

## REASONED OPINION

### **Reasoned opinion on the modification of the existing MRLs for acetamiprid in purslane, legume vegetables and pulses (beans and peas)<sup>1</sup>**

**European Food Safety Authority<sup>2</sup>**

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#### **ABSTRACT**

In accordance with Article 6 of Regulation (EC) No 396/2005, Greece, hereafter referred to as the evaluating Member State (EMS), received an application from Nisso Chemical Europe GmbH to modify the existing MRLs for the active substance acetamiprid in purslane, legume vegetables and pulses (beans and peas). In order to accommodate the intended uses of acetamiprid, Greece proposed to raise the existing MRLs of acetamiprid from 0.01\* mg/kg to 3 mg/kg in purslane, from 0.01\* mg/kg in peas (with pods) and 0.06 mg/kg in beans (with pods) to 0.5 mg/kg, from 0.01\* mg/kg to 0.05 mg/kg in beans (without pods) and from 0.05 mg/kg to 0.1 mg/kg in pulses (dry beans and peas). Greece 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. According to EFSA the data are sufficient to derive MRL proposals of 0.15 mg/kg on beans (with pods), 0.4 mg/kg on peas (with pods), 0.07 mg/kg on beans (without pods), 0.15 mg/kg on peas (without pods) and 0.07 mg/kg on pulses (dry beans and peas); these MRL proposals reflect the intended uses in southern EU only. In addition, a MRL proposal for purslane (3 mg/kg) was derived by extrapolation from trials on lettuce. A deficiency was noted in some trials concerning the storage conditions of the samples prior analysis. Information needs to be provided to confirm that samples were effectively stored under conditions for which integrity of residues is demonstrated. Adequate analytical enforcement methods are available to control the residues of acetamiprid in the commodities under consideration at the validated LOQ of 0.01 mg/kg. Based on the risk assessment results, EFSA concludes that the proposed uses will not result in a consumer exposure exceeding the toxicological reference values.

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#### **KEY WORDS**

Acetamiprid, purslane, beans and peas, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, neonicotinoid.

<sup>1</sup> On request from European Commission, Question No EFSA-Q-2012-00503, approved on 14 December 2012.

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## SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Greece, hereafter referred to as the evaluating Member State (EMS), received an application from Nisso Chemical Europe GmbH to modify the existing MRLs for the active substance acetamiprid in purslane, legume vegetables and pulses (beans and peas). In order to accommodate the intended uses of acetamiprid, Greece proposed to raise the existing MRLs of acetamiprid from 0.01\* mg/kg to 3 mg/kg in purslane, from 0.01\* mg/kg in peas (with pods) and 0.06 mg/kg in beans (with pods) to 0.5 mg/kg, from 0.01\* mg/kg to 0.05 mg/kg in beans (without pods) and from 0.05 mg/kg to 0.1 mg/kg in pulses (dry beans and peas). Greece 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 18 April 2012.

EFSA bases its assessment on the evaluation report submitted by the EMS, the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC and its addendum, the Commission Review Report on acetamiprid, the JMPR Evaluation report as well as the conclusions from previous EFSA opinions on acetamiprid.

The toxicological profile of acetamiprid was assessed in the framework of the peer review under Directive 91/414/EEC and data were sufficient to derive an ADI of 0.07 mg/kg bw per day and an ARfD of 0.1 mg/kg bw.

The metabolism of acetamiprid was investigated in primary crops following foliar applications on fruiting crops (eggplant, apple), leafy vegetables (cabbage), root/tuber vegetables (carrot) and on pulses/oilseeds crops (cotton). In addition, the metabolism was also studied on cabbage following soil application. From these studies the peer review concluded to establish the residue definition for enforcement and risk assessment as acetamiprid. For the uses on purslane, beans and peas, EFSA concludes that the metabolism of acetamiprid in primary crops is sufficiently addressed and that the derived residue definitions are applicable.

EFSA considers that the submitted supervised residue trials are sufficient to derive MRL proposals of 0.15 mg/kg on beans (with pods), 0.4 mg/kg on peas (with pods), 0.07 mg/kg on beans (without pods), 0.15 mg/kg on peas (without pods) and 0.07 mg/kg on pulses (dry beans and peas); these MRL proposals reflect the intended uses in southern EU only, since an insufficient number of trials was provided to support the uses in northern EU. In addition, a MRL proposal for purslane (3 mg/kg) was derived by extrapolation from trials on lettuce. Adequate analytical enforcement methods are available to control the residues of acetamiprid in the commodities under consideration at the validated LOQ of 0.01 mg/kg. A deficiency was noted in some trials concerning the storage conditions of the samples prior analysis. **Information needs to be provided to confirm that samples were effectively stored under conditions for which integrity of residues is demonstrated.**

Specific studies investigating the magnitude of acetamiprid residues in processed commodities were not provided and are not required, as the consumer exposure to acetamiprid residues resulting from the intake of purslane, beans and peas is insignificant (0.1% ADI).

The occurrence of acetamiprid residues in rotational crops was investigated in the framework of the peer review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residues of acetamiprid are unlikely to occur in rotational crops, provided that the compound is used on the relevant crops according to the proposed GAPs. However, enough information is not available to exclude the possible presence of the soil metabolite IM-1-5 in rotational crops. Therefore, EFSA recommends the Member States, when granting an authorisation for acetamiprid, to take the necessary risk mitigation measures to avoid residues of IM-1-5 in rotational crops.

Residues of acetamiprid in commodities of animal origin were not assessed in the framework of this application, since the contribution of acetamiprid residues in pulses does not change the dietary

burdens for ruminant, poultry and pig calculated in the course of the peer review of the existing MRLs under Article 12 of Regulation (EC) No 396/2005.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMo). In the framework of the review of the existing MRLs for acetamiprid according to Article 12 of Regulation (EC) No 396/2005, comprehensive short-term and long-term exposure assessments were performed taking into account the existing uses of acetamiprid at EU level. Those food commodities for which no uses of acetamiprid were reported, were excluded from the exposure calculation. EFSA now updates this risk assessments with the median and highest residue values derived from the supervised residue trials conducted on beans, peas and lettuce (purslane).

Under the assumption that the MRLs will be amended as proposed in the Article 12 review, the total calculated intake accounted for up to 6% of the ADI (DE, child). Thus, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The contribution of residues on purslane, beans and peas to the total consumer exposure was insignificant, accounting for a maximum of 0.1 % of the ADI. No acute consumer risk was identified in relation to the proposed MRLs, the maximum calculated exposure in percentage of the ARfD being 29 % for purslane (DE, child).

EFSA concludes that the proposed uses of acetamiprid on purslane, beans and peas will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

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

#### Summary table

| Code Number<br>(a)                                 | Commodity            | Existing EU MRL<br>(mg/kg) | Proposed EU MRL<br>(mg/kg) | Justification for the proposals  |
|--|----------------------|----------------------------|----------------------------|--|
| <b>Enforcement residue definition:</b> Acetamiprid |                      |                            |                            |  |
| 252020   | Purslane             | 0.01*                      | 3.0                        | MRL proposal extrapolated from the residues trials conducted on lettuce grown under indoor conditions and according to the intended GAPs.  |
| 260010   | Beans (with pods)    | 0.06                       | 0.15                       | The residue data sets are sufficient to support the MRL proposals for the intended uses on beans and peas in southern EU only. In contrast, the number of trials is insufficient to derive MRLs for northern EU. |
| 260020   | Beans (without pods) | 0.01*                      | 0.07                       |  |
| 260030   | Peas (with pods)     | 0.01*                      | 0.4                        |  |
| 260040   | Peas (without pods)  | 0.01*                      | 0.15                       |  |
| 300010   | Beans (pulses)       | 0.05                       | 0.07                       | No risk for the consumer was identified for the intended uses of acetamiprid in southern EU. Confirmation that the residue trials are valid with regard to the storage conditions needs to be provided.          |
| 300030   | Peas (pulses)        | 0.05                       | 0.07                       |  |

(a): According to Annex I of Regulation (EC) No 396/2005.

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

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## BACKGROUND

Regulation (EC) No 396/2005<sup>3</sup> establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC<sup>4</sup>, repealed by Regulation (EC) No 1107/2009<sup>5</sup>, shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of that Regulation.

Greece, hereafter referred to as the evaluating Member State (EMS), received an application from the company Nisso Chemical Europe GmbH<sup>6</sup> to modify the existing MRLs for the active substance acetamiprid in purslane, legume vegetables (beans and peas) and pulses (dry beans and peas). This application was notified to the European Commission and EFSA, and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 18 April 2012.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2012-00503 and the following subject:

*Acetamiprid – Application to modify the existing MRLs in various crops*

Greece proposed to raise the existing MRLs of acetamiprid from 0.01\* mg/kg to 3 mg/kg in purslane, from 0.01\* mg/kg in peas (with pods) and 0.06 mg/kg in beans (with pods) to 0.5 mg/kg, from 0.01\* mg/kg to 0.05 mg/kg in beans (without pods) and from 0.05 mg/kg to 0.1 mg/kg in pulses (dry beans and peas).

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

## TERMS OF REFERENCE

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the deadline for providing the reasoned opinion is 18 July 2012.

<sup>3</sup> Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005. OJ L 70, 16.03.2005, p. 1-16.

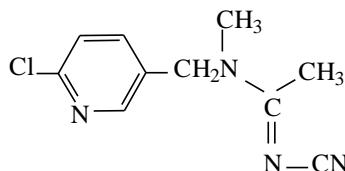
<sup>4</sup> Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32.

<sup>5</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009. OJ L 309, 24.11.2009, p. 1-50.

<sup>6</sup> Nisso Chemical Europe GmbH, Berliner Allee 42, 40212, Düsseldorf, Germany

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Acetamiprid is the ISO common name for (*E*)-*N*<sup>1</sup>-[(6-chloro-3-pyridyl)methyl]-*N*<sup>2</sup>-cyano-*N*<sup>1</sup>-methylacetamidine (IUPAC). The chemical structure of the compound is reported below.



Molecular weight: 222.68 g/mol

Acetamiprid belongs to the group of neonicotinoid compounds which are used as insecticide. Acetamiprid is a systemic active substance with translaminar activity and with contact and stomach action. It is used to control *Hemiptera*, *Lepidoptera*, *Thysanoptera* and *Coleoptera*. It is an agonist of the nicotinic acetylcholine receptor, affecting the synapses in the insect central nervous system.

Acetamiprid was evaluated in the framework of Directive 91/414/EEC with Greece being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process were foliar applications on various fruits crops, some fruiting vegetables, cotton and tobacco at rates ranging from 25 to 100 g a.s./ha in northern and/or southern Europe. Following the peer review, which was not carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2004/99/EC<sup>7</sup>, entering into force on 01 January 2005. According to Regulation (EU) No 540/2011<sup>8</sup>, acetamiprid is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. This approval is restricted to uses as insecticide. Since, the Draft Assessment Report (DAR) of acetamiprid was not peer reviewed by EFSA, no EFSA conclusion is available.

EU MRLs for acetamiprid in products of plant and animal origin have been set for the first time in 2007 by means of Directive 2007/11/EC<sup>9</sup>. These MRLs were modified on several occasions and subsequently transferred to Annex II of Regulation (EC) No 396/2005. Additional MRLs for commodities that were not covered by the former European MRL legislation are established in Annex IIIB of the Regulation. Following MRL requests, EFSA recommended the modification of the existing MRLs for large number of crop commodities (EFSA 2009a, 2009b, 2010a, 2010b, 2010c, 2011a) which were legally implemented in Regulations (EC) No 1050/2009<sup>10</sup> and (EU) No 750/2010<sup>11</sup>, 508/2011<sup>12</sup> and 978/2011<sup>13</sup>. In addition, all existing MRLs have been recently reviewed by EFSA according to Article 12 of the Regulation (EC) No 396/2005 (EFSA, 2011b), but these proposals have not yet been implemented in the EU legislation.

Acetamiprid has been recently evaluated by JMPR (FAO, 2011) and CXLs were adopted for a wide range of crops, among others for peas and beans (succulent seeds) (0.3 mg/kg), beans with pods (0.4 mg/kg) and leafy vegetables which would comprise also purslane (3 mg/kg). For the latter the EU delegation expressed a reservation because of intake concerns related to scarole, another crop comprised in this crop category. However, for purslane the MRL was acceptable for the EU. The implementation of the CXLs is under preparation, but a vote has not yet been taken in the SCFCAH. The details of the intended GAPs for acetamiprid are given in Appendix A.

<sup>7</sup> Commission Directive 2004/99/EC of 01 October 2004, OJ L 309, 6.10.2004, p. 6-8.

<sup>8</sup> Regulation (EU) No 540/2011 of 25 May 2011, OJ L 153, 11.6.2011, p. 1-186.

<sup>9</sup> Commission Directive 2007/11/EC of 21 February 2007, OJ L 63, 1.3.2007, p. 26-37.

<sup>10</sup> Commission Regulation (EC) 1050/2009 of 28 October 2009, OJ L 290, 6.11.2009, p. 7-55.

<sup>11</sup> Commission Regulation (EU) 750/2010 of 07 July 2010, OJ L 220, 21.8.2010, p. 1-56.

<sup>12</sup> Commission Regulation (EU) 508/2011 of 24 May 2011, OJ L 137, 25.5.2011, p. 3-52.

<sup>13</sup> Commission Regulation (EU) 978/2011 of 03 October 2011, OJ L 258, 04.10.2011, p. 12-69.



## ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Greece, 2012), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Greece, 2001) and its addendum (Greece, 2003), the Commission Review Report on acetamiprid (EC, 2004), the JMPR Evaluation report (FAO, 2011) as well as the conclusions from previous EFSA opinions on acetamiprid (EFSA, 2009a, 2009b, 2010a, 2010b, 2010c, 2011a and 2011b). 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>14</sup> and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

### 1. Method of analysis

#### 1.1. Methods for enforcement of residues in food of plant origin

Analytical methods for the determination of acetamiprid residues in plant commodities were assessed in the DAR and during the peer review under Directive 91/414/EEC (Greece, 2001; EC 2004). It was concluded that the multi-residue method DFG S19 using GC-ECD was sufficiently validated for the determination of parent acetamiprid in high water content commodities with a LOQ of 0.01 mg/kg for apple and of 0.05 mg/kg for tomato. An ILV demonstrated the robustness of the method.

The multi-residue QuEChERS method using HPLC-MS/MS described in the European Standard EN 15662:2008 for the determination of residues in high water, high acid and dry content commodities is also applicable, achieving a LOQ of 0.01 mg/kg.

There are adequate validated analytical enforcement methods available to monitor acetamiprid residues in high water-, high fat- content matrices and in acidic and dry commodities and with an LOQ of 0.01 mg/kg (EFSA, 2011b).

Since the commodities under consideration belong to the group of high water content and dry commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRLs for acetamiprid on the purslane, legume vegetables (beans and peas) and pulses (dry beans and peas) are available.

#### 1.2. Methods for enforcement of residues in food of animal origin

Analytical methods for the determination of residues in food of animal origin for the residue definition acetamiprid and N-desmethylacetamiprid (IM-2-1) were assessed in the previous EFSA reasoned opinion (EFSA, 2011b). It was concluded that a suitable method for enforcement purpose is available, but a confirmatory method needs to be provided.

### 2. Mammalian toxicology

The toxicological profile of the active substance acetamiprid was assessed in the framework of the peer review under Directive 91/414/EEC/Regulation (EC, 2004). The data were sufficient to derive toxicological reference values for acetamiprid which are compiled in Table 2-1.

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<sup>14</sup> Commission Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

**Table 2-1:** Overview of the toxicological reference values

|             | Source | Year | Value                 | Study relied upon                   | Safety factor |
|-------------|--------|------|-----------------------|-------------------------------------|---------------|
| Acetamiprid |        |      |                       |                                     |               |
| ADI         | EC     | 2004 | 0.07 mg/kg bw per day | Rat, 2 y and 2 y reproduction study | 100           |
| ARfD        | EC     | 2004 | 0.1 mg/kg bw          | Rat, acute neurotoxicity study      | 100           |

It is noted that JMPR established in 2011 the same ADI and ARfD values for acetamiprid (FAO, 2011).

### 3. Residues

#### 3.1. Nature and magnitude of residues in plant

##### 3.1.1. Primary crops

###### 3.1.1.1. Nature of residues

The metabolism of acetamiprid in primary crops was evaluated in the framework of the peer review under Directive 91/414/EEC (EC, 2004) and reconsidered during the review of the existing MRLs under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011b).

Metabolism of acetamiprid was investigated using foliar applications on fruiting vegetables (eggplant, apple), leafy vegetables (cabbage), root/tuber vegetables (carrot) and on pulses/oilseeds crops (cotton). In addition, the metabolism was also studied on cabbage following soil application. Since acetamiprid was seen to be the main component of the radioactive residues after foliar or soil application (minimum 33% TRR), the residue definitions for all plant groups for both, monitoring and risk assessment, were limited to acetamiprid.

The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review.

For the uses on purslane, beans and peas, EFSA concludes that the metabolism of acetamiprid is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed in the peer review are applicable.

###### 3.1.1.2. Magnitude of residues

###### a. Beans (with pods)

- Northern Europe: (cGAP: 2x 65 g/ha, PHI 14 days, major crop)

Four trials were submitted to support the use of acetamiprid in northern EU, conducted with a total of 2 applications at 47 to 55 g/ha (72% to 85% of the cGAP). As green beans (with pods) are a major crop in northern EU, this data set is not sufficient to derive a MRL as at least, 8 trials are required.

The EMS proposes to complete the residue data set with the results from four trials<sup>15</sup> conducted on peas, as an extrapolation from peas to beans would be possible according to the EU guidance document (EC, 2011). However, in these trials, the residue levels were reported separately for "empty pods" and "green seeds", and no information was given on the residue levels in "pea with pods". As residue levels in "empty pods" cannot be representative of the levels in "pea with pods", EFSA is of the opinion that the proposed extrapolation is not acceptable.

<sup>15</sup> A total of six trials was reported by the EMS in the evaluation report. However, in two locations the reported values refer to replicates and not to separate trials. EFSA has disregarded the replicates, resulting in a total of 4 trials.



- Southern Europe: (*cGAP: 2x 65 g/ha, PHI 7 days, major crop*)

The southern GAP is defined with a shorter PHI of 7 days compare to the northern one. A total of 10 trials conducted over three growing seasons from 2006 to 2008 were provided. All trials were conducted in compliance with the supported GAP, with a total of 2 applications at a rate of 49 to 68 g a.s./ha (75% to 105% cGAP). In two locations, two different formulations (SL and SP) were experimented and the highest value was considered for the MRL calculations. This residue data set is sufficient to derive a MRL proposal of 0.15 mg/kg for "beans with pods" reflecting the southern EU GAP.

b. Peas (with pods) (*cGAP N&SEU: 2x 65 g/ha, PHI 14 days, minor crop N&SEU*)

- Northern Europe: Five northern trials were submitted (see also previous paragraph on beans with pods) where the results were reported separately for "empty pods", and "green seeds" and no data are available for "pea with pods". Hence, the available residue trials are not appropriate to propose a MRL for "peas with pods" in northern EU.

- Southern Europe: A total of 10 trials conducted over 4 growing seasons from 2005 to 2008 were submitted. These trials were performed in compliance with the supported GAP, using 2 treatments at a rate of 49 to 71 g a.s./ha (75% to 109% cGAP). However, **only 4 valid trials are available to derive a MRL for "peas (with pods)"**, as the residue levels in the other trials were only reported separately for "pods without seeds" and "seeds", but not for "peas with pods". These four residue trials are however sufficient to propose a MRL of 0.4 mg/kg, as peas (with pods) is considered as minor crops in southern EU.

c. Beans (without pods) (*cGAP: 2x 65 g/ha, PHI 14 days NEU, 7 days SEU, minor crop N&SEU*)

- Northern Europe: No residue trials for beans (without pods) were submitted, but the applicant referred to the trials reported in the previous section for beans (with pods). However, as no results are available for beans (without pods), no MRL proposal is derived for northern EU.

- Southern Europe: Seven compliant GAP trials are available in southern EU, where residues levels in seeds were detected in the range of <0.01 to 0.04 mg/kg. This residue data set is sufficient to derive a MRL proposal of 0.07 mg/kg, as beans (without pods) are considered as a minor crop in SEU.

d. Peas (without pods) (*cGAP N&SEU: 2x 65 g/ha, PHI 14, major crop NEU, minor crop SEU*)

The same residue trials as examined above to propose MRL for "peas with pods" are considered in this section.

- For northern EU, 4 residues trials are available. This data set is not sufficient to derive a MRL proposal for "peas without pods" since peas are a major crop in northern EU. Four additional trials are required.

- For southern EU, 6 GAP compliant trials<sup>16</sup> are available, where residues levels in seeds were detected in the range of <0.01 to 0.06 mg/kg. At present, this residue data set is sufficient to derive a MRL proposal of 0.15 mg/kg, as peas (without pods) are considered as a minor crop in SEU. However it should be highlighted that this data set will be no longer sufficient as of 1<sup>st</sup> April 2013 when the version 9 of the guideline SANCO 7525/VI/95 enters into force (EC, 2011). Peas will be then considered as a major crop in both, the southern and northern EU.

<sup>16</sup> The EMS counted two replicate trials performed on the same location as separate trials. Therefore the EMS reported eight trials in the evaluation report. Replicates were disregarded by EFSA, resulting in a total of 6 trials only.

e. Beans and peas (Pulses) (*cGAP SEU: 2x 65 g/ha, PHI 28 days, major crop SEU*)

The MRL proposal for pulses is derived from the same residue trials as presented above to derive MRLs for legume vegetables (with and without pods). Samples were however collected at a later growth stage (dry seeds) and considering a PHI of 28 days. One trial on pea conducted in northern EU and wrongly reported as in southern EU has been disregarded. A MRL proposal of 0.07 mg/kg is therefore derived for SEU from a total of 12 trials conducted on beans and peas, where residues in dry seeds were in the range of <0.01 mg/kg to 0.05 mg/kg.

f. Purslane (*cGAP indoor: 2x 50 g/ha, PHI 7 days, BBCH 40-41*)  
(*cGAP outdoor: 2x 50 g/ha, PHI 3 days, BBCH 40-41*)

No residue trials were submitted for purslane. The EMS proposes to extrapolate from trials performed on lettuce under indoor conditions to purslane, since identical cGAPs are proposed for lettuce and purslane. The residue data set provided for lettuce and reported in the table 3-1 has already been assessed by EFSA in previous opinions (EFSA, 2009a; 2011b). The proposed extrapolation is acceptable, as it is in compliance with the extrapolation rules listed in the EU guidance document (EC, 2011). A MRL proposal of 3 mg/kg is therefore proposed for purslane grown indoor.

For the outdoor use on purslane in NEU no specific trials are available. However, the lettuce trials assessed in a previous opinion (EFSA, 2009a) indicated that the residues would be lower compared to the indoor use. For the SEU, trials on lettuce reflecting the intended outdoor GAP on purslane are available which have already been assessed in the framework of the MRL review and also, significantly lower residues were observed. However, EFSA noted in its previous assessment, that additional trials on open-leaf varieties should be submitted to ensure that the available trials do not underestimate the residues on the small leafy crops (EFSA, 2011b). This recommendation would also be applicable to purslane.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 3-1.

The storage stability of acetamiprid in plant commodities was evaluated in the framework of the peer review under Directive 91/414/EEC (EC, 2004) and of the review of the existing MRLs under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011b). Stability of acetamiprid residues was demonstrated for at least 12-13 months in high water-, high oil-content commodities and in acid and dry matrices, when stored at or below -18°C. The length of time the samples were stored frozen prior analyses was reported for *ca.* half of the trials, where the duration of 3 to 10 months was in line with the storage study results. However, as this information was not provided for the rest of the trials the validity of the results cannot be assessed by EFSA. **Before the MRLs are amended in the EU MRL legislation, the EMS has to confirm that all samples were stored under conditions for which integrity of the samples is demonstrated.**

According to the EMS, the analytical methods used to analyse the supervised residue trial samples have been sufficiently validated and were proven to be fit for purpose (Greece, 2012).

Provided that all samples were effectively stored under frozen conditions less than 13 months prior analysis, EFSA considers that data are sufficient to derive MRL proposals of 0.15 mg/kg on beans (with pods), 0.4 mg/kg on peas (with pods), 0.07 mg/kg on beans (without pods), 0.15 mg/kg on peas (without pods) and 0.07 mg/kg on pulses (dry beans and peas), for the intended uses of acetamiprid **in southern EU only**, since an insufficient number of trials was provided to support the uses in northern EU. In addition, the extrapolation to purslane of the MRL of 3 mg/kg proposed for lettuce in framework of the review of the existing MRLs under article 12 (EFSA, 2011b), is recommended.

**Table 3-1:** Overview of the available residues trials data

| Commodity                                   | Residue region<br>(a) | Outdoor /Indoor | Individual trial results (mg/kg)       |                                  | Median residue<br>(mg/kg)<br>(b) | Highest residue<br>(mg/kg)<br>(c) | MRL proposal<br>(mg/kg) | Median CF<br>(d) | Comments<br>(e)   |
|---|-----------------------|-----------------|--|----------------------------------|----------------------------------|-----------------------------------|-------------------------|------------------|---|
|   |                       |                 | Enforcement<br>(acetamiprid)           | Risk assessment<br>(acetamiprid) |                                  |                                   |                         |                  |   |
| Enforcement residue definition: Acetamiprid |                       |                 |  |                                  |                                  |                                   |                         |                  |   |
| Beans<br>(with pods)                        | NEU<br>(PHI 14 d)     | Outdoor         | 2x <0.01, 0.01, 0.02                   | idem                             | 0.01                             | 0.02                              | -                       | 1                | Insufficient number of trials to derive MRL proposal.                                 |
|   | SEU<br>(PHI 7 d)      | Outdoor         | 5x <0.01; 0.01; 0.02; 0.03; 0.06; 0.09 | idem                             | 0.01                             | 0.09                              | 0.15                    | 1                | R <sub>ber</sub> = 0.08<br>R <sub>max</sub> = 0.11<br>MRL <sub>OECD</sub> = 0.14/0.15 |
| Peas<br>(with pods)                         | NEU<br>(PHI 14 d)     | Outdoor         | No data available                      | -                                | -                                | -                                 | -                       | -                | Insufficient number of trials to derive MRL proposal.                                 |
|   | SEU<br>(PHI 14 d)     | Outdoor         | 0.01, 0.02, 0.03, 0.16                 | idem                             | 0.03                             | 0.16                              | 0.4                     | 1                | R <sub>ber</sub> = 0.26<br>R <sub>max</sub> = 0.42<br>MRL <sub>OECD</sub> = 0.34/0.40 |
| Beans<br>(without pods)                     | NEU<br>(PHI 14 d)     | Outdoor         | No data available                      | -                                | -                                | -                                 | -                       | -                | Insufficient number of trials to derive MRL proposal.                                 |
|   | SEU<br>(PHI 7 d)      | Outdoor         | 5x <0.01; 0.02; 0.04                   | idem                             | 0.01                             | 0.04                              | 0.07                    | 1                | R <sub>ber</sub> = 0.04<br>R <sub>max</sub> = 0.05<br>MRL <sub>OECD</sub> = 0.06/0.07 |
| Peas<br>(without pods)                      | NEU<br>(PHI 14 d)     | Outdoor         | 0.01; 0.02; 2x 0.03                    | Idem                             | 0.03                             | 0.03                              | -                       | 1                | Insufficient number of trials to derive MRL proposal.                                 |
|   | SEU<br>(PHI 14 d)     | Outdoor         | 3x <0.01; 0.05; 2x 0.06                | idem                             | 0.03                             | 0.06                              | 0.15                    | 1                | R <sub>ber</sub> = 0.12<br>R <sub>max</sub> = 0.13<br>MRL <sub>OECD</sub> = 0.14/0.15 |

| Commodity             | Residue region<br>(a) | Outdoor /Indoor | Individual trial results (mg/kg)   |                                  | Median residue<br>(mg/kg)<br>(b) | Highest residue<br>(mg/kg)<br>(c) | MRL proposal<br>(mg/kg) | Median CF<br>(d) | Comments<br>(e)   |
|-----------------------|-----------------------|-----------------|--|----------------------------------|----------------------------------|-----------------------------------|-------------------------|------------------|---|
|                       |                       |                 | Enforcement<br>(acetamiprid)   | Risk assessment<br>(acetamiprid) |                                  |                                   |                         |                  |   |
| Beans and Peas (dry)  | SEU                   | Outdoor         | Beans: 7x <0.01; 0.05<br>Peas: 3x <0.01; 0.04  | idem                             | 0.01                             | 0.05                              | <b>0.07</b>             | 1                | R <sub>ber</sub> = 0.02<br>R <sub>max</sub> = 0.05<br>MRL <sub>OECD</sub> = 0.07/0.07 |
| Lettuce<br>→ Purslane | EU <sup>(g)(h)</sup>  | Indoor          | 0.33; 0.41 <sup>(f)</sup> ; 0.5; 0.78 <sup>(f)</sup> ;<br>2x 0.88; 1.1; 1.9 <sup>(f)</sup> | idem                             | 0.83                             | 1.9                               | <b>3</b>                | 1                | R <sub>ber</sub> = 2.1<br>R <sub>max</sub> = 2.4<br>MRL <sub>OECD</sub> = 2.9/3.0     |
|                       | NEU <sup>(g)(h)</sup> | Outdoor         | 0.08; 0.14; 0.15; 0.16; 0.24;<br>0.25; 0.28; 0.31  | idem                             | 0.20                             | 0.31                              | 0.6                     | 1                | R <sub>ber</sub> = 0.55<br>R <sub>max</sub> = 0.46<br>MRL <sub>OECD</sub> = 0.6/0.6   |
|                       | SEU <sup>(h)</sup>    | Outdoor         | 0.04; 2x 0.06; 0.10; 0.11;<br>0.14; 0.17; 0.30   | idem                             | 0.11                             | 0.3                               | 0.5                     | 1                | R <sub>ber</sub> = 0.33<br>R <sub>max</sub> = 0.39<br>MRL <sub>OECD</sub> = 0.46/0.5  |

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (*i.e.* outdoor use) or Import (country code) (EC, 2011).

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial.

(e): Statistical estimation of MRLs according to the EU methodology (R<sub>ber</sub>, R<sub>max</sub>; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).

(f): Values at PHI 7 days, since higher than at PHI 3 days.

(g): Residue trials presented in EFSA, 2009a.

(h): Residue trials presented in EFSA, 2011b (trials on open leaf varieties were not highlighted).

### 3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of acetamiprid residues was investigated in the DAR and in the conclusion on the peer review (Greece, 2001; EC, 2004). Acetamiprid is hydrolytically stable under the standard hydrolysis conditions and it was concluded that the residue definitions proposed for primary crops are also applicable for processed commodities.

Specific studies to assess the magnitude of acetamiprid residues during the processing of beans and peas were not provided and are not necessary as the consumer exposure to acetamiprid residues resulting from the intake of beans and peas is insignificant (<0.1% ADI).

### 3.1.2. Rotational crops

Residues in rotational crops were investigated in the framework of the peer review under Directive 91/414/EEC (EC, 2004) and reconsidered in the framework of the review of the existing MRLs under Article 12 of (EFSA, 2011b). The parent compound acetamiprid is rapidly degraded in soils ( $DT_{90}$  67 days) and therefore, of no relevance for rotational crops. However, the metabolite IM-1-5 (decyano-acetamiprid) was shown to be more persistent and identified as a major metabolite in calcareous soils (Greece, 2003). The relevance of the soil metabolites was discussed during the peer review, but no final decision was taken about the need for further investigations. Since no studies are available to conclude that metabolite IM-1-5 is of no concern in rotational crops, EFSA recommends that Member States granting an authorisation for acetamiprid should take the necessary risk mitigation measures (e.g. definition of pre-plant intervals) in order to avoid residues of IM-1-5 in rotational crops.

## 3.2. Nature and magnitude of residues in livestock

The contribution of acetamiprid residues in pulses (dry beans and peas) resulting from the uses of the active substance according to the intended uses does not change the dietary burdens calculated for ruminants, poultry and pigs in the course of the peer review of the existing MRLs under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011b). The nature and magnitude of acetamiprid residues in livestock were therefore not assessed in the framework of this MRL application.

## 4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population<sup>17</sup> (EFSA, 2007).

In the framework of the review of the existing MRLs for acetamiprid according to Article 12 of Regulation (EC) No 396/2005, comprehensive short-term and long-term exposure assessments were performed taking into account the existing uses of acetamiprid at EU level. Those food commodities for which no uses of acetamiprid were reported were excluded from the exposure calculation (EFSA, 2011b). EFSA now updates this risk assessment with the median and highest residue values derived from the supervised residue trials conducted on beans, peas and lettuce (purslane) (see Table 3-1).

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at the median residue levels identified in supervised trials. EFSA is of the opinion that if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (*i.e.* the ADI), a consumer health risk can be excluded with a high probability.

<sup>17</sup> The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

The acute exposure assessment was performed only with regard to the commodities under consideration, assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items contained residues at the highest level as observed in supervised field trials. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 4-1.

**Table 4-1:** Input values for the consumer dietary exposure assessment

| Commodity  | Chronic exposure assessment   |                          | Acute exposure assessment |                           |
|--|---|--------------------------|---------------------------|---------------------------|
|  | Input value (mg/kg)   | Comment                  | Input value (mg/kg)       | Comment                   |
| <b>Risk assessment residue definition: Acetamiprid</b> |   |                          |                           |                           |
| Beans (with pods)                                      | 0.01  | Median residue           | 0.09                      | Highest residue           |
| Peas (with pods)                                       | 0.03  | Median residue           | 0.16                      | Highest residue           |
| Beans (without pods)                                   | 0.01  | Median residue           | 0.04                      | Highest residue           |
| Peas (without pods)                                    | 0.03  | Median residue           | 0.06                      | Highest residue           |
| Beans (pulses)   | 0.01  | Median residue           | 0.05                      | Highest residue           |
| Pea (Pulses)   | 0.01  | Median residue           | 0.05                      | Highest residue           |
| Purslane   | 0.83  | Median residue (Lettuce) | 1.9                       | Highest residue (lettuce) |
| Other plant or animal commodities                      | Input values listed in table 4-1 of the reasoned opinion on the review of the existing MRLs according Article 12 of Reg. (EC) No 396/2005 (EFSA, 2011b) |                          |                           |                           |

The estimated exposure was then compared with the toxicological reference values derived for acetamiprid (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intakes accounted for up to 6 % of the ADI (DE, child). The contribution of residues in purslane, legume vegetables and pulses (beans and peas) to the total consumer exposure accounted for a maximum of 0.1 % of the ADI.

No acute consumer risk was identified in relation to the MRL proposals for purslane, legume vegetables and pulses (beans and peas). The calculated maximum exposure in percentage of the ARfD was 29 % for purslane (DE, child).

EFSA concludes that the intended use of acetamiprid on purslane, legume vegetables (beans and peas) and pulses (dry beans and peas) will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.



## CONCLUSIONS AND RECOMMENDATIONS

### CONCLUSIONS

The toxicological profile of acetamiprid was assessed in the framework of the peer review under Directive 91/414/EEC and data were sufficient to derive an ADI of 0.07 mg/kg bw per day and an ARfD of 0.1 mg/kg bw.

The metabolism of acetamiprid was investigated in primary crops following foliar applications on fruiting crops (eggplant, apple), leafy vegetables (cabbage), root/tuber vegetables (carrot) and on pulses/oilseeds crops (cotton). In addition, the metabolism was also studied on cabbage following soil application. From these studies the peer review concluded to establish the residue definition for enforcement and risk assessment as acetamiprid. For the uses on purslane, beans and peas, EFSA concludes that the metabolism of acetamiprid in primary crops is sufficiently addressed and that the derived residue definitions are applicable.

EFSA considers that the submitted supervised residue trials are sufficient to derive MRL proposals of 0.15 mg/kg on beans (with pods), 0.4 mg/kg on peas (with pods), 0.07 mg/kg on beans (without pods), 0.15 mg/kg on peas (without pods) and 0.07 mg/kg on pulses (dry beans and peas); these MRL proposals reflect the intended uses in southern EU only, since an insufficient number of trials was provided to support the uses in northern EU. In addition, a MRL proposal for purslane (3 mg/kg) was derived by extrapolation from trials on lettuce. Adequate analytical enforcement methods are available to control the residues of acetamiprid in the commodities under consideration at the validated LOQ of 0.01 mg/kg. A deficiency was noted in some trials concerning the storage conditions of the samples prior analysis. Information needs to be provided to confirm that samples were effectively stored under conditions for which integrity of residues is demonstrated.

Specific studies investigating the magnitude of acetamiprid residues in processed commodities were not provided and are not required, as the consumer exposure to acetamiprid residues resulting from the intake of purslane, beans and peas is insignificant (0.1% ADI).

The occurrence of acetamiprid residues in rotational crops was investigated in the framework of the peer review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residues of acetamiprid are unlikely to occur in rotational crops, provided that the compound is used on the relevant crops according to the proposed GAPs. However, enough information is not available to exclude the possible presence of the soil metabolite IM-1-5 in rotational crops. Therefore, EFSA recommends the Member States, when granting an authorisation for acetamiprid, to take the necessary risk mitigation measures to avoid residues of IM-1-5 in rotational crops.

Residues of acetamiprid in commodities of animal origin were not assessed in the framework of this application, since the contribution of acetamiprid residues in pulses does not change the dietary burdens for ruminant, poultry and pig calculated in the course of the peer review of the existing MRLs under Article 12 of Regulation (EC) No 396/2005.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMO). In the framework of the review of the existing MRLs for acetamiprid according to Article 12 of Regulation (EC) No 396/2005, comprehensive short-term and long-term exposure assessments were performed taking into account the existing uses of acetamiprid at EU level. Those food commodities for which no uses of acetamiprid were reported, were excluded from the exposure calculation. EFSA now updates this risk assessments with the median and highest residue values derived from the supervised residue trials conducted on beans, peas and lettuce (purslane).

Under the assumption that the MRLs will be amended as proposed in the Article 12 review, the total calculated intake accounted for up to 6% of the ADI (DE, child). Thus, no long-term consumer intake

concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The contribution of residues on purslane, beans and peas to the total consumer exposure was insignificant, accounting for a maximum of 0.1 % of the ADI. No acute consumer risk was identified in relation to the proposed MRLs, the maximum calculated exposure in percentage of the ARfD being 29 % for purslane (DE, child).

EFSA concludes that the proposed uses of acetamiprid on purslane, beans and peas will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

## RECOMMENDATIONS

| Code Number<br>(a)                                 | Commodity            | Existing EU MRL<br>(mg/kg) | Proposed EU MRL<br>(mg/kg) | Justification for the proposals   |
|--|----------------------|----------------------------|----------------------------|---|
| <b>Enforcement residue definition: Acetamiprid</b> |                      |                            |                            |   |
| 252020   | Purslane             | 0.01*                      | 3.0                        | MRL proposal extrapolated from the residues trials conducted on lettuce grown under indoor conditions and according to the intended GAPs.   |
| 260010   | Beans (with pods)    | 0.06                       | 0.15                       | The residue data sets are sufficient to support the MRL proposals for the intended uses on beans and peas in southern EU only. In contrast, the number of trials is insufficient to derive MRLs for northern EU.<br><br>No risk for the consumer was identified for the intended uses of acetamiprid in southern EU. Confirmation that the residue trials are valid with regard to the storage conditions needs to be provided. |
| 260020   | Beans (without pods) | 0.01*                      | 0.07                       |   |
| 260030   | Peas (with pods)     | 0.01*                      | 0.4                        |   |
| 260040   | Peas (without pods)  | 0.01*                      | 0.15                       |   |
| 300010   | Beans (pulses)       | 0.05                       | 0.07                       |   |
| 300030   | Peas (pulses)        | 0.05                       | 0.07                       |   |

(a): According to Annex I of Regulation (EC) No 396/2005.

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

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## APPENDICES

### A. GOOD AGRICULTURAL PRACTICE (GAPs)

| Crop and/or situation (a)              | Member State or Country | F G or I (b) | Pest or group of pests controlled (c) | Formulation |                   | Application       |                           |                    |                         | Application rate per treatment |                    |                    | PHI (days) (l)  | Remarks (m) |
|--|-------------------------|--------------|---------------------------------------|-------------|-------------------|-------------------|---------------------------|--------------------|-------------------------|--------------------------------|--------------------|--------------------|-----------------|-------------|
|  |                         |              |                                       | type (d-f)  | conc. of a.s. (i) | Method kind (f-h) | Growth stage & season (j) | number min-max (k) | interval (days) min-max | kg as/hL min-max               | water L/ha min-max | kg a.s./ha min-max |                 |             |
| Beans green                            | NEU & SEU               | F            | Aphids                                | SG /SP      | 200               | foliar            | BBCH 64-85                | 2                  | 14                      | 0.016                          | 400                | 0.065              | 14 NEU<br>7 SEU |             |
| Peas green                             | NEU & SEU               | F            | Aphids                                | SG /SP      | 200               | foliar            | BBCH 64-85                | 2                  | 14                      | 0.016                          | 400                | 0.065              | 14              |             |
| Beans & Peas (dry)                     | SEU                     | F            | Aphids                                | SG /SP      | 200               | foliar            | BBCH 64-85                | 2                  | 14                      | 0.016                          | 400                | 0.065              | 28              |             |
| Spinach & Similar (leaves)<br>Purslane | NEU & SEU               | F            | Aphids                                | SG /SP      | 200               | foliar            | BBCH 41-40                | 2                  | 10-20 NEU<br>7 SEU      | 0.008-0.011                    | 450-600            | 0.050              | 7               |             |
|  | EU                      | G            | Aphids                                | SG /SP      | 200               | foliar            | BBCH 41-40                | 2                  | 14                      | 0.025                          | 200                | 0.050              | 3               |             |

#### Remarks:

- (a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Technical Monograph No 2, 4<sup>th</sup> Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (i) g/kg or g/l
- (j) Growth stage at last treatment (Growth stages of mono- and dicotyledonous plants. BBCH Monograph, 2<sup>nd</sup> Ed., 2001), including where relevant, information on season at time of application
- (k) The minimum and maximum number of application possible under practical conditions of use must be provided
- (l) PHI - minimum pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/restrictions (*i.e.* feeding, grazing)

