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Modification of the existing maximum residue levels for acetamiprid in leafy brassicas

European Food Safety Authority (EFSA)

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), Germany, received an application from Nisso Chemical Europe to modify the existing maximum residue levels (MRL) for the active substance acetamiprid in leafy brassica (Chinese cabbages, kales). In order to accommodate for the intended uses of acetamiprid, Germany proposed to raise the existing MRLs from the limit of quantification of 0.01 mg/kg to 1.5 mg/kg. Germany 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. The intended use on leafy brassica is adequately supported by residue data but no MRL is recommended by EFSA since an acute consumer intake concern cannot be excluded when considering the acute reference dose for acetamiprid proposed by the EFSA PPR panel in a previous assessment.

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Keywords: acetamiprid, various crops, MRL application, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS) Germany, received an application from Nisso Chemical Europe to modify the existing maximum residue level (MRL) for the active substance acetamiprid in leafy brassicas. In order to accommodate for the intended use of acetamiprid, Germany proposed to raise the existing MRL from the limit of quantification (LOQ) to 1.5 mg/kg. Germany drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 3 June 2015.

EFSA bases its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) (and its addendum/addenda) prepared under Council Directive 91/414/EEC, the Commission review report on acetamiprid, the JMPR Evaluation report, the Scientific Opinion of the EFSA PPR Panel 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 the data were sufficient to derive an acceptable daily intake (ADI) of 0.07 mg/kg bw per day and an acute reference dose (ARfD) of 0.1 mg/kg bw. However, in 2013, based on additional information on the developmental neurotoxicity potential, the EFSA PPR Panel recommended to lower the ADI and ARfD to a value of 0.025 mg/kg bw per day.

The metabolism of acetamiprid in primary crops was investigated in the fruit, root, leafy and pulses/oilseeds crop groups following foliar applications. From these studies the residue definition for enforcement and for risk assessment was proposed as acetamiprid. These residue definitions were confirmed during the MRL review. EFSA concluded that the metabolism of acetamiprid in primary crops has been sufficiently addressed and that the residue definitions derived are applicable.

The submitted supervised residue trials would be sufficient to derive an MRL proposal of 1.5 mg/kg on leafy brassica, however since an acute risk for the consumers cannot be excluded, EFSA does not recommend changing of the MRL for the crops under consideration.

Studies investigating the nature of acetamiprid residues under standard hydrolysis conditions were assessed during peer review and showed the active substance to be hydrolytically stable. Therefore, the same residue definitions as for raw commodities are applicable to process commodities.

The occurrence of acetamiprid residues in rotational crops was investigated in the framework of the peer review. During Article 12 MRL review and due to insufficient information on the persistent soil metabolite IM-1-5, EFSA recommended for Member States granting an authorisation for acetamiprid, to take the necessary risk mitigation measures in order to avoid residues in rotational crops.

Since EFSA does not recommend the change of the MRL for kales, crop used as feed product, a potential carry-over into food of animal origin was not assessed in the framework of this MRL application.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 a comprehensive dietary exposure assessment was performed, taking into account the existing uses for acetamiprid. EFSA updates the long-term consumer exposure assessment taking into account the median residue level (STMR) derived for leafy brassicas, and including the STMRs calculated for bananas pulp, the median residue values for the commodities assessed in the two previous EFSA reasoned opinions under art 10 of the Regulation (EU) 396/2005 and the STMR values corresponding to the CXLs that have been taken over in the EU legislation in 2012.

The consumer risk assessment calculations were performed considering the current and the new recommended toxicological reference values, respectively. No long term consumer intake concerns were identified, the highest chronic intake accounting for 18 % of the ADI (DE child) while an acute consumer intake concern was identified using the more conservative toxicological reference value of 0.025 mg/kg bw, accounting 197 % of the ARfD for kales and 108 % for Chinese cabbages.

Consequently, EFSA does not recommend changing the MRL for leafy brassicas (Chinese cabbage and kales) since an acute intake concern cannot be excluded for consumers.

EFSA proposes to maintain the existing MRLs at the LOQ value of 0.01 mg/kg, as reported in the summary table below.

