-01 applied once provided the optimum overall control and should be considered as effective against pollen beetle in winter oilseed rape. The higher lower, recommended dose is to be used in conditions of increased decreased risk of infestation.

Efficacy tests

Apple and codling moth

A total of 7 trials were carried out to evaluate the efficacy of ASA-01 for the control of codling moth in apple. All trials have been conducted between 2019-2021 in Poland.
Data demonstrated that the efficacy of ASA-01 at the proposed rates of 0.07 L/10000 m2 LWA and 0.09 L/10000 m2 LWA 22-37 after last treatment were 98.9% and 100%, respectively. The efficacy of both dose rates was similar to the efficacy reference product Mospilan 20 SP at rate 0.2 kg/ha against codling moth. Assessment of efficacy conducted on 300 harvested fruits showed that ASA-01 at both recommended doses and reference product provided high control codling moth in apple.

ASA-01 at 0,07-0,09 L/10000 m^2 LWA effectively (**E**) protected the crop against CARPO from the second week after two applications of the product until the harvest time and performed comparable to the reference product. The higher dose rate is propose to be use in case of higher density of the pest.
In a first week after the product application, efficacy was medium effective and statistically lower than for the reference product. The number of trials for that time is limited, but the efficacy of the product in the first week after application is clearly lower in comparison to the reference product – ME. This information should be incorporated in the label.

Apple and green apple aphid

A total of 8 trials were carried out to evaluate the efficacy of ASA-01 for the control of green apple aphids in apple. All trials have been conducted between 2019-2023 in Poland.
Data demonstrated that average efficacy of ASA-01 at the proposed rate of 0.03 L/10000 m^2 LWA was 95.1 % and average efficacy of the product at the proposed rate of 0.05 L/10000 m^2 LWA was 98.0%. Both dose rates provided similar control of green apple aphids to reference product Mospilan 20 SP at rate 0.2 kg/ha.

ASA-01 at 0,03-0,05 L/10000 m2 LWA effectively (E) protected the crop against APHIPO and performed comparable to the reference product. The higher dose rate is propose to be use in case of higher density of the pest.

Winter oilseed rape and pollen beetle

8 efficacy trials were conducted in years 2020-2023 in Poland to present the control of pollen beetle in winter oilseed rape.

Average efficacy of ASA-01 against *Brassicogethes aeneus* in winter oilseed rape for dose rate 0.08 L/ha was 80.2% (in range 64.7-91.7%), for dose rate 0.1 L/ha was 88.2 % (in range 79.6-94.4%) and was similar to efficacy of standard reference product Mospilan 20 SP.

ASA-01 at 0,1 L/ha, applied one time in winter oilseed rape, controlled MELIAE effectively (**E**) and performed comparable to the reference product. Lower dose 0,08L/ha performed medium effectively, giving less consistent results (68,2%-76,8%) 1-6 DAA and achieved 80,2% 7-9 DAA. It may be considered sufficient in case of lower density of the pest.

Conclusions

On the basis of obtained results, ASA-01 in doses of 0.07-0.09 L/10000 m^2 LWA applied twice in spring from butterflies' flight beginning is recommended for control *Cydia pomonella* in apple. The higher, recommended dose is to be used in conditions of increased risk of infestation.

On the basis of obtained results, ASA-01 applied once in spring (from BBCH 56) in dose rates 0.03-0.05 L/10000 m^2 LWA is recommended for control *Aphis pomi* in apple. The higher, recommended dose is to be used in conditions of increased risk of infestation.
On the basis of obtained results, ASA-01 in doses 0.08-0.1 L/ha applied once in BBCH 50-60, from inflorescence emergence to beginning of flowering is recommended for control of *Brassicogethes aeneus* in winter oilseed rape. The lower ~~higher~~, recommended dose is to be used in conditions of ~~increased~~ decreased risk of infestation.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Acetamiprid is a broad-spectrum insecticide with both contact systemic. It belongs to nicotinic acetocholine receptor (NACHR) competitive modulators, chemical family- neonicotinoids (IRAC group 4A). Neonicotinoids mimic the agonist action of acetylcholine at nAChRs (Nicotinic acetylcholine receptor), causing hyperexcitation. Acetyl choline is the major excitatory neurotransmitter in the insect central nervous system. Neonicotinoids such as acetamiprid bind to the same site as acetylcholine at the nAChRs and causing a range of symptoms from hyper-excitation to lethargy and paralysis. Desensitized nAChR-neonicotinoid complexes no longer conduct ions and are essentially inhibited. It is used to control *Hemiptera*, *Lepidoptera*, *Thysanoptera* and *Coleoptera*. For neonicotinoids metabolic resistance as well as target-site resistance has been observed. According to the Arthropod Pesticide Resistance Database (APRD), in case of acetamiprid the metabolism resistance was more frequent than the target-site resistance.

So far, no resistance cases of CARPPO against acetamiprid were reported in European countries. No resistances of *Aphis pomi* and *Brassicogethes aeneus* against acetamiprid are known so far.

The resistance management strategy consists of:
- use product on the basis of label recommendations and GAP (Good Agricultural Practices). Using at rates lower or higher than recommended on the label can results in resistance or/and unwanted effects on non-target organism and the environment.
- Mode of action alternation is recommended.
- The use of mixtures containing two effective components with different mode of action increase the spectrum of controlled insects and prevent the development of resistance
- Monitoring and adhering to recommended pest and/or damage thresholds, respecting the usefulness of natural enemies, simple sanitation and removal of post-harvest residues in the fields,
- The use of resistant crop varieties and crop rotation can help to slow down and even prevent resistance development.

3.3.2 Adverse effects on treated crops

Phytotoxicity effect on apple was evaluated in 8 efficacy trials against green apple aphid where tested product was applied once in BBCH 55-76 and in 7 efficacy trials against codling moth where tested product was applied twice with interval ~~7~~ 8-10 days in BBCH 7~~1~~2-74. Phytotoxicity effect on winter oilseed rape was evaluated in 8 efficacy trials against pollen beetle where ASA-01 was used in one application in BBCH 52-60.

No phytotoxicity symptoms caused by ASA-01 at all tested dose rates were observed in all trials conducted in winter oilseed rape and in apple.

Moreover, in 7 efficacy trials conducted in apple against codling moth and 8 trials conducted in winter oilseed rape against pollen beetle yield was assessed. No negative impact on yield was observed. Additionally, in some trials conducted in apple quality parameters, such as: colour of fruits (2 trials), % of russeting (2 trials), BRIX degree and firmness of fruits (1 trial) were assessed. No negative impact of ASA-01 was observed on these quality traits of apple.

In winter oilseed rape in some trials quality traits, such as: thousand grain weight (7 trials), moisture content (6 trials), oil content (8 trials), protein content (2 trials), fiber and neutral detergent (1 trial) were assessed. No negative impact on these traits after application of ASA-01 was observed.

3.3.3 Observations on other undesirable or unintended side-effects

Acetamiprid has been applied for many years not only in Poland but also in other countries of Europe. So far, any negative impact of acetamiprid on succeeding crops is not known. Acetamiprid decomposes in soil rapidly and does not pose risk for succeeding plants. ASA-01 is an insecticide without any herbicidal action and therefore it is not expected to be harmful for any succeeding crop.

Any negative side effects on target or adjacent crops have not been reported in the efficacy trials. In order to avoid any adverse impact on adjacent crops, drift of working solution to adjacent crops should not be allowed. Application of ASA-01 according to recommendations included in the label-instruction poses no unacceptable threat to beneficial organisms and no threat to earthworms.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

The analytical method HPLC with DAD detection method used to quantify active substance acetamiprid in ASA-01 product was fully validated. The methods fulfil requirements of SANCO/3030/99 rev.5 and is acceptable.