## B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO )

|  |  |  |  |                                 |  |          |  |                     |  |      |  |  |  |
|--|--|--|--|---------------------------------|--|----------|--|---------------------|--|------|--|--|--|
|  |  |  |  | <b>Acetamiprid</b>              |  |          |  |                     |  |      |  | <b>Prepare workbook for refined calculations</b> |  |
|  |  |  |  | Status of the active substance: |  | Included |  | Code no.            |  |      |  |  |  |
|  |  |  |  | LOQ (mg/kg bw):                 |  |          |  | proposed LOQ:       |  |      |  |  |  |
|  |  |  |  | <b>Toxicological end points</b> |  |          |  |                     |  |      |  | <b>Undo refined calculations</b>                 |  |
|  |  |  |  | ADI (mg/kg bw/day):             |  | 0.07     |  | ARfD (mg/kg bw):    |  | 0.1  |  |  |  |
|  |  |  |  | Source of ADI:                  |  | EC       |  | Source of ARfD:     |  | EC   |  |  |  |
|  |  |  |  | Year of evaluation:             |  | 2004     |  | Year of evaluation: |  | 2004 |  |  |  |

| Chronic risk assessment - refined calculations |  |                                       |  |   |  |                                     |  |                                     |                                  |
|--|--|---------------------------------------|--|---|--|-------------------------------------|--|-------------------------------------|----------------------------------|
|  |  |                                       |  | TMDI (range) in % of ADI<br>minimum - maximum |  |                                     |  |                                     |                                  |
|  |  |                                       |  | 0      6                                      |  |                                     |  |                                     |                                  |
|  |  |                                       |  | No of diets exceeding ADI:                    |  | ---                                 |  |                                     |                                  |
|  | Highest calculated<br>TMDI values in %<br>of ADI | MS Diet                               | Highest contributor<br>to MS diet<br>(in % of ADI) | Commodity /<br>group of commodities           | 2nd contributor to<br>MS diet<br>(in % of ADI) | Commodity /<br>group of commodities | 3rd contributor to<br>MS diet<br>(in % of ADI) | Commodity /<br>group of commodities | pTMRs at<br>LOQ<br>(in % of ADI) |
|  | 6  | DE child                              | 4.0  | Apples  | 0.4  | Milk and milk products: Cattle      | 0.2  | Spinach                             |                                  |
|  | 4  | NL child                              | 2.1  | Apples  | 0.8  | Milk and milk products: Cattle      | 0.4  | Spinach                             |                                  |
|  | 2  | FR infant                             | 0.8  | Apples  | 0.7  | Milk and milk products: Cattle      | 0.5  | Spinach                             |                                  |
|  | 2  | FR toddler                            | 0.9  | Apples  | 0.8  | Spinach                             | 0.1  | Strawberries                        |                                  |
|  | 2  | WHO Cluster diet B                    | 0.4  | Lettuce                                       | 0.3  | Apples                              | 0.2  | Wine grapes                         |                                  |
|  | 2  | ES child                              | 0.5  | Lettuce                                       | 0.4  | Apples                              | 0.4  | Milk and milk products: Cattle      |                                  |
|  | 2  | ES adult                              | 0.6  | Lettuce                                       | 0.3  | Apples                              | 0.1  | Milk and milk products: Cattle      |                                  |
|  | 2  | DK child                              | 0.8  | Apples  | 0.2  | Pears                               | 0.2  | Lettuce                             |                                  |
|  | 2  | WHO regional European diet            | 0.4  | Lettuce                                       | 0.2  | Apples                              | 0.1  | Milk and milk products: Cattle      |                                  |
|  | 1  | IE adult                              | 0.3  | Apples  | 0.2  | Pears                               | 0.1  | Spinach                             |                                  |
|  | 1  | NL general                            | 0.4  | Apples  | 0.2  | Milk and milk products: Cattle      | 0.2  | Spinach                             |                                  |
|  | 1  | SE general population 90th percentile | 0.4  | Milk and milk products: Cattle                | 0.3  | Apples                              | 0.1  | Pears                               |                                  |
|  | 1  | WHO cluster diet E                    | 0.3  | Apples  | 0.2  | Wine grapes                         | 0.1  | Lettuce                             |                                  |
|  | 1  | IT adult                              | 0.4  | Lettuce                                       | 0.3  | Apples                              | 0.1  | Spinach                             |                                  |
|  | 1  | IT kids/toddler                       | 0.3  | Lettuce                                       | 0.3  | Apples                              | 0.1  | Pears                               |                                  |
|  | 1  | WHO Cluster diet F                    | 0.4  | Lettuce                                       | 0.2  | Apples                              | 0.1  | Milk and milk products: Cattle      |                                  |
|  | 1  | LT adult                              | 0.6  | Apples  | 0.1  | Milk and milk products: Cattle      | 0.1  | Lettuce                             |                                  |
|  | 1  | FR all population                     | 0.4  | Wine grapes                                   | 0.2  | Apples                              | 0.1  | Lettuce                             |                                  |
|  | 1  | PL general population                 | 0.7  | Apples  | 0.1  | Pears                               | 0.0  | Head cabbage                        |                                  |
|  | 1  | PT General population                 | 0.3  | Apples  | 0.2  | Wine grapes                         | 0.1  | Pears                               |                                  |
|  | 1  | UK Toddler                            | 0.6  | Apples  | 0.1  | Pears                               | 0.1  | Wheat                               |                                  |
|  | 1  | WHO cluster diet D                    | 0.2  | Apples  | 0.1  | Milk and milk products: Cattle      | 0.1  | Wheat                               |                                  |
|  | 1  | UK Infant                             | 0.5  | Apples  | 0.1  | Pears                               | 0.0  | Potatoes                            |                                  |
|  | 1  | UK vegetarian                         | 0.2  | Apples  | 0.2  | Lettuce                             | 0.1  | Wine grapes                         |                                  |
|  | 1  | DK adult                              | 0.3  | Apples  | 0.1  | Wine grapes                         | 0.1  | Pears                               |                                  |
|  | 1  | UK Adult                              | 0.1  | Lettuce                                       | 0.1  | Apples                              | 0.1  | Wine grapes                         |                                  |
|  | 0  | FI adult                              | 0.1  | Apples  | 0.1  | Lettuce                             | 0.0  | Wine grapes                         |                                  |

|   |  |  |  |  |  |  |  |  |  |
|---|--|--|--|--|--|--|--|--|--|
| <b>Conclusion:</b><br>The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI.<br>A long-term intake of residues of Acetamiprid is unlikely to present a public health concern. |  |  |  |  |  |  |  |  |  |
|---|--|--|--|--|--|--|--|--|--|



| Acute risk assessment /children - refined calculations   |   |                       |                                   |   |                      | Acute risk assessment / adults / general population - refined calculations |   |                       |                                   |   |                     |                                  |
|--|---|-----------------------|-----------------------------------|---|----------------------|--|---|-----------------------|-----------------------------------|---|---------------------|----------------------------------|
| The acute risk assessment is based on the ARfD.  |   |                       |                                   |   |                      |  |   |                       |                                   |   |                     |                                  |
| For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation. |   |                       |                                   |   |                      |  |   |                       |                                   |   |                     |                                  |
| In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.   |   |                       |                                   |   |                      |  |   |                       |                                   |   |                     |                                  |
| In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.   |   |                       |                                   |   |                      |  |   |                       |                                   |   |                     |                                  |
| Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.  |   |                       |                                   |   |                      |  |   |                       |                                   |   |                     |                                  |
| Unprocessed commodities  | No of commodities for which ARfD/ADI is exceeded (IESTI 1): |                       |                                   | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |                      |  | No of commodities for which ARfD/ADI is exceeded (IESTI 1): |                       |                                   | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |                     |                                  |
|  | ---   |                       |                                   | ---   |                      |  | ---   |                       |                                   | ---   |                     |                                  |
|  | IESTI 1   | *)                    | **) pTMRL/ threshold MRL (mg/kg)  | IESTI 2   | *)                   | **) pTMRL/ threshold MRL (mg/kg)   | IESTI 1   | *)                    | **) pTMRL/ threshold MRL (mg/kg)  | IESTI 2   | *)                  | **) pTMRL/ threshold MRL (mg/kg) |
|  | Highest % of ARfD/ADI                                       | Commodities           |                                   | Highest % of ARfD/ADI                                       | Commodities          |  | Highest % of ARfD/ADI                                       | Commodities           |                                   | Highest % of ARfD/ADI                                       | Commodities         |                                  |
|  | 29  | Purslane              | 1.9 / -                           | 22  | Purslane             | 1.9 / -  | 20  | Purslane              | 1.9 / -                           | 18  | Purslane            | 1.9 / -                          |
|  | 1   | Beans (with pods)     | 0.09 / -                          | 1   | Beans (with pods)    | 0.09 / -   | 1   | Peas (with pods)      | 0.16 / -                          | 1   | Peas (with pods)    | 0.16 / -                         |
|  | 1   | Beans                 | 0.05 / -                          | 1   | Beans                | 0.05 / -   | 0.5   | Beans (with pods)     | 0.09 / -                          | 0.5   | Beans (with pods)   | 0.09 / -                         |
|  | 1   | Peas (with pods)      | 0.16 / -                          | 1   | Peas (with pods)     | 0.16 / -   | 0.3   | Beans                 | 0.05 / -                          | 0.3   | Beans               | 0.05 / -                         |
|  | 0.5   | Peas (without pods)   | 0.06 / -                          | 0.5   | Peas (without pods)  | 0.06 / -   | 0.2   | Peas (without pods)   | 0.06 / -                          | 0.2   | Peas (without pods) | 0.06 / -                         |
|  | 0.3   | Beans (without pods)  | 0.04 / -                          | 0.3   | Beans (without pods) | 0.04 / -   |   |                       |                                   |   |                     |                                  |
|  | 0.2   | Peas                  | 0.05 / -                          | 0.2   | Peas                 | 0.05 / -   |   |                       |                                   |   |                     |                                  |
| No of critical MRLs (IESTI 1)  |   |                       | ---                               |   |                      | No of critical MRLs (IESTI 2)  |   |                       | ---                               |   |                     |                                  |
| Processed commodities  | No of commodities for which ARfD/ADI is exceeded:           |                       |                                   | No of commodities for which ARfD/ADI is exceeded:           |                      |  | No of commodities for which ARfD/ADI is exceeded:           |                       |                                   | No of commodities for which ARfD/ADI is exceeded:           |                     |                                  |
|  | ---   |                       |                                   | ---   |                      |  | ---   |                       |                                   | ---   |                     |                                  |
|  | Highest % of ARfD/ADI                                       | Processed commodities | ***) pTMRL/ threshold MRL (mg/kg) |   |                      |  | Highest % of ARfD/ADI                                       | Processed commodities | ***) pTMRL/ threshold MRL (mg/kg) |   |                     |                                  |
| *) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.  |   |                       |                                   |   |                      |  |   |                       |                                   |   |                     |                                  |
| **) pTMRL: provisional temporary MRL   |   |                       |                                   |   |                      |  |   |                       |                                   |   |                     |                                  |
| ***) pTMRL: provisional temporary MRL for unprocessed commodity  |   |                       |                                   |   |                      |  |   |                       |                                   |   |                     |                                  |

