

REASONED OPINION

Modification of the existing MRL for mandipropamid in garden cress¹

European Food Safety Authority²

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

According to Article 6 of Regulation (EC) No 396/2005, Belgium, hereafter referred to as the Evaluating Member State (EMS), has compiled an application to modify the existing MRL for mandipropamid in cress (*Lepidium sativum*). In order to accommodate for a new use of mandipropamid in Belgium, it was proposed to raise the existing MRL for cress from 0.01 mg/kg to 10 mg/kg. Belgium elaborated an evaluation report according to Article 8 of the regulation which was submitted to the European Commission and forwarded to EFSA on 29 May 2009.

EFSA derives the following conclusions regarding the application, based on the abovementioned evaluation report as well as the Draft Assessment Report (DAR) prepared by Rapporteur Member State (RMS) Austria and the JMPR evaluation 2008. As the peer review under Directive 91/414/EEC is not yet finalised, conclusions reached in this reasoned opinion are temporary and might be reconsidered in the light of the outcome of the peer review.

The toxicological profile of mandipropamid was assessed by the RMS. The data were sufficient to conclude on an ADI value 0.03 mg/kg. Because of the low acute toxicity of the active substance, the RMS is of the opinion that it is not necessary to establish an ARfD.

The metabolism of mandipropamid was investigated in potatoes, grapes, lettuce and tomatoes. The main component identified was the parent active substance. Thus, the RMS proposed to restrict the residue definitions for enforcement and risk assessment to mandipropamid. For this residue definition a validated analytical method is available to be used by enforcement laboratories.

No specific supervised field trials on cress are available, but the EMS proposed to use the indoor and outdoor trials performed in lettuce to estimate the expected residues in cress. Although the GAPs of lettuce and cress are comparable in terms of the application rate and the PHI, the growth stage of the crops at the time of the pesticide application is significantly different. Thus, EFSA is of the opinion that the trials on lettuce are not representative for the residue situation in cress; these trials are expected to underestimate the residues in garden cress if treated in the same way as lettuce, because cress has a very short vegetation period of two to four weeks only and is characterised by a more critical ratio of leaf surface exposed to the foliar application and leaf mass (yield) compared with lettuce. In order to establish a MRL for garden cress, specific supervised residue trials in cress or a crop with similar growth characteristic should be provided.

1 On request from the European Commission , Question No EFSA-Q-2009-00647, issued on 10 September 2009.

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Lacking reliable data on the magnitude of residues in cress, a consumer risk assessment was not performed.

EFSA concludes that the data provided in the framework of the application are not sufficient to recommend a MRL for cress.

KEY WORDS

Mandipropamid, cress, *Lepidium sativum*, MRL application, Regulation (EC) No 396/2005, consumer risk assessment

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BACKGROUND

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

Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRL for the active substance mandipropamid in garden cress. This application was notified to the European Commission and EFSA and subsequently evaluated 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 29 May 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00647 and the following subject:

Mandipropamid - Application to modify the existing MRL for mandipropamid in cress from 0.01 mg/kg to 10 mg/kg*

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

TERMS OF REFERENCE

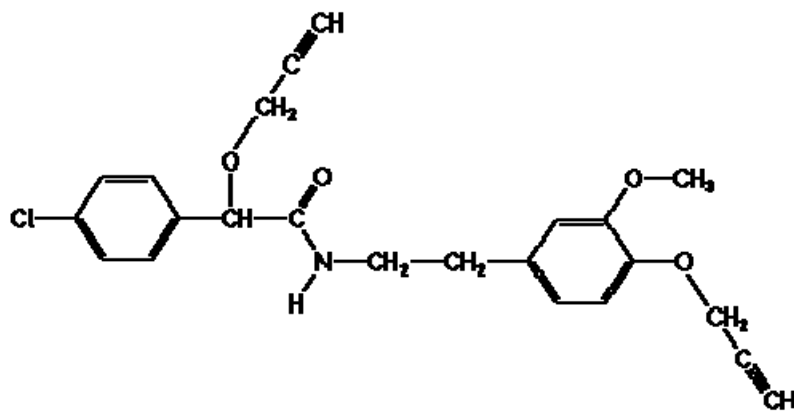
According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

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 date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion is 29 August 2009.

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.



Mandipropamid is a fungicide belonging to the class of mandelamides. It is used to control foliar *Oomycete* pathogens in different crops. Its activity is presumably by interfering with the biosynthesis of phospholipids.

Mandipropamide is a new active substance according to the definition of Directive 91/414/EEC with Austria being the designated as Rapporteur Member State (RMS). The representative uses supported for the peer review process are foliar applications on potato, tomato, melon, cucumber, lettuce and vines. Currently a range of provisional authorisations have been granted in European Member States for which temporary MRLs have been established in Annex III of Regulation (EC) No 396/2005. The currently valid EC MRLs are listed in Appendix C. It is noted that Codex Alimentarius recently adopted MRLs for grapes and a wide range of vegetables.

In January 2009, EFSA has issued a reasoned opinion regarding the modification of existing MRLs for mandipropamid in leafy vegetables (EFSA, 2009). The amendment of the MRLs for red mustard, leaves and sprouts of *Brassica spp.*, spinach, purslane and beet leaves is currently under preparation.

Belgium intends authorising the use of a mandipropamid containing plant protection product to protect garden cress grown indoor and outdoor against mildew. The product should be applied once or twice to the crop with an application rate of 150 g/ha seven days before the harvest. More details of the GAP are reported in Appendix A. EFSA asked for further clarifications regarding the agricultural practice, in particular on the cultivation conditions. The EMS provided the following explanations: Cress is mainly cultivated under glass in soil bound culture, but also on substrate. Cress grown in the soil is mainly used in mass catering and restaurants, whereas cress grown on substrate is mainly used for supermarkets and specialist stores. Garden cress is sown and harvested the year round. In the winter season, the duration of the culture is three to four week. The time between sowing and emergence is *ca.* five days. In the summer period the duration of the culture is *ca.* 15 days, the time between sowing and emergence is *ca.* three day.

The current MRL for garden cress (*Lepidium sativum*, Code no. 0251040 in Annex I of Regulation 396/2005) is established at the level of 0.01 mg/kg which is equivalent to the limit of quantification. According to the EMS it would be necessary to raise the MRL to 10 mg/kg to accommodate for the intended use in Belgium. Codex has established a group tolerance of 25 mg/kg for leafy vegetables which would also be applicable to garden cress.

EFSA based its assessment on the evaluation report submitted by Belgium, the Draft Assessment Report prepared by the RMS Austria (2006) and the JMPR report (WHO/FAO, 2008). As the peer

review is not yet finalised, the conclusions reached in this reasoned opinion are temporary and might be reconsidered after the finalisation of the peer review.

ASSESSMENT

1. Methods of analysis

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

The availability of analytical methods for enforcement of mandipropamid residues was not addressed in the evaluation report prepared by Belgium.

According to the DAR prepared by Austria (2006), a sufficiently validated method for enforcement of mandipropamid is available for matrices with a high water, high acid and high oil content as well as for dry commodities. The LOQ achievable in routine monitoring is 0.01 mg/kg in all matrices.

Garden cress is a crop belonging to the crop group with high water content. Thus, it is concluded that the validated method would be also applicable to enforce MRLs in garden cress for the enforcement residue definition mandipropamid.

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

Analytical methods for food of animal origin are not relevant in the framework of this application since garden cress is not fed to livestock.

2. Mammalian toxicology

The toxicological properties of mandipropamid have been evaluated in the DAR prepared under Directive 91/414/EEC (Austria, 2006) and a ADI proposal has been derived (Table 2.1). Due to the low acute toxicity it was concluded by the RMS that no ARfD is necessary. Awaiting the peer review to be finalised, EFSA will base its preliminary risk assessment on the ADI and ARfD proposed by the RMS.

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		Not necessary	

It is noted that JMPR derived an ADI of 0.4 mg/kg b.w. based on the NOAEL of 15.2 mg/kg bw/d, identified on the basis of decreased body weight and kidney effects at 61.3 mg/kg bw/d in the long-term dietary study in rats and using a safety factor of 100. JMPR also concluded that the setting of an ARfD was not necessary (WHO/FAO, 2008).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

In the framework of including mandipropamid in Annex I of Directive 91/414/EEC, the manufacturer provided plant metabolism studies in grapes, lettuce, potatoes and tomatoes to the RMS Austria, who has evaluated these studies in the DAR (Austria, 2006). Since mandipropamid was the major component identified, the RMS proposed to establish the residue definitions for enforcement and risk assessment as parent compound in both cases. EFSA followed the proposal of the RMS in the assessment of the MRL application on leafy vegetables (EFSA, 2009). Thus, no further metabolism data are currently required for the application on cress.

3.1.1.2. Magnitude of residues

The EMS did not report specific supervised field trials performed on garden cress but refers to indoor and outdoor trials performed in lettuce which were already evaluated by the RMS in the Draft Assessment Report (Austria, 2006) and which were the basis for the temporary MRLs proposed for several crops belonging to the group of leafy vegetables (EFSA, 2009). In total, eight Northern outdoor trials and eight indoor trials performed in 2003 and 2004 in France, Switzerland, Spain and Italy were reported. These trials are identical with the trials reported in the the DAR (Austria, 2006). No information could be derived on the lettuce varieties whether they belong to the head forming or on open leaf varieties. The results of the reported lettuce trials are summarised in Table 3-1.

Although the intended GAP for cress is comparable with the treatment regime in the supervised field trials on lettuce in terms of application rate (1 or 2 *150 g a.s./ha) and PHI (7 d PHI), a significant difference might exist with regard to the growth stage of the crop at the time of the treatment. The growth stage in the supervised field trials in lettuce as reported in the DAR was BBCH 41 to 49 (in head forming leaf vegetables this corresponds to “heads begin to form to typical size” to “form and firmness of heads reached”); the growth stage of cress seven days before harvest is expected not reported in the GAP table.

It is noted that an extrapolation from lettuce to garden cress is not explicitly mentioned in the guidance document (European Commission, 2008); a general extrapolation is possible from lettuce to the whole group of lettuce and other salad plants in case the active substance is used up to or close to the harvest, but possible residues in lamb’s lettuce and cress should be considered. In addition, the guidance document allows extrapolation from lettuce to herbs.

EFSA is of the opinion that the supervised trials on lettuce are not representative for the residue situation in cress; these trials are expected to underestimate the residues in garden cress if treated in the same way as lettuce, because cress has a very short vegetation period of two to four weeks only and is characterised by a critical ratio of leaf surface to leaf mass (low yield) compared with lettuce (vegetation period 5 to 12 weeks). Thus, EFSA does not recommend MRL extrapolation from lettuce to garden cress.

EFSA recommends that specific supervised residue trials in cress or a crop with similar growth characteristic (e.g. lamb’s lettuce) should be provided for establishing a MRL for garden cress.

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 (mandipropamid)	Risk assessment (mandipropamid)					
Lettuce → garden cress	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	R _{ber} = 3.05 R _{max} =3.54 No MRL proposed	1	The trials were performed on lettuce. EFSA does not recommend extrapolating the results to cress because due to the nature of the crop, higher residues are likely on cress than on lettuce. Thus, no MRL proposal is derived.
Lettuce → garden cress	EU	Indoor	0.93; 1.3; 1.8; 2.5; 3.0; 2*3.2; 3.3	0.93; 1.3; 1.8; 2.5; 3.0; 2*3.2; 3.3	2.8	3.3	R _{ber} =6.40 R _{max} =5.40 No MRL proposed		

(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

Garden cress is a crop that is not expected to be consumed in processed form. Processing studies are therefore not required.

3.1.2. Rotational crops

The nature of residues in rotational crops was evaluated by the RMS in the DAR (Austria, 2006). Based on the available studies it is concluded that metabolism in rotational crops is similar to the metabolism observed in primary crops.

Regarding the magnitude of residues in succeeding crops data are available on lettuce, radish and wheat planted 29, 58, 120 and 365 days after the treatment of soil with 900 g/kg. These studies demonstrate that residues exceeding the LOQ of 0.01 mg/kg are expected only in wheat straw at plant back intervals shorter or equal to 29 and 58 days. (Austria, 2006).

For garden cress grown on substrate, rotational crop studies are not relevant. However, for cress grown in soil, the possible occurrence of residues in rotational crops should be addressed. Although the intended application rate is significantly lower than the application rate applied in the rotational crop studies, the potential of residues in succeeding crops cannot be excluded because of the short the vegetation period for garden cress (15 to 28 days) compared with the minimum plant back interval investigated in the confined rotational crop study (29 days). EFSA therefore concludes that further data would be required demonstrating that no residues are expected in rotational crops grown after cress.

3.2. Nature and magnitude of residues in livestock

The nature and magnitude of residues in livestock was not further considered in the framework of this application because the crops under evaluation are normally not fed to animals and therefore residues in animal commodities resulting from the use on garden cress are not expected.

4. Consumer risk assessment

EFSA performed a chronic consumer risk assessment in the framework of the assessment of leafy vegetables (EFSA, 2009). Since the data provided in support of this application on cress are considered not sufficient, no updated consumer risk assessment is calculated.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

As the peer review under Directive 91/414/EEC is not yet finalised, conclusions reached in this reasoned opinion are temporary and might be reconsidered in the light of the outcome of the peer review.

The toxicological profile of mandipropamid was assessed by the RMS. The data were sufficient to conclude on an ADI value 0.03 mg/kg. Because of the low acute toxicity of the active substance, the RMS is of the opinion that it is not necessary to establish an ARfD.

The metabolism of mandipropamid was investigated in potatoes, grapes, lettuce and tomatoes. The main component identified was the parent active substance. Thus, the RMS proposed to restrict the residue definitions for enforcement and risk assessment to mandipropamid. For this residue definition a validated analytical method is available to be used by enforcement laboratories.

No specific supervised field trials on cress are available, but the EMS proposed to use the indoor and outdoor trials performed in lettuce to estimate the expected residues in cress. Although the GAPs of lettuce and cress are comparable in terms of the application rate and the PHI, the growth stage of the crops at the time of the pesticide application is significantly different. Thus, EFSA is of the opinion that the trials on lettuce are not representative for the residue situation in cress; these trials are expected to underestimate the residues in garden cress if treated in the same way as lettuce, because cress has a very short vegetation period of two to four weeks only and is characterised by a more critical ratio of leaf surface exposed to the foliar application and leaf mass (yield) compared with lettuce. In order to establish a MRL for garden cress, specific supervised residue trials in cress or a crop with similar growth characteristic should be provided.

Lacking reliable data on the magnitude of residues in cress, a consumer risk assessment was not performed.

RECOMMENDATIONS

EFSA concludes that the data provided in the framework of the application are not sufficient to recommend a MRL for cress.

REFERENCES

- Austria, 2006. Draft Assessment Report (DAR) on the active substance mandipropamid prepared by the rapporteur Member State Austria in the framework of Directive 91/414/EEC, November 2006.
- Belgium, 2009. Evaluation report on the modification of a MRL for mandipropamid in garden cress prepared by the evaluating Member State Belgium under Article 8 of Regulation (EC) No 396/2005, April 2009.
- EFSA (European Food Safety Authority), 2009. 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.
- European Commission, 2008. Guidance Document- Guidelines on comparability, extrapolation group tolerances and data requirements for setting MRLs. SANCO 7525/VI/95 rev.8, 1 February 2008.

WHO/FAO, 2008. Pesticide residues in food – 2008. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 193, 2008.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES

(Application on agricultural and horticultural crops)

Federal Public Service Health, Food Chain Safety and Environment,
 DG Plants, Animals and Food
 Eurostation Bloc II
 Place Victor Horta, 40 bte 10
 1060 BRUSSELS

Date : April 2009
 Country : Belgium
 Reference : Ch. Vervaeet

Pesticide(s) (common name(s)) : Mandipropamid
 Trade name(s) : REVUS
 Main Uses e.g. insecticide, fungicide : Fungicide

Crop and/or situation (a)	Member State or Country	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		
Garden cress	Belgium (Northern EU)	F	mildew	SC	250 g/l	Spraying		1-2	7 days			0.15	7 days	
Garden cress	Belgium (Northern EU)	G	mildew	SC	250 g/l	Spraying		1				0.15	7 days	

(a) For crops, the EU and Codex classifications (both) should be used; where (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of relevant, the use situation should be described (e.g. fumigation of a structure) equipment used must be indicated

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I) (i) g/kg or g/l

(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell,

(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989 (k) Indicate the minimum and maximum number of application possible under practical conditions of use

(f) All abbreviations used must be explained (l) PHI - minimum pre-harvest interval

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (m) Remarks may include: Extent of use/economic importance/restrictions

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

See EFSA, 2009, Appendix C.

No new consumer risk assessment was performed because no reliable residue values for mandipropamid in cress are available.

APPENDIX C – EXISTING EC MRLs

Pesticides - Web Version - EU MRLs (File created on 04/09/2009 15:34)

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	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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Mandipropamid
140040	Plums (Damsun, 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 cloudberries)	0,01*
153030	Raspberries (Wineberries)	0,01*
153990	Others	0,01*
154000	(d) Other small fruit & berries	0,01*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,01*
154020	Cranberries	0,01*
154030	Currants (red, black and white)	0,01*
154040	Gooseberries (Including hybrids with other ribes species)	0,01*
154050	Rose hips	0,01*
154060	Mulberries (arbutus berry)	0,01*
154070	Azarole (mediteranean medlar)	0,01*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea shallowthorn), hawthorn, service berries, and other treeberries)	0,01*
154990	Others	0,01*
160000	(vi) Miscellaneous fruit	0,01*
161000	(a) Edible peel	0,01*
161010	Dates	0,01*
161020	Figs	0,01*
161030	Table olives	0,01*
161040	Kumquats (Marumi)	0,01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Mandipropamid
	kumquats, nagami kumquats)	
161050	Carambola (Bilimbi)	0,01*
161060	Persimmon	0,01*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grunichama), 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 mammy sapote)	0,01*
162990	Others	0,01*
163000	(c) Inedible peel, large	0,01*
163010	Avocados	0,01*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,01*
163030	Mangoes	0,01*
163040	Papaya	0,01*
163050	Pomegranate	0,01*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,01*
163070	Guava	0,01*
163080	Pineapples	0,01*
163090	Bread fruit (Jackfruit)	0,01*
163100	Durian	0,01*
163110	Soursop (guanabana)	0,01*
163990	Others	0,01*
200000	2. VEGETABLES FRESH OR FROZEN	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Mandipropamid
210000	(i) Root and tuber vegetables	0,01*
211000	(a) Potatoes	0,01*
212000	(b) Tropical root and tuber vegetables	0,01*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,01*
212020	Sweet potatoes	0,01*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,01*
212040	Arrowroot	0,01*
212990	Others	0,01*
213000	(c) Other root and tuber vegetables except sugar beet	0,01*
213010	Beetroot	0,01*
213020	Carrots	0,01*
213030	Celeriac	0,01*
213040	Horseradish	0,01*
213050	Jerusalem artichokes	0,01*
213060	Parsnips	0,01*
213070	Parsley root	0,01*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,01*
213090	Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant))	0,01*
213100	Swedes	0,01*
213110	Turnips	0,01*
213990	Others	0,01*
220000	(ii) Bulb vegetables	0,01*
220010	Garlic	0,01*
220020	Onions (Silverskin onions)	0,01*
220030	Shallots	0,01*
220040	Spring onions (Welsh onion and similar varieties)	0,01*
220990	Others	0,01*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	1
231020	Peppers (Chilli peppers)	0,01*
231030	Aubergines (egg plants) (Pepino)	1

Code number	Groups and examples of individual products to which the MRLs apply (a)	Mandipropamid
231040	Okra, lady's fingers	0,01*
231990	Others	0,01*
232000	(b) Cucurbits - edible peel	
232010	Cucumbers	0,2
232020	Gherkins	0,1
232030	Courgettes (Summer squash, marrow (patisson))	0,1
232990	Others	0,1
233000	(c) Cucurbits-inedible peel	0,3
233010	Melons (Kiwano)	0,3
233020	Pumpkins (Winter squash)	0,3
233030	Watermelons	0,3
233990	Others	0,3
234000	(d) Sweet corn	0,01*
	(e) Other fruiting vegetables	0,01*
	(iv) Brassica vegetables	0,01*
	(a) Flowering brassica	0,01*
	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,01*
	Cauliflower	0,01*
	Others	0,01*
	(b) Head brassica	0,01*
	Brussels sprouts	0,01*
	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,01*
	Others	0,01*
	(c) Leafy brassica	0,01*
	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,01*
	Kale (Borecole (curly kale), collards)	0,01*
	Others	0,01*
	(d) Kohlrabi	0,01*
	(v) Leaf vegetables & fresh herbs	
	(a) Lettuce and other salad plants including Brassicacea	
	Lamb's lettuce (Italian comsalad)	0,01*
	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	10
	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf)	10

Code number	Groups and examples of individual products to which the MRLs apply (a)	Mandipropamid
	endive, sugar loaf)	
	Cress	0,01*
	Land cress	0,01*
	Rocket, Rucola (Wild rocket)	10
	Red mustard	0,01* / 7 ³
	Leaves and sprouts of Brassica spp (Mizuna)	0,01* / 7 ⁴
	Others	0,01*
	(b) Spinach & similar (leaves)	0,01*
	Spinach (New Zealand spinach, tumip greens (tumip tops))	0,01* / 7 ⁵
	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,01* / 7 ⁶
	Beet leaves (chard) (Leaves of beetroot)	0,01* / 7 ⁷
	Others	0,01*
	(c) Vine leaves (grape leaves)	0,01*
	(d) Water cress	0,01*
	(e) Witloof	0,01*
	(f) Herbs	10
	Chervil	10
	Chives	10
	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	10
	Parsley	10
	Sage (Winter savory, summer savory,)	10
	Rosemary	10
	Thyme (marjoram, oregano)	10
	Basil (Balm leaves, mint, peppermint)	10
	Bay leaves (laurel)	10
	Tarragon (Hyssop)	10

³ MRL voted on 9 March 2009, not yet published

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⁶ and

⁷: see "red mustard"

Code number	Groups and examples of individual products to which the MRLs apply (a)	Mandipropamid
	Others	10
	(vi) Legume vegetables (fresh)	0,01*
	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,01*
	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,01*
	Peas (with pods) (Mangetout (sugar peas))	0,01*
	Peas (without pods) (Garden pea, green pea, chickpea)	0,01*
	Lentils	0,01*
	Others	0,01*
	(vii) Stem vegetables (fresh)	0,01*
	Asparagus	0,01*
	Cardoons	0,01*
	Celery	0,01*
	Fennel	0,01*
	Globe artichokes	0,01*
	Leek	0,01*
	Rhubarb	0,01*
	Bamboo shoots	0,01*
	Palm hearts	0,01*
	Others	0,01*
	(viii) Fungi	0,01*
	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,01*
	Wild (Chanterelle, Truffle, Morel,)	0,01*
	Others	0,01*
	(ix) Sea weeds	0,01*
	3. PULSES, DRY	0,01*
	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,01*
	Lentils	0,01*
	Peas (Chickpeas, field peas, chickling vetch)	0,01*
	Lupins	0,01*
	Others	0,01*
	4. OILSEEDS AND OILFRUITS	0,01*
	(i) Oilseeds	0,01*
	Linseed	0,01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Mandipropamid
	Peanuts	0,01*
	Poppy seed	0,01*
	Sesame seed	0,01*
	Sunflower seed	0,01*
	Rape seed (Bird rapeseed, tumip rape)	0,01*
	Soya bean	0,01*
	Mustard seed	0,01*
	Cotton seed	0,01*
	Pumpkin seeds	0,01*
	Safflower	0,01*
	Borage	0,01*
	Gold of pleasure	0,01*
	Hempseed	0,01*
	Castor bean	0,01*
	Others	0,01*
	(ii) Oilfruits	0,01*
	Olives for oil production	0,01*
	Palm nuts (palmoil kernels)	0,01*
	Palmfruit	0,01*
	Kapok	0,01*
	Others	0,01*
	5. CEREALS	0,01*
	Barley	0,01*
	Buckwheat	0,01*
	Maize	0,01*
	Millet (Foxtail millet, teff)	0,01*
	Oats	0,01*
	Rice	0,01*
	Rye	0,01*
	Sorghum	0,01*
	Wheat (Spelt Triticale)	0,01*
	Others	0,01*
	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,02*
	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,02*
	(ii) Coffee beans	0,02*
	(iii) Herbal infusions (dried)	0,02*
	(a) Flowers	0,02*
	Camomille flowers	0,02*
	Hybiscus flowers	0,02*
	Rose petals	0,02*
	Jasmine flowers	0,02*
	Lime (linden)	0,02*
	Others	0,02*
	(b) Leaves	0,02*
	Strawberry leaves	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Mandipropamid
	Rooibos leaves	0,02*
	Maté	0,02*
	Others	0,02*
	(c) Roots	0,02*
	Valerian root	0,02*
	Ginseng root	0,02*
	Others	0,02*
	(d) Other herbal infusions	0,02*
	(iv) Cocoa (fermented beans)	0,02*
	(v) Carob (st johns bread)	0,02*
	7. HOPS (dried), including hop pellets and unconcentrated powder	0,02*
	8. SPICES	0,02*
	(i) Seeds	0,02*
	Anise	0,02*
	Black caraway	0,02*
	Celery seed (Lovage seed)	0,02*
	Coriander seed	0,02*
	Cumin seed	0,02*
	Dill seed	0,02*
	Fennel seed	0,02*
	Fenugreek	0,02*
	Nutmeg	0,02*
	Others	0,02*
	(ii) Fruits and berries	0,02*
	Allspice	0,02*
	Anise pepper (Japan pepper)	0,02*
	Caraway	0,02*
	Cardamom	0,02*
	Juniper berries	0,02*
	Pepper, black and white (Long pepper, pink pepper)	0,02*
	Vanilla pods	0,02*
	Tamarind	0,02*
	Others	0,02*
	(iii) Bark	0,02*
	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 (Curcuma)	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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Mandipropamid
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*
100000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
101000	(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*
101100	(a) Swine	0,02*
101101	Meat	0,02*
101102	Fat free of lean meat	0,02*
101103	Liver	0,02*
101104	Kidney	0,02*
101105	Edible offal	0,02*
101199	Others	0,02*
101200	(b) Bovine	0,02*
101201	Meat	0,02*
101202	Fat	0,02*
101203	Liver	0,02*
101204	Kidney	0,02*
101205	Edible offal	0,02*
101299	Others	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Mandipropamid
101300	(c) Sheep	0,02*
101301	Meat	0,02*
101302	Fat	0,02*
101303	Liver	0,02*
101304	Kidney	0,02*
101305	Edible offal	0,02*
101399	Others	0,02*
101400	(d) Goat	0,02*
101401	Meat	0,02*
101402	Fat	0,02*
101403	Liver	0,02*
101404	Kidney	0,02*
101405	Edible offal	0,02*
101499	Others	0,02*
101500	(e) Horses, asses, mules or hinnies	0,02*
101501	Meat	0,02*
101502	Fat	0,02*
101503	Liver	0,02*
101504	Kidney	0,02*
101505	Edible offal	0,02*
101599	Others	0,02*
101600	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,02*
101601	Meat	0,02*
101602	Fat	0,02*
101603	Liver	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Mandipropamid
0		
101604	Kidney	0,02*
101605	Edible offal	0,02*
101699	Others	0,02*
101700	(g) Other farm animals (Rabbit, Kangaroo)	0,02*
101701	Meat	0,02*
101702	Fat	0,02*
101703	Liver	0,02*
101704	Kidney	0,02*
101705	Edible offal	0,02*
101799	Others	0,02*
102000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,02*
102001	Cattle	0,02*
102002	Sheep	0,02*
102003	Goat	0,02*
102004	Horse	0,02*
102099	Others	0,02*
103000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,02*
103001	Chicken	0,02*
103002	Duck	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Mandipropamid
103003 0	Goose	0,02*
103004 0	Quail	0,02*
103099	Others	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Mandipropamid
0		
104000 0	(iv) Honey (Royal jelly, pollen)	
105000 0	(v) Amphibians and reptiles (Frog legs, crocodiles)	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Mandipropamid
106000 0	(vi) Snails	
107000 0	(vii) Other terrestrial animal products	

(*) Indicates lower limit of analytical determination

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany
Bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council Limited
CS	capsule suspension
CXL	codex maximum residue limit
D	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DM	dry matter
DP	dustable powder
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
DTU	Danish Technical University
dw	dry weight
EC	European Community
EC	emulsifiable concentrate
ECD	electron capture detection
EDI	estimated daily intake
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FID	flame ionization detection
GAP	good agricultural practice
GC	gas chromatography
GR	granule
GS	growth stage

ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K _{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
ppm	parts per million (10 ⁻⁶)
PRIMo	Pesticide Residues Intake Model
PSD	Pesticide Safety Directorate, United Kingdom
RMS	rappporteur Member State
SC	suspension concentrate
SEU	Southern European Union
SG	water soluble granule
SL	soluble concentrate
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet detection
WG	water dispersible granule

WHO World Health Organisation
WP wettable powder