

## REASONED OPINION

### Modification of the existing MRL for acetamiprid in beet leaves (chard)<sup>1</sup>

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

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#### SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, Belgium compiled an application to modify the existing MRL for the active substance acetamiprid in beet leaves (chard). In order to accommodate for the intended use of acetamiprid, it is proposed to raise the existing MRL in beet leaves from 0.01 (set at the limit of quantification) to 5 mg/kg. Belgium drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 3 September 2009.

EFSA derived the following conclusions based on the submitted evaluation report prepared by Belgium, the Draft Assessment Report (DAR) prepared under the Directive 91/414/EEC by Greece as well as the list of end points included in the Review Report on acetamiprid.

The toxicological profile of acetamiprid was investigated in the peer review and the data were sufficient to conclude on an ADI value of 0.07 mg/kg bw/d and an ARfD value of 0.1 mg/kg bw.

Metabolism of acetamiprid in plants has been investigated in three crop categories (fruit, leafy vegetable and root group) and a general residue definition for risk assessment and monitoring was proposed by the peer review as acetamiprid. Sufficiently validated analytical enforcement methods are available to control the compliance of the proposed MRL for acetamiprid in the crop under consideration.

A sufficient number of supervised residue trials on lettuce has been submitted and, considering the comparability of the GAPs, the results of these trials can be extrapolated to beet leaves. EFSA concludes that a higher EC MRL of 3 mg/kg for beet leaves (chard) would be necessary to accommodate the intended use of acetamiprid.

The occurrence of acetamiprid or its metabolites in rotational crops was also investigated. The occurrence of acetamiprid residues in rotational crops is not expected due to the rapid degradation of the parent compound in soil. However, based on the information currently available, the possibility of the two major soil metabolites (IM-I-4 and IM-I-5) to be present in rotational crops cannot be excluded. Therefore EFSA concluded that Member States granting an authorization for acetamiprid should take the necessary risk mitigation measures (e.g. definition of pre-plant intervals) in order to avoid residues of IM-I-4 and IM-I-5 in rotational crops.

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1 On request from the European Commission, Question No EFSA-Q-2009-00794, issued on 18 December 2009.

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Residues in commodities of animal origin were not assessed in the framework of this application since the crop under consideration is not a livestock feeding item.

Effects of processing on the nature of acetamiprid were assessed in the peer review. Buffer solutions spiked with radio labeled acetamiprid were subjected to conditions simulating sterilization, baking and boiling and pasteurization. In all cases, acetamiprid accounted for the majority of the radioactivity (93-98%). A change in the nature of residues after industrial or household processing is therefore not expected. Thus, for processed commodities the same residue definition as for raw agricultural commodities is applicable.

No studies have been submitted to assess the magnitude of acetamiprid residues during the processing of beet leaves. Such studies however are not necessary considering the low individual contribution of this crop to the total dietary intake.

The consumer risk assessment regarding the parent compound acetamiprid was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model, EFSA, 2007). For the chronic intake assessment, EFSA used the existing MRLs as established in Annex II and in Annex IIIB of the Regulation (EC) 396/2005 as well as the STMR values derived for beet leaves (chard). This STMR value was also applicable for the chronic risk assessment of spinach and herbs.

The acute intake assessment was performed only with regard to the crop under consideration. The relevant HR value for beet leaves as derived for the intended GAPs were used as input values in the acute intake calculation.

No long-term intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated dietary intake ranged from 1.0 to 12.2% of the ADI. The contribution of beet leaves (chard) to the total consumer exposure of acetamiprid accounted for a maximum of 0.09% of the ADI (ES adult and child diets).

No acute intake concerns were identified in relation to the MRL proposal for acetamiprid on beet leaves. The acute intake of acetamiprid residues via beet leaves is calculated to be 33.4% or 14.1% of the ARfD for children and adults, respectively.

Consequently EFSA concludes that the intended use of acetamiprid on beet leaves is acceptable as it will not result in an exceedance of the toxicology reference values. EFSA derived the following recommendations:

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
<b>Enforcement residue definition: acetamiprid</b>			
Beet leaves (chard)	0.01*	3 <sup>(a)</sup>	The proposed MRL is sufficiently supported by the data. No risk for the consumer was identified. Appropriate measures should be taken to ensure that residues of soil metabolites in succeeding or rotational crops do not occur. EMS should confirm that storage stability and analytical methods for supervised field trials were acceptable.

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

(a): Applicant proposed 5 mg/kg; however, according to the MRL calculation, 3 mg/kg would be sufficient.