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: Acetamiprid				
0243010	Chinese cabbages	0.01*	No proposal	An MRL is not recommended by EFSA as an acute intake concern for consumers cannot be excluded, using the ARfD value proposed by the EFSA PPR Panel in 2013 (108 % and 197 % of the ARfD for kales and Chinese cabbages).
0243020	Kales	0.01*	No proposal	

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

(*): indicates that the MRL is set at the limit of analytical quantification (LOQ)

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Background

Regulation (EC) No 396/2005¹ establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the 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,² repealed by Regulation (EC) No 1107/2009³ shall submit to a Member State, when appropriate, an application to modify an MRL in accordance with the provisions of Article 7 of the Regulation.

Germany, hereafter referred to as the evaluating Member State (EMS), received an application from the company Nisso Chemical Europe⁴ to modify the existing MRLs for the active substance acetamiprid in leafy brassicas. This application was notified to the European Commission and the European Food Safety Authority (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 and to EFSA on 3 June 2015.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2015-00356 and the following subject:

Acetamiprid - Modification of the existing MRLs in various crops

Germany proposed to raise the existing MRLs of acetamiprid in leafy brassicas from the limit of quantification of 0.01 mg/kg to 1.5 mg/kg. EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the EMS, provide a reasoned opinion on the risks to the consumer associated with the application. In accordance with Article 11 of the 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 if more detailed evaluations need to be carried out) from the date of receipt of the application. If EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

The active substance and its use pattern

Acetamiprid is the ISO common name for (*E*)-*N*-(6-chloro-3-pyridyl)methyl]-*N*-cyano-*N*-methylacetamidine (IUPAC). The chemical structures of the active substance and its main metabolites are reported in appendix C. Acetamiprid has been approved for the uses as insecticide only.

Acetamiprid was evaluated in the framework of Directive 91/414/EEC with Greece designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2004/99/EC⁵ which entered into force on 10 January 2005 for use as insecticide only. In accordance with Regulation (EU) No 540/2011⁶ acetamiprid is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

The representative uses evaluated in the peer review were foliar applications on various fruit crops, some fruiting vegetables, cotton and tobacco. The Draft Assessment Report (DAR) of acetamiprid was not peer reviewed by EFSA and therefore, no EFSA conclusion is available at present.

¹ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.

² Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–32.

³ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

⁴ Nisso Chemical Europe, Berliner Allee 42, 40212, Dusseldorf, Germany.

⁵ Commission Directive 2004/99/EC of 1 October 2004 amending Council Directive 91/414/EEC to include acetamiprid and thiacloprid as active substances. OJ L 309, 6.10.2004, p. 6–8.

⁶ Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.06.2011, p. 1–186.

The EU MRLs for acetamiprid are established in Annexes II of Regulation (EC) No 396/2005. Since the entry into force of this regulation, EFSA has issued several reasoned opinions on the modification of MRLs for acetamiprid, whose proposals have been considered in the EU legislation. The MRL changes that were reported in the EU legislation after the Article 12 review of existing MRLs are summarised in Table 1.

Table 1: Overview of the MRL changes after the Article 12 (Regulation (EC) No 396/2005) review of existing MRLs

Procedure ^(a)	Considered by Regulation	Remarks
Art. 12 (EFSA, 2011)	(EC) No 87/2014	Review of existing of MRLs
Implementation of CXL (EFSA, 2012a)	(EC) No 500/2013	CAC 2012
Art.10 (EFSA, 2012b)	(EC) No 500/2013	Purslane, legume vegetables and pulses
Art. 10 (EFSA, 2013)	(EC) No 87/2014	Apricots and tree nuts
Art. 10 (EFSA, 2014)	(EC) No 846/2015	Bananas

(a): Art. 10: Assessment of MRL application according to Article 6 to 10 of Regulation (EC) No 396/2005
 Art. 12: Review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005

Codex Alimentarius has established maximum residue limits (CXL) for a wide range of commodities, but no CXLs have been set for the crops under consideration.

The details of the intended GAPS for acetamiprid are given in Appendix A.

Assessment

EFSA bases its assessment on the evaluation report submitted by the EMS (Germany, 2015), the DAR (and its addendum/addenda) prepared under Directive 91/414/EEC (Greece, 2001, 2003), the Commission review report on acetamiprid (European Commission, 2004), the JMPR Evaluation report (FAO, 2011), the EFSA PPR Panel (2013), as well as the conclusions from previous EFSA opinions on acetamiprid (EFSA, 2011, 2012a,b, 2013, 2014). 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 546/2011⁷ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a, b, 2011; OECD, 2011).

