REASONED OPINION

Modification of the existing MRLs for phosmet in various crops[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, Spain, hereafter referred to as the evaluating Member State (EMS), received an application from the company Gowan Comércio Internacional e Serviços to modify the existing MRLs for the active substance phosmet in potatoes, apricots, peaches, table olives, olives for oil production and rape seed. In order to accommodate for the intended uses of phosmet on these crops in various northern and southern Member States, the EMS proposed to raise the existing MRL in peaches, apricots and olives for oil production and to lower the existing MRL in table olives, rape seed and potatoes. The EMS Spain drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 11 July 2011.

EFSA derives the following conclusions based on the submitted evaluation report prepared by the EMS, the EFSA conclusion on the peer review of phosmet as well as the Draft Assessment Report (DAR) prepared by the rapporteur Member State (RMS) Spain under Directive 91/414/EEC.

The toxicological profile of phosmet was recently reassessed in the framework of the peer review by Member States and EFSA and the submitted data were sufficient to derive an ADI of 0.01 mg/kg bw/day and an ARfD of 0.045 mg/kg bw.

The metabolism of phosmet in cherries, potatoes and maize following the foliar application was evaluated in the framework of the peer review under Directive 91/414/EEC. Except phosmet oxon, other metabolites observed in the metabolism studies were considered to be of no toxicological relevance. Pending the outcome of the study aimed to address the relative potency of phosmet oxon and the parent compound, the peer review experts concluded to include phosmet oxon in the residue definition for the risk assessment and monitoring purposes, considering that it is at least as toxic as parent compound. Thus the enforcement and provisional risk assessment residue definition in all plant commodities was established as "phosmet including phosmet oxon, expressed as phosmet". Phosmet and phosmet oxon in food can be monitored in matrices with high acid-, high fat- and high water content at a validated individual LOQ of 0.01 mg/kg (the combined LOQ is thus 0.02 mg/kg).

The intended uses are sufficiently supported by residue data and would require an MRL of 1 mg/kg in peaches, 3 mg/kg in table olives and olives for oil production and 0.02* mg/kg in oilseed rape. In potatoes the MRL of 0.02 mg/kg (at the LOQ) as derived by the peer review in support of the intended use is proposed. The intended use on apricots is not supported by residue data. It is noted that the

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derived MRLs in rape seed and table olives are lower than the existing EU MRLs. As there might exist more critical uses of phosmet on these crops requiring maintaining the existing MRLs, EFSA did not propose the lowering of MRLs in the framework of the current application.

The effect of processing on the nature of phosmet residues was investigated in hydrolysis studies. Under pasteurisation conditions phosmet is stable; under boiling conditions it partially degrades to phthalimide. Under sterilization conditions phosmet almost fully degrades to various metabolites, none of which was considered of a toxicological relevance by the peer review. Phosmet oxon was not identified. Thus, parent phosmet is the relevant residue in processed commodities.

EFSA notes that phthalimide is included in the risk assessment and enforcement residue definitions of the active substance folpet both for raw and processed commodities. That means that in the processed commodities the residues of phthalimide could occur both from the degradation of phosmet and folpet. EFSA thus proposes to reconsider the residue definitions for folpet and phosmet with regard to a common metabolite phthalimide in the framework of Article 12 of Regulation (EC) No 396/2005.

In the framework of the current application, the applicant submitted studies where the effect of processing on the magnitude of phosmet and phosmet oxon residues was investigated in processing of olives into canned olives and oil. In general, a reduction of phosmet residues was observed in canned olives and in refined oil whereas a concentration of residues was observed in raw oil. EFSA proposes to include the following processing factors in Annex VI of Regulation (EC) No 396/2005:

- Olives, canned olives: 0.15
- Olives, canned sterilized olives: 0.10
- Olives, virgin oil: 2.9
- Olives, refined oil: 0.04

Studies on succeeding/rotational crops are not required due to a fast degradation of phosmet in the soil. From all the crops under consideration, potatoes and oilseed rape and its by-products can be fed to livestock. The contribution of residues in potatoes to livestock exposure was assessed by the peer review. For rape seed a more critical EU MRL is currently in place and therefore it can be concluded that residues from the intended use on oilseed rape will not significantly contribute to the livestock dietary burden and will not result in a need to modify the existing MRLs in commodities of animal origin.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the calculation of the chronic exposure EFSA used the median residue values as derived from the residue trials on peaches; for olives for oil production the median residue value as derived from the residue trials on table olives was used as an input value. For potatoes the risk assessment values as reported in the EFSA conclusion on the peer review were used as input values. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values. The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys containing residues at the highest level as observed in supervised field trials. The estimated exposure was then compared with the toxicological reference values derived for phosmet.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values ranged from 10 to 65% of the ADI (DE child diet). The contribution of residues in the crops under consideration to the total consumer exposure (% of the ADI) accounted for a maximum of 17% for olives for oil production (WHO Cluster diet B), 8%

for table olives (WHO Cluster diet B), 3% for rape seed (WHO Cluster diet E), 2% for peaches (IE adult diet) and 1% for potatoes (NL child diet).

No acute consumer risk was identified regarding phosmet residues in the crops under consideration. The calculated maximum exposure in percentage of the ARfD was 91% for peaches, 75% for table olives, 7% for potatoes, 4% for olives for oil production and 1% for rape seed.

EFSA concludes that the intended use of phosmet on peaches and olives for oil production will not result in a consumer exposure exceeding the toxicological reference values and therefore will not pose a public health concern. No consumer intake concerns have been identified for the existing MRLs for table olives, rape seed and the proposed lower MRL for potatoes.

The recommendations of EFSA are compiled in the table below:

Code number[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Phosmet and phosmet oxon, expressed as phosmet				
140010	Apricots	0.05*	No new proposal	The intended use is not sufficiently supported by data.
140030	Peaches	0.05*	1	The MRL proposal is sufficiently supported by data and no risk for consumers was identified.
161030	Table olives	10	No new proposal	For the intended use a MRL proposal of 3 mg/kg was derived. The lowering of the existing MRL is acceptable provided that there are no other uses authorized which would require maintaining the existing MRL.
211000	Potatoes	0.05*	0.02*	The peer review concluded that the intended use is sufficiently supported and derived an MRL proposal at the LOQ (0.02 mg/kg).
401060	Rape seed	0.5	No new proposal	For the intended use a MRL proposal of 0.02* mg/kg was derived. The lowering of the existing MRL is acceptable provided that there are no other uses authorized which would require maintaining the existing MRL.
402010	Olives for oil production	2	3	The MRL proposal is sufficiently supported by data and no risk for consumers was identified.

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

KEY WORDS

Phosmet, peaches, apricots, table olives, olives for oil production, potatoes, rape seed, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, phosmet oxon, organothiophosphate insecticide and acaricide

TABLE OF CONTENTS

BACKGROUND

Commission Regulation (EC) No 396/2005[3] establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that a party requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC[4], currently replaced by Regulation (EC) No 1107/2009[5], shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

Spain, hereafter referred to as the evaluating Member State (EMS), received an application from the company Gowan Comércio Internacional e Serviços[6] to modify the existing MRLs for the active substance phosmet in potatoes, peaches, apricots, table olives and olive for oil production and oilseed rape. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 11 July 2011. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2011-00887 and the following subject:

Phosmet - Application to modify the existing MRLs in various crops.

The EMS proposed the following MRLs: 1 mg/kg in peaches, apricots, 0.02 mg/kg in oilseed rape, 3 mg/kg in table olives and olives for oil production and 0.02* mg/kg in potatoes.

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

TERMS OF REFERENCE

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

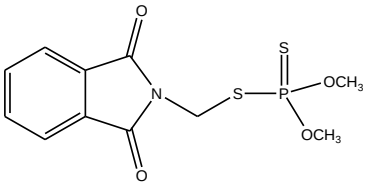
In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests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

In this particular case the calculated deadline for providing the reasoned opinion is 11 October 2011.

[3] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005. OJ L 70, 16.3.2005, p. 1-16.
[4] Council Directive 91/414/EEC of 15 July 1991, OJ L 230, 19.8.1991, p. 1-32.
[5] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009. OJ L 309, 24.11.2009, p. 1-50.
[6] Gowan Comércio Internacional e Serviços, Cueva de Menga 1, blq.5, 1°C, 41020, Sevilla, Spain

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Phosmet is the ISO common name for *O,O*-dimethyl S-phthalimidomethyl phosphorodithioate or *N*-(dimethoxyphosphinothioylthiomethyl)phatalimide (IUPAC). The chemical structure of the compound is herewith reported:



Molecular weight: 317.33 g/mol

Phosmet belongs to organothiophosphate chemical group and is used as an insecticide and an acaricide. Phosmet is non-systemic and works mainly by contact action. It is a cholinesterase inhibitor.

Phosmet is a stage 2 active substance evaluated according to Directive 91/414/EEC with Spain designated as a rapporteur Member State (RMS). EFSA was involved in the peer review of phosmet and therefore an EFSA conclusion is available (EFSA, 2006). Phosmet was included in Annex I of this Directive by Directive 2007/25/EC[7] for use as an insecticide. The evaluated representative uses were foliar application of phosmet on pome fruit, citrus fruit and potatoes.

In March 2010 the European Commission received a request to modify the ADI for phosmet, based on an evaluation of new toxicological data carried out by the United Kingdom following an application from Gowan Comércio Internacional e Serviços. The European Commission invited all Member States and EFSA to provide comments on the new evaluation. Following consideration of the comments received, the European Commission requested EFSA to organize a peer review of the new evaluation and to deliver its conclusions on the new proposed ADI for phosmet. As an outcome of the new evaluation the EFSA conclusion on the review was issued in 2011 and the ADI value for phosmet was amended from 0.003 mg/kg to 0.01 mg/kg (EFSA, 2011).

The existing EU MRLs for phosmet are established in Annex IIIA of Regulation (EC) No 396/2005 (see Appendix C). For the crops under consideration the existing EU MRLs are set at 0.05 mg/kg (at the LOQ) in peaches, apricots, and potatoes, 10 mg/kg in table olives, 0.5 mg/kg in rape seed and 2 mg/kg in olives for oil production. Codex Alimentarius Commission has established CXLs for several commodities, including apricots and peaches for which a CXL of 10 mg/kg is set.

The intended GAPs in various southern and northern European Member States for which a modification of the existing MRLs of phosmet is requested refer to a foliar application of the active substance on potatoes, peaches, apricots, oilseed rape and olives. The details of the GAPs are given in Appendix A.

[7] Commission Directive 2007/25/EC of 23 April 2007, OJ L 106, 24.4.2007, p.34-42.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Spain, 2011), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Spain, 2004), the EFSA conclusion on the peer review of the pesticide risk assessment of the active substance phosmet (EFSA, 2006, 2011) The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products set out in Regulation (EU) No 546/2011[8] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2004, 2008, 2010, 2011; OECD 2011a, 2011b).

1. Methods of analysis

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

Analytical methods for the determination of phosmet residues in plant commodities were assessed in the framework of the peer review of phosmet under Directive 91/414/EEC (Spain, 2004). The peer review concluded that residues of phosmet and phosmet oxon in food can be monitored by HPLC-MS/MS method at a validated individual LOQ of 0.01 mg/kg in matrices with high acid and high water content (EFSA, 2011). The combined LOQ is thus 0.02 mg/kg.

In the framework of the current application, the applicant performed method validation to test the applicability of HPLC-MS/MS method for the determination of phosmet and phosmet oxon residues in the crops under consideration. Validation data demonstrated that method is specific and properly validated for the determination of phosmet and phosmet oxon residues also in matrices with high oil content. The validated individual LOQ is 0.01 mg/kg.

EFSA concludes that sufficiently validated analytical methods are available to monitor all compounds given in the enforcement residue definition for the crops under consideration.

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

Analytical methods for the determination of residues in food of animal origin are not assessed since in the framework of the current application MRLs for phosmet in commodities of animal origin are not proposed.

[8] Commission Regulation (EU) No 546/2011 of 10 June 2011, OJ L 155,11.6.2011, p.127-174

2. Mammalian toxicology

The toxicological profile of the active substance phosmet was reassessed in the framework of the peer review (EFSA, 2011). The derived toxicological reference values for phosmet are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Phosmet					
ADI	EFSA	2011	0.01 mg/kg bw/d	Rat multigeneration, supported by short term rat and dog and long term rat	100
ARfD	EFSA	2011	0.045 mg/kg bw	Rat, acute neurotoxicity study	100

Plant metabolite of phosmet – phosmet oxon[9]- was considered by the peer review as a toxicologically relevant compound. It is likely to be formed in vivo in rat urine as well as in vitro in a rat liver microsomal metabolism system. However, the available studies were not considered scientifically valid and the peer review could not conclude that phosmet oxon had equivalent acetyl-cholinesterase (AChE) inhibitory activity with that of parent phosmet. Consequently, the peer review required the notifier to address the relative potency of the oxon and parent (EFSA, 2011). This data requirement, according to EFSAs current knowledge has so far not been addressed and is still considered as a data gap.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of phosmet in cherries, potatoes and maize following the foliar application was evaluated in the framework of the peer review under Directive 91/414/EEC (Spain, 2004). The overview of the metabolism study designs is presented in the table below.

[9] O,O-dimethyl-S-phthalimidomethyl phosphorothioate(MW 285.19 g/mol):

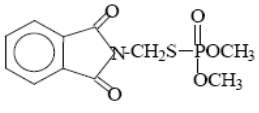


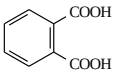
Table 3-1: Summary of available metabolism studies in plants

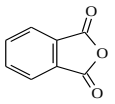
Group	Crop	Label position	Application details				
			Method, F, G or P[(a)]	Rate (kg a.s./ha)	No/ Interval	Sampling (DAT)	Remarks
Fruits and fruiting vegetable	Cherries	Carbonyl position	Foliar; G	0.42 kg a.s./hL	1	0.17, 7 and 14	
Root and tuber vegetables	Potatoes	Carbonyl position	Foliar; F	1) 2 2) 1.9 3) 1.7 4) 1.9	4 (40 days after the first appl. and 20 days between other appl.)	Prior to 2nd and 3rd appl.; 7 days after 3rd appl.; 7 DAT	
Cereals	Maize	In two carbonyl positions	Foliar; F/G	1.12	2 (<BBCH 60) and at 14 d PHI)	28 (forage harvest) and 76 days after 1st , and 14 DAT (harvest)	

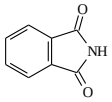
(a): Outdoor/field use (F) or glasshouse/ /indoor application (G) or protected (P)

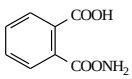
In cherries after application the compound was rapidly translocated to the interior of the fruit where the majority of the metabolism took place. 4 h after treatment 44% of the TRR penetrated the fruit skin; 14 days after the treatment, this percentage increased to 92%. Also in potatoes an uptake in the foliage was observed, however, transport to the tubers was very limited. This finding is supported by the maize study where the major amount of the labelled residues was detected on the forage and only low levels occurred in corn grain and cobs, indicating only a small degree of transport within the plant.

In **cherries**, the major compound on the fruit surface was parent phosmet (6.7% of TRR, 14 DAT). In whole fruits phosmet was extensively metabolised mainly via hydrolysis reactions producing phthalic acid[10] (17-21% of TRR) and conjugates that could be converted to phthalic acid by acid hydrolyis. Phthalic acid accounted for 85-90% of the extractable radioactivity after hydrolysis. In addition, phthalic anhydride[11] (4.7% of TRR), phthalimide[12] (1.5% of TRR), a complex of phthalamic acid[13]

[10] Phthalic acid (benzene-1,2-dicarboxylic acid): 

[11] Phthalic anhydride (2-benzofuran-1,3-dione): 

[12] Phthalimide: 

[13] Phthalamic acid: 

and N-hydroxyphthalamic acid (9.8% of TRR) and several other minor metabolites were detected. Phosmet oxon was present at one-tenth the level of phosmet. The peer review noted that oxidative reactions are only a minor metabolic pathway, whereas hydrolytic reactions were predominant.

In **potato** tubers neither parent compound nor phosmet oxon were identified. Phthalic acid (17-38% TRR) and phthalamic acid (18- 50% TRR) were major metabolites.

Phosmet occurred as a major residue in **maize** fodder (53% TRR) and in the cob (27% TRR), but was not observed in grain. Phthalic acid was a common metabolite in all corn matrices and in grain, accounting for 6-61% of TRR. Phosmet oxon was detected in corn fodder at 1.2% of TRR, but it was not found in other matrices.

The main metabolites observed in metabolism studies were phthalic acid, phthalamic acid and other metabolites without the phosphorodithioate group which are considered to be less toxic than the parent compound. The results of the metabolism studies support the conclusion that phosmet oxon might be present on products of plant origin to a moderate extent (EFSA, 2011). Pending the outcome of the study aimed to address the relative potency of phosmet oxon and the parent compound, the peer review experts concluded to include phosmet oxon in the residue definition for the risk assessment and monitoring purposes, considering that it is at least as toxic as parent compound. Thus the enforcement and provisional risk assessment residue definition in all plant commodities was established as "phosmet including phosmet oxon, expressed as phosmet". The residue definition established in the Regulation (EC) No 396/2005 is identical to the residue definition concluded by the peer review.

For the uses on the crops under consideration, EFSA concludes that the metabolism of phosmet is sufficiently addressed and the residue definitions agreed in the peer review are applicable.

3.1.1.2. Magnitude of residues

a. Peaches, apricots

The applicant submitted in total 8 GAP compliant residue trials on peaches, which were performed in various southern European countries (Spain, Italy, Greece and France) in 2006-2007. Samples were analysed for phosmet and phosmet oxon. In all residue trial samples phosmet oxon was below the LOQ of 0.01 mg/kg. The applicant proposes to extrapolate the residue data to apricots. Peaches and apricots according to the EU guidance document are major crops in SEU and therefore at least 8 residue trials on each crop have to be provided to derive MRL proposals; to support the extrapolation of residue data from peaches to apricots, at least 4 residue trials on apricots are required (EC, 2011). EFSA is of the opinion that data are insufficient to support the intended use on apricots. The intended use on peaches is sufficiently supported by residue data.

b. Oilseed rape

The applicant submitted 4 GAP compliant residue trials on oilseed rape supporting NEU use and 4 GAP compliant residue trials supporting SEU use. Trials have been performed in northern France and Germany and in southern France, Spain and Italy in 2006-2007. In all residue trial samples the residues both of phosmet and phosmet oxon were below the LOQ of 0.01 mg/kg. Oilseed rape is a major crop in northern part of Europe and therefore at least 8 GAP compliant residue trials on oilseed rape would have to be submitted according to the EU guidance document (EC, 2011). According to the same guidance document, oilseed rape is still (until April 2013) a minor crop in SEU and therefore the southern use is sufficiently supported by data. EFSA is of the opinion that residue trials provide sufficient evidence that the application of phosmet on oilseed rape before flowering will not result in

quantifiable residues and therefore the additional 4 trials required to support NEU use is considered as a minor data gap.

c. Table olives, olives for oil production

The applicant submitted in total 8 GAP compliant residue trials on olives. Trials have been performed in Spain, Italy and Greece in 2006-2007. Table olives are a minor crop in SEU requiring 4 trials to be submitted to derive an MRL proposal, whereas olives for oil production are major crop in SEU according to EU guidance document and at least 8 residue trials are required to derive MRL proposal (EC, 2011). The applicant proposes to extrapolate the residue data from table olives to olives for oil production. According to the above mentioned EU guidance document such an extrapolation is acceptable. Thus the submitted residue data are sufficient to support the intended use of phosmet on olives. According to the EMS, the highest observed residue value (3.73 mg/kg) was considered as an outlier and was therefore disregarded.

d. Potatoes

The SEU GAP reported in the framework of the current application is identical to the SEU GAP evaluated in the framework of the peer review (EFSA, 2011). In compliance with the conclusions of the peer review, the applicant now proposes to set an MRL in potatoes at the LOQ of 0.02 mg/kg. In the framework of the peer review in total 3 overdosed residue trials on potatoes have been submitted for the SEU use. Residues of phosmet were below the limit of quantification (<0.01 mg/kg) and no residues of phosmet oxon were detected (<0.0005 mg/kg). In addition, 7 US trials with exaggerated dose rates have been reported with no measurable residues of phosmet and phosmet oxon detected. These findings were confirmed by four additional trials on potatoes in Germany and northern France, two of them with samples taken according to the GAP, two with a PHI of 14 days. The peer review concluded that the use of phosmet in potatoes is supported by residue data and derived an MRL proposal of <0.02 mg/kg (EFSA, 2011). Although at least 8 GAP compliant residues on potatoes have to be submitted to derive an MRL proposal according to EU guidance documents (EC, 2011), due to no residues identified at exaggerated dose rates, EFSA agrees with the conclusions of the peer review experts to propose an MRL of 0.02 mg/kg (at the LOQ) in potatoes.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarized in Table 3-2.

The storage stability of phosmet in primary crops was investigated in the DAR according to Directive 91/414/EEC (Spain, 2004). The storage stability studies indicated that residues of phosmet and phosmet oxon are stable in matrices with high water-, high acid-, high oil content commodities and in dry commodities for 12- 24 months when stored deep frozen. As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability. According to the EMS, the analytical methods used to analyse supervised residue trial samples have been sufficiently validated and were proven to be fit for purpose (Spain, 2011).

The intended uses on peaches, olives and rape seed are sufficiently supported by residue data and would require an MRL of 1 mg/kg, 3 mg/kg and 0.02* mg/kg, respectively. The intended use on apricots is not supported by residue data. In potatoes the MRL proposal of 0.02 mg/kg (at the LOQ) as derived by the peer review is supported. It is noted that the derived MRLs in rape seed and table olives are lower than the existing EU MRLs. As there might exist more critical uses of phosmet on these crops in Europe requiring maintaining the existing MRLs, EFSA did not propose the lowering of MRLs in the framework of the current application.

Table 3-2: Overview of the available residues trials data

Commodity	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 (phosmet and phosmet oxon, expressed as phosmet)	**Risk assessment** (phosmet and phosmet oxon, expressed as phosmet)					
Peaches	SEU	Outdoor	0.08; 0.15; 0.16; 0.26; 0.38; 0.49; 0.55; 0.69	0.08; 0.15; 0.16; 0.26; 0.38; 0.49; 0.55; 0.69	**0.32**	**0.69**	**1**	**1**	R_{ber}=1.07 R_{max}=1.04 OECD MRL[e] =1.5 Unrounded OECD MRL=1.22
Oilseed rape	NEU	Outdoor	4 x <0.02	4 x <0.02	<0.02	<0.02	0.02*	1	Additional 4 GAP compliant residue trials would be recommended (EC, 2011)
	SEU	Outdoor	4 x <0.02	4 x <0.02	**<0.02**	**<0.02**	**0.02***	**1**	The existing MRL for rape seed is higher (0.5 mg/kg).
Table olives → Olives for oil production	SEU	Outdoor	0.38; 0.58; 0.69; 0.87; 1.01; 1.22; 1.55	0.38; 0.58; 0.69; 0.87; 1.01; 1.22; 1.55	**0.87**	**1.55**	**3**	**1**	R_{ber}=2.44 R_{max}=2.26 OECD MRL[e] =3 The existing MRL in table olives is higher (10 mg/kg).
Potatoes	South	Outdoor	See EFSA conclusion on the peer review of phosmet (EFSA, 2011).						

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.
(e) : The MRL calculated using the OECD MRL calculator (OECD, 2011b)
(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of phosmet residues was investigated in studies performed at three test conditions representing pasteurization, baking/brewing/boiling and sterilization (20 minutes at 90°C, pH 4; 60 minutes at 100°C pH 5; 20 minutes at 120°C, pH 6). The studies were submitted and evaluated in the framework of the peer review (Spain, 2004).

Under hydrolytic conditions phosmet degraded to several compounds to a different extent. Under pasteurisation conditions phosmet was stable (75-84%), but under boiling conditions phosmet (42%) partially degraded to phthalimide (30%). Under sterilization conditions, a significant degradation was observed, as phosmet accounted for only 2%, but the rest of the applied radioactivity consisted mainly from phthalimide (23%), phthalic acid (16%), N-hydroxymethyl phthalamic acid together with phthalamic acid (70%). The peer review considered all identified metabolites of no toxicological relevance (EFSA, 2011). In none of the hydrolysis studies phosmet oxon was identified. Thus, parent phosmet is the relevant residue in processed commodities.

EFSA notes that phthalimide is included in the risk assessment and enforcement residue definitions for the active substance folpet as a relevant degradation product under processing conditions (EFSA, 2009). It means that in processed commodities the residues of phthalimide could occur both from the degradation of phosmet and folpet. EFSA thus proposes to reconsider the residue definitions for folpet and phosmet with regard to a common metabolite phthalimide in the framework of Article 12 of Regulation (EC) No 396/2005.

In the framework of the current application, the applicant submitted studies where the effect of processing on the magnitude of phosmet residues was investigated in the processing of olives into canned olives and oil. One balance and three follow-up studies were performed in Spain and Greece in 2008/2009. Olives were treated according to the intended GAP and samples prior and after the processing were analyzed for phosmet and its metabolite phosmet oxon. In a balance study, samples of canned olives and canned sterilized olives were taken at the day of processing, 10 and 90 days after the processing. In canned olives residues decreased from 0.12 mg/kg (0 day) to 0.09 mg/kg (90 days after processing); in canned sterilized olives residues decreased from 0.07 mg/kg to 0.06 mg/kg. In the follow-up studies samples of canned olives were taken 90 days after canning. Phosmet residues in raw olives were within a range of 0.69 to 1.87 mg/kg.

In general, a reduction of phosmet residues was observed in canned olives and in refined oil. Higher residues in raw and virgin olive oil is resulting from the concentration of oil and corresponds to the fat content in raw olives (35-58%). After decantation and filtration olive oil contains very low residue levels. Residues of phosmet oxon in all samples were below either the LOQ (0.01 mg/kg) or the LOD (0.001 mg/kg). The derived processing factors are compiled in a table below.

Table 3-3: Overview of the available processing studies

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Enforcement residue definition: Phosmet and phosmet oxon, expressed as phosmet				
Olives, canned olives	4	0.15	1	Residues of phosmet oxon in all samples were below LOQ of 0.01 mg/kg or below LOD of 0.001 mg/kg.
Olives, canned sterilized olives	4	0.1	1	
Olives, raw oil	3	2.7	1	
Olives, virgin olive oil	4	2.9	1	

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Olives, refined oil	4	0.04	1	

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

EFSA proposes to include the derived processing factors (except for raw oil) in Annex VI of Regulation (EC) No 396/2005.

3.1.2. Rotational crops

Studies on succeeding and/or rotational crops are not required due to the fast degradation of phosmet in soil (max DT_{90f} of 65 days) (EFSA, 2011).

3.2. Nature and magnitude of residues in livestock

From all the crops under consideration, potatoes and oilseed rape (and its by-products) can be fed to livestock. The contribution of residues in potatoes (at the LOQ of 0.02 mg/kg) to livestock exposure was already assessed by the peer review (EFSA, 2011). For rape seed a more critical EU MRL (0.5 mg/kg) is currently in place and therefore it can be concluded that residues from the intended use on oilseed rape (at the LOQ of 0.02 mg/kg) will not contribute significantly to the livestock dietary burden and will not result in a need to modify the existing MRLs in commodities of animal origin.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population[14] (EFSA, 2007).

For the calculation of the chronic exposure, EFSA used the median residue values as derived from the residue trials on peaches; for olives for oil production the median residue value as derived from the residue trials on table olives was used as an input value (see Table 3-2). For potatoes the risk assessment values as reported in the EFSA conclusion on the peer review were used as input values (EFSA, 2011). For oilseed rape and table olives the existing EU MRLs were used as input values. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values. The model assumptions for the long-term exposure assessment are considered to be rather conservative, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment, does not exceed the toxicological reference value for long-term exposure (i.e. the ADI), a consumer health risk can be excluded with a high probability.

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

The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys containing residues at the highest level as observed in supervised field trials.

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

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

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Phosmet and phosmet oxon, expressed as phosmet				
Peaches	0.32	Median residue (Table 3-2)	0.69	Highest residue (Table 3-2)
Olives for oil production	0.87	Median residue (table olives) (Table 3-2)	1.55	Median residue (table olives) (Table 3-2)
Rape seed	0.5	MRL	0.5	MRL
Table olives	10	MRL	10	MRL
Potatoes	0.02	Median residue (EFSA, 2011)	0.02	Highest residue (EFSA, 2011)
Other commodities of food and animal origin	MRL	See Appendix C	Acute risk assessment was undertaken only with regard to the crops under consideration.	

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

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values ranged from 10 to 65% of the ADI (DE child diet). The contribution of residues in the crops under consideration to the total consumer exposure (% of the ADI) accounted for a maximum of 17% for olives for oil production (WHO Cluster diet B), 8% for table olives (WHO Cluster diet B), 3% for rape seed (WHO Cluster diet E), 2% for peaches (IE adult diet) and 1% for potatoes (NL child diet).

No acute consumer risk was identified regarding phosmet residues in the crops under consideration. The calculated maximum exposure in percentage of the ARfD was 91% for peaches[15], 75% for table olives, 7% for potatoes, 4% for olives for oil production and 1% for rape seed.

EFSA concludes that the intended use of phosmet on peaches and olives for oil production will not result in a consumer exposure exceeding the toxicological reference values and therefore will not pose a public health concern. No consumer intake concerns have been identified for the existing MRLs for table olives, rape seed and the proposed lower MRL for potatoes.

[15] EFSA notes that acute consumer intake concerns cannot be excluded when the proposed MRL of 1 mg/kg for peaches is used as an input value in the consumer exposure calculation (131.8%).

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of phosmet was recently reassessed in the framework of the peer review by Member States and EFSA and the submitted data were sufficient to derive an ADI of 0.01 mg/kg bw/day and an ARfD of 0.045 mg/kg bw.

The metabolism of phosmet in cherries, potatoes and maize following the foliar application was evaluated in the framework of the peer review under Directive 91/414/EEC. Except phosmet oxon, other metabolites observed in the metabolism studies were considered to be of no toxicological relevance. Pending the outcome of the study aimed to address the relative potency of phosmet oxon and the parent compound, the peer review experts concluded to include phosmet oxon in the residue definition for the risk assessment and monitoring purposes, considering that it is at least as toxic as parent compound. Thus the enforcement and provisional risk assessment residue definition in all plant commodities was established as "phosmet including phosmet oxon, expressed as phosmet". Phosmet and phosmet oxon in food can be monitored in matrices with high acid-, high fat- and high water content at a validated individual LOQ of 0.01 mg/kg (the combined LOQ is thus 0.02 mg/kg).

The intended uses are sufficiently supported by residue data and would require an MRL of 1 mg/kg in peaches, 3 mg/kg in table olives and olives for oil production and 0.02* mg/kg in oilseed rape. In potatoes the MRL of 0.02 mg/kg (at the LOQ) as derived by the peer review in support of the intended use is proposed. The intended use on apricots is not supported by residue data. It is noted that the derived MRLs in rape seed and table olives are lower than the existing EU MRLs. As there might exist more critical uses of phosmet on these crops requiring maintaining the existing MRLs, EFSA did not propose the lowering of MRLs in the framework of the current application.

The effect of processing on the nature of phosmet residues was investigated in hydrolysis studies. Under pasteurisation conditions phosmet is stable; under boiling conditions it partially degrades to phthalimide. Under sterilization conditions phosmet almost fully degrades to various metabolites, none of which was considered of a toxicological relevance by the peer review. Phosmet oxon was not identified. Thus, parent phosmet is the relevant residue in processed commodities.

EFSA notes that phthalimide is included in the risk assessment and enforcement residue definitions of the active substance folpet both for raw and processed commodities. That means that in processed commodities the residues of phthalimide could occur both from the degradation of phosmet and folpet. EFSA thus proposes to reconsider the residue definitions for folpet and phosmet with regard to a common metabolite phthalimide in the framework of Article 12 of Regulation (EC) No 396/2005.

In the framework of the current application, the applicant submitted studies where the effect of processing on the magnitude of phosmet and phosmet oxon residues was investigated in the processing of olives into canned olives and oil. In general, a reduction of phosmet residues was observed in canned olives and in refined oil whereas a concentration of residues was observed in raw oil. EFSA proposes to include the following processing factors in Annex VI of Regulation (EC) No 396/2005:

- Olives, canned olives: 0.15
- Olives, canned sterilized olives: 0.10
- Olives, virgin oil: 2.9
- Olives, refined oil: 0.04

Studies on succeeding/rotational crops are not required due to a fast degradation of phosmet in the soil. From all the crops under consideration, potatoes and oilseed rape and its by-products can be fed to livestock. The contribution of residues in potatoes to livestock exposure was assessed by the peer review. For rape seed a more critical EU MRL is currently in place and therefore it can be concluded that residues from the intended use on oilseed rape will not significantly contribute to the livestock dietary burden and will not result in a need to modify the existing MRLs in commodities of animal origin.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the calculation of the chronic exposure EFSA used the median residue values as derived from the residue trials on peaches; for olives for oil production the median residue value as derived from the residue trials on table olives was used as an input value. For potatoes the risk assessment values as reported in the EFSA conclusion on the peer review were used as input values. For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values. The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys containing residues at the highest level as observed in supervised field trials. The estimated exposure was then compared with the toxicological reference values derived for phosmet.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values ranged from 10 to 65% of the ADI (DE child diet). The contribution of residues in the crops under consideration to the total consumer exposure (% of the ADI) accounted for a maximum of 17% for olives for oil production (WHO Cluster diet B), 8% for table olives (WHO Cluster diet B), 3% for rape seed (WHO Cluster diet E), 2% for peaches (IE adult diet) and 1% for potatoes (NL child diet).

No acute consumer risk was identified regarding phosmet residues in the crops under consideration. The calculated maximum exposure in percentage of the ARfD was 91% for peaches, 75% for table olives, 7% for potatoes, 4% for olives for oil production and 1% for rape seed.

EFSA concludes that the intended use of phosmet on peaches and olives for oil production will not result in a consumer exposure exceeding the toxicological reference values and therefore will not pose a public health concern. No consumer intake concerns have been identified for the existing MRLs for table olives, rape seed and the proposed lower MRL for potatoes.

RECOMMENDATIONS

Code number[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Phosmet and phosmet oxon, expressed as phosmet				
140010	Apricots	0.05*	No new proposal	The intended use is not sufficiently supported by data.
140030	Peaches	0.05*	1	The MRL proposal is sufficiently supported by data and no risk for consumers was identified.
161030	Table olives	10	No new proposal	For the intended use a MRL proposal of 3 mg/kg was derived. The lowering of the existing MRL is acceptable provided that there are no other uses authorized which would require maintaining the existing MRL.

Code number[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
211000	Potatoes	0.05*	0.02*	The peer review concluded that the intended use is sufficiently supported and derived an MRL proposal at the LOQ (0.02 mg/kg).
401060	Rape seed	0.5	No new proposal	For the intended use a MRL proposal of 0.02* mg/kg was derived. The lowering of the existing MRL is acceptable provided that there are no other uses authorized which would require maintaining the existing MRL.
402010	Olives for oil production	2	3	The MRL proposal is sufficiently supported by data and no risk for consumers was identified.

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

REFERENCES

EC (European Commission), 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95 rev.4. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm.

EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev.4. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 2004. Residue analytical methods. For post-registration control. SANCO/825/00-rev.7. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 2008. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.8. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 2010. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, finalized in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010.

EC (European Commission), 2011. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.9. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EFSA (European Food Safety Authority), 2006. Conclusion on the peer review of the pesticide risk assessment of the active substance phosmet. EFSA Scientific Report (2006) 75, 1-72 pp.

EFSA (European Food Safety Authority), 2007. Pesticide Residues Intake Model for assessment of acute and chronic consumer exposure to pesticide residues-rev.2. Available from http://www.efsa.europa.eu/en/mrls/mrlteam.htm

EFSA (European Food Safety Authority), 2009. Conclusion on the peer review of the pesticide risk assessment of the active substance folpet. EFSA Scientific Report (2009) 297, 1-80 pp.

EFSA (European Food Safety Authority), 2011. Conclusion on the peer review of the pesticide risk assessment of the active substance phosmet. EFSA Journal 2011; 9(5):2162, 70 pp.

Spain, 2011. Evaluation report on the setting/modification of MRLs for phosmet in peach, apricot, olive, potato and oil seed rape prepared by the evaluating Member State Spain under Article 8 of Regulation (EC) No 396/2005, June 2011, 80 pp.

Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., Federal Biological Research Centre of Agriculture and Forest. Braunschweig, Germany. Available from: http://www.jki.bund.de/fileadmin/dam_uploads/_veroeff/bbch/BBCH-Skala_englisch.pdf

OECD (Organization for Economic Co-operation and Development), 2011a. OECD MRL Calculator: User Guide. Series of pesticides No. 56, ENV/JM/MONO(2011)2, 1 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available from: http://www.oecd.org/env/pesticides

OECD (Organization for Economic Co-operation and Development), 2011b. OECD MRL Calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available from: http://www.oecd.org/env/pesticides

Spain, 2004. Draft assessment report on the active substance phosmet prepared by the rapporteur Member State Spain in the framework of Council Directive 91/414/EEC, May, 2004.

Appendix A. GOOD AGRICULTURAL PRACTICES (GAPS)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Potatoes	SEU	F	Biting and sucking insects	WP	500 g/kg	Spraying	nr	1	nr	0.1	500	0.5	7	
Peaches and apricot	SEU	F	Biting and sucking insects	WP	500 g/kg	Spraying	nr	2	10	0.075	1000	0.75	14	
Oilseed rapes	NEU/SEU	F	Biting and sucking insects	WP	500 g/kg	Spraying	59	1	nr	0.25	200	0.5	nr*	*The waiting period is covered by the application conditions and/or the vegetation period remaining between application and harvest, the setting of a waiting period is not required.
Table Olives	SEU	F	Biting and sucking insects	WP	500 g/kg	Spraying	nr	2	10	0.035	2000	0.75	14	

Remarks:
(a) For crops, EU or other classifications, e.g.Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (Growth stages of mono-and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions (i.e. feeding, grazing)

Appendix B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

				Phosmet					Prepare workbook for refined calculations	
				Status of the active substance:	**Included**	Code no.				
				LOQ (mg/kg bw):		proposed LOQ:				
				Toxicological end points					Undo refined calculations	
				ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.045**			
				Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**			
				Year of evaluation:	**2011**	Year of evaluation:	**2011**			
				Chronic risk assessment - refined calculations						
				TMDI (range) in % of ADI minimum - maximum						
					10	64				
				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)	
	64.5	DE child	24.1	Apples	7.6	Oranges	7.1	Milk and cream,		
	60.3	NL child	14.7	Milk and cream,	12.7	Apples	6.2	Oranges		
	57.9	WHO Cluster diet B	16.7	Olives for oil production	8.0	Table olives	4.3	Wheat		
	45.9	IE adult	6.1	Table olives	2.7	Figs	2.3	Currants (red, black and white)		
	43.9	FR toddler	19.8	Milk and cream,	5.2	Apples	4.0	Oranges		
	40.6	UK Infant	19.4	Milk and cream,	5.0	Sugar beet (root)	3.1	Apples		
	40.2	UK Toddler	11.4	Sugar beet (root)	10.3	Milk and cream,	4.0	Oranges		
	38.3	ES child	6.4	Olives for oil production	6.3	Milk and cream,	4.4	Table olives		
	29.5	FR infant	12.9	Milk and cream,	5.0	Apples	1.8	Oranges		
	28.6	WHO regional European diet	4.7	Table olives	2.4	Milk and cream,	1.7	Other miscellaneous fruit (edible		
	28.1	SE general population 90th percentile	6.2	Milk and cream,	5.0	Table olives	2.1	Apples		
	27.5	WHO cluster diet E	3.0	Rape seed	2.0	Wheat	1.7	Apples		
	27.3	DK child	6.3	Milk and cream,	4.6	Apples	2.8	Wheat		
	24.2	ES adult	3.7	Olives for oil production	3.4	Table olives	2.6	Oranges		
	24.1	PT General population	5.5	Table olives	3.3	Figs	2.2	Olives for oil production		
	22.8	WHO Cluster diet F	2.0	Milk and cream,	1.8	Wheat	1.7	Oranges		
	20.2	WHO cluster diet D	3.3	Wheat	2.5	Milk and cream,	1.3	Apples		
	18.9	NL general	3.3	Milk and cream,	3.0	Oranges	2.4	Apples		
	17.1	FI adult	2.9	Blueberries	2.8	Milk and cream,	1.9	Oranges		
	15.8	IT kids/toddler	3.3	Wheat	1.8	Apples	1.3	Table olives		
	15.8	FR all population	2.0	Wine grapes	1.7	Olives for oil production	1.6	Wheat		
	13.0	IT adult	2.1	Wheat	1.8	Table olives	1.6	Apples		
	12.9	UK vegetarian	1.9	Sugar beet (root)	1.7	Oranges	1.6	Milk and cream,		
	12.0	LT adult	3.7	Apples	2.0	Milk and cream,	1.1	Swine		
	11.4	DK adult	2.7	Milk and cream,	1.6	Apples	1.0	Wheat		
	10.8	UK Adult	2.0	Sugar beet (root)	1.5	Milk and cream,	1.1	Oranges		
	10.4	PL general population	4.1	Apples	1.0	Plums	0.9	Cherries		
	Conclusion:									
	The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.									
	A long-term intake of residues of Phosmet 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)
	91.0	Peaches	0.69 / -	74.9	Table olives	10 / -	29.6	Table olives	10 / -	29.6	Table olives	10 / -
	74.9	Table olives	10 / -	66.7	Peaches	0.69 / -	26.8	Peaches	0.69 / -	20.8	Peaches	0.69 / -
	6.8	Potatoes	0.02 / -	4.9	Potatoes	0.02 / -	2.7	Olives for oil	1.55 / -	2.7	Olives for oil production	1.55 / -
	4.4	Olives for oil	1.55 / -	4.4	Olives for oil	1.55 / -	1.3	Potatoes	0.02 / -	1.0	Potatoes	0.02 / -
	1.2	Rape seed	0.5 / -	1.2	Rape seed	0.5 / -						
	No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:**		---				**No of commodities for which ARfD/ADI is exceeded:**		---			
			*****)**						*****)**			
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
	*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.											
	**) pTMRL: provisional temporary MRL											
	***) pTMRL: provisional temporary MRL for unprocessed commodity											
	Conclusion:											
	For Phosmet 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)

(Pesticides - Web Version - EU MRLs (File created on 19/01/2012 15:55))

Code number	Groups and examples of individual products to which the MRLs apply (a)	Phosmet (phosmet and phosmet oxon expressed as phosmet) (R)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,2
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)	0,2
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,2
110030	Lemons (Citron, lemon)	0,2
110040	Limes	0,2
110050	Mandarins (Clementine, tangerine, mineola and other hybrids)	0,2
110990	Others	0,2
120000	(ii) Tree nuts (shelled or unshelled)	
120010	Almonds	2
120020	Brazil nuts	0,05*
120030	Cashew nuts	0,05*
120040	Chestnuts	2
120050	Coconuts	0,05*
120060	Hazelnuts (Filbert)	0,1
120070	Macadamia	0,05*
120080	Pecans	0,05*
120090	Pine nuts	0,05*
120100	Pistachios	2
120110	Walnuts	2
120990	Others	0,05*
130000	(iii) Pome fruit	0,2
130010	Apples (Crab apple)	0,2
130020	Pears (Oriental pear)	0,2
130030	Quinces	0,2
130040	Medlar	0,2
130050	Loquat	0,2
130990	Others	0,2
140000	(iv) Stone fruit	
140010	Apricots	0,05*
140020	Cherries (sweet cherries, sour cherries)	1
140030	Peaches (Nectarines and similar hybrids)	0,05*
140040	Plums (Damson, greengage, mirabelle, sloe)	0,6
140990	Others	0,05*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	0,05*
151010	Table grapes	0,05*
151020	Wine grapes	0,05*
152000	(b) Strawberries	0,05*
153000	(c) Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, boysenberries, and cloudberries)	0,05*
153030	Raspberries (Wineberries, arctic bramble/raspberry, (Rubus arcticus), nectar raspberries (Rubus arcticus x idaeus))	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries)	10
154020	Cranberries (Cowberries (red bilberries))	10
154030	Currants (red, black and white)	2
154040	Gooseberries (Including hybrids with other ribes species)	0,05*
154050	Rose hips	2
154060	Mulberries (arbutus berry)	2
154070	Azarole (mediteranean medlar) (Kiwiberry (Actinidia arguta))	2
154080	Elderberries (Black chokeberry (appleberry), mountain ash, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	2
154990	Others	2
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	
161010	Dates	0,05*
161020	Figs	2
161030	Table olives	10
161040	Kumquats (Marumi kumquats, nagami kumquats, limequats (Citrus aurantifolia x Fortunella spp.))	2
161050	Carambola (Bilimbi)	2
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry Surinam cherry (grumichama Eugenia uniflora),)	2
161990	Others	2
162000	(b) Inedible peel, small	
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi), mangosteen)	2
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	2
162050	Star apple	2
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	2
162990	Others	2
163000	(c) Inedible peel, large	
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,05*
163040	Papaya	2
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	2
163070	Guava (Red pitaya or dragon fruit (Hylocereus undatus))	2
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	0,05*
210000	(i) Root and tuber vegetables	0,05*
211000	(a) Potatoes	0,05*
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	0,05*
213010	Beetroot	0,05*
213020	Carrots	0,05*
213030	Celeriac	0,05*
213040	Horseradish (Angelica roots, lovage roots, gentiana roots,)	0,05*
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,05*
213070	Parsley root	0,05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties, tiger nut (Cyperus esculentus))	0,05*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,05*
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	0,05*
220010	Garlic	0,05*
220020	Onions (Silverskin onions)	0,05*
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	0,05*
220990	Others	0,05*
230000	(iii) Fruiting vegetables	0,05*
231000	(a) Solanacea	0,05*
231010	Tomatoes (Cherry tomatoes, tree tomato, Physalis, gojiberry, wolfberry (Lycium barbarum and L. chinense))	0,05*
231020	Peppers (Chilli peppers)	0,05*
231030	Aubergines (egg plants) (Pepino)	0,05*
231040	Okra, lady's fingers	0,05*
231990	Others	0,05*
232000	(b) Cucurbits - edible peel	0,05*
232010	Cucumbers	0,05*
232020	Gherkins	0,05*
232030	Courgettes (Summer squash, marrow (patisson))	0,05*
232990	Others	0,05*
233000	(c) Cucurbits-inedible peel	0,05*
233010	Melons (Kiwano)	0,05*
233020	Pumpkins (Winter squash)	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	0,05*
241000	(a) Flowering brassica	0,05*
241010	Broccoli (Calabrese, Chinese broccoli, broccoli raab)	0,05*

241020	Cauliflower	0,05*
241990	Others	0,05*
242000	(b) Head brassica	0,05*
242010	Brussels sprouts	0,05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), choi sum, peking cabbage (pe-tsai),)	0,05*
243020	Kale (Borecole (curly kale), collards, Portuguese Kale, Portuguese cabbage, cow cabbage)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	0,05*
251000	(a) Lettuce and other salad plants including Brassicacea	0,05*
251010	Lamb´s lettuce (Italian cornsalad)	0,05*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,05*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,05*
251040	Cress	0,05*
251050	Land cress	0,05*
251060	Rocket, Rucola (Wild rocket)	0,05*
251070	Red mustard	0,05*
251080	Leaves and sprouts of Brassica spp (Mizuna, leaves of peas and radish and other babyleaf brassica crops (crops harvested up to 8 true leaf stage))	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, amaranthus spinach)	0,05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth, Agretti (Salsola soda))	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	0,05*
256010	Chervil	0,05*
256020	Chives	0,05*
256030	Celery leaves (Fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea leaves)	0,05*
256040	Parsley	0,05*
256050	Sage (Winter savory, summer savory,)	0,05*
256060	Rosemary	0,05*
256070	Thyme (Marjoram, oregano)	0,05*
256080	Basil (Balm leaves, mint, peppermint)	0,05*
256090	Bay leaves (laurel)	0,05*
256100	Tarragon (Hyssop)	0,05*
256990	Others (Edible flowers)	0,05*
260000	(vi) Legume vegetables (fresh)	0,05*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout (sugar peas, snow peas))	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	0,05*
270010	Asparagus	0,05*
270020	Cardoons	0,05*
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes	0,05*
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel, Cep)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,5
401070	Soya bean	0,05*
401080	Mustard seed	0,05*
401090	Cotton seed	0,05*
401100	Pumpkin seeds (Other seeds of cucurbitacea)	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	
402010	Olives for oil production	2
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	
500010	Barley	0,05*
500020	Buckwheat (Amaranthus, quinoa)	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0,05*
500060	Rice	0,05*
500070	Rye	0,05*
500080	Sorghum	0,2
500090	Wheat (Spelt, triticale)	0,05*
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers (Elderflowers (Sambucus nigra))	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves (Ginkgo leaves)	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,1*
800000	8. SPICES	0,1*
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*

830000	(iii) Bark	0,1*
830010	Cinnamon (Cassia)	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*
840040	Horseradish	0,1*
840990	Others	0,1*
850000	(v) Buds	0,1*
850010	Cloves	0,1*
850020	Capers	0,1*
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*
860990	Others	0,1*
870000	(vii) Aril	0,1*
870010	Mace	0,1*
870990	Others	0,1*
900000	9. SUGAR PLANTS	0,05*
900010	Sugar beet (root)	0,05*
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,1
1011000	(a) Swine	0,1
1011010	Meat	0,1
1011020	Fat free of lean meat	0,1
1011030	Liver	0,1
1011040	Kidney	0,1
1011050	Edible offal	0,1
1011990	Others	0,1
1012000	(b) Bovine	0,1
1012010	Meat	0,1
1012020	Fat	0,1
1012030	Liver	0,1
1012040	Kidney	0,1
1012050	Edible offal	0,1
1012990	Others	0,1
1013000	(c) Sheep	0,1
1013010	Meat	0,1
1013020	Fat	0,1
1013030	Liver	0,1
1013040	Kidney	0,1
1013050	Edible offal	0,1
1013990	Others	0,1
1014000	(d) Goat	0,1
1014010	Meat	0,1
1014020	Fat	0,1
1014030	Liver	0,1
1014040	Kidney	0,1
1014050	Edible offal	0,1
1014990	Others	0,1
1015000	(e) Horses, asses, mules or hinnies	0,1
1015010	Meat	0,1
1015020	Fat	0,1
1015030	Liver	0,1
1015040	Kidney	0,1
1015050	Edible offal	0,1
1015990	Others	0,1
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,1
1016010	Meat	0,1
1016020	Fat	0,1
1016030	Liver	0,1
1016040	Kidney	0,1
1016050	Edible offal	0,1
1016990	Others	0,1
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,1
1017010	Meat	0,1
1017020	Fat	0,1
1017030	Liver	0,1
1017040	Kidney	0,1
1017050	Edible offal	0,1
1017990	Others	0,1
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,05*
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,05*
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	0,05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05*
1060000	(vi) Snails	0,05*
1070000	(vii) Other terrestrial animal products	0,05*
(R) The residue definition differs for the following combinations pesticide-code number: for code 1000000: Phosmet		
(*) Indicates lower limit of analytical determination		

ABBREVIATIONS

ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
ca.	circa, approximately
CAC	Codex Alimentarius Commission
CEN	European Committee for Standardization (Comité Européen de Normalisation, *French*)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DE	Germany
DM	dry matter
DT_{90f}	period required for 90% dissipation (field method)
EFSA	European Food Safety Authority
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EU	European Union
GAP	good agricultural practice
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
IE	Ireland
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram

L	litre
LC	liquid chromatography
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
MRL	maximum residue limit
MS	Member States
MS/MS	tandem mass spectrometry
NEU	northern European Union
NL	The Netherlands
NOAEL	no observed adverse effect level
OECD	Organization for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
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
RD	residue definition
RMS	rapporteur Member State
SEU	Southern European Union
TRR	total radioactive residue
WHO	World Health Organisation
wk	week
WP	wettable powder
yr	year