European Food Safety Authority

EFSA Journal 2013;11(9):3384

REASONED OPINION

Reasoned opinion on the modification of the existing MRL for folpet in table grapes [1]

European Food Safety Authority[2,]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Austria, hereafter referred to as the evaluating Member State (EMS), received an application from the company Makhteshim Agan Holding B.V. to modify the existing MRLs for the active substance folpet in table grapes. In order to accommodate for the intended uses of folpet on table grapes in Europe, the EMS proposed to raise the existing MRL in grapes to 3 mg/kg for folpet and to 5 mg/kg for folpet and phthalimide, expressed as folpet. The EMS 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. According to EFSA the data are sufficient to derive for table grapes a MRL proposal of 3 mg/kg or 4 mg/kg for the residue definition "folpet" and 5 mg/kg or 6 mg/kg for the residue definition "folpet and phthalimide, expressed as folpet". Based on the risk assessment results, EFSA concludes that according to the internationally agreed methodology for estimation of the consumer exposure, the expected residues in table grapes do not result in an exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern. However, the safety margin for the acute exposure is very narrow.

KEY WORDS

Folpet, table grapes, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, phthalimide fungicide, phthalimide

[1] On request from European Commission, Question No EFSA-Q-2013-00315, approved on 27 September 2013.

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Suggested citation: European Food Safety Authority, 2013. Reasoned opinion on the modification of the existing MRL for folpet in table grapes . EFSA Journal 2013;11(9):3384, 27 pp. doi:10.2903/j.efsa.2013.3384

Available online: www.efsa.europa.eu/efsajournal

SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Austria, hereafter referred to as the evaluating Member State (EMS), received an application from the company Makhteshim Agan Holding B.V. to modify the existing MRLs for the active substance folpet in table grapes. In order to accommodate for the intended uses of folpet on table grapes in Europe, the EMS proposed to raise the existing MRL in grapes to 3 mg/kg for folpet and to 5 mg/kg for folpet and phthalimide, expressed as folpet. The EMS 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 2 April 2013.

EFSA bases its assessment on the evaluation report submitted by the EMS, the Draft Assessment Report (DAR) prepared by the rapporteur Member State Italy under Council Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment of the active substance folpet as well as the conclusions from previous EFSA reasoned opinions on folpet.

The toxicological profile of folpet was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.1 mg/kg bw per day and an ARfD of 0.2 mg/kg bw. For the metabolite phthalimide which is observed in primary crops and which is extensively formed in processed commodities there is some evidence that the substance is of a lower toxicity compared with folpet. However, as no full toxicological data package was available, it was not possible to derive specific toxicological reference values. Therefore the peer review proposed to apply the toxicological reference values agreed for folpet also for phthalimide.

The metabolism of folpet in primary crops was investigated in grapes, avocado, tomato, potato and wheat. From these studies the peer review concluded to establish the residue definition for enforcement and risk assessment as "sum of folpet and phthalimide, expressed as folpet". For the use on table grapes, EFSA concludes that the metabolism of folpet in primary crops is sufficiently elucidated and no further metabolism data are necessary. The current residue definition for most plant products, including grapes, established in Regulation (EC) No 396/2005 is parent compound folpet. Pending the revision of the existing residue definition, EFSA derived a MRL proposal according to the existing and the proposed new residue definition. The latter MRL is to be taken into account when the residue definition is amended in the framework of the comprehensive review under Article 12(2) of the above cited Regulation.

EFSA concludes that the submitted supervised residue trials are sufficient to derive for table grapes a MRL proposal of 3 mg/kg or 4 mg/kg for the residue definition "folpet" and 5 mg/kg or 6 mg/kg for the residue definition "folpet and phthalimide, expressed as folpet". Adequate analytical enforcement methods are available to control the residues of folpet and phthalimide in the grapes.

Studies investigating the nature of folpet residues in processed commodities demonstrated that under processing conditions involving heat treatment the parent compound almost totally converts to phthalimide and to a certain extent to phthalic acid and phthalic anhydride. Therefore for processed commodities derived from grapes the residue definition for enforcement and risk assessment is defined as sum of folpet and phthalimide, expressed as folpet.

In the framework of the current application one study was submitted with grapes being processed to raisins. Another study was available from the peer review but residue data on phthalimide were not provided. Considering the limited number of studies available, the diverging results and the limited validity of the study where phthalimide was not quantified, EFSA is of the opinion that the data are not sufficient to derive reliable processing factor for raisins which can be recommended for inclusion in Annex VI of Regulation (EC) No 396/2005.

Grape is a permanent crop and therefore the investigations of residues in rotational crops are not required.

Since grapes and their by-products are normally not fed to livestock, the nature and magnitude of folpet residues in livestock was not assessed in the framework of this application.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The chronic exposure calculations performed in the framework of previous MRL applications were now updated to take into account the residues of folpet and phthalimide in table grapes from the new intended use.

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 up to 81% of the ADI (DE child diet). The contribution of residues in table grapes to the total consumer exposure accounted for a maximum of 1.5% of the ADI (DE child diet). No acute consumer risk was identified in relation to the intended use on table grapes as the calculated maximum exposure in percentage of the ARfD was 93%. EFSA notes that the short term exposure related to table grapes exceeds the ARfD if grapes contain residues at the proposed MRL of 3 mg/kg or 4 mg/kg (for folpet), taking into account the variability factor of 3 and the conversion factor of 1.8 for the risk assessment residue definition. The acute exposure accounts for 106% ARfD and 141% ARfD for the respective MRL proposals for folpet.

EFSA concludes that, according to the internationally agreed methodology for estimation of the consumer exposure, the expected residues in table grapes do not result in an exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern. However, the safety margin for the acute exposure is very narrow.

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: Folpet (Regulation EC (No) 396/2005)				
0151010	Table grapes	0.02*	3 or 4	The MRL proposals are sufficiently supported by data. The MRL of 4 mg/kg is derived using the OECD calculator. The MRL of 3 mg/kg was proposed by the EMS and can be considered as an alternative risk management option. EFSA notes that using the proposed MRLs as input values for the acute exposure calculation, the ARfD is exceeded.
Enforcement residue definition: Folpet and phthalimide, expressed as folpet (EFSA, 2009)				
0151010	Table grapes	-	5 or 6	The MRL proposals are sufficiently supported by data. The MRL of 6 mg/kg is derived using the OECD calculator. The MRL of 5 mg/kg was proposed by the EMS and can be considered as an alternative risk management option. EFSA notes that using the proposed MRLs as input values for the acute exposure calculation, the ARfD is exceeded.

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.

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BACKGROUND

Regulation (EC) No 396/2005[3] 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/EEC[4], repealed by Regulation (EC) No 1107/2009[5], shall submit to a Member State, when appropriate, an application to set or to modify a MRL in accordance with the provisions of Article 7 of that Regulation.

Austria, hereafter referred to as the evaluating Member State (EMS), received an application from the company Makhteshim Agan Holding B.V.[6] to modify the existing MRLs for the active substance folpet in table grapes, blueberries and several stone fruits. 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 2 April 2013.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2013-00315 and the following subject:

Folpet - Application to set new MRLs in table grapes, apricots, peaches, plums and blueberries.

Austria proposed to raise the existing MRLs of folpet from the limit of quantification at 0.02 mg/kg to 3 mg/kg in table grapes, 0.04 mg/kg in peaches and nectarines, 0.1 mg/kg in plums and 0.15 mg/kg in blueberries.

On 6 May 2013 some data requirements were identified, which prevented EFSA to start the assessment of the MRL application. As a result of these data requirements the applicant on 7 May 2013 withdrew the MRL application on peaches, apricots, plums and blueberries, leaving a valid application on the modification of existing MRLs for folpet in table grapes only.

EFSA proceeded with the assessment of the application and the evaluation report 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.

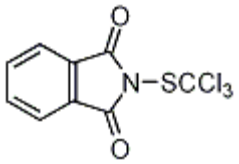
In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the deadline for providing the reasoned opinion is 3 September 2013.

[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] Malhteshim Agan Holding B.V., c/o Feinchemie Schwebda gMbH, Edmund Rumpler Str.6, 51149, Köln

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Folpet is the ISO common name for *N*-(trichloromethylthio) phthalimide (IUPAC). The chemical structure of the compound is herewith reported.



Molecular weight: 296.6

Folpet is a broad-spectrum contact fungicide belonging to the class of phthalimide fungicides. Folpet acts against many leaf diseases of cereals and fruit by binding to sulphur-hydrogen bonds and thus interfering with the respiratory process in fungi.

Folpet is an active substance which was evaluated according to Directive 91/414/EEC with Italy designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2007/5/EC[7] which entered into force on 1 October 2007 for use as fungicide only. The representative uses evaluated in the peer review for Annex I inclusion were foliar applications to winter wheat, tomatoes and wine grapes. The Draft Assessment Report (DAR) of folpet has been peer reviewed by EFSA. The conclusion of EFSA was finalised on 24 April 2006 and was re-issued on 4 June 2009 (EFSA, 2009), following amendments in the sections of mammalian toxicology and residues concerning a modification of the acute reference dose (ARfD) for folpet.

The EU MRLs for folpet are established in Annexes II and IIIB of Regulation (EC) No 396/2005 (Appendix C). For pome fruits, strawberries, blackberries, raspberries, currants, gooseberries, tomatoes, beans (with and without pods) the residue definition for enforcement established in Regulation (EC) No 396/2005 is the sum of captan and folpet; for the remaining crops (including table grapes) the residue definition comprises the parent compound folpet only.

EFSA has issued two reasoned opinions on the modification of existing MRLs for folpet in wine grapes, garlic, tomatoes (EFSA, 2011a) and wine grapes (EFSA, 2012). The recommended MRLs for these crops were taken over in the EU legislation. The existing EU MRL for folpet in table grapes is set at the LOQ of 0.02 mg/kg. Codex Alimentarius has established a CXL of 10 mg/kg for table and wine grapes. The MRL review according to Article 12 of Regulation (EC) No 396/2005 is not yet finalized.

The intended GAP applied for in Germany, Austria, Romania, Luxembourg, Hungary, France, Italy, Spain, Portugal and Greece for which a modification of the existing MRLs is required refers to four foliar applications of a water dispersible granule formulation with an application rate of 1.6 kg/ha. The PHI is specified with 56 days. The details of the GAPs are given in Appendix A.

[7] Commission Directive 2007/5/EC of 7 February 2007. OJ L 35, 08.02.2007, p. 11-17.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Austria, 2013), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Italy, 2004), the conclusion on the peer review of the pesticide risk assessment of the active substance folpet (EFSA, 2009) as well as the conclusions from previous EFSA reasoned opinions on folpet (EFSA, 2011a, 2012). 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 546/2011[8] 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

Analytical methods for the determination of folpet residues in plant matrices (for the existing residue definition (parent folpet) and for the extended residue definition (sum of folpet and phthalimide[9], expressed as folpet)) were assessed in the DAR (Italy, 2004), in the conclusion on the peer review under Directive 91/414/EEC (EFSA, 2009) and in the previously issued reasoned opinion on folpet (EFSA, 2011a).

It was concluded that for grapes (high water content matrix) sufficiently validated analytical methods for enforcing the MRL according to the current residue definition (i.e. folpet) are available (EFSA, 2011a). The LOQ for folpet achieved in routine monitoring in matrices with high water content is 0.05 mg/kg; the confirmatory method was successfully validated at the level of 0.01 mg/kg (EFSA, 2011a).

For the determination of phthalimide, the primary method was validated with an LOQ of 0.2 mg/kg and the ILV confirmed the LOQ of 0.05 mg/kg (EFSA, 2009). In the framework of the current application the applicant submitted new validation data of the analytical method for the determination of folpet and phthalimide in grapes. The EMS assessed the studies and concluded that folpet and phthalimide can be determined in grapes with GC/ECD and GC/MS methods, respectively, at the validated LOQ of 0.02 mg/kg for folpet and 0.05 mg/kg for phthalimide. The ILV and confirmatory methods confirm the applicability of this method to analyse phthalimide residues in grapes at the LOQ of 0.05 mg/kg.

EFSA concludes that sufficiently validated analytical methods are available to control residues of folpet and phthalimide in grapes.

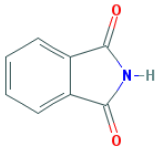
1.2. Methods for enforcement of residues in food of animal origin

Analytical methods for the determination of residues in food of animal origin were not assessed in the current application, since grapes are normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance folpet was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2009). The data were sufficient to derive toxicological reference values for folpet which are compiled in Table 2-1.

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



[9] Phthalimide: Mol. weight: 147.13

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Folpet					
ADI	EFSA	2009	0.1 mg/kg bw per day	52 weeks oral dog study	100
ARfD	EFSA	2009	0.2 mg/kg bw	teratogenicity study in rabbits	100

For the metabolite phthalimide, which occurs to a certain extent in primary crops and which is extensively formed in processed commodities produced with a heating step, the experts agreed that the results of the existing studies demonstrate a lower toxicity compared with folpet. Phthalimide is not acutely toxic, its LD_{50} in mice is above 5 mg/kg bw, it is not mutagenic when tested in the multiple strains in the Ames Assey and it is not a developmental toxin; no effects were elicited at the maximum dose tested, *i.e.* 30 mg/kg bw per day. In addition, the data indicated that phthalimide does not have the potential to induce carcinogenic effects. However, since no full toxicological data package was available to derive specific toxicological reference values, the peer review concluded, as a worst case scenario, that the toxicological reference values agreed for folpet apply to the metabolite as well (EFSA, 2009).

EFSA concludes that assuming the same toxicity for phthalimide is a conservative assumption which contributes to the overall conservatism of the risk assessment to a high extent. It is recommended to reconsider this assumption in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005, desirably on the basis of additional toxicological studies which should be provided by the applicant to characterise and quantify the hazard of phthalimide unequivocally (EFSA, 2012).

3. Residues

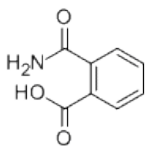
3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

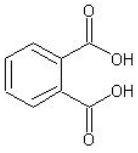
3.1.1.1. Nature of residues

The metabolism of folpet in primary crops (grapes, avocado, tomatoes, potatoes and wheat) was in detail reported in the previously issued reasoned opinion (EFSA, 2011a). The proposed metabolic pathway involved in a first step the formation of phthalimide and thiophosgene through release of the trichloromethylthio- side chain following cleavage of the N-S bond. Phthalimide is further hydrolysed to phthalamic acid[10], phthalic acid[11] and related conjugates. The thiophosgene is assumed to be rapidly transformed into CO_2 and incorporated in natural plant components. It is noted that metabolites identified in the metabolism of folpet (*e.g.* phthalic acid, phthalamic acid, phthalimide) were also observed as metabolites resulting from the use of phosmet.

[10] Phthalamic acid:



[11] Phthalic acid:



During the peer review the experts concluded that phthalimide should be considered as having the same toxicological profile as folpet, unless differently proven, and agreed to establish the residue definition for enforcement and risk assessment as "*sum of folpet and phthalimide, expressed as folpet*" (EFSA, 2009).

For the use on table grapes, which belong to the group of fruits and fruiting vegetables, EFSA concludes that the metabolism of folpet is sufficiently elucidated. It is noted that the plant residue definition for enforcement currently established in Regulation (EC) No 396/2005 is folpet, with the exception of pome fruits, strawberries, blackberries, raspberries, currants, gooseberries, tomatoes, beans with and without pods, where it is defined as the sum of captan and folpet[12].

Pending a final decision on the residue definition for enforcement and risk assessment, EFSA will perform the consumer risk assessment according to the residue definition proposed in the EFSA conclusion, *i.e.* sum of folpet and phthalimide expressed as folpet, based on the assumption that phthalimide has the same toxicological properties as the parent compound folpet.

3.1.1.2. Magnitude of residues

The submitted residue trials on grapes were analysed for folpet and phthalimide separately. EFSA derived two MRL proposals - one for the existing enforcement residue definition according to Regulation (EC) No 396/2005 (folpet) and another one for the enforcement residue definition proposed by the peer review (folpet and phthalimide, expressed as folpet). To express phthalimide residues as folpet, a molecular weight ratio of 2.02 was applied[13].

For the NEU use the applicant submitted in total eight residue trials on table grapes. Trials were performed in Germany and Hungary in 2010 and 2011. Two residue trials were disregarded by the EMS and EFSA due to a contamination, resulting in residue levels of 0.17 and 0.39 mg/kg of folpet in the control sample. Table grape is a minor crop in the NEU according to EU guidance document (EC, 2011) and thus the number of submitted residue trials is sufficient to derive a MRL proposal of 1.5 mg/kg for "folpet" and 2 mg/kg for "folpet and phthalimide, expressed as folpet".

For the SEU use the applicant submitted in total eight residue trials on table grapes. Trials were performed in Spain, Italy and France in 2008 and 2011. One residue trial was disregarded by the EMS since it was considered to be an outlier; sufficient explanation was provided, proving this decision. Table grape is a major crop in the SEU according to the EU guidance document (EC, 2011) and thus at least eight GAP compliant residue trials have to be submitted. Although one additional residue trial would be required, EFSA considered this as a minor data gap and derived a MRL proposal of 4 mg/kg for "folpet" and 6 mg/kg for "folpet and phthalimide, expressed as folpet". Since the margin between the highest residue and the MRL proposals was found to be rather wide, EFSA derived, on the basis of the previously used methodology (Rber and Rmax method), alternative MRL proposals of 3 mg/kg and 5 mg/kg for the two residue definitions to be considered by risk managers.

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

The storage stability of folpet in primary crops was investigated in the DAR under Directive 91/414/EEC (Italy, 2004). Additional studies were evaluated in support of the previous MRL application (EFSA, 2011a). Residues of folpet were found to be stable at ≤ -18°C for up to 15 months in grapes. The storage stability study for phthalimide which was referred to in the previous EFSA reasoned opinion (EFSA, 2012) has now been finalized, demonstrating that phthalimide is stable in

[12] A combined enforcement residue definition comprising captan and folpet for these commodities causes problems for MRL enforcement. It is therefore recommended to set a separate residue definitions "captan" and "folpet" for these crops as soon as possible (EFSA, 2013).
[13] MW folpet (296.6)/MW phthalimide (147.13)

grapes for at least 13 months in samples stored at -18°C (Austria, 2013). 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 the purpose (Austria, 2013).

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	Risk assessment					
Enforcement residue definition: Folpet (Regulation (EC) No 396/2005) **Risk assessment residue definition:** Sum of folpet and phthalimide, expressed as folpet									
Table grapes	NEU	Outdoor	0.09; 0.17; 0.21; 0.22; 0.62; 0.75	0.19; 0.27; 0.47; 0.75; 0.73; 0.85	0.22	0.75	1.5	1.9	R_{ber}= 1.31 R_{max}= 1.35 MRL_{OECD} = 1.43/1.5
Table grapes	SEU	Outdoor	<0.02; 0.32; 0.56; 1.0; 1.2; 1.4[f]; 1.5[f]	<0.12; 0.42; 1.0; 1.18; 2.19; 2.09[f]; 2.85[f]	**1.0**	**1.5**	**3[g] or 4**	**1.8**	R_{ber}=2.8 R_{max}=2.78 MRL_{OECD} = 3.1/4.0
Enforcement residue definition: Sum of folpet and phthalimide, expressed as folpet (EFSA, 2009) **Risk assessment residue definition**: Sum of folpet and phthalimide, expressed as folpet									
Table grapes	NEU	Outdoor	0.19; 0.27; 0.47; 0.73; 0.75; 0.85	0.19; 0.27; 0.47; 0.73; 0.75; 0.85	0.60	0.85	2	1.0	R_{ber}=1.55 R_{max}=1.56 MRL_{OECD} = 1.6/2.0
Table grapes	SEU	Outdoor	<0.12; 0.42; 1.0; 1.18; 2.09[f]; 2.19; 2.85[f]	<0.12; 0.42; 1.0; 1.18; 2.09[f]; 2.19; 2.85[f]	**1.18**	**2.85**	**5[g] or 6**	**1.0**	R_{ber}=4.38 R_{max}=4.81 MRL_{OECD} = 5.4/6.0

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e. indoor 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): Residue value within a trial higher at a longer PHI of 69/70 days.
(g): Considering the high margin between the highest residues observed in residue trials and the MRL proposal derived with the OECD calculator, EFSA and the EMS derived alternative MRL proposals, based on the previously used calculation methodology. Risk managers should consider these proposals as possible alternatives.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of folpet was investigated in studies performed at three test conditions representing pasteurization, baking/brewing/boiling and sterilization (20 minutes at 90°C, pH 4; 60 minutes at 100°C, pH 5; 20 minutes at 120°C, pH 6). The studies were reported in the framework of the previous EFSA reasoned opinion (EFSA, 2011a). Under representative processing conditions folpet was completely degraded forming phthalimide and phthalic acid as the major products. Phthalimide was formed predominantly under conditions of pasteurisation (92% AR) and seemed to be further converted into phthalic acid with increasing temperatures and pH (42% at 100C°, 81% at 120°C). Under conditions simulating sterilization (120°C, pH6), an unidentified product was found and attributed to phthalic anhydride[14] (18% AR). It is assumed that phthalic anhydride is formed reversibly from phthalic acid by dehydration with heat, with both compounds being in chemical equilibrium depending on pH and temperature (EFSA, 2011a). The study demonstrated that the main compounds present after processing have also been identified as metabolites in the plant metabolism studies. EFSA therefore proposes for processed products to set the residue definition for enforcement and risk assessment as "*sum of folpet and phthalimide, expressed as folpet*", according to the proposals derived by the peer review.

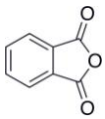
In the framework of the current application, the applicant provided a processing study for raisins. The effect of drying of a grape sample taken form one SEU residue trial was investigated. The EMS calculated a processing factor by comparing the residues in raisins with the residues in grape bunches, including the stalks and stems. Since according to Regulation (EC) No 396/2005 the MRL applies to the berries without stalks and stems, the residues in the unprocessed berries need to be considered for deriving the processing factor. Using this approach, a processing factor of 0.54 is derived; the conversion factor for taking into account the residue definition for risk assessment is calculated to be 2.3.

Additional processing study with raisins has been assessed in the framework of the peer review which indicates a significant concentration of residues in dried grapes. The results, however, do not provide information on residues of phthalimide in grapes and raisins (EFSA, 2009). The study is thus of limited validity.

The results of these studies are presented in Table 3-2.

Table 3-2: Overview of the available processing studies

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Enforcement residue definition (unprocessed commodity): Folpet (Regulation (EC) No 396/2005) **Risk assessment residue definition (processed commodity):** Sum of folpet and phthalimide, expressed as folpet				
Table grape, raisins	2	3.2	-	PF derived by the peer review which does not consider residues of phthalimide (EFSA, 2009)
Table grapes, raisins	1	0.54	2.3[c]	
Enforcement residue definition (unprocessed commodity): Sum of folpet and phthalimide, expressed as folpet (EFSA, 2009) **Risk assessment residue definition (processed commodity):** Sum of folpet and phthalimide, expressed as folpet				

[14] Phthalic anhydride: 

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Table grapes, raisins	1	0.9	1	

(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.
(c): The conversion factors are derived as a ratio of residues in processed commodity according to risk assessment residue definition/ residues in processed commodity according to enforcement residue definition

Considering the limited number of processing studies for raisins, the diverging results and the limited validity of the study where phthalimide was not quantified, EFSA is of the opinion that the data are not sufficient to derive reliable processing factor for raisins which can be recommended for inclusion in Annex VI of Regulation (EC) No 396/2005.

3.1.2. Rotational crops

Grape is a permanent crop and therefore the investigation of residues in rotational crops is not required.

3.2. Nature and magnitude of residues in livestock

Since grapes and their by-products are not normally fed to livestock, the nature and magnitude of folpet residues in livestock was not assessed in the framework of this application.

4. Consumer risk assessment

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 population[15] (EFSA, 2007).

For the chronic exposure assessment EFSA used the median residue value as derived from the residue trials on table grapes (Table 3-1). For wine grapes, tomatoes, onions and garlic, the median residue values were available from the previously issued EFSA reasoned opinions to refine the consumer exposure calculation (EFSA, 2011a, 2012).

For the crops for which the existing EU MRL is set above the LOQ for residue definition "folpet" (cherries, potatoes, cucurbits (inedible peel), kohlrabi, lettuce, barley, wheat, spinach and hops) a conversion factor (CF) of 1.5 was applied to account for residues of phthalimide and represents the highest median CF derived from the available residue data in plants (EFSA, 2011a). For those crops for which the MRL is established for the residue definition "captan and folpet" (pome fruit, strawberries, blackberries, raspberries, currants, gooseberries, beans (with pods), beans (without pods)), it was assumed that only residues of folpet are present in the crop; the conversion factor of 1.5 was applied to all these crops, except for currants, gooseberries, blackberries and raspberries where the MRL is based on the use of captan (EFSA, 2011b) and the application of a conversion factor would overestimate the actual residues of folpet in the crop. For the remaining commodities of plant origin the existing EU MRL at the LOQ was used as an input value. For animal commodities no EU MRLs are currently set, according to Regulation (EC) No 396/2005.

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed

[15] 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).

will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier 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 table grapes assuming the consumption of a large portion of the food item as reported in the national food surveys, containing residues at the highest level as observed in supervised field trials. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised 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: Folpet and phthalimide, expressed as phthalimide				
Table grapes	1.18	Median residue (SEU use)	2.85	Highest residue (SEU use)
Wine grapes	1.66	EFSA, 2012	Acute risk assessment was undertaken only with regard to table grapes.	
Garlic, onions	0.12	EFSA, 2011a		
Tomatoes[(a)]	0.63	EFSA, 2011a		
Pome fruit[(a)]	4.5	MRL*CF		
Cherries	3	MRL*CF		
Strawberries[(a)]	4.5	MRL*CF		
Blackberries, raspberries[(a)]	10	MRL[(b)]		
Currants, gooseberries[(a)]	15	MRL[(b)]		
Potatoes	0.15	MRL*CF		
Cucurbits-inedible peel	1.5	MRL*CF		
Kohlrabi	0.075	MRL*CF		
Lettuce, barley, wheat, beans (with pods) [(a)], beans (without pods) [(a)]	3	MRL*CF		
Spinach	15	MRL*CF		
Hops	225	MRL*CF		
Other commodities of plant origin	MRL (=LOQ)	See Appendix C		

(a): The current MRL for these crops is expressed as sum of folpet and captan. For the risk assessment it is assumed that only residues of folpet are present on the crops

(b): The MRL values for these commodities are based on the use of captan (EFSA, 2011b). The conversion factor was not applied to the MRL as this would overestimate the actual residues of folpet.

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

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 up to 81% of the ADI (DE child diet). The contribution of residues in table grapes to the total consumer exposure accounted for a maximum of 1.5 % of the ADI (DE child diet). No acute consumer risk was identified in relation to the intended use on table grapes as the calculated maximum exposure in percentage of the ARfD was 93%.

EFSA notes that the short term exposure related to table grapes exceeds the ARfD if grapes contain residues at the proposed MRL of 3 mg/kg or 4 mg/kg (for folpet), taking into account the variability factor of 5 and the conversion factor of 1.8 for the risk assessment residue definition. The acute exposure accounts for 177% ARfD and 236% ARfD, respectively. In case the variability factor of 3 is used instead of 5, the acute exposure accounts for 106% ARfD and 141% ARfD for the respective MRL proposals for folpet.

EFSA concludes that, according to the internationally agreed methodology for estimation of the consumer exposure, the expected residues in table grapes do not result in an exposure exceeding the toxicological reference value and therefore is unlikely to pose a public health concern. However, the safety margin for the acute exposure is very narrow.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of folpet was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.1 mg/kg bw per day and an ARfD of 0.2 mg/kg bw. For the metabolite phthalimide which is observed in primary crops and which is extensively formed in processed commodities there is some evidence that the substance is of lower toxicity compared with folpet. However, as no full toxicological data package was available, it was not possible to derive specific toxicological reference values. Therefore the peer review proposed to apply the toxicological reference values agreed for folpet also for phthalimide.

The metabolism of folpet in primary crops was investigated in grapes, avocado, tomato, potato and wheat. From these studies the peer review concluded to establish the residue definition for enforcement and risk assessment as "sum of folpet and phthalimide, expressed as folpet". For the use on table grapes, EFSA concludes that the metabolism of folpet in primary crops is sufficiently elucidated and no further metabolism data are necessary. The current residue definition for most plant products, including grapes, established in Regulation (EC) No 396/2005 is parent compound folpet. Pending the revision of the existing residue definition, EFSA derived a MRL proposal according to the existing and the proposed new residue definition. The latter MRL is to be taken into account when the residue definition is amended in the framework of the comprehensive review under Article 12(2) of the above cited Regulation.

EFSA concludes that the submitted supervised residue trials are sufficient to derive for table grapes a MRL proposal of 3 mg/kg or 4 mg/kg for the residue definition "folpet" and 5 mg/kg or 6 mg/kg for the residue definition "folpet and phthalimide, expressed as folpet". Adequate analytical enforcement methods are available to control the residues of folpet and phthalimide in the grapes.

Studies investigating the nature of folpet residues in processed commodities demonstrated that under processing conditions involving heat treatment the parent compound almost totally converts to phthalimide and to a certain extent to phthalic acid and phthalic anhydride. Therefore for processed commodities derived from grapes the residue definition for enforcement and risk assessment is defined as sum of folpet and phthalimide, expressed as folpet.

In the framework of the current application one study was submitted with grapes being processed to raisins. Another study was available from the peer review but residue data on phthalimide were not provided. Considering the limited number of studies available, the diverging results and the limited validity of the study where phthalimide was not quantified, EFSA is of the opinion that the data are not sufficient to derive reliable processing factor for raisins which can be recommended for inclusion in Annex VI of Regulation (EC) No 396/2005.

Grape is a permanent crop and therefore the investigations of residues in rotational crops are not required.

Since grapes and their by-products are normally not fed to livestock, the nature and magnitude of folpet residues in livestock was not assessed in the framework of this application.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the chronic exposure assessment the calculations performed in the framework of the previous MRL applications were updated to take into account the residues of folpet and phthalimide in table grapes from the new intended use.

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 up to 81% of the ADI (DE child diet). The contribution of residues in table grapes to the total consumer exposure accounted for a maximum of

1.5% of the ADI (DE child diet). No acute consumer risk was identified in relation to the intended use on table grapes as the calculated maximum exposure in percentage of the ARfD was 93%. EFSA notes that the short term exposure related to table grapes exceeds the ARfD if grapes contain residues at the proposed MRL of 3 mg/kg or 4 mg/kg (for folpet), taking into account the variability factor of 3 and the conversion factor of 1.8 for the risk assessment residue definition. The acute exposure accounts for 106% ARfD and 141% ARfD for the respective MRL proposals for folpet.

EFSA concludes that, according to the internationally agreed methodology for estimation of the consumer exposure, the expected residues in table grapes do not result in an exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern. However, the safety margin for the acute exposure is very narrow.

RECOMMENDATIONS

Code number[(a)]	**Commodity**	**Existing EU MRL (mg/kg)**	**Proposed EU MRL (mg/kg)**	**Justification for the proposal**
Enforcement residue definition: Folpet (Regulation EC (No) 396/2005)				
0151010	Table grapes	0.02*	3 or 4	The MRL proposals are sufficiently supported by data. The MRL of 4 mg/kg is derived using the OECD calculator. The MRL of 3 mg/kg was proposed by the EMS and can be considered as an alternative risk management option. EFSA notes that using the proposed MRLs as input values for the acute exposure calculation, the ARfD is exceeded.
Enforcement residue definition: Folpet and phthalimide, expressed as folpet (EFSA, 2009)				
0151010	Table grapes	-	5 or 6	The MRL proposals are sufficiently supported by data. The MRL of 6 mg/kg is derived using the OECD calculator. The MRL of 5 mg/kg was proposed by the EMS and can be considered as an alternative risk management option. EFSA notes that using the proposed MRLs as input values for the acute exposure calculation, the ARfD is exceeded.

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.

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APPENDICES

Appendix 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		
Table grapes	NEU (DE, AT, RO, LU, HU)	F	Downy mildew (*Plasmopara viticola*) Red fire disease (*Pseudopeziza tracheiphila*)	WG	80%	Airblast spray; directing spray upwards/sideways	Shoot emergence to before ripening BBCH 14-79	4	7	0.16	1000	1.6	56	Total seasonal application rate 6.4 kg a.s./ha
	SEU (FR, IT, ES, PT, EL)	F		WG	80%	Airblast spray; directing spray upwards/sideways	Shoot emergence to before ripening BBCH 14-79	4	7-10	0.16	400-1000	1.6	56	

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)

Appendix B. Pesticide Residue Intake Model (PRIMo)

				Folpet					**Prepare workbook for refined calculations**	
				Status of the active substance:	**Included**	Code no.				
				LOQ (mg/kg bw):		proposed LOQ:				
				Toxicological end points					**Undo refined calculations**	
				ADI (mg/kg bw/day):	**0.1**	ARfD (mg/kg bw):	**0.2**			
				Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**			
				Year of evaluation:	**2009**	Year of evaluation:	**2009**			
Risk assessment performed for the residue definition" Folpet and phthalmide, expressed as folpet".										
Chronic risk assessment - refined calculations										
				TMDI (range) in % of ADI minimum - maximum						
					8	81				
				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)	
	81	DE child	54.3	Apples	12.3	Wheat	3.1	Spinach		
	61	NL child	28.5	Apples	14.2	Wheat	5.6	Spinach		
	49	WHO Cluster diet B	25.6	Wheat	4.5	Apples	3.0	Gooseberries		
	40	FR toddler	11.8	Apples	10.6	Spinach	7.9	Wheat		
	33	DK child	16.5	Wheat	10.5	Apples	3.0	Pears		
	30	IT kids/toddler	19.9	Wheat	4.0	Apples	1.6	Pears		
	29	IE adult	6.9	Wheat	3.7	Barley	3.7	Apples		
	29	WHO cluster diet D	19.5	Wheat	3.0	Apples	0.7	Barley		
	28	WHO cluster diet E	11.8	Wheat	3.8	Apples	2.7	Wine grapes		
	28	FR infant	11.3	Apples	6.6	Spinach	2.5	Beans (with pods)		
	27	UK Toddler	11.8	Wheat	7.7	Apples	2.0	Currants (red, black and white)		
	26	ES child	13.3	Wheat	5.1	Apples	2.0	Pears		
	25	PT General population	11.8	Wheat	4.7	Apples	4.1	Wine grapes		
	22	IT adult	12.4	Wheat	3.6	Apples	1.4	Spinach		
	22	FR all population	9.9	Wheat	6.6	Wine grapes	2.1	Apples		
	21	WHO Cluster diet F	10.8	Wheat	3.0	Apples	1.8	Barley		
	21	SE general population 90th percentile	9.6	Wheat	4.7	Apples	1.5	Pears		
	20	NL general	6.2	Wheat	5.3	Apples	2.1	Spinach		
	20	WHO regional European diet	8.9	Wheat	3.0	Apples	1.1	Lettuce		
	20	UK Infant	7.9	Wheat	7.0	Apples	1.1	Pears		
	19	ES adult	7.0	Wheat	3.5	Apples	1.6	Lettuce		
	14	LT adult	8.4	Apples	3.2	Wheat	0.7	Pears		
	14	UK vegetarian	6.1	Wheat	2.7	Apples	1.4	Wine grapes		
	14	DK adult	6.0	Wheat	3.5	Apples	2.3	Wine grapes		
	13	PL general population	9.2	Apples	1.3	Pears	0.6	Gooseberries		
	13	UK Adult	5.0	Wheat	1.8	Apples	1.8	Wine grapes		
	8	FI adult	3.0	Wheat	1.8	Apples	1.1	Currants (red, black and white)		
	Conclusion:									
	The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.									
	A long-term intake of residues of Folpet 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)
	93	Table grapes	2.85 / -	93	Table grapes	2.85 / -	45	Table grapes	2.85 / -	45	Table grapes	2.85 / -
	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 Folpet 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 EU maximum residue levels (MRLs)

(Pesticides - Web Version - EU MRLs (Pesticides - Web Version - EU MRLs (File created on 09/09/2013 13:50))

Code number	Groups and examples of individual products to which the MRLs apply	Folpet (R)
100000	1. FRUIT FRESH OR FROZEN NUTS	
110000	(i) Citrus fruit	0,02*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)	0,02*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,02*
110030	Lemons (Citron, lemon, Buddha's hand (Citrus medica var. sarcodactylis))	0,02*
110040	Limes	0,02*
110050	Mandarins (Clementine, tangerine, mineola and other hybrids tangor (Citrus reticulata x sinensis))	0,02*
110990	Others	0,02*
120000	(ii) Tree nuts	0,02*
120010	Almonds	0,02*
120020	Brazil nuts	0,02*
120030	Cashew nuts	0,02*
120040	Chestnuts	0,02*
120050	Coconuts	0,02*
120060	Hazelnuts (Filbert)	0,02*
120070	Macadamia	0,02*
120080	Pecans	0,02*
120090	Pine nuts	0,02*
120100	Pistachios	0,02*
120110	Walnuts	0,02*
120990	Others	0,02*
130000	(iii) Pome fruit	3
130010	Apples (Crab apple)	3
130020	Pears (Oriental pear)	3
130030	Quinces	3
130040	Medlar	3
130050	Loquat	3
130990	Others	3
140000	(iv) Stone fruit	
140010	Apricots	0,02*
140020	Cherries (Sweet cherries, sour cherries)	2
140030	Peaches (Nectarines and similar hybrids)	0,02*
140040	Plums (Damson, greengage, mirabelle, sloe, red date/Chinese date/Chinese jujube (Ziziphus zizyphus))	0,02*
140990	Others	0,02*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	
151010	Table grapes	0,02*
151020	Wine grapes	10
152000	(b) Strawberries	3
153000	(c) Cane fruit	
153010	Blackberries	10
153020	Dewberries (Loganberries, tayberries, boysenberries, cloudberries and other Rubus hybrids)	0,02*
153030	Raspberries (Wineberries, arctic bramble/raspberry, (Rubus arcticus), nectar raspberries (Rubus arcticus x Rubus idaeus))	10
153990	Others	0,02*
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries)	0,02*
154020	Cranberries (Cowberries/red bilberries (V. vitis-idaea))	0,02*
154030	Currants (red, black and white)	15
154040	Gooseberries (Including hybrids with other Ribes species)	15
154050	Rose hips	0,02*
154060	Mulberries (Arbutus berry)	0,02*
154070	Azarole (mediteranean medlar) (Kiwiberry (Actinidia arguta))	0,02*
154080	Elderberries (Black chokeberry/appleberry, mountain ash, buckthorn/sea sallowthorn, hawthorn, serviceberries, and other treeberries)	0,02*
154990	Others	0,02*
160000	(vi) Miscellaneous fruit	0,02*
161000	(a) Edible peel	0,02*
161010	Dates	0,02*
161020	Figs	0,02*
161030	Table olives	0,02*
161040	Kumquats (Marumi kumquats, nagami kumquats, limequats (Citrus aurantifolia x Fortunella spp.))	0,02*
161050	Carambola (Bilimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (java plum) (Java apple/water apple, pomerac, rose apple, Brazilean cherry, Surinam cherry/grumichama (Eugenia uniflora))	0,02*
161990	Others	0,02*
162000	(b) Inedible peel, small	0,02*
162010	Kiwi	0,02*
162020	Lychee (Litchi) (Pulasan, rambutan/hairy litchi, longan, mangosteen, langsat, salak)	0,02*
162030	Passion fruit	0,02*
162040	Prickly pear (cactus fruit)	0,02*
162050	Star apple	0,02*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel/yellow sapote, mammey sapote)	0,02*
162990	Others	0,02*
163000	(c) Inedible peel, large	0,02*
163010	Avocados	0,02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,02*
163030	Mangoes	0,02*
163040	Papaya	0,02*
163050	Pomegranate	0,02*
163060	Cherimoya (Custard apple, sugar apple/sweetsop, ilama (Annona diversifolia) and other medium sized Annonaceae fruits)	0,02*
163070	Guava (Red pitaya/dragon fruit (Hylocereus undatus))	0,02*
163080	Pineapples	0,02*
163090	Bread fruit (Jackfruit)	0,02*
163100	Durian	0,02*
163110	Soursop (guanabana)	0,02*
163990	Others	0,02*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,1
212000	(b) Tropical root and tuber vegetables	0,02*
212010	Cassava (Dasheen, eddoe/Japanese taro, tannia)	0,02*
212020	Sweet potatoes	0,02*
212030	Yams (Potato bean/yam bean, Mexican yam bean)	0,02*
212040	Arrowroot	0,02*
212990	Others	0,02*
213000	(c) Other root and tuber vegetables except sugar beet	0,02*
213010	Beetroot	0,02*
213020	Carrots	0,02*
213030	Celeriac	0,02*
213040	Horseradish (Angelica roots, lovage roots, gentiana roots)	0,02*
213050	Jerusalem artichokes (Crosne)	0,02*
213060	Parsnips	0,02*
213070	Parsley root	0,02*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties, tiger nut (Cyperus esculentus))	0,02*
213090	Salsify (Scorzonera, Spanish salsify/Spanish oysterplant, edible burdock)	0,02*
213100	Swedes	0,02*
213110	Turnips	0,02*
213990	Others	0,02*
220000	(ii) Bulb vegetables	
220010	Garlic	0,1
220020	Onions (Other bulb onions, silverskin onions)	0,1
220030	Shallots	0,02*
220040	Spring onions and welsh onions (Other green onions and similar varieties)	0,02*
220990	Others	0,02*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes, Physalis spp., gojiberry, wolfberry (Lycium barbarum and L. chinense), tree tomato)	3
231020	Peppers (Chilli peppers)	0,02*
231030	Aubergines (egg plants) (Pepino, antroewa/white eggplant (S. macrocarpon))	0,02*
231040	Okra (lady's fingers)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Folpet (R)
231990	Others	0,02*
232000	(b) Cucurbits — edible peel	0,02*
232010	Cucumbers	0,02*
232020	Gherkins	0,02*
232030	Courgettes (Summer squash, marrow (patisson), lauki (Lagenaria siceraria), chayote, sopropo/bitter melon, snake gourd, angled luffa/teroi)	0,02*
232990	Others	0,02*
233000	(c) Cucurbits-inedible peel	1
233010	Melons (Kiwano)	1
233020	Pumpkins (Winter squash, marrow (late variety))	1
233030	Watermelons	1
233990	Others	1
234000	(d) Sweet corn (Baby corn)	0,02*
239000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	0,02*
241010	Broccoli (Calabrese, Broccoli raab, Chinese broccoli)	0,02*
241020	Cauliflower	0,02*
241990	Others	0,02*
242000	(b) Head brassica	0,02*
242010	Brussels sprouts	0,02*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,02*
242990	Others	0,02*
243000	(c) Leafy brassica	0,02*
243010	Chinese cabbage (Indian or Chinese) mustard, pak choi, Chinese flat cabbage/ai goo choi), choi sum, Peking cabbage/pe-tsai)	0,02*
243020	Kale (Borecole/curly kale, collards, Portuguese Kale, Portuguese cabbage, cow cabbage)	0,02*
243990	Others	0,02*
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 corn salad)	0,02*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	2
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curly leaf endive, sugar loaf (C. endivia var. crispum/C. intybus var. foliosum), dandelion greens)	
251040	Cress (Mung bean sprouts, alfalfa sprouts)	0,02*
251050	Land cress	0,02*
251060	Rocket, Rucola (Wild rocket (Diplotaxis spp.))	0,02*
251070	Red mustard	0,02*
251080	Leaves and sprouts of Brassica spp, including turnip greens (Mizuna, leaves of peas and radish and other babyleaf crops, including brassica crops (crops harvested up to 8 true leaf stage), kohlrabi leaves)	0,02*
251990	Others	0,02*
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, amaranthus spinach (pak-khom, tampara), tajer leaves, bitterblad/bitawiri)	10
252020	Purslane (Winter purslane/miner's lettuce, garden purslane, common purslane, sorrel, glassworth, agretti (Salsola soda))	0,02*
252030	Beet leaves (chard) (Leaves of beetroot)	0,02*
252990	Others	0,02*
253000	(c) Vine leaves (grape leaves) (Malabar nightshade, banana leaves, climbing wattle (Acacia pennata))	0,02*
254000	(d) Water cress (Morning glory/Chinese convolvulus/water convolvulus/water spinach/kangkung (Ipomea aquatica), water clover, water mimosa)	0,02*
255000	(e) Witloof	0,02*
256000	(f) Herbs	0,02*
256010	Chervil	0,02*
256020	Chives	0,02*
256030	Celery leaves (Fennel leaves, coriander leaves, dill leaves, caraway leaves, lovage, angelica, sweet cisely and other Apiacea leaves, culantro/stinking/long coriander/stink weed (Eryngium foetidum))	0,02*
256040	Parsley (leaves of root parsley)	0,02*
256050	Sage (Winter savory, summer savory, Borago officinalis leaves)	0,02*
256060	Rosemary	0,02*
256070	Thyme (Marjoram, oregano)	0,02*
256080	Basil (Balm leaves, mint, peppermint, holy basil, sweet basil, hairy basil, edible flowers (marigold flower and others), pennywort, wild betel leaf, curry leaves)	0,02*
256090	Bay leaves (laurel) (Lemon grass)	0,02*
256100	Tarragon (Hyssop)	0,02*
256990	Others	0,02*
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean/French beans/snap beans, scarlet runner bean, slicing bean, yard long beans, guar beans, soya beans)	2
260020	Beans (without pods) (Broad beans, flageolets, jack bean, lima bean, cowpea)	2
260030	Peas (with pods) (Mangetout/sugar peas/snow peas)	0,02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,02*
260050	Lentils	0,02*
260990	Others	0,02*
270000	(vii) Stem vegetables (fresh)	0,02*
270010	Asparagus	0,02*
270020	Cardoons (Borago officinalis stems)	0,02*
270030	Celery	0,02*
270040	Fennel	0,02*
270050	Globe artichokes (Banana flower)	0,02*
270060	Leek	0,02*
270070	Rhubarb	0,02*
270080	Bamboo shoots	0,02*
270090	Palm hearts	0,02*
270990	Others	0,02*
280000	(viii) Fungi	0,02*
280010	Cultivated fungi (Common mushroom, oyster mushroom, shiitake, fungus mycelium (vegetative parts))	0,02*
280020	Wild fungi (Chanterelle, truffle, morel, cep)	0,02*
280990	Others	0,02*
290000	(ix) Sea weeds	
300000	3. PULSES, DRY	0,02*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,02*
300020	Lentils	0,02*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,02*
300040	Lupins	0,02*
300990	Others	0,02*
400000	4. OILSEEDS AND OILFRUITS	0,02*
401000	(i) Oilseeds	0,02*
401010	Linseed	0,02*
401020	Peanuts	0,02*
401030	Poppy seed	0,02*
401040	Sesame seed	0,02*
401050	Sunflower seed	0,02*
401060	Rape seed (Bird rapeseed, turnip rape)	0,02*
401070	Soya bean	0,02*
401080	Mustard seed	0,02*
401090	Cotton seed	0,02*
401100	Pumpkin seeds (Other seeds of Cucurbitaceae)	0,02*
401110	Safflower	0,02*
401120	Borage (Purple viper's bugloss/Canary flower (Echium plantagineum), Corn Gromwell (Buglossoides arvensis))	0,02*
401130	Gold of pleasure	0,02*
401140	Hempseed	0,02*
401150	Castor bean	0,02*
401990	Others	0,02*
402000	(ii) Oilfruits	0,02*
402010	Olives for oil production	0,02*
402020	Palm nuts (palmoil kernels)	0,02*
402030	Palmfruit	0,02*
402040	Kapok	0,02*
402990	Others	0,02*
500000	5. CEREALS	
500010	Barley	2
500020	Buckwheat (Amaranthus, quinoa)	0,02*
500030	Maize	0,02*
500040	Millet (Foxtail millet, teff, finger millet, pearl millet)	0,02*
500050	Oats	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Folpet (R)
500060	Rice (Indian/wild rice (Zizania aquatica))	0,02*
500070	Rye	0,02*
500080	Sorghum	0,02*
500090	Wheat (Spelt, triticale)	2
500990	Others (Canary grass seeds (Phalaris canariensis))	0,02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
610000	(i) Tea	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 (Elderflowers (Sambucus nigra))	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves (Ginkgo leaves)	0,05*
632030	Maté	0,05*
632990	Others	0,05*
633000	(c) 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) Cocoabeans (fermented or dried)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried)	150
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	Sichuan pepper (Anise pepper, Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black, green 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*
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	0,02*
900010	Sugar beet (root)	0,02*
900020	Sugar cane	0,02*
900030	Chicory roots	0,02*
900990	Others	0,02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
1010000	(i) Tissue	
1011000	(a) Swine	
1011010	Muscle	
1011020	Fat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offal	
1011990	Others	
1012000	(b) Bovine	
1012010	Muscle	
1012020	Fat	
1012030	Liver	
1012040	Kidney	
1012050	Edible offal	
1012990	Others	
1013000	(c) Sheep	
1013010	Muscle	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offal	
1013990	Others	
1014000	(d) Goat	
1014010	Muscle	
1014020	Fat	
1014030	Liver	
1014040	Kidney	
1014050	Edible offal	
1014990	Others	
1015000	(e) Horses, asses, mules or hinnies	
1015010	Muscle	
1015020	Fat	
1015030	Liver	
1015040	Kidney	
1015050	Edible offal	
1015990	Others	
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
1016010	Muscle	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offal	
1016990	Others	
1017000	(g) Other farm animals (Rabbit, kangaroo, deer)	
1017010	Muscle	
1017020	Fat	
1017030	Liver	
1017040	Kidney	
1017050	Edible offal	
1017990	Others	
1020000	(ii) Milk	
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others	
1030000	(iii) Bird eggs	
1030010	Chicken	
1030020	Duck	
1030030	Goose	
1030040	Quail	
1030990	Others	
1040000	(iv) Honey (Royal jelly, pollen, honey comb with honey (comb honey))	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products (Wild game)	

(*) Indicates lower limit of analytical determination

(R): The enforcement residue definition for the following codes is " the sum of captan and folpet": 0130000; 0152000; 0153010; 0153030; 0154030; 0154040; 0231010; 0260010.

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
AT	Austria
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
DAR	Draft Assessment Report
DE	Germany
EC	European Community
EFSA	European Food Safety Authority
EL	Greece
EMS	evaluating Member State
ES	Spain
EU	European Union
FR	France
GAP	good agricultural practice
GC-ECD	gas chromatography with electron capture detector
GC-MS	gas chromatography with mass spectrometry detector
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre
HU	Hungary
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IT	Italy
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PF	processing factor

PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PT	Portugal
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
RD	residue definition
RMS	rapporteur Member State
RO	Romania
SEU	Southern European Union
WG	water dispersible granule