European Food Safety Authority

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CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance phosmet[1]

European Food Safety Authority[2]

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SUMMARY

Phosmet is one of the 52 substances of the second stage of the review programme covered by Commission Regulation (EC) No 451/2000[3], as amended by Commission Regulation (EC) No 1490/2002[4]. This Regulation requires the European Food Safety Authority (EFSA) to organise a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the European Commission.

Spain being the designated rapporteur Member State submitted the DAR on phosmet in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 23 August 2004. Following a quality check on the DAR, the peer review was initiated on 03 September 2004 by dispatching the DAR for consultation of the Member States and the sole applicant Margarita Internacional. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed in an evaluation meeting on 18 May 2005. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in September 2005.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 6 April 2006 leading to the conclusions set out in the EFSA Conclusion finalised on 12 May 2006 (EFSA Scientific Report (2006) 75).

Phosmet was included in Annex I of Directive 91/414 by Commission Directive 2007/25/EC of 23 April, 2007[5]. The entry into force of the Annex I inclusion was 1 October 2007.

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. In compliance with the Guidance Document SANCO 10328/2006 rev.6, 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 organise a peer review of the new evaluation and to deliver its conclusions on the new proposed ADI for phosmet.

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[1] On request from the European Commission, Question No EFSA-Q-2011-00139, issued on 11 May 2011.

[2] Correspondence: pesticides.peerreview@efsa.europa.eu

[3] OJ No L 53, 29.02.2000, p. 25

[4] OJ No L 224, 21.08.2002, p. 25

[5] OJ No L 106, 24.02.2007, p.41

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The conclusion was reached on the basis of the evaluation of the representative uses as an acaracide and insecticide as proposed by the applicant which comprises tractor-mounted spraying and airblast assisted sprayers in orchards. Application is made to citrus fruit at a rate of 0.5 kg phosmet per hectare, pome fruit at 0.3 kg phosmet per hectare and potatoes at 0.5 kg phosmet per hectare.

The representative formulated product for the evaluation was Imidan 50 WP a wettable powder (WP) registered under different trade names in Europe. The representative uses assessed were located in southern Europe only as stated in the application for annex 1 listing. No conclusion on the equivalence of the two sources could be made as some mammalian toxicology data were missing.

In the main adequate methods are available to monitor all compounds given in the respective residue definition. The residue definition for water can not be finalised due to outstanding ecotoxicology data. The method for body fluids and tissues is currently only validated for phosmet and as the oxon is in the residue definition further validation data will be required. Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues. Limited analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible. There are some outstanding issues related to the relevant impurities.

The toxicological risk assessment is based on the assumption that the studies have been performed with a test material that covers the current technical specification.

The absorption is rapid and almost complete, there is no accumulation in tissues and the excretion is mainly via urine. Phosmet is toxic by oral administration and the proposed classification is T, R25. It is non-irritant to skin and eyes and does not cause sensitisation by skin contact.

The critical effect after repeated exposure is depression of the plasma, erythrocyte and brain acetylcholinesterase activities. The most sensitive species is the dog. Phosmet is an *in vitro* but not *in vivo* genotoxic agent. Increased incidence of liver tumours is observed in mice at the highest dose level (14 mg/kg bw/day), higher than controls but within the same range as historical control data. In a two-generation study with rats, the fertility parameters and the offspring are not directly affected. Phosmet shows no evidence of teratogenicity in rat or rabbits, and no potential to induce delayed neurotoxicity. The Acceptable Daily Intake (ADI) is 0.01 mg/kg bw/day, based on a NOAEL of 1 mg/kg bw/day from the rat multigeneration study, supported by short-term studies in dogs and rats and a long-term study in rats. The Acute Reference Dose (ARfD) is 0.045 mg/kg bw and the Acceptable Operator Exposure Level (AOEL) 0.02 mg/kg bw/day.

For the use on potatoes and pomes, exposure estimates according to the German model are below the AOEL for operators wearing personal protective equipment and respiratory protective equipment. In spite of these high protection measures, the operator exposure is above the AOEL during application on citrus fruits. Estimates of worker and bystander exposure are below the AOEL for all the supported uses.

Plant metabolism studies with ^{14}C-phosmet in cherries, potatoes and corn are available covering the representative uses. A common metabolic pathway is proposed. Phosmet is able to penetrate through the plant surface where the main metabolic reactions take place. Within the plant tissues only a limited transport is observed. The primary metabolic reactions are hydrolysis and conjugation reactions which produce phthalic acid and a range of related compounds, none of them containing the phosphorodithioate group. Oxidation reaction leading to the oxygen analogue phosmet oxon is a minor metabolic reaction. Considering the fact that oxygen analogue compounds are of high toxicity and the fact that no specific information on the toxicological significance of this compound is available, it was concluded to include phosmet oxon in the residue definition for risk assessment and monitoring purposes. However, pending on the outcome of the study aimed to address the relative potency of phosmet oxon in comparison with the parent compound, it might be necessary to reconsider the residue definitions.

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Supervised residue trials in oranges, apples and potatoes have been submitted, which allow the proposal of the following MRLs: oranges and pome fruit: 0.2 mg/kg, respectively, potatoes: 0.02* mg/kg. No MRLs are proposed for other citrus fruit as the available trials in oranges are not suitable for extrapolation to the whole crop group.

The effects of processing on the nature and the level of residues were investigated. Under conditions simulating pasteurisation, baking/brewing/boiling and sterilisation, phosmet degraded to less toxic compounds or compounds that occurred also in animal metabolism studies. The transfer factors to apple juice, apple pure and canned apples were very low, with residues essentially left in the pomace and peel fractions.

Studies on succeeding or rotational crops are not required due to the fast degradation of phosmet in soil.

Livestock can be exposed to residues of phosmet through consumption of fruit pomace and potatoes. Metabolism studies in lactating goat and laying hens demonstrated that phosmet will not occur in animal tissues, milk and eggs when livestock is fed with feed produced according to GAP for the supported use.

The consumer risk assessment was carried out taking into account chronic and acute exposures according to the provisional residue definition (sum of phosmet and phosmet oxon, expressed as phosmet). The calculations indicate that the exposure will be below the ADI and the ARfD, respectively.

In aerobic laboratory soil degradation studies (20°C, 21-50% soil maximum water holding capacity) phosmet exhibited low persistence and did not form any major (>10%AR) extractable non volatile soil metabolites. The major sink for the radiolabels used in the experiments was mineralisation to CO_2 (53-77%applied radioactivity (AR) at 120-150 days). Residue not extracted by acetone / acidified acetone accounted for 17-38%AR at 150 days. In field dissipation studies carried out in the USA phosmet also exhibited low persistence. Under laboratory (23°C) anaerobic soil conditions the major (14.5%AR) metabolite N-hydroxymethyl phthalamic acid was identified.

Based in the results of laboratory batch adsorption studies phosmet exhibited low mobility being considered immobile in one of the four soils tested. In a BBA guideline lysimeter study carried out in Switzerland that covers the applied for representative uses if applications are made in July, there was no leaching of radioactivity (excluding CO_2) in collected leachate samples >0.06 µg/L, confirming the results of FOCUS scenario groundwater modelling for parent phosmet and indicating leaching of the soil metabolites that are formed at low levels is unlikely to be significant. All this information indicates, that for the applied for intended uses, the potential for groundwater exposure above the parametric drinking water limit of 0.1µg/L is negligible.

In laboratory (20°C) natural sediment water systems phosmet both dissipated rapidly by partitioning to sediment and degraded rapidly, resulting in it exhibiting very low persistence. The major (>10%AR) metabolites identified were: phthalamic acid phthalic acid and N-hydroxymethyl phthalimide. Based on the available sterile hydrolysis studies and laboratory aqueous photolysis study O,O-dimethylphosphorodithioc acid and O,O-dimethylphosphoric acid may also be formed as major metabolites in natural surface waters. In sediment the only major component of the residue in addition to phosmet was phthalamic acid. All these identified breakdown products were themselves relatively labile. CO_2 from the carbonyl radiolabel used in the natural sediment water studies was the major sink for the applied radioactivity (accounting for 80-92%AR at 100 days). FOCUS step 2 to 4 surface water assessments have been completed for parent phosmet (with step 4 just considering spray drift mitigation) but only southern European scenarios and then only early season application timings were simulated. As the applied for representative southern European uses assessed are not restricted to applications only being made–later in the growing season, if phosmet is included in annex 1, then southern member states where later season uses are applied for, should carry out national assessments of the potential for surface water exposure and associated aquatic risk assessments from the drainage

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and runoff routes of entry to surface water, as it is not clear that the available EU level assessment covers these situations. Also the current assessment identifies that for the early season application southern European scenarios assessed, only 1 scenario for each crop (D6 potatoes, R4 citrus and pome fruit), represented a low risk to aquatic organisms without mitigation to reduce runoff input to surface water being considered. For all other geoclimatic situations assessed high risk was identified when only the spray drift risk was mitigated.

A high acute risk to insectivorous birds was identified for all evaluated uses and also for herbivorous birds in potatoes. The initially identified high long-term risk to birds for all evaluated uses was reassessed based on measured residues in insects and grass. The refined long-term TER values for birds are above the Annex VI trigger. For a generic herbivorous mammal a potential high long-term risk was identified for all uses. The refined assessment based on selected focal mammalian species needs to be further justified.

Phosmet is very toxic to aquatic organisms. Since data on acute toxicity to seven fish species are available the safety factor was lowered from 100 to 20. Risk mitigation measures to reduce spray drift input corresponding to 40 m in orchards and 20 m in potatoes are needed in order to meet this trigger for one FOCUS scenario in each crop. Based on data from an available mesocosm study, the same buffer zones will also be sufficient to protect aquatic invertebrates in southern Europe in case of early application for one FOCUS scenario in each crop. The risk assessment for the aquatic environment needs to be complemented with scenarios for later in the season, when drainage and runoff routes of entry are likely to contribute to the concentration in surface water from the assessed uses in southern Europe.

Phosmet is very toxic to bees. The high risk needs to be managed at Member State level. Application should be avoided when there are likely to be any bees in the crop and a withholding period needs to be established. The risk to non-target arthropods is high. A potential for in-field recolonisation has been demonstrated, however further data is required to address the impact off-field and the potential for recolonisation from off-field areas.

The risk to earthworms, other non-target soil macro-organisms, soil micro-organisms, non-target plants and biological methods of sewage treatment is considered to be low.

KEY WORDS

Phosmet, peer review, risk assessment, pesticide, insecticide, acaricide.

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BACKGROUND

Commission Regulation (EC) No 451/2000[6] laying down the detailed rules for the implementation of the second and third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC, as amended by Commission Regulation (EC) No 1490/2002[7], regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Phosmet is one of the 52 substances of the second stage covered by the amended Regulation (EC) No 451/2000 designating Spain as rapporteur Member State.

In accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, Spain submitted the report of its initial evaluation of the dossier on phosmet, hereafter referred to as the draft assessment report, to the EFSA on 23 August 2004. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report (Spain, 2004). In accordance with Article 8(5) of the amended Regulation (EC) No 451/2000 the revised version of the draft assessment report was distributed for consultation on 03 September 2004 to the Member States and the main applicant Margarita Internacional as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives from Member States identified and agreed in an evaluation meeting on 18 May 2005 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level. A representative of the notifier attended this meeting.

Taking into account the information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in expert meetings organised on behalf of the EFSA by the EPCO-Team of the Pesticide Safety Directorate (PSD) in York, United Kingdom in September 2005. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 6 April 2006 leading to the conclusions set out in the EFSA Conclusion finalised on 12 May 2006 (EFSA Scientific Report (2006) 75) (EFSA, 2006).

Phosmet was included in Annex I of Directive 91/414 by Commission Directive 2007/25/EC of 23 April, 2007[8]. The entry into force of the Annex I inclusion was 1 October 2007.

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 (United Kingdom, 2010). In compliance with the Guidance Document SANCO 10328/2006 rev.6 (European Commission, 2006), 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 decided to further consult the EFSA. By written request, received by the EFSA on 11 February 2011, the European Commission requested the EFSA to organise a peer review of the new evaluation and to deliver its conclusions on the new proposed ADI for phosmet.

The new evaluation and proposed ADI for phosmet provided by the United Kingdom was discussed at the PRAPeR 86 Experts' Meeting on mammalian toxicology. Details of the issues discussed, together with the outcome of these discussions were recorded in the meeting report.

[6] OJ No L 53, 29.02.2000, p. 25
[7] OJ No L 224, 21.08.2002, p. 25
[8] OJ No L 106, 24.02.2007, p.41

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A final consultation on the conclusion arising from the peer review of the new evaluation and proposed ADI for phosmet took place with Member States via a written procedure in April 2011.

The conclusion was reached on the basis of the evaluation of the representative uses as an acaracide and insecticide as proposed by the applicant, which comprises tractor-mounted spraying and airblast assisted sprayers in orchards. Application is made to citrus fruit at a rate of 0.5 kg phosmet per hectare, pome fruit at 0.3 kg phosmet per hectare and potatoes at 0.5 kg phosmet per hectare. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A.

The documentation developed during the peer review, including the re-consideration of the ADI, was compiled as a **peer review report** (EFSA, 2011) comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received
- the resulting reporting table (rev. 1-1 of 7 June 2005)
- the consultation report

as well as the documents summarising the follow-up of the issues identified as not finalised at the end of the commenting period:

- the reports of the scientific expert consultation (including the re-consideration of the ADI)
- the evaluation table (rev. 2-1 of 8 May 2006)

Given the importance of the draft assessment report including its addendum (compiled version of April 2011 containing all individually submitted addenda, together with the new evaluation and proposed ADI) (Spain/United Kingdom, 2011) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

By the time of the presentation of this conclusion to the European Commission, the rapporteur Member State has made available amended parts of the draft assessment report (Vol.1, 2, 3 of July 2005) which take into account mostly editorial changes. Since these revised documents still contain confidential information, the documents cannot be made publicly available. However, the information given can basically be found in the original draft assessment report together with the peer review report which both is publicly available.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Phosmet is the ISO common name for O,O-dimethyl-S-phthalimidomethyl phosphorodithioate (IUPAC) or N-(dimethoxyphosphinothioylthiomethyl)phthalimide (IUPAC).

Phosmet belongs to the class of organothiophosphate insecticides and acaricides such as diazinon and malathion. Phosmet is non-systemic and works mainly by contact action, it is a cholinesterase inhibitor.

The representative formulated product for the evaluation was Imidan 50 WP, a wettable powder (WP), registered under different trade names in Europe.

The evaluated representative uses as an acaricide and insecticide as proposed by the applicant which comprises tractor-mounted spraying devices and airblast assisted sprayers in orchards. Application is made to citrus fruit at a rate of 0.5 kg phosmet per hectare, pome fruit at 0.3 kg phosmet per hectare

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and potatoes at 0.5 kg phosmet per hectare. The intended uses assessed were located in southern Europe only as stated in the application for Annex 1 listing.

CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The minimum purity of phosmet as manufactured should not be less than 950 g/kg. There is currently no FAO specification available for phosmet. Currently the batch data do not support the current specification as it was agreed by EFSA and Member States that 3 impurities should not be in the specification namely, impurities 1.2.2.6, 1.2.2.7 and 1.2.2.22. If a revised specification is submitted deleting these impurities then the specification would be acceptable.

Only one source of phosmet is being considered however all the toxicology data are based on another source. According to the equivalence assessment of the different technical materials, the rapporteur Member State concluded that they can not be regarded as analytically equivalent. Mammalian toxicology and Ecotoxicology in a Tier II assessment were also unable to conclude on the equivalence of the two technical materials. The content of phosmet in the representative formulation is 50 % w/w (pure).

The assessment of the data package revealed no critical areas of concern with respect to the identity, physical, chemical and technical properties of phosmet or the respective formulation.

Methods of analysis for the relevant impurities in the formulation, shelf life data and storage stability data for the relevant impurities have been evaluated by the rapporteur and are available as an addendum. However, it should be noted that they have not been considered at an expert meeting and have not been peer reviewed.

The main data regarding the identity of phosmet and its physical and chemical properties are given in Appendix A.

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of phosmet in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material. The only gap in the data is acceptance of the methods for the relevant impurities in the formulation.

Therefore, some data are available to ensure that quality control measurements of the plant protection product are possible.

Residues of phosmet and phosmet oxon in food are determined by HPLC-MS/MS with a limit of determination of 0.01 mg/kg. For products of animal origin a method is neither supplied or required as MRLs will not be set (See 3.4).

Methods of analysis are available for soil, water and air with validation data being provided for appropriate LOQs. These methods are GC-FPD for soil and water and GC-NPD for air. However, it should be noted that no conclusion can be made on the method for water as the residue definition has not been finalised due to outstanding ecotoxicology concerns. As phosmet is classified as toxic methods are available for body fluids and tissues. However as this method is only validated for phosmet and does not include analysis of the oxon further data are required.

The discussion in the meeting of experts EPCO 35 19/09/05 on identity, physical and chemical properties and analytical methods was limited to the specification of the technical material and the missing data on the relevant impurities.

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2. Mammalian toxicity

Phosmet was discussed at EPCO experts' meeting for mammalian toxicology (EPCO 33) in September 2005, and at the PRAPeR 86 Experts' Meeting for mammalian toxicology in March 2011.

The toxicological equivalence of the current technical material has not been fully demonstrated according to the Guidance Document on the Assessment of the Equivalence of Technical Materials of Substances Regulated under Council Directive 91/414/EEC (SANCO/1059/2003). Acute and subacute oral studies show similar results, but the whole acute toxicity profile has not been assessed. Further clarification (available information, structure-activity relationship assessment, …) would be helpful to have a full picture of the toxicological equivalence (see 2.8.).

2.1. Absorption, Distribution, Excretion and Metabolism (Toxicokinetics)

The absorption is rapid and almost complete within 24h (84%), based on urinary excretion, cage wash and tissue radioactivity. The maximum concentration in plasma is attained at 0.5 h, with high affinity to red blood cells, followed by a biphasic decline. Small amounts of radioactivity are detected in tissues and therefore, accumulation is not assumed. The excretion is mainly via urine (70 to 80% at 24 hr) and to a lesser extent via faeces (5-10% at 24 hr).

The proposed metabolic pathway is thiophosphoryl hydrolysis, S-methylation, oxidation of the sulfur to sulfoxide and then to sulfone, and hydrolysis of the phthalamide ring to the respective phthalamide acid. Two metabolites are identified in urine: N-(methylsulfinylmethyl)-phthalamic acid (PaAMS(O)M) (U3) and the corresponding sulfoxide N-(methylsulfonylmethyl)-phthalamic acid (PaAMS(O2)M) (U6).

2.2. Acute toxicity

Phosmet is toxic by oral administration (LD_{50} 113 mg/kg bw) and **the proposed classification is T, R25 'Toxic if swallowed'.** Similar results were obtained with the new technical material from [redacted] (LD_{50} 230 mg/kg bw/day). It is not toxic during acute dermal exposure in rats (LD_{50} > 1000 mg/kg bw), as well as in rabbits (LD_{50} > 5000 mg/kg bw). The LC_{50} by inhalation is greater than 0.152 mg/L, which is the maximum concentration attainable. Consequently, the experts agreed not to classify for dermal toxicity or toxicity by inhalation.

Phosmet is non-irritant to skin and eyes and does not cause sensitisation by skin contact. While there were limitations in the modified Buehler test, this was considered acceptable by the experts, and supported by the absence of reports of sensitization in humans.

EFSA notes: for information, in the 29th ATP published in 2004, the ECB has adopted the classification **Xn; R21/22 "Harmful in contact with skin and if swallowed"**.

2.3. Short-term toxicity

In studies with rats, mice and dogs, the critical effect is depression of plasma, erythrocyte and brain acetylcholinesterase (AChE) activity. The most sensitive species appears to be the dog. Thus, the proposed overall NOAEL is 1.88 mg/kg bw/day from the 90-day study with dogs, based on a decrease in erythrocyte and brain AChE activity at 14 mg/kg bw/day.

From dermal studies in rats and rabbits, the relevant dermal NOAEL agreed by the experts is 22.5 mg/kg bw/day, based on the inhibition of the brain AChE activity in the rat study.

2.4. Genotoxicity

The genotoxicity of phosmet has been investigated in a battery of in vitro and in vivo assays, including gene mutation, chromosomal aberration, and DNA damage as endpoints.

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With respect to gene mutation, phosmet is positive in bacterial (TA100 and TA97 ±S9) systems, and in the cultured mammalian cells (-S9).

In a chromosome aberration study in vitro with mouse lymphoma cells, negative results are obtained. On the other hand, phosmet is not genotoxic for somatic cells in mouse bone marrow micronucleus test in vivo.

In relation with DNA damage in vitro, negative results are obtained in tests with Bacillus subtilis and diploid human fibroblast cells; but a clear positive response is observed in the sister chromatid exchange assay in mouse lymphoma cells. However, this result is not confirmed in vivo where negative results are obtained in UDS and DNA alkylation assays.

In conclusion, based on the available data, the experts agreed that phosmet has a genotoxic potential in vitro but not in vivo.

2.5. Long-term toxicity

The effects observed during oral administration of phosmet to rats and mice for 2 years are reductions of AChE activity and body weight.

The 2-year rat study shows high mortality in all groups, but the experts concluded that it was adequate for the assessment of carcinogenicity. Based on the dose-related erythrocyte AChE inhibition at 1.8 mg/kg bw/day, the agreed NOAEL is 1.1 mg/kg bw/day.

In the 2-year mouse study, the liver is the target organ. Degenerative changes are observed as well as increased incidence of liver tumours. In the DAR, the proposed NOAEL is 4 mg/kg bw/day, based on brain and plasma AChE inhibition and hepatocellular cytoplasmic vacuolar degeneration observed at 14 mg/kg bw/day. The EPCO 33 Experts' Meeting originally considered that a NOAEL could not be established since the brain AChE activity was decreased in the low dose group at 12 months, and therefore the agreed LOAEL was 1 mg/kg bw/day. However, during the re-discussion at the PRAPeR 86 Experts' Meeting in March 2011, it was agreed that the brain cholinesterase inhibition at the low and mid doses, only observed at the interim kill, not dose-related and not associated to convulsions, was not an adverse effect. Therefore the agreed NOAEL is 4 mg/kg bw/day based on an increased incidence of convulsions in males, brain cholinesterase inhibition in females, and histopathological findings in the liver at the high dose.

The carcinogenic potential of phosmet in mice was discussed by the experts. At the high dose (14 mg/kg bw/day), the incidence of hepatocellular adenomas is higher (27/60 in males, 11/60 in females) than in the control group (13/60 in males, 5/60 in females). Compared with control values of another group of mice housed in the same laboratory at approximately the same time (25/60 in males, 9/60 in females), the incidence was still slightly increased. Therefore, the experts could not agree on the proposed classification as carcinogenic with the application of R40.

2.6. Reproductive toxicity

In a two-generation reproduction study in rats, parental effects are decreased body weight and decreased erythrocyte AChE activity (reduction of 37 to 48% at the intermediate dose level, i.e. ~5 mg/kg bw/day, and 74 to 85% at the high dose, i.e. ~25 mg/kg bw/day). The fertility is also affected at the same doses (mating and gestation indices, number of females that delivered), whereas adverse effects on the offspring are only observed at the high dose (reduced mean number of live pups and pup weight per litter, reducing the pup survival index for the two generations). Therefore, the agreed NOAEL for parental and reproductive toxicity is 1 mg/kg bw/day and the NOAEL for offspring toxicity 4.2 mg/kg bw/day.

Phosmet shows no evidence of teratogenicity in rats or rabbits, even in the presence of maternal toxic effects (reduced body weight, body weight gain and food consumption). As a result, the proposed

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overall NOAEL for maternal toxicity is 5 mg/kg bw/day and the overall NOAEL for developmental toxicity is 15 mg/kg bw/day.

2.7. Neurotoxicity

Phosmet does not induce delayed neurotoxicity in two studies with adult domestic hens.

The acute oral administration to rats or administration for 13 weeks do not induce specific changes within the functional observation battery (FOB) or locomotor activity measurements, but confirms the potential of AChE inhibition (erythrocyte, brain and plasma). The NOAEL for acute neurotoxicity is 22.5 mg/kg bw, and the overall NOAEL for cholinesterase inhibition is 1.5 mg/kg bw/day.

2.8. Further studies

Impurities (and equivalence of technical materials)

The relevant impurities **isophosmet** (or isoimidan) and **phosmet oxon** have been discussed by the experts. In an acute oral study, the LD_{50} of isophosmet is 171 mg/kg bw, with the proposed classification T, R25 "Toxic if swallowed". The study was not considered as acceptable due to a lack of data, and the experts concluded that the presence of isophosmet in the toxicological batches should be confirmed by the notifier. This information has not been provided to the rapporteur Member State until now (April 2006). No toxicological data are available for phosmet oxon, but oxons are generally more potent than the parent compound, which is already toxic if swallowed.

Nevertheless, according to the results of a new batch analysis of the current technical material, the maximum levels for isophosmet and phosmet oxon are lower than in the material from the previous production site. Considering that most of the toxicological studies were carried out with technical material from the first production site, the maximum limits for these impurities in the new technical material can be considered as acceptable.

It should be noted that three **new impurities** were detected in the new technical material (less than 1% for each one); and another impurity, only detected qualitatively in the old technical material, was quantified up to 1.9% (w/w) in the new technical material.

The assessment of the toxicological equivalence of the two technical materials for these impurities is based on acute and subacute toxicological data. The oral LD_{50} in rats is 230 mg/kg bw for the current source and 113 mg/kg bw for the old source, the 28-day NOAEL in dogs is 1.5 mg/kg bw/day for the current source and the 90-day NOAEL in dogs is 1.9 mg/kg bw/day for the old source. The experts agreed that the two sources were comparable for acute and subacute toxicity.

EFSA notes: according to the Guidance Document on the Assessment of the Equivalence of Technical Materials of Substances Regulated under Council Directive 91/414/EEC (SANCO/1059/2003), the complete acute toxicity profile would need to be assessed in order to demonstrate clearly the toxicological equivalence of the two materials. Further clarification (available information, structure-activity relationship assessment, …) would also be helpful to confirm the toxicological equivalence.

Plant metabolites

It seems that phosmet oxon is formed *in vivo* in rat urine as well as *in vitro* in a rat liver microsomal metabolism system. However, the studies are not considered scientifically valid and it could not be concluded that phosmet oxon had equivalent AChE inhibitory activity than parent phosmet. Consequently, the notifier was required to address the relative potency of the oxon and parent. Actually, a new *in vitro* metabolism study in rat liver microsomes has been provided to the rapporteur Member State (March 2006) but not evaluated.

Mechanistic studies

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Two assays were performed with BALB/3T3 mouse cells in culture, in order to evaluate the carcinogenic potential of phosmet (by induction of morphological transformation of the cells). A positive result is found at one dose level in the first assay, but not reproduced in the second. Therefore, it was concluded that phosmet had no transformation activity in this test.

Human studies

A randomized double blind ascending single oral dose study has been performed with 36 human volunteers (in 1999). Some adverse events, transient and not serious, were observed after administration, and were considered possibly related to the test compound. Based on plasma and RBC AChE inhibition, the minimum NOAEL is 4 mg/kg bw in males and 2 mg/kg bw in females (highest doses administered). As the brain AChE activity was not measured, the experts considered that the human study did not provide a complete scientific picture of the adverse effects related to phosmet.

EFSA notes: JMPR / WHO (2003) recently evaluated the phosmet mammalian data package and agreed to use the human volunteer study to derive the ARfD. With a NOAEL of 2 mg/kg bw, based on RBC AChE inhibition, the proposed ARfD is 0.2 mg/kg bw, with the use of a safety factor of 10.

2.9. Medical data

There were no incidents, illness or deaths reported during phosmet production in manufacturing plant personnel. When periodic blood AChE checks were performed on involved persons, results demonstrated a normal distribution of plasma and red blood cell AChE values.

However, many cases of accidental poisonings were reported from several databases in US between 1986 and 1997.

2.10. Acceptable daily intake (ADI), acceptable operator exposure level (AOEL) and acute reference dose (ARfD)

ADI

The rapporteur Member State proposed initially to use the NOAEL of 1 mg/kg bw/day from the two-generation reproduction study in rats, with the safety factor 100. The EPCO 33 Experts' Meeting originally agreed to derive the ADI from the LOAEL of 1 mg/kg bw/day from the mouse carcinogenicity study, with an additional safety factor of 300. However, during the re-discussion at the PRAPeR 86 Experts' Meeting, it was agreed to derive the ADI based on the NOAEL of 1 mg/kg bw/day from the rat multigeneration study, supported by short-term studies in dogs and rats and the long-term study in rats. **The agreed ADI is 0.01 mg/kg bw/day, with the use of a safety factor of 100**.

AOEL

The AOEL is based on the overall NOAEL of 2.0 mg/kg bw/day, from the short term studies in dogs, mice and rats, supported by the subchronic neurotoxicity study in rats. **The agreed AOEL is 0.02 mg/kg bw/day, with the safety factor of 100.**

ARfD

The ARfD is derived from the acute neurotoxicity study in rats, with a NOAEL of 4.5 mg/kg bw based on RBC and brain AChE inhibition. **With the use of a safety factor of 100, the agreed ARfD is 0.045 mg/kg bw.**

2.11. Dermal absorption

One *in vitro* study on rat and human skin and one *in vivo* study with rats are presented in the DAR.

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In the *in vitro* study, the estimated dermal absorption includes the amount of test substance located in the skin for both the concentrate and the dilution (1:1000).

For the concentrated Imidan 50WP, a value of 0.1% is derived from the *in vivo* rat data corrected by the *in vitro* rat/human data. For the dilution 1:1000 of Imidan 50WP, the *in vivo* results were considered as not acceptable, and the results with a lower dilution (1:100) as not appropriate. Thus the experts agreed for a default dermal absorption value of 100%.

2.12. Exposure to operators, workers and bystanders

The representative plant protection product Imidan 50 WP is a wettable powder containing 500 g phosmet/ kg for use on potatoes, citrus fruits and pomes.

Operator exposure

According to the intended uses submitted by the applicant, the maximum applied dose is 300 g a.s./ha for pomes and 500 g a.s./ha for citrus fruits and potatoes; with a minimum volume of 500 L/ha for potatoes and 1000 L/ha for pomes and citrus fruits. Imidan is applied only once per season, with the use of tractor-mounted equipment (tractor mounted boom with hydraulic nozzles and tractor drawn air blast orchard sprayer).

Estimated exposure presented as % of AOEL (0.02 mg/kg bw/day), according to calculations with the German BBA and UK POEM model. The use of PPE (personal protective equipment) is considered obligatory during the use of anticholinesterase compounds, the use of RPE (respiratory protective equipment) is also considered.

POTATOES	**With PPE+RPE[1]**	**With PPE+RPE[2]**	**With PPE+RPE[3]**
German BBA	nd	85	65
UK POEM	600	nd	nd
POMES	**With PPE+RPE[1]**	**With PPE+RPE[2]**	**With PPE+RPE[3]**
German BBA	nd	nd	90
UK POEM	2150	nd	nd
CITRUS FRUITS	With PPE+RPE[1]	With PPE+RPE[2]	With PPE+RPE[3]
German BBA	nd	nd	150
UK POEM	3600	nd	nd

PPE[1] (personal protective equipment): gloves during M/L and application, RPE (FFP3) during M/L.
PPE[2] : gloves during M/L and application, RPE (P2) during M/L, broad-brimmed headwear, coverall and sturdy footwear during application.
PPE[3] : gloves during M/L and application, RPE (P2) during M/L, hood and visor, coverall and sturdy footwear during application.
nd : not determined.

In order to have exposure estimates below the AOEL for the application on potatoes and pomes with the German model, the protective measures are extremely high since RPE is used in the mixing/loading process, gloves in both processes and protection for the head and the body. In spite of these measures, the estimated exposure during application on citrus fruits is exceeding the AOEL even in the German model.

Worker exposure

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According to the German BBA model[9] for re-entry tasks estimates, the worker exposure ranged from 0.8 to 0.97% of the AOEL for field crops and orchards (according to the recommended GAPS, when spray solution has dried).

Bystander exposure

Estimates of bystander exposure were calculated for the orchard and field crops, according to the recent MAFF recommendations using drift data by Rautmann et al. (2001). The resulting exposures amount to 65% of the AOEL for orchard applications, and 5% of the AOEL for field applications.

3. Residues

Phosmet was discussed at EPCO experts' meeting for residues (EPCO 34) in September 2005.

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

The metabolism of phosmet was investigated in tree different crops - cherries, potatoes and corn - following foliar application. As these crops are representative for fruits, root and tuber and cereals, the three representative uses proposed for Annex I inclusion (citrus, pome fruit and potatoes) are covered. The active substance was labelled in the carbonyl position. Compared with the supported GAP in citrus and pome fruits, a roughly ten fold application rate was applied. In the potato metabolism study, a 4 – 15 fold exaggerated seasonal dose rate was used.

In cherries, the compound was rapidly translocated to the interior of the fruit after application, 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 the whole fruits, phosmet was extensively metabolised mainly via hydrolysis reactions producing phthalic acid (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 (4.7% of TRR), phthalimide (1.5%of TRR), a complexe of 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. It can be concluded 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 observed as major metabolites in potato tubers. The major portion of the radiocarbon on the unassigned metabolites could be accounted for as phthalic acid after acid hydrolysis. This indicates that the metabolites are derivatives of phthalic acid.

Phosmet occurred as a major residue in corn 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.

[9] Hoenicke *et al*., 1998. Hinweise in der Gebrauchsanleitung zum Schutz von Personen bei Nachfolgearbeiten in mit Pflantzenschutzmitteln behandelten Kulturen. Nachrichtenbl. Deut. Pflantzenschutzd. 50 (10), p 267.

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The main metabolites observed in these metabolism studies phthalic acid, phthaliamic acid and the other metabolites without the phosphorodithioate group 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. In the absence of data on the toxicity of phosmet oxon, the contribution of phosmet oxon to the toxicological burden cannot be quantified, but it is considered by the experts' meeting to be at least as toxic as phosmet parent. Considering these facts, the EPCO experts' meeting confirmed to include phosmet oxon in the residue definition for risk assessment and monitoring purposes unless the notifier provides information to prove that the toxicity profile of phosmet oxon is less critical compared with parent phosmet. As no such data have been submitted, the proposed residue definition is phosmet including phosmet oxon, expressed as phosmet. However, the residue definition for risk assessment has to be considered as provisional. Pending on the outcome of the study aimed to address the relative potency of phosmet oxon and the parent compound (section 2.8) it might be necessary to re-evaluate the residue definition for risk assessment.

The representative use in citrus is supported by ten residue trials in oranges which were carried out in 2002 and 2003 in Spain and Italy according to the proposed GAP. No data are available for mandarins or other small citrus fruits. As an extrapolation from oranges to the whole citrus group is not possible a data requirement is identified (8 trials on mandarins). In course of the evaluation procedure the notifier amended the table of representative uses supporting only oranges for Annex I inclusion purposes. However, in the future, the notifier will apply for the use on mandarins at Member State level and aspire at establishing of import tolerances as this compound is still used in third countries on different commodities. The available data are sufficient to estimate a MRL for oranges; however, if additional uses on other citrus crops are envisaged, additional trials have to be requested on MS level.

The highest residue (HR) detected in oranges according to the residue definition is 0.122 mg/kg. The major part of the residue consisted of phosmet (0.12 mg/kg) whereas phosmet oxon residue accounts only for 0.002 mg/kg (equal to the limit of quantification). The STMR (Supervised Trials Median Residue) was 0.072 mg/kg. Information on the distribution between pulp and peel has been provided, too. The average sum of phosmet and phosmet oxon residues in the peel were at a level of 0.47 mg/kg whereas the residues in the pulp were significantly lower (0.004 mg/kg).

10 trials in apples with test locations in Italy and Spain have been provided in order to support the use in pome fruit in Southern Europe. The HR according to the residue definition was at a level of 0.11 mg/kg and the STMR was calculated to be 0.051 mg/kg.

For the use in potatoes, 7 US trials with exaggerated dose rates have been reported. No measurable residues of phosmet and phosmet oxon were detected in potato tubers. To support the use on potatoes in southern Europe the notifier submitted three additional field trials performed in Spain, Greece and southern France, one of them with a significant longer PHI than the supported use. Although the application rate and the number of applications were higher than the envisaged GAP (5 fold application rate per season), 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). 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. For potatoes the EPCO experts' meeting confirmed that data are sufficient to establish a MRL.

The presented residue trials in oranges, apples and potatoes can be considered as reliable on the basis of storage stability studies, indicating that residues of phosmet and phosmet oxon are stable in water-, oil-, protein- or starch- containing materials for up to 24 months. However, it should be mentioned that in a study with dried peaches significant losses of phosmet and phosmet oxon were observed after 4 months.

Altogether, the information provided is sufficient to propose MRLs for oranges, pome fruit and potatoes and to perform a risk assessment.

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Hydrolysis studies in standard buffer solutions have been submitted in order to investigate the nature of the residue after pasteurisation, baking/brewing/boiling and sterilisation. Under the hydrolytic conditions employed radio labelled phosmet degraded to several compounds to a different extent. At pH 4 under pasteurisation conditions the main compound was phosmet (75 – 84%). At higher temperatures and pH the percentage of parent compound decreased (*ca* 2% in sterilisation conditions at pH 6) whereas the degradation products increased. The predominant compound under sterilisation conditions at pH 6 was N-hydrxymethyl phthalamic acid and phthalic acid. N-hydroxymethyl phthalimid, phthalimide and phthalamic acid were also identified. These metabolites were also found in animal metabolism studies or they have been shown to have no toxicological relevance. It can be concluded that the degradation is pH- and temperature dependent. In no case phosmet oxon was identified.

The effects of processing on the levels of residues were investigated in apples and in potatoes. Transfer factors were established for apple juice, canned apples and apple puree and for the relevant by products occurring at the different processing steps. The results provide evidence that phosmet and phosmet oxon are transferred to a very little extent to apple juice, canned apples and apple puree (transfer factor for juice 0.07 to 0.15, for canned apples 0.019 and for apple puree 0.01). In other products which contain peel fractions like wet and dry pomace the concentration of phosmet and oxon increased (maximum transfer factor 3.23 for wet pomace and 12.03 for dry pomace). A processing study in potatoes demonstrated that the phosmet and phosmet oxon concentrations did non increase in chips and granules.

No processing studies are available for citrus crops.

3.1.2. Succeeding and rotational crops

Studies on rotational crops are not triggered since a rapid break down of phosmet in soil was demonstrated. As DT_{90} of phosmet is below the trigger value, no significant residues are expected in succeeding and rotational crops.

3.2. Nature and magnitude of residues in livestock

The metabolism of phosmet has been investigated in lactating goats and laying hens using ^{14}C-phosmet labelled in the carbonyl group.

Phosmet was administered to two goats for four consecutive days at a dose level of 8.0 to 8.8 mg/kg diet, corresponding to *ca* 0.3 mg/kg bw/day. Approximately 86 to 88% of the administered dose was recovered in this goat study. The majority of the radioactivity was observed in urine (*ca* 60%) and faeces (16 -19 %).

The TRR in milk ranged from 0.008 to 0.017 mg/kg depending on the collecting time; the highest levels were measured the fourth day of dosing. Cumulative radioactivity recovered in milk accounted for less than 0.25% of the administered dose. Accumulation of phosmet or its metabolites in milk is not expected.

The mean TRRs in tissues were 0.24 mg/kg in kidney, 0.2 mg/kg in liver, 0.13 mg/kg in blood, 0.14 mg/kg in muscle and 0.06 mg/kg in fat (expressed as phosmet equivalent). In liver and muscle *ca* 70% of TRR was bound. Also in kidney and milk a significant portion of the TRR was bound (40% and 8-19%, respectively).

Parent phosmet and phosmet oxon were not identified in any extracts of milk and tissues. Each of the tissue and milk samples contained the same array of metabolites, but the relative amounts varied. The most abundant metabolite in liver was N-Methlythiomethyl phthalimide (0.007 – 0.009 mg/kg). Kidney and muscle contained larger amounts of the more polar metabolites, especially N-methylsulfonylmethyl phthalamic acid (average levels of 0.02 mg/kg, respectively). The main metabolite in kidney tissue was a derivative of phthalamic acid with an acidic N-substituent (0.036 mg/kg). In milk the predominant compound was the polar metabolite N-methylsulfonylmethyl

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phthalamic acid, however the concentration was low (0.005 mg/kg). Based on the obtained findings the following metabolic pathway in milk and tissues goats is proposed: hydrolytic displacement of the phosphorus-containing moiety to yield N-mercaptromethyl phthalimid, followed by methylation and oxidation of the thiol group. Also hydrolytic degradation via N-hydroxymethyl phthalimid occurred. These reactions generated a series of phthalamid derivates which hydrolysed to the analogous phthalamic acids.

Laying hens were dosed at a level equivalent to 10.5 mg/kg in the diet (corresponding to 0.73 mg/kg bw) for seven consecutive days. They excreted 89.6% of the cumulative dose. Edible tissues collected at slaughter and eggs accounted for 0.3% of the cumulative dose.

In egg yolks the highest level of radioactivity (as phosmet equivalents) was 0.04 mg/kg on day 7 and in egg whites 0.007 mg/kg on day 4. At slaughter, the levels of radioactivity expressed as phosmet were 0.24 mg/kg in liver, 0.21 mg/kg in kidney, 0.021 mg/kg in breast muscle and 0.015 mg/kg in thigh muscle. In fat lower concentrations were measured (0.005 mg/kg). Phosmet itself was not detected (<0.005 mg/kg) in any of the edible tissues, only in egg yolks 0.001 mg/kg were found. Oxon was not detected in hen tissues or eggs. None of the metabolites exceeded 0.005 mg/kg in the edible tissues or eggs. The metabolites identified in edible tissues and eggs are phthalimid and phthalic acid.

The metabolism seems to be comparable in the goat, hens and rats.

The metabolism studies with goats and hens demonstrate that phosmet is extensively metabolised in animals, generating different metabolites, none of them containing the phosphorous group and no one exceeding a level of 0.05 mg/kg.

The residue definition for food of animal origin proposed by the rapporteur Member State is phosmet only. In cases where no active substance is present and many metabolites are formed in minor amounts usually the residue should be expressed in terms of the active substance. Therefore the rapporteur Member State's proposal was supported by the group of experts.

The expected dietary burden for livestock animals due to residues in feed, resulting from use of phosmet in the supported crops, is significantly lower than the dose levels administered in metabolism studies. Based on the livestock metabolism data submitted with domestic animals it was concluded that the supported uses in oranges, apples and potatoes do not give rise to significant residues in animal products and therefore no MRLs have to be proposed.

3.3. Consumer risk assessment

Amended calculations of potential intakes of residues resulting from the use of phosmet have been provided by the rapporteur Member State after the EPCO experts' meeting taking into account the revised ADI of 0.003 mg/kg, as originally set by the EPCO 33 Experts' Meeting on mammalian toxicology, and the results of the supervised residue trials in oranges, apples and potatoes. The TMDI was calculated using the WHO/FAO model based on the GEMS/Food European regional diet (60 kg bw adult) and the proposed MRLs for plant products. The TMDI estimates that for adult consumers the intake is well below the original ADI of 0.003 mg/kg bw/day (12%). It is noted that as a result of the re-discussions at the PRAPeR 86 Experts' Meeting on mammalian toxicology the ADI has been revised and is now set at 0.01 mg/kg bw/day, however, it was not considered necessary to update the consumer risk assessment since no exceedence was observed with the previous (lower) ADI value.

Since the TMDI is representing an overestimate of exposure, refined risk assessment IEDI/NEDI calculations were provided using the WHO/FAO model, the Spanish diet for adults and the German BBA model based on dietary risk assessment for a 4-6 year old girl with a body weight of 13.5 kg. In these calculations the STMR values were used instead of the MRL. The calculations demonstrated that the exposure is below the original ADI (2% for the Spanish diet, 6% for the WHO/FAO model and 11% for the German model).

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Based on these results, it is concluded that the use of phosmet on oranges, pome fruit and potatoes according to the supported use is not likely to pose a chronic risk.

The acute exposure was performed using the consumption data from the UK model for adults and toddlers. The NESTI calculations showed potential exposures below the ARfD for both adults (5% , 3% and 4% of the ARfD for oranges, apples and pears, respectively) and toddlers (21%, 13% and 18% of the ARfD for oranges, apples and pears respectively). The calculation for potatoes was performed with the LOQ of 0.02 mg/kg, which is considered as the highest possible residue level did not lead to an exceedance of the ARfD (1% for adults and 5% for toddlers).

Based upon these calculations it is concluded that the use of phosmet in oranges, apples and potatoes according to the supported GAP is not likely to cause an acute health risk to the consumers.

3.4. Proposed MRLs

Considering the results of supervised residue trials on oranges, apples and potatoes the following MRLs are proposed on the basis of the agreed residue definition (phosmet and phosmet oxon, expressed as phosmet):

Oranges: 0.2 mg/kg

Pome fruit: 0.2 mg/kg

Potatoes: 0.02* mg/kg

The MRL for potatoes has to be considered as limit of quantification.

No MRL is proposed for other citrus commodities due to the lack of residue trials in small citrus fruit crops.

For animal commodities no MRLs are proposed. The information available from the metabolism in goat and hens suggests a no- residue situation for all animal commodities taking into account the expected dietary burden for livestock animals from the supported uses of phosmet on fruit and potatoes.

4. Environmental fate and behaviour

The fate and behaviour in the environment of phosmet was discussed in the experts' meeting (EPCO 31) of September 2005 on basis of the updated DAR of July 2005.

4.1. Fate and behaviour in soil

4.1.1. Route of degradation in soil

The metabolism of phosmet in soil under dark aerobic conditions at 20-27 ºC and 44-50% maximum water holding capacity (MWHC) or an EFSA estimated soil moisture content of around 21% MWHC[10] was investigated in four different soils. A number of metabolites were formed (up to 17 are proposed in the degradation pathway) none of them reach levels above 10 % of the applied radioactivity or 5% of the applied radioactivity in two consecutive data points or were increasing at the end of the experiments. These metabolites were further degraded to CO_2 (53 % - 77% AR carbonyl radiolabel and 47% AR methylene radiolabel at 120-150 days) and residue not extracted by acetone followed by acidified acetone (17-38% AR carbonyl radiolabel and 17% AR methylene radiolabel at

[10] Reported gravimetric water content at study initiation of 6.4%/ gravimetric MWHC for a typical USDA loam soil of 31% (as identified in Table 2.2 version 1.1 of generic guidance for FOCUS groundwater scenarios dated April 2002). It should be noted this estimate has uncertainty as the initial soil moisture content reported may not have been accurately maintained throughout the study.

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120-150 days). Based on these experimental results it was proposed that phosmet was desulfurated to form the oxon and one of the ester bonds was cleaved to produce a dialkylphosphate moiety and an aryl moiety.

Anaerobic soil degradation was also investigated. The same minor metabolites were identified under anaerobic conditions as were identified in the aerobic experiments. However, N-hydroxymethyl phtalamic acid (maximum = 14.5 % AR after 6 d of anaerobic conditions) occurred at levels above 10 % AR so is considered a major metabolite under anaerobic conditions.

Photodegradation may contribute to the environmental degradation of phosmet but novel photodegradation products were not generated in the available satisfactory laboratory study.

4.1.2. Persistence of the active substance and their metabolites, degradation or reaction products

In laboratory studies to investigate the dark aerobic degradation of phosmet in three soils at 20 ºC and 44-50% MWHC phosmet exhibited low persistence (single first order DT_{50} = 1.65 d (pH7.6), 2.67 d (pH 6.2) and 5.01 d (pH 5.7)). In a fourth soil incubated in the dark at 27°C at an EFSA estimated 21% MWHC, a single first order DT_{50} of 3.6 days was estimated. When normalised to a reference conditions of 20°C and 40%MWHC using a Q10 of 2.2 and Walker equation coefficient of 0.7[11] this DT_{50} is estimated to be 3.8 d (pH 7.4). When only normalised to 20°C without standardisation to an estimated reference soil moisture content this value is 6.03 days. The member state experts considered contrary to the evaluation made by the rapporteur Member State in the DAR, that a pH relationship with degradation rate had not been demonstrated. Therefore the EFSA calculated a geometric mean laboratory soil DT_{50} after normalisation to FOCUS reference conditions[12] (20°C and -10kPa soil moisture content) of 2.67 days that is appropriate for use in FOCUS modelling. No degradation studies on the metabolites were available but based on the evidence of the relatively rapid formation of CO_2 (28 % - 69 % AR after 30 d) none of the minor extracted identified metabolites were very persistent in soil under aerobic conditions. Maximum amounts of phosmet-oxon (a relevant moiety based on toxicological information) were low, always representing ≤ 0.5 % AR in the available laboratory studies.

Degradation was slower under anaerobic conditions but it was not possible to calculated a half life with the available data.

Field studies from six locations in the USA were available in the dossier (exaggerated dosing rate 2.4-90N compared to the applied for intended uses). Single first order DT_{50} calculated using residues in an analysed soil core of 0-18cm depth were between 1.5 d and 13.8 d. Among the field studies phosmet-oxon was found at levels above the limit of analytical quantification (0.05 mg / kg) in one sample (0.06 mg / kg).

The member state experts considered that for PEC soil calculations a reasonable worst case single first order DT_{50} would be the longest value from field trials where a single application of 1.2 kg a.s./ha (2.4N) had been applied. This value is 9.6 days (corresponding DT_{90} 31.9 days). Whilst no comparison of geoclimatic conditions between the US trial sites and EU regions was provided, as this value is longer than the available laboratory values, the use of this value provides a more precautionary EU level assessment. At the Member State product decision making level the applicant could make the case where appropriate (with the necessary evidence) that the conditions (soil temperature and soil moisture content) of the US trials did not correspond to these parameters in a particular EU territory. In this situation the rapporteur Member State proposes (and the EFSA agrees) the longest single first order laboratory value normalised from 27 to 20°C but not to soil moisture reference conditions of 6.03 days would be appropriate. The experts agreed that for the applied for intended uses crop

[11] Using section 2.4.2 of the generic guidance for FOCUS groundwater scenarios, version 1.1 dated April 2002.
[12] Using section 2.4.2 of the generic guidance for FOCUS groundwater scenarios, version 1.1 dated April 2002.

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interception values of 70% for pome fruit and citrus and 15% for potatoes[13] were appropriate to use in PEC soil calculations.

4.1.3. Mobility in soil of the active substance and their metabolites, degradation or reaction products

In laboratory batch adsorption studies on four soils K_{foc} were determined in the range 716 – 10400 mL/g (arithmetic mean 3212mL/g, 1/n 0.89-0.98 arithmetic mean 0.94).

In laboratory column (4 soils) and aged column (1 soil) leaching studies most of the applied phosmet remained associated with the upper (0-20cm) soil column layers. However, an average 13 % AR was detected in the leachate of the aged column study, indicating potential mobility of phosmet metabolites. Analysis of the leachate characterised the residue as polar metabolites, as found in the aerobic soil degradation studies. 5 % if the radioactivity found in the leachate was tentatively identified as phthalic acid.

A satisfactorily completed BBA guideline lysimeter study carried out in Switzerland was available. The lysimeters were cropped with potatoes and alfalfa in rotation. An application of carbonyl-^{14}C-phosmet was made once at the end of July to potatoes at growth stage BBCH 19 at an application rate of 0.512 kg a.s./ha (1.02N). The collected lysimeter leachate (recharge) volume was 60% of precipitation + irrigation (1079L) in the first year of the experiment and 32% of precipitation + irrigation (845L) in the second year. In all leachate samples total radioactivity in leachate excluding CO_2 was ≤0.059µg parent equivalents/L. The nature of this radioactivity was therefore not investigated further as annual average radioactive leachate concentrations were ≤0.036µg parent equivalents/L. This study indicates that for the applied for intended uses (single applications up to 0.5kg a.s./ha) when applications are made in the summer (end of July), that leaching to groundwater of phosmet or its breakdown products containing the carbonyl moiety above the parametric drinking water limit of 0.1 µg/L is unlikely even under vulnerable geoclimatic conditions.

4.2. Fate and behaviour in water

4.2.1. Surface water and sediment

In sterile aqueous buffer solutions at 25 ºC, phosmet hydrolysed with single first order DT_{50} of is less than five minutes at pH 9, 7.8 h at pH 7 and 7.5 d at pH 5. At pH 9 the only major hydrolytic degradation product was phthalamic acid. At pH 7 the major breakdown products were phthalamic acid, phthalimide and N-hydroxymethyl phthalamic acid. At pH 5 they were O,O-dimethyl phosphorodithioic acid and phthalamic acid.

Aqueous photolysis studies indicate that photolysis may contribute to the degradation of phosmet in the environment. The novel photolytic breakdown product O,O-dimethyl phosphoric acid was identified. The other major breakdown products identified were the same as those discussed above that were formed in the sterile hydrolysis studies.

Phosmet is not readily biodegradable in water based on the results of an OECD 301D guideline ready biodegradability study.

The water-sediment study (2 systems studied at 20°C in the laboratory sediment pH 6.2 and 8, water ca. pH 8) demonstrated rapid degradation of phosmet in both the water phase (single first order DT_{50} were 2.2-9.6 hours) and in the total system (single first order DT_{50} were 2.4-21.8 hours). In sediment a DT50 could not be estimated for 1 of the systems due to rapid dissipation leading to too few data points in the decline phase. In the second system a single first order DT_{50} of 11.2 days (treating the sediment as a single compartment) was estimated taking the maximum measured concentration in

[13] Values originate from tables 1.5 and 1.6 of 'Generic guidance for FOCUS groundwater scenarios, version 1.1 dated April 2002'

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sediment as the first time point for the assessment. This value was used in FOCUS surface water modelling and was considered by the member state experts and the EFSA a conservative estimate appropriate to use in this context. For the water phase in FOCUS surface water modelling again as a conservative value the longest whole system single first order DT_{50} value of 0.9 days was agreed as an appropriate value to use as modelling input. The phthalamic acid (max. 75.8 % AR at 6 hours), phthalic acid (37.6-35.8 % AR at 1&15 days) and N-hydroxymethyl phthalimide (max. 12.2 % AR at 3 days) metabolites were detected in the water phase and all the substances had declined to <5 % AR after 100 days. Phosmet oxon was not detected in the study. The terminal metabolite, CO_2, was the most significant degradation product containing the carbonyl radiolabel accounting for 80-92 % AR by the end of the study (100 days). Radioactive residues not extracted from sediment by acidified acetone were also a sink for radioactivity representing 6-12%AR at study end. In sediment extracts phthalamic acid reached a maximum of 12.6 % AR at 7 days but had declined to 1.3%AR by 60 days. The member state experts' discussed whether degradation rates might be slower and the nature of the breakdown products might be different in acidic natural water systems than in the systems tested (neither was acidic from 3 days after treatment). They concluded that taking all the available evidence together, particularly that from the sterile aqueous hydrolysis studies, that for this active ingredient it was unlikely to be significantly more persistent in acidic natural water systems. They also concluded that the nature and levels of the metabolites formed (though not necessarily the time frame over which they reached their maximum concentrations) would also be likely to be comparable in natural acidic systems to that in the available studies. The experts were content that further data was not necessary to address this issue. The EFSA agrees with this conclusion for this active substance, however it was noted that based on the available data, where surface water exposure occurs to parent phosmet and there is strong sunlight and acidic conditions, there is experimental evidence that the metabolites O,O-dimethylphosphorodithioc acid and O,O-dimethylphosphoric acid are probably formed in natural aquatic systems. Also these metabolites may also be formed in the dark under neutral and alkali conditions. There is no direct experimental evidence for this, but as the radiolabel used in the available sediment water studies (carbonyl position) would mean these metabolites would not have been identified in the study design, (as they do not contain the carbonyl radiolabel) their presence cannot be excluded.

FOCUS step 2, 3 and 4 surface water exposure assessments have been completed for parent phosmet. Only southern European scenarios were simulated in line with the applied for representative uses. At step 3 and 4 the application window defined for the Pesticide Application Timer (PAT) routine was only early season applications. It is accepted that this probably represents the worst case application timing in Step 3 calculations when spray drift is the major input route for surface water exposure. However in the available step 4 simulations where just drift mitigation was implemented, rainfall events later in the season may result in higher calculated exposure concentrations than are currently presented in the simulations with early season application timings. The EFSA therefore considers this needs to be investigated by carrying out further appropriate simulations for the later application window. Therefore member states in southern Europe where a later season application window is possible, would need to carry out national assessments of the potential for surface water exposure and associated aquatic risk assessments from the drainage and runoff routes of entry to surface water for phosmet, should it be included in annex 1, as it is not clear that the available southern EU level assessment covers these situations. The key phosmet input values used in the modelling provided by the applicant were all considered acceptable by the rapporteur Member State and the EFSA but were conservative. With the available study database and following FOCUS guidance the EFSA considers it would have been appropriate to use a soil DT50 of 2.67 days (as opposed to the 5 days used) and K_{foc} of 3212mL/g 1/n=0.94 (as opposed to 716mL/g & 1/n=0.9 that were used). There would also be the possibility of determining less conservative water and sediment degradation DT_{50} for use in any future assessment, however these would require additional kinetic analysis that has not been provided by the applicant. It should be noted that for the limited application timing and geoclimatic situations in the available assessment in southern Europe at step 4, only 1 scenario for each crop (D6 potatoes, R4 citrus and pome fruit), were identified as representing low aquatic risk when only spray drift input was mitigated. (Note the use of FOCUS guidance derived phosmet input parameters rather than the conservative values selected by the applicant might change this picture?) Therefore should phosmet be

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included in annex 1 an aquatic risk assessment at the member state level for geoclimatic regions represented by the R2, R3 and D6 FOCUS scenarios is required, (see section 5.2) and mitigation for the runoff and drainage inputs to surface water in addition to spray drift is likely to be necessary.

Initial PEC surface water for the major metabolites formed in the water phase of the sediment water studies were appropriately calculated based on spray drift values at 3 metres for the fruit crops assessed and 1m for potatoes to a static 30cm deep water body using agreed spray drift values for a single application[14] using their maximum observed water formation fraction in the sediment water studies and relative molecular weights (see DAR as amended July 2005 table 8.6.2-24). This is appropriate in this case, as when drift mitigation is not considered (as is the case here) drainage and runoff inputs to surface water will be low for parent phosmet compared to the drift input and no major (>10%AR) metabolites were formed in soil so there is no concern for soil metabolites moving from soil to surface water. A PEC sediment for the major metabolite phthalamic acid or PEC surface water for the potential metabolites (O,O-dimethylphosphorodithioc acid and O,O-dimethylphosphoric acid) have not been calculated. However because of the demonstrated low acute toxicity of these metabolites to aquatic invertebrates and the fact that the endpoints from the mesocosm study cover the risk to sediment dwellers from phthalamic acid (see section 5.2), a PEC sediment value for phthalamic acid or PEC surface water for these other 2 metabolites are not required to complete the risk assessment to aquatic organisms.

4.2.2. Potential for groundwater contamination of the active substance their metabolites, degradation or reaction products

Predicted concentrations in groundwater for phosmet were calculated with FOCUS PELMO 3.3.2. Worst case laboratory soil single first order DT_{50} (5 days) and Koc (716mL/g 1/n, 0.9) were used instead of means but annual average concentrations of phosmet leaving the top 1m soil layer were calculated to always be <0.001 µg / L, i.e. far below parametric drinking water limit of 0.1 µg / L in all 9 FOCUS groundwater scenarios modelled for the applied for representative uses. The results of a satisfactory BBA guideline lysimeter study (see section 4.1.3) support these modelling results and provided evidence that minor soil degradation products that contain the carbonyl radiolabel also have a limited potential to contaminate vulnerable groundwater when summer applications are made in line with a use on potatoes under northern European climatic conditions. Whilst the lysimeter study design is not directly applicable to the representative uses, particularly citrus as applications will be made in the autumn / winter period, the potential for leaching to groundwater from soil metabolites from these other uses is also probably low. In addition the levels of separately resolved components (excluding parent phosmet) in the available soil laboratory route of degradation studies (see section 4.1.1) were lower than the triggers requiring further assessment that are specified in the EU guidance document on the assessment of metabolites in groundwater[15].

4.3. Fate and behaviour in air

Concentrations of phosmet in the air compartment are expected to be negligible, due to its very slightly volatile nature. Any phosmet that was to reach the upper atmosphere would not be expected to be subject to long range transport as a result of its calculated rapid photochemical oxidative reaction with hydroxyl radicals in the upper atmosphere.

5. Ecotoxicology

Phosmet was discussed at the EPCO experts' meeting for ecotoxicology (EPCO 32) 5-9 September 2005. The two sources of technical material were considered ecotoxicologically equivalent based on similar toxicity in studies with *Daphnia magna* and information on acute and sub-acute toxicity obtained in the section "mammalian toxicology". For long-term effects, and other groups of

[14] Appendix 1, Guidance document on aquatic ecotoxicology in the frame of the directive 91/414/EEC SANCO/3268/2001 dated 1 October 2001

[15] SANCO/221/2000-rev.10 dated 25 February 2003.

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organisms, further information is needed to fully assess the equivalence of the two sources. The ecotoxicological assessment is based on the assumption that the studies have been performed with a test material that covers the technical specification.

5.1. Risk to terrestrial vertebrates

The first tier risk to generic species, representing insectivorous and herbivorous birds as well as herbivorous mammals in all crops was assessed according to SANCO/4145/2000. An application rate of 0.5 (citrus and potato) and 0.3 (pome fruit) kg phosmet per hectare was assumed. All acute and long-term TER values except the acute value for herbivorous mammals in potato were below the Annex VI triggers in the first tier assessment, hence indicating a potential high risk. All short-term TER values were above the trigger. A miscalculation of the LC_{50} is corrected in addendum 1 of February 2006 but has no impact on the outcome of the assessment.

No bird acute toxicity study with the formulation Imidan 50WP is available. However, since the acute oral and dermal toxicity studies with rats didn't reveal any indication of significantly higher toxicity from the formulation compared to phosmet alone, no further consideration is necessary.

A refined assessment for birds, presented in the revised DAR of July 2005, was discussed by the Member State experts. It was agreed that experimental residue values could be accepted and that a deposition factor could be applied for grass but not for insects due to the experimental conditions. The conditions in the available avoidance study were not considered relevant and hence the avoidance factor was not accepted. The meeting did not accept the use of blue tit as focal species or the refinement of the "proportion of diet obtained in the treated area (PT)" without further justification. A new assessment based on the accepted refinements is presented in addendum 1 of February 2006. In this assessment a PT factor of 0.61 was used for the long-term assessment for insectivorous birds in orchards. However, even with a PT factor of 1, TER values above the Annex VI trigger would be derived for the long-term. Acute TER values below the Annex VI trigger were obtained for a generic medium herbivorous bird in potatoes and for a generic insectivorous bird in orchards. Additionally, an assessment was performed for the non-standard scenario of herbivorous bird in orchards. Both acute and long-term TER values are above the trigger.

In summary, there is a high acute risk to insectivorous birds for all evaluated uses and to herbivorous birds in potatoes. The short- and long-term risk is considered to be low.

The refined risk assessment for mammals as presented in the revised DAR of July 2005 was not accepted by member state experts. It was concluded that residue values used for the acute assessment should be 90^{th} percentile values and not mean values, in line with the assessment for birds. Furthermore, for the long-term assessment the initial mean residue values should be used rather than the 7-day values used in the DAR. As for birds, a deposition factor was considered appropriate only for grass and not for insects. The experts agreed that in order to accept data for refinement of PT generated on wood mice in northern MS for use in southern Europe, additional supportive data is needed. Based on the recommendations from the experts' meeting a revised assessment for mammals was presented by the rapporteur Member State in addendum 1 of February 2006. The acute TER values are 11.2 (citrus and pome) and 19.7 (potato). Using accepted residue values, the long-term TER values are 1.9 in orchards and 3.4 in potato. Since the additional information regarding the relevance of the focal species and their respective diets in the crops have not been peer reviewed, no final conclusion on the long-term risk to mammals can be drawn at this stage.

The $logP_{ow}$ for phosmet is 2.96 which are very close to the SANCO/4145/2000 trigger of 3 where the potential for bioaccumulation and secondary poisoning should be considered. The expert's meeting agreed that fish bioconcentration studies with phosmet or its metabolites are not necessary as the water/sediment DT_{50} for phosmet was determined to be 0.5 days (mean of the whole system values in the 2 available water/sediment studies) and only one application per year is proposed. Log P_{ow} for the metabolites are all <3. The EFSA calculated the risk for earthworm eating birds and mammals

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according to the guidance in SANCO/4145/2000, and the TER values are well above the Annex VI trigger.

No assessment of the risk to birds and mammals from intake of contaminated drinking water is available. This issue needs to be addressed before a final conclusion can be drawn.

5.2. Risk to aquatic organisms

Based on the available acute toxicity data, phosmet is classified as very toxic to aquatic organisms with a LC_{50} of 0.0021 mg/L for *Daphnia magna*, the most sensitive species tested. The formulation is not more toxic than expected based on the content of the active substance.

For the intended uses first tier TER values were calculated by comparing the toxicity endpoints with PEC_{sw} calculated from spray drift at different distances from the treated crop to a 30cm deep static water body (see DAR as amended July 2005 table 8.6.2-23). Large buffer zones (150 to 200 m) would be required to meet the Annex VI trigger.

The rapporteur Member State proposed to lower the acute trigger value for fish from 100 to 20 since toxicity values were available for 7 different species. The most sensitive species was bluegill sunfish (*Lepomis macrochirus*) with LC_{50} values in the range 0.020 to 0.12 mg/L while the least sensitive fish species tested (Chinook salmon (*Oncorhynchus tskawytcha*) and Smallmouth bass (*Micropterus dolomieui*) both had a LC_{50} of 150 mg/L. Buffer zones of 40 and 20 m respectively (based on FOCUS PEC_{sw}) would then be needed to meet the trigger in orchards and potatoes respectively. The assessment was discussed by Member State experts and it was agreed to await the PPR Panel opinion on lowering of safety factors. The opinion was adopted on 14 December 2005[16]. Since data from 7 different species are available the second lowest toxicity value should be selected according to the opinion and compared to the original trigger. Since the LC_{50} for the next most sensitive species (*Cyprinodon variegates*) is 0.17 mg/L it can concluded that in this case the assessment performed by the rapporteur Member State is the more conservative.

An available mesocosm study conducted in Germany was discussed by the Member State experts. The rapporteur Member State considered it more appropriate to use the NOEC from the study rather than an endpoint based on recovery. Indirect effects such as algal blooms were considered likely to be more severe in southern Europe. It was agreed to apply a safety factor of 2 to the NOEC value in this specific study. The comparison of the NOEC with PEC_{sw} from FOCUS Step 4 calculations (that have only been provided for southern European scenarios and early season application timings, see section 4.2.1) gave TER values that meet the agreed trigger if buffer zones of 40 m are applied for citrus and pome fruit and 20 m for potatoes at a single FOCUS scenario for each crop. In order to complete the assessment TER values should be calculated also with PEC_{sw} values with applications later in the season since drainage and runoff routes of entry are likely to contribute to the contamination of surface water.

Phosmet partitioned into sediment with a maximum value 11.5% after 0 to 1 days in the water/sediment study. Potential effects on sediment dwelling organisms are considered to be covered by the mesocosm study.

The $logP_{ow}$ for phosmet is 2.96 which is very close to the SANCO/4145/2000 trigger of 3 where the potential for bioaccumulation and secondary poisoning should be considered. The expert's meeting agreed that bioconcentration studies with phosmet or its metabolites are not necessary as the water/sediment DT_{50} for phosmet was determined to be 0.5 days (mean of the whole system values in the 2 available water/sediment studies) and only one application per year is proposed. Log P_{ow} for the metabolites are all <3.

[16] http://www.efsa.eu.int/science/ppr/ppr_opinions/1332/ppr_op_ej301_aquatic_ecotox_en1.pdf

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Five major metabolites (≥10%AR) were identified as potentially being present in natural sediment water systems (see section 4.2.1.). For three of these (O,O-dimethylphosphoric acid, O,O-dimethylphosphorodithioc acid, and phthalamic acid, acute toxicity studies were available with fish and *Daphnia* showing a low toxicity. For phthalic acid, the result from a study with *Daphnia* showed low acute toxicity. Data on toxicity to fish were not available for the major water sediment breakdown product N-hydroxymethyl phthalimide, so this needs to be addressed. Even if this metabolite has a short DT_{50}, it was detected above 10% in the water/sediment study and was present for about 15 days. For aquatic invertebrates it was assumed that the potential effects from this metabolite were covered by the mesocosm study.

5.3. Risk to bees

Exposure of bees is from the evaluated representative uses is possible by overspraying of foraging bees, by ingestion of contaminated nectar, pollen or honey dew and by contact with residues on plants. Phosmet is very toxic to bees. The oral and contact HQ quotients are 1351 and 2272 respectively, which is far above the trigger of 50. A semi field study was considered by the Member State experts' to have shortcomings with regard to statistical analysis of data. It was agreed that the high risk to bees needs to be managed at Member State level. Application should be avoided when there are likely to be any bees in the crop. Currently, no data are available to establish a withholding period.

5.4. Risk to other arthropod species

Aphidius rhopalosiphi was the more sensitive of the two standard species (*Aphidius rhopalosiphi* and *Typhlodromus pyri*) in laboratory tests. Hazard quotients (HQ) for in-field and off-field were calculated based on the LR_{50} for *A. rhopalosiphi,* taking into account 29.20% drift for orchards and 2.77% drift for potato. A vegetation distribution factor of 10 and correction factor of 10 in accordance with ESCORT II were applied for the off-field calculations. In-field HQ values of 256 (citrus and potatoes) and 154 (apples), and off-field HQ values of 75, 45 and 7.1 for citrus, apples and potatoes respectively indicates a high risk for non-target arthropods. Results from extended laboratory studies with *A. rophalosiphi, Crysoperla carnea* and *Coccinella septempunctata* on treated natural substrate confirms the high in-field risk.

An off field assessment was performed for the two most sensitive species *A. rhopalosiphi* and *C. septempunctata*. In the case of *A. rhopalosiphi* no vegetation distribution factor was used since application had been done to whole plants (3-dimensional application). A correction factor of 5 accounting for species sensitivity variation was applied. Risk mitigation measures comparable to buffer zones of 5m for potatoes, 40 and 30 m for citrus early and late application respectively, and 30 and 20 m for apples early and late application respectively, are needed to meet the ESCORT II trigger of 2.

An aged residue study with *A. rhopalosiphi* was used to demonstrate the possibility for recovery. Twenty-eight days after treatment with 500 g phosmet/ha mortality was 10% and the reproduction reduced with 47% compared to the control. The Member State experts agreed that potential for recolonisation had been demonstrated. However, further data by means of semi-field or field studies are required to address the impact off-field and the potential for recolonisation from off-field areas.

5.5. Risk to earthworms

The acute toxicity of phosmet to earthworms is low and the TER value calculated based on initial PEC_{soil} is in potatoes which represents the worst case is 91.2 and thus well above the Annex VI trigger of 10. Since the acute toxicity is low, the DT_{90} in soil is <100 days and only one application is proposed, no chronic toxicity study is considered necessary. No major soil metabolites were detected in the soil degradation studies.

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5.6. Risk to other soil non-target macro-organisms

No further studies on soil macro-organisms are considered necessary since the DT_{90} in soil is <100 days and only one application is proposed.

5.7. Risk to soil non-target micro-organisms

The effect on soil respiration was tested with technical phosmet. Although temporary effects were observed at days 7 and 14 of the test the rapporteur Member State concluded that no adverse effects will occur. The effect on nitrification was tested with a WP formulation containing 500 g/kg phosmet and only transient effects >25% were observed at an exaggerated dose rate.

5.8. Risk to other non-target-organisms (flora and fauna)

A vegetative vigour test with Imidan 50 WP on 10 plant species showed no effects >21% at an application rate of 0.5 kg a.s./ha. Since the dose rate to off-field plants will be lower, no adverse effects on non-target plants are expected.

5.9. Risk to biological methods of sewage treatment

Data from a test with phosmet on effects on activated sludge respiration rate are available and indicate that the risk to biological methods of sewage treatment is low.

6. Residue definitions

6.1. Soil

Definitions for risk assessment: phosmet

Definitions for monitoring: phosmet

6.2. Water

6.2.1. Ground water

Definitions for exposure assessment: phosmet

Definitions for monitoring: as the DT_{90} for phosmet in sterile 25°C pH 7 water was < 3 days an appropriate indicator compound for monitoring could be phthalmic acid. However this compound is unlikely to be a specific marker for phosmet. In acidic groundwaters, parent phosmet might be detected following accident or misuse.

6.2.2. Surface water

Definitions for risk assessment:

Neutral / alkaline conditions:

water: phosmet, phthalamic acid, phthalic acid, N-hydroxmethyl phthalimide, O,O-dimethylphosphorodithioc acid and O,O-dimethylphosphoric acid

sediment: phosmet, phthalamic acid

Definitions for monitoring:

Water: as the DT_{90} for phosmet in natural water was < 3 days an appropriate indicator compound for monitoring could be phthalmic acid. However this compound is unlikely to be a specific marker for phosmet. An identified ecotoxicological data gap relating to N-hydroxmethyl phthalimide needs to be closed before a final residue definition can be proposed.

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Sediment: phosmet

6.3. Air

Definitions for risk assessment: phosmet

Definitions for monitoring: phosmet

6.4. Food of plant origin

Definitions for risk assessment: phosmet including phosmet oxon, expressed as phosmet (provisional residue definition, pending the results study aimed to compare the relative potency of phosmet oxon and parent phosmet) (refer to point 2.8)

Definitions for monitoring: phosmet including phosmet oxon, expressed as phosmet

6.5. Food of animal origin

Definitions for risk assessment: phosmet

Definitions for monitoring: phosmet

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7. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

7.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
phosmet	low persistence ($DT_{50\ lab}$ = 1.65-6.03 d, 20°C, 21-50% MWHC); ($DT_{50\ field}$ = 1.5-9.6 d)	See sections 5.5 to 5.7

7.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological relevance
phosmet	low mobility to immobile (Kfoc = 1016-10400 mL/g)	FOCUS modelling and lysimeter: No	Yes	Yes	Relevant.

7.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology

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phosmet	See section 5.2
phthalamic acid	More than one order of magnitude less toxic to fish and daphnids than phosmet
Phthalic acid	More than one order of magnitude less toxic to daphnids than phosmet
N-hydroxmethyl phthalimide	No data on toxicity to fish available Toxicity to invertebrates covered by mesocosm study with phosmet
O,O-dimethylphosphorodithioc acid	More than one order of magnitude less toxic to fish and daphnids than phosmet
O,O-dimethylphosphoric acid	More than one order of magnitude less toxic to fish and daphnids than phosmet

7.4. Air

Compound (name and/or code)	**Toxicology**
phosmet	Not acutely toxic by inhalation, no data on repeat exposure

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LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- A revised technical specification is required where impurities 1.2.2.6, 1.2.2.7 and 1.2.2.22 are removed (date of submission unknown, data gap identified by EPCO 35 September 2005).
- A method of analysis for phosmet-oxon in tissues and body fluids (date of submission unknown, data gap identified by EPCO 35 September 2005).
- Methods of analysis for the relevant impurities in the formulation (data submitted and evaluated by the rapporteur but has not been peer reviewed, data gap identified by EFSA and confirmed by EPCO 35 September 2005).
- Shelf life study to include analysis of the relevant impurities (data submitted and evaluated by the rapporteur but has not been peer reviewed, data gap identified in the DAR and confirmed by EPCO 35 September 2005).
- A new in vitro metabolism study in rat liver microsomes (conducted in February 2006, date of submission unknown, data gap confirmed by EPCO 33 September 2005, refer to point 2.8).
- The residue data available support only the use in oranges. At least 8 supervised field trials in mandarins are necessary in order to establish a MRL for the whole citrus group (data requirement on MS level, refer to point 3.1.1).
- An assessment of the non applicability of US field trial to European geoclimatic conditions has been provided by the applicant and summarised by the rapporteur Member State in the addendum B.8 dated March 2006 but has not been peer reviewed, (data requirement on MS level, refer to point 4.1.2). Note, based on a brief initial consideration, the EFSA would not agree that the information presented is sufficient to conclude that the results of the U.S. trials are not applicable to all southern European conditions.
- The acute risk to insectivorous birds need to be further addressed (relevant for the use in orchards; no submission date proposed by the applicant; refer to point 5.1)
- The acute risk to herbivorous birds need to be further addressed (relevant for the use in potato; no submission date proposed by the applicant; refer to point 5.1)
- The long-term risk to herbivorous mammals need to be further addressed (relevant for all representative uses evaluated; refined assessment available in addendum 1 of February but not peer reviewed; refer to point 5.1)
- The risk to birds and mammals from intake of contaminated drinking water should be addressed (relevant for all representative uses evaluated; data gap identified by the EFSA; no submission date proposed by the applicant; refer to point 5.1)
- The risk to fish from exposure to the metabolite N-hydroxmethyl phthalimide needs to be addressed (relevant for all representative uses evaluated; data gap identified by the EFSA; no submission date proposed by the applicant; refer to point 5.2)
- Withholding periods for bees need to be established by means of appropriate semi-field or field studies (relevant for all representative uses evaluated; data gap identified by EFSA at drafting of conclusion report; no submission date proposed by the applicant; refer to point 5.3)
- The risk to non-target arthropods off-field and the potential for recolonisation and recovery needs to be further addressed by means of semi-field or field studies with a sufficient number of species

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(relevant for all representative uses evaluated; no submission date proposed by the applicant; refer to point 5.4)

CONCLUSIONS AND RECOMMENDATIONS

OVERALL CONCLUSIONS

The conclusion was reached on the basis of the evaluation of the representative uses as an acaracide and insecticide as proposed by the applicant which comprises tractor-mounted spraying and airblast assisted sprayers in orchards. Application is made to citrus fruit at a rate of 0.5 kg phosmet per hectare, pome fruit at 0.3 kg phosmet per hectare and potatoes at 0.5 kg phosmet per hectare.

The representative formulated product for the evaluation was Imidan 50 WP a wettable powder (WP) registered under different trade names in Europe. The representative uses assessed were located in southern Europe only as stated in the application for annex 1 listing. No conclusion on the equivalence of the two sources could be made as some mammalian toxicology data were missing.

In the main adequate methods are available to monitor all compounds given in the respective residue definition. The residue definition for water can not be finalised due to outstanding ecotoxicology data. The method for body fluids and tissues is currently only validated for phosmet and as the oxon is in the residue definition further validation data will be required. Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues. Limited analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible. There are some outstanding issues related to the relevant impurities.

The toxicological risk assessment is based on the assumption that the studies have been performed with a test material that covers the current technical specification.

The absorption is rapid and almost complete, there is no accumulation in tissues and the excretion is mainly via urine. Phosmet is toxic by oral administration and the proposed classification is T, R25. It is non-irritant to skin and eyes and did not cause sensitisation by skin contact.

The critical effect after repeated exposure is depression of the plasma, erythrocyte and brain acetylcholinesterase activities. The most sensitive species is the dog. Phosmet is an *in vitro* but not *in vivo* genotoxic agent. Increased incidence of liver tumours is observed in mice at the highest dose level (14 mg/kg bw/day), higher than controls but within the same range as historical control data. In a two-generation study with rats, the fertility parameters and the offspring are not directly affected. Phosmet shows no evidence of teratogenicity in rat or rabbits, and no potential to induce delayed neurotoxicity. The Acceptable Daily Intake (ADI) is 0.01 mg/kg bw/day, based on a NOAEL of 1 mg/kg bw/day from the rat multigeneration study, supported by short-term studies in dogs and rats and the long-term study in rats. The Acute Reference Dose (ARfD) is 0.045 mg/kg bw and the Acceptable Operator Exposure Level (AOEL) 0.02 mg/kg bw/day.

For the use on potatoes and pomes, exposure estimates according to the German model are below the AOEL for operators wearing personal protective equipment and respiratory protective equipment. In spite of these high protection measures, the operator exposure is above the AOEL during application on citrus fruits. Estimates of worker and bystander exposure are below the AOEL for all the supported uses.

Plant metabolism studies with ^{14}C-phosmet in cherries, potatoes and corn are available covering the representative uses. A common metabolic pathway is proposed. Phosmet is able to penetrate through the plant surface where the main metabolic reactions take place. Within the plant tissues only a limited transport is observed. The primary metabolic reactions are hydrolysis and conjugation reactions which produce phthalic acid and a range of related compounds, none of them containing the

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phosphorodithioate group. Oxidation reaction leading to the oxygen analogue phosmet oxon is a minor metabolic reaction. Considering the fact that oxygen analogue compounds are of high toxicity and the fact that no specific information on the toxicological significance of this compound is available, it was concluded to include phosmet oxon in the residue definition for risk assessment and monitoring purposes. However, pending on the outcome of the study aimed to address the relative potency of phosmet oxon in comparison with the parent compound, it might be necessary to reconsider the residue definitions.

Supervised residue trials in oranges, apples and potatoes have been submitted, which allow the proposal of the following MRLs: oranges and pome fruit: 0.2 mg/kg, respectively, potatoes: 0.02* mg/kg. No MRLs are proposed for other citrus fruit as the available trials in oranges are not suitable for extrapolation to the whole crop group.

The effects of processing on the nature and the level of residues were investigated. Under conditions simulating pasteurisation, baking/brewing/boiling and sterilisation, phosmet degraded to less toxic compounds or compounds that occurred also in animal metabolism studies. The transfer factors to apple juice, apple pure and canned apples were very low, with residues essentially left in the pomace and peel fractions.

Studies on succeeding or rotational crops are not required due to the fast degradation of phosmet in soil.

Livestock can be exposed to residues of phosmet through consumption of fruit pomace and potatoes. Metabolism studies in lactating goat and laying hens demonstrated that phosmet will not occur in animal tissues, milk and eggs when livestock is fed with feed produced according to GAP for the supported use.

The consumer risk assessment was carried out taking into account chronic and acute exposures according to the provisional residue definition (sum of phosmet and phosmet oxon, expressed as phosmet). The calculations indicate that the exposure will be below the ADI and the ARfD, respectively.

The information available on the fate and behaviour in the environment is sufficient to carry out an appropriate environmental exposure assessment at the EU level. The drainage and runoff routes of exposure to surface water for parent phosmet have not been covered for uses under northern European geoclimatic conditions or later season uses in southern Europe in the available EU level assessment. (Note use in northern Europe was not applied for, for annex 1 listing). These exposure assessments and the associated risk assessment to aquatic organisms from phosmet should be completed in national assessments made by the member states should phosmet be included in annex 1. Also, even for the limited application timing and geoclimatic situations in the available assessment in southern Europe at step 4, only 1 scenario for each crop ((D6 potatoes, R4 citrus and pome fruit), were identified as representing low aquatic risk when only spray drift input was mitigated. Careful consideration of runoff and drainage mitigation will therefore be necessary at the member state level, should phosmet be included in annex 1, for geoclimatic regions represented by the R2, R3 and D6 FOCUS scenarios. For the notified intended field uses, the potential for groundwater exposure by phosmet above the parametric drinking water limit of 0.1μg/L, is considered negligible.

A high acute risk to insectivorous birds was identified for all evaluated uses and also for herbivorous birds in potatoes. The initially identified high long-term risk to birds for all evaluated uses was reassessed based on measured residues in insects and grass. The refined long-term TER values for birds are above the Annex VI trigger. For a generic herbivorous mammal a potential high long-term risk was identified for all uses. The refined assessment based on selected focal mammalian species needs to be further justified.

Phosmet is very toxic to aquatic organisms. Since data on acute toxicity to seven fish species are available the safety factor was lowered from 100 to 20. Risk mitigation measures to reduce spray drift

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corresponding to 40 m in orchards and 20 m in potatoes are needed in order to meet this trigger for one scenario in each crop. Based on data from an available mesocosm study, the same buffer zones will also be sufficient to protect aquatic invertebrates in southern Europe in case of early application. The risk assessment for the aquatic environment needs to be complemented with scenarios for northern Europe and application later in the season, when drainage and runoff routes of entry are likely to contribute to the concentration in surface water.

Phosmet is very toxic to bees. The high risk needs to be managed at Member State level. Application should be avoided when there are likely to be any bees in the crop and a withholding period needs to be established. The risk to non-target arthropods is high. A potential for in-field recolonisation has been demonstrated, however further data is required to address the impact off-field and the potential for recolonisation from off-field areas.

The risk to earthworms, other non-target soil macro-organisms, soil micro-organisms, non-target plants and biological methods of sewage treatment is considered to be low.

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- Appropriate PPE and RPE is needed in order to have an estimated operator exposure below the AOEL for the use on potatoes and pomes (refer to point 2.12).
- Risk mitigation measures to reduce spray drift inputs comparable to 40 m buffer zones in orchards and 20 m buffer zones in potato are required to protect aquatic organisms.
- Risk mitigation measures to reduce runoff and drainage inputs to surface water are probably required to protect aquatic organisms (except when applications are made early in the growing season in geoclimatic areas that are represented by the FOCUS D6 scenario for the potato use and the R4 scenariofor the tree fruit uses).
- The risk to bees is high. Application should be avoided when there are likely to be any bees present in the crop.

CRITICAL AREAS OF CONCERN

- Phosmet is toxic if swallowed.
- The estimated operator exposure exceeds the AOEL during use on citrus fruits, even when PPE and RPE are worn.
- High acute risk to insectivorous birds in orchards and potato.
- High acute risk to herbivorous birds in potato.
- Potential high risk to generic herbivorous mammals for all uses. Data on selected focal species needs to be justified/peer reviewed.
- High risk to aquatic organisms. Risk mitigation to reduce spray drift comparable to 40 m buffer zones in orchards and 20 m in potato is required.
- Risk mitigation measures to reduce runoff and drainage inputs to surface water are probably required to protect aquatic organisms (except when applications are made early in the growing season in geoclimatic areas that are represented by the FOCUS D6 scenario for the potato use and the R4 scenario for the tree fruit uses).

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- High risk to bees. Application should be avoided when there are likely to be any bees present in the crop.
- High risk to non-target arthropods. Effects off-field and potential for recolonisation need to be further addressed.

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APPENDICES

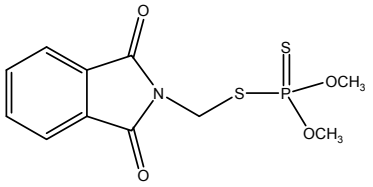
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Phosmet
Function (e.g. fungicide)	Insecticide and acaricide

Rapporteur Member State	Spain/United Kingdom
Co-rapporteur Member State	--

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	O,O-dimethyl S-phthalimidomethyl phosphorodithioate; N-(dimethoxyphosphinothioylthiomethyl)phatalimide
Chemical name (CA) ‡	S-[(1,3-dihydro-1,3-dioxo-2H-isoindol-2-yl)methyl] O,O-dimethyl phosphorodithioate
CIPAC No ‡	318
CAS No ‡	732-11-6
EEC No (EINECS or ELINCS) ‡	211-987-4
FAO Specification ‡ (including year of publication)	Not available
Minimum purity of the active substance as manufactured ‡ (g/kg)	950 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	Phosmet Oxon: 0.8 g/Kg max. Iso Phosmet: 0.4 g/Kg
Molecular formula ‡	$C_{11}H_{12}NO_4PS_2$
Molecular mass ‡	317.33 g/mol
Structural formula ‡	

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Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	71.6-72.0 °C (99.8%) 66.0-69 °C (94.3%)
Boiling point (state purity) ‡	Not applicable
Temperature of decomposition	208.5ºC (100%)
Appearance (state purity) ‡	Clear colourless, crystalline, solid at room temperature (99.8%)
Relative density (state purity) ‡	Density = 1.439 g/cm^3 (20°C; 99.8 %)
Surface tension	71.8 mN/m for a 90% saturated solution (20ºC, 97%)
Vapour pressure (in Pa, state temperature) ‡	6.5 × 10^{-5} Pa (25°C, 99.8%)
Henry's law constant (Pa m^3 mol $^{-1}$) ‡	H = 1.36 x 10^{-3} Pa × m^3 /mol (25ºC)
Solubility in water ‡ (g /L or mg /L, state temperature)	pH 4.4: 15.2 ± 0.68 mg/L (20 °C, 99.8%)
Solubility in organic solvents ‡ (in g /L or mg /L, state temperature)	Xylene: 50-57 g/L (20ºC, 97%) Ethyl Acetate: 57-67 g/L (20ºC, 97%) Acetone: 143-167 g/L (20ºC, 97%) 1,2-Dichloroethane: 400-500 g/L (20ºC, 97%) Methanol: 29.2 g/L (20ºC, 97%) n-Heptane: 1.04 g/L (20ºC, 97%)
Partition co-efficient (log POW) ‡ (state pH and temperature)	pH 7: log P_{ow} = 2.96 (25ºC, 99.8%)
Hydrolytic stability (DT_{50}) ‡ (state pH and temperature)	pH 5: 179 h (25ºC); 50 h (40ºC) pH 7: 9.4 h (25ºC); 149 min (40ºC)
	pH 9: 5.5 min (25ºC); 1.6 min (40ºC)
Dissociation constant ‡	Not applicable
UV/VIS absorption (max.) ‡ (if absorption > 290 nm state ε at wavelength)	λ_{max} (nm) / ε (L mol^{-1}cm^{-1}) Methanol 221.9 / 44668 294.6 / 1259 Acidic methanol 222.6 / 42658 295.6 / 2399 Basic methanol (97%) 218.5 / 16595
Photostability (DT_{50}) ‡ (aqueous, sunlight, state pH)	DT_{50}= 4.5 days (pH 5, 97.9%)
Quantum yield of direct phototransformation in water at Σ > 290 nm ‡	0.01443 molecules degraded/photon

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Flammability ‡	Not flammable
Explosive properties ‡	Not explosive

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List of representative uses evaluated*

Crop and/or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
(a)			(b)	(c)	Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max	(l)	(m)
Citrus FC 0001	SE	Imidan 50 WP	F	Biting and sucking insects	WP	500 g/kg	Spraying	nr	1	nr	0.05	1000	0.5	28	[1] [2] [3]
Pome FP 0009	SE	Imidan 50 WP	F	Biting and sucking insects	WP	500 g/kg	Spraying	nr	1	nr	0.03	1000	0.3	28	[2]
Potatoes VR 0589	SE	Imidan 50 WP	F	Biting and sucking insects	WP	500 g/kg	Spraying	nr	1	nr	0.1	500	0.5	7	[2]

[1] Risk assessment for citrus could not be concluded as no residue trials are available on mandarins.
[2] The risk assessment revealed risks and data gaps in section 5.
[3] The risk assessment revealed a risk in section 2 (operator exposure).

Remarks:				
	*	Uses for which risk assessment could not been concluded due to lack of essential data are marked grey	(h)	Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
	(a)	For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)	(i)	g/kg or g/L
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(j)	Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	(c)	*e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds		
	(d)	*e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		
	(f) Metho	d, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench	(l)	PHI - minimum pre-harvest interval
	(g)	All abbreviations used must be explained	(m)	Remarks may include: Extent of use/economic importance/restrictions

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Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (principle of method)	HPLC-UV
Impurities in technical as (principle of method)	HPLC-UV Confirmation by HPLC/MS **Relevant impurities**: Phosmet Oxon: HPLC/UV, confirmation by HPLC/MS Isophosmet: HPLC/UV, confirmation by HPLC/PDA
Plant protection product (principle of method)	Phosmet: HPLC-UV **Relevant impurities**: Phosmet Oxon: GC-FID Isophosmet: HPLC/UV (data submitted for the impurities in recent addendum, not yet peer reviewed)

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	HPLC-MS/MS, LOQ: 0.01 mg/kg (for each compound: phosmet and phosmet-oxon) (orange and apple and potatoes)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required
Soil (principle of method and LOQ)	GC-FPD, LOQ: 0.05 mg/kg, phosmet (clay and sandy loam)
Water (principle of method and LOQ)	GC-FPD, LOQ: 0.05 µg/L, phosmet (surface water, ground water and drinking water)
Air (principle of method and LOQ)	GC-NPD, LOQ: 0.3 mg/m^3, phosmet
Body fluids and tissues (principle of method and LOQ)	GC-FPD, LOQ: 0.01 mg/L, phosmet (plasma and urine) GC-FPD, LOQ: 0.1 mg/kg (swine liver). Confirmation by GC/MSD. Data gap for a method for the phosmet-oxon

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	No required

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Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of absorption ‡	Rapid and almost complete (84% within 24h). Tmax: 0.5 hr.
Distribution ‡	Widely distributed. Highest levels in whole blood.
Potential for accumulation ‡	No evidence of accumulation.
Rate and extent of excretion ‡	Mainly via urine (70-80% at 24h) but also via faeces (5-10% at 24h). Biliary excretion not measured.
Metabolism in animals ‡	Involved thiophosphoryl hydrolysis, S-methylation, oxidation of the sulfur to the sulfoxide and to the sulfone (U6), hydrolysis of the phthalimide ring to the respective phthalimide acid.
Toxicologically significant compounds ‡ (animals, plants and environment)	Phosmet and phosmet-oxon

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	113 mg/kg bw **T; R25**
Rat LD_{50} dermal ‡	> 1000 mg/kg bw
Rabbit LD_{50} dermal	> 5000 mg/kg bw
Rat LC_{50} inhalation ‡	LC_{50}> 0.152 mg/L
Skin irritation ‡	Non-irritant
Eye irritation ‡	Moderate irritant
Skin sensitization ‡ (test method used and result)	Non-sensitising (Modified Buehler test, 10-induction)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Plasma, RBC and Brain acetyl cholinesterase
Lowest relevant oral NOAEL / NOEL ‡	Overall NOAEL: 2 mg/kg bw/day (90 day rat, 28-day mouse and dog)
Lowest relevant dermal NOAEL / NOEL ‡	22.5 mg/kg bw/day (rat 21-days, brain ChE)
Lowest relevant inhalation NOAEL / NOEL ‡	No data. Not required

Genotoxicity ‡ (Annex IIA, point 5.4)

.....	Positive *in vitro*. Negative *in vivo*. Weight of evidence indicates no significant genotoxic

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	potential.

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Cholinesterase inhibition in rats and mice Mice: Convulsions (males), liver/ cytoplasmic hepatocellular vacuolated degeneration and hepatocellular adenomas
Lowest relevant NOAEL / NOEL ‡	Rat: 1.1 mg/kg bw/day (2-yr, supportive) Mouse: 4 mg/kg bw/day (2-yr)
Carcinogenicity ‡	Negative in rats. Increased liver tumours at 14 mg/kg bw/day (highest dose level) in mice.

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	Decreased fertility index and No. females delivered at maternal toxic doses (with >30% inhibition of RBC AChE). Pup survival reduction and the mean pup bodyweight decreased at maternal toxic dose (with >70% inhibition of RBC AChE).
Lowest relevant reproductive NOAEL / NOEL ‡	Parental/reproductive toxicity: 1 mg/kg bw/day Offspring: 4.2 mg/kg bw/day (2-generation study in rats)
Developmental target / critical effect ‡	Not teratogenic in rat and rabbit. Decreased BWG in the dams (by 20%).
Lowest relevant developmental NOAEL / NOEL ‡	Maternal: 5 mg/kg bw/day Offspring: 15 mg/kg bw/day in the rat/rabbit studies (highest dose tested)

Neurotoxicity / Delayed neurotoxicity ‡ (Annex IIA, point 5.7)

Acute and repeated neurotoxicity	Acute NOAEL = 4.5 mg/kg bw (rat) 13-week NOAEL = 1.5 mg/kg bw/day (rat) based on plasma, RBC and Brain AChE activity inhibition. Time peak effect between 2-6 hr.
Delayed neurotoxicity	No potential to produce delayed neurotoxicity in hens

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Other toxicological studies ‡ (Annex IIA, point 5.8)

Human study (1999)	Acute NOAEL = 2 mg/kg bw/day (based on plasma and RBC AChE inhibition)
Equivalence of technical materials	Old source: rat oral LD_{50} is 113 mg/kg bw dog 90-day NOAEL is 1.9 mg/kg bw/d New source: rat oral LD_{50} is 230 mg/kg bw dog 28-day NOAEL is 1.5 mg/kg bw/d
Mechanistic studies	Negative results in morphological transformation assays with BALB/3T3 mouse cells.

Medical data ‡ (Annex IIA, point 5.9)

.....	There were no incidents, illness, side effects or deaths reported during Phosmet production in manufacturing plant personnel. However, many cases of accidental poisonings were reported from several data base. Symptoms of poisoning were typical of ChE inhibition.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.01 mg/kg bw/d	Rat multigeneration, supported by short term rat and dog, and long term rat	100
AOEL ‡	0.02 mg/kg bw/d	13-week rat neurotoxicity, 90-day rat and 28-day mouse and dog studies	100
ARfD ‡ (acute reference dose)	0.045 mg/kg bw	acute neurotoxicity study in rat	100

Dermal absorption (Annex IIIA, point 7.3)

Imidan 50-WP	0.1% for concentrate, 10% for 1/100 dilution based on in vivo rat data corrected for in vitro rat and human data 100% for 1/1000 dilution, based on default value due to lack of adequate data

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Acceptable exposure scenarios (including method of calculation)

Operator	
Scenario 1: potatoes	
Tractor mounted boom with hydraulic nozzles. 0.5 kg a.s./ha	600% AOEL UK-POEM (PPE+RPE) 85% AOEL BBA-MODEL (PPE+RPE)
Scenario 2: Citrus	
Tractor drawn air blast orchard sprayer. 0.5 kg a.s./ha	3600% AOEL UK-POEM (PPE+RPE) 150% AOEL BBA-MODEL (PPE+RPE)
Scenario 3: Pome Fruits	
Tractor drawn air blast orchard sprayer. 0.3 kg a.s./ha	2150% AOEL UK-POEM (PPE+RPE) 90% AOEL BBA-MODEL (PPE+RPE)
Workers	0.8% AOEL for field crops 0.97% AOEL for citrus, pome-fruits
Bystanders	5% AOEL for field crops 65% AOEL for citrus, pome-fruits

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data	T; Toxic R25 Toxic if swallowed

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Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Fruits (cherries), root and tuber (potatoes), cereals (maize), foliar application, respectively
Rotational crops	No data required
Plant residue definition for monitoring	Phosmet and phosmet oxon, expressed as phosmet
Plant residue definition for risk assessment	Phosmet and phosmet oxon, expressed as phosmet
Conversion factor (monitoring to risk assessment)	None

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Lactating ruminants (goats), poultry (laying hens)
Animal residue definition for monitoring	Phosmet
Animal residue definition for risk assessment	Phosmet
Conversion factor (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No (log P_{ow} = 2,96 at pH)

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

.....	Not required

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

.....	Phosmet and phosmet oxon are stable up to 12 – 24 months in the crops representing • water containing matrices (grapes, apples, peppers, oranges) • oil containing matrices (soy beans, almonds) • protein- or starch containing matrices (potatoes, wheat, corn) Stability in canned peaches: up to 28 months, in dried peaches: for 1 month

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Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
Intakes by livestock ≥ 0.1 mg/kg diet/day (dry weight basis):	Yes *)	No *)	Yes *)
Muscle	Not required.		
Liver	Based on the results of ruminant and poultry metabolism studies no significant residues are expected in animal matrices.		
Kidney			
Fat			
Milk			
Eggs			

*) Dietary burden calculations based on results of trials for fruit pomace and potatoes (US trials only).

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Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Oranges	S Europe	**Phosmet:** whole fruit: 3 x 0.05; 1 x 0.06; 1 x 0.07; 2 x 0.07[1], 1 x 0.09, 2 x 0.12 peel: 1 x 0.21[1]; 1 x 0.27[1]; 1 x 0.38[1]; 1 x 0.4; 2 x 0.43; 1 x 0.52; 1 x 0.69;1 x 0.62; 1 x 0.74 pulp: 7 x <0.002; 3 x <0.01 **Phosmet oxon** whole fruit: 10 x <0.002 peel: 9 x <0.002; 1 x <0.01 pulp: 10 x <0.002	PHI 28	0.2	0.072	
Pome fruit (apples)	S Europe	**Phosmet:** 1 x 0.01;1 x 0.021;1 x 0.02; 1 x 0.041; 1 x 0.04; 1 x 0.05;1 x 0.06; 1 x 0.07; 1 x 0.09;1 x 0.10 **Phosmet oxon:** 4 x <0.002; 6 x <0.01	PHI 28	0.2	0.051	
Potatoes	S Europe	**Phosmet:** 3 x <0.01 **Phosmet oxon:** 3 x <0.01	PHI 7	0.02	0.02	
	N Europe[2]	**Phosmet:** 4 x <0.01 **Phosmet oxon:** 4 x	Two trials PHI 7 Two trials PHI 14			

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		<0.01				
	US[2]	**Phosmet :** 7x<0.05 **Phosmet oxon:** 7x > 0.05	PHI 7			

[1] data from sample taken 35 days after treatment
[2] confirmatory data for the use of phosmet on potatoes in S Europe
(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical GAP

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Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)[7]

ADI	0.003 mg/kg bw day[1]		
TMDI (% ADI)	WHO/FAO European diet (adult):		12 %
NEDI (% ADI)	WHO/FAO European diet (adult):		6 %
	Spanish diet (adult):		2 %
	German diet (child):		11 %
Factors included in NEDI	STMR		
ARfD	0.045 mg/kg bw		
Acute exposure (% ARfD)	NESTI calculation		
		Adult	Toddler
	Orange:	5 %	21 %
	Apple:	3 %	13 %
	Pears:	4 %	18 %
	Potatoes:	1 %	5 %

1. It is noted that as a result of the re-discussions at the PRAPeR 86 Experts' Meeting on mammalian toxicology the ADI has been revised and is now set at 0.01 mg/kg bw/day, however, it was not considered necessary to update the consumer risk assessment since no exceedence was observed with the previous (lower) ADI.

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/processed crop	Number of studies	Transfer factor	% Transference*
Apple juice			
Juice unqualified after pasteurisation/packing	1 balance and 3 follow up	0.15	10.12
Juice clarified (after pasteurisation/packing)	1 balance and 3 follow up	0.07	4.00
Wet pomace	1 balance and 3 follow up	1.07	35.03
Dry pomace	1 balance and 3 follow up	3.03	19.24
Canned apples			
Peeled apples	1 balance and 3 follow up	0.12	10.59
Canned apple	1 balance and 3 follow up	0.02	2.21
Wet pomace	1 balance and 3 follow up	3.23	51.94
Dry pomace	1 balance and 3 follow up	12.03	33.73

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Crop/processed crop	Number of studies	Transfer factor	% Transference*
Apple puree processing			
Apple puree	1 balance and 3 follow up	0.01	0.47
Wet pomace	1 balance and 3 follow up	0.43	15.19
Dry pomace	1 balance and 3 follow up	1.90	11.08
Wet pomace (total)		1.92	-
Dry pomace (total)		6.32	-
Citrus	No data required		
Potatoes			
Chips		0.51	
Granules		0.51	

* Calculated on the basis of distribution in the different portions, parts or products as determined through balance studies

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

	Phosmet and phosmet oxon, expressed as phosmet
Oranges	0.2 mg/kg
Other citrus fruit: e.g. mandarins	No MRL proposal as no residue data are available
Pome fruit	0.2 mg/kg
Potatoes	0.02* mg/kg

*) LOQ

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Fate and behaviour in the environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡	52.09-77.15% after 120 days (^{14}C- carbonyl-labelled phosmet; n=3). 73.5% after 150 days (^{14}C- carbonyl-labelled phosmet; n=1). 46.8% after 150 days (^{14}C-methylene-labelled phosmet; n=1)
Non-extractable residues after 100 days ‡	16.88-37.93% after 120 days (^{14}C- carbonyl-labelled phosmet; n=3). 16.3% after 150 days (^{14}C- carbonyl-labelled phosmet; n=1). 17.2% after 150 days (^{14}C-methylene-labelled phosmet; n=1)
Relevant metabolites - name and/or code, % of applied ‡ (range and maximum)	No major (>10%AR) metabolites were detected

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡	Mineralisation 39.2% after 63 days (^{14}C- carbonyl-labelled phosmet; n=1). 8.28% after 10 days (^{14}C- carbonyl-labelled phosmet; n=1). Non extractable residues 29.6% after 63 days (^{14}C- carbonyl-labelled phosmet; n=1). 11.6% after 10 days (^{14}C- carbonyl-labelled phosmet; n=1). Metabolites N-hydroxymethyl phthalamic acid (PAaMOH)14.15% at 10 days
Soil photolysis ‡	Mineralisation No data <1% (^{14}C- carbonyl-labelled phosmet; n=1). Non extractable residues 14.4% (^{14}C- carbonyl-labelled phosmet; n=1). 51 % at 30 days (^{14}C- carbonyl-labelled phosmet; n=1). Metabolites No novel metabolites present in irradiated samples compared to dark controls

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Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	Laboratory: SFO (non-linear regression/ModelManager Field studies: SFO
Laboratory studies ‡ (range or median, with n value, with r^2 value)	Parent DT_{50lab} (20°C, aerobic): 1.65-5.01 days (n=3; r^2= 0.99-0.97); mean 3.11 days (20 ºC @ 40% MWHC) parent DT_{50lab} (20°C, aerobic, by Arrhenius and estimated 21%MWHC): 6.03 days(n=1; r^2= 0.985) For FOCUS modelling – parent DT_{50lab} (aerobic, 1st order kinetics): geometric mean 2.67 days (normalisation to -10kPa & 20°C with Q10 of 2.2 and Walker coefficient 0.7). Metabolites: not applicable parent DT_{90lab} (20°C, aerobic): 5.48-20.3 d (n= 4, r^2 = 0.99-0.97 according to DT_{50} quoted above) DT_{50cal} (10°C, aerobic): 10.56 d (Q10=2.2; DT_{50} (20 ºC)= 5.01d) DT_{50lab} (23±1°C, anaerobic): 34.6 d (n= 1, r^2= 0.84) Study with aerobic+anaerobic phases DT_{50} refers only to the anaerobic phase (sampling points=3). If the whole sampling points are considered DT50= 9.12d
	Degradation in the saturated zone: no data submitted, not required

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Field studies ‡ (state location, range or median with n value)	DT_{50f}: Mississippi/USA, bare soil, 1x1.2 kg/ha: 9.63d (n= 5, r^2=0.936) Florida/USA, bare soil, 1x1.2 kg/Ha: 1.5 d (n= 5, r^2=0.953) [1] Orange Cove, California/USA, bare soil, 3x 3.36 Kg/ha interval between applic: 14: 7.4 d after 2nd applic (n= 3; r^2=1.00) 13.8 d after 3th applic (n= 5; r^2 0.961). Leland, Mississippi/USA, bare soil , 3x0.84 kg/ha interval between applic. 14 d. 4.1d after 1st applic (n=3; r^2=0.988); 2.3 d after 2nd applic (n=3; r^2=0.986) 8.2 d after 3th applic (n=4; r^2= 0.983) Leland, Mississippi/USA, cotton , 10x1.2 kg/ha interval between applications 3d ; 5.12 days (n=8;r^2= 0.844) Visalia, California/USA, bare soil, 8x5.6 kg/Ha interval between applic 7d; 8.44 days (n=7; r^2=0.988) For PEC soil calculation – Parent: 9.63 days longest value from trials with an application rate of 1.2 kg/ha. Metabolites: no applicable DT_{90f}: Mississippi/USA, 5.64 d; Florida/USA, 4.98 d; Orange Cove, California/USA, 24.6-65.1 d; Leland, Mississippi/USA, 13.6-28.9 d; Leland, Mississippi/USA, 26.5 d; Visalia, California/USA, 16.6 d
Soil accumulation and plateau concentration ‡	No required

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Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡	K_{oc}: parent 716-10400 mL/g (mean 3212mL/g, $^1/_n$= 0.892-0.968, mean 1/.n =0.94, 4 soils) K_f: parent 1.17-15.8mL/g (mean 10.7mL/g, 4 soils)
K_d ‡	K_d: parent 2.6- 27.7mL/g (mean 18.03mL/g, 4 soils)
pH dependence ‡ (yes / no) (if yes type of dependence)	No *For FOCUS modelling – K_{foc}: parent, 3212mL/g, $^1/_n$= 0.94. g (arithmetic means) Metabolites: not applicable

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	Guideline: EPA § 163-1 Precipitation (mm): 508 mm Time period (d): no reported Leachate: 0.02-2.68% total radioactivity in leachate 0.3-0.7% phthalic acid (Pa), >58% total radioactivity retained in top 10 cm
Aged residues leaching ‡	Guideline: EPA § 163-1 Aged for (d): 6 d Precipitation (mm): 508 mm Time period (d): no reported Leachate: 13 % total radioactivity in leachate 5 % phthalic acid (Pa), 0.4% N-hydroxymethyl phthalamic acid (PaAMOH), 0.55% N-hydroxymethyl phthalimide (PiMOH), 0.3% Phthalimide (Pi), 0.65% unknown. 69 % total radioactivity retained in top 10 cm
Lysimeter/ field leaching studies ‡	Location: Switzerland Study type: lysimeter Number of replicates: 2 Number of applications: 1 Application rate: 500 g/ha/year Crop : potatoes Duration: 2 years Total annual rainfall (mm): Year 1 1052.8mm ; Year 2: 770.5 mm Lysimeter I Average annual leachate volume (% of

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	precipitation) 56-39 % radioactivity in leachate (maximum/year): 0.04-<0.01% AR Max. annual average concentrations: 0.036-0.02 µg /L (parent equivalent, without volatiles) Lysimeter II Average annual leachate volume (% of precipitation): 61.6-52.3% %radioactivity in leachate (maximum/year): 0.05-<0.01% AR Max. annual average concentrations: 0.033-0.015 µg /L (parent equivalent, without volatiles)

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation	Initial PEC 5cm soil incorporation 1.5g cm-^{3} soil density
Application rate	Crop: potatoes, citrus and pome fruits % plant interception: 70% in citrus and pome fruit,15% in potatoes. Number of applications: 1 Interval (d): no applicable Application rate(s): 500 g as/ha in citrus and potatoes; 300g as /Ha in pome fruits

	Citrus (1x0.5 kg as/ha, 70% interception)	
PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Actual
Initial	0.2	0.2

	Pome fruits (1x0.3 kgas/ha, 70% interception)	
PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Actual
Initial	0.120	0.120

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	Potatoes (1x0.5 kg as /ha, 15% interception)	
$PEC_{(s)}$ (mg/kg)	Single application Actual	Single Time weighted average
Initial	0.57	-

Metabolite

Method of calculation	Not applicable
Application rate	Not applicable

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolysis of active substance and relevant metabolites (DT_{50}) ‡ (state pH and temperature)	pH5: 25°C DT_{50} 7.5 days (1^{st} order, r^2=98.38) 43.9 % Phosmet (at 11 d); 34.3% Phthalamic acid (PaA; at 11 d); 8.8% Phthalic acid (Pa; at 11 d); 9.8% Phthalimide (PI; at 11 d); 79.4% O,O-dimethyl phosphorodithioic acid (at 11 d) pH7: 25°C 7.8 h (1^{st} order, r^2=90.58) No data with regard to the metabolites in the main report In a supplementary study: 25% N-hydroxymethyl phthalamic acid (PaAMOH): (at 50 d); 72% Phthalamic acid (PaA): (at 50 d. Potential accumulation); 21% Phthalimide (Pi) (at 50 d) pH9: 25°C DT_{50} 4.5 min (1^{st} order, r^2=97.5) phthalic acid though %AR not reported

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Photolytic degradation of active substance and relevant metabolites ‡	Experiments in pH5 buffer Black light; DT_{50} 46 h 72.3 % O, O –dimethyl phosphoric acid (5 d); 33% phosphoric acid (at 5 d); 12.7% PAa (at 5 d); 15.7% PA (at 5d); 62% Pi (at 5 days). Xenon arc lamp, DT50 4.5 d (1st order, r^2=99.6) 10% Pi (at 10 days. potential accumulation); 18.31% PaAMOH (at 10 days. Potential accumulation); 7.6% PaA (at 10 days. Potential accumulation). 6.06% Pa (at 10 days . Potential accumulation). Xenon arc lamp, DT50 23.9 h (1st order, r^2=99.6) Natural light, 37N; DT50 no determined 76.5% PaAMOH at 20 h. Potential accumulation ; 13.4% PaA at 20 h. Potential accumulation. 18.3 % Pi at 1.5 h
Readily biodegradable (yes/no)	No
Degradation in water/sediment	
- DT_{50} water ‡	0.4 -0.092 days (pH 8); mean 0.546 d
- DT_{90} water ‡	0.3 -1.5 days (1st order; r^2= 99%, n=2)
- DT_{50} whole system ‡	0.91-0.1 days (pH 8); mean: 0.505 days
- DT_{90} whole system ‡	0.3-3.045 days (1st order, r^2= 99, n= 2)
Mineralization	Max 80-92.5 %AR (at study end 100 days, n= 2)
Non-extractable residues	20.68-14.63% AR (at 15 and 30 d, n=2)
Distribution in water / sediment systems (active substance) ‡	Maximum of 9.25-11.51 %AR in sediment after 0-1 days.
Distribution in water / sediment systems (metabolites) ‡	Water: Phthalamic acid: max 75.78% AR (6 h) Phthalic acid max 37.59 % AR (1 DAT) N-hydroxymethyl phthalimide 12.2% AR (3 DAT) Sediment: Phthalamic acid: max 12.6 % AR (7 DAT) DT_{50} selected for FOCUSsw modelling Water DT_{50} 0.9 days (conservative value longest whole system) Sediment DT_{50} 11.2 days (conservative value longest sediment)

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PEC (surface water) (Annex IIIA, point 9.2.3)

Parent

Method of calculation	Molecular weight: 317.3(g/mol) Water solubility (mg/L): 20 Vapour pressure: $6.5x10^{-5}$ Pa Koc/Kom (L/kg): 716 1/n: 0.9(Freundlich exponent general) DT_{50} soil (d): 5.0 days (Lab) DT_{50} water (d): 0.9 days DT_{50} sediment (d): 11.2 days
Application rate	Crop: Potatoes, Citrus and Pomes fruits Number of applications: *1* Application rate(s): Citrus and Potatoes: 500 g as/ha; Pome fruits: 300 g as/ha Application dates: according to PAT
Main routes of entry	Drift from 10, 20 and 40 meters

Crop	Buffer zones	Spray input %	Scenario	Water body	Time of application	PECsw	PECsed
Potatoes	20 m	0.144	Thiva D6	Ditch	Early application	0.232	0.043
					Late application	0.232	0.036
		0.172*	Porto R2	Stream	-	0.751	2.293
			Bologna R3	Stream	-	2.968	2.498
Citrus	10 m	3.356	Thiva D6	Ditch	-	5.512	2.184
		4.028*	Roujan R4	Stream	-	4.867	0.534
	40 m	0.312	Thiva D6	Ditch	-	0.513	0.216
		0.374*	Roujan R4	Stream	-	0.452	0.05
Pome fruit	20 m	3.123*	Porto R2	Stream	Early application	3.007	0.297
			Bologna R3	Stream	Early application	3.211	0.620
			Roujan R4	Stream	Early application	2.27	0.266
	40 m	0.603*	Porto R2	Stream	Early application	0.581	0.280
			BolognaR3	Stream	Early application	0.859	0.522
			Roujan R4	Stream	Early application	0.438	0.064

* For Streams the areic mean deposition, as calculated by the FOCUS Drift Calculator, have been multiplied by a factor 1.2 to account for pesticide mass incoming from the upstream catchments.

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.*	For FOCUS gw modelling, values used –

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modelling, monitoring, lysimeter)	Modelling using FOCUS model(s), with appropriate FOCUS gw scenarios, according to FOCUS guidance. Model(s) used: PELMO 3.3.2 (Pesticide leaching model) Scenarios (list of names): Châteaudun, Piacenza, Porto, Sevilla, Thiva, Hamburg, Joikoinen, Kremsmünster, Okehampton Crop: Citrus, Pome fruits and Potatoes worst case DT_{50lab} : 5 d K_{foc}: parent, worst case 716 ml/g , $^1/_n$= 0.9.
Application rate	Application rate: 500 g/ha (citrus and potatoes); 300 g/ha (pome fruit) No. of applications: 1 Time of application (month or season): date of leaf emergence for pome and potatoes; 01 March for citrus

$PEC_{(gw)}$

Maximum concentration	<0.001 µg/L
Average annual concentration (Results quoted for modelling with FOCUS gw scenarios, according to FOCUS guidance)	Annual average concentrations (80th percentile) according to FOCUS guidance: active substance: <0.001 µg/L Model: FOCUS PELMO 3.3.2

PEC(gw) - FOCUS modelling results

Scenario [µg/L]	Citrus	Pome fruit	Potatoes
Northern European Scenarios			
Hamburg (H)	*	< 0.001	< 0.001
Jokioinen (J)	*	< 0.001	< 0.001
Kremsmünster (K)	*	< 0.001	< 0.001
Okehampton (N)	*	< 0.001	< 0.001
Southern European Scenarios			
Châteaudun	*	< 0.001	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001
Porto	< 0.001	< 0.001	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001
Thiva	< 0.001	< 0.001	< 0.001

* no scenarios exist for this crop/location combination

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Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	Not studied
Quantum yield of direct phototransformation	Aactive substance: 0.01443 molecules degraded/photon
Photochemical oxidative degradation in air ‡	DT_{50} of 0.84 hours derived by the Atkinson method of calculation
Volatilization ‡	From plant surfaces: no data from soil (EPA § 163-2 guideline): <1% after 24 hours

PEC (air)

Method of calculation	The volatility of phosmet is low (<1%) Vapour Pressure: 6.5 $x10^{-5}$ Pa (25ºC) Henry's Law constant 10.31$x10^{-4}$ Pa m^3 mol^{-1} reactivity with OH radicals in the troposphere is predicted to be rapid. No significant residues will occur on air.

$PEC_{(a)}$

Maximum concentration	Negligible

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	Soil: phosmet Groundwater: phosmet Surfacewater: phosmet and the metabolites phthalamic acid (R2) (PaA), (N-(hydroxy methyl) phthalimide (PiMOH, R8), and phthalic acid (PA, R3) O,O-dimethylphosphorodithioic acid, O,O-dimethylphosphoric acid, Sediment: phosmet and phthalamic acid (R2) Air: phosmet

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	No data provided
Surface water (indicate location and type of study)	No data provided
Ground water (indicate location and type of study)	No data provided
Air (indicate location and type of study)	No data provided

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Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	N; Dangerous for the environment Candidate for R53 May cause long-term adverse effects in the aquatic environment

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Ecotoxicology

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Acute toxicity to mammals ‡	LD_{50}: 113 mg/kg bw (rats)
Acute toxicity to birds ‡	LD_{50}: 57 mg/kg bw (Bobwhite quail)
Dietary toxicity to birds ‡	LC_{50}: 406 mg/kg bw/d (Japanese quail)
Reproductive toxicity to birds ‡	NOEC: 7.5 mg/kg bw/d (Bobwhite quail)
Reproductive toxicity to mammals ‡	NOAEC - LOEC: 1.5 mg/kg bw/d (rat, 2-generation study)

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Application rate (kg a.s./ha)	Crop	Category (e.g. insectivorous bird)	Time-scale	TER (worst case)	TER after refinement[1]	Annex VI Trigger
0.5	Citrus	insectivorous birds	acute	2.1	**2.4**	10
0.5	Citrus	insectivorous birds	short-term	27		10
0.5	Citrus	insectivorous birds	long-term	0.49	5.3	5
0.5	Citrus	herbivorous mammals	acute	3.8	11.2	10
0.5	Citrus	herbivorous mammals	long-term	0.18	**1.9**	5
0.3	Pomes	insectivorous birds	acute	3.5	**4.07**	10
0.3	Pomes	insectivorous birds	short-term	45		10
0.3	Pomes	insectivorous birds	long-term	0.83	8.9	5
0.3	Pomes	herbivorous mammals	acute	3.8	11.2	10
0.3	Pomes	herbivorous mammals	long-term	0.18	**1.9**	5
0.5	Potatoes	insectivorous birds	acute	2.1	**2.4**	10
0.5	Potatoes	insectivorous birds	short-term	27		10
0.5	Potatoes	insectivorous birds	long-term	0.49	5.3	5
0.5	Potatoes	herbivorous birds	acute	1.7	**3.6**	10
0.5	Potatoes	herbivorous birds	short-term	27		10
0.5	Potatoes	herbivorous birds	long-term	0.93	6.5	5
0.5	Potatoes	herbivorous mammals	acute	10.9	19.7	10
0.5	Potatoes	herbivorous mammals	long-term	0.6	**3.4**	5

[1] Parameters for refinement. Birds in orchards: RUD and DT_{50} (both, experimental values); Birds in Potato field: RUD and DT_{50} (experimental values) together with DF because the particular conditions of RUD study. Mammals in orchards:-RUD (experimental values) and DT_{50} (experimental values) together with DF.

A revised assessment is available in addendum 1 of February 2006 but has not been peer reviewed.

Toxicity data for aquatic species (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
Laboratory tests ‡				
Lepomis macrochirus	Phosmet	96 h	Mortality, LC_{50}	**0.0197**; 0.070; 0.12
Oncorhynchus mykiss	Phosmet	96 h	Mortality, LC_{50}	0.23; 0.24; 0.56
Cyprinodon variegatus	Phosmet	96 h	Mortality, LC_{50}	0.17
Ictalarus punctatus	Phosmet	96 h	Mortality, LC_{50}	11.0
Pimephales promelas	Phosmet	96 h	Mortality, LC_{50}	7.3
Oncorhynchus tskawytscha	Phosmet	96 h	Mortality, LC_{50}	150
Micropterus dolomieu	Phosmet	96 h	Mortality, LC_{50}	150
Oncorhynchus mykiss	Phosmet	ELS-96 d	Growth juveniles, NOEC	0.0032
Daphnia magna	Phosmet	48 h	Mortality, EC_{50}	0.0021
Daphnia magna	Phosmet	21 d	Reproduction, NOEC	0.00078
Algae	Phosmet	72 h	Biomass, ECb_{50}	0.51[1]
Rainbow trout (*O. mykiss*)	Imidan (48.5% a.s.)	96 h	Mortality, LC_{50}	0.152
Daphnia magna	Imidan (51%a.s.)	48 h	Mortality, EC_{50}	0.0044
Algae	Imidan (48.5% a.s.)	72 h	ECb_{50}	3.7
Metabolites:				
Fish / Daphnia	O,O-Dimethylphosphoric acid	Acute static	LC_{50} / EC_{50}	> 100
Fish / Daphnia	Dimethylphosphorodithioic acid	Acute static	LC_{50} / EC_{50}	> 100
Fish / Daphnia	Phthalamic acid	Acute static	LC_{50} / EC_{50}	> 100
Daphnia	Phthalic acid	Acute static	EC_{50}	105

Microcosm or mesocosm tests				
	Test substance	Time-scale	Endpoint	Toxicity (mg/L)

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	WP formulation containing 500 g/kg Phosmet	12 weeks	NOEC	0.000813[2] 0.001[3]

[1] based on initial measured concentration and it's the most sensitive of observed AUC at 24, 48 and 72 h observation.
[2] based on initial measured value.
[3] based on measured. No NOEAEC has been accepted due to the recovery of species at the mesocosm study in Germany is not representative of recovery at south Europe areas.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Application rate (kg a.s./ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
0.5	Citrus	*Lepomis macrochirus*	96 h	50	38	20
0.3	Pomes				63	
0.5	Citrus	*Daphnia magna*	48 h	200	111	100
0.3	Pomes			150	95	
0.5	Citrus	*Selenastrum capricornutum*	72 h	3	10.5	10
0.3	Pomes				17	
0.5	Citrus	*Oncorhynchus mykiss*	96 d	75	17	10
0.3	Pomes			50	10.6	
0.5	Citrus	*Daphnia magna*	21 d	150	22	10
0.3	Pomes			100	13	
0.5	Potatoes	*Lepomis macrochirus*	96 h	20	76	20
		Daphnia magna	48 h	250	100	100
		Selenastrum capricornutum	72h	1	110	10
		Oncorhynchus mykiss	96 d	20	13	10
		Daphnia magna	21 d	50	7.8	10
				200	29	

A higher tier study **Mesocosm** was provided. The comparison between toxicity (NOECmes.) and exposure (PECsw) from step 4 FOCUS modelling gave TERmes. (citrus and pomes) > 2 at 40 m far from a water body at an application rate of 0.5 kg a.s./ha and 0.3 Kg a.s/ha, respectively. And TERmes. (potatoes) > 2 at 20 m far from water body at an application rate of 0.5 kg a.i/ha.

Trigger mesocosm =1 was proposed by Rapporteur. However, the expert meeting EPCO 32 concluded that the trigger value for mesocosm should be **2** when the toxicity value is a NOEC.

As conclusion based on microcosm study a safe use was identified for citrus and pome fruit at the R4 FOCUS scenario with a spray drift buffer zone of 40 m and for potatoes at the D6 FOCUS scenario with spray drift buffer zone of 20 m.

Bioconcentration

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Bioconcentration factor (BCF) ‡	Not relevant
Annex VI Trigger:for the bioconcentration factor	Not relevant
Clearance time (CT_{50}) (CT_{90})	Not relevant
Level of residues (%) in organisms after the 14 day depuration phase	Not relevant

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity ‡	LD_{50} = 0.37 µg a.s./bee
Acute contact toxicity ‡	LD_{50} = 0.22 µg a.s./bee

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
500	Citrus, apple, potato	oral	1351	50
500	Citrus, apple, potato	contact	2272	50

Field or semi-field tests Field study not available, the submitted semi-field study does not demonstrate a harmless effect of phosmet on bees

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

HQ calculated for citrus scenario early application (worst case)

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	HQ in citrus	Annex VI Trigger
Laboratory tests ‡							
Aphidius rhopalosiphi	Adult	WP Formulat. 500 g/kg Phosmet	Dose response test: 2.1 – 8.25	Mortality, R.C, % reduction	LR_{50} 1.95 g a.i/ha 38% at 1.41 g a.s./ha	256 (in) 75 (off)	2 < 50%
Typhlodromus pyri	Adult	WP Formulat. 500 g/kg Phosmet	Dose response test: 103-1031	Mortality, R.C, % reduction	LR_{50} 301 g a.i/ha 24.1% at 281 g a.s./ha	< 2 (both in/off)	n.a. < 50%
Extended laboratory studies ‡							

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Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	HQ in citrus	Annex VI Trigger
Aphidius rhopalosiphi	Adult	WP Formulat. 500 g a.i/kg	Dose- resp. test on leaf surface: 30 - 500	Mortality, R.C, % reduction	LR_{50} 10.3 g a.s./ha 47 % at 8.11 g a.s./ha	48 (in) 70.8 (off)	2 < 50%
Chrysoperla carnea	Adult	WP Formulat 500 g a.i/kg	Dose- resp. test on leaf surface: 50 - 800	Mortality, R.C, % reduction	LR_{50} 80 g a.s./ha no sig. effects up to 100 g a.s./ha (highest rate tested)	6 (in) 9 (off)	2 < 50%
Coccinella septempunctata	Adult	WP Formulat 500 g a.i/kg	Dose- resp. test on leaf surface: 0.6 – 3.5 (2-dimensio. application)	Mortality, R.C, % reduction	LR_{50} 2.64 g a.s./ha no sig. effects up to 2.25 g a.s./ha (highest rate tested)	190 (in) 27 (off)	2 < 50%
Extended laboratory studies (aged residue) ‡							
Aphidius rhopalosiphi	Adult	WP Formulat 500 g a.i/kg	Aged residue 30 - 500	Mortality (M) R.C, % reduction	**after 28 d** M=10% at max. 500 g a.s./ha RC =47% at max 500 g a.s./ha	< 50% < 50%	*Aphidius rhopalosiphi*

Field or semi-field tests
Not available, will be done, if necessary

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity ‡	LC_{50} corr 52 mg/kg dry soil
Reproductive toxicity ‡	Not necessary

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Application rate (kg as/ha)	Crop	Time-scale	TER	Annex VI Trigger
0.5	potatoes	acute	91.2	10
0.5	citrus	acute	260	10
0.3	pome	acute	433	10

*EPCO 31 (fate) stated a 70% interception for citrus and pomes for calculation of PECsoil.

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Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization ‡	No effects up to 2.5 kg a.s./ha
Carbon mineralization ‡	No effects at least up to 3.4 kg a.s./ha

Effects on other non-target organisms believed to be at risk (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Vegetative vigour test	No effects at least up to 0.5 kg a.s./ha

Effects on biological methods for sewage treatments (Annex IIA, point 8.7)

Respiration inhibition test	No effects at least up to 1000 mg a.s./L

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	R50 Very toxic for aquatic organisms

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ABBREVIATIONS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval

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pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year

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