## KEY WORDS

Acetamiprid, beet leaves, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, neonicotinoid, insecticide

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## **BACKGROUND**

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that where a Member State considers that the modification of an MRL is necessary, that Member State may compile and evaluate an application to modify the MRL in accordance with the provisions of Article 7 of that regulation.

Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRL for the active substance acetamiprid in beet leaves (chard). This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 3 September 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-794 and the following subject:

*Acetamiprid - Application to modify the existing MRL for acetamiprid in beet leaves (chard).*

EFSA then proceeded with the assessment of the application as required by Article 10 of the Regulation.

## **TERMS OF REFERENCE**

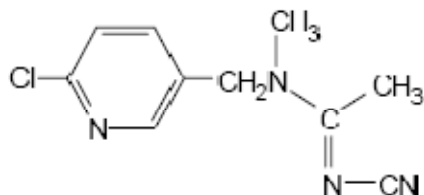
According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months 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 calculated deadline for providing the reasoned opinion is 3 December 2009.

## 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).



Molecular mass: 222.67 g/mol

Acetamiprid is a systemic insecticide with translaminar activity and with contact and stomach action belonging to the group of neonicotinoids. 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 has been evaluated in the framework of Directive 91/414/EEC as a new active substance with Greece being the designated Rapporteur Member State (RMS) and France the Co-Rapporteur Member State (Co-RMS). Acetamiprid has been included in Annex I to this Directive by the Commission Directive 2004/99/EC of 1 October 2004 for use as an insecticide only. The representative uses assessed under the peer review of the Directive 91/414/EEC included outdoor and indoor applications (only for fruiting vegetables) on oranges, mandarins, lemons, apples, pears, peaches, nectarines, cherries plums, tomatoes, peppers, aubergines, cotton and tobacco. Acetamiprid was not peer review by EFSA and therefore no EFSA conclusion is available for this compound.

MRLs for acetamiprid were set at EC level for the first time by Directive 2007/11/EC. They were amended by Directives 2007/73/EC and 2008/17/EC. MRLs have been transferred to Annex II of Regulation (EC) No 396/2005 by Regulation (EC) No 149/2008 and amended by Regulation (EC) No 839/2008. MRL proposals for cress, spinach and herbs were recently evaluated by EFSA (EFSA, 2009) and new MRLs were set on 28 October 2009 through the Regulation (EC) 1050/2009. The existing MRLs for acetamiprid are summarized in Appendix C to this reasoned opinion. The existing EC MRL for beet leaves is set at the LOQ of 0.01 mg/kg. No CXLs for acetamiprid have been set by the Codex Alimentarius Commission.

The submitted GAPs according to which the modification of the existing MRL is requested are summarized in Appendix A. It concerns a maximum of two spray applications, both indoor and outdoor, at an application rate of 50 g a.s./ha. The treatments are performed close to the harvest with a PHI of 7 days.

EFSA bases its assessment on the evaluation report submitted by Belgium (Belgium, 2009), the Draft Assessment Report prepared under the Directive 91/414/EEC (Greece, 2001) and the list of end points included in the Review Report on acetamiprid (European Commission, 2004). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products set out in Annex VI to Directive 91/414/EEC and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2008).

## ASSESSMENT

### 1. Methods of analysis

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

According to the DAR prepared by Greece (2001) several analytical methods for enforcement of acetamiprid are available, two of which have been sufficiently validated. The first method using florisil and silica gel for clean up and GC-ECD or HPLC-UV for the determination of acetamiprid was validated at an LOQ of 0.01 mg/kg for diverse commodities with high water or oil content and at an LOQ of 0.05 mg/kg in citrus. HPLC/MS or HPLC/MS/MS were used for confirmation. An independent laboratory validation for this method was submitted for cotton seeds (commodity with high oil content) and evaluated in addendum 1 to the DAR (Greece, 2001). Ideally, the independent validation study should also cover a commodity with high water content as this is relevant for the crop under evaluation.

The second method (DFG S19 modified) also uses GC-ECD for the determination of acetamiprid and was validated at an LOQ of 0.01 mg/kg and 0.05 mg/kg for apples and tomatoes respectively. GC-MS was used for the confirmation of the results. An independent laboratory validation study for this method was submitted for apples and tomatoes and evaluated in addendum 1 to the DAR (Greece, 2001).

Aside from the methods provided by the applicant in the framework of the peer review, laboratories responsible for the official control of MRLs have developed their own methods or have included the active substance in the established multi-methods. In the database developed by the Community Reference Laboratories (CRL) for Residue of Pesticides ([www.crl-pesticides.eu](http://www.crl-pesticides.eu)) in total 917 validation data sets have been submitted regarding methods routinely used to determine acetamiprid in different matrices (EFSA, 2009).

