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## Modification of the existing maximum residue levels for acetamiprid in various crops

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### Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicants Nisso Chemical Europe GmbH and Sipcam Italia S.p.A. submitted requests to the competent national authority in the Netherlands and in Italy, respectively, to modify the existing maximum residue levels (MRLs) for the active substance acetamiprid in various crops. The data submitted in support of these requests were found to be sufficient to derive MRL proposals for plums, aubergines, peppers, cucumbers, courgettes, other cucurbits with edible peel, poppy seeds, mustard seeds, pomegranates and honey. Adequate analytical methods for enforcement are available to control the residues of acetamiprid in the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of acetamiprid according to the reported agricultural practices is unlikely to present a risk to consumer health.

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## Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Nisso Chemical Europe GmbH submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance acetamiprid in various crops. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 13 April 2021. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data requirements, which were requested from the EMS. On 24 June 2021, the EMS submitted a revised evaluation report (Netherlands, 2021), which replaced the previously submitted evaluation report.

Moreover, still in accordance with Article 6 of Regulation (EC) No 396/2005, Sipcam Italia S.p.A. submitted another application to the competent national authority in Italy (EMS) to modify the existing MRL for the active substance acetamiprid in pomegranates. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 27 May 2021. To accommodate for the intended use of acetamiprid, the EMS proposed to raise the existing MRL for pomegranates from the limit of quantification (LOQ) of 0.01 to 0.3 mg/kg. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA requested some clarifications from the EMS on 28 June 2021. On 7 July 2021, the EMS submitted a revised evaluation report (Italy, 2021), which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009, the data evaluated under previous MRL assessments and the additional data provided by the EMSs in the framework of these applications, the following conclusions are derived.

The metabolism of acetamiprid following foliar applications was investigated in crops belonging to the groups of fruit crops, root crops, leafy crops and pulses/oilseeds indicating acetamiprid as the main metabolite in primary crops. Studies investigating the effect of processing on the nature of acetamiprid (hydrolysis studies) demonstrated that the active substance is stable. In rotational crops, the major residue identified in metabolism studies was the metabolite IM-1-5, the presence of which was not confirmed in the rotational crop field studies. It is also expected that residues in floral nectar resulting from the use of acetamiprid in primary crops consists mainly of acetamiprid; the absence of metabolites IM-1-4 and IM-1-5 in honey was confirmed by the submitted residue trials. 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. Since there is a limited information available whether the enzymatic processes occurring in the bee gut or the storage in the beehive have an impact on the nature of residues in honey, it would be desirable to further investigate these aspects.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and the stability of acetamiprid during storage, the residue definitions for plant products were proposed as 'acetamiprid' for both enforcement and risk assessment. These residue definitions are applicable to primary crops, rotational crops and processed products as well as honey. The current enforcement residue definition in Regulation (EC) No 396/2005 is also acetamiprid. EFSA concluded that for the crops assessed in these applications, the metabolism of acetamiprid in primary and in rotational crops and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable and could be considered valid also for honey.

Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectroscopy (HPLC-MS/MS) are available to quantify residues of acetamiprid at or above 0.01 mg/kg (LOQ) in the crops assessed in these applications as well as in honey according to the enforcement residue definition.

The available residue trials are sufficient to derive MRL proposals for all crops under consideration. Since some of the crops under consideration are melliferous crops, the applicant investigated the potential carry-over of residues from treated primary crops into honey. A sufficient number of semi-field (tunnel) trials were provided. In these trials, beehives were placed in tunnels where *Phacelia tanacetifolia* was treated with acetamiprid during flowering. The study design of the trials was considered appropriate to use the results for deriving an MRL proposal of 0.3 mg/kg in honey. In addition, EFSA assessed the monitoring data from official EU National control programmes conducted by several Member States during 2012–2018, to check the plausibility of the residues found in the

supervised residue trials. The data indicated that in the vast majority of honey samples of acetaminiprid residues were below the LOQ of 0.05 mg/kg (0.26% exceedance of all analysed samples in 2018).

Specific studies investigating the magnitude of acetaminiprid residues in processed commodities were assessed in the framework of the MRL review and the EU pesticides peer review. No new data were submitted in the framework of the current applications. Nevertheless, further processing studies for the commodities under assessment are not required as they are not expected to affect the outcome of the risk assessment.

The occurrence of acetaminiprid residues in rotational crops was investigated in the framework of the EU pesticides peer review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance on primary crop is used according to the proposed Good Agricultural Practice (GAP).

Residues of acetaminiprid in commodities of animal origin were not assessed since the crops under consideration are normally not fed to livestock. An exception is the use on mustard seeds, since mustard seed meal can be used as fish feed item. However, since acetaminiprid is not fat soluble and the calculated potential exposure did not exceed the trigger values, further data on the nature and magnitude of residues in fish are not required.

The toxicological profile of acetaminiprid was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) value of 0.025 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.025 mg/kg bw.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMO). The short-term exposure assessment was performed only for the commodities assessed in the present MRL applications and the short-term exposure did not exceed the ARfD for any of the crops assessed. In the framework of the focused MRLs review according to Art. 43 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level and the acceptable Codex maximum residue limits (CXLs). EFSA updated this calculation with the relevant supervised trials median residue values (STMRs) derived from the residue trials submitted on the crops under consideration. The crops on which no uses were reported in the MRL review were excluded from the exposure calculation. The estimated long-term dietary intake accounted for 16% of the ADI (NL toddler diet).

EFSA concluded that the proposed use of acetaminiprid on various crops as well as the potential transfer of residues into honey will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

It must be noted that the investigation of possible risk to honeybees related to the use of acetaminiprid is outside the scope of this reasoned opinion. The evaluation of the risk to honeybees was evaluated in the framework of the peer review of acetaminiprid at EU level. Additionally, national competent authorities at Member State level should pay attention to the bee health and bee protection when granting authorisations for plant protection products according to the provisions laid out in the Regulation (EU) 2018/113.

The EFSA Panel on Plant Protection Products and their Residues (PPR) is also currently assessing new available information on acetaminiprid and considering any other information available from the recent evaluations by EFSA and the European Chemicals Agency (ECHA), to check whether there are indications of a serious risk to human or animal health or the environment from the use of acetaminiprid. Therefore, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of this evaluation.

EFSA proposes to amend the existing MRLs as reported in the summary table below.

Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
<b>Enforcement residue definition:</b> Acetaminiprid				
0140040	Plums	0.03	0.04	The submitted data are sufficient to derive an MRL proposal for the intended NEU/SEU use. Risk for consumers unlikely.

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0231030	Aubergines	0.2	0.4	Data on tomatoes extrapolated to aubergines. The MRL proposal reflects the more critical residue situation of the intended indoor use. Risk for consumers unlikely.
0231020	Sweet peppers/bell peppers	0.3	0.4	The submitted data are sufficient to derive an MRL proposal for the intended indoor use. Risk for consumers unlikely.
0232010	Cucumbers	0.3	0.4	The MRL proposal reflects the most critical residue situation of the intended indoor use. Risk for consumers unlikely. A separate MRL is currently set on gherkins at 0.6 mg/kg, which is not exceeded by the submitted residue data set.
0232030	Courgettes	0.3	0.4	
0232090	Other cucurbits with edible peel	0.3	0.4	
0401030	Poppy seeds	0.01*	0.3	Data on oilseed rape extrapolated to poppy seeds. The submitted data are sufficient to derive an MRL proposal for the intended NEU use. Risk for consumers unlikely.
0401080	Mustard seeds	0.01*	0.15	Data on oilseed rape extrapolated to mustard seeds. The submitted data are sufficient to derive an MRL proposal for the intended NEU use. Risk for consumers unlikely.
163050	Granate apples/pomegranates	0.01*	0.3	The submitted data are sufficient to derive an MRL proposal for the intended SEU use. Risk for consumers unlikely.
1040000	Honey and other apiculture products	0.05*	0.3	The MRL proposal reflects residues in honey from the critical authorised use and intended EU uses of acetamiprid on melliferous crops. MRL in honey is derived from semi-field/tunnel trials performed on <i>Phacelia tanacetifolia</i> . Risk for consumers unlikely.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.

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

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

(F): Fat soluble.

## Table of contents

Abstract.....	1
Summary.....	3
Assessment.....	7
1. Residues in plants .....	8
1.1. Nature of residues and methods of analysis in plants.....	8
1.1.1. Nature of residues in primary crops .....	8
1.1.2. Nature of residues in rotational crops .....	8
1.1.3. Nature of residues in processed commodities .....	9
1.1.4. Methods of analysis in plants/honey.....	9
1.1.5. Storage stability of residues in plants/honey.....	9
1.1.6. Proposed residue definitions.....	10
1.2. Magnitude of residues in plants/honey .....	10
1.2.1. Magnitude of residues in primary crops/honey.....	10
1.2.2. Magnitude of residues in rotational crops .....	13
1.2.3. Magnitude of residues in processed commodities.....	13
1.2.4. Proposed MRLs .....	14
2. Residues in livestock.....	14
3. Consumer risk assessment .....	14
4. Conclusion and Recommendations.....	15
References.....	15
Abbreviations.....	16
Appendix A – Summary of intended GAPS triggering the amendment of existing EU MRLs .....	18
Appendix B – List of end points .....	23
Appendix C – Pesticide Residue Intake Model (PRIMo) .....	30
Appendix D – Input values for the exposure calculations .....	33
Appendix E – Used compound codes.....	38

## Assessment

The European Food Safety Authority (EFSA) received two applications to modify the existing maximum residue levels (MRLs) for acetamiprid in various crops and in honey. The detailed description of the intended uses of acetamiprid, which are the basis for the current MRL applications, is reported in Appendix A.

Acetamiprid is the ISO common name for (*E*)-*N*1-[(6-chloro-3-pyridyl)methyl]-*N*2-cyano-*N*1-methylacetamidine (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Acetamiprid is an insecticide, which was evaluated for renewal of the approval in the framework of Regulation (EC) No 1107/2009<sup>1</sup> with the Netherlands designated as rapporteur Member State (RMS) for the representative uses as foliar treatments on pome fruits, tomatoes and potatoes. The renewal assessment report (RAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2016). The decision on the renewal of acetamiprid entered into force on 1 March 2018.<sup>2</sup>

The EU MRLs for acetamiprid are established in Annex II of Regulation (EC) No 396/2005<sup>3</sup>. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2011) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for acetamiprid. In addition, certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation.<sup>4</sup> Moreover, a focused MRL review according to Art. 43 of Regulation (EC) No 396/2005 and based on the new toxicological reference values agreed as part of the renewal of approval has been performed (EFSA, 2018b) and the proposed modifications have been implemented in the MRL legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005, Nisso Chemical Europe GmbH submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS-Netherlands) to modify the existing maximum residue levels (MRLs) for the active substance acetamiprid in various crops. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 13 April 2021. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data requirements, which were requested from the EMS. On 24 June 2021, the EMS submitted a revised evaluation report (Netherlands, 2021), which replaced the previously submitted evaluation report.

Moreover, still in accordance Article 6 of Regulation (EC) No 396/2005, Sipcam Italia S.p.A. submitted an application to the competent national authority in Italy (EMS-Italy) to modify the existing MRL for the active substance acetamiprid in pomegranates. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 27 May 2021. To accommodate for the intended use of acetamiprid, the EMS proposed to raise the existing MRL for pomegranates from LOQ of 0.01 mg/kg to 0.3 mg/kg. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA requested some clarifications from the EMS on 28 June 2021. On 7 July 2021, the EMS submitted a revised evaluation report (Italy, 2021), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation reports submitted by the EMSs (Netherlands, 2021; Italy, 2021), the renewal assessment report (RAR) and its addenda (Netherlands, 2015, 2016) prepared under Regulation (EC) 1107/2009, the Commission review report on acetamiprid (European Commission, 2018a), the conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid (EFSA, 2016), as well as the conclusions from previous EFSA opinions on

<sup>1</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

<sup>2</sup> Commission Implementing Regulation (EU) 2018/113 of 24 January 2018 renewing the approval of the active substance acetamiprid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 20, 25.1.2018, p. 7–10.

<sup>3</sup> Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

<sup>4</sup> For an overview of all MRL Regulations on this active substance, please consult: <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as>

acetamiprid, including the reasoned opinion on the MRL review according to Article 12 of Regulation No 396/2005 (EFSA, 2011) and the focused MRL review according to Art. 43 of Regulation (EC) 396/2005 (EFSA, 2018b).

For these applications, the data requirements established in Regulation (EU) No 283/2013<sup>5</sup> and the guidance documents applicable at the date of submissions of the applications to the EMSs are applicable (European Commission, 2000, 2010a,b, 2019b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011<sup>6</sup>.

A selected list of end points of relevant studies assessed previously is presented in Appendix B.

The evaluation reports submitted by the EMSs (Netherlands, 2021, Italy, 2021) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMO) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

## 1. Residues in plants

### 1.1. Nature of residues and methods of analysis in plants

#### 1.1.1. Nature of residues in primary crops

The metabolism of acetamiprid in primary crops belonging to the groups of fruit crops, root crops, leafy crops and pulses/oilseeds has been investigated in the framework of the MRL review (EFSA, 2011) and the EU pesticides peer review (EFSA, 2016).

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 are 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.

#### 1.1.2. Nature of residues in rotational crops

Acetamiprid is proposed to be used on several crops that can be grown in rotation with other crops and therefore, residues in rotational crops need to be investigated.

The nature of residues in rotational crops (confined studies) has been evaluated during the peer review (EFSA, 2016). Since acetamiprid has a low persistence in soil (highest field  $DT_{90}$  43 days and 20°C lab  $DT_{90}$  54 days), the metabolism study in rotational crops was not conducted with acetamiprid but using the more persistent soil metabolite IM-1-5 ( $DT_{50}$  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.

<sup>5</sup> Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 93, 3.4.2013, p. 1–84.

<sup>6</sup> Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.



The field rotational crop studies conducted in northern and southern EU with acetamiprid applied onto the bare soil at ca. 300 g/ha (1.5N overdosed with respect to the critical use under consideration), demonstrated that acetamiprid and metabolite IM-1-5 are not expected to be present in rotational crops (EFSA, 2016). Considering that the conditions of application of the representative uses assessed during the renewal cover the new intended uses, this conclusion is still considered relevant in the framework of the present assessment; therefore, no further information is required.

### 1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of acetamiprid was investigated in the framework of the MRL review (EFSA, 2011) and the EU pesticides peer review (EFSA, 2016). 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.

### 1.1.4. Methods of analysis in plants/honey

Analytical methods for the determination of acetamiprid residues in plants were assessed during the MRL review (EFSA, 2011). These analytical methods based on gas chromatography with electron capture detector (GC-ECD) and HPLC-MS/MS are sufficiently validated to enforce acetamiprid residues in high water, high acid, high oil content commodities and in dry commodities, at a validated LOQ of 0.01 mg/kg. Additionally, in the framework of the EU pesticides peer review (EFSA, 2016) and the focused MRL review according to Art. 43 (EFSA, 2018b), it was concluded that acetamiprid residues can be monitored in food and feed of plant origin with the multi-residue method QuEChERS by HPLC-MS/MS with an LOQ of 0.01 mg/kg in all plant commodity groups as well as in honey.

Moreover, a new analytical method (RD-11285) for the determination of acetamiprid and its metabolites IM-1-4 and IM-1-5 in honey is provided in the evaluation report submitted by the Netherlands in support of one of the applications under the current assessment (Netherlands, 2021). This new analytical method based on HPLC-MS/MS was fully validated in terms of specificity, linearity, accuracy and repeatability according to SANCO/3029/99 rev. 4 (European Commission, 2000) and SANCO/825/00 rev. 8.1 (European Commission, 2010b) for the determination of acetamiprid and its metabolites IM-1-4 and IM-1-5 in honey individually with an LOQ of 0.05 mg/kg.

Therefore, EFSA concludes that sufficiently validated analytical methods are available to monitor residues of acetamiprid in the plant commodities under consideration as well as in honey at or above the LOQ of 0.01 mg/kg. EFSA further notes that the extraction efficiency for the analytical methods applied for enforcement and used for the residue trials is not sufficiently proven for all commodities groups according to the requirements of the extraction efficiency Guidance, SANTE 2017/10632 (European Commission, 2017). Further investigation on this matter would in principle be required.

### 1.1.5. Storage stability of residues in plants/honey

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). Acetamiprid residues are stable in plant matrices stored at  $\leq -18^{\circ}\text{C}$  for up to 12–15 months in high water content matrices, for 8 months in high starch content matrices and for up to 12 months in high acid- and high oil content matrices. All plant commodities assessed in the present applications are of either high water, high oil or high acid content and all residue trials were performed in accordance with conditions ensuring the stability of acetamiprid residues.

Additionally, a new study assessing the stability of acetamiprid residues in honey was submitted with one of the current applications (Netherlands, 2021). Acetamiprid and the two metabolites IM-1-4 and IM-1-5 in honey were shown to be stable for at least 4 months when stored at  $\leq -18^{\circ}\text{C}$ . The semi-field/tunnel trials to determine the acetamiprid residues in honey have been performed in accordance with these storage conditions.

### 1.1.6. Proposed residue definitions

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 (European Commission, 2018b), 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 agrees with the EMS that the above plant residue definitions could be considered valid also for honey and other apicultural products. Moreover, in residue trials to investigate the transfer of residues in honey, samples were analysed for acetamiprid and the two metabolites I-M-1-4 and I-M-1-5 and no residues for these two metabolites were detected confirming the applicability of the plant residue definition also for honey.

## 1.2. Magnitude of residues in plants/honey

### 1.2.1. Magnitude of residues in primary crops/honey

In support of the MRL applications, the applicants submitted residue trials performed in various crops. Moreover, in order to determine acetamiprid residues in honey, semi-field/tunnel residue trials with *Phacelia tanacetifolia* as a surrogate crop were submitted. The residue trial samples were analysed for the parent compound as included in the residue definitions for enforcement and risk assessment.

According to the assessment of the EMSs, the methods used were sufficiently validated and fit for purpose (Netherlands, 2021, Italy, 2021). The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

#### Plums

*NEU/SEU outdoor cGAP: 1 × 75 g a.s./ha, BBCH 71–89, PHI 14 days*

The applicant provided eight NEU residue trials and eight SEU residue trials to determine the residues of acetamiprid in plums after the application of acetamiprid according to the intended GAPs as reported in Appendix A. Half of these residue trials were conducted as decline studies, indicating that residues decline between 7 and 14 days after the treatment. All residue trials are considered independent as they were performed in different geographical locations. The number of trials is also sufficient for plums which is a major crop in both the NEU and SEU.

The applicant proposed to derive an MRL in plums from the merged NEU and SEU data sets. EFSA agreed with the proposal to merge the NEU and SEU data sets since (i) these two data sets are based on the same GAPs, (ii) the data sets belong to the same statistical population (U-test) and (iii) the MRL proposal derived from the individual data sets fall into the same MRL class. Therefore, an MRL of 0.04 mg/kg is derived for acetamiprid in plums.

#### Aubergines

*Indoor cGAP: 2 × 100 g a.s./ha, interval = 14 days, BBCH 51–89, PHI 3 days*

The applicant provided eight indoor residue trials to determine the residues of acetamiprid in tomatoes after application of acetamiprid according to the intended GAP as reported in Appendix A; and proposed to extrapolate these data to aubergines. Half of these residue trials were conducted as

decline studies, indicating limited decline of residues within 7 days after the treatment. All residue trials are considered independent as they were performed in different geographical locations. The number of trials is also sufficient for aubergine which is a minor crop in both NEU and SEU.

In line with the applicable EU guidance document on setting MRLs, comparability of residue trials and extrapolation (European Commission, 2020), EFSA agrees that the extrapolation from tomatoes to aubergines is acceptable. Therefore, an MRL of 0.4 mg/kg is derived for acetamiprid in aubergines.

## Peppers

*Indoor cGAP: 2 × 50 g a.s./ha, interval = 14 days, BBCH 40–89, PHI 3 days*

The applicant provided 14 indoor residue trials to determine the residues of acetamiprid in peppers. All these trials have been overdosed compared to the intended GAP as reported in Appendix A (with an application rate in trials of 2 × 100 g a.s./ha vs. an application rate of 2 × 50 g a.s./ha in the intended GAP).

The EMS excluded four residue trials since in addition to the overdosed application rate also the interval between the two applications differs from the intended GAP (21- to 30-day interval in the trials vs. 14-day interval in the intended GAP). Moreover, the EMS also considered two of the remaining ten trials not independent since they were performed at the same geographical location and time with the same pepper variety. Hence, only the trial with the highest residue level from these two was considered for the MRL derivation.

EFSA agrees with the EMS assessment. Firstly, regarding the overdosed trials, EFSA notes that according to the use of the proportionality approach (EFSA, 2018c), a deviation of the application rate from the ± 25% boundaries is only acceptable if no other parameter deviates from the GAP. It is therefore correct to exclude the four overdosed trials performed with a deviation on the application interval. Secondly, regarding the independence of residue trials, EFSA notes that according to the EU guidance document on setting MRLs, comparability of residue trials and extrapolation (European Commission, 2020) residue field trials – including indoor trials – need to be performed at different geographical sites/facilities to reflect the variability in production system, soil conditions and/or weather conditions. Hence, EFSA agrees with the selection of the highest residue level from these two non-independent trials.

Therefore, nine independent and overdosed residue trials were considered to derive an MRL for peppers after scaling down the residue levels according to the proportionality approach. Five of these residue trials were conducted as decline studies, indicating decline of residues between 7 and 14 days after the treatment. All these selected residue trials are considered independent as they were performed in different geographical locations. The number of trials is also sufficient for pepper which is a major crop in both NEU and SEU. Therefore, an MRL of 0.4 mg/kg is derived for acetamiprid in peppers.

## Cucumbers, courgettes and other cucurbits with edible peel (except gherkins)

*Indoor cGAP: 2 × 100 g a.s./ha, interval = 14 days, BBCH 40–89, PHI 3 days*

The applicant provided eight indoor residue trials (five in cucumbers and three in courgettes) to determine the residues of acetamiprid in cucumbers and courgettes after application of acetamiprid according to the intended GAP as reported in Appendix A and proposed to extrapolate combined residue data to cucumbers, courgettes and other cucurbits with edible peel. Half of these residue trials were conducted as decline studies, indicating limited decline of residues within 7 days after the treatment. All residue trials are considered independent as they were performed in different geographical locations. The number of trials is also sufficient to support the intended uses on cucumbers, courgettes and other cucurbits with edible peel (except gherkins).

The extrapolation as proposed above by the applicant is supported according to the EU guidance document on setting MRLs, comparability of residue trials and extrapolation (European Commission, 2020). An MRL of 0.4 mg/kg is derived for acetamiprid in cucumbers, courgettes and other cucurbits with edible peel, except for gherkins where a separate EU MRL at 0.6 mg/kg is currently set and is not exceeded by this data set.

## Poppy seeds

*NEU outdoor cGAP: 2 × 30 g a.s./ha, interval = 14 days, BBCH 50–59 and 60–80, PHI n.a.*

The applicant provided eight residue trials in NEU on oilseed rape and proposed to extrapolate these data to poppy seeds. All these trials have been overdosed compared to the intended GAP as

reported in Appendix A (with an application rate in trials of  $2 \times 50$  g a.s./ha vs. an application rate of  $2 \times 30$  g a.s./ha in the intended GAP).

The EMS excluded three of these eight trials since in addition to the overdosed application rate at least another parameter in the use pattern differs of more than  $\pm 25\%$  from the intended GAP (either the application rate or the PHI). EFSA agrees with the EMS assessment since according to the use of the proportionality approach (EFSA, 2018c) a deviation of the application rate from the  $\pm 25\%$  boundaries is only acceptable if no other parameter deviates from the GAP. It is therefore correct to exclude the three overdosed trials performed with also a deviation on either the application interval or the PHI.

Therefore, five overdosed residue trials were considered overall to derive an MRL for poppy seeds after scaling down the residue levels according to the proportionality approach. Three of these residue trials were conducted as decline studies, indicating decline of residues between 7 and 28 days after the treatment. All these five residue trials selected are considered independent as they were performed in different geographical locations. The number of trials is also sufficient to support the intended use on poppy seeds which is a minor crop in NEU and to derive an MRL of 0.3 mg/kg.

### Mustard seeds

*NEU outdoor cGAP:  $1 \times 40$  g a.s./ha, BBCH 50–80, PHI 28 days*

The applicant provided eight residue trials in NEU on oilseed rape and proposed to extrapolate these data to mustard seeds. All submitted trials have been slightly overdosed compared to the intended GAP as reported in Appendix A (with an application rate in trials of  $1 \times 50$  g a.s./ha vs. an application rate of  $1 \times 40$  g a.s./ha in the intended GAP) while all other parameters are GAP compliant.

All these overdosed residue trials were considered to derive an MRL for mustard seeds after scaling down the residue levels according to the proportionality approach. Four of these residue trials were conducted as decline studies, indicating decline of residues between 7 and 28 days after the treatment. All these eight residue trials are considered independent as they were performed in different geographical locations. The number of trials is sufficient as mustard seeds is a minor crop in the NEU. Therefore, an MRL of 0.15 mg/kg is derived for acetamiprid in mustard seeds.

### Pomegranates

*SEU outdoor cGAP:  $1 \times 75$  g a.s./ha, BBCH 51–85, PHI 14 days*

The applicant provided four residue trials performed in Southern Italy in 2017 and 2018 to determine the residues of acetamiprid in pomegranates after application of the active substance according to the intended GAP as reported in Appendix A. Three of the residue trials were conducted as decline studies, indicating limited decline of residues between 14 and 28 or 35 days after the treatment.

EFSA notes that the two residue trials performed in 2018 in Southern Italy (R33AG18-01 and R33AG18-02) were performed in close geographical locations. However, considering that the residue trials were performed on different pomegranate varieties, with different treatment dates (15 days apart) and with different years of planting (2012 and 2017), in this specific case, EFSA considers the deviation of using close geographical locations acceptable for a minor crop such as pomegranate. Therefore, as an MRL of 0.3 mg/kg is derived for acetamiprid in pomegranates.

### Honey

*Surrogate crop: *Phacelia tanacetifolia*,  $2 \times 100$  g a.s./ha, interval = 10–13 days, BBCH 61 and 63–67, PHI 4–24 days*

Since current MRL applications concern uses on melliferous crops and the application of acetamiprid occurs before and during the flowering stage, residues in bee products need to be addressed in line with the requirements of the Technical Guideline SANTE/11956/2016 (European Commission, 2018b, hereafter refer to as 'honey guidelines').

In order to investigate the extent to which the transfer of residues occurs in bee products, the applicant provided four residue trials (two conducted in NEU and two in SEU) on *Phacelia tanacetifolia* treated at the application rate of  $2 \times 100$  g/ha. The applicant calculated the critical application rate of  $2 \times 100$  g a.s./ha on *Phacelia tanacetifolia* at and during the flowering stage to determine the transfer of residues in honey, in line with the most critical authorised and intended GAPs for melliferous crops.

Acetamiprid was applied under semi-field conditions (tunnel trials). The nature of the residues in honey is determined by the major constituent of the residues detected in primary crops, rotational crops and processed crops, that is the parent acetamiprid in line with the enforcement and risk assessment residue definitions.

EFSA agrees with the approach proposed by the applicant and supported by the EMS both in relation to the use of *Phacelia tanacetifolia* as a surrogate crop as well as on the most critical GAP identified.

EFSA further assessed the four provided semi-field/tunnel trials in line with the requirements of the honey guidelines. As described above, the test substance was applied in a realistic worst-case scenario with respect to residues in honey. All tunnel trials were conducted with two foliar applications performed either immediately before or during flowering of *Phacelia tanacetifolia*, at an application rate of 100 g a.s./ha, with an interval of 10–13 days between the treatments. The four submitted trials were also performed with a correct design for these semi-field/tunnel trials. On each trial site one tunnel confining the bees was established for both the control and the treated plot. Tunnels were of the required size and access to water was provided. The minimum number of four trials is also met with trials conducted in the same growing season but in different geographical locations. Honeybee colonies were brought to the test sites one day before the first application and remained in the tunnels until the end of sampling. Collection of honey samples was rightly performed when honey reached maturity at the end of flowering (i.e. water content below 20%). The honey guidelines recommend sampling of at least 100 g honey for each sample. EFSA noted that the samples collected ranged from 32 to 176 g in the different trials but considered this only as a minor deviation, not affecting the validity of the trials. The colony assessment was performed before set-up of the beehives and after sampling of the honey. Finally, the samples were then analysed for residues of acetamiprid and metabolites I-M-1-4 and I-M-1-5 with a validated analytical method to generate data in honey (method RD-11285) which is suitable for both enforcement and risk assessment with an LOQ of 0.05 mg/kg (Netherlands, 2021). Residues of acetamiprid ranged from < 0.05 mg/kg (LOQ) to 0.162 mg/kg while metabolites I-M-1-4 and I-M-1-5 were not detected above the LOQ in any sample confirming the applicability of the plant residue definition also for honey. The maximum storage period of honey samples prior to analysis was 83 days, which is well below the demonstrated storage stability period of 4 months. The control samples of honey did not contain residues of acetamiprid.

The submitted residue data indicates that in order to account for the transfer of residues from a melliferous crop into honey, an MRL of 0.3 mg/kg would be required. EFSA notes that, as indicated in the honey guidelines, consumption of pollen (including pollen present in honey), royal jelly, propolis, bee wax and honeycomb is negligible. Therefore, there is no need to generate experimental residue data for these commodities.

#### *Magnitude of residues from EU national monitoring program*

In the framework of Article 32 of Regulation (EC) No 396/2005 (official national control programmes), monitoring data were submitted to EFSA. The vast majority of the honey samples analysed resulted in acetamiprid residue levels below the LOQ of 0.05 mg/kg with the highest fraction of samples with MRL exceedance accounting for 0.26% of all analysed samples in 2018. The data demonstrated that the MRL proposal for honey derived from the valid semi-field/tunnel residue trials presented in this application is higher than the residue found in market samples of honey.

#### **1.2.2. Magnitude of residues in rotational crops**

The possible transfer of acetamiprid residues to crops that are grown in crop rotation has been assessed in the EU pesticides peer review (EFSA, 2016). The available studies demonstrated that significant residues (above 0.01 mg/kg) are not expected in succeeding crops (turnip, spinaches and wheat) planted in soil treated at 300 g a.s./ha.

Since the maximum annual application rate for the crops under consideration (i.e. 200 g a.s./ha) is lower than the application rate tested in the rotational crop study, it is concluded that no residues are expected in rotational crops, provided that the active substance on primary crop is applied according to the proposed GAPs.

#### **1.2.3. Magnitude of residues in processed commodities**

Processing studies with several crops have been assessed in the EU pesticides peer review (EFSA, 2016). Amongst these studies, processing studies in apples (juicing) and gherkins (cooking and pickling/canning) demonstrated a reduction of the acetamiprid residues in these processed products.

Additional and more specific processing studies for the crops under assessment are not available and not needed since it is expected that processing of these commodities by juicing, cooking and pickling/canning will also lead to a reduction of the acetamiprid residues in line with the studies already available and assessed in the EU pesticides peer review.

#### 1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all crops under evaluation as well as for residues in honey (see Appendix B.3). In Section 3 EFSA assessed whether residues on these commodities resulting from the intended uses of acetamiprid are likely to pose a consumer health risk.

## 2. Residues in livestock

None of the crops under consideration is used as a feed item for livestock, therefore residues in livestock in principle would not need to be assessed.

However, according to the new data requirement of Regulation (EC) 283/2013, a feeding study may be triggered where the plant protection product is used in crops whose parts or products, also after processing, are fed to fish and where residues in feed may occur from the intended application. Processed mustard seeds may be used as fish feed item according to the working document on the nature of pesticides residues in fish (SANCO/11187/2013, European Commission, 2013). As acetamiprid is not fat soluble (EFSA 2016) investigation of the nature and magnitude of residues in fish in principle would not be required according to SANCO/11187/2013. The applicant nevertheless assessed the exposure of fish to acetamiprid residues via intake of feed containing treated mustard seeds.

Fish dietary burden from the intake of mustard seed was calculated with the STMR value of 0.03 mg/kg as derived from the submitted residue trials. The maximum dietary burden for common carp and rainbow trout was calculated to be 0.003 and 0.002 mg/kg DM, respectively and the calculated worst case intakes for both fish species are not significant (< 0.1 mg/kg DM) (Netherlands, 2021) thus demonstrating that further studies investigating the nature and magnitude of residues in fish are not required.

## 3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for acetamiprid used in the risk assessment (i.e. ADI of 0.025 mg/kg bw per day and ARfD of 0.025 mg/kg bw) were derived in the framework of the EU pesticides peer review (European Commission, 2018a).

### Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed only for the commodities assessed in the present MRL applications. The calculations were based on the highest residue (HR) (for plums, aubergines, peppers, cucurbits with edible peel (except gherkins), pomegranates) or medium residue (STMR) (for poppy seeds, mustard seeds) values as derived from the submitted supervised field trials and the complete list of input values can be found in Appendix D.1.

The short-term exposure did not exceed the ARfD for any of the crops/commodities assessed in these applications (see Appendix C).

### Long-term (chronic) dietary risk assessment

In the framework of the focused MRL review according to Art. 43 of Regulation (EC) 396/2005, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level and the acceptable CXLs (EFSA, 2018b). Reviewed MRLs were then implemented into Regulation (EU) 2019/88<sup>7</sup>.

<sup>7</sup> Commission Regulation (EU) 2019/88 of 18 January 2019 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid in certain products. C/2019/140. OJ L 22, 24.1.2019, p. 1–12.

EFSA updated this calculation with the relevant STMR values derived from the residue trials submitted in support of the present MRL applications. The crops on which no uses were reported in the MRL review were excluded from the exposure calculation. The input values used in the exposure calculations are summarised in Appendix D.1.

The estimated long-term dietary intake accounted for 16% of the ADI (NL toddler diet). The contribution of residues expected in the commodities assessed in these applications to the overall long-term exposure is presented in more detail in Appendix C.

EFSA concluded that the long-term intake of residues of acetamiprid resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

## 4. Conclusion and Recommendations

The data submitted in support of present MRL applications were found to be sufficient to derive MRL proposals for various crops and honey.

EFSA concluded that the proposed use of acetamiprid on various crops and the potential transfer of residues into honey will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

It must be also noted that the investigation of possible risk to bees related to the use of acetamiprid is outside the scope of this reasoned opinion. The evaluation of the risk to honeybees was evaluated in the framework of the peer review of the approval of acetamiprid at EU level. Additionally, national competent authorities at Member State level should pay attention to the bee health and bee protection when granting authorisations for plant protection products.

The MRL recommendations are summarised in Appendix B.3.

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## Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
CIRCA	(EU) Communication & Information Resource Centre Administrator
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT <sub>90</sub>	period required for 90% dissipation (define method of estimation)
EC	emulsifiable concentrate
ECD	electron capture detector
EDI	estimated daily intake
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GR	granule
HPLC	high-performance liquid chromatography
HPLC-MS	high-performance liquid chromatography with mass spectrometry
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake



IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rappporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
SG	water-soluble granule
SL	soluble concentrate
SP	water-soluble powder
STMR	supervised trials median residue
TAR	total applied radioactivity
TRR	total radioactive residue
UV	ultraviolet (detector)
WHO	World Health Organization

**Appendix A – Summary of intended GAPs triggering the amendment of existing EU MRLs**

Crop and/or situation	NEU, SEU, MS or country	F G or I <sup>(a)</sup>	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days) <sup>(d)</sup>	Remarks	
				Type <sup>(b)</sup>	Conc. a.s. (g/kg)	Method kind	Range of growth stages and season <sup>(c)</sup>	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max			Unit
Plums	RO, SI, SK, CZ, LU	F	<i>Cydia pomonella</i> , <i>Phyllonorycter blancardella</i> , <i>Cacopsylla pyri</i>	SG	200 g/kg	Foliar treatment – general (see also comment field)	BBCH 71–89	1			500	75	g a.i./ha	14	Foliar spray Atomising
Plums	PL, SK, CZ	F	<i>Cydia pomonella</i> , <i>Phyllonorycter blancardella</i> , <i>Cacopsylla pyri</i>	SP	200 g/kg	Foliar treatment – general (see also comment field)	BBCH 71–89	1			500	75	g a.i./ha	14	Foliar spray Atomising
Plums	GR, ES, FR, PT, BG, HR, MT	F	Aphids ( <i>Myzus persicae</i> , <i>Aphis pomi</i> , <i>Aphis spiraecola</i> , <i>Myzus cerasi</i> ), Leaf miners ( <i>Leucoptera malifoliella</i> , <i>Phyllonorycter blancardella</i> ), Sawfly, Scales, <i>Drosophila suzukii</i> DROSSU, <i>Capnodis tenebrionis</i>	SG	200 g/kg	Foliar treatment – broadcast spraying	BBCH 71–89	1			1,000	75	g a.i./ha	14	

Crop and/or situation	NEU, SEU, MS or country	F G or I <sup>(a)</sup>	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days) <sup>(d)</sup>	Remarks	
				Type <sup>(b)</sup>	Conc. a.s. (g/kg)	Method kind	Range of growth stages and season <sup>(c)</sup>	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max			Unit
Plums	EL, ES, FR, HR, IT, PT	F	Aphids ( <i>Myzus persicae</i> , <i>Aphis pomi</i> , <i>Aphis spiraecola</i> , <i>Myzus cerasi</i> ), Leaf miners ( <i>Leucoptera malifoliella</i> , <i>Phyllonorycter blancardella</i> ), Sawfly, Scales, <i>Capnodis tenebrionis</i> , <i>Asymmetrasca decedens</i>	SP	200 g/kg	Foliar treatment – broadcast spraying	BBCH 71–89	1			80–1,200	75	g a.i./ha	14	
Tomatoes	CY, BG, ES, FR, GR, PT, DE, UK, RO, HR, MT, LU, LT	G	Whitefly ( <i>Bemisia tabaci</i> , <i>Trialeurodes vaporariorum</i> )	SG	200 g/kg	Foliar treatment – broadcast spraying	Beginning of infestation (BBCH 51–89)	2	14		150–1,700	70–100	g a.i./ha	3	
Aubergines/egg plants	CY, BG, ES, FR, GR, PT, DE, UK, RO, HR, MT, LU, LT	G	Whitefly ( <i>Bemisia tabaci</i> , <i>Trialeurodes vaporariorum</i> )	SG	200 g/kg	Foliar treatment – broadcast spraying	Beginning of infestation (BBCH 51–89)	2	14		150–1,700	70–100	g a.i./ha	3	

Crop and/or situation	NEU, SEU, MS or country	F G or I <sup>(a)</sup>	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days) <sup>(d)</sup>	Remarks
				Type <sup>(b)</sup>	Conc. a.s. (g/kg)	Method kind	Range of growth stages and season <sup>(c)</sup>	Number min-max	Interval between application (days) min-max	g a.s./hL min-max	Water (L/ha) min-max	Rate min-max	Unit		
Tomatoes	ES, FR, GR, PT, IT, PL, BG	G	Whitefly ( <i>Bemisia tabaci</i> , <i>Trialeurodes vaporariorum</i> )	SP	200 g/kg	Foliar treatment – broadcast spraying	Beginning of infestation (BBCH 51–89)	2	14		150–1,700	70–100	g a.i./ha	3	
Aubergines/egg plants	ES, FR, GR, PT, IT, PL, BG	G	Whitefly ( <i>Bemisia tabaci</i> , <i>Trialeurodes vaporariorum</i> )	SP	200 g/kg	Foliar treatment – broadcast spraying	Beginning of infestation (BBCH 51–89)	2	14		150–1,700	70–100	g a.i./ha	3	
Sweet peppers/bell peppers	BG, ES, FR, GR, PT, BE, NL, RO, UK, MT, LU, LT	G	Aphids ( <i>Myzus persicae</i> , <i>Aphis gossypii</i> )	SG	200 g/kg	Foliar treatment – broadcast spraying	Beginning of infestation (BBCH 40–89)	2	14		150–1,700	50	g a.i./ha	3	
Sweet peppers/bell peppers	ES, FR, GR, PT, IT, BG, PL	G	Aphids ( <i>Myzus persicae</i> , <i>Aphis gossypii</i> )	SP	200 g/kg	Foliar treatment – broadcast spraying	Beginning of infestation (BBCH 40–89)	2	14		150–1,700	50	g a.i./ha	3	
Cucumber, courgette and other cucurbits with edible peel	SE, BG, ES, GR, PT, AT, DE, CY, MT, LU, LT	G	Whitefly ( <i>Trialeurodes vaporariorum</i> , <i>Bemisia tabaci</i> )	SG	200 g/kg	Foliar treatment – broadcast spraying	Beginning of infestation (BBCH 40–89)	2	14		200–1,700	70–100	g a.i./ha	3	

Crop and/or situation	NEU, SEU, MS or country	F G or I <sup>(a)</sup>	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days) <sup>(d)</sup>	Remarks
				Type <sup>(b)</sup>	Conc. a.s. (g/kg)	Method kind	Range of growth stages and season <sup>(c)</sup>	Number min-max	Interval between application (days) min-max	g a.s./hL min-max	Water (L/ha) min-max	Rate min-max	Unit		
Cucumber, courgette and other cucurbits with edible peel	ES, GR, PT, PL	G	Whitefly ( <i>Trialeurodes vaporariorum</i> , <i>Bemisia tabaci</i> )	SP	200 g/kg	Foliar treatment – broadcast spraying	Beginning of infestation (BBCH 40–89)	2	14		200–1,700	70–100	g a.i./ha	3	
Poppy seeds	SK, CZ	F	Aphids Ceutorhynchus	SG	200 g/kg	Foliar treatment – broadcast spraying	BBCH 50–59 BBCH 60–80	2	14		300	30	g a.i./ha	n.a.	
Poppy seeds	SK, CZ	F	Aphids Ceutorhynchus	SP	200 g/kg	Foliar treatment – broadcast spraying	BBCH 50–59 BBCH 60–80	2	14		300	30	g a.i./ha	n.a.	
Mustard seeds	RO, BE, AT, DE, HU, CZ, SK, LU	F	Pollen beetle, Pod pests	SG	200 g/kg	Foliar treatment – broadcast spraying	BBCH 50–80	1			200–600	40	g a.i./ha	28	
Mustard seeds	PL, HU, CZ, SK, UK	F	Pollen beetle, Pod pests	SP	200 g/kg	Foliar treatment – broadcast spraying	BBCH 50–80	1			200–600	40	g a.i./ha	28	
Granate apples/pomegranates	SEU	F	Aphids, mealybug ( <i>Planococcus</i> sp.)	SL	200 g/L	Foliar treatment – ultra low volume spraying	BBCH 51–85	1	n.a.	5–7,5	1,000–1,500	75	g a.i./ha	14	

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI – minimum preharvest interval.

*In the framework of the review of existing MRLs according to Art. 12 of EU Regulation 396/2005 (EFSA, 2011), subsequent MRL applications and the focused assessment of certain existing MRLs under Art.43 (EFSA, 2018b), numerous GAPs were reported for crops that might be attractive to bees for food foraging and that might contribute to the final residues of acetamiprid in honey. However, since the MRL application in honey is not linked to one specific GAP and applies to honey as food item for consumers, the use pattern in phacelia tanacetifolia as surrogate crop with high melliferous capacity is not included in this Appendix but described in the section 1.2 of the reasoned opinion.*

## Appendix B – List of end points

### B.1. Residues in plants

#### B.1.1. Nature of residues and methods of analysis in plants

##### B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

Primary crops (available studies)	Crop groups	Crop(s)	Application(s)	Sampling (DAT)	Comment/Source
	Fruit crops	Eggplants		Dotting on leave and fruit surface, 1 × 9.5 g a.s./hl	7, 14
	Apples		Foliar, 1 × 208 g/ha	0, 7, 14, 28, 62, 90	Radiolabelled active substance: pyridine-2,6- <sup>14</sup> C acetamiprid (EFSA, 2011, 2016)
			Fruit dotting, 1 × 104 g/ha	0, 14, 28, 62	
Root crops	Carrots		Foliar, 2 × 100 g/ha	14	Radiolabelled active substance: pyridine-2,6- <sup>14</sup> C acetamiprid (EFSA, 2011, 2016)
Leafy crops	Cabbages		Foliar, 1 × 302 g/ha	0, 7, 14, 21, 28, 63	Radiolabelled active substance: pyridine-2,6- <sup>14</sup> C acetamiprid (EFSA, 2011, 2016)
			Soil treatment, 1 × 5,940 g/ha	7, 14, 28	
			Foliar, 1 × 299 g/ha	0, 7, 14, 28, 63	
Pulses/oilseeds	Cotton		Foliar, 4 × 123 Foliar, 4 × 1,230 g/ha	14, 28 DAT	Radiolabelled active substance: pyridine-2,6- <sup>14</sup> C acetamiprid (EFSA, 2011, 2016)
Rotational crops (available studies)	Crop groups	Crop(s)	Application(s)	PBI (DAT)	Comment/Source
	Root/tuber crops	Turnips		Bare soil, 266 g a.s./ha	0
Leafy crops	Spinaches		Bare soil, 266 g a.s./ha	0	
Cereal (small grain)	Wheat		Bare soil, 266 g a.s./ha	0	
Processed commodities (hydrolysis study)	Conditions			Stable?	Comment/Source
	Pasteurisation (20 min, 90°C, pH 4)			Yes	Acetamiprid was stable under standard hydrolysis conditions. Pasteurisation, baking/brewing/boiling and sterilisation are unlikely to result in any significant metabolites (EFSA, 2011, 2016)
	Baking, brewing and boiling (60 min, 100°C, pH 5)			Yes	
	Sterilisation (20 min, 120°C, pH 6)			Yes	

Can a general residue definition be proposed for primary crops?	Yes	Acetamiprid was identified as the major component of the residues in almost all plant matrices (EFSA, 2011, 2016)
Rotational crop and primary crop metabolism similar?	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, 2016)
Residue pattern in processed commodities similar to residue 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, 2016)
Plant residue definition for monitoring (RD-Mo)	Acetamiprid	
Plant residue definition for risk assessment (RD-RA)	Acetamiprid	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	<p><u>Multiresidues (QuEChERS)</u></p> <p>HPLC-MS/MS (LOQ: 0.01 mg/kg for apples, potatoes, oranges, maize grain, sunflower seeds and honey) (EFSA, 2016).</p> <p>HPLC-MS/MS (LOQ: 0.01 mg/kg for dry beans, dry beans straw, mandarin, oilseed rapes, olives and olive oil) (EFSA, 2018b).</p> <p>HPLC-MS/MS (individual LOQ: 0.05 mg/kg) for determination of acetamiprid and its metabolites IM-1-4 and IM-1-5 in honey; ILV provided (Netherlands, 2021)</p>	

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; GC-MS: gas chromatography with mass spectrometry; LC-MS/MS: liquid chromatography with tandem mass spectrometry; HPLC-MS/MS: high performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; ILV: independent laboratory validation.



### B.1.1.2. Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
	High water content	Cabbage, cucumber	-18	12	Months	Parent	EFSA (2016)
		Apple, tomato	-18	≤ 13	Months	Parent	EFSA (2016)
		Lettuce	-18	15	Months	Parent	EFSA (2016)
	High oil	Cotton seed, cotton oil, orange oil	-18	12	Months	Parent	EFSA (2016)
	High protein content	Fodder peas	-18	12	Months	Parent	EFSA (2016)
	Dry/high starch	Potato tuber	-18	8	Months	Parent	EFSA (2016)
	High acid content	Orange, orange juice	-18	12	Months	Parent	EFSA (2016)
	Specific matrices	Dry bean straw	-18	12	Months	Parent	EFSA (2018b)
		Honey	-18	4	Months	Parent, IM-1-4 and IM-1-5	Netherlands (2021)
Processed products	Apple juice/wet pomace Cotton gin trash/hulls/meal Orange dried pulp, orange juice	-18	12	Months	Parent	EFSA (2016)	

### B.1.2. Magnitude of residues in plants

#### B.1.2.1. Summary of residues data from the supervised residue trials

Commodity	Region/ <sup>(a)</sup>	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR <sup>(b)</sup> (mg/kg)	STMR <sup>(c)</sup> (mg/kg)	CF <sup>(d)</sup>
Plums	NEU	3 × < 0.01, 3 × 0.01, 2 × 0.02	Since the NEU and SEU data sets are similar (Mann–Whitney U-test) and based on the same GAPs, data are combined for the MRL proposal	<b>0.04</b>	0.03	0.01	n/a
	SEU	5 × < 0.01, 0.01, 0.02, 0.03					
Aubergines	Indoor	2 × 0.06, 0.07, 0.11, 2 × 0.13, 0.15, 0.19	Residue trials on tomatoes are compliant with the GAP and the residue data can be extrapolated to aubergines.	<b>0.4</b>	0.19	0.12	n/a

Commodity	Region/ <sup>(a)</sup>	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR <sup>(b)</sup> (mg/kg)	STM <sup>(c)</sup> (mg/kg)	CF <sup>(d)</sup>
Peppers	Indoor	< 0.01, 0.05, 0.06, 0.09, 0.11, 0.17, 0.19, 0.25, 0.45  Residues scaled to GAP rate: < 0.01, 2 × 0.03, 0.04, 0.05, 2 × 0.08, 0.13, 0.23	Residue trials on pepper are overdosed compared to the GAP, all other parameters are compliant. Residue levels are scaled down according to proportionality principle	<b>0.4</b>	0.23	0.05	n/a
Cucumbers, courgettes, other cucurbits with edible peel	Indoor	Cucumbers: 0.02, 0.05, 0.07, 0.08, 0.14  Courgettes: 0.03, 0.05, 0.20  Combined data set: 0.02, 0.03, 2 × 0.05, 0.07, 0.08, 0.14, 0.20	Residue trials on cucumbers and courgettes are compliant with the GAP, combined and extrapolated to cucumbers, courgettes, other cucurbits with edible peel. A separate MRL is currently set on gherkins (EFSA, 2016, 2018b) at 0.6 mg/kg, which is not exceeded by this residue data set.	<b>0.4</b>	0.20	0.06	n/a
Poppy seeds	NEU	0.02, 0.021, 0.05, 0.11, 0.20  Residues scaled to GAP rate: 2 × 0.01, 0.03, 0.07, 0.13	Residue trials on oilseed rape are overdosed compared to the GAP, all other parameters are compliant. Residue levels are scaled down according to proportionality principle and extrapolated to poppy seeds	<b>0.3</b>	0.13	0.03	n/a
Mustard seeds	NEU	3 × < 0.01, 0.03, 0.04, 2 × 0.08, 0.10  Residues scaled to GAP rate: 3 × < 0.01, 2 × 0.03, 2 × 0.06, 0.08	Residue trials on oilseed rape are overdosed compared to the GAP, all other parameters are compliant. Residue levels are scaled down according to proportionality principle and extrapolated to mustard seeds	<b>0.15</b>	0.08	0.03	n/a
Pomegranates	SEU	0.06, 0.08, 0.09, 0.16	Residue trials on pomegranates are compliant with the GAP	<b>0.3</b>	0.16	0.09	n/a
<i>Phacelia tanacetifolia</i> (surrogate crop for determination of residues in honey)	NEU/SEU	Residues in honey: 2 × 0.05, 0.051, 0.162	Residue trials performed in semi-field/tunnels using phacelia as surrogate crops with melliferous properties	<b>0.3</b>	0.16	0.05	n/a

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment n/a: not applicable.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

### B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes	TRR in the range of 0.096–0.531 mg eq/kg in feed and of 0.004–0.100 mg eq/kg in food commodities. 77–94% of TRR extractable (acetonitrile:water), with IM-1-5 as the sole metabolite identified (0.09–0.41 mg eq/kg in feed and 0.01–0.09 mg eq/kg in food commodities) (EFSA, 2016)
Residues in rotational and succeeding crops expected based on field rotational crop study	No	Field rotational crop studies conducted in NEU and SEU with acetamiprid applied on 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 (EFSA, 2016)

### B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL applications.

## B.2. Consumer risk assessment

ARfD	0.025 mg/kg bw (European Commission, 2018)
Highest IESTI, according to EFSA PRIMo	Sweet peppers/bell peppers: 54.7% of ARfD (children) Cucumbers: 52.4% of ARfD (children) Courgettes: 37.2% of ARfD (children) Granate apples/pomegranates: 35.2% of ARfD (children) Aubergines/egg plants: 20.6% of ARfD (adults) Plums: 5.1% of ARfD (children) Honey and other apiculture products: 2.3% of ARfD (children) Mustard seeds: 0.1% of ARfD (children) Poppy seeds: 0.1% of ARfD (adults)
Assumptions made for the calculations	<p>The short-term exposure assessment was calculated only for the crops under assessment, by updating the input values for the risk assessment derived in the recent focused MRL review according to Art. 43 (EFSA, 2018b) with the highest residue levels (for plums, aubergines, peppers, cucurbits with edible peel (except gherkins), pomegranates) or medium residue levels (for poppy seeds, mustard seeds) derived from the submitted residue trials for the commodities assessed under the present MRL applications. For honey the input value was the HR as derived from the residue trials on <i>Phacelia tanacetifolia</i>.</p> <p>It is noted that when performing the calculations with PRIMo version 3.1, for two commodities not under assessment within the present applications an exceedance of the ARfD is observed (pears: 116% of ARfD, NL toddler diet and lettuce: 114% of ARfD, NL child diet).</p> <p>Calculations performed with PRIMo revision 3.1.</p>

ADI	0.025 mg/kg bw (European Commission, 2018)
Highest IEDI, according to EFSA PRIMo	16% of ADI (NL toddler diet)  Contribution of crops assessed: Cucumbers: 0.39% of ADI Aubergines/egg plants: 0.16% of ADI Courgettes: 0.11% of ADI Sweet peppers/bell peppers: 0.11% of ADI Granate apples/pomegranates: 0.06% of ADI Honey and other apiculture products: 0.02% of ADI Plums: 0.01% of ADI Poppy seeds: 0.00% of ADI Mustard seeds: 0.00% of ADI
Assumptions made for the calculations	The long-term exposure assessment was calculated by updating the risk assessment values derived in the recent focused MRL review according to Art. 43 (EFSA, 2018b) with the median residue levels derived from the residue trials for the commodities assessed under present MRL applications. For honey the input value was the STMR as derived from the residue trials on <i>Phacelia tanacetifolia</i> . The crops for which no uses were reported in the MRL review were excluded from the exposure calculation.  Calculations performed with PRIMo revision 3.1.

ARFD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue; CXL: codex maximum residue limit.

### B.3. Recommended MRLs

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
<b>Enforcement residue definition: Acetamiprid</b>				
0140040	Plums	0.03	0.04	The submitted data are sufficient to derive an MRL proposal for the intended NEU/SEU use. Risk for consumers unlikely.
0231030	Aubergines	0.2	0.4	Data on tomatoes extrapolated to aubergines. The MRL proposal reflects the more critical residue situation of the intended indoor use. Risk for consumers unlikely.
0231020	Sweet peppers/bell peppers	0.3	0.4	The submitted data are sufficient to derive an MRL proposal for the intended indoor use. Risk for consumers unlikely.
0232010	Cucumbers	0.3	0.4	The MRL proposal reflects the most critical residue situation of the intended indoor use. Risk for consumers unlikely. A separate MRL is currently set on gherkins at 0.6 mg/kg, which is not exceeded by the submitted residue data set.
0232030	Courgettes	0.3	0.4	
0232090	Other cucurbits with edible peel	0.3	0.4	
0401030	Poppy seeds	0.01*	0.3	Data on oilseed rape extrapolated to poppy seeds. The submitted data are sufficient to derive an MRL proposal for the intended NEU use. Risk for consumers unlikely.
0401080	Mustard seeds	0.01*	0.15	Data on oilseed rape extrapolated to mustard seeds. The submitted data are sufficient to derive a MRL proposal for the intended NEU use. Risk for consumers unlikely.
163050	Granate apples/pomegranates	0.01*	0.3	The submitted data are sufficient to derive a MRL proposal for the intended SEU use. Risk for consumers unlikely.

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
1040000	Honey and other apiculture products	0.05*	0.3	The MRL proposal reflects residues in honey from the critical authorised use and intended EU uses of acetamiprid on melliferous crops. MRL in honey is derived from semi-field/tunnel trials performed on <i>Phacelia tanacetifolia</i> . Risk for consumers unlikely.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.

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

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

(F): Fat soluble.

# Appendix C – Pesticide Residue Intake Model (PRIMo)

Acetamiprid\_EFSA\_PRIMo\_rev3.1\_v1.xlsm



EFSA PRIMo revision 3.1; 2019/03/19

Acetamiprid			
LOQs (mg/kg) range from:	0.01	to:	0.10
Toxicological reference values			
ADI (mg/kg bw per day):	0.025	ARID (mg/kg bw):	0.025
Source of ADI:	EC, 2018	Source of ARID:	EC, 2018
Year of evaluation:		Year of evaluation:	

Input values

- Details – chronic risk assessment
- Supplementary results – chronic risk assessment
- Details – acute risk assessment/children
- Details – acute risk assessment/adults

Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
No of diets exceeding the ADI: ---											Exposure resulting from
TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)		Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)		2nd contributor to MS diet (in % of ADI)		3rd contributor to MS diet (in % of ADI)		MRLs set at commodities not under assessment (in % of ADI)	
	MS Diet			MS diet	Commodity/ group of commodities	MS diet	Commodity/ group of commodities	MS diet	Commodity/ group of commodities	MS diet	Commodity/ group of commodities
16%	NL toddler		4.04	5%	Milk: Cattle	3%	Apples	1%	Pears	0.2%	16%
11%	DE child		2.64	3%	Apples	2%	Milk: Cattle	0.7%	Cherries (sweet)	0.3%	11%
8%	NL child		2.12	2%	Milk: Cattle	2%	Apples	0.6%	Currants (red, black and white)	0.2%	8%
7%	GEMS/Food G08		1.84	3%	Olives for oil production	0.6%	Tomatoes	0.4%	Milk: Cattle	0.2%	7%
7%	ES child		1.78	2%	Olives for oil production	1.0%	Milk: Cattle	0.8%	Lettuces	0.2%	7%
7%	GEMS/Food G06		1.73	2%	Tomatoes	1%	Olives for oil production	0.4%	Table grapes	0.1%	7%
6%	UK infant		1.53	3%	Milk: Cattle	0.6%	Bovine: Edible offals (other than liver and ki	0.4%	Apples	0.3%	6%
6%	GEMS/Food G07		1.45	0.9%	Olives for oil production	0.6%	Tomatoes	0.5%	Wine grapes	0.3%	6%
6%	GEMS/Food G10		1.45	1%	Olives for oil production	0.7%	Tomatoes	0.6%	Lettuces	0.2%	6%
5%	FR child 3–15 years		1.37	2%	Milk: Cattle	0.5%	Apples	0.4%	Tomatoes	0.2%	5%
5%	FR toddler 2–3 years		1.34	2%	Milk: Cattle	0.9%	Apples	0.2%	Tomatoes	0.2%	5%
5%	GEMS/Food G15		1.29	0.6%	Tomatoes	0.6%	Olives for oil production	0.6%	Milk: Cattle	0.2%	5%
5%	ES adult		1.27	1%	Olives for oil production	1%	Lettuces	0.4%	Tomatoes	0.1%	5%
5%	SE general		1.23	1.0%	Milk: Cattle	0.8%	Lettuces	0.4%	Tomatoes	0.2%	5%
5%	IE adult		1.21	0.5%	Wine grapes	0.4%	Sheep: Edible offals (other than liver and ki	0.3%	Milk: Cattle	0.1%	5%
5%	GEMS/Food G11		1.21	0.8%	Olives for oil production	0.6%	Milk: Cattle	0.5%	Tomatoes	0.2%	5%
5%	RO general		1.18	1%	Tomatoes	0.9%	Milk: Cattle	0.6%	Wine grapes	0.3%	5%
5%	DE women 14–50 years		1.16	1.0%	Milk: Cattle	0.7%	Apples	0.4%	Tomatoes	0.1%	5%
5%	UK toddler		1.15	2%	Milk: Cattle	0.5%	Apples	0.3%	Currants (red, black and white)	0.3%	5%
4%	DE general		1.10	1.0%	Milk: Cattle	0.7%	Apples	0.3%	Tomatoes	0.1%	4%
4%	DK child		1.03	1%	Milk: Cattle	0.7%	Apples	0.4%	Cucumbers	0.2%	4%
4%	PT general		0.97	0.9%	Wine grapes	0.8%	Olives for oil production	0.5%	Tomatoes	0.2%	4%
3%	NL general		0.82	0.7%	Milk: Cattle	0.4%	Apples	0.2%	Tomatoes	0.2%	3%
3%	FR adult		0.79	0.8%	Wine grapes	0.4%	Milk: Cattle	0.2%	Tomatoes	0.1%	3%
3%	FR infant		0.75	1%	Milk: Cattle	0.5%	Apples	0.2%	Spinaches	0.1%	3%
3%	IT toddler		0.75	0.7%	Tomatoes	0.6%	Lettuces	0.3%	Wheat	0.0%	3%
3%	IT adult		0.71	0.7%	Lettuces	0.6%	Tomatoes	0.2%	Apples	0.0%	3%
3%	FI 3 years		0.71	0.5%	Raspberries (red and yellow)	0.3%	Tomatoes	0.3%	Bananas	0.2%	3%
2%	DK adult		0.58	0.4%	Milk: Cattle	0.3%	Wine grapes	0.3%	Tomatoes	0.1%	2%
2%	UK vegetarian		0.52	0.3%	Tomatoes	0.3%	Wine grapes	0.3%	Lettuces	0.1%	2%
2%	FI 6 years		0.52	0.3%	Raspberries (red and yellow)	0.2%	Tomatoes	0.2%	Cucumbers	0.2%	2%
2%	LT adult		0.50	0.5%	Apples	0.3%	Tomatoes	0.3%	Tomatoes	0.2%	2%
2%	PL general		0.48	0.6%	Apples	0.5%	Tomatoes	0.2%	Cherries (sweet)	0.1%	2%
2%	UK adult		0.46	0.4%	Wine grapes	0.2%	Milk: Cattle	0.2%	Lettuces	0.1%	2%
1%	FI adult		0.37	0.3%	Tomatoes	0.3%	Lettuces	0.2%	Apples	0.0%	1%
0.8%	IE child		0.20	0.3%	Milk: Cattle	0.1%	Apples	0.1%	Currants (red, black and white)	0.1%	0.8%

**Conclusion:**  
 The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.  
 The long-term intake of residues of Acetamiprid is unlikely to present a public health concern.

<b>Acute risk assessment/children</b>	<b>Acute risk assessment/adults/general population</b>
<b>Details – acute risk assessment/children</b>	<b>Details – acute risk assessment/adults</b>

The acute risk assessment is based on the ARID.  
The calculation is based on the large portion of the most critical consumer group.

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

Unprocessed commodities	Results for children					Results for adults				
	No. of commodities for which ARID/ADI is exceeded (IESTI):					No. of commodities for which ARID/ADI is exceeded (IESTI):				
	IESTI		MRL/input for RA (mg/kg)	Exposure (µg/kg bw)		IESTI		MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	
Highest % of ARID/ADI	Commodities				Highest % of ARID/ADI	Commodities				
116%	Pears	0.4/0.21	29		42%	Head cabbages	0.4/0.25	11		
114%	Lettuces	1.5/0.75	29		40%	Red mustards	3/1.9	10		
91%	Apples	0.4/0.21	23		39%	Quinces	0.8/0.64	9.7		
80%	Apricots	0.8/0.57	20		36%	Blueberries	2/1	9.1		
73%	Table grapes	0.5/0.25	18		36%	Lettuces	1.5/0.75	9.1		
67%	Melons	0.2/0.11	17		35%	Cherries (sweet)	1.5/0.88	8.8		
65%	Tomatoes	0.5/0.28	16		34%	Table grapes	0.5/0.25	8.5		
63%	Quinces	0.8/0.64	16		33%	Blackberries	2/1	8.2		
55%	Sweet peppers/bell peppers	0.4/0.23	14		26%	Currants (red, black and white)	2/1	6.6		
54%	Watermelons	0.2/0.11	13		26%	Pears	0.4/0.21	6.4		
52%	Cucumbers	0.4/0.2	13		25%	Apricots	0.8/0.57	6.2		
51%	Cauliflowers	0.4/0.22	13		24%	Broccoli	0.4/0.25	6.0		
44%	Head cabbages	0.4/0.25	11		24%	Wine grapes	0.5/0.25	5.9		
43%	Cherries (sweet)	1.5/0.88	11		24%	Apples	0.4/0.21	5.9		
43%	Blackberries	2/1	11		23%	Chards/beet leaves	0.6/0.31	5.9		
42%	Bananas	0.4/0.11	10		22%	Cucumbers	0.4/0.2	5.6		
42%	Broccoli	0.4/0.25	10		22%	Raspberries (red and yellow)	2/1	5.4		
40%	Escaroles/broad-leaved endives	0.4/0.25	10		21%	Aubergines/egg plants	0.4/0.19	5.1		
38%	Peaches	0.2/0.1	9.5		20%	Cauliflowers	0.4/0.22	5.1		
37%	Courgettes	0.4/0.2	9.3		20%	Escaroles/broad-leaved endives	0.4/0.25	5.0		
37%	Raspberries (red and yellow)	2/1	9.2		19%	Courgettes	0.4/0.2	4.7		
35%	Medlar	0.8/0.64	8.9		18%	Gooseberries (green, red and yellow)	2/1	4.5		
35%	Granate apples/pomegranates	0.3/0.16	8.8		18%	Watermelons	0.2/0.11	4.5		
33%	Asparagus	0.8/0.43	8.3		18%	Tomatoes	0.5/0.28	4.4		
32%	Currants (red, black and white)	2/1	7.9		18%	Medlar	0.8/0.64	4.4		
29%	Bovine: Edible offals (other than liver and kidney)	1/1	7.3		17%	Melons	0.2/0.11	4.3		
29%	Bovine: Liver	1/0.89	7.2		15%	Sweet peppers/bell peppers	0.4/0.23	3.8		
28%	Spinaches	0.6/0.31	7.0		14%	Lamb's lettuce/corn salads	3/1.9	3.6		
24%	Blueberries	2/1	6.0		14%	Bovine: Liver	1/0.89	3.6		
24%	Gooseberries (green, red and yellow)	2/1	5.9		13%	Bovine: Edible offals (other than liver and kidney)	1/1	3.3		
21%	Lamb's lettuce/corn salads	3/1.9	5.3		13%	Asparagus	0.8/0.43	3.3		
20%	Roman rocket/ruccola	3/1.9	5.1		13%	Globe artichokes	0.7/0.25	3.2		
19%	Chards/beet leaves	0.6/0.31	4.8		11%	Granate apples/pomegranates	0.3/0.16	2.8		
19%	Aubergines/egg plants	0.4/0.19	4.8		11%	Other farmed animals: Muscle/meat	0.5/0.5	2.8		
18%	Cranberries	2/1	4.5		10%	Swine: Edible offals (other than liver and kidney)	1/1	2.6		
18%	Globe artichokes	0.7/0.25	4.4		10%	Sheep: Liver	1/0.89	2.5		
18%	Table olives	3/1.3	4.4		10%	Beans (with pods)	0.6/0.32	2.5		
16%	Strawberries	0.5/0.25	4.1		9%	Strawberries	0.5/0.25	2.3		
15%	Beans (with pods)	0.6/0.32	3.7		9%	Bananas	0.4/0.11	2.3		
14%	Other farmed animals: Muscle/meat	0.5/0.5	3.5		9%	Parsley	3/1.9	2.3		
13%	Bovine: Kidney	1/0.89	3.4		9%	Roman rocket/ruccola	3/1.9	2.2		
13%	Swine: Muscle/meat	0.5/0.27	3.3		9%	Gherkins	0.6/0.37	2.2		
12%	Swine: Edible offals (other than liver and kidney)	1/1	3.0		9%	Rose hips	2/1	2.2		
12%	Pumpkins	0.2/0.11	2.9		8%	Swine: Kidney	1/0.89	2.0		
11%	Oranges	0.9/0.02	2.9		7%	Bovine: Kidney	1/0.89	1.9		
10%	Peas (with pods)	0.6/0.32	2.6		7%	Peaches	0.2/0.1	1.9		
10%	Milk: Cattle	0.2/0.02	2.5		6%	Pumpkins	0.2/0.11	1.6		
10%	Chervil	3/1.9	2.5		6%	Bovine: Muscle	0.5/0.27	1.5		
9%	Wine grapes	0.5/0.25	2.3		6%	Dewberries	2/1	1.4		
8%	Parsley	3/1.9	2.1		5%	Swine: Muscle/meat	0.5/0.27	1.3		
8%	Bovine: Muscle/meat	0.5/0.27	1.9		5%	Table olives	3/1.3	1.3		
7%	Dewberries	2/1	1.8		5%	Equine: Muscle/meat	0.5/0.27	1.3		
7%	Grapefruits	0.9/0.02	1.7		5%	Sheep: Muscle/meat	0.5/0.27	1.3		
6%	Equine: Muscle/meat	0.5/0.27	1.6		5%	Swine: Liver	1/0.89	1.3		
6%	Chives	3/1.9	1.6		5%	Spinaches	0.6/0.31	1.2		
6%	Potatoes	0.01/0.01	1.5		5%	Cranberries	2/1	1.1		
6%	Peas (without pods)	0.3/0.18	1.5		4%	Peas (with pods)	0.6/0.32	1.1		
6%	Sheep: Muscle/meat	0.5/0.27	1.5		4%	Peas (without pods)	0.3/0.18	0.96		
6%	Sage	3/1.9	1.4		3%	Milk: Cattle	0.2/0.02	0.77		
6%	Beans (without pods)	0.3/0.18	1.4		3%	Cress and other sprouts and shoots	3/1.9	0.72		
6%	Basil and edible flowers	3/1.9	1.4		3%	Beans (without pods)	0.3/0.18	0.71		
5%	Mandarins	0.9/0.02	1.3		3%	Sheep: Edible offals (other than liver and kidney)	1/1	0.68		
5%	Plums	0.04/0.03	1.3		3%	Oranges	0.9/0.02	0.66		
5%	Swine: Kidney	1/0.89	1.1		2%	Olives for oil production	3/0.8	0.62		
4%	Swine: Liver	1/0.89	1.1		2%	Celery leaves	3/1.9	0.62		
4%	Gherkins	0.6/0.37	1.0		2%	Pursianes	0.6/0.31	0.59		
4%	Olives for oil production	3/0.8	1.0		2%	Plums	0.04/0.03	0.53		

4%	Celery leaves	3/1.9	0.91	2%	Poultry: Liver	0.1/0.1	0.47
3%	Lemons	0.9/0.02	0.74	2%	Coconuts	0.07/0.05	0.43
3%	Coconuts	0.07/0.05	0.72	2%	Goat: Muscle	0.5/0.27	0.42
2%	Honey and other apiculture products	0.3/0.16	0.57	2%	Mandarins	0.9/0.02	0.39
2%	Cress and other sprouts and shoots	3/1.9	0.56	2%	Grapefruits	0.9/0.02	0.39
2%	Milk: Goat	0.2/0.02	0.48	2%	Sage	3/1.9	0.38
2%	Onions	0.02/0.02	0.45	1%	Milk: Goat	0.2/0.02	0.37
2%	Sweet corn	0.01/0.01	0.43	1%	Swine: Fat tissue	0.3/0.16	0.32
2%	Limes	0.9/0.02	0.43	1%	Chives	3/1.9	0.32
1%	Beans	0.15/0.02	0.37	1%	Milk: Sheep	0.2/0.02	0.30
1%	Poultry: Muscle/meat	0.02/0.02	0.34	1%	Potatoes	0.01/0.01	0.30
1%	Bovine: Fat tissue	0.3/0.16	0.33	1%	Onions	0.02/0.02	0.30
1%	Pistachios	0.07/0.05	0.29	0.9%	Poultry: Muscle	0.02/0.02	0.23
1%	Swine: Fat tissue	0.3/0.16	0.27	0.9%	Basil and edible flowers	3/1.9	0.23
1%	Brussels sprouts	0.05/0.03	0.25	0.9%	Chestnuts	0.07/0.05	0.23
1.0%	Eggs: Chicken	0.02/0.02	0.25	0.9%	Honey and other apiculture products	0.3/0.16	0.22
0.8%	Chestnuts	0.07/0.05	0.21	0.8%	Lemons	0.9/0.02	0.19
0.7%	Walnuts	0.07/0.05	0.17	0.8%	Rosemary	3/1.9	0.19
0.7%	Hazelnuts/cobnuts	0.07/0.05	0.16	0.8%	Rosemary	3/1.9	0.19
0.6%	Almonds	0.07/0.05	0.14	0.8%	Rosemary	3/1.9	0.19
0.6%	Wheat	0.1/0.01	0.14	0.8%	Rosemary	3/1.9	0.19
0.6%	Pecans	0.07/0.05	0.14	0.7%	Brussels sprouts	0.05/0.03	0.18
0.5%	Lentils	0.15/0.02	0.13	0.6%	Sweet corn	0.01/0.01	0.16
0.5%	Peas	0.15/0.02	0.13	0.6%	Bovine: Fat tissue	0.3/0.16	0.16
0.5%	Cashew nuts	0.07/0.05	0.13	0.6%	Chervil	3/1.9	0.15
0.5%	Figs	0.03/0.01	0.12	0.6%	Limes	0.9/0.02	0.15
0.5%	Thyme	3/1.9	0.11	0.5%	Pistachios	0.07/0.05	0.13
0.4%	Poultry: Liver	0.1/0.1	0.11	0.5%	Beans	0.15/0.02	0.13
0.3%	Milk: Sheep	0.2/0.02	0.07	0.5%	Lentils	0.15/0.02	0.12
0.2%	Rosemary	3/1.9	0.06	0.5%	Pecans	0.07/0.05	0.11
0.2%	Barley	0.05/0.01	0.06	0.4%	Figs	0.03/0.01	0.11
0.2%	Brazil nuts	0.07/0.05	0.04	0.4%	Walnuts	0.07/0.05	0.11
0.2%	Rapeseeds/canola seeds	0.4/0.03	0.04	0.4%	Macadamia	0.07/0.05	0.11
0.1%	Garlic	0.02/0.01	0.04	0.4%	Sheep: Kidney	1/0.89	0.09
0.1%	Mustard seeds	0.15/0.03	0.03	0.3%	Eggs: Chicken	0.02/0.02	0.09
0.1%	Macadamia	0.07/0.05	0.03	0.3%	Cashew nuts	0.07/0.05	0.09
0.08%	Laurel/bay leaves	3/1.9	0.02	0.3%	Wheat	0.1/0.01	0.08
0.07%	Pine nut kernels	0.07/0.05	0.02	0.3%	Almonds	0.07/0.05	0.07
0.04%	Oat	0.05/0.01	0.01	0.3%	Peas	0.15/0.02	0.07
0.02%	Peppercorn (black, green and white)	0.1/0.1	0.00	0.2%	Hazelnuts/cobnuts	0.07/0.05	0.06
0.01%	Poultry: Fat tissue	0.02/0.02	0.00	0.2%	Pine nut kernels	0.07/0.05	0.05
0.00%	Cardamom	0.1/0.1	0.00	0.2%	Barley	0.05/0.01	0.05
				0.1%	Brazil nuts	0.07/0.05	0.03
				0.1%	Eggs: Quail	0.02/0.02	0.03
				0.08%	Poppy seeds	0.3/0.03	0.02
				0.08%	Poppy seeds	0.3/0.03	0.02
				0.06%	Rapeseeds/canola seeds	0.4/0.03	0.02
				0.04%	Cardamom	0.1/0.1	0.01
				0.04%	Eggs: Goose	0.02/0.02	0.01
				0.03%	Garlic	0.02/0.01	0.01
				0.03%	Oat	0.05/0.01	0.01
				0.02%	Poultry: Fat tissue	0.02/0.02	0.01
				0.01%	Peppercorn (black, green and white)	0.1/0.1	0.00
Expand/collapse list							
<b>Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)</b>							
				2			

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	
79%	Broccoli/boiled	0.4/0.25	20	37%	Cauliflowers/boiled	0.4/0.22	9.2	
73%	Currants (red, black and white)/juice	2/0.64	18	33%	Currants (red, black and white)/juice	2/0.64	8.2	
66%	Escaroles/broad-leaved endives/boiled	0.4/0.25	17	24%	Pumpkins/boiled	0.2/0.11	6.1	
61%	Cauliflowers/boiled	0.4/0.22	15	24%	Broccoli/boiled	0.4/0.25	6.0	
41%	Elderberries/juice	2/0.64	10	24%	Elderberries/juice	2/0.64	5.9	
40%	Oranges/juice	0.9/0.19	10	20%	Escaroles/broad-leaved endives/boiled	0.4/0.25	5.1	
39%	Pumpkins/boiled	0.2/0.11	9.8	18%	Courgettes/boiled	0.4/0.2	4.6	
39%	Chards/beet leaves/boiled	0.6/0.31	9.6	16%	Chards/beet leaves/boiled	0.6/0.31	3.9	
34%	Gherkins/pickled	0.6/0.37	8.5	11%	Oranges/juice	0.9/0.19	2.9	
30%	Raspberries/juice	2/0.64	7.5	10%	Spinaches/frozen; boiled	0.6/0.31	2.6	
28%	Courgettes/boiled	0.4/0.2	7.1	9%	Wine grapes/wine	0.5/0.25	2.4	
17%	Spinaches/frozen; boiled	0.6/0.31	4.3	9%	Apples/juice	0.4/0.07	2.3	
16%	Beans (with pods)/boiled	0.6/0.32	4.0	8%	Grapefruits/juice	0.9/0.19	2.1	
16%	Wine grapes/juice	0.5/0.09	3.9	7%	Wine grapes/juice	0.5/0.09	1.9	
15%	Apples/juice	0.4/0.07	3.8	6%	Table grapes/raisins	0.5/1.18	1.4	
Expand/collapse list								
<b>Conclusion:</b>								
The estimated short term intake (IESTI) exceeded the toxicological reference value for 2 commodities.								
For processed commodities, no exceedance of the ARfD/ADI was identified.								



## Appendix D – Input values for the exposure calculations

### D.1. Consumer risk assessment

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment <sup>(a)</sup>
<b>Risk assessment residue definition: acetamiprid</b>						
Grapefruits	0.9	EFSA (2018b)	0.00494	STMR-RAC*PeF	0.02158	HR-RAC*PeF
Oranges	0.9	EFSA (2018b)	0.00494	STMR-RAC*PeF	0.02158	HR-RAC*PeF
Lemons	0.9	EFSA (2018b)	0.00494	STMR-RAC*PeF	0.02158	HR-RAC*PeF
Limes	0.9	EFSA (2018b)	0.00494	STMR-RAC*PeF	0.02158	HR-RAC*PeF
Mandarins	0.9	EFSA (2018b)	0.00494	STMR-RAC*PeF	0.02158	HR-RAC*PeF
Other citrus fruit	0.9	EFSA (2018b)	0.00494	STMR-RAC*PeF		
Almonds	0.07	EFSA (2018b)	0.01	STMR-RAC	0.05	HR-RAC
Brazil nuts	0.07	EFSA (2018b)	0.01	STMR-RAC	0.05	HR-RAC
Cashew nuts	0.07	EFSA (2018b)	0.01	STMR-RAC	0.05	HR-RAC
Chestnuts	0.07	EFSA (2018b)	0.01	STMR-RAC	0.05	HR-RAC
Coconuts	0.07	EFSA (2018b)	0.01	STMR-RAC	0.05	HR-RAC
Hazelnuts/cobnuts	0.07	EFSA (2018b)	0.01	STMR-RAC	0.05	HR-RAC
Macadamia	0.07	EFSA (2018b)	0.01	STMR-RAC	0.05	HR-RAC
Pecans	0.07	EFSA (2018b)	0.01	STMR-RAC	0.05	HR-RAC
Pine nut kernels	0.07	EFSA (2018b)	0.01	STMR-RAC	0.05	HR-RAC
Pistachios	0.07	EFSA (2018b)	0.01	STMR-RAC	0.05	HR-RAC
Walnuts	0.07	EFSA (2018b)	0.01	STMR-RAC	0.05	HR-RAC
Other tree nuts	0.07	EFSA (2018b)	0.01	STMR-RAC		
Apples	0.4	EFSA (2018b)	0.07	STMR-RAC	0.21	HR-RAC
Pears	0.4	EFSA (2018b)	0.07	STMR-RAC	0.21	HR-RAC
Quinces	0.8	EFSA (2018b)	0.23	STMR-RAC	0.64	HR-RAC
Medlar	0.8	EFSA (2018b)	0.23	STMR-RAC	0.64	HR-RAC
Loquats/Japanese medlars	0.8	EFSA (2018b)	0.23	STMR-RAC	0.64	HR-RAC
Other pome fruit	0.8	EFSA (2018b)	0.23	STMR-RAC		
Apricots	0.8	EFSA (2018b)	0.22	STMR-RAC	0.57	HR-RAC
Cherries (sweet)	1.5	EFSA (2018b)	0.45	STMR-RAC	0.88	HR-RAC
Peaches	0.2	EFSA (2018b)	0.06	STMR-RAC	0.1	HR-RAC
<b>Plums</b>	<b>0.04</b>	<b>Proposed</b>	<b>0.01</b>	<b>STMR-RAC</b>	<b>0.03</b>	<b>HR-RAC</b>
Table grapes	0.5	EFSA (2018b)	0.09	STMR-RAC	0.25	HR-RAC
Wine grapes	0.5	EFSA (2018b)	0.09	STMR-RAC	0.25	HR-RAC
Strawberries	0.5	EFSA (2018b)	0.1	STMR-RAC	0.25	HR-RAC
Blackberries	2	EFSA (2018b)	0.64	STMR-RAC	1	HR-RAC
Dewberries	2	EFSA (2018b)	0.64	STMR-RAC	1	HR-RAC
Raspberries (red and yellow)	2	EFSA (2018b)	0.64	STMR-RAC	1	HR-RAC
Other cane fruit	2	EFSA (2018b)	0.64	STMR-RAC		
Blueberries	2	EFSA (2018b)	0.64	STMR-RAC	1	HR-RAC
Cranberries	2	EFSA (2018b)	0.64	STMR-RAC	1	HR-RAC
Currants (red, black and white)	2	EFSA (2018b)	0.64	STMR-RAC	1	HR-RAC
Gooseberries (green, red and yellow)	2	EFSA (2018b)	0.64	STMR-RAC	1	HR-RAC

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment <sup>(a)</sup>
Rose hips	2	EFSA (2018b)	0.64	STMR-RAC	1	HR-RAC
Mulberries (black and white)	2	EFSA (2018b)	0.64	STMR-RAC	1	HR-RAC
Elderberries	2	EFSA (2018b)	0.64	STMR-RAC	1	HR-RAC
Figs	0.03	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Table olives	3	EFSA (2018b)	0.8	STMR-RAC	1.3	HR-RAC
Bananas	0.4	EFSA (2018b)	0.04949	STMR-RAC*PeF	0.1078	HR-RAC*PeF
<b>Granate apples/ pomegranates</b>	<b>0.3</b>	<b>Proposed</b>	<b>0.09</b>	<b>STMR-RAC</b>	<b>0.16</b>	<b>HR-RAC</b>
Potatoes	0.01	EFSA (2018b)	0.01	LOQ	0.01	LOQ
Garlic	0.02	EFSA (2018b)	0.01	STMR-RAC	0.01	HR-RAC
Onions	0.02	EFSA (2018b)	0.01	STMR-RAC	0.02	HR-RAC
Tomatoes	0.5	EFSA (2018b)	0.13	STMR-RAC	0.28	HR-RAC
<b>Sweet peppers/bell peppers</b>	<b>0.4</b>	<b>Proposed</b>	<b>0.05</b>	<b>STMR-RAC</b>	<b>0.23</b>	<b>HR-RAC</b>
<b>Aubergines/egg plants</b>	<b>0.4</b>	<b>Proposed</b>	<b>0.12</b>	<b>STMR-RAC</b>	<b>0.19</b>	<b>HR-RAC</b>
Okra/lady's fingers	0.2	EFSA (2018b)	0.04	STMR-RAC	0.14	HR-RAC
Other solanacea	0.2	Reg. (EU) 2019/ 88	0.2	MRL		
<b>Cucumbers</b>	<b>0.4</b>	<b>Proposed</b>	<b>0.06</b>	<b>STMR-RAC</b>	<b>0.2</b>	<b>HR-RAC</b>
Gherkins	0.6	EFSA (2018b)	0.14	STMR-RAC	0.37	HR-RAC
<b>Courgettes</b>	<b>0.4</b>	<b>Proposed</b>	<b>0.06</b>	<b>STMR-RAC</b>	<b>0.2</b>	<b>HR-RAC</b>
<b>Other cucurbits – edible peel</b>	<b>0.4</b>	<b>Proposed</b>	<b>0.06</b>	<b>STMR-RAC</b>		
Melons	0.2	EFSA (2018b)	0.05	STMR-RAC	0.11	HR-RAC
Pumpkins	0.2	EFSA (2018b)	0.05	STMR-RAC	0.11	HR-RAC
Watermelons	0.2	EFSA (2018b)	0.05	STMR-RAC	0.11	HR-RAC
Other cucurbits – inedible peel	0.2	EFSA (2018b)	0.05	STMR-RAC		
Sweet corn	0.01	EFSA (2018b)	0.01	LOQ	0.01	LOQ
Broccoli	0.4	EFSA (2018b)	0.03	STMR-RAC	0.25	HR-RAC
Cauliflowers	0.4	EFSA (2018b)	0.02	STMR-RAC	0.22	HR-RAC
Other flowering brassica	0.4	EFSA (2018b)	0.03	STMR-RAC		
Brussels sprouts	0.05	EFSA (2018b)	0.02	STMR-RAC	0.03	HR-RAC
Head cabbages	0.4	EFSA (2018b)	0.02	STMR-RAC	0.25	HR-RAC
Lamb's lettuce/corn salads	3	EFSA (2018b)	0.83	STMR-RAC	1.9	HR-RAC
Lettuces	1.5	EFSA (2018b)	0.49	STMR-RAC	0.75	HR-RAC
Escaroles/broad- leaved endives	0.4	EFSA (2018b)	0.1	STMR-RAC	0.25	HR-RAC
Cress and other sprouts and shoots	3	EFSA (2018b)	0.83	STMR-RAC	1.9	HR-RAC
Land cress	3	EFSA (2018b)	0.81	STMR-RAC	1.9	HR-RAC
Roman rocket/rucola	3	EFSA (2018b)	0.83	STMR-RAC	1.9	HR-RAC
Red mustards	3	EFSA (2018b)	0.81	STMR-RAC	1.9	HR-RAC

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment <sup>(a)</sup>
Baby leaf crops (including brassica species)	3	EFSA (2018b)	0.83	STMR-RAC	1.9	HR-RAC
Spinaches	0.6	EFSA (2018b)	0.2	STMR-RAC	0.31	HR-RAC
Purslanes	0.6	EFSA (2018b)	0.2	STMR-RAC	0.31	HR-RAC
Chards/beet leaves	0.6	EFSA (2018b)	0.2	STMR-RAC	0.31	HR-RAC
Other spinach and similar	0.6	EFSA (2018b)	0.2	STMR-RAC		
Chervil	3	EFSA (2018b)	0.83	STMR-RAC	1.9	HR-RAC
Chives	3	EFSA (2018b)	0.83	STMR-RAC	1.9	HR-RAC
Celery leaves	3	EFSA (2018b)	0.83	STMR-RAC	1.9	HR-RAC
Parsley	3	EFSA (2018b)	0.83	STMR-RAC	1.9	HR-RAC
Sage	3	EFSA (2018b) EFSA (2018b)	0.83	STMR-RAC	1.9	HR-RAC
Rosemary	3	EFSA (2018b)	0.83	STMR-RAC	1.9	HR-RAC
Thyme	3	EFSA (2018b)	0.83	STMR-RAC	1.9	HR-RAC
Basil and edible flowers	3	EFSA (2018b)	0.83	STMR-RAC	1.9	HR-RAC
Laurel/bay leaves	3	EFSA (2018b)	0.83	STMR-RAC	1.9	HR-RAC
Tarragon	3	EFSA (2018b)	0.83	STMR-RAC	1.9	HR-RAC
Other herbs	3	EFSA (2018b)	0.83	STMR-RAC		
Beans (with pods)	0.6	EFSA (2018b)	0.06	STMR-RAC	0.32	HR-RAC
Beans (without pods)	0.3	EFSA (2018b)	0.03	STMR-RAC	0.18	HR-RAC
Peas (with pods)	0.6	EFSA (2018b)	0.06	STMR-RAC	0.32	HR-RAC
Peas (without pods)	0.3	EFSA (2018b)	0.03	STMR-RAC	0.18	HR-RAC
Asparagus	0.8	EFSA (2018b)	0.26	STMR-RAC	0.43	HR-RAC
Globe artichokes	0.7	EFSA (2018b)	0.11	STMR-RAC	0.25	HR-RAC
Beans	0.15	EFSA (2018b)	0.02	STMR-RAC	0.02	STMR-RAC
Lentils	0.15	EFSA (2018b)	0.02	STMR-RAC	0.02	STMR-RAC
Peas	0.15	EFSA (2018b)	0.02	STMR-RAC	0.02	STMR-RAC
Lupins/lupini beans	0.15	EFSA (2018b)	0.02	STMR-RAC	0.02	STMR-RAC
Other pulses	0.15	EFSA (2018b)	0.02	STMR-RAC		
<b>Poppy seeds</b>	<b>0.3</b>	<b>Proposed</b>	<b>0.03</b>	<b>STMR-RAC</b>	<b>0.03</b>	<b>STMR-RAC</b>
Rapeseeds/canola seeds	0.4	EFSA (2018b)	0.03	STMR-RAC	0.03	STMR-RAC
<b>Mustard seeds</b>	<b>0.15</b>	<b>Proposed</b>	<b>0.03</b>	<b>STMR-RAC</b>	<b>0.03</b>	<b>STMR-RAC</b>
Cotton seeds	0.7	EFSA (2018b)	0.09	STMR-RAC	0.09	STMR-RAC
Olives for oil production	3	EFSA (2018b)	0.8	STMR-RAC	0.8	STMR-RAC
Barley	0.05	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Oat	0.05	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Wheat	0.1	EFSA (2018b)	0.01	STMR-RAC	0.01	STMR-RAC
Cardamom	0.1	Reg. (EU) 2019/ 88	0.1	MRL	0.1	MRL
Peppercorn (black, green and white)	0.1	Reg. (EU) 2019/ 88	0.1	MRL	0.1	MRL

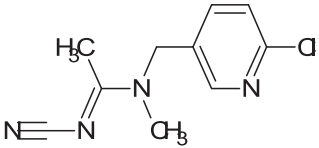
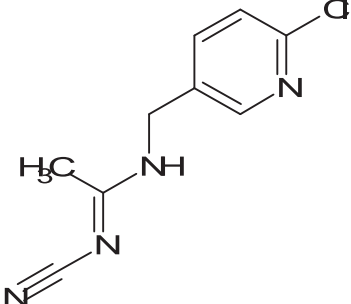
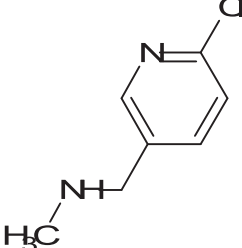
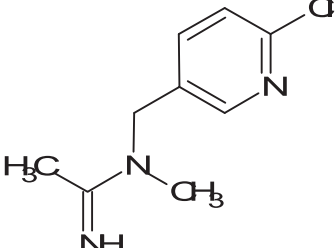
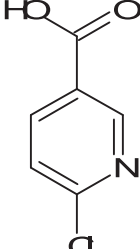
Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment <sup>(a)</sup>
Horseradish, root spices	0.07	Reg. (EU) 2019/ 88	0.07	MRL	0.07	MRL
Swine: Muscle/meat	0.5	EFSA (2018b)	0.02	STMR-RAC	0.27	HR-RAC
Swine: Fat tissue	0.3	EFSA (2018b) EFSA (2018b)	0.02	STMR-RAC	0.16	HR-RAC
Swine: Liver	1	EFSA (2018b)	0.11	STMR-RAC	0.89	HR-RAC
Swine: Kidney	1	EFSA (2018b)	0.11	STMR-RAC	0.89	HR-RAC
Swine: Edible offals (other than liver and kidney)	1	Reg. (EU) 2019/ 88	1	MRL	1	MRL
Bovine: Muscle/meat	0.5	EFSA (2018b)	0.02	STMR-RAC	0.27	HR-RAC
Bovine: Fat tissue	0.3	EFSA (2018b)	0.02	STMR-RAC	0.16	HR-RAC
Bovine: Liver	1	EFSA (2018b)	0.11	STMR-RAC	0.89	HR-RAC
Bovine: Kidney	1	EFSA (2018b)	0.11	STMR-RAC	0.89	HR-RAC
Bovine: Edible offals (other than liver and kidney)	1	Reg. (EU) 2019/ 88	1	MRL	1	MRL
Sheep: Muscle/meat	0.5	EFSA (2018b)	0.02	STMR-RAC	0.27	HR-RAC
Sheep: Fat tissue	0.3	EFSA (2018b)	0.02	STMR-RAC	0.16	HR-RAC
Sheep: Liver	1	EFSA (2018b)	0.11	STMR-RAC	0.89	HR-RAC
Sheep: Kidney	1	EFSA (2018b)	0.11	STMR-RAC	0.89	HR-RAC
Sheep: Edible offals (other than liver and kidney)	1	Reg. (EU) 2019/ 88	1	MRL	1	MRL
Goat: Muscle/meat	0.5	EFSA (2018b)	0.02	STMR-RAC	0.27	HR-RAC
Goat: Fat tissue	0.3	EFSA (2018b)	0.02	STMR-RAC	0.16	HR-RAC
Goat: Liver	1	EFSA (2018b)	0.11	STMR-RAC	0.89	HR-RAC
Goat: Kidney	1	EFSA (2018b)	0.11	STMR-RAC	0.89	HR-RAC
Goat: Edible offals (other than liver and kidney)	1	Reg. (EU) 2019/ 88	1	MRL	1	MRL
Equine: Muscle/meat	0.5	EFSA (2018b)	0.02	STMR-RAC	0.27	HR-RAC
Equine: Fat tissue	0.3	EFSA (2018b)	0.02	STMR-RAC	0.16	HR-RAC
Equine: Liver	1	EFSA (2018b)	0.11	STMR-RAC	0.89	HR-RAC
Equine: Kidney	1	EFSA (2018b)	0.11	STMR-RAC	0.89	HR-RAC
Equine: Edible offals (other than liver and kidney)	1	Reg. (EU) 2019/ 88	1	MRL	1	MRL
Poultry: Muscle/meat	0.02	EFSA (2018b)	0.02	LOQ	0.02	LOQ
Poultry: Fat tissue	0.02	EFSA (2018b)	0.02	LOQ	0.02	LOQ
Poultry: Liver	0.1	EFSA (2018b) EFSA (2018b)	0.1	LOQ	0.1	LOQ
Other farmed animals: Muscle/ meat	0.5	Reg. (EU) 2019/ 88	0.3	MRL	0.5	MRL
Other farmed animals: Fat tissue	0.3	Reg. (EU) 2019/ 88	0.3	MRL	0.3	MRL
Other farmed animals: Liver	1	Reg. (EU) 2019/ 88	1	MRL	1	MRL

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment <sup>(a)</sup>
Other farmed animals: Kidney	1	Reg. (EU) 2019/88	1	MRL	1	MRL
Other farmed animals: Edible offals (other than liver and kidney)	1	Reg. (EU) 2019/88	1	MRL	1	MRL
Milk: Cattle	0.2	EFSA (2018b)	0.02	STMR-RAC	0.02	STMR-RAC
Milk: Sheep	0.2	EFSA (2018b)	0.02	STMR-RAC	0.02	STMR-RAC
Milk: Goat	0.2	EFSA (2018b)	0.02	STMR-RAC	0.02	STMR-RAC
Milk: Horse	0.2	EFSA (2018b)	0.02	STMR-RAC	0.02	STMR-RAC
Milk: Others	0.2	EFSA (2018b)	0.02	STMR-RAC	0.02	STMR-RAC
Eggs: Chicken	0.02	EFSA (2018b) EFSA (2018b)	0.02	LOQ	0.02	LOQ
Eggs: Duck	0.02	EFSA (2018b)	0.02	LOQ	0.02	LOQ
Eggs: Goose	0.02	EFSA (2018b)	0.02	LOQ	0.02	LOQ
Eggs: Quail	0.02	EFSA (2018b)	0.02	LOQ	0.02	LOQ
Eggs: Others	0.02	EFSA (2018b)	0.02	LOQ		
<b>Honey and other apiculture products</b>	<b>0.3</b>	<b>Proposed</b>	<b>0.05</b>	<b>STMR-RAC</b>	<b>0.16</b>	<b>HR-RAC</b>

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PeF: Peeling factor.

(a): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

## Appendix E – Used compound codes

Code/trivial name <sup>(a)</sup>	IUPAC name/SMILES notation/InChiKey <sup>(b)</sup>	Structural formula <sup>(c)</sup>
<b>acetamiprid</b>	(E)-N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine <chem>Clc1ccc(CN(C)C(\C)=N\C#N)cn1</chem> WCXDHFDTOYPNIE-RIYZIHGNSA-N	
<b>N-desmethyl-acetamiprid</b> (IM-2-1)	(E)-N-[(6-chloro-3-pyridyl)methyl]-N'-cyanoacetamidine <chem>Clc1ccc(CNC(\C)=N\C#N)cn1</chem> AYEAUPRZTZWBBF-UHFFFAOYSA-N	
IM-1-4	1-(6-chloro-3-pyridyl)-N-methylmethanamine <chem>Clc1ccc(CNC)cn1</chem> XALCOJXGWJXWBL-UHFFFAOYSA-N	
IM-1-5	N-[(6-chloro-3-pyridyl)methyl]-N-methylacetamidine <chem>Clc1ccc(CN(C)C(C)=N)cn1</chem> JHZWQGRBAHJYZ-UHFFFAOYSA-N	
6-chloronicotinic acid (IC-0)	6-chloronicotinic acid <chem>OC(=O)c1cnc(Cl)cc1</chem> UAWMVMPAYRWUFX-UHFFFAOYSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

(a): The metabolite name in bold is the name used in the conclusion.

(b): ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).

(c): ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).