## C. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 27/11/2012 17:46))

| Code number | Groups and examples of individual products to which the MRLs apply         | Acetamiprid MRLs (R) |                   |
|-------------|--|----------------------|-------------------|
|             |  | Reg. 396/2005        | Proposals Art. 12 |
| 100000      | 1. FRUIT FRESH OR FROZEN; NUTS   |                      |                   |
| 110000      | (i) Citrus fruit   | 1                    |                   |
| 110010      | Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids) | 1                    | 0.9               |
| 110020      | Oranges (Bergamot, bitter orange, chinotto and other hybrids)              | 1                    | 0.9               |
| 110030      | Lemons (Citron, lemon)   | 1                    | 0.9               |
| 110040      | Limes  | 1                    | 0.9               |
| 110050      | Mandarins (Clementine, tangerine and other hybrids)                        | 1                    | 0.9               |
| 110990      | Others   | 1                    |                   |
| 120000      | (ii) Tree nuts (shelled or unshelled)                                      | 0.01 *               |                   |
| 120010      | Almonds  | 0.01 *               |                   |
| 120020      | Brazil nuts  | 0.01 *               |                   |
| 120030      | Cashew nuts  | 0.01 *               |                   |
| 120040      | Chestnuts  | 0.01 *               |                   |
| 120050      | Coconuts   | 0.01 *               |                   |
| 120060      | Hazelnuts (Filbert)  | 0.01 *               |                   |
| 120070      | Macadamia  | 0.01 *               |                   |
| 120080      | Pecans   | 0.01 *               |                   |
| 120090      | Pine nuts  | 0.01 *               |                   |
| 120100      | Pistachios   | 0.01 *               |                   |
| 120110      | Walnuts  | 0.01 *               |                   |
| 120990      | Others   | 0.01 *               |                   |
| 130000      | (iii) Pome fruit   | 0.7                  |                   |
| 130010      | Apples (Crab apple)  | 0.7                  | 0.7               |
| 130020      | Pears (Oriental pear)  | 0.7                  | 0.7               |
| 130030      | Quinces  | 0.7                  | 0.7               |
| 130040      | Medlar   | 0.7                  | 0.7               |
| 130050      | Loquat   | 0.7                  | 0.7               |
| 130990      | Others   | 0.7                  |                   |
| 140000      | (iv) Stone fruit   |                      |                   |
| 140010      | Apricots   | 0.1                  | 0.1               |
| 140020      | Cherries (sweet cherries, sour cherries)                                   | 0.5                  | 0.5               |
| 140030      | Peaches (Nectarines and similar hybrids)                                   | 0.1                  | 0.1               |
| 140040      | Plums (Damson, greengage, mirabelle)                                       | 0.03                 | 0.03              |
| 140990      | Others   | 0.01 *               |                   |
| 150000      | (v) Berries & small fruit  |                      |                   |

| Code number | Groups and examples of individual products to which the MRLs apply   | Acetamiprid MRLs (R) |                   |
|-------------|--|----------------------|-------------------|
|             |  | Reg. 396/2005        | Proposals Art. 12 |
| 151000      | (a) Table and wine grapes  | 0.2                  | 0.2               |
| 151010      | Table grapes   | 0.2                  | 0.2               |
| 151020      | Wine grapes  | 0.2                  | 0.2               |
| 152000      | (b) Strawberries   | 0.5                  | 0.5               |
| 153000      | (c) Cane fruit   | 0.01 *               |                   |
| 153010      | Blackberries   | 0.01 *               |                   |
| 153020      | Dewberries (Loganberries, Boysenberries, and cloudberrys)  | 0.01 *               |                   |
| 153030      | Raspberries (Wineberries)  | 0.01 *               |                   |
| 153990      | Others   | 0.01 *               |                   |
| 154000      | (d) Other small fruit & berries  |                      |                   |
| 154010      | Blueberries (Bilberries cowberries (red bilberries))   | 1.5                  | 1.5               |
| 154020      | Cranberries  | 0.01 *               |                   |
| 154030      | Cumants (red, black and white)   | 0.01 *               |                   |
| 154040      | Gooseberries (Including hybrids with other ribes species)  | 0.01 *               |                   |
| 154050      | Rose hips  | 0.01 *               |                   |
| 154060      | Mulberries (arbutus berry)   | 0.01 *               |                   |
| 154070      | Azarole (mediterranean medlar)   | 0.01 *               |                   |
| 154080      | Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries) | 0.01 *               |                   |
| 154990      | Others   | 0.01 *               |                   |
| 160000      | (vi) Miscellaneous fruit   |                      |                   |
| 161000      | (a) Edible peel  |                      |                   |
| 161010      | Dates  | 0.01 *               |                   |
| 161020      | Figs   | 0.03                 | 0.03              |
| 161030      | Table olives   | 0.01 *               |                   |
| 161040      | Kumquats (Marumi kumquats, nagami kumquats)  | 0.01 *               |                   |
| 161050      | Carambola (Bilimbi)  | 0.01 *               |                   |
| 161060      | Persimmon  | 0.01 *               |                   |
| 161070      | Jambolan (java plum) (Java apple (water apple), pomarac, rose apple, Brazilian cherry (grumichama), Surinam cherry)                                | 0.01 *               |                   |
| 161990      | Others   | 0.01 *               |                   |
| 162000      | (b) Inedible peel, small   | 0.01 *               |                   |
| 162010      | Kiwi   | 0.01 *               |                   |
| 162020      | Lychee (Litchi) (Pulasan, rambutan (hairy litchi))   | 0.01 *               |                   |
| 162030      | Passion fruit  | 0.01 *               |                   |

| Code number | Groups and examples of individual products to which the MRLs apply  | Acetamiprid MRLs (R) |                   |
|-------------|---|----------------------|-------------------|
|             |   | Reg. 396/2005        | Proposals Art. 12 |
| 162040      | Prickly pear (cactus fruit)   | 0.01 *               |                   |
| 162050      | Star apple  | 0.01 *               |                   |
| 162060      | American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mamme sapote) | 0.01 *               |                   |
| 162990      | Others  | 0.01 *               |                   |
| 163000      | (c) Inedible peel, large  | 0.01 *               |                   |
| 163010      | Avocados  | 0.01 *               |                   |
| 163020      | Bananas (Dwarf banana, plantain, apple banana)  | 0.01 *               |                   |
| 163030      | Mangoes   | 0.01 *               |                   |
| 163040      | Papaya  | 0.01 *               |                   |
| 163050      | Pomegranate   | 0.01 *               |                   |
| 163060      | Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)                                | 0.01 *               |                   |
| 163070      | Guava   | 0.01 *               |                   |
| 163080      | Pineapples  | 0.01 *               |                   |
| 163090      | Bread fruit (Jackfruit)   | 0.01 *               |                   |
| 163100      | Durian  | 0.01 *               |                   |
| 163110      | Soursop (guanabana)   | 0.01 *               |                   |
| 163990      | Others  | 0.01 *               |                   |
| 200000      | 2. VEGETABLES FRESH OR FROZEN   |                      |                   |
| 210000      | (i) Root and tuber vegetables   | 0.01 *               |                   |
| 211000      | (a) Potatoes  | 0.01 *               | 0.01              |
| 212000      | (b) Tropical root and tuber vegetables  | 0.01 *               |                   |
| 212010      | Cassava (Dasheen, eddoe (Japanese taro), tannia)  | 0.01 *               |                   |
| 212020      | Sweet potatoes  | 0.01 *               |                   |
| 212030      | Yams (Potato bean (yam bean), Mexican yam bean)   | 0.01 *               |                   |
| 212040      | Arrowroot   | 0.01 *               |                   |
| 212990      | Others  | 0.01 *               |                   |
| 213000      | (c) Other root and tuber vegetables except sugar beet   | 0.01 *               |                   |
| 213010      | Beetroot  | 0.01 *               |                   |
| 213020      | Carrots   | 0.01 *               |                   |
| 213030      | Celeriac  | 0.01 *               |                   |
| 213040      | Horseradish   | 0.01 *               |                   |
| 213050      | Jerusalem artichokes  | 0.01 *               |                   |
| 213060      | Parsnips  | 0.01 *               |                   |
| 213070      | Parsley root  | 0.01 *               |                   |

| Code number | Groups and examples of individual products to which the MRLs apply             | Acetamiprid MRLs (R) |                   |
|-------------|--|----------------------|-------------------|
|             |  | Reg. 396/2005        | Proposals Art. 12 |
| 213080      | Radishes (Black radish, Japanese radish, small radish and similar varieties)   | 0.01 *               |                   |
| 213090      | Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))                    | 0.01 *               |                   |
| 213100      | Swedes   | 0.01 *               |                   |
| 213110      | Turnips  | 0.01 *               |                   |
| 213990      | Others   | 0.01 *               |                   |
| 220000      | (ii) Bulb vegetables   |                      |                   |
| 220010      | Garlic   | 0.01 *               |                   |
| 220020      | Onions (Silverskin onions)   | 0.02                 | 0.02              |
| 220030      | Shallots   | 0.01 *               |                   |
| 220040      | Spring onions (Welsh onion and similar varieties)                              | 0.01 *               |                   |
| 220990      | Others   | 0.01 *               |                   |
| 230000      | (iii) Fruiting vegetables  |                      |                   |
| 231000      | (a) Solanacea  |                      |                   |
| 231010      | Tomatoes (Cherry tomatoes, )   | 0.15                 | 0.15              |
| 231020      | Peppers (Chilli peppers)   | 0.3                  | 0.3               |
| 231030      | Aubergines (egg plants) (Pepino)   | 0.15                 | 0.15              |
| 231040      | Okra, lady's fingers   | 0.01 *               |                   |
| 231990      | Others   | 0.01 *               |                   |
| 232000      | (b) Cucurbits - edible peel  | 0.3                  |                   |
| 232010      | Cucumbers  | 0.3                  | 0.3               |
| 232020      | Gherkins   | 0.3                  | 0.3               |
| 232030      | Courgettes (Summer squash, marrow (patisson))                                  | 0.3                  | 0.3               |
| 232990      | Others   | 0.3                  |                   |
| 233000      | (c) Cucurbits-inedible peel  | 0.01 *               |                   |
| 233010      | Melons (Kiwano )   | 0.01 *               | 0.01              |
| 233020      | Pumpkins (Winter squash)   | 0.01 *               |                   |
| 233030      | Watermelons  | 0.01 *               | 0.01              |
| 233990      | Others   | 0.01 *               |                   |
| 234000      | (d) Sweet corn   | 0.01 *               |                   |
| 239000      | (e) Other fruiting vegetables  | 0.01 *               |                   |
| 240000      | (iv) Brassica vegetables   |                      |                   |
| 241000      | (a) Flowering brassica   |                      |                   |
| 241010      | Broccoli (Calabrese, Chinese broccoli, Broccoli raab)                          | 0.3                  | 0.3               |
| 241020      | Cauliflower  | 0.15                 | 0.15              |
| 241990      | Others   | 0.15                 |                   |
| 242000      | (b) Head brassica  |                      |                   |
| 242010      | Brussels sprouts   | 0.05                 | 0.05              |
| 242020      | Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage) | 0.6                  | 0.6               |
| 242990      | Others   | 0.01 *               |                   |
| 243000      | (c) Leafy brassica   | 0.01 *               |                   |
| 243010      | Chinese cabbage (Indian  | 0.01 *               |                   |

