

REASONED OPINION OF EFSA

Modification of the existing MRL for mepanipyrim in courgettes¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00214)

Issued on 15 April 2009

SUMMARY

According to Article 6(1) of Regulation (EC) No 396/2005, the United Kingdom received an application from the Horticultural Development Council (HDC) to modify the existing MRL for mepanipyrim in courgettes. In order to accommodate for a new use in this crop, the applicant proposes to raise the existing MRL from 0.01* to 0.5 mg/kg. The evaluation report drafted by the United Kingdom was forwarded to EFSA on 14 January 2009 according to Article 9 of the Regulation. Based on this evaluation report, the Draft Assessment Report (DAR) and the addenda to the DAR prepared by the Rapporteur Member State (RMS) Italy under Directive 91/414/EEC, EFSA derives the following conclusions regarding this application.

The metabolism of mepaniryrim was investigated only in the fruit crop group following foliar applications (grapes, apples and tomatoes). The parent mepanipyrim was shown to be the major component of the residue accounting for up to 70% of the TRR in tomatoes. However, due to the longer PHI intervals investigated, the metabolite 2-anilino-4(2-hydroxypropyl)-6-methylpyrimidine (M-31) was observed in significant proportions (20-30% TRR) on grapes at harvest while it was less than 1% of the TRR in apples and tomatoes. The initial proposal suggested by the RMS to include this metabolite in the residue definition was finally not supported in the course of the peer review. Taking into account information on its toxicological relevance and the fact that M-31 was detected in low amounts in the supervised residue trials performed in compliance with the GAPs, the residue definition for enforcement and risk assessment was limited to the parent only. However, this final residue definition resulting from the peer review process performed in the framework of Directive 91/414/EEC was not taken into account when MRLs were proposed at European Community level and the residue definition stated in Regulation (EC) N° 396/2005 refers to the sum of the parent and its metabolite M-31, expressed as mepanipyrim.

Since there is clear evidence from the metabolism studies and the supervised residue trials that mepanipyrim alone is a good marker for the residues in fruit crops, EFSA proposes that

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the residue definition for enforcement stated in Annex II to Regulation (EC) No 396/2005 should be limited to the parent compound only.

The residue trials provided were considered sufficient to derive an MRL for courgettes grown outdoor. Although an MRL of 0.5 mg/kg is proposed by the applicant, EFSA is of the opinion that an MRL of 0.6 mg/kg would be more appropriate. Adequate analytical methods for enforcement of the proposed MRL are available.

In the framework of Directive 91/414/EEC, it was concluded that no residues are expected in rotational crops following 2 applications of mepanipyrim at a rate of 0.4 kg/ha on tomatoes. EFSA is of the opinion that the conclusion reached for tomatoes considering 2 applications is not relevant for courgettes since the GAP includes a total of 4 applications. It is therefore concluded that Member States should reconsider the possible occurrence of residues in rotational crops when granting an authorisation on courgettes based on a total of 4 application at a rate of 0.4 kg a.s./ha.

Residues in commodities of animal origin were not assessed considering that courgettes are usually not fed to livestock.

The chronic and acute intake resulting from the proposed MRL were calculated using revision 2 of the EFSA PRIMo and the existing MRLs listed in Annex II to Regulation (EC) No 396/2005. No chronic or acute concerns were identified for all available European diets. 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
<u>Residue definition for enforcement: mepanipyrim</u>			
Courgettes	0.01*	0.6	The proposed MRL is fully supported by data and no risk for consumers was identified. However, the possible occurrence of residues in rotational crops based on a total of 4 applications (4x 0.4 kg a.s./ha) has not been evaluated.

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

Key words: mepanipyrim, courgette, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, anilino-pyrimidine 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.

United Kingdom, hereafter referred to as the Evaluating Member State (EMS), received an application from the Horticultural Development Council (HDC)² to set a new MRL for the active substance mepanipyrim in courgettes. 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-2009-00214 and the following subject:

Mepanipyrim – Application to modify the existing MRL for mepanipyrim (mepanipyrim and its metabolite (2-anilino-4(2-hydroxypropyl)-6-methylpyrimidine)³ expressed as mepanipyrim) in courgettes from 0.01 mg/kg to 0.5 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.

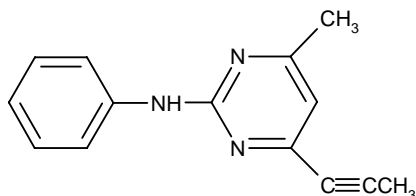
In this particular case the calculated deadline for providing the reasoned opinion is 14 April 2009.