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.
References were made to the existing and EU approved analytical methods provided in RAR 2015 for all monitoring enforcements methods for all matrices. No new active substance data are submitted in this application.
New analytical methods to determine residues of acetamiprid for crop matrices, water, arthropods and honey related to product were developed. The methods have been conducted in accordance with SANCO/3029/99 rev. 4 and SANTE/2020/12830 guidelines and therefore considered to be adequate. These methods are based on HPLC-MS/MS and HPLC-DAD methods which are highly specific and therefore considered acceptable.

zRMS: acceptable.

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

No acute toxicity studies were performed for ASA-01. The classification was based on the composition of

the product and was performed according to the Regulation (EC) of the European Parliament and of the Council No. 1272/2008 of December 16th, 2008 *on classification, labelling and packaging of substances and mixtures*. Details on composition and classification of formulants are provided in dRR Part C.

According to Regulation (EC) 1272/2008, the proposed toxicological classification of ASA-01 is:

- Skin Sens. 1, H317 - May cause an allergic skin reaction
- Acute Tox. 4, H302 - Harmful if swallowed.
- Repr. 2, H361d - Suspected of damaging the unborn child.

3.5.2 Operator exposure

Operator exposure to ASA-01 was not evaluated as part of the EU review of acetamiprid. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

The operator exposure was assessed against the AOEL and AAOEL agreed in the EU review acetamiprid (EFSA Journal 2016;14(11):4610). Operator exposure calculations were performed using the AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032).

Performed calculations indicate an acceptable exposure risk for an operator using work wear (arms, body and legs covered) even without RPE/PPE, when the product ASA-01 is used acc. to GAP table. However, it's recommended for operator to wear also protective gloves during mixing/loading and during application.

zRMS:
The acute and longer term exposures to acetamiprid (an active substance of formulation ASA-01 (product VIARES) of operator not wearing PPE, but wearing a work clothing (long sleeved shirt, long trousers) and applying formulation ASA-01 in line with GAP on oilseed rape at dose of max. 0.1 L product/ha (0.03 kg a.s./ha) using tractor-mounted/trailed sprayer (downward spraying, or on apples (pome fruits) at dose of max. 0.09 L product/ha) (0.027 kg a.s./ha) using tractor-mounted/trailed sprayer (upward spraying) calculated with the EFSA AOEM 2022 are below AAOEL and below AOEL (both 0.025 mg/kg bw/d), therefore it is concluded that operator is not at risk when applying ASA-01 (product VIARES) according to its intended use on oilseed rape or apples.
Taking into account that product is classified as Skin Sens.1, H317 and Repr. 2, H361d it is recommended that operator should wear work wear covering arms, body and legs and protective gloves during mixing/loading and application.

3.5.3 Worker exposure

Worker exposure to ASA-01 was not evaluated as part of the EU review of acetamiprid. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

The worker exposure was assessed against the AOEL and AAOEL agreed in the EU review acetamiprid (EFSA Journal 2016;14(11):4610). Worker exposure calculations were performed using the AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032).

The results of the exposure estimations performed by AOEM EFSA models show that the use of ASA-01 according to the list of intended uses presented in GAP Table, causes no health risk for the worker assuming the workwear (arms, body and legs covered) and no gloves are used.
However, it's recommended for worker to wear also protective gloves during field activities.
As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

zRMS:
The potential exposure to acetamiprid (an active substance of formulation ASA-01 product VIARES) of worker) entering for 2 hours for inspection/irrigation a field of oilseed rape treated with this product at at dose of max. 0.1 L product/ha (0.03 kg a.s./ha) using tractor-mounted/trailed sprayer (downward spraying) calculated with the EFSA AOEM 2022 is below AOEL of acetamiprid, thus does not pose a systemic health risk.
The potential exposure to acetamiprid (an active substance of formulation ASA-01 product VIARES) of worker) entering for 8 hours for searching, reaching, picking an orchard (pome trees) treated with this product at dose of max. 0.09L product/ha (0.027 kg a.s./ha) using tractor-mounted/trailed sprayer (upward spraying) calculated with the EFSA AOEM 2022 is below AOEL of acetamiprid, thus does not pose a systemic health risk. Wearing a work wear (arms, body and legs covered) and protective gloves further reduce exposure and health risk of worker.