Considering, that the crop supported in the framework of this application belongs to the group of commodities with high water content, it is possible to monitor residues in this crop with a LOQ of 0.01 mg/kg by the single residue method and with a LOQ of 0.01-0.05 mg/kg with the multi residue method.

EFSA concluded that sufficiently validated methods are available to control the compliance of the proposed MRL for acetamiprid in the crop under consideration.

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

An analytical method for the enforcement of acetamiprid residues in food of animal origin is not relevant for the current application as beet leaves (chard) are usually not fed to animals and residues in animal commodities resulting from the proposed GAPs are therefore not expected.

## 2. Mammalian toxicology

The toxicological properties of acetamiprid have been evaluated in the DAR prepared under Directive 91/414/EEC (Greece, 2001) and reference values have been derived. The proposal of the RMS was confirmed in the peer review (European Commission, 2004). The reference values derived are summarised in the table below.

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

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
<b>Acetamiprid</b>					
ADI	COM	2004	0.07	2 year rat and 2- generation rat reproductive	100
ARfD	COM	2004	0.1	Acute neurotoxicity in rats	100

## 3. Residues

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

#### 3.1.1. Primary crops

##### 3.1.1.1. Nature of residues

Under the peer review of Directive 91/414/EEC, metabolism studies were submitted for three crop categories:

- Fruits and fruiting vegetables (dotting application on aubergine - 9.5 g a.s./100L and dotting application on apples – 104 g a.s./1000L/ha)
- Root vegetables (spray application on carrot - 2 x 100 g a.s./ha)
- Leafy crops (spray foliar application on cabbage - 301 g a.s./1500L/ha and soil application – 5.94 kg a.s. /ha)

Aubergine, apples, cabbage and carrots have been treated with foliar applications, cabbage also with soil applications of radio labelled acetamiprid in the pyridine ring. For cabbage an additional study was carried out with acetamiprid labelled in the cyano-group.

Metabolism was shown to be moderate. Acetamiprid was the main component of the radioactive residues in directly treated crop parts (up to almost 100% of TRR), but also in cabbage after soil treatment and in carrot roots (min. 33% of TRR). The metabolism studies show a gradual break down of the side chain to 6-chloro-3-pyridylmethanol (which is conjugated to glucose) and to 6-chloronicotinic acid. Concentrations of metabolites were generally low in edible parts of crops with maximum levels of 7% of the TRR found for the demethylated acetamiprid (metabolite IM-2-1<sup>3</sup>) in cabbage and 26% TRR for 6-chloronicotinic acid in carrots. The metabolism studies on cabbage (leafy vegetables, relevant for the evaluated crop) were carried out with three times the notified seasonal application rate. Metabolism was shown to be similar in all metabolism studies.

As acetamiprid was the main component of the radioactive residues in all crops, the following residue definitions for enforcement and risk assessment were proposed for all crop groups: acetamiprid only. EFSA is of the opinion that the same residue definition can be applied also on the intended use on beet leaves. An analytical method is available for enforcement of acetamiprid in the crop under consideration for this application (see also section 1.1).

<sup>3</sup> N1-[(6-chloro-3-pyridyl)methyl]-N2-cyanoacetamide)



### 3.1.1.2. Magnitude of residues

The applicant submitted eleven indoor and eight outdoor supervised residue trials on different lettuce varieties (including open leaf varieties) carried out in different locations in Northern and Southern Europe in the years between 1998 and 2001 and in Northern Europe in the years between 1998 and 2002, respectively. Eight of the indoor trials were recently evaluated by EFSA to set a new MRL on spinach (EFSA, 2009).

The proposed indoor and outdoor GAPs on beet leaves (chard) refer to the application rate of 2 x 0.05 kg a.s./ha and a PHI of 7 days. According to the Guidance document SANCO 7525/VI/95 – rev.8 (European Commission, 2008) and considering the comparability of the GAPs, for the proposed use on beet leaves (chard), extrapolation from residues trials on lettuce is possible for late applications of plant protection products, with half of the trials carried out on open leaves varieties. Five indoor residues trials were carried out on head forming varieties and four on open leaf varieties. For two trials no detailed information regarding varieties could be retrieved.