As the peer review on the renewal of the approval of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised, the conclusions reported in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the peer review.

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 during the MRL review under Article 12 of Regulation No 396/2005; there are adequate analytical methods based on GC-ECD and HPLC-MS/MS, to enforce acetamiprid residues in high water, high acid, high oil content commodities and in dry commodities, at a validated LOQ of 0.01 mg/kg (EFSA, 2011).

⁷ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127–175.

The multi-residue QuEChERS method described in the European Standard EN 15662:2008 using HPLC-MS/MS detection is also applicable to analyse acetamiprid residues in high water, high acid, high and dry matrices (CEN, 2008).

As the commodities under consideration belong to high water content commodity group, EFSA concludes that sufficiently validated analytical methods are available for enforcing the proposed MRLs for acetamiprid in leafy crops.

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

Analytical methods for the determination of residues in food of animal origin are not assessed in the current application, since no MRLs are proposed for the crops under evaluation.

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 and toxicological reference values were derived for acetamiprid (EFSA, 2011). In 2013, based on additional information on developmental neurotoxicity potential, the EFSA PPR Panel recommended a more conservative NOAEL of 2.5 mg/kg bw per day as point of departure for the derivation of the ADI and ARfD which both, should be set at 0.025 mg/kg bw (per day), pending the availability of new and more reliable studies (EFSA PPR Panel, 2013). Therefore, EFSA conducted two separate consumer risk assessment calculations, using the current and the new recommended toxicological reference values respectively (see Section 4). The toxicological reference values are compiled in Table 2.

Table 2: Overview of the toxicological reference values

	Source	Year	Value	Study	Safety factor
Acetamiprid					
ADI	EC	2004	0.07 mg/kg bw per day	Rat: 2 year study and 2- generation reproduction study	100
	EFSA PPR	2013	0.025 mg/kg bw per day	developmental neurotoxicity potential	100
ARfD	EC	2004	0.1 mg/kg bw	Rat, acute neurotoxicity study	100
	EFSA PPR	2013	0.025 mg/kg bw	developmental neurotoxicity potential	100

It is noted that JMPR established an ADI of 0.07 mg/kg bw (per day) for the active substance and an ARfD of 0.1 mg/kg bw (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 (DAR, 2001) in the fruit, root and leafy crop groups. In addition a study on pulses/oilseeds was assessed during the Art. 12 MRL review. An overview of the available metabolism studies is presented in Table 3.

Table 3: Summary of available metabolism studies in plants

Crop group	Crops	Application	Sampling (day, DAT)	Comments
Fruit	Eggplant	Foliar & fruit (1 × 9.5 g/100L)	7, 14 DAT	(Greece 2001)
	Apple	Foliar (1 × 208 g/ha)	0, 7, 14, 28, 62, 90 DAT	(Greece 2001)
		Fruit dotting (1 × 104 g/ha)	0, 14, 28, 62 DAT	
Root	Carrot	Foliar (2 × 100g/ha)	14 DAT	(Greece 2001)
Leafy	Cabbage	Foliar (1 × 301.5 g/ha)	0, 7, 14, 21, 28 DAT	(Greece 2001)
		Soil treatment (1 × 5940 g/ha)	7, 14, 28 DAT	
		Foliar (298.5 g/ha)	0, 7, 14, 28, 63 DAT	
Pulses/Oilseeds	Cotton	Foliar (4 × 123 g/ha)	14, 28 DAT	(EFSA, 2011)

Based on these metabolism studies, the residue definition was proposed as acetamiprid for monitoring and for risk assessment. 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 leafy brassicas, EFSA concludes that the metabolism of acetamiprid is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed during the peer review and confirmed under MRL review are applicable.

3.1.1.2. Magnitude of residues

In support of the MRL application, the EMS submitted six residue trials performed on leafy brassicas according with the intended GAP during the growing seasons 2008-2009 in northern Europe (NEU). All samples were analysed for acetamiprid. Residue levels were in the range of 0.01 to 0.73 mg/kg, resulting in an MRL proposal of 1.5 mg/kg.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposal are summarised in Table 4.