| Code number | Groups and examples of individual products to which the MRLs apply   | Acetamiprid MRLs (R) |                   |
|-------------|--|----------------------|-------------------|
|             |  | Reg. 396/2005        | Proposals Art. 12 |
|             | (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)                       |                      |                   |
| 243020      | Kale (Borecole (curly kale), collards)   | 0.01 *               |                   |
| 243990      | Others   | 0.01 *               |                   |
| 244000      | (d) Kohlrabi   | 0.01 *               |                   |
| 250000      | (v) Leaf vegetables & fresh herbs  |                      |                   |
| 251000      | (a) Lettuce and other salad plants including Brassicacea   |                      |                   |
| 251010      | Lamb's lettuce (Italian cornsalad)   | 5                    | 3                 |
| 251020      | Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)                                  | 5                    | 3                 |
| 251030      | Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leave endive, sugar loaf)                       | 1.5                  | 1.4               |
| 251040      | Cress  | 3                    | 3                 |
| 251050      | Land cress   | 3                    | 3                 |
| 251060      | Rocket, Rucola (Wild rocket)   | 5                    | 3                 |
| 251070      | Red mustard  | 3                    | 3                 |
| 251080      | Leaves and sprouts of Brassica spp (Mizuna)  | 5                    | 3                 |
| 251990      | Others   | 0.01 *               |                   |
| 252000      | (b) Spinach & similar (leaves)   |                      |                   |
| 252010      | Spinach (New Zealand spinach, turnip greens (turnip tops))   | 4                    | 5                 |
| 252020      | Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)                              | 0.01 *               | 0.5               |
| 252030      | Beet leaves (chard) (Leaves of beetroot)   | 3                    | 3                 |
| 252990      | Others   | 0.01 *               |                   |
| 253000      | (c) Vine leaves (grape leaves)   | 0.01 *               |                   |
| 254000      | (d) Water cress  | 0.01 *               |                   |
| 255000      | (e) Witloof  | 0.01 *               |                   |
| 256000      | (f) Herbs  |                      |                   |
| 256010      | Chervil  | 3                    | 3                 |
| 256020      | Chives   | 3                    | 3                 |
| 256030      | Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea) | 3                    | 3                 |
| 256040      | Parsley  | 5                    | 3                 |
| 256050      | Sage (Winter savory, summer savory, )  | 3                    | 3                 |
| 256060      | Rosemary   | 3                    | 3                 |

| Code number | Groups and examples of individual products to which the MRLs apply   | Acetamiprid MRLs (R) |                   |
|-------------|--|----------------------|-------------------|
|             |  | Reg. 396/2005        | Proposals Art. 12 |
| 256070      | Thyme ( marjoram, oregano)   | 3                    | 3                 |
| 256080      | Basil (Balm leaves, mint, peppermint)  | 3                    | 3                 |
| 256090      | Bay leaves (laurel)  | 3                    | 3                 |
| 256100      | Tarragon (Hyssop)  | 3                    | 3                 |
| 256990      | Others   | 3                    |                   |
| 260000      | (vi) Legume vegetables (fresh)   |                      |                   |
| 260010      | Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans) | 0.06                 | 0.06              |
| 260020      | Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)                                 | 0.01 *               |                   |
| 260030      | Peas (with pods) (Mangetout (sugar peas))  | 0.01 *               |                   |
| 260040      | Peas (without pods) (Garden pea, green pea, chickpea)  | 0.01 *               |                   |
| 260050      | Lentils  | 0.01 *               |                   |
| 260990      | Others   | 0.01 *               |                   |
| 270000      | (vii) Stem vegetables (fresh)  |                      |                   |
| 270010      | Asparagus  | 0.01 *               |                   |
| 270020      | Cardoons   | 0.01 *               |                   |
| 270030      | Celery   | 1                    | 1                 |
| 270040      | Fennel   | 0.01 *               |                   |
| 270050      | Globe artichokes   | 0.6                  | 0.7               |
| 270060      | Leek   | 0.01 *               |                   |
| 270070      | Rhubarb  | 0.01 *               |                   |
| 270080      | Bamboo shoots  | 0.01 *               |                   |
| 270090      | Palm hearts  | 0.01 *               |                   |
| 270990      | Others   | 0.01 *               |                   |
| 280000      | (viii) Fungi   | 0.01 *               |                   |
| 280010      | Cultivated (Common mushroom, Oyster mushroom, Shi-take)  | 0.01 *               |                   |
| 280020      | Wild (Chanterelle, Truffle, Morel )  | 0.01 *               |                   |
| 280990      | Others   | 0.01 *               |                   |
| 290000      | (ix) Sea weeds   | 0.01 *               |                   |
| 300000      | 3. PULSES, DRY   |                      |                   |
| 300010      | Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)                    | 0.05                 | 0.05              |
| 300020      | Lentils  | 0.01 *               |                   |
| 300030      | Peas (Chickpeas, field peas, chickling vetch)  | 0.05                 | 0.05              |
| 300040      | Lupins   | 0.01 *               |                   |
| 300990      | Others   | 0.01 *               |                   |
| 400000      | 4. OILSEEDS AND OILFRUITS  |                      |                   |
| 401000      | (i) Oilseeds   |                      |                   |

| Code number | Groups and examples of individual products to which the MRLs apply             | Acetamiprid MRLs (R) |                   |
|-------------|--|----------------------|-------------------|
|             |  | Reg. 396/2005        | Proposals Art. 12 |
| 401010      | Linseed  | 0.01 *               |                   |
| 401020      | Peanuts  | 0.01 *               |                   |
| 401030      | Poppy seed   | 0.01 *               |                   |
| 401040      | Sesame seed  | 0.01 *               |                   |
| 401050      | Sunflower seed   | 0.01 *               |                   |
| 401060      | Rape seed (Bird rapeseed, turnip rape)   | 0.2                  | 0.2               |
| 401070      | Soya bean  | 0.01 *               |                   |
| 401080      | Mustard seed   | 0.01 *               |                   |
| 401090      | Cotton seed  | 0.5                  | 0.5               |
| 401100      | Pumpkin seeds  | 0.01 *               |                   |
| 401110      | Safflower  | 0.01 *               |                   |
| 401120      | Borage   | 0.01 *               |                   |
| 401130      | Gold of pleasure   | 0.01 *               |                   |
| 401140      | Hempseed   | 0.01 *               |                   |
| 401150      | Castor bean  | 0.01 *               |                   |
| 401990      | Others   | 0.01 *               |                   |
| 402000      | (ii) Oilfruits   | 0.01 *               |                   |
| 402010      | Olives for oil production  | 0.01 *               |                   |
| 402020      | Palm nuts (palmoil kernels)  | 0.01 *               |                   |
| 402030      | Palmfruit  | 0.01 *               |                   |
| 402040      | Kapok  | 0.01 *               |                   |
| 402990      | Others   | 0.01 *               |                   |
| 500000      | 5. CEREALS   |                      |                   |
| 500010      | Barley   | 0.01 *               |                   |
| 500020      | Buckwheat  | 0.01 *               |                   |
| 500030      | Maize  | 0.01 *               |                   |
| 500040      | Millet (Foxtail millet, teff)  | 0.01 *               |                   |
| 500050      | Oats   | 0.01 *               |                   |
| 500060      | Rice   | 0.01 *               |                   |
| 500070      | Rye  | 0.01 *               |                   |
| 500080      | Sorghum  | 0.01 *               |                   |
| 500090      | Wheat (Spelt Triticale)  | 0.03                 | 0.02              |
| 500990      | Others   | 0.01 *               |                   |
| 600000      | 6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA                                     | 0.1 *                |                   |
| 610000      | (i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis) | 0.1 *                |                   |
| 620000      | (ii) Coffee beans  | 0.1 *                |                   |
| 630000      | (iii) Herbal infusions (dried)   | 0.1 *                |                   |
| 631000      | (a) Flowers  | 0.1 *                |                   |
| 631010      | Camomille flowers  | 0.1 *                |                   |
| 631020      | Hybiscus flowers   | 0.1 *                |                   |
| 631030      | Rose petals  | 0.1 *                |                   |
| 631040      | Jasmine flowers  | 0.1 *                |                   |
| 631050      | Lime (linden)  | 0.1 *                |                   |
| 631990      | Others   | 0.1 *                |                   |
| 632000      | (b) Leaves   | 0.1 *                |                   |

| Code number | Groups and examples of individual products to which the MRLs apply | Acetamiprid MRLs (R) |                   |
|-------------|--|----------------------|-------------------|
|             |  | Reg. 396/2005        | Proposals Art. 12 |
| 632010      | Strawberry leaves  | 0.1 *                |                   |
| 632020      | Rooibos leaves   | 0.1 *                |                   |
| 632030      | Maté   | 0.1 *                |                   |
| 632990      | Others   | 0.1 *                |                   |
| 633000      | (c) Roots  | 0.1 *                |                   |
| 633010      | Valerian root  | 0.1 *                |                   |
| 633020      | Ginseng root   | 0.1 *                |                   |
| 633990      | Others   | 0.1 *                |                   |
| 639000      | (d) Other herbal infusions   | 0.1 *                |                   |
| 640000      | (iv) Cocoa (fermented beans)                                       | 0.1 *                |                   |
| 650000      | (v) Carob (st. johns bread)  | 0.1 *                |                   |
| 700000      | 7. HOPS (dried), including hop pellets and unconcentrated powder   | 0.1 *                |                   |
| 800000      | 8. SPICES  | 0.1 *                |                   |
| 810000      | (i) Seeds  | 0.1 *                |                   |
| 810010      | Anise  | 0.1 *                |                   |
| 810020      | Black caraway  | 0.1 *                |                   |
| 810030      | Celery seed (Lovage seed)  | 0.1 *                |                   |
| 810040      | Coriander seed   | 0.1 *                |                   |
| 810050      | Cumin seed   | 0.1 *                |                   |
| 810060      | Dill seed  | 0.1 *                |                   |
| 810070      | Fennel seed  | 0.1 *                |                   |
| 810080      | Fenugreek  | 0.1 *                |                   |
| 810090      | Nutmeg   | 0.1 *                |                   |
| 810990      | Others   | 0.1 *                |                   |
| 820000      | (ii) Fruits and berries  | 0.1 *                |                   |
| 820010      | Allspice   | 0.1 *                |                   |
| 820020      | Anise pepper (Japan pepper)  | 0.1 *                |                   |
| 820030      | Caraway  | 0.1 *                |                   |
| 820040      | Cardamom   | 0.1 *                |                   |
| 820050      | Juniper berries  | 0.1 *                |                   |
| 820060      | Pepper, black and white (Long pepper, pink pepper)                 | 0.1 *                |                   |
| 820070      | Vanilla pods   | 0.1 *                |                   |
| 820080      | Tamarind   | 0.1 *                |                   |
| 820990      | Others   | 0.1 *                |                   |
| 830000      | (iii) Bark   | 0.1 *                |                   |
| 830010      | Cinnamon (Cassia)  | 0.1 *                |                   |
| 830990      | Others   | 0.1 *                |                   |
| 840000      | (iv) Roots or rhizome  | 0.1 *                |                   |
| 840010      | Liquorice  | 0.1 *                |                   |
| 840020      | Ginger   | 0.1 *                |                   |
| 840030      | Turmeric (Curcuma)   | 0.1 *                |                   |
| 840040      | Horseradish  | 0.1 *                |                   |
| 840990      | Others   | 0.1 *                |                   |
| 850000      | (v) Buds   | 0.1 *                |                   |
| 850010      | Cloves   | 0.1 *                |                   |
| 850020      | Capers   | 0.1 *                |                   |

| Code number | Groups and examples of individual products to which the MRLs apply   | Acetamiprid MRLs (R) |                   |
|-------------|--|----------------------|-------------------|
|             |  | Reg. 396/2005        | Proposals Art. 12 |
| 850990      | Others   | 0.1 *                |                   |
| 860000      | (vi) Flower stigma   | 0.1 *                |                   |
| 860010      | Saffron  | 0.1 *                |                   |
| 860990      | Others   | 0.1 *                |                   |
| 870000      | (vii) Aril   | 0.1 *                |                   |
| 870010      | Mace   | 0.1 *                |                   |
| 870990      | Others   | 0.1 *                |                   |
| 900000      | 9. SUGAR PLANTS  | 0.01 *               |                   |
| 900010      | Sugar beet (root)  | 0.01 *               |                   |
| 900020      | Sugar cane   | 0.01 *               |                   |
| 900030      | Chicory roots  | 0.01 *               |                   |
| 900990      | Others   | 0.01 *               |                   |
| 1000000     | 10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS  |                      |                   |
| 1010000     | (i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these | -                    |                   |
| 1011000     | (a) Swine  |                      |                   |
| 1011010     | Meat   | 0.05 *               | 0.02              |
| 1011020     | Fat free of lean meat  | 0.05 *               | 0.02              |
| 1011030     | Liver  | 0.1                  | 0.1               |
| 1011040     | Kidney   | 0.2                  | 0.2               |
| 1011050     | Edible offal   | 0.05 *               |                   |
| 1011990     | Others   | 0.05 *               |                   |
| 1012000     | (b) Bovine   |                      |                   |
| 1012010     | Meat   | 0.05 *               | 0.05              |
| 1012020     | Fat  | 0.05 *               | 0.05              |
| 1012030     | Liver  | 0.1                  | 0.1               |
| 1012040     | Kidney   | 0.2                  | 0.2               |
| 1012050     | Edible offal   | 0.05 *               |                   |
| 1012990     | Others   | 0.05 *               |                   |
| 1013000     | (c) Sheep  |                      |                   |
| 1013010     | Meat   | 0.05 *               | 0.05              |
| 1013020     | Fat  | 0.05 *               | 0.05              |
| 1013030     | Liver  | 0.1                  | 0.1               |
| 1013040     | Kidney   | 0.2                  | 0.2               |
| 1013050     | Edible offal   | 0.05 *               |                   |
| 1013990     | Others   | 0.05 *               |                   |
| 1014000     | (d) Goat   |                      |                   |
| 1014010     | Meat   | 0.05 *               | 0.05              |
| 1014020     | Fat  | 0.05 *               | 0.05              |
| 1014030     | Liver  | 0.1                  | 0.1               |
| 1014040     | Kidney   | 0.2                  | 0.2               |
| 1014050     | Edible offal   | 0.05 *               |                   |

| Code number | Groups and examples of individual products to which the MRLs apply          | Acetamiprid MRLs (R) |                   |
|-------------|---|----------------------|-------------------|
|             |   | Reg. 396/2005        | Proposals Art. 12 |
| 1014990     | Others  | 0.05*                |                   |
| 1015000     | (e) Horses, asses, mules or hinnies   |                      |                   |
| 1015010     | Meat  | 0.05*                |                   |
| 1015020     | Fat   | 0.05*                |                   |
| 1015030     | Liver   | 0.1                  |                   |
| 1015040     | Kidney  | 0.2                  |                   |
| 1015050     | Edible offal  | 0.05*                |                   |
| 1015990     | Others  | 0.05*                |                   |
| 1016000     | (f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon |                      |                   |
| 1016010     | Meat  | 0.05*                | 0.02              |
| 1016020     | Fat   | 0.05*                | 0.02              |
| 1016030     | Liver   | 0.1                  | 0.1               |
| 1016040     | Kidney  | 0.2                  |                   |
| 1016050     | Edible offal  | 0.05*                |                   |
| 1016990     | Others  | 0.05*                |                   |
| 1017000     | (g) Other farm animals (Rabbit,   |                      |                   |

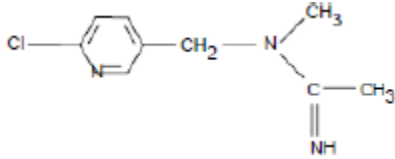
| Code number | Groups and examples of individual products to which the MRLs apply   | Acetamiprid MRLs (R) |                   |
|-------------|--|----------------------|-------------------|
|             |  | Reg. 396/2005        | Proposals Art. 12 |
|             | Kangaroo)  |                      |                   |
| 1017010     | Meat   | 0.05*                |                   |
| 1017020     | Fat  | 0.05*                |                   |
| 1017030     | Liver  | 0.1                  |                   |
| 1017040     | Kidney   | 0.2                  |                   |
| 1017050     | Edible offal   | 0.05*                |                   |
| 1017990     | Others   | 0.05*                |                   |
| 1020000     | (ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd | 0.05*                |                   |
| 1020010     | Cattle   | 0.05*                | 0.05              |
| 1020020     | Sheep  | 0.05*                | 0.05              |
| 1020030     | Goat   | 0.05*                | 0.05              |
| 1020040     | Horse  | 0.05*                |                   |
| 1020990     | Others   | 0.05*                |                   |
| 1030000     | (iii) Birds' eggs, fresh preserved   | 0.05*                | 0.02              |

| Code number | Groups and examples of individual products to which the MRLs apply   | Acetamiprid MRLs (R) |                   |
|-------------|--|----------------------|-------------------|
|             |  | Reg. 396/2005        | Proposals Art. 12 |
|             | or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter |                      |                   |
| 1030010     | Chicken  | 0.05*                |                   |
| 1030020     | Duck   | 0.05*                |                   |
| 1030030     | Goose  | 0.05*                |                   |
| 1030040     | Quail  | 0.05*                |                   |
| 1030990     | Others   | 0.05*                |                   |
| 1040000     | (iv) Honey (Royal jelly, pollen)   | 0.05*                |                   |
| 1050000     | (v) Amphibians and reptiles (Frog legs, crocodiles)  | 0.05*                |                   |
| 1060000     | (vi) Snails  | 0.05*                |                   |
| 1070000     | (vii) Other terrestrial animal products  | 0.05*                |                   |

(\*) Indicates lower limit of analytical determination

(R) Residue definition for food of animal origin: Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid

#### D. LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

| Common name                                | IUPAC name  | Structure  |
|--|---|--|
| <b>IM-1-5</b><br>(decyano-<br>acetamiprid) | N-(6-chloropyridin-3-ylmethyl)-N-methyl-<br>acetamidine |  |



## ABBREVIATIONS

|                  |   |
|------------------|---|
| ADI              | acceptable daily intake   |
| ARfD             | acute reference dose  |
| a.s.             | active substance  |
| BBCH             | growth stages of mono- and dicotyledonous plants  |
| bw               | body weight   |
| CEN              | European Committee for Standardisation (Comité Européen de Normalisation, <i>French</i> ) |
| cGAP             | critical GAP  |
| CIPAC            | Collaborative International Pesticide Analytical Council                                  |
| CXL              | Codex Maximum Residue Limit (Codex MRL)   |
| d                | day   |
| DAR              | Draft Assessment Report   |
| DT <sub>90</sub> | period required for 90 % dissipation (define method of estimation)                        |
| EC               | European Community  |
| ECD              | electron capture detector   |
| EFSA             | European Food Safety Authority  |
| EMS              | evaluating Member State   |
| eq               | residue expressed as a.s. equivalent  |
| EU               | European Union  |
| FAO              | Food and Agriculture Organisation of the United Nations                                   |
| GAP              | good agricultural practice  |
| GC               | gas chromatography  |
| GCPF             | Global Crop Protection Federation (former GIFAP)  |
| GS               | growth stage  |
| ha               | hectare   |
| hL               | hectolitre  |
| HPLC             | high performance liquid chromatography  |
| HR               | highest residue   |
| i.e.             | that is (id est, <i>Latin</i> )   |
| ILV              | independent laboratory validation   |
| ISO              | International Organisation for Standardisation  |
| IUPAC            | International Union of Pure and Applied Chemistry   |
| JMPR             | Joint FAO/WHO Meeting on Pesticide Residues   |
| kg               | kilogram  |
| L                | litre   |
| LOQ              | limit of quantification   |
| MRL              | maximum residue level   |
| MS               | Member States   |
| MS/MS            | tandem mass spectrometry  |
| NEU              | northern European Union   |
| OECD             | Organisation for Economic Co-operation and Development                                    |

|                  |   |
|------------------|---|
| PHI              | pre-harvest interval  |
| PRIMo            | (EFSA) Pesticide Residues Intake Model                              |
| QuEChERS         | Quick, Easy, Cheap, Effective, Rugged, and Safe (method)            |
| R <sub>ber</sub> | statistical calculation of the MRL by using a non-parametric method |
| R <sub>max</sub> | statistical calculation of the MRL by using a parametric method     |
| RAC              | raw agricultural commodity  |
| RD               | residue definition  |
| RMS              | rapporteur Member State   |
| SCFCAH           | Standing Committee on the Food Chain and Animal Health              |
| SEU              | Southern European Union   |
| SG               | water soluble granule   |
| SP               | water soluble powder  |
| STMR             | supervised trials median residue                                    |
| TMDI             | theoretical maximum daily intake                                    |
| TRR              | total radioactive residue   |
| WHO              | World Health Organisation   |
| yr               | year  |