The number of submitted trials is sufficient to support the proposed MRL modification (European Commission, 2008). Trial designs are representative of the intended GAP with regard to application rate and PHI. Application method is not reported in residue trials data but EFSA supposes that acetamiprid was applied by spraying. Despite in the submitted GAPs growth stage at application is not reported, for all trials the PHI has been respected and residues data correctly reported. The residue levels measured in the indoor trials were generally higher than the levels derived from the outdoor trials. Consequently, MRL proposals and risk assessment values are derived from the indoor trials.

The results of the residue trials, as well as the derived MRL proposals and values used in the risk assessment, are summarized in Table 3-1. The MRL proposals were derived using the statistical methodologies agreed at European level. EFSA is of the opinion that an MRL of 3 mg/kg would be sufficient to cover the intended use.

According to the DAR (Greece, 2001) storage stability has been demonstrated for a period of one year at -18 °C in commodities with high content of water (apples and tomatoes). Information concerning the duration of storage of samples before analysis is not available. The evaluation report of the EMS (Belgium, 2009) does not include an evaluation if these storage stability studies are sufficient to support the residue trials on lettuce. Despite these data gaps, EFSA assumes that, since the studies were accepted for the setting of MRLs in lettuce in 2005, the RMS has checked the validity of the supervised trials at that time.

Information whether the analytical methods used in the residue trials were sufficiently validated is not available.



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

Commodity	Region <sup>(a)</sup>	Outdoor/Indoor	Individual trial results (mg/kg)		STMR <sup>(b)</sup> (mg/kg)	HR <sup>(c)</sup> (mg/kg)	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement (acetamiprid)	Risk assessment (acetamiprid)					
<b>Enforcement residue definition : acetamiprid</b>									
Lettuce → Beet leaves (chard)	NEU	Outdoor	0.08; 0.14; 0.15; 0.16 <sup>(e)</sup> ; 0.24; 0.25 <sup>(e)</sup> ; 0.28; 0.31 <sup>(e)</sup>	0.08; 0.14; 0.15; 0.16; 0.24; 0.25; 0.28; 0.31	0.2	0.31	0.5	1.0	R <sub>max</sub> = 0.46 R <sub>ber</sub> = 0.55
	NEU and SEU	Indoor	0.25, 0.32, 0.41, 0.78, 0.8, 0.81, 1.0 <sup>(e)</sup> , 1.1, 1.5 <sup>(e)</sup> , 1.6 <sup>(e)</sup> , 1.91 <sup>(e)</sup>	0.25, 0.32, 0.41, 0.78, 0.8, 0.81, 1.0 <sup>(e)</sup> , 1.1, 1.5 <sup>(e)</sup> , 1.6 <sup>(e)</sup> , 1.91 <sup>(e)</sup>	<b>0.81</b>	<b>1.9</b>	<b>3</b>	1.0	R <sub>max</sub> = 2.47 R <sub>ber</sub> = 3.0

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.

(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 residues trial.

(e): Open leaf varieties

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

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

In the peer review the effect of processing on the nature of acetamiprid was studied (Greece, 2001). Buffer solutions spiked with radio labeled acetamiprid were subjected to conditions simulating sterilization (20 min at 120 °C, pH 6), baking and boiling (60 min at 100 °C, pH 5) and pasteurization (20 min at 90 °C, pH 4). In all cases, acetamiprid accounted for the majority of the radioactivity (93-98%). All metabolites were at concentrations lower than 0.05 mg/kg, the trigger value for identification set by the Guidance document 7035/VI/95 rev. 5 (European Commission, 1997d). A change in the nature of residues after industrial or household processing is therefore not expected. Thus, for processed commodities the same residue definition as for raw agricultural commodities is applicable.

No studies have been submitted to assess the magnitude of acetamiprid residues during the processing of beet leaves. Such studies however are not necessary considering the low individual contribution of this crop to the total dietary intake (European Commission, 1997d).

## 3.1.2. Rotational crops

### 3.1.2.1. Preliminary considerations

The crop under consideration can be grown in crop rotation. Therefore the possible occurrence of acetamiprid residues in rotational crops or succeeding crops has to be considered.

According to the soil degradation studies performed in the framework of the peer review, the highest DT<sub>90</sub> value of acetamiprid was 67.3 days based on laboratory studies (European Commission, 2004). However it is noted that acetamiprid metabolites are more persistent in the soil. In particular the DT<sub>90f</sub> values of metabolite IM-I-4<sup>4</sup> were 166.5 (United Kingdom) and 142.7 (France), meaning that rotational crop studies are required. Moreover, it is noted that the relevance of the major metabolites IM-I-4 and IM-I-5<sup>5</sup> in soil for rotational crops was discussed in the peer review but no final decision was taken.

### 3.1.2.2. Nature of residues

No studies have been submitted to assess the nature of acetamiprid residues in rotational or succeeding crops.

### 3.1.2.3. Magnitude of residues

No studies have been submitted to assess the magnitude of acetamiprid residues in rotational or succeeding crops.

EFSA concluded that, based on the information currently available, the possibility of residues of these soil metabolites to be present in rotational crops cannot be excluded. Member States granting an authorization for acetamiprid should take the necessary risk mitigation measures (e.g. definition of pre-plant intervals) in order to avoid residues of IM-I-4 and IM-I-5 in rotational crops.

## 3.2. Nature and magnitude of residues in livestock

Applicant submitted several residue studies carried out on commodities of animal origin. However, according to the EU Guidance document on livestock feeding studies (European Commission, 1996),

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<sup>4</sup> IM-I-4: N-methyl-(6-chloro-3-pyridyl)-methylamine

<sup>5</sup> IM-I-5: N-(6-chloropyridin-3-methyl)-N-methyl-acetamidine

the crop under consideration is not used as feed; therefore the nature and magnitude of acetamiprid residues in livestock was not evaluated for the current application.

#### 4. Consumer risk assessment

The consumer risk assessment regarding the parent compound acetamiprid was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model, EFSA, 2007). For the chronic intake assessment, EFSA used the existing MRLs as established in Annex II and in Annex IIIB of the Regulation (EC) 396/2005 as well as the STMR values derived for beet leaves (chard). This STMR value was also applicable for the chronic risk assessment of spinach and herbs.

The acute intake assessment was performed only with regard to the crop under consideration. The relevant HR value for beet leaves (see Table 3-1) as derived from the intended GAPs were used as input values in the acute intake calculation.

Input values are summarized in Table 4-1.

**Table 4-1.** Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definition: acetamiprid</b>				
Beet leaves (chard)	0.81	STMR	1.9	HR
Spinach	0.81	STMR	Not relevant	
Herbs	0.81	STMR	Not relevant	
Other commodities of plant and animal origin	MRL	See Appendix C	Not relevant	

The results of the intake calculations are reported in Appendix B to this reasoned opinion.

No long-term intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated dietary intake ranged from 1.0 to 12.2% of the ADI. The contribution of beet leaves (chard) to the total consumer exposure to acetamiprid accounted for a maximum of 0.09% of the ADI (ES adult and child diets).

No acute intake concerns were identified in relation to the MRL proposal for acetamiprid on beet leaves (chard). The acute intake of acetamiprid residues via beet leaves is calculated to be 33.4% or 14.1% of the ARfD for children and adults, respectively.

Consequently EFSA concludes that the intended use of acetamiprid on beet leaves (chard) is acceptable as they will not result in an exceedance of the toxicology reference values.

The EMS highlighted an acute intake concern for scarole. The scarole MRL is not subject of this assessment and will be therefore assessed in detail under the art. 12 of Regulation 396/2005 (MRL review).

## CONCLUSIONS AND RECOMMENDATIONS

### CONCLUSIONS

The toxicological profile of acetamiprid was investigated in the peer review and the data were sufficient to conclude on an ADI value of 0.07 mg/kg bw/d and an ARfD value of 0.1 mg/kg bw.

Metabolism of acetamiprid in plants has been investigated in three crop categories (fruit, leafy vegetable and root group) and a general residue definition for risk assessment and monitoring was proposed by the peer review as acetamiprid. Sufficiently validated analytical enforcement methods are available to control the compliance of the proposed MRL for acetamiprid in the crop under consideration.

A sufficient number of supervised residue trials on lettuce have been submitted and, considering the comparability of the GAPs, the results of these trials can be extrapolated to beet leaves. EFSA concludes that a higher EC MRL of 3 mg/kg for beet leaves (chard) would be necessary to accommodate the intended use of acetamiprid.

The occurrence of acetamiprid or its metabolites in rotational crops was also investigated. The occurrence of acetamiprid residues in rotational crops is not expected due to the rapid degradation of the parent compound in soil. However, based on the information currently available, the possibility of the two major soil metabolites (IM-I-4 and IM-I-5) to be present in rotational crops cannot be excluded. Therefore EFSA concluded that Member States granting an authorization for acetamiprid should take the necessary risk mitigation measures (e.g. definition of pre-plant intervals) in order to avoid residues of IM-I-4 and IM-I-5 in rotational crops.

Residues in commodities of animal origin were not assessed in the framework of this application since the crop under consideration is not a livestock feeding item.

Effects of processing on the nature of acetamiprid were assessed in the peer review. Buffer solutions spiked with radio labeled acetamiprid were subjected to conditions simulating sterilization, baking and boiling and pasteurization. In all cases, acetamiprid accounted for the majority of the radioactivity (93-98%). A change in the nature of residues after industrial or household processing is therefore not expected. Thus, for processed commodities the same residue definition as for raw agricultural commodities is applicable.

No studies have been submitted to assess the magnitude of acetamiprid residues during the processing of beet leaves. Such studies however are not necessary considering the low individual contribution of this crop to the total dietary intake.

The consumer risk assessment regarding the parent compound acetamiprid was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model, EFSA, 2007). For the chronic intake assessment, EFSA used the existing MRLs as established in Annex II and in Annex IIIB of the Regulation (EC) 396/2005 as well as the STMR values derived for beet leaves (chard). This STMR value was also applicable for the chronic risk assessment of spinach and herbs.

The acute intake assessment was performed only with regard to the crop under consideration. The relevant HR value for beet leaves as derived for the intended GAPs were used as input values in the acute intake calculation.

No long-term intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated dietary intake ranged from 1.0 to 12.2% of the ADI. The contribution of beet leaves (chard) to the total consumer exposure of acetamiprid accounted for a maximum of 0.09% of the ADI (ES adult and child diets).

No acute intake concerns were identified in relation to the MRL proposal for acetamiprid on beet leaves. The acute intake of acetamiprid residues via beet leaves is calculated to be 33.4% or 14.1% of the ARfD for children and adults, respectively.

Consequently EFSA concludes that the intended use of acetamiprid on beet leaves is acceptable as it will not result in an exceedance of the toxicology reference values.

## RECOMMENDATIONS

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
<b>Enforcement residue definition: acetamiprid</b>			
Beet leaves (chard)	0.01*	3 <sup>(a)</sup>	The proposed MRL is sufficiently supported by the data. No risk for the consumer was identified. Appropriate measures should be taken to ensure that residues of soil metabolites in succeeding or rotational crops do not occur. EMS should confirm that storage stability and analytical methods for supervised field trials were acceptable.

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

(a): Applicant proposed 5 mg/kg; however, according to the MRL calculation, 3 mg/kg would be sufficient.

## REFERENCES

- Belgium, 2009. Evaluation report on the modification of MRLs for acetamiprid in beet leaves (chard) prepared by the evaluating Member State Belgium under Article 8 of Regulation (EC) No 396/2005, 18 August 2009.
- Greece, 2001. Draft Assessment Report (DAR) on the active substance acetamiprid prepared by the rapporteur Member State Greece in the framework of Directive 91/414/EEC, March 2001.
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**APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)**

Crop and/or situation	Member State or Country	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)
				Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	
Swiss chard	Belgium (NEU)	F & G	aphids	SP	20%	Spraying		1-2				0.05	7



**APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)**

Acetaminiprid									
Status of the active substance:		Annex I		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:		COM		Source of ARfD:		COM			
Year of evaluation:		2004		Year of evaluation:		2004			
Chronic risk assessment - refined calculations									
				TMDI (range) in % of ADI minimum - maximum					
				1      12					
				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)	
12.2	NL child	4.5	Oranges	2.1	Milk and cream,	1.5	Scarole (broad-leaf endive)		
11.4	DE child	5.4	Oranges	1.7	Apples	1.0	Milk and cream,		
8.5	FR toddler	2.9	Oranges	2.8	Milk and cream,	0.8	Spinach		
8.2	ES child	3.1	Oranges	3.0	Lettuce	0.9	Milk and cream,		
7.2	WHO Cluster diet B	2.6	Lettuce	1.2	Oranges	0.5	Mandarins		
7.0	ES adult	3.8	Lettuce	1.8	Oranges	0.4	Milk and cream,		
6.0	UK Toddler	2.8	Oranges	1.5	Milk and cream,	0.4	Mandarins		
5.9	IE adult	1.5	Oranges	1.0	Grapefruit	0.8	Mandarins		
5.6	NL general	2.1	Oranges	0.9	Lettuce	0.8	Scarole (broad-leaf endive)		
5.5	UK Infant	2.8	Milk and cream,	1.9	Oranges	0.2	Apples		
5.2	WHO regional European diet	2.7	Lettuce	0.7	Oranges	0.3	Milk and cream,		
4.8	FR infant	1.8	Milk and cream,	1.3	Oranges	0.5	Spinach		
4.7	WHO Cluster diet F	2.1	Lettuce	1.2	Oranges	0.3	Milk and cream,		
4.5	IT adult	2.7	Lettuce	0.5	Oranges	0.2	Mandarins		
4.1	IT kids/toddler	2.1	Lettuce	0.7	Oranges	0.3	Mandarins		
4.0	DK child	1.0	Lettuce	0.9	Milk and cream,	0.7	Cucumbers		
4.0	SE general population 90th percentile	1.1	Oranges	0.9	Milk and cream,	0.6	Mandarins		
3.3	WHO cluster diet E	0.7	Lettuce	0.6	Oranges	0.4	Scarole (broad-leaf endive)		
3.3	UK vegetarian	1.2	Oranges	1.0	Lettuce	0.2	Milk and cream,		
3.0	FI adult	1.4	Oranges	0.6	Lettuce	0.4	Milk and cream,		
2.6	FR all population	0.7	Lettuce	0.4	Oranges	0.3	Mandarins		
2.4	UK Adult	0.8	Lettuce	0.8	Oranges	0.2	Milk and cream,		
2.1	WHO cluster diet D	0.4	Milk and cream,	0.3	Oranges	0.2	Limes		
1.8	PT General population	0.9	Oranges	0.2	Apples	0.1	Tomatoes		
1.6	LT adult	0.5	Lettuce	0.3	Milk and cream,	0.3	Apples		
1.3	DK adult	0.4	Milk and cream,	0.2	Oranges	0.1	Cucumbers		
1.0	PL general population	0.3	Apples	0.1	Tomatoes	0.1	Lettuce		
<p><b>Conclusion:</b>            The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI.            A long-term intake of residues of Acetaminiprid is unlikely to present a public health concern.</p>									

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	*)	**)	IESTI 2	*)	**)	IESTI 1	*)	**)	IESTI 2	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
33.4	Beet leaves (chard)	1.9 / -	25.3	Beet leaves	1.9 / -	14.1	Beet leaves (chard)	1.9 / -	11.9	Beet leaves (chard)	1.9 / -	
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)	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												
<b>Conclusion:</b>												
For Acetamiprid IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.												
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.												
For processed commodities, no exceedance of the ARfD/ADI was identified.												

APPENDIX C – EXISTING EC MRLs

Code number	Groups and examples of individual products to which the MRLs apply (a)	
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	1
110010	Grapefruit (Shaddock, pomelos, sweeties, tangelo, ugli and other hybrids)	1
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	1
110030	Lemons (Citron, lemon)	1
110040	Limes	1
110050	Mandarins (Clementine, tangerine and other hybrids)	1
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	0,1
130010	Apples (Crab apple)	0,1
130020	Pears (Oriental pear)	0,1
130030	Quinces	0,1
130040	Medlar	0,1
130050	Loquat	0,1
130990	Others	0,1
140000	(iv) Stone fruit	
140010	Apricots	0,1
140020	Cherries (sweet cherries, sour cherries)	0,2
140030	Peaches (Nectarines and similar hybrids)	0,1
140040	Plums (Damson, greengage, mirabelle)	0,02
140990	Others	0,01*
150000	(v) Berries & small fruit	0,01*
151000	(a) Table and wine grapes	0,01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	
151010	Table grapes	0,01*
151020	Wine grapes	0,01*
152000	(b) Strawberries	0,01*
153000	(c) Cane fruit	0,01*
153010	Blackberries	0,01*
153020	Dewberries (Loganberries, Boysenberries, and cloudberry)	0,01*
153030	Raspberries (Wineberries)	0,01*
153990	Others	0,01*
154000	(d) Other small fruit & berries	0,01*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,01*
154020	Cranberries	0,01*
154030	Currants (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	Azrole (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	0,01*
161000	(a) Edible peel	0,01*
161010	Dates	0,01*
161020	Figs	0,01*
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), pomeraç, 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*
162040	Prickly pear (cactus fruit)	0,01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	
162050	Star apple	0,01*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammy 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*
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*
213080	Radishes (Black radish, Japanese)	0,01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	
	radish, small radish and similar varieties)	
213090	Salsify (Scorzoner, Spanish salsify (Spanish oysterplant))	0,01*
213100	Swedes	0,01*
213110	Turnips	0,01*
213990	Others	0,01*
220000	(ii) Bulb vegetables	0,01*
220010	Garlic	0,01*
220020	Onions (Silverskin onions)	0,01*
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	0,1
231010	Tomatoes (Cherry tomatoes, )	0,3
231020	Peppers (Chilli peppers)	0,1
231030	Aubergines (egg plants) (Pepino)	0,01*
231040	Okra, lady's fingers	0,01*
231990	Others	0,3
232000	(b) Cucurbits - edible peel	0,3
232010	Cucumbers	0,3
232020	Gherkins	0,3
232030	Courgettes (Summer squash, marrow (patisson))	0,3
232990	Others	0,3
233000	(c) Cucurbits-inedible peel	0,01*
233010	Melons (Kiwano)	0,01*
233020	Pumpkins (Winter squash)	0,01*
233030	Watermelons	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	0,01*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,01*
241020	Cauliflower	0,01*
241990	Others	0,01*
242000	(b) Head brassica	
242010	Brussels sprouts	0,05
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	
242990	Others	0,01*
243000	(c) Leafy brassica	0,01*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,01*
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 Brassicaceae	
251010	Lamb's lettuce (Italian comsalad)	5
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	5
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)	5
251040	Cress	3
251050	Land cress	0,01*
251060	Rocket, Rucola (Wild rocket)	5
251070	Red mustard	0,01*
251080	Leaves and sprouts of Brassica spp (Mizuna)	5
251990	Others	0,01*
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, tumip greens (tumip tops))	3
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,01*
252030	Beet leaves (chard) (Leaves of beetroot)	0,01*
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
256020	Chives	3
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	3
256040	Parsley	5
256050	Sage (Winter savory, summer	3

Code number	Groups and examples of individual products to which the MRLs apply (a)	
	savory,)	
256060	Rosemary	3
256070	Thyme ( marjoram, oregano)	3
256080	Basil (Balm leaves, mint, peppermint)	3
256090	Bay leaves (laurel)	3
256100	Taragon (Hyssop)	3
256990	Others	3
260000	(vi) Legume vegetables (fresh)	0,01*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,01*
260020	Beans (without pods) (Broad beans, Flageolet, 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)	0,01*
270010	Asparagus	0,01*
270020	Cardoons	0,01*
270030	Celery	0,01*
270040	Fennel	0,01*
270050	Globe artichokes	0,01*
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	0,01*
300010	Beans (Broad beans, navy beans, flageolet, jack beans, lima beans, field beans, cowpeas)	0,01*
300020	Lentils	0,01*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,01*
300040	Lupins	0,01*
300990	Others	0,01*
400000	4. OILSEEDS AND	

Code number	Groups and examples of individual products to which the MRLs apply (a)	
	OILFRUITS	
401000	(i) Oilseeds	0,01*
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, tumip rape)	0,01*
401070	Soya bean	0,01*
401080	Mustard seed	0,01*
401090	Cotton seed	0,02
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	0,01*
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)	0,01*
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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	
632000	(b) Leaves	0,1*
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	Curmin 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*

## Modification of the existing MRL for acetamiprid in beet leaves (chard)

Code number	Groups and examples of individual products to which the MRLs apply (a)	
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*
1011020	Fat free of lean meat	0,05*
1011030	Liver	01

Code number	Groups and examples of individual products to which the MRLs apply (a)	
1011040	Kidney	0,2
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,1
1012040	Kidney	0,2
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,1
1013040	Kidney	0,2
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,1
1014040	Kidney	0,2
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	
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*
1016020	Fat	0,05*
1016030	Liver	0,1
1016040	Kidney	0,2
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, 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	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	
	milk, cheese and curd	
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
1030000	(iii) Birds' eggs, fresh preserved 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	0,05*
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)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

(\* ) Indicates lower limit of analytical determination

## ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
bw	body weight
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
DAR	Draft Assessment Report (prepared under Directive 91/414/EEC)
DT <sub>90</sub>	period required for 90 percent dissipation (define method of estimation)
EC	European Community
EDI	estimated daily intake
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
GAP	good agricultural practice
GC-ECD	gas chromatography with electron capture detector
GC-MS	gas chromatography with mass spectrometry
GS	growth stage
ha	hectare
hL	hectolitre
HPLC-MS	high performance liquid chromatography with mass spectrometry
HPLC-MS-MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UV	high performance liquid chromatography with ultra-violet detector
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
L	litre
LOQ	limit of quantification
LC-MS-MS	liquid chromatography with tandem mass spectrometry
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
PF	processing factor

PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
RA	Risk assessment
$R_{ber}$	statistical calculation of the MRL by using a no parametric method
$R_{max}$	statistical calculation of the MRL by using a parametric method
RMS	rapporteur Member State
SEU	Southern European Union
SP	soluble powder
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue