REASONED OPINION

Modification of the existing MRLs for dimethomorph in peas (without pods) and leeks [1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, France received an application from BASF AGRO sas to modify the existing MRLs for dimethomorph in peas without pods and leeks. In order to accommodate for intended uses of dimethomorph in Northern and Southern Europe, it is proposed to raise the existing MRLs in peas without pods and leeks from 0.05 (set at the limit of quantification) to 0.1 mg/kg and from 0.2 to 1 mg/kg, respectively. France drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 3 September 2009.

EFSA derived the following conclusions based on the submitted evaluation report prepared by France, the Draft Assessment Report (DAR) prepared under the Directive 91/414 by Germany as well as the EFSA conclusions on the peer review of dimethomorph risk assessment finalised on 23 June 2006.

The toxicological profile of dimethomorph was investigated in the peer review and the data were sufficient to conclude on an ADI value of 0.05 mg/kg bw/d and an ARfD value of 0.6 mg/kg bw.

Metabolism of dimethomorph in plants has been investigated in three crop categories and a general residue definition for risk assessment and monitoring was proposed by the peer review as dimethomorph. Sufficiently validated analytical enforcement methods are available to control the compliance of the proposed MRLs for dimethomorph in all crops under consideration.

The submitted supervised residue field trials indicate that higher EC MRLs of 0.1 mg/kg for fresh peas without pods and 1.5 mg/kg for leeks would be necessary to accommodate the intended uses of dimethomorph.

The occurrence of dimethomorph or its metabolites in rotational crops was also investigated. EFSA concluded that residues in rotational crops above the LOQ may be expected in particular in leafy crops. It is therefore recommended that MS, before granting an authorization for the intended uses of dimethomorph, should consider the need of establishing the plant back intervals. Residues in commodities of animal origin were not assessed in the framework of this application since crops under consideration are not livestock feeding items.

Effects of processing on the nature of dimethomorph were peer reviewed. Hydrolysis studies simulating sterilisation, baking, brewing, boiling and pasteurisation showed that dimethomorph is

1 On request from the European Commission, Question No EFSA-Q-2009-00792, issued on 11 December 2009.
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hydrolytically stable under these conditions and that no formation of toxicologically relevant metabolites occurs.

No studies have been submitted to assess the magnitude of dimethomorph residues during the processing of peas without pods and leeks. Such studies however are not necessary considering the low individual contribution of these crops to the total dietary intake.

The consumer risk assessment regarding the parent compound dimethomorph was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the existing MRLs as established in Annex III of the Regulation (EC) 396/2005 as well as the STMR values derived from the supervised field trials on peas without pods and leeks.

The acute intake assessment was performed only with regard to the crops under consideration. The relevant HR values for peas without pods and leeks, as derived from the intended GAPs, were used as input values in the acute intake calculation.

No long-term intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated dietary intake ranged from 7.4 to 36.4% of the ADI. The contributions of peas without pods and leeks to the total consumer exposure to dimethomorph accounted for a maximum of 0.01% (UK infant diet) and 0.27% (FR toddler diet) of the ADI, respectively.

No acute intake concerns were identified in relation to the MRL proposals for dimethomorph on fresh peas without pods and leeks. Peas and leeks accounted to the acute consumer exposure for 0.1% and 6.8% of the ARfD, respectively.

Consequently EFSA concludes that the intended uses of dimethomorph on peas without pods and leeks are acceptable as they will not result in an exceedance of the toxicology reference values. EFSA derived the following recommendations:

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: dimethomorph			
Peas without pods	0.05*	0.1	MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended uses.
Leeks	0.2	1.5	

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

KEY WORDS

Dimethomorph, peas without pods, leeks, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, morpholine 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.

France, hereafter referred to as the evaluating Member State (EMS), received an application from the company BASF AGRO sas[3] to modify the existing MRLs for the active substance dimethomorph in peas (without pods) and leeks. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 3 September 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-792 and the following subject:

Dimethomorph – Application to modify the existing MRLs in peas (without pods) and leeks.

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

TERMS OF REFERENCE

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

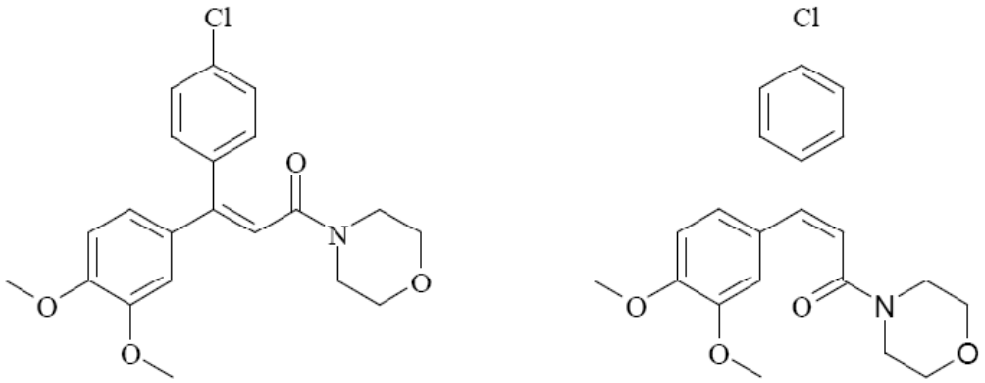
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been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

In this particular case the calculated deadline for providing the reasoned opinion is 3 December 2009.

3 BASF AGRO sas, 21 chemin de la Sauvegarde, 69134, ECULLY, France

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Dimethomorph is the ISO common name for (E,Z)-4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl) acryloyl]morpholine (IUPAC).



Molecular mass: 376.9 g/mol

Dimethomorph belongs to the class of morpholine fungicides such as tridemorph and fenpropimorph. Dimethomorph is active against fungi in the family of Peronosporaceae and the genus *Phytophthora* by inhibiting the formation of the fungal cell wall. When applied to foliage, dimethomorph penetrates leaf surfaces and is translocated within the leaf by diffusion. When applied to the roots, the compound is systemically translocated acropetally in the plant.

Dimethomorph is an existing active substance for which Germany is RMS. It has been peer reviewed under Directive 91/414/EEC and included in Annex I to this Directive by the Commission Directive 2007/25/EC of 23 April 2007. The evaluated representative uses were as a fungicide only, with application by foliar spray via tractor mounted hydraulic sprayer to hops, grapes and potatoes. Dimethomorph was peer reviewed by EFSA and the EFSA conclusion was adopted on 23 June 2006.

At EC level, MRLs for dimethomorph were set for the first time in the Annex III of the Regulation (EC) No 396/2005. The existing MRLs for dimethomorph are summarized in Appendix C to this reasoned opinion. The existing EC MRLs for the crops under consideration are set at 0.05 mg/kg (LOQ) for peas (without pods) and at 0.2 mg/kg for leeks.

Codex Alimentarius has established CXLs for dimethomorph in a wide range of commodities but there are no CXLs set for the crops under consideration.

The submitted GAPs according to which the modification of the existing MRLs is requested are summarized in Appendix A.

EFSA bases its assessment on the evaluation report submitted by France (France, 2009), the Draft Assessment Report (DAR) prepared under the Directive 91/414/EEC (Germany, 2004), the EFSA conclusion on the peer review of dimethomorph risk assessment finalised on 23 June 2006 (EFSA, 2006). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of Authorization of PPP set out in Annex VI to Directive 91/414/EEC and the currently applicable guidance documents relevant for the consumer RA of pesticide residues (European Commission, 1997).

ASSESSMENT

1. Methods of analysis

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

For the determination of dimethomorph in leeks, a method using analysis by GC-NPD with the LOQ of 0.02 mg/kg was sufficiently validated. The main recoveries range from 70 to 110% with RSD below 20%. For the determination of dimethomorph in peas, a method using analysis by HPLC MS/MS was sufficiently validated. The main recoveries range from 70 to 110% with RSD below 20%. The LOQ for the determination of dimethomorph in high water content commodities (lettuce, tomato, pea, onion, potato and grape) is 0.01 mg/kg.

EFSA concluded that sufficiently validated methods are available to enforce the proposed MRLs for dimethomorph in peas without pods and leeks at 0.1 mg/kg and 1.5 mg/kg, respectively.

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

The availability of analytical methods for the determination of dimethomorph residues in foodstuffs of animal origin was not investigated for the current application since no MRLs for commodities of animal origin are proposed.

2. Mammalian toxicology

The toxicological reference values for dimethomorph were derived in the peer review under Directive 91/414 and are reported in Table 2-1 (EFSA, 2006).

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Dimethomorph					
ADI	EFSA	2006	0.05	1 year dog study	100
ARfD	EFSA	2006	0.6	Developmental toxicity study in rats	100

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

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

- fruits (spray application on grapes – 4 x 0.900 kg a.s./ha);
- root vegetables (spray application on potato – 4 x 0.6 or 3 x 0.3 kg a.s./ha);
- leafy crops (spray application on lettuce – 4 x 1.14 kg a.s./ha)

After foliar application the degradation of dimethomorph was limited and the parent compound was the major constituent of the residue in all investigated plant parts, including potato tubers.
Two degradation pathways were identified:
- Demethylation of the 2 methoxy groups of the dimethoxyphenyl ring to produce metabolites Z67[4] and Z69[5], resulting in a hydroxyl group that most likely forms the corresponding glucose conjugate.
- Hydrolysis of dimethomorph to form metabolite Z7[6].
- Oxydation of the morpholine ring to lead to metabolite Z37[7].

An additional metabolism study on tomatoes although not representative of the supported representative uses (the product was applied in a nutrient solution) indicated that the compound is taken up by the roots and translocated to the fruits. Some metabolites were present at levels similar to that of the parent compound and an additional degradation pathway based on a stepwise degradation of the morpholine ring was observed (EFSA, 2006).

Results indicated the main route of degradation to be similar in all three categories (EFSA, 2006). Therefore the metabolism of dimethomorph is sufficiently addressed and no additional metabolism studies are necessary to support uses on fresh peas and leeks (European Commission, 1997a).

Peer review concluded that metabolism of dimethomorph was sufficiently elucidated in the three crop categories to propose a general residue definition for risk assessment and monitoring as parent dimethomorph. EFSA is of the opinion that the same residue definition can be applied also for the intended uses on peas without pods and leeks. This definition is valid when the product is applied by foliar spray. Other methods of application involving uptake by the roots and acropetal translocation of the compound would necessitate a re-evaluation of the residue definition for risk assessment.

3.1.1.2. Magnitude of residues

Peas without pods

The applicant submitted ten supervised field trials on peas without pods conducted in Northern Europe and four conducted in Southern Europe. The proposed GAPs on fresh peas refers to the application rate of 2 x 0.18 kg a.s./ha and a PHI of 21 days.
The number of submitted trials was sufficient to support the proposed MRLs modifications (European Commission, 2008). Trial designs were representative of the intended GAPs with regard to application rate and PHI. In all trials, the last application was done at a later growing stage compared with the GAP (BBCH 67-75 instead of BBCH 15-60) but since the PHI was respected, the trials were

[4] Z67: 4-[(E)-and(Z)-beta-(p-chlorophenyl)-3-hydroxy-4-methoxycinnamoyl]morpholine
[5] Z69: 4-[(E)-and(Z)-beta-(p-chlorophenyl)-4-hydroxy-3-methoxycinnamoyl]morpholine
[6] Z7: 4-chloro-3',4'-dimethoxy-benzophenone
[7] Z37: 4-[3-(4-chlorophenyl)-3-3,4-dimethoxy-phenyl)-1-oxo-2-propenyl]-2-oxo-morpholine

considered acceptable. The residue levels in fresh peas, expressed as dimethomorph, from all trials were in the range of <0.01-0.071 mg/kg. The STMR and HR were 0.01 mg/kg and 0.071 mg/kg respectively. On fresh peas without pods the statistical methodology R_{ber} and R_{max} would justify an MRL proposal of 0.1 mg/kg.

Leeks

The applicant submitted fifteen supervised field trials on leeks conducted in Northern Europe and four conducted in Southern Europe. The proposed GAP on leeks refers to the application rate of 3 x 0.18 kg a.s./ha and a PHI of 14 days.
The number of submitted trials was sufficient to support the proposed MRLs modifications (European Commission, 2008). Trial designs were representative of the intended GAPs. For four trials carried out in Germany, application growth stages were not indicated; however, PHI was respected and residues data correctly reported. The residue levels on leeks, expressed as dimethomorph, were in the range of 0.01-0.694 mg/kg. The STMR and HR were 0.187 mg/kg and 0.694 mg/kg respectively. On leeks the statistical methodology R_{ber} and R_{max} would justify an MRL proposal of 1.5 mg/kg. EFSA is of the opinion that this MRL proposal is more appropriate than 1 mg/kg for a data set with lower number of trials.

Supervised field trials residue data are summarized in Table 3-1. The submitted supervised residue field trials indicate that higher EC MRLs of 0.1 mg/kg for fresh peas without pods and 1.5 mg/kg for leeks would be necessary to accommodate the intended uses of dimethomorph.

The storage stability data of dimethomorph for high water content commodities (potatoes) were already submitted and evaluated under the peer review of Directive 91/414/EEC. It has been demonstrated that under conditions of frozen storage residues of dimethomorph are stable for a period of 18-24 months. Since fresh peas and leeks belong to the group of commodities with high water content, the storage stability demonstrated for potatoes is representative also for fresh peas and leeks.
The supervised field trial samples were stored for a maximum of 245 days at temperature ≤-18°C. It is concluded that analytical results are reliable with regard to storage stability.

Methods which complied with the residue definition established for enforcement purposes (dimethomorph) were used for the analysis of supervised field trial samples. The residue levels were reported as dimethomorph and the analytical methods applied for analysing supervised field trial samples are sufficiently validated and fit for purpose.

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) I	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement (Dimethomorph)	Risk assessment (Dimethomorph)					
Enforcement residue definition: dimethomorph									
Fresh peas without pods	NEU	Outdoor	6x <0.01; 0.02(e); 0.044; 0.063; 0.071	6x <0.01; 0.02(e); 0.044; 0.063; 0.071	0.01	0.071	**0.1**	1.0	R_{ber}=0.1 mg/kg R_{max}=0.1 mg/kg
Fresh peas without pods	SEU	Outdoor	4x <0.01	4x <0.01	0.01	0.01	0.01*	1.0	R_{ber}=0.02 mg/kg R_{max}=0.01 mg/kg
Leeks	NEU	Outdoor	0.01(e); <0.02; <0.02; 0.03; 0.035; 0.036; 0.05(e); 0.05; 0.07; 0.08; 0.083; 0.1; 0.104; 0.111; 0.133	0.0(e)1; <0.02; <0.02; 0.03; 0.035; 0.036; 0.05(e); 0.05; 0.07; 0.08; 0.083; 0.1; 0.104; 0.111; 0.133	0.05	0.133	0.2	1.0	R_{ber}=0.2 mg/kg R_{max}=0.16 mg/Kg
Leeks	SEU	Outdoor	0.061; 0.076; 0.297(e); 0.694	0.061; 0.076; 0.297(e); 0.694	0.187	0.694	**1.5**	1.0	R_{ber}=1.2 mg/kg R_{max}=1.8 mg/Kg

(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.
I: Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.
(e): Residue concentration measured at longer PHI with respect to GAPs.
(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

Under the peer review, effects of processing on the nature of the residues were investigated through hydrolysis studies simulating sterilisation, baking, brewing, boiling and pasteurisation. These studies showed that dimethomorph is hydrolytically stable under these conditions and that no formation of toxicologically relevant metabolites occurs (EFSA, 2006). Thus, for processed commodities the same residue definition as for raw agricultural commodities is applicable.

No studies have been submitted to assess the magnitude of dimethomorph residues during the processing of fresh peas and leeks. Such studies however are not necessary since residue levels in fresh peas are below 0.1 mg/kg (European Commission, 1997d).
For leeks, processing studies are not required considering the low individual contribution of this crop to the total dietary intake (European Commission, 1997d).

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

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

According to the soil degradation studies performed in the framework of the peer review, the highest DT_{90} values of dimethomorph were 176 (Germany) and 203 (United Kingdom, France and Spain) days based on field studies and 319 days (aerobic) based on laboratory studies. Therefore rotational crop studies are required.

3.1.2.2. Nature of residues

In the peer review the metabolism of dimethomorph in succeeding and rotational crops has been investigated in two studies with radioactive material. In the first study ^{14}C-dimethomorph was applied to sandy loam soil at 4 kg a.s./ha (corresponding to 7.4 N application rate compared with the leek GAP). Soil was aged for 29, 120 and 371 days prior planting of rotational crops. The treated soil was mixed with untreated soil (1:6.5 ratio) to simulate tilling. The rotational crops, carrot (root group), precultivated young lettuce (leafy group) and wheat (grain group), were grown under laboratory conditions. Radioactive residue declined in all sample materials (soil and crops) with increasing aging time. Dimethomorph was the only identified (but not quantified) compound of the residue.
In the second study ^{14}C-dimethomorph was applied to sandy clay loam soil at 1.7 kg a.s./ha. The rotational crops, wheat, radishes, lettuce and soybean, were grown outdoor. Crop samples were collected at 30, 60, 181, 274 and 394 DALA. Dimethomorph as well as its two metabolites Z67 and Z69 (free or conjugated to glucose) resulting from demethylation of the phenolic methoxy groups were identified in small amounts (at <0.01 to 0.04 mg/kg) in the rotational crops indicating that dimethomorph is taken up by the roots. Peer review concluded that the metabolic pathway in following crops is similar to that observed in primary crops and the same residue definition is applicable (EFSA, 2006).

3.1.2.3. Magnitude of residues

Four field trials were carried out in Germany during two different years and using carrots, spinach and beans as following crops sowed within 47 days after last application of dimethomorph on potatoes at 3 x 0.18 kg as/ha. Results indicate that residues of dimethomorph are generally below the LOQ (0.01 mg/kg), but also in some circumstances (for instance in dry beans or in case of early harvest of carrots or spinach) present at measurable levels in following crops. The highest residues were found to be 0.09 mg/kg and 0.21 mg/kg in spinach samples proceeding from two different trials and analysed 72 and 76 days after the last treatment, respectively.

The studies on the magnitude of residues in rotational and succeeding crops were already evaluated under the peer review framework and EFSA concluded that these residue levels in following crops were not a concern (EFSA, 2006) as far as the safety of the consumer was concerned. Considering a contamination of 0.02 mg/kg of vegetables and a consumption of 1 kg vegetables per day by an adult of 60 kg, the dietary burden of dimethomorph would be lower than 1 % of the ADI of the compound. However, the decision on whether the plant back intervals for rotational crops should be set following the proposed use of dimethomorph, should be considered by the Member State before granting an authorization of dimethomorph containing plant protection products.

3.2. Nature and magnitude of residues in livestock

Since fresh peas without pods and leeks are not used as livestock feeding stuffs the nature and magnitude of dimethomorph residues in livestock was not assessed with regard to the current application.

4. Consumer risk assessment

The consumer risk assessment regarding the parent compound dimethomorph was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model, EFSA, 2007). For the chronic intake assessment EFSA used the existing MRLs as established in Annex III of the Regulation (EC) 396/2005 as well as the STMR values derived from the supervised field trials on peas without pods and leeks (see Table 3-1).

The acute intake assessment was performed only with regard to the crops under consideration. The relevant HR values for peas without pods and leeks (see Table 3-1) as derived from the intended GAPs were used as input values in the acute intake calculation.

Input values are summarized in Table 4-1.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue: dimethomorph				
Fresh peas without pods	0.01	STMR	0.071	HR
Leeks	0.187	STMR	0.694	HR
Other commodities of plant and animal origin	MRL	See Appendix C	-	-

Summary of intake calculations is available in Appendix B.

No long-term intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated dietary intake ranged from 7.4 to 36.4% of the ADI. The contributions of peas without pods and leeks to the total consumer exposure to dimethomorph accounted for a maximum of 0.01% (UK infant diet) and 0.27% (FR toddler diet) of the ADI, respectively.

No acute intake concerns were identified in relation to the MRL proposals for dimethomorph on fresh peas without pods and leeks. Peas and leeks accounted to the acute consumer exposure for 0.1% and 6.8% of the ArfD, respectively.

Consequently EFSA concludes that the intended uses of dimethomorph on peas without pods and leeks are acceptable as they will not result in an exceeding of the toxicology reference values.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of dimethomorph was investigated in the peer review and the data were sufficient to conclude on an ADI value of 0.05 mg/kg bw/d and an ArfD value of 0.6 mg/Kg bw.

Metabolism of dimethomorph in plants has been investigated in three crop categories and a general residue definition for risk assessment and monitoring was proposed by the peer review as dimethomorph. Sufficiently validated analytical enforcement methods are available to control the compliance of the proposed MRLs for dimethomorph in all crops under consideration.

The submitted supervised residue field trials indicate that higher EC MRLs of 0.1 mg/kg for fresh peas without pods and 1.5 mg/kg for leeks would be necessary to accommodate the intended uses of dimethomorph.

The occurrence of dimethomorph or its metabolites in rotational crops was also investigated. EFSA concluded that residues in rotational crops above the LOQ may be expected in particular in leafy crops. It is therefore recommended that MS, before granting an authorization for the intended uses of dimethomorph, should consider the need of establishing the plant back intervals. Residues in commodities of animal origin were not assessed in the framework of this application since crops under consideration are not livestock feeding items.

Effects of processing on the nature of dimethomorph were peer reviewed. Hydrolysis studies simulating sterilisation, baking, brewing, boiling and pasteurisation showed that dimethomorph is hydrolytically stable under these conditions and that no formation of toxicologically relevant metabolites occurs. No studies have been submitted to assess the magnitude of dimethomorph residues during the processing of peas without pods and leeks. Such studies however are not necessary considering the low individual contribution of these crops to the total dietary intake.

The consumer risk assessment regarding the parent compound dimethomorph was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the existing MRLs as established in Annex III of the Regulation (EC) 396/2005 as well as the STMR values derived from the supervised field trials on peas without pods and leeks.
The acute intake assessment was performed only with regard to the crops under consideration. The relevant HR values for peas without pods and leeks, as derived from the intended GAPs, were used as input values in the acute intake calculation.

No long-term intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated dietary intake ranged from 7.4 to 36.4% of the ADI. The contributions of peas without pods and leeks to the total consumer exposure to dimethomorph accounted for a maximum of 0.01% (UK infant diet) and 0.27% (FR toddler diet) of the ADI, respectively.

No acute intake concerns were identified in relation to the MRL proposals for dimethomorph on fresh peas without pods and leeks. Peas and leeks accounted to the acute consumer exposure for 0.1% and 6.8% of the ArfD, respectively.

Consequently EFSA concludes that the intended uses of dimethomorph on peas without pods and leeks are acceptable as they will not result in an exceeding of the toxicology reference values.

RECOMMENDATIONS

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: dimethomorph			
Peas without pods	0.05*	0.1	MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended uses.
Leeks	0.2	1.5	

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

REFERENCES

France, 2009. Evaluation report on the modification of MRLs for dimethomorph in fresh peas without pods and leeks prepared by the evaluating Member State France under Article 8 of Regulation (EC) No 396/2005, 3 August 2009.

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European Commission, 1997g. Appendix I – Calculation of maximum residue level and safety intervals. 7039/VI/95, 22 July 1997.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

1	2	3	4	5	6			7			8	9
Crop and / or situation	F G or I	Pest or group of pests controlled	Formulation		Application			Application rate per treatment			PHI (days)	Remarks:
			Type	Conc. of a.i.	method, kind	growth stage	number (range)	kg a.i./hl	water l/ha	kg a.i./ha		
(a)	(b)	(c)	(d - f)	(i)	(f - h)	(j)					(k)	(l)
Leek	F	*Phytophtora porri*	WG	90	spray	BBCH 14-48	3	0.023-0.04	500-800	0.18	14	
Canned peas	F	*Peronospora pisi*	WG	90	spray	BBCH 15-60	2	0.05-0.09	200-400	0.18	21	

Remarks:
(a) In case of group of crops the Codex classification should be used
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
I e.g. biting and sucking insects, soil born insects, foliar fungi
(d) e.g. wettable powder (WP), emulsifiable concentration (EC), granule (GR)
(e) Use CIPAC/FAO Codes where appropriate
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants
(i) g/kg or g/l
(j) Growth stage at last treatment
(k) PHI = Pre-harvest interval
(l) Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Dimethomorph			
Status of the active substance:	Annex I	Code no.	53
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.05	ARfD (mg/kg bw):	0.6
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2006	Year of evaluation:	2006

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
7	36
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)
36.4	WHO Cluster diet B	10.8	Wine grapes	7.2	Lettuce	6.2	Tomatoes	
33.9	FR all population	24.0	Wine grapes	2.8	Witloof	1.8	Lettuce	
25.4	PT General population	14.9	Wine grapes	5.3	Potatoes	1.8	Tomatoes	
25.2	NL child	5.9	Potatoes	4.6	Table grapes	3.7	Witloof	
22.6	WHO cluster diet E	9.6	Wine grapes	3.8	Potatoes	1.8	Lettuce	
21.3	DE child	7.6	Table grapes	2.6	Potatoes	1.9	Tomatoes	
20.8	IE adult	7.5	Wine grapes	2.3	Potatoes	1.7	Lettuce	
20.4	WHO regional European diet	7.5	Lettuce	4.0	Potatoes	2.2	Tomatoes	
18.4	ES adult	10.7	Lettuce	2.5	Wine grapes	1.6	Tomatoes	
17.9	WHO Cluster diet F	6.0	Lettuce	3.6	Wine grapes	3.4	Potatoes	
16.9	NL general	3.8	Wine grapes	2.9	Witloof	2.7	Potatoes	
16.2	ES child	8.3	Lettuce	2.0	Tomatoes	1.8	Potatoes	
15.5	WHO cluster diet D	4.1	Potatoes	2.2	Wine grapes	2.0	Tomatoes	
15.4	FR toddler	5.1	Potatoes	4.0	Milk and cream,	1.5	Tomatoes	
15.0	DK child	3.3	Cucumbers	2.8	Lettuce	2.4	Potatoes	
14.0	IT adult	7.5	Lettuce	2.3	Tomatoes	0.8	Table grapes	
13.7	UK Adult	6.5	Wine grapes	2.3	Lettuce	1.4	Potatoes	
13.4	DK adult	8.4	Wine grapes	1.5	Potatoes	0.8	Tomatoes	
13.4	UK vegetarian	4.9	Wine grapes	2.8	Lettuce	1.4	Potatoes	
13.1	UK Toddler	3.5	Potatoes	2.3	Sugar beet (root)	2.1	Milk and cream,	
12.9	IT kids/toddler	5.8	Lettuce	2.9	Tomatoes	0.9	Potatoes	
12.0	FR infant	4.1	Potatoes	2.6	Milk and cream,	1.6	Witloof	
11.1	SE general population 90th percentile	4.2	Potatoes	1.5	Tomatoes	1.2	Milk and cream,	
10.8	UK Infant	3.9	Milk and cream,	3.3	Potatoes	1.0	Sugar beet (root)	
8.4	PL general population	3.4	Potatoes	1.9	Table grapes	1.8	Tomatoes	
7.8	LT adult	3.2	Potatoes	1.3	Lettuce	1.2	Tomatoes	
7.4	FI adult	1.8	Wine grapes	1.6	Lettuce	1.2	Potatoes	

Conclusion:

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

	Acute risk assessment /children - refined calculations						Acute risk assessment / adults / general population - refined calculations					
	The acute risk assessment is based on the ARfD.											
	For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.											
	In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty 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)
	6.8	Leek	0.694 / -	4.9	Leek	0.694 / -	2.2	Leek	0.694 / -	1.7	Leek	0.694 / -
	0.1	Peas (without pods)	0.071 / -	0.1	Peas (without	0.071 / -	0.0	Peas (without pods)	0.071 / -	0.0	Peas (without pods)	0.071 / -
	No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:**		---				**No of commodities for which ARfD/ADI is exceeded:**		---			
			*****)**						*****)**			
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
	*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.											
	**) pTMRL: provisional temporary MRL											
	***) pTMRL: provisional temporary MRL for unprocessed commodity											
	Conclusion:											
	For Dimethomorph IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.											
	No exceedance of the ARfD/ADI was identified for any unprocessed commodity.											
	For processed commodities, no exceedance of the ARfD/ADI was identified.											

APPENDIX C – EXISTING EC MRLS

Pesticides – Web version – EU MRLs (File created on 4.12.2009)

Code number	Groups and examples of individual products to which the MRLs apply (a)	
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0.05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0.05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0.05*
110030	Lemons (Citron, lemon)	0.05*
110040	Limes	0.05*
110050	Mandarins (Clementine, tangerine and other hybrids)	0.05*
110990	Others	0.05*
120000	(ii) Tree nuts (shelled or unshelled)	0.05*
120010	Almonds	0.05*
120020	Brazil nuts	0.05*
120030	Cashew nuts	0.05*
120040	Chestnuts	0.05*
120050	Coconuts	0.05*
120060	Hazelnuts (Filbert)	0.05*
120070	Macadamia	0.05*
120080	Pecans	0.05*
120090	Pine nuts	0.05*
120100	Pistachios	0.05*
120110	Walnuts	0.05*
120990	Others	0.05*
130000	(iii) Pome fruit	0.05*
130010	Apples (Crab apple)	0.05*
130020	Pears (Oriental pear)	0.05*
130030	Quinces	0.05*
130040	Medlar	0.05*
130050	Loquat	0.05*
130990	Others	0.05*
140000	(iv) Stone fruit	0.05*
140010	Apricots	0.05*
140020	Cherries (sweet cherries, sour cherries)	0.05*
140030	Peaches (Nectarines and similar hybrids)	0.05*
140040	Plums (Damson, greengage, 18huckling)	0.05*
140990	Others	0.05*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	3
151010	Table grapes	3
151020	Wine grapes	3
152000	(b) Strawberries	0.05*
153000	© Cane fruit	0.05*
153010	Blackberries	0.05*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0.05*
153030	Raspberries (Wineberries)	0.05*
153990	Others	0.05*
154000	(d) Other small fruit & berries	0.05*
154010	Blueberries (Bilberries cowberries (red bilberries))	0.05*
154020	Cranberries	0.05*
154030	Currants (red, black and white)	0.05*
154040	Gooseberries (Including hybrids with other ribes species)	0.05*
154050	Rose hips	0.05*
154060	Mulberries (arbutus berry)	0.05*
154070	Azarole (mediteranean medlar)	0.05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0.05*
154990	Others	0.05*
160000	(vi) Miscellaneous fruit	0.05*
161000	(a) Edible peel	0.05*
161010	Dates	0.05*
161020	Figs	0.05*
161030	Table olives	0.05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0.05*
161050	Carambola (Bilimbi)	0.05*
161060	Persimmon	0.05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0.05*
161990	Others	0.05*
162000	(b) Inedible peel, small	0.05*
162010	Kiwi	0.05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0.05*
162030	Passion fruit	0.05*
162040	Prickly pear (cactus fruit)	0.05*
162050	Star apple	0.05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and 18huck sapote)	0.05*
162990	Others	0.05*
163000	© Inedible peel, large	0.05*
163010	Avocados	0.05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0.05*
163030	Mangoes	0.05*
163040	Papaya	0.05*
163050	Pomegranate	0.05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0.05*
163070	Guava	0.05*
163080	Pineapples	0.05*
163090	Bread fruit (Jackfruit)	0.05*
163100	Durian	0.05*
163110	Soursop (guanabana)	0.05*
163990	Others	0.05*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0.5
212000	(b) Tropical root and tuber vegetables	0.05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0.05*
212020	Sweet potatoes	0.05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0.05*
212040	Arrowroot	0.05*
212990	Others	0.05*
213000	© Other root and tuber vegetables except sugar beet	
213010	Beetroot	0.05*
213020	Carrots	0.05*
213030	Celeriac	0.05*
213040	Horseradish	0.05*
213050	Jerusalem artichokes	0.05*
213060	Parsnips	0.05*
213070	Parsley root	0.05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	1
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0.05*
213100	Swedes	0.05*
213110	Turnips	0.05*
213990	Others	0.05*
220000	(ii) Bulb vegetables	
220010	Garlic	0.1
220020	Onions (Silverskin onions)	0.1
220030	Shallots	0.1
220040	Spring onions (Welsh onion and similar varieties)	0.3
220990	Others	0.1
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	1
231020	Peppers (Chilli peppers)	0.5
231030	Aubergines (egg plants) (Pepino)	0.05*
231040	Okra, lady's fingers	0.05*
231990	Others	0.05*
232000	(b) Cucurbits – edible peel	1
232010	Cucumbers	1
232020	Gherkins	1
232030	Courgettes (Summer squash, marrow (patisson))	1
232990	Others	1
233000	© Cucurbits-inedible peel	
233010	Melons (Kiwano)	1
233020	Pumpkins (Winter squash)	0.05*
233030	Watermelons	0.05*
233990	Others	0.05*
234000	(d) Sweet corn	0.05*
239000	(e) Other fruiting vegetables	0.05*
240000	(iv) Brassica vegetables	0.05*
241000	(a) Flowering brassica	0.05*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0.05*
241020	Cauliflower	0.05*
241990	Others	0.05*
242000	(b) Head brassica	0.05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	
242010	Brussels sprouts	0.05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0.05*
242990	Others	0.05*
243000	© Leafy brassica	0.05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0.05*
243020	Kale (Borecole (curly kale), collards)	0.05*
243990	Others	0.05*
244000	(d) Kohlrabi	0.05*
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	
251010	Lamb´s lettuce (Italian cornsalad)	1
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	10
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	1
251040	Cress	1
251050	Land cress	1
251060	Rocket, Rucola (Wild rocket)	10
251070	Red mustard	1
251080	Leaves and sprouts of Brassica spp (Mizuna)	1
251990	Others	1
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0.1
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	1
252030	Beet leaves (chard) (Leaves of beetroot)	0.05*
252990	Others	0.05*
253000	© Vine leaves (grape leaves)	10
254000	(d) Water cress	10
255000	(e) Witloof	10
256000	(f) Herbs	10
256010	Chervil	10
256020	Chives	10
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	10
256040	Parsley	10
256050	Sage (Winter savory, summer savory,)	10
256060	Rosemary	10
256070	Thyme (marjoram, oregano)	10
256080	Basil (Balm leaves, mint, peppermint)	10
256090	Bay leaves (laurel)	10
256100	Tarragon (Hyssop)	10
256990	Others	10
260000	(vi) Legume vegetables (fresh)	0.05*
260010	Beans (with pods) (Green bean (19huckl beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0.05*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0.05*
260030	Peas (with pods) (Mangetout (sugar peas))	0.05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0.05*
260050	Lentils	0.05*
260990	Others	0.05*
270000	(vii) Stem vegetables (fresh)	0.05*
270010	Asparagus	0.05*
270020	Cardoons	0.05*
270030	Celery	0.05*
270040	Fennel	0.05*
270050	Globe artichokes	0.05*
270060	Leek	0.2
270070	Rhubarb	0.05*
270080	Bamboo shoots	0.05*
270090	Palm hearts	0.05*
270990	Others	0.05*
280000	(viii) Fungi	0.05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0.05*
280020	Wild (Chanterelle, Truffle, Morel)	0.05*
280990	Others	0.05*
290000	(ix) Sea weeds	0.05*
300000	3. PULSES, DRY	0.05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0.05*
300020	Lentils	0.05*
300030	Peas (Chickpeas, field peas, 19huckling vetch)	0.05*
300040	Lupins	0.05*
300990	Others	0.05*
400000	4. OILSEEDS AND OILFRUITS	0.05*
401000	(i) Oilseeds	0.05*
401010	Linseed	0.05*
401020	Peanuts	0.05*
401030	Poppy seed	0.05*
401040	Sesame seed	0.05*
401050	Sunflower seed	0.05*
401060	Rape seed (Bird rapeseed, turnip rape)	0.05*
401070	Soya bean	0.05*
401080	Mustard seed	0.05*
401090	Cotton seed	0.05*
401100	Pumpkin seeds	0.05*
401110	Safflower	0.05*
401120	Borage	0.05*
401130	Gold of pleasure	0.05*
401140	Hempseed	0.05*
401150	Castor bean	0.05*
401990	Others	0.05*
402000	(ii) Oilfruits	0.05*
402010	Olives for oil production	0.05*
402020	Palm nuts (palmoil kernels)	0.05*
402030	Palmfruit	0.05*
402040	Kapok	0.05*
402990	Others	0.05*
500000	5. CEREALS	0.05*
500010	Barley	0.05*
500020	Buckwheat	0.05*
500030	Maize	0.05*
500040	Millet (Foxtail millet, teff)	0.05*
500050	Oats	0.05*
500060	Rice	0.05*
500070	Rye	0.05*
500080	Sorghum	0.05*
500090	Wheat (Spelt Triticale)	0.05*
500990	Others	0.05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0.05*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0.05*
620000	(ii) Coffee beans	0.05*
630000	(iii) Herbal infusions (dried)	0.05*
631000	(a) Flowers	0.05*
631010	Camomille flowers	0.05*
631020	Hybiscus flowers	0.05*
631030	Rose petals	0.05*
631040	Jasmine flowers	0.05*
631050	Lime (linden)	0.05*
631990	Others	0.05*
632000	(b) Leaves	0.05*
632010	Strawberry leaves	0.05*
632020	Rooibos leaves	0.05*
632030	Maté	0.05*
632990	Others	0.05*
633000	© Roots	0.05*
633010	Valerian root	0.05*
633020	Ginseng root	0.05*
633990	Others	0.05*
639000	(d) Other herbal infusions	0.05*
640000	(iv) Cocoa (fermented beans)	0.05*
650000	(v) Carob (st johns bread)	0.05*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	50
800000	8. SPICES	0.05*
810000	(i) Seeds	0.05*
810010	Anise	0.05*
810020	Black caraway	0.05*
810030	Celery seed (Lovage seed)	0.05*
810040	Coriander seed	0.05*
810050	Cumin seed	0.05*
810060	Dill seed	0.05*
810070	Fennel seed	0.05*
810080	Fenugreek	0.05*
810090	Nutmeg	0.05*
810990	Others	0.05*
820000	(ii) Fruits and berries	0.05*
820010	Allspice	0.05*
820020	Anise pepper (Japan pepper)	0.05*
820030	Caraway	0.05*
820040	Cardamom	0.05*
820050	Juniper berries	0.05*
820060	Pepper, black and white (Long pepper, pink pepper)	0.05*
820070	Vanilla pods	0.05*
820080	Tamarind	0.05*
820990	Others	0.05*
830000	(iii) Bark	0.05*
830010	Cinnamon (Cassia)	0.05*
830990	Others	0.05*
840000	(iv) Roots or rhizome	0.05*
840010	Liquorice	0.05*
840020	Ginger	0.05*
840030	Turmeric (Curcuma)	0.05*
840040	Horseradish	0.05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	
840990	Others	0.05*
850000	(v) Buds	0.05*
850010	Cloves	0.05*
850020	Capers	0.05*
850990	Others	0.05*
860000	(vi) Flower stigma	0.05*
860010	Saffron	0.05*
860990	Others	0.05*
870000	(vii) Aril	0.05*
870010	Mace	0.05*
870990	Others	0.05*
900000	9. SUGAR PLANTS	0.05*
900010	Sugar beet (root)	0.05*
900020	Sugar cane	0.05*
900030	Chicory roots	0.05*
900990	Others	0.05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	0.05*
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	0.05*
1011000	(a) Swine	0.05*
1011010	Meat	0.05*
1011020	Fat free of lean meat	0.05*
1011030	Liver	0.05*
1011040	Kidney	0.05*
1011050	Edible offal	0.05*
1011990	Others	0.05*
1012000	(b) Bovine	0.05*
1012010	Meat	0.05*
1012020	Fat	0.05*
1012030	Liver	0.05*
1012040	Kidney	0.05*
1012050	Edible offal	0.05*
1012990	Others	0.05*
1013000	© Sheep	0.05*
1013010	Meat	0.05*
1013020	Fat	0.05*
1013030	Liver	0.05*
1013040	Kidney	0.05*
1013050	Edible offal	0.05*
1013990	Others	0.05*
1014000	(d) Goat	0.05*
1014010	Meat	0.05*
1014020	Fat	0.05*
1014030	Liver	0.05*
1014040	Kidney	0.05*
1014050	Edible offal	0.05*
1014990	Others	0.05*
1015000	(e) Horses, asses, mules or hinnies	0.05*
1015010	Meat	0.05*
1015020	Fat	0.05*
1015030	Liver	0.05*
1015040	Kidney	0.05*
1015050	Edible offal	0.05*
1015990	Others	0.05*
1016000	(f) Poultry –chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0.05*
1016010	Meat	0.05*
1016020	Fat	0.05*
1016030	Liver	0.05*
1016040	Kidney	0.05*
1016050	Edible offal	0.05*
1016990	Others	0.05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0.05*
1017010	Meat	0.05*
1017020	Fat	0.05*
1017030	Liver	0.05*
1017040	Kidney	0.05*
1017050	Edible offal	0.05*
1017990	Others	0.05*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter,	0.05*
	butter and other fats derived from milk, cheese and curd	
1020010	Cattle	0.05*
1020020	Sheep	0.05*
1020030	Goat	0.05*
1020040	Horse	0.05*
1020990	Others	0.05*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0.05*
1030010	Chicken	0.05*
1030020	Duck	0.05*
1030030	Goose	0.05*
1030040	Quail	0.05*
1030990	Others	0.05*
1040000	(iv) Honey (Royal jelly, pollen)	0.05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0.05*
1060000	(vi) Snails	0.05*
1070000	(vii) Other terrestrial animal products	0.05*

(*) Indicates lower limit of analytical determination

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ArfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
DALA	days after last treatment
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DT_{90}	period required for 90 percent dissipation (define method of estimation)
EC	European Community
EDI	estimated daily intake
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
GAP	good agricultural practice
GC-NDP	gas chromatography with nitrogen-phosphorus detector
GS	growth stage
ha	hectare
hL	hectolitre
HPLC MS-MS	high performance liquid chromatography with tandem mass spectrometry
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
PF	processing factor
PHI	pre harvest interval
PPP	Plant protection product
PRIMo	Pesticide Residues Intake Model

RA	Risk assessment
R_{ber}	statistical calculation of the MRL by using a no parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RMS	rapporteur Member State
SEU	Southern European Union
RSD	relative standard deviation
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
WG	water dispersible granule