

REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for dimethomorph in several vegetable crops¹

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Germany received three applications from BASF SE to modify or set MRLs for the active substance dimethomorph. In order to accommodate for the intended uses of dimethomorph, Germany proposed to raise the existing MRL from the LOQ of 0.05 mg/kg to 3 mg/kg in leafy brassica, from 1 mg/kg to 5 mg/kg on scarole, whereas an amendment of the existing MRLs was not necessary for cress and land cress, and to set import tolerances at 4 mg/kg on flowering brassica, 15 mg/kg on lettuce and celery and 0.6 mg/kg on garlic, onions and shallots. Germany drafted three separate evaluation reports according to Article 8 of Regulation (EC) No 396/2005 which were submitted to the European Commission and forwarded to EFSA, which addressed these applications in a single reasoned opinion. According to EFSA the data are sufficient to derive MRL proposals of 3 mg/kg for leafy brassica, 6 mg/kg for scarole (outdoor use in Southern Europe), while the existing MRL of 10 mg/kg supports the intended indoor/outdoor uses on cress and land cress and no amendment is necessary. The following import tolerances are proposed: 0.6 mg/kg for onion, garlic and shallot, 15 mg/kg for lettuce and celery. The values of 7 mg/kg and 5 mg/kg for head cabbage and broccoli, respectively, are proposed assuming that the modification of the GAP authorised in the USA will be approved. Adequate analytical methods are available to monitor the residues of dimethomorph in the commodities under consideration at the validated LOQ of 0.01 mg/kg. Based on the risk assessment results, EFSA concludes that the proposed uses under consideration (except the indoor use on scarole) will not result in a consumer exposure exceeding the toxicological reference values and therefore will not pose a public health concern.

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KEY WORDS

Dimethomorph, flowering and leafy brassica, lettuce and other salad plants, bulb vegetables, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, morpholine fungicide.

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Germany, hereafter referred to as the evaluating Member State (EMS), received an application from BASF SE to set a MRL for the active substance dimethomorph in leafy brassica. In order to accommodate for the intended use of dimethomorph, Germany proposed to raise the existing MRL from the limit of quantification value of 0.05* mg/kg to 3 mg/kg. Germany 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 6 January 2012.

In accordance with Article 6 of Regulation (EC) No 396/2005, the EMS Germany, received an application from BASF SE to set import tolerances for the active substance dimethomorph in flowering brassicas, bulb vegetables, head cabbage, lettuce and celery imported from the United States of America and Canada at the level of 4 mg/kg on flowering brassica, 15 mg/kg on lettuce and celery and 0.6 mg/kg on garlic, onions and shallots. Germany drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 29 February 2012.

In accordance with Article 6 of Regulation (EC) No 396/2005, the EMS Germany, received a further application from BASF SE to modify the MRLs for the active substance dimethomorph in scarole, cress and land cress. In order to accommodate for the intended use of dimethomorph, Germany proposed to raise the existing MRL from 1 mg/kg to 5 mg/kg on scarole, whereas an amendment of the existing MRLs was not necessary for cress and land cress. Germany 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 29 February 2012.

Considering that the three applications refer to MRLs for the active substance dimethomorph, EFSA addressed these applications in a single reasoned opinion.

EFSA bases its assessment on the three evaluation reports, the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC, the Commission Review Report on dimethomorph, the conclusion on the peer review of the pesticide risk assessment of the active substance dimethomorph, the JMPR evaluation report as well as the conclusions from previous EFSA reasoned opinions, including the EFSA reasoned opinion on the review of the existing MRLs for dimethomorph according to Article 12 of Regulation (EC) No 396/2005.

The toxicological profile of dimethomorph was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.05 mg/kg bw per day and an ARfD of 0.6 mg/kg bw.

The metabolism of dimethomorph in primary crops was investigated in three crop groups after foliar application and in tomatoes following application through a hydroponic system. The review of the existing MRLs for dimethomorph performed under Article 12 of Regulation (EC) No 396/2005 confirmed the conclusion of the peer review that the relevant residue definition for both enforcement and risk assessment in all plant commodities is dimethomorph (sum of isomers). For the use on the crops under consideration, EFSA concludes that the metabolism of dimethomorph in primary crops is sufficiently addressed and that the derived residue definitions are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 3 mg/kg for the intended use on leafy brassica and 10 mg/kg for the intended uses on scarole, while the existing MRL of 10 mg/kg supports the intended uses on cress and land cress and no amendment is necessary. The following import tolerances are proposed: 0.6 mg/kg for onion, garlic and shallot, 15 mg/kg for lettuce and celery. The values of 7 mg/kg and 5 mg/kg for head cabbage and broccoli, respectively, are proposed assuming that the modification of the GAP authorised in the USA will be approved. Adequate analytical methods are available to monitor the residues of dimethomorph in the commodities under consideration at the validated LOQ of 0.01 mg/kg.

The peer review concluded that the dimethomorph is hydrolytically stable during pasteurisation, baking, boiling, brewing and sterilisation and the same residue definition as for raw agricultural commodities (RAC) is applicable. Studies investigating the magnitude of residues in washed lettuce leaves and dried and peeled onions showed that dimethomorph residues were significantly reduced.

For leafy brassicas, scarole, cress and land cress, EFSA concludes that residues of dimethomorph in rotational crops resulting from the uses according to the proposed GAP (Good Agricultural Practice) can not be excluded and the plant-back restrictions should be considered when granting an authorisation for dimethomorph at national level.

Residues of dimethomorph in commodities of animal origin were not assessed in the framework of this application, since the crops under consideration are not normally fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). The risk assessment performed in the framework of the review of the existing MRLs for dimethomorph according to Article 12 under of Regulation (EC) No 396/2005 taking into account the existing uses at EU level and the existing Codex limits (CXLs) sufficiently supported by data. EFSA now updates the risk assessment with the median and the highest residue values as derived from the submitted supervised residue trials. The acute exposure assessment was performed only with regard to the commodities under consideration. The estimated exposure was then compared with the toxicological reference values derived for dimethomorph.

It is noted that the long-term consumer exposure calculation is based on the conclusions and recommendations derived in the review of the existing MRLs for dimethomorph under Article 12 of Regulation (EC) No 396/2005. Under the assumption that the MRLs will be amended as proposed in the Article 12 review, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMO. The total calculated intake accounted for less than 10 % of the ADI (WHO cluster diet B).

The short-term risk assessment confirmed a potential consumer health risk resulting from the residues of dimethomorph in scarole (105 % of the ARfD) in the Dutch diet for children. A second exposure calculation was therefore performed considering the outdoor use in SEU for scarole and the calculated maximum exposure for scarole dropped down to 46 % of the ARfD. With regard to the other crops under consideration no short-term consumer intake concerns were identified.

EFSA concludes that the proposed uses on the vegetables under consideration (except the indoor use on scarole), will not result in a consumer exposure exceeding the toxicological reference values and therefore will not pose a public health concern.

Thus EFSA proposes to amend the existing MRLs as reported in the summary table.

Summary table

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: dimethomorph (sum of isomers)				
0243010	Chinese cabbage	0.05* / 0.01* ^(b)	3	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended use on leafy brassica.
0243020	Kale	0.05* / 0.01* ^(b)	3	
0243990	Others	0.05* / 0.01* ^(b)	3	
0251030	Scarole	1 / 0.1 ^(b)	6	An acute consumer intake concern was associated with the MRL proposal of 10 mg/kg (derived by extrapolation from lettuce) for the indoor use.

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
				EFSA derived an alternative MRL proposal for the outdoor use in SEU based on extrapolation from data on lettuce/lamb's lettuce and no risk for consumers was identified for the proposed fall-back MRL. Additional residue trials would be desirable to confirm this MRL proposal.
0251040	Cress	10	10	The submitted data support the proposed uses and an amendment of the existing MRLs is not necessary. The MRL proposals were extrapolated from data on open leaf lettuce.
0251050	Land cress	10	10	
0241010	Broccoli	0.05* / 1 ^(b)	2 / 5	The proposal of 2 mg/kg for the import tolerance is sufficiently supported by data and no risk for consumers was identified. The value of 5 mg/kg is applicable if the modification of the GAP authorised in the USA has meanwhile been approved.
0241020	Cauliflower	0.05* / 0.05 ^(b)	No new proposal	No import tolerance proposal is derived. The submitted data are not sufficient to derive a MRL for the group of flowering brassicas.
0241990	Others (flowering brassica)	0.05* / 0.05 ^(b)	No new proposal	
0242020	Head cabbage	0.05* / 2 ^(b)	2 / 7	The submitted data are sufficient to propose 2 mg/kg for the import tolerance; an amendment of the MRL proposed under the Article 12 review is not necessary. A higher MRL of 7 mg/kg would be appropriate if the modification of the GAP requested in the USA (reduction of the PHI from 7 days to 0 days) is approved.
0251020	Lettuce	10	20	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the import tolerance requests.
0256030	Celery	10	15	
0220010	Garlic	0.15	0.6	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the import tolerance requests. The MRL proposals were extrapolated from data on onions.
0220020	Onions	0.15	0.6	
0220030	Shallots	0.15	0.6	

(a): According to Annex I of Regulation (EC) No 396/2005.

(b): MRLs recommended in the framework of the MRL review (EFSA, 2011c).

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

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BACKGROUND

Regulation (EC) No 396/2005³ establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC⁴, repealed by Regulation (EC) No 1107/2009⁵, shall submit to a Member State, when appropriate, an application to modify a MRL or to set an import tolerance in accordance with the provisions of Article 7 of that Regulation.

Germany, hereafter referred to as the evaluating Member State (EMS), received an application from the company BASF SE⁶ to modify the existing MRL for the active substance dimethomorph in leafy brassica. This application was notified to the European Commission and EFSA and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 6 January 2012.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2012-00019 and the following subject:

Dimethomorph - Application to modify the existing MRL in leafy brassica

Afterwards, the evaluating Member State Germany received an additional application from the company BASF SE to set import tolerances for the active substance dimethomorph in flowering brassica, bulb vegetables, head cabbage, lettuce and celery. This application was notified to the European Commission and EFSA and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 29 February 2012.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2012-00361 and the following subject:

Dimethomorph - Application to modify the existing MRLs in various crops

Germany received a further application from the company BASF SE to modify the existing MRL for the active substance dimethomorph in scarole, cress and land cress. This application was notified to the European Commission and EFSA and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 29 February 2012.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2012-00362 and the following subject:

Dimethomorph - Application to modify the existing MRLs in scarole, land cress and cress

Germany proposed to modify the existing MRLs of dimethomorph as reported in the table below.

³ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005. OJ L 70, 16.03.2005, p. 1-16.

⁴ Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32

⁵ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009. OJ L 309, 24.11.2009, p. 1-50.

⁶ BASF SE, Carl-Bosch-Straße 64, 67117, Limburgerhof, Germany.

Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL by EMS (mg/kg)	EFSA question number
Leafy brassica	0.05*	3	EFSA-Q-2012-00019
Scarole	1	5	EFSA-Q-2012-00362
Cress	10 ^(a)	10	EFSA-Q-2012-00362
Land cress	10 ^(a)	10	EFSA-Q-2012-00362
Broccoli	0.05*	4	EFSA-Q-2012-00361
Cauliflower	0.05*	4	EFSA-Q-2012-00361
Others (flowering brassica)	0.05*	4	EFSA-Q-2012-00361
Head cabbage	0.05*	7	EFSA-Q-2012-00361
Lettuce	10	15	EFSA-Q-2012-00361
Celery	10	15	EFSA-Q-2012-00361
Garlic, onions, shallots	0.15	0.6	EFSA-Q-2012-00361

(a): The MRL of 1 mg/kg was legally in force when the EMS drafted the evaluation report (Germany, 2012a).

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

Considering that the three applications refer to the same active substance, EFSA addressed them in a single reasoned opinion.

EFSA proceeded with the assessment of the applications and the evaluation reports as required by Article 10 of the Regulation.

TERMS OF REFERENCE

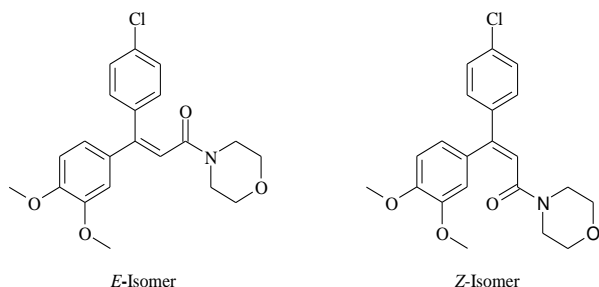
In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) 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 deadlines for providing the reasoned opinions are 6 April 2012 for the first application and 29 May 2012 for the other two applications.

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) and consists of a mixture of two isomers, *Z*-isomer and *E*-isomer (*E:Z* isomer ratio 44:56, EC, 2006). The chemical structure of the compound is reported below.



Molecular weight: 387.9 g/mol

Dimethomorph is a systemic fungicide belonging to the morpholine chemical class. Dimethomorph is active against fungi of 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 was evaluated in the framework of Council Directive 91/414/EEC with Germany designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Commission Directive 2007/25/EC⁷ which entered into force on 1st October 2007 for use as fungicide only. In accordance with Commission Implementing Regulation (EU) No 540/2011⁸ dimethomorph is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The representative use supported for the peer review process was the use on potatoes in northern and southern Europe. The Draft Assessment Report (DAR) of dimethomorph has been peer reviewed by EFSA (EFSA, 2006).

The EU MRLs for dimethomorph are established in Annex IIIA of Regulation (EC) No 396/2005 (Appendix C). EFSA recommendations to modify the existing MRLs on various crops (EFSA, 2009, 2010, 2011a, 2011b, 2011d) have been implemented in five Regulations adopted between 2010 and 2012. EFSA recently issued a reasoned opinion for dimethomorph which reviews all uses authorised at EU level and Codex limits (CXLs) according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011c). Modifications of the existing MRLs were proposed for several crops (see Appendix C) which are currently under discussion at the Standing Committee on the Food Chain and Animal Health (draft Regulation SANCO/10392/2012 (Article 12 MRLs) rev3). Codex Alimentarius has established CXLs for a range of commodities, including broccoli (CXL of 1 mg/kg), head cabbage (CXL of 2 mg/kg) and lettuce (CXL of 10 mg/kg).

The details of the proposed GAPs for the European uses and the authorised GAPs for the import tolerance requests are given in Appendix A.

⁷ Commission Directive 2007/25/EC of 23 April 2007. OJ L 106. 24.04.2007, p. 34-42.

⁸ Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011. OJ L 153, 11.06.2011, p. 1-186.

ASSESSMENT

EFSA bases its assessment on the three evaluation reports submitted by the EMS (Germany, 2011, 2012a, 2012b), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Germany, 2004), the Commission Review Report on dimethomorph (EC, 2006), the conclusion on the peer review of the pesticide risk assessment of the active substance dimethomorph (EFSA, 2006), the JMPR Evaluation report (FAO, 2007) as well as the conclusions from previous EFSA reasoned opinions, including the EFSA reasoned opinion on the review of the existing MRLs for dimethomorph according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2009, 2010, 2011a, 2011b, 2011c, 2011d). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁹ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

1. Method of analysis

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

The multi-residue analytical method DFG S19 was accepted by the peer review to monitor and control dimethomorph (as sum of isomers) residues with an LOQ of 0.02 mg/kg in high water content (onions), high acid content (grapes) and high fat content (rape seed) commodities and 0.2 mg/kg in hops (EFSA, 2006; EFSA, 2011c).

The multi-residue QuEChERS method described in the European Standard EN 15662:2008 is also applicable. The liquid chromatography coupled with tandem mass spectrum detection (LC-MS/MS) method analyses residues of dimethomorph (sum of isomers) in matrices with high water, high acid and in dry content at the LOQ of 0.01 mg/kg (CEN, 2008).

Since the commodities under consideration belong to the group of high water content commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRLs for dimethomorph are available.

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

The availability of analytical methods for the enforcement of residues in products of animal origin was not discussed here because the crops under consideration are not used as livestock feed.

2. Mammalian toxicology

The toxicological profile of the active substance dimethomorph was assessed in the framework of the peer review under Directive 91/414/EEC (Germany, 2004; EFSA, 2006; EC, 2006). The data were sufficient to derive toxicological reference values for dimethomorph which are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Dimethomorph					
ADI	EC	2006	0.05 mg/kg bw per day	Dog, 1 yr study	100
ARfD	EC	2006	0.6 mg/kg bw	Rat, developmental toxicity	100

⁹ Commission Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of dimethomorph in primary crops was investigated during the peer review in grapes (fruit and fruiting vegetables), potatoes (root and tuber vegetables) and lettuce (leafy vegetables) after foliar application. In addition, a study on tomatoes in a hydroponic system was performed to investigate the absorption of dimethomorph via the roots and the distribution in the plant. The details of the metabolism studies are reported in the DAR and the EFSA reasoned opinion on the review of the existing MRLs (Germany, 2004; EFSA, 2011c). The metabolic pathway showed to be similar in all investigated crop groups with a limited degradation of dimethomorph (EFSA, 2006). The review of the existing MRLs for dimethomorph performed under Article 12 of Regulation (EC) No 396/2005 confirmed the conclusion of the peer review that the relevant residue definition for both enforcement and risk assessment in all plant commodities is dimethomorph (sum of isomers). The current residue definition according to Regulation (EC) No 396/2005 is established as dimethomorph.

For the use on the crops under consideration, EFSA concludes that the metabolism of dimethomorph in primary crops is sufficiently addressed and that the derived residue definitions are applicable.

3.1.1.2. Magnitude of residues

a. Leafy brassica

Nine supervised residue trials (four designed as residue decline studies) on kale conducted in Germany over two seasons reflect the intended GAP. The results can be extrapolated to the whole group of leafy brassica (EC, 2011). The data are sufficient to derive the MRL proposal and the risk assessment input values for the leafy brassica vegetables.

b. Scarole, cress, land cress

Indoor - EU: in support to the intended indoor use 13 supervised residue trials on open leaf varieties of lettuce conducted with different formulations (EC, SC and WG) were submitted. All trials were considered representative for the GAP notified for these crops. Data on open leaf lettuce allow extrapolation to the whole group of lettuce, thus including scarole, cress and land cress (EC, 2011). The result (7.2 mg/kg, WG formulation) from one trial conducted with two instead of three applications was identified as potential outlier (Dixon's text). Since there were no explanations and no obvious deficiencies in the trial to justify its exclusion, the value was maintained in the dataset (EC, 1997g; FAO, 2009).

Outdoor - SEU: in support of the intended outdoor use two supervised residue trials on open leaf varieties of lettuce conducted with different formulations (EC, WG) were submitted. The trials were considered representative for the proposed GAP but the number of trials was not sufficient to extrapolate to the whole group of salad plants (*i.e.* scarole, cress and land cress). In accordance with the EU guideline in force at time of application eight trials on open leaf lettuce are required to allow the extrapolation (EC, 2011).

These crops are classified as minor crops in Europe. EFSA is of the opinion that the dataset of two trials on open leaf lettuce can be completed using six trials on lamb's lettuce conducted according to the intended GAP for scarole, cress and land cress. Thus, taking into account the yield and the morphological similarities among the baby-leaf lettuce, such as cress and land cress. It is likely that residues in lamb's lettuce would be higher than those in these vegetables. However, the applicant is recommended to provide data reflecting the expected residues in scarole, cress and land cress to ensure that dimethomorph residues are not overestimated.

EFSA concludes the MRL of 10 mg/kg would be the appropriate level for the proposed uses on scarole, cress and land cress based on the more critical indoor use.

c. Lettuce

In support of the import tolerance request 17 supervised residue decline trials on lettuce (9 on open leaf varieties and 8 on head varieties) were submitted. The trials were conducted almost exclusively during 2008 in the United States of America (USA) and were considered representative for the GAP authorised in the USA and Canada. Based on the combined dataset the MRL proposal of 15 mg/kg is derived.

d. Head cabbage

In support of the import tolerance request 10 supervised residue decline trials conducted on head cabbage during 2008 in the USA were provided. The data were considered representative for the GAP authorised in the USA and Canada and are sufficient to derive the MRL proposal and the risk assessment input values for head cabbage. Since the EMS announced that the applicant requested a modification of the GAP in the USA reducing the PHI from 7 to 0 days, EFSA has derived the import tolerance also for the more critical use.

e. Flowering brassica

In support of the import tolerance request 10 supervised residue decline trials on broccoli were provided. The trials were conducted almost exclusively during 2008 in the USA (nine trials) and Canada (one trial) and are GAP-compliant. Since none of the trials is conducted on cauliflower, the extrapolation to the whole group of flowering brassica is not acceptable in the EU (EC, 2011). However, the data are sufficient to derive the MRL proposal and the risk assessment input values for broccoli. Since the EMS announced that the applicant requested a modification of the GAP in the USA reducing the PHI from 7 to 0 days, EFSA has derived the import tolerance also for the more critical use.

f. Celery

In support of the import tolerance request 9 supervised residue decline trials conducted on celery over a single season (2008) in the USA (eight trials) and Canada (one trial) were submitted. The trials were considered representative for the GAP authorised in the USA and Canada and are sufficient to derive the MRL proposal and the risk assessment input values for celery.

g. Onion, garlic, shallot

In support of the import tolerance request 10 supervised residue decline trials conducted on onions almost exclusively during 2008 in the USA (nine trials) and Canada (one trial) were submitted. Data from the trials on onions allow extrapolation to garlic and shallot (EC, 2011). The trials were considered representative for the GAP authorised in the USA and Canada and are sufficient to derive the MRL proposal and the risk assessment input values for onions, garlic and shallot.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 3-1.

The storage stability of dimethomorph residues was demonstrated in matrices with high water (potatoes, tomatoes, broccoli, spinach), high acid (grapes), high oil (rape seed) content commodities as well as in dry matrices (hops) for up to 24 months at -18°C (EFSA, 2006; 2011c). As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

According to the EMS, the analytical methods used to analyse the supervised residue trial samples have been sufficiently validated and were proven to be fit for purpose (Germany, 2011, 2012a, 2012b).

EFSA concludes that the data are sufficient to derive a MRL proposal of 3 mg/kg for the intended use on leafy brassica in Germany and 10 mg/kg for the intended uses on scarole, while the existing MRL of 10 mg/kg supports the intended uses on cress and land cress and no amendment is necessary. The following import tolerances are proposed: 0.6 mg/kg for onion, garlic and shallot, 15 mg/kg for lettuce and celery. The values of 7 mg/kg and 5 mg/kg for head cabbage and broccoli, respectively, are proposed assuming that the modification of the GAP authorised in the USA will be approved. The data on broccoli do not support the proposed extrapolation to the group of flowering brassica according to the EU guidance document (EC, 2011).

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

Commodity	Residue region (a)	Outdoor/ Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement (dimethomorph)	Risk assessment (dimethomorph)					
Enforcement residue definition: dimethomorph (sum of isomers)									
Kale → Leafy brassica	NEU	Outdoor	0.03; 0.04; 0.30; 0.32; 0.38; 0.51; 0.63; 1.4; 1.73	0.03; 0.04; 0.30; 0.32; 0.38; 0.51; 0.63; 1.4; 1.73	0.38	1.73	3	1	R _{ber} = 2.03 R _{max} = 2.38 MRL _{OECD} = 2.95/3
(Lettuce →) Scarole, Cress, Land cress	EU	Indoor	<i>Open leaf lettuce:</i> ^(f) 0.13; 0.77; 2 x 0.86; 0.99; 1.12; 1.17; 1.26; 1.5; 1.7; 2.2; 5.9; 7.2 ^{(g)(i)}	0.13; 0.77; 2 x 0.86; 0.99; 1.12; 1.17; 1.26; 1.5; 1.7; 2.2; 5.9; 7.2 ^{(g)(i)}	1.17	7.2	10	1	R _{ber} = 3.9 R _{max} = 7.6 MRL _{OECD} = 10.4/10 Safety concerns identified for scarole.
(Lettuce/ Lamb's lettuce →) Scarole, Cress, Land cress	SEU	Outdoor	<i>Open leaf lettuce:</i> ^(f) 0.13; 0.45 <i>Lamb's lettuce:</i> ^(f) 0.08; 0.1; 0.28; 1.21; 2.49; 3.16	0.08; 0.1; 0.13; 0.28; 0.45; 1.21; 2.49; 3.16	0.37	3.16	6	1	Specific extrapolation is proposed from the combined datasets. R _{ber} = 4.34 R _{max} = 4.83 MRL _{OECD} = 5.81/6
Lettuce	Import	Outdoor	<i>Open leaf lettuce:</i> 3.44; 3.48 ^(h) ; 3.69; 4.68; 5.6; 5.66; 6.05; 10.42; 10.7 ^(h) <i>Head lettuce:</i> 1.23; 1.42; 1.77; 1.83; 2.3 ^(h) ; 2.43; 3.14; 4.1	1.23; 1.42; 1.77; 1.83; 2.3 ^(h) ; 2.43; 3.14; 3.44; 3.48 ^(h) ; 3.69; 4.1; 4.68; 5.6; 5.66; 6.05; 10.42; 10.7 ^(h)	3.48	10.7	15	1	Combined datasets. R _{ber} = 11.26 R _{max} = 11.21 MRL _{OECD} = 15.5/15
Head cabbage	Import	Outdoor	<i>GAP: 3x0.225 kg a.s./ha; PHI 7 days (authorised)</i> 2 x 0.05; 0.11; 0.12; 0.19; 0.20; 0.22; 0.23; 0.80; 1.27	2 x 0.05; 0.11; 0.12; 0.19; 0.20; 0.22; 0.23; 0.80; 1.27	0.2	1.27	2	1	R _{ber} = 0.75 R _{max} = 1.48 MRL _{OECD} = 1.91/2

Commodity	Residue region (a)	Outdoor/ Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement (dimethomorph)	Risk assessment (dimethomorph)					
			<i>GAP: 3x0.225 kg a.s./ha; PHI 0 days (in progress)</i> 0.19 ^(h) ; 0.48 ^(h) ; 0.52; 0.97; 1.15; 1.25 ^(h) ; 1.28 ^(h) ; 1.49; 1.54; 4.61	0.19 ^(h) ; 0.48 ^(h) ; 0.52; 0.97; 1.15; 1.25 ^(h) ; 1.28 ^(h) ; 1.49; 1.54; 4.61	1.2	4.61	7	1	R _{ber} = 3,01 R _{max} = 4.94 MRL _{OECD} = 6.28/7
Broccoli	Import	Outdoor	<i>GAP: 3x0.225 kg a.s./ha; PHI 7 days (authorised)</i> 0.05; 0.09; 0.15; 2 x 0.16; 0.20; 0.31; 0.46; 0.85; 0.98	0.05; 0.09; 0.15; 2 x 0.16; 0.20; 0.31; 0.46; 0.85; 0.98	0.18	0.98	2	1	R _{ber} = 1.12 R _{max} = 1.29 MRL _{OECD} = 1.64/2
			<i>GAP: 3x0.225 kg a.s./ha; PHI 0 days (in progress)</i> 0.3; 0.71; 0.84; 0.93; 0.98; 1.62; 1.64; 1.82; 1.89; 2.62 ^(h)	0.3; 0.71; 0.84; 0.93; 0.98; 1.62; 1.64; 1.82; 1.89; 2.62 ^(h)	1.30	2.62	5	1	Extrapolation to the group of flowering brassica is not acceptable (EC, 2011). R _{ber} = 3.68 R _{max} = 3.36 MRL _{OECD} = 4.12/5
Celery	Import	Outdoor	1.28; 1.62; 1.97; 2.1; 2.48; 3.34 ^(h) ; 4.05; 5.8; 8.82	1.28; 1.62; 1.97; 2.1; 2.48; 3.34 ^(h) ; 4.05; 5.8; 8.82	2.48	8.82	15	1	R _{ber} = 9.85 R _{max} = 10.09 MRL _{OECD} = 13.27/15
Onion → Garlic, Shallot	Import	Outdoor	0.06; 0.09; 0.16; 0.16 ^(h) ; 0.19 ^(h) ; 0.2; 0.21 ^(h) ; 0.24; 0.29 ^(h) ; 0.4	0.06; 0.09; 0.16; 0.16 ^(h) ; 0.19 ^(h) ; 0.2; 0.21 ^(h) ; 0.24; 0.29 ^(h) ; 0.4	0.2	0.4	0.6	1	R _{ber} = 0.51 R _{max} = 0.48 MRL _{OECD} = 0.6/0.6

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (*i.e.* outdoor use) or Import (country code) (EC, 2011).

(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 residue trial.

(e): Statistical estimation of MRLs according to the EU methodology (R_{ber}, R_{max}; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).

(f): Combined dataset of EC, WG or SC formulations of dimethomorph.

(g): Results from trial conducted with two instead of three applications.

(h): The highest values measured at a longer PHI.

(i): Statistically detected as potential outlier (Dixon's Q-test) but no information and no obvious deficiencies in the trial justified its exclusion from the calculation (EC, 1997g; FAO, 2009).

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of dimethomorph was investigated during the peer review in studies performed at three test conditions representing pasteurisation, baking/brewing/boiling and sterilisation (20 minutes at 90°C, pH 4; 60 minutes at 100°C pH 5; 20 minutes at 120°C, pH 6) (Germany, 2004). The compound was shown to be hydrolytically stable under the representative processing conditions. Thus, for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable (EFSA, 2006; 2011c).

Specific studies to assess the magnitude of dimethomorph residues during the processing of the vegetables under consideration, which may be eaten cooked, are not necessary as the total theoretical maximum daily intake (TMDI) amounts to less than 10 % of the ADI (EC, 1997d). Nevertheless, studies on the distribution of residues between the unwashed and washed outer and inner leaves on lettuce indicated that the washing step significantly decreases the residue levels in leaves (Germany, 2012b). Processing studies with onions demonstrated that dimethomorph residues do not accumulate in peeled onions. Data for dried onions also gave an indication that residues of dimethomorph are significantly reduced (Germany, 2102b). However, lacking a detailed description of the processing conditions applied in the onion studies, the processing factors are not recommended to be included in Annex VI of Regulation (EC) No 396/2005.

An overview of all available processing studies is summarised in Table 3-2.

Table 3-2: Overview of the available processing studies

Processed commodity	Number of studies	Median PF ^(a)	Median CF ^(b)	Individual PFs
Enforcement residue definition: dimethomorph				
Lettuce, unwashed outer leaves	4	0.17	1	0.08; 0.1; 0.24; 0.25
Lettuce, unwashed inner leaves	4	1.81	1	0.96; 1.75; 1.87; 2.13
Lettuce, washed outer leaves	4	0.09	1	<0.04; <0.07; 0.11; 0.14
Lettuce, washed inner leaves	4	0.7	1	0.3; 0.66; 0.73; 0.99
Onion, dried	4	<0.08	1	0.03; <0.04; <0.12; <0.34
Onion, peeled	4	<0.08	1	0.02; <0.04; <0.12; <0.34

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Considering the intended European GAPs, leafy brassica, scarole, cress and land cress may be grown in (short) rotation with other plants. In soil degradation studies a moderate persistency of dimethomorph (maximum DT₉₀ in field studies: 203 days; EFSA, 2006) was observed, indicating that the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed (EC, 1997c).

3.1.2.2. Nature and magnitude of residues

The nature and magnitude of dimethomorph residues in rotational crops was investigated during the peer review. The details of the studies are reported in the DAR and the EFSA reasoned opinion on the

review of the existing MRLs (Germany, 2004; EFSA, 2011c). The metabolism in rotational crops was shown to be similar to that observed in primary crop and dimethomorph residues in the tested crops (carrots, spinach and beans sowed within 30 days after the last application of the active substance on potatoes treated three times at an application rate of 0.18 kg a.s./ha) were generally below the LOQ (0.01 mg/kg) except in dry beans or in case of early harvest of carrots or spinach. The highest residues of 0.09 mg/kg and 0.21 mg/kg were found in spinach sampled 72–76 days, respectively. In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005, EFSA confirmed the need for plant-back restriction at national level when granting an authorisation of dimethomorph (EFSA, 2006; 2011c).

For leafy brassica, scarole, cress and land cress, EFSA concludes that residues of dimethomorph in rotational crops resulting from the uses according to the proposed GAP (Good Agricultural Practice) can not be excluded and plant-back restrictions should be considered when granting an authorisation for dimethomorph at national level.

3.2. Nature and magnitude of residues in livestock

Since the products under consideration are not normally fed to livestock, the nature and magnitude of dimethomorph residues in livestock are not assessed (EC, 1996).

4. Consumer risk assessment

In the framework of the review of the existing MRLs for dimethomorph according to Article 12 of Regulation (EC) No 396/2005 a comprehensive long-term exposure assessment was performed taking into account the existing uses of dimethomorph at EU level and the existing CXLs sufficiently supported by data. Those food commodities for which no uses of dimethomorph were reported in the framework of Article 12 of Regulation (EC) No 396/2005 were excluded from the exposure calculation, assuming that there is no use on these crops (EFSA, 2011c). The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population¹⁰ (EFSA, 2007).

The risk assessment performed under Article 12 review was recently updated in the framework of the application for the modification of the existing MRLs for dimethomorph in spinach and beet leaves (EFSA, 2011d). EFSA now updates the most recent risk assessment with the median residue values for leafy brassicas, scarole, cress, land cress, lettuce, head cabbage, broccoli, celery and bulb vegetables (see Table 3-1). The model assumptions for the long-term exposure assessment are considered to be rather conservative. In reality, it is not likely that an individual will consume every food for which a MRL exists and is proposed containing residues at the levels of the median residue values identified in supervised field trials over the lifetime. However, if this exposure assessment does not exceed the toxicological reference value for long-term exposure (*i.e.* the ADI), a consumer health risk can be excluded with a high probability.

The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys containing residues at the highest level as observed in supervised field trials (see Table 3-1). In addition, when required, a variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation.

The input values used for the dietary exposure calculation are summarized in Table 4-1.

Table 4-1: Input values for the consumer dietary exposure assessment

Commodity		Chronic exposure assessment		Acute exposure assessment	
		Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: dimethomorph (sum of isomers)					
Leafy brassica		0.38	Median residue (kale, NEU)	1.73	Highest residue (kale, NEU)
Scarole	Scenario 1	1.27	Median residue ^(a) (EFSA, 2011c)	7.2	Highest residue (lettuce, indoor)
	Scenario 2	0.75	Median residue (lettuce/lamb's lettuce, SEU)	3.16	Highest residue (lettuce/lamb's lettuce, SEU)
Cress		1.27	Median residue ^(a) (EFSA, 2011c)	7.2	Highest residue (lettuce, indoor)
Land cress		1.27	Median residue ^(a) (EFSA, 2011c)	7.2	Highest residue (lettuce, indoor)

¹⁰ The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMO is given in its reference section (EFSA, 2007).

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Onion, garlic, shallot	0.2	Median residue (onion, import)	0.4	Highest residue (onion, import)
Lettuce	3.6	Median residue ^(a) (EFSA, 2011c)	10.7	Highest residue (import)
Head cabbage	1.2	Median residue (import, PHI 0 d)	4.61	Highest residue (import, PHI 0 d)
Broccoli	1.3	Median residue (import, PHI 0 d)	2.62	Highest residue (import, PHI 0 d)
Celery	2.48	Median residue (import)	8.82	Highest residue (import)
Other commodities of food and animal origin	See Appendix D		Acute risk assessment was undertaken only for the crops under consideration.	

(a): The slightly more conservative median residue values reported in the EFSA reasoned opinion on the review of the existing MRLs for dimethomorph according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011c) were used as input values for the chronic risk assessment.

The estimated exposure was then compared with the toxicological reference values derived for dimethomorph (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

It is noted that the long-term consumer exposure calculation is based on the conclusions and recommendations derived in the review of the existing MRLs for dimethomorph under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011c). Under the assumption that the MRLs will be amended as proposed in the Article 12 review, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for less than 10 % of the ADI (WHO cluster diet B). Among the crops under consideration, the major contribution of residues to the total consumer exposure was for lettuce and accounted for a maximum of 3.9 % of the ADI (ES adult).

The short-term risk assessment confirmed a potential consumer health risk resulting from the residues of dimethomorph in scarole (105 % of the ARfD) in the Dutch diet for children (Scenario 1) identified by the EMS (Germany, 2012b). A second exposure calculation (Scenario 2) was therefore performed considering the outdoor use in SEU for scarole¹¹ (see Table 4-1) and the calculated maximum exposure for scarole dropped down to 46 % of the ARfD. With regard to the other crops under consideration no short-term consumer intake concerns were identified and the calculated maximum exposure in percentage of the ARfD was 67.5 % for celery, 48 % for lettuce, 40.4 % for head cabbage, 24.5 % for broccoli, 19.5 % for kale, 10.7 % for Chinese cabbage, 2.7 % for onion, 0.4 % for cress.

EFSA concludes that the intended uses on the vegetables under consideration (except the indoor use on scarole) will not result in a consumer exposure exceeding the toxicological reference values and therefore will not pose a public health concern.

The above risk assessment was performed disregarding the possible impact of the isomer ratios due to plant or livestock metabolism. The same approach was taken in the framework of the MRL review (EFSA, 2011c).

¹¹ It is noted that no significant change to the long term consumer exposure was observed using the median residue value of 0.75 mg/kg for scarole (Scenario 2).

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of dimethomorph was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.05 mg/kg bw per day and an ARfD of 0.6 mg/kg bw.

The metabolism of dimethomorph in primary crops was investigated in three crop groups after foliar application and in tomatoes following application through a hydroponic system. The review of the existing MRLs for dimethomorph performed under Article 12 of Regulation (EC) No 396/2005 confirmed the conclusion of the peer review that the relevant residue definition for both enforcement and risk assessment in all plant commodities is dimethomorph (sum of isomers). For the use on the crops under consideration, EFSA concludes that the metabolism of dimethomorph in primary crops is sufficiently addressed and that the derived residue definitions are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 3 mg/kg for the intended use on leafy brassica and 10 mg/kg for the intended uses on scarole, while the existing MRL of 10 mg/kg supports the intended uses on cress and land cress and no amendment is necessary. The following import tolerances are proposed: 0.6 mg/kg for onion, garlic and shallot, 15 mg/kg for lettuce and celery. The values of 7 mg/kg and 5 mg/kg for head cabbage and broccoli, respectively, are proposed assuming that the modification of the GAP authorised in the USA will be approved. Adequate analytical methods are available to monitor the residues of dimethomorph in the commodities under consideration at the validated LOQ of 0.01 mg/kg.

The peer review concluded that the dimethomorph is hydrolytically stable during pasteurisation, baking, boiling, brewing and sterilisation and the same residue definition as for raw agricultural commodities (RAC) is applicable. Studies investigating the magnitude of residues in washed lettuce leaves and dried and peeled onions showed that dimethomorph residues were significantly reduced.

For leafy brassicas, scarole, cress and land cress, EFSA concludes that residues of dimethomorph in rotational crops resulting from the uses according to the proposed GAP (Good Agricultural Practice) can not be excluded and the plant-back restrictions should be considered when granting an authorisation for dimethomorph at national level.

Residues of dimethomorph in commodities of animal origin were not assessed in the framework of this application, since the crops under consideration are not normally fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The risk assessment performed in the framework of the review of the existing MRLs for dimethomorph according to Article 12 under of Regulation (EC) No 396/2005 taking into account the existing uses at EU level and the existing Codex limits (CXLs) sufficiently supported by data. EFSA now updates the risk assessment with the median and the highest residue values as derived from the submitted supervised residue trials. The acute exposure assessment was performed only with regard to the commodities under consideration. The estimated exposure was then compared with the toxicological reference values derived for dimethomorph.

It is noted that the long-term consumer exposure calculation is based on the conclusions and recommendations derived in the review of the existing MRLs for dimethomorph under Article 12 of Regulation (EC) No 396/2005. Under the assumption that the MRLs will be amended as proposed in the Article 12 review, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for less than 10 % of the ADI (WHO cluster diet B).

The short-term risk assessment confirmed a potential consumer health risk resulting from the residues of dimethomorph in scarole (105 % of the ARfD) in the Dutch diet for children. A second exposure calculation was therefore performed considering the outdoor use in SEU for scarole and the calculated

maximum exposure for scarole dropped down to 46 % of the ARfD. With regard to the other crops under consideration no short-term consumer intake concerns were identified.

EFSA concludes that the proposed uses on the vegetables under consideration (except the indoor use on scarole), will not result in a consumer exposure exceeding the toxicological reference values and therefore will not pose a public health concern.

RECOMMENDATIONS

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: dimethomorph (sum of isomers)				
0243010	Chinese cabbage	0.05* / 0.01 ^{*(b)}	3	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended use on leafy brassica.
0243020	Kale	0.05* / 0.01 ^{*(b)}	3	
0243990	Others	0.05* / 0.01 ^{*(b)}	3	
0251030	Scarole	1 / 0.1 ^(b)	6	An acute consumer intake concern was associated with the MRL proposal of 10 mg/kg (derived by extrapolation from lettuce) for the indoor use. EFSA derived an alternative MRL proposal for the outdoor use in SEU based on extrapolation from data on lettuce/lamb's lettuce and no risk for consumers was identified for the proposed fall-back MRL. Additional residue trials would be desirable to confirm this MRL proposal.
0251040	Cress	10	10	The submitted data support the proposed uses and an amendment of the existing MRLs is not necessary. The MRL proposals were extrapolated from data on open leaf lettuce.
0251050	Land cress	10	10	
0241010	Broccoli	0.05* / 1 ^(b)	2 / 5	The proposal of 2 mg/kg for the import tolerance is sufficiently supported by data and no risk for consumers was identified. The value of 5 mg/kg is applicable if the modification of the GAP authorised in the USA has meanwhile been approved.
0241020	Cauliflower	0.05* / 0.05 ^(b)	No new proposal	No import tolerance proposal is derived. The submitted data are not sufficient to derive a MRL for the group of flowering brassicas.
0241990	Others (flowering brassica)	0.05* / 0.05 ^{*(b)}	No new proposal	
0242020	Head cabbage	0.05* / 2 ^(b)	2 / 7	The submitted data are sufficient to propose 2 mg/kg for the import tolerance; an amendment of the MRL proposed under the Article 12 review is not necessary. A higher MRL of 7 mg/kg would be appropriate if the modification of the GAP requested in the USA (reduction of the PHI from 7 days to 0 days) is approved.
0251020	Lettuce	10	20	The MRL proposals are sufficiently supported by data and no risk for
0256030	Celery	10	15	

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
				consumers was identified for the import tolerance requests.
0220010	Garlic	0.15	0.6	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the import tolerance requests. The MRL proposals were extrapolated from data on onions.
0220020	Onions	0.15	0.6	
0220030	Shallots	0.15	0.6	

(a): According to Annex I of Regulation (EC) No 396/2005.

(b): MRLs recommended in the framework of the MRL review (EFSA, 2011c).

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

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APPENDICES

A. GOOD AGRICULTURAL PRACTICE (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d-f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Leafy brassica	DE	F	<i>Peronospora parasitica</i>	DC	150 g/L	Foliar spray	begin of infestation, as from BBCH 14	2	7-14 d	0.075-0.05	400-600	0.3	14	
Lettuce and other salad plants, including Land cress	IT, ES, EL, PT	I	<i>Bremia lectuca</i>	SC	225 g/L	Foliar spray	BBCH 19-49	1-3	7-10 d	0.018-0.09	200-1000	0.18	7	
Scarole, Cress,	IT, ES, EL	I	<i>Bremia lectuca</i>	EC	72 g/L	Foliar spray	BBCH 10-49	1-3	7-10 d	0.018	1000	0.18	7	
Lettuce and other salad plants, including Land cress	IT, ES, EL, PT	F	<i>Bremia lectuca</i>	SC	225 g/L	Foliar spray	BBCH 19-49	1-3	7-10 d	0.018-0.09	200-1000	0.18	7	
Scarole, Cress	IT, ES, EL	F	<i>Bremia lectuca</i>	EC	72 g/L	Foliar spray	BBCH 10-49	1-3	7-10 d	0.018	1000	0.18	7	
Lettuce	USA, CA	F	Downy mildew (<i>B. lectuca</i>)	SC	225 g/L	Foliar spray	Not specified. (prior to disease development)	2-3	7 d	Max. 0.12	min 187	0.225	0	Max. two (2) sequential applications
Onion, Garlic, Shallot	USA, CA	F	Downy mildew (<i>P. destructor</i>)	SC	225 g/L	Foliar spray	Not specified. (prior to disease development)	2-3	5-7 d	Max. 0.12	min 187	0.225	0	Max. two (2) sequential applications

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d-f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Cauliflowers, Broccoli, Head cabbage	USA, CA	F	Downy mildew (<i>P. parasitica</i>)	SC	225 g/L	Foliar spray	Not specified. (prior to disease development)	2-3	7 d	Max. 0.12	min 187	0.225	7 ⁽ⁿ⁾	Max. two (2) sequential applications
Celery	USA, CA	F	Downy mildew (<i>B. lectuca</i>)	SC	225 g/L	Foliar spray	Not specified. (prior to disease development)	2-3	5-7 d	Max. 0.12	min 187	0.225	0	

- Remarks:
- (a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
 - (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 - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at last treatment (Growth stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) Remarks may include: Extent of use/economic importance/restrictions (*i.e.* feeding, grazing)
 - (n) The EMS Germany reported that the applicant was in the process to obtain the modification of the GAP authorised in the USA from 7 days to 0 day PHI.

B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Dimethomorph									
Status of the active substance:		included		Code no.					
LOQ (mg/kg bw):		0.01		proposed LOQ:					
Toxicological end points									
ADI (mg/kg bw/day):		0.05		ARfD (mg/kg bw):		0.6			
Source of ADI:		EC		Source of ARfD:		EC			
Year of evaluation:		2006		Year of evaluation:		2006			
Chronic risk assessment - refined calculations									
TMDI (range) in % of ADI minimum - maximum									
2 10									
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	pTMRs at LOQ (in % of ADI)	
9.7	WHO Cluster diet B	2.6	Lettuce	2.1	Wine grapes	1.7	Tomatoes	0.1	
7.3	NL child	1.2	Oranges	0.9	Table grapes	0.8	Head cabbage	0.7	
6.7	FR all population	4.7	Wine grapes	0.7	Lettuce	0.2	Tomatoes	0.1	
6.5	WHO regional European diet	2.7	Lettuce	0.9	Head cabbage	0.6	Tomatoes	0.2	
6.0	ES adult	3.9	Lettuce	0.5	Wine grapes	0.5	Oranges	0.2	
5.9	DE child	1.5	Table grapes	1.4	Oranges	0.5	Tomatoes	0.3	
5.8	IE adult	1.5	Wine grapes	0.6	Celery	0.6	Lettuce	0.1	
5.6	WHO cluster diet E	1.9	Wine grapes	0.7	Lettuce	0.6	Head cabbage	0.1	
5.5	WHO Cluster diet F	2.2	Lettuce	0.7	Wine grapes	0.7	Head cabbage	0.2	
5.3	ES child	3.0	Lettuce	0.8	Oranges	0.5	Tomatoes	0.4	
4.9	FR toddler	1.0	Broccoli	0.8	Milk and cream,	0.8	Oranges	0.9	
4.8	PT General population	2.9	Wine grapes	0.5	Potatoes	0.5	Tomatoes	0.0	
4.7	NL general	0.9	Lettuce	0.7	Wine grapes	0.6	Oranges	0.2	
4.4	IT adult	2.7	Lettuce	0.6	Tomatoes	0.2	Table grapes	0.0	
4.1	SE general population 90th percentile	1.5	Head cabbage	0.4	Potatoes	0.4	Tomatoes	0.3	
4.0	UK vegetarian	1.0	Lettuce	1.0	Wine grapes	0.3	Tomatoes	0.1	
3.8	IT kids/toddler	2.1	Lettuce	0.8	Tomatoes	0.2	Oranges	0.0	
3.7	UK Adult	1.3	Wine grapes	0.8	Lettuce	0.3	HOPS (dried),	0.1	
3.6	WHO cluster diet D	0.5	Tomatoes	0.4	Head cabbage	0.4	Wine grapes	0.1	
3.4	DK child	1.0	Lettuce	0.7	Cucumbers	0.3	Tomatoes	0.3	
3.2	UK Toddler	0.8	Oranges	0.4	Milk and cream,	0.3	Potatoes	0.4	
2.9	FR infant	0.8	Broccoli	0.5	Milk and cream,	0.4	Potatoes	0.6	
2.8	DK adult	1.6	Wine grapes	0.2	Tomatoes	0.1	Head cabbage	0.1	
2.5	PL general population	0.9	Head cabbage	0.5	Tomatoes	0.4	Table grapes	0.0	
2.4	LT adult	1.0	Head cabbage	0.5	Lettuce	0.3	Tomatoes	0.1	
2.4	UK Infant	0.8	Milk and cream,	0.5	Oranges	0.3	Potatoes	0.8	
2.3	FI adult	0.6	Lettuce	0.4	Oranges	0.4	Wine grapes	0.1	
Conclusion:									
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI.									
A long-term intake of residues of Dimethomorph is unlikely to present a public health concern.									

SCENARIO 1

Acute risk assessment /children - refined calculations						Acute risk assessment / adults / general population - refined calculations						
SCENARIO 1												
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 lead 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):		
	1			1			---			---		
	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)
	104.9	Scarole (broad-leaf)	7.2 / 6.86	104.9	Scarole (broad-leaf)	7.2 / 6.86	33.9	Celery	8.82 / -	25.0	Celery	8.82 / -
	67.5	Celery	8.82 / -	67.5	Celery	8.82 / -	24.4	Head cabbage	4.61 / -	14.6	Head cabbage	4.61 / -
	48.0	Lettuce	10.7 / -	28.8	Lettuce	10.7 / -	19.6	Lettuce	10.7 / -	11.8	Lettuce	10.7 / -
	40.4	Head cabbage	4.61 / -	24.3	Head cabbage	4.61 / -	10.6	Scarole (broad-leaf)	7.2 / -	10.6	Scarole (broad-leaf endive)	7.2 / -
	25.4	Broccoli	2.62 / -	18.2	Broccoli	2.62 / -	10.3	Chinese cabbage	1.73 / -	10.3	Chinese cabbage	1.73 / -
	19.5	Kale	1.73 / -	13.9	Kale	1.73 / -	9.3	Broccoli	2.62 / -	9.3	Broccoli	2.62 / -
10.7	Chinese cabbage	1.73 / -	10.7	Chinese cabbage	1.73 / -	5.9	Kale	1.73 / -	4.4	Kale	1.73 / -	
2.7	Onions	0.4 / -	1.9	Onions	0.4 / -	1.0	Onions	0.4 / -	0.7	Onions	0.4 / -	
0.4	Cress	7.2 / -	0.4	Cress	7.2 / -	0.5	Cress	7.2 / -	0.5	Cress	7.2 / -	
0.0	Garlic	0.4 / -	0.0	Garlic	0.4 / -	0.0	Garlic	0.4 / -	0.0	Garlic	0.4 / -	
0.0	Shallots	0.4 / -	0.0	Shallots	0.4 / -	0.0	Shallots	0.4 / -	0.0	Shallots	0.4 / -	
No of critical MRLs (IESTI 1)			1			No of critical MRLs (IESTI 2)			1			
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:		
	---			---			---			---		
	IESTI 1 ***)			IESTI 2 ***)			IESTI 1 ***)			IESTI 2 ***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	16.4	Grape juice	3 / -				1.9	Wine	3 / -			
	6.6	Orange juice	0.8 / -				1.3	Orange juice	0.8 / -			
2.9	Tomato juice	1 / -				0.3	Tomato (preserved-	1 / -				
0.2	Wine	3 / -				0.2	Raisins	3 / -				
0.2	Potato puree (flakes)	0.1 / -				0.0	Potato uree (flakes)	0.1 / -				
*) 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.												
The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 1 commodities.												
Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.												

SCENARIO 2

Acute risk assessment /children - refined calculations						Acute risk assessment / adults / general population - refined calculations						
SCENARIO 2												
The acute risk assessment is based on the ARfD.												
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.												
In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.												
In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.												
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.												
Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	---			---			---			---		
	IESTI 1 *)		**)	IESTI 2 *)		**)	IESTI 1 *)		**)	IESTI 2 *)		**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	67.5	Celery	8.82 / -	67.5	Celery	8.82 / -	33.9	Celery	8.82 / -	25.0	Celery	8.82 / -
	48.0	Lettuce	10.7 / -	46.0	Scarole (broad-leaf	3.16 / -	24.4	Head cabbage	4.61 / -	14.6	Head cabbage	4.61 / -
	46.0	Scarole (broad-leaf	3.16 / -	28.8	Lettuce	10.7 / -	19.6	Lettuce	10.7 / -	11.8	Lettuce	10.7 / -
	40.4	Head cabbage	4.61 / -	24.3	Head cabbage	4.61 / -	10.3	Chinese cabbage	1.73 / -	10.3	Chinese cabbage	1.73 / -
	25.4	Broccoli	2.62 / -	18.2	Broccoli	2.62 / -	9.3	Broccoli	2.62 / -	9.3	Broccoli	2.62 / -
	19.5	Kale	1.73 / -	13.9	Kale	1.73 / -	5.9	Kale	1.73 / -	4.7	Scarole (broad-leaf endive)	3.16 / -
10.7	Chinese cabbage	1.73 / -	10.7	Chinese cabbage	1.73 / -	4.7	Scarole (broad-leaf	3.16 / -	4.4	Kale	1.73 / -	
2.7	Onions	0.4 / -	1.9	Onions	0.4 / -	1.0	Onions	0.4 / -	0.7	Onions	0.4 / -	
0.4	Cress	7.2 / -	0.4	Cress	7.2 / -	0.5	Cress	7.2 / -	0.5	Cress	7.2 / -	
0.0	Garlic	0.4 / -	0.0	Garlic	0.4 / -	0.0	Garlic	0.4 / -	0.0	Garlic	0.4 / -	
0.0	Shallots	0.4 / -	0.0	Shallots	0.4 / -	0.0	Shallots	0.4 / -	0.0	Shallots	0.4 / -	
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)
	16.4	Grape juice	3 / -	1.9	Wine	3 / -	1.3	Orange juice	0.8 / -	0.3	Tomato (preserved-	1 / -
	6.6	Orange juice	0.8 / -	0.3	Tomato (preserved-	1 / -	0.2	Raisins	3 / -	0.2	Potato uree (flakes)	0.1 / -
	2.9	Tomato juice	1 / -	0.0	Potato uree (flakes)	0.1 / -						
0.2	Wine	3 / -										
0.2	Potato puree (flakes)	0.1 / -										
*) 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.												

C. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 07/07/2012 10:38))

Code number	Groups and examples of individual products to which the MRLs apply	Dimethomorph	Dimethomorph (sum of isomers) ^(a)
100000	1. FRUIT FRESH OR FROZEN; NUTS		
110000	(i) Citrus fruit		
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,05*	0.01*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,8	0,8
110030	Lemons (Citron, lemon)	0,05*	0.01*
110040	Limes	0,05*	0.01*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,05*	0.01*
110990	Others	0,05*	0.01*
120000	(ii) Tree nuts (shelled or unshelled)	0,05*	0.02*
120010	Almonds	0,05*	0.02*
120020	Brazil nuts	0,05*	0.02*
120030	Cashew nuts	0,05*	0.02*
120040	Chestnuts	0,05*	0.02*
120050	Coconuts	0,05*	0.02*
120060	Hazelnuts (Filbert)	0,05*	0.02*
120070	Macadamia	0,05*	0.02*
120080	Pecans	0,05*	0.02*
120090	Pine nuts	0,05*	0.02*
120100	Pistachios	0,05*	0.02*
120110	Walnuts	0,05*	0.02*
120990	Others	0,05*	0.02*
130000	(iii) Pome fruit	0,05*	0.01*
130010	Apples (Crab apple)	0,05*	0.01*
130020	Pears (Oriental pear)	0,05*	0.01*
130030	Quinces	0,05*	0.01*
130040	Medlar	0,05*	0.01*
130050	Loquat	0,05*	0.01*
130990	Others	0,05*	0.01*
140000	(iv) Stone fruit	0,05*	0.01*
140010	Apricots	0,05*	0.01*
140020	Cherries (sweet cherries, sour cherries)	0,05*	0.01*
140030	Peaches (Nectarines and similar hybrids)	0,05*	0.01*
140040	Plums (Damson, greengage, mirabelle)	0,05*	0.01*
140990	Others	0,05*	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Dimethomorph	Dimethomorph (sum of isomers) ^(a)
150000	(v) Berries & small fruit		
151000	(a) Table and wine grapes	3	3
151010	Table grapes	3	3
151020	Wine grapes	3	3
152000	(b) Strawberries	0,7	0,7
153000	(c) Cane fruit	0,05*	0.01*
153010	Blackberries	0,05*	0.01*
153020	Dewberries (Loganberries, Boysenberries, and cloudberrries)	0,05*	0.01*
153030	Raspberries (Wineberries)	0,05*	0.01*
153990	Others	0,05*	0.01*
154000	(d) Other small fruit & berries	0,05*	0.01*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,05*	0.01*
154020	Cranberries	0,05*	0.01*
154030	Currants (red, black and white)	0,05*	0.01*
154040	Gooseberries (Including hybrids with other ribes species)	0,05*	0.01*
154050	Rose hips	0,05*	0.01*
154060	Mulberries (arbutus berry)	0,05*	0.01*
154070	Azarole (mediterranean medlar)	0,05*	0.01*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,05*	0.01*
154990	Others	0,05*	0.01*
160000	(vi) Miscellaneous fruit	0,05*	0.01*
161000	(a) Edible peel	0,05*	0.01*
161010	Dates	0,05*	0.01*
161020	Figs	0,05*	0.01*
161030	Table olives	0,05*	0.01*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*	0.01*
161050	Carambola (Bilimbi)	0,05*	0.01*
161060	Persimmon	0,05*	0.01*
161070	Jambolan (java plum) (Java apple (water apple),	0,05*	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Dimethomorph	Dimethomorph (sum of isomers) ^(a)
	pomerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)		
161990	Others	0,05*	0.01*
162000	(b) Inedible peel, small	0,05*	0.01*
162010	Kiwi	0,05*	0.01*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*	0.01*
162030	Passion fruit	0,05*	0.01*
162040	Prickly pear (cactus fruit)	0,05*	0.01*
162050	Star apple	0,05*	0.01*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*	0.01*
162990	Others	0,05*	0.01*
163000	(c) Inedible peel, large	0,05*	0.01*
163010	Avocados	0,05*	0.01*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*	0.01*
163030	Mangoes	0,05*	0.01*
163040	Papaya	0,05*	0.01*
163050	Pomegranate	0,05*	0.01*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,05*	0.01*
163070	Guava	0,05*	0.01*
163080	Pineapples	0,05*	0.01*
163090	Bread fruit (Jackfruit)	0,05*	0.01*
163100	Durian	0,05*	0.01*
163110	Soursop (guanabana)	0,05*	0.01*
163990	Others	0,05*	0.01*
200000	2. VEGETABLES FRESH OR FROZEN		
210000	(i) Root and tuber vegetables		
211000	(a) Potatoes	0,5	0.05
212000	(b) Tropical root and tuber vegetables	0,05*	0.01*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*	0.01*
212020	Sweet potatoes	0,05*	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Dimethomorph	Dimethomorph (sum of isomers) ^(a)
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*	0.01*
212040	Arrowroot	0,05*	0.01*
212990	Others	0,05*	0.01*
213000	(c) Other root and tuber vegetables except sugar beet		
213010	Beetroot	0,05*	0.01*
213020	Carrots	0,05*	0.01*
213030	Celeriac	0,05*	0.01*
213040	Horseradish	0,05*	0.01*
213050	Jerusalem artichokes	0,05*	0.01*
213060	Parsnips	0,05*	0.01*
213070	Parsley root	0,05*	0.01*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	1	1.5
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,05*	0.01*
213100	Swedes	0,05*	0.01*
213110	Turnips	0,05*	0.01*
213990	Others	0,05*	0.01*
220000	(ii) Bulb vegetables		
220010	Garlic	0,15	0,15
220020	Onions (Silverskin onions)	0,15	0,15
220030	Shallots	0,15	0,15
220040	Spring onions (Welsh onion and similar varieties)	0,3	0.2
220990	Others	0,1	0.15
230000	(iii) Fruiting vegetables		
231000	(a) Solanacea		1
231010	Tomatoes (Cherry tomatoes)	1	1
231020	Peppers (Chilli peppers)	0,5	1
231030	Aubergines (egg plants) (Pepino)	0,3	1
231040	Okra, lady's fingers	0,05*	1
231990	Others	0,05*	1
232000	(b) Cucurbits - edible peel	1	0.5
232010	Cucumbers	1	0.5
232020	Gherkins	1	0.5
232030	Courgettes (Summer squash, marrow (patisson))	1	0.5
232990	Others	1	0.5
233000	(c) Cucurbits-inedible peel		0.5
233010	Melons (Kiwano)	1	0.5
233020	Pumpkins (Winter squash)	0,05*	0.5
233030	Watermelons	0,05*	0.5
233990	Others	0,05*	0.5

Code number	Groups and examples of individual products to which the MRLs apply	Dimethomorph	Dimethomorph (sum of isomers) ^(a)
234000	(d) Sweet corn	0,05*	0.01*
239000	(e) Other fruiting vegetables	0,05*	0.01*
240000	(iv) Brassica vegetables	0,05*	
241000	(a) Flowering brassica	0,05*	
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*	1
241020	Cauliflower	0,05*	0.05
241990	Others	0,05*	0.01*
242000	(b) Head brassica	0,05*	
242010	Brussels sprouts	0,05*	0.01*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*	2
242990	Others	0,05*	0.01*
243000	(c) Leafy brassica	0,05*	0.01*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,05*	0.01*
243020	Kale (Borecole (curly kale), collards)	0,05*	0.01*
243990	Others	0,05*	0.01*
244000	(d) Kohlrabi	0,05*	0.02
250000	(v) Leaf vegetables & fresh herbs		
251000	(a) Lettuce and other salad plants including Brassicacea		
251010	Lamb's lettuce (Italian cornsalad)	10	10
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	10	10
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)	1	0.1
251040	Cress	10	10
251050	Land cress	10	10
251060	Rocket, Rucola (Wild rocket)	10	10
251070	Red mustard	10	10
251080	Leaves and sprouts of Brassica spp (Mizuna)	10	10
251990	Others	1	10

Code number	Groups and examples of individual products to which the MRLs apply	Dimethomorph	Dimethomorph (sum of isomers) ^(a)
252000	(b) Spinach & similar (leaves)		
252010	Spinach (New Zealand spinach, tumip greens (tumip tops))	1	1
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	1	0.01*
252030	Beet leaves (chard) (Leaves of beetroot)	1	1
252990	Others	0,05*	0.01*
253000	(c) Vine leaves (grape leaves)	10	0.01*
254000	(d) Water cress	10	0.01*
255000	(e) Witloof	10	0.05
256000	(f) Herbs	10	10
256010	Chervil	10	10
256020	Chives	10	10
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	10	10
256040	Parsley	10	10
256050	Sage (Winter savory, summer savory,)	10	10
256060	Rosemary	10	10
256070	Thyme (marjoram, oregano)	10	10
256080	Basil (Balm leaves, mint, peppermint)	10	10
256090	Bay leaves (laurel)	10	10
256100	Tamagon (Hyssop)	10	10
256990	Others	10	10
260000	(vi) Legume vegetables (fresh)		
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*	0.01*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,05*	0.04
260030	Peas (with pods) (Mangetout (sugar peas))	0,05*	0.01*
260040	Peas (without pods) (Garden pea, green pea,	0,1	0,1

Code number	Groups and examples of individual products to which the MRLs apply	Dimethomorph	Dimethomorph (sum of isomers) ^(a)
	chickpea)		
260050	Lentils	0,05*	0.01*
260990	Others	0,05*	0.01*
270000	(vii) Stem vegetables (fresh)		
270010	Asparagus	0,05*	0.01*
270020	Cardoons	0,05*	0.01*
270030	Celery	0,05*	0.01*
270040	Fennel	0,05*	0.01*
270050	Globe artichokes	2	2
270060	Leek	1,5	1,5
270070	Rhubarb	0,05*	0.01*
270080	Bamboo shoots	0,05*	0.01*
270090	Palm hearts	0,05*	0.01*
270990	Others	0,05*	0.01*
280000	(viii) Fungi	0,05*	0.01*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*	0.01*
280020	Wild (Chanterelle, Truffle, Morel.)	0,05*	0.01*
280990	Others	0,05*	0.01*
290000	(ix) Sea weeds	0,05*	0.01*
300000	3. PULSESES, DRY	0,05*	0.01*
300010	Beans (Broad beans, navy beans, flageolet, jack beans, lima beans, field beans, cowpeas)	0,05*	0.01*
300020	Lentils	0,05*	0.01*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*	0.01*
300040	Lupins	0,05*	0.01*
300990	Others	0,05*	0.01*
400000	4. OILSEEDS AND OILFRUITS	0,05*	0.02*
401000	(i) Oilseeds	0,05*	0.02*
401010	Linseed	0,05*	0.02*
401020	Peanuts	0,05*	0.02*
401030	Poppy seed	0,05*	0.02*
401040	Sesame seed	0,05*	0.02*
401050	Sunflower seed	0,05*	0.02*
401060	Rape seed (Bird rapeseed, turnip rape)	0,05*	0.02*
401070	Soya bean	0,05*	0.02*
401080	Mustard seed	0,05*	0.02*
401090	Cotton seed	0,05*	0.02*
401100	Pumpkin seeds	0,05*	0.02*
401110	Safflower	0,05*	0.02*
401120	Borage	0,05*	0.02*
401130	Gold of pleasure	0,05*	0.02*

Code number	Groups and examples of individual products to which the MRLs apply	Dimethomorph	Dimethomorph (sum of isomers) ^(a)
401140	Hempseed	0,05*	0.02*
401150	Castor bean	0,05*	0.02*
401990	Others	0,05*	0.02*
402000	(ii) Oilfruits	0,05*	0.02*
402010	Olives for oil production	0,05*	0.02*
402020	Palm nuts (palmoil kernels)	0,05*	0.02*
402030	Palmfruit	0,05*	0.02*
402040	Kapok	0,05*	0.02*
402990	Others	0,05*	0.02*
500000	5. CEREALS	0,05*	0.01*
500010	Barley	0,05*	0.01*
500020	Buckwheat	0,05*	0.01*
500030	Maize	0,05*	0.01*
500040	Millet (Foxtail millet, teff)	0,05*	0.01*
500050	Oats	0,05*	0.01*
500060	Rice	0,05*	0.01*
500070	Rye	0,05*	0.01*
500080	Sorghum	0,05*	0.01*
500090	Wheat (Spelt Triticale)	0,05*	0.01*
500990	Others	0,05*	0.01*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*	0.01*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*	0.01*
620000	(ii) Coffee beans	0,05*	0.01*
630000	(iii) Herbal infusions (dried)	0,05*	0.01*
631000	(a) Flowers	0,05*	0.01*
631010	Camomille flowers	0,05*	0.01*
631020	Hybiscus flowers	0,05*	0.01*
631030	Rose petals	0,05*	0.01*
631040	Jasmine flowers	0,05*	0.01*
631050	Lime (linden)	0,05*	0.01*
631990	Others	0,05*	0.01*
632000	(b) Leaves	0,05*	0.01*
632010	Strawberry leaves	0,05*	0.01*
632020	Rooibos leaves	0,05*	0.01*
632030	Maté	0,05*	0.01*
632990	Others	0,05*	0.01*
633000	(c) Roots	0,05*	0.01*
633010	Valerian root	0,05*	0.01*
633020	Ginseng root	0,05*	0.01*
633990	Others	0,05*	0.01*
639000	(d) Other herbal infusions	0,05*	0.01*
640000	(iv) Cocoa (fermented beans)	0,05*	0.01*
650000	(v) Carob (st johns bread)	0,05*	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Dimethomorph	Dimethomorph (sum of isomers) ^(a)
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	50	80
800000	8. SPICES	0,05*	0.01*
810000	(i) Seeds	0,05*	0.01*
810010	Anise	0,05*	0.01*
810020	Black caraway	0,05*	0.01*
810030	Celery seed (Lovage seed)	0,05*	0.01*
810040	Coriander seed	0,05*	0.01*
810050	Cumin seed	0,05*	0.01*
810060	Dill seed	0,05*	0.01*
810070	Fennel seed	0,05*	0.01*
810080	Fenugreek	0,05*	0.01*
810090	Nutmeg	0,05*	0.01*
810990	Others	0,05*	0.01*
820000	(ii) Fruits and berries	0,05*	0.01*
820010	Allspice	0,05*	0.01*
820020	Anise pepper (Japan pepper)	0,05*	0.01*
820030	Caraway	0,05*	0.01*
820040	Cardamom	0,05*	0.01*
820050	Juniper berries	0,05*	0.01*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*	0.01*
820070	Vanilla pods	0,05*	0.01*
820080	Tamarind	0,05*	0.01*
820990	Others	0,05*	0.01*
830000	(iii) Bark	0,05*	0.01*
830010	Cinnamon (Cassia)	0,05*	0.01*
830990	Others	0,05*	0.01*
840000	(iv) Roots or rhizome	0,05*	0.01*
840010	Liquorice	0,05*	0.01*
840020	Ginger	0,05*	0.01*
840030	Turmeric (Curcuma)	0,05*	0.01*
840040	Horseradish	0,05*	0.01*
840990	Others	0,05*	0.01*
850000	(v) Buds	0,05*	0.01*
850010	Cloves	0,05*	0.01*
850020	Capers	0,05*	0.01*
850990	Others	0,05*	0.01*
860000	(vi) Flower stigma	0,05*	0.01*
860010	Saffron	0,05*	0.01*
860990	Others	0,05*	0.01*
870000	(vii) Aril	0,05*	0.01*
870010	Mace	0,05*	0.01*
870990	Others	0,05*	0.01*
900000	9. SUGAR PLANTS	0,05*	0.01*
900010	Sugar beet (root)	0,05*	0.01*
900020	Sugar cane	0,05*	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Dimethomorph	Dimethomorph (sum of isomers) ^(a)
900030	Chicory roots	0,05*	0.01*
900990	Others	0,05*	0.01*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	0,05*	0.01*
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*	0.01*
1011000	(a) Swine	0,05*	0.01*
1011010	Meat	0,05*	0.01*
1011020	Fat free of lean meat	0,05*	0.01*
1011030	Liver	0,05*	0.01*
1011040	Kidney	0,05*	0.01*
1011050	Edible offal	0,05*	0.01*
1011990	Others	0,05*	0.01*
1012000	(b) Bovine	0,05*	0.01*
1012010	Meat	0,05*	0.01*
1012020	Fat	0,05*	0.01*
1012030	Liver	0,05*	0.01*
1012040	Kidney	0,05*	0.01*
1012050	Edible offal	0,05*	0.01*
1012990	Others	0,05*	0.01*
1013000	(c) Sheep	0,05*	0.01*
1013010	Meat	0,05*	0.01*
1013020	Fat	0,05*	0.01*
1013030	Liver	0,05*	0.01*
1013040	Kidney	0,05*	0.01*
1013050	Edible offal	0,05*	0.01*
1013990	Others	0,05*	0.01*
1014000	(d) Goat	0,05*	0.01*
1014010	Meat	0,05*	0.01*
1014020	Fat	0,05*	0.01*
1014030	Liver	0,05*	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Dimethomorph	Dimethomorph (sum of isomers) ^(a)
1014040	Kidney	0,05*	0.01*
1014050	Edible offal	0,05*	0.01*
1014990	Others	0,05*	0.01*
1015000	(e) Horses, asses, mules or hinnies	0,05*	0.01*
1015010	Meat	0,05*	0.01*
1015020	Fat	0,05*	0.01*
1015030	Liver	0,05*	0.01*
1015040	Kidney	0,05*	0.01*
1015050	Edible offal	0,05*	0.01*
1015990	Others	0,05*	0.01*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*	0.01*
1016010	Meat	0,05*	0.01*
1016020	Fat	0,05*	0.01*
1016030	Liver	0,05*	0.01*
1016040	Kidney	0,05*	0.01*
1016050	Edible offal	0,05*	0.01*
1016990	Others	0,05*	0.01*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*	0.01*
1017010	Meat	0,05*	0.01*
1017020	Fat	0,05*	0.01*
1017030	Liver	0,05*	0.01*
1017040	Kidney	0,05*	0.01*
1017050	Edible offal	0,05*	0.01*
1017990	Others	0,05*	0.01*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,05*	0.01*
1020010	Cattle	0,05*	0.01*
1020020	Sheep	0,05*	0.01*
1020030	Goat	0,05*	0.01*
1020040	Horse	0,05*	0.01*
1020990	Others	0,05*	0.01*
1030000	(iii) Birds' eggs, fresh	0,05*	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Dimethomorph	Dimethomorph (sum of isomers) ^(a)
	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		
1030010	Chicken	0,05*	0.01*
1030020	Duck	0,05*	0.01*
1030030	Goose	0,05*	0.01*
1030040	Quail	0,05*	0.01*
1030990	Others	0,05*	0.01*
1040000	(iv) Honey (Royal jelly, pollen)	0,05*	0.01*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05*	0.01*
1060000	(vi) Snails	0,05*	0.01*
1070000	(vii) Other terrestrial animal products	0,05*	0.01*

(*) Indicates lower limit of analytical determination.

^(a) Modifications of the existing MRLs (EFSA, 2011c) and footnote under discussion at the Standing Committee on the Food Chain and Animal Health. Draft Regulation SANCO/10392/2012 (Article 12 MRLs) rev3.

Footnote:

0153010 Confirmatory data on residue trials to be submitted to the Rapporteur Member State, the Authority and the Commission by 31 December 2014 at the latest. Reassessment of data may lead to modification of the MRL.

0153030 Confirmatory data on residue trials to be submitted to the Rapporteur Member State, the Authority and the Commission by 31 December 2014 at the latest. Reassessment of data may lead to modification of the MRL.

D. LIST OF AVAILABLE MEDIAN RESIDUE VALUES FOR CHRONIC RISK ASSESSMENT

Dimethomorph uses assessed under Article 12 (EFSA, 2011c) and Article 10 (EFSA, 2011d) of Regulation (EC) No 396/2005

Commodity	Input value (mg/kg)	Comments
Oranges	0.19	Median residue
Table and wine grapes	0.59	Median residue
Strawberries	0.13	Median residue
Blackberries	0.01	EU MRL
Raspberries	0.01	EU MRL
Pineapples	0.01	STMR (CXL)
Potatoes	0.05	Median residue
Radishes	0.27	Median residue
Swedes	0.01	EU MRL
Turnips	0.01	EU MRL
Spring onions	0.02	Median residue
Tomatoes	0.27	Median residue
Peppers	0.22	STMR (CXL)

Commodity	Input value (mg/kg)	Comments
Aubergines	0.22	STMR (CXL)
Okra	0.22	STMR (CXL)
Cucurbits with edible peel	0.21	Median residue
Melons	0.04	STMR-inedible (CXL)
Pumpkins	0.02	STMR-inedible (CXL)
Watermelons	0.02	STMR-inedible (CXL)
Cauliflower	0.02	Median residue
Kohlrabi	0.02	Median residue
Lamb's lettuce	3.35	STMR (CXL)
Rocket, Rucola	1.27	Median residue
Red mustard	1.27	Median residue

Commodity	Input value (mg/kg)	Comments
Leaves and sprouts of Brassica spp	1.27	Median residue
Spinach	0.02	Median residue (EFSA, 2011d)
Beet leaves	0.02	Median residue (EFSA, 2011d)
Witloof	0.03	Median residue
Fresh herbs	1.27	Median residue
Beans (fresh, without pods)	0.02	Median residue
Peas (fresh, without pods)	0.01	Median residue
Globe artichokes	0.26	Median residue
Leek	0.19	Median residue
Poppy seed	0.02	Median residue
Rape seed	0.02	Median residue

Commodity	Input value (mg/kg)	Comments
Hops (dried)	26.00	STMR (CXL)
Swine meat, liver and kidneys	0.01	Median (=LOQ)
Swine fat	0.01	Median (=LOQ)
Ruminant meat, liver and kidneys	0.01	Median (=LOQ)
Ruminant fat	0.01	Median (=LOQ)
Poultry meat and liver	0.01	STMR (CXL)
Poultry fat	0.01	Median (=LOQ)
Bird's eggs	0.01	STMR (CXL)
Milk	0.01	Median (=LOQ)

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CA	Canada
CEN	European Committee for Standardisation (Comité Européen de Normalisation, <i>French</i>)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report
DC	dispersible concentrate
DE	Germany
EC	European Community
EC	emulsifiable concentrate
EFSA	European Food Safety Authority
EL	Greece
EMS	evaluating Member State
ES	Spain
EU	European Union
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre
HR	highest residue
<i>i.e.</i>	that is (id est, <i>Latin</i>)
ISO	International Organization for Standardization
IT	Italy
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues

kg	kilogram
L	litre
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS/MS	tandem mass spectrometry
OECD	Organization for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PT	Portugal
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (method)
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RAC	raw agricultural commodity
RMS	rapporteur Member State
SC	suspension concentrate
SCFCAH	Standing Committee on the Food Chain and Animal Health
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
USA	United States of America
WG	water dispersible granule
yr	year