The storage stability of acetamiprid in primary crops was investigated in the DAR under Directive 91/414/EEC (Greece, 2003). Residues of acetamiprid were found to be stable at $\leq -18^{\circ}\text{C}$ for up to 13 months in matrices with high water content and for up to 12 months in matrices with high acid and high oil content. As the samples from the residue trials were stored under frozen conditions for up to eight months, the residue data are concluded to be valid with regard to storage stability.

According to the EMS, the analytical method used to analyse the residue trial samples has been sufficiently validated and was proven to be fit for the purpose (Germany, 2015).

Although a sufficient number of residue trials were submitted to derive an MRL value for leafy brassicas, EFSA does not recommend changing of the MRL value, as a possible acute risk for the consumers cannot be excluded (see Section 4):

Table 4: Overview of the available residues trials data

Crop (GAPs)	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments ^(b)	MRL proposal (mg/kg)	HR ^(c) (mg/kg)	STMR ^(d) (mg/kg)
Leafy brassicas (2x 60 g/ha, PHI 7 days)	NEU	Kale: <0.01; 0.11; 0.08 Pak choi: 0.73; 0.14 Chinese cabbage: <0.01	MRLOECD: 1.3/1.5 As an acute risk for the consumers cannot be excluded, (see Section 4) EFSA does not recommend the setting on the derived MRL of 1.5 mg/kg on leafy brassicas	No proposal	0.73	0.08

(a): NEU: Outdoor trials conducted in northern Europe

(b): Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values)

(c): HR: Highest residue level according to the residue definition for risk assessment

(d): STMR: Median residue level according to residue definition for risk assessment

3.1.1.3. Effect of industrial processing and/or household preparation

Standard hydrolysis studies simulating the effect on the nature of acetamiprid residues under processing conditions representative of pasteurisation, boiling and sterilisation were assessed during the peer review (Greece, 2001) and it was concluded that the compound is hydrolytically stable under the representative conditions. Thus, for processed commodities, the same residue definition as for raw agricultural commodities (RAC) is applicable.

During MRL review several processing factors were derived but not for the crops under consideration (EFSA, 2011)

3.1.2. Rotational crops

Leafy brassicas can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. The soil degradation studies demonstrated that the degradation rate of acetamiprid is moderate, with a maximum DT₉₀ of 67 days (EFSA, 2011), below the trigger value of 100 days. Thus, further studies on rotational crops are not required (EC, 1997c).

However, some soil metabolites showed to be more persistent, especially metabolites IM-1-4 and IM-1-5 with DT₉₀ exceeding the trigger value of 100 days (EC, 2004). IM-1-4 was considered as less toxic than acetamiprid and therefore no further data were requested with regard to rotational crops. In contrast, for metabolite IM-1-5, identified as a major metabolite in calcareous soils, no final decision was taken during the peer review and on the need for further investigations. Therefore, EFSA keep the recommendation for 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 decyano-acetamiprid (IM-1-5) in rotational crops (EFSA, 2011).

3.2. Nature and magnitude of residues in livestock

Since EFSA does not recommend the change of the MRL for leafy brassicas, residues in livestock have not been investigated 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 population⁸ (EFSA, 2007).

In the framework of the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses at the EU level and the acceptable CXLs (EFSA, 2011). The food commodities, for which no uses were reported in the framework of the Article 12 review, were excluded from the exposure assessment, assuming that there is no use of acetamiprid on these crops. Now, EFSA updated this risk assessment with the median residue level (STMR) derived from the residue trials conducted on leafy brassicas (Table 4) and the food commodities on which MRLs or CXLs have been adopted after the Article 12 MRL review (EFSA, 2014).

The acute exposure assessment was performed only with regard to the commodities under consideration (leafy brassicas) 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 residue level (HR) as observed in supervised field trials (see Table 4). 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 5.

⁸ 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).

Table 5: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment residue definition: acetaminiprid				
Kale	0.08	STMR	0.73	HR
Chinese cabbage	0.08	STMR	0.73	HR
Other plant or animal commodities	Input values listed in table 4-1 of the reasoned opinion issued under art 10 of Regulation (EC) 396/2005 (EFSA, 2014)			

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

Scenario 1: ADI 0.07 mg/kg bw per day; ARfD: 0.1 mg/kg bw (EC, 2004)

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The highest calculated intake accounted for 6 % of the ADI (DE child). The contribution of the residues in leafy brassicas (Chinese cabbage) to the total consumer exposure accounted for a maximum of 0.02 % of the ADI (SE general population).

No exceedance of ARfD was identified in relation to the MRL proposal for leafy brassicas, since the maximum acute exposure was calculated to be 49 % of the ARfD (NL diet).

Scenario 2: ADI 0.025 mg/kg bw per day; ARfD: 0.025 mg/kg bw (EFSA PPR Panel, 2013)

No chronic risk was identified using this more conservative toxicological reference value of 0.025 mg/kg bw per day recommended by EFSA (EFSA PPR Panel, 2013), as the maximum chronic intake accounted up to 18 % of the ADI (DE child). For the acute intake a possible concern was identified, the ARfD accounted up to **197 %** for kale and **108 %** for Chinese cabbage (NL diet) using the HR observed in the field trials.

Considering the highest residue level of 0.73 mg/kg observed in the submitted residue trials and the ARfD value recommended by EFSA in its 2013 evaluation, acute intake concerns cannot be excluded for the following crops:

- Kale: 197 % of the ARfD (NL, diet)
- Chinese cabbage: 108 % of the ARfD (NL, diet)

Therefore, EFSA would not recommend the setting of MRL of 1.5 mg/kg on kale and Chinese cabbage.

Conclusions and recommendations

The intended use on leafy brassicas is adequately supported by residue data but no MRL proposals can be derived due to a possible acute reference dose exceedance by using the most recent recommended toxicological reference values by EFSA and therefore a consumer health concern cannot be excluded.

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Abbreviations

ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CXL	Codex maximum residue limit (Codex MRL)
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT90	period required for 90 % dissipation (define method of estimation)
EFSA	European Food Safety Authority
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
HPLC	high performance liquid chromatography
HR	highest residue
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
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RMS	rappporteur Member State
SANCO	Directorate-General for Health and Consumers

STMR supervised trials median residue
TMDI theoretical maximum daily intake

Appendix A – Good Agricultural Practice (GAPs)

Crop and/or situation ^(a)	MS or NEU/SEU or Country	F G or I ^(b)	Pest or group of pests controlled ^(c)	Formulation		Application			Application rate per treatment			PHI ^(l) (days)	Remarks ^(m)	
				type ^(d-f)	conc. a.s. ⁽ⁱ⁾	Method kind ^(f-h)	Growth stage & season ^(j)	Number min-max ^(k)	Interval min-max	g/hL min-max	Water L/ha min-max			g/ha min-max
Kale	DE	F	Brevicoryne brassicae, (cabbage aphid) Aleyrodidae (white fly)	spraying			BBCH 12 onwards	2	14 days			60	7	
Chinese cabbage	DE	F	Brevicoryne brassicae, (cabbage aphid) Aleyrodidae (white fly)	spraying			BBCH 12 onwards	2	14 days			65	7	

Remarks:

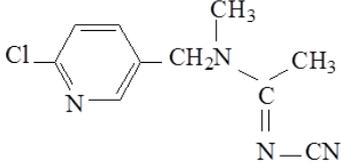
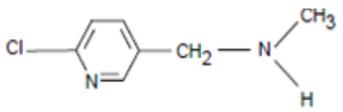
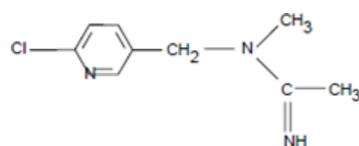
- (a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the usage situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) e.g. biting and sucking insects, soil-born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), water soluble granule (WG)
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f) all abbreviations 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 µg/L
- (j) Growth stage at last treatment (Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., Federal Biological Research Centre of Agriculture and Forestry, Braunschweig, Germany, 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

Appendix B – Pesticide Residue Intake Model (PRIMO) Scenario 1

Acetaminiprid (first scenario)																								
Status of the active substance:			Included			Code no.																		
LOQ (mg/kg bw):						proposed LOQ:																		
Toxicological end points																								
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 minimum - maximum 1 --- 6																								
No of diets exceeding ADI: ---																								
Highest calculated TMDI values in % of ADI		MS Diet		Highest contributor to MS diet (in % of ADI)		Commodity / group of commodities		2nd contributor to MS diet (in % of ADI)		Commodity / group of commodities		3rd contributor to MS diet (in % of ADI)		Commodity / group of commodities		pTMRs at LOQ (in % of ADI)								
6.3	DE child			3.9	Apples			0.4	Milk and milk products: Cattle			0.2	Spinach											
4.9	NL child			2.0	Apples			0.8	Milk and milk products: Cattle			0.4	Spinach											
2.6	WHO Cluster diet B			0.4	Lettuce			0.3	Apples			0.2	Wine grapes											
2.5	FR infant			0.8	Apples			0.7	Milk and milk products: Cattle			0.5	Spinach											
2.4	FR toddler			0.8	Apples			0.8	Spinach			0.1	Strawberries											
2.4	IE adult			0.3	Apples			0.2	Cane fruit			0.2	Pears											
2.2	ES child			0.5	Lettuce			0.4	Apples			0.4	Milk and milk products: Cattle											
1.8	ES adult			0.6	Lettuce			0.2	Apples			0.1	Milk and milk products: Cattle											
1.7	DK child			0.7	Apples			0.2	Pears			0.2	Lettuce											
1.6	WHO regional European diet			0.4	Lettuce			0.2	Apples			0.1	Milk and milk products: Cattle											
1.6	SE general population 90th percentile			0.4	Milk and milk products: Cattle			0.3	Apples			0.1	Bananas											
1.5	NL general			0.4	Apples			0.2	Milk and milk products: Cattle			0.2	Spinach											
1.5	WHO cluster diet E			0.3	Apples			0.2	Wine grapes			0.1	Lettuce											
1.4	UK Toddler			0.5	Apples			0.1	Cane fruit			0.1	Cane fruit											
1.4	IT adult			0.4	Lettuce			0.3	Apples			0.1	Spinach											
1.4	IT kids/toddler			0.3	Lettuce			0.3	Apples			0.1	Pears											
1.3	WHO Cluster diet F			0.4	Lettuce			0.2	Apples			0.1	Milk and milk products: Cattle											
1.3	WHO cluster diet D			0.2	Apples			0.1	Milk and milk products: Cattle			0.1	Wheat											
1.2	FR all population			0.5	Wine grapes			0.2	Apples			0.1	Lettuce											
1.2	PT General population			0.3	Apples			0.3	Wine grapes			0.1	Pears											
1.2	UK Infant			0.5	Apples			0.1	Apples			0.1	Bananas											
1.1	PL general population			0.7	Apples			0.1	Pears			0.1	Cherries											
1.1	LT adult			0.6	Apples			0.1	Milk and milk products: Cattle			0.1	Lettuce											
0.8	UK vegetarian			0.2	Apples			0.2	Lettuce			0.1	Wine grapes											
0.7	DK adult			0.3	Apples			0.2	Wine grapes			0.1	Pears											
0.7	UK Adult			0.1	Lettuce			0.1	Apples			0.1	Wine grapes											
0.5	FI adult			0.1	Apples			0.1	Lettuce			0.1	Currants (red, black and white)											
Conclusion:																								
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI.																								
A long-term intake of residues of Acetaminiprid (first scenario) 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):					
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	IESTI 1		*)		**)		IESTI 2		*)		**)		IESTI 1		*)		**)		IESTI 2		*)		**)	
Highest % of ARfD/ADI		Commodities		pTMR/ threshold MRL (mg/kg)		Highest % of ARfD/ADI		Commodities		pTMR/ threshold MRL (mg/kg)		Highest % of ARfD/ADI		Commodities		pTMR/ threshold MRL (mg/kg)		Highest % of ARfD/ADI		Commodities		pTMR/ threshold MRL (mg/kg)		
49.3		Kale		0.73 / -		35.3		Kale		0.73 / -		26.1		Chinese cabbage		0.73 / -		26.1		Chinese cabbage		0.73 / -		

Appendix C – Used compound codes

Code/Trivial name	Chemical name ^(a)	Structural formula ^(a)
Acetamiprid	(E)-N1-[[6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine	
IM-1-4	N-methyl-(6-chloro-3-pyridyl)-methylamine	
IM-1-5	N-(6-chloropyridin-3-ylmethyl)-N-methyl-acetamidine	

(a): ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).