² Horticultural Development Council (HDC), Bradbourne House, East Malling, ME19 6DZ Kent, United Kingdom

³ Metabolite also referenced as M-31 or KIF-3535-M-31 in different documents.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Mepanipyrim is the ISO common name for N-(4-methyl-6-prop-1-ynylpyrimidin-2-yl) aniline (IUPAC).



Mepanipyrim belongs to the class of anilino-pyrimidine fungicides. This non-systemic substance is highly active against the mycelial growth and is effective to control several diseases, especially grey mould (*Botrytis cinerea*) of vines and vegetables but also scab (*Venturia sp.*) of apples and pears and brown rot (*Monilinia fructicola*) of peaches. The effect on the uptake of various substances into mycelia and the effect on transport mechanisms are likely responsible for its antifungal activity.

Mepanipyrim has been peer reviewed in the framework of Directive 91/414/EEC as a new active substance, Italy being designated as Rapporteur Member State (RMS) and United Kingdom as Co-Rapporteur. Following the peer review, the active substance was included in Annex I to this Directive by Commission Directive 2004/62/EC for use as a fungicide only. The representative uses evaluated under this peer review refer to foliar applications on grape, tomato and strawberry. Both indoor and outdoor uses with two applications close to harvest were supported on tomato and strawberry. On grape, northern and southern uses were supported with a single application and a pre-harvest interval (PHI) of 21 days.

In the European Community, MRLs for mepanipyrim have been established on grapes (3 mg/kg), strawberries (2 mg/kg) and tomatoes (1 mg/kg) by Commission Directive 2005/70/EC of 20 October 2005 and on aubergines (1 mg/kg) by Commission Directive 2008/17/EC of 19 February 2008, the other values being at the LOQ. These MRLs have been transferred to Annex II of Regulation (EC) 396/2005 by Regulation EC 149/2008 of 29 January 2008. No CXLs have been established for mepanipyrim.

The United Kingdom has authorised the outdoor use of mepanipyrim on courgettes with a total of 4 applications at a rate of 0.400 kg a.s./ha, a pre-harvest interval of 2 day and an interval of 7 days between applications. The requested GAP is summarized in the appendix A.

ASSESSMENT

1. Methods of analysis

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

In the second addendum to the DAR (Italy, 2003), information was provided on a multi-residue method based on an ethyl acetate extraction, a GPC clean up and a quantification by GC/MS. This multi-residue method was shown to be suitable for quantifying the parent mepanipyrim only in grape and tomato puree with an LOQ of 0.01 mg/kg, but was not satisfactory to analyse strawberry jam (recoveries <70% and RDS >20%). In addition, EFSA notes that no ILV study was provided in the DAR to confirm the suitability of this method for enforcement.

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-residue methods. In the database developed by the Community Reference Laboratories for Residues of Pesticides (CRL, 2009), in total 702 data sets have been submitted regarding methods routinely used to determine mepanipyrim residues in different matrices. For water containing matrices the validation data have been obtained for several commodities (cucumber, apples, pears, carrots, lettuce, asparagus, aubergines etc). The validation data refer to the QuEChERS method and the ChemElut method. An overview is provided in Table 1-1.

Based on the overall availability of data it is concluded that sufficient analytical methods are available to enforce mepanipyrim in commodities with high water content, including courgettes.

Table 1-1. Validation data for analytical methods for mepanipyrim (CRL, 2009)

Chr	Matrix Type	Level min	Level max	Rec Median	Rec Mean	CV [%]	# of rec	% Rec (70-120%)	# of Labs
GC	Acidic	0,005	0,2	99	99	4,9	82	99	2
GC	Dry (cereals, dry pulses)	0,01	0,2	105	106	8,1	75	97	1
GC	Sugar containing	0,01	0,2	102	103	5,4	84	100	1
GC	Water containing	0,005	0,2	100	100	8,2	114	97	2
LC	Acidic	0,01	0,1	96	94	13,3	78	97	6
LC	Dry (cereals, dry pulses)	0,01	0,2	102	100	10	49	98	5
LC	Sugar containing	0,01	0,1	99	98	7,9	50	100	6
LC	Water containing	0,01	0,1	94	93	15	170	92	8

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

Analytical methods for the products of animal origin were not submitted since courgettes are not used as a livestock feed.

2. Mammalian toxicology

The toxicological reference values for mepanipyrim were derived in the peer review process of Directive 91/414/EEC (European Commission, 2004) and are compiled in Table 2-1 below.

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Parent compound mepanipyrim					
ADI	COM	2004	0.02	Rat, 2 years	100
ARfD	COM	2004	0.30	Rabbit, teratogenesis	100

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 performed with foliar applications on grapes, tomatoes and apples using radio-labelled forms of the active ingredient on both the aniline and the pyrimidine moiety.

Parent mepanipyrim was the major component of the radioactive residues, accounting for 23-38% and 56-70% of the TRR in tomatoes and apples respectively. The other identified compounds were observed in low proportions, none of them being more than 10% of the TRR. In grape, parent mepanipyrim was also found to be the main compound, accounting for 39-44% TRR, but with significant proportions of metabolite M-31⁴ (20-30% TRR). These highest residue levels of M-31 in grapes are the consequence of the longer intervals between applications and harvest investigated in the grape studies (3 applications, the first more than 100 days before harvest) rather than a specific metabolic profile of mepanipyrim in this crop. Considering the above studies and the fact that metabolite M-31 was not observed in the rodent metabolism, the RMS proposed in the DAR to set the plant residue definition as the “*sum of mepanipyrim + its metabolite M-31 expressed as mepanipyrim*”.

However, taking into account the addenda to the DAR, the discussions and the conclusions of the peer review process (European Commission, 2003), the residue for enforcement and risk assessment in plants was finally defined as the parent mepanipyrim alone considering that:

- Although M-31 was not identified as a rat metabolite, it was considered not to raise any additional toxicological concerns as it is structurally very similar to rat metabolites M-45⁵, M-36⁶ and is also considered likely to be an intermediate rat metabolite. Moreover, in specific studies it was found to be of low acute oral toxicity and was shown not to be mutagenic in an Ames test.

⁴ 2-anilino-4-(2-hydroxypropyl)-6-methylpyrimidine

⁵ 2-(4-hydroxyanilino)-4-(2-hydroxypropyl)-6-methylpyrimidine

⁶ 2-anilino-4-(2,3-dihydroxypropyl)-6-methylpyrimidine

- In the supervised residue trials performed in compliance with the proposed GAPs, M-31 was always observed in lower amounts than mepanipyrim, representing less than 13%, 9% and 5% of the parent residue levels in grape, tomato and strawberry respectively.

The final residue definition resulting from the peer review and limited to the parent mepanipyrim was however not taken into account when MRLs were proposed at European level. The residue definition stated in Commission Directives 2005/70/EC, 2008/17/EC and subsequently transposed to Regulation (EC) 396/2005, refers to the sum of the parent and its metabolite M-31. Since there is clear evidence from the metabolism studies and the supervised residue trials that mepanipyrim alone is a good marker for the residues in fruit crops, EFSA proposes that the current residue definition for enforcement stated in Annex II to Regulation (EC) No 396/2005 is reconsidered and limited to the parent compound only.

The residue definition proposed for the fruit crop group in the framework of the peer review is also relevant for courgettes.

3.1.1.2. Magnitude of residues

In support to the proposed GAP on courgettes, 4 supervised residue trials performed in the United Kingdom over 2 years have been reported in the evaluation report submitted by the United Kingdom. Trials were conducted outdoor on 4 different varieties with a total of 4 treatments at a rate of 0.400 kg a.s./ha. The number of trials is deemed to be sufficient to derive an MRL, since courgette is considered as a minor crop.

Samples were analysed for the parent mepanipyrim only according to the residue definition as stated in the full report (European Commission, 2003). The method involving an ethyl acetate extraction followed by GC-MS analyse (m/z 222) was considered sufficiently validated with recoveries in the range of 75% to 97% and a LOQ of 0.01 mg/kg.

According to the DAR (Italy, 2000), the stability of mepanipyrim residues has been demonstrated over a storage period of 19 months at -20°C in high water content matrices (grapes, tomatoes and strawberries) and in some processed commodities. These results are relevant for the trials performed on courgettes where samples were stored frozen for up to 3 months before being analysed.

The results of the residue trials and the MRL proposal are summarized in the table 3-1. Although the applicant proposes an MRL of 0.5 mg/kg, EFSA is of the opinion that an MRL of 0.6 mg/kg would be more appropriate based on the R_{ber} calculation, which is considered to be the most reliable for small data sets.

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					
<u>Residue definition for enforcement and risk assessment: mepanipyrim</u>									
Courgettes	NEU	Outdoor	0.07; 0.09; 0.17; 0.31	0.07; 0.09; 0.17; 0.31	0.13	0.31	0.6	1.0	PHI 2 days Rmax: 0.72 Rber: 0.55

(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.

3.1.1.3. Effect of industrial processing and/or household preparation

No standard hydrolytic study (simulating sterilisation, baking and pasteurisation) on the nature of the residues has been reported in the DAR (Italia, 2000), although residues in the RAC from the supported uses were observed at significant amounts.

Studies on the magnitude of the residues in processed commodities were investigated on grape, tomato and strawberry and processing factors were derived for the parent mepanipyrim in the relevant processed products. These processing studies are not relevant for courgettes but considering the low contribution of this crop to the consumer intake (see section 4) EFSA is of the opinion that no additional information is necessary in the framework of this application.

3.1.2. Rotational crops

Courgettes are grown in rotation with other crops and taking into account the mean DT_{90} value for mepanipyrim of 188 days (range 114-249 days) derived from the aerobic field studies, investigation of residue in rotational crop is required. Relevant soil metabolites were not identified.

No rotational crop studies were reported in the DAR (Italy, 2000), but an argumentation was provided by the applicant and evaluated in the first addendum to the DAR (Italy, 2002). Following a step by step approach and taking into account the results from a plant absorption study showing that mepanipyrim is not a systemic product when applied onto the soil, it was concluded that following two applications on tomato at a rate of 0.400 kg/ha, no quantifiable residues are expected in the rotational crops and no specific studies are necessary.

These conclusions however, based on 2 applications only, do not cover the GAP proposed for courgettes, which includes a total of 4 applications. EFSA is therefore not able to conclude whether significant residues might be expected in rotational crops after the use of mepanipyrim in courgettes. It is proposed that Member States take the appropriate measures in order to avoid occurrence of mepanipyrim residues in rotational crops.

3.2. Nature and magnitude of residues in livestock

Occurrence of mepanipyrim residues in food of animal origin was not considered in the framework of this application. Courgettes are usually not fed to animals and residues in animal commodities resulting from the reported GAP are therefore not expected.

4. Consumer risk assessment

The chronic and acute consumer risk assessments were performed with revision 2 of the EFSA PRIMo using the MRLs as established in Annex II of Regulation (EC) No 396/2005 and the STMR and HR values derived for the intended use on courgettes. Input values are summarized in Table 4-1.

The results of the chronic intake and acute calculations are reported in Appendix C. No chronic concern was identified for any of the European diets, the maximum TMDI value representing 31% of the ADI for the German child and courgettes contributing to a minor extent to the overall dietary burden (maximum 0.4% of the ADI for the French infant). No acute intake risk was identified for courgette as the IESTI is 4.8% of the ARfD.

It is concluded that the proposed use of mepanipyrim on courgettes is acceptable with regard to the consumer safety.

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: <i>mepanipyrim</i>				
Courgettes	0.13	STMR	0.31	HR

CONCLUSIONS AND RECOMMENDATIONS

According to Article 6(1) of Regulation (EC) No 396/2005, the United Kingdom received an application from the Horticultural Development Council (HDC) to modify the existing MRL for mepanipyrim in courgettes. In order to accommodate for a new use in this crop, the applicant proposes to raise the existing MRL from 0.01* to 0.5 mg/kg. The evaluation report drafted by the United Kingdom was forwarded to EFSA on 14 January 2009 according to Article 9 of the Regulation. Based on this evaluation report, the Draft Assessment Report (DAR) and the addenda to the DAR prepared by the Rapporteur Member State (RMS) Italy under Directive 91/414/EEC, EFSA derives the following conclusions regarding this application.

The metabolism of mepaniryrim was investigated only in the fruit crop group following foliar applications (grapes, apples and tomatoes). The parent mepanipyrim was shown to be the major component of the residue accounting for up to 70% of the TRR in tomatoes. However, due to the longer PHI intervals investigated, the metabolite 2-anilino-4(2-hydroxypropyl)-6-methylpyrimidine (M-31) was observed in significant proportions (20-30% TRR) on grapes at harvest while it was less than 1% of the TRR in apples and tomatoes. The initial proposal suggested by the RMS to include this metabolite in the residue definition was finally not supported in the course of the peer review. Taking into account information on its toxicological relevance and the fact that M-31 was detected in low amounts in the supervised residue trials performed in compliance with the GAPs, the residue definition for enforcement and risk assessment was limited to the parent only. However, this final residue definition resulting from the peer review process performed in the framework of Directive 91/414/EEC was not taken into account when MRLs were proposed at European Community level and the residue definition stated in Regulation (EC) N° 396/2005 refers to the sum of the parent and its metabolite M-31, expressed as mepanipyrim.

Since there is clear evidence from the metabolism studies and the supervised residue trials that mepanipyrim alone is a good marker for the residues in fruit crops, EFSA proposes that the residue definition for enforcement stated in Annex II to Regulation (EC) No 396/2005 should be limited to the parent compound only.

The residue trials provided were considered sufficient to derive an MRL for courgettes grown outdoor. Although an MRL of 0.5 mg/kg is proposed by the applicant, EFSA is of the opinion that an MRL of 0.6 mg/kg would be more appropriate. Adequate analytical methods for enforcement of the proposed MRL are available.

In the framework of Directive 91/414/EEC, it was concluded that no residues are expected in rotational crops following 2 applications of mepanipyrim at a rate of 0.4 kg/ha on tomatoes. EFSA is of the opinion that the conclusion reached for tomatoes considering 2 applications is not relevant for courgettes since the GAP includes a total of 4 applications. It is therefore concluded that Member States should reconsider the possible occurrence of residues in rotational crops when granting an authorisation on courgettes based on a total of 4 application at a rate of 0.4 kg a.s./ha.

Residues in commodities of animal origin were not assessed considering that courgettes are usually not fed to livestock.

The chronic and acute intake resulting from the proposed MRL were calculated using revision 2 of the EFSA PRIMo and the existing MRLs listed in Annex II to Regulation (EC) No

396/2005. No chronic or acute concerns were identified for all available European diets. 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
<u>Residue definition for enforcement: mepanipyrim</u>			
Courgettes	0.01*	0.6	The proposed MRL is fully supported by data and no risk for consumers was identified. However, the possible occurrence of residues in rotational crops based on a total of 4 applications (4x 0.4 kg a.s./ha) has not been evaluated.

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

DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report on the modification of a MRL for mepanipyrim on courgettes prepared under Regulation (EC) No 396/2005 by the Pesticide Safety Directorate, UK. Forwarded to EFSA on 14 January 2009.

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Crop and/or situation	Member state or Country	Product name	F G or I (a)	Pests or Groups of pests controlled	Formulation		Application			Application rate per treatment			PHI (days) (b)	Remarks
					Type	Conc. of as	method kind	growth stage	number min max	kg as/hL min max	water L/ha min max	kg as/ha max min		
Courgettes	UK (NEU)	FRUPICA SC	F	<i>Botrytis cinerea</i>	SC	449g/L	foliar application	-	1 - 4	0.04	1000	0.4	2	

(a): Outdoor or field use (F), Glasshouse application (G) or indoor application (I)

(b): PHI - minimum pre-harvest interval

APPENDIX B – LIST OF EXISTING EC MRLs

Pesticides-Web Version-EU MRLs (File created on 17/03/2009 17:46)		
Code number	Groups and examples of individual products to which the MRLs apply (a)	MRL (1)
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	Mandarins (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	3
151010	Table grapes	3
151020	Wine grapes	3
152000	(b) Strawberries	2

153000	(c) Cane fruit	0,01*
153010	Blackberries Dewberries (Loganberries, Boysenberries, and cloudberrries)	0,01*
153020	Raspberries (Wineberries)	0,01*
153030	Others	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) Gooseberries (Including hybrids with other ribes species)	0,01*
154040	Rose hips	0,01*
154050	Mulberries (arbutus berry)	0,01*
154060	Azarole (mediteranean medlar)	0,01*
154070	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,01*
154080	Others	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, Brazilean 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*	231040	Okra, lady's fingers	0,01*
163040	Papaya	0,01*	231990	Others	0,01*
163050	Pomegranate	0,01*	232000	(b) Cucurbits - edible peel	0,01*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,01*	232010	Cucumbers	0,01*
163070	Guava	0,01*	232020	Gherkins	0,01*
163080	Pineapples	0,01*	232030	Courgettes (Summer squash, marrow (patisson))	0,01*
163090	Bread fruit (Jackfruit)	0,01*	232990	Others	0,01*
163100	Durian	0,01*	233000	(c) Cucurbits-inedible peel	0,01*
163110	Soursop (guanabana)	0,01*	233010	Melons (Kiwano)	0,01*
163990	Others	0,01*	233020	Pumpkins (Winter squash)	0,01*
200000	2. VEGETABLES FRESH OR FROZEN		233030	Watermelons	0,01*
210000	(i) Root and tuber vegetables	0,01*	233990	Others	0,01*
211000	(a) Potatoes	0,01*	234000	(d) Sweet corn	0,01*
212000	(b) Tropical root and tuber vegetables	0,01*	239000	(e) Other fruiting vegetables	0,01*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,01*	240000	(iv) Brassica vegetables	0,01*
212020	Sweet potatoes	0,01*	241000	(a) Flowering brassica	0,01*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,01*	241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,01*
212040	Arrowroot	0,01*	241020	Cauliflower	0,01*
212990	Others	0,01*	241990	Others	0,01*
213000	(c) Other root and tuber vegetables except sugar beet	0,01*	242000	(b) Head brassica	0,01*
213010	Beetroot	0,01*	242010	Brussels sprouts	0,01*
213020	Carrots	0,01*	242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,01*
213030	Celeriac	0,01*	242990	Others	0,01*
213040	Horseradish	0,01*	243000	(c) Leafy brassica	0,01*
213050	Jerusalem artichokes	0,01*	243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,01*
213060	Parsnips	0,01*	243020	Kale (Borecole (curly kale), collards)	0,01*
213070	Parsley root	0,01*	243990	Others	0,01*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,01*	244000	(d) Kohlrabi	0,01*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,01*	250000	(v) Leaf vegetables & fresh herbs	0,01*
213100	Swedes	0,01*	251000	(a) Lettuce and other salad plants including Brassicacea	0,01*
213110	Turnips	0,01*	251010	Lamb's lettuce (Italian cornsalad)	0,01*
213990	Others	0,01*	251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,01*
220000	(ii) Bulb vegetables	0,01*	251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,01*
220010	Garlic	0,01*	251040	Cress	0,01*
220020	Onions (Silverskin onions)	0,01*	251050	Land cress	0,01*
220030	Shallots	0,01*	251060	Rocket, Rucola (Wild rocket)	0,01*
220040	Spring onions (Welsh onion and similar varieties)	0,01*	251070	Red mustard	0,01*
220990	Others	0,01*	251080	Leaves and sprouts of Brassica spp (Mizuna)	0,01*
230000	(iii) Fruiting vegetables				
231000	(a) Solanacea				
231010	Tomatoes (Cherry tomatoes,)	1			
231020	Peppers (Chilli peppers)	0,01*			
231030	Aubergines (egg plants) (Pepino)	1			

251990	Others	0,01*	270090	Palm hearts	0,01*
252000	(b) Spinach & similar (leaves)	0,01*	270990	Others	0,01*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,01*	280000	(viii) Fungi	0,01*
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	
254000	(d) Water cress	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	0,01*	300020	Lentils	0,01*
256010	Chervil	0,01*	300030	Peas (Chickpeas, field peas, chickling vetch)	0,01*
256020	Chives	0,01*	300040	Lupins	0,01*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,01*	300990	Others	0,01*
256040	Parsley	0,01*	400000	4. OILSEEDS AND OILFRUITS	
256050	Sage (Winter savory, summer savory,)	0,01*	401000	(i) Oilseeds	0,02*
256060	Rosemary	0,01*	401010	Linseed	0,02*
256070	Thyme (marjoram, oregano)	0,01*	401020	Peanuts	0,02*
256080	Basil (Balm leaves, mint, peppermint)	0,01*	401030	Poppy seed	0,02*
256090	Bay leaves (laurel)	0,01*	401040	Sesame seed	0,02*
256100	Tarragon (Hysstop)	0,01*	401050	Sunflower seed	0,02*
256990	Others	0,01*	401060	Rape seed (Bird rapeseed, turnip rape)	0,02*
260000	(vi) Legume vegetables (fresh)	0,01*	401070	Soya bean	0,02*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,01*	401080	Mustard seed	0,02*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,01*	401090	Cotton seed	0,02*
260030	Peas (with pods) (Mangetout (sugar peas))	0,01*	401100	Pumpkin seeds	0,02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,01*	401110	Safflower	0,02*
260050	Lentils	0,01*	401120	Borage	0,02*
260990	Others	0,01*	401130	Gold of pleasure	0,02*
270000	(vii) Stem vegetables (fresh)	0,01*	401140	Hempseed	0,02*
270010	Asparagus	0,01*	401150	Castor bean	0,02*
270020	Cardoons	0,01*	401990	Others	0,02*
270030	Celery	0,01*	402000	(ii) Oilfruits	
270040	Fennel	0,01*	402010	Olives for oil production	0,01*
270050	Globe artichokes	0,01*	402020	Palm nuts (palmoil kernels)	0,02*
270060	Leek	0,01*	402030	Palmfruit	0,02*
270070	Rhubarb	0,01*	402040	Kapok	0,02*
270080	Bamboo shoots	0,01*	402990	Others	0,02*
			500000	5. CEREALS	0,01*
			500010	Barley	0,01*
			500020	Buckwheat	0,01*
			500030	Maize	0,01*
			500040	Millet (Foxtail millet, teff)	0,01*
			500050	Oats	0,01*
			500060	Rice	0,01*
			500070	Rye	0,01*
			500080	Sorghum	0,01*
			500090	Wheat (Spelt Triticale)	0,01*
			500990	Others	0,01*

600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,02*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i>)	0,02*
620000	(ii) Coffee beans	0,02*
630000	(iii) Herbal infusions (dried)	0,02*
631000	(a) Flowers	0,02*
631010	Camomille flowers	0,02*
631020	Hybiscus flowers	0,02*
631030	Rose petals	0,02*
631040	Jasmine flowers	0,02*
631050	Lime (linden)	0,02*
631990	Others	0,02*
632000	(b) Leaves	0,02*
632010	Strawberry leaves	0,02*
632020	Rooibos leaves	0,02*
632030	Maté	0,02*
632990	Others	0,02*
633000	(c) Roots	0,02*
633010	Valerian root	0,02*
633020	Ginseng root	0,02*
633990	Others	0,02*
639000	(d) Other herbal infusions	0,02*
640000	(iv) Cocoa (fermented beans)	0,02*
650000	(v) Carob (st johns bread)	0,02*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,02*
800000	8. SPICES	0,02*
810000	(i) Seeds	0,02*
810010	Anise	0,02*
810020	Black caraway	0,02*
810030	Celery seed (Lovage seed)	0,02*
810040	Coriander seed	0,02*
810050	Cumin seed	0,02*
810060	Dill seed	0,02*
810070	Fennel seed	0,02*
810080	Fenugreek	0,02*
810090	Nutmeg	0,02*
810990	Others	0,02*
820000	(ii) Fruits and berries	0,02*
820010	Allspice	0,02*
820020	Anise pepper (Japan pepper)	0,02*
820030	Caraway	0,02*
820040	Cardamom	0,02*
820050	Juniper berries	0,02*
820060	Pepper, black and white (Long pepper, pink pepper)	0,02*
820070	Vanilla pods	0,02*
820080	Tamarind	0,02*
820990	Others	0,02*
830000	(iii) Bark	0,02*
830010	Cinnamon (Cassia)	0,02*

830990	Others	0,02*
840000	(iv) Roots or rhizome	0,02*
840010	Liquorice	0,02*
840020	Ginger	0,02*
840030	Turmeric (<i>Curcuma</i>)	0,02*
840040	Horseradish	0,02*
840990	Others	0,02*
850000	(v) Buds	0,02*
850010	Cloves	0,02*
850020	Capers	0,02*
850990	Others	0,02*
860000	(vi) Flower stigma	0,02*
860010	Saffron	0,02*
860990	Others	0,02*
870000	(vii) Aril	0,02*
870010	Mace	0,02*
870990	Others	0,02*
900000	9. SUGAR PLANTS	0,01*
900010	Sugar beet (root)	0,01*
900020	Sugar cane	0,01*
900030	Chicory roots	0,01*
900990	Others	0,01*
1000000	10. PRODUCTS of ANIMAL ORIGIN-TERRESTRIAL ANIMALS	no MRLs

Pesticide residues and maximum residue levels (mg/kg)

(*) Indicates lower limit of analytical determination

(1): Residue defined as Mepanipyrim and its metabolite (2-anilino-4-(2-hydroxypropyl)-6-methylpyrimidine) expressed as mepanipyrim)

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

mepanipyrim			
Status of the active substance:	Included	Code no.:	
LOQ (mg/kg bw):	0.01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	0.3
Source of ADI:	Review Report 2004	Source of ARfD:	Review Report 2004
Year of evaluation:	2004	Year of evaluation:	2004

Explain choice of toxicological reference values. MRL values for table grape, strawberries, tomatoes, aubergines and courgettes and MRL^p for wine grapes

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

		TMDI (range) in % of ADI minimum - maximum						
		4 31						
		No of diets exceeding ADI:						

Highest calculated TMDI values in % of ADI	MS Diet	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)
		Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities			
30.5	DE child	19.0	Table grapes	4.9	Strawberries	4.8	Tomatoes	1.7
26.4	WHO Cluster diet B	15.4	Tomatoes	5.2	Table grapes	1.6	Wine grapes	1.6
18.4	NL child	11.4	Table grapes	3.1	Tomatoes	2.3	Strawberries	1.5
14.7	FR toddler	6.2	Strawberries	3.9	Tomatoes	3.1	Table grapes	1.1
12.3	IE adult	3.9	Table grapes	2.5	Strawberries	2.0	Tomatoes	1.2
12.0	PT General population	4.5	Tomatoes	4.2	Table grapes	2.2	Wine grapes	0.7
11.2	IT kids/toddler	7.1	Tomatoes	1.6	Table grapes	1.2	Strawberries	0.7
11.0	UK Toddler	3.7	Table grapes	2.9	Tomatoes	2.0	Strawberries	2.0
9.9	WHO regional European diet	5.5	Tomatoes	2.3	Table grapes	0.9	Strawberries	0.8
9.9	PL general population	4.8	Table grapes	4.4	Tomatoes	0.2	Root and tuber vegetables	0.4
9.8	WHO cluster diet D	5.1	Tomatoes	2.8	Table grapes	0.4	CEREALS	0.9
9.5	IT adult	5.8	Tomatoes	2.0	Table grapes	0.6	Aubergines (egg plants)	0.5
9.0	FR all population	3.6	Wine grapes	2.2	Tomatoes	1.6	Table grapes	0.4
8.5	WHO cluster diet E	2.6	Tomatoes	2.3	Table grapes	1.4	Wine grapes	0.9
8.1	FR infant	4.9	Strawberries	1.2	Table grapes	0.7	Tomatoes	0.8
7.6	NL general	3.4	Table grapes	2.1	Tomatoes	0.8	Strawberries	0.6
7.6	DK child	2.7	Table grapes	2.7	Tomatoes	1.0	Strawberries	1.1
7.3	WHO Cluster diet F	3.4	Tomatoes	1.7	Table grapes	0.7	Strawberries	0.7
7.1	ES child	4.9	Tomatoes	0.7	Strawberries	0.5	Table grapes	0.8
6.9	SE general population 90th percentile	3.8	Tomatoes	1.7	Strawberries	0.3	Aubergines (egg plants)	1.0
6.5	UK vegetarian	3.1	Tomatoes	1.1	Table grapes	0.7	Strawberries	0.6
6.3	ES adult	3.9	Tomatoes	0.7	Table grapes	0.6	Strawberries	0.5
5.9	UK Infant	2.2	Strawberries	1.8	Tomatoes	0.5	SUGAR PLANTS	1.3
5.3	DK adult	2.1	Tomatoes	1.3	Wine grapes	1.2	Table grapes	0.4
5.1	UK Adult	2.2	Tomatoes	1.0	Wine grapes	0.8	Table grapes	0.5
4.3	LT adult	3.1	Tomatoes	0.4	Strawberries	0.2	Table grapes	0.5
3.8	FI adult	2.1	Tomatoes	0.8	Strawberries	0.3	Table grapes	0.3

Conclusion:

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

Acute risk assessment /children	Acute risk assessment / adults / general population
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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):		
	---			---			---			---		
	**)			**)			**)			**)		
	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)
4.8	Courgettes	0.31 / -	3.4	Courgettes	0.31 / -	2.8	Courgettes	0.31 / -	2.1	Courgettes	0.31 / -	
No of critical MRLs (IESTI 1)			---			No of critical MRLs (IESTI 2)			---			

Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	---			---			---			---		
	***)			***)			***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL

***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For 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.

GLOSSARY / ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/EEC)
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	European union
GAP	good agricultural practice
GC	gas chromatography
ha	hectare
hl	hectolitre
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
L	litre
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
PSD	Pesticide Safety Directorate, United Kingdom
RMS	Rapporteur Member State
SC	suspension concentrate
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue