European Food Safety Authority

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REASONED OPINION

Reasoned opinion on the review of the existing maximum residue levels (MRLs) for folpet according to Article 12 of Regulation (EC) No 396/2005[1]

European Food Safety Authority[2, 3]

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ABSTRACT

According to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) has reviewed the Maximum Residue Levels (MRLs) currently established at European level for the pesticide active substance folpet. In order to assess the occurrence of folpet residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission as well as the European authorisations reported by Member States (incl. the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was found to be missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

KEY WORDS

folpet, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, phthalimide, fungicide

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SUMMARY

Folpet was included in Annex I to Directive 91/414/EEC on 01 October 2007, which is before the entry into force of Regulation (EC) No 396/2005 on 02 September 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(2) of the aforementioned regulation. In order to collect the relevant pesticide residues data, EFSA asked Italy, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 12 December 2008 and, after having considered several comments made by EFSA, the RMS provided on 26 July 2011 a revised PROFile.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS, EFSA issued on 28 October 2013 a draft reasoned opinion that was circulated to Member States' experts for consultation. Comments received by 10 January 2014 were considered in the finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of folpet was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI of 0.1 mg/kg bw per d and an ARfD of 0.2 mg/kg bw. Both toxicological reference values were established for folpet. The metabolite phthalimide was demonstrated to be of lower toxicity compared to folpet but data were not sufficient to derive specific reference values for this compound. It was therefore concluded that reference values for folpet can be applied to this metabolite as a worst-case assumption.

Primary crop metabolism of folpet was investigated following foliar application on wheat, potatoes and several fruit and fruiting vegetables (grapes, avocados, tomatoes). Translocation from soil application was also investigated in tomatoes. Metabolic patterns in the different studies were shown to be similar and three crop groups were covered. The relevant residue for enforcement and risk assessment in all plant commodities was therefore defined as the sum of folpet and phthalimide, expressed as folpet. Although not fully validated in all matrices, analytical methods for enforcement of the proposed residue definition are available.

The available residues trials allowed EFSA to derive MRLs and risk assessment values for all commodities under evaluation, except for bulb vegetables, kohlrabi, lettuce, scarole, spinach and fresh beans without pods. Moreover, considering the data gaps identified for analytical methods, residues trials and storage stability studies, all MRL proposals are considered tentative, except for table and wine grapes.

The hydrolysis studies demonstrate that folpet is completely degraded during processing; phthalimide is formed predominantly under conditions of pasteurisation, while levels of phthalic acid increase under conditions simulating boiling/brewing/baking and sterilisation. Considering that phthalamide was the only compound of toxicological relevance, the relevant residue for enforcement and risk assessment is processed commodities was also defined as the sum of folpet and phthalimide, expressed as folpet. Magnitude of residues in processed commodities was also investigated and robust processing factors could be derived for grapes juice, wine and beer as well as for canned tomatoes, tomato juice and tomato paste.

According to the soil degradation studies evaluated in the framework of the peer review, DT_{90} values of folpet, phthalimide and their relevant soil metabolites (phthalic acid and phthalamic acid) are all below the trigger value of 100 days. Further investigation of residues in rotational crops is therefore not required and relevant residues in rotational crops are not expected.

Based on the uses reported by the RMS, significant exposures are expected for dairy ruminants, meat ruminants, poultry and pigs. Metabolism in lactating ruminants was sufficiently investigated and findings can be extrapolated to pigs as well. The relevant residue definition for enforcement and risk assessment in pigs and ruminants was defined as phthalimide, expressed as folpet. Analytical methods for enforcement of the proposed residue definition are available with an LOQ of 0.05 mg/kg in milk, meat, fat, liver and kidney. No livestock feeding studies were deemed necessary and, based on the available metabolism studies, MRLs and risk assessment values for the relevant commodities in ruminants and pigs can be established at the LOQ level. The nature and the magnitude of folpet residues in poultry commodities were not investigated. Further investigation on the nature and magnitude of residues in poultry commodities should be carried out in order to establish appropriate residue definitions and MRLs in these commodities.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For bulb vegetables, kohlrabi, lettuce, scarole, spinach and beans (fresh without pods), where data were insufficient to derive an MRL, EFSA could not consider the existing EU MRLs as they do not cover the total residue compliant with the proposed residue definition. The risk assessment for these commodities could therefore not be finalised.

In a first tier calculation, an exceedance of the ARfD was identified for wine grape, representing 105.8 % of the ARfD. The highest chronic exposure represented 22.4 % of the ADI (French population). A second tier exposure calculation was therefore performed using a refining approach for the food item "wine grapes". The highest acute exposure was then calculated for table grapes, representing 93.3 % of the ARfD.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for folpet. Additional calculations of the consumer exposure, including these CXLs, should therefore in principle be performed. Nevertheless, since the residue definitions derived by JMPR (folpet alone) and derived at EU level (sum of folpet and phtalimide, expressed as folpet) are different, and no data on the occurrence phtalimide were evaluated by the JMPR, it is not possible to perform a risk assessment with consideration of the exiting CXLs.

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, some tentative MRLs or existing EU MRLs need to be confirmed by the following data:

- ILVs for the determination of folpet in dry commodities and in hops as well ILVs for the determination of phtalimide in high water content, dry commodities and hops;
- confirmatory methods for the determination of folpet and phtalimide in high oil content and dry commodities and for the determination of phthalimide in high water content commodities;
- a storage stability study for folpet and phthalimide in high oil content commodities;
- further investigation on the nature and magnitude of residues in poultry;
- additional residues trials, with analysis of both folpet and phthalimide, and supporting the southern authorisations on strawberries, potatoes, tomatoes, melons, wheat (grain and straw).

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

In addition, EFSA identified several crops where data were insufficient to derive tentative MRLs and where the safety of the existing EU MRL could not be demonstrated by EFSA. In order to derive MRLs in these crops, the following data would be required:

- additional residue trials, with analysis of both folpet and phthalimide, and supporting authorisations on bulb vegetables, kohlrabi, lettuce, scarole, spinach and fresh beans without pods.

Meanwhile, Member States are recommended to reconsider or withdraw their national authorisations on onions, garlic, shallots, spring onions, kohlrabi, lettuce, scarole, spinach and beans (fresh without pods).

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the 'Recommended' MRLs or on the national authorisations. The following actions are therefore considered desirable but not essential:

- a detailed evaluation report of the reported analytical method for determination of phthalimide in animal matrices;
- a detailed evaluation report of the storage stability study for phthalimide in high water content, high acid content and dry commodities;
- 1 additional residue trial with analysis of both folpet and phthalimide, and compliant with the southern GAP on table grapes;
- 8 residue trials performed with a lower LOQ (at least 0.10* mg/kg), and compliant with the southern GAP on olives (table olive and olives for oil production).

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition (existing): folpet **Enforcement residue definition (proposed):** sum of folpet and phthalimide, expressed as folpet					
130010	Apples	3	10	-	Further consideration needed [(a)]
151010	Table grapes	0.02*	10	6	Recommended [(b)]
151020	Wine grapes	5	10	20	Recommended [(b)]
152000	Strawberries	3	5	5	Further consideration needed [(c)]
161030	Table olives	0.02*	-	0.15	Further consideration needed [(d)]
211000	Potatoes	0.1	0.1	0.1*	Further consideration needed [(c)]
231080	Radishes	0.02*	-	0.1*	Further consideration needed [(d)]
213090	Salsify	0.02*	-	0.1*	Further consideration needed [(d)]
220010	Garlic	0.02*	-	-	Further consideration needed [(e)]
220020	Onions	0.1	1	-	Further consideration needed [(f)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
220030	Shallots	0.02*	-	-	Further consideration needed [e]
220040	Spring onions	0.02*	-	-	Further consideration needed [e]
231010	Tomatoes	2	3	5	Further consideration needed [c]
232010	Cucumbers	0.02*	1	-	Further consideration needed [a]
233010	Melons	1	3	0.4	Further consideration needed [c]
244000	Kohlrabi	0.05	-	-	Further consideration needed [e]
251020	Lettuce	2	50	-	Further consideration needed [f]
251030	Scarole	0.02*	-	-	Further consideration needed [e]
252010	Spinach	10	-	-	Further consideration needed [e]
260020	Beans (fresh, without pods)	2	-	-	Further consideration needed [e]
402010	Olives for oil production	0.02*	-	0.15	Further consideration needed [d]
500010	Barley grain	2	-	1	Further consideration needed [d]
500090	Wheat grain	2	-	0.4	Further consideration needed [d]
700000	Hops (dried)	150	-	400	Further consideration needed [d]
-	Other products of plant origin	See App. C1	-	-	Further consideration needed [g]
Enforcement residue definition (proposed): phthalimide, expressed as folpet					
1012010	Bovine meat	-	-	0.05*	Recommended [h]
1012020	Bovine fat	-	-	0.05*	Recommended [h]
1012030	Bovine liver	-	-	0.05*	Recommended [h]
1012040	Bovine kidney	-	-	0.05*	Recommended [h]
1013010	Sheep meat	-	-	0.05*	Recommended [h]
1013020	Sheep fat	-	-	0.05*	Recommended [h]
1013030	Sheep liver	-	-	0.05*	Recommended [h]
1013040	Sheep kidney	-	-	0.05*	Recommended [h]
1014010	Goat meat	-	-	0.05*	Recommended [h]
1014020	Goat fat	-	-	0.05*	Recommended [h]
1014030	Goat liver	-	-	0.05*	Recommended [h]
1014040	Goat kidney	-	-	0.05*	Recommended [h]
1016010	Poultry meat	-	-	0.05*	Further consideration needed [i]
1016020	Poultry fat	-	-	0.05*	Further consideration needed [i]
1016030	Poultry liver	-	-	0.05*	Further consideration needed [i]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1020010	Cattle milk	-	-	0.05*	Recommended (h)
1020020	Sheep milk	-	-	0.05*	Recommended (h)
1020030	Goat milk	-	-	0.05*	Recommended (h)
1030000	Birds' eggs	-	-	0.05*	Further consideration needed (i)
-	Other products of animal origin	-	-	-	Further consideration needed (g)

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): There are no relevant authorisations or import tolerances reported at EU level; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-II in Appendix D).
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; CXL is not compatible with EU residue definitions (combination G-II in Appendix D)
(c): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; CXL is not compatible with EU residue definitions (combination E-II in Appendix D).
(d): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).
(e): GAP evaluated at EU level is not supported by data, the existing EU MRL is not expected to cover the proposed residue definition and no CXL is available; the consumer risk assessment for this crop can therefore not be finalised. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination D-I in Appendix D).
(f): GAP evaluated at EU level is not supported by data, the existing EU MRL is not expected to cover the proposed residue definition and CXL is not compatible with EU residue definitions; the consumer risk assessment for this crop can therefore not be finalised. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination D-I in Appendix D).
(g): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).
(h): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(i): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition and rounded up to the enforcement LOQ of 0.05 mg/kg); no CXL is available (combination C-I in Appendix D).

TABLE OF CONTENTS

BACKGROUND

Regulation (EC) No 396/2005[4] establishes the rules governing the setting and the review of pesticide MRLs at European level. Article 12(2) of that regulation lays down that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC[5] before 02 September 2008. As folpet was included in Annex I to the above mentioned directive on 01 October 2007, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-553 was included in the EFSA Register of Questions.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that in the framework of Directive 91/414/EEC only a few representative uses are evaluated, while MRLs set out in Regulation (EC) No 396/2005 should accommodate for all uses authorised within the EU, and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

In order to gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residue Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities and;
- the analytical methods for enforcement of the proposed MRLs.

Italy, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for folpet. The requested information was submitted to EFSA on 12 December 2008 and subsequently checked for completeness. On 26 July 2011, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 28 October 2013 and submitted to Member States (MS) for commenting. All MS comments received by 10 January 2014 were considered by EFSA in the finalisation of the reasoned opinion.

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1-16.

[5] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32.

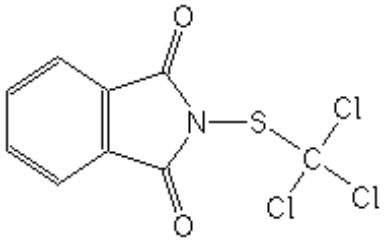
TERMS OF REFERENCE

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Folpet is the ISO common name for N-(trichloromethylthio) phthalimide or N-(trichloromethanesulfenyl) phthalimide (IUPAC).



Folpet belongs to the group of phthalimide compounds which are used as fungicide. Folpet is a contact fungicide that controls a wide range of fungi. It inhibits many oxidative enzymes, carboxylases and enzymes involved with phosphate metabolism and citrate synthesis.

Folpet was evaluated in the framework of Directive 91/414/EEC with Italy being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process were foliar spraying to control various fungi in winter wheat, tomatoes and wine grapes at application rates of up to 750 g/ha in winter cereals, up to 1.6 kg/ha in tomatoes and 1.5 kg/ha in wine grapes. Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2007/5/EC[6], which entered into force on 01 October 2007. According to Regulation (EU) No 540/2011[7], folpet is deemed to have been approved under Regulation (EC) No 1107/2009[8]. This approval is restricted to uses as fungicide only.

The EU MRLs for folpet are established in Annexes II and IIIB of Regulation (EC) No 396/2005. Since the entry into force of that regulation, EFSA recommended the modification of the existing MRLs for garlic, tomatoes and wine grapes (EFSA, 2011a, 2012) which was legally implemented in

[6] Commission Directive 2007/5/EC of 7 February 2007 amending Council Directive 91/414/EEC to include captan, folpet, formetanate and methiocarb as active substances. OJ L 35, 8.2.2007, p. 11-17.

[7] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1-186.

[8] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ 309, 24.11.2009, p. 1–50.

Regulations (EU) No 322/2012/EC[9], 34/2013/EC[10]. EFSA also recommended the modification of the existing MRL for table grapes (EFSA, 2014) but this recommendation was not yet approved by the Standing Committee on the Food Chain and Animal Health. It also noted that the existing MRLs for folpet in blackberries, raspberries, currants and gooseberries were modified by means of Regulation (EU) No 251/2013/EC[11], based on the EFSA recommendations for both captan and folpet (EFSA, 2011b). All existing EU MRLs, which are established for folpet alone or for the sum of folpet and captan, are summarized in Appendix C.1 to this document. CXLs for folpet were also established by the Codex Alimentarius Commission and are reported in Appendix C.2 to this reasoned opinion. These CXLs refer to folpet only.

For the purpose of this MRL review, the critical uses of folpet currently authorized within the EU, have been collected by the RMS and reported in the PROFile. The additional GAPs reported during the consultation of Member States were also considered (see Appendix A). Folpet is authorised for outdoor foliar treatments on several crops in northern and southern Europe. Indoor applications are also authorised on tomatoes. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

It is also noted that national re-registration of plant protection products containing folpet is still ongoing in Italy. Italy therefore requested EFSA to consider the indoor and outdoor GAPs for tomatoes in this framework. Although these GAPs might become authorised when the re-registration process will be finalised, they cannot be considered in the present review as only the current authorisations can be.

[9] Commission Regulation (EU) No 322/2012 of 16 April 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clopyralid, dimethomorph, fenpyrazamine, folpet and pendimethalin in or on certain products. OJ L 105, 17.4.2012, p. 1-40.

[10] Commission Regulation (EU) No 34/2013 of 16 January 2013 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2-phenylphenol, ametoctradin, Aureobasidium pullulans strains DSM 14940 and DSM 14941, cyproconazole, difenoconazole, dithiocarbamates, folpet, propamocarb, spinosad, spirodiclofen, tebufenpyrad and tetraconazole in or on certain products. OJ L 25, 26.1.2013, p. 1-48.

[11] Commission Regulation (EU) No 252/2013 of 22 March 2013 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, bifenazate, captan, fluazinam, fluopicolide, folpet, kresoxim-methyl, penthiopyrad, proquinazid, pyridate and tembotrione in or on certain products. OJ L 88, 27.3.2013, p. 1-44.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the Draft Assessment Report (DAR) and its addenda prepared under Council Directive 91/414/EEC (Italy, 2004, 2005, 2008), the conclusion on the peer review of the pesticide risk assessment of the active substance folpet (EFSA, 2009), the JMPR Evaluation report (FAO, 1998) as well as the previous reasoned opinions on folpet (EFSA, 2011a, 2012, 2013) as well as the evaluation reports submitted during the consultation of Member States (France, 2014a, 2014b; Germany, 2014; Italy, 2014). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[12] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a-g, 2000, 2010a,b, 2011).

1. Methods of analysis

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

During the peer review under Directive 91/414/EEC, analytical methods using GC-ECD were evaluated for the determination of folpet and phthalimide with an LOQ of 0.05 mg/kg for each compound in plant matrices. This method was however not fully validated as the number of tested samples was insufficient, and linearity and specificity data were not reported. Confirmatory method and ILV were also not provided (Italy, 2004, 2005; EFSA, 2007).

In addition, an analytical method using GC-ECD was evaluated and validated for the determination of folpet only in plant matrices with an LOQ of 0.01 mg/kg in dry commodities (cereals) and straw. Neither a confirmatory method nor an ILV were however available (Italy, 2004).

An analytical method using LC-MS/MS and GC-MS was evaluated and validated for the determination of folpet and phtalimide in plant matrices with an LOQ of 0.05 mg/kg in dry commodities (cereal grain), high water content commodities (cereal green plant), of 0.1 mg/kg in cereal straw for folpet an LOQ of 0.01 mg/kg in dry commodities (cereal grain), cereal straw, high water content commodities (cereal green plant) for phthalimide (France, 2014b). Nevertheless, a confirmatory method and an ILV are missing and are required.

An analytical method and its ILV using GC-MS were evaluated and validated for the determination of folpet and phthalimide in plant matrices with LOQs of 0.05 mg/kg for each compound in high oil content commodities (olives) (France, 2014b). Nevertheless, a confirmatory method is missing and is required.

An analytical method and its ILV using GC-MS was evaluated and fully validated for the determination of phthalimide in plant matrices with an LOQ of 0.05 mg/kg in high acid content commodities (grapes) (France, 2014b).

An analytical method using GC-MS was evaluated and fully validated for the determination of folpet and phthalimide in plant matrices with an LOQ of 0.05 mg/kg for folpet and an LOQ of 0.1 mg/kg for phthalimide in green and dry hop cones (France, 2014b). Nevertheless, an ILV is missing and is required.

[12] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.

The multi-residue QuEChERS method in combination with GC-MS, as described by CEN (2008), is also reported for analysis of folpet only with an LOQ of 0.005 mg/kg in acidic and 0.05 mg/kg in high water content commodities (see Table 1-1). This method is also available to analyse folpet in high oil content and dry commodities but validation data reported are too limited to conclude on the validity of the analytical method (EURL, 2013).

Table 1-1: Recovery data for the analysis of folpet in different crop groups using the QuEChERS method in combination with GC-MS (EURL, 2013)

Commodity group	Spiking levels (mg/kg)	Recoveries			No of labs
		Mean (%)	RSD (%)	n	
Acidic	0.002 0.2	95.4 81.3	17.6 15.6	5 4	1
Acidic	0.005 0.1	92.0 85.4	4.5 11.3	5 12	1
High water	0.05 0.1	85.7 100.8	17.7 17.6	49 8	1
High water	0.002 0.1	95.4 85.6	17.6 19.4	5 8	1

Hence, it is concluded that folpet can be enforced in food of plant origin with an LOQ of 0.05 mg/kg in high water content commodities and 0.005 mg/kg in acidic commodities. There are indications that folpet can be enforced with an LOQ of 0.05 mg/kg in high oil content commodities and in hops. Nevertheless, ILV in hops as well as confirmatory method in high oil content commodities are still required. There are also indications that folpet can be enforced with an LOQ of 0.05 mg/kg in dry commodities but a confirmatory method and an ILV are still required.

Regarding phthalamide, it is concluded that this compound can be enforced in food of plant origin with an LOQ of 0.05 mg/kg in acidic matrices. There are indications that phthalimide can be enforced with an LOQ of 0.01 mg/kg in dry commodities and in high water content matrices but a confirmatory method and an ILV are still required. There are also indications that phthalimide can be enforced with an LOQ of 0.05 mg/kg in high oil content commodities and 0.1 mg/kg in hops. Nevertheless, ILV in hops as well as confirmatory method in high oil content commodities are still required.

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

During the peer review under Directive 91/414/EEC, analytical methods using GC-ECD were evaluated for the determination of phthalimide, metabolite of folpet, in food of animal origin. This method was not validated as the number of tested samples was insufficient, neither linearity nor specificity data are reported, neither a confirmatory method nor an ILV were provided (Italy, 2003, 2005, 2005; EFSA, 2009).

An analytical method using GC-MS and its ILV, submitted to the central zone RMS, were reported as validated with an LOQ of 0.05 mg/kg for phthalimide in milk, meat, fat, liver and kidney. However, this method was not reported in detail. A detailed evaluation report is desirable.

Hence, it is concluded that phthalimide can be enforced in food of animal origin with an LOQ of 0.05 mg/kg in milk, meat, fat, liver and kidney but a detailed evaluation report of the reported analytical method (GC-MS) is still desirable.

2. Mammalian toxicology

The toxicological assessment of folpet was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by EFSA (2009). These toxicological reference values are summarized in Table 2-1.

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 d	1 year dog study	100
ARfD	EFSA	2009	0.2 mg/kg bw	Teratogenicity study in rabbits [(a)]	100

(a): Based on the occurrence of hydrocephalus at higher doses

The metabolite phthalimide (see further) was also extensively discussed during the peer review and it was agreed that the available studies demonstrate a lower toxicity of phthalimide compared to parent folpet. Phthalimide does not present acute toxicity, its LD_{50} in mice is above 5 mg/kg bw, it is not mutagenic when tested in the multiple strains of the Ames essay and it does not exhibit developmental toxicity; no effects were observed 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, it was decided, as a worst case assumption, to apply the toxicological reference values agreed for folpet to the metabolite phthalimide (EFSA, 2009).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism of folpet was investigated for foliar application on cereals (winter wheat), fruits and fruiting vegetables (grapes and avocados) and root and tuber vegetables (potatoes) using U-^{14}C-phenyl and ^{14}C-carbonyl labelled folpet. Metabolism for soil application was also investigated in fruit and fruiting vegetables (tomatoes) (EFSA, 2009). The characteristics of these studies are summarised in Table 3-1.

In wheat samples taken at normal harvest, the highest residue levels were identified in both grain and straw (23 and 15 mg eq/kg, respectively). Folpet (35.8 % TRR) and its metabolites phthalimide[13] (31.6 % TRR) and phthalic acid[14] (11.2 % TRR) were the major compounds in grain. The situation was similar in straw.

Metabolism studies in grapes and avocados showed that folpet residues readily translocate to the fruit pulp. In these crops, parent compound was further degraded, accounting for only 0.5 to 12.8 % of the

[13] 1*H*-isoindole-1,3(2*H*)-dione, see appendix E
[14] phthalic acid, see appendix E

TRR in mature fruits (max 0.97 mg/kg). The main identified metabolites were phthalic acid (81.9 % TRR in avocado) and its conjugate (41.4 % TRR in grape), both resulting from phthalimide hydrolyse. Phthalimide only accounted for 0.86 to 3.9 % of the TRR in fruits (max 0.22 mg eq/kg). Other metabolites were found in amounts not exceeding 10 % of the TRR.

Table 3-1: Summary of available metabolism studies in plants

Group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate	No	Sampling	Remarks
Fruits and fruiting vegetable	Grapes	U-^{14}C-phenyl	Foliar treatment, F	1.5 kg a.s./ha	3	Fruits and leaves: 23 DAT	-
	Avocados	U-^{14}C-phenyl	Foliar treatment, F	3.36 kg a.s./ha	3	Mature and immature fruits and leaves: 21 and 97 DAT	-
	Tomatoes	^{14}C-carbonyl	Soil treatment, G [(b)]	0.1 mg/ plants	1	Plants (roots and tops): 1, 4, 7 and 11 DAT	-
Root and tuber vegetables	Potatoes	U-^{14}C-phenyl	Foliar treatment [(c)]	2 kg a.s./ha	5	Foliage and tubers: -1 DAT (after 1st, 2nd and 3rd application) -3 and 5 DAT (after last application)	-
Cereals	Winter wheat	U-^{14}C-phenyl	Foliar treatment [(c)]	1.6 kg a.s./ha	2 [(d)]	Straw/ roots/ grain: -1 DAT (each treatment) -BBCH 83 -Harvest	-

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): 25 mL of 4 mg folpet/L solution was applied to the roots of seven week old glasshouse grown tomato plants
(c): The treated pots were covered with polythene for 2 or 24 hours then maintained outdoors
(d): 2nd application at BBCH 69

Metabolism studies in tomatoes and potatoes gave information on the nature of residues translocated from roots to foliar parts and from leaves to tubers. Residues were rapidly absorbed from the nutrient solution by tomato roots and translocated to tops. However, translocation from foliar parts to roots is limited. In these conditions, phthalic acid and phthalamic acid[15] were the most important components of the residues. About 63 to 80 % of the TRR is due to these compounds in tomato roots and potatoes tubers. Very low levels of parent compound (<0.1 % TRR) indicate that folpet does not translocate from fruits to tubers nor from roots to tops. Phthalimide accounted for 0.5 % of the TRR in potato tubers (0.005 mg eq/kg) and up to 5.9 % TRR in tomato tops. In tomato tops, unknown metabolites were also present at 2.9 to 14.1 % of the TRR. These were tentatively identified as phthalamic acid derivatives.

Consequently, the metabolism of folpet was found similar in all investigated crops. The parent compound is first degraded to phthalimide, hereby releasing the trichloromethylthio-side chain. The

[15] 2-carbamoylbenzoic acid, see appendix E

thiophosgene[16] produced through this cleavage is assumed to be rapidly transformed into CO_2 and incorporated in natural plant components, as demonstrated with metabolism studies on captan. Phthalimide is further hydrolysed to phthalamic acid, phthalic acid and related conjugates (EFSA, 2009). Phthalic acid and phthalamic acid are of no particular concern. Furthermore, phthalic acid and phthalamic acid can naturally occur in the environment and they cannot be considered as specific to folpet. Therefore, both phthalic acid and phthalimic acid should not be taken into account in the residue definition. The toxicological relevance of phthalimide was extensively discussed during the peer review and additional toxicological data were assessed following the inclusion of folpet (Italy, 2008). Based on these studies, it was agreed that phthalimide is less toxic than folpet. However, a complete toxicological assessment of this metabolite was not available and no toxicological endpoints specific to phthalamide could be derived. In the absence of such data, the toxicological endpoints of folpet were used for phthalimide (see also section 2).

Consequently, folpet is extensively degraded in all crops, especially in fruits and potatoes, phthalimide being the only relevant metabolite to be taken into account. Based on these findings, EFSA already concluded that the residue definition for enforcement and risk assessment in all plant commodities should be the sum of folpet and phthalimide, expressed as folpet (EFSA, 2009). Although not fully validated for all matrices, analytical methods for enforcement of the proposed residue definition are available (see also section 1.1).

The conclusion reached by EFSA does not reflect the views of the RMS which still consider that the residue definition for both enforcement and risk assessment could be restricted to folpet only based on the fact that phthalimide is significantly less toxic that folpet (Italy, 2010). Regarding the risk assessment, EFSA agrees that assuming the same toxicity for phthalimide as for folpet is a conservative assumption. However, this assumption can be reconsidered on the basis of additional toxicological studies characterising and quantifying the hazard of phthalimide unequivocally. Regarding the enforcement, although no validated analytical methods for the analysis of phtalimide are currently available, EFSA does not expect that the metabolite phthalimide would result in a real increase of the burden of laboratories as the two compounds are analysed within the same analytical conditions. Furthermore, it is noted that, during routine analyses, metabolite phthalimide is generally formed by degradation of folpet in the injector. Therefore, restricting the residue definition to parent folpet only will not necessarily simplify the enforcement of residues.

3.1.1.2. Magnitude of residues

According to the RMS, the active substance folpet is authorised for outdoor foliar treatments on table and wine grapes, strawberries, olives, potatoes, radishes, salsify, bulb vegetables, tomatoes, melons, several leafy crops, beans (fresh, without pods), hops and cereals. Indoor applications are also authorised on tomatoes (see Appendix A). To assess the magnitude of folpet residues resulting from these GAPs, EFSA considered all residues trials reported in the PROFile, including residues trials evaluated in the framework of the peer review (EFSA, 2009) and in the framework of a previous MRL application (EFSA, 2011a, 2012, 2013) and additional data submitted during the consultation of Member States (France, 2014a; Germany, 2014; Italy, 2014). All available residues trials that, according to the RMS, comply with the authorised GAPs, are summarized in Table 3-2.

The number of residues trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). For most of the reported GAPs (on grapes, olives, potatoes, radishes, salsify, tomatoes, barley, wheat and hops), sufficient trials compliant with the proposed residue definition are available

[16] carbonothioyl dichloride, see appendix E

to derive (tentative) MRLs and risk assessment values, and the following considerations were made by EFSA:

- Table grapes: The number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop (7 trials instead of 8). Although appropriate MRL and risk assessment values can be derived from this data set, 1 additional trial compliant with the southern GAP is still desirable (minor deficiency).

- Table olives and olives for oil production: A sufficient number of residue trials supporting the authorised GAP (southern zone) is available to derive MRL and risk assessment values. However, as these trials were performed with a combined LOQ of 0.15 mg/kg (for the sum of folpet and phthalimide), only an MRL of 0.15 mg/kg can be proposed. In order to lower the MRL and risk assessment values, 8 residue trials performed with a lower LOQ (at least 0.10* mg/kg), and compliant with the southern GAP, are still desirable (minor deficiency). During the consultation for Member States, Italy also reported 8 residue trials performed on olives but these trials were found to be the same as the ones already considered in this review.

- Potatoes: Only 4 residue trials analysing for parent folpet are available to support the authorised GAP (southern zone). However, according to the metabolism study, levels of parent folpet and its metabolite phthalimide are not likely to exceed the expected combined LOQ value of 0.10* mg/kg (for the sum of of folpet and phthalimide); the translocation of folpet residues into tubers is very limited (see also section 3.1.1.1). This is confirmed by the 4 available residue trials analysing for parent folpet. Therefore, tentative MRL and risk assessment values of 0.10* mg/kg can be derived by EFSA. Considering that potatoes is a major crops in southern Europe, 8 residue trials analysing for folpet and its metabolite phthalimide and compliant with the southern GAP are still required.

- Salsify: The number of residue trials supporting the northern outdoor GAP on salsify is not compliant with the data requirements for this crop (only 2 trials). However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ for both folpet and its metabolite phtalimide, and a no residues situation is expected from the metabolism study performed on potatoes. Further residue trials are therefore not required.

- Tomatoes: The number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop (3 trials instead of 8). Although MRL and risk assessment values can be derived from the indoor data, 5 additional residue trials compliant with the southern outdoor GAP are still required. All trials should analyse for folpet and its metabolite phthalimide. During the consultation of Member States, Italy informed EFSA that other GAPs, for which more compliant residue trials are available, are currently under evaluation at national level. Although these GAPs might become authorised in the future, EFSA highlights that only the current authorisations can be taken in to consideration. Therefore, this Italian GAP was not considered in the present review.

- Wheat: The number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop (5 trials instead of 8). Although tentative MRL and risk assessment values can be derived, 3 additional trials compliant with the southern GAP are still required.

For strawberries and melons, only residue trials analysing for parent folpet are available. Therefore, the results of these trials cannot be taken into account as such to derive MRL and risk assessment values. Nevertheless, for fruits and fruiting vegetables, factors for recalculating parent folpet to the proposed residue definition were already derived by EFSA in previous assessments (EFSA, 2011a,

2012, 2014). In these reasoned opinions, such factors were derived in different fruit crops based on a high number of residue data, factors ranging between 1.3 (tomatoes), 1.6 (wine grapes) and 1.9 (table grapes). These results are consistent with the findings of the metabolism studies performed on these crops (see also section 3.1.1.1). As a conservative approach, a tentative factor of 1.9 was proposed by EFSA to recalculate the available trial results for strawberries and melons according to the proposed residue definition; the following considerations were made by EFSA:

- Strawberries: 4 residue trials analysing for parent folpet only were reported by Italy during the consultation for Member States (Italy, 2014). Although the recalculated data can be used to derive tentative MRL and risk assessment values, 8 residue trials analysing for folpet and its metabolite phthalimide and compliant with the southern GAP are still required.

- Melons: 4 residue trials analysing for parent folpet only were reported by Italy during the consultation for Member States (Italy, 2014). Furthermore, these trials were performed at a more critical GAP compared to the current critical authorisation: 5 x 1.5 g a.s./ha instead of 2 x 0.96 g a.s./ha. Therefore, the recalculated data are expected to overestimate the residue levels in melons and they can be used to derive tentative MRL and risk assessment values. Nevertheless, 8 residue trials analysing folpet and its metabolite phthalimide, and compliant with the southern GAP are still required.

For the remaining crops, mainly residue trials analysing for parent folpet are available, which is not in accordance with the proposed residue definition. For these crops, EFSA was not able to estimate a factor for recalculating the trial results from parent folpet to the proposed residue definition. Therefore, neither MRL nor risk assessment values can be derived for these crops. The following data gaps were also identified:

- Onions, garlic and shallots: One trial analysing for parent folpet only was reported by Germany during the consultation for Member States to support the northern GAP for these crops (Germany, 2014). A southern GAP is also authorised for onions and garlic but only 2 residue trials are available (EFSA, 2011a). Although these trials indicate residue levels below the LOQ (<0.12 mg/kg), it is not deemed sufficient to derive MRL and risk assessment values as northern data clearly indicate that significant residue levels can occur in these crops. Considering that onions and garlic are major crops in northern and southern Europe, 8 residue trials compliant with the northern GAP and 6 additional residue trials compliant with the southern GAP are required, all trials analysing for folpet and its metabolite phthalimide.

- Spring onions: Considering that spring onion is a minor crop in northern Europe, 4 residue trials analysing for folpet and its metabolite phthalimide, and compliant with the northern GAP are required.

- Kohlrabi: Considering that kohlrabi is a minor crop in northern Europe, 4 residue trials analysing for folpet and its metabolite phthalimide, and compliant with the northern GAP are required.

- Lettuce and scarole: Considering that lettuce is a major crop in northern Europe, 8 residue trials analysing for folpet and its metabolite phthalimide and compliant with the northern GAP are still required.

- Spinach: Considering that spinach is a minor crop in northern Europe, 4 residue trials analysing for folpet and its metabolite phthalimide and compliant with the northern GAP are required.

- Beans (fresh, without pods): Considering that fresh beans without pods are major crop in northern Europe, 8 residue trials analysing for folpet and its metabolite phthalimide and compliant with the northern GAP are still required.

The potential degradation of residues during storage of the residues trials samples was also assessed. In the framework of the peer review, storage stability of folpet was demonstrated for a period of 6 months at -18°C in commodities with high water content (tomatoes), for a period of 14 months in commodities with high acid content (grapes) and for a period of 12 months at -20°C in dry commodities (Italy, 2004). After the peer review, additional data were evaluated in the framework of a routine MRL application, where the storage stability of folpet was demonstrated up to 18 months in high water content commodities (tomatoes) and to 15 months in high acid content commodities (grapes) (EFSA, 2011a). The RMS also evaluated the storage stability of the metabolite phthalimide in high water and high acid content commodities (for a period of 13 months) and in dry commodities (for a period of 18 months) but a detailed evaluation report of this study is still desirable. According to the RMS, all residues trial samples reported in the PROFile were stored in compliance with the storage conditions reported above and degradation of folpet and phthalamide during storage of the trial samples is therefore not expected in acidic and high water content commodities. Considering however that the use of folpet is also authorised in olives, a storage stability study for folpet and phthalamide in high oil content commodities is still required.

Consequently, the available residues data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for bulb vegetables, kohlrabi, lettuce, scarole, spinach and fresh beans without pods. Moreover, considering the data gaps identified for analytical methods, residues trials and storage stability studies, all MRL proposals are considered tentative, except for table and wine grapes (see also Table 3-2). In case where several uses are supported for one commodity, the final MRL proposal was derived from the most critical use and indicated in bold in Table 3-2. Tentative MRLs were also derived for cereal straw in view of the future need to set MRLs in feed items.

Table 3-2: 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
			Enforcement (sum of folpet and phthalimide, expressed as folpet)	Risk assessment (sum of folpet and phthalimide, expressed as folpet)					
Wine grapes	NEU	Outdoor	2.5; 2.6; 4.95; 5.1; 5.27; 6.0; 6.4; 6.94; 8.92	2.5; 2.6; 4.95; 5.1; 5.27; 6.0; 6.4; 6.94; 8.92	**5.27**	**8.92**	**20**	**1.00**	Trials on wine grapes compliant with GAP (EFSA, 2012). R_{ber}= 13.3 R_{max}= 11.5 MRL_{OECD} = 16.2
	SEU	Outdoor	0.77; 0.82; 1.09; 1.30; 1.34; 2.29; 2.34; 4.74; 5.50; 6.87	0.77; 0.82; 1.09; 1.30; 1.34; 2.29; 2.34; 4.74; 5.50; 6.87	1.82	6.87	15	1.00	Trials on wine grapes compliant with GAP (EFSA, 2011a; France, 2014a). R_{ber}= 9.86 R_{max}= 9.09 MRL_{OECD} = 11.5
Table grape	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	1.00	Trials on table grapes compliant with GAP (EFSA, 2013). R_{ber}= 1.55 R_{max}= 1.56 MRL_{OECD} = 1.64
	SEU	Outdoor	<0.12; 0.42; 1.0; 1.18; 2.09; 2.19; 2.85	<0.12; 0.42; 1.0; 1.18; 2.09; 2.19; 2.85	**1.18**	**2.85**	**6**	**1.00**	Trials on table grapes compliant with GAP (EFSA, 2013). R_{ber}= 4.38 R_{max}= 4.81 MRL_{OECD} = 5.41

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
			Enforcement (sum of folpet and phthalimide, expressed as folpet)	Risk assessment (sum of folpet and phthalimide, expressed as folpet)					
Strawberries	SEU	Outdoor	Trial results for folpet only: 0.53; 0.58; 0.82; 1.18 Recalculated results (tentative): 1.0; 1.1; 1.5; 2.2	Trial results for folpet only: 0.53; 0.58; 0.82; 1.18 Recalculated results (tentative): 1.0; 1.1; 1.5; 2.2	1.3	2.2	5 (tentative)	1.00	Trials on strawberries compliant with GAP but there is no data for phthalimide (Italy, 2014); results were recalculated in line with the proposed residue definition, using a tentative factor of 1.9. Additional trials are anyhow still required; see also body text. R_{ber}= 4.05 R_{max}= 4.25 MRL_{OECD} = 4.35
Table olives/ Olives for oil production	SEU	Outdoor	8 x <0.15	8 x <0.15	0.15	0.15	0.15 [e; f] (tentative)	1.00	Trials on olives for oil production compliant with GAP.
Potatoes	SEU	Outdoor	4 x <0.05	4 x <0.05	0.10	0.10	0.1* (tentative)	1.00	Trials on potatoes compliant with GAP. Residue levels for parent folpet are <0.05 mg/kg. There is no data for phthalimide but according to the metabolism study it is not expected to exceed 0.05 mg/kg either. Additional trials are anyhow still required; see also body text.
Radishes	NEU	Outdoor	4 x <0.04	4 x <0.04	0.04	0.04	0.1* [e] (tentative)	1.00	Trials on radishes compliant with GAP (Germany, 2014).

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
			Enforcement (sum of folpet and phthalimide, expressed as folpet)	Risk assessment (sum of folpet and phthalimide, expressed as folpet)					
Salsify	NEU	Outdoor	2 x <0.04	2 x <0.04	0.04	0.04	0.1* [e] (tentative)	1.00	Trials on salsifiy compliant with GAP (Germany, 2014).
Garlic Onions Shallots	NEU	Outdoor	Trial results for folpet only: 0.15	Trial results for folpet only: 0.15	-	-	-	-	One trial performed on onion analysing for parent folpet only, which is not sufficient for deriving an MRL proposal (Germany, 2014); see also body text.
	SEU	Outdoor	2 x <0.12	2 x <0.12	-	-	-	-	Insufficient trials to derive MRL and risk assessment values as northern data clearly indicate that measurable residues may occur; see also body text. No authorised use for shallots in southern EU.
Spring onions	NEU	Outdoor	Trial results for folpet only: <0.02; 0.91	Trial results for folpet only: <0.02; 0.91	-	-	-	-	2 trials performed on spring onion analysing for parent folpet only, which is not sufficient for deriving an MRL proposal (Germany, 2014); see also body text.

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
			Enforcement (sum of folpet and phthalimide, expressed as folpet)	Risk assessment (sum of folpet and phthalimide, expressed as folpet)					
Tomatoes	SEU	Outdoor	0.24; 0.62; 0.80	0.24; 0.62; 0.80	-	-	-	-	Number of trials is not sufficient for deriving an MRL proposal (Italy, 2014).
	EU	Indoor	<0.12; 0.33; 0.46; 0.55; 0.7; 0.7; 1.3; 1.8; 2.8	<0.12; 0.33; 0.46; 0.55; 0.7; 0.7; 1.3; 1.8; 2.8	0.70	2.80	5 [e] (tentative)	1.00	Trials on tomatoes compliant with GAP (EFSA, 2011a; Italy, 2014). R_{ber}= 3.10 R_{max}= 3.57 MRL_{OECD} = 4.40
Melons	SEU	Outdoor	Trial results for folpet only: <0.01; <0.01; 0.02; 0.09 Recalculated results (tentative): 0.02; 0.02; 0.04; 0.17	Trial results for folpet only: <0.01; <0.01; 0.02; 0.09 Recalculated results (tentative): 0.02; 0.02; 0.04; 0.17	0.03	0.17	0.4 (tentative)	1.00	Overdosed trials on melons without data for phthalimide (Italy, 2014); results were recalculated in line with the proposed residue definition, using a tentative factor of 1.9. Additional trials are anyhow still required; see also body text. R_{ber}= 0.28 R_{max}= 0.43 MRL_{OECD} = 0.35

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
			Enforcement (sum of folpet and phthalimide, expressed as folpet)	Risk assessment (sum of folpet and phthalimide, expressed as folpet)					
Kohlrabi	NEU	Outdoor	Trial results for folpet only: 3x<0.05; 0.05	Trial results for folpet only: 3x<0.05; 0.05	-	-	-	-	4 trials performed on kohlrabi analysing for parent folpet only. Not appropriate for deriving an MRL proposal (Germany, 2014); see also body text. R_{ber} (indicative) = 0.10 R_{max} (indicative) = 0.05 MRL_{OECD} (indicative) = 0.08
Lettuce/ Scarole	NEU	Outdoor	Trial results for folpet only: 2x<0.01; 3x0.02; 2x0.06; 0.67	Trial results for folpet only: 2x<0.01; 3x0.02; 2x0.06; 0.67	-	-	-	-	8 trials performed on head lettuce analysing for parent folpet only. Not appropriate for deriving an MRL proposal (Germany, 2014); see also body text. R_{ber} (indicative) = 0.12 R_{max} (indicative) = 0.83 MRL_{OECD} (indicative) = 1.02
Spinach	NEU	Outdoor	Trial results for folpet only: 0.10; 1.7; 4.9; 5.1	Trial results for folpet only: 0.10; 1.7; 4.9; 5.1	-	-	-	-	4 trials performed on spinach analysing for parent folpet only. Not appropriate for deriving an MRL proposal (Germany, 2014); see also body text. R_{ber} (indicative) = 10.1 R_{max} (indicative) = 15.6 MRL_{OECD} (indicative) = 12.8

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
			Enforcement (sum of folpet and phthalimide, expressed as folpet)	Risk assessment (sum of folpet and phthalimide, expressed as folpet)					
Fresh beans, without pods	NEU	Outdoor	Trial results for folpet only: 4x<0.05	Trial results for folpet only: 4x<0.05	-	-	-	-	4 trials performed on fresh beans without pods analysing for parent folpet only. Not appropriate for deriving an MRL proposal (Germany, 2014); see also body text.
Barley grain	NEU	Outdoor	8 x <0.11; 0.04; 0.11; 0.87	8 x <0.11; 0.04; 0.11; 0.87	0.11	0.87	1 [e] (tentative)	1.00	Trials on barley compliant with GAP. R_{ber}= 0.22 R_{max}= 0.83 MRL_{OECD} = 1.10
Barley straw	NEU	Outdoor	<0.13; <0.15; <0.23; <0.25; <0.41; <0.55; <1.6; 0.15; 1.4; 1.7; 6.9	<0.13; <0.15; <0.23; <0.25; <0.41; <0.55; <1.6; 0.15; 1.4; 1.7; 6.9	0.41	6.90	10 (tentative)	1.00	Trials on barley compliant with GAP. R_{ber}= 3.20 R_{max}= 6.80 MRL_{OECD} = 9.14
Wheat grain	NEU	Outdoor	13 x <0.11; <0.13; <0.17	13 x <0.11; <0.13; <0.17	0.11	0.17	0.20 [e] (tentative)	1.00	Trials on wheat compliant with GAP. R_{ber}= - R_{max}= - MRL_{OECD} = 0.17
	SEU	Outdoor	<0.11; 3x<0.12; 0.23	<0.11; 3x<0.12; 0.23	**0.12**	**0.23**	**0.4 (tentative)**	**1.00**	Trials on wheat compliant with GAP (France, 2014a). R_{ber}= 0.35 R_{max}= 0.35 MRL_{OECD} = 0.34

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
			Enforcement (sum of folpet and phthalimide, expressed as folpet)	Risk assessment (sum of folpet and phthalimide, expressed as folpet)					
Wheat straw	NEU	Outdoor	<0.17; <0.26; <0.26; <0.61; <0.76; 0.67; 0.68; 0.82; 0.73; 1.1; 1.2; 1.6; 2.5; 4.6; 9.1	<0.17; <0.26; <0.26; <0.61; <0.76; 0.67; 0.68; 0.82; 0.73; 1.1; 1.2; 1.6; 2.5; 4.6; 9.1	**0.76**	**9.10**	**10 (tentative)**	**1.00**	Trials on wheat compliant with GAP. R_{ber}= 3.20 R_{max}= 7.68 MRL_{OECD} = 11.04
	SEU	Outdoor	0.70; 0.74; 0.76; 0.93; 1.28	0.74; 0.74; 0.76; 0.93; 1.28	0.76	1.28	3 (tentative)	1.00	Trials on wheat compliant with GAP (France, 2014a). R_{ber}= 2.21 R_{max}= 1.89 MRL_{OECD} = 2.65
Hops (dried)	NEU	Outdoor	52; 67; 96; 192	52; 67; 96; 192	82	192	400 [e] (tentative)	1.00	Trials on hops compliant with GAP. R_{ber}= 336 R_{max}= 425 MRL_{OECD} = 353

(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 residues trial.
(e): Although a sufficient number of trials is available, MRL proposal is tentative because analytical method for enforcement of the proposed residue definition is not fully validated.
(f): Although a sufficient number of trials is available, MRL proposal is tentative because no storage stability study for folpet and phthalimide in high oil content commodities is available.
(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

In the framework of the peer review, only studies conducted at room temperature were available to investigate the effect of processing on the nature of folpet. Although these studies indicate the transformation of folpet into phthalimide and phtalic acid, they were not deemed sufficient to conclude on the nature of the residue in processed commodities (EFSA, 2009). In the framework of an MRL application, studies simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6) were provided and evaluated (EFSA, 2011a). The results of the studies indicated that folpet is completely degraded during processing; phthalimide is formed predominantly under conditions of pasteurisation (92 % TRR) while levels of phthalic acid increase under conditions simulating boiling/brewing/baking (42.2 % TRR) and sterilisation (91.4 % TRR). After processing, the main residues are therefore composed of metabolites already identified in the plant metabolism study where phthalimide was found to be the only metabolite of toxicological relevance (see also section 3.1.1.1). Consequently, as for the primary crops, the relevant residue for enforcement and risk assessment in processed commodities is defined as the sum of folpet and phthalimide, expressed as folpet.

Studies investigating the magnitude of residues in processed commodities of wine grapes and tomatoes were also reported in the framework of the peer review (Italy, 2004, 2005). In these studies, processing commodities were analysed for folpet only. Consequently, no processing factor can be derived from these studies. In the framework of two MRL applications, additional data on processed commodities of tomatoes and wine grapes were evaluated (EFSA, 2011a, 2012). According to the RMS, a processing study on hops was also submitted and evaluated after the peer review process. In the studies recently evaluated, both folpet and phthalimide were analysed. An overview of all available processing studies is available in Table 3-3. Robust processing factors for enforcement and risk assessment were derived for grapes juice, wine and beer as well as for canned tomatoes, tomato juice and tomato paste.

Table 3-3: Overview of the available processing studies

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Residue definition for enforcement and risk assessment: sum of folpet and phthalimide, expressed as folpet				
Processing factors recommended (sufficiently supported by data)				
Wine grapes, juice	25	0.82	1.00	Merged dataset for juice and must since the processing conditions are deemed similar (EFSA, 2012).
Wine grapes, red wine (unheated)	21	0.45	1.00	EFSA, 2012
Tomatoes, peeled and canned	4	<0.44	1.00	Folpet and phthalimide levels were below the LOQ in canned tomatoes (EFSA, 2011a).
Tomatoes, juice	4	<0.44	1.00	Folpet and phthalimide levels were below the LOQ in tomato juice (EFSA, 2011a).
Tomatoes, paste	3	2	1.00	One more trial was reported but not considered as residues were below the LOQ for all analyte in both RAC and processed commodity (EFSA, 2011a).

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Hops, beer	4	0.0013	1.00	Since residues sum of folpet and phthalimide expressed as folpet in beer were <0.13, <0.17, <0.19 and <0.11 mg/kg (folpet residues always < 0.01 mg/kg), the derived PF for beer are 0.0013, 0.001, 0.0013 and 0.0016.

(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

All crops under consideration, except grapes and olives, may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, DT_{90} values of folpet, phthalimide and their relevant soil metabolites (phthalic acid and phthalamic acid) are all expected to range between 1 and 94 days (under laboratory conditions) which is just below the trigger value of 100 days. It was also demonstrated that folpet and phthalimide half lives are < 3 days under field conditions (EFSA, 2009). According to the European guidelines on rotational crops (EC, 1997b), further investigation of residues in rotational crops is not required and relevant residues in rotational crops are not expected.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

Folpet is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (EC, 1996).The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarized in Table 3-4. For wheat bran, the default processing factor of 8 has been included in the calculation in order to consider potential concentration of residues in this commodity.

Table 3-4: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of folpet and phthalimide, expressed as folpet				
Wheat grain	0.12	Median residue	0.12	Median residue
Barley grain	0.11	Median residue	0.11	Median residue
Wheat bran	0.96	Median residue x 8	0.96	Median residue x 8
Wheat straw	0.76	Median residue	9.10	Highest residue
Barley straw	0.41	Median residue	6.90	Highest residue
Potatoes	0.1	Median residue	0.1	Highest residue

The results of the calculations are reported in Table 3-5. The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore required in all commodities of animal origin.

Table 3-5: Results of the dietary burden calculation

	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: sum of folpet and phthalimide, expressed as folpet					
Dairy ruminants	0.0215	0.0921	Potatoes	2.56	Y
Meat ruminants	0.0368	0.2446	Wheat straw	5.69	Y
Poultry	0.0186	0.0186	Wheat bran	0.30	Y
Pigs	0.0247	0.0247	Potatoes	0.62	Y

3.2.2. Nature of residues

The nature of folpet residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (EFSA, 2009). Reported metabolism studies include two studies in lactating goats using U-^{14}C-phenyl and ^{14}C-trichloromethyl labelled folpet. The characteristics of these studies are summarized in Table 3-6.

Table 3-6: Summary of available metabolism studies in livestock

Group	Species	Label position	No of animal	Application details		Sample details	
				Rate (mg/kg diet)	Duration (days)	Commodity	Time
Lactating ruminants	Goat	U-^{14}C-phenyl and ^{14}C-trichloromethyl	2	14 24	6	Milk	Twice a day
						Urine and faeces	Daily
						Tissues	At sacrifice (23 hours after the final dose)
		^{14}C-trichloromethyl	1	20	3	Milk	Twice a day
						Urine and faeces	Daily
						Expired CO_2	Daily
						Tissues	At sacrifice (23 hours after the final dose)

Lactating goats were dosed with 14 - 24 mg folpet/kg diet, corresponding to approximately 2.5 - 4 times the exposure of meat ruminant. Studies demonstrated that the transfer of residues to milk and tissues was very low. The majority of the TRR was found in faeces, urine, expired CO_2 and gastrointestinal tract (95 – 98 % TRR). In milk and tissues, the recovered residues amounted to less than 2 % of the TRR. After an administration rate of 14 mg/kg diet, only liver and kidney were

containing more than 0.01 mg folpet eq/kg (0.02 mg eq/kg and 0.05 mg eq/kg respectively). Folpet was not detected in tissues or milk. The major metabolites in liver, kidney and milk were phthalimide (0.7 - 5.8 % TRR) and either phthalamic acid, phthalic anhydride[17] or phthalic acid (27.8 % TRR in liver; 69.1 % TRR in kidney; 7.2 % in milk). The remaining radioactivity was incorporated into naturally occurring compounds (amino acids, glucose, cholesterol and lactose).

The observed levels of parent compound indicate an extensive metabolism. Folpet is rapidly degraded by hydrolysis of the trichloromethyl moiety leading to thiophosgen and phthalimide. Thiophosgen leads to thiazolidine[18] which is incorporated into natural products such as amino acids, sugars and fats. Phthalimide is further metabolised to phthalamic acid and phthalic acid. The formation of phthalic anhydride might be caused by dehydration of phthalic acid. It is not expected to be a significant product in any consumable commodity because the reaction is readily reversible and phthalic acid is likely to be formed again via hydrolysis in aqueous solutions. The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs. According to the guidance recommendations, goats should have been fed with both folpet and phthalimide since the residue definition for risk assessment in plant commodities includes the metabolite phthalimide (see also section 3.1.1.1). Nevertheless, considering the above results, this deviation is not of concern because phthalimide is rapidly generated *in vivo* following exposure to folpet.

Considering that parent compound is totally metabolised into phthalimide, it was concluded that phthalimide is the most appropriate indicator of the residue in commodities of animal origin. Phthalimide is the only metabolite of toxicological relevance (see also section 3.1.1.1). Consequently, the residue for enforcement and risk assessment in commodities of ruminants and pigs was defined as phthalimide, expressed as folpet (EFSA, 2009). Validated analytical method for enforcement of the proposed residue definition in animal commodities is available but a detailed evaluation report for this method is still desirable (see also section 1.1).

In the framework of the peer review, the proposed residue was not considered to be fat soluble (EFSA, 2009).

Considering that the dietary burden of poultry is also triggered (see also section 3.2.1), investigation on the fate of residues in this group of livestock is also necessary. However, no study on the nature of folpet residues in poultry is available. In the absence of this data, the same residue definition as for ruminants and pigs is assumed on a tentative basis for poultry commodities.

3.2.3. Magnitude of residues

According to the above mentioned metabolism studies, it is concluded that, after exposure to the maximum dietary burden (about 2.5 - 4 times lower than the dose level of the metabolism studies; see also section 3.2.1), residue levels in ruminant and pigs commodities are expected to remain below the enforcement LOQ of 0.05 mg/kg in milk, muscle, fat, liver and kidney. Hence, no livestock feeding study needs to be performed; MRLs and risk assessment values for the relevant commodities in ruminants and pigs can be established at the LOQ level.

Considering that the dietary burden of poultry is also triggered (see also section 3.2.1), investigation on the fate of residues in this group of livestock is necessary. However, the nature and the magnitude of folpet residues in this group of livestock were not investigated. Further investigation on the nature and magnitude of residues in poultry should be carried out in order to establish appropriate residue definitions and MRLs in these commodities.

[17] 2-benzofuran-1,3-dione, see appendix E
[18] 1,3-thiazolidine, see appendix E

4. Consumer risk assessment

In the framework of this review, only the uses of folpet reported by the RMS in Appendix A were considered but the use of folpet was previously also assessed by the JMPR (FAO, 1998). The CXLs, resulting from these assessments by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. Nevertheless, since the residue definitions derived by JMPR (folpet alone) and derived at EU level (sum of folpet and phthalimide, expressed as phthalimide) are different, and no data on the occurrence of phthalimide levels were evaluated by the JMPR, it is not possible to perform a risk assessment with consideration of the exiting CXLs. Therefore, the consumer risk assessment was carried out without consideration of these CXLs.

Chronic and acute exposure calculations for all crops supported in the framework of this review were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007). Input values for the intake calculations were derived in compliance with Appendix D and are summarized in Table 4-1. In a first tier exposure assessment, the tentative median and highest residue values selected for chronic and acute intake calculations are based on the residue levels in the raw agricultural commodities reported in section 3.

For those commodities where data were insufficient to derive an MRL in section 3 (bulb vegetables, kohlrabi, lettuce, scarole, spinach and fresh beans without pods), EFSA would normally consider the existing EU MRL for an indicative calculation. However, MRLs for these crops are currently defined for folpet alone while the proposed residue definition now includes the metabolite phthalamide. Moreover, the available data for folpet (without consideration of phthalamide) already indicated that the existing MRLs for most of these crops may be exceeded with the GAP reported in this review (see also section 3.1.1.2). Consequently, these MRLs cannot be used for indicative risk assessment. The contributions of other commodities, for which no GAP was reported in the framework of this review, were not included in the calculation.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition: sum of folpet and phthalimide, expressed as folpet				
Wine grapes	5.3	Median residue [(a)]	8.9	Highest residue [(a)]
			2.8 [(e)]	Highest x PF x 0.7 (refined input value for adults) [(e)]
			5.5 [(f)]	Highest x PF x 0.75 (refined input value children) [(f)]
Table grapes	1.2	Median residue [(a)]	2.9	Highest residue [(a)]
Strawberries	1.3	Median residue (tentative) [(b)]	2.2	Highest residue (tentative) [(b)]
Table olives	0.15	Median residue (tentative) [(b)]	0.15	Highest residue (tentative) [(b)]
Potatoes	0.10*	Median residue (tentative) [(b)]	0.10*	Highest residue (tentative) [(b)]
Radishes	0.04*	Median residue (tentative) [(b)]	0.04*	Highest residue (tentative) [(b)]
Salsify	0.04*	Median residue (tentative) [(b)]	0.04*	Highest residue (tentative) [(b)]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Garlic Onions Shallots Spring onions	-	No input value possible [g]	-	No input value possible [g]
Tomatoes	0.70	Median residue (tentative) [b]	2.8	Highest residue (tentative) [b]
Melons	0.03	Median residue (tentative) [b]	0.17	Highest residue (tentative) [b]
Kohlrabi Lettuce Scarole Spinach Beans, fresh without pods	-	No input value possible [g]	-	No input value possible [g]
Olives for oil production	0.15	Median residue (tentative) [b]	0.15	Highest residue (tentative) [b]
Barley grain	0.11	Median residue (tentative) [b]	0.87	Highest residue (tentative) [b]
Wheat grain	0.12	Median residue (tentative) [b]	0.23	Highest residue (tentative) [b]
Hops (dried)	82	Median residue (tentative) [b]	192	Highest residue (tentative) [b]
Risk assessment residue definition: phthalimide, expressed as folpet				
Swine meat	0.05*	Median residue [c]	0.05*	Highest residue [c]
Swine fat	0.05*	Median residue [c]	0.05*	Highest residue [c]
Swine liver	0.05*	Median residue [c]	0.05*	Highest residue [c]
Swine kidney	0.05*	Median residue [c]	0.05*	Highest residue [c]
Ruminant meat	0.05*	Median residue [c]	0.05*	Highest residue [c]
Ruminant fat	0.05*	Median residue [c]	0.05*	Highest residue [c]
Ruminant liver	0.05*	Median residue [c]	0.05*	Highest residue [c]
Ruminant kidney	0.05*	Median residue [c]	0.05*	Highest residue [c]
Poultry meat	0.05*	EU MRL [d]	0.05*	EU MRL [d]
Poultry fat	0.05*	EU MRL [d]	0.05*	EU MRL [d]
Poultry liver	0.05*	EU MRL [d]	0.05*	EU MRL [d]
Ruminant's milk	0.05*	Median residue [c]	0.05*	Highest residue [c]
Bird's eggs	0.05*	EU MRL [d]	0.05*	EU MRL [d]

(*): Indicates that the input value is proposed at the limit of analytical quantification.
(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.
(b): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.
(c): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS is fully supported by data; the risk assessment values derived in section 3 are used for the exposure calculations.
(d): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not supported by data; the existing EU MRL (rounded up to the enforcement LOQ of 0.05 mg/kg) is used for indicative exposure calculations (also assuming the existing residue definition).

(e): Highest residue value for RAC leads to an exceedance of the ARfD in this commodity; a refined risk assessment value is used for a second tier exposure calculation considering that the consumption of wine grapes by adults exclusively refers to wine. PF was derived in section 3.1.1.3 and a yield factor of 0.7 is applied.
(f): Highest residue value for RAC leads to an exceedance of the ARfD in this commodity; a refined risk assessment value is used for a second tier exposure calculation considering that the consumption of wine grapes by children exclusively refers to juice. PF was derived in section 3.1.1.3 and a yield factor of 0.75 is applied.
(g): Use reported by the RMS is not supported by data and the existing EU MRL is not expected to cover the total residue (see also section 3.1.1.2); the existing EU MRL cannot be used for indicative and conservative exposure calculations.

The calculated exposures were compared with the toxicological reference values derived for folpet (see Table 2-1); detailed results of the calculations are presented as EU scenario 1 in Appendix B.1. The highest chronic exposure was calculated for the French population, representing 22.4 % of the ADI. With regard to the acute exposure, however, an exceedance of the ARfD was identified for wine grape, representing 105.8 % of the ARfD.

A second tier exposure calculation was therefore performed using a refining approach previously proposed by EFSA, in the framework of the MRL application for wine grapes (EFSA, 2012). For the food item "wine grapes", the highest consumption data normalised per body weight was reported for British infants and British adults. Furthermore, it was noted that the consumption of wine grapes by children refers to grape juice while the consumption of wine grapes by adults exclusively refers to wine. Therefore, the processing factors derived in section 3.1.1.3 should be used to refine the input values for wine grapes. Moreover, in the consumption data base, the consumption is expressed as raw wine grapes equivalent but it was highlighted that 1 kg of wine grapes does not exactly produce 1 kg of wine or juice. To take this into account, the consumption data need to be corrected by using a yield factor (0.7 for wine and 0.75 for juice). These considerations allowed EFSA to propose refined input values for wine grapes for British infants and adults which are the worst conservative acute diets for wine grapes (see also footnotes d and e in Table 4.1). According to the results of this second calculation (see Appendix B.2 – EU scenario 2), the highest acute exposure is then calculated for table grapes, representing 93.3 % of the ARfD. As the input values for chronic calculation were not modified, the highest chronic exposure remained unchanged (22.4 % ADI).

Based on the above calculations, EFSA concludes that the risk assessment for bulb vegetables, kohlrabi, lettuce, scarole, spinach and beans (fresh, without pods) could not be finalised. However, the use of folpet on table and wine grapes, and the livestock dietary burden for swine and ruminants (all fully supported by data; see footnotes (a) and (c) in Table 4-1), are acceptable with regard to consumer exposure. For the remaining commodities, major uncertainties remain due to the data gaps identified in section 3, but considering tentative MRLs or existing EU MRLs (for poultry commodities) in the exposure calculation did not indicate a risk to consumers.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of folpet was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI of 0.1 mg/kg bw per d and an ARfD of 0.2 mg/kg bw. Both toxicological reference values were established for folpet. The metabolite phthalimide was demonstrated to be of lower toxicity compared to folpet but data were not sufficient to derive specific reference values for this compound. It was therefore concluded that reference values for folpet can be applied to this metabolite as a worst-case assumption.

Primary crop metabolism of folpet was investigated following foliar application on wheat, potatoes and several fruit and fruiting vegetables (grapes, avocados, tomatoes). Translocation from soil application was also investigated in tomatoes. Metabolic patterns in the different studies were shown to be similar and three crop groups were covered. The relevant residue for enforcement and risk

assessment in all plant commodities was therefore defined as the sum of folpet and phthalimide, expressed as folpet. Although not fully validated in all matrices, analytical methods for enforcement of the proposed residue definition are available.

The available residues trials allowed EFSA to derive MRLs and risk assessment values for all commodities under evaluation, except for bulb vegetables, kohlrabi, lettuce, scarole, spinach and fresh beans without pods. Moreover, considering the data gaps identified for analytical methods, residues trials and storage stability studies, all MRL proposals are considered tentative, except for table and wine grapes.

The hydrolysis studies demonstrate that folpet is completely degraded during processing; phthalimide is formed predominantly under conditions of pasteurisation, while levels of phthalic acid increase under conditions simulating boiling/brewing/baking and sterilisation. Considering that phthalamide was the only compound of toxicological relevance, the relevant residue for enforcement and risk assessment is processed commodities was also defined as the sum of folpet and phthalimide, expressed as folpet. Magnitude of residues in processed commodities was also investigated and robust processing factors could be derived for grapes juice, wine and beer as well as for canned tomatoes, tomato juice and tomato paste.

According to the soil degradation studies evaluated in the framework of the peer review, DT_{90} values of folpet, phthalimide and their relevant soil metabolites (phthalic acid and phthalamic acid) are all below the trigger value of 100 days. Further investigation of residues in rotational crops is therefore not required and relevant residues in rotational crops are not expected.

Based on the uses reported by the RMS, significant exposures are expected for dairy ruminants, meat ruminants, poultry and pigs. Metabolism in lactating ruminants was sufficiently investigated and findings can be extrapolated to pigs as well. The relevant residue definition for enforcement and risk assessment in pigs and ruminants was defined as phthalimide, expressed as folpet. Analytical methods for enforcement of the proposed residue definition are available with an LOQ of 0.05 mg/kg in milk, meat, fat, liver and kidney. No livestock feeding studies were deemed necessary and, based on the available metabolism studies, MRLs and risk assessment values for the relevant commodities in ruminants and pigs can be established at the LOQ level. The nature and the magnitude of folpet residues in poultry commodities were not investigated. Further investigation on the nature and magnitude of residues in poultry commodities should be carried out in order to establish appropriate residue definitions and MRLs in these commodities.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For bulb vegetables, kohlrabi, lettuce, scarole, spinach and beans (fresh without pods), where data were insufficient to derive an MRL, EFSA could not consider the existing EU MRLs as they do not cover the total residue compliant with the proposed residue definition. The risk assessment for these commodities could therefore not be finalised.

In a first tier calculation, an exceedance of the ARfD was identified for wine grape, representing 105.8 % of the ARfD. The highest chronic exposure represented 22.4 % of the ADI (French population). A second tier exposure calculation was therefore performed using a refining approach for the food item "wine grapes". The highest acute exposure was then calculated for table grapes, representing 93.3 % of the ARfD.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for folpet. Additional calculations of the consumer exposure, including these CXLs, should therefore in principle be performed. Nevertheless, since the residue definitions derived by JMPR (folpet alone) and derived at EU level (sum of folpet and phtalimide, expressed as

folpet) are different, and no data on the occurrence phtalimide were evaluated by the JMPR, it is not possible to perform a risk assessment with consideration of the exiting CXLs.

RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, some tentative MRLs or existing EU MRLs need to be confirmed by the following data:

- ILVs for the determination of folpet in dry commodities and in hops as well ILVs for the determination of phtalimide in high water content, dry commodities and hops;
- confirmatory methods for the determination of folpet and phtalimide in high oil content and dry commodities and for the determination of phthalimide in high water content commodities;
- a storage stability study for folpet and phthalimide in high oil content commodities;
- further investigation on the nature and magnitude of residues in poultry;
- additional residues trials, with analysis of both folpet and phthalimide, and supporting the southern authorisations on strawberries, potatoes, tomatoes, melons, wheat (grain and straw).

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

In addition, EFSA identified several crops where data were insufficient to derive tentative MRLs and where the safety of the existing EU MRL could not be demonstrated by EFSA. In order to derive MRLs in these crops, the following data would be required:

- additional residue trials, with analysis of both folpet and phthalimide, and supporting authorisations on bulb vegetables, kohlrabi, lettuce, scarole, spinach and fresh beans without pods.

Meanwhile, Member States are recommended to reconsider or withdraw their national authorisations on onions, garlic, shallots, spring onions, kohlrabi, lettuce, scarole, spinach and beans (fresh without pods).

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the 'Recommended' MRLs or on the national authorisations. The following actions are therefore considered desirable but not essential:

- a detailed evaluation report of the reported analytical method for determination of phthalimide in animal matrices;
- a detailed evaluation report of the storage stability study for phthalimide in high water content, high acid content and dry commodities;

- 1 additional residue trial with analysis of both folpet and phthalimide, and compliant with the southern GAP on table grapes;

- 8 residue trials performed with a lower LOQ (at least 0.10* mg/kg), and compliant with the southern GAP on olives (table olive and olives for oil production).

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition (existing): folpet **Enforcement residue definition (proposed):** sum of folpet and phthalimide, expressed as folpet					
130010	Apples	3	10	-	Further consideration needed [a]
151010	Table grapes	0.02*	10	6	Recommended [b]
151020	Wine grapes	5	10	20	Recommended [b]
152000	Strawberries	3	5	5	Further consideration needed [c]
161030	Table olives	0.02*	-	0.15	Further consideration needed [d]
211000	Potatoes	0.1	0.1	0.1*	Further consideration needed [c]
231080	Radishes	0.02*	-	0.1*	Further consideration needed [d]
213090	Salsify	0.02*	-	0.1*	Further consideration needed [d]
220010	Garlic	0.02*	-	-	Further consideration needed [e]
220020	Onions	0.1	1	-	Further consideration needed [f]
220030	Shallots	0.02*	-	-	Further consideration needed [e]
220040	Spring onions	0.02*	-	-	Further consideration needed [e]
231010	Tomatoes	2	3	5	Further consideration needed [c]
232010	Cucumbers	0.02*	1	-	Further consideration needed [a]
233010	Melons	1	3	0.4	Further consideration needed [c]
244000	Kohlrabi	0.05	-	-	Further consideration needed [e]
251020	Lettuce	2	50	-	Further consideration needed [f]
251030	Scarole	0.02*	-	-	Further consideration needed [e]
252010	Spinach	10	-	-	Further consideration needed [e]
260020	Beans (fresh, without pods)	2	-	-	Further consideration needed [e]
402010	Olives for oil production	0.02*	-	0.15	Further consideration needed [d]
500010	Barley grain	2	-	1	Further consideration needed [d]
500090	Wheat grain	2	-	0.4	Further consideration needed [d]
700000	Hops (dried)	150	-	400	Further consideration needed [d]
-	Other products of plant origin	See App. C1	-	-	Further consideration needed [g]
Enforcement residue definition (proposed): phthalimide, expressed as folpet					
1012010	Bovine meat	-	-	0.05*	Recommended [h]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1012020	Bovine fat	-	-	0.05*	Recommended [h]
1012030	Bovine liver	-	-	0.05*	Recommended [h]
1012040	Bovine kidney	-	-	0.05*	Recommended [h]
1013010	Sheep meat	-	-	0.05*	Recommended [h]
1013020	Sheep fat	-	-	0.05*	Recommended [h]
1013030	Sheep liver	-	-	0.05*	Recommended [h]
1013040	Sheep kidney	-	-	0.05*	Recommended [h]
1014010	Goat meat	-	-	0.05*	Recommended [h]
1014020	Goat fat	-	-	0.05*	Recommended [h]
1014030	Goat liver	-	-	0.05*	Recommended [h]
1014040	Goat kidney	-	-	0.05*	Recommended [h]
1016010	Poultry meat	-	-	0.05*	Further consideration needed [i]
1016020	Poultry fat	-	-	0.05*	Further consideration needed [i]
1016030	Poultry liver	-	-	0.05*	Further consideration needed [i]
1020010	Cattle milk	-	-	0.05*	Recommended [h]
1020020	Sheep milk	-	-	0.05*	Recommended [h]
1020030	Goat milk	-	-	0.05*	Recommended [h]
1030000	Birds' eggs	-	-	0.05*	Further consideration needed [i]
-	Other products of animal origin	-	-	-	Further consideration needed [g]

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): There are no relevant authorisations or import tolerances reported at EU level; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-II in Appendix D).
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; CXL is not compatible with EU residue definitions (combination G-II in Appendix D)
(c): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; CXL is not compatible with EU residue definitions (combination E-II in Appendix D).
(d): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).
(e): GAP evaluated at EU level is not supported by data, the existing EU MRL is not expected to cover the proposed residue definition and no CXL is available; the consumer risk assessment for this crop can therefore not be finalised. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination D-I in Appendix D).
(f): GAP evaluated at EU level is not supported by data, the existing EU MRL is not expected to cover the proposed residue definition and CXL is not compatible with EU residue definitions; the consumer risk assessment for this crop can therefore not be finalised. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination D-I in Appendix D).
(g): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).
(h): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(i): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition and rounded up to the enforcement LOQ of 0.05 mg/kg); no CXL is available (combination C-I in Appendix D).

DOCUMENTATION PROVIDED TO EFSA

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APPENDICES

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Table grapes	*Vitis euvitis*	NEU	Outdoor	DE, AT, RO, LU, HU	Downy mildew (Plasmopara viticola)	WG	800,0	g/kg	Foliar treatment - spraying	14	79		4	7			1,60	kg a.i./ha	56	EFSA Journal 2013;11(9):3384
Wine grapes	*Vitis euvitis*	NEU	Outdoor	DE, LU, HU, CZ, SK, RO	Red fire disease (Pseudopeziza tracheiphila)	WG	800,0	g/kg	Foliar treatment - spraying	14	83		10	7	10	1,50	1,50	kg a.i./ha	28	EFSA Journal 2012; 10(6):2769
Radishes	*Raphanus sativus var. saitvus*	NEU	Outdoor	DE	Downy mildew of crucifers (Peronospora parasitica), White rust of crucifers (Albugo candida)	WG	400,0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2	7	14		0,80	kg a.i./ha	14	
Salsify	*Tragopogon porrifolius*	NEU	Outdoor	DE	White rust of salsify	WG	400,0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2	14	21		0,80	kg a.i./ha	21	
Garlic	*Allium sativum*	NEU	Outdoor	DE	Downy mildew	WG	400,0	g/kg	Foliar treatment - spraying	n.a.	n.a.		3	n.a.	n.a.		0,80	kg a.i./ha	21	
Onions	*Allium cepa*	NEU	Outdoor	DE	Downy mildew	WG	400,0	g/kg	Foliar treatment - spraying	n.a.	n.a.		3	n.a.	n.a.		0,80	kg a.i./ha	21	
Shallots	*Allium ascalonicum (Allium cepa var. aggregatum)*	NEU	Outdoor	DE	Downy mildew	WG	400,0	g/kg	Foliar treatment - spraying	n.a.	n.a.		3	n.a.	n.a.		0,80	kg a.i./ha	21	
Spring onions	*Allium cepa*	NEU	Outdoor	DE	Downy mildew	WG	400,0	g/kg	Foliar treatment - spraying	n.a.	n.a.		3	n.a.	n.a.		0,80	kg a.i./ha	21	
Kohlrabi	*Brassica oleracea convar. acephala, var. gongylodes*	NEU	Outdoor	DE	Downy mildew of crucifers (Peronospora parasitica); White rust of crucifers (Albugo candida)	WG	400,0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2	10	14		0,80	kg a.i./ha	14	
Lettuce	*Lactuca sativa*	NEU	Outdoor	DE	Downy mildew	WG	400,0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2	n.a.	n.a.		0,80	kg a.i./ha	21	
Scarole (broad-leaf endive)	*Cichorium endiva*	NEU	Outdoor	DE	Downy mildew	WG	400,0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2	n.a.	n.a.		0,80	kg a.i./ha	21	
Spinach	*Spinacia oleracea*	NEU	Outdoor	DE	Downy mildew	WG	400,0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2	1	14		0,80	kg a.i./ha	14	
Beans (without pods)	*Phaseolus vulgaris*	NEU	Outdoor	DE	Downy mildew	WG	400,0	g/kg	Foliar treatment - spraying	n.a.	n.a.		3	8	14		0,80	kg a.i./ha	14	
Barley	*Hordeum spp.*	NEU	Outdoor	BE, LU, NL, UK	Rhynchosporium secalis, Puccinia hordei	WG	800,0	g/kg	Foliar treatment - spraying	30	65		2	7	10	0,75	0,75	kg a.i./ha	42	Last application should be defined by growth stage with a min PHI of 42 days
Wheat	*Triticum aestivum*	NEU	Outdoor	BE, LU, NL, UK, FR	Septoria tritici, Septoria nodorum, Puccinia striiformis, Puccinia triticina	WG	800,0	g/kg	Foliar treatment - spraying	30	65		2	7	10	0,75	0,75	kg a.i./ha	42	Last application should be defined by growth stage with a min PHI of 42 days
Hops	*Humulus lupulus*	NEU	Outdoor	DE, CZ	Pseudoperonospora humuli	WG	800,0	g/kg	Foliar treatment - spraying	33	85		5	7	14	1,80	4,00	kg a.i./ha	14	Up to BBCH 37 - 1x 1.8 kg a.i./ha BBCH 38 to 55 - 2x 2.68 kg a.i./ha After BBCH 55 - 2x 4 kg a.i./ha

n.a.: not applicable

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Table grapes	*Vitis euvitis*	SEU	Outdoor	FR, IT, ES, PT, EL	Downy mildew (Plasmopara viticola)	WG	800,0	g/kg	Foliar treatment - spraying	14	79		4	7	10		1,60	kg a.i./ha	56	EFSA Journal 2013;11(9):3384
Wine grapes	*Vitis euvitis*	SEU	Outdoor	EL, ES,FR, IT, PT	Downy mildew (Plasmopara viticola) Rot Brenner (Pseudopeziza tracheiphila) Black rot, Botrytis cinerea phomosis. Dead-arm disease (Cryptosporella viticola)	WG	800,0	g/kg	Foliar treatment - spraying	14	83		10	7	10		1,60	kg a.i./ha	28	EFSA Journal 2011; 9(9):2391
Strawberries	*Fragaria x ananassa*	SEU	Outdoor	IT	Botrytis cinerea, Mycosphaerella fragariae, Colletotrichum fragariae	SC	480,0	g/l	Foliar treatment - spraying	n.a.	n.a.	3	4	7	10		1,60	kg a.i./ha	10	
Table olives	*Olea europaea*	SEU	Outdoor	EL, ES, IT	Spilocaea oleagina	WG	800,0	g/kg	Foliar treatment - spraying	n.a.	75		2	7	10		1,60	kg a.i./ha	120	
Potatoes	*Tuber form Solanum Spp*	SEU	Outdoor	BG, EL, ES, IT, PT	Late blight	WG	800,0	g/kg	Foliar treatment - spraying	n.a.	48		3	7	10		1,25	kg a.i./ha	7	
Garlic	*Allium sativum*	SEU	Outdoor	EL, ES, IT, PT	Peronospora destructor	WG	800,0	g/kg	Foliar treatment - spraying	n.a.	49		2	7	10		1,20	kg a.i./ha	14	EFSA Journal 2011; 9(9):2391
Onions	*Allium cepa*	SEU	Outdoor	EL, ES, IT, PT	Peronospora destructor	WG	800,0	g/kg	Foliar treatment - spraying	n.a.	49		2	7	10		1,20	kg a.i./ha	14	EFSA Journal 2011; 9(9):2391
Tomatoes	*Lycopersicum esculentum*	SEU	Outdoor	IT	Phytophthora infestans, Alternaria solani, Cladisporium fulvum, Septoria lycopersici, Botrytis cinerea	SC	480,0	g/l	Foliar treatment - spraying	n.a.	n.a.		4	7	10		1,20	kg a.i./ha	7	
Melons	*Cucumis melo*	SEU	Outdoor	IT	Pseudoperonospora cubensis, Colletotrichum lagenarium, Botrytis cinerea	SC	480,0	g/l	Foliar treatment - spraying	n.a.	n.a.		2	7	10		0,96	kg a.i./ha	21	
Olives for oil production	*Olea europaea*	SEU	Outdoor	EL, ES, IT	Spilocaea oleagina	WG	800,0	g/kg	Foliar treatment - spraying	n.a.	75		2	7	10		1,60	kg a.i./ha	120	
Wheat	*Triticum aestivum*	SEU	Outdoor	FR	Yellow rust, brown rust, septoria	SC	375,0	g/l	Foliar treatment - spraying	31	59		2	14			0,75	kg a.i./ha	42	

n.a.: not applicable

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Tomatoes	*Lycopersicum esculentum*	NEU/SEU	Indoor	EL, ES, IT, PT	Alternaria solanum, Cladospora, Colletotrichum, Septoria, Botrytis	WG	800,0	g/kg	Foliar treatment - spraying	71	87		3	7	10		1,60	kg a.i./ha	10	EFSA Journal 2011; 9(9):2391

n.a.: not applicable

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Appendix B.1 – EU scenario 1 including all EU MRL proposals resulting from the GAPs reported by the RMS

Appendix B.2 – EU scenario 2 including a refined approach for wine grapes

APPENDIX B.1 – EU SCENARIO 1 INCLUDING ALL EU MRL PROPOSALS RESULTING FROM THE GAPS REPORTED BY THE RMS

Folpet			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0,05	proposed LOQ:	0,05
Toxicological end points			
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**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum
1 22

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)
22,4	FR all population	21,1	Wine grapes	0,4	Wheat	0,3	Tomatoes	0,2
15,2	PT General population	13,1	Wine grapes	0,6	Tomatoes	0,5	Potatoes	0,0
14,2	WHO Cluster diet B	9,4	Wine grapes	2,2	Tomatoes	1,0	Wheat	0,4
10,8	WHO cluster diet E	8,5	Wine grapes	0,5	Wheat	0,4	HOPS (dried),	0,3
8,5	DK adult	7,3	Wine grapes	0,3	Tomatoes	0,3	Milk and cream,	0,3
8,4	IE adult	6,6	Wine grapes	0,3	Strawberries	0,3	Table grapes	0,3
7,1	UK Adult	5,7	Wine grapes	0,5	HOPS (dried),	0,3	Tomatoes	0,2
5,7	UK vegetarian	4,3	Wine grapes	0,4	Tomatoes	0,2	Wheat	0,2
5,2	WHO Cluster diet F	3,1	Wine grapes	0,5	Tomatoes	0,4	Wheat	0,4
5,1	NL general	3,3	Wine grapes	0,3	Milk and cream,	0,3	Tomatoes	0,4
5,0	NL child	1,5	Milk and cream,	0,9	Table grapes	0,6	Potatoes	1,7
4,6	FR toddler	2,0	Milk and cream,	0,8	Strawberries	0,5	Tomatoes	2,2
4,6	WHO cluster diet D	1,9	Wine grapes	0,8	Wheat	0,7	Tomatoes	0,4
4,4	DE child	1,5	Table grapes	0,7	Milk and cream,	0,7	Tomatoes	0,8
3,8	ES adult	2,2	Wine grapes	0,5	Tomatoes	0,3	Wheat	0,4
3,7	WHO regional European diet	1,2	Wine grapes	0,8	Tomatoes	0,4	Potatoes	0,5
3,3	UK Infant	1,9	Milk and cream,	0,3	Potatoes	0,3	Wheat	2,0
3,0	UK Toddler	1,0	Milk and cream,	0,5	Wheat	0,4	Tomatoes	1,1
2,7	FR infant	1,3	Milk and cream,	0,6	Strawberries	0,4	Potatoes	1,4
2,6	ES child	0,7	Tomatoes	0,6	Milk and cream,	0,5	Wheat	0,9
2,6	FI adult	1,6	Wine grapes	0,3	Tomatoes	0,3	Milk and cream,	0,3
2,3	DK child	0,7	Wheat	0,6	Milk and cream,	0,4	Tomatoes	0,7
2,2	SE general population 90th percentile	0,6	Milk and cream,	0,5	Tomatoes	0,4	Potatoes	0,7
2,2	IT kids/toddler	1,0	Tomatoes	0,8	Wheat	0,2	Strawberries	0,0
1,6	IT adult	0,8	Tomatoes	0,5	Wheat	0,2	Table grapes	0,0
1,4	PL general population	0,6	Tomatoes	0,4	Table grapes	0,3	Potatoes	0,0
1,2	LT adult	0,4	Tomatoes	0,3	Potatoes	0,2	Milk and cream,	0,3

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):**		1	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		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)
93,3	Table grapes	2,85 / -	93,3	Table grapes	2,85 / -	105,8	Wine grapes	8,92 / 8,43	105,8	Wine grapes	8,92 / 8,43
81,4	Tomatoes	2,8 / -	59,0	Tomatoes	2,8 / -	45,2	Table grapes	2,85 / -	45,2	Table grapes	2,85 / -
34,7	Wine grapes	8,92 / -	34,7	Wine grapes	8,92 / -	21,3	Tomatoes	2,8 / -	17,6	HOPS (dried),	192 / -
17,2	Strawberries	2,2 / -	17,2	Strawberries	2,2 / -	17,6	HOPS (dried),	192 / -	17,2	Tomatoes	2,8 / -
12,9	Melons	0,17 / -	12,9	Melons	0,17 / -	5,8	Strawberries	2,2 / -	5,8	Strawberries	2,2 / -
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:		1				**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)			
146,7	Grape juice	8,92 / 6,07				17,2	Wine	8,92 / -			
24,4	Tomato juice	2,8 / -				2,7	Tomato (preserved-fresh)	2,8 / -			
2,1	Wine	8,92 / -				1,8	Raisins	8,92 / -			
1,8	Grapes (raisins)	8,92 / -				0,5	Bread/pizza	0,23 / -			
1,4	Wheat flour	0,23 / -				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 Folpet 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.

For processed commodities, the ARfD/ADI was exceeded in one or several cases.

APPENDIX B.2 – EU SCENARIO 2 INCLUDING A REFINED APPROACH FOR WINE GRAPES

Folpet			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0,05	proposed LOQ:	0,05
Toxicological end points			
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**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum
1 22

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)
22,4	FR all population	21,1	Wine grapes	0,4	Wheat	0,3	Tomatoes	0,2
15,2	PT General population	13,1	Wine grapes	0,6	Tomatoes	0,5	Potatoes	0,0
14,2	WHO Cluster diet B	9,4	Wine grapes	2,2	Tomatoes	1,0	Wheat	0,4
10,8	WHO cluster diet E	8,5	Wine grapes	0,5	Wheat	0,4	HOPS (dried),	0,3
8,5	DK adult	7,3	Wine grapes	0,3	Tomatoes	0,3	Milk and cream,	0,3
8,4	IE adult	6,6	Wine grapes	0,3	Strawberries	0,3	Table grapes	0,3
7,1	UK Adult	5,7	Wine grapes	0,5	HOPS (dried),	0,3	Tomatoes	0,2
5,7	UK vegetarian	4,3	Wine grapes	0,4	Tomatoes	0,2	Wheat	0,2
5,2	WHO Cluster diet F	3,1	Wine grapes	0,5	Tomatoes	0,4	Wheat	0,4
5,1	NL general	3,3	Wine grapes	0,3	Milk and cream,	0,3	Tomatoes	0,4
5,0	NL child	1,5	Milk and cream,	0,9	Table grapes	0,6	Potatoes	1,7
4,6	FR toddler	2,0	Milk and cream,	0,8	Strawberries	0,5	Tomatoes	2,2
4,6	WHO cluster diet D	1,9	Wine grapes	0,8	Wheat	0,7	Tomatoes	0,4
4,4	DE child	1,5	Table grapes	0,7	Milk and cream,	0,7	Tomatoes	0,8
3,8	ES adult	2,2	Wine grapes	0,5	Tomatoes	0,3	Wheat	0,4
3,7	WHO regional European diet	1,2	Wine grapes	0,8	Tomatoes	0,4	Potatoes	0,5
3,3	UK Infant	1,9	Milk and cream,	0,3	Potatoes	0,3	Wheat	2,0
3,0	UK Toddler	1,0	Milk and cream,	0,5	Wheat	0,4	Tomatoes	1,1
2,7	FR infant	1,3	Milk and cream,	0,6	Strawberries	0,4	Potatoes	1,4
2,6	ES child	0,7	Tomatoes	0,6	Milk and cream,	0,5	Wheat	0,9
2,6	FI adult	1,6	Wine grapes	0,3	Tomatoes	0,3	Milk and cream,	0,3
2,3	DK child	0,7	Wheat	0,6	Milk and cream,	0,4	Tomatoes	0,7
2,2	SE general population 90th percentile	0,6	Milk and cream,	0,5	Tomatoes	0,4	Potatoes	0,7
2,2	IT kids/toddler	1,0	Tomatoes	0,8	Wheat	0,2	Strawberries	0,0
1,6	IT adult	0,8	Tomatoes	0,5	Wheat	0,2	Table grapes	0,0
1,4	PL general population	0,6	Tomatoes	0,4	Table grapes	0,3	Potatoes	0,0
1,2	LT adult	0,4	Tomatoes	0,3	Potatoes	0,2	Milk and cream,	0,3

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)
93.3	Table grapes	2.85 / -	93.3	Table grapes	2.85 / -	45.2	Table grapes	2.85 / -	45.2	Table grapes	2.85 / -
81.4	Tomatoes	2.8 / -	59.0	Tomatoes	2.8 / -	33.2	Wine grapes	2.8 / -	33.2	Wine grapes	2.8 / -
21.3	Wine grapes	5.47 / -	21.3	Wine grapes	5.47 / -	21.3	Tomatoes	2.8 / -	17.6	HOPS (dried),	192 / -
17.2	Strawberries	2.2 / -	17.2	Strawberries	2.2 / -	17.6	HOPS (dried),	192 / -	17.2	Tomatoes	2.8 / -
12.9	Melons	0.17 / -	12.9	Melons	0.17 / -	5.8	Strawberries	2.2 / -	5.8	Strawberries	2.2 / -
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)			
90.3	Grape juice	5.49 / -				7.7	Wine	4.01 / -			
24.4	Tomato juice	2.8 / -				2.7	Tomato (preserved-fresh)	2.8 / -			
1.8	Grapes (raisins)	8.92 / -				1.8	Raisins	8.92 / -			
1.4	Wheat flour	0.23 / -				0.5	Bread/pizza	0.23 / -			
1.0	Wine	4.01 / -				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 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 LIMITS (MRLS) AND CODEX LIMITS (CXLS)

Appendix C.1 – Existing EU MRLs

Appendix C.2 – Existing CXLs

APPENDIX C.1 – EXISTING EU MRLS

(Pesticides - Web Version - EU MRLs (File created on 17/09/2013 15:30)

Code number	Groups and examples of individual products to which the MRLs apply (a)	folpet
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,02*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,02*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,02*
110030	Lemons (Citron, lemon)	0,02*
110040	Limes	0,02*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,02*
110990	Others	0,02*
120000	(ii) Tree nuts (shelled or unshelled)	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 [a]
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)	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 [a]
153000	(c) Cane fruit	
153010	Blackberries	10 [a]
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,02*
153030	Raspberries (Wineberries)	10 [a]
153990	Others	0,02*
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries cowberries (red bilberries))	0,02*
154020	Cranberries	0,02*
154030	Currants (red, black and white)	15 [a]
154040	Gooseberries (Including hybrids with other ribes species)	15 [a]
154050	Rose hips	0,02*
154060	Mulberries (arbutus berry)	0,02*
154070	Azarole (mediteranean medlar)	0,02*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, 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)	0,02*
161050	Carambola (Bilimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,02*
161990	Others	0,02*
162000	(b) Inedible peel, small	0,02*
162010	Kiwi	0,02*
162020	Lychee (Litchi) (Pulasan,	0,02*
	rambutan (hairy litchi))	
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), and 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) , llama and other medium sized Annonaceae)	0,02*
163070	Guava	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	0,02*
213050	Jerusalem artichokes	0,02*
213060	Parsnips	0,02*
213070	Parsley root	0,02*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,02*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,02*
213100	Swedes	0,02*
213110	Turnips	0,02*
213990	Others	0,02*
220000	(ii) Bulb vegetables	
220010	Garlic	0,1
220020	Onions (Silverskin onions)	0,1
220030	Shallots	0,02*
220040	Spring onions (Welsh onion and similar varieties)	0,02*
220990	Others	0,02*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	3 [a]
231020	Peppers (Chilli peppers)	0,02*
231030	Aubergines (egg plants) (Pepino)	0,02*
231040	Okra, lady's fingers	0,02*
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))	0,02*
232990	Others	0,02*
233000	(c) Cucurbits-inedible peel	1
233010	Melons (Kiwano)	1
233020	Pumpkins (Winter squash)	1
233030	Watermelons	1
233990	Others	1
234000	(d) Sweet corn	0,02*
239000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	0,02*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	folpet
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 (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,02*
243020	Kale (Borecole (curly kale), collards)	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 comsalad)	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, curld leave endive, sugar loaf)	0,02*
251040	Cress	0,02*
251050	Land cress	0,02*
251060	Rocket, Rucola (Wild rocket)	0,02*
251070	Red mustard	0,02*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,02*
251990	Others	0,02*
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	10
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	0,02*
252030	Beet leaves (chard) (Leaves of beetroot)	0,02*
252990	Others	0,02*
253000	(c) Vine leaves (grape leaves)	0,02*
254000	(d) Water cress	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)	0,02*
256040	Parsley	0,02*
256050	Sage (Winter savory, summer savory,)	0,02*
256060	Rosemary	0,02*
256070	Thyme (marjoram, oregano)	0,02*
256080	Basil (Balm leaves, mint, peppermint)	0,02*
256090	Bay leaves (laurel)	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, yardlong beans)	2 (a)
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	2 (a)
260030	Peas (with pods) (Mangetout (sugar 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	0,02*
270030	Celery	0,02*
270040	Fennel	0,02*
270050	Globe artichokes	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 (Common mushroom, Oyster mushroom, Shi-take)	0,02*
280020	Wild (Chanterelle, Truffle, Morel ,)	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	0,02*
401110	Safflower	0,02*
401120	Borage	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	0,02*
500030	Maize	0,02*
500040	Millet (Foxtail millet, teff)	0,02*
500050	Oats	0,02*
500060	Rice	0,02*
500070	Rye	0,02*
500080	Sorghum	0,02*
500090	Wheat (Spelt Triticale)	2
500990	Others	0,02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	0,05*
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine flowers	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	(b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves	0,05*
632030	Maté	0,05*
632990	Others	0,05*
633000	(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) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	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	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	folpet
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) 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	
1011000	(a) Swine	
1011010	Meat	
1011020	Fat free of lean meat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offal	
1011990	Others	
1012000	(b) Bovine	
1012010	Meat	
1012020	Fat	
1012030	Liver	
1012040	Kidney	
1012050	Edible offal	
1012990	Others	
1013000	(c) Sheep	
1013010	Meat	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offal	
1013990	Others	
1014000	(d) Goat	
1014010	Meat	
1014020	Fat	
1014030	Liver	
1014040	Kidney	
1014050	Edible offal	
1014990	Others	
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	
1015020	Fat	
1015030	Liver	
1015040	Kidney	
1015050	Edible offal	
1015990	Others	
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
1016010	Meat	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offal	
1016990	Others	
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	
1017020	Fat	
1017030	Liver	
1017040	Kidney	
1017050	Edible offal	
1017990	Others	
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others	
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	
1030010	Chicken	
1030020	Duck	
1030030	Goose	
1030040	Quail	
1030990	Others	
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

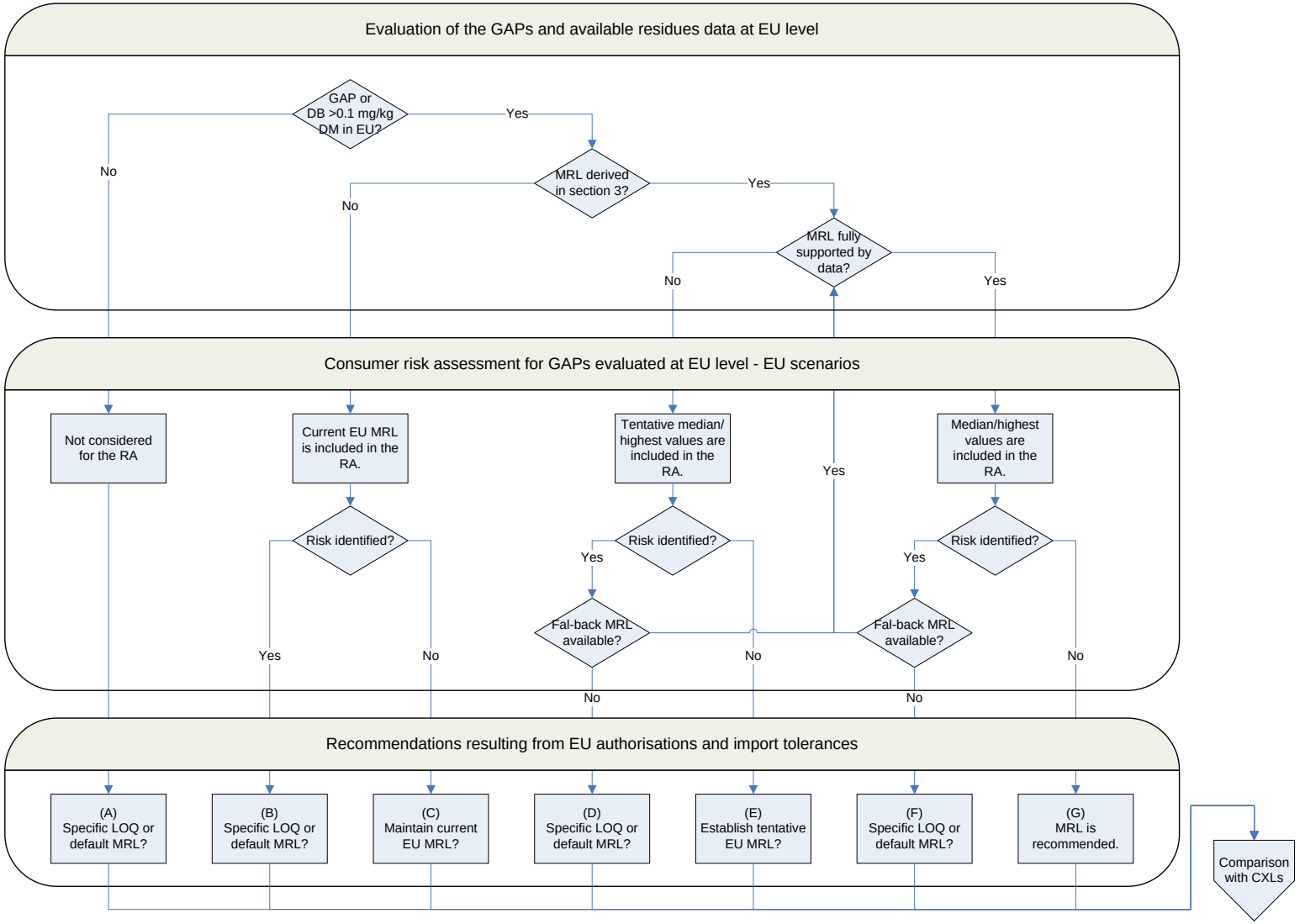
(*) Indicates lower limit of analytical determination
(a): Sum of captan and folpet

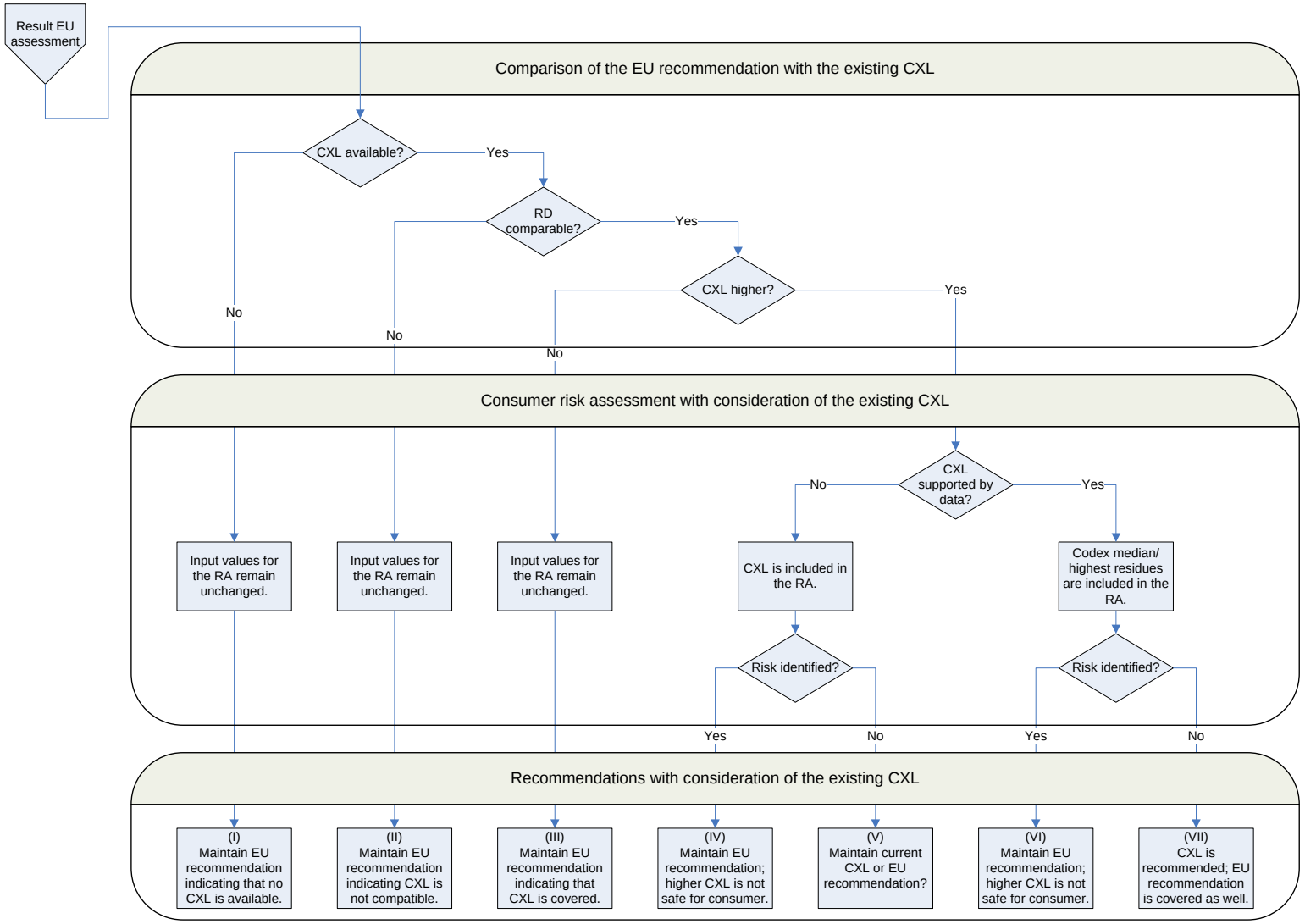
APPENDIX C.2 – EXISTING CXLS

Summary of CXLs for folpet in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
130010	Apples	Folpet	10	Folpet	3.1	8	7	n.c.	3.1	8	n.a.	1	1999	No	Trials were conducted according to GAP in a number of EU and non-EU countries.
151010	Table grapes	Folpet	10	Folpet	2.5	5.9	7	n.c.	2.5	5.9	n.a.	1	1999	No	Trials were conducted according to GAP in a number of EU and non-EU countries.
151020	Wine grapes	Folpet	10	Folpet	2.5	5.9	7	n.c.	2.5	5.9	n.a.	1	1999	No	
152000	Strawberries	Folpet	5	Folpet	1.6	2.2	1	n.c.	1.6	2.2	n.a.	1	1999	No	Trials were conducted in the EU and Mexico according to GAP.
211000	Potatoes	Folpet	0.1	Folpet	0.01	0.08	7	n.c.	0.01	0.1	n.a.	1	1999	No	Trials were conducted according to GAP in a number of EU and non-EU countries.
220020	Onions	Folpet	1	Folpet	0.07	0.41	7	n.c.	0.07	0.41	n.a.	1	1999	No	Trials were conducted according to GAP in a number of EU and non-EU countries.
231010	Tomatoes	Folpet	3	Folpet	0.9	2.4	7	n.c.	0.9	2.4	n.a.	1	1999	No	Trials were conducted according to GAP in a number of EU and non-EU countries.
232010	Cucumbers	Folpet	1	Folpet	0.36	0.7	5	n.c.	0.36	0.7	n.a.	1	1999	No	GAP-compliant trials were conducted in Cyprus and Mexico.
233010	Melons	Folpet	3	Folpet	0.41	2.2	5	n.c.	0.41	2.2	n.k.	1	1999	No	Trials were conducted outside of the EU in accordance with GAP. No data were provided on the peel/pulp distribution, therefore no MPF could be determined
251020	Lettuce	Folpet	50	Folpet	14	39	5	n.c.	14	39	n.a.	1	1999	No	Trials were conducted in the EU and Mexico according to GAP.

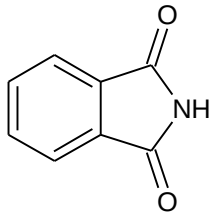
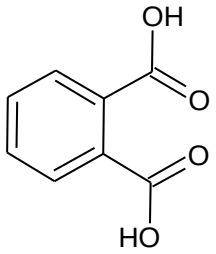
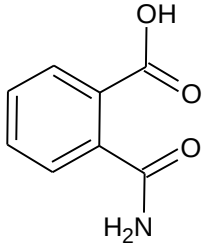
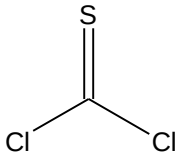
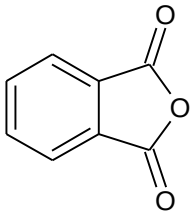
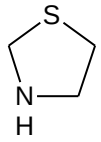
(*) Indicates the lower limit of analytical quantification.
n.a.: not applicable
n.c.: not considered
n.k.: not known

APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL supported by data?
No
Yes
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name*	Structural formula
Phthalimide	1*H*-isoindole-1,3(2*H*)-dione	
Phthalic acid	phthalic acid	
Phthalamic acid	2-carbamoylbenzoic acid	
Thiophosgene	carbonothioyl dichloride	
Phthalic anhydride	2-benzofuran-1,3-dione	
Thiazolidine	1,3-thiazolidine	

* ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DB	dietary burden
DM	dry matter
DT_{90}	period required for 90 percent dissipation (define method of estimation)
EC	European Commission
EFSA	European Food Safety Authority
eq	residue expressed as a.s. equivalent
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC-ECD	gas chromatography with electron capture detector
GC-MS	gas chromatography with mass spectrometry
ha	hectare
ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry

JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PROFile	(EFSA) Pesticide Residue Overview File
PRIMo	(EFSA) Pesticide Residues Intake Model
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
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SEU	Southern European Union
TRR	total radioactive residue
WG	water dispersible granule
WHO	World Health Organization