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| REGISTRATION REPORT  Part B  Section 7  Metabolism and Residues  Detailed summary of the risk assessment |
| Product code: ADM.00150.I.2.A  Product name: LEAXO  Chemical active substance:  Acetamiprid, 200 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  (authorisation according to Art. 33) |
| Applicant: Country organisation / representative of ADAMA,  as given in Part A  Submission date: November 2023, updated December 2023, July 2024  MS Finalisation date: July 2024 (initial Core Assessment)  December 2024 (final Core Assessment), updated June 2025,  updated August 2025 |

Version history

|  |  |
| --- | --- |
| When | What |
| November 2023 | Applicant version |
| December 2023 | Update of final storage stability study 000107275 on honey 18 months. |
| July 2024 | Update of residue definition, ADI and ARfD and dietary exposure assessment to cover proposals made by EFSA in 2024 Statement: [Statement on the toxicological properties and maximum residue levels of acetamiprid and its metabolites (wiley.com)](https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2024.8759) |
| July 2024 | Initial zRMS assessment  The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~. |
| December 2024 | Final report (Core Assessment updated following the commenting period)  Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency. |
| June 2025 | Applicant’s update requested by zRMS  Update to take account of new MRL regulations (Reg. (EU) 2025/158 and PLAN/2024/2431). Minor changes are introduced directly in the text and highlighted in blue. No longer relevant information is ~~struck through~~ and shaded for transparency. |
| June 2025 | Final report (Core Assessment updated following changes to the residue definition and MRL values)  The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in green. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency. |
| August 2025 | Final report (Core Assessment updated following the commenting period)  Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in purple. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency. |

Table of Contents

[7 Metabolism and residue data (KCA section 6) 5](#_Toc206412610)

[7.1 Summary and zRMS Conclusion 5](#_Toc206412611)

[7.1.1 Critical GAP(s) and overall conclusion 5](#_Toc206412612)

[7.1.2 Summary of the evaluation 9](#_Toc206412613)

[7.1.2.1 Summary for acetamiprid 9](#_Toc206412614)

[7.1.2.2 Summary for ADM.00150.I.2.A 10](#_Toc206412615)

[7.2 Acetamiprid 12](#_Toc206412616)

[7.2.1 Stability of Residues (KCA 6.1) 12](#_Toc206412617)

[7.2.1.1 Stability of residues during storage of samples 12](#_Toc206412618)

[7.2.1.2 Stability of residues in sample extracts (KCA 6.1) 16](#_Toc206412619)

[7.2.2 Nature of residues in plants, livestock and processed commodities 17](#_Toc206412620)

[7.2.2.1 Nature of residue in primary crops (KCA 6.2.1) 17](#_Toc206412621)

[7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1) 20](#_Toc206412622)

[7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1) 22](#_Toc206412623)

[7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1) 23](#_Toc206412624)

[7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5) 24](#_Toc206412625)

[7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1) 26](#_Toc206412626)

[7.2.3 Magnitude of residues in plants (KCA 6.3) 27](#_Toc206412627)

[7.2.3.1 Summary of European data and new data supporting the intended uses 27](#_Toc206412628)

[7.2.3.2 Conclusion on the magnitude of residues in plants 32](#_Toc206412629)

[7.2.4 Magnitude of residues in livestock 36](#_Toc206412630)

[7.2.4.1 Dietary burden calculation 36](#_Toc206412631)

[7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3) 41](#_Toc206412632)

[7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3) 50](#_Toc206412633)

[7.2.5.1 Available data for all crops under consideration 50](#_Toc206412634)

[7.2.5.2 Conclusion on processing studies 52](#_Toc206412635)

[7.2.6 Magnitude of residues in representative succeeding crops 52](#_Toc206412636)

[7.2.6.1 Field rotational crop studies (KCA 6.6.2) 52](#_Toc206412637)

[7.2.7 Other / special studies (KCA6.10, 6.10.1) 55](#_Toc206412638)

[7.2.8 Estimation of exposure through diet and other means (KCA 6.9) 58](#_Toc206412639)

[7.2.8.1 Input values for the consumer risk assessment 58](#_Toc206412640)

[7.2.8.2 Conclusion on consumer risk assessment 65](#_Toc206412641)

[7.3 Combined exposure and risk assessment 67](#_Toc206412642)

[7.4 References 68](#_Toc206412643)

[Appendix 1 Lists of data considered in support of the evaluation 70](#_Toc206412644)

[Appendix 2 Detailed evaluation of the additional studies relied upon 79](#_Toc206412645)

[A 2.1 Acetamiprid 79](#_Toc206412646)

[A 2.1.1 Stability of residues 79](#_Toc206412647)

[A 2.1.1.1 Stability of residues during storage of samples 79](#_Toc206412648)

[A 2.1.2 Nature of residues in plants, livestock and processed commodities 82](#_Toc206412649)

[A 2.1.2.1 Nature of residue in plants 82](#_Toc206412650)

[A 2.1.2.2 Nature of residues in livestock 82](#_Toc206412651)

[A 2.1.3 Magnitude of residues in plants 82](#_Toc206412652)

[A 2.1.3.1 Apple 82](#_Toc206412653)

[A 2.1.3.2 Potato 93](#_Toc206412654)

[A 2.1.3.3 Oilseed rape 98](#_Toc206412655)

[A 2.1.3.4 Barley 109](#_Toc206412656)

[A 2.1.3.5 Maize/Corn 117](#_Toc206412657)

[A 2.1.3.6 Wheat 136](#_Toc206412658)

[A 2.1.3.7 Sugar beet 144](#_Toc206412659)

[A 2.1.4 Magnitude of residues in livestock 150](#_Toc206412660)

[A 2.1.4.1 Livestock feeding studies 150](#_Toc206412661)

[A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) 150](#_Toc206412662)

[A 2.1.5.1 Distribution of the residue in peel/pulp 150](#_Toc206412663)

[A 2.1.5.2 Processing studies on a core set of representative processes 150](#_Toc206412664)

[A 2.1.6 Magnitude of residues in representative succeeding crops 155](#_Toc206412665)

[A 2.1.7 Other/Special Studies 155](#_Toc206412666)

[A 2.1.7.1 Study 1 155](#_Toc206412667)

[Appendix 3 Pesticide Residue Intake Model (PRIMo) 161](#_Toc206412668)

[A 3.1 TMDI calculations 161](#_Toc206412669)

[A 3.2 IEDI calculations ~~(Scenario 1 – with apple)~~ 162](#_Toc206412670)

[~~A 3.3~~ IESTI calculations - Raw commodities ~~(Scenario 1 – with apple)~~ 164](#_Toc206412671)

[~~A 3.4~~ IESTI calculations - Processed commodities ~~(Scenario 1 – with apple)~~ 166](#_Toc206412672)

[~~A 3.5~~ ~~IEDI calculations (Scenario 2 – without apple)~~ 167](#_Toc206412673)

[~~A 3.6~~ ~~IESTI calculations - Raw commodities (Scenario 2 – without apple)~~ 168](#_Toc206412674)

[~~A 3.7~~ ~~IESTI calculations - Processed commodities (Scenario 2 – without apple)~~ 169](#_Toc206412675)

[Appendix 4 Additional information provided by the applicant 170](#_Toc206412676)

# Metabolism and residue data (KCA section 6)

ADM.00150.I.2.A and former MCW-2222 are the same product.

The risk assessment for all crops was updated based on the new toxicological reference values, residue definition and conversion factors proposed by EFSA in the 2024 Statement (EFSA, 2024). The conclusions above reflect the outcomes based on these proposed endpoints. As the residues arising from the proposed GAP for apples lead to an exceedance of the ARfD and no suitable fallback GAP could be derived, this proposed use was not accepted. The associated residues trials and risk assessments based on these residues are retained for completeness.

## Summary and zRMS Conclusion

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| **Evaluator comments:**  The update of final Registration Report is related to new MRL regulations for acetamiprid. Currently, two documents concerning acetamiprid have been published in the European Commission database: Reg. (EU) 2025/158 and PLAN/2024/2431.  The new MRLs were voted at the SCOPAFF residue and published in the Commission Regulation 2025/158 of 29 January 2025. New MRL values for acetamiprid will apply on 19 August 2025.  The planned date of entry into force of the PLAN/2024/2431 project is probably to coincide exactly with the date of entry into force of Regulation 2025/158.  In addition, the new Commission Regulation (EU) 2025/1212 of 24 June 2025 has already been published in the Official Journal of the European Union. This Regulation shall enter into force on 20 August 2025. |

### 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 ADM.00150.I.2.A / ~~Acetamiprid 200 SL~~ Leaxo are presented in Table 7.1‑1. They have been selected from the individual GAPs in the Central Zone for apples, potatoes, oilseed rape, barley, oat, maize/corn, wheat (including durum wheat, triticale and spelt), rye and sugar beet.

A list of all intended uses within the Central Zone is given in Part B, Section 0.

Justification for the selection of the critical GAP:

The most critical application rates (max) are presented in Table 7.1‑1. If identical application rates were given in Appendix 1 of Part B, Section 0 for a specific crop, the use number with the minimum water volume, which result in a maximum application rate of the active substance/hL, was identified as critical use. This was the case for apple.

If identical application rates were given in Appendix 1 of Part B, Section 0 for a specific crop, and the minimum water volume were also identical, all the corresponding use numbers were provided.

Overall conclusion

The data available are considered sufficient for risk assessment, except for apples.

An exceedance of the current MRL of the intended crops for acetamiprid as laid down in ~~SANTE/11278/2021~~ ~~Reg. (EU) 2019/88 and 2025/158 and PLAN/2024/2431~~ Reg. (EU) 2025/1212 is not expected, except for apples ~~and honey~~. For more details, please see remark below.

The chronic and the short-term intakes of acetamiprid residues are unlikely to present a public health concern, except for apples.

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended uses, except for apples ~~and oilseed rape in application rate 2 x 60 g as/ha~~.

**Remark:**

The current assessment of residues in honey based on the proposed GAPs for ADM.00150.I.2.A / Leaxo shows that the in force MRL of acetamiprid on honey of 0.05\* mg/kg (Reg. (EU) 2019/88 and 2025/158) is potentially exceeded. For products with melliferous capacity (~~apples and~~ oilseed rape in application rate 2 x 60 g as/ha) no authorisation is proposed until MRL for honey is raised.

~~However, for lower dose for oilseed rape (max 1 x 40 – 48 g as/ha) the in force MRL of acetamiprid on honey of 0.05\* mg/kg (Reg. (EU) 2019/88~~ ~~and 2025/158) will not be exceeded and this use can be accepted.~~

However EFSA concluded in Statement on the toxicological properties and maximum residue levels of acetamiprid and its metabolites (EFSA Journal. 2024;22:e8759) that „*Furthermore, for plums (0.04 mg/kg), poppy seeds (0.3 mg/kg), mustard seed (0.15 mg/kg) and* ***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*.”**

Subsequently, at the Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Pesticide Residues 17 - 18 February 2025, a new proposal received a favourable outcome in the vote and raises the MRL for honey to 0.3 mg/kg from 0.05\* mg/kg. This voted proposal (PLAN/2024/2431) is now displayed in the European Commission MRL database and is expected to enter into force in July/August 2025. The current assessment of residues in honey based on the proposed GAPs for ADM.00150.I.2.A / Leaxo shows that all of the intended uses would be in compliance with the MRL of 0.3 mg/kg.

**~~According to the harmonization arrangements of the Ministry of Agriculture and Rural Development of 14 May 2025 regarding the requirement for honey, the use of Leaxo on oilseed rape at a higher dose of 2 x 60 g as/ha can be accepted under the following condition:~~**

*~~"In view of the ongoing process of establishing MRL values for acetamiprid in honey and the application submitted by the authorisation holder to increase the MRL to 0.3 mg/kg, in accordance with Article 6 of Regulation (EC) No 396/2005, it will be necessary to verify the assessment of the Leaxo dossier in this regard for the uses covered by this decision after the entry into force of the new MRL. Failure to submit the relevant information or failure to evaluate it positively may result in a change to the conditions of this authorisation."~~*

August 2025:

It should be noted that the new Commission Regulation (EU) 2025/1212 of 24 June 2025 has already been published in the Official Journal of the European Union. This Regulation shall enter into force on 20 August 2025. The MRL for honey has been raised from 0.05\* mg/kg to 0.3 mg/kg. The current assessment of residues in honey based on the proposed GAPs for ADM.00150.I.2.A / Leaxo shows that all of the intended uses are in compliance with the MRL of 0.3 mg/kg.

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

Data gaps

Noticed data gaps are:

* ~~lack of a Letter of Access to study of Williams M., 1999; Study No 98514428 & Williams M., 1999; Report No RD-09988;~~

~~Information on ongoing negotiations were provided by the applicant. For the time being, this is considered to be sufficient. The LoA needs to be provided to MSs in the frame of the product authorisation procedure.~~

* additional supervised residue trials analysing simultaneously for acetamiprid and N-desmethyl- acetamiprid (IM-2-1), supporting intended use on apples;

According to the „*Statement on the toxicological properties and maximum residue levels of acetamiprid and its metabolites*” for the consumer risk assessment it is recommended to require additional supervised residue trials analysing simultaneously for acetamiprid and N-desmethyl-acetamiprid (IM-2-1), supporting intended use on apples.

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | | 8 | | | | 9 | | | 10 | 11 |
| GAP number (see part B.0)\* | Crop and/  or situation \*\* | Zone | Product code | F, Fn, Fpn G, Gn, Gpn or I\*\*\* | Pests or  Group of pests  controlled | Formulation | | Application | | | | Application rate per treatment | | | PHI  (days) | Conclusion |
| Type | Conc.  of as | method  kind | growth  stage & season | number  min max | interval between applications (min) | kg as/hL  min max | water L/ha  min max | kg as/ha  min max |
| No. 4, 6, 11, 13, 15 | Apples  (0130010) | CEU | ADM.00150.I.2.A | F | Please refer to Appendix 1 in Part B, Section 0 | SL | 200 g/L | Foliar spraying, overall | BBCH 71-PHI | 1 (max) | n.a. | 0.016 (max) | 500 (min) | 0.08 (max) | 14 | N  Remark 1 – see below the Table 7.1-1 |
| No. 17-22 | Potatoes  (0211000) | CEU | ADM.00150.I.2.A | F | Please refer to Appendix 1 in Part B, Section 0 | SL | 200 g/L | Foliar spraying, overall | BBCH 12-79 | 1 (max) | n.a. | 0.036 (max) | 100 (min) | 0.036 (max) | 7 | A |
| No. 43, 50, 55, 58, 64, 68, 70, 73, 76, 79 | Oilseed rape (0401060) | CEU | ADM.00150.I.2.A | F | Please refer to Appendix 1 in Part B, Section 0 | SL | 200 g/L | Foliar spraying, overall | BBCH 61-71 | 2 (max) | 7 | 0.06 (max) | 100 (min) | 0.06 (max) | 28 | A  ~~R~~  ~~N~~  Remark 2 – see below the Table 7.1-1  ~~A~~  ~~only for application rate 1x 0.04-0.048 g as/ha~~ |
| No. 32, 34, 36, 39 | Barley (0500010), Oat (0500050) | CEU | ADM.00150.I.2.A | F | Please refer to Appendix 1 in Part B, Section 0 | SL | 200 g/L | Foliar spraying, overall | BBCH 40-69 | 2 (max) | 10 | 0.036 (max) | 100 (min) | 0.036 (max) | Follow crop BBCH | A |
| No. 1-3 | Maize/Corn  (0500030) | CEU | ADM.00150.I.2.A | F | Please refer to Appendix 1 in Part B, Section 0 | SL | 200 g/L | Foliar spraying, overall | BBCH 51-75 | 1 (max) | n.a. | 0.02 (max) | 300 (min) | 0.06 (max) | 56 | A |
| No. 32, 34, 36, 39 | Wheat (0500090), Triticale (0500090-006), Spelt (0500090-005), Rye (0500070), | CEU | ADM.00150.I.2.A | F | Please refer to Appendix 1 in Part B, Section 0 | SL | 200 g/L | Foliar spraying, overall | BBCH 40-69 | 2 (max) | 10 | 0.036 (max) | 100 (min) | 0.036 (max) | Follow crop BBCH | A |
| No. 80-84 | Sugar beet (0900010) | CEU | ADM.00150.I.2.A | F | Please refer to Appendix 1 in Part B, Section 0 | SL | 200 g/L | Foliar spraying, overall | BBCH 12-39 | 2 (max) | 7 | 0.025 (max) | 200 (min) | 0.05 (max) | 35 | A |

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

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

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

Remark 1 - Use on apple was proposed in the original dossier but following the dossier update of July 2024, to apply the EFSA proposed ARfD, ADI and amended residue definition, residues generated according to the intended GAP no longer pass the acute risk assessment and no alternative GAP could be determined, so proposed use of ADM.00150.I.2.A / LEAXO on apple is not accepted according to the proposed GAP.

Remark 2 - Available results show that the in force MRL of acetamiprid on honey of 0.05\* mg/kg (Reg. (EU) 2019/88 and 2025/158) is potentially exceeded. Reg. (EU) 2025/1212 was published on 31/07/2025 and a higher MRL of 0.3 mg/kg for honey enters into force on 20/08/2025 which covers all of the proposed uses without restriction. ~~Until the new MRL has been set for honey, use on oilseed rape and apples cannot be authorized (see point 7.2.7). However EFSA concluded in Statement on the toxicological properties and maximum residue levels of acetamiprid and its metabolites (EFSA Journal. 2024;22:e8759) that „~~*~~Furthermore, for plums (0.04 mg/kg), poppy seeds (0.3 mg/kg), mustard seed (0.15 mg/kg) and 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.~~*~~”~~ ~~At the February 2025 Standing Committee, PLAN/2024/2431 received a favourable vote and an MRL of 0.3 mg/kg is now indicated in the EU Commission MRL database and expected to enter into force in July/August 2025. The current assessment of residues in honey based on the proposed GAPs for ADM.00150.I.2.A / LEAXO shows that all of the intended uses would be in compliance with the MRL of 0.3 mg/kg.~~ ~~According to the harmonization arrangements of the Ministry of Agriculture and Rural Development of 14 May 2025 regarding the requirement for honey, the use of Leaxo on oilseed rape at a higher dose of 2 x 60 g as/ha can be accepted under the condition (please see point 7.1.1).~~

Explanation for Column 11 “Conclusion”

|  |  |
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| 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 |

### Summary of the evaluation

The preparation ADM.00150.I.2.A 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 - Parent compound | | | | | |
| ~~ADI~~ | ~~Reg. (EU) 2018/113~~ | ~~2018~~ | ~~0.025 mg/kg bw/day~~ | ~~Rat, developmental neurotoxicity study~~ | ~~100~~ |
| ~~ARfD~~ | ~~Reg. (EU) 2018/113~~ | ~~2018~~ | ~~0.025 mg/kg bw~~ | ~~Rat, developmental neurotoxicity study~~ | ~~100~~ |
| ADI | EFSA | 2024 | 0.005 mg/kg bw/day | Rat, developmental neurotoxicity study | 500 |
| ARfD | EFSA | 2024 | 0.005 mg/kg bw | Rat, developmental neurotoxicity study | 500 |

#### 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? |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| No. 4–16 | Apples | Yes | Yes (8) \*\*  determination of acetamiprid only | Yes | Yes | Yes | No | ~~No~~ Yes |
| No. 17-22 | Potatoes | Yes | Yes (4, residues <LOQ) | Yes | Yes | Yes | No |
| No. 41–79 | Oilseed rape | Yes | Yes (8) | Yes | Yes | Yes | No |
| No. 23–40 | Barley, Oat | Yes | Yes (8) | Yes | Yes | Yes | No |
| No. 1–3 | Corn/maize | Yes | Yes (8) | Yes | Yes | Yes | No |
| No. 23–40 | Wheat, Rye | Yes | Yes (8) | Yes | Yes | Yes | No |
| No. 80–84 | Sugar beet | Yes | Yes (4, residues <LOQ) | Yes | Yes | Yes | No |
| Not applicable | Honey | Not applicable | Yes (4) | Not applicable | Yes | ~~Yes~~ ~~No~~ 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

\*\* It is recommended to require additional supervised residue trials analysing simultaneously for acetamiprid and N-desmethyl-acetamiprid (IM-2-1), supporting intended use on apples.

\*\*\* An updated MRL of 0.3 mg/kg for honey was voted by SCoPAFF in February 2025. This MRL is now available in the European commission MRL database under PLAN/2024/2431 and expected to enter into force in July/August 2025. Reg. (EU). 2025/1212 raises the honey MRL to 0.3 mg/kg effective from 20/08/2025.

Use on apple was proposed in the original dossier but following the dossier update of July 2024, to apply the EFSA proposed ARfD, ADI and amended residue definition, residues generated according to the intended GAP no longer pass the acute risk assessment, so proposed use of ADM.00150.I.2.A / LEAXO on apple is not accepted according to the proposed GAP.

The effects of processing on the nature of acetamiprid residues have been investigated. Data on effects of processing on the amount of residue have been submitted. These data were partly considered for dietary burden calculation. No further studies investigating the effect of processing on the magnitude of the residues are required, as they are not expected to affect the outcome of the risk assessment significantly.

Residues in succeeding crops have been sufficiently investigated with application rates reflecting the maximum critical GAP rate for crops growing in rotation. It is very unlikely that residues of acetamiprid and its soil persistent metabolites IM-1-4 and IM-1-5 will be present in succeeding crops.

The intended uses of acetamiprid will not modify the dietary burden for livestock being calculated and evaluated in the past. Therefore, further investigation of residues as well as the modification of MRLs in commodities of animal origin are not necessary. For fish no metabolism study is required according to SANTE/10254/2021 since acetamiprid is not fat soluble (log Pow of 0.8 for acetamiprid is <3).

Since applications during flowering are intended with acetamiprid on melliferous crops like oilseed rape ~~and apple~~, a study for determining the magnitude of residues of ADM.00150.I.2.A in honey was conducted in compliance with current guidelines. The current assessment of residues in honey based on the proposed GAPs for ADM.00150.I.2.A / Leaxo shows that the in force MRL of acetamiprid on honey of 0.05\* mg/kg (Reg. (EU) 2019/88 and 2025/158) is potentially exceeded, however Reg. (EU) 2025/1212 was published on 31/07/2025 and a higher MRL of 0.3 mg/kg for honey enters into force on 20/08/2025 which covers all of the proposed uses on oilseed rape without restriction.

~~For products with melliferous capacity (oilseed rape (2 x 60 g as/ha) and apples) no authorisation is proposed until MRL for honey is raised. Based on the four honey residue trials, the calculated MRL does not exceed the upcoming EU MRL of 0.3 mg/kg (PLAN/2024/2431, expected to enter into force in July/August 2025). According to the harmonization arrangements of the Ministry of Agriculture and Rural Development of 14 May 2025 regarding the requirement for honey, the use of Leaxo on oilseed rape at a higher dose of 2 x 60 g as/ha can be accepted under the condition (please see point 7.1.1).~~

~~However, for lower dose for oilseed rape (max 1 x 40 – 48 g as/ha) the in force MRL of acetamiprid on honey of 0.05\* mg/kg (Reg. (EU) 2019/88) will not be exceeded and this use can be accepted.~~

Additionally, two new stability studies on honey have been submitted by the applicant in the framework of this application.

~~No new MRLs have been proposed.~~

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.

The intended uses, except ~~oilseed rape (2 x 60 g as/ha) and~~ apples, are accepted.

#### Summary for ADM.00150.I.2.A

Table 7.1‑4: Information on ADM.00150.I.2.A (KCA 6.8)

| Crop | PHI for ADM.00150.I.2.A  proposed by applicant | PHI/ Withholding period\* sufficiently supported for | PHI for ADM.00150.I.2.A  proposed by zRMS | zRMS Comments  (if different PHI proposed) |
| --- | --- | --- | --- | --- |
| Acetamiprid |
| ~~Apples~~ | ~~14 days~~ | ~~Yes~~ | ~~14 days~~ | ~~-~~ |
| Potatoes | 7 days | Yes | 7 days | - |
| Oilseed rape | 28 days | Yes | 28 days | - |
| Barley, Oat | F | Yes | F | - |
| Corn/maize | 56 days | Yes | 56 days | - |
| Wheat, Durum wheat, Triticale, Spelt, Rye | F | Yes | F | - |
| Sugar beet | 35 days | Yes | 35 days | - |

NR: not relevant

\* Purpose of withholding period to be specified

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

## Acetamiprid

General data on acetamiprid are summarized in the table below (last updated 2022/06/17)

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

|  |  |
| --- | --- |
| Active substance (ISO Common Name) | Acetamiprid |
| IUPAC | (E)-N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine |
| Chemical structure |  |
| Molecular formula | C10H11ClN4 |
| Molar mass | 222.68 |
| Chemical group | Neonicotinoid |
| Mode of action (if available) | Systemic with translaminar activity having both contact and stomach action. Acetylcholine receptor (nAChR) agonist. |
| Systemic | Yes |
| Company | Nippon Soda Co. Ltd., is the owner of the active substance.  Nisso Chemical Europe GmbH, a wholly owned subsidiary of Nippon Soda Co., Ltd was the notifier for the Annex I inclusion and in the AIR process. |
| Rapporteur Member State (RMS) | The Netherlands |
| Approval status | Approved  01/01/2005  [Commission Directive 2004/99/EC](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004L0099&from=EN)  Renewed  01/03/2018 [Regulation (EU) No 2018/113](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0113&from=EN) |
| Restriction | See Commission Implementing Regulation (EU) 2018/113 |
| Review Report | SANTE/10502/2017 Rev 4  13/12/2017 |
| Current MRL regulation | Reg. (EU) 2019/88; ~~SANTE/11278/2021 (pending)~~  Reg. (EU) 2025/158 will apply on 19 August 2025  PLAN/2024/2431  Reg. (EU) 2025/1212 (effective 20 August 2025) |
| Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed | Yes |
| EFSA Journal: Conclusion on the peer review | EFSA 2016a |
| EFSA Journal: conclusion on article 12 | EFSA 2011, updated 2012 |
| Current MRL applications on intended uses | None |

### Stability of Residues (KCA 6.1)

#### Stability of residues during storage of samples

Available data

Two new stability studies on honey have been submitted by the applicant in the framework of this application. Results are summarized in Table 7.2‑2 below. The detailed assessment of these studies are presented in Appendix 2. According to EU requirements a study investigating the storage stability of acetamiprid in high starch content matrices (Netzband 2003, Report No RD-00243) was required and submitted for the purpose of the renewal assessment. As the study remains under data protection, the applicant has conducted its own study (Barbier 2018, Report No B17G-A4-A-02 / R-38589) for the purpose of data matching. Nevertheless, this study has previously been evaluated at EU level (Austria, 2021 updated 2022; EFSA, 2022) and is therefore also included in the table below for reference.

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 | | | |
| Cabbage, cucumber | High water content | 12 months | Gieseke L.D., 1999  Report No 10201  The Netherlands, 2015, updated 2016  EFSA, 2016b |
| Apple, tomato | ≤13 months | Goller G., 1999  Report No RPA/NI-25/97051, 97-75  The Netherlands, 2015, updated 2016  EFSA, 2016b |
| Apple | 12 months | Lefresne S., 2014  Report No B13-M1-A-02 / R-33766  Italy, 2016; Poland, 2016; Austria, 2021, updated 2022  EFSA, 2018; 2022 |
| Lettuce | 15~~2~~ months | Gieseke L.D., 1999  Report No 10201  The Netherlands, 2015, updated 2016  EFSA, 2016b |
| Cotton seed, cotton oil, orange oil | High oil content | 12 months | Gieseke L.D., 1999  Report No 10201  The Netherlands, 2015, updated 2016  EFSA, 2016b |
| Olive whole fruits | 12 months | Lefresne S., 2014  Report No B13-M1-A-02 / R-33766  Italy, 2016; Poland, 2016; Austria, 2021, updated 2022  EFSA, 2018; 2022 |
| Fodder peas | High protein | 12 months | Jean-Baptiste C., 2009  Report No. A7125, Document No. RD-01936  The Netherlands, 2015, updated 2016  EFSA, 2016b |
| Dry bean seed | 12 months | Lefresne, S., 2014  Report No B13-M1-A-02 / R-33766  Italy, 2016; Poland, 2016; Austria, 2021, updated 2022  EFSA, 2018; 2022 |
| Potato tuber | Dry/high starch | 8 months | Netzband D.J., 2003  Report No RD-00243  The Netherlands, 2015, updated 2016  EFSA, 2016b |
| Dry bean straw | 12 months | Lefresne, S., 2014  Report No B13-M1-A-02 / R-33766  Italy, 2016; Poland, 2016; Austria, 2021, updated 2022  EFSA, 2018; 2022 |
| Wheat (grain) | 15 months | $Barbier, G., 2018  Report No B17G-A4-A-02  Austria, 2021, updated 2022  EFSA, 2022 |
| Orange, orange juice | High acid | 12 months | Gieseke L.D., 1999  Report No 10201  The Netherlands, 2015, updated 2016  EFSA, 2016b |
| Orange peel and pulp | 12 months | Lefresne, S., 2014  Report No B13-M1-A-02 / R-33766  Italy, 2016; Poland, 2016; Austria, 2021, updated 2022  EFSA, 2018; 2022 |
| Apple juice/wet pomace, cotton gin trash/hulls/ meal, orange dried pulp, orange juice | Processed commodities | 12 months | Gieseke L.D., 1999  Report No 10201  The Netherlands, 2015, updated 2016  EFSA, 2016b |
| Animal Products | | | |
| Samples of the livestock feeding studies were stored for less than 1 month under freezer conditions, therefore storage stability studies are not required (Poland, 2016; EFSA 2016b). | | | |
| **New data** | | | |
| Plant products | | | |
| Honey | Honey | 6 months | Filed as KCP 8.1/01  Lindner M., Grewe D., 2017  Report No S16-02170 (MAC-1608L),  Sponsor No R-37693 |
| 18 months | Filed as KCP 8.1/02  Schrag K., 2022  Report No 21A14030-01-SSHN,  Sponsor No 000107275 |
| Animal Products | | | |
| No new storage stability studies have been conducted in animals. | | | |

$Study owned by ADAMA and previously submitted by Nufarm (Austria, 2021 updated 2022; EFSA, 2022). Herein relied on for data matching of Netzband, D. J., 2003.

Conclusion on stability of residues during storage

The storage stability of acetamiprid residues in plants stored under frozen conditions was investigated in the framework of the MRL review and the EU pesticides peer review (EFSA, 2011, updated 2012; EFSA, 2016b) as well as in subsequent Reasoned Opinions (EFSA, 2018, 2022). The stability of acetamiprid residues was demonstrated in plant matrices stored at≤-18°C for up to 12–15 months in high water, high acid, high oil and high protein content matrices and for up to 8–15 months in dry/high starch content matrices.

According to OECD Guideline 506, a study on one commodity from each of the five commodity categories is acceptable, if residues are shown to be stable in all commodities studied. In such cases, residues in all other commodities would be assumed to be stable for the same duration of time under the same storage conditions. Therefore, the available studies cover the length of time the samples were stored frozen during the magnitude of residues studies in primary and rotational crops for the intended uses of acetamiprid in the product ADM.00150.I.2.A (200 g/L acetamiprid) on the crops presented in the GAP.

In the new study of Lindner M. and Grewe D., (2017), the storage stability of acetamiprid in honey was tested for a period of 6 months. No significant degradation of the test item during storage at ≤ -18 °C was observed over this storage period (KCP 8.1/01). A second study was conducted, investigating the storage stability of acetamiprid in honey for a period of 18 months (KCP 8.1/02). In the report of this study no degradation of acetamiprid during storage at ≤ -18 °C was observed after 18 months, in line with the previous study. Therefore, acetamiprid can be regarded as stable for ~~6~~ 18 months at deep frozen storage in matrix honey. Samples from the residues in honey studies were stored for 52-384 days and appropriate stability data ~~to confirm stability at the longer storage intervals will be provided when~~ are available.

|  |
| --- |
| **Evaluator comments:**  Plant products:  In accordance with OECD Guideline for Stability of Pesticide Residues in Stored Commodities (OECD 506, 2007) barley, oat, wheat, rye, corn/maize grain, sugar beet root and potatoes belong to high starch content commodity category, oilseed rape belongs to high oil content commodity category and apples belong to high water content commodity category.  The storage stability of acetamiprid residues in plants stored under frozen conditions was investigated in the framework of the MRL review (EFSA, 2011) and the EU pesticides peer review (EFSA, 2016). In EFSA Journal 2016;14(11):4610 it is stated that in storage stability studies acetamiprid residues were concluded to be stable up to 1 year in high water-, high oil- and high acid-content commodities and up to 8 months in high starch-content matrices (potato tuber). Part of the studies is out of data protection and is not required to be matched. However study of residues in potatoes of Netzband D.J., 2003 (Report No RD-00243) is protected (Acetamiprid, List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the renewal of the active substance, October 2016, RMS: The Netherlands), so zRMS does not accept the reference to this study (to cover uses on high starch content commodities).  The Applicant has conducted its own study (Barbier 2018, Report No B17G-A4-A-02 / R-38589) for the purpose of data matching.  **The RMS - The Netherlands** has assessed the data matching study for acetamiprid necessary for the renewal of the approval of acetamiprid in product of Adama (June 2023). According to the RMS - The Netherlands opinion (February 2020): “*Extrapolation from storage stability data in wheat grain to potato tubers as suggested by the applicant is not acceptable since the crops do not belong to the same sub-category of high starch content crops (cereal grains vs. starchy root crops). Member States are advised to evaluate the available data on product level and to verify the applicant’s access to all data.*  *For the time being, data matching is sufficiently demonstrated*.”  Applicant has submitted additional study of Lefresne, S. (2014): “*Freezing storage stability of acetamiprid in 4 plant matrices: dry (dry bean seed and straw), water (apple), fat (olive whole fruit) and acid (orange peel and pulp) at/below -18°C during 1 year (0, 3, 6 and 12 months)”.*  **The RMS - The Netherlands (June, 2023):** “*The applicant provided the storage stability study (R-33766) which was conducted in line with OECD 506. Data matching sufficiently demonstrated, however, Member States are advised to evaluate the studies at product level.”*  **zRMS-PL:** Both studies have been evaluated and accepted in Registration Report, Section 4 for MCW-2222, Adama Makhteshim Ltd. (10.05.2018).  In two study submitted by Applicant storage stability has been covered in one commodity from each of the five commodity categories: in dry (dry bean seed and straw), water (apple), fat (olive whole fruit), acid (orange peel and pulp) and starch (wheat) at/below -18°C during 1 year.  It should be highlighted that according to the OECD 506, point 25:  “25. If residues are shown to be stable in all commodities studied, a study on one commodity from each of the five commodity categories is acceptable. In such cases, residues in all other commodities (see Annex 1) would be assumed to be stable for the same duration of time under the same storage conditions.”  In our opinion, taking the above into account (point 25 of OECD 506), these two studies (which were accepted) are sufficient to demonstrate the storage stability of acetamiprid in all commodities.  The studies on the magnitude of residues are valid with regard to storage stability.  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.  Honey  The applicant submitted two new studies on honey of Lindner M., Grewe D. (2017) and Schrag K. (2022). No significant degradation of acetamiprid during storage at ≤ -18 °C was observed within 18 months for matrix honey. Therefore, acetamiprid in honey can be regarded as stable within 18 months storage at deep frozen storage (≤ -18 °C) (see Appendix 2).  In the study of Boileau G. (2022, Study No GBU-21-48185 for determining the magnitude of residues of acetamiprid in honey) max. storage interval between sampling and analysis was 384 days, so it is valid with regard to storage stability.  Additional studies are not required. |

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

Available data

In the recent active substance renewal, stability of the analytes was adequately demonstrated by procedural recoveries running concurrently within each analytical set (The Netherlands, 2015 updated 2016).

No new studies specifically addressing storage stability in extracts were conducted. The stability of the analytes through the analytical procedures is adequately demonstrated by the procedural recovery efficiencies obtained during routine analysis of residue samples. Recovery samples were worked up, stored and analysed together with the field samples of the respective study to have a check on the stability of the analyte in the final extracts. For a better overview, details on stability in extracts are summarized in Table 7.2‑3 below.

Table 7.2‑3: Summary of stability data achieved at ≤ ‑ 18°C (unless stated otherwise)

| Matrix | Characteristics of the extract | Acceptable Maximum Storage duration | Reference |
| --- | --- | --- | --- |
| Data relied on in EU | | | |
| **New data** | | | |
| **Plant products** | | | |
| Apple extract  (at < 8 °C in the dark) | Dilution of external standard solutions in methanol with matrix extract | 17 days | Filed as KCP 8.3.1/01  Méric D., 2014  Report No DMC-13-16134, Sponsor No R-33599 |
| 7 days | Filed as KCP 8.3.1/02  Roussel Ch.H., 2014 Report No ChR-14-17311, Sponsor No R-34915 |
| Potato extract | Dilution of external standard solutions in methanol with matrix extract | 1 day | Filed as KCP 8.3.2/01  Bousquet C., 2014  Report No 13SGS102, Sponsor No R-33600 |
| Oilseed rape extract | Dilution of external standard solutions in methanol with matrix extract | Seeds: 2 days  Whole plant: 8 days  Pods: 8 days  Whole plant w/o pod: 9 days | Filed as KCP 8.3.3/01  Méric D., 2014  Report No DMC-13-16129, Sponsor No R-33598 |
| seeds: 1 day  whole plant: 32 days  pods: 36 days  whole plant w/o pod: 47 days | Filed as KCP 8.3.3/02  Chevallier E., 2014  Report No 14SGS035, Sponsor No R-34910 |
| Barley extract | Dilution of external standard solutions in methanol with matrix extract | grains: 77 days  straw: 78 days  whole plant: 10 days | Filed as KCP 8.3.4/01  Chevallier E., 2014  Report No 14SGS034, Sponsor No R-34898 |
| Maize extract | Dilution of external standard solutions in methanol with matrix extract | 4 days | Filed as KCP 8.3.5/01  Lebrun F., 2014  Report No 14SGS039, Sponsor No R-34912 |
| Wheat extract | Dilution of external standard solutions in methanol with matrix extract | grains: 76 days  straw: 108 days  whole plant: 84 days | Filed as KCP 8.3.6/01  Chevallier E., 2014  Report No 14SGS033, Sponsor No R-34897 |
| Sugar beet extract | Dilution of external standard solutions in methanol with matrix extract | root: 18 days  whole plant: 7 days | Filed as KCP 8.3.7/01  Roussel Ch.H., 2022  Report No SPK-20-46380, Sponsor No 000105979  Filed as KCP 8.3.7/02  Roussel Ch.H., 2022  Report No ChR-21-48246, Sponsor No 000107604 |

Conclusion on stability of residues in sample extracts

Residues in the analysed sample extracts, which were used to support the intended uses of acetamiprid in the product ADM.00150.I.2.A (200 g/L acetamiprid) on the crops presented in the GAP are considered stable during the respective time of storage.

|  |
| --- |
| **Evaluator comments:**  Information given by the Applicant is sufficient.  No further data are required. |

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

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

Available data

No new data submitted in the framework of this application.

Table 7.2‑4: Summary of plant metabolism studies

| Crop Group | Crop | Label position | Application and sampling details | | | | | Reference |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method,  F or G | Rate  (kg a.s./ha) | No | Sampling (DAT, DALA)(a) | Remarks |
| **EU data** | | | | | | | | |
| Fruits and fruiting vegetable | Eggplant | Pyridine-2,6-14C | Dotting to the leaf surface (foliar + fruit), G | 1x 0.0095 kg a.s/ha | 1 | 7, 14 | - | Saito H., 1997a  Report No EC-391-3  The Netherlands, 2015, updated 2016  EFSA, 2016b |
| Apple | Pyridine-2,6-14C | Dotting to surface (foliar), G | 1x 0.208 kg a.s./ha | 1 | 0, 7, 14, 28, 62, 90 | - | Saito H., 1997b  Report No EC-742-1  The Netherlands, 2015, updated 2016  EFSA, 2016b |
| Dotting to surface (fruit), G | 1x 0.104 kg a.s./ha | 1 | 0, 14, 28, 62 | - |
| Leafy vegetables | Cabbage | Pyridine-2,6-14C | Aerial treatment, G | 1x 0.301 kg a.s./ha | 1 | 0, 7, 14, 21, 28, 63 | - | Saito H., 1997c  Report No EC-743-1  The Netherlands, 2015, updated 2016  EFSA, 2016b |
| Root treatment, G | 1x 5.940 kg a.s./ha | 1 | 7, 14, 28 | - |
| Cyano-14C | Foliar treatment, G | 1x 0.298 kg a.s./ha | 1 | 0, 7, 14, 28, 63 | - | Kawai T., 1995  Report No EC-617-1  The Netherlands, 2015, updated 2016  EFSA, 2016b |
| Root and tuber vegetables | Carrot | Pyridine-2,6-14C | Foliar treatment, F | 2x 0.1 kg a.s./ha | 2 | -0, 14 | - | Austin D.J., McMillan-Staff S.L., Lingwood A., 1997  Report No 11253  The Netherlands, 2015, updated 2016  EFSA, 2016b |
| Pulses and oilseeds | Cotton | Pyridine-2,6-14C | Foliar treatment, G | 4x 0.127 kg a.s./ha | 4 | 14 and 28 days | -- | Miller N., 1999  Report No EC-97-367  The Netherlands, 2015, updated 2016  EFSA, 2016b |
| 4x 1.127 kg a.s./ha | 4 | 28 days | -- |

(a) DAT = days after treatment, DALA = days after last application

Summary of plant metabolism studies reported in the EU

EFSA (2022) concludes: “The metabolism of acetamiprid in primary crops belonging to the groups of fruit crops (eggplants, apples), root crops (carrots), leafy crops (cabbages) and pulses/oilseeds (cotton) has been investigated in the framework of the MRL review and the EU pesticides peer review (EFSA, 2011, 2016b).”

“In the crops tested, acetamiprid was identified as the major component of the total radioactive residues (TRR) accounting for *ca.* 30–90 % TRR 14–90 days after the last application, except in head cabbages 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). As acetamiprid was identified as the major component of the residues in almost all plant matrices and since the toxicity of the IC-0 metabolite is covered by the toxicity of the parent acetamiprid, no further metabolism data were required.” Therefore, for the intended uses, the metabolic behaviour in primary crops is sufficiently addressed.

“Regarding honey, honey is a product originated from sugary secretions of plants (floral nectar mainly). Based on the similar results of metabolism studies in four different primary crop groups, EFSA expects that residues in floral nectar resulting from the use of acetamiprid in primary crops would also consist mainly of acetamiprid. The nectar is processed by bees following a process of regurgitation and then the honey is stored under specific conditions in the beehives before harvesting. Further information, whether enzymatic processes occurring in the bee gut involved in the production of honey or the storage in the beehive have an impact on the nature of residues is not available, but in principle would be desirable.”

“Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions were proposed

* residue definition for risk assessment: acetamiprid;
* residue definition for enforcement: acetamiprid.

The same residue definitions are applicable to rotational crops and processed products. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

EFSA notes that similar to other food products, residue definitions need to be derived for honey which should cover the toxicologically relevant compounds occurring in honey following the use of acetamiprid on crops foraged by bees. Honey is produced by bees following sugary secretions of plants (mainly nectar) through regurgitation, enzymatic conversion and water evaporation followed by storage of honey in beehives. As indicated in the Technical Guidelines for determining the magnitude of pesticide residues in honey and setting MRL in honey, in the absence of specific metabolism studies with honey bees, the residue definition for risk assessment needs to be derived taking into account other sources of information such as studies on the nature of residues in primary and rotational crops and degradation during pasteurisation. As the same residue definition (acetamiprid) applies both in primary and rotational crops, and acetamiprid is stable under pasteurisation condition, EFSA considers that the above plant residues definitions could be considered valid also for honey and apicultural products.”

On 27 March 2024, EFSA adopted a Statement on the toxicological properties and maximum residues levels of acetamiprid and its metabolites (EFSA, 2024).

A revised residue definition for risk assessment was proposed for leafy and fruit crops as sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid. Regarding pulses/oilseeds, root crops and cereals, the new data received did not indicate a need to modify the existing residue definition for risk assessment, which therefore remains as parent acetamiprid. Regarding the residue definition for enforcement, the available data did not indicate a need to modify the existing definition because acetamiprid is still a sufficient marker of the residues in all crop groups.

At the request of the zRMS, this dossier has been updated (July 2024) to take account of the proposed residue definition as well as new toxicological reference values proposed during the same assessment.

Summary of new plant metabolism studies

No new data submitted.

Conclusion on metabolism in primary crops

Based on the available metabolism data, a general residue definition was derived for all crops and this was concluded as applicable also to honey and apicultural products.

Therefore, the monitoring and risk assessment residue definition for primary crops and honey, which is defined as acetamiprid only, is applicable for the intended uses of acetamiprid in the product ADM.00150.I.2.A (200 g/L acetamiprid) according to the proposed GAP.

Subsequently, EFSA concluded that the residue definition for risk assessment in fruit and leafy crops should be updated to include IM-2-1 and this definition has therefore been taken account of in this dossier (July 2024 update). The residue definition for other crops and livestock are unchanged.

|  |
| --- |
| **Evaluator comments:**  The metabolism in plants for acetamiprid was reviewed during the Annex I inclusion and renewal process. No new data submitted in the framework of this application. All studies mentioned in the Table 7.2-4 are out of data protection and are not required to be matched.  Metabolism in primary crops was investigated in the fruit, leafy, root and oilseeds/pulses crop groups.  The existing risk assessment and enforcement residue definition in plant commodities has been set by the EU pesticides peer review and is limited to parent acetamiprid (EFSA, 2016).  The current residue definition set in Regulation (EC) No 396/2005 (Commission Regulation (EU) 2019/88 of 18 January 2019) is identical to the residue definition for enforcement derived by the peer review ( EFSA Journal 2016;14(11):4610).  In the Statement on the active substance acetamiprid and its metabolites (EFSA, 2024) EFSA concluded that *In the framework of the present mandate, monitoring data on the metabolite IM-2-1 were collected which confirm*  *the occurrence of this metabolite in several commodities belonging to the groups of leafy and fruit commodities (see Section 3.1). Furthermore, in 6 commodities belonging to the leafy crops group and in 9 commodities belonging to the fruit crops group, the concentration of metabolite IM-2-1 was found to be above the concentration of acetamiprid in at least one sample (see Section 3.1.3). In each of these commodities, the average proportion of metabolite IM-2-1 compared to parent compound (mean ratio ‘IM-2-1/acetamiprid’) has been found to be above 30% (see Section 3.1.3). This information was considered sufficiently relevant to reconsider the conclusions of the EU pesticide peer review from the renewal on the relevance of metabolite IM-2-1 residues in plant commodities.*  *Based on these findings, it is therefore proposed* ***to include metabolite IM-2-1 in the residue definition for risk assessment in leafy and fruit crops*** *(Table 32), which is currently limited to acetamiprid.*  *Regarding pulses/oilseeds, root crops and cereals, the collected monitoring data do not reveal a significant occurrence of IM-2-1 in commodities belonging to these categories. Therefore,* ***it is not proposed to modify the residue definition for risk assessment in pulses/oilseeds, root crops and cereals, which therefore remains acetamiprid.***  Additional studies are not required. |

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

Available data

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

According to EU requirements a study investigating the nature of residues in rotational (Hobbs 2012, Report No RD-02391) was required and submitted for the purpose of the renewal assessment. As the study remains under data protection, the applicant has conducted its own study (Hobbs 2017, Report No 38356/R-37756) for the purpose of data matching. Nevertheless, this study has previously been evaluated at EU level (Austria, 2021 updated 2022; EFSA, 2022) and is therefore also included in the table below for reference.

Table 7.2‑5: Summary of metabolism studies in rotational crops

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Crop group | Crop | Label position | Application and sampling details | | | | | Reference |
| Method,  F or G \* | Rate  (kg a.s./ha) | Sowing intervals  (DAT) | Harvest  Intervals (DAT) | Remarks |
| **EU data** | | | | | | | | |
| Leafy vegetables | Spinach | Pyridine-2,6-14C | bare soil, G | 1x 0,266 kg a.s./ha | 0 | BBCH 49 | Study conducted with IM-1-5 | Hobbs G., Inns L., 2012  Report No RD-02391 \*\*  The Netherlands, 2016  EFSA, 2016b |
| Root and tuber vegetables | Turnip | BBCH 49 |
| Cereals | Wheat | BBCH 30, BBCH 69, BBCH 89 |
| Leafy vegetables | Spinach | [Pyridyl-2,6-14C] IM-1-5 | Bare soil  G | 1 x 160 g a.s./ha | 0 | BBCH 33 (immature) and 49 (mature) | Study conducted with IM-1-5 | $Hobbs, G., 2017  Report No. 38356  Austria, 2021, updated 2022  EFSA, 2022 |
| Root and tuber vegetables | Turnip | BBCH 49 (roots and tops) |
| Cereals | Wheat | BBCH 30 (forage), 65 (hay) and 89 (straw and grain) |

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

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

$Study owned by ADAMA and previously submitted by Nufarm (Austria, 2021 updated 2022; EFSA, 2022). Herein relied on for data matching of Hobbs, G. & Inns, L., 2012.

Summary of plant metabolism studies reported in the EU in rotational crops

EFSA (2022) concludes: “The nature of residues in rotational crops (confined studies) has been evaluated during the peer review (EFSA, 2016b). Since acetamiprid has a low persistence in soil (highest field DT90 43 days and 20 °C lab DT90 54 days), the metabolism study in rotational crops was not conducted with acetamiprid but using the more persistent soil metabolite IM-1-5 (DT50 ranging from 319 to 663 days). In the different rotational crops investigated (wheat, turnip, spinaches), the metabolite IM-1-5 was the main component of the radioactive residues accounting in mature plant at harvest for 77–94 % TRR. No other metabolites or unidentified residues were observed in any crop commodity.

Moreover, a new metabolism study performed with [14C]-IM-1-5 with the same succeeding crops was provided with the <present> application (Austria, 2021) confirming the finding of the previous study assessed during the peer-review. In this new study, [14C]-IM-1-5 was applied to the soil as a single spray application at a nominal rate of 160 g a.s/ha. The study was designed to only investigate the fate of this metabolite and therefore no ageing of the soil was required following application. IM-1-5 was confirmed as the major component of the total radioactive residue, accounting for 6.3–86.6 % of the TRR. Only limited metabolism of IM-1-5 was observed in the rotational crops and no metabolic pathway was proposed for IM-1-5. The metabolic behaviour of acetamiprid and its major soil metabolite (IM-1-5) in rotational crops is considered as sufficiently addressed.”

Summary of new plant metabolism studies in rotational crops

No new data submitted.

Conclusion on metabolism in rotational crops

Soil metabolite IM-1-5 is the major compound in all rotational crops. No other metabolites were identified.

No risk mitigation measures are required, as uptake into rotational crops was found to be insignificant (see chapter 7.2.6). The residue definition for rotational crops is the same as for primary crops.

Therefore, the monitoring and risk assessment residue definition for rotational crops, which is defined as acetamiprid only, is applicable for the intended uses of acetamiprid in the product ADM.00150.I.2.A (200 g/L acetamiprid) according to the proposed GAP.

The recent EFSA Statement (EFSA, 2024) does not modify the residues definition for rotated crops.

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| --- |
| **Evaluator comments:**  In EFSA Journal 2016;14(11):4610 it is stated that “*Having regard to the low persistence of acetamiprid in soil (highest field period required for 90% dissipation (DT90) 43 days and 20°C lab DT90 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 (DT50) 319–663 days) at a*  *single plant back interval of 0 days. In the different rotational crops investigated (wheat, turnip, spinach), IM-1-5 was shown to remain the main component of the radioactive residues accounting in mature plant at harvest for 77–94% TRR. Additional field rotational crop studies conducted in northern and southern EU with acetamiprid applied onto the bare soil at ca. 300 g/ha, confirmed that acetamiprid, IM-1-4 and IM-1-5 residues are not expected to be present in rotational crops.”*  The presented data is from the protected study of Hobbs, G., Inns, L., 2012 (Report No RD-02391; “[14C]-IM-1-5: Uptake and Metabolism of Soil Residues in Confined Rotational Crops”) (see Acetamiprid, List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the renewal of the active substance, October 2016, RMS: The Netherlands), so zRMS-PL does not accept the reference to this study and new data was required to identify the plant uptake of a metabolite unique for calcareous soils. Equivalent study should be provided by the Applicant.  According to the evaluation presented in “Matching active substance data necessary for the renewal of the approval of acetamiprid” (RMS: The Netherlands, June 2023) the endpoints seem to be equivalent to study RD-02391 (Hobbs & Inns, 2012). RMS - The Netherlands concluded that “*A GLP-compliant study conducted according to OECD 502 was provided by the applicant. Data matching sufficiently demonstrated*.”  The study R-37756 (Hobbs, 2017) has been evaluated and accepted in Registration Report, Section 7 for CA3573/Carnadine/Kestrel, Nufarm (13.01.2022).  The study was designed to quantify the total radioactive residue levels in appropriate crop parts (i.e. immature and mature spinach; turnip leaves and tuberous roots; wheat forage, hay, straw and grain) and to determine the extractability and nature of the residues. A single application of [14C]-IM-1-5 made to bare soil, at a nominal application rate of 160 g /ha. The crops used in this study were spring wheat, spinach and turnip to represent cereal, leafy vegetable and root vegetable crops, respectively. Total radioactive residues in the human food commodities (wheat grain, spinach and turnip tubers) were reasonably low (0.025 – 0.131 mg/kg).  Animal feed commodities (wheat forage, hay, straw and turnip foliage) showed higher TRRs (0.050 – 0.450 mg/kg).  zRMS confirms that the study R-37756 (Hobbs, 2017) is acceptable to support the intended GAP of the ADM.00150.I.2.A/Leaxo.  Additional studies are not required. |

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

Available data

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

Table 7.2‑6: Nature of the residues in processed commodities

| Conditions (Duration, Temperature, pH) | Identified compound(s) (%) | Reference |
| --- | --- | --- |
| **EU data** | | |
| **Pasteurisation** (20 minutes, 90°C, pH 4)  Test system 0.1 mg/kg  Test system 1.0 mg/kg | Acetamiprid (95.6 %), IM-1-3 (≤ 1.33 %)  Acetamiprid (93.3 %), IM-1-3 (≤ 1.33 %) | McMillan-Staff, Austin, D.J., 1997  RPAL study No 13442  The Netherlands, 2015, updated 2016  EFSA, 2016b |
| **Baking, boiling, brewing** (60 minutes, 100°C, pH 5)  Test system 0.1 mg/kg  Test system 1.0 mg/kg | Acetamiprid (95.1 %), IM-1-3 (≤ 1.33 %)  Acetamiprid (95.59 %), IM-1-3 (≤ 1.33 %) |
| **Sterilisation** (20 minutes, 120°C, pH 6)  Test system 0.1 mg/kg  Test system 1.0 mg/kg | Acetamiprid (98.08 %), IM-1-3 (≤ 1.33 %)  Acetamiprid (97.57 %), IM-1-3 (≤ 1.33 %) |

EFSA (2022) concluded: “The effect of processing on the nature of acetamiprid was investigated in the framework of the MRL review and the EU pesticides peer review (EFSA, 2011, 2016b). These studies showed that acetamiprid is hydrolytically stable under standard processing conditions representative of pasteurisation, baking/brewing/boiling and sterilisation.

The process of converting nectar to honey does not involve hydrolytic conditions at elevated temperature; however, honey may be used as an ingredient in processed products that are heat treated. Considering the available studies addressing the nature of residues in processed commodities, it is unlikely that in processed honey products, residues of acetamiprid are degraded to other compounds.”

Conclusion on nature of residues in processed commodities

In the available hydrolysis study it was demonstrated that acetamiprid was stable under standard hydrolysis conditions. Pasteurisation, baking/brewing/boiling and sterilisation are unlikely to result in any significant metabolites. The residue definition for processed commodities is the same as for primary crops.

Therefore, the monitoring and risk assessment residue definition for processed commodities, which is defined as acetamiprid only, is applicable for the intended uses of acetamiprid in the product ADM.00150.I.2.A (200 g/L acetamiprid) according to the proposed GAP.

Since an amendment to the residue definition for risk assessment in fruit and leafy crops was proposed by EFSA (EFSA, 2024) it is assumed that the same definition will apply to processed commodities arising from these crop types. Therefore, the residues definition for risk assessment of processed fruit and leafy crops considered in this dRR is the sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid.

|  |
| --- |
| **Evaluator comments:**  No new data submitted in the framework of this application. Data on processing studies were evaluated at the EU level. The study McMillan-Staff, Austin, D.J., 1997, RPAL study No 13442 is out of data protection and is not required to be matched.  Information given by the Applicant is sufficient.  No further data are required. |

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

Table 7.2‑7: Summary of the nature of residues in commodities of plant origin

|  |  |
| --- | --- |
| **Endpoints** | |
| Plant groups covered | Fruits (apple) and fruiting vegetables (eggplant)  Leafy vegetables (cabbage)  Root and tuber vegetables (carrot)  Pulses and oilseeds (cotton) |
| Rotational crops covered | Leafy vegetables (spinach)  Root and tuber vegetables (turnip)  Cereals (wheat) |
| Metabolism in rotational crops similar to metabolism in primary crops? | Yes  Since acetamiprid has a low persistence in soil the metabolism study in rotational crops was conducted using the more persistent soil metabolite IM-1-5 which was the only residue found. No other metabolites or unidentified residues were observed in any crop commodity in the rotational crop metabolism study (EFSA, 2016b) |
| Processed commodities | Acetamiprid is stable under standard hydrolysis conditions of pasteurisation, baking, brewing and boiling, and sterilisation. |
| Residue pattern in processed commodities similar to pattern in raw commodities? | Yes  Acetamiprid is hydrolytically stable under standard processing condition. Thus, the same residue definition as for raw commodities also applies to processed commodities (EFSA, 2011, EFSA, 2016b) |
| Plant residue definition for monitoring | Acetamiprid (~~SANTE/11278/2021~~, Reg. EU 2019/88, ~~and~~ 2025/158 and 2025/1212) |
| Plant residue definition for risk assessment | Acetamiprid (EFSA, 2016b; EFSA, 2018; EFSA, 2022)  Fruit, leafy crops: sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid (EFSA, 2024)  Pulses/oilseeds, root crops, cereals: acetamiprid (EFSA, 2022, 2024) |
| Conversion factor from enforcement to RA | Fruit crops: 1.21 (EFSA, 2024)  Leafy crops: 1.44 (EFSA, 2024)  Pulses/oilseeds, root crops, cereals: Not applicable (EFSA, 2022, 2024) |

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

Available data

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

Table 7.2‑8: 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 samp-ling |
| **EU data** | | | | | | | | |
| Lactating ruminants | Goat | Pyridine-2,6-14C | 1  1 | 1 mg/kg  10 mg/kg | 7  7 | Milk | Twice daily | xxxxx R., 1997  Report No 628132  The Netherlands, 2015, updated 2016  EFSA, 2016b |
| Urine and faeces | Daily |
| Tissues | At sacrifice (22 hour after final administra-tion) |
| Laying poultry | Hens | Pyridine-2,6-14C | 5  5 | 1 mg/kg  10 mg/kg | 14  14 | Eggs | Daily | xxxxx R., 1997  Report No 628143  The Netherlands, 2015, updated 2016  EFSA, 2016b |
| Excreta | Daily -  24h following the first of the daily administrations and at 24h intervals thereafter |
| Tissues | At sacrifice (24 hour after final administra-tion) |

Summary of livestock metabolism studies reported in the EU

EFSA (2016b) concluded: “Metabolism studies on livestock conducted on animals dosed with 14C-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. 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.”

EFSA (2011, updated 2012) concluded: “The metabolic patterns identified for goats and hens were consistent with the rat metabolism and acetamiprid and *N*-desmethyl-acetamiprid (IM-2-1) are considered as the major indicator compounds in commodities of animal origin.”

Summary of new animal metabolism studies

No new animal metabolism studies were available.

Conclusion on metabolism in livestock

According to the dietary burden calculation, presented in Chapter 7.2.4.1, the trigger of 0.004 mg/kg bw/day is exceeded for ruminants, poultry and pigs. Hence, investigation on the fate of residues in these animals is necessary. Since the metabolic pathways in ruminants and rat are considered to be comparable, a metabolism study in pig is not required.

No new studies were conducted since the metabolism of acetamiprid in livestock was sufficiently investigated in the studies presented in the RAR (The Netherlands, 2015, updated 2016) which are no longer subject to data protection. Therefore, the residue definition for animals (ruminants, poultry and pigs) for enforcement and risk assessment, which is defined as sum of acetamiprid and metabolite IM-2-1 (*N*-desmethyl-acetamiprid), expressed as acetamiprid, is also applicable in the context of this evaluation. [Note that the enforcement definition of “IM-2-1 expressed as acetamiprid” as proposed in the RAR has never been formally adopted and the legally enforceable definition remains including acetamiprid.]

Based on the metabolism studies presented in the RAR (The Netherlands, 2015, updated 2016) residue levels in the animal commodities ruminant liver, kidney and milk and in poultry egg yolk are expected to be >0.01 mg/kg at the calculated dietary burden (1x dose rate) based on the intended uses in the proposed GAP. Thus, feeding studies in ruminants and in poultry (The Netherlands, 2015, updated 2016) are presented in Chapter 7.2.4.2.

For fish no metabolism study is required according to SANTE/10254/2021 since acetamiprid is not fat soluble (log Pow of 0.8 for acetamiprid is <3).

|  |
| --- |
| **Evaluator comments:**  No new data submitted in the framework of this application.  The metabolism in livestock for acetamiprid was reviewed during the Annex I inclusion and renewal process.  For animal products, EFSA ( EFSA Journal 2016;14(11):4610) proposes to limit the enforcement residue definition to the N-desmethyl metabolite (IM-2-1), expressed as acetamiprid since acetamiprid is extensively metabolised by animals and not detected in any animal matrices, except in milk.  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).  *Remark:*  It is highlighted that RMS (Netherlands) expressed its disagreement on the livestock residue definition for risk assessment and proposes to include IM-2-1 compound only.  For enforcement of animal products, it is proposed to limit the residue definition to metabolite IM-2-1 only, while the residue definition recommended under the Article 12 MRL review and currently implemented in the EU legislation (Reg. (EU) 2019/88) also includes acetamiprid (Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid). |

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

Table 7.2‑9: Summary on the nature of residues in commodities of animal origin

|  |  |
| --- | --- |
|  | Endpoints |
| Animals covered | Lactating goats |
| Laying hens |
| Time needed to reach a plateau concentration | 1-3 days to reach a steady state in milk |
| 4-8 days to reach a steady state in eggs |
| Animal residue definition for monitoring | Sum of acetamiprid and metabolite IM-2-1 (*N*-desmethyl-acetamiprid), expressed as acetamiprid (~~SANTE/11278/2021,~~ Reg. EU 2019/88, ~~and~~ 2025/158 and 2025/1212) |
| Animal residue definition for risk assessment | Sum of acetamiprid and metabolite IM-2-1 (*N*-desmethyl-acetamiprid), expressed as acetamiprid (EFSA, 2018) |
| Conversion factor | Not applicable (EFSA, 2018)  EFSA, 2016b:  Milk: 1.3  Other mammalian products: 1.1  Poultry matrices: not required |
| Metabolism in rat and ruminant similar | Yes |
| Fat soluble residue | No, log P O/W = 0.8 at 25 °C |

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

#### 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 summarised in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.2‑10: Summary of EU reported and new data supporting the intended uses of ADM.00150.I.2.A 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)  (a) | MRL compliance |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Apple | The Netherlands, 2015, updated 2016  EFSA, 2016b | NEU | GAP on which EU a.s. assessment is based: 2 x 0.075 kg as/ha (14 d), BBCH 77-87, PHI 14d, outdoor  *Pome fruit:*  E/RA: 0.010, 2 x 0.020, 0.025, 0.026, 2 x 0.030, 2 x 0.031, 0.034, 0.040, 2 x 0.056, 0.071 | N/A | | | | |
| EFSA, 2011, updated 2012 | NEU | GAP on which MRL assessment is based: 2 x 0.030-0.080 kg as/ha (n.r.), BBCH 57-88, PHI 14d, outdoor  *Pome fruit:*  E/RA: 0.01, 2 x 0.02, 7 x 0.03, 0.04, 2 x 0.06, 0.07 |
| New trials  (KCP 8.3.1/01, 8.3.1/02) | NEU | Trials GAP:  1-2 x 0.098-0.104 kg as/ha, BBCH 81-87, PHI 14d, outdoor  E/RA: 0.030, 0.060, 0.070, 2 x 0.080, 0.090, 0.120, 0.210  RA (CF:1.21; 2024): 0.036; 0.073; 0.085; 2x0.097; 0.109; 0.145; 0.254 |
| Overall supporting data for cGAP | NEU | Intended cGAP: 1 x 0.080 kg a.s./ha, BBCH 62-PHI, PHI 14d, outdoor  E/RA: 0.030, 0.060, 0.070, 2 x 0.080, 0.090, 0.120, 0.210  RA (CF:1.21; 2024): 0.036; 0.073; 0.085; 2x0.097; 0.109; 0.145; 0.254 | E/RA: 0.080  RA (CF:1.21; 2024): 0.097 | E/RA: 0.120  0.21  RA(CF:1.21; 2024): 0.254 | 0.3 | 0.4  (Reg. (EU) 2019/88)  0.07  (Reg. (EU) 2025/158, 2025/1212) | Yes  No |
| Potato | The Netherlands, 2015, updated 2016  EFSA, 2016b | NEU | GAP on which EU a.s. assessment is based: 3 x 0.050 kg as/ha (7 d), BBCH 45-93, PHI 7d, outdoor  E/RA: 8 x <LOQ | N/A | | | | |
| EFSA, 2011, updated 2012 | NEU | GAP on which MRL assessment is based: 2 x 0.050 kg as/ha (7 d), BBCH 60-69, PHI 7d, outdoor  E/RA: 4 x <LOQ |
| New trials  (KCP 8.3.2/01) | NEU | Trials GAP:  1 x 0.601 kg as/ha, BBCH 45, PHI 10d, outdoor  2 x 0.0594-0.0619 kg as/ha, BBCH 43-49, PHI 7-11d, outdoor  E/RA: 4 x <LOQ |
| Overall supporting data for cGAP | NEU | Intended cGAP: 1 x 0.036 kg a.s./ha, BBCH 12-79, PHI 7d, outdoor  E/RA: 4 x <LOQ | E/RA: 0.010 | E/RA: <0.010 | 0.01\* | 0.01\*  (Reg. (EU) 2019/88, ~~and~~ 2025/158 and 2025/1212) | Yes |
| Oilseed Rape | EFSA, 2016a | NEU | GAP on which MRL assessment is based: 2 x 0.042 kg as/ha (n.r.), BBCH 59-80, PHI n.r., outdoor  E/RA: < 0.01, 2 x 0.02, 0.021, 0.036, 0.05, 0.11, 0.20 | N/A | | | | |
| New trials  (KCP 8.3.3/01, 8.3.4/02) | NEU | Trials GAP: 2 x 0.057-0.065 kg as/ha, BBCH 73-82, PHI 27-31d, outdoor  E/RA: 2 x <LOQ, 0.017, 0.022, 0.028, 0.031, 0.032, 0.052 |
| Overall supporting data for cGAP | NEU | Intended cGAP: 2 x 0.060 kg a.s./ha (7 d), BBCH 11-71, PHI 28d, outdoor  E/RA: 2 x <LOQ, 0.017, 0.022, 0.028, 0.031, 0.032, 0.052 | E/RA: 0.025 | E/RA: 0.052 | 0.08 | 0.4  (Reg. (EU) 2019/88, ~~and~~ 2025/158 and 2025/1212) | Yes |
| Barley 🡢 extrapolated to Oat | EFSA, 2018 | NEU | GAP on which MRL assessment is based: 2 x 0.040 kg as/ha (10 d), BBCH 12-69, PHI n.a., outdoor  *Barley grain:*  E/RA: 6 x <0.01, 0.03, 0.022  *Barley straw:*  E/RA: 0.044, 0.066, 0.077, 0.14, 0.21, 0.23, 0.30, 0.32 | N/A | | | | |
| New trials  (KCP 8.3.4/01) | NEU | Trials GAP: 2 x 0.0387-0.0420 kg a.s./ha, BBCH 65-83, PHI n.a., outdoor  *Barley grain:*  E/RA: 6 x <LOQ, 0.021(b), 0.029(c)  *Barley straw:*  E/RA: 0.044, 0.066, 0.077, 0.140, 0.210, 0.230, 0.300, 0.320 |  | | | | |
| Overall supporting data for cGAP | NEU | Intended cGAP: 2 x 0.036 kg a.s./ha (10 d), BBCH 12-69, PHI n.a., outdoor  *Barley grain:*  E/RA: 6 x <LOQ, 0.021(b), 0.029(c)  *Barley straw:*  E/RA: 0.044, 0.066, 0.077, 0.140, 0.210, 0.230, 0.300, 0.320 | E/RA (grain): 0.010 | E/RA: 0.029 | 0.05 | *Barley, Oat:*  0.05  (Reg. (EU) 2019/88, ~~and~~ 2025/158 and 2025/1212) | Yes |
| E/RA (straw): 0.175 | E/RA: 0.320 | Not applicable | Not applicable | Not applicable |
| Maize/Corn | New trials  (KCP 8.3.5/01) | NEU | Trials GAP: 2 x 0.0572-0.0626 kg a.s./ha, BBCH 71-75, PHI 53-58d, outdoor  *Maize grain:*  E/RA: 8 x <LOQ  *Maize stover(d):*  2 x 0.04, 0.08, 0.10, 0.23, 0.37, 0.50, 0.83 | N/A | | | | |
| Overall supporting data for cGAP | NEU | Intended cGAP: 1 x 0.060 kg a.s./ha, BBCH 51-75, PHI 56, outdoor  *Maize grain:*  E/RA: 8 x <LOQ  *Maize stover(d):*  2 x 0.04, 0.08, 0.10, 0.23, 0.37, 0.50, 0.83 | E/RA (grain): 0.010 | E/RA: 0.010 | 0.01\* | 0.01\*  (Reg. (EU) 2019/88, ~~and~~ 2025/158 and 2025/1212) | Yes |
| E/RA (stover): 0.17 | E/RA: 0.83 | Not applicable | Not applicable | Not applicable |
| Wheat (including Triticale and Spelt) 🡢 extrapolated to Rye | EFSA, 2016a | NEU | GAP on which MRL assessment is based: 2 x 0.042 kg as/ha (14 d), BBCH 51-79, PHI 28d, outdoor  *Wheat grain:*  E/RA: 6 x <0.01, 0.03, 0.06  *Wheat straw:*  E/RA: 0.02, 0.16, 0.17, 0.18, 0.20, 0.55, 0.86, 1.09 | N/A | | | | |
| New trials  (KCP 8.3.6/01) | NEU | Trials GAP: 2 x 0.0391-0.0419 kg as/ha, BBCH 65-77, PHI n.a., outdoor  *Wheat grain:*  E/RA: 8 x <LOQ  *Wheat straw:*  E/RA: 0.031, 0.049, 0.056, 0.120, 0.210, 0.230, 0.510, 0.710 |
| Overall supporting data for cGAP | NEU | Intended cGAP: 2 x 0.036 kg a.s./ha (10 d), BBCH 12-69, PHI n.a., outdoor  *Wheat grain:*  E/RA: 8 x <LOQ  *Wheat straw:*  E/RA: 0.031, 0.049, 0.056, 0.120, 0.210, 0.230, 0.510, 0.710 | E/RA (grain): 0.010 | E/RA: <0.010 | 0.01\* | *Wheat:*  0.1  *Rye:*  0.01\*  (Reg. (EU) 2019/88, ~~and~~ 2025/158 and 2025/1212) | Yes |
| E/RA (straw): 0.165 | E/RA: 0.710 | Not applicable | Not applicable | Not applicable |
| Sugar Beet | EFSA, 2011 updated 2012 | NEU | GAP on which MRL assessment is based: 2 x 0.050 kg as/ha (n.r.), BBCH n.r., PHI 7d, indoor  *Beet leaves:*  E/RA: 0.08, 0.14, 2 x 0.16, 0.24, 0.25, 0.28, 0.31 | N/A | | | | |
| New trials  (KCP 8.3.7/01, 8.3.7/02) | NEU | Trials GAP: 2 x 0.049-0.053 kg as/ha, BBCH 36-48, PHI 32-35d, indoor  *Sugar beet roots:*  E/RA: 4 x <LOQ  *Sugar beet tops:*  0.012, 0.052, 0.081, ~~0.120,~~ 0.185 |
| Overall supporting data for cGAP | NEU | Intended cGAP: 2 x 0.050 kg a.s./ha (7 d), BBCH 12-39, PHI 35d, outdoor  *Sugar beet roots:*  E/RA: 4 x <LOQ  *Sugar beet tops:*  0.012, 0.052, 0.081, ~~0.120~~, 0.185 | E/RA (roots): 0.010 | E/RA: <0.010 | 0.01\* | 0.01\*  (Reg. (EU) 2019/88, ~~and~~ 2025/158 and 2025/1212) | Yes |
| E/RA (tops): ~~0.101~~ 0.067 | E/RA: 0.185 | Not applicable | Not applicable | Not applicable |

(a) Source of EU MRL: Reg. (EU) 2019/88 ~~and~~ 2025/158 and 2025/1212

(b) Rounded-up mean value of the “mean of two extractions” values (0.019 and 0.022)

(c) Rounded-up mean value of the “retain specimen” values (0.028 and 0.029)

(d) -Residues in maize stover were estimated from residues in whole plant (at a slightly earlier sampling time) multiplied by the dry matter conversion from forage to stover [2.075 = 83 % DM in maize stover / 40 % DM in maize forage/silage]

\* Indicates lower limit of analytical determination

n.a not applicable

n.r. not relevant

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

Apple

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

Since apples are a major crop in northern Europe, as specified in SANTE/2019/12752, usually eight trials have to be submitted for each crop to estimate the residues which will be found after application of the product.

Eight residue trials on apples were performed in northern Europe that were overdosed according to the intended GAP uses of acetamiprid in the product ADM.00150.I.2.A (200 g/L acetamiprid). Individual application rates in four out of eight trials (nominally 0.100 kg as/ha) were within the ±25 % GAP rate (0.080 kg as/ha) in accordance with SANTE/2019/12752. Individual application rates in the remaining four trials (nominally 2 x 0.100 kg as/ha) were exceeding the ±25 % GAP rate. Nevertheless, the full set of eight residue trials demonstrate that even based on overdosed data the intended critical GAP for apples is within the risk envelope of the GAP on which the MRL is based. No exceedance of the EU MRLs for apples would be expected and the intended GAP may be considered to be fully supported.

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| **Evaluator comments:**  **Apple**  Apple is a major crop in northern Europe. A minimum of eight trials representative of the proposed growing area are required (SANTE/2019/12752).  Applicant submitted sufficient number of residue trials (8 outdoor apples trials conducted in northern EU 2222 in the growing seasons 2013 and 2014) to support the proposed use of ADM.00150.I.2.A / LEAXO on apple in Central Europe. The studies have been evaluated and accepted in Registration Report, Section 4 for MCW-2222, Adama Makhteshim Ltd. (10.05.2018).  Some trials are overdosed and the trials are not within the ± 25% (in accordance with the SANTE/2019/12752) but represents the worst case.  After two treatments with MCW-2222 (200 g a.i./ha) the residues of acetamiprid in apples ranged from 0.06 mg/kg to 0.21 mg/kg at 14 DALA.  After one treatment with MCW-2222 (100 g a.i./ha), the residues of acetamiprid in apples ranged from 0.03 to 0.12 mg/kg at 14 DALA (normal commercial harvest).  The value of EU MRL for acetamiprid in apple equals 0.4 mg/kg (Commission Regulation (EU) 2019/88 of 18 January 2019). The residues arising from the proposed use will not exceed the MRL for acetamiprid established for apple. According to Regulation (EU) 2025/158 for acetamiprid the value of MRL for apples has been changed from 0.4 mg/kg to 0.07 mg/kg. New MRL values for acetamiprid will apply on 19 August 2025. It should be noted that the new Commission Regulation (EU) 2025/1212 of 24 June 2025 has already been published in the Official Journal of the European Union. This Regulation enters into force on 20 August 2025. The value of MRL for apples will be 0.07 mg/kg, the same as under the Reg. (EU) 2025/158. The available results show that the MRL for acetamiprid published in Regulation (EU) 2025/158 and Reg.2025/1212 on proposed apples may be exceeded and the use of Leaxo on apples cannot be accepted.  **Remark:**  The EFSA published Statement on the toxicological properties and maximum residue levels of acetamiprid and its metabolites (EFSA Journal. 2024;22:e8759).  EFSA Working Group proposed to lower the acceptable daily intake (ADI) and acute reference dose (ARfD) from 0.025 to 0.005 mg/kg body weight (per day). A revised residue definition for risk assessment was proposed for leafy and fruit crops as sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1),expressed as acetamiprid.  Samples from all residue trials have been analysed for parent acetamiprid only. No data on the magnitude of metabolite IM-2-1 are available. Tentative conversion factor from enforcement to risk assessment derived in the EFSA statement (2024) are based on monitoring data. For fruits crops median CF equals 1.21.  Trials GAP:  1-2 x 0.098-0.104 kg as/ha, BBCH 81-87, PHI 14d, outdoor  E: 0.030, 0.060, 0.070, 2 x 0.080, 0.090, 0.120, 0.210 mg/kg.  RA (CF:1.21; 2024): 0.036; 0.073; 0.085; 2x0.097; 0.109; 0.145; 0.254 mg/kg.  According to the „*Statement on the toxicological properties and maximum residue levels of acetamiprid and its metabolites*” for the consumer risk assessment it is recommended to require additional supervised residue trials analysing simultaneously for acetamiprid and N-desmethyl-acetamiprid (IM-2-1), supporting intended use on apples (data gap).  **Use on apple was proposed in the original dossier but following the dossier update of July 2024, to apply the EFSA proposed ARfD, ADI and amended residue definition, residues generated according to the intended GAP no longer pass the acute risk assessment and no alternative GAP could be determined.**  **Proposed use of ADM.00150.I.2.A / LEAXO on apple is not accepted according to the proposed GAP.**  ~~Additional remark:~~  ~~The current assessment of residues in honey based on the proposed GAPs for ADM.00150.I.2.A / Leaxo shows that the in force MRL of acetamiprid on honey of 0.05\* mg/kg (Reg. (EU) 2019/88) is potentially exceeded, so until the new MRL has been set for honey, use on apples cannot be authorized.~~ |

Potato

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

Since potatoes are a major crop in northern Europe, as specified in SANTE/2019/12752, usually eight trials have to be submitted to estimate the residues which will be found after application of the product. However, if residues are <LOQ the number of trials may be reduced to four.

Four residue trials on potatoes were performed in northern Europe according to the intended GAP use of acetamiprid in the product ADM.00150.I.2.A (200 g/L acetamiprid). The application rates were not within the ±25 % in accordance with SANTE/2019/12752 (2 x 0.060 vs. 1 x 0.036 kg a.s./ha), but represent the worst-case and clearly demonstrate that even at exaggerated application rates, residues in treated potatoes would not be expected above the LOQ.

Therefore, sufficient residue trials are available to support the intended GAP use on potatoes. The data submitted show that no exceedance of the EU MRL for potatoes will occur.

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| **Evaluator comments:**  **Potatoes**  Potatoes are the major crops in northern Europe. A minimum of eight trials representative of the proposed growing area are required (SANTE/2019/12752).  Applicant submitted 4 outdoor potatoes trials conducted in northern EU in 2013 to support the proposed use of ADM.00150.I.2.A / LEAXO on potatoes in Central Europe.  The residue trials have been conducted at a significantly higher application rate (2x 60 g a.s./ha) than proposed application rate (1x 36 g a.s./ha; see table GAP) and the trials are not within the ± 25% (in accordance with the SANTE/2019/12752) but represent the “worst scenario”.  Residues of acetamiprid in untreated and treated specimens were below the limit of detection (<30% of limit of quantification, i.e. 0.003 mg/kg).  The reduced number of residue trials is considered acceptable in this case, because all results were below the LOQ and no residues situation is expected. Further residue trials are therefore not required.  The value of EU MRL for acetamiprid in potatoes equals 0.01\* mg/kg (Commission Regulation (EU) 2019/88 of 18 January 2019). According to Regulation (EU) 2025/158 and Reg.2025/1212 for acetamiprid the value of MRL for potatoes has not been changed .The residues arising from the proposed use will not exceed the MRL for acetamiprid established for potatoes.  **Proposed use of ADM.00150.I.2.A / LEAXO** **on potatoes is accepted according to the proposed GAP.**  \* Indicates lower limit of analytical determination |

Oilseed Rape

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

Since oilseed rape is a major crop in northern Europe, as specified in SANTE/2019/12752, usually eight trials have to be submitted to estimate the residues which will be found after application of the product.

Eight residue trials on oilseed rape were performed in northern Europe according to the intended GAP use of acetamiprid in the product ADM.00150.I.2.A (200 g/L acetamiprid).

Therefore, sufficient residue trials are available to support the intended GAP use on oilseed rape.

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

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| **Evaluator comments:**  **Oilseed rape**  Oilseed rape is a major crop in northern Europe. A minimum of eight trials representative of the proposed growing area are required (SANTE/2019/12752).  Applicant submitted 8 outdoor oilseed rape trials conducted in northern EU in 2013 and 2014 to support the proposed use of ADM.00150.I.2.A / LEAXO on oilseed rape in Central Europe.  The plots were treated once or twice with MCW-2222 at the rate of 0.3 L/ha (60 g a.i./ha of acetamiprid; 35 (±2) and 28 (±3) days before harvest). Seeds were collected at harvest between 28 to 31 days after last application.  Residues of acetamiprid in untreated specimens were below the limit of detection (<30% of limit of quantification, i.e. 0.003 mg/kg).  After one treatment with MCW-2222, the residues of acetamiprid in seeds specimens were from <0.01 mg/kg to 0.037 mg/kg at DALA 28-31.  After two treatments with MCW-2222, the residues of acetamiprid in seeds specimens were from <0.01 mg/kg to 0.052 mg/kg at DALA 28-31.  The value of EU MRL for acetamiprid in oilseed rape equals 0.4 mg/kg (Commission Regulation (EU) 2019/88 of 18 January 2019). According to Regulation (EU) 2025/158 and Reg.2025/1212 for acetamiprid the value of MRL for oilseed rape has not been changed. The residues arising from the proposed use will not exceed the MRL for acetamiprid established for oilseed rape.  **Proposed use of ADM.00150.I.2.A / LEAXO** **on oilseed rape is accepted according to the proposed GAP.**  Remark:  The current assessment of residues in honey based on the proposed critical GAPs for ADM.00150.I.2.A / Leaxo (application rate 2 x 60 g as/ha) shows that the in force MRL of acetamiprid on honey of 0.05\* mg/kg (Reg. (EU) 2019/88 and 2025/158) is potentially exceeded. ~~In our opinion, until the new MRL has been set for honey, use on oilseed rape cannot be authorized.~~  ~~For lower dose for oilseed rape (max 1 x 40 – 48 g as/ha) the in force MRL of acetamiprid on honey of 0.05\* mg/kg (Reg. (EU) 2019/88) will not be exceeded and this use can be accepted.~~  The European Commission MRL database now indicates the voted MRL of 0.3 mg/kg (PLAN/2024/2431) which is expected to enter into force in July/August 2025 and will cover the full range of proposed uses on oilseed rape.  It should be noted that the new Commission Regulation (EU) 2025/1212 of 24 June 2025 has already been published in the Official Journal of the European Union. This Regulation enters into force on 20 August 2025. The MRL for honey has been raised from 0.05\* mg/kg to 0.3 mg/kg. The current assessment of residues in honey based on the proposed GAPs for ADM.00150.I.2.A / Leaxo shows that all of the intended uses on oilseed rape are in compliance with the MRL of 0.3 mg/kg.  ~~The current assessment of residues in honey based on the proposed GAPs for ADM.00150.I.2.A / LEAXO shows that all of the intended uses would be in compliance with the MRL of 0.3 mg/kg. According to the harmonization arrangements of the Ministry of Agriculture and Rural Development of 14 May 2025 regarding the requirement for honey, the use of Leaxo on oilseed rape at a higher dose of 2 x 60 g as/ha can be accepted under the condition (please see point 7.1.1).~~ |

Barley and oats

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

Since barley is a major crop in northern Europe, as specified in SANTE/2019/12752, usually eight trials have to be submitted to estimate the residues which will be found after application of the product. Extrapolation from barley to oat is possible (SANTE/2019/12752).

Eight residue trials on barley were performed in northern Europe according to the intended GAP use of acetamiprid in the product ADM.00150.I.2.A (200 g/L acetamiprid). The timing of the final application was more critical compared to the proposed GAP (BBCH 65-83 compared to BBCH 69 proposed), but the trials clearly show that the intended GAP is within the risk envelope of the fully supported EU GAP on which the MRL is based.

Therefore, sufficient residue trials are available to support the intended GAP use on barley and oat.

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

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| **Evaluator comments:**  **Barley, oat**  Barley and oat are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight independent trials representative of the proposed growing area for outdoor are required.  The Applicant provided one study covered a total of 8 independent field trials conducted on barley in Northern Europe in accordance (within 25% deviation) with the intended GAP of the product ADM.00150.I.2.A / LEAXO (2x36 g as/ha with 10 days interval between applications, BBCH 12-69, PHI – not applicable).  The residues of acetamiprid in barley grain samples were from below 0.01 mg/kg to 0.029 mg/kg.  Extrapolation from barley to oat is possible (according to the SANTE/2019/12752).  The current MRL for acetamiprid for barley and oat is 0.05 mg/kg (Reg. (EU) 2019/88). According to Regulation (EU) 2025/158 and Reg.2025/1212 for acetamiprid the value of MRL for barley has not been changed. An exceedance of the current MRL of 0.05 mg/kg is not expected.  **Proposed uses of ADM.00150.I.2.A / LEAXO** **on barley and oat are accepted according to the proposed GAP.** |

Maize/Corn

According to the available data, the intended uses on maize/corn are considered acceptable for outdoor uses.

Since maize/corn is a major crop in northern Europe, as specified in SANTE/2019/12752, usually eight trials have to be submitted to estimate the residues which will be found after application of the product.

Eight residue trials on maize/corn were performed in northern Europe according to the intended GAP use of acetamiprid in the product ADM.00150.I.2.A (200 g/L acetamiprid).

Therefore, sufficient residue trials are available to support the intended GAP use on maize/corn.

The data submitted show that no exceedance of the EU MRL for maize/corn will occur.

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| **Evaluator comments:**  **Maize/corn**  Maize is a major crop in northern Europe. A minimum of eight trials representative of the proposed growing area are required (SANTE/2019/12752).  Applicant has submitted eight residue trials which were conducted in compliance with the intended GAP use (1x60 g as/ha, BBCH 51-75, PHI – 56 days).  Residues of acetamiprid in untreated specimens were below the limit of detection (<30% of limit of quantification, i.e. 0.003 mg/kg).  After one treatment with MCW-2222, the residues of acetamiprid in grain and cobs were below the LOQ of 0.01 mg/kg.  The value of EU MRL for acetamiprid in maize equals 0.01\* mg/kg (Commission Regulation (EU) 2019/88 of 18 January 2019). According to Regulation (EU) 2025/158 and Reg.2025/1212 acetamiprid the value of MRL for maize has not been changed. The residues arising from the proposed use will not exceed the MRL for acetamiprid established for maize.  **Proposed use of ADM.00150.I.2.A / LEAXO** **on maize/corn is accepted according to the proposed GAP.**  \* Indicates lower limit of analytical determination |

Wheat, rye, triticale and spelt

According to the available data, the intended uses on wheat (including triticale and spelt) are considered acceptable for outdoor uses.

Since wheat is a major crop in northern Europe, as specified in SANTE/2019/12752, usually eight trials have to be submitted to estimate the residues which will be found after application of the product. Extrapolation from wheat to rye is possible (SANTE/2019/12752).

Eight residue trials on wheat were performed in northern Europe according to the intended GAP use of acetamiprid in the product ADM.00150.I.2.A (200 g/L acetamiprid).

Therefore, sufficient residue trials are available to support the intended GAP use on wheat and rye.

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

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| **Evaluator comments:**  **Wheat, rye, triticale and spelt**  Wheat and rye are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight independent trials representative of the proposed growing area for outdoor are required.  The Applicant provided one study covered a total of 8 independent field trials conducted on wheat in Northern Europe in accordance (within 25% deviation) with the intended GAP of the product ADM.00150.I.2.A / LEAXO (2x36 g as/ha with 10 days interval between applications, BBCH 12-69, PHI – not applicable).  The residues of acetamiprid in wheat grain samples were from below 0.01 mg/kg.  Extrapolation from wheat to rye, triticale and spelt is possible (according to the SANTE/2019/12752).  Available results show that the in force MRLs of acetamiprid (Reg. (EU) 2019/88) on wheat of 0.1 mg/kg and on rye of 0.01\* mg/kg will not be exceeded. According to Regulation (EU) 2025/158 and Reg.2025/1212 for acetamiprid the values of MRL for wheat and rye have not been changed .  According to Commission Regulation (EU) No 752/2014 replacing Annex I to Regulation (EC) No 396/2005, MRLs for wheat (code number: 0500090) are also applicable to spelt (code number: 0500090-005) and to triticale (code number: 0500090-006).  Therefore, sufficient residue trials are available to support the intended GAP uses on wheat rye, triticale and spelt and these uses are accepted.  \* Indicates lower limit of analytical determination |

Sugar beet

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

Since sugar beet is a major crop in northern Europe, as specified in SANTE/2019/12752, usually eight trials have to be submitted to estimate the residues which will be found after application of the product. However, if residues are <LOQ the number of trials may be reduced to four.

Four residue trials on sugar beet were performed in northern Europe according to the intended GAP use of acetamiprid in the product ADM.00150.I.2.A (200 g/L acetamiprid), and residues in treated sugar beet were <LOQ.

Therefore, sufficient residue trials are available to support the intended GAP use on sugar beet. The data submitted show that no exceedance of the EU MRL for sugar beet will occur.

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| **Evaluator comments:**  **Sugar beet**  Sugar beet is the major crop in northern Europe (SANTE/2019/12752). A minimum of eight independent trials representative of the proposed growing area for outdoor are required.  The Applicant provided one study covered a total of 4 field trials conducted on sugar beet in Northern Europe in accordance (within 25% deviation) with the intended GAP of the product ADM.00150.I.2.A / LEAXO (2x50 g as/ha with 7 days interval between applications, BBCH 12-39, PHI – 35 days).  The residues of acetamiprid in sugar beet roots were 4x<0.01 mg/kg.  In leaves + tops samples, the residues of acetamiprid ranged from 0.012 mg/kg to 0.081 mg/kg.  All residues in sugar beet roots are below the limit of quantification, therefore, a reduced dataset is acceptable.  Available results show that the in force MRL of acetamiprid on sugar beet roots of 0.01\* mg/kg (Reg. (EU) 2019/88) will not be exceeded. According to Regulation (EU) 2025/158 and Reg.2025/1212 acetamiprid the value of MRL for sugar beet has not been changed. Therefore, sufficient residue trials are available to support the intended GAP use of ADM.00150.I.2.A / LEAXO on sugar beet.  \* Indicates lower limit of analytical determination |

### Magnitude of residues in livestock

#### Dietary burden calculation

Table 7.2‑11: ~~Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure (EFSA, 2011, updated 2012), in the focussed assessment of certain existing MRLs of concern for acetamiprid (EFSA, 2018) and the uses under consideration)~~ Input values for the dietary burden calculation (considering the uses evaluated in EFSA (2024) Statement and the uses under consideration)

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| --- | --- | --- | --- | --- |
| **Feed commodity** | **Median dietary burden** | | **Maximum dietary burden** | |
| **Input value** (mg/kg) | **Comment** | **Input value** (mg/kg) | **Comment** |
| **Newly proposed 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   **Notes:**   * **All inputs from EFSA (2024) unless indicated** * **No default processing factor used for processed sugar beet commodities as residues were <LOQ in all trials** | | | | |
| Alfalfa forage (green) | 0.13 | STMRMo x CF (1.44) | 0.59 | HRMo x CF (1.44) |
| Alfalfa hay (fodder) | 0.32 | STMRMo x CF (1.44) x default PF (2.5) | 1.48 | HRMo x CF (1.44) x default PF (2.5) |
| Alfalfa meal | 0.32 | STMRMo x CF (1.44) x default PF (2.5) | 1.48 | HRMo x CF (1.44) x default PF (2.5) |
| Alfalfa silage | 0.14 | STMRMo x CF (1.44) x default PF (1.1) | 0.65 | HRMo x CF (1.44) x default PF (1.1) |
| Barley straw | 0.25 | STMRMo x CF (1.44)  (current submission) | 0.46 | HRMo x CF (1.44)  (current submission) |
| Beet, sugar, tops | 0.10 | STMRMo x CF (1.44)  (current submission) | 0.27 | HRMo x CF (1.44)  (current submission) |
| Cabbage, heads leaves | 0.01 | STMRMo x CF (1.44) | 0.03 | HRMo x CF (1.44) |
| Maize (corn) stover | 0.24 | STMRMo x CF (1.44)  (current submission) | 1.2 | HRMo x CF (1.44)  (current submission) |
| Oat straw | 0.25 | STMRMo x CF (1.44)  (current submission) | 0.46 | HRMo x CF (1.44)  (current submission) |
| Rye straw | 0.39 | STMRMo x CF (1.44)  [current submission less critical] | 2.3 | HRMo x CF (1.44)  [current submission less critical] |
| Triticale straw | 0.39 | STMRMo x CF (1.44)  [current submission less critical] | 2.3 | HRMo x CF (1.44)  [current submission less critical] |
| Wheat straw | 0.39 | STMRMo x CF (1.44)  [current submission less critical] | 2.3 | HRMo x CF (1.44)  [current submission less critical] |
| Potato culls | 0.01 | STMR (current submission) | 0.01 | HR (current submission) |
| Barley grain | 0.01 | STMR (current submission) | 0.01 | STMR (current submission) |
| Bean seed (dry) | 0.02 | STMR | 0.02 | STMR |
| Cotton undelinted seed | 0.09 | STMR | 0.09 | STMR |
| Cowpea seed | 0.02 | STMR | 0.02 | STMR |
| Lupin seed | 0.02 | STMR | 0.02 | STMR |
| Maize (corn) grain | 0.01 | STMR (current submission) | 0.01 | STMR (current submission) |
| Oat grain | 0.01 | STMR | 0.01 | STMR |
| Pea (Field pea) seed (dry) | 0.02 | STMR | 0.02 | STMR |
| Rye grain | 0.01 | STMR (current submission) | 0.01 | STMR (current submission) |
| Triticale grain | 0.01 | STMR (current submission) | 0.01 | STMR (current submission) |
| Wheat grain | 0.01 | STMR (current submission) | 0.01 | STMR (current submission) |
| Apple pomace, wet | 0.03 | STMRMo x CF (1.21) x PF (1.3) | 0.03 | STMRMo x CF (1.21) x PF (1.3) |
| Beet, sugar, dried pulp | 0.01 | STMR (current submission) | 0.01 | STMR (current submission) |
| Beet, sugar, ensiled pulp | 0.01 | STMR (current submission) | 0.01 | STMR (current submission) |
| Beet, sugar, molasses | 0.01 | STMR (current submission) | 0.01 | STMR (current submission) |
| Brewer's grain dried | 0.03 | STMR x default PF (3.3) | 0.03 | STMR x default PF (3.3) |
| Canola (Rape seed) meal | 0.06 | STMR x default PF (2)  [current submission less critical] | 0.06 | STMR x default PF (2)  [current submission less critical] |
| Citrus dried pulp | 2.3 | STMRMo x CF (1.21) x PF (10) | 2.3 | STMRMo x CF (1.21) x PF (10) |
| Coconut meal | 0.02 | STMRMo x CF (1.21) x default PF (1.5) | 0.02 | STMRMo x CF (1.21) x default PF (1.5) |
| Cotton meal | 0.04 | STMR x PF (0.4) | 0.04 | STMR x PF (0.4) |
| Distiller's grain dried | 0.03 | STMR x default PF (3.3) | 0.03 | STMR x default PF (3.3) |
| Lupin seed meal | 0.02 | STMR x default PF (1.1) | 0.02 | STMR x default PF (1.1) |
| Potato process waste | 0.01 | STMR | 0.01 | STMR |
| Potato dried pulp | 0.01 | STMR | 0.01 | STMR |
| Rape meal | 0.06 | STMR x default PF (2)  [current submission less critical] | 0.06 | STMR x default PF (2)  [current submission less critical] |
| Wheat gluten meal | 0.02 | STMR x default PF (1.8) | 0.02 | STMR x default PF (1.8) |
| Wheat milled by-pdts | 0.07 | STMR x default PF (7) | 0.07 | STMR x default PF (7) |

| ~~Feed Commodity~~ | ~~Median dietary burden~~ | | ~~Maximum dietary burden~~ | |
| --- | --- | --- | --- | --- |
| ~~Input value (mg/kg)~~ | ~~Comment~~ | ~~Input value (mg/kg)~~ | ~~Comment~~ |
| **~~Risk assessment residue definition~~**~~:~~  ~~Fruit, leafy crops: sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid (EFSA, 2024)~~~~$~~  ~~Pulses/oilseeds, root crops, cereals: acetamiprid (EFSA, 2022)~~ | | | | |
| ~~Alfalfa, forage (green)~~ | ~~0.13~~  ~~[0.09 x 1.44]~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ | ~~0.59~~  ~~[0.41 x 1.4]~~ | ~~HR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Alfalfa, hay (fodder)~~ | ~~0.32~~  ~~[0.09 x 2.5 x 1.44]~~ | ~~STMR x default PF~~ ~~a)~~ ~~x CF~~  ~~(EFSA, 2018)~~ | ~~1.48 [0.41 x 2.5 x 1.44]~~ | ~~HR x default PF~~ ~~a)~~ ~~x CF~~  ~~(EFSA, 2018)~~ |
| ~~Alfalfa, meal~~ | ~~0.32~~  ~~[0.09 x 2.5 x 1.44]~~ | ~~STMR x default PF~~ ~~a)~~ ~~x CF~~  ~~(EFSA, 2018)~~ | ~~1.48 [0.41 x 2.5 x 1.44]~~ | ~~HR x default PF~~ ~~a)~~ ~~x CF~~  ~~(EFSA, 2018)~~ |
| ~~Alfalfa, silage~~ | ~~0.14~~  ~~[0.09 x 1.1 x 1.44]~~ | ~~STMR x default PF~~ ~~a)~~ ~~x CF~~  ~~(EFSA, 2018)~~ | ~~0.65~~  ~~[0.41 x 1.1 x 1.44]~~ | ~~STMR x default PF~~ ~~a)~~ ~~x CF~~  ~~(EFSA, 2018)~~ |
| ~~Barley, straw~~  ~~Oat, straw~~ ~~b)~~ | ~~0.26~~  ~~[0.18 x 1.44]~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ | ~~0.46~~  ~~[0.32 x 1.44]~~ | ~~HR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Sugar beet (tops)~~ | ~~0.14~~  ~~[0.10 x 1.44]~~ | ~~STMR x CF~~  ~~(see Table 7.2‑10)~~ | ~~0.27~~  ~~[0.19 x 1.44]~~ | ~~HR x CF~~  ~~(see Table 7.2‑10)~~ |
| ~~Cabbage, heads leaves~~ | ~~0.14~~  ~~[0.14 x 1.44]~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ | ~~0.72~~  ~~[0.50 x 1.44]~~ | ~~HR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Corn, field (stover)~~  ~~Corn, pop (stover)~~ | ~~0.24~~  ~~[0.17 x 1.44]~~ | ~~STMR~~ ~~c)~~ ~~x CF~~  ~~(see Table 7.2‑10)~~ | ~~1.2~~  ~~[0.83 x 1.44]~~ | ~~HR~~ ~~c)~~ ~~x 1.44~~  ~~(see Table 7.2‑10)~~ |
| ~~Kale, leaves (forage)~~ | ~~0.14~~  ~~[0.10 x 1.44]~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ | ~~1.1~~  ~~[0.73 x 1.44]~~ | ~~HR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Wheat (straw)~~  ~~Triticale (straw)~~  ~~Rye (straw)~~ ~~d)~~ | ~~0.39~~  ~~[0.27 x 1.44]~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ | ~~2.3~~  ~~[1.6 x 1.44]~~ | ~~HR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Potato (culls)~~ | ~~0.01~~ | ~~STMR~~  ~~(see Table 7.2‑10)~~ | ~~0.01~~ | ~~STMR~~  ~~(see Table 7.2‑10)~~ |
| ~~Barley (grain)~~  ~~Oat (grain)~~ ~~e)~~ | ~~0.01~~ | ~~STMR~~  ~~(see Table 7.2‑10)~~ | ~~0.01~~ | ~~STMR~~  ~~(see Table 7.2‑10)~~ |
| ~~Bean (seed dry)~~ | ~~0.02~~ | ~~STMR~~  ~~(EFSA, 2018)~~ | ~~0.02~~ | ~~STMR~~  ~~(EFSA, 2018)~~ |
| ~~Maize/Corn, field (grain)~~  ~~Maize/Corn, pop (grain)~~ | ~~0.01~~ | ~~STMR~~  ~~(see Table 7.2‑10)~~ | ~~0.01~~ | ~~STMR~~  ~~(see Table 7.2‑10)~~ |
| ~~Cotton (undelinted seed)~~ | ~~0.09~~ | ~~STMR~~  ~~(EFSA, 2018)~~ | ~~0.09~~ | ~~STMR~~  ~~(EFSA, 2018)~~ |
| ~~Cowpea (seed)~~ | ~~0.02~~ | ~~STMR~~  ~~(EFSA, 2018)~~ | ~~0.02~~ | ~~STMR~~  ~~(EFSA, 2018)~~ |
| ~~Lupin (seed)~~ | ~~0.02~~ | ~~STMR~~  ~~(EFSA, 2018)~~ | ~~0.02~~ | ~~STMR~~  ~~(EFSA, 2018)~~ |
| ~~Pea (Field pea), seed (dry)~~ | ~~0.02~~ | ~~STMR~~  ~~(EFSA, 2018)~~ | ~~0.02~~ | ~~STMR~~  ~~(EFSA, 2018)~~ |
| ~~Wheat (grain)~~  ~~Triticale (grain)~~  ~~Rye (grain)~~ ~~f)~~ | ~~0.010~~ | ~~STMR~~  ~~(see Table 7.2‑10)~~ | ~~0.010~~ | ~~STMR~~  ~~(see Table 7.2‑10)~~ |
| ~~Apple (pomace, wet)~~ | ~~0.35~~  ~~[0.23 x 1.25 x 1.21]~~ | ~~STMR (EFSA, 2011, updated 2012) x PF (see Table 7.2‑14) x CF~~ | ~~0.35~~  ~~[0.23 x 1.25 x 1.21]~~ | ~~STMR (EFSA, 2011 updated 2012) x PF (see Table 7.2‑14) x CF~~ |
| ~~Sugar beet (dried pulp)~~ | ~~0.01~~ | ~~STMR~~ ~~g)~~  ~~(see Table 7.2‑10)~~ | ~~0.01~~ | ~~STMR~~ ~~g)~~  ~~(see Table 7.2‑10)~~ |
| ~~Sugar beet (ensiled pulp)~~ | ~~0.01~~ | ~~STMR~~ ~~g)~~  ~~(see Table 7.2‑10)~~ | ~~0.01~~ | ~~STMR~~ ~~g)~~  ~~(see Table 7.2‑10)~~ |
| ~~Sugar beet (molasses)~~ | ~~0.01~~ | ~~STMR~~ ~~g)~~  ~~(see Table 7.2‑10)~~ | ~~0.01~~ | ~~STMR~~ ~~g)~~  ~~(see Table 7.2‑10)~~ |
| ~~Brewer’s grain, dried~~  ~~Wheat, distiller’s grain (dry)~~ | ~~0.03~~  ~~[0.01 x 3.3]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(see Table 7.2‑10)~~ | ~~0.03~~  ~~[0.01 x 3.3]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(see Table 7.2‑10)~~ |
| ~~Rape seed/Canola (meal)~~ | ~~0.06~~  ~~[0.03 x 2]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(EFSA, 2022)~~ | ~~0.06~~  ~~[0.03 x 2]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(EFSA, 2022)~~ |
| ~~Citrus fruits (dried pulp)~~ | ~~2.3 [0.19 x 10 x 1.21]~~ | ~~STMR x default PF~~ ~~a)~~ ~~x CF~~  ~~(EFSA, 2018)~~ | ~~2.3 [0.19 x 10 x 1.21]~~ | ~~STMR x default PF~~ ~~a)~~ ~~x CF~~  ~~(EFSA, 2018)~~ |
| ~~Coconut (meal)~~ | ~~0.02 [0.01 x 1.21]~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ | ~~0.02 [0.01 x 1.21]~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Corn, field (milled by-products)~~ | ~~0.01 [0.01 x 1]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(see Table 7.2‑10)~~ | ~~0.01~~  ~~[0.01 x 1]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(see Table 7.2‑10)~~ |
| ~~Corn, field (hominy meal)~~ | ~~0.06 [0.01 x 6]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(see Table 7.2‑10)~~ | ~~0.06 [0.01 x 6]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(see Table 7.2‑10)~~ |
| ~~Corn, field (gluten feed)~~ | ~~0.03 [0.01 x 2.5]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(see Table 7.2‑10)~~ | ~~0.03 [0.01 x 2.5]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(see Table 7.2‑10)~~ |
| ~~Corn, field (gluten meal)~~ | ~~0.01 [0.01 x 1]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(see Table 7.2‑10)~~ | ~~0.01 [0.01 x 1]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(see Table 7.2‑10)~~ |
| ~~Cotton, meal~~ | ~~0.04 [0.09 x 0.4]~~ | ~~STMR x PF~~  ~~(EFSA, 2011, updated 2012)~~ | ~~0.04 [0.09 x 0.4]~~ | ~~STMR x PF~~  ~~(EFSA, 2011, updated 2012)~~ |
| ~~Lupin seed, meal~~ | ~~0.02 [0.02 x 1.1]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(EFSA, 2018)~~ | ~~0.02 [0.02 x 1.1]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(EFSA, 2018)~~ |
| ~~Potato, process waste~~ | ~~0.01~~ | ~~STMR~~ ~~g)~~  ~~(see Table 7.2‑10)~~ | ~~0.01~~ | ~~STMR~~ ~~g)~~  ~~(see Table 7.2‑10)~~ |
| ~~Potato, dried pulp~~ | ~~0.01~~ | ~~STMR~~ ~~g)~~  ~~(see Table 7.2‑10)~~ | ~~0.01~~ | ~~STMR~~ ~~g)~~  ~~(see Table 7.2‑10)~~ |
| ~~Rape, meal~~ | ~~0.06~~  ~~[0.03 x 2]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(EFSA, 2022)~~~~)~~ | ~~0.06~~  ~~[0.03 x 2]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(EFSA, 2022)~~ |
| ~~Wheat gluten, meal~~ | ~~0.02 [0.01 x 1.8]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(see Table 7.2‑10)~~ | ~~0.02 [0.01 x 1.8]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(see Table 7.2‑10)~~ |
| ~~Wheat, milled by-pdts~~ | ~~0.07 [0.01 x 7]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(see Table 7.2‑10)~~ | ~~0.07 [0.01 x 7]~~ | ~~STMR x default PF~~ ~~a)~~  ~~(see Table 7.2‑10)~~ |
| Flaxseed/Linseed, meal | 0.01 | STMR  (EFSA, 2022) | 0.01 | STMR  (EFSA, 2022) |

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

$ Forage crops have been considered as leafy crops and conversion factors of 1.21 and 1.44 have been applied for fruit and leafy crops respectively

a) Default processing factors were included in the calculation to consider the potential concentration of residues

b) Extrapolated from barley straw

c) Retrieved from maize grain

d) Extrapolated from wheat straw

e) Extrapolated from barley grain

f) Extrapolated from wheat grain

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

Table 7.2‑12: Results of the dietary burden calculationa)

| **Relevant groups** | **Dietary burden expressed in** | | | | **Most critical dietb)** | **Most critical commodityc)** | **Trigger (0.004 mg/kg bw) exceeded (Yes/No)** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **mg/kg bw per day** | | **mg/kg DM** | |
| **Median** | **Maximum** | **Median** | **Maximum** |
| **Risk assessment residue definition:**  Fruit, leafy crops: sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid (EFSA, 2024)  Pulses/oilseeds, root crops, cereals: acetamiprid (EFSA, 2022) | | | | | | | |
| Cattle  (all diets) | 0.026 | 0.046 | 0.68 | 1.21 | Dairy cattle | Citrus dried pulp | Y |
| Cattle  (dairy only) | 0.026 | 0.046 | 0.68 | 1.21 | Dairy cattle | Citrus dried pulp | Y |
| Sheep  (all diets) | 0.0094 | 0.046 | 0.22 | 1.09 | Lamb | Wheat straw | Y |
| Sheep  (ewe only) | 0.0073 | 0.036 | 0.22 | 1.10 | Ewe | Wheat straw | Y |
| Swine  (all diets) | 0.011 | 0.016 | 0.47 | 0.69 | Breeding swine | Citrus dried pulp | Y |
| Poultry  (all diets) | 0.005 | 0.020 | 0.07 | 0.29 | Layer poultry | Wheat straw | Y |
| Poultry  (layer only) | 0.005 | 0.020 | 0.07 | 0.29 | Layer poultry | Wheat straw | Y |

| **~~Relevant groups~~** | **~~Dietary burden expressed in~~** | | | | **~~Most critical diet~~~~b)~~** | **~~Most critical commodity~~~~c)~~** | **~~Trigger (0.004 mg/kg bw) exceeded (Yes/No)~~** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **~~mg/kg bw per day~~** | | **~~mg/kg DM~~** | |
| **~~Median~~** | **~~Maximum~~** | **~~Median~~** | **~~Maximum~~** |
| **~~Risk assessment residue definition:~~**  ~~Fruit, leafy crops: sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid (EFSA, 2024)~~  ~~Pulses/oilseeds, root crops, cereals: acetamiprid (EFSA, 2022)~~ | | | | | | | |
| ~~Cattle~~  ~~(all diets)~~ | ~~0.031~~ | ~~0.074~~ | ~~0.80~~ | ~~1.93~~ | ~~Dairy cattle~~ | ~~Kale leaves~~ | ~~Yes~~ |
| ~~Cattle~~  ~~(dairy only)~~ | ~~0.031~~ | ~~0.074~~ | ~~0.80~~ | ~~1.93~~ | ~~Dairy cattle~~ | ~~Kale leaves~~ | ~~Yes~~ |
| ~~Sheep~~  ~~(all diets)~~ | ~~0.012~~ | ~~0.049~~ | ~~0.28~~ | ~~1.15~~ | ~~Lamb~~ | ~~Rye straw~~ | ~~Yes~~ |
| ~~Sheep~~  ~~(ewe only)~~ | ~~0.009~~ | ~~0.038~~ | ~~0.28~~ | ~~1.15~~ | ~~Ram/Ewe~~ | ~~Rye straw~~ | ~~Yes~~ |
| ~~Swine~~  ~~(all diets)~~ | ~~0.013~~ | ~~0.026~~ | ~~0.54~~ | ~~1.11~~ | ~~Swine (breeding)~~ | ~~Kale leaves~~ | ~~Yes~~ |
| ~~Poultry~~  ~~(all diets)~~ | ~~0.007~~ | ~~0.020~~ | ~~0.10~~ | ~~0.29~~ | ~~Poultry layer~~ | ~~Wheat straw~~ | ~~Yes~~ |
| ~~Poultry~~  ~~(layer only)~~ | ~~0.007~~ | ~~0.020~~ | ~~0.10~~ | ~~0.29~~ | ~~Poultry layer~~ | ~~Wheat straw~~ | ~~Yes~~ |

a) Performed according to “OECD Guidance Document, series on testing and assessment number 64, series on pesticides 32” and “OECD Guidance 73 on Residue in livestock”, calculated with Animal model 2017.xls.

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

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

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

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

Available data

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

Table 7.2‑13: Overview of the values derived from livestock feeding studies

| **Commodity** | **Dietary burden** | | **Results of the livestock feeding study** | | | | | | **Median  residue**  **(mg/kg)(b)** | **Highest  residue**  **(mg/kg)(c)** | **Calculated MRL**  **(mg/kg)** | **Current MRL**  **(mg/kg)** | **CF for RA(d)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Med. (mg/kg bw/d)** | **Max. (mg/kg bw/d)** | **Dose Level (mg/kg bw/d)(a)** | **No** | **Result for enforcement(f)** | | **Result for RA** | |  |  |  |  |  |
| **Mean (mg/kg)** | **Max. (mg/kg)** | **Mean (mg/kg)** | **Max. (mg/kg)** |  |  |  |  |  |
| **EU data (EFSA, 2011, updated 2012; The Netherlands, 2015, updated 2016(R))** | | | | | | | | | | | | | |
| **Enforcement residue definition (Regulation (EU) 2019/88, 2025/158 and Reg. (EU) 2025/1212):** Sum of acetamiprid and metabolite IM-2-1 (N-desmethyl-acetamiprid), expressed as acetamiprid | | | | | | | | | | | | | |
| **Pig meat**  **(Breeding)** | 0.011 | 0.016 | 0.21 | 3 | 0.05 | 0.05 | See results for enforcement residue definition | | 0.002 | 0.003 | 0.02\* | 0.50 | 1 |
| 0.63 | 3 | 0.18 | 0.29 |
| 2.13 | 3 | 0.97 | 1.1 |
| **Pig fat**  **(Breeding)** | 0.21 | 3 | 0.03 | 0.06 | 0.001 | 0.004 | 0.02\* | 0.30 | 1 |
| 0.63 | 3 | 0.07 | 0.15 |
| 2.13 | 3 | 0.36 | 0.71 |
| **Pig liver**  **(Breeding)** | 0.21 | 3 | 0.15 | 0.15 | 0.006 | 0.008 | 0.02\* | 1.0 | 1 |
| 0.63 | 3 | 0.45 | 0.64 |
| 2.13 | 3 | 2.3 | 2.7 |
| **Pig kidney**  **(Breeding)** | 0.21 | 3 | 0.24 | 0.25 | 0.010 | 0.014 | 0.02\* | 1.0 | 1 |
| 0.63 | 3 | 0.70 | 0.86 |
| 2.13 | 3 | 2.4 | 2.5 |
| **Sheep meat**  **(Lamb)** | 0.009 | 0.046 | 0.21 | 3 | 0.05 | 0.05 |  | | 0.002 | 0.008 | 0.02\* | 0.50 | 1 |
| 0.63 | 3 | 0.18 | 0.29 |
| 2.13 | 3 | 0.97 | 1.1 |
| **Sheep fat**  **(Lamb)** | 0.21 | 3 | 0.03 | 0.06 | 0.001 | 0.010 | 0.02\* | 0.30 | 1 |
| 0.63 | 3 | 0.07 | 0.15 |
| 2.13 | 3 | 0.36 | 0.71 |
| **Sheep liver**  **(Lamb)** | 0.21 | 3 | 0.15 | 0.15 | 0.005 | 0.023 | 0.030 | 1.0 | 1 |
| 0.63 | 3 | 0.45 | 0.64 |
| 2.13 | 3 | 2.3 | 2.7 |
| **Sheep kidney**  **(Lamb)** | 0.21 | 3 | 0.24 | 0.25 | 0.008 | 0.039 | 0.040 | 1.0 | 1 |
| 0.63 | 3 | 0.70 | 0.86 |
| 2.13 | 3 | 2.4 | 2.5 |
| **Sheep Milk**  **(Ewe)** | 0.007 | 0.036 | 0.21 | 3 | 0.081 | N/A |  | | 0.002 | 0.010 | 0.02\* | 0.20 | 1 |
| 0.63 | 3 | 0.37 | N/A |
| 2.13 | 3 | 1.3 | N/A |
| **Bovine/cattle meat**  **(dairy)** | 0.026 | 0.046 | 0.21 | 3 | 0.05 | 0.05 |  | | 0.004 | 0.008 | 0.02\* | 0.50 | 1 |
| 0.63 | 3 | 0.18 | 0.29 |
| 2.13 | 3 | 0.97 | 1.1 |
| **Bovine/cattle fat**  **(dairy)** | 0.21 | 3 | 0.03 | 0.06 | 0.003 | 0.011 | 0.02\* | 0.30 | 1 |
| 0.63 | 3 | 0.07 | 0.15 |
| 2.13 | 3 | 0.36 | 0.71 |
| **Bovine/cattle liver**  **(dairy)** | 0.21 | 3 | 0.15 | 0.15 | 0.015 | 0.025 | 0.03 | 1.0 (Reg. (EU) 2019/88)  0.03 (Reg. (EU) 2025/158 and 2025/1212) | 1 |
| 0.63 | 3 | 0.45 | 0.64 |
| 2.13 | 3 | 2.3 | 2.7 |
| **Bovine/cattle kidney**  **(dairy)** | 0.21 | 3 | 0.24 | 0.25 | 0.024 | 0.042 | 0.05 | 1.0 | 1 |
| 0.63 | 3 | 0.70 | 0.86 |
| 2.13 | 3 | 2.4 | 2.5 |
| **Bovine/cattle Milk**  **(dairy)** | 0.026 | 0.046 | 0.21 | 3 | 0.081 | N/A |  | | 0.008 | 0.014 | 0.02\* | 0.20 | 1 |
| 0.63 | 3 | 0.37 | N/A |
| 2.13 | 3 | 1.3 | N/A |
| **Poultry(g) meat**  **(layer)** | 0.005 | 0.020 | 0.079 | 10 | <0.02 | <0.02 | <0.020 | <0.020 | 0.02\* | 0.02\* | 1 |
| 0.240 | 10 | 0.034 | 0.039 |
| 0.821 | 10 | 0.084 | 0.090 |
| **Poultry(g) fat**  **(layer)** | 0.079 | 10 | <0.02 | <0.02 | <0.020 | <0.020 | 0.02\* | 0.02\* | 1 |
| 0.240 | 10 | <0.02 | <0.02 |
| 0.821 | 10 | 0.022 | 0.023 |
| **Poultry(g) liver**  **(layer)** | 0.079 | 10 | 0.12 | 0.15 | 0.008 | 0.038 | 0.04 | 0.1\* | 1 |
| 0.240 | 10 | 0.24 | 0.27 |
| 0.821 | 10 | 0.55 | 0.58 |
| **Eggs(g)**  **(layer)** | 0.005 | 0.020 | 0.079 | 10 | 0.039 | 0.041 | 0.002 | 0.010 | 0.015 | 0.02\* | 1 |
| 0.240 | 10 | 0.103 | 0.11 |
| 0.821 | 10 | 0.33 | 0.36 |

| ~~Commodity~~ | ~~Dietary burden~~ | | ~~Results of the livestock feeding study~~ | | | | | | ~~Median  residue~~  ~~(mg/kg)~~~~(b)~~ | ~~Highest  residue~~  ~~(mg/kg)~~~~(c)~~ | ~~Calculated MRL~~  ~~(mg/kg)~~ | ~~Current MRL~~  ~~(mg/kg)~~ | ~~CF for RA~~~~(d)~~ |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | ~~Med. (mg/kg bw/d)~~ | ~~Max. (mg/kg bw/d)~~ | ~~Dose Level (mg/kg bw/d)~~~~(a)~~ | ~~No~~ | ~~Result for enforcement~~~~(f)~~ | | ~~Result for RA~~ | |  |  |  |  |  |
| ~~Mean (mg/kg)~~ | ~~Max. (mg/kg)~~ | ~~Mean (mg/kg)~~ | ~~Max. (mg/kg)~~ |  |  |  |  |  |
| **~~EU data (EFSA, 2011, updated 2012; The Netherlands, 2015, updated 2016~~~~(R)~~~~)~~** | | | | | | | | | | | | | |
| **~~Enforcement residue definition (SANTE/11278/2021, Regulation (EU) 2019/88 and 2025/158):~~** ~~Sum of acetamiprid and metabolite IM-2-1 (N-desmethyl-acetamiprid), expressed as acetamiprid~~ | | | | | | | | | | | | | |
| ~~Pig meat~~  ~~(Breeding)~~ | ~~0.013~~ | ~~0.026~~ | ~~0.21~~ | ~~3~~ | ~~0.05~~ | ~~0.05~~ | ~~See results for enforcement residue definition~~ | | ~~0.003~~ | ~~0.006~~ | ~~0.007~~ | ~~0.50~~ | ~~1~~ |
| ~~0.63~~ | ~~3~~ | ~~0.19~~ | ~~0.31~~ |
| ~~2.13~~ | ~~3~~ | ~~1.03~~ | ~~1.18~~ |
| ~~Pig fat~~  ~~(Breeding)~~ | ~~0.21~~ | ~~3~~ | ~~0.04~~ | ~~0.08~~ | ~~0.002~~ | ~~0.010~~ | ~~0.015~~ | ~~0.30~~ | ~~1~~ |
| ~~0.63~~ | ~~3~~ | ~~0.08~~ | ~~0.16~~ |
| ~~2.13~~ | ~~3~~ | ~~0.38~~ | ~~0.76~~ |
| ~~Pig liver~~  ~~(Breeding)~~ | ~~0.21~~ | ~~3~~ | ~~0.16~~ | ~~0.16~~ | ~~0.010~~ | ~~0.020~~ | ~~0.030~~ | ~~1.0~~ | ~~1~~ |
| ~~0.63~~ | ~~3~~ | ~~0.45~~ | ~~0.68~~ |
| ~~2.13~~ | ~~3~~ | ~~2.43~~ | ~~2.81~~ |
| ~~Pig kidney~~  ~~(Breeding)~~ | ~~0.21~~ | ~~3~~ | ~~0.24~~ | ~~0.26~~ | ~~0.015~~ | ~~0.032~~ | ~~0.040~~ | ~~1.0~~ | ~~1~~ |
| ~~0.63~~ | ~~3~~ | ~~0.75~~ | ~~0.91~~ |
| ~~2.13~~ | ~~3~~ | ~~2.55~~ | ~~2.70~~ |
| ~~Sheep meat~~  ~~(Lamb)~~ | ~~0.012~~ | ~~0.049~~ | ~~0.21~~ | ~~3~~ | ~~0.05~~ | ~~0.05~~ |  | | ~~0.003~~ | ~~0.012~~ | ~~0.015~~ | ~~0.50~~ | ~~1~~ |
| ~~0.63~~ | ~~3~~ | ~~0.19~~ | ~~0.31~~ |
| ~~2.13~~ | ~~3~~ | ~~1.03~~ | ~~1.18~~ |
| ~~Sheep fat~~  ~~(Lamb)~~ | ~~0.21~~ | ~~3~~ | ~~0.04~~ | ~~0.08~~ | ~~0.002~~ | ~~0.019~~ | ~~0.020~~ | ~~0.30~~ | ~~1~~ |
| ~~0.63~~ | ~~3~~ | ~~0.08~~ | ~~0.16~~ |
| ~~2.13~~ | ~~3~~ | ~~0.38~~ | ~~0.76~~ |
| ~~Sheep liver~~  ~~(Lamb)~~ | ~~0.21~~ | ~~3~~ | ~~0.16~~ | ~~0.16~~ | ~~0.009~~ | ~~0.037~~ | ~~0.040~~ | ~~1.0~~ | ~~1~~ |
| ~~0.63~~ | ~~3~~ | ~~0.45~~ | ~~0.68~~ |
| ~~2.13~~ | ~~3~~ | ~~2.43~~ | ~~2.81~~ |
| ~~Sheep kidney~~  ~~(Lamb)~~ | ~~0.21~~ | ~~3~~ | ~~0.24~~ | ~~0.26~~ | ~~0.014~~ | ~~0.061~~ | ~~0.070~~ | ~~1.0~~ | ~~1~~ |
| ~~0.63~~ | ~~3~~ | ~~0.75~~ | ~~0.91~~ |
| ~~2.13~~ | ~~3~~ | ~~2.55~~ | ~~2.70~~ |
| ~~Sheep Milk~~  ~~(Ewe)~~ | ~~0.009~~ | ~~0.038~~ | ~~0.21~~ | ~~3~~ | ~~0.07~~~~(e)~~ | ~~N/A~~ |  | | ~~0.003~~ | ~~0.013~~ | ~~0.015~~ | ~~0.20~~ | ~~1~~ |
| ~~0.63~~ | ~~3~~ | ~~0.24~~~~(e)~~ | ~~N/A~~ |
| ~~2.13~~ | ~~3~~ | ~~1.09~~~~(e)~~ | ~~N/A~~ |
| ~~Bovine/cattle meat~~  ~~(dairy)~~ | ~~0.031~~ | ~~0.074~~ | ~~0.21~~ | ~~3~~ | ~~0.05~~ | ~~0.05~~ |  | | ~~0.007~~ | ~~0.018~~ | ~~0.020~~ | ~~0.50~~ | ~~1~~ |
| ~~0.63~~ | ~~3~~ | ~~0.19~~ | ~~0.31~~ |
| ~~2.13~~ | ~~3~~ | ~~1.03~~ | ~~1.18~~ |
| ~~Bovine/cattle fat~~  ~~(dairy)~~ | ~~0.21~~ | ~~3~~ | ~~0.04~~ | ~~0.08~~ | ~~0.006~~ | ~~0.028~~ | ~~0.030~~ | ~~0.30~~ | ~~1~~ |
| ~~0.63~~ | ~~3~~ | ~~0.08~~ | ~~0.16~~ |
| ~~2.13~~ | ~~3~~ | ~~0.38~~ | ~~0.76~~ |
| ~~Bovine/cattle liver~~  ~~(dairy)~~ | ~~0.21~~ | ~~3~~ | ~~0.16~~ | ~~0.16~~ | ~~0.024~~ | ~~0.056~~ | ~~0.060~~ | ~~1.0 (Reg. (EU) 2019/88)~~  ~~0.03 (Reg. (EU) 2025/158~~ | ~~1~~ |
| ~~0.63~~ | ~~3~~ | ~~0.45~~ | ~~0.68~~ |
| ~~2.13~~ | ~~3~~ | ~~2.43~~ | ~~2.81~~ |
| ~~Bovine/cattle kidney~~  ~~(dairy)~~ | ~~0.21~~ | ~~3~~ | ~~0.24~~ | ~~0.26~~ | ~~0.035~~ | ~~0.092~~ | ~~0.10~~ | ~~1.0~~ | ~~1~~ |
| ~~0.63~~ | ~~3~~ | ~~0.75~~ | ~~0.91~~ |
| ~~2.13~~ | ~~3~~ | ~~2.55~~ | ~~2.70~~ |
| ~~Bovine/cattle Milk~~  ~~(dairy)~~ | ~~0.031~~ | ~~0.074~~ | ~~0.21~~ | ~~3~~ | ~~0.07~~~~(e)~~ | ~~N/A~~ |  | | ~~0.010~~ | ~~0.025~~ | ~~0.030~~ | ~~0.20~~ | ~~1~~ |
| ~~0.63~~ | ~~3~~ | ~~0.24~~~~(e)~~ | ~~N/A~~ |
| ~~2.13~~ | ~~3~~ | ~~1.09~~~~(e)~~ | ~~N/A~~ |
| ~~Poultry~~~~(g)~~ ~~meat~~  ~~(layer)~~ | ~~0.007~~ | ~~0.020~~ | ~~0.079~~ | ~~10~~ | ~~<0.02~~ | ~~<0.02~~ | ~~<0.020~~ | ~~<0.020~~ | ~~0.020~~ | ~~0.020\*~~ | ~~1~~ |
| ~~0.240~~ | ~~10~~ | ~~0.034~~ | ~~0.039~~ |
| ~~0.821~~ | ~~10~~ | ~~0.084~~ | ~~0.090~~ |
| ~~Poultry~~~~(g)~~ ~~fat~~  ~~(layer)~~ | ~~0.079~~ | ~~10~~ | ~~<0.02~~ | ~~<0.02~~ | ~~<0.020~~ | ~~<0.020~~ | ~~0.020~~ | ~~0.020\*~~ | ~~1~~ |
| ~~0.240~~ | ~~10~~ | ~~<0.02~~ | ~~<0.02~~ |
| ~~0.821~~ | ~~10~~ | ~~0.022~~ | ~~0.023~~ |
| ~~Poultry~~~~(g)~~ ~~liver~~  ~~(layer)~~ | ~~0.079~~ | ~~10~~ | ~~0.12~~ | ~~0.15~~ | ~~0.011~~ | ~~0.038~~ | ~~0.040~~ | ~~0.10\*~~ | ~~1~~ |
| ~~0.240~~ | ~~10~~ | ~~0.24~~ | ~~0.27~~ |
| ~~0.821~~ | ~~10~~ | ~~0.55~~ | ~~0.58~~ |
| ~~Eggs~~~~(g)~~  ~~(layer)~~ | ~~0.007~~ | ~~0.020~~ | ~~0.079~~ | ~~10~~ | ~~0.039~~ | ~~0.041~~ | ~~0.003~~ | ~~0.010~~ | ~~0.015~~ | ~~0.020\*~~ | ~~1~~ |
| ~~0.240~~ | ~~10~~ | ~~0.103~~ | ~~0.11~~ |
| ~~0.821~~ | ~~10~~ | ~~0.33~~ | ~~0.36~~ |

(R): Reference: xxxxx 1999; Study No 98514428 & xxxxx 1999; Report No RD-09988

~~Remark: Information on ongoing negotiations were provided by the applicant. For the time being, this is considered to be sufficient. The LoA needs to be provided to MSs in the frame of the product authorisation procedure.~~

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

n.r.: Not reported

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

(a): Based on nine 562-688 kg lactating cows consuming 6, 18 and 60 mg acetamiprid per kg DM per day (mg/kg DM/day).

(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

(d): The median conversion factor for enforcement to risk assessment.

(e): Mean residue level from day 1 until day 28 (3 cows, 11 sampling days).

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

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

Conclusion on feeding studies

The livestock dietary burden for acetamiprid has been updated, taking into account the previous dietary burden calculated by EFSA (~~2022~~ 2024) together with the uses presented in this dossier and the newly proposed residue definition for leafy and fruit crops (EFSA, 2024). Based on the proposed GAP, residues arising from the intended uses do not modify the most recent animal dietary burden for acetamiprid calculated by EFSA (~~2022~~ 2024). The results of the feeding studies in ruminants and poultry and the results of the dietary burden calculation (see Table 7.2‑13), were, for completeness, used to calculate the MRLs for pigs, ruminants (cattle and sheep) and poultry. The intended uses of acetamiprid in the product ADM.00150.I.2.A do not lead to an exceedance of the existing EU MRL for animal commodities.

Residues in bovine liver based on the current dietary burden do not exceed the lowered MRL of 0.03 mg/kg set under Reg, (EU) 2025/158 that enters into force on 19/08/2025.

It should be noted that the new Commission Regulation (EU) 2025/1212 of 24 June 2025 has already been published in the Official Journal of the European Union. This Regulation enters into force on 20 August 2025. The values of MRL for animal commodities will be the same as under the Reg. (EU) 2025/158.

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| **Evaluator comments:**  Data presented by Applicant in point 7.2.4 have been accepted and are sufficient to support the proposed uses.  Since proposed uses of ADM.00150.I.2.A/Leaxo and their by-products might be fed to livestock, the impact of the intended uses on the livestock exposure needs to be assessed.  An actual calculation of the dietary burden is provided in Table 7.2-11. The input values were taken from EFSA (2011, 2012, 2018, 2022) as well as the uses under consideration. The calculated dietary burden for acetamiprid was found to exceed the trigger value of 0.1 mg/kg DM (or 0.004 mg/kg bw/d, respectively) for all groups of livestock. Therefore, further investigation of residues is required.  The calculated dietary burden was then compared to the intakes considered to derive the current MRLs for animal commodities. No residues above the MRLs of acetamiprid in tissues, milk and eggs have to be expected after application of ADM.00150.I.2.A/Leaxoaccording to the intended GAP uses.  No further data are required |

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

#### Available data for all crops under consideration

A new processing study is submitted in the framework of this application. This study is summarized in the table below. The detailed results are presented in Appendix 2.

Table 7.2‑14: Overview of the available processing studies

| Processed commodity | Number of studies | | Median PF (a) | Median CF (b) | Comments | Reference |
| --- | --- | --- | --- | --- | --- | --- |
| **EU data** | | | | | | |
| **Enforcement residue definition:** Acetamiprid | | | | | | |
| Orange, peel | 2 | 2.87 | | 1 | - | Fraschini C., 1998a  Report No SIP1124  Fraschini C., 1998b  Report No SIP1128  Greece, 2001 |
| Orange, pulp | 2 | 0.21 | | 1 | - |
| Orange, juice | 1 | 0.13 | | 1 | - | Fraschini C., 1998a  Report No SIP1124  Fraschini C., 1998b  Report No SIP1128  Greece, 2001  EFSA, 2011, updated 2012 |
| Apple, juice | 2 | 0.80 | | 1 | - | Kowite W.J., 1999  Report No 97512650  Venet C., Barriere I., 2000  Report No R&D/CRLD/AN/mba/0015360  The Netherlands, 2015, updated 2016  EFSA, 2011, updated 2012; 2016b |
| Apple, wet pomace | 2 | 1.30 | | 1 | - |
| Apple, puree | 1 | 0.73 | | 1 | - | Venet C., Barriere I., 2000  Report No R&D/CRLD/AN/mba/0015360  The Netherlands, 2015, updated 2016  EFSA, 2011, updated 2012 |
| Gherkins/canned gherkins | 4 | 0.37 | | 1 | - | EFSA, 2016a |
| Cotton seed, hulls | 1 | 0.80 | | 1 | - | Macy, L. J., 1999  Report No 97512105  Greece, 2001 |
| Cotton seed, refined oil(c) | 1 | 0.04 | | 1 | - | Macy, L. J., 1999  Report No 97512105  Greece, 2001  EFSA, 2011, updated 2012 |
| Cotton seed, meal(c) | 1 | 0.40 (c) | | 1 | - |
| Olives/raw oil | 6 | 0.13 | | 1 | - | EFSA, 2016a  EFSA, 2018 |
| Olives/canned olives | 4 | 0.15 | | 1 | - | EFSA, 2016a |
| Olives/cake | 1 | 1.36 | | 1 | - |
| **New data** | | | | | | |
| **Enforcement residue definition:** Acetamiprid | | | | | | |
| Apple, juice | 2 | | 0.48 | 1 | - | KCP 8.5.3/01  Roussel Ch. H., 2014a  Report No ChR-14-17311/ R-34915 |
| Apple, wet pomace | 2 | | 1.08 | 1 | - |
| Apple, dry pomace | 2 | | 3.73 | 1 | - |
| Apple, puree | 2 | | 0.60 | 1 | - |
| Apple, washed | 2 | | 0.68 | 1 | - |
| Washing water | 2 | | 0.05 | 1 | - |
| Apple, dried | 2 | | 3.15 | 1 | - |
| **Combined data** | | | | | | |
| **Enforcement residue definition:** Acetamiprid | | | | | | |
| Apple, juice | 4 | 0.61 | | 1 | - | Kowite W.J., 1999  Report No 97512650  Venet C., Barriere I., 2000  Report No R&D/CRLD/AN/mba/0015360 The Netherlands, 2015, updated 2016  EFSA, 2011, updated 2012; 2016b  KCP 8.5.3/02  Roussel Ch. H., 2014  Report No ChR-14-17311 / R-34915 |
| Apple, wet pomace | 4 | 1.25 | | 1 | - |
| Apple, puree | 3 | 0.62 | | 1 | - | Venet C., Barriere I., 2000  Report No R&D/CRLD/AN/mba/0015360  The Netherlands, 2015, updated 2016  EFSA, 2011, updated 2012  KCP 8.5.3/02  Roussel Ch. H., 2014  Report No ChR-14-17311 / R-34915 |

(a) The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

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

(c) Extrapolation of the processing factor for cotton seed meal to rape seed meal is possible, according to OECD Guideline 508, Table 1.

#### Conclusion on processing studies

Processing studies investigating the magnitude of residues in processed commodities are presented in the DAR (Greece, 2001) and the RAR (The Netherlands, 2015, updated 2016).

New processing studies have been performed in apple and new processing factors were derived for this crop. Combined processing factors were calculated in the case that both EU data and data from the new study exist for the respective commodities.

Further processing studies are not considered necessary to support the intended uses of acetamiprid in the product ADM.00150.I.2.A (200 g/L acetamiprid), since the magnitude of residues in processed commodities was sufficiently investigated in the studies presented above.

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| **Evaluator comments:**  Information given by the Applicant is sufficient.  Residues in most of the intended crops (potato, oilseed rape, barley, oat, maize, wheat, triticale, spelt, rye, sunflower and sugar beet) do not exceed the trigger value for processing studies (<0.1 mg/kg). For these crops the processing studies are not required.  For apples, the Applicant has submitted processing study on apples (Roussel, Ch. H. 2014; Study number: ChR-14-17311, see Appendix 2, point A 2.1.5.2.1). The study has been evaluated and accepted in Registration Report, Section 4 for MCW-2222, Adama Makhteshim Ltd. (10.05.2018).  Residues of acetamiprid were analysed in processed samples / processing fractions (dry apples, washing water, apple juice, apple puree, wet apple pomaces and dry apple pomaces).  Acetamiprid residues in washed fruits, washing water, wet pomaces, dry pomaces, juice, puree and dried apples ranged between 0.24 – 0.26 mg/kg, < 0.01 – 0.03 mg/kg, 0.33 – 0.47 mg/kg, 1.36 – 1.4 mg/kg, 0.17 – 0.18 mg/kg, 0.21 – 0.23 mg/kg and 1.15 – 1.18 mg/kg, respectively.  The average transfer factor is 3.73 for dry pomace and 3.15 for dried fruits which show a concentration of acetamiprid during drying.  The residues in other processed products are likely stable.  No further data are required. |

### Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation. Studies on magnitude of residues in succeeding crops are available and are summarised hereafter.

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

Available data

No new data submitted in the framework of this application. As residues ≥0.01 mg/kg for edible plant parts and ≥0.05 mg/kg for feed-relevant plant parts were detected in the available confined rotational crop studies, a field rotational crop study is required. Such a study is available and was previously evaluated (Raufer 2013, Report No RD-02495N2). As the study remains under data protection, the applicant has conducted its own study (Semrau 2017, Report No S15-02364/R-35750) for the purpose of data matching. Nevertheless, this study has previously been evaluated at EU level (Austria, 2021 updated 2022; EFSA, 2022) and is therefore also included in the table below for reference.

Table 7.2‑15: Summary of available studies in field rotational crops

| Primary crop | Rate (kg a.s./ha)  (GS at application or PHI) | Residue levels in succeeding crops | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Succeeding crop group | Succeeding crop1) | Sowing intervals  (DAT) | Residues2)  (mg/kg) | Reference /  Remarks |
| **EU data** | | | | | | |
| n.a.3) | 0.302-0.322 (bare soil) | Leafy vegetables | Spinach (leaves) | 31-32  72-73  122  367 | <0.01  <0.01  <0.01  <0.01 | Raufer B., 2013  Report No RD-02495N2\*\*  The Netherlands, 2015, updated 2016  EFSA, 2016b  EFSA, 2018  EFSA, 2021 |
| 0.282-0.313 (bare soil) | Root and tuber vegetables | Turnip (plant, top and roots) | 29  69  119  410 | <0.01  <0.01  <0.01  <0.01 |
| 0.291-0.314 (bare soil) | Cereals | Wheat (forage, hay, grain and straw) | 30-32  63-70  119-132  364-377 | <0.01  <0.01  <0.01  <0.01 |
| n.a.3) | 0.291-0.313 (bare soil) | Root and tuber vegetables | Turnip (plant, top and roots) | 30  69  120  363 | <0.01  <0.01  <0.01  <0.01 | The Netherlands, 2015, 2016  Raufer, B., 2014  Report No RD-02930\*\*  EFSA, 2016a  EFSA, 2018  EFSA, 2021 |
| n.a.3) | 0.200 (bare soil) | Leafy vegetables | Spinach (leaves) | 30  120  270 | <0.01  <0.01  <0.01  <0.01 | Semrau, J., 2017  Report No S15-02364  Austria, 2021, updated 2022  EFSA, 2022 |
| Root and tuber vegetables | Radish (roots and tops) | <0.01  <0.01  <0.01  <0.01 |
| Cereals | Wheat (grain and straw) | <0.01  <0.01  <0.01  <0.01 |
| **New data** | | | | | | |
| No new data was submitted. | | | | | | |

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

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

3) Application to bare soil

n.a. not applicable

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

Conclusion on rotational crops studies

EFSA (2022) concluded: “The possible transfer of acetamiprid residues to crops that are grown in crop rotation has been assessed in the EU pesticides peer review (EFSA, 2016b). The available studies demonstrated that significant residues (residues below 0.01 mg/kg) of acetamiprid or the metabolites IM-14 and IM-1-5 are expected in succeeding crops (turnip, spinaches and wheat) planted in soil treated at 300 g a.s./ha.

Moreover, a new field rotational study was provided in the context of the <present> application (Austria, 2021). In this new study, acetamiprid was applied to bare soil at a target rate of 200 g a.s./ha and crops were sown at different plant-back intervals (29–32, 69–73, 119–132 and 363–410 days). Succeeding crops (radish, spinach and wheat) as well as soil were analysed for residues of acetamiprid and its soil persistent metabolites IM-1-4 and IM-1-5. Residue levels for acetamiprid were not detectable (<0.003 mg/kg) and residues for its metabolites were below the LOQ (<0.01 mg/kg) or also not detectable with only IM-1-5 at the LOQ level in radish leaves 160 days after application. The results of this new rotational field study are in line with the results of the previous study assessed in the framework of the EU pesticides peer review (EFSA, 2016) with no residues of acetamiprid and its soil persistent metabolites (IM-1-4 and IM-1-5) expected in rotational crops.”

For the intended uses of acetamiprid in the product ADM.00150.I.2.A (200 g/L acetamiprid) on the crops presented in the GAP, no residues are expected in rotational crops. No further studies are required.

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| **Evaluator comments:**  The presented data in EFSA (2016) is from the protected study of Raufer B., 2013 and 2014 (Report No RD-02495N2 and Report No RD-02930) (see Acetamiprid, List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the renewal of the active substance, October 2016, RMS: The Netherlands), so zRMS-PL does not accept the reference to this study and new data was required to identify the plant uptake of a metabolite unique for calcareous soils. Equivalent study has been provided by the Applicant.  According to the evaluation presented in “Matching active substance data necessary for the renewal of the approval of acetamiprid” (RMS: The Netherlands, June 2023) the endpoints seem to be equivalent to studies RD-02495N2 and RD-02930 (Raufer, 2013 and 2014). RMS - The Netherlands concluded that *“A GLP-compliant study conducted according to OECD 504 was provided by the applicant. Data matching sufficiently demonstrated.”*  The study of Semrau, J., 2017 (Report No S15-02364) has been evaluated by Austria, 2021 and presented in EFSA, 2022.  Results:  Two rotational crop trials were conducted during 2015 and 2016 in Germany and in France to determine residue levels of acetamiprid and its metabolites IM-1-4 and IM-1-5 in soil and in the raw agricultural commodities: root and tuber vegetables (radish), leafy vegetables (spinach) and cereals (wheat) grown as rotational crops at harvest after one application of MCW-2222 to bare soil. Each trial comprised three plant back intervals of nominal 30, 120 and 270 days.  Residue levels for acetamiprid were not detectable (<0.003 mg/kg) and residues for its metabolites were at (IM-1-5, radish leaves, 160 DAA) or below the LOQ (<0.01 mg/kg) or also not detectable.  For the intended uses of acetamiprid in the product ADM.00150.I.2.A , no residues are expected in rotational crops.  Taking into account the above information, zRMS does not propose a restriction with regard to the succeeding crops. No waiting periods beyond normal agricultural practice are proposed for succeeding crops to be planted.  Additional studies are not required. |

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

A new study investigating the potential residues of acetamiprid in honey following application to phacelia is provided. This study is summarised in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.2‑16: Summary new data supporting the intended uses of ADM.00150.I.2.A 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)  (a) | MRL compliance |
| Honey | New trials  (KCP 8.10.1/01) | SEU | Trials GAP: 2 x 0.079-0.085 kg as/ha, BBCH 61-65, PHI 10-31d, outdoor  E/RA: <0.010, 0.016, 0.047, 0.143 | 0.032 | 0.143 | 0.300 | ~~0.30~~  0.05\* (Reg. (EU) 2019/88 and 2025/158)  0.3 ~~(PLAN/2024/2431~~ (Reg. (EU) 2025/1212) | ~~Yes~~  No  Yes |

(a) Source of EU MRL: ~~SANTE/11278/2021 (pending)~~ Reg. (EU) 2019/88 and 2025/158.

Following a positive vote at the February 2025 SCOPAFF, PLAN/2024/2431 is now presented in the EU Commission MRL database and expected to enter into force in July/August 2025.

The new Commission Regulation (EU) 2025/1212 of 24 June 2025 has already been published in the Official Journal of the European Union. This Regulation enters into force on 20 August 2025. The MRL for honey has been raised from 0.05\* mg/kg to 0.3 mg/kg. The current assessment of residues in honey based on the proposed GAPs for ADM.00150.I.2.A / Leaxo shows that all of the intended uses on oilseed rape are in compliance with the MRL of 0.3 mg/kg.

Results and discussions

Based on the four honey residue trials, the calculated STMR, HR and MRL were 0.032 mg/kg, 0.143 mg/kg, and 0.3 mg/kg, respectively. The calculated MRL does ~~not~~ exceed the EU MRL of ~~0.3~~ 0.05 mg/kg (Reg. (EU) 2019/88 and 2025/158). Regulation (EU) 2025/1212 raises the honey MRL to 0.3 mg/kg effective from 20/08/2025 and will cover the full range of proposed uses on oilseed rape.

Conclusion

Residue study in honey showed that impending EU MRL is notexceeded based on the intended uses of acetamiprid in the product ADM.00150.I.2.A (200 g/L acetamiprid) on the crops presented in the GAP.

~~The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of ADM.00150.I.2.A. Therefore, other special studies are not needed.~~

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| **Evaluator comments:**  New study for the determination of residues of acetamiprid in samples of honey specimens following exposure of honeybees to Phacelia after two foliar applications of Acetamiprid 200 SL at the target rate of 0.4 L/ha per application corresponding to 80 g acetamiprid/ha per application was conducted. The target application growth stage was the beginning of flowering (BBCH 61) for the first application. The second application was performed 7 +/-1 days after the first one.  After two foliar applications of Acetamiprid 200 SL on phacelia, residues in honey ranged from below LOQ (0.01 mg/kg) to 0.143 mg/kg in treated specimens (in three of the four trials residues were below the existing MRL of 0.05 mg/kg (<0.01, 0.016 and 0.047 mg/kg). Only in one trial was a residue measured at a level above the MRL (0.143 mg/kg) (Reg. (EU) 2019/88 and 2025/158). The study is acceptable (more details – see Appendix 2).  It should be noted that the new Commission Regulation (EU) 2025/1212 of 24 June 2025 has already been published in the Official Journal of the European Union. This Regulation enters into force on 20 August 2025. The MRL for honey has been raised from 0.05\* mg/kg to 0.3 mg/kg and will cover the full range of proposed uses on oilseed rape.  **Conclusion:**  The current assessment of residues in honey based on the proposed GAPs for ADM.00150.I.2.A / Leaxo shows that all of the intended uses on oilseed rape are in compliance with the MRL of 0.3 mg/kg.  ~~All trials are highly overdosed in comparison with the proposed critical GAPs for Leaxo for apples (1x80 g as/ha) and oilseed rape (2x60 g as/ha).~~  ~~Applying the principles of proportionality, the acetamiprid residue values for apples and oilseeds are respectively:~~  ~~Apples:~~  ~~0.16 kg/ha – 0.143 mg/kg~~  ~~0.08 kg/ha – x (mg/kg)~~  ~~x = 0.0715 mg/kg~~  ~~Oilseed rape:~~  ~~0.16 kg/ha – 0.143 mg/kg~~  ~~0.12 kg/ha – x (mg/kg)~~  ~~x = 0.107 mg/kg~~  ~~It should be highlighted that proposed uses on apples are always after flowering stage (from BBCH 70), therefore the potential occurrence of residues in honey should not be considered for the proposed uses on apples.~~  ~~Available results show that the in force MRL of acetamiprid on honey of 0.05\* mg/kg (Reg. (EU) 2019/88 and 2025/158) is potentially exceeded. In our opinion, until the new MRL has been set for honey, use on oilseed rape and apples cannot be authorized.~~  ~~For proposed lower application rate for oilseed: 1 x 40 – 48 g as/ha applying the principles of proportionality, the acetamiprid residue values for oilseeds are respectively :~~  ~~Oilseed rape:~~  ~~0.16 kg/ha – 0.143 mg/kg~~  ~~0.048 kg/ha – x (mg/kg)~~  ~~x = 0.043 mg/kg~~  ~~In this case,~~ ~~for lower dose for oilseed rape (max 1 x 40 – 48 g as/ha) the in force MRL of acetamiprid on honey of 0.05\* mg/kg (Reg. (EU) 2019/88 and 2025/158) will not be exceeded and this use can be accepted.~~  ~~Additional remark:~~  ~~EFSA concluded in Statement on the toxicological properties and maximum residue levels of acetamiprid and its metabolites (EFSA Journal. 2024;22:e8759) that~~ *~~„Furthermore, for plums (0.04 mg/kg), poppy seeds (0.3 mg/kg), mustard seed (0.15 mg/kg) and~~* ***~~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.”~~***  ~~The European Commission MRL database now indicates the voted MRL of 0.3 mg/kg (PLAN/2024/2431) which is expected to enter into force in July/August 2025 and will cover the full range of proposed uses on oilseed rape.~~  ~~The current assessment of residues in honey based on the proposed GAPs for ADM.00150.I.2.A / Leaxo shows that all of the intended uses would be in compliance with the MRL of 0.3 mg/kg.~~  **~~According to the harmonization arrangements of the Ministry of Agriculture and Rural Development of 14 May 2025 regarding the requirement for honey, the use of Leaxo on oilseed rape at a higher dose of 2 x 60 g as/ha can be accepted under the following condition:~~**  *~~"In view of the ongoing process of establishing MRL values for acetamiprid in honey and the application submitted by the authorisation holder to increase the MRL to 0.3 mg/kg, in accordance with Article 6 of Regulation (EC) No 396/2005, it will be necessary to verify the assessment of the Leaxo dossier in this regard for the uses covered by this decision after the entry into force of the new MRL. Failure to submit the relevant information or failure to evaluate it positively may result in a change to the conditions of this authorisation."~~* |

### 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).

#### Input values for the consumer risk assessment

A chronic dietary exposure assessment (IEDI) was performed for acetamiprid covering all commodities of plant and animal origin. Input values are summarised in the table below. Reference is made to the STMR values calculated within this submission and also to those previously assessed by EFSA that correspond to a substantive EU MRL (summarised in full in EFSA, 2022). Where the STMR from a previous submission is higher than the STMR calculated according to the intended GAPs in this submission, the higher value is used. If no STMR is available for a crop then the EU MRL/LOQ is used.

For the acute risk assessment an IESTI has been performed based on the HR values derived based on the GAPs in the current submission. Only the crops under consideration are included in the risk assessment and although higher HR values may have been identified in previous submissions the IESTI calculation is only made based on the HRs derived from the intended GAPs. ~~The table below indicates the previously assessed HR values for completeness. Values given in italics are provided for information but not included in the assessment for the reason given in the table. Where the STMR and HR values derived for the GAPs under consideration are the critical EU values (e.g. potato, maize/corn) a separate row summarising the previous STMR and HR is not included.~~

Intakes of apple based on the GAP in the original submission are not included since acute exposure exceeds the ARfD and the MRL was lowered during the recent EFSA review (EFSA, 2024). A use on apples is therefore no longer sought as part of this submission.

~~Two scenarios are assessed; (1) including the residues for apple based on the current submission for acute and chronic risk assessment, and (2) removing apple from the acute risk assessment and relying on previously assessed data (EFSA, 2018) for apple for the chronic assessment. The second assessment (scenario 2) is performed since acute intakes for apple, based on scenario 1, exceed the ARfD.~~

Table 7.2‑17: Input values for the consumer risk assessment

| **Commodity** | **Chronic risk assessment** | | **Acute risk assessment** | |
| --- | --- | --- | --- | --- |
| **Input value (mg/kg)** | **Comment** | **Input value (mg/kg)** | **Comment** |
| **Risk assessment residue definition 1:** Acetamiprid  (applicable to pulses/oilseeds, root crops, cereals/grass and honey) | | | | |
| Potatoes | 0.01 | STMR-RAC  (current submission) | 0.01 | HR-RAC  (current submission) |
| Rapeseeds/canola seeds | 0.03 | STMR-RAC  (EFSA, 2018) | 0.03 | STMR-RAC  (current submission) |
| Barley, oat | 0.01 | STMR-RAC  (current submission) | 0.01 | STMR-RAC  (current submission) |
| Maize | 0.01 | STMR-RAC  (current submission) | 0.01 | STMR-RAC  (current submission) |
| Rye, wheat | 0.01 | STMR-RAC  (current submission) | 0.01 | STMR-RAC  (current submission) |
| Sugar beet root | 0.01 | STMR-RAC  (current submission) | 0.01 | HR-RAC  (current submission) |
| Honey | 0.05 | STMR-RAC  (EFSA, 2022) | 0.143 | HR-RAC  (current submission) |
| Garlic | 0.01 | STMR-RAC  (FAO/WHO, 2011) | Acute assessment performed only for the crops under consideration. | |
| Onions | 0.01 | STMR-RAC  (EFSA, 2018) |
| Beans (with pods) | 0.06 | STMR-RAC  (EFSA, 2018) |
| Beans (without pods) | 0.03 | STMR-RAC  (FAO/WHO, 2011) |
| Peas (with pods) | 0.06 | STMR-RAC  (EFSA, 2018) |
| Peas (without pods) | 0.03 | STMR-RAC  (FAO/WHO, 2011) |
| Beans, lentils, peas, lupins/lupini seeds, other pulses | 0.02 | STMR-RAC  (EFSA, 2018) |
| Linseeds, gold of pleasure seeds | 0.01 | STMR-RAC  (EFSA, 2022) |
| Poppy seeds | 0.03 | STMR-RAC  (EFSA, 2021) |
| Soyabeans | 0.01 | STMR-RAC  (FAO/WHO, 2024) |
| Mustard seeds | 0.03 | STMR-RAC  (EFSA, 2021) |
| Cotton seeds | 0.09 | STMR-RAC  (FAO/WHO, 2011) |
| Anise/aniseed, black caraway/black cumin, celery seed, coriander seed, cumin seed, dill seed, fennel seed, fenugreek seed, nutmeg, other spices (seeds) | 0.57 | STMR-RAC  (FAO/WHO, 2020) |
| Cardamom, peppercorn (black, green and white) | 0.1 | Codex MRL  (FAO/WHO, 2015) |
| Risk assessment residue definition 2: Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid  (applicable to fruits, leafy crops and commodities of animal origin) | | | | |
| Grapefruits, oranges, lemons, limes, mandarins, other citrus fruit | 0.006 | STMR-RAC\*CF\*PeF  (EFSA, 2018; 2024) | Acute assessment performed only for the crops under consideration. | |
| Almonds, Brazil nuts, cashew nuts, chestnuts, coconuts, hazelnuts/cobnuts, macadamia, pecans, pine nut kernels, walnuts, other tree nuts | 0.012 | STMR-RAC\*CF  (EFSA, 2018; 2024) |
| Pistachios | 0.399 | STMR-RAC\*CF  (FAO/WHO, 2021; EFSA, 2024) |
| Apples, pears | 0.07 | STMR-RAC\*CF  (EFSA, 2024) |
| Quinces | 0.036 | STMR-RAC\*CF  (EFSA, 2024) |
| Medlars | 0.079 | STMR-RAC\*CF  (EFSA, 2024) |
| Loquats/Japanese medlars, other pome fruit | 0.278 | STMR-RAC\*CF  (EFSA, 2018, 2024; FAO/WHO, 2011) |
| Apricots, peaches | 0.030 | STMR-RAC\*CF  (EFSA, 2024) |
| Cherries (sweet) | 0.260 | STMR-RAC\*CF  (EFSA, 2024) |
| Plums | 0.012 | STMR-RAC\*CF  (EFSA, 2021, 2024) |
| Table grapes, wine grapes | 0.024 | STMR-RAC\*CF  (EFSA, 2024) |
| Strawberries | 0.121 | STMR-RAC\*CF  (EFSA, 2024; FAO/WHO, 2011) |
| Blackberries, raspberries | 0.212 | STMR-RAC\*CF  (EFSA, 2024) |
| Dewberries, other can fruit | 0.774 | STMR-RAC\*CF  (EFSA, 2024; FAO/WHO, 2011) |
| Blueberries, cranberries, gooseberries (green, red and yellow) | 0.247 | STMR-RAC\*CF  (EFSA, 2024) |
| Rose hips, mulberries | 0.774 | STMR-RAC\*CF  (EFSA, 2024; FAO/WHO, 2011) |
| Elderberries | 0.206 | STMR-RAC\*CF  (EFSA, 2024; FAO/WHO, 2011) |
| Figs | 0.012 | STMR-RAC\*CF  (EFSA, 2018. 2024) |
| Table olives | 0.290 | STMR-RAC\*CF  (EFSA, 2024) |
| Granate apples/pomegranates | 0.010 | STMR-RAC (LOQ) |
| 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, other solanacea | 0.048 | STMR-RAC\*CF  (EFSA, 2024; FAO/WHO, 2011) |
| Cucumbers, courgettes | 0.024 | STMR-RAC\*CF  (EFSA, 2024) |
| Gherkins | 0.169 | STMR-RAC\*CF  (EFSA, 2018. 2024) |
| Other cucurbits – edible peel | 0.061 | STMR-RAC\*CF  (EFSA, 2018. 2024) |
| Melons, pumpkins, watermelons | 0.012 | STMR-pulp\*CF  (EFSA, 2024) |
| Other cucurbits – inedible peel | 0.061 | STMR-RAC\*CF  (EFSA, 2018; 2024) |
| Sweet corn | 0.012 | Codex MRL\*CF  (FAO/WHO, 2015; EFSA, 2024) |
| Broccoli, cauliflower | 0.022 | STMR-RAC\*CF  (EFSA, 2024) |
| Other flowering brassica | 0.043 | STMR-RAC\*CF  (EFSA, 2024; FAO/WHO, 2011) |
| Brussels sprouts | 0.029 | STMR-RAC\*CF  (EFSA, 2018; 2024) |
| Head cabbages | 0.014 | STMR-RAC\*CF  (EFSA, 2024) |
| Lamb’s lettuce/corn salads, Roman rocket/rucola | 0.706 | STMR-RAC\*CF  (EFSA, 2024) |
| Cress and other sprouts and shoots, land cress, baby leaf crops (including brassica species) | 1.20 | STMR-RAC\*CF  (EFSA, 2018; 2024) |
| Red mustards | 0.216 | STMR-RAC\*CF  (EFSA, 2024) |
| Purslanes, other spinach and similar | 0.288 | STMR-RAC\*CF  (EFSA, 2018; 2024) |
| Chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil and edible flowers, laurel/bay leaves, tarragon, other herbs | 1.20 | STMR-RAC\*CF  (EFSA, 2018; 2024) |
| Asparagus | 0.01 | STMR-RAC (LOQ) |
| Globe artichokes | 0.11 | STMR-RAC  (EFSA, 2018, 2024) |
| Olives for oil production | 0.968 | STMR-RAC\*CF  (EFSA, 2018; 2024) |
| Swine, bovine, sheep, goat, equine, other farmed animals: muscle/meat | 0.02 | STMR-RAC  (FAO/WHO, 2015) |
| Swine, bovine, sheep, goat, equine, other farmed animals: fat tissue | 0.02 | STMR-RAC  (FAO/WHO, 2015) |
| Swine, sheep, goat, equine, other farmed animals: liver | 0.11 | STMR-RAC  (FAO/WHO, 2015) |
| Swine, bovine, sheep, goat, equine, other farmed animals: kidney | 0.11 | STMR-RAC  (FAO/WHO, 2015) |
| Swine, sheep, goat, equine, other farmed animals: edible offal (other than liver and kidney) | 0.11 | STMR-RAC  (FAO/WHO, 2015) |
| Bovine: liver, edible offal (other than liver and kidney) | 0.02 | STMR-RAC  (EFSA, 2024) |
| Poultry: muscle/meat, fat tissue | 0.02 | LOQ  (EFSA, 2018) |
| Poultry: liver | 0.1 | LOQ  (EFSA, 2018) |
| Milks | 0.02 | STMR-RAC  (FAO/WHO, 2015) |
| Eggs | 0.02 | LOQ  (EFSA, 2018) |
| All other commodities of plant and animal origin | MRL | Regulation (EU) 2025/1212 |

| **~~Commodity~~** | **~~Chronic risk assessment~~** | | **~~Acute risk assessment~~** | |
| --- | --- | --- | --- | --- |
| **~~Input value (mg/kg)~~** | **~~Comment~~** | **~~Input value (mg/kg)~~** | **~~Comment~~** |
| ~~Risk assessment residue definition 1 (in plant commodities): acetamiprid~~ | | | | |
| ~~Apples~~  ~~[Scenario 1]~~ | *~~0.07~~* | *~~Less critical STMR (from EFSA 2018, covered by higher input value from current submission in the row below)~~* | *~~0.21~~* | *~~More critical HR (from EFSA 2018 but acute risk assessment performed based on HR from current submission in the row below)~~* |
| ~~Apples~~ *~~(new)~~*  ~~[Scenario 1]~~ | ~~0.097~~  ~~(0.080 x 1.21)~~ | ~~STMR x CF~~  ~~(current submission)~~ | ~~0.25~~  ~~(0.21 x 1.21)~~ | ~~HR x CF~~  ~~(current submission)~~ |
| ~~Potatoes~~ *~~(new)~~* | ~~0.010~~ | ~~STMR~~  ~~(current submission)~~ | ~~0.010~~ | ~~HR~~  ~~(current submission)~~ |
| ~~Rapeseeds/~~  ~~Canola seeds~~ | ~~0.03~~ | ~~More critical STMR~~  ~~(EFSA, 2018)~~ | ~~0.03~~ | ~~More critical STMR~~~~2)~~  ~~(EFSA, 2018)~~ |
| ~~Rapeseeds/~~  ~~Canola seeds~~ *~~(new)~~* | *~~0.025~~* | *~~STMR~~*  *~~(current submission)~~* | *~~0.025~~* | *~~STMR~~*  *~~(current submission)~~* |
| ~~Barley~~ | ~~0.18~~ | ~~More critical STMR~~  ~~(EFSA, 2018)~~ | ~~0.18~~ | ~~More critical STMR~~~~2)~~  ~~(EFSA, 2018)~~ |
| ~~Barley~~ *~~(new)~~* | *~~0.010~~* | *~~STMR (from current submission, but covered by higher input value from EFSA 2018 in the row above)~~* | *~~0.01~~* | *~~STMR~~~~2)~~ ~~(current submission)~~* |
| ~~Maize/Corn~~ *~~(new)~~* | ~~0.010~~ | ~~STMR~~  ~~(current submission)~~ | ~~0.010~~ | ~~STMR~~~~2)~~  ~~(current submission)~~ |
| ~~Oat~~ | ~~0.01~~ | ~~STMR~~  ~~(EFSA, 2018)~~ | ~~0.01~~ | ~~STMR~~  ~~(EFSA, 2018)~~ |
| ~~Oat~~ *~~(new)~~* | ~~0.010~~ | ~~STMR~~  ~~(current submission)~~ | ~~0.01~~ | ~~STMR~~~~2)~~  ~~(current submission)~~ |
| ~~Rye~~ *~~(new)~~* | ~~0.010~~ | ~~STMR~~  ~~(current submission)~~ | ~~0.010~~ | ~~STMR~~~~2)~~  ~~(current submission)~~ |
| ~~Wheat~~ | ~~0.01~~ | ~~STMR~~  ~~(EFSA, 2018)~~ | ~~0.01~~ | ~~STMR~~  ~~(EFSA, 2018)~~ |
| ~~Wheat~~ *~~(new)~~* | ~~0.010~~ | ~~STMR~~  ~~(current submission)~~ | ~~0.010~~ | ~~STMR~~~~2)~~  ~~(current submission)~~ |
| ~~Sugar Beet root~~ *~~(new)~~* | ~~0.010~~ | ~~STMR~~  ~~(current submission)~~ | ~~0.010~~ | ~~HR~~  ~~(current submission)~~ |
| ~~Honey and other apiculture products (~~*~~new~~*~~)~~ | ~~0.032~~ | ~~STMR~~  ~~(current submission)~~ | ~~0.143~~ | ~~HR~~  ~~(current submission)~~ |
| ~~Citrus fruits~~ | ~~0.0069~~  ~~(0.190 x 0.03 x 1.21)~~ | ~~STMR-RAC x PeF x CF~~  ~~(EFSA, 2011, updated 2012)~~ | ~~Acute risk assessment only performed for the crops under consideration in this submission~~ | |
| ~~Tree nuts~~ | ~~0.012~~  ~~(0.01 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Apples~~  ~~[Scenario 2]~~ | ~~0.085~~  ~~(0.07 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Pears~~ | ~~0.085~~  ~~(0.07 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Pome fruits (except apples, pears)~~ | ~~0.28~~  ~~(0.23 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Apricots~~ | ~~0.27~~  ~~(0.22 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Cherries (sweet)~~ | ~~0.54~~  ~~(0.45 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Peaches~~ | ~~0.073~~  ~~(0.06 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Plums~~ | ~~0.012~~  ~~(0.01 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2011)~~ |
| ~~Grapes (table, wine)~~ | ~~0.11~~  ~~(0.09 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Strawberries~~ | ~~0.12~~  ~~(0.1 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Cane fruit~~ | ~~0.77~~  ~~(0.64 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Other small fruits and berries (except azaroles)~~ | ~~0.77~~  ~~(0.64 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Figs~~ | ~~0.012~~  ~~(0.01 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Bananas~~ | ~~0.60~~  ~~(0.101 x 0.49 x 1.21)~~ | ~~STMR-RAC x PeF x CF~~  ~~(EFSA, 2014)~~ |
| ~~Garlic, onions~~ | ~~0.01~~ | ~~STMR~~  ~~(EFSA, 2018)~~ |
| ~~Tomatoes~~ | ~~0.16~~  ~~(0.13 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2016)~~ |
| ~~Sweet peppers/bell peppers~~ | ~~0.12~~  ~~(0.10 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2011)~~ |
| ~~Aubergines/egg plants~~ | ~~0.048~~  ~~(0.04 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2011)~~ |
| ~~Okra~~ | ~~0.048~~  ~~(0.04 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Cucumbers, courgettes~~ | ~~0.073~~  ~~(0.06 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2011)~~ |
| ~~Gherkins~~ | ~~0.17~~  ~~(0.14 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Other cucurbits – edible peel~~ | ~~0.061~~  ~~(0.05 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Cucurbits – inedible peel~~ | ~~0.061~~  ~~(0.05 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Sweet corn~~ | ~~0.012~~  ~~(0.01 x 1.21)~~ | ~~LOQ x CF~~  ~~(EFSA, 2018)~~ |
| ~~Broccoli~~ | ~~0.043~~  ~~(0.03 x 1.44)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Cauliflower~~ | ~~0.029~~  ~~(0.02 x 1.44)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Other flowering brassica~~ | ~~0.043~~  ~~(0.03 x 1.44)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Brussels sprouts~~ | ~~0.029~~  ~~(0.02 x 1.44)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Head cabbages~~ | ~~0.029~~  ~~(0.02 x 1.44)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Lamb’s lettuce/corn salad, Cress and other sprout and shoots, Roman rocket/rucola, baby leaf crops (incl. Brassica species)~~ | ~~1.2~~  ~~(0.83 x 1.44)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Lettuces~~ | ~~0.71~~  ~~(0.49 x 1.44)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Escaroles/broad leaved endives~~ | ~~0.14~~  ~~(0.1 x 1.44)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Land cress, red mustards~~ | ~~1.2~~  ~~(0.81 x 1.44)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Spinaches and similar leaves~~ | ~~0.29~~  ~~(0.2 x 1.44)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Herbs and edible flowers~~ | ~~1.2~~  ~~(0.83 x 1.44)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Bean and peas (with pods)~~ | ~~0.06~~ | ~~STMR~~  ~~(EFSA, 2018)~~ |
| ~~Beans and peas (without pods)~~ | ~~0.03~~ | ~~STMR~~  ~~(EFSA, 2018)~~ |
| ~~Asparagus~~ | ~~0.37~~  ~~(0.26 x 1.44)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Globe artichokes~~ | ~~0.16~~  ~~(0.11 x 1.44)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Pulses~~ | ~~0.02~~ | ~~STMR~~  ~~(EFSA, 2018)~~ |
| ~~Cotton seeds~~ | ~~0.09~~ | ~~STMR~~  ~~(EFSA, 2018)~~ |
| ~~Olives for oil production~~ | ~~0.97~~  ~~(0.8 x 1.21)~~ | ~~STMR x CF~~  ~~(EFSA, 2018)~~ |
| ~~Seed spices~~ | ~~0.57~~ | ~~STMR~~  ~~(CXL (FAO, 2019))~~ |
| ~~All other commodities of plant origin~~ | ~~MRL~~~~1)~~ ~~x CF~~ | ~~Reg. (EU) 2019/88~~ |
| ~~Risk assessment definition 2 (in animal commodities): sum of acetamiprid and metabolite IM-2-1 (~~*~~N~~*~~-desmethyl-acetamiprid) expressed as acetamiprid~~ | | | | |
| ~~Swine, bovine, sheep, goat equine muscle/meat~~ | ~~0.02~~ | ~~STMR~~  ~~(EFSA, 2018; 2022)~~ | ~~0.27~~ | ~~HR~~  ~~(EFSA, 2018; 2022)~~ |
| ~~Swine, bovine, sheep, goat equine fat~~ | ~~0.02~~ | ~~STMR~~  ~~(EFSA, 2018; 2022)~~ | ~~0.16~~ | ~~HR~~  ~~(EFSA, 2018; 2022)~~ |
| ~~Swine, bovine, sheep, goat equine liver~~ | ~~0.11~~ | ~~STMR~~  ~~(EFSA, 2018; 2022)~~ | ~~0.89~~ | ~~HR~~  ~~(EFSA, 2018; 2022)~~ |
| ~~Swine, bovine, sheep, goat equine kidney~~ | ~~0.11~~ | ~~STMR~~  ~~(EFSA, 2018; 2022)~~ | ~~0.89~~ | ~~HR~~  ~~(EFSA, 2018; 2022)~~ |
| ~~Poultry muscle/meat, fat~~ | ~~0.02~~ | ~~STMR (LOQ)~~  ~~(EFSA, 2018; 2022)~~ | ~~0.02~~ | ~~HR (LOQ)~~  ~~(EFSA, 2018; 2022)~~ |
| ~~Milks (all)~~ | ~~0.02~~ | ~~STMR~~  ~~(EFSA, 2018; 2022)~~ | ~~0.02~~ | ~~STMR~~  ~~(EFSA, 2018; 2022)~~ |
| ~~Eggs (all)~~ | ~~0.02~~ | ~~STMR (LOQ)~~  ~~(EFSA, 2018; 2022)~~ | ~~0.02~~ | ~~HR (LOQ)~~  ~~(EFSA, 2018; 2022)~~ |
| ~~All other products of animal origin~~ | ~~MRL~~~~1)~~ | ~~Reg. (EU) 2019/88~~ | ~~MRL~~~~1)~~ | ~~Reg. (EU) 2019/88~~ |

PeF = Peeling factor.

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

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

2) STMR instead of HR has been taken into account for all bulked commodities

#### Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2‑18: Consumer risk assessment

|  |  |
| --- | --- |
| **~~Scenario 1 (including apple residues from this submission)~~** | |
| TMDI (% ADI) according to EFSA PRIMo | Not performed – see IEDI (A.3.~~2~~5) |
| IEDI (% ADI) according to EFSA PRIMo | ~~99~~50% (based on NL toddler) |
| IESTI (% ARfD) according to EFSA PRIMo, refined | Raw commodities:  ~~Apple: 652% (NL toddler)~~  Potatoes: 31% (UK infant)  Honey: 11% (NL toddler)  Wheat: 3% (UK 4-6 year)  Maize/corn: 1% (UK infant)  Rye: 1% (UK infant)  Barley: 1% (UK 7-10 year)  Rapeseeds/canola: 0.8% (DE child)  Oat: 0.2% (DE child)  Processed commodities:  Potatoes / fried: 19% for children  Potatoes / chips: 2% for adults  ~~Apples / juice: 17 % (DE child) 105% for children~~  ~~Apples / juice: 65% for adults~~  ~~Sugar beets (root) / sugar: 2 % (NL child)~~ |
| **~~Scenario 2 (excluding apple residues from this submission)~~** | |
| ~~TMDI (% ADI) according to EFSA PRIMo~~ | ~~Not performed – see IEDI (A.3.5)~~ |
| ~~IEDI (% ADI) according to EFSA PRIMo~~ | ~~97% (based on NL toddler)~~ |
| ~~IESTI (% ARfD) according to EFSA PRIMo, refined~~ | ~~Raw commodities:~~  ~~Potatoes: 31% (UK infant)~~  ~~Honey: 11% (NL toddler)~~  ~~Wheat: 3% (UK 4-6 year)~~  ~~Maize/corn: 1% (UK infant)~~  ~~Rye: 1% (UK infant)~~  ~~Barley: 1% (UK 7-10 year)~~  ~~Rapeseeds/canola: 0.8% (DE child)~~  ~~Oat: 0.2% (DE child)~~  ~~Processed commodities:~~  ~~Potatoes / fried: 19% for children~~  ~~Sugar beets (root) / sugar: 2 % (NL child)~~  ~~Potatoes / chips: 2% for adults~~ |

~~In scenario1, considering the apple residues arising from the GAP proposed in this submission, acute dietary intakes exceeded the proposed ARfD of 0.005 mg/kg be (EFSA, 2024). Therefore, in scenario 2 this use was not considered further and removed from the acute assessment (still considered for chronic exposure based on residues from EFSA, 2018). Following this revision the proposed uses of acetamiprid in the formulation ADM.00150.I.2.A (SL) do not represent unacceptable acute and chronic risks for the consumer.~~

The dietary risk assessment was updated to take account of the proposed uses, the MRLs agreed in Regulation (EU) 2025/1212 and the STMR/HR values considered in EFSA, 2025 (where these apply to in force MRLs). The proposed uses of acetamiprid in the formulation ADM.00150.I.2.A (SL) do not represent unacceptable acute and chronic risks for the consumer.

|  |
| --- |
| **Evaluator comments:**  A consumer risk assessment was performed with revision 3.1 of EFSA Pesticide Residues Intake Model (PRIMo Rev. 3.1).  ~~The Reg. (EU) 2019/88 for acetamiprid is now in force.~~ The new MRLs were voted at the SCOPAFF residue and published in the Commission Regulation 2025/158 of 29 January 2025. New MRL values for acetamiprid will apply on 19 August 2025.  It should be noted that the new Commission Regulation (EU) 2025/1212 of 24 June 2025 has already been published in the Official Journal of the European Union. This Regulation enters into force on 20 August 2025.  Calculations presented by Applicant are acceptable.  The proposed use on apples of acetamiprid in the product ADM.00150.I.2.A/ Leaxo represents unacceptable acute risks for the consumer, so this use is not accepted.  The proposed other uses of acetamiprid in the product ADM.00150.I.2.A / Leaxo do not represent unacceptable acute and chronic risks for the consumer. |

## Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

## References

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1. Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| KCP 8.1/01 | Lindner M.,  Grewe D. | 2017 | Storage stability of acetamiprid in honey bee related matrices, arthropods and ground vegetation under deep frozen conditions  Report No S16-02170 (MAC-1608L)  Sponsor No R-37693  Eurofins Agroscience Services Chem GmbH  GLP  Unpublished | N | ADAMA Makhteshim Ltd. |
| KCP 8.1/02 | Schrag K. | 2022 | Determination of the Storage Stability of Acetamiprid in Honey at ≤ -18 °C.  Report No 21A14030-01-SSHN  Sponsor No 000107275  Chemisches Institut Pforzheim GmbH  GLP  Unpublished | N | ADAMA Makhteshim Ltd. |
| KCP 8.3.1/01 | Méric D | 2014a | Magnitude of the residues of acetamiprid in apples (RAC fruits), following one or two applications of MCW-2222 in two trials (1 DCS + 1 HS), Northern Europe (Northern France)  Report No DMC-13-16134  Sponsor No R-33599  STAPHYT  GLP  Unpublished | N | ADAMA Makhteshim Ltd. |
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| KCP 8.3.4/01 | Chevallier E. | 2014 | Magnitude of the residue of acetamiprid in barley (Raw Agricultural Commodity) after two applications of MCW-2222 – four decline curve trials and four harvest trials in Northern Europe (Northern France, Poland, Germany, Hungary and Austria) – 2014  Chevallier E., 2014  Report No 14SGS034  SGS AGRI MIN  GLP  Unpublished | N | ADAMA Makhteshim Ltd. |
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| KCP 8.3.7/01 | Roussel Ch.H. | 2022 | Magnitude of the residues of acetamiprid in sugar beet (RAC whole plants, roots and leaves+tops), following two applications of Acetamiprid 200 SL in three trials (two HS + one DCS) - Northern Europe (Poland and Hungary) – 2020  Report No SPK-20-46380  Sponsor No 000105979  STAPHYT  GLP  Unpublished | N | ADAMA Makhteshim Ltd. |
| KCP 8.3.7/02 | Roussel Ch.H. | 2022 | Magnitude of the residues of acetamiprid, after application of Acetamiprid 200 SL in sugar beet in Northern Europe – 2021  Report No ChR-21-48246  Sponsor No 000107604  STAPHYT  GLP  Unpublished | N | ADAMA Makhteshim Ltd. |
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List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
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| CP 8.2.2 | xxxxx | 1997b | 14C-NI-25 (Acetamiprid): Absorption, Distribution, Metabolism and Excretion  after Repeated Oral Administration to Laying Hens  Report/file: RCC N°: 628143  xxxxx  GLP  Unpublished | Y | Nippon  Soda |
| CP 8.4.1 | xxxxx | 1999a | Acetamiprid (Code No.: NI-25) – Magnitude of Residues in Poultry Tissue and Eggs.  Report no RD-09988  GLP: Yes  Unpublished | Y | Nippon  Soda  No LoA  Information on ongoing negotiations were provided by the applicant. |
| CP 8.4.2 | xxxxx | 1999b | Acetamiprid : Magnitude of Residues in Dairy Cow Milk and Tissues.  Report no 98514428 (File no 45649)  GLP: Yes  Unpublished | Y | Nippon  Soda  The study is out of data protection and is not required to be matched. |
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| CP 8.5.3 | Fraschini C | 1998a | Analysis of NI-25 (Acetamiprid) Residues in orange (Whole fruit, pulp, peel)  Report/file: SIP1124  Sipcam Spa  GLP  Unpublished | N | Nippon  Soda |
| CP 8.5.3 | Fraschini C | 1998b | Analysis of NI-25 (Acetamiprid) Residues in orange (Whole fruit, pulp, peel, juice)  Report/file: SIP1128  Sipcam Spa  GLP  Unpublished | N | Nippon  Soda |
| CP 8.5.3 | Kowite W.J. | 1999 | NI-25: Magnitude of Residues in Apple Processed Commodities Resulting from Foliar Applications of EXP 80667A Insecticide Generated by: Rhône- Poulenc Agriculture Ltd  Report/file: Study No 97512650  Rhône- Poulenc Agriculture Ltd  GLP  Unpublished | N | Nippon  Soda  The study is out of data protection and is not required to be matched. |
| CP 8.5.3 | Venet C.,  Barriere I. | 2000 | Acetamiprid (NI-25) – Formulation EXP60707A (SP) - Trials France 1999 - Residues in Apple + Processed products  Report/file: R&D/CRLD/AN/mba  0015360,  Aventis CropScience  GLP  Unpublished | N | Nippon  Soda  The study is out of data protection and is not required to be matched |
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| CP 8.6.2 | Raufer B | 2014 | Residue study on rotational crop (turnip) after one application of Acetamiprid on bare soil at 1 site in Europe in 2012 to 2013.  Report no. RD-02930  GLP: Yes  Unpublished | N | Nippon  Soda  (Data matching Semrau, J. 2017) |

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

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

1. Detailed evaluation of the additional studies relied upon
   1. Acetamiprid
      1. Stability of residues
         1. Stability of residues during storage of samples
            1. Storage stability of residues in plant products

Study 1

|  |  |
| --- | --- |
| Comments of zRMS: | The study demonstrated that acetamiprid is stable in flowers, pollen, nectar, honey, bee larvae, wax, arthropods and ground vegetation upon storage at ≤ -18 °C for 6 months.  The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix.  Acceptance criteria for method validation were met, with average recoveries ranging from 70% to 110% and relative standard deviations ≤ 20%.  The study has been accepted. |

|  |  |
| --- | --- |
| Reference: | KCP 8.1/01 |
| Report | Storage stability of acetamiprid in honey bee related matrices, arthropods and ground vegetation under deep frozen conditions; Lindner M. and Grewe D., 2017, Report No S16-02170 (MAC-1608L), Sponsor No R-37693 |
| Guideline(s): | Yes  Regulation (EC) No. 1107/2009  7032/VI/95 rev.5  1607/VI/97, rev. 2  OECD Guideline 506/2007 |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

Materials and methods

The storage stability of acetamiprid was determined in fortified honey under deep frozen conditions (≤ -18 °C) in the dark over a storage period up to 6 months.

Residues of acetamiprid were extracted from homogenised honey. Determination of residues were performed according to an analytical procedure that is based on the multi-residue QuEChERS. Quantification was performed by use of LC-MS/MS detection.

The analytical method used in the study was validated in the reports S16-02168-L1 (MAC-1606) / R-37336 (Mayer O., 2018). See Section 5.1.2. in order to confirm the analytical method was functioning correctly when used in the current study, procedural recovery samples were processed and analysed concurrently with the test sample and are summarised in the table below.

**Table A 1: Summary of procedural recoveries for acetamiprid in honey** **reported in study S16-02170 (MAC-1608L), Sponsor No R-37693**

| **Matrix** | **Fortification level (mg/kg)** | **Storage interval (months)** | **Mean Recovery (%)** | **RSD (%)** | **n** |
| --- | --- | --- | --- | --- | --- |
| Honey | 0.1 | 3 | 102 | - | 2 |
| 6 | 100 | - | 2 |

Results and discussions

For acetamiprid the mean recovery of acetamiprid for storage stability samples at day 0, after 3 months storage, and 6 months storage was 98 %, 102 % and 112 % respectively.

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

| Matrix | Spike level (mg/kg) | Storage interval (months) | Individual  recovered residues (%) | Mean recoveries  (%) |
| --- | --- | --- | --- | --- |
| Acetamiprid | | | | |
| Honey | 0.1 | 0 | 100, 95, 98 | 98 |
| 3 | 102, 101 | 102 |
| 6 | 112, 111 | 112 |

Conclusion

Acetamiprid stability was demonstrated in honey upon storage at ≤ -18 °C for 6 months.

Study 2

|  |  |
| --- | --- |
| Comments of zRMS: | No degradation of acetamiprid during storage at ≤ -18 °C was observed within 18 months in matrix honey (not more than 30% as demanded in guideline 7032/VI/95 rev.5).  The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg.  Mean recovery values obtained by HPLC-MS/MS for acetamiprid complied with the standard acceptance criteria of guideline SANTE/2020/12830 rev.1 , which requires mean recoveries in the range of 70 – 120%. All relative standard deviations (RSDs) meet the acceptance criterion of < 20%.  The study demonstrated that acetamiprid is stable in honey upon storage at ≤ -18 °C for 18 months.  The study has been accepted. |

|  |  |
| --- | --- |
| Reference: | KCP 8.1/02 |
| Report | Determination of the Storage Stability of Acetamiprid in Honey at ≤ -18 °C; Schrag K., 2022; Report No 21A14030-01-SSHN, Sponsor No 000107275 |
| Guideline(s): | Regulation (EC) No 1107/2009  Commision Regulation (EU) No 283/2013  7032/VI/95 rev.5  SANTE/2020/12830 rev.1  OECD Test Number 506 |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

Materials and methods

The storage stability of acetamiprid was determined in fortified honey under deep frozen conditions (≤ -18 °C) over a storage period up to 18 months.

Residues of acetamiprid were extracted from homogenised honey. Determination of residues were performed according to an analytical procedure that is based on the multi-residue QuEChERS. Quantification was performed by use of HPLC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix.

The analytical method used in the study was validated in the reports 21A14030-01-VMHN / 000107274 (Schrag K., 2022). In order to confirm the analytical method was functioning correctly when used, procedural recovery samples were processed and analysed concurrently with the test sample and are summarised in the table below.

**Table A 3: Summary of procedural recoveries for acetamiprid in honey reported in study 21A14030-01-SSHN, Sponsor No 000107275**

| Matrix | Storage period | Fortification level (mg/kg) | Recovery (%) | Mean (%) | Overall RSD (%) | n |
| --- | --- | --- | --- | --- | --- | --- |
| Honey | 3 | **m/z 223 → 126 (quantification)** | | | | |
| 0.1 | 111, 107 | 109 | 2.6 | 2 |
| **m/z 223 → 90 (confirmation)** | | | | |
| 0.1 | 108, 102 | 105 | 4.0 | 2 |
| 6 | **m/z 223 → 126 (quantification)** | | | | |
| 0.1 | 99, 99 | 99 | 0.0 | 2 |
| **m/z 223 → 90 (confirmation)** | | | | |
| 0.1 | 96, 98 | 97 | 1.5 | 2 |
| 12 | **m/z 223 → 126 (quantification)** | | | | |
| 0.1 | 105, 104 | 105 | 0.7 | 2 |
| **m/z 223 → 90 (confirmation)** | | | | |
| 0.1 | 105, 105 | 105 | 0.0 | 2 |
| 18 | **m/z 223 → 126 (quantification)** | | | | |
| 0.01 | 97, 97, 94 | 96 | 1.8 | 3 |
| 0.1 | 101, 98 | 100 | 2.1 | 2 |
| **m/z 223 → 90 (confirmation)** | | | | |
| 0.01 | 97, 97, 94 | 96 | 1.8 | 3 |
| 0.1 | 101, 101 | 101 | 0.0 | 2 |

Results and discussions

For acetamiprid the mean procedural recovery for samples extracted at day 0, after 3 months and after 6 months was 96 %, 109 % and 99 % respectively. The mean recovery of acetamiprid for storage stability samples at day 0, after 3 months storage, and 6 months storage was 96 %, 105 % and 104 % respectively.

Table A 4: Summary of procedural recoveries of acetamiprid from honey

| Matrix | Spike level (mg/kg) | Storage Interval (months) | Sample size (n) | Mean procedural recoveries (%) |
| --- | --- | --- | --- | --- |
| Acetamiprid | | | | |
| Honey | 0.1 | 0 | 2 | 96 |
| 3 | 2 | 109 |
| 6 | 2 | 99 |
| 12 | 2 | 105 |
| 18 | 2 | 100 |

Table A 5: Stability of acetamiprid residues in honey following storage at -18°C

| Matrix | Spike level (mg/kg) | Storage interval (months) | Individual  recovered residues (%) | Mean recoveries  (%) |
| --- | --- | --- | --- | --- |
| Acetamiprid | | | | |
| Honey | 0.1 | 0 | 92, 100 | 96 |
| 3 | 104, 105 | 105 |
| 6 | 104, 104 | 104 |
| 12 | 83, 96 | 89 |
| 18 | 102, 104 | 103 |

Conclusion

Acetamiprid stability was demonstrated in honey upon storage at ≤ -18 °C for 18 months.

* + - * 1. Storage stability of residues in animal products

No new studies were conducted.

* + 1. Nature of residues in plants, livestock and processed commodities
       1. Nature of residue in plants
          1. Nature of residue in primary crops

No new studies were conducted.

* + - * 1. Nature of residue in rotational crops

No new studies were conducted.

* + - * 1. Nature of residues in processed commodities

No new studies were conducted.

* + - 1. Nature of residues in livestock

No new studies were conducted.

* + 1. Magnitude of residues in plants
       1. Apple

Table A 6: Comparison of intended and critical EU GAPs

| Type of GAP | Number of aplications | Application rate per treatment  (kg a.s./ha) | Interval between application (days) | Growth stage at last application | PHI (days) |
| --- | --- | --- | --- | --- | --- |
| cGAP EU (RAR, The Netherlands, 2015, updated 2016) | 2 | 0.075 | 14 | BBCH 77–87 | 14 |
| cGAP EU (Art. 12, EFSA, 2011, updated 2012) | 2 | 0.030-0.080 | Not reported | BBCH 57–88 | 14 |
| Intended cGAP (IIa–IIb; 4–16)\* | 1 | 0.080 | Not applicable | BBCH 62–PHI | 14 |

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

* + - * 1. Study 1

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been evaluated and accepted in Registration Report, Section 4 for MCW-2222, Adama Makhteshim Ltd. (10.05.2018).  Two residue trials have been performed in Northern Europe (Northern France): one decline trial (DMC-13-16134 FR01) and one harvest trial (DMC-13-16134 FR02).  T1 plot was treated once with MCW-2222 at the rate of 0.5 L/ha (100 g a.i./ha of acetamiprid) 14 days before harvest at BBCH 85; the plot T2 was treated twice at 0.5 L/ha (200 g a.i./ha of acetamiprid), 22 (±1) and 14 days before harvest at BBCH 85.  For decline trial, fruits specimens were collected at 0, 3, 7, 14 and 21 days after last application (DALA). For harvest trial, fruits specimens were collected 14 days after last application, at normal commercial harvest.  No residue of acetamiprid was found in any untreated specimen.  After one treatment with MCW-2222 (plot T1), the residues of acetamiprid in treated specimens were 0.11 mg/kg at 0 DALA and ranged from 0.06 to 0.08 mg/kg at 14 DALA (normal commercial harvest).  After two treatments with MCW-2222 (plot T2), the residues of acetamiprid in treated specimens were 0.17 mg/kg at 0 DALA and ranged from 0.11 to 0.21 mg/kg at 14 DALA (normal commercial harvest).  The acetamiprid LOQ was 0.01 mg/kg and the LOD defined as 0.003 mg/kg.  Acceptance criteria for method validation were met, with average recoveries ranging from 70% to 110% and relative standard deviations ≤ 20%.  The study has been accepted.  Remark:  Samples from all residue trials have been analysed for parent acetamiprid only. No data on the magnitude of metabolite IM-2-1 are available. |

|  |  |
| --- | --- |
| Reference: | KCP 8.3.1/01 |
| Report | Magnitude of the residues of acetamiprid in apples (RAC fruits), following one or two applications of MCW-2222 in two trials (1 DCS + 1 HS), Northern Europe (Northern France) – 2013, Méric D., 2014, Report No DMC-13-16134, Sponsor No R-33599 |
| Guideline(s): | Yes  ENV/MC/CHEM(98)17 GLP Principles.  ENV/JM/MONO(99)22 Application of GLP Principles.  ENV/JM/MONO(2002)9 Application of the OECD GLP Principles  ENV/JM/MONO(2007)17 Guidance on Pesticide Residue Analytical Methods.  1607/VI/97 rev. 2, guidelines for the generation of data concerning residues.  7029/VI/95 rev. 5, general recommendations for the design, preparation and realization of residue trials.  SANCO 3029/99, rev. 4, 2000 guidance for generating and reporting methods of analysis in support of pre-registration data requirements.  SANCO 825/00, 2004, guidance document on residue analytical methods. |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

The analytical method used in the current study was previously validated in apple fruits in study 13M06017-01-VMPL / R-33644 (Lang A., 2014). The same method was used to provide additional validation data for a higher fortification level (5.0 mg/kg) in study DMC-13-16126 / R-33596 (Méric D., 2013). See Section 5.1.2. in order to confirm the analytical method was functioning correctly when used in the current study, procedural recovery samples were processed and analysed at LOQ level (0.01 mg/kg) concurrently with the test sample and are summarised in the table below.

Table A 7: Summary of procedural recoveries for acetamiprid in apples reported in study DMC-13-16134, Sponsor No. R-33599

| Matrix | Fortification level (mg/kg) | Mean  recovery (%) | RSD (%) | n |
| --- | --- | --- | --- | --- |
| Apple fruits | m/z 223 → 126 (quantification) | | | |
| 0.01 | 98 | 5.1 | 3 |
| **m/z 223 → 90 (confirmation)** | | | |
| 0.01 | 98 | 6.6 | 3 |

Table A 8: Summary of the study 1 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 treat-ment or no. of treatments and last date**  (c) | **Growth stage at last treat-ment or date** | **Portion analyzed** | **Residues (mg/kg)** | **PHI (days)**  (d) | **Details on trial**  (e) |
| **kg a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **Acetamiprid** |
| DMC-13-16134 FR01  Northern France  37110 Dame Marie les Bois  NEU  2014  Plot T1: 1x 0.1 kg/ha  Plot T2: 2x 0.1 kg/ha | Apple / Antares | 1- 2005  2- from 22/04/2013 to 05/05/2013  3- from 30/09/2013 to 06/10/2013 | Plot T1  0.098 | Plot T1  969 | Plot T1  0.010 | Plot T1  24/09/2013 | Plot T1  BBCH 85 | Fruits  Fruits  Fruits  Fruits  Fruits | 0.11  0.09  0.07  0.06  0.06 | 0  3  7  14 - NCH  22 | Report: R-33599  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method (13M06017-01-VMPL) and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL)  Method: Foliar broadcast application  Max. Storage Interval between sampling and analysis: 100 days |
| Plot T2  0.097  0.102 | Plot T2  958  1008 | Plot T2  0.010  0.010 | Plot T2  17/09/2013  24/09/2013 | Plot T2  BBCH 85  BBCH 85 | Fruits  Fruits  Fruits  Fruits  Fruits | 0.17  0.15  0.18  0.11  0.12 | 0  3  7  14 – NCH  22 |

| 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) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| DMC-13-16134 FR02  Northern France  37110 Dame Marie les Bois  NEU  2014  Plot T1: 1x 0.1 kg/ha  Plot T2: 2x 0.1 kg/ha | Apple / Golden 972 | 1- 2011  2- from 29/04/2013 to 15/05/2013  3- from 16/09/2013 to 29/09/2013 | Plot T1  0.100 | Plot T1  982 | Plot T1  0.010 | Plot T1  04/09/2013 | Plot T1  BBCH 85 | Fruits | 0.08 | 14 - NCH | Report: R-33599  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method (13M06017-01-VMPL) and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL)  Method: Foliar broadcast application  Max. Storage Interval between sampling and analysis: 106 days |
| Plot T2  0.098  0.099 | Plot T2  971  981 | Plot T2  0.010  0.010 | Plot T2  27/08/2013  04/09/2013 | Plot T2  BBCH 81  BBCH 85 | Fruits | 0.21 | 14 - NCH |

(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

NCH: Normal Commercial Harvest

* + - * 1. Study 2

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

|  |  |
| --- | --- |
| Reference: | KCP 8.3.1/02 |
| Report | Magnitude of the residues of acetamiprid in apple (RAC fruits and processed fractions), following one or two applications of MCW-2222 in six trials (3 DCS + 3 HS), Northern Europe (Northern France, Germany, Poland and Belgium) – 2014, Roussel Ch.H., 2014, Report No ChR-14-17311, Sponsor No R-34915 |
| Guideline(s): | Yes  ENV/MC/CHEM(98)17 GLP Principles.  ENV/JM/MONO(99)22 Application of GLP Principles.  ENV/JM/MONO(2002)9 Application of the OECD GLP Principles  ENV/JM/MONO(2007)17 Guidance on Pesticide Residue Analytical Methods.  1607/VI/97 rev. 2, guidelines for the generation of data concerning residues.  7029/VI/95 rev. 5, general recommendations for the design, preparation and realization of residue trials.  SANCO 3029/99, rev. 4, 2000 guidance for generating and reporting methods of analysis in support of pre-registration data requirements.  SANCO 825/00, 2004, guidance document on residue analytical methods. |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 9: Summary of the study 2 trials

| Trial No./  Location/  EU zone/  Year | Commodity/ Variety | Date of  1.Sowing or planting  2.Flowering  3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analyzed | Residues (mg/kg) | PHI (days) | Details on trial |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| kg a.s./ ha | Water (l/ha) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  | (d) | (e) |
| ChR 14 17311  FR01  Northern France  Nord Pas de Calais  59400 Fontaine Notre  Dame  NEU  2014  Plot T1: 1x 0.1 kg/ha  Plot T2: 2x 0.1 kg/ha | Apple / Idared | 1- 2000  2- 03-25/04/2014  3- weeks 40-41 | Plot T1  0.104 | Plot T1  1027 | Plot T1  0.010 | Plot T1  08/09/2014 | Plot T1  BBCH 85 | Fruits  Fruits  Fruits  Fruits  Fruits | 0.08  0.09  0.07  0.03  0.03 | 0  3  7  14  21 | Report: R-34915  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method (13M06017-01-VMPL) and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL)  Method: Foliar broadcast application  Max. Storage Interval between sampling and analysis: 74-77 days |
| Plot T2  0.104  0.105 | Plot T2  1027  1033 | Plot T2  0.010  0.010 | Plot T2  29/08/2014  08/09/2014 | Plot T2  BBCH 81  BBCH 85 | Fruits  Fruits  Fruits  Fruits  Fruits | 0.11  0.11  0.11  0.06  0.07 | 0  3  7  14  21 |

| 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) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  | (d) | (e) |
| ChR 14 17311  FR06  Northern France  Centre  37110 Dame Marie  les Bois  NEU  2014  Plot T1: 1x 0.1 kg/ha  Plot T2: 2x 0.1 kg/ha | Apple / Antares | 1- 2005  2- 11-30/04/2014  3- 13-20/10/2014 | Plot T1  0.099 | Plot T1  979 | Plot T1  0.010 | Plot T1  03/10/2014 | Plot T1  BBCH 85 | Fruits | 0.12 | 14 | Report: R-34915  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method (13M06017-01-VMPL) and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL)  Method: Foliar broadcast application  Max. Storage Interval between sampling and analysis: 37 days |
| Plot T2  0.099  0.099 | Plot T2  976  979 | Plot T2  0.010  0.010 | Plot T2  25/09/2014  03/10/2014 | Plot T2  BBCH 85  BBCH 85 | Fruits | Not reported | 14 |
| ChR 14 17311  DE02  Germany  Rheinland-Pfalz  67551 Worms  Pfeddersheim  NEU  2014  Plot T2: 2x 0.1 kg/ha | Apple / Braeburn | 1- 1999  2- 24/04 – 12/05/2014  3- 10/10/2014 | Plot T2  0.102  0.103 | Plot T2  1005  1013 | Plot T2  0.010  0.010 | Plot T2  17/09/2014  26/09/2014 | Plot T2  BBCH 85-87  BBCH 87 | Fruits  Fruits  Fruits  Fruits  Fruits | 0.20  0.18  0.16  0.21  0.20 | 0  3  7  14  21 | Report: R-34915  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method (13M06017-01-VMPL) and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL)  Method: Foliar broadcast application  Max. Storage Interval between sampling and analysis: 58 days |

| Trial No./  Location/  EU zone/  Year | Commodity/ Variety | Date of  1.Sowing or planting  2.Flowering  3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analyzed | Residues (mg/kg) | PHI (days) | Details on trial |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| kg a.s./ ha | Water (l/ha) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  | (d) | (e) |
| ChR 14 17311  PL03  Poland  Lodzkie  99307 Strzelce  NEU  2014  Plot T2: 2x 0.1 kg/ha | Apple / Topaz | 1- 2002  2- week 20  3- 17/10/2014 | Plot T2  0.101  0.101 | Plot T2  994  999 | Plot T2  0.010  0.010 | Plot T2  22/09/2014  30/09/2014 | Plot T2  BBCH 85  BBCH 85 | Fruits  Fruits  Fruits  Fruits  Fruits | 0.09  0.10  0.08  0.08  0.06 | 0  3  7  14  21 | Report: R-34915  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method (13M06017-01-VMPL) and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL)  Method: Foliar broadcast application  Max. Storage Interval between sampling and analysis: 54 days |
| ChR 14 17311  BE04  Belgium  Hainaut  6220 Fleurus  NEU  2014  Plot T2: 2x 0.1 kg/ha | Apple / Rubinola | 1- before 1999  2- April 2014  3- 27/08/2014 | Plot T2  0.106  0.099 | Plot T2  1045  980 | Plot T2  0.010  0.010 | Plot T2  30/07/2014  07/08/2014 | Plot T2  BBCH 81  BBCH 85 | Fruits | 0.07 | 14 | Report: R-34915  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method (13M06017-01-VMPL) and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL)  Method: Foliar broadcast application  Max. Storage Interval between sampling and analysis: 95-96 days |
| ChR 14 17311  BE05  Belgium  Brabant wallon  1320 Nodebois  NEU  2014  Plot T2: 2x 0.1 kg/ha | Apple / Jonagold | 1- 1999  2- 6-25/04/2014  3- 27/09 –  08/10/2014 | Plot T2  0.100  0.103 | Plot T2  984  1013 | Plot T2  0.010  0.010 | Plot T2  03/09/2014  11/09/2014 | Plot T2  BBCH 85  BBCH 87 | Fruits | 0.09 | 14 | Report: R-34915  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method (13M06017-01-VMPL) and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL)  Method: Foliar broadcast application  Max. Storage Interval between sampling and analysis: 59 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

NCH: Normal Commercial Harvest

* + - 1. Potato

Table A 10: Comparison of intended and critical EU GAPs

| Type of GAP | Number of applica­tions | Application rate per treatment  (kg a.s./ha) | Interval between application (days) | Growth stage at last application | PHI (days) |
| --- | --- | --- | --- | --- | --- |
| cGAP EU (RAR, The Netherlands, 2015, updated 2016) | 3 | 0.050 | 7 | BBCH 45–93 | 7 |
| cGAP EU (Art. 12, EFSA, 2011, updated 2012) | 2 | 0.050 | 7 | BBCH 60–69 | 7 |
| Intended cGAP (III, 17–22)\* | 1 | 0.036 | Not applicable | BBCH 12–79 | 7 |

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

* + - * 1. Study 1

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

|  |  |
| --- | --- |
| Reference: | KCP 8.3.2/01 |
| Report | Magnitude of the Residue of acetamiprid in potato Raw Agricultural Commodity after two applications of MCW-2222 in three decline curve trials (Poland, United Kingdom and Northern France) and in one harvest trial (Poland) in Northern Europe – 2013, Bousquet C., 2014, Report No 13SGS102, Sponsor No R-33600 |
| Guideline(s): | Yes  ENV/MC/CHEM(98)17 GLP Principles.  ENV/JM/MONO(99)22 Application of GLP Principles.  ENV/JM/MONO(2002)9 Application of the OECD GLP Principles  ENV/JM/MONO(2007)17 Guidance on Pesticide Residue Analytical Methods.  7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials.  SANCO 3029/99, rev. 4, 2000 guidance for generating and reporting methods of analysis in support of pre-registration data requirements. |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

The analytical method used in the current study was previously validated in high water matrices in study 13M06017-01-VMPL / R-33644 (Lang A., 2014). See Section 5.1.2. in order to confirm the analytical method was functioning correctly when used in the current study, quality control recovery samples were processed and analysed concurrently with the test sample and are summarised in the table below.

Table A 11: Summary of quality control recoveries for acetamiprid in potato tubers reported in study 13SGS102, Sponsor No. R-33600

| Matrix | Fortification level (mg/kg) | Mean  recovery (%) | RSD (%) | n |
| --- | --- | --- | --- | --- |
| Potato tubers | **m/z 223 → 126 (quantification)** | | | |
| 0.01 | 87 | - | 1 |
| 1.0 | 85 | - | 1 |
| **m/z 223 → 90 (confirmation)** | | | |
| 0.01 | 90 | - | 1 |
| 1.0 | 85 | - | 1 |

Table A 12: Summary of the study 1 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) |  | Acetamiprid |
|  | (a) | (b) |  |  |  |  | (c) |  |  |  | (e) |
| 13SGS102 PL01  Poland  05-850 Ozarow  Mazowiecki (Mazowiekie)  NEU  2013 | Potato / Irga | 1- 07/05/2013  2- 27/06/2013 to 01/07/2013  3- 28/08/2013 to 30/08/2013 | 0.0611  0.0613 | 407  409 | 0.0150  0.0150 | 14/08/2013  22/08/2013 | BBCH 49  BBCH 49 | Tuber | <LOD  <LOD  <LOD  <LOD  <LOD | 0 DALA  1 DALA  3 DALA  7 DALA  (harvest)  10 DALA | Report: R-33600  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method, clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar broadcast application.  Max. Storage Interval between sampling and analysis: 41 days. |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 13SGS102 UK02  United Kingdom  OX15 6EP Alkerton  (Oxfordshire)  NEU  2013 | Potato / Arran Pilot | 1- 07/05/2013  2- 20/07/2013 to 04/08/2013  3- 27/08/2013 | 0.0603  0.0594 | 301  297 | 0.0200  0.0200 | 08/08/2013  16/08/2013 | BBCH 46  BBCH 46 | Tuber | <LOD  <LOD  <LOD  <LOD  <LOD | 0 DALA  1 DALA  3 DALA  7 DALA  (harvest)  11 DALA | Report: R-33600  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method, clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar broadcast application.  Max. Storage Interval between sampling and analysis: 47 days. |
|  |  |  |  |  |  |  |  |  |  |  |  |

| Trial No./  Location/  EU zone/  Year | Commodity/ Variety | Date of  1.Sowing or planting  2.Flowering  3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analyzed | Residues (mg/kg) | PHI (days) | Details on trial |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| kg a.s./ ha | Water (l/ha) |  | Acetamiprid |
|  | (a) | (b) |  |  |  |  | (c) |  |  |  | (e) |
| 13SGS102 FR03  Northern France  49650 Allonnes (Pays de Loire)  NEU  2013 | Potato / Spunta | 1- 22/04/2013  2- 20/06/2013 to 15/07/2013  3- 31/07/2013 to 15/08/2013 | 0.0609  0.0601 | 304  300 | 0.0200  0.0200 | 22/07/2013  29/07/2013 | BBCH 43  BBCH 45 | Tuber | <LOD  <LOD  <LOD  <LOD  <LOD | 0 DALA  1 DALA  3 DALA  7 DALA  (harvest)  10 DALA | Report: R-33600  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method, clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar broadcast application.  Max. Storage Interval between sampling and analysis: 65 days. |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 13SGS102 PL04  Poland  96-323 Piekary (Mazowieckie)  NEU  2013 | Potato / Irga | 1- 10/05/2013  2- 21/06/2013 to 10/07/2013  3- 28/08/2013 to 30/08/2013 | 0.0619  0.0606 | 413  404 | 0.0150  0.0150 | 14/08/2013  21/08/2013 | BBCH 49  BBCH 49 | Tuber | <LOD | 7 DALA  (harvest) | Report: R-33600  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method, clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar broadcast application.  Max. Storage Interval between sampling and analysis: 35 days. |
|  |  |  |  |  |  |  |  |  |  |  |  |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

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

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

(f) Calculated values on whole fruit with the formula: [whole fruit]residue = (([pulp]residue x [pulp]weight) + ([peel]residue x [peel]weight)) / ([pulp]weight + [peel]weight). Values <LOD or LOQ are counted as 0.01

* + - 1. Oilseed rape

Table A 12: Comparison of intended and critical EU GAPs

| Type of GAP | Number of applications | Application rate per treatment  (kg a.s./ha) | Interval between application  (days) | Growth stage at last application | PHI (days) |
| --- | --- | --- | --- | --- | --- |
| cGAP EU (EFSA, 2016a) | 2 | 0.042 | 14 | BBCH 59–80 | Not reported |
| Intended cGAP (VIa-VIIa, 41–79)\* | 2 | 0.060 | 7 | BBCH 11–71 | 28 |

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

* + - * 1. Study 1

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

|  |  |
| --- | --- |
| Reference: | KCP 8.3.3/01 |
| Report | Magnitude of the residues of acetamiprid in oilseed rape (RAC whole plants, pods and seeds), following one or two applications of MCW-2222 in two trials (1 DCS + 1 HS), Northern Europe (Germany and Northern France) – 2013, Méric D., 2014, Report No DMC-13-16129, Sponsor No R-33598 |
| Guideline(s): | Yes  ENV/MC/CHEM(98)17 GLP Principles.  ENV/JM/MONO(99)22 Application of GLP Principles.  ENV/JM/MONO(2002)9 Application of the OECD GLP Principles  ENV/JM/MONO(2007)17 Guidance on Pesticide Residue Analytical Methods.  1607/VI/97 rev. 2, guidelines for the generation of data concerning residues.  7029/VI/95 rev. 5, general recommendations for the design, preparation and realization of residue trials.  SANCO 3029/99, rev. 4, 2000 guidance for generating and reporting methods of analysis in support of pre-registration data requirements.  SANCO 825/00, 2004, guidance document on residue analytical methods. |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

The analytical method used in the current study was previously validated in oilseed rape (whole plant, high water content), olive (whole fruit, high oil content), dry bean seed (high dry content), orange (peel and pulp, high acid content), dry bean (straw) in study B13-M1-A-01 / R-33645 (Lefresne S., 2014). See Section 5.1.2. in order to confirm the analytical method was functioning correctly when used in the current study, procedural recovery samples were processed and analysed concurrently with the test sample and are summarised in the table below.

Table A 13: Summary of procedural recoveries for acetamiprid in oilseed rape (whole plant, seed, pods and plant without pods) reported in study DMC-13-16129, Sponsor No. R-33598

| Matrix | Fortification level (mg/kg) | Mean  recovery (%) | RSD (%) | n |
| --- | --- | --- | --- | --- |
| Oilseed rape (seed) | 0.01 | 70 | - | 1 |
| Oilseed rape (whole plant) | 0.01 | 89 | - | 1 |
| 3.0 | 86 | - | 1 |
| Oilseed rape (pods) | 0.01 | 71 | - | 1 |
| 3.0 | 86 | - | 1 |
| Oilseed rape (plant without pods) | 0.01 | 79 | - | 2 |
| 3.0 | 72 | - | 1 |

Table A 14: Summary of the study 1 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) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| DMC-13-16129 DE01  Germany  Lower Saxony  31608 Marklohe  NEU  2013  Plot T1: 1x 0.06 kg/ha  Plot T2: 2x 0.06 kg/ha | Oilseed rape / Visby | 1- 23/08/2012  2- from 02/05/2013 to 01/06/2013  3- 31/07/2013 | Plot T1  0.066 | Plot T1  217 | Plot T1  0.030 | Plot T1  27/06/2013 | Plot T1  BBCH 75 | Whole plant  Whole plant  Whole plant without pods  Pods  Whole plant without pods  Pods  Seeds | 1.1  0.55  0.11  0.41  0.03  0.45  <LOQ | 0  6  14  14  21  21  28-NCH | Report: R-33598  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method (GIRPA  B-13-M1-A-01), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar broadcast application.  Max. Storage Interval between sampling and analysis: 134 days. |
| Plot T2  0.065  0.063 | Plot T2  213  207 | Plot T2  0.031  0.030 | Plot T2  20/06/2013  27/06/2013 | Plot T2  BBCH 73  BBCH 75 | Whole plant  Whole plant  Whole plant without pods  Pods  Whole plant without pods  Pods  Seeds | 1.0  0.46  0.16  0.34  0.067  0.35  0.017 | 0  6  14  14  21  21  28-NCH |

| 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) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| DMC-13-16129 FR02  Northern France  Champagne- Ardennes  08310 Annelles  NEU  2013  Plot T1: 1x 0.06 kg/ha  Plot T2: 2x 0.06 kg/ha | Oilseed rape / DK Explicit | 1- 26/08/2012  2- From 10/05/2013 to 29/05/2013  3- 01/08/2013 | Plot T1  0.064 | Plot T1  236 | Plot T1  0.027 | Plot T1  02/07/2013 | Plot T1  BBCH 80 | Seeds | 0.037 | 31-NCH | Report: R-33598  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method (GIRPA  B-13-M1-A-01),, clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar broadcast application.  Max. Storage Interval between sampling and analysis: 81 days. |
|  | Plot T2  0.058  0.057 | Plot T2  216  209 | Plot T2  0.027  0.027 | Plot T2  26/06/2013  02/07/2013 | Plot T2  BBCH 80  BBCH 80 | Seeds | 0.052 | 31-NCH |
|  |  |  |  |  |  |  |  |  |  |  |  |

(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

* + - * 1. Study 2

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

|  |  |
| --- | --- |
| Reference: | KCP 8.3.3/02 |
| Report | Magnitude of the residue of acetamiprid in winter oil seed rape (Raw Agricultural Commodity) after one or two applications of MCW-2222 – three decline curve trials and three harvest trials in Northern Europe (Northern France, Poland, Germany, Czech Republic and Hungary) – 2014, Chevallier E., 2014, Report No 14SGS035, Sponsor No R-34910 |
| Guideline(s): | Yes  ENV/MC/CHEM(98)17 GLP Principles.  ENV/JM/MONO(99)22 Application of GLP Principles.  ENV/JM/MONO(2002)9 Application of the OECD GLP Principles  ENV/JM/MONO(2007)17 Guidance on Pesticide Residue Analytical Methods.  7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials.  SANCO 3029/99, rev. 4, 2000 guidance for generating and reporting methods of analysis in support of pre-registration data requirements. |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

The analytical method used in the current study was previously validated in oilseed rape (whole plant, high water content), olive (whole fruit, high oil content), dry bean seed (high dry content), orange (peel and pulp, high acid content), dry bean (straw) in study B13-M1-A-01 / R-33645 (Lefresne S., 2014). See Section 5.1.2. in order to confirm the analytical method was functioning correctly when used in the current study, procedural recovery samples were processed and analysed concurrently with the test sample and are summarised in the table below.

Table A 15: Summary of procedural recoveries for acetamiprid in oilseed rape (whole plant, seed, pods and plant without pods) reported in study 14SGS035, Sponsor No R-34910

| Matrix | Fortification level (mg/kg) | Recovery (%) | | Overall RSD (%) | n |
| --- | --- | --- | --- | --- | --- |
| Single values | Mean |
| Oilseed rape (seed) | 0.01 | 90, 107 | 101a) | 9.2 | 2 |
| 0.1 | 93, 112 | 2 |
| Oilseed rape (whole plant) | 0.01 | 97, 90 | 94a) | 4.6 | 2 |
| 0.1 | 99 | 1 |
| 3.0 | 89 | 1 |
| Oilseed rape (pods) | 0.01 | 94, 70, 72 | 82a) | 12.6 | 3 |
| 0.1 | 94 | 1 |
| 7.0 | 81 | 1 |
| Oilseed rape (plant without pods) | 0.01 | 90, 70, 70 | 77 | 12.3 | 3 |
| 0.1 | 95, 81, 92 | 89 | 6.7 | 3 |

a) Overall mean calculated from recovery results of both fortification levels

Table A 16: Summary of the study 2 trials

| Trial No./  Location/  EU zone/  Year | Commodity/ Variety | Date of  1.Sowing or planting  2.Flowering  3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analyzed | Residues (mg/kg) | PHI (days) | Details on trial |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| kg a.s./ ha | Water (l/ha) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| 14SGS035  FR01  Northern France  Champagne Ardenne  08310 La Neuville  en Tourne à Fuy  NEU  2014  Plot Ta: two applications with 7±1 days interval, last application 28±2 days before harvest  Plot Tb: one application 28 ±2 days before harvest with MCW-2222 | Oilseed rape / DK  Explicit | 1- 27/08/2013  2- 28/03/2014 to 08/04/2014  3- 15/07/2014 | Ta  0.0592  0.0585 | Ta  246.7  243.3 | Ta  0.0240  0.0241 | Ta  11/06/2014  18/06/2014 | Ta  BBCH 80  BBCH 82 | Ta  Wh. plant  Wh. plant  Pl.w pod  Pods  Pl.w pod  Pods  Seeds | Ta  1.5  1.5  0.089  2.0  0.034  0.39  0.032 | Ta  0 DALA  6 DALA  15 DALA  22 DALA  27 DALA  (harvest) | Report: R-34910  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method (GIRPA  B-13-M1-A-01), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 76 days. |
| Tb  0.0612 | Tb  255.0 | Tb  0.0240 | Tb  18/06/2014 | Tb  BBCH 82 | Tb  Wh. plant  Wh. plant  Pl.w pod  Pods  Pl.w pod  Pods  Seeds | Tb  0.86  0.63  0.073  0.87  0.020  0.19  0.010 | Tb  0 DALA  6 DALA  15 DALA  22 DALA  27 DALA  (harvest) |

| 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) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| 14SGS035  GE02  Germany  Brandenburg  16818 Wahlendorf  NEU  2014  Plot Ta: two applications with 7±1 days interval, last application 28±2 days before harvest | Oilseed rape / NK LINUS | 1- 03/09/2013  2- 10/04/2014 to 21/04/2014  3- 19/07/2014 | Ta  0.0605  0.0611 | Ta  201.7  203.3 | Ta  0.0300  0.0300 | Ta  12/06/2014  19/06/2014 | Ta  BBCH 75  BBCH 78 | Ta  Wh. plant  Wh. plant  Pl.w pod  Pods  Pl.w pod  Pods  Seeds | Ta  1.2  0.81  0.054  0.69  0.023  0.23  <LOQ | Ta  0 DALA  7 DALA  14 DALA  23 DALA  30 DALA  (harvest) | Report: R-34910  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method (GIRPA  B-13-M1-A-01), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 62 days. |
| 14SGS035  CZ03  Czech Republic  Zlinsky kraj  687 24 Uhersky Ostroh  NEU  2014  Plot Ta: two applications with 7±1 days interval, last application 28±2 days before harvest | Oilseed rape / DK  EXPOWER | 1- 10/09/2013  2- 10/04/2014 to 05/05/2014  3- 10/07/2014 to 15/07/2014 | Ta  0.0577  0.0616 | Ta  288.5  308.0 | Ta  0.0200  0.0200 | Ta  06/06/2014  13/06/2014 | Ta  BBCH 75  BBCH 79 | Ta  Wh. plant  Wh. plant  Pl.w pod  Pods  Pl.w pod  Pods  Seeds | Ta  1.1  1.1  0.032  1.3  0.047  0.44  0.028 | Ta  0 DALA  7 DALA  13 DALA  20 DALA  27 DALA  (harvest) | Report: R-34910  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method (GIRPA  B-13-M1-A-01), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 69 days. |
| 14SGS035  PL04  Poland  Kujawsko-  Pomoroskie  88-400 Murczyn  NEU  2014  Plot Ta: two applications with 7±1 days interval, last application 28±2 days before harvest  Plot Tb: one application 28 ±2 days before harvest with MCW-2222 |  |  | Ta  0.0595  0.0574 | Ta  297.5  286.7 | Ta  0.0200  0.0200 | Ta  04/06/2014  12/06/2014 | Ta  BBCH 79  BBCH 80 | Ta  Seeds | Ta  0.031 | Ta  28 DALA  (harvest) | Report: R-34910  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method (GIRPA  B-13-M1-A-01), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 41 days. |
| Tb  0.0628 | Tb  313.9 | Tb  0.0200 | Tb  12/06/2014 | Tb  80 | Tb  Seeds | Tb  <LOQ | Tb  28 DALA  (harvest) |
| 14SGS035  GE05  Germany  Lower Saxony  49661 Cloppenburg  NEU  2014  Plot Ta: two applications with 7±1 days interval, last application 28±2 days before harvest | Oilseed rape / VISION | 1- 05/09/2013  2- 24/04/2014 to 10/05/2014  3- 14/07/2014 to 16/07/2014 | Ta  0.0600  0.0590 | Ta  200.0  196.7 | Ta  0.0300  0.0300 | Ta  13/06/2014  19/06/2014 | Ta  BBCH 75  BBCH 82 | Ta  Seeds | Ta  0.022 | Ta  27 DALA  (harvest) | Report: R-34910  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method (GIRPA  B-13-M1-A-01), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 35 days. |
| 14SGS035  HU06  Hungary  North-East  H-4482 Kόtaj  NEU  2014  Plot Ta: two applications with 7±1 days interval, last application 28±2 days before harvest | Oilseed rape /  PT200 CL | 1- 04/09/2013  2- 20/04/2014 to 10/05/2014  3- 28/06/2014 to 30/06/2014 | Ta  0.0615  0.0617 | Ta  306.9  308.3 | Ta  0.0200  0.0200 | Ta  26/05/2014  02/06/2014 | Ta  BBCH 74  BBCH 76 | Ta  Seeds | Ta  <LOQ | Ta  26 DALA  (harvest) | Report: R-34910  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method (GIRPA  B-13-M1-A-01), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 53 days. |
|  |  |  |  |  |  |  |  |  |  |  |  |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

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

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

* + - 1. Barley

Table A 17: Comparison of intended and critical EU GAPs

| Type of GAP | Number of applications | Application rate per treatment  (kg a.s./ha) | Interval between application  (days) | Growth stage at last application | PHI (days) |
| --- | --- | --- | --- | --- | --- |
| cGAP EU (EFSA, 2018) | 2 | 0.040 | 10 | BBCH 12–69 | Not applicable |
| Intended cGAP  (IVa–Vb, 23–40)\* | 2 | 0.036 | 10 | BBCH 12–69 | Not applicable |

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

* + - * 1. Study 1

|  |  |
| --- | --- |
| Comments of zRMS: | A study on magnitude of the residue of acetamiprid in barley was conducted in Northern Europe following two applications of MCW-2222 containing 200 g/L acetamiprid.  Eight independent field trials (4 DCS+ 4 HS) were set up on barley in Northern France, Poland, Germany, Hungary and Austria. The foliar applications of MCW-2222 were performed on the treated plot at the target dose rate of 0.2 L/ha FP (equivalent to 40 g a.s./ha).  Applications were performed using boom sprayers, following the target schedule:  - 1st foliar application performed 10 ± 1 days before the 2nd application (actually 9 to 11 days)  - 2nd foliar application performed at BBCH 77  In the decline curve trials (DCS), RAC specimens for analyses (whole plants, grain and straw) were collected following the target schedule:  - at 0 DALA (Days After Last Application)  - at 7 DALA  - at 10 ± 1DBH (Day before harvest) (actually 14 to 21 DALA)  - at 7 ±1 DBH (actually 18 to 24 DALA)  - at the time of commercial harvest BBCH 89 (actually 24 to 31 DALA)  In the harvest trial (HS), RAC specimens for analyses (grain and straw) were collected following the target schedule:  - at the time of commercial harvest BBCH 89 (actually 25 to 36 DALA).  The method was successfully validated with the limit of quantification (LOQ) of 0.01 mg/kg.  Recoveries and relative standard deviations at each fortification level were therefore within the accepted ranges of 70 – 110% and ≤ 20%, respectively.  No residues of acetamiprid were detected above the limit of detection (LOD = 0.0033 mg/kg) in the untreated specimens.  Residues of acetamiprid were determined in the treated specimens:  Barley grain (mg/kg):  6 x <LOQ, 0.021 (rounded-up mean value of the “mean of two extractions” values (0.019 and 0.022), 0.029 (rounded-up mean value of the “retain specimen” values (0.028 and 0.029))  Barley straw (mg/kg):  0.044, 0.066, 0.077, 0.140, 0.210, 0.230, 0.300, 0.320  The study is acceptable. |

|  |  |
| --- | --- |
| Reference: | KCP 8.3.4/01 |
| Report | Magnitude of the residue of acetamiprid in barley (Raw Agricultural Commodity) after two applications of MCW-2222 – four decline curve trials and four harvest trials in Northern Europe (Northern France, Poland, Germany, Hungary and Austria) – 2014, Chevallier E., 2014, Report No 14SGS034, Sponsor No R-34898 |
| Guideline(s): | Yes  ENV/MC/CHEM(98)17 GLP Principles.  ENV/JM/MONO(99)22 Application of GLP Principles.  ENV/JM/MONO(2002)9 Application of the OECD GLP Principles  ENV/JM/MONO(2007)17 Guidance on Pesticide Residue Analytical Methods.  7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials.  SANCO 3029/99, rev. 4, 2000 guidance for generating and reporting methods of analysis in support of pre-registration data requirements. |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

The analytical method used was validated in barley (whole plant, grain and straw) in the current study. See Section 5.1.2. in order to confirm the analytical method was functioning correctly when used, quality control recovery samples were processed and analysed concurrently with the test sample and are summarised in the table below.

Table A 18: Summary of procedural recoveries for acetamiprid in barley (whole plant, grain and straw) reported in study 14SGS034, Sponsor No R-34898A

| Matrix | Fortification level (mg/kg) | Mean Recovery (%) | Overall Mean (%) | Overall RSD (%) | n |
| --- | --- | --- | --- | --- | --- |
| Barley (whole plant) | 0.01 | 80 | 81 | 15 | 2 |
| 0.1 | 94 | 1 |
| 2.0 | 70 | 1 |
| Barley (straw) | 0.01 | 74 | 88 | 14 | 2 |
| 0.1 | 93 | 1 |
| 0.5 | 98 | 1 |
| Barley (grain) | 0.01 | 83 | 82 | 15 | 2 |
| 0.1 | 81 | 2 |

Table A 19: Summary of the study 1 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) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| 14SGS034  FR01  Northern France  Champagne Ardenne  51110 Bourgogne  NEU  2014 | Barley / EXPLORER | 1- 08/03/2014  2- 01/06/2014 to 15/06/2014  3- 17/07/2014 | 0.0403  0.0404 | 251.7  251.7 | 0.0160  0.0160 | 12/06/2014  23/06/2014 | BBCH 71  BBCH 77 | Whole plant  Grain  Straw | 1.3  0.27  0.43  0.069  <LOQ  0.077(f) | 0 DALA  7 DALA  14 DALA  18 DALA  24 DALA  24 DALA | Report: R-34898  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (EN 15662:2009-02, GIR/MET/MULTIQVA/01V2, GIR/MET/ACETAMIP/03V1), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 61 days. |

| Trial No./  Location/  EU zone/  Year | Commodity/ Variety | Date of  1.Sowing or planting  2.Flowering  3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analyzed | Residues (mg/kg) | PHI (days) | Details on trial |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| kg a.s./ ha | Water (l/ha) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| 14SGS034  PL02  Poland  Łόdzkie  99-440 Łażniki  NEU  2014 | Barley / SKARB | 1- 27/03/2014  2- 04/06/2014 to 12/06/2014  3- 29/07/14 | 0.0414  0.0404 | 310.7  303.2 | 0.0133  0.0133 | 19/06/2014  28/06/2014 | BBCH 73  BBCH 77 | Whole plant  Grain  Straw | 0.89  0.057  0.049  0.026  <LOQ  0.044 | 0 DALA  7 DALA  21 DALA  24 DALA  31 DALA  31 DALA | Report: R-34898  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (EN 15662:2009-02, GIR/MET/MULTIQVA/01V2, GIR/MET/ACETAMIP/03V1), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 58 days. |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 14SGS034  GE03  Germany  Brandenburg  16818 Kränzlin  NEU  2014 | Barley /  CAMPANILE | 1- 10/10/2013  2- 04/05/2014 to 15/05/2014  3- 02/07/2014 | 0.0417  0.0404 | 208.3  201.7 | 0.0200  0.0200 | 27/05/2014  07/06/2014 | BBCH 73  BBCH 77 | Whole plant  Grain  Straw | 0.59  0.76  0.66  0.20  0.028 (g) /  0.029 (h)  0.23 (g) | 0 DALA  7 DALA  16 DALA  19 DALA  25 DALA  25 DALA | Report: R-34898  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (EN 15662:2009-02, GIR/MET/MULTIQVA/01V2, GIR/MET/ACETAMIP/03V1), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 82 days. |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 14SGS034  HU04  Hungary  North  H-3397 Maklar  NEU  2014 | Barley /  SCARLETT | 1- 06/03/2014  2- 31/05/2014 to 10/06/2014  3- 10/07/2014 to 12/07/2014 | 0.0388  0.0411 | 242.7  256.9 | 0.0160  0.0160 | 03/06/2014  13/06/2014 | BBCH 65  BBCH 77 | Whole plant  Grain  Straw | 1.2  0.94  0.67  0.56  <LOQ  0.30 (f) | 0 DALA  7 DALA  17 DALA  21 DALA  27 DALA  27 DALA | Report: R-34898  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (EN 15662:2009-02, GIR/MET/MULTIQVA/01V2, GIR/MET/ACETAMIP/03V1), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 71 days. |
| 14SGS034 FR05  Northern France  Pays de la Loire  49490 Meigne le  Vicomte  NEU  2014 | Barley /  SUNSHINE | 1- 14/03/2014  2- 15/06/2014 to 16/06/2014  3- 26/07/2014 | 0.0404  0.0407 | 400.0  406.7 | 0.0101  0.0100 | 19/06/2014  30/06/2014 | BBCH 71  BBCH 77 | Grains  Straw | <LOQ  0.32 (f) | 25 DALA  25 DALA | Report: R-34898  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (EN 15662:2009-02, GIR/MET/MULTIQVA/01V2, GIR/MET/ACETAMIP/03V1), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 39 days. |
| 14SGS034 PL06  Poland  Kujawskopomorskie  88-400 Murczyn  NEU  2014 | Barley /  FLAVOUR | 1- 22/03/2014  2- 01/06/2014 to 09/06/2014  3- 27/07/2014 | 0.0387  0.0406 | 290.0  304.7 | 0.0133  0.0133 | 11/06/2014  21/06/2014 | BBCH 73  BBCH 77 | Grains  Straw | <LOQ  0.14 (f) | 36 DALA  36 DALA | Report: R-34898  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (EN 15662:2009-02, GIR/MET/MULTIQVA/01V2, GIR/MET/ACETAMIP/03V1), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 37 days. |
| 14SGS034 GE07  Germany  Lower Saxony  49685 Bühren  NEU  2014 | Barley /  SOULEYKA | 1- 27/09/2013  2- 15/05/2014 to 23/05/2014  3- 11/07/2014 | 0.0420  0.0393 | 210.0  196.7 | 0.0200  0.0200 | 02/06/2014  11/06/2014 | BBCH 71  BBCH 77 | Grain  Straw | 0.019 (g) /  0.022 (h)  0.21 | 30 DALA  30 DALA | Report: R-34898  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (EN 15662:2009-02, GIR/MET/MULTIQVA/01V2, GIR/MET/ACETAMIP/03V1), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 73 days. |
| 14SGS034 AU08  Austria  Upper Austria  4651 Bad Wimsbach-Neydharting  NEU  2014 | Barley /  SY LEOO | 1- 08/10/2013  2- 05/05/2014 to 10/05/2014  3- 18/07/2014 | 0.0416  0.0413 | 312.1  310.0 | 0.0133  0.0133 | 06/06/2014  16/06/2014 | BBCH 75  BBCH 77-83 | Grain  Straw | <LOQ  0.066 | 31 DALA  31 DALA | Report: R-34898  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (EN 15662:2009-02, GIR/MET/MULTIQVA/01V2, GIR/MET/ACETAMIP/03V1), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 47 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

(f) mean of two injections

(g) mean of two extractions

(h) retain specimen

* + - 1. Maize/Corn

Table A 20: Comparison of intended and critical EU GAPs

| Type of GAP | Number of applications | Application rate per treatment  (kg a.s./ha) | Interval between application  (days) | Growth stage at last application | PHI (days) |
| --- | --- | --- | --- | --- | --- |
| Intended cGAP (I, 1–3)\* | 1 | 0.060 | Not applicable | BBCH 51–75 | 56 |

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

* + - * 1. Study 1

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

|  |  |
| --- | --- |
| Reference: | KCP 8.3.5/01 |
| Report | Magnitude of the residue of acetamiprid in maize (Raw Agricultural Commodity) after one application of MCW-2222 - four semi decline curve trials and four decline curve trials in Northern Europe (Northern France, Poland, Germany, Hungary and Austria) – 2014, Lebrun F., 2014, Report No 14SGS039, Sponsor No R-34912 |
| Guideline(s): | Yes  ENV/MC/CHEM(98)17 GLP Principles.  ENV/JM/MONO(99)22 Application of GLP Principles.  ENV/JM/MONO(2002)9 Application of the OECD GLP Principles  ENV/JM/MONO(2007)17 Guidance on Pesticide Residue Analytical Methods.  7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials.  SANCO 3029/99, rev. 4, 2000 guidance for generating and reporting methods of analysis in support of pre-registration data requirements. |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 21: Summary of the study 1 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) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| 14SGS039  FR01  Northern France  Centre  41500 Suevre  NEU  2014 | Maize / DKC 3930 | 1- 12/04/2014  2- 10/07/2014 to 24/07/2014  3- 17/10/2014 to 20/10/2014 | 0.0592 | 445.6 | 0.0133 | 20/08/2014 | BBCH 75 | Whole plant  Whole plant  Whole plant w/o cobs and w/o kernel  Cobs w/o husk  Whole plant  Grain | 0.43  0.34  0.35  <LOQ  0.40  <LOQ | 0 DAA  5 DAA  9 DAA  9 DAA  27 DAA  58 DAA | Report: R-34912  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (13M06017-01-VMPL), and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 72 days. |

| Trial No./  Location/  EU zone/  Year | Commodity/ Variety | Date of  1.Sowing or planting  2.Flowering  3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analyzed | Residues (mg/kg) | PHI (days) | Details on trial |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| kg a.s./ ha | Water (l/ha) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| 14SGS039  PL02  Poland  Mazowieckie  05180 Pomiechowek  NEU  2014 | Maize / P8057 | 1- 25/04/2014  2- 09/07/2014 to 23/07/2014  3- 26/09/2014 to 03/10/2014 | 0.0572 | 381.9 | 0.0150 | 31/07/2014 | BBCH 71 | Whole plant  Whole plant  Whole plant w/o cobs and w/o kernel  Cobs w/o husk  Whole plant  Grain | 0.63  0.09  0.08  <LOQ  0.02  <LOQ | 0 DAA  6 DAA  11 DAA  11 DAA  33 DAA  55 DAA | Report: R-34912  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (13M06017-01-VMPL), and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 92 days. |
| 14SGS039  GE03  Germany  Lower Saxony  49685 Emstek  NEU  2014 | Maize /  SY COMANDOR MESUROL | 1- 05/05/2014  2- 28/07/2014 to 11/08/2014  3- 27/10/2014 | 0.0594 | 395.6 | 0.0150 | 03/09/2014 | BBCH 71 | Whole plant  Whole plant  Whole plant w/o cobs and w/o kernel  Cobs w/o husk  Whole plant  Grain | 0.77  0.59  0.65  <LOQ  0.24  <LOQ | 0 DAA  5 DAA  9 DAA  9 DAA  29 DAA  54 DAA | Report: R-34912  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (13M06017-01-VMPL), and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 58 days. |
| 14SGS039  HU04  Hungary  Szabolcs- Szatmar- Bereg County  H-4461 Nyirtelek- Ferenctanya  NEU  2014 | Maize / P0017 | 1- 18/04/2014  2- 10/07/2014 to 26/07/2014  3- 22/09/2014 to 24/09/2014 | 0.0622 | 621.1 | 0.0100 | 28/07/2014 | BBCH 71 | Whole plant  Whole plant  Whole plant w/o cobs and w/o kernel  Cobs w/o husk  Whole plant  Grain | 0.42  0.10  0.16  <LOQ  0.02  <LOQ | 0 DAA  5 DAA  8 DAA  8 DAA  30 DAA  56 DAA | Report: R-34912  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (13M06017-01-VMPL), and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 95 days. |
| 14SGS039  FR05  Northern France  Centre  37380 REUGNY NEU  2014 | Maize / DKC4117 | 1- 10/04/2014  2- 18/07/2014 to 26/07/2014  3- 12/10/2014 to 15/10/2014 | 0.0597 | 496.7 | 0.0120 | 19/08/2014 | BBCH 71 | Whole plant w/o cobs and w/o kernel  Cobs w/o husk  Whole plant  Grain | 0.57  <LOQ  0.18  <LOQ | 6 DAA  6 DAA  29 DAA  58 DAA | Report: R-34912  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (13M06017-01-VMPL), and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 67 days. |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 14SGS039  PL06  Poland  Lubelskie  21307 Kleböw  NEU  2014 | Maize / SILIEN | 1- 21/04/2014  2- 05/07/2014  to 27/07/2014  3- 26/09/2014  to 03/10/2014 | 0.0626 | 417.0 | 0.0150 | 01/08/2014 | BBCH 71 | Whole plant w/o cobs and w/o kernel  Cobs w/o husk  Whole plant  Grain | 0.37  <LOQ  0.04  <LOQ | 9 DAA  9 DAA  31 DAA  53 DAA | Report: R-34912  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method (13M06017-01-VMPL), and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 82 days. |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 14SGS039  GE07  Germany  Brandenburg  16818 Kränzlin  NEU  2014 | Maize / LG31.85 | 1- 25/04/2014  2- 10/07/2014 to 27/07/2014  3- 21/09/2014 to 26/09/2014 | 0.0602 | 300.0 | 0.0200 | 01/08/2014 | BBCH 71 | Whole plant w/o cobs and w/o kernel  Cobs w/o husk  Whole plant  Grain | 0.28  <LOQ  0.05  <LOQ | 19 DAA  19 DAA  42 DAA  53 DAA | Report: R-34912  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (13M06017-01-VMPL), and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 72 days. |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 14SGS039  AU08  Austria  Upper Austria  4614 Marchtrenk  NEU  2014 | Maize / P 8400 | 1- 08/04/2014  2-10/07/2014  to 15/07/2014  3- end of Sept to early Oct 2014 | 0.0629 | 313.7 | 0.0201 | 06/08/2014 | BBCH 73 | Whole plant w/o cobs and w/o kernel  Cobs w/o husk  Whole plant  Grain | 0.27  <LOQ  0.11  <LOQ | 8 DAA  8 DAA  23 DAA  55 DAA | Report: R-34912  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (13M06017-01-VMPL), and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 78 days. |
|  |  |  |  |  |  |  |  |  |  |  |  |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

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

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

* + - 1. Wheat

Table A 22: Comparison of intended and critical EU GAPs

| Type of GAP | Number of applications | Application rate per treatment  (kg a.s./ha) | Interval between application  (days) | Growth stage at last application | PHI (days) |
| --- | --- | --- | --- | --- | --- |
| cGAP EU (EFSA, 2016a) | 2 | 0.042 | 14 | BBCH 51-79 | 28 |
| Intended cGAP  (Iva-Vb, 23-40)\* | 2 | 0.036 | 10 | BBCH 12-69 | Not applicable |

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

* + - * 1. Study 1

|  |  |
| --- | --- |
| Comments of zRMS: | A study on magnitude of the residue of acetamiprid in wheat was conducted in Northern Europe following two applications of MCW-2222 containing 200 g/L acetamiprid.  Eight independent field trials (4 DCS+ 4 HS) were set up on wheat in Northern France, Poland, Germany, Hungary and Austria. The foliar applications of MCW-2222 were performed on the treated plot at the target dose rate of 0.2 L/ha FP (equivalent to 40 g a.s./ha).  Applications were performed using boom sprayers, following the target schedule:  - 1st foliar application performed 10 ± 1 days before the 2nd application (actually 9 to 11 days)  - 2nd foliar application performed at BBCH 77.  In the decline curve trials (DCS), RAC specimens for analyses (whole plants, grain and straw) were collected following the target schedule:  - at 0 DALA (Days After Last Application)  - at 7 DALA  - at 10 ± 1DBH (Day before harvest)  - at 7 ±1 DBH  - at the time of commercial harvest BBCH 89 (actually 20 to 39 DALA).  In the harvest trial (HS), RAC specimens for analyses (grain and straw) were collected following the target schedule:  - at the time of commercial harvest BBCH 89 (actually 16 to 31 DALA).  The method was successfully validated according to the guidance document SANCO/3029/99 rev4 on barley (whole plant, grains and straw) and reported in GIRPA report B14C-S1-A-03, SGS Agri min study 14SGS034. The limit of quantification (LOQ) for acetamiprid was 0.01 mg/kg.  The validity of the analytical method in this study was confirmed by procedural recovery determinations for each analytical set.  Recoveries and relative standard deviations at each fortification level were therefore within the accepted ranges of 70 – 110% and ≤ 20%, respectively.  No residues of acetamiprid were detected above the limit of detection (LOD = 0.0033 mg/kg) in the untreated specimens.  Residues of acetamiprid were determined in the treated specimens:  Wheat grain (mg/kg):  8 x <LOQ  Wheat straw (mg/kg):  0.031, 0.049, 0.056, 0.120, 0.210, 0.230, 0.510, 0.710  The study is acceptable. |

|  |  |
| --- | --- |
| Reference: | KCP 8.3.6/01 |
| Report | Magnitude of the residue of acetamiprid in wheat (Raw Agricultural Commodity) after two applications of MCW-2222 - four decline curve trials and four harvest trials in Northern Europe (Northern France, Poland, Germany, Hungary and Austria) – 2014, Chevallier E., 2014, Report No 14SGS033, Sponsor No R-34897 |
| Guideline(s): | Yes  ENV/MC/CHEM(98)17 GLP Principles.  ENV/JM/MONO(99)22 Application of GLP Principles.  ENV/JM/MONO(2002)9 Application of the OECD GLP Principles  ENV/JM/MONO(2007)17 Guidance on Pesticide Residue Analytical Methods.  7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials.  SANCO 3029/99, rev. 4, 2000 guidance for generating and reporting methods of analysis in support of pre-registration data requirements. |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

The analytical method used in the current study was previously validated in barley (whole plant, grain and straw) in study 14SGS034 / R-34898 (Chevallier E., 2014). See Section 5.1.2. in order to confirm the analytical method was functioning correctly when used in the current study, quality control recovery samples were processed and analysed concurrently with the test sample and are summarised in the table below.

Table A 23: Summary of quality control recoveries for acetamiprid in wheat (whole plant, grain and straw) reported in study 14SGS033, Sponsor No. R-34897A

| Matrix | Fortification level (mg/kg) | Mean recovery (%) | Overall Mean (%) | Overall RSD (%) | n |
| --- | --- | --- | --- | --- | --- |
| Wheat (grain) | 0.01 | 70 | 74 | - | 1 |
| 0.1 | 77 | 1 |
| Wheat (whole plant) | 0.01 | 83 | 93 | 15 | 2 |
| 4.0 | 102 | 1 |
| 2.0 | 102 | 1 |
| Wheat (straw) | 0.01 | 90 | 94 | 15 | 2 |
| 0.1 | 104 | 1 |
| 1.0 | 85 | 2 |

Table A 24: Summary of the study 1 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) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| 14SGS033  FR01  Northern France  Picardie  02190 Amifontaine  NEU  2014 | Wheat / TRAPEZ | 1- 20/10/2013  2-15/05/2014 to 05/06/2014  3- 21/07/2014 | 0.0396  0.0393 | 198.0  196.0 | 0.0200  0.0200 | 05/06/2014  16/06/2014 | BBCH 69  BBCH 77 | Whole plant  Grains  Straw | 0.48  0.41  0.097  0.23  <LOQ  0.23 | 0 DALA  7 DALA  25 DALA  29 DALA  35 DALA  35 DALA | Report: R-34897  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (EN 15662:2009-02, GIR/MET/MULTIQVA/01V2, GIR/MET/ACETAMIP/03V1), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 78 days. |

| Trial No./  Location/  EU zone/  Year | Commodity/ Variety | Date of  1.Sowing or planting  2.Flowering  3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analyzed | Residues (mg/kg) | PHI (days) | Details on trial |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| kg a.s./ ha | Water (l/ha) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| 14SGS033 PL02  Poland  Mazowieckie  05-860 Plochocin  NEU  2014 | Wheat / MUSZELKA | 1- 20/09/13  2- 04/06/14 to 08/06/14  3- 28/07/14 | 0.0419  0.0391 | 314.2  293.2 | 0.0133  0.0133 | 10/06/2014  19/06/2014 | BBCH 73  BBCH 77 | Whole plant  Grains  Straw | 0.60  0.31  0.034  0.021  <LOQ  0.031 | 0 DALA  7 DALA  29 DALA  33 DALA  39 DALA  39 DALA | Report: R-34897  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (EN 15662:2009-02, GIR/MET/MULTIQVA/01V2, GIR/MET/ACETAMIP/03V1), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 78 days. |
| 14SGS033 GE03  Germany  Brandenburg  14641 Nauen  NEU  2014 | Wheat / CUBUS | 1- 05/10/2013  2- 15/06/2014 to 25/06/2014  3- 02/08/2014 | 0.0414  0.0407 | 206.7  203.3 | 0.0200  0.0200 | 01/07/2014  12/07/2014 | BBCH 73  BBCH 77 | Whole plant  Grains  Straw | 0.56  1.0  0.70  0.17  <LOQ  0.51 | 0 DALA  7 DALA  11 DALA  14 DALA  20 DALA  20 DALA | Report: R-34897  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (EN 15662:2009-02, GIR/MET/MULTIQVA/01V2, GIR/MET/ACETAMIP/03V1), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 61 days. |
| 14SGS033 HU04  Hungary  North-East  4461 Ferenctanya  NEU  2014 | Wheat / MV  CSARDAS | 1- 19/10/2013  2- 19/05/2014 to 24/05/2014  3- 30/06/2014 to 02/07/2014 | 0.0408  0.0395 | 255.0  247.2 | 0.0160  0.0160 | 19/05/2014  29/05/2014 | BBCH 65  BBCH 77 | Whole plant  Grains  Straw | 1.1  0.45  0.70  0.71  <LOQ  0.71 | 0 DALA  7 DALA  22 DALA  25 DALA  32 DALA  32 DALA | Report: R-34897  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (EN 15662:2009-02, GIR/MET/MULTIQVA/01V2, GIR/MET/ACETAMIP/03V1), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 99 days. |
| 14SGS033 FR05  Northern France  Pays de la Loire  72500 La Bruère sur  Loir  NEU  2014 | Wheat / HYSTAR | 1- 09/10/2013  2- 20/05/2014 to 28/05/2014  3- 17/07/2014 | 0.0397  0.0417 | 198.3  208.3 | 0.0200  0.0200 | 05/06/2014  16/06/2014 | BBCH 73  BBCH 77 | Grain  Straw | <LOQ  0.12 | 30 DALA  30 DALA | Report: R-34897  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (EN 15662:2009-02, GIR/MET/MULTIQVA/01V2, GIR/MET/ACETAMIP/03V1), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 51 days. |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 14SGS033 PL06  Poland  Lodzkie  99-440 Lazniki  NEU  2014 | Wheat / TONACJA | 1- 28/09/2013  2- 02/06/2014 to 12/06/2014  3- 29/07/2014 | 0.0399  0.0412 | 298.9  309.2 | 0.0133  0.0133 | 18/06/2014  28/06/2014 | BBCH 73  BBCH 77 | Grain  Straw | <LOQ  0.049 | 31 DALA  31 DALA | Report: R-34897  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (EN 15662:2009-02, GIR/MET/MULTIQVA/01V2, GIR/MET/ACETAMIP/03V1), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 62 days. |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 14SGS033 GE07  Germany  Lower Saxony  49 685 Bühren  NEU  2014 | Wheat /  SMARAGD | 1- 18/10/2013  2- 06/06/2014 to 11/06/2014  3- 23/07/2014 | 0.0393  0.0413 | 196.7  206.7 | 0.0200  0.0200 | 27/06/2014  07/07/2014 | 73  77 | Grain  Straw | <LOQ  0.056 | 16 DALA  16 DALA | Report: R-34897  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (EN 15662:2009-02, GIR/MET/MULTIQVA/01V2, GIR/MET/ACETAMIP/03V1), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 44 days. |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 14SGS033 AU08  Austria  Upper Austria  4614 Marchtrenk  NEU  2014 | Wheat / PEDRO | 1- 23/10/2013  2- 29/05/2014 to 06/06/2014  3- 20/07/2014 | 0.0401  0.0413 | 301.0  310.0 | 0.0133  0.0133 | 16/06/2014  25/06/2014 | BBCH 73-75  BBCH 77 | Grain  Straw | <LOQ  0.21 | 25 DALA  25 DALA | Report: R-34897  Untreated specimens: <LOD  Analytical Method:  QuEChERS multi-residue method (EN 15662:2009-02, GIR/MET/MULTIQVA/01V2, GIR/MET/ACETAMIP/03V1), clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): MCW-2222 (SL).  Method: Foliar application boom sprayer.  Max. Storage Interval between sampling and analysis: 43 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

* + - 1. Sugar beet

Table A 25: Comparison of intended and critical EU GAPs

| Type of GAP | Number of applications | Application rate per treatment  (kg a.s./ha) | Interval between application (days) | Growth stage at last application | PHI (days) |
| --- | --- | --- | --- | --- | --- |
| cGAP EU (Art. 12, EFSA, 2011, updated 2012) | 2 | 0.050 | Not reported | Not reported | 7 |
| Intended cGAP (VIIIa, 80–84)\* | 2 | 0.050 | 7 | BBCH 12–39 | 35 |

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

* + - * 1. Study 1

|  |  |
| --- | --- |
| Comments of zRMS: | A study on magnitude of the residue of acetamiprid in sugar beet was conducted in Northern Europe following two applications of Acetamiprid 200 SL at 0.25 L/ha representing 50 g a.s./ha per application.  Three independent field trials (1 DCS+ 2 HS) were set up on sugar beet in Poland and Hungary.  Plot T was treated twice with 7 days interval, last application 32 to 35 days before harvest with Acetamiprid 200 SL at a target rate of 0.25 L/ha (representing 50 g/ha acetamiprid).  The method was successfully validated with the limit of quantification (LOQ) of 0.01 mg/kg for all matrices.  Recoveries and relative standard deviations at each fortification level were therefore within the accepted ranges of 70 – 110% and ≤ 20%, respectively.  No residues of acetamiprid were detected above the limit of detection (LOD = 0.0033 mg/kg) in the untreated specimens.  At commercial harvest, 32 to 35 days after last application, no residue of acetamiprid was detected in sugar beet roots.  In leaves + tops samples, the residues of acetamiprid ranged from 0.012 mg/kg to 0.081 mg/kg.  The study is acceptable. |

|  |  |
| --- | --- |
| Reference: | KCP 8.3.7/01 |
| Report | Magnitude of the residues of acetamiprid in sugar beet (RAC whole plants, roots and leaves+tops), following two applications of Acetamiprid 200 SL in three trials (two HS + one DCS) - Northern Europe (Poland and Hungary) – 2020, Roussel Ch.H., 2022, Report No SPK-20-46380, Sponsor No 000105979 |
| Guideline(s): | Yes  ENV/MC/CHEM(98)17 GLP Principles.  ENV/JM/MONO(99)22 Application of GLP Principles.  ENV/JM/MONO(2002)9 Application of the OECD GLP Principles  ENV/JM/MONO(2007)17 Guidance on Pesticide Residue Analytical Methods.  7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials.  OECD Guideline TG 509, 2009.  SANCO 3029/99, rev. 4, 2000 guidance for generating and reporting methods of analysis in support of pre-registration data requirements. |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 26: Summary of the study 1 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) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| SPK-20-46380  PL01  Poland  Warminski -Mazurskie  11-015 Gasiorowo  NEU  2020 | Sugar beet /  Jagger RH | 1- 20/04/2020  2- not applicable  3- 29/09/2020 | 0.050  0.050 | 302  298 | 0.017  0.017 | 19/08/2020  25/08/2020 | BBCH 45  BBCH 46 | Whole plant  Whole plant  Whole plant  Whole plant  Roots  Leaves + tops | 0.474  0.046  0.025  <LOQ  <LOQ  0.012 | 0  8  13  21  34  34 | Report: 000105979  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method, clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery : Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): ADM.00150.I.2.A (SL).  Method: Foliar broadcast application.  Max. Storage Interval between sampling and analysis: 138 days.  Max. Storage Interval between extraction and analysis: 2 days for whole plant and leaves + tops 18 days for sugar beet roots. |
|  |  |  |  |  |  |  |  |  |  |  |  |

| 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) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| SPK-20-46380  PL03  Poland  Wielkopolskie  63220 Slawoszew  NEU  2020 | Sugar beet /  Leandrus | 1- 26/03/2020  2- not applicable  3- 23/09/2020 | 0.051  0.049 | 307  297 | 0.017  0.017 | 12/08/2020  19/08/2020 | BBCH 47  BBCH 48 | Roots  Leaves + tops | < LOQ  0.081 | 35  35 | Report: 000105979  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method, clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): ADM.00150.I.2.A (SL). Method: Foliar broadcast application.  Max. Storage Interval between sampling and analysis: 124 days.  Max. Storage Interval between extraction and analysis: 2 days for whole plant and leaves + tops 18 days for sugar beet roots. |
|  |  |  |  |  |  |  |  |  |  |  |  |

| 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) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| SPK-20-46380  HU04  Hungary  5137 Jaszkiser  NEU  2020 | Sugar beet /  Strube | 1- 10/03/2020  2- not applicable  3- 22/09/2020 | 0.053  0.053 | 317  317 | 0.017  0.017 | 13/08/2020  20/08/2020 | BBCH 36  BBCH 41 | Roots  Leaves + tops | < LOQ  0.052 | 32  32 | Report: 000105979  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method, clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): ADM.00150.I.2.A (SL).  Method: Foliar broadcast application.  Max. Storage Interval between sampling and analysis: 126 days.  Max. Storage Interval between extraction and analysis: 2 days for whole plant and leaves + tops 18 days for sugar beet roots. |

(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

* + - * 1. Study 2

|  |  |
| --- | --- |
| Comments of zRMS: | A study on magnitude of the residue of acetamiprid in sugar beet was conducted in Northern Europe following two applications of Acetamiprid 200 SL at 0.25 L/ha representing 50 g a.s./ha per application.  One field trial was set up on sugar beet in Hungary.  Plot T was treated twice with 7 days interval, last application 35 days before harvest with Acetamiprid 200 SL at a target rate of 0.25 L/ha (representing 50 g/ha acetamiprid).  The method for the determination of acetamiprid was fully validated with the limit of quantification (LOQ) of 0.01 mg/kg according to SANCO/3029/99 rev.4 in study SPK-20-46380 (sponsor reference 000105979) for the matrix sugar beet roots belonging to the group of plant commodities with high water content.  A reduced validation was carried out in this study according to guideline SANTE/2020/12830 rev.1.  The maximum storage interval from sampling to analysis was 97 days for all specimens. The extracts were analysed within 2 days of extraction.  No residues of acetamiprid were detected above the limit of detection (LOD = 0.0033 mg/kg) in the untreated specimens.  At commercial harvest, 35 days after last application, no residue of acetamiprid was detected in sugar beet roots. In leaves + tops samples, the residues of acetamiprid was 0.185 mg/kg.  The study is acceptable. |

|  |  |
| --- | --- |
| Reference: | KCP 8.3.7/02 |
| Report | Magnitude of the residues of acetamiprid, after application of Acetamiprid 200 SL in sugar beet in Northern Europe – 2021, Roussel Ch.H., 2022, Report No ChR-21-48246, Sponsor No 000107604 |
| Guideline(s): | Yes  ENV/MC/CHEM(98)17 GLP Principles.  ENV/JM/MONO(99)22 Application of GLP Principles.  ENV/JM/MONO(2002)9 Application of the OECD GLP Principles  ENV/JM/MONO(2007)17 Guidance on Pesticide Residue Analytical Methods.  7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials.  OECD Guideline TG 509, 2009.  SANCO 3029/99, rev. 4, 2000 guidance for generating and reporting methods of analysis in support of pre-registration data requirements. |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 27: Summary of the study 2 trials

| Trial No./  Location/  EU zone/  Year | Commodity/ Variety | Date of  1.Sowing or planting  2.Flowering  3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analyzed | Residues (mg/kg) | PHI (days) | Details on trial |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| kg a.s./ ha | Water (l/ha) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| ChR-21-48246  HU01  Hungary  7465 Szentgalosker  NEU  2021 | Sugar beet / Barna | 1- 15/04/2021  2- not applicable  3- 17/10/2021 | 0.053  0.051 | 311  300 | 0.017  0.017 | 03/09/2021  10/09/2021 | BBCH 39  BBCH 39 | Whole plant  Whole plant  Whole plant  Whole plant  Roots  Leaves + tops | 0.555  0.480  0.155  0.0594  <LOQ  0.185 | 0  6  14  21  35  35 | Report: 000107604  Untreated specimens: <LOQ  Analytical Method:  QuEChERS multi-residue method, clean-up by dispersive SPE, and HPLC-MS/MS.  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): ADM.00150.I.2.A (SL).  Method: Foliar broadcast application.  Max. Storage Interval between sampling and analysis: 97 days.  Max. Storage Interval between extraction and analysis: 24 hours. |
|  |  |  |  |  |  |  |  |  |  |  |  |

(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

* + 1. Magnitude of residues in livestock
       1. Livestock feeding studies

No new studies were conducted.

* + 1. Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)
       1. Distribution of the residue in peel/pulp

No new studies were conducted.

* + - 1. Processing studies on a core set of representative processes
         1. Study 1

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

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

Materials and methods

In the growing season 2014, two follow-up trials were established on apple in Northern Europe (Northern France and Belgium), intended to determine acetamiprid residues in processed fractions. The sites were representative of apple grown in a way typical of the producing region in the test countries. One plot was foliar treated twice with MCW-2222 at the rate of 1.250 L/ha (equivalent to 250 g acetamiprid/ha) 22 and 14 days before harvest. A second plot was left untreated. The specimens for processing were taken 14 ± 1 days after last application and were transported under ambient conditions to the processing site. Samples were stored for max. 96 days in frozen conditions (<-18°C). The acetamiprid LOQ was 0.01 mg/kg and the LOD defined as 0.003 mg/kg (30 % of the LOQ).

Two trials were processed into washed fruits, juice, puree, and dried fruits. The specimens for processing were considered in excellent conditions at their arrival at processing site. The apples were processed on the day of their arrival and kept unwashed for each process.

**Washed fruits:** At reception, the apples were washed thoroughly with water sprayed at the rate of approximately 0.5 L/kg of fruits (BE04) or 0.75 L/kg of fruits (FR01). Apples were then strained. Washing water and fruits were collected separately.

**Juice:** At reception, unwashed apples were crushed and pressed. Wet pomaces were collected, sampled and the remaining was dried during approximately one day at 60 °C in order to generate dry pomace specimens. The juice was depectinised with enzymes and clarified before being bottled and pasteurized at approximately 85 °C during 1 minute.

**Puree:** At reception, unwashed apples were blanched 2 minutes in boiling water, then crushed and sieved to separate pips and peel. Waste was discarded. Sugar was added according to their sugar content and the mix was reduced in a saucepan in order to reach 24 % Brix. Puree was bottled and sterilized at 115/125 °C for 10 minutes.

**Dried fruits:** At reception, the fruits were cored and cut in slice about 3 mm thick. Cores were removed and discarded. The slices were placed in an oven at approximately 60 °C and left for drying until the humidity loss was more than 60 % of original weight.

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

Results and discussions

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

Table A 28: Residue data from apple processing study with acetamiprid

| **RAC** | **Residues in RAC(unwashed sample, mg/kg)** | **PHI**  **(days)** | **Processed commodity** | **Residue**  **(mg/kg)** | **Processing Factor(a)** | **Average**  **Processing**  **Factor** |
| --- | --- | --- | --- | --- | --- | --- |
| Apple | 0.37 | 13 | Whole fruit before processing | 0.37 | - | - |
| 0.37 | 14 | 0.37 | - |
| 0.37 | 13 | Washed fruits | 0.26 | 0.70 | 0.68 |
| 0.37 | 14 | 0.24 | 0.65 |
| 0.37 | 13 | Washing water | 0.03 | 0.08 | 0.06 |
| 0.37 | 14 | <0.01 (LOQ) | 0.03 |
| 0.37 | 13 | Wet pomace | 0.47 | 1.27 | 1.08 |
| 0.37 | 14 | 0.33 | 0.89 |
| 0.37 | 13 | Dry pomace | 1.36 | 3.68 | 3.73 |
| 0.37 | 14 | 1.4 | 3.78 |
| 0.37 | 13 | Juice | 0.18 | 0.49 | 0.48 |
| 0.37 | 14 | 0.17 | 0.46 |
| 0.37 | 13 | Puree | 0.21 | 0.57 | 0.60 |
| 0.37 | 14 | 0.23 | 0.62 |
| 0.37 | 13 | Dried apples | 1.18 | 3.19 | 3.15 |
| 0.37 | 14 | 1.15 | 3.11 |

(a) Processing factor: calculated by dividing the residue of acetamiprid determined for each crop matrix after processing by the initial content of acetamiprid determined in apple matrix

Figure A 1: Processing flowchart for apple distribution

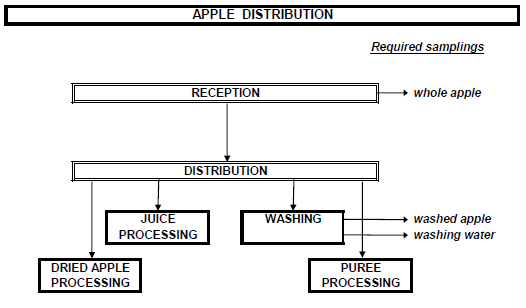


Figure A 2: Processing flowchart for apple juice

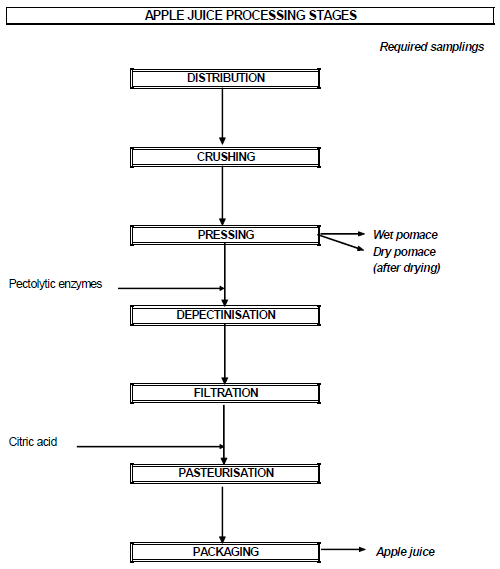


Figure A 3: Processing flowchart for apple puree

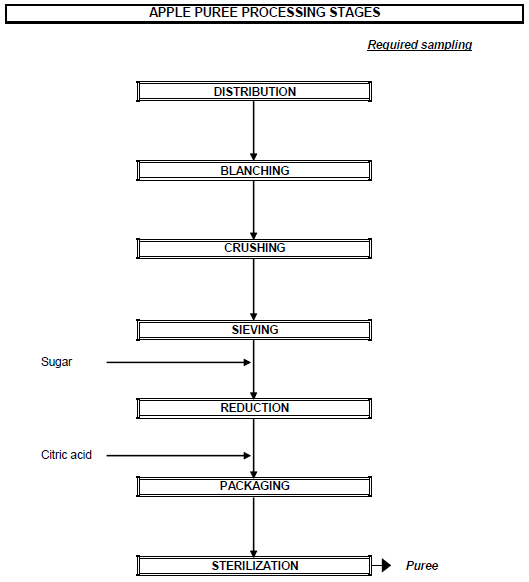
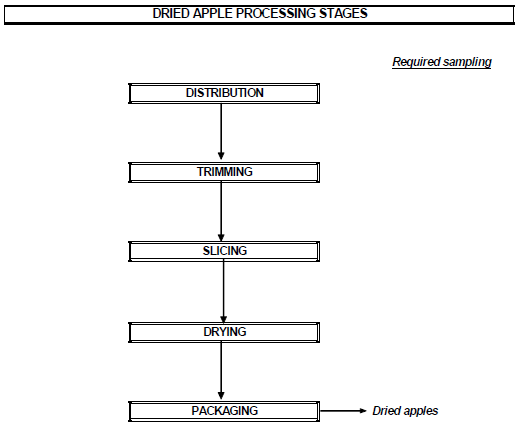


Figure A 4: Processing flowchart for dried apple



Conclusion

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

* + 1. Magnitude of residues in representative succeeding crops

No new studies were submitted.

* + 1. Other/Special Studies

One honey study has been conducted at critical GAP for acetamiprid (Sponsor No 000107273).

* + - 1. Study 1

|  |  |
| --- | --- |
| Comments of zRMS: | The objective of the study is to determine the magnitude of the residues acetamiprid in mature honey specimens following exposure of honeybees to Phacelia after two foliar applications of Acetamiprid 200 SL (acetamiprid 200 g/L SL) at the target rate of 0.4 L/ha per application corresponding to 80 g acetamiprid/ha per application.  The study consisted of four residue trials conducted in Northern and Southern Europe (Italy,  Austria and Spain; location of tunnel trials were located at least 10 km apart) in order to represent a common situation of honey obtained from honeybee colonies confined under light plastic gauze tunnels on phacelia fields.  The target application growth stage was the beginning of flowering (BBCH 61) for the first  application. The second application was performed 7 +/-1 days after the first one.  No residues of acetamiprid were found above LOQ (0.01 mg/kg) in untreated specimens.  After two foliar applications of ACETAMIPRID 200 SL on phacelia, residues in honey ranged from below LOQ (0.01 mg/kg) to 0.143 mg/kg in treated specimens.  The analytical method for analysis of residues of acetamiprid was fully validated for the matrix honey according to SANTE/2020/12830 rev.1 at a limit of quantification (LOQ) of 0.01 mg/kg for honey. Final determination was performed using LC-MS/MS.  Max. storage interval between sampling and analysis was 384 days. The study on the magnitude of residues are valid with regard to storage stability.  The study is acceptable. |

|  |  |
| --- | --- |
| Reference: | KCP 8.10.1/01 |
| Report | Magnitude of the residues of acetamiprid after application of ACETAMIPRID 200 SL in honey of phacelia in Northern and Southern Europe – 2021-2022; Boileau G. 2022; Study No GBU-21-48185, Sponsor No 000107273 |
| Guideline(s): | Yes  ENV/MC/CHEM(98)17 GLP Principles.  ENV/JM/MONO(99)22 Application of GLP Principles.  ENV/JM/MONO(2002)9 Application of the OECD GLP Principles  ENV/JM/MONO(2007)17 Guidance on Pesticide Residue Analytical Methods.  7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials.  OECD Guideline TG 509, 2009.  SANCO 3029/99, rev. 4, 2000 guidance for generating and reporting methods of analysis in support of pre-registration data requirements. |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

The analytical method used was fully validated on the matrix honey in the current study. See Section 5.1.2. In order to confirm the analytical method was functioning correctly when used, procedural recovery samples were processed and analysed concurrently with the field samples and are summarised in the table below.

Table A 29: Summary of procedural recoveries for acetamiprid in honey reported in study GBU-21-48185, Sponsor No 000107273

| Matrix | Fortification level (mg/kg) | Mean Recovery (%) | RSD (%) | n |
| --- | --- | --- | --- | --- |
| Honey | m/z 223 → 126 (quantification) | | | |
| 0.01 | 103 | - | 1 |
| 0.1 | 109 | - | 1 |
| **m/z 223 → 90 (confirmation)** | | | |
| 0.01 | 99 | - | 1 |
| 0.1 | 106 | - | 1 |

**Table A 30: Summary of the study 1 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) | g a.s./hl | Acetamiprid |
|  | (a) | (b) |  |  |  |  | (c) |  |  |  | (e) |
| GBU-21-48185  IT01  Italy  Piedmont  14100 Asti  SEU  2022 | Phacelia  Lilla | 1- 15/03/2021  2- from 16/06 to  28/06/2021  3- n.a. | 0.083  0.083 | 304  308 | 0.027  0.027 | 28/05/2021  04/06/2021 | BBCH 61  BBCH 65 | Honey | 0.143 (f)  (0.156 (g) / 0.129 (h)) | 12 | Report: 000107273  Untreated specimens: <LOQ  Analytical Method:  Extraction with acetonitrile/water, phase separation with buffer salt mixture, clean-up and  detection with LC MS/MS.  Method validated within CIP  study 21A14030-01-VMHN  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): ADM.00150.I.2.A (SL).  Method: Foliar broadcast application.  Max. Storage Interval between  sampling and analysis:  384 days  Max. Storage Interval between  extraction and analysis: 1 day |
|  |  |  |  |  |  |  |  |  |  |  |  |
| GBU-21-48185  IT02  Italy  Veneto  37060 Nogarole Rocca  SEU  2022 | Phacelia  Lilla | 1- 26/02/2021  2- from17/05 to 09/06/2021  3- n.a. | 0.079  0.083 | 242  256 | 0.033  0.032 | 21/05/2021  28/05/2021 | BBCH 61  BBCH 65 | Honey | <LOQ | 11 | Report: 000107273  Untreated specimens: <LOQ  Analytical Method:  Extraction with acetonitrile/water, phase separation with buffer salt mixture, clean-up and detection with LC MS/MS.  Method validated within CIP  study 21A14030-01-VMHN  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): ADM.00150.I.2.A (SL).  Method: Foliar broadcast application.  Max. Storage Interval between  sampling and analysis:  234 days  Max. Storage Interval between  extraction and analysis: 1 day |
|  |  |  |  |  |  |  |  |  |  |  |  |
| GBU-21-48185  AT04  Austria  Niederrösterreich  2471 Gerhaus / Parndorf  CEU  2022 | Phacelia  Angelia | 1- 08/06/2021  2- from 29/07 to 20/08/2021  3- n.a. | 0.083  0.082 | 304  303 | 0.027  0.027 | 02/08/2021  10/08/2021 | BBCH 61  BBCH 64 | Honey | 0.0472 | 10 | Report: 000107273  Untreated specimens: <LOQ  Analytical Method:  Extraction with acetonitrile/water, phase separation with buffer salt mixture, clean-up and detection with LC MS/MS.  Method validated within CIP  study 21A14030-01-VMHN  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): ADM.00150.I.2.A (SL).  Method: Foliar broadcast application.  Max. Storage Interval between  sampling and analysis:  161 days  Max. Storage Interval between  extraction and analysis: 1 day |
|  |  |  |  |  |  |  |  |  |  |  |  |
| GBU-21-48185  ES05  Spain  Andalucia  41720 Los Palacios  SEU  2022 | Phacelia  NAV | 1- 30/11/2021  2- from 07/04 to 14/05/2022  3- n.a. | 0.085  0.081 | 263  250 | 0.032  0.033 | 07/04/2022  13/04/2022 | BBCH 61  BBCH 63 | Honey | 0.0163 | 31 | Report: 000107273  Untreated specimens: <LOQ  Analytical Method:  Extraction with acetonitrile/water, phase separation with buffer salt mixture, clean-up and detection with LC MS/MS.  Method validated within CIP  study 21A14030-01-VMHN  Procedural Recovery: Mean recovery 70- 110 %, RSD ≤20 %  LOQ: 0.01 mg/kg  LOD: 0.003 mg/kg  Commercial Product (Formulation): ADM.00150.I.2.A (SL).  Method: Foliar broadcast application.  Max. Storage Interval between  sampling and analysis:  52 days  Max. Storage Interval between  extraction and analysis: 1 day |
|  |  |  |  |  |  |  |  |  |  |  |  |

(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

(f) Mean value = (initial ship value + retain value)/2

(g) Initial ship value

(h) Retain value

n.a. not applicable

Results and discussion

The purpose of this study was to determine the magnitude of residues of acetamiprid in mature honey specimens following exposure of honeybees to phacelia after two foliar applications of ACETAMIPRID 200 SL (acetamiprid 200 g/L SL).

Four harvest trials were settled in Northern and Southern Europe (Italy, Austria and Spain) in 2021 and 2022 in order to represent a common situation of honey obtained from honeybee colonies confined under light plastic gauze tunnels on phacelia fields.

Two plots were established in each trial site: U plot was left untreated while T plots were treated twice at 0.4 L/ha (80 g a.s./ha) at the crop growth stage of BBCH 61 and seven days after. One honeybee colony per plot was installed in the tunnels before the first application. Each honeybee colony was assessed two times: once just after set-up in the tunnels and once shortly before sampling of honey. Additional assessments were performed every seven days in order to check the evolution of the storage of honey. For all trials, one sampling of mature honey was performed.

The analytical method used for sample extraction and determination of residues was fully validated within this study. Quantification was performed by use of LC with MS/MS detection.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg and with a limit of detection (LOD) was set at 0.003 mg/kg (30 % of the LOQ).

The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 94 – 101 % and the mean recoveries at each fortification level were in the range of 70 – 110 % with relative standard deviation(s) below 20 %.

Due to unforeseen delay in delivery of specimen 4 from trial IT01, this specimen arrived thawed in the analytical laboratory. It was decided to conduct a storage stability experiment to check the stability of acetamiprid following a storage period of 7 days at 30 °C before refreezing and analysis. Stability was demonstrated therefore specimen 4 from trial IT01 could be used to determine the residue of acetamiprid in honey.

Conclusion

No residues of acetamiprid were found above the limit of quantification (LOQ = 0.01 mg/kg) in untreated specimens.

Residues of acetamiprid in treated specimens were of 0.143 mg/kg acetamiprid (study field 1), <0.010 mg/kg acetamiprid (study field 2), 0.0472 mg/kg acetamiprid (study field 3) and 0.0163 mg/kg acetamiprid (study field 4).

1. Pesticide Residue Intake Model (PRIMo)
   1. TMDI calculations

Not performed – see IEDI (A.3.2).

* 1. IEDI calculations ~~(Scenario 1 – with apple)~~





* 1. IESTI calculations - Raw commodities ~~(Scenario 1 – with apple)~~





* 1. IESTI calculations - Processed commodities ~~(Scenario 1 – with apple)~~





* 1. ~~IEDI calculations (Scenario 2 – without apple)~~



* 1. ~~IESTI calculations - Raw commodities (Scenario 2 – without apple)~~



* 1. ~~IESTI calculations - Processed commodities (Scenario 2 – without apple)~~



1. Additional information provided by the applicant