3.5.4 Bystander and resident exposure

Bystander and resident exposure to ASA-01 was not evaluated as part of the EU review of acetamiprid. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

The bystander and resident exposure was assessed against the AOEL and AAOEL agreed in the EU review acetamiprid (EFSA Journal 2016;14(11):4610). Bystander and resident exposure calculations were performed using the AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032).

The exposure of bystander and resident (children and adult) to acetamiprid contained in the formulation ASA-01 causes no risk to human health if the product is used in accordance with the intended uses listed in the GAP Table.

zRMS
The exposure estimation of residents (adult and child) to acetamiprid (an active substance of formulation ASA-01, product VIARES) applied on an orchard (pome trees at dose of max. 0.09L product/ha (0.027 kg a.s./ha) being a critical application using tractor-mounted/trailed sprayer (upward calculated with the EFSA AOEM 2022 demonstrates that such a exposure in all cases is well below AOEL, therefore the application of formulation ASA-01, product VIARES) does not pose an unacceptable risk to the health of adult and child residents for its intended use within good agricultural practice.

The exposure estimation of bystanders (adult and child) to acetamiprid (an active substance of formulation ASA-01, product VIARES) applied on an orchard (pome trees at dose of max. 0.09L product/ha (0.027 kg a.s./ha) being a critical application using tractor-mounted/trailed sprayer (upward calculated with the EFSA AOEM 2022 demonstrates that such a exposure in all cases is well below AAOEL, therefore the application of formulation ASA-01, product VIARES) does not pose an unacceptable risk to the health of adult and child bystanders for its intended use within good agricultural practice.

Summing up an application of a formulation ASA-01 (product VIARES) on orchard (pome trees) at dose of max. 0.09L product/ha (0.027 kg a.s./ha) (upward spraying) or on oilseed rape at dose of max. 0.1 L product/ha (0.03 kg a.s./ha) (downward spraying) does not pose an unacceptable health risk for residents and bystanders.

3.6 Residues and consumer exposure (Part B, Section 7)

New comments and changes from zRMS are on yellow background.. For details see B7.

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.

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 of apples and 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 (2.6). According to available data, no specific mitigation measures should apply.

~~Acetamiprid is a systemic substance. The residue data for rapeseed and apples are currently sufficient (see the table of MRLs in the B7) to grant the approval for these uses. However, because the presented in the B7 Appendix 2 tunnel studies indicate the possibility of exceeding the MRL in honey (0.05), the product, as the systemic one, 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 treatments must commence from BBCH 70.~~
~~Thus PL agrees with the authorization of the intended uses after the flowering period with the complete exclusion of rapeseed.~~

3.6.1 Residues

Stability of Residues
In storage stability studies acetamiprid residues were concluded to be stable up to 1 year in high water-, high oil- and high acid-content commodities and up to 8 months in high starch-content matrices (potato tuber) (EFSA Journal 2016;14(11):4610).
Sufficient stability has been demonstrated to support the residue data presented in this document.
No further data are required to support the proposed uses.

Metabolism in plants and animals
The metabolism in plants and livestock for acetamiprid was reviewed during the Annex I inclusion and renewal process.
No additional studies are available in the framework of this application.
Metabolism in primary crops was investigated in the fruit, leafy, root and oilseeds/pulses crop groups. Metabolism in rotational crops was investigated in the root/tuber crops, leafy crops and cereal (small grain).

Plant residue definition for monitoring	Acetamiprid (Reg. (EU) 2019/88) 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))

Animal residue definition for monitoring: acetamiprid except honey: the sum of acetamiprid and IM-2-1, expressed as acetamiprid (Reg. (EU) 2019/88).
Based on animal metabolism studies, the residue definition was proposed by EFSA as 'IM-2-1 expressed as acetamiprid' for monitoring and as 'the sum of acetamiprid and IM-2-1, expressed as acetamiprid' for risk assessment (EFSA Journal 2016;14(11):4610).

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

Magnitude of residues in plants
Oilseeds (winter oilseed rape)
Proposed GAP: BBCH 50-60 in spring, 1 application, 24-30 g as/ha, PHI: N/A.
Critical GAP in NEU (EFSA Journal 2010; 8(11):1898, EFSA Journal 2011;9(7):2328): BBCH 75-81 (PHI: 28 days); 1 application, Application rate per treatment: 0.05 kg as/ha. 2 applications were made in some of trials used for the active substance assessment instead of once.

New acceptable studies on the magnitude of residue have been submitted by the applicant in the framework of this application. All trials are valid regarding storage stability data. Sufficient trials on oilseed rape are available to support the proposed uses. The residues arising from the proposed uses will not exceed the MRL for acetamiprid established for oilseed rape.

Orchards (apple, wild apple, pear, Chinese pear, quince and medlar)
Proposed GAP:
BBCH 56-75 in spring, 1 application, max. 22.5 g as/ha, PHI: N/A.
BBCH 57-75 in spring, 2 applications, max. 27 g as/ha, interval 7-10 days, PHI: N/A.
EU GAP: 2 x 0.075 kg as/ha, BBCH 77-87 (List of Endpoints, Acetamiprid, The Netherlands, 2016)

New acceptable studies on the magnitude of residue in apple have been submitted by the applicant in the framework of this application. Sufficient trials on apple are available to support the proposed uses. All trials are valid regarding storage stability data.
According to SANTE/2019/12752 Rev.01 extrapolation from apple to wild apple, pear, Chinese pear, quince and medlar is possible (before and after forming of the edible part).
The residues arising from the proposed uses will not exceed the MRL for acetamiprid established for these crops.

Magnitude of residues in livestock
The metabolism in livestock for acetamiprid was reviewed during the Annex I inclusion and renewal process.
No new data submitted in the framework of this application.
For animal products EFSA Journal 2016;14(11):4610) proposes to limit the enforcement residue definition to the N-desmethyl metabolite (IM-2-1), expressed as acetamiprid since acetamiprid is extensively metabolised by animals and not detected in any animal matrices, except in milk.

The current residue definition set in Regulation (EC) No 396/2005 (Reg. (EU) 2019/88) 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.

Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)
Data on processing studies were evaluated at the EU level. The stability of acetamiprid during pasteurisation, baking, boiling, brewing and sterilisation was sufficiently investigated. Acetamiprid is stable under standard hydrolysis conditions. Pasteurisation, boiling and sterilisation are unlikely to result in any significant metabolites. A different residue definition for processed commodities is not required.

Magnitude of residues in representative succeeding crops
Acetamiprid, IM-1-4 and IM-1-5 residues are not expected to be present in rotational crops. No waiting periods beyond normal agricultural practice are proposed for succeeding crops to be planted.

3.6.2 Consumer exposure

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).

The proposed uses of acetamiprid in the formulation ASA-01 do not represent unacceptable acute and chronic risks for the consumer.

