

REASONED OPINION OF EFSA

Modification of the existing MRLs for acetamiprid in cress, spinach and herbs¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00204)

Issued on 12 March 2009

SUMMARY

According to Article 6(2) of Regulation (EC) No 396/2005, The United Kingdom received an application from the Horticultural Development Council to modify the existing MRLs for acetamiprid in cress, spinach and herbs. The applicant proposes to raise the existing MRLs, which are currently set at the analytical limit of quantification of 0.01 mg/kg, to 5 mg/kg. The subsequent evaluation report drafted by The United Kingdom was forwarded to EFSA on 14/01/2009 according to Article 9 of the Regulation.

Based on the evaluation report of The United Kingdom, the Draft Assessment Report (DAR) prepared by the Rapporteur Member State (RMS) Greece under Directive 91/414/EEC and evaluation reports prepared by Greece and France in 2005 in support of MRL proposals for lettuce, EFSA derives the following conclusion regarding the application.

The metabolism of acetamiprid was investigated for foliar applications close to harvest in eggplants, apples, cabbage and carrots. Three crop groups (fruit, leafy vegetable and root group) are covered by the available study. Metabolism was shown to be similar and acetamiprid was the main component in all investigated crops. Therefore, the parent compound acetamiprid was proposed as a general residue definition for all crop groups for enforcement and risk assessment. An analytical method is available for enforcement of MRLs for acetamiprid in leafy crops.

A sufficient amount of supervised residue trials on lettuce is available and considering the comparability of the GAPs, the results of these trials can be extrapolated to cress, spinach and herbs. EFSA concludes that a MRL of 3 or 5 mg/kg would be required to accommodate for the intended uses of acetamiprid in cress, spinach and herbs.

The possible occurrence of acetamiprid residues in rotational crops is not expected due to the rapid degradation of the parent compound in soil. However, the relevance of the major metabolites in soil IM-1-4 (N-methyl-(6-chloro-3-pyridyl)-methylamine) and IM-1-5 (N-(6-chloropyridin-3-ylmethyl)-N-methyl-acetamide) for rotational crops was discussed in the

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peer review, but a final conclusion could not be derived. Therefore EFSA recommends that the United Kingdom should consider appropriate risk mitigation measures (e.g. by defining pre-planting 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 considering that the crops under evaluation are usually not fed to livestock.

Chronic and acute intake calculations were performed using revision 2 of the EFSA PRIMo. The chronic intake calculations considered the newly proposed MRLs as well as all existing MRLs for the active substance. No chronic intake concerns were identified for all available European diets. The potential chronic exposure was not higher than 11% of the ADI. The contribution of spinach and the other crops concerned was less than 1%. Also the acute intake calculations for the crops under assessment on the basis of the HR values did not reveal potential consumer health risks.

EFSA recommendations resulting from the assessment are summarized in the table below.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: acetamiprid			
Cress	0.01*	3 or 5^a	The proposed MRLs are supported by the data provided. No risk for consumers was identified. Appropriate measures should be taken to ensure that residues of soil metabolites in succeeding or rotational crops do not occur.
Spinach	0.01*	3 or 5^a	
Herbs	0.01*	3 or 5^a	

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

(F): MRL is expressed as mg/kg of fat contained in the whole product.

^a – the applicant proposed 5 mg/kg, however, according to the MRL calculation, 3 mg/kg would be sufficient.

Key words: Acetamiprid, spinach, cress, herbs, 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 a party requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

The United Kingdom, hereafter referred to as the Evaluating Member State (EMS), received an application from the Horticultural Development Council² to modify the existing MRLs for the active substance acetamiprid in cress, spinach and herbs. 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 14 January 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-204 and the following subject:

- *Acetamiprid - Application to modify the existing MRLs for acetamiprid in cress from 0.01* mg/kg to 5 mg/kg, in spinach from 0.01* mg/kg to 5 mg/kg, in chervil from 0.01* mg/kg to 5 mg/kg, in chives from 0.01* mg/kg to 5 mg/kg, in celery leaves from 0.01* mg/kg to 5 mg/kg, in sage from 0.01* mg/kg to 5 mg/kg, in rosemary from 0.01* mg/kg to 5 mg/kg, in thyme from 0.01* mg/kg to 5 mg/kg, in basil from 0.01* mg/kg to 5 mg/kg, in bay leaves (laurel) from 0.01* mg/kg to 5 mg/kg and in tarragon from 0.01* mg/kg to 5 mg/kg.*

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.

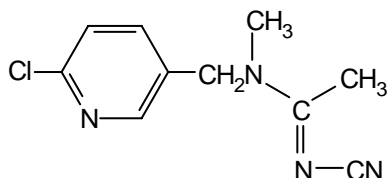
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the data of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion is 14 April 2009.

² Horticultural Development Council, Bradbourne House, East Malling, ME19 6DZ, Kent, UK

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Acetamiprid is the ISO common name for (E)-N¹-[(6-chloro-3-pyridyl)methyl]-N²-cyano-N¹-methylacetamidine (IUPAC).



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). The representative uses supported for the peer review were applications on oranges, mandarins, lemons, apple, pears, peaches, nectarines, cherries plums, tomatoes, peppers, aubergines, cotton and tobacco. Outdoor and for fruiting vegetables also indoor applications close to harvest have been supported. Since EFSA was not yet involved in the peer review, no EFSA conclusion is available for this compound. The peer review for this active substance has been finalised and it has been decided to include acetamiprid in Annex I of Directive 91/414/EEC. Only uses as insecticide may be authorized. Commission Directive 2004/99/EC amending the Directive accordingly entered into force on 1 January 2005.

MRLs for acetamiprid were set for the first time by Directive 2007/11/EC. They were amended by Directives 2007/73/EC and 2008/17/EC. They have been transferred to Annex II of Regulation (EC) No 396/2005 by Regulation (EC) No 149/2008 and have been amended by Regulation (EC) No 839/2008. No MRLs for acetamiprid have been set so far by the Codex Alimentarius Commission.

The United Kingdom now considers authorizing new uses for acetamiprid in cress, spinach and herbs. Referring to the MRL for lettuce, which has been already set at 5 mg/kg, a modification of the existing MRL for cress, spinach and herbs from 0.01 mg/kg* to 5 mg/kg is requested. A detailed overview of the proposed GAPs is available in Appendix A to this document. It concerns foliar 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 3 days for protected crops and 7 days for crops grown outdoors.

In support of the MRL application an evaluation report has been submitted by the United Kingdom. EFSA also relied on the DAR prepared by Greece under Directive 91/414/EEC (2001) and the list of end points included in the report on acetamiprid conclusions (WG evaluation) from 16 September 2003. A report in support of an MRL proposal for lettuce prepared by France (December 2005) and comments prepared by Sweden (December 2005) on this proposal were also considered in this evaluation.

ASSESSMENT

1. Methods of analysis

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

The availability of an analytical method for enforcement of acetamiprid was not addressed by the United Kingdom in its evaluation report.

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 florisol 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 study for this method for the analysis of cotton seed (commodity with high oil content) was submitted and evaluated in addendum 1 to the DAR (October 2001). Ideally, the independent validation study should also cover a commodity with high water content as this is relevant for the crops 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 for the analysis of apples and tomatoes was submitted and evaluated in addendum 1 to the DAR (October 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) in total 917 validation data sets have been submitted regarding methods routinely used to determine acetamiprid in different matrices. An overview of the validation data is provided in Table 1-1.

Table 1-1 Available validation data for analytical methods for teflubenzuron³

Pesticide	Chr	Matrix Type	Level min	Level max	Rec Median	Rec Mean	CV [%]	# of rec	% Rec (70-120%)	# of Labs
Acetamiprid			0,01	0,4	97	95	12,2	917	97	15
	LC	Acidic	0,01	0,25	98	97	9,9	192	97	12
	LC	Dry (cereals, dry pulses)	0,01	0,1	94	95	15,9	67	97	4
	LC	Other	0,02	0,03	84	84	6,7	7	100	2
	LC	Sugar containing	0,01	0,1	101	99	9,6	77	100	5
	LC	Water containing	0,01	0,4	96	94	12,6	574	96	15

Considering, that all crops supported in the framework of this application belong to the group of commodities with high water content, it is possible to monitor residues in these crops with

³ Source: Website of Community Reference Laboratories (CRL) for Pesticide Residues, www.crl-pesticides.eu, March 2009

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.

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 the crops under evaluation 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 (EC, 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
Acetamiprid					
ADI	COM	2004	0.07	2 year rat study and 2-generation rat reproductive study	100
ARfD	COM	2004	0.1	Acute neurotoxicity stud 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

Metabolism studies on primary crops have been evaluated in the DAR (Greece, 2001). Eggplants, apples, cabbage and carrots have been treated with foliar applications, cabbage also with soil applications of acetamiprid radio labelled in the 2 and 6 positions of the pyridine ring. For cabbage an addition 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% TRR found for the de-

methylated acetamiprid (metabolite IM-2-1, N1-[(6-chloro-3-pyridyl)methyl]-N2-cyanoacetamidine) in cabbage and 26% TRR for 6-chloronicotinic acid in carrots.

The evaluated studies cover fruit, leafy vegetables and root crops. The metabolism studies on cabbage (relevant for the evaluated crops) 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.

An analytical method is available for enforcement of acetamiprid in the crops under consideration for this application (see also section 1.1).

3.1.1.2. Magnitude of residues

A total of 17 supervised residue trials on different lettuce varieties, including open leaf varieties, are reported in the evaluation report of The United Kingdom (dated 2006) and in the MRL proposal provided by France (2005) respectively. Eight of eleven indoor trials were carried out in accordance with the proposed indoor GAP on different locations in northern and southern Europe in the years 1998 to 2000. In three further indoor trials no samples were taken at a PHI of three days. Eight outdoor trials on lettuce were carried out following the proposed outdoor GAP in Northern Europe in the years 1998, 2000 and 2002.

The residue levels measured in the indoor trials are generally higher than the levels derived from the outdoor trials. Consequently, MRL proposals and risk assessment values are derived from the indoor trials.

Extrapolation from residue trials on lettuce to herbs is possible. The EMS argues that extrapolation from results of trials on lettuce to spinach and cress is possible for late applications of plant protection products (with half of the trials conducted on open leaf varieties). However, according to draft guidance document SANCO 7525/VI/95 – rev.8 (February 2008), this applies only for spinach. Extrapolation from a complete residue trial database on lettuce to cress is acceptable if possible residues in lamb's lettuce and cress have been considered. The available database does not include residue trials on lamb's lettuce or cress. However, it is noted that MRLs on lamb's lettuce have been already established on the basis of these residue trials.

For the proposed uses in cress, spinach and herbs the findings for lettuce can be extrapolated to these crops. However, it is noted that ideally the database should also include residue trials for cress or lamb's lettuce.

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 to EFSA. The evaluation report of the EMS and the RMS proposals France (2005) do not include an evaluation if these storage stability studies are sufficient to support the residue trials on lettuce. However, since the studies were accepted for the setting of MRLs in lettuce in 2005, EFSA assumes that the RMS has checked the validity of the supervised trials at that time.

Information if the analytical methods used in the residue trials were demonstrated to be valid is not available to EFSA.

The results of the residue trials, as well as the derived MRL proposals and values used in the risk assessment are summarised in Table 3-1. The MRL proposals were derived using the statistical methodologies agreed at European level. An MRL of 3 would be sufficient to cover the intended uses; however taking into consideration the MRL classes that are currently used by risk managers for the MRL setting, a MRL proposal of 5 mg/kg would be also appropriate.

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

Commodity	Region (a)	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement	Risk assessment					
Residue definition for enforcement and risk assessment: acetamiprid									
Spinach Cress Herbs	NEU	Outdoor	0.08; 0.14; 0.15; 0.16; 0.24; 0.25; 0.28; 0.31	0.08; 0.14; 0.15; 0.16; 0.24; 0.25; 0.28; 0.31	0.20	0.31	0.5	1	Rmax = 0.46 Rber = 0.55
		Indoor	0.33; 0.41 ⁽¹⁾ ; 0.50; 0.78 ⁽¹⁾ ; 2 x 0.88; 1.1; 1.9 ⁽¹⁾	0.33; 0.41; 0.50; 0.78; 2 x 0.88; 1.1; 1.9	0.83	1.9	5 (or 3)	1	All trials were performed on lettuce, but can be extrapolated to the proposed crops. MRL proposals and risk assessment values are based on the indoor use, considering that it is the most critical (indicated in bold)

(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.

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

(1) The results were measured at a PHI of 7 d. Since the values are higher than the residues measured after 3 d PHI, they were included in the calculation of the MRL and the related intake values for risk assessment.

3.1.1.3. Effect of industrial processing and/or household preparation

From the crops under consideration it is assumed that cress is usually consumed raw as salad plant. Herbs are usually only consumed in small quantities. Processing crops for these crops are therefore not required. Spinach on the other hand is often cooked or canned, processes that might alter the nature of the residues.

A study investigating the effect of processing on the nature of residues is reported in the DAR (Greece, 2001). Buffer solutions spiked with acetamiprid, radio labelled in 2 and 6 positions of the pyridine ring, were subjected to conditions simulating sterilisation (20 min at 120 °C, pH6), baking and boiling (60 min at 100 °C, pH5) and pasteurisation (20 min at 90 °C, pH4). 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 according to draft guidance document 7035/VI/95 rev. 5. A change in the nature of residues after industrial or household processing is therefore not expected.

Specific studies investigating the effect of processing on the magnitude of acetamiprid residues in spinach are not available.

3.1.2. Rotational crops

The RMS concluded in the DAR (Greece, 2001) that no studies on rotational crops are required for acetamiprid as the DT₉₀ value for acetamiprid is 20.2 days. However, it is noted that discussions concerning the relevance of the major metabolites in soil IM-I-4⁴ and IM-I-5⁵ for rotational crops which have been started during the peer review have not yet been finalised. The EMS did not provide any further information on the possible occurrence and the toxicological relevance of the more stable soil metabolites in rotational crops. EFSA therefore concludes that based on the information currently available, the possibility of residues of these soil metabolites in rotational crops cannot be excluded. Member States granting an authorisation for acetamiprid should therefore 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

Occurrence of acetamiprid residues in food of animal origin was not further considered in the framework of this application. The crops under evaluation are usually not fed to animals and residues in animal commodities resulting from the reported GAPs are therefore not expected.

4. Consumer risk assessment

Chronic and acute intake calculations were carried out using revision 2 of the EFSA PRIMo. The input values for the crops under assessment for this application are summarized in Table 4-1. The STMR value derived in the assessment was also used for lettuce, lamb's lettuce, scarole and rocket/rucola for the chronic risk assessment as the MRLs for these commodities were set on the basis of the same residue trials. For all remaining commodities no STMR was derived in the respective MRL proposals. Chronic exposure calculations have therefore been conducted using the existing MRLs as input values (Appendix B). Considering that the

⁴ N-methyl-(6-chloro-3-pyridyl)-methylamine

⁵ N-(6-chloropyridin-3-ylmethyl)-N-methyl-acetamidine

residue definitions for enforcement and risk assessment are the same, this approach is expected to overestimate real chronic exposure to acetamiprid residues.

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
Risk assessment residue definition: acetamiprid				
Lettuce lamb's lettuce scarole rocket, rucola spinach herbs	0.83	STMR	1.9	HR
Other crops	MRLs (see Appendix B)		Not relevant	

The results of the intake calculations are reported in Appendix C to this document. Intake calculations for all European diets resulted in a chronic exposure not higher than 11% of the ADI. The contribution of spinach was less than 1% of the ADI. Because of the low consumption of cress and herbs, the contribution of these crops to the dietary burden was insignificant. The acute intake of acetamiprid residues via spinach is calculated to be 43% or 17 % of the ARfD for children and adults, respectively. Herbs, in particular celery leaves, chervil, parsley and basil account for 11 to 1.3 % of the ARfD in the children's diet.

EFSA concludes that the intended use of acetamiprid on cress, spinach and herbs is acceptable with regard to consumer safety.

CONCLUSIONS AND RECOMMENDATIONS

According to Article 6(2) of Regulation (EC) No 396/2005, The United Kingdom received an application from the Horticultural Development Council to modify the existing MRLs for acetamiprid in cress, spinach and herbs. The applicant proposes to raise the existing MRLs, which are currently set at the analytical limit of quantification of 0.01 mg/kg, to 5 mg/kg. The subsequent evaluation report drafted by The United Kingdom was forwarded to EFSA on 14/01/2009 according to Article 9 of the Regulation.

Based on the evaluation report of The United Kingdom, the Draft Assessment Report (DAR) prepared by the Rapporteur Member State (RMS) Greece under Directive 91/414/EEC and evaluation reports prepared by Greece and France in 2005 in support of MRL proposals for lettuce, EFSA derives the following conclusion regarding the application.

The metabolism of acetamiprid was investigated for foliar applications close to harvest in eggplants, apples, cabbage and carrots. Three crop groups (fruit, leafy vegetable and root group) are covered by the available study. Metabolism was shown to be similar and acetamiprid was the main component in all investigated crops. Therefore, the parent compound acetamiprid was proposed as a general residue definition for all crop groups for enforcement and risk assessment. An analytical method is available for enforcement of MRLs for acetamiprid in leafy crops.

A sufficient amount of supervised residue trials on lettuce is available and considering the comparability of the GAPs, the results of these trials can be extrapolated to cress, spinach and herbs. EFSA concludes that a MRL of 3 or 5 mg/kg would be required to accommodate for the intended uses of acetamiprid in cress, spinach and herbs.

The possible occurrence of acetamiprid residues in rotational crops is not expected due to the rapid degradation of the parent compound in soil. However, the relevance of the major metabolites in soil IM-1-4 (N-methyl-(6-chloro-3-pyridyl)-methylamine) and IM-1-5 (N-(6-chloropyridin-3-ylmethyl)-N-methyl-acetamidine) for rotational crops was discussed in the peer review, but a final conclusion could not be derived. Therefore EFSA recommends that the United Kingdom should consider appropriate risk mitigation measures (e.g. by defining pre-planting 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 considering that the crops under evaluation are usually not fed to livestock.

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EFSA recommendations resulting from the assessment are summarized in the table below.

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Spinach	0.01*	3 or 5^a	
Herbs	0.01*	3 or 5^a	

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

(F): MRL is expressed as mg/kg of fat contained in the whole product.

^a – the applicant proposed 5 mg/kg, however, according to the MRL calculation, 3 mg/kg would be sufficient.

DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report has been submitted by the United Kingdom (dated 2006): Request for a change to an EC MRL, acetamiprid; residue file note (recommendation).
2. MRL proposal for acetamiprid prepared by Greece (November 2005)
3. MRL proposal for acetamiprid prepared by France (December 2005).
4. Comments prepared by Sweden on the MRL proposal for acetamiprid prepared by France (December 2005)
5. Report on acetamiprid conclusions (WG evaluation) from 16 September 2003 including evaluation table and list of end points.

REFERENCES

- Greece, 2001. Draft Assessment Report on acetamiprid prepared under Directive 91/414/EEC. March 2001.
- European Commission, 2004. Review report for the active substance acetamiprid; SANCO/1392/2001 – Final (16 June 2004).

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Crop and/or situation (a)	F or G (b)	Pest or group of pests controlled (c)	Formulation rate per treatment		Application			Application rate per treatment			PHI (days) (k)	Remarks: (l) e.g. minimum realistic PHI
			Type (d-f)	Conc. of a.s. (i)	method, kind, if other than spray (f-h)	growth stage (j)	number (range)	kg a.s./ha, where appropriate	water L/ha	kg a.s./hL, where appropriate		
Cress, spinach and herbs	G	Insects	WP	20 % w/w	spray	3 days before harvest	2	50 g as/ha	200	-	3	
Cress, spinach and herbs	F	Insects	WP	20 % w/w	spray	7 days before harvest	2	50 g as/ha	200	-	7	

APPENDIX B – LIST OF EXISTING EC MRLs

Pesticides - Web Version - EU MRLs (File created on 16/02/2009 19:52)		
Code number	Groups and examples of individual products to which the MRLs apply (a)	EU MRLs
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	1
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, uglis 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*

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	Azarole (mediteranean medlar)	0,01*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea shallowthorn), 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), pomerac, 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*
162050	Star apple	0,01*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,01*

162990	Others	0,01*			
163000	(c) Inedible peel, large	0,01*	220040	Spring onions (Welsh onion and similar varieties)	0,01*
163010	Avocados	0,01*	220990	Others	0,01*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,01*	230000	(iii) Fruiting vegetables	
163030	Mangoes	0,01*	231000	(a) Solanacea	
163040	Papaya	0,01*	231010	Tomatoes (Cherry tomatoes,)	0,1
163050	Pomegranate	0,01*	231020	Peppers (Chilli peppers)	0,3
	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,01*	231030	Aubergines (egg plants) (Pepino)	0,1
163060		0,01*	231040	Okra, lady s fingers	0,01*
163070	Guava	0,01*	231990	Others	0,01*
163080	Pineapples	0,01*	232000	(b) Cucurbits - edible peel	0,3
163090	Bread fruit (Jackfruit)	0,01*	232010	Cucumbers	0,3
163100	Durian	0,01*	232020	Gherkins	0,3
163110	Soursop (guanabana)	0,01*	232030	Courgettes (Summer squash, marrow (patisson))	0,3
163990	Others	0,01*	232990	Others	0,3
200000	2. VEGETABLES FRESH OR FROZEN		233000	(c) Cucurbits-inedible peel	0,01*
210000	(i) Root and tuber vegetables	0,01*	233010	Melons (Kiwano)	0,01*
211000	(a) Potatoes	0,01*	233020	Pumpkins (Winter squash)	0,01*
	(b) Tropical root and tuber vegetables	0,01*	233030	Watermelons	0,01*
212000		0,01*	233990	Others	0,01*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,01*	234000	(d) Sweet corn	0,01*
212020	Sweet potatoes	0,01*	239000	(e) Other fruiting vegetables	0,01*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,01*	240000	(iv) Brassica vegetables	
212040	Arrowroot	0,01*	241000	(a) Flowering brassica	0,01*
212990	Others	0,01*	241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,01*
	(c) Other root and tuber vegetables except sugar beet	0,01*	241020	Cauliflower	0,01*
213010	Beetroot	0,01*	241990	Others	0,01*
213020	Carrots	0,01*	242000	(b) Head brassica	
213030	Celeriac	0,01*	242010	Brussels sprouts	0,05
213040	Horseradish	0,01*	242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,01*
213050	Jerusalem artichokes	0,01*	242990	Others	0,01*
213060	Parsnips	0,01*	243000	(c) Leafy brassica	0,01*
213070	Parsley root	0,01*	243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,01*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,01*	243020	Kale (Borecole (curly kale), collards)	0,01*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,01*	243990	Others ()	0,01*
213100	Swedes	0,01*	244000	(d) Kohlrabi	0,01*
213110	Turnips	0,01*	250000	(v) Leaf vegetables & fresh herbs	
213990	Others	0,01*	251000	(a) Lettuce and other salad plants including Brassicacea	
220000	(ii) Bulb vegetables	0,01*	251010	Lamb's lettuce (Italian cornsalad)	5
220010	Garlic	0,01*			
220020	Onions (Silverskin onions)	0,01*			
220030	Shallots	0,01*			

251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	5	260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,01*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	5	260030	Peas (with pods) (Mangetout (sugar peas))	0,01*
251040	Cress	0,01*	260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,01*
251050	Land cress	0,01*	260050	Lentils	0,01*
251060	Rocket, Rucola (Wild rocket)	5	260990	Others	0,01*
251070	Red mustard	0,01*	270000	(vii) Stem vegetables (fresh)	0,01*
251080	Leaves and sprouts of Brassica spp (Mizuna)	5	270010	Asparagus	0,01*
251990	Others	0,01*	270020	Cardoons	0,01*
252000	(b) Spinach & similar (leaves)	0,01*	270030	Celery	0,01*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,01*	270040	Fennel	0,01*
252020	Purslane (Winter purslane (miner s lettuce), garden purslane, common purslane, sorrel, glassworth)	0,01*	270050	Globe artichokes	0,01*
252030	Beet leaves (chard) (Leaves of beetroot)	0,01*	270060	Leek	0,01*
252990	Others	0,01*	270070	Rhubarb	0,01*
253000	(c) Vine leaves (grape leaves)	0,01*	270080	Bamboo shoots	0,01*
254000	(d) Water cress	0,01*	270090	Palm hearts	0,01*
255000	(e) Witloof	0,01*	270990	Others	0,01*
256000	(f) Herbs		280000	(viii) Fungi	0,01*
256010	Chervil	0,01*	280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,01*
256020	Chives	0,01*	280020	Wild (Chanterelle, Truffle, Morel ,)	0,01*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,01*	280990	Others	0,01*
256040	Parsley	5	290000	(ix). Sea weeds	
256050	Sage (Winter savory, summer savory,)	0,01*	300000	3. PULSES, DRY	0,01*
256060	Rosemary	0,01*	300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,01*
256070	Thyme (marjoram, oregano)	0,01*	300020	Lentils	0,01*
256080	Basil (Balm leaves, mint, peppermint)	0,01*	300030	Peas (Chickpeas, field peas, chickling vetch)	0,01*
256090	Bay leaves (laurel)	0,01*	300040	Lupins	0,01*
256100	Tarragon (Hyssop)	0,01*	300990	Others	0,01*
256990	Others	0,01*	400000	4. OILSEEDS AND OILFRUITS	
260000	(vi) Legume vegetables (fresh)	0,01*	401000	(i) Oilseeds	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	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, turnip 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*	810000	(i) Seeds	0,1*
401140	Hempseed	0,01*	810010	Anise	0,1*
401150	Castor bean	0,01*	810020	Black caraway	0,1*
401990	Others	0,01*	810030	Celery seed (Lovage seed)	0,1*
402000	(ii) Oilfruits	0,01*	810040	Coriander seed	0,1*
402010	Olives for oil production	0,01*	810050	Cumin seed	0,1*
402020	Palm nuts (palmoil kernels)	0,01*	810060	Dill seed	0,1*
402030	Palmfruit	0,01*	810070	Fennel seed	0,1*
402040	Kapok	0,01*	810080	Fenugreek	0,1*
402990	Others	0,01*	810090	Nutmeg	0,1*
500000	5. CEREALS	0,01*	810990	Others	0,1*
500010	Barley	0,01*	820000	(ii) Fruits and berries	0,1*
500020	Buckwheat	0,01*	820010	Allspice	0,1*
500030	Maize	0,01*	820020	Anise pepper (Japan pepper)	0,1*
500040	Millet (Foxtail millet, teff)	0,01*	820030	Caraway	0,1*
500050	Oats	0,01*	820040	Cardamom	0,1*
500060	Rice	0,01*	820050	Juniper berries	0,1*
500070	Rye	0,01*	820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
500080	Sorghum	0,01*	820070	Vanilla pods	0,1*
500090	Wheat (Spelt Triticale)	0,01*	820080	Tamarind	0,1*
500990	Others	0,01*	820990	Others	0,1*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*	830000	(iii) Bark	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*	830010	Cinnamon (Cassia)	0,1*
620000	(ii) Coffee beans	0,1*	830990	Others	0,1*
630000	(iii) Herbal infusions (dried)	0,1*	840000	(iv) Roots or rhizome	0,1*
631000	(a) Flowers	0,1*	840010	Liquorice	0,1*
631010	Camomille flowers	0,1*	840020	Ginger	0,1*
631020	Hybiscus flowers	0,1*	840030	Turmeric (Curcuma)	0,1*
631030	Rose petals	0,1*	840040	Horse-radish	0,1*
631040	Jasmine flowers	0,1*	840990	Others	0,1*
631050	Lime (linden)	0,1*	850000	(v) Buds	0,1*
631990	Others	0,1*	850010	Cloves	0,1*
632000	(b) Leaves	0,1*	850020	Capers	0,1*
632010	Strawberry leaves	0,1*	850990	Others	0,1*
632020	Rooibos leaves	0,1*	860000	(vi) Flower stigma	0,1*
632030	Maté	0,1*	860010	Saffron	0,1*
632990	Others	0,1*	860990	Others	0,1*
633000	(c) Roots	0,1*	870000	(vii) Aril	0,1*
633010	Valerian root	0,1*	870010	Mace	0,1*
633020	Ginseng root	0,1*	870990	Others	0,1*
633990	Others	0,1*	900000	9. SUGAR PLANTS	0,01*
639000	(d) Other herbal infusions	0,1*	900010	Sugar beet (root)	0,01*
640000	(iv) Cocoa (fermented beans)	0,1*	900020	Sugar cane	0,01*
650000	(v) Carob (st johns bread)	0,1*	900030	Chicory roots	0,01*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,1*	900990	Others	0,01*
800000	8. SPICES	0,1*	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	0,1
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*
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 milk, cheese and curd	0,05*
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	

Footnotes:

Acetamiprid (R)

(R) = The residue definition differs for the following combinations pesticide-code number: Acetamiprid - code 1000000: Acetamiprid and IM-2-1 metabolite

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Acetamiprid			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.07	ARfD (mg/kg bw):	0.1
Source of ADI:	DAR	Source of ARfD:	DAR
Year of evaluation:	2001	Year of evaluation:	2001

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum							
		1 11							
		No of diets exceeding ADI:		---					
	Highest calculated TMDI values in % of ADI	Highest contributor to MS diet (in % of ADI)		2nd contributor to MS diet (in % of ADI)		3rd contributor to MS diet (in % of ADI)		pTMRLs at LOQ (in % of ADI)	
	MS Diet	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities
	10.9	DE child	5.4	Oranges	1.7	Apples	1.0	Milk and cream,	0.2
	10.4	NL child	4.5	Oranges	2.1	Milk and cream,	1.1	Mandarins	0.3
	8.1	FR toddler	2.9	Oranges	2.8	Milk and cream,	0.8	Spinach	0.2
	5.9	UK Toddler	2.8	Oranges	1.5	Milk and cream,	0.4	Mandarins	0.5
	5.6	ES child	3.1	Oranges	0.9	Milk and cream,	0.5	Lettuce	0.2
	5.5	UK Infant	2.8	Milk and cream,	1.9	Oranges	0.2	Apples	0.3
	5.4	IE adult	1.5	Oranges	1.0	Grapefruit	0.8	Mandarins	0.4
	4.8	WHO Cluster diet B	1.2	Oranges	0.5	Mandarins	0.4	Tomatoes	0.4
	4.8	FR infant	1.8	Milk and cream,	1.3	Oranges	0.5	Spinach	0.2
	4.2	NL general	2.1	Oranges	0.5	Milk and cream,	0.3	Mandarins	0.1
	3.9	SE general population 90th percentile	1.1	Oranges	0.9	Milk and cream,	0.6	Mandarins	0.2
	3.7	ES adult	1.8	Oranges	0.6	Lettuce	0.4	Milk and cream,	0.1
	3.1	DK child	0.9	Milk and cream,	0.7	Cucumbers	0.3	Apples	0.2
	2.9	WHO Cluster diet F	1.2	Oranges	0.4	Lettuce	0.3	Milk and cream,	0.2
	2.7	WHO regional European diet	0.7	Oranges	0.4	Lettuce	0.3	Milk and cream,	0.2
	2.5	FI adult	1.4	Oranges	0.4	Milk and cream,	0.2	Mandarins	0.1
	2.5	WHO cluster diet E	0.6	Oranges	0.2	Mandarins	0.2	Grapefruit	0.3
	2.4	UK vegetarian	1.2	Oranges	0.2	Milk and cream,	0.2	Lettuce	0.2
	2.3	IT kids/toddler	0.7	Oranges	0.3	Lettuce	0.3	Mandarins	0.2
	2.1	IT adult	0.5	Oranges	0.4	Lettuce	0.2	Mandarins	0.1
	2.0	WHO cluster diet D	0.4	Milk and cream,	0.3	Oranges	0.2	Limes	0.2
	1.8	PT General population	0.9	Oranges	0.2	Apples	0.1	Tomatoes	0.2
	1.8	FR all population	0.4	Oranges	0.3	Mandarins	0.2	Milk and cream,	0.2
	1.7	UK Adult	0.8	Oranges	0.2	Milk and cream,	0.1	Lettuce	0.1
	1.3	DK adult	0.4	Milk and cream,	0.2	Oranges	0.1	Cucumbers	0.1
	1.2	LT adult	0.3	Milk and cream,	0.3	Apples	0.2	Cucumbers	0.1
	0.9	PL general population	0.3	Apples	0.1	Tomatoes	0.1	Lemons	0.1

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. 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	*)	**)	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)			
	42.9	Spinach	1.9 / -	42.9	Spinach	1.9 / -	17.0	Spinach	1.9 / -	17.0	Spinach	1.9 / -			
	10.9	Celery leaves	1.9 / -	10.9	Celery leaves	1.9 / -	2.3	Parsley	1.9 / -	2.3	Parsley	1.9 / -			
	2.5	Chervil	1.9 / -	2.5	Chervil	1.9 / -	0.7	Cress	1.9 / -	0.7	Cress	1.9 / -			
	1.4	Parsley	1.9 / -	1.4	Parsley	1.9 / -	0.3	Herbs	1.9 / -	0.3	Herbs	1.9 / -			
	1.3	Basil	1.9 / -	1.3	Basil	1.9 / -	0.3	Celery leaves	1.9 / -	0.3	Celery leaves	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:		
	---			---		
	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

Conclusion:

For Acetamidrid 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.

GLOSSARY / ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DT90	period required for 90 percent dissipation (define method of estimation)
EC	European Community
ECD	electron capture detection
EFSA	European Food Safety Authority
EMS	Evaluating Member State
GAP	good agricultural practice
GC	gas chromatography
ha	hectare
HPLC	high performance liquid chromatography
HR	highest residue
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
MS	mass selective detector
NEU	Northern European Union
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
PSD	Pesticide Safety Directorate, United Kingdom
RMS	Rapporteur Member State
STMR	supervised trials median residue
TRR	total radioactive residue
UV	ultra-violet detection