

REASONED OPINION OF EFSA

Modification of the existing MRLs for mandipropamid in several leafy vegetables¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2008-734)

Issued on 21 January 2009

SUMMARY

According to Article 6(2) of Regulation (EC) No 396/2005, The United Kingdom received an application from the company Syngenta Crop Protection UK Ltd to modify the existing MRLs of mandipropamid in red mustard, leaves and sprouts of Brassica spp, spinach, purslane and beet leaves (chard). The applicant proposes to raise the existing MRLs, which are currently set at the analytical limit of quantification of 0.01 mg/kg, to 10 mg/kg. The subsequent evaluation report drafted by The United Kingdom was forwarded to EFSA on 26 September 2008 according to Article 9 of the Regulation. On 18 December 2008 EFSA noted that the Good Agricultural Practices (GAP) for mandipropamid in leafy vegetables were not properly reported. Updated GAPs were submitted by The United Kingdom on 23 December 2008.

Based on the evaluation report and the Draft Assessment Report (DAR) prepared by the Rapporteur Member State (RMS) Austria under Directive 91/414/EEC, EFSA derives the following conclusions regarding the application. As the DAR has not yet been fully peer reviewed by EFSA at this stage, conclusions reached in this reasoned opinion are temporary and might be reconsidered after finalization of the peer review.

Metabolism of mandipropamid was investigated for foliar applications close to the harvest in lettuce, tomatoes, grapes and potatoes. Three different crop groups are covered by the available studies but a general residue definition for all plant commodities could not be proposed because the metabolite (4-chlorophenyl)(prop-2-yn-1-yloxy)acetic acid was found at significant levels in potatoes only (>10% of the TRR). Awaiting the peer review to be finalised on this issue, it is proposed in the framework of this application to define the relevant residue in leafy vegetables as mandipropamid based on the lettuce metabolism study. An analytical method for enforcement of mandipropamid in leafy vegetables is available.

A sufficient amount of supervised residues trials on lettuce was submitted and considering the comparability of the GAPs, these trials can be extrapolated to red mustard, leaves and sprouts

¹ For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRLs for mandipropamid in several leafy vegetables. *EFSA Scientific Report* (2009) 229, 1-25

of Brassica spp, spinach, purslane and beet leaves (chard). Although an MRL of 7 mg/kg would be sufficient to cover the reported uses, EFSA also took into consideration the MRL classes that are currently used by risk managers for the MRL setting. Consequently, it is acceptable to set the MRL at 10 mg/kg for the fore mentioned crops.

The possible occurrence of mandipropamid residues in rotational crops was also investigated. It was concluded that the nature of residues in rotational crops and primary crops is expected to be similar but significant residue levels in rotational crops (exceeding 0.01 mg/kg) will not occur provided that the active substance is applied according to the proposed GAP.

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.

Finally, chronic intake calculations were performed considering the new proposed MRLs as well as all the existing MRLs for the active substance. The calculations are based on revision 2 of the EFSA PRIMo and no chronic intake concerns were identified for all available European diets. Acute intake calculations were not undertaken due to the low acute toxicity of the active substance.

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

Table 5-1. Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Residue definition for enforcement: mandipropamid			
Red mustard	0.01*	10	The proposed MRLs are fully supported by data and no risk for consumers was identified.
Leaves and sprouts of <i>Brassica</i> spp	0.01*	10	
Spinach	0.01*	10	
Purslane	0.01*	10	
Beet leaves (chard)	0.01*	10	

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

Key words: mandipropamid, leafy vegetables, MRL application, Regulation (EC) No 396/2005, amide fungicides

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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.

In particular, The United Kingdom, hereafter referred to as the Evaluating Member State (EMS), received from the company Syngenta Crop Protection UK Ltd² an application to modify the existing MRL for the active substance mandipropamid in several leafy vegetables. 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 26 September 2008. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2008-734 and the following subject:

Mandipropamid – Application to modify the existing MRLs for mandipropamid in red mustard from 0.01 mg/kg to 10 mg/kg, in leaves and sprouts of Brassica spp from 0.01* mg/kg to 10 mg/kg, in spinach from 0.01* mg/kg to 10 mg/kg, in purslane from 0.01* mg/kg to 10 mg/kg and in beet leaves (chard) from 0.01* mg/kg to 10 mg/kg.*

EFSA finally proceeded with the assessment of the application as required by Article 10 of the Regulation but on 18 December 2008 EFSA noted that the good agricultural practices for mandipropamid in leafy vegetables were not properly reported which prevented EFSA to conclude on the consumer risk assessment. The updated good agricultural practices were submitted by the EMS on 23 December 2008.

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. Particular attention shall be given to the requirements set out in that Article.

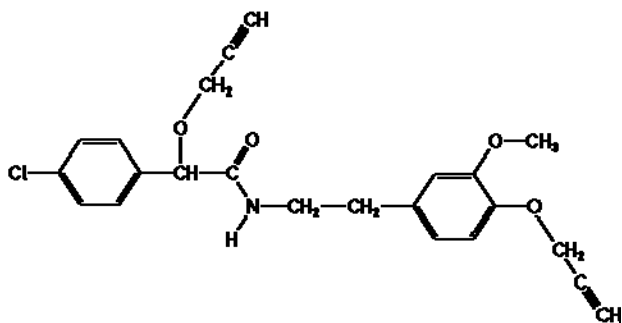
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the data of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been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

In this particular case the calculated deadline for providing the reasoned opinion is 31 December 2008.

² Syngenta Crop Protection UK Ltd, CB224QT Whittlesford, Cambridgeshire, The United Kingdom

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Mandipropamid is the ISO common name for (RS)-2-(4-chlorophenyl)-N-[3-methoxy-4-(prop-2-ynyloxy)phenethyl]-2-(prop-2-ynyloxy)acetamide (IUPAC).



Mandipropamid belongs to the class of amide fungicides. The active substance is effective against most foliar Oomycete pathogens and is highly active against spore germination. It also inhibits mycelial growth and sporulation. The effect is presumably obtained by interfering with the biosynthesis of phospholipids.

Mandipropamid is being evaluated in the framework of Directive 91/414/EEC as a new active substance with Austria being the designated Rapporteur Member State (RMS). The representative uses supported for the peer review process are foliar applications on potato, tomato, melon, cucumber, lettuce and vines. Both indoor and outdoor applications close to the harvest are supported. The peer review for this active substance is however not yet finalised by EFSA and a decision on inclusion of the active substance in Annex I of the Directive is not yet taken.

Awaiting the final decision on the Annex I inclusion of the active substance, provisional authorisations for mandipropamid in several fruit and vegetable crops have already been issued by some Member States and temporary EC MRLs accommodating for these provisional authorisations have been set by Regulation (EC) No 839/2008, which entered into force on 01 September 2008 (Appendix B).

The United Kingdom now considers authorizing new uses for mandipropamid in lettuce, scarole, rocket (rucola), red mustard, leaves and sprouts of *Brassica* spp, spinach, purslane and beet leaves (chard). Considering that MRLs of 10 mg/kg are already set for lettuce, scarole and rocket, only a modification of the existing MRLs for the remaining crops from 0.01* mg/kg to 10 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 0.15 kg a.i./ha. The treatments are performed close to the harvest with a PHI of 7 days.

In support of the MRL application an evaluation report has been submitted by The United Kingdom. EFSA also relied on the DAR prepared by Austria under Directive 91/414/EEC. As the DAR has not yet been fully peer reviewed by EFSA at this stage, conclusions reached in this reasoned opinion are temporary and might be reconsidered after finalization of the peer review.

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 mandipropamid residues was not addressed by The United Kingdom in its evaluation report.

According to the DAR prepared by Austria (2006) an analytical method for enforcement of mandipropamid is reported and sufficiently validated for matrices with a high content of water, acid or oil as well as for dry commodities. The analytical method uses liquid chromatography with detection by double mass spectrometry and a LOQ of 0.01 mg/kg was derived for all commodities. An independent laboratory validation of the analytical method is also available and the applicability of the German multi-residue method (S19) was demonstrated.

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 enforce mandipropamid in these crops with a LOQ of 0.01 mg/kg.

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

The availability of an analytical method for enforcement of residues in food of animal origin was not 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 proposed GAPs are therefore not expected.

2. Mammalian toxicology

The toxicological properties of mandipropamid have been evaluated in the DAR prepared under Directive 91/414/EEC (Austria, 2006) and reference values have been derived. Awaiting the peer review to be finalised by EFSA, it is proposed to rely on the conclusions of the RMS. The reference values derived by Austria are summarized 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
ADI	DAR	2006	0.03	104-week rat study	100
ARfD	DAR	2006	n.n.	-	-

n.n.: not necessary

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Plant metabolism studies have been provided with foliar applications of mandipropamid in grapes, lettuce, potatoes and tomatoes (Austria, 2006). Apart from the tomato study, the test substance has been labelled with a radioactive marker both on the chlorophenyl and the methoxyphenyl moiety.

Parent mandipropamid is the major component found in most metabolism studies and the number of different metabolites depends on the length of the time between application and harvest of the crops. When this time period is short, as for lettuce and tomatoes, mandipropamid is the main compound identified (up to 93.5% TRR). Other metabolites are also identified, but they are present at low levels and chemical structures were found to be similar to that of mandipropamid. Longer intervals between application and harvest were investigated in the grape and potato metabolism studies where a more extensive metabolism took place. In grapes, mandipropamid levels in the fruit samples decreased from 80% TRR at a 0 day PHI to 59% TRR at a 28 days PHI. Nevertheless, unchanged mandipropamid remained the major component in grapes and other metabolites, none of which exceeded 5% TRR or 0.05 mg/kg, were identified as being more polar than the parent molecule.

In potatoes however significant levels of unchanged parent compound were only identified in the foliage. Levels of parent mandipropamid in potato peel are very low and it is not even detectable in flesh. On the other hand, the metabolite (4-chlorophenyl)(prop-2-yn-1-yl)oxy)acetic acid (IUPAC) was detected at a level of 10.1% TRR in flesh and 14.2% in peel, representing 0.0042 and 0.006 mg mandipropamid-equiv/kg. It is proposed by Austria not to include this metabolite in the residue definition considering that it is present at very low levels only and that it was not identified in any other plant metabolism study. But still, quantifiable levels have been identified in two supervised residues trials and questions regarding this metabolite have been raised in the framework of the peer review, both by EFSA and other commenting Member States.

It is proposed to define the relevant residue for enforcement and risk assessment in the framework of this application as the parent compound only. Awaiting the peer review of mandipropamid to be finalised, this residue definition is only applied to leafy vegetables based on the lettuce metabolism study.

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

3.1.1.2. Magnitude of residues

A total of 16 supervised residues trials performed on different lettuce varieties, including open leaf varieties, are reported in the evaluation report of The United Kingdom (2008). 8 outdoor trials, complying with the proposed outdoor GAP, have been performed on different locations in the northern European region while 8 indoor trials, complying with the proposed

indoor GAP, have been performed on different locations in the northern and southern European region. All trials were performed over 2 years. The residue levels measured in the indoor residue trials are generally higher than the levels measured in the outdoor trials. Consequently, MRL proposals and risk assessment values are derived from the indoor trials. As the proposed GAP is the same for all crops supported in the framework of this application, findings for lettuce can be extrapolated to all the leafy crops under consideration.

According to the DAR (Austria, 2008) storage stability of mandipropamid residues has been demonstrated for a period of 12 months at -18°C in commodities with high content of water, acid and oil as well as dry commodities. This was considered sufficient by the RMS for assessment of the available residues trials on lettuce.

The analytical method used in these residues trials was also demonstrated to be valid (Austria, 2006).

The results of the residues trials, as well as the derived MRL proposals and risk assessment values, are summarized in Table 3-1. The MRL proposals were derived using the statistical methodologies agreed at European level. Although an MRL of 7 mg/kg would be sufficient to cover the uses reported by the EMS, EFSA also took into consideration the MRL classes that are currently used by risk managers for the MRL setting. Consequently, it is concluded that for lettuce, scarole and rocket the existing MRL of 10 mg/kg is confirmed while for the remaining crops under evaluation the MRL of 0.01* mg/kg can be raised to 10 mg/kg.

3.1.1.3. Effect of industrial processing and/or household preparation

From the crops under consideration it is assumed that lettuce, rocket, red mustard and leaves and sprouts of *Brassica* spp. are usually eaten raw as salad plants. Processing studies for these crops are therefore not required.

Scarole, spinach, purslane and beet leaves on the other hand are often cooked or canned, processes that might alter the nature of the residue. Moreover, it is noted that spinach in particular has a significant contribution to the exposure of French toddlers to mandipropamid residues. A study investigating the effect of processing on the nature of residues is reported in the DAR (Austria, 2006). Buffer solutions spiked with mandipropamid, labelled on both the chlorophenyl and the methoxyphenyl moiety, were subject to conditions simulating sterilisation (20 min at 120°C, pH6), baking (60 min at 100°C, pH5) and pasteurisation (20 min at 90°C, pH4). In all cases, radioactivity recovered was proven to be unchanged parent compound. A change in the nature of residues after industrial or household processing is therefore not expected.

Studies investigating the effect of processing on the magnitude of residues in these commodities are not available. Considering however that degradation of the compound does not occur, concentration of mandipropamid in the final processed commodities might be expected. From a risk assessment point of view, this is not of concern as the intake calculations are performed based on the consumption of the raw agricultural commodity but from a risk management point of view there might be the wish to enforce mandipropamid in the processed commodities available on the market (e.g. canned spinach). If that would be the case, studies allowing the setting of the appropriate processing factors should be submitted.

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: mandipropamid									
Lettuce Scarole Rocket (rucola) Red mustard Leaves and sprouts of <i>Brassica</i> spp Spinach Purslane Beet leaves (chard)	NEU	Outdoor	0.11; 0.27; 0.43; 0.47; 0.50; 1.2; 1.3; 1.6	0.11; 0.27; 0.43; 0.47; 0.50; 1.2; 1.3; 1.6	0.48	1.6	3	1.0	Trials were performed on lettuce but can be extrapolated to all proposed crops as the GAPs are similar. MRL proposal and risk assessment values are based on the indoor use, considering that it is the most critical (indicated in bold). $R_{max} = 5.402$ $R_{ber} = 6.400$
	EU	Indoor	0.93; 1.3; 1.8; 2.5; 3.0; 3.2; 3.2; 3.3	0.93; 1.3; 1.8; 2.5; 3.0; 3.2; 3.2; 3.3	2.8	3.3	10 (or 7)	1.0	

(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.

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

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

All crops supported in the framework of this application might be grown in rotation with other crops. In particular for this type of leafy vegetables, crops might be rotated over very short time frames. As a DT_{90} value of mandipropamid, based on an aerobic field study, amounts to 240 days (Austria, 2006), investigation of residues in rotational crops is required.

3.1.2.2. Nature of residues

Confined rotational crop studies are reported in the DAR (Austria, 2006). Mandipropamid was applied to bare soil at a rate of 900 g a.i./ha and lettuce, radish and wheat were planted into the treated soil plots at plant intervals of 29, 58, 120 and 365 days. Studies were performed using ^{14}C -mandipropamid marked on the chlorophenyl moiety or on the methoxyphenyl moiety.

Uptake of residues in rotational crops was low, except for wheat straw where higher TRR levels were observed. In all cases unchanged mandipropamid was found to be the main constituent of the residue. Two other metabolites were also found in minor amounts but both were already identified in the primary crop metabolism. High amounts of unextractable residues were also observed, in particular in wheat grain and wheat straw where unextracted residues amounted respectively to 95% and 77% of the TRR. Further investigation of these unextracted residues demonstrated however that in grains unextracted radioactivity was mainly associated with proteins, cellulose and starch while in straw radioactivity was partially incorporated in glucose, pectin and lignin. Also in grains a large portion of the unextractable residues was found to be highly polar, probably having undergone some significant metabolism.

Based on the available studies it is concluded that metabolism in rotational crops is similar to the one observed in primary crops. The same residue definition as for the primary crops can therefore be applied, being the mandipropamid only.

3.1.2.3. Magnitude of residues

The confined rotational crop study was performed on bare soil with an application rate of 900 g a.i./ha. According to these application conditions, levels of mandipropamid exceeding the enforcement LOQ of 0.01 mg/kg are only expected in wheat straw at plant back intervals of 29 and 58 days. Considering that application rates proposed in the framework of this application are significantly lower and that a part of the applied substance is intercepted by the treated crop, it is concluded that significant residue levels in rotation crops are not expected provided that mandipropamid is applied according to the proposed GAPs.

3.2. Nature and magnitude of residues in livestock

Occurrence of mandipropamid 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 intake calculations considering the MRLs proposed for the crops under consideration were performed using revision 2 of the EFSA PRIMo. Acute intake calculations were not conducted because an ARfD for mandipropamid was not deemed necessary.

The input values for the several crops under assessment for this application are summarized in Table 4-1. For all remaining commodities EFSA has no data on the registered uses and STMRs. Exposure calculations have therefore been conducted using the existing MRLs as input values (Appendix B). Considering that the residue definitions for enforcement and risk assessment are the same, this approach is expected to overestimate real exposure to mandipropamid residues.

The results of the chronic intake calculations are reported in Appendix C to this document. Intake calculations for all European diets resulted in a chronic exposure not higher than 35% of the ADI.

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
Residue definition for risk assessment: mandipropamid				
Lettuce	2.8	STMR	n.n.	n.n.
Scarole	2.8	STMR	n.n.	n.n.
Rocket (rucola)	2.8	STMR	n.n.	n.n.
Red mustard	2.8	STMR	n.n.	n.n.
Leaves and sprouts of <i>Brassica</i> spp	2.8	STMR	n.n.	n.n.
Spinach	2.8	STMR	n.n.	n.n.
Purslane	2.8	STMR	n.n.	n.n.
Beet leaves (chard)	2.8	STMR	n.n.	n.n.

n.n. not necessary

CONCLUSIONS AND RECOMMENDATIONS

According to Article 6(2) of Regulation (EC) No 396/2005, The United Kingdom received an application from the company Syngenta Crop Protection UK Ltd to modify the existing MRLs of mandipropamid in red mustard, leaves and sprouts of Brassica spp, spinach, purslane and beet leaves (chard). The applicant proposes to raise the existing MRLs, which are currently set at the analytical limit of quantification of 0.01 mg/kg, to 10 mg/kg. The subsequent evaluation report drafted by The United Kingdom was forwarded to EFSA on 26 September 2008 according to Article 9 of the Regulation. On 18 December 2008 EFSA noted that the Good Agricultural Practices (GAP) for mandipropamid in leafy vegetables were not properly reported. Updated GAPs were submitted by The United Kingdom on 23 December 2008.

Based on the evaluation report and the Draft Assessment Report (DAR) prepared by the Rapporteur Member State (RMS) Austria under Directive 91/414/EEC, EFSA derives the following conclusions regarding the application. As the DAR has not yet been fully peer reviewed by EFSA at this stage, conclusions reached in this reasoned opinion are temporary and might be reconsidered after finalization of the peer review.

Metabolism of mandipropamid was investigated for foliar applications close to the harvest in lettuce, tomatoes, grapes and potatoes. Three different crop groups are covered by the available studies but a general residue definition for all plant commodities could not be proposed because the metabolite (4-chlorophenyl)(prop-2-yn-1-yloxy)acetic acid was found at significant levels in potatoes only (>10% of the TRR). Awaiting the peer review to be finalised on this issue, it is proposed in the framework of this application to define the relevant residue in leafy vegetables as mandipropamid based on the lettuce metabolism study. An analytical method for enforcement of mandipropamid in leafy vegetables is available.

A sufficient amount of supervised residues trials on lettuce was submitted and considering the comparability of the GAPs, these trials can be extrapolated to red mustard, leaves and sprouts of Brassica spp, spinach, purslane and beet leaves (chard). Although an MRL of 7 mg/kg would be sufficient to cover the reported uses, EFSA also took into consideration the MRL classes that are currently used by risk managers for the MRL setting. Consequently, it is acceptable to set the MRL at 10 mg/kg for the fore mentioned crops.

The possible occurrence of mandipropamid residues in rotational crops was also investigated. It was concluded that the nature of residues in rotational crops and primary crops is expected to be similar but significant residue levels in rotational crops (exceeding 0.01 mg/kg) will not occur provided that the active substance is applied according to the proposed GAP.

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.

Finally, chronic intake calculations were performed considering the new proposed MRLs as well as all the existing MRLs for the active substance. The calculations are based on revision 2 of the EFSA PRIMo and no chronic intake concerns were identified for all available European diets. Acute intake calculations were not undertaken due to the low acute toxicity of the active substance.

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

Table 5-1. Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Residue definition for enforcement: mandipropamid			
Red mustard	0.01*	10	The proposed MRLs are fully supported by data and no risk for consumers was identified.
Leaves and sprouts of <i>Brassica</i> spp	0.01*	10	
Spinach	0.01*	10	
Purslane	0.01*	10	
Beet leaves (chard)	0.01*	10	

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

REFERENCES

Austria, 2006. Draft Assessment Report prepared under Directive 91/414/EEC.

The United Kingdom, 2008. Request for a change to an EC definitive MRL for mandipropamid in leafy vegetables and herbs prepared under Regulation (EC) No 396/2005.

APPENDICES

Appendix A – Good Agricultural Practices (GAPs)

Appendix B – List of existing EC MRLs

Appendix C – Pesticide Residues Intake Model (PRIMo)

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

(a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
0251020 Lettuce 0251030 Scarole (broad-leaf endive) 0251060 Rocket, Rucola 0251070 Red mustard 0251080 Leaves and sprouts of Brassica spp	EU (N+S)	Revus	F	<i>Bremia lactucae</i>	SC	250	Foliar spray	From beginning of infection	2	7	0.015 – 0.0375	400-1000	0.15	7	Spraying from April until October
0251020 Lettuce 0251030 Scarole (broad-leaf endive) 0251060 Rocket, Rucola	EU (N+S)	Revus	G	<i>Bremia lactucae</i>	SC	250	Foliar spray	From beginning of infection	1		0.015 – 0.0375	400-1000	0.15	7	

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
0251070 Red mustard 0251080 Leaves and sprouts of Brassica spp															
0252010 Spinach 0252020 Purslane 0252030 Beet leaves (chard)	EU (N+S)	Revus	F	<i>Bremia lactucae</i>	SC	250	Foliar spray	From beginning of infection	2	7	0.015 – 0.0375	400-1000	0.15	7	Spraying from April until October
0252010 Spinach 0252020 Purslane 0252030 Beet leaves (chard)	EU (N+S)	Revus	G	<i>Bremia lactucae</i>	SC	250	Foliar spray	From beginning of infection	1		0.015 – 0.0375	400-1000	0.15	7	

APPENDIX B – LIST OF EXISTING EC MRLS

Pesticides - Web Version - EU MRLs (File created on 19/01/2009 12:04)		
Code number	Groups and examples of individual products to which the MRLs apply (a)	Mandipropamid
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,01*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,01*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,01*
110030	Lemons (Citron, lemon)	0,01*
110040	Limes	0,01*
110050	Mandairns (Clementine, tangerine and other hybrids)	0,01*
110990	Others	0,01*
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	0,01*
130010	Apples (Crab apple)	0,01*
130020	Pears (Oriental pear)	0,01*
130030	Quinces	0,01*
130040	Medlar	0,01*
130050	Loquat	0,01*
130990	Others	0,01*
140000	(iv) Stone fruit	0,01*
140010	Apricots	0,01*
140020	Cherries (sweet cherries, sour cherries)	0,01*
140030	Peaches (Nectarines and similar hybrids)	0,01*
140040	Plums (Damson, greengage, mirabelle)	0,01*
140990	Others	0,01*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	2
151010	Table grapes	2
151020	Wine grapes	2
152000	(b) Strawberries	0,01*
153000	(c) Cane fruit	0,01*

153010	Blackberries	0,01*
153020	Dewberries (Loganberries, Boysenberries, and cloudberrys)	0,01*
153030	Raspberries (Wineberries)	0,01*
153990	Others	0,01*
154000	(d) Other small fruit & berries	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	Azorele (mediterranean medlar)	0,01*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sawtooth), 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), pomegranate, 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*
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	Cheimoya (Custard apple, sugar apple (sweetsop), lama and other medium sized Annonaceae)	0,01*	232020	Gherkins	0,1
163070	Guava	0,01*	232030	Courgettes (Summer squash, marrow (patisson))	0,1
163080	Pineapples	0,01*	232990	Others	0,1
163090	Bread fruit (Jackfruit)	0,01*	233000	(c) Cucurbits - inedible peel	0,3
163100	Durian	0,01*	233010	Melons (Kiwano)	0,3
163110	Soursop (guanabana)	0,01*	233020	Pumpkins (Wintersquash)	0,3
163990	Others	0,01*	233030	Watermelons	0,3
200000	2. VEGETABLES FRESH OR FROZEN		233990	Others	0,3
210000	(i) Root and tuber vegetables	0,01*	234000	(d) Sweet corn	0,01*
211000	(a) Potatoes	0,01*	239000	(e) Other fruiting vegetables	0,01*
212000	(b) Tropical root and tuber vegetables	0,01*	240000	(iv) Brassica vegetables	0,01*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,01*	241000	(a) Flowering brassica	0,01*
212020	Sweet potatoes	0,01*	241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,01*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,01*	241020	Cauliflower	0,01*
212040	Arrowroot	0,01*	241990	Others	0,01*
212990	Others	0,01*	242000	(b) Head brassica	0,01*
213000	(c) Other root and tuber vegetables except sugar beet	0,01*	242010	Brussels sprouts	0,01*
213010	Beetroot	0,01*	242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,01*
213020	Carrots	0,01*	242990	Others	0,01*
213030	Celeriac	0,01*	243000	(c) Leafy brassica	0,01*
213040	Horseradish	0,01*	243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,01*
213050	Jerusalem artichokes	0,01*	243020	Kale (Borecole (curly kale), collards)	0,01*
213060	Parsnips	0,01*	243990	Others ()	0,01*
213070	Parsley root	0,01*	244000	(d) Kohlrabi	0,01*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,01*	250000	(v) Leafy vegetables & fresh herbs	
213090	Salsify (Scorzonera, Spanish salsify (Spanish oyster plant))	0,01*	251000	(a) Lettuce and other salad plants including Brassicaceae	
213100	Swedes	0,01*	251010	Lamb's lettuce (Italian corn salad)	0,01*
213110	Tunips	0,01*	251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	10
213990	Others	0,01*	251030	Scarole (broad leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leave endive, sugar leaf)	10
220000	(i) Bulb vegetables	0,01*	251040	Cress	0,01*
220010	Garlic	0,01*	251050	Land cress	0,01*
220020	Onions (Silverskin onions)	0,01*	251060	Rocket, Rucola (Wild rocket)	10
220030	Shallots	0,01*	251070	Red mustard	0,01*
220040	Spring onions (Welsh onion and similar varieties)	0,01*	251080	Leaves and sprouts of Brassica spp (Mizuna)	0,01*
220990	Others	0,01*	251990	Others	0,01*
230000	(ii) Fruiting vegetables		252000	(b) Spinach & similar (leaves)	0,01*
231000	(a) Solanacea		252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,01*
231010	Tomatoes (Cherry tomatoes,)	1			
231020	Peppers (Chili peppers)	0,01*			
231030	Aubergines (egg plants) (Pepino)	1			
231040	Okra, lady fingers	0,01*			
231990	Others	0,01*			
232000	(b) Cucurbits - edible peel				
232010	Cucumbers	0,2			

252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,01*	280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,01*
252030	Beet leaves (chard) (Leaves of beetroot)	0,01*	280020	Wild (Chanterelle, Truffle, Morel,)	0,01*
252990	Others	0,01*	280990	Others	0,01*
253000	(c) Vine leaves (grape leaves)	0,01*	290000	(ix) Sea weeds	0,01*
254000	(d) Watercress	0,01*	300000	3. PULSES, DRY	0,01*
255000	(e) Witloof	0,01*	300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,01*
256000	(f) Herbs	10	300020	Lentils	0,01*
256010	Chervil	10	300030	Peas (Chickpeas, field peas, chickling vetch)	0,01*
256020	Chives	10	300040	Lupins	0,01*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	10	300990	Others	0,01*
256040	Parsley	10	400000	4. OILSEEDS AND OILFRUITS	0,01*
256050	Sage (Winter savory, summer savory,)	10	401000	(j) Oilseeds	0,01*
256060	Rosemary	10	401010	Linseed	0,01*
256070	Thyme (majoram, oregano)	10	401020	Peanuts	0,01*
256080	Basil (Balm leaves, mint, peppermint)	10	401030	Poppy seed	0,01*
256090	Bay leaves (laurel)	10	401040	Sesame seed	0,01*
256100	Tarragon (Hyssop)	10	401050	Sunflower seed	0,01*
256990	Others	10	401060	Rape seed (Bird rapeseed, turnip rape)	0,01*
260000	(vi) Legume vegetables (fresh)	0,01*	401070	Soya bean	0,01*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,01*	401080	Mustard seed	0,01*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,01*	401090	Cotton seed	0,01*
260030	Peas (with pods) (Mangelout (sugar peas))	0,01*	401100	Pumpkin seeds	0,01*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,01*	401110	Safflower	0,01*
260050	Lentils	0,01*	401120	Borage	0,01*
260990	Others	0,01*	401130	Gold of pleasure	0,01*
270000	(vii) Stem vegetables (fresh)	0,01*	401140	Hempseed	0,01*
270010	Asparagus	0,01*	401150	Castor bean	0,01*
270020	Carboons	0,01*	401990	Others	0,01*
270030	Celery	0,01*	402000	(i) Oilfruits	0,01*
270040	Fennel	0,01*	402010	Olives for oil production	0,01*
270050	Globe artichokes	0,01*	402020	Palm nuts (palm oil kernels)	0,01*
270060	Leek	0,01*	402030	Palmfruit	0,01*
270070	Rhubarb	0,01*	402040	Kapok	0,01*
270080	Bamboo shoots	0,01*	402990	Others	0,01*
270090	Palm hearts	0,01*	500000	5. CEREALS	0,01*
270990	Others	0,01*	500010	Barley	0,01*
280000	(viii) Fungi	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	0,02*

610000	(i) Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i>)	0,02*	840000	(iv) Roots or rhizome	0,02*
620000	(i) Coffee beans	0,02*	840010	Liquorice	0,02*
630000	(ii) Herbal infusions (dried)	0,02*	840020	Ginger	0,02*
631000	(a) Flowers	0,02*	840030	Turmeric (Curcuma)	0,02*
631010	Camomile flowers	0,02*	840040	Horse-radish	0,02*
631020	Hibiscus flowers	0,02*	840990	Others	0,02*
631030	Rose petals	0,02*	850000	(v) Buds	0,02*
631040	Jasmine flowers	0,02*	850010	Cloves	0,02*
631050	Lime (linden)	0,02*	850020	Capers	0,02*
631990	Others	0,02*	850990	Others	0,02*
632000	(b) Leaves	0,02*	860000	(vi) Flower stigma	0,02*
632010	Strawberry leaves	0,02*	860010	Saffron	0,02*
632020	Rooibos leaves	0,02*	860990	Others	0,02*
632030	Maté	0,02*	870000	(vii) Ail	0,02*
632990	Others	0,02*	870010	Mace	0,02*
633000	(c) Roots	0,02*	870990	Others	0,02*
633010	Valerian root	0,02*	900000	9. SUGAR PLANTS	0,01*
633020	Ginseng root	0,02*	900010	Sugarbeet (root)	0,01*
633990	Others	0,02*	900020	Sugarcane	0,01*
639000	(d) Other herbal infusions	0,02*	900030	Chicory roots	0,01*
640000	(iv) Cocoa (fermented beans)	0,02*	900990	Others	0,01*
650000	(v) Carb (stjohns bread)	0,02*	1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,02*	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	0,02*
800000	8. SPICES	0,02*	1011000	(a) Swine	0,02*
810000	(i) Seeds	0,02*	1011010	Meat	0,02*
810010	Anise	0,02*	1011020	Fat free of lean meat	0,02*
810020	Black caraway	0,02*	1011030	Liver	0,02*
810030	Celery seed (Lovage seed)	0,02*	1011040	Kidney	0,02*
810040	Coriander seed	0,02*	1011050	Edible offal	0,02*
810050	Cumin seed	0,02*	1011990	Others	0,02*
810060	Dill seed	0,02*	1012000	(b) Bovine	0,02*
810070	Fennel seed	0,02*	1012010	Meat	0,02*
810080	Fenugreek	0,02*	1012020	Fat	0,02*
810090	Nutmeg	0,02*	1012030	Liver	0,02*
810990	Others	0,02*	1012040	Kidney	0,02*
820000	(ii) Fruits and berries	0,02*	1012050	Edible offal	0,02*
820010	Allspice	0,02*	1012990	Others	0,02*
820020	Anise pepper (Japan pepper)	0,02*	1013000	(c) Sheep	0,02*
820030	Caraway	0,02*	1013010	Meat	0,02*
820040	Cardamom	0,02*	1013020	Fat	0,02*
820050	Juniper berries	0,02*	1013030	Liver	0,02*
820060	Pepper, black and white (Long pepper, pink pepper)	0,02*	1013040	Kidney	0,02*
820070	Vanilla pods	0,02*	1013050	Edible offal	0,02*
820080	Tamarind	0,02*	1013990	Others	0,02*
820990	Others	0,02*	1014000	(d) Goat	0,02*
830000	(iii) Bark	0,02*	1014010	Meat	0,02*
830010	Cinnamon (Cassia)	0,02*	1014020	Fat	0,02*
830990	Others	0,02*			

1014030	Liver	0,02*	Pesticide residues and maximum residue levels (mg/kg) (* Indicates lower limit of analytical determination)
1014040	Kidney	0,02*	
1014050	Edible offal	0,02*	
1014990	Others	0,02*	
1015000	(e) Horses, asses, mules or hinnies	0,02*	
1015010	Meat	0,02*	
1015020	Fat	0,02*	
1015030	Liver	0,02*	
1015040	Kidney	0,02*	
1015050	Edible offal	0,02*	
1015990	Others	0,02*	
1016000	(f) Poultry - chicken, geese, duck, turkey and Guinea fowl, ostrich, pigeon	0,02*	
1016010	Meat	0,02*	
1016020	Fat	0,02*	
1016030	Liver	0,02*	
1016040	Kidney	0,02*	
1016050	Edible offal	0,02*	
1016990	Others	0,02*	
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,02*	
1017010	Meat	0,02*	
1017020	Fat	0,02*	
1017030	Liver	0,02*	
1017040	Kidney	0,02*	
1017050	Edible offal	0,02*	
1017990	Others	0,02*	
1020000	(i) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,02*	
1020010	Cattle	0,02*	
1020020	Sheep	0,02*	
1020030	Goat	0,02*	
1020040	Horse	0,02*	
1020990	Others	0,02*	
1030000	(ii) 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	0,02*	
1030010	Chicken	0,02*	
1030020	Duck	0,02*	
1030030	Goose	0,02*	
1030040	Quail	0,02*	
1030990	Others	0,02*	
1040000	(iv) Honey (Royal jelly, pollen)		
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)		
1060000	(vi) Snails		
1070000	(vii) Other terrestrial animal products		

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Mandipropamid			
Status of the active substance:	Pending	Code no.	
LOQ (mg/kg bw):	0.01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.03	ARfD (mg/kg bw):	n.n.
Source of ADI:	DAR	Source of ARfD:	DAR
Year of evaluation:	2006	Year of evaluation:	2006

Explain choice of toxicological reference values.

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						
		4 35						
		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	pTMRLs at LOQ (in % of ADI)
34.9	WHO Cluster diet B	11.9	Wine grapes	10.3	Tomatoes	3.3	Lettuce	1.0
31.2	FR all population	26.7	Wine grapes	1.4	Tomatoes	0.9	Lettuce	0.3
22.3	PT General population	16.6	Wine grapes	3.0	Tomatoes	1.9	Table grapes	0.6
18.8	DE child	8.5	Table grapes	3.2	Tomatoes	1.9	Spinach	1.1
18.4	WHO cluster diet E	10.7	Wine grapes	1.8	Tomatoes	1.7	Herbs	0.6
18.0	IE adult	8.3	Wine grapes	1.7	Table grapes	1.5	Herbs	0.9
17.1	NL child	5.1	Table grapes	3.5	Spinach	2.1	Tomatoes	1.0
14.9	FR toddler	6.6	Spinach	2.6	Milk and cream,	2.6	Tomatoes	0.7
13.4	ES adult	5.0	Lettuce	2.8	Wine grapes	2.6	Tomatoes	0.3
13.4	WHO regional European diet	3.7	Tomatoes	3.5	Lettuce	1.5	Wine grapes	0.5
12.3	DK adult	9.3	Wine grapes	1.4	Tomatoes	0.5	Table grapes	0.2
11.9	NL general	4.2	Wine grapes	1.5	Table grapes	1.4	Tomatoes	0.4
11.9	WHO cluster diet D	3.4	Tomatoes	2.4	Wine grapes	2.2	Herbs	0.6
11.8	IT adult	3.9	Tomatoes	3.5	Lettuce	0.9	Spinach	0.3
11.2	WHO Cluster diet F	4.0	Wine grapes	2.8	Lettuce	2.3	Tomatoes	0.5
11.1	IT kids/toddler	4.8	Tomatoes	2.7	Lettuce	0.7	Herbs	0.5
11.1	ES child	3.9	Lettuce	3.3	Tomatoes	0.8	Milk and cream,	0.5
11.0	UK Adult	7.2	Wine grapes	1.5	Tomatoes	1.1	Lettuce	0.4
10.7	UK vegetarian	5.4	Wine grapes	2.1	Tomatoes	1.3	Lettuce	0.4
7.8	FR infant	4.1	Spinach	1.7	Milk and cream,	0.5	Table grapes	0.5
7.6	DK child	1.8	Tomatoes	1.3	Lettuce	1.2	Table grapes	0.7
7.2	UK Toddler	2.0	Tomatoes	1.6	Table grapes	1.4	Milk and cream,	1.3
6.1	SE general population 90th percentile	2.6	Tomatoes	0.8	Milk and cream,	0.6	Spinach	0.6
6.0	PL general population	2.9	Tomatoes	2.1	Table grapes	0.4	Herbs	0.3
5.3	FI adult	2.0	Wine grapes	1.4	Tomatoes	0.7	Lettuce	0.2
5.2	UK Infant	2.6	Milk and cream,	1.2	Tomatoes	0.3	Sugar beet (root)	0.9
3.8	LT adult	2.1	Tomatoes	0.6	Lettuce	0.3	Milk and cream,	0.3

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Mandipropamid is unlikely to present a public health concern.

Acute risk assessment /children - refined calculations

Acute risk assessment / adults / general population - refined calculations

Acute risk assessment is not necessary.

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)
No of critical MRLs (IESTI 1)			No of critical MRLs (IESTI 2)			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:	
	IESTI 1	IESTI 2	IESTI 1	IESTI 2
	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:

As no ARfD was considered necessary, it is concluded that the short-term intake of Mandipropamid residues is unlikely to present a public health concern.

GLOSSARY / ABBREVIATIONS

ADI	Acceptable Daily Intake
ARfD	Acute Reference Dose
CXL	Codex Maximum Residue Limit
DAR	Draft Assessment Report (prepared under Directive 91/414/EEC)
DT ₉₀	Degradation Time required for a given chemical compound to achieve 90 % of degradation compared to the amount initially present
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
GAP	Good Agricultural Practice
HR	Highest Residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LOQ	Limit Of Quantification
MRL	Maximum Residue Limit.
PHI	Pre Harvest Interval
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
STMR	Supervised Trials Median Residue
TRR	Total Radioactive Residue