3.7 Environmental fate and behaviour (Part B, Section 8)

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

The predicted environmental concentrations in soil PECs of acetamiprid and its metabolites were calculated using excel calculation sheet which is in line with Ctgb Evaluation Manual version 2.2 (January 2018) and FOCUS guidance – FOCUS (1997): Soil persistence models and EU registration. For further risk assessment worst case PECs values were used.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

Based on FOCUS PEARL, PELMO and MACRO simulations values of PEC_{gw} for acetamiprid and its metabolites are far below the threshold concentration of 0.1 µg/L for all scenarios and crops with exception of metabolite IM-1-5. At tier 1, metabolite IM-1-5 showed PEC_{gw} value greater than trigger of 0.1 µg/L in some scenarios for use in apple against codling moth. PEC_{gw} value in PEARL model for Châteaudun was 0.1122682 µg/L, for Hamburg was 0.115439 µg/L, for Piacenza was 0.105152 µg/L and for Thiva was 0.133604 µg/L. At tier 2, PEC_{gw} value for IM-1-5 did not exceed trigger value 0.1 µg/L.
IM-1-5 metabolite only appears in calcareous soils with pH (water) > 8 and none of the FOCUS scenarios has pH greater than 8, only Châteaudun has pH = 8 and Hamburg has a pH of 6.5. Therefore, under realistic conditions this metabolite will never be found in Hamburg scenario.
Relevance evaluation of IM-1-5 was conducted in dRR Part 10.

At the request of the Polish Ministry of Agriculture and Rural Development and the evaluator, the PECgw calculations for the application of 2 x 27 g as/ha at BBCH 57 in orchards were carried out taking into account every 2 years application and the value of PUF = 0. The results indicate that the PECgw for the active substance and its metabolites, including metabolite IM-1-5, are below the trigger value of 0.1 µg/L, which indicates that there is no unacceptable risk of groundwater contamination. Additional modelling with PELMO was not required since all PECgw values in every year calculation with PUF=0 were below the trigger value 0.1 µg/L.

The formulation application every 2 years is concluded for apples, wild apples, pears, Chinese pears, quince and medlar at multiple application (Use No 3 and 5).
In Use No 1, 2 and 4 the application every year is admissible.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

PEC_{sw} for acetamipryd and its metabolites IM-1-2, IM-1-4, IC-0, IM-1-5 and IB-1-1 were calculated with FOCUS STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v.5.0.1. PEC_{sw} values were used in aquatic risk assessment.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The fate and behaviour of acetamipryd in air was evaluated during the EU review. The vapour pressure at 20°C of the active substance acetamiprid is < 10-5 Pa. Hence, the active substance acetamiprid is regarded as non-volatile. Its volatilisation from plant and soil surfaces is regarded to be very low. Additionally, it is rapidly degraded in air (DT_{50} = 0.14 days). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance acetamiprid due to volatilization with subsequent deposition does not have to be considered.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Birds

Effects on birds for ASA-01 were not evaluated as part of the EU review of acetamiprid. However further data on ASA-01 is not relevant as data for the active substance on toxicity to birds are considered essential. It is possible to extrapolate from data for the active substance. Therefore, all relevant data were assessed in the EU review. Risk assessments for ASA-01 with the proposed use pattern and EU agreed endpoints have been provided and are considered adequate.

The risk assessment for effects on birds was carried out according to the latest guidance for risk assessment for birds and mammals EFSA Journal 2009; 7(12): 1438.

The acute and reproductive risks of ASA-01 to birds were assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with active substance, as well as SV_{90} and SV_{m}.

Drinking water exposure leaf scenario has not been performed since ASA-01 is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later. Drinking water exposure puddle scenario has not been performed since the ratios of effective application rates to relevant endpoints do not exceed 50 (Koc < 500 L/kg).

Exposure for earthworm-eating birds and fish-eating birds via secondary poisoning was not required since log P_{ow} of acetamiprid are blow the trigger value of 3.

The TER values where applicable exceed the trigger values of 10 for acute and 5 for reproductive and long-term risk, thus indicating no unacceptable risk to birds from the proposed use of ASA-01. No risk management measures are required.

Terrestrial vertebrates (other than birds)

Effects on mammals for ASA-01 were not evaluated as part of the EU review of acetamiprid. However further data on ASA-01 is not relevant as data for the active substance on toxicity to mammals are considered essential. It is possible to extrapolate from data for the active substance. Therefore, all relevant data were assessed in the EU review. Risk assessments for ASA-01 with the proposed use pattern and EU agreed endpoints have been provided and are considered adequate.

The risk assessment for effects on terrestrial vertebrates other than birds was carried out according to the latest guidance for risk assessment for birds and mammals EFSA Journal 2009; 7(12): 1438.

The acute and reproductive risks of ASA-01 to mammals were assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with active substance, as well as SV_{90} and SV_m.

Drinking water exposure puddle scenario has not been performed since the ratios of effective application rates to relevant endpoints do not exceed 50 (Koc < 500 L/kg).

Exposure for earthworm-eating mammals and fish-eating mammals via secondary poisoning was not required since log P_{ow} of acetamiprid are blow the trigger value of 3.

The TER values where applicable exceed the trigger values of 10 for acute and 5 for reproductive and long-term risk, thus indicating no unacceptable risk to mammals from the proposed use. No risk management measures are required.

3.8.2 Effects on aquatic species

Effects on aquatic organisms for ASA-01 were not evaluated as part of the EU review of acetamiprid. Acute toxicity studies of ASA-01 to invertebrates and algae were submitted in this dossier.

Risk assessments for ASA-01 with the proposed use pattern was carried out according to the latest guidance for risk assessment for aquatic organisms in edge-of-field surface water EFSA Journal 2013; 11(7):3290.

PECsw/RAC values were calculated with PECsw values obtained for active substance and its metabolites calculated in Steps 1, 2, 3 and 4 were below the 1 for acute and long-term risk indicating no unacceptable risk to aquatic organisms for most scenarios. For scenarios with PEC/RAC above 1 safe use has not been confirmed so further risk mitigations from and risk refinement is required at national level.

For Poland D3, D4 and R1 scenarios are relevant so it can be concluded that ASA-01 in accordance with GAP does not pose unacceptable risk to aquatic organisms under condition following risk mitigations measures are applied ~~in orchards (use no. 2, 3)~~:

- ~~20m no spray buffer zone or~~
- ~~15m no spray buffer zone + 50% nozzle reduction or~~
- ~~10m no spray buffer zone + 75% nozzle reduction or~~
- ~~5m no spray buffer zone + 90% nozzle reduction.~~

~~In case of rape (use no. 1) no risk mitigations measures are required.~~

Use no. 1
~~-unsprayed buffer zone of 10m + 50% nozzle reduction or~~
~~-unsprayed vegetated buffer zone of 20m~~
unsprayed vegetated buffer zone of 20m or
unsprayed vegetated buffer zone of 10m + 50% nozzle reduction

Use no. 2, 4
-unsprayed vegetated buffer zone of 20m + 90% nozzle reduction or
-unsprayed buffer zone of 50m with vegetated buffer zone of 20m + 50% nozzle reduction or
-unsprayed buffer zone of 100m with vegetated buffer zone of 20m

Use no. 3, 5
-unsprayed buffer zone of 50m with vegetated buffer zone of 20m + 90% nozzle reduction or
-unsprayed buffer zone of 100m with vegetated buffer zone of 20m

Classification of ASA-01 was done on the basis of formulation test results as well as active substance properties. The proposed classification of the product ASA-01 is:

Aquatic Chronic 1, H410

3.8.3 Effects on bees

Effects on bees for ASA-01 were not evaluated as part of the EU review of acetamiprid. Toxicity studies of ASA-01 to bees and bumblebees were submitted in this dossier.

The evaluation of the acute risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

The risks of ASA-01 to honeybees was assessed from Hazard Quotients (HQ) and Exposure Toxicity Ratio (ETR) between toxicity endpoints, estimated from acute oral and contact studies with formulated product as well as the maximum single application rate.

All the hazard quotients were considerably less than the respective triggers, indicating that ASA-01 in accordance with GAP poses a low risk to bees. No risk management measures are required.

3.8.4 Effects on other arthropod species other than bees

Effects on non-target arthropods for ASA-01 were not evaluated as part of the EU review of acetamiprid. Toxicity studies of ASA-01 to non-target arthropods were submitted in this dossier.

Risk assessments for ASA-01 with the proposed use pattern was carried out according to the guidance for risk assessment for arthropods "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002) and in consideration of the recommendations of the guidance document ESCORT 2.

The in-field risk of ASA-01 to non-target arthropods was evaluated by comparison of % effects rate with derived from laboratory tests and in-field predicted rate. The off-field risk of ASA-01 to non-target arthropods was assessed from Hazard Quotients (HQ) between toxicity endpoints estimated from laboratory tests with the formulated product ASA-01 as well as off-field predicted environmental rate. No risk was determined in-field and off-field after application of ASA-01 in accordance with GAP. No risk management measures are required.

3.8.5 Effects on soil organisms

Effects on earthworms and other soil micro-organisms for ASA-01 were not evaluated as part of the EU review of acetamiprid. The toxicity studies to earthworm, *Folsomia candida* and *Hypoaspis aculeifer* as well as nitrogen transformation test for ASA-01 were submitted in this dossier.

Risk assessments for ASA-01 with the proposed use pattern was carried out according to the guidance for risk assessment for terrestrial ecotoxicology "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002).

Earthworms, *Folsomia candida* and *Hypoaspis aculeifer*
The risk of ASA-01 to earthworms, *Folsomia candida* and *Hypoaspis aculeifer* was assessed from toxicity exposure ratio (TER) between the selected toxicity endpoints for metabolite IM-1-5 s and the formulated product ASA-01 as well as the maximum soil PECs.

The chronic TER values were greater than the trigger of 5, indicating an acceptable risk to earthworms, *Folsomia candida* and *Hypoaspis aculeifer* following application of ASA-01 in accordance with GAP. No risk management measures are required.

Micro-organisms
The risk of ASA-01 to soil micro-organisms was evaluated by comparison of no-effect concentration in soil, derived from laboratory tests for metabolite IM-1-5 and the formulated product ASA-01 with the maximum soil PECs.

According to the performed risk assessment it was assessed that the application of ASA-01 in accordance with GAP does not pose unacceptable risk to soil micro-organisms. No risk management measures are required.

3.8.6 Effects on non-target terrestrial plants

Effects on non-target terrestrial plants for ASA-01 were not evaluated as part of the EU review of acetamiprid. The studies on seedling emergence and vegetative vigour for ASA-01 were submitted in this dossier.

The risk of ASA-01 to non-target plants was assessed from toxicity exposure ratios between toxicity endpoints for the formulation ASA-01 and off-field predicted environmental rate. The TER values were greater than the trigger of 5, indicating an acceptable risk to non-target terrestrial plants following application of ASA-01 in accordance with GAP. No risk management measures are required.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.9 Relevance of metabolites (Part B, Section 10)

PEC_{gw} values for metabolite IM-1-5 were above 0.1 µg/L but below 0.75 µg/L for some scenarios. However, on the basis of relevance assessment according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.10, this metabolite is not relevant.

zRMS:
The metabolite IM-1-5 of acetamiprid is a relevant groundwater metabolite however according to Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater Of Substances

Regulated Under Regulation (EC) No 1107/2009 (Sanco/221/2000 – rev.11; 21 October 2021), its concentration in the ground waters does not exceeds the concentration of 0.1 µg/l), thus it is below the maximum permissible concentration (0.1 µg/l) for groundwater and it does not pose health risk to consumers. It is concluded that the application of formulation ASA-01 (product VIARES) in line with GAP does not pose an unacceptable health risk for consumers due to drinking of water.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

ASA-01 contains active substance acetamiprid, which is not candidate for substitution. A comparative assessment was therefore considered not necessary.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

MS assessor to present a copy of the approved product label for MS country.

Appendix 3 Letter of Access

Not relevant.

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
XXXX	XXXX	XXX	XXXX	XX	XX	XXXX	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner