Conclusion regarding the peer review of the pesticide risk assessment of the active substance

dimethoate

finalised: 23 June 2006

(version of 20 July 2006 with minor editorial changes marked yellow)

SUMMARY

Dimethoate is one of the 52 substances of the second stage of the review programme covered by Commission Regulation (EC) No 451/2000[1], as amended by Commission Regulation (EC) No 1490/2002[2]. 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 EU-Commission.

The United Kingdom being the designated rapporteur Member State submitted the DAR on dimethoate in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 4 August 2004. The peer review was initiated on 4 August 2004 by dispatching the DAR for consultation of the Member States and the applicant the Dimethoate EU Joint Submission Group consisting of BASF Aktiengesellschaft, Cheminova A/S and ISAGRO S.p.A.. The Dimethoate EU Joint Submission Group which was represented by Scientific Consulting Company (SCC). 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 7 June 2006 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as an insecticide which comprises broadcast spraying to control biting and sucking insects in wheat, olives, sugar beet, tomatoes and lettuce. Dimethoate can be used as acaricide and insecticide. It should be noted that the applicant is supporting only the use as insecticide in the EU review process.
The representative formulated product for the evaluation was "Dimethoate 400 EC" ("400 g/L EC"), an emulsifiable concentrate (EC), registered under different trade names in Europe.

[1] OJ No L 53, 29.02.2000, p. 25
[2] OJ No L 224, 21.08.2002, p. 25

Adequate methods are available to monitor all compounds given in the respective residue definition. Only validated single methods for the determination of residues are available. Sufficient 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.

Dimethoate is of moderate acute oral toxicity to rats (LD_{50} = 245 mg/kg bw) and mice (LD_{50} = 160 mg/kg bw) (R22 "Harmful if swallowed" proposed); it is of low toxicity to rats following acute dermal administration (LD_{50} >2000 mg/kg bw). Inhalation LC_{50} is 1.68 mg/L (R20 "Harmful by inhalation" was proposed). Dimethoate is not irritating to skin or eyes; a data requirement for a Local Lymph Node Assay (LLNA) was set due to the inconclusive results of skin sensitisation (R43 "May cause sensitisation by skin contact" proposed). Dimethoate is genotoxic *in vitro* but not *in vivo*; the overall weight of evidence indicated no significant genotoxic potential. Dimethoate did not show any evidence of carcinogenic, reproductive and developmental toxicity potential. The acute neurotoxicity NOAEL is 1 mg/kg bw/day, and the neuro-developmental NOAEL is 0.1 mg/kg bw/day. With the exception of omethoate, all of the metabolites investigated were of lower acute oral toxicity than dimethoate. The ADI and AOEL are 0.001 mg/kg bw/day, while the ARfD is 0.01 mg/kg bw (safety factor of 100). The overall dermal absorption is 0.15% for the concentrate and 2.0% for the dilution.
The operator exposure assessment shows levels below the AOEL only for automatic application on lettuce in greenhouses and for sprayer application on wheat (German model, PPE worn). Bystander exposure and exposure for re-entry workers hand harvesting tomato and lettuce are estimated to be below the AOEL.

Sufficient information has been provided on the metabolism of dimethoate in cereal, root and leafy crops. Several metabolic pathways have been identified including oxidation, demethylation, hydroxylation and hydrolysis. At PHI relevant for the supported representative uses, the metabolic pattern is consisting of a mixture of parent compound and a wide range of metabolites. Omethoate is the most toxic metabolite identified, but other metabolites (metabolites XX and XII) presenting a lower potential for cholinesterase inhibition may bring a significant contribution to the toxicological burden given their presence in significantly higher amounts, in particular in cereals. Their relative toxicity to the parent compound needs to be clarified on the basis of further appropriate studies.
The proposed residue definition for monitoring is dimethoate and omethoate to be determined separately. Metabolites XX, XII (and possibly III, which is a major rat metabolite, depending on its potential for cholinesterase inhibition potential) should be considered for inclusion in the residue definition for risk assessment, on the basis of the information to be provided on their relative toxicity to parent compound and their possible specific impact on the toxicological burden. A final decision on the appropriate wording of this residue definition is not possible at this stage, as clear differences in the toxicity levels of dimethoate and its metabolites exist but are reflected by scientifically-based toxicity equivalence factors for omethoate only.
Supervised residue trials have been provided allowing the establishment of MRLs in olives, tomatoes, lettuce and wheat for both dimethoate and omethoate. It must be noted that for wheat grown in

Southern Europe, the latest application should be limited to growth stage BBCH 69 (end of flowering, as for Northern region) as the provided data do not cover adequately later use until growth stage BBCH 75 (milky grain stage). The nature of residues is affected by processing but only to a significant extent when severe conditions such as sterilisation are applied. However, no specific residue definition is needed for processed commodities as the metabolites formed are similar to those observed in raw commodities under environmental conditions.

No significant residues are expected in following crops and in products of animal origin. The expected absence of residues in animal commodities should however be confirmed by a feeding study carried out at the expected rate of exposure of ruminants.

Only preliminary acute and chronic exposure and risk assessments could be carried out, taking into account the combined effect of dimethoate and omethoate, using toxicity equivalence factors of 3 and 6 for chronic and acute exposures respectively, to take into account the higher toxicity of omethoate. Final and robust assessments will be only possible when the required information concerning metabolites XX, XII and III will be available.

At this stage, considering that the exposure to the combined residues of dimethoate and omethoate only is already close to the ADI and the ARfD for some specific population sub-groups, it cannot be excluded that the contribution of further metabolites leads to a global exceedence of the toxicological trigger values for those sub-groups depending on which crops are authorised.

Sufficient data were available to demonstrate that dimethoate exhibits low persistence in soil. The primary route of dissipation appeared to be microbially-mediated hydrolytic and oxidative degradation in aerobic soil, with a half-life ranging from 2.0 to 4.1 days. Low levels of metabolites were found in the laboratory aerobic degradation study, with two individual metabolites being identified. These were O-desmethyl dimethoate being found at maximum 2.0% AR at day 2 and O,O-dimethyl thiophosphoric acid found at maximum 0.7% AR also on day 2. Other metabolites were detected with the maximum level of individual components at any time being 2.0% AR. However, under field conditions representative for Southern European conditions, the metabolite omethoate was found (peak occurrence of 30.6-67.7% w/w compared to the peak dimethoate levels) though it hadn't been detected in laboratory studies. Because of its toxic potential, further environmental fate testing on this compound was performed. In soil omethoate exhibited very low to low persistence.

Anaerobic soil metabolism is a route of dissipation for dimethoate, though less important than aerobic soil metabolism. However, given the supported uses proposed, it appears unlikely that applications of dimethoate will occur during or close to periods when soils experience anaerobic conditions.

Dimethoate does not photodegrade on soil.

Dimethoate is highly soluble in water and it adsorbs very weakly to soil particles (based on evidence from laboratory soil batch adsorption studies) and therefore it may be subject to leaching. A column leaching study confirmed the high mobility of dimethoate in soil, with 71.8-100.6% AR eluted from the columns, the majority of which was present as dimethoate. However, in a lysimeter study dimethoate itself was not present in leachate, and a large number of metabolites, including omethoate, could be excluded. Groundwater modelling of the proposed GAPs indicates that contamination of groundwater by either dimethoate or omethoate is unlikely to be a concern, with the exception that

exceedance of 0.1 µg/L may be possible with the proposed GAP with olives. Thus, it is demonstrated that safe uses with respect to groundwater contamination exist for the proposed GAPs, although Member States must reassure themselves that actual use at vulnerable sites under their own local conditions will not lead to exceedance of 0.1 µg/L.

Dimethoate will hydrolyze fairly rapidly in highly alkaline waters (half life at pH 9 is 4.4 days at 25ºC), forming O-desmethyl dimethoate and O,O-dimethyl thiophosphoric acid. However, in neutral to acidic waters that also have low microbiological activities, dimethoate can be more persistent.

Dimethoate is not susceptible to photodegradation in water.

In natural sediment water systems (dark aerobic laboratory study) dimethoate dissipated from the water relatively rapid and incorporation into unextracted residues appeared to be the major route of dissipation. In surface water, dimethoate and O-desmethyl dimethoate were present, with dimethoate in sediment.

The available aquatic exposure assessment is appropriate for addressing the spray drift route of entry to surface water for dimethoate and metabolites O-desmethyl dimethoate and O,O-dimethyl thiophosphoric acid. However, Member States need to carry out aquatic exposure and risk assessments form the drainage and runoff routes of exposure to surface water as these routes of entry have not been considered in the EU level assessment available.

Based on the available volatilisation experiment and the calculated atmospheric half life, contamination in air compartment and long transport trough air are not expected.

The applicant should provide a clarification that the test material used in the studies in the section on ecotoxicology covers the specification of the technical material regarding impurities.

The risk to birds and mammals from the glasshouse use in lettuce is considered to be low. A potential high risk to birds and mammals was identified in the first tier risk assessment for the representative uses outdoors. A revised refined risk assessment is considered necessary. This should include for birds a more detailed justification for e.g. selection of focal species for all representative outdoor crops, refinements of PD and PT, residues decline (residue data should not be pooled, DT_{50} for omethoate in ground vegetation from the residue trial in citrus), extrapolation of citrus residues data from southern to northern Europe, use of a dehusking factor. If use is to be made of the HD5-approach then full details of all toxicity values must be provided, the dietary endpoints must be expressed as daily dietary doses and further support for any claimed reduction in uncertainty factors must be presented. The revised refined risk assessment for mammals should address the concerns regarding the residue data and include a better justification for the selection of focal species and for the proposed refinements of PD and PT.

The risk to aquatic organisms can be considered as low for the representative uses in lettuce, wheat in southern Europe and sugar beet in northern Europe. The risk to aquatic organisms has to be considered as high for the representative uses in wheat in northern Europe, olives, sugar beet in southern Europe and in tomatoes for which risk mitigation measures such as a bufferzone of 5 metres, 20 metres, 5 metres and 10 metres respectively are considered necessary.

The risk to bees is considered to be low for the use in lettuce under glasshouse conditions and the use in sugar beet. For the representative uses outdoors a high risk to bees present in the field at the time of

application and for short periods after the treatment(s) was observed in the submitted higher tier studies. The experts' meeting recommends risk mitigation measures such as to avoid all contact with bees. The available data are not sufficient to establish precise withholding periods.

A high risk to NTA was observed in the standard first tier laboratory data. The available field studies demonstrated a potential for recovery within one year for uses up to 500 g a.s./ha. The applicant needs to further address the in-field risk to NTA from uses above 500 g a.s./ha. The available field studies at low dose rates were considered sufficient to demonstrate that with appropriate risk mitigation measures such as bufferzones the off-field risk is addressed. Bufferzones of 10 m in wheat (SE) and sugar beet (NE), of 15 m in wheat (NE) and sugar beet (SE), of 30 m in tomatoes and of 75 m in olives are proposed based on the lowest NOEC of 1.44 g a.s./ha from the cereal field trial.

The risk to earthworms from dimethoate is considered to be low but a long term toxicity study with the soil metabolite omethoate on earthworms is considered necessary for uses with more than 3 applications per year.

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

Key words: dimethoate, omethoate, peer review, risk assessment, pesticide, insecticide, acaricide

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BACKGROUND

Commission Regulation (EC) No 451/2000 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, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Dimethoate is one of the 52 substances of the second stage covered by the amended Regulation (EC) No 451/2000 designating United Kingdom as rapporteur Member State.

In accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, the United Kingdom submitted the report of its initial evaluation of the dossier on dimethoate, hereafter referred to as the draft assessment report, to the EFSA on 4 August 2004. In accordance with Article 8(5) of the amended Regulation (EC) No 451/2000 the draft assessment report was distributed for consultation on 4 August 2004 to the Member States and the main applicant Dimethoate EU Joint Submission Group consisting of BASF Aktiengesellschaft, Cheminova A/S and ISAGRO S.p.A., which was represented by Scientific Consulting Company (SCC) 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 7 June 2006 leading to the conclusions as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR).

In accordance with Article 8(7) of the amended Regulation (EC) No 451/2000, this conclusion summarises the results of the peer review on the active substance and the representative formulation

evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the peer review was compiled as a **peer review report** 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 8 June 2005)
- the consultation report

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation
- the evaluation table (rev. 2-1 of 19 June 2006)

Given the importance of the draft assessment report including its addendum (compiled version of May 2006 containing all individually submitted addenda) 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.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Dimethoate is the ISO common name for *O*,*O*-dimethyl *S*-methylcarbamoylmethyl phosphorodithioate or 2-dimethoxyphosphinothioylthio-*N*-methylacetamide (IUPAC).

Dimethoate belongs to the class of aliphatic amide organothiophosphate insecticides such as omethoate and mecarbam. It belongs also to the classes of organothiophosphate acaricides. Dimethoate acts by contact and systemic action by inhibiting the enzyme acetylcholinesterase.

The representative formulated product for the evaluation was "Dimethoate 400 EC" ("400 g/L EC"), an emulsifiable concentrate (EC), registered under different trade names in Europe.

The evaluated representative uses as insecticide comprise broadcast spraying to control biting and sucking insects in wheat, olives, sugar beet, tomatoes and lettuce. Dimethoate can be used as acaricide and insecticide. It should be noted that the applicant is supporting only the use as an insecticide in the EU review process.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of dimethoate as manufactured should not be less than 960 g/kg, which is higher than the minimum purity given in the FAO specification 59/TC (2005) of 950 g/kg. The higher value relates to the submitted results of current batch analysis and not to any toxicological concern to increase the minimum purity. It should be noted that the FAO specification is applicable only for the technical material of BASF, Cheminova and Isagro.

The technical material contains omethoate[3],[4] and isodimethoate[5], which have to be regarded as relevant impurities. The maximum content in the technical material should not be higher than 2 g/kg omethoate and 3 g/kg isodimethoate (FAO 59/TC).
However, the technical specification must be regarded as provisional, due to the fact that for the moment it cannot be concluded that the technical specification is covered by the material used in the studies for ecotoxicology (see chapter 5).

According to the FAO specification 59/EC (2005) the maximum content of omethoate and isodimethoate should not exceed 0.4% and 7% of the dimethoate content, respectively.
It should be noted that the content of isodimethoate is increasing during storage (from *ca* 0.7 g/kg to 4.3 g/kg), but it is still below the acceptable maximum content as defined by FAO (28 g/kg). No data are available with respect to the content of omethoate, but this issue was not stressed by a MS or during the meeting of experts. However, due to the decrease of dimethoate during storage, it is possible that a significant amount of omethoate can be formed. Taken the observed decrease of dimethoate and the increase of isodimethoate into account a maximum of 4.9 g/kg omethoate could be formed. This theoretical possible content is above the maximum limit of 1.6 g/kg as defined by FAO. Therefore, data on the content of omethoate in the formulation during storage are necessary. However, the RMS has stated that the omethoate levels were measured in the shelf life study Sorensen 2002 (DTF 245-014) and were below 150 mg/kg throughout. This information was not included in the DAR and therefore neither peer reviewed nor discussed in a meeting of experts.

The content of dimethoate in the representative formulation is 400 g/L (pure).

Beside the lacking data on the content of omethoate and the possible increase in the content of omethoate in the formulation during storage, the assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of methomyl or the respective formulations.

[3] Omethoate: *O,O*-dimethyl *S*-[2-(methylamino)-2-oxoethyl] phosphorothioate (CAS)
[4] It should be noted that *omethoate* is listed in annex I of Commission Regulation 2076/2002. However, the COM has confirmed that Article 2 of Commission Regulation 2076/2002 is not applicable in a similar situation.
[5] Isodimethoate: phophorodithioic acid, *O,S*-diemthyl S-[2-(methylamino)-2-oxoethyl]ester (CAS)

The main data regarding the identity of dimethoate and its physical and chemical properties are given in appendix 1.

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of dimethoate in the technical material and in the representative formulation as well as for the determination of the relevant impurities in the technical material as well as in the formulation.
Therefore, enough data are available to ensure that quality control measurements of the plant protection product are possible. However, it should be noted that the method for the determination of the relevant impurities in the formulation that is referred to in the FAO evaluation, has been included in the submitted dossier, but was not evaluated by the RMS.

However, sufficient test methods and data relating to physical, chemical and technical properties and analytical methods are available to ensure that quality control measurements of the plant protection product are possible.

Adequate methods are available to monitor all compounds given in the respective residue definition, i.e. dimethoate plus omethoate in food of plant and animal origin; dimethoate and omethoate in soil, ground water and air; dimethoate in surface water.

The methodology used is HPLC with MS and GC with FP or MS detection.
It was demonstrated that the German S19 multi-method6 is applicable for the determination of residues dimethoate and omethoate in food of plant origin, but the published validation data are insufficient to accept the method according to the requirements of Directive 91/414/EEC (e.g. the given LOQ is too high).

The discussion in the meeting of experts (EPCO 35, September 2005) on identity, physical and chemical properties and the analytical method was limited to some clarification on specification of the technical material, certain properties of dimethoate and the respective formulation and the missing validation data for the method for the determination of residues in tomatoes.

2. Mammalian toxicology

Dimethoate was discussed in the EPCO experts' meeting in September 2005 (EPCO 33).

[6] Collection of Official Methods under Article 35 of the German Federal Food Act, Method L 00.00.34 (Extended and Revised Version of the DFG Method S19)

2.1. ABSORPTION, DISTRIBUTION, EXCRETION AND METABOLISM (TOXICOKINETICS)

Dimethoate is rapidly absorbed and excreted following oral administration in the rat. There is no evidence for accumulation; it is extensively metabolised in the rat. Limited data indicate that absorption and excretion are also rapid and extensive in humans following oral dosing.

2.2. ACUTE TOXICITY

Dimethoate is of moderate acute oral toxicity to rats (LD_{50} =245 mg/kg bw) and mice (LD_{50} = 160 mg/kg bw), therefore the classification **R22 "Harmful if swallowed"** was proposed. It is of low toxicity to rats following acute dermal administration (LD_{50} >2000 mg/kg bw). Inhalation studies with a manufacturing concentrate indicate LC_{50} values of 1.68 mg/L (the classification **R20 "Harmful by inhalation"** was proposed). Dimethoate is not irritating to skin or eyes and was not shown to be a sensitiser in a 3-induction Buehler study. During the EPCO meeting, a concern was raised with regard to skin sensitisation of dimethoate in combination with the co-formulants. The Buehler test with three applications was considered not to fulfil the requirements. The meeting noted that the formulation was positive in a Buehler (9-induction) assay, while dimethoate was negative in a Buehler (3 induction) study conducted with 10 animals. Therefore it was considered necessary to address the skin sensitisation potential for the active ingredient, and a data requirement for an LLNA on the active was set. The meeting also agreed that dimethoate should be classified with respect to skin sensitisation (**R43**), and that the issue should be forwarded to ECB.

2.3. SHORT TERM TOXICITY

The main finding in short-term toxicity studies was the inhibition of erythrocyte and brain cholinesterase activity. No significant species differences in sensitivity were seen between rats and dogs. The relevant short term NOAEL was 0.18 mg/kg bw/day (1 year dog study).

2.4. GENOTOXICITY

Dimethoate is genotoxic *in vitro* but not *in vivo*, including bone marrow cytogenetics and UDS assays in rats and a micronucleus assay in mice. The overall weight of evidence indicated no genotoxic potential.

2.5. LONG TERM TOXICITY

Cholinesterase activity was identified as the most sensitive endpoint of dimethoate toxicity. The relevant NOAEL is 0.04 mg/kg bw/day based on RBC and brain cholinesterase inhibition at 0.2 mg/kg bw/day in the chronic rat study. Dimethoate did not show any evidence of carcinogenic potential.

2.6. REPRODUCTIVE TOXICITY

The meeting discussed the parental and reproductive NOAELs. The experts confirmed the parental NOAEL of 0.2 mg/kg bw/day, based on the inhibition of brain cholinesterase at 1 mg/kg bw/day. The meeting agreed that the lower NOAEL of 0.08 mg/kg bw/day derived in a second study was the result

of dose spacing (LOAEL of 1.2 mg/kg bw/day). The reduction in pup survival was considered treatment-related, and a reproductive NOAEL of 1.2 mg/kg bw/day was agreed on.

No evidence of teratogenicity was seen in developmental toxicity studies in rats and rabbits or in other published studies in rats and mice. The maternal NOAEL was 6 mg/kg bw/day based on clinical signs and reduced bodyweight in rats; the developmental NOAEL was 18 mg/kg bw/day (highest dose tested in rat).

2.7. NEUROTOXICITY

The meeting confirmed an acute neurotoxicity NOAEL of 1 mg/kg bw/day based on a biologically significant decrease in RBC cholinesterase.

In the developmental neurotoxicity study, 3 litters were lost at the higher dose. Similar effects were seen in the rat multigeneration study. Effects were consistent with a dose-response effect. The RMS proposal for a NOAEL of 0.1 mg/kg bw/day was confirmed.

2.8. FURTHER STUDIES

Acute toxicity and cholinesterase inhibition studies were performed with a number of metabolites of dimethoate. With the exception of omethoate, which was found to be more a potent cholinesterase inhibitor than dimethoate, all of the metabolites investigated were of lower acute oral toxicity than dimethoate.

The toxicity of metabolite XX (O-desmethyl omethoate carboxylic acid) and metabolite XII (O-desmethyl isodimethoate) was addressed in a rat study indicating that they were both less potent cholinesterase inhibitors than dimethoate (25% vs ~50% inhibition).

As a result of the comparative cholinesterase inhibition profiles *in vivo*, the meeting concluded that the significance of the contribution of the metabolites to the toxicological burden depends on the relative ratio of metabolite to parent.

The meeting agreed on setting reference values for omethoate as follows:

ADI	0.0003 mg/kg bw/day	SF 100
ARfD	0.002 mg/kg bw/day	SF 100
AOEL	0.0003 mg/kg bw	SF 100

EFSA note:

The comparative toxicity of dimethoate vs omethoate was considered by RMS and different approaches were proposed.

In the toxicology section, an estimate of the threshold for the toxicologically relevant inhibition of erythrocyte and/or brain cholinesterase activity was made by comparison of NOAELs and LOAELs for cholinesterase inhibition as well as the cholinesterase activity recovery in repeat-dose studies. Omethoate is more toxic than dimethoate and the relative toxicity of omethoate compared to dimethoate following chronic and acute were found to be about ~3:1 and ~6:1, respectively.

In the residue section the above mentioned values were used.

In the ecotoxicology section, Addendum Aug 2005, the RMS summarised a position paper provided by the applicant with regard to the application of a Toxicity Equivalence Factor (TEF) to assess the relative toxicity of dimethoate and omethoate. It is stated that the deductions described are based upon several studies and consider the most sensitive parameter cholinesterase inhibition and are therefore considered to be more reliable than NOAEL comparison. With regard to the acute mammalian risk assessment, the acute oral LD_{50} in rats for omethoate was compared to the acute oral LD_{50} for dimethoate in the mouse resulting in TEF of 7. With regard to the long-term mammalian risk assessment conducted by the RMS, the TEF is based upon the NOAELs derived from multi-generation studies with dimethoate and omethoate, respectively, resulting in a TEF of 2.9 for chronic exposure. The long-term risk assessment for mammals was therefore also based upon a TEF of 3.

The TEF approach is useful to estimate the hazards/risks of complex chemical mixtures where there is insufficient information to evaluate the chemicals that compose a mixture. The TEF approach has been used for evaluating health risks posed by dioxins and dioxin-like PCBs; it has been refined through the years and has been adopted by regulatory agencies at the international levels.
However, in the field of risk assessment of pesticide under the Directive 91/414, this approach was not validated and there are no common criteria available. The use of TEF methodology is still under discussion at an international level and its reliability and applicability to the current example was not even discussed by the experts. The description of the relative potency of dimethoate and omethoate is based on a rough estimate of the toxicological results.
In conclusion, it should be stressed that a full data package for omethoate is available and that reference values for omethoate were agreed on during the toxicology meeting.

2.9. MEDICAL DATA

The very few reports of delayed neuropathy in humans associated with exposure to dimethoate all appear to follow severe poisoning. Dimethoate may also cause an 'intermediate syndrome' of significant toxicity in humans, which was reported after suicide attempts and/or involved ingestion of a large volume of dimethoate. A human volunteer study identified a toxicologically relevant inhibition of cholinesterase activity at dose levels of 0.6 mg/kg bw/day following dosing for up to 57 days.

2.10. ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) AND ACUTE REFERENCE DOSE (ARFD)

In the DAR, all the reference values were derived based on the human volunteer study NOAEL of 0.2 mg/kg bw/day, based on cholinesterase inhibition. The values proposed were:

ADI	0.002 mg/kg bw/day	SF 100
ARfD	0.03 mg/kg bw/day	SF 10
AOEL	0.01 mg/kg bw	SF 30

The meeting discussed the study, and noted that it was not scientifically valid for the derivation of human reference doses because of many scientific limitations.

ADI

The meeting considered the studies available for the derivation of the ADI. It was considered that the critical effect was cholinesterase inhibition, and a combined NOAEL of 0.1 mg/kg bw/day was derived from the chronic rat study, the rat multigeneration study, the subchronic neurotoxicity study and the neurotoxicity study, taking into account dose spacing. A safety factor of 100 was applied to derive an ADI of 0.001 mg/kg bw/day.

ARfD

The meeting confirmed the ARfD of 0.01 mg/kg bw proposed by the RMS, based on a NOAEL of 1 mg/kg bw day in the acute dietary neurotoxicity study, with a safety factor of 100.

AOEL

The meeting discussed the studies available for the derivation of the AOEL and the value proposed by the RMS. The NOAEL of 0.1 mg/kg bw/day derived from the developmental neurotoxicity study and interim cholinesterase measurements in the 2 year rat study were used in the derivation of the AOEL, with a safety factor of 100, to set an AOEL of 0.001 mg/kg bw/day.

2.11. DERMAL ABSORPTION

Dermal absorption values were calculated from the results of an *in vivo* study in rat, corrected for the comparative permeability of rat and human skin *in vitro*, leading to an overall absorption of 0.15% for the concentrate and 2.0% for the dilution.

Concern was raised that while the RMS had used 24 hour values in the derivation of dermal absorption values from the *in vivo* study, a slightly higher value was derived from the use of 8 hour values (0.15% and 2% for concentrate and dilution using 24 hour values and 0.3% and 5% for concentrate and dilution using 8 hour values). However, the meeting noted that values are typically taken at 24 hours, and that the residue in the skin was taken into account with the *in vitro* studies. Therefore the dermal absorption values proposed by the RMS were confirmed.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative product Danadim Dimethoate 40 is applied on wheat, olive, sugar beet, tomatoes and lettuce with tractor-mounted spraying devices, knapsack-sprayers and airblast assisted sprayer in orchards. The recommended application rate of Dimethoate is in the range from 0.084 to 0.72 kg a.s./ha.

DAR

Based on German model data, for all methods of application (with the exception of broadcast air-assisted equipment) total systemic exposure for operators wearing gloves when handling the concentrate was below the AOEL of 0.01 mg/kg bw/day proposed in the DAR. For application via

broadcast air-assisted sprayers, exposure is estimated to be 40% of the proposed short term systemic AOEL for operators wearing additional PPE of gloves, coveralls and sturdy footwear during application.

Based on UK POEM data, total systemic exposure was estimated to exceed the short term systemic AOEL of 0.01 mg/kg bw/day (i.e. 110% and 200%) when wearing gloves during all operations. For handheld applications the risk assessment was further refined by considering the use of impermeable coveralls. In this case estimated exposure was 140% and 90% of the systemic AOEL for lettuce and tomato respectively.

According to the outcomes of the EPCO expert's meetings with regard to a new AOEL setting, the RMS was asked to provide recalculations beside an explanation for the reduction in work rate for tomatoes and lettuce, and include calculations conducted without the application of a reduction factor.

Recalculation after the experts' meeting

According to the RMS, German model estimates of exposure suggest exposure scenarios below the AOEL for use on lettuce in greenhouses via automated gantry sprayers (no PPE) and on wheat (and sugar beet) via field crop (boom) sprayers (operators wearing additional PPE of gloves, coveralls and sturdy footwear during application).

For all methods of application, with the exception of application via automated gantry sprayers in greenhouses, total systemic exposure predicted by UK POEM was estimated to exceed the short term systemic AOEL of 0.001 mg/kg bw/day for operators wearing PPE.

Model	Method	% of the AOEL No PPE	% of the AOEL With PPE*
German	Lettuce/GS greenhouse	40	
	Wheat/FCS		90*
	Tomato/KS		410*
	Olives/BAS		430*
UK POEM	Lettuce/GS greenhouse	90	
	Wheat/FCS		1100°
	Olives/BAS		2000°
	Tomato/KS		900§
	Lettuce/KS		1400§

*Gloves when handling the concentrate and gloves, coveralls and sturdy footwear during application

°Gloves when handling the concentrate and during application

§ Gloves when handling the concentrate and gloves and impermeable coveralls during application

FCS=field crop sprayer; BAS=broadcast air-assisted sprayer; KS=knapsack sprayer; GS=gantry sprayer

EFSA notes that the refinement provided by the RMS considers a standard work rate of 1 ha in the German model and a work rate of 0.67 ha/day in the UK POEM for use on lettuce (greenhouse); only estimated exposure for automatic applications showed levels below the AOEL.

Bystanders (DAR)

Exposure of unprotected bystanders arising from application via tractor mounted/trailed field crop sprayers and broadcast air-assisted sprayers are estimated to be below the AOEL.

Recalculation after the experts' meeting

In the addendum submitted in March 2006, the RMS provide recalculation of bystander exposure, showing estimate levels of 45% and 76% of the AOEL for field crops and orchards, respectively.

Workers (DAR)

Trials conducted in the US demonstrate the presence of both dimethoate and omethoate residues on the surface of treated foliage. For workers re-entering treated areas therefore it is necessary to consider exposure to both dimethoate and omethoate residues. Based on maximum measured levels of foliar residues immediately following application worker exposure is estimated to be below the AOEL for all proposed uses and no minimum re-entry period is required.

According to the EPCO experts' meeting outcomes and in relation to worker exposure, the RMS was asked to include in the assessment the omethoate fraction, and timing of reentry has to be considered.

Recalculation after the experts' meeting

Levels of exposure for re-entry workers hand harvesting tomato and lettuce are expected to be below the AOEL. According to the RMS, further information is required to confirm levels of exposure for workers re-entering cereal and olive crops.

EFSA notes that the DFR values considered in the assessment were measured immediately after treatment; it can be therefore assumed that dimethoate levels will decrease over time, and in consideration of the PHI indicated in the GAPs.

EFSA notes that the RMS assessed the exposure levels to both dimethoate and omethoate by assuming that omethoate is 6 times more toxic than dimethoate and compared the estimates to dimethoate AOEL. A risk assessment using the AOEL of omethoate as established during the meeting was not presented.

3. Residues

Dimethoate was discussed in the EPCO experts' meeting in September 2005 (EPCO 34).

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

The metabolism of dimethoate has been investigated in potatoes and cereals after spray applications. These studies provide information on the residue situation in foliar parts of plants (potato foliage and cereal plant) directly exposed to the spray treatment during the 40 days following the treatment, as well as in tubers and cereal grains as a result of translocation up to 30 days after the application.

Dimethoate is rapidly degraded to a wide range of metabolites, and similar routes of degradation were found in potatoes and wheat:

- oxidation to yield omethoate (metabolite II);
- Hydroxylation of the N-methyl leading to hydroxydimethoate (metabolite V), which is further conjugated to glucose;
- *O*- and *N*-demethylation of omethoate to yield *O*-desmethyl-*N*-desmethyl omethoate (metabolite XXIII);
- hydrolysis of the amide bond to give dimethoate carboxylic acid (metabolite III) and subsequent degradation to give *O*,*O*-dimethyl dithiophosphoric acid (metabolite XV);
- demethylation and rearrangement to yield *O*-desmethyl dimethoate (metabolite X) or *O*-desmethyl isodimethoate (metabolite XII)
- demethylation of omethoate to give *O*-desmethyl omethoate (metabolite XI) and subsequent hydrolysis of the amide bond to give *O*-desmethyl omethoate carboxylic acid (metabolite XX).

Isodimethoate was not found in the plant metabolism.

The metabolic profile in the foliar plant part investigated is consisting of a complex mixture of the parent compound and the here above mentioned metabolites and is varying with time. Dimethoate is rather rapidly degraded and after 14 days PHI, the parent compound represented 15% and 4% of the Total Radioactive Residues (TRR), in potato leaves and whole cereal plants respectively (plant parts directly exposed to the spray solution). Corresponding levels of omethoate were reaching 9% and 8% of the TRR. No dimethoate or omethoate was detected in the edible parts of potatoes and wheat (i.e. tubers or grains) at any time, indicating that translocation of dimethoate or omethoate did not take place to a significant extent.

At PHI relevant for the representative uses (ranging from 21 to 35 days) the metabolic pattern is consisting of a complex mixture of compounds, depending on the crop and plant part. Particular metabolites (metabolites XXIII, XX, XV, as well as the group of two metabolites XII and III which were not resolved as individual compounds) may be present at similar or higher level (up to one order of magnitude higher) than the parent compound and its oxon metabolite omethoate. This is in particular the case for cereal grains. Quantitatively, metabolite XXIII was the major residue at harvest in potato tubers as well as in wheat grain and straw.

Extensive toxicological information is available for omethoate, and specific ADI and ARfD can be set at 0.0003 and 0.002 mg/kg bw/d respectively, indicating a higher toxicity than the parent compound. Metabolite XXIII has no anticholinesterase activity in the rat on the basis of toxicological testing at 30 mg/kg body weight. Metabolite XV is not expected to be a cholinesterase inhibitor on the basis of its structure. No information is available on metabolite III which is a major rat metabolite.

Metabolites XX and XII are cholinesterase inhibitors, with a NOAEL below 30 mg/kg but less potent than dimethoate.

For monitoring it was recommended to consider not only the parent compound, but also its metabolite omethoate given its clearly higher toxicity. The levels of both compounds should be monitored separately, and not as a sum. Otherwise, residues consisting of omethoate only at the maximum level proposed for the sum would be legal, although not necessarily safe for the health of the consumer. As far as omethoate is concerned, MRLs related to the representative uses can be based on the levels recorded at respective proposed PHIs (21 to 35 days, depending on the crop) because these levels are expected to be the highest to be found under legal use (omethoate is peaking within the first 4 weeks after the application of dimethoate).

The expert meeting on toxicology (EPCA 33) recommended that the significance of the metabolites was dependent on the ratio of metabolite to parent, and that if they were present at higher levels than the parent, the notifier would be required to further address their relative toxicity to parent compound. The expert meeting on residues (EPCO 34) did not consider this advice due to lack of time.

Considering the results of metabolism studies, indicating that metabolite XX and the group of metabolites XII and III are present in amounts significantly higher than dimethoate and omethoate in cereal grains and, in some instances in foliar plant parts, it is therefore the opinion of EFSA, that the definition for risk assessment should include the parent compound and omethoate, at least, and, depending on their relative toxicity to parent, that should be further investigated, metabolites XX, XII and III to take into account their toxicological burden.

As the compounds included in the residue definition have additional effects, but are of different toxicities, a toxic equivalence factor based approach was adopted for risk assessment. Toxicity Equivalence Factors of 6 and 3 in respectively acute and chronic risk assessment should be used for accounting the contribution of omethoate. These TEF were established on the basis of a comparison of their respective cholinesterase inhibition potential rather than on the basis of direct comparison of ADI's and ARfDs. Similarly specific toxicity equivalence factors should be established for metabolites XX and XII (and III if this metabolite is a cholinesterase inhibitor) based on further toxicological testing to be carried out in order to address their relative toxicity to parent compound.

Due to the complexity of the residue pattern observed in wheat and potatoes, and in line with the discussions during EPCO 33 and 34, it is considered by the EFSA that representative uses supported in tomatoes and olives should be documented by a specific metabolism study on a fruiting crop. The representative use in lettuce is considered as covered by the data on foliar parts of metabolism in potatoes and wheat.

Supervised residue trials in accordance with the supported representative uses in olives, tomatoes, lettuce, wheat and sugar beets were submitted. In all these trials only dimethoate and omethoate were determined and levels of metabolites XX, XII and III are unknown. Therefore this information can be used as basis for MRL setting, but not for risk assessment.

For olives, 9 trials were carried out covering 3 years. Five of these trials were conducted with an application rate 40 % lower than the intended rate, but were used for evaluation. Generally omethoate residues were higher than dimethoate residues with Highest Residues (HR) found at 0.34 and 0.44

mg/kg and Supervised Trial Median Residues (STMR) found at 0.04 and 0.22 mg/kg for dimethoate and omethoate respectively.

Eight trials are available for tomatoes with dimethoate residues always below the Limit of Quantification (LOQ) of 0.01 mg/kg and omethoate residues generally below the LOQ of 0.01 mg/kg with the exception of 2 trials where low, but measurable residues were found (0.01 and 0.02 mg/kg).

For lettuce 11 trials were submitted. For a PHI of 28 days, there is a clear dependency of the final residue level on the stage of application of the product. Four trials show that residues of dimethoate and omethoate are both ranging from <0.01 to 0.02 mg/kg for treatment occurring at or shortly before growth stage BBCH 14 (4^{th} true leave unfold). Four trials indicate higher levels for both dimethoate and omethoate at harvest (ranging from 0.07 to 0.17 mg/kg and from 0.01 to 0.04 mg/kg for dimethoate and omethoate respectively) when the product is applied at growth stage BBCH 19 (9^{th} true leave unfold). After starting of the head formation, residues of dimethoate and omethoate are still considerably higher and reach 1.1 to 2.2 mg/kg and 0.17 to 0.29 mg/kg respectively.

For wheat, the applicant is supporting different GAPs for Northern and Southern regions. An early application at growth stage BBCH 23-30 (tillering) is supported for Northern Europe only, but this application is not influencing the final residue level. More important is the fact that the summer application is proposed to be carried out until growth stage BBCH 69 (end of flowering) for Northern Europe and until growth stage BBCH 75 (milky grain stage) for Southern Europe. However for the South, only 2 trials are available to support application up to growth stage BBCH 75, and it is only possible to assess the residue situation for the South for applications until growth stage 69, as for the Northern region. Eight trials were considered as valid for each region. The results obtained indicate that residues in wheat grains are very low, with residues of both dimethoate and omethoate generally below the LOQ of 0.01 mg/kg, with only 2 samples from Southern Europe with measurable dimethoate residues (0.014 and 0.024 mg/kg). In wheat straw residues were found to be higher in Southern region with a HR measured at 0.45 mg/kg.

In sugar beets, despite slight differences in the application rates and PHIs supported for Northern and Southern regions, residues in roots are always below the LOQ (0.01 or 0.02 mg/kg depending on the trial) of dimethoate and omethoate in both regions. Measurable residue levels, not exceeding 0.05 mg/kg for both dimethoate and omethoate are possible in sugar beet tops.

The reliability of the results of these supervised residue trials is supported by deep freeze storage stability studies indicating that dimethoate and omethoate residues are stable in a range of commodities (potatoes, oranges, sorghum grain and forage, cottonseed and cherries) for periods up to 27 months (6 months in the case of cherries).

The effects of processing on the nature of the residues were investigated through hydrolysis studies simulating sterilisation, baking, brewing, boiling and pasteurisation. These studies showed that dimethoate and omethoate are degraded to an extent which depends on the severity of the pH and temperature conditions. Both compounds undergo demethylations leading to metabolite X and XII in the case of dimethoate and to metabolite XI in the case of omethoate. Dimethoate and omethoate were at the end of the processing the major constituent of the residue, except under the most severe processing conditions (sterilisation) where metabolites X and XI were major. Based on the way the nature of residues is affected during processing there is no need to set specific residue definitions for

processed commodities and the definitions proposed for raw commodities are applicable. Metabolites X and XII are candidates for inclusion in the residue definition for risk assessment given their presence in raw commodities while metabolite XI is a weak cholinesterase inhibitor.

Several studies investigating the effect of processing on the residue levels under practical conditions were submitted. Wheat was processed according to commercial practices in 4 studies, however the results are not reliable to set transfer factors, given analytical difficulties at very low residue levels and given that the last treatment was applied after growth stage BBCH 75. Three studies on olive processing are available and allow processing factors for dimethoate and omethoate to be established for refined olive oil and canned olives (sterilised or not). These transfer factor are low (maximum 0.3) and lower for omethoate than for dimethoate. No processing study is available for tomatoes, but there is no related requirement as residues are low in raw tomatoes and information is present on the possible effect of processing applicable to tomatoes on the nature of residues.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

A confined rotational crop study has been submitted with lettuce, turnip and wheat planted 30 and 120 days after application of 0.56 kg dimethoate/ha (0.82 – 1.6 N dose rate) on bare soil. At maturity, TRR were below 0.05 mg/kg in all parts of the tested plants. The extractable material was polar in nature but could not be identified. Nevertheless, given the low levels of TRR, no further information needs to be requested, and no MRL or plant-back restriction is needed.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

Dimethoate metabolism studies in the goat and hen have been submitted. The exposure rates were 30 and 10 mg/kg feed for goat and hen respectively. Both studies show that dimethoate is rapidly absorbed and excreted. The highest levels of TRR were found in the liver for both species (1.2 and 0.71 mg/kg in goat and hen respectively). TRR in the other edible tissues were consistently below 0.2 mg/kg.

Dimethoate was not found in any tissues. The only structurally related metabolites identified were omethoate in goat liver, hen liver and egg whites, and dimethoate carboxylic acid (metabolite III), present in the same tissues as well as in milk.

The RMS proposed to consider in the residue definition dimethoate and omethoate only. Metabolite III is of no concern given the expected extremely low exposure of consumers. Consistently with the residue definitions proposed for plant commodities, the 2 compounds should be monitored separately while for risk assessment additive effects should be considered.

Based on information reported under point 3.1.1, the highest potential exposure level of dairy cattle, beef cattle and pigs to dimethoate and omethoate resulting from the representative uses in wheat and sugar beets and related residues in wheat straw and grains, sugar beet tops and pulp, is in the range of 0.2 to 0.5 mg/kg dry feed for both compounds. This means 2 orders of magnitude lower than the exposure used in the metabolism studies. The potential exposure of poultry is still lower as only cereal grains are a possible source of exposure. As no sign of accumulation in the animals were observed in the metabolism studies, it can be postulated that in practical conditions no residues above the LOQ of methods of analysis are to be expected. Nevertheless as extrapolations to doses 2 orders

of magnitude lower are questionable, it was the view of the expert meeting (EPCO 34) that a feeding study in lactating cows should be carried out at normal rate with simultaneous administration of dimethoate and omethoate at a ratio representative of the practical conditions.

3.3. CONSUMER RISK ASSESSMENT

Only a preliminary consumer risk assessment can be performed at this stage as insufficient reliable information is available on the relative toxicity to the parent compound of metabolites XX, XII and III and on their levels in plant commodities.

Therefore the RMS has carried out exposure assessments taking into account the combined effect of dimethoate and omethoate, using toxicity equivalence factors of 3 and 6 for chronic and acute exposures respectively, to take into account the higher toxicity of omethoate.

Chronic exposure.

The chronic dietary exposure assessment has been carried out according to the WHO guidelines for calculating National Estimated Daily Intakes (NEDI). The consumption pattern in UK for 10 population subgroups including infants, toddlers, children and adults was used, which take into consideration high individual consumption levels (at the 97.5th percentile of the distribution of consumptions in the respective populations). Residues of dimethoate and omethoate in raw commodities were considered to be at the STMR found in residue trials in wheat, olives, tomatoes and lettuce. In addition, the transfer factors determined for olive oil and canned (not sterilised) olives were used. Animal commodities were not included in the calculations, but the expected practical exposure is very low and not of nature of influencing significantly the total dietary burden. Under these conditions the most exposed consumer groups were toddlers and 4-6 year old children with respective combined intakes of combined dimethoate and omethoate amounting to 84 and 86 % of the dimethoate ADI.

Acute exposure.

The acute exposure to residues of dimethoate and omethoate in wheat grains, olive oil, canned (not sterilised) olives, tomatoes and lettuce has been assessed according to the WHO model for conducting National Estimates of Short Term Intakes (NESTI) calculations. Large portion consumption data for 10 population subgroups (including infants, toddlers, children and adults) in UK were used. Calculations were carried out considering residues of dimethoate and omethoate in composite samples of treated commodities at the level of the HR found in supervised trials (which is slightly lower than the proposed MRL). In addition, the transfer factors determined for olive oil and canned (not sterilised) olives were used. The unit to unit variability factor used was 7 for tomatoes and 5 for lettuce. Under these conditions none of the calculated NESTI of combined dimethoate and omethoate exceeded the ARfD of dimethoate. The highest NESTI value (71% of the ARfD) was calculated for the 4-6 year old child consuming treated lettuce.

It must be kept in mind that the exposure assessments summarised here above might represent an underestimation of the actual toxicological burden as metabolites XX, XII and III of dimethoate were

not included in the calculations. Considering that the chronic and the acute exposures to combined residues of dimethoate and omethoate is already close the respective toxicological trigger values for some population sub groups, it cannot be excluded that the contribution of further metabolites leads to a global exceedence of the ADI and/or exceedence of the ARfD for particular commodities and particular categories of consumers, depending on which crops are authorised.

3.4. PROPOSED MRLS

Based on the results of supervised residue trials the following MRLs are needed to accommodate the representative uses supported by the applicant:

	Dimethoate	*Omethoate*
Olives	0.5	0.5
Tomatoes	0.01*	0.02
Lettuce	0.2	0.05
Wheat	0.03	0.01*

* indicates that the MRL is set at the level of the LOQ

It must be noted that the proposal made for lettuce is valid for the use of dimethoate at growth stage BBCH 19 at the latest, and that, similarly, the proposal for wheat covers uses of the compound until growth stage 69 at the latest in both Northern and Southern Europe. Any use of dimethoate in lettuce after starting of the head formation may lead to much higher residues even for a PHI of 28 days, with potential high exceedence of the ARfD.

4. Environmental fate and behaviour

Dimethoate was discussed at the EPCO experts' meeting for Fate and Behaviour in the environment (EPCO 31) in September 2005.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

The aerobic metabolism of ^{14}C-dimethoate labelled in both methoxy groups was investigated in one soil (pH 6.2, organic matter 3.1%, clay 11%) at 22 ºC and at a soil moisture content of 75% of 1/3 bar potential. The proportion of dimethoate in soil declined rapidly to 1.9% AR at day 7. The primary degradate was CO_2, which accounted for 70% AR after 90 days. Thirteen non-volatile, extractable degradation products were found, with two individual metabolites being identified. These were O-desmethyl dimethoate (max. 2% AR at 2d) and O,O-dimethyl thiophosphoric acid (max. 0.7% AR at 2d). No unknown component accounted for more than 2% of the applied radioactivity at any time. Only 2% AR was extractable form the soil at the study end (181 days), while non-extractable residues accounted for a maximum of 21% AR after 30 days.

A study investigating the route of degradation under anaerobic conditions was conducted at 25 ºC in the dark with dimethoate radiolabelled in the methoxy groups. During the anaerobic phase of the experiment (2 days), dimethoate declined to 40% AR and O-desmethyl dimethoate and O,O-dimethyl thiophosphoric acid were identified (3.2% and 1.4% AR, respectively). During anaerobic incubation, O-desmethyl dimethoate increased up to 9.6% AR (14d post-flooding) and O,O-dimethyl thiophosphoric acid reached 4.4% AR (14d post-flooding). Two unknown metabolites reached maxima of 8.4% AR and 5.2% AR.

A soil photolysis study using thin soil layers under natural sunlight (37.5ºN latitude, California, USA) is available. Results showed that photolytic degradation on soil surfaces is unlikely to be a major route of degradation of dimethoate.

Dissipation of dimethoate under field conditions was investigated in three field studies in USA, covering five trials sites (sandy loam, silty clay loam and loamy fine sand soils). Dimethoate was applied post-emergence to green beans, grapes and bare ground in California, grain sorghum in Texas, and bare ground in New York. RMS noticed that temperatures experienced in these studies are unlikely to be representative of Northern Europe, although it is possible that the results may be of pertinence to Southern European situations. Results tended to confirm that dimethoate dissipated relatively rapidly (first order DT_{50f} values ranged from 4.6 to 9.8 days). The studies did not include analysis for any of the metabolites (all < 5% AR) observed in the laboratory soil studies. However, analysis at all five sites was conducted for omethoate, a closely related compound that has been used as a pesticide in its own right within the EU (withdrawn from the EU market with “essential use” derogations until December 2007). Omethoate was never observed in the laboratory soil incubations with dimethoate, but has been observed to be a metabolite of dimethoate in plants (refer to section 3.1). In the three sites in California, peak occurrence of omethoate was 30.6 – 67.7% w/w compared to the peak dimethoate levels. Field dissipation rates of omethoate were calculated at two of the sites, these being first order DT_{50} values of 15.0 days and 22.7 days.

The conditions and mechanisms leading to omethoate production in the environment have not been elucidated. Because of its relatively high toxicity compared to dimethoate, the RMS considered that omethoate as a soil metabolite of dimethoate must be addressed by appropriate risk assessment. In response, the applicant submitted data on the degradation of omethoate in soil under laboratory conditions. The data were from three studies predating GLP requirements and were all poorly reported. Two of the studies did not allow the calculation of reliable degradation rates due to the presence of only three or four time points. A third study allowed calculation of degradation DT_{50} values on two soils at 22ºC, these being 0.8 day and 2.4 days.

4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

In the aerobic laboratory soil degradation study with radiolabelled dimethoate described in 4.1.1 above, calculation of the degradation rate using 1st order linear regression gave a DT_{50} of 2.4 days. Three further soils were investigated (dark, aerobic conditions at 20ºC and 40% MWHC), with non-radiolabelled dimethoate to characterize the rate of degradation of the active substance. DT_{50} values

were calculated by non-linear regression using first order degradation kinetics and ranged from 2.0 to 4.1 days, indicating that dimethoate is low persistent.
Degradation of dimethoate is slower under anaerobic conditions (1st order DT_{50} = 18 days).
In the soil photolysis study, dimethoate experienced a slightly slower rate of degradation (1st order DT_{50} = 10.5 days) compared with dark control samples (1st order DT_{50} = 7.9 days).
Laboratory studies on omethoate with two soils allowed calculation of the rate of degradation for this metabolite. DT_{50} values were 0.9 days and 2.8 days, indicating that omethoate is low persistent.
PECsoil calculations were performed assuming a worst case first-order DT_{50} of 9.8 days from field studies; this is the longest DT_{50} value from either field studies or aerobic soil laboratory degradation studies.

4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The adsorption/desorption characteristics of dimethoate radiolabelled in the carboxy position were investigated on five different soils and one sediment (pH ranging from 5.7 to 7.7 and organic carbon contents of 0.48 – 2.05%). Dimethoate can be classified as high to very high mobile in soil (K_{foc} ranged from 16.25 to 51.88 mL/g for the soils with 1/n of 0.965-1.05; the sediment had a K_{foc} of 19.5 mL/g with 1/n of 0.989). There was no apparent relationship between K_{foc} and soil pH.
A batch adsorption study with three soils was conducted also with the unlabelled metabolite omethoate. The K_{oc} values established on three soils using a single concentration were 16-87 mL/g, indicating that a high to very high mobility in soil also for omethoate.
A column leaching study was performed with dimethoate radiolabelled in both methoxy groups using four different soil types (sand, sandy silt loam, clay loam, and sandy loam). The study confirmed the leaching potential of dimethoate as indicated by the batch sorption study, with 77 – 93% AR eluted from the columns as dimethoate. As part of the same study, aged (30 days of aerobic incubation) soil column leaching was investigated. Dimethoate accounted for 4.9% AR in the extracted radioactivity, dimethyl phosphoric acid 3.3% AR and “other” 0.8% AR. Following leaching, only 5.1% AR was found in leachate (presumed to be unchanged dimethoate), compared to 86.7% AR from the non-aged. The study suggested that aerobic degradation in soil prior to rainfall can significantly reduce the leaching potential of dimethoate.
A lysimeter study was conducted on two sandy soil monoliths in Switzerland. Radiolabelled dimethoate was applied at a rate corresponding to 1.2 kg a.s./ha to the lysimeter soil cropped with white cabbage until the end of a second cropping year. A second application was not made in the second year. In the first year, annual average concentrations of radioactivity in leachate were 0.697 * 0.752 µg/L dimethoate equivalents, and in the second year 0.220 – 0.301 µg/L dimethoate equivalents. Dimethoate itself was not present in leachate, and a large number of metabolites, including omethoate, could be excluded. The radiolabelled material in the leachate appeared to be variable, mostly polar, some of which was anionic with a wide range of molecular weights. Whilst the possibility of discreet metabolites exceeding 0.1 µg/L as an annual average based on their true molecular weight cannot be excluded, the overall database on dimethoate suggests that the radiolabelled components are likely to be transient or impersistent. Because of some shortcomings of

the study (such as the application rate not corresponding to the highest total dose proposed in the GAP, no mass balances were given, and analytical techniques limitations), its reliability was discussed at the meeting of experts. It was concluded that the lysimeter study can be utilised in a qualitative manner in respect of the representative uses and whether the study is included or not does not affect the outcome of the risk assessment.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

A hydrolysis study conducted at 25ºC in sterile buffer solution at pH 5, 7 and 9 is available. The study indicated that hydrolysis of dimethoate was pH dependent, with relatively slow degradation at pH 5 and 7 (1^{st} order half-lives of 156 days and 68 days respectively), but much faster degradation at pH 9 (1^{st} order DT_{50} = 4.4 days). At all three pH conditions investigated, O-desmethyl dimethoate was found to exceed 10% AR by study end (30 days); maximum formation was at pH 9 where peak formation was 62.2% AR. In addition, O,O-dimethyl thiophosphoric acid was also formed at maximum of 36.0% AR at pH 9. This indicated that both O-desmethyl dimethoate and O,O-dimethyl thiophosphoric acid are relatively stable to hydrolysis.

In an aqueous photolysis study conducted at 25ºC dimethoate showed less than 10% degradation over 100 days when illuminated (xenon arc lamp, equivalent clear sunny day in equatorial regions); there was very little difference between the degradation in illuminated and dark control samples. The photolytic half-life was estimated as greater than 175 days, and the quantum yield was estimated as being close to zero. In total, photolytic metabolites accounted for maximum 5.7% AR. Thus, under environmental conditions, photolysis would not be expected to be a major route of dissipation in surface water.

A ready biodegradability study demonstrated that dimethoate would be classified as not readily biodegradable.

Degradation in two laboratory water/sediment systems was studied (20ºC): one with Rhine water (pH 8.2) and loamy sand sediment (0.9% organic carbon), and another with pond water (pH 7.2) and sandy clay sediment (5.4% organic carbon). The systems were dosed with ^{14}C dimethoate radiolabelled in both methoxy groups. The water phase 1^{st} order DT_{50} were 14.8 days and 12.5 days for the Rhine and pond systems respectively (r^2>0.9). The RMS noted that in practice the water phase DT_{50} values do not reflect the hydrolytic degradation that may be expected from the pH, and other factors and process may have a greater influence on fate of dimethoate in natural aquatic systems than hydrolysis alone. Mineralisation appeared to be relatively extensive with up to 28.0% AR recovered as CO_2. Incorporation into unextracted residues appears to be the major route of dissipation as up to 51.5% AR was present as unextracted residues at the study end (105 days). In the water phase, up to eight metabolites were detected. Only one metabolite occurred at greater than 3.7% AR on an individual basis at any time in the water phase, this being O-desmethyl dimethoate which occurred at a maximum of 17.6% AR at 30 days and declined to < 2% AR by 105 days. A similar situation occurred in sediment where up to 11 metabolites were detected, with only O-desmethyl dimethoate occurring at maximum 4.6% AR (day 30). Estimated (maximum concentration occurred with only

three time points before the end of the study) DT_{50} values for O-desmethyl dimethoate for the total system were <30 days and <23 days in the Rhine-river system and pond system respectively.

The exposure assessment to surface water (calculation of predicted environmental concentrations (PEC) in surface water and sediment) has been appropriately completed for the spray drift route of entry assuming 1st order DT_{50} in water phase of 14.8 days (worst case lab water/sediment study). The meeting of experts agreed that contamination of surface waters via sub-surface drainflow or surface run-off is presently addressed at Member State level. For this reason, no consideration of potential contamination of surface waters by the soil metabolite omethoate has been made in this evaluation. In addition, a conservative approach to calculate pseudo accumulated PEC_{sw} for multiple application regimes was performed for sediment dwelling organism risk assessment purposes (refer to section 5.2).

Because reliable dissipation rate for the metabolite O-desmethyl dimethoate was not available, only initial PEC_{sw} values were calculated, assuming that there is no degradation of the metabolite between applications. Likewise, the maximum concentration in surface water of the major metabolite detected in the sterile aqueous hydrolysis study O,O-dimethyl thiophosphoric acid, was calculated for the olive use.

Environmental monitoring data on dimethoate, deriving from a number of European countries over a long time period, were provided by the applicant. Contamination of surface waters was confirmed, and may have been due to combinations of spray drift, surface run-off and sub-surface drainage. However, the monitored concentrations were generally less than or comparable to the surface water PEC values calculated in this evaluation.

4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The simulation model FOCUS PELMO 2.2.2 was used to estimate the concentrations of dimethoate and its metabolite omethoate in the leachate at one metre soil depth following use according to the proposed GAPs under consideration. PEC_{gw} for dimethoate were calculated for all representative uses in Southern and Northern Europe except for dimethoate use in lettuce which is restricted to the greenhouse. As the use on olives gave the highest predicted concentrations of dimethoate leaching to 1m depth, groundwater modelling for the metabolite omethoate was restricted to this use. The RMS recalculated PEC_{gw} using more appropriate input parameters of DT_{50} (2.6 days as the mean DT_{50lab} value derived from the degradation rates normalised to 20ºC and pF2), K_{oc} (30.1 mL/g as the mean K_{oc} value, excluding the value derived from the sediment) and 1/n (1.019 as the appropriate mean value obtained from the available 1/n values) for dimethoate, and appropriate input parameters of DT_{50} (2.8 days), and 1/n (1.0) for omethoate. In addition, different application dates were set for olives and Northern European crops of sugar beet and winter wheat. The EPCO experts' meeting discussed the relevance of dimethoate field studies to derive degradation rates in soil. Following enquiries from the experts', the RMS provided in an addendum (May 2006) the specific rationale for using laboratory derived DT_{50} values rather than the longer field DT_{50} value for $FOCUS_{gw}$ modelling. It is the opinion of the EFSA that the argument presented by the RMS is appropriate and satisfactory. With the exception of olives, all crops and scenarios indicated that contamination would be less than

0.1 µg/L for both the active substance and omethoate. For the Piacenza scenario with olives, the 80th percentile concentration for dimethoate was 0.148 µg/L and 0.412 µg/L for omethoate. Thus, it is demonstrated that safe uses with respect to groundwater contamination exist for the proposed GAPs, although Member States must reassure themselves that actual use at vulnerable sites under their own local conditions will not lead to exceedance of 0.1 µg/L.
The overview of the monitoring data on dimethoate in groundwater indicated that, where results were present, none indicated groundwater contamination at > 0.1 µg/L.

4.3. FATE AND BEHAVIOUR IN AIR

The vapour pressure indicates that dimethoate would be classified as "slightly volatile" (2.46 x 10^{-4} Pa at 25ºC), although the Henry's Law coefficient suggests that the extent of volatilisation loss from moist soil or water surfaces is likely to be relatively low. This was supported by specific volatility studies using soils (1.3% AR 24 hours after application). However, volatilisation from plant surfaces was greater than from soil (13.8% AR 24 hours after application).
The calculated half-life for photochemical oxidative degradation in the atmosphere by the method of Atkinson was 1.6 hours. This suggested that even if dimethoate were to enter the atmosphere, it would be degraded quickly and would not be subject to long-range transport.

5. Ecotoxicology

Dimethoate was discussed at the EPCO experts' meeting for ecotoxicology (EPCO 32) in September 2005 in York (UK). The discussion was based on the data in the DAR and addendum 1. New data, submitted by the notifier a few days before the meeting, was not taken into account as this new data was not evaluated by the RMS in an addendum and not all experts had sufficient time to consider this new information.

The EPCO Experts' meeting decided that the applicant should provide a clarification that the test material used in the studies in the section on ecotoxicology covers the specification of the technical material regarding impurities.

5.1. RISK TO TERRESTRIAL VERTEBRATES

The risk to birds and mammals was calculated according to the Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC (SANCO/4145/2000). The risk was calculated for insectivorous birds and mammals in tomatoes as the foliage of tomatoes is considered to be a non-attractive food source at the time of application. In wheat the risk was calculated for an insectivorous and large herbivorous bird and a small insectivorous and herbivorous mammal. The risk was calculated for a small herbivorous mammal and an insectivorous bird for the use in olives and for an insectivorous bird, a medium herbivorous bird and a medium herbivorous mammal in sugar beet. No risk assessment was considered necessary for the use in lettuce as this is a glasshouse use. As the entry of birds and mammals to permanent glasshouse structures is limited,

exposure will be low and hence also the risk is considered to be low. This was accepted by the EPCO experts' meeting.

The risk was assessed for dimethoate and its major plant metabolite omethoate. Both substances are cholinesterase inhibitors. Omethoate is considered to be of similar toxicity to birds as the parent dimethoate. Omethoate is considered to be 7 times more acutely toxic than dimethoate to mammals and 3 times more toxic on a chronic time-scale based on acute LD_{50}-values and chronic NOEC values respectively. There was a discussion about the use of a toxic equivalence factor (TEF) of omethoate and dimethoate in the risk assessment at the EPCO experts' meeting. The meeting agreed that advice should be sought from the mammalian toxicology expert meeting. EPCO 33 on toxicology agreed on the order of magnitude of 7 and 3 for the difference in acute and chronic toxicity respectively between dimethoate and omethoate for mammals but did not discuss the principle of a TEF. See also note by the EFSA in section 2.8 of this conclusion. A combined residue for dimethoate and omethoate was used without adjustment (TEF=1) in the risk assessment for birds. In the risk assessment for mammals omethoate residue was multiplied by 7 (TEF=7) and added to the dimethoate residue for the acute risk assessment. Likewise a combined residue with a TEF of 3 was calculated for the long term risk assessment for mammals. These combined residue values were compared to endpoints for dimethoate.

Based on the first tier risk assessment for birds a further refinement is necessary for all representative uses evaluated except for lettuce (see above) (TER = 0.27 – 7.91).
Several refinement options are proposed by the applicant. All options reviewed by the experts' meeting will be discussed below.
The applicant proposed to use the LC_{50} of the dietary study with birds to refine the acute risk assessment. This was not accepted by the experts' meeting. The LD_{50} should be used for the acute risk assessment as was proposed by the RMS.
The meeting accepted the greylag goose as a focal species for herbivorous birds in cereals. The mean weight for geese, and consequently the FIR/bw, was not accepted as the mean for male and female geese was used instead of the lowest value for female geese. Furthermore the meeting accepted the wood pigeon as a focal species for herbivorous birds in sugar beet in northern Europe. The use of blue tit as an insectivorous species for all outdoor representative uses was not agreed in the meeting. It was decided that the applicant should provide further evidence to support their choice of focal species, both for herbivorous and for insectivorous species and both for northern and southern Europe.
A next refinement step is the use of measured residue values. It was noted by the EFSA that the proposed RUD values in the addendum 1 do not correspond to the residue trials listed in the DAR, i.e. they are lower than expected based on the residue data in Table B.9.11 in the DAR. This should be clarified when the refined risk assessment is revised. The experts' meeting considered that regarding the DT_{50} values, pooling of residue data from separate trials should be avoided as it can influence the resultant DT_{50}-value used in the refined risk assessment. Thus the meeting concluded that the DT_{50}-values should be calculated for the individual studies. It must be made more transparent how the

DT_{50}-values for wheat and sugar beet were calculated and the risk assessment needs to be revised accordingly if necessary. The DT_{50} for omethoate in ground vegetation does not appear to fit the actual data which should be verified. Furthermore the meeting expressed a concern about extrapolating the new residue data on citrus to northern Europe. This concern needs to be addressed.
AT pointed out in the reporting table that the use of time weighted average factors (ftwa) for the short term risk assessment is not in line with the guidance document. The EFSA noted that the interval of 21 days, taken into account for the ftwa for the long term risk assessment, exceeds the interval between two applications in tomatoes. Furthermore the EFSA doubts the extrapolation from the residue data from sugar beet leaves to small seeds. It should be noted that the use of the focal species blue tit, consuming small seeds, was not agreed by the experts' meeting (see above).
As further refinement options FIR (Food Intake Rate), PD (Proportion in the Diet), PT (Proportion in the Treated area) and a dehusking factor for several focal species were proposed.
The meeting did not accept the applicants' reductions of PT and PD as there were doubts on the relevance of the data to support these assumptions. The applicant must submit further data to support their proposals.
The meeting considered dehusking as highly variable even within the same species. A justification of the proposed use of a dehusking factor of 0.13 by the blue tit is considered necessary.
The applicant proposed an HD5-approach, making the case that this was supported by toxicity data for several species. The meeting noted that multiple acute toxicity values had been included for the same species, and that, in some cases it was unclear which species had been tested (i.e. wild duck). In the dietary studies the endpoints had not been expressed as daily dietary doses. Overall the range of species/families tested was narrow. The applicant also proposed to reduce the uncertainty factor to 1 as there are toxicity data on several species. The expert meeting did not accept this approach as it stands and made the point that for the long term risk there are unlikely to be sufficient toxicity values. Some of the studies are old and may not be acceptable according to the guidelines. All the studies from which endpoints are used should be made available.

In conclusion, to address the risk to birds, the applicant should provide a revised assessment of the risk to birds from the outdoor uses. This revised assessment should include a more detailed justification for: selection of focal species for all representative outdoor crops, refinements of PD and PT, residue decline (residue data should not be pooled, DT_{50} for omethoate in ground vegetation from the residue trial in citrus), extrapolation of citrus residues data from southern to northern Europe, use of a dehusking factor… If use is to be made of the HD5-approach then full details of all toxicity values must be provided, the dietary endpoints must be expressed as daily dietary doses and further support for any claimed reduction in uncertainty factors must be presented.

Based on the first tier risk assessment for mammals a further refinement is necessary for the acute and long term risk to small herbivorous mammals (TER = 0.18 – 7.47) and the long term risk to small insectivorous mammals in wheat (TER = 3.87 for northern Europe), the acute and long term risk to small herbivorous mammals in olives (TER = 3.68 and 0.14 resp.), the long term risk to medium

herbivorous mammals in sugar beet (TER = 1.67- 2.0) and the long term risk to small insectivorous mammals in tomatoes (TER = 4.44).
Several refinement options are proposed by the applicant. All options reviewed by the experts' meeting will be discussed below.
The meeting had the same comments on the residue decline data as for birds (see above). The EFSA noted that the interval of 21 days, taken into account for the refined ftwa for the long term risk assessment, exceeds the interval between two applications in tomatoes. As for birds, the EFSA doubts the extrapolation from the residue data from leafy crops to small seeds and noted furthermore that for the acute risk not the default RUD of 87 mg/kg was taken into account but the lower 90th percentile for leaves of 71 mg/kg from table 10 on p. II-9 of appendix II to SANCO/4145/2000.
Regarding the focal species, the meeting considered that the choice appeared reasonable but was not fully supported by data by the applicant. The choice of the hare as a small herbivorous mammal in cereals was debated during the meeting. Smaller mammals in cereals are actually omnivorous so the hare might be the smallest totally herbivorous species. The applicant must provide evidence to support their choices.
As for birds, the applicant must more fully justify the reduction of the PD and PT values.
Body weights should be the lowest rather than the mean where there is a difference between male and female body weights with regard to refining FIR/bw.
In conclusion the experts' meeting asked for a revised risk assessment for mammals which should address the concerns regarding the residue data and include a better justification for the selection of focal species and for the proposed refinements of PD and PT.

The EPCO experts' meeting requested the RMS to make an assessment available of the risk to birds and mammals from contaminated drinking water. This assessment was not made available yet.

As the logPow is below 3 the risk from secondary poisoning to birds and mammals is considered to be low.

5.2. RISK TO AQUATIC ORGANISMS

Daphnia magna is the most sensitive aquatic organism on an acute and chronic time-scale when tested with dimethoate and the formulation Roxion (400 g a.s./L EC formulation). This formulation is considered to be similar to the lead formulation Danadim dimethoate 40. The NOEC for *D. magna* is the pivotal endpoint which drives the risk assessment. In the risk assessment the NOEC for *D. magna* from the study with the active substance was taken into account. Expressed in mg active substance per L, the NOEC from the study with the formulation is lower but this can be attributed to the larger gap between concentrations tested in the formulation study compared to the active substance study.

Based on this assessment, the risk can be considered as low for the representative uses in wheat in southern Europe and sugar beet in northern Europe. No TER-values were calculated for the use in lettuce. But also for the use in lettuce the risk to aquatic organisms is considered to be low as the intended use rate is lower than in wheat for southern Europe. Also only one application is intended

and drift is expected to be much lower from a greenhouse than from a wheat field. The risk to aquatic organisms has to be considered as high for the representative uses in wheat in northern Europe, olives, sugar beet in southern Europe and in tomatoes for which risk mitigation measures such as a bufferzone of 5 metres, 20 metres, 5 metres and 10 metres respectively are considered necessary.

Dimethoate can be found in concentrations above 10% in the sediment and therefore a risk assessment for sediment dwelling organisms was performed. The NOEC from the study with *Chironomus riparius* was discussed at the EPCO experts' meeting. There was a statistically significant difference from the control group for the two lowest concentrations tested of 0.05 and 0.1 mg/L. However the effects at these concentrations were still within the criteria for acceptability of the control and there was no dose- response at these rates. The meeting agreed that because of the potential effects seen at the lowest doses then in this case the EC_{10} of 0.08 mg/L should be used. When writing this conclusion the EFSA noted that 0.08 mg/L corresponds to the EC_{05} of this study and that the EC_{10} mentioned in the original study report equals 0.096 mg/L. Which of these values is taken into account in the risk assessment for aquatic organisms will not change the outcome as this risk assessment is driven by the NOEC of 0.04 mg a.s./L for *D. magna* (see above).

Two major metabolites, O-desmethyl dimethoate and O,O-dimethyl thiophosphoric acid, were identified in the water/sediment study (see 4.2). Acute toxicity studies on *O. mykiss* and *D. magna* are available for both metabolites. Additionally a study on *S. subspicatus* is available for O-desmethyl dimethoate. From these studies it can be concluded that both metabolites are less toxic to aquatic organisms than the parent compound. The risk from these metabolites is covered by the risk assessment from the parent.
Omethoate is considered a major metabolite in groundwater. No studies on aquatic organisms are available for this metabolite. Therefore the EFSA proposes that the applicant should address the risk to aquatic organisms from this metabolite.

Dimethoate is not an herbicide so studies on aquatic plants are not considered necessary.

As the log Pow is below 3 for dimethoate and O-desmethyl dimethoate, no studies on bioconcentration in fish are considered necessary for these substances. The Log Pow for O,O-dimethyl thiophosphoric acid is not known but as this metabolite is more polar than the parent it is considered unlikely that it will bioaccumulate.

5.3. RISK TO BEES

Acute contact and oral toxicity studies with dimethoate are available. Dimethoate is recommended as the toxic standard in the OECD Guidelines 213 and 214 (oral and acute toxicity to bees respectively). In these guidelines the range given for the 24 hour LD_{50} is 0.1-0.35 µg a.s./bee and 0.1-0.30 µg a.s./bee for the oral and acute toxicity respectively. Therefore the acute and oral LD_{50} was set at 0.1 µg a.s./bee. The resulting HQ values breach the appropriate Annex VI trigger value indicating a high risk to bees for the representative outdoor uses evaluated.

No HQ values were calculated for the glasshouse use in lettuce. The risk for this use is considered to be low as it is not expected that bees will come in contact with the product due to the use in a glasshouse and lettuce is not likely to be pollinated.

Sugar beet is regarded to be unattractive to bees in general. Furthermore there is a high control of weeds in this crop. Therefore the risk to bees in sugar beet is regarded to be low due to the limited exposure situation. During the second evaluation meeting the Netherlands reported that several incidents with high bee mortality were observed in the Netherlands in potatoes. Potatoes is normally also regarded as a non-attractive crop to bees but in the incidents the bees were attracted by honeydew to the potato crops. The Netherlands expressed a concern that this might also be the case for sugar beet and therefore does not agree with the reasoning discussed above.

Several higher tier studies were submitted to address the risk to bees.

A high mortality was observed for bees exposed to residues aged for up to 120 hours on detached apple leaves previously treated with Dimethoate 40% EC at 720 g a.s./ha. Effects were below 20% following continuous exposure for 24 h to 12 day old aged residues on apple leaves. After continuous exposure for 48 hours, mortality was 35% when exposed to 12 day old residues and 10% when exposed to 14 day old residues.

Mortality levels in bees ranged from 5 to 95% when exposed for 24 hours to flowering oilseed rape treated the previous day with Dimethoate 40% EC at 890 g a.s./ha.

Results from a study during which bees were fed on nectar from glasshouse grown Bluebell and oilseed rape, treated previously with 0.1 and 0.2% dimethoate solutions respectively, indicate that residues of dimethoate remain toxic to bees for several days.

In a field study in apple orchards there is evidence of a weak repellency effect to bees, but results are difficult to relate to the representative uses due to differential attractiveness of crops and the presence in the trials of high proportions of untreated trees.

In a tunnel test over 50% mortality and subsequent loss of hive condition was observed following application of Dimethoate 40% EC at 500 g a.s./ha whilst bees were actively foraging on artificial aphid honeydew in cereals. Effects were less pronounced but still high at 400 g a.s./ha.

The risk to bees from the plant metabolite omethoate is considered to be covered by the available field studies.

The submitted higher tier studies indicate a high risk to bees present in the field at the time of application and for short periods after the treatment(s). The EPCO experts' meeting recommends risk mitigation measures such as to avoid all contact with bees. The available data are not sufficient to establish precise withholding periods.

5.4. RISK TO OTHER ARTHROPOD SPECIES

Standard laboratory studies with *Aphidius rhopalosiphi* and *Typhlodromus pyri* are available during which a high toxicity to these standard indicator species was observed. Effects on mortality were below 50% at in-field dose rates if the residues were aged for 21 days in an extended laboratory study with *A. rhopalosiphi* and *Chrysoperla carnea*.

A large number of cereal field trials examining the effects on non-target arthropod populations of a single spray of 340-500g dimethoate/ha are available. These studies took place mostly in the spring or

early summer, with a few trials including autumn application. High initial levels of mortality of a broad range of non-target arthropods were observed, with recovery or partial recovery of the vast majority of groups within 4-7 weeks. Lack of prey sometimes accounted for incomplete in-crop recovery of predator numbers. Ground dwelling predators (e.g. carabids) showed a variable recovery rate in the reported trials, with re-establishment times of between 7 days and 6 months.
Details from cereal and apple orchard field trials using low doses of dimethoate indicate no effects on non-target arthropods from respective use rates of 1.44 g and 10.8 g a.s./ha.

The risk to non-target arthropods was discussed at the EPCO experts' meeting. The first tier HQ values exceed the Escort II trigger value of 2. The available field studies to address this first tier risk were not conducted at sufficiently high dose rates to address all uses. The meeting agreed that the field studies demonstrated potential for recovery within one year for uses up to 500 g a.s./ha. However the applicant needs to address the in-field risk to NTA from uses above 500 g a.s./ha.
There was detailed discussion of the field studies to address the off-field risk. These field studies included applications at low rates on multiple species. The meeting agreed that the studies were valid since significant impacts were observed in the toxic standards. Furthermore the meeting agreed that the endpoint from the study was a NOEC based on initial effects and not on recovery and that the species most sensitive in the lab studies were present in the field studies. The meeting agreed that due to the short DT_{50}-value (available in the risk assessment for birds and mammals) there is no requirement for a MAF. Therefore the needed bufferzones were recalculated in addendum 3 of May 2006 based on spray drift values for one application. Bufferzones of 10 m in wheat (SE) and sugar beet (NE), of 15 m in wheat (NE) and sugar beet (SE), of 30 m in tomatoes and of 75 m in olives are proposed based on the lowest NOEC of 1.44 g a.s./ha from the cereal field trial. In conclusion the meeting considered the field studies sufficient to demonstrate that with appropriate risk mitigation measures such as bufferzones the off-field risk is addressed.
The risk to non-target arthropods for the glasshouse use in lettuce is considered to be low due to the limited exposure situation in glasshouses.

5.5. RISK TO EARTHWORMS

Studies on the acute toxicity of dimethoate and the formulation Roxion (400 g a.s./L EC formulation) to earthworms are available. This formulation is considered to be similar to the lead formulation Danadim dimethoate 40. Based on these studies the acute risk to earthworms from dimethoate can be regarded as low.

Studies on the long term toxicity of dimethoate and the formulation Perfekthion (400 g a.s./L EC formulation) to earthworms are available. This formulation is considered to be similar to the lead formulation Danadim dimethoate 40. Based on the study with the active substance the long term risk to earthworms can be considered as low for all representative uses evaluated except for the use in sugar beet (southern Europe). This assessment was refined by using the study with the formulation during which 2 soils, a standard artificial Lufa soil and a 50:50 mix standard artificial soil/sandy loam soil, were tested. The test on the standard artificial Lufa soil resulted in a NOEC below 5.2 mg a.s./kg

soil. The second part of the study with a 50:50 mix standard artificial soil/sandy loam soil resulted in a NOEC = 5.2 mg a.s./kg soil. The experts' meeting agreed to use the endpoint from the study with the mixed soil as it is considered to reflect more closely an agricultural soil. Based on the NOEC of 5.2 mg a.s./kg soil also the long term risk for the use in sugar beet (southern Europe) can be regarded as low (TER = 8.1).

Omethoate was identified as a major metabolite in soil in the aerobic soil degradation study. To address the risk from this metabolite an acute toxicity study with the formulation Folimat (50% SL omethoate) was submitted. The rapporteur noted the apparent 2.7 fold increase in acute toxicity of dimethoate in the acute toxicity study with the active substance compared to the formulated product endpoint when expressed in terms of active substance and therefore proposed to apply a similar factor to the endpoint of the Folimat study. Based on this corrected endpoint the acute toxicity to earthworms from omethoate can be considered as low. No studies on the long term toxicity from omethoate to earthworms are available. The maximum DT_{90} for soil in the field equals 75.4 days for omethoate. Therefore the experts' meeting agreed with the RMS that a long term toxicity study with omethoate on earthworms is only necessary for uses with more than 3 applications per year. This is only the case for olives for the representative uses evaluated.

5.6. RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

The maximum DT_{90} for soil in the field equals 32.6 days for dimethoate and 75.4 days for the soil metabolite omethoate. Therefore no studies on the effects of dimethoate and omethoate on other soil non-target macro-organisms were considered necessary and hence the risk is considered to be low.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The effects of dimethoate, Dimethoate 40% EC and Folimat, a formulation containing 51.1% omethoate, were tested on soil microbial respiration and nitrogen transformation. No deviations of more than 25% after 28 days were observed at concentrations of 8.0 mg a.s./kg soil and above which is above the initial PEC-values in soil (highest PEC_{soil} = 0.64 mg/kg soil for dimethoate and 0.78 mg/kg soil for omethoate), i.e. no breaching of the Annex VI trigger value. Therefore the risk to soil non-target micro-organisms from dimethoate is considered to be low for the representative uses evaluated.

5.8. RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

The effects of the formulation Perfekthion (400 g a.s./L EC formulation) was tested post-emergence on six crop species. Phototoxic effects were below 25% at 1800 g a.s./ha. For one plant species (sunflower) an effect of 28% on plant weight was observed. The risk to non-target plants is considered to be low as effects were below 50% at a dose rate which exceeds the in-field dose rates for the representative uses.

The EFSA does not consider it necessary to submit biological screening data for the groundwater metabolite omethoate as this substance is a known pesticide.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

The 3 hour EC_{50} for dimethoate on the activity of activated sludge exceeds 1000 mg/L. Based on this study the risk to biological methods of sewage treatment is considered to be low.

6. Residue definitions

Soil

Definitions for risk assessment: dimethoate, omethoate
Definitions for monitoring: dimethoate, omethoate

Water

Ground water

Definitions for exposure assessment: dimethoate, omethoate
Definitions for monitoring: dimethoate, omethoate

Surface water

Definitions for risk assessment:
surface water and sediment: dimethoate
surface water only: O-desmethyl dimethoate, O,O-dimethyl thiophosphoric acid
Definitions for monitoring: dimethoate

Air

Definitions for risk assessment: dimethoate, omethoate
Definitions for monitoring: dimethoate, omethoate[7]

Food of plant origin

Definitions for risk assessment: Sum of dimethoate and 6 x omethoate expressed as dimethoate for acute risk assessment; Sum of dimethoate and 3 x omethoate expressed as dimethoate for chronic risk assessment ***(depending on their relative toxicity to parent to be determined on the basis of appropriate toxicological testing and their possible specific impact on the toxicological burden, metabolites XX, XII and possibly III to be included in the definition with appropriate toxicity equivalence factors)***
Definitions for monitoring: Dimethoate and omethoate to be determined separately

[7] The inclusion of the metabolite omethoate in the definition for air is precautionary since omethoate has been withdrawn from List 2 as an active substance and is not included on Annex I.

Food of animal origin

Definitions for risk assessment: Sum of dimethoate and 6 x omethoate expressed as dimethoate for acute risk assessment; Sum of dimethoate and 3 x omethoate expressed as dimethoate for chronic risk assessment

Definitions for monitoring: Dimethoate and omethoate to be determined separately

Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

Soil

Compound (name and/or code)	**Persistence**	**Ecotoxicology**
Dimethoate	Low persistence ($DT_{50\ lab}$ = 2.0-4.1 d, 20-22°C, variable soil moisture content)	See 5.5, 5.6 and 5.7.
Omethoate	Very low to low persistence ($DT_{50\ lab}$ = 0.8-2.4 d, 22°C, soil moisture status unclear)	Relevant due to the similar acute risk to earthworms than the parent.

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**
Dimethoate	high to very high mobile (Koc = 16.25 – 51.88 mL/g)	FOCUS PELMO: 0.1 µg/L trigger exceeded in 1 out of 9 pertinent FOCUS groundwater scenario (Piacenza scenario for olives use; 80th percentile concentration = 0.148 µg/L) Lysimeter: no, annual average concentrations < 0.1 µg/L	Yes	Yes	See 5.2.

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
Omethoate	high to very high mobile (Koc = 16.0 – 87.0 mL/g)	FOCUS PELMO: 0.1 µg/L trigger exceeded in 1 out of 9 pertinent FOCUS groundwater scenario (Piacenza scenario for olives use; 80th percentile concentration = 0.412 µg/L) Lysimeter: no, annual average concentrations < 0.1 µg/L	Yes	Yes	No conclusion possible as no data on aquatic organisms is available.

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Dimethoate	See 5.2.
O-desmethyl dimethoate (water phase only)	Not relevant.
O,O-dimethyl thiophosphoric acid (from hydrolysis study)	Not relevant.

Air

Compound (name and/or code)	**Toxicology**
Dimethoate	Harmful by inhalation LC_{50} 1.68 mg/L (4 hours, whole body) No short term data
Omethoate[8]	Acutely toxic by inhalation LC_{50} =0.287 mg/L No short term data available

[8] The inclusion of the metabolite omethoate in the definition for air is precautionary since omethoate has been withdrawn from List 2 as an active substance and is not included on Annex I.

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

- It could be necessary to require a new shelf-life study to demonstrate that the content of the relevant impurity omethoate is upon storage in compliance with the maximum content as defined by FAO (data gap identified after the meeting of experts; date of submission unknown; refer to chapter 1).
- Clarification of the sensitising properties of dimethoate (relevant for all used; a Local Lymphnode Assay (LLNA) was provided to the RMS in May 2006; the study was not evaluated not peer reviewed, refer to point 2.2).
- A metabolism study on a plant belonging to the fruit category and carried out under conditions representative of the supported uses in tomatoes and olives (relevant for representative uses in tomatoes and olives; data gap proposed by EFSA, in line with discussions in expert meetings on toxicology and residues; a study on olives has been made available to the RMS, but was not evaluated nor peer reviewed; refer to point 3.1.1).
- Further information to determine the relative toxicity (cholinesterase inhibition) of metabolites III, XII and XX to parent compound in order to define appropriate Toxicity Equivalence Factors for acute and chronic risk assessments (relevant for all representative uses; data gap identified in experts' meeting; submission date unknown; refer to point 3.1.1).
- Depending on the required information on their relative toxicity to parent compound, supervised residue trials with analysis of metabolites XII and XX, and if relevant of metabolite III (relevant for all representative uses; data gap proposed by EFSA, in line with discussions in expert meetings on toxicology and residues; submission date unknown; refer to point 3.1.1).
- A feeding in lactating cows study carried out at normal rate with simultaneous administration of dimethoate and omethoate at a ratio representative of the practical conditions (relevant for uses in wheat and sugar beets; data gap identified in expert meeting; submission date unknown; refer to point 3.2).
- A clarification that the test material used in the ecotox studies covers the specification of the technical material regarding impurities (relevant for all representative uses; position paper submitted by the applicant, not evaluated; refer to section 5).
- A revised assessment of the risk to birds from the outdoor uses. This revised assessment should include a more detailed justification for e.g. selection of focal species for all representative outdoor crops, refinements of PD and PT, residues decline (residue data should not be pooled, DT_{50} for omethoate in ground vegetation from the residue trial in citrus), extrapolation of citrus residues data from southern to northern Europe, use of a dehusking factor. If use is to be made of the HD5-approach then full details of all toxicity values must be provided, the dietary endpoints must be expressed as daily dietary doses and further support for any claimed reduction in uncertainty factors must be presented (relevant for all outdoor uses; position paper submitted by the applicant, not evaluated; refer to point 5.1).
- A revised risk assessment for mammals which should address the concerns regarding the residue data and include a better justification for the selection of focal species and for the

proposed refinements of PD and PT (relevant for all outdoor uses; position paper submitted by the applicant, not evaluated; refer to point 5.1).

- The risk to aquatic organisms for the ground water metabolite omethoate needs to be addressed (relevant for the use in olives; proposed by the EFSA, not discussed at an experts' meeting; submission date not known; refer to point 5.2).
- The in-field risk to NTA from uses above 500 g a.s./ha needs to be addressed (relevant for the uses in wheat in northern Europe, olives, sugar beet in southern Europe and tomatoes; position paper submitted by the applicant, not evaluated; refer to point 5.4).
- To support uses of more than 3 applications per year a chronic earthworm study using omethoate is required (relevant for the use in olives; submission date not known; refer to point 5.5).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as an insecticide which comprises broadcast spraying to control biting and sucking insects in wheat, olives, sugar beet, tomatoes and lettuce. Dimethoate can be used as acaricide and insecticide. It should be noted that the applicant is supporting only the use as insecticide in the EU review process.
The representative formulated product for the evaluation was "Dimethoate 400 EC" ("400 g/L EC "), an emulsifiable concentrate (EC), registered under different trade names in Europe.

Adequate methods are available to monitor all compounds given in the respective residue definition. Only validated single methods for the determination of residues are available. Sufficient 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.

Dimethoate is of moderate acute oral toxicity to rats (LD_{50} = 245 mg/kg bw) and mice (LD_{50} = 160 mg/kg bw) (R22 "Harmful if swallowed" proposed); it is of low toxicity to rats following acute dermal administration (LD_{50} >2000 mg/kg bw). Inhalation LC_{50} is 1.68 mg/L (R20 "Harmful by inhalation" was proposed). Dimethoate is not irritating to skin or eyes; a data requirement for a Local Lymph Node Assay (LLNA) was set due to the inconclusive results of skin sensitisation (R43 "May cause sensitisation by skin contact" proposed). Dimethoate is genotoxic *in vitro* but not *in vivo*; the overall weight of evidence indicated no significant genotoxic potential. Dimethoate did not show any evidence of carcinogenic, reproductive and developmental toxicity potential. The acute neurotoxicity NOAEL is 1 mg/kg bw/day, and the neuro-developmental NOAEL is 0.1 mg/kg bw/day. With the exception of omethoate, all of the metabolites investigated were of lower acute oral toxicity than dimethoate. The ADI and AOEL are 0.001 mg/kg bw/day, while the ARfD is 0.01 mg/kg bw (safety factor of 100). The overall dermal absorption is 0.15% for the concentrate and 2.0% for the dilution.

The operator exposure assessment shows levels below the AOEL only for automatic application on lettuce in greenhouses and for sprayer application on wheat (German model, PPE worn). Bystander exposure and exposure for re-entry workers hand harvesting tomato and lettuce are estimated to be below the AOEL.

Sufficient information has been provided on the metabolism of dimethoate in cereal, root and leafy crops. Several metabolic pathways have been identified including oxidation, demethylation, hydroxylation and hydrolysis. At PHI relevant for the supported representative uses, the metabolic pattern is consisting of a mixture of parent compound and a wide range of metabolites. Omethoate is the most toxic metabolite identified, but other metabolites (metabolites XX and XII) presenting a lower potential for cholinesterase inhibition may bring a significant contribution to the toxicological burden given their presence in significantly higher amounts, in particular in cereals. Their relative toxicity to the parent compound needs to be clarified on the basis of further appropriate studies.

The proposed residue definition for monitoring is dimethoate and omethoate to be determined separately. Metabolites XX, XII (and possibly III, which is a major rat metabolite, depending on its potential for cholinesterase inhibition potential) should be considered for inclusion in the residue definition for risk assessment, on the basis of the information to be provided on their relative toxicity to parent compound and their possible specific impact on the toxicological burden. A final decision on the appropriate wording of this residue definition is not possible at this stage, as clear differences in the toxicity levels of dimethoate and its metabolites exist but are reflected by scientifically-based toxicity equivalence factors for omethoate only.

Supervised residue trials have been provided allowing the establishment of MRLs in olives, tomatoes, lettuce and wheat for both dimethoate and omethoate. It must be noted that for wheat grown in Southern Europe, the latest application should be limited to growth stage BBCH 69 (end of flowering, as for Northern region) as the provided data do not cover adequately later use until growth stage BBCH 75 (milky grain stage). The nature of residues is affected by processing but only to a significant extent when severe conditions such as sterilisation are applied. However, no specific residue definition is needed for processed commodities as the metabolites formed are similar to those observed in raw commodities under environmental conditions.

No significant residues are expected in following crops and in products of animal origin. The expected absence of residues in animal commodities should however be confirmed by a feeding study carried out at the expected rate of exposure of ruminants.

Only preliminary acute and chronic exposure and risk assessments could be carried out, taking into account the combined effect of dimethoate and omethoate, using toxicity equivalence factors of 3 and 6 for chronic and acute exposures respectively, to take into account the higher toxicity of omethoate. Final and robust assessments will be only possible when the required information concerning metabolites XX, XII and III will be available.

At this stage, considering that the exposure to the combined residues of dimethoate and omethoate only is already close to the ADI and the ARfD for some specific population sub-groups, it cannot be excluded that the contribution of further metabolites leads to a global exceedence of the toxicological trigger values for those sub-groups depending on which crops are autorised.

Sufficient data were available to satisfy the data requirements and characterise the fate and behaviour of dimethoate in the environment as required by the current regulatory framework. The drainage and runoff routes of exposure to surface water have not been covered for dimethoate and its metabolites O-desmethyl dimethoate and O,O-dimethyl thiophosphoric acid in the available EU level assessment. This exposure assessment and the associated risk assessment to aquatic organisms should be completed in national assessments made by Member States. Among the notified intended uses, the standard FOCUS modelling identified for olives use a high potential for groundwater contamination by both the parent dimethoate and its relevant breakdown product omethoate, above the parametric drinking water limit of 0.1µg/L. Member States must reassure themselves that actual use at vulnerable sites under their own local conditions will not lead to exceedance of 0.1 µg/L.

The EPCO Experts' meeting on ecotoxicology decided that the applicant should provide a clarification that the test material used in the studies in this section covers the specification of the technical material regarding impurities.

The risk to birds and mammals from the glasshouse use in lettuce is considered to be low. A potential high risk to birds and mammals was identified in the first tier risk assessment for the representative uses outdoors. A revised refined risk assessment is considered necessary. This should include for birds a more detailed justification for e.g. selection of focal species for all representative outdoor crops, refinements of PD and PT, residues decline (residue data should not be pooled, DT_{50} for omethoate in ground vegetation from the residue trial in citrus), extrapolation of citrus residues data from southern to northern Europe, use of a dehusking factor. If use is to be made of the HD5-approach then full details of all toxicity values must be provided, the dietary endpoints must be expressed as daily dietary doses and further support for any claimed reduction in uncertainty factors must be presented. The revised refined risk assessment for mammals should address the concerns regarding the residue data and include a better justification for the selection of focal species and for the proposed refinements of PD and PT.

The risk to aquatic organisms can be considered as low for the representative uses in lettuce, wheat in southern Europe and sugar beet in northern Europe. The risk to aquatic organisms has to be considered as high for the representative uses in wheat in northern Europe, olives, sugar beet in southern Europe and in tomatoes for which risk mitigation measures such as a bufferzone of 5 metres, 20 metres, 5 metres and 10 metres respectively are considered necessary.

The risk to bees is considered to be low for the use in lettuce under glasshouse conditions and the use in sugar beet. For the representative uses outdoors a high risk to bees present in the field at the time of application and for short periods after the treatment(s) was observed in the submitted higher tier studies. The experts' meeting recommends risk mitigation measures such as to avoid all contact with bees. The available data are not sufficient to establish precise withholding periods.

A high risk to NTA was observed in the standard first tier laboratory data. The available field studies demonstrated a potential for recovery within one year for uses up to 500 g a.s./ha. The applicant needs to further address the in-field risk to NTA from uses above 500 g a.s./ha. The available field studies at low dose rates were considered sufficient to demonstrate that with appropriate risk

mitigation measures such as bufferzones the off-field risk is addressed. Bufferzones of 10 m in wheat (SE) and sugar beet (NE), of 15 m in wheat (NE) and sugar beet (SE), of 30 m in tomatoes and of 75 m in olives are proposed based on the lowest NOEC of 1.44 g a.s./ha from the cereal field trial.
The risk to earthworms from dimethoate is considered to be low but a long term toxicity study with the soil metabolite omethoate on earthworms is considered necessary for uses with more than 3 applications per year.
The risk to soil non-target macro-organisms, soil non-target 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

- Estimated exposure is below the AOEL for use in greenhouses lettuce only via automatic gantry sprayers without PPE; for application with boom sprayers on wheat PPE must be worn (gloves when handling the concentrate and gloves, coveralls and sturdy footwear during application).
- For lettuce, consideration should be given by the Member State on the need to mention a PHI 28 days, which may be misleading and may weaken the recommendation to use dimethaote at the latest until growth stage 19 (9^{th} true leave unfold). Application after the starting of the head formation, even with a PHI of 28 days, may results in much higher residue levels, with potential large exceedence of the ARfD.
- The risk to birds and mammals in lettuce is considered to be low as this use is intended in glasshouses which are regarded as permanent structures (refer to point 5.1).
- The risk to aquatic organisms has to be considered as high for the representative uses in wheat in northern Europe, olives, sugar beet in southern Europe and in tomatoes for which risk mitigation measures such as a bufferzone of 5 metres, 20 metres, 5 metres and 10 metres respectively are considered necessary (refer to point 5.2).
- A high risk to bees for the uses in wheat, olives and tomatoes was observed. Risk mitigation measures such as to avoid all contact with bees are recommended. The available data are not sufficient to establish precise withholding periods (refer to point 5.3).
- Risk mitigation measures such as bufferzones are considered necessary to address the off-field risk to NTA. Bufferzones of 10 m in wheat (SE) and sugar beet (NE), of 15 m in wheat (NE) and sugar beet (SE), of 30 m in tomatoes and of 75 m in olives are proposed based on the lowest NOEC of 1.44 g a.s./ha from the cereal field trial. (refer to point 5.4).

Critical areas of concern

- For the moment no final specification can be set, due to outstanding data on ecotoxicology (refer to chapter 1 and 5).
- A robust risk assessment for the safety of the consumer is not possible due to the lack of information on the relative toxicity to parent compound and actual levels of metabolites XX, XII and III in plant commodities. Considering that the exposure to the combined residues of

dimethoate and omethoate only is close to the ADI and the ARfD for some specific population sub-groups, it cannot be excluded that the contribution of further metabolites leads to a global exceedence of the ADI and/or exceedence of the ARfD for particular commodities and particular categories of consumers depending on which crops are authorised.

- A potential for groundwater contamination by both the parent dimethoate and its relevant breakdown product omethoate, above the parametric drinking water limit of 0.1µg/L is identified by standard FOCUS modelling for olives use under vulnerable conditions (Piacenza scenario).
- A potential high risk to birds and mammals was identified in the first tier risk assessment. Further justifications, for the proposed refinement options by the applicant, were considered necessary by the experts' meeting.
- The risk to aquatic organisms has to be considered as high for the representative uses in wheat in northern Europe, olives, sugar beet in southern Europe and in tomatoes for which risk mitigation measures such as a bufferzone of 5 metres, 20 metres, 5 metres and 10 metres, respectively, are considered necessary.
- A high risk to bees for the uses in wheat, olives and tomatoes was observed. Risk mitigation measures such as to avoid all contact with bees are recommended. The available data are not sufficient to establish precise withholding periods.
- Risk mitigation measures such as bufferzones are considered necessary to address the off-field risk to NTA. Bufferzones of 10 m in wheat (SE) and sugar beet (NE), of 15 m in wheat (NE) and sugar beet (SE), of 30 m in tomatoes and of 75 m in olives are proposed based on the lowest NOEC of 1.44 g a.s./ha from the cereal field trial. Further data to address the in-field risk to NTA from uses above 500 g a.s./ha is considered necessary.

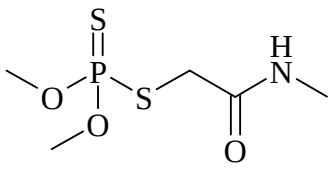
APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

(Abbreviations used in this list are explained in appendix 2)

Appendix 1.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Dimethoate
Function (e.g. fungicide)	Insecticide and acaricide
Rapporteur Member State	UK
Co-rapporteur Member State	--

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	*O*,*O*-Dimethyl-*S*-(*N*-methylcarbamoylmethyl) phosphorodithioate; 2-Dimethoxy-phosphinothioylthio-*N*-methylacetamide
Chemical name (CA) ‡	Phosphorodithioic acid, O,O-dimethyl S-[2-(methylamino)-2-oxoethyl] ester
CIPAC No ‡	59
CAS No ‡	60-51-5
EEC No (EINECS or ELINCS) ‡	200-480-3
FAO Specification ‡ (including year of publication)	>950 g/kg 2005 FAO specification Omethoate max 2 g/kg Isodimethoate max 3 g/kg Water max 2 g/kg
Minimum purity of the active substance as manufactured ‡ (g/kg)	960 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	Omethoate max 2 g/kg Isodimethoate max 3 g/kg
Molecular formula ‡	$C_5H_{12}NO_3PS_2$
Molecular mass ‡	229.3
Structural formula ‡	

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	49.0 – 52.0 (99.4%)
Boiling point (state purity) ‡	No boiling observed up to decomposition at 113 ºC (99.4%)
Temperature of decomposition	113 ºC (99.4%) with a change in colour from white to pale yellow at 115 ºC
Appearance (state purity) ‡	White solid (99.5%), white, palletised solid with mercaptanic odour (97-99%)
Relative density (state purity) ‡	1.31 (99.1%)
Surface tension	2% w/v = 69.5 mN/m (98.0%) new GLP study
Vapour pressure (in Pa, state temperature) ‡	2.47 x 10^{-4} Pa @ 25 ºC 1.57x10^{-3} Pa @ 35 ºC
Henry's law constant (Pa m^3 mol^{-1}) ‡	1.42 x 10^{-6} Pa·m^3·mol^{-1}
Solubility in water ‡ (g/L or mg/L, state temperature)	pH 7: 39.8 g/L at 25 ºC: No other pH tested
	No other pH tested
Solubility in organic solvents ‡ (in g/L or mg/L, state temperature)	at 25 °C aliphatic hydrocarbon: n-hexane: 0.295 g/L n-heptane: 0.242 g/L dodecane: 0.430 g/L aromatic hydrocarbon: xylene: 313 g/L toluene: 1030 g/L halogenated hydrocarbon: 1,2-dichloroethane: 1210 g/L dichloromethane: 1500 g/L alcohol: methanol: 1590 g/L isopropyl alcohol: 1200 g/L 1-octanol: 522 g/L ketone: acetone: 1390 g/L ester: ethyl acetate: 1240 g/L others: acetonitrile: 1420 g/L cyclohexanone: 1220 g/L

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Partition co-efficient (log POW) ‡ (state pH and temperature)	pH 7: log Kow: 0.704
Hydrolytic stability (DT_{50}) ‡ (state pH and temperature)	pH 9: 4.4 days at 25 ºC pH 7: 68 days at 25 ºC pH 5: 156 days at 25 ºC
Dissociation constant ‡	Dimethoate does not dissociate
UV/VIS absorption (max.) ‡ (if absorption > 290 nm state ε at wavelength)	No maxima observed above 200 nm.
Photostability (DT_{50}) ‡ (aqueous, sunlight, state pH)	175 days at pH 5
Quantum yield of direct phototransformation in water at ☒ > 290 nm ‡	Not required because ε < 10 L × (mol × cm)-1 at λ > 290 nm
Flammability ‡	Not highly flammable (98.0%)
Explosive properties ‡	Not explosive to thermal or mechanical shock or friction (98.0%)

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

List of representative uses evaluated (active substance)*

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)
Wheat	South	Danadim Dimethoate 40	F	Biting and sucking insects	EC	400 g/L	Spraying	BBCH < 75	1	-	0.1	400	0.4	28	[1] [2] [3]
Wheat	North	Danadim Dimethoate 40	F	Biting and sucking insects	EC	400 g/L	Spraying	1st appl.: BBCH 23/30 2nd appl.: BBCH ≤ 69	2	30d	1st appl.: 0.34 2nd appl.: 0.17	200	1st appl.: 0.68 2nd appl.: 0.34	nr*	[1] [2] [3]
Olives	South	Danadim Dimethoate 40	F	Biting and sucking insects	EC	400 g/L	Spraying	nr	4	> 20 d	0.06	1200[1)]	0.72	28	[1] [2] [3] [4]
Sugar beet	South	Danadim Dimethoate 40	F	Biting and sucking insects	EC	400 g/L	Spraying	1. 16 – 18 2. 35 – 43	2	30 d	0.06	1000	0.6	30	[1] [2] [3] [4]

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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)
Sugar beet	North	Danadim Dimethoate 40	F	Biting and sucking insects	EC	400 g/L	Spraying	1. 16 – 18 2. 34 – 43	2	30 d	1st appl.: 0.0084-0.042 2nd appl.: 0.04-0.2	200-1000	1st appl.: 0.084 2nd appl.: 0.4	35	[1] [2] [3] [4]
Tomatoes	South	Danadim Dimethoate 40	F	Biting and sucking insects	EC	400 g/L	Spraying	69 – 81	2	15 d	0.1	600	0.6	21	[1] [2] [3] [4]
Lettuce	North	Danadim Dimethoate 40	G	Biting and sucking insects	EC	400 g/L	Gantry Spraying	GS19 †	1	nr	0.17	200	0.34	28	[1] [2]

[1] The risk assessment has revealed a data gap in section 3.
[2] The risk assessment has revealed a data gap(s) in section 5.
[3] The risk assessment has revealed a risk (exceedance of relevant threshold) in section 5.
[4] The operator exposure assessment exceeds the AOEL

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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)	Method, *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

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.2: Methods of Analysis

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

Technical as (principle of method)	Samples were dissolved in acetonitrile and dimethoate determined by HPLC-UV. Samples were dissolved in xylene and dimethoate determined by GC-FID.
Impurities in technical as (principle of method)	Samples were dissolved in acetonitrile and omethoate was analysed by GC-FPD. Samples were dissolved in acidified water and acetonitrile and isodimethoate, omethoate, ~~XX-XXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXX~~ were determined by HPLC-UV.
Plant protection product (principle of method)	Samples were dissolved in acetonitrile and dimethoate determined by HPLC-UV. Samples were dissolved in xylene and dimethoate determined by GC-FID.

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Samples were extracted with dichloromethane, dimethoate and omethoate were determined by LC-MS. LOQ was 0.01 mg/kg for both dimethoate and omethoate in wheat, sugar beet, tomatoes, olives, olive oil and lettuce.
	Samples were extracted with aqueous acetone, dimethoate and omethoate were determined by GC-FPD. LOQ was 0.01 mg/kg for both dimethoate and omethoate in sugar beet.
	Samples were extracted with ethyl acetate, dimethoate and omethoate were determined by GC-FPD. LOQ was 0.01 mg/kg for both dimethoate and omethoate in lettuce.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

	Samples were extracted with acetone or ethyl acetate, dimethoate and omethoate were determined by GC-FPD. LOQ was 0.01 mg/kg for both dimethoate and omethoate sorghum, peas, wheat, corn, orange, potato, tomato (including various processed fractions for all crops).
	Samples were mixed with hexane (olive oil) or ethyl acetate (olives, lettuce, orange and wheat grain) and then extracted with acetonitrile, dimethoate and omethoate were determined by GC-FPD. LOQ was 0.01 mg/kg for both dimethoate and omethoate for all crops.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Samples were extracted with acetone or acetonitrile, dimethoate and omethoate were determined by GC-FPD. LOQ for both dimethoate and omethoate was 0.001 mg/kg (milk and egg white), 0.01 mg/kg (goat liver, kidney, fat) and 0.05 mg/kg in whole egg).
Soil (principle of method and LOQ)	Samples were extracted with acetone and water, dimethoate and omethoate were determined by GC-FPD. LOQ for both dimethoate and omethoate was 0.01 mg/kg.
Water (principle of method and LOQ)	Samples of tap water and surface water were extracted by SPE (activated charcoal) and eluted from the charcoal with a mixture of dichloromethane and methanol, dimethoate and omethoate were determined by SIM GC-MS. LOQ for both dimethoate and omethoate was 0.05 µg/L.
Air (principle of method and LOQ)	Samples were extracted with acetone, dimethoate and omethoate were determined by GC-FPD. LOQ for both dimethoate and omethoate was 0.01 µg/m^3.
Body fluids and tissues (principle of method and LOQ)	No data necessary.

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	None

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.3: Impact on Human and Animal Health

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

Rate and extent of absorption ‡	Rapidly and extensively absorbed, > 90% within 24 hours (rat urine, 10 mg/kg bw)
Distribution ‡	Widely and evenly distributed, highest concentration in liver
Potential for accumulation ‡	No evidence for accumulation
Rate and extent of excretion ‡	Rapidly excreted (90% in urine within 24h)
Metabolism in animals ‡	Cleavage to dimethoate carboxylic acid; oxidation to omethoate (~5%).
Toxicologically significant compounds ‡ (animals, plants and environment)	Parent, omethoate, O-desmethyl omethoate carboxylic acid, O-desmethyl isodimethoate

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	245 mg/kg bw (R22)
Rat LD_{50} dermal ‡	>2000 mg/kg bw
Rat LC_{50} inhalation ‡	1.68 mg/L (4 hours, whole body); study with a manufacturing concentrate (R20)
Skin irritation ‡	Minimal irritant
Eye irritation ‡	Mild irritant
Skin sensitization ‡ (test method used and result)	No evidence (3-induction Buehler), study insufficient (provisional R43)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Inhibition of erythrocyte and brain cholinesterase activity
Lowest relevant oral NOAEL / NOEL ‡	0.18 mg/kg bw/day (1 year dog study)
Lowest relevant dermal NOAEL / NOEL ‡	5 mg/kg bw/day (5-day rat study with a formulation)
Lowest relevant inhalation NOAEL / NOEL ‡	No data

Genotoxicity ‡ (Annex IIA, point 5.4)

.....	Positives in vitro, negative in vivo. Weight of evidence indicates no significant genotoxic potential

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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

Target/critical effect ‡	Inhibition of erythrocyte and brain cholinesterase activity.
Lowest relevant NOAEL / NOEL ‡	0.04 mg/kg bw/day (rat chronic), LOAEL = 0.2 mg/kg bw/day
Carcinogenicity ‡	No evidence of carcinogenicity.

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	Parent: Brain and RBC ChE inhibition Reproduction: Reduced pregnancy rate and reduced litter size at birth Offspring: Reduced survival, reduced pup weights
Lowest relevant reproductive NOAEL / NOEL ‡	Parent: 0.2 mg/kg bw/day Reproduction: 1.2 mg/kg bw/day Offspring: 1.2 mg/kg bw/day
Developmental target / critical effect ‡	Maternal: Clinical signs, reduced bodyweight Developmental: No evidence of fetotoxicity
Lowest relevant developmental NOAEL / NOEL ‡	Maternal: 6 mg/kg bw/day (rat) Developmental: 18 mg/kg bw/day (highest dose tested) (rat)

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

.....	No evidence for delayed neurotoxicity in the hen, although NTE inhibition was seen. Acute neurotoxicity gavage (rats): NOAEL = 2 mg/kg bw, reduced pupil response (ChE not measured) Acute neurotoxicity diet (rats): NOAEL = 1 mg/kg bw, RBC ChE 13 week dietary neurotoxicity: NOAEL = 0.06 mg/kg bw/day, RBC ChE Developmental neurotoxicity: NOAEL = 0.1 mg/kg bw/day, reduced pup survival No evidence for neurotoxicity

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Other toxicological studies ‡ (Annex IIA, point 5.8)

Studies on omethoate

Acute toxicity	
Oral (rat)	LD_{50} =22 mg/kg bw, LD_{50} =28 mg/kg bw (2 studies)
Dermal (rat)	LD_{50} =232 mg/kg bw, LD_{50} =145 mg/kg bw (2 studies)
Inhalation (rat)	LC_{50} =0.287 mg/L
Short term toxicity	
Rat 90-day	Overall NOAEL approximately 0.1 mg/kg bw/day, based on RBC cholinesterase and brain cholinesterase inhibition
Dog 12-month (gavage)	NOAEL: 0.025 mg/kg bw/day, LOAEL 0.125 mg/kg b/day, based on decreased RBC & brain cholinesterase (cholinesterase data may be unreliable)
Rabbit 21-day dermal	NOAEL: 2.5 mg/kg bw/day, LOAEL: 20 mg/kg bw/day, based on clinical signs and decreased RBC & brain cholinesterase (cholinesterase data may be unreliable)
Genotoxicity	Weight of evidence indicates that omethoate is mutagenic in vitro but not in vivo
Carcinogenicity	
Rat	LOAEL: 0.04 mg/kg bw/day, based on a borderline effect on RBC ChE in males No evidence of carcinogenicity
Reproductive toxicity	
Multigeneration study (rats)	Parental NOAEL: 0.03 mg/kg bw/day, based on ChE inhibition Developmental NOAEL: 0.2 mg/kg bw/day, based on increased post-natal loss and decreased pup weight Reproductive NOAEL: 0.2 mg/kg bw/day, based on adverse effects on mating and fertility parameters
Developmental toxicity (rabbits)	Maternal NOAEL: 0.2 mg/kg bw/day, based on clinical signs and cholinesterase inhibition Developmental NOAEL: 0.2 mg/kg bw/day, based on increased post-implantation loss Malformations recorded at 1.0 and 5.0 mg/kg bw/day (primarily arthrogyrposis) are of questionable significance

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Neurotoxicity

Acute neurotoxicity (rat)	NOAEL: 0.2 mg/kg bw, based on effects in the pupil consistent with ChE inhibition, 0.25 mg/kg bw based on ChE inhibition No evidence of neuropathology or neurotoxicity
Delayed neurotoxicity (hen)	No evidence of delayed neurotoxicity No measurement of ChE activity or NTE inhibition

Summary	Value	Study	Safety factor
ADI for omethoate	0.0003 mg/kg bw/day	Rat multigeneration study and 2 year rat study	100
ARfD for omethoate	0.002 mg/kg bw/day	Acute neurotoxicity	100
AOEL for omethoate	0.0003 mg/kg bw/day	12 month dog study	100

EFSA note: In the toxicology section, an estimate of the threshold for the toxicologically relevant inhibition of erythrocyte and/or brain cholinesterase activity was made by comparison of NOAELs and LOAELs for cholinesterase inhibition as well as the cholinesterase activity recovery in repeat-dose studies. Omethoate is more toxic than dimethoate and the relative toxicity of omethoate compared to dimethoate following chronic and acute were found to be about ~3:1 and ~6:1, respectively.
In the residue section the above mentioned values were used for the consumers' risk assessment.
In the ecotoxicology section, with regard to the acute mammalian risk assessment, the acute oral LD_{50} in rats for omethoate was compared to the acute oral LD_{50} for dimethoate in the mouse resulting in TEF of 7. With regard to the long-term mammalian risk assessment conducted by the RMS, the TEF is based upon the NOAELs derived from multi-generation studies with dimethoate and omethoate, respectively, resulting in a TEF of 3.

Medical data ‡ (Annex IIA, point 5.9)

.....	No indications of adverse effects in manufacturing plant personnel. Some reports of intermediate syndrome following dimethoate poisoning.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.001 mg/kg bw/day	Overall NOAEL from rat chronic, reproduction, neurotoxicity and developmental neurotoxicity*	100

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

ARfD ‡ (acute reference dose)	0.01 mg/kg bw/day	Acute dietary neurotoxicity	100
AOEL ‡	0.001 mg/kg bw/day	Developmental neurotoxicity and interim values in 2 year rat	100

* Derived from these studies taking account of the NOAELs and LOAELs

Dermal absorption (Annex IIIA, point 7.3)

.....	0.15% [concentrate], 2.0% [dilution]. Based on rat in vivo and rat/human in vitro (Dimethoate 400 EC)

Acceptable exposure scenarios (including method of calculation)

Danadim Dimethoate 40 is applied on wheat, olive, sugar beet, tomatoes and lettuce with tractor-mounted spraying devices, knapsack-sprayers and airblast assisted sprayer in orchards.
Recommended application rate of dimethoate from 0.084 to 0.72 kg a.s./ha

Operator	Exposure below the AOEL in protected lettuce only by automatic gantry sprayer application (German and UK models, work rate of 1 ha/day and 0.67 ha/day, respectively, without PPE) and for application on wheat with boom sprayers (German model, PPE worn).
Workers	Exposure for re-entry workers hand harvesting tomato and lettuce is estimated to be below the AOEL.
Bystanders	Estimated exposure below the AOEL

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data	Xn;	Harmful
	R22	Harmful if swallowed
	R20	Harmful by inhalation
	R43	May cause sensitisation by skin contact (provisional)

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.4: Residues

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

Plant groups covered	Potato (R & L) and wheat (C) extrapolated leafy crops
Rotational crops	Wheat (C) , lettuce (L) and turnip (R)
Plant residue definition for monitoring	Dimethoate and omethoate to be determined separately
Plant residue definition for risk assessment	***Provisionally:*** Sum of dimethoate and 6 x omethoate expressed as dimethoate for acute risk assessment Sum of dimethoate and 3 x omethoate expressed as dimethoate for chronic risk assessment ***(Depending on their relative toxicity to parent to be determined on the basis of appropriate toxicological testing, metabolites XX, XII and possibly III to be included in the definition with appropriate toxicity equivalence factors).***
Conversion factor (monitoring to risk assessment)	Not applicable

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

Animals covered	Goat and hen
Animal residue definition for monitoring	Dimethoate and omethoate to be determined separately
Animal residue definition for risk assessment	Sum of dimethoate and 6 x omethoate expressed as dimethoate for acute risk assessment Sum of dimethoate and 3 x omethoate expressed as dimethoate for chronic risk assessment
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} <4)

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

.....	The studies show metabolism in succeeding crops is similar to that seen in primary crops.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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

.....	Dimethoate and omethoate residues have been shown to be stable when frozen between -10ºC and -20ºC for up to 27 months in potato, orange fruit, sorghum grain/forage and cottonseed as well as cherries stored for 6 months. These data are sufficient to cover the storage periods for the sample in the residues trials (wheat grain and straw – 9.5 months; olive – 6.5 months; sugar beet roots and tops – 8 months; Tomatoes – 5.5 months and protected lettuce – 4.5 months).

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes	No	Yes
	Dietary burdens are for dimethoate 0.3, 0.5 and 0.2 mg/kg dry feed for diary cattle, beef cattle and pig resp. and for omethoate 0.2 mg/kg dry feed for diary cattle, beef cattle and pig.		
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No	No	No
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	Feeding study required as extrapolation from high to low exposure rates may be questionable	Not required	Feeding study required as extrapolation from high to low exposure rates may be questionable
Liver		Not required	
Kidney		Not required	
Fat		Not required	
Milk			
Eggs		Not required	

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Summary of critical residues data for dimethoate MRL setting (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Wheat grain	North	6 x <0.001, 2 x 0.001		0.01*	0.001
Wheat straw	North	5 x <0.01, 0.01, 0.02, 0.05, 0.07	No MRLs set for straw	0.07 (HR)	0.01
Wheat grain	South	<0.001, 0.007, 4 x <0.01, 0.014, 0.024	Data base supporting the use of dimethoate until GS BBCH 69	0.03	0.01
Wheat straw	South	<0.01, 2 x 0.03, 0.05, 0.11, 0.15, 0.37, 0.45	Data base supporting the use of dimethoate until GS BBCH 69 No MRLs set for straw	0.45 (HR)	0.08
Olive	South	2 x <0.01, 0.01, 0.03, 0.04, 0.13, 0.15, 0.21, 0.34	5 trials were carried out at 0.44 kg dimethoate/ha (about 60% of the intended application rate)	0.5	0.04
Sugar beet root	North	3 x <0.02, 5 x <0.01	MRLs not set for beet or tops	0.01 (HR)	0.01
Sugar beet tops	North	4 x <0.01, 0.03, 3 x <0.1	MRLs not set for beet or tops	0.1 (HR)	0.02
Sugar beet root	South	8 x <0.01	MRLs not set for beet or tops	0.01 (HR)	0.01
Sugar beet tops	South	8 x <0.01	MRLs not set for beet or tops	0.01 (HR)	0.01
Tomato	South	8 x <0.01		0.01*	0.01
Lettuce (protected)	North	<0.01, 0.01, 2x0.02	application at GS BBCH 12-14	0.2	0.02
		0.01, 0.06, 0.16, 0.17	application at GS BBCH 19		
		2x1.1, 2.2	application at GS BBCH 41	Not GAP	

(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

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Summary of critical residues data for omethoate MRL setting (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Wheat grain	North	5 x <0.001, 2 x 0.001, 0.002		0.01*	0.001
Wheat straw	North	8 x <0.01	No MRLs set for straw	0.01 (HR)	0.01
Wheat grain	South	<0.001, 0.001, 2 x 0.002, 4 x <0.01	Data base supporting the use of dimethoate until GS BBCH 69	0.01*	0.006
Wheat straw	South	4 x <0.01, 0.01, 0.05, 0.07, 0.08	Data base supporting the use of dimethoate until GS BBCH 69 No MRLs set for straw	0.08 (HR)	0.01
Olive	South	2 x 0.06, 0.07, 0.20, 0.22, 0.26, 0.33, 0.40, 0.44	5 trials were carried out at 0.44 kg dimethoate/ha (about 60% of the intended application rate)	0.5	0.22
Sugar beet root	North	3 x <0.02, 5 x <0.01	MRLs not set for beet or tops	0.01 (HR)	0.01
Sugar beet tops	North	3 x <0.01, 0.01, 0.02, 3 x <0.1	MRLs not set for beet or tops	0.1 (HR)	0.01
Sugar beet root	South	8 x <0.01	MRLs not set for beet or tops	0.01 (HR)	0.01
Sugar beet tops	South	4 x <0.01, 2 x 0.02, 0.03, 0.04	MRLs not set for beet or tops	0.04 (HR)	0.015
Tomato	South	6 x <0.01, 0.01, 0.02		0.02	0.01
Lettuce (protected)	North	3x<0.01, 0.01	application at GS BBCH 12-14	0.05	0.01
		<0.01, 2x0.03, 0.04	application at GS BBCH 19		
		0.17, 0.20, 0.29	application at GS BBCH 41	Not GAP	

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Summary of critical residues data for ACUTE RISK ASSESSMENT (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	HR	STMR (b)
Wheat grain	North	6x<0.007, 0.007, 0.013		0.013	0.007
Wheat grain	South	<0.007, 0.013, 0.026, 0.036, 4x<0.07	Data base supporting the use of dimethoate until GS BBCH 69	0.07	0.036
Olive	South	0.37, 0.37, 0.45, 1.21, 1.36, 1.71, 2.19, 2.74, 2.79	5 trials were carried out at 0.44 kg dimethoate/ha (about 60% of the intended application rate)	2.79	1.36
Sugar beet root	North				
Sugar beet root	South				
Tomato	South	6x<0.07, 0.07, 0.13		0.13	0.07
Lettuce (protected)	North	<0.07, 0.07, 2x0.09	application at GS BBCH 12-14	0.40	0.09
		0.07, 0.24, 0.35, 0.40	application at GS BBCH 19		
		2.12, 2.84, 3.40	application at GS BBCH 41	Not GAP	
* Note that omethoate residues were not corrected to be expressed as dimethoate, given that the MW of omethoate is very close (93%) to the MW of dimethoate.					
HRs and STMRs reported in this table do not include the contribution of metabolites XX and XII. Therefore they may represent an underestimation of the the actual toxicological&l burden the consumer is exposed to.					

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Summary of critical residues data for CHRONIC RISK ASSESSMENT (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	HR	STMR (b)
Wheat grain	North	6x<0.004, 0.004, 0.007		0.007	0.004
Wheat grain	South	<0.004, 0.010, 0.020, 0.030, 4x<0.04	Data base supporting the use of dimethoate until GS BBCH 69	0.04	0.035
Olive	South	0.19, 0.19, 0.24, 0.61, 0.70, 0.93, 1.20, 1.45, 1.54	5 trials were carried out at 0.44 kg dimethoate/ha (about 60% of the intended application rate)	1.54	0.70
Sugar beet root	North				
Sugar beet root	South				
Tomato	South	6x<0.04, 0.04, 0.07		0.07	0.04
Lettuce (protected)	North	<0.04, 0.04, 2x0.05	application at GS BBCH 12-14	0.28	0.05
		0.04, 0.15, 0.26, 0.28	application at GS BBCH 19		
		1.61, 1.97, 2.80	application at GS BBCH 41	Not GAP	
* Note that omethoate residues were not corrected to be expressed as dimethoate, given that the MW of omethoate is very close (93%) to the MW of dimethoate.					
HRs and STMRs reported in this table do not include the contribution of metabolites XX and XII. Therefore they may represent an underestimation of the the actual toxicological burden the consumer is exposed to.					

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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

ADI	0.001 mg/kg bw/day		
TMDI (European diet) (% ADI)	Not calculated		
NEDI (% ADI) based on UK diet of 10 population subgroups	Highest intakes calculated for toddlers and 4-6 yr old children (84 and 86%)		
Factors included in NEDI	STMR on raw commodities, transfer factors of dimethoate and omethoate for processing of olive oil and canned (non sterilised) olives		
ARfD	0.01 mg/kg bw/day		
Acute exposure (% ARfD)	Oils	3.9%	4-6 year old child
	Olives	13.2%	4-6 year old child
	Tomato	62.7%	infant
	Lettuce	71.1%	4-6 year old child
	Wheat	10.2%	4-6 year old child
	Sugar beet (as RAC)	54.4%	toddler

Note that these chronic and acute exposure assessments must be considered as provisional and may represent underestimations of the actual toxicological burden the consumer is exposed to, as they consider only the combined effect of dimethoate and omethoate. Further data on metabolites XX, XII and III are needed before a robust risk assessment can be carried out.

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

Crop/processed crop	Number of studies	Transfer factor	% Transference *
Olive	3		
RAC prior to processing		1.00	1.00
Raw olive oil		0.30	<0.01
Refined olive oil		0.27	0.01
6 month canned olives (sterilised)		0.09	0.01
6 month canned olives (non sterilised)		0.30	0.12
6 month canned brine (sterilised)		0.04	0.01
6 month canned brine (non sterilised)		0.16	0.08

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

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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

	Dimethoate	Omethoate
Olives	0.5	0.5
Tomatoes	0.01*	0.02
Lettuce	0.2	0.05
Wheat	0.03	0.01*

* indicates that the MRL is set at the level of the LOQ

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.5: Fate and Behaviour in the Environment

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

Mineralization after 100 days ‡	72.8% AR at 120 DAT (methoxy-labelled)
Non-extractable residues after 100 days ‡	15.3% AR at 120 DAT (maximum 20.9% AR at 30 days; methoxy-labelled)
Relevant metabolites - name and/or code, % of applied ‡ (range and maximum)	Methoxy-labelled. No 'major' metabolites; O-desmethyl dimethoate max 2.0% AR at 2 DAT; O,O-dimethyl thiophosphoric acid max 0.7% AR at 2 DAT. Note: omethoate found up to 67.7% w/w in US field study

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

Anaerobic degradation ‡	Methoxy-labelled, 25 °C, 2 day aerobic phase followed by 60 days anaerobic phase (soil flooded). Volatiles 41.0% AR at study end (26.7% AR at beginning of anaerobic phase). Unextracted residues 2.0 % AR at study end (0.8% AR at beginning of anaerobic phase). Metabolites O-desmethyl dimethoate max 9.6% AR at 14 days after flooding; O,O-dimethyl thiophosphoric acid 4.4% AR at 14 days after flooding; Unknown 1 at 8.4% AR at 32 days after flooding; Unknown 2 at 5.2% AR at 14 days after flooding.
Soil photolysis ‡	Slower degradation in light exposed samples compared to dark control: no significant effect of light with respect to soil photolysis.

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

Method of calculation	1st order kinetics
Laboratory studies ‡ (range or median, with n value, with r^2 value)	DT_{50lab} dimethoate (20-22 °C, aerobic, variable moisture content): 2.0 – 4.1 days, r^2 >0.9, n = 4. Mean of values corrected to 20°C and pF2 for use in FOCUS groundwater modelling is 2.6 days DT_{90lab} dimethoate (20 °C or normalized to 20°C, aerobic, variable moisture content): 6.8 – 13.5 days DT_{50lab} dimethoate (10 °C, aerobic): no data; 4.4 – 9.0 days by calculation (Q10 = 2.2) DT_{50lab} dimethoate (25 °C, anaerobic): 18.0 days, r^2 = 0.92
	DT_{50lab} omethoate (22 °C): 0.8 – 2.4 days, n=2, r^2 = 0.82 – 0.97. Longest DT_{50} corrected to 20°C appropriate for gw modelling is 2.8 days

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

	degradation in the saturated zone: no information submitted, no information required
Field studies ‡ (state location, range or median with n value)	DT_{50f} dimethoate: USA (California, Texas, New York); 4.6 – 9.8 days, r^2 = 0.79 – 0.99, n = 5 DT_{90f} dimethoate: 14.9 – 32.6 days
	DT_{50}f omethoate: 15.0 – 22.7 days, r2 = 0.81 – 0.89, n=2, other sites not calculable
	DT_{90f} omethoate: 49.8 – 75.4 days
Soil accumulation and plateau concentration ‡	Not required

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡ K_d ‡ pH dependence ‡ (yes / no) (if yes type of dependence)	Koc dimethoate, soil: 16.25 – 51.88 mL/g, mean for use in FOCUSgw modelling 30.1 mL/g (n=4) 1/n 0.965 – 1.050, mean 1.019; value of 1.019 appropriate for gw modelling In sediment, Koc 19.5 mL/g, 1/n 0.989 (n=1). Value excluded from derivation of Koc for groundwater modelling. No pH dependence Koc omethoate: 16 – 87 mL/g, mean for use in FOCUSgw modelling 41.3 mL/g (n=3) No 1/n information due to testing at a single concentration, thus 1/n of 1.0 appropriate for FOCUSgw modelling. No pH dependence.

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

Column leaching ‡	4 soils, 1 litre of leaching water, 71.8 – 100.6% AR in leachate, of which 77 – 93% of radioactivity in leachate present as unchanged dimethoate
Aged residues leaching ‡	1 soil, 30 day ageing period, 4.9% AR as dimethoate in aged soil prior to leaching. 5.1% AR in leachate after leaching, presumed to be unchanged dimethoate

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Lysimeter/ field leaching studies ‡	Two sandy soil lysimeters in Switzerland. 1.2 kg dimethoate applied to white cabbage in year 1 only. 1028mm & 874 mm precipitation in 1st and 2nd years respectively. 0.697-0.752 µg/L annual average dimethoate equivalents in leachate in year 1, 0.220 – 0.301 µg/L annual average dimethoate equivalents in leachate in year 2. No dimethoate or expected metabolites, including omethoate, detected. Up to 0.559 µg/L dimethoate equivalents present as chromatographic region M2 – expected to be a number of fragments.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation	Equal distribution in 5cm soil layer, bulk density 1.5 g/cm^3. Dimethoate: worst case 1st order field DT_{50} = 9.8 days
Application rate	See below for application details.

Crop	No. appns	Min interval between appns	Appn rate per treat (kg as/ha)	Growth stage (BBCH)	Interceptn (%)	Dimethoate reaching soil surface (kg as/ha)
Southern Europe						
Olives	4	21	0.72	-	70 all stages	0.22
Sugar beet	2	30	0.60	16-18 / 35-43	20 / 70	0.48 / 0.18
Tomatoes	2	15	0.60	69-81	80 / 80	0.12 / 0.12
Wheat	1	-	0.40	69	70	0.12
Northern Europe						
Lettuce* (greenhouse)	1	-	0.34	-	-	-
Sugar beet	2	30	0.084 / 0.40	16-18 / 34-43	20 / 70	0.07 / 0.12
Wheat	2	30	0.68 / 0.34	23-30 / 69	50 / 70	0.34 / 0.1

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

PECsoil for dimethoate on olives after 4 applications

PECinitial	0.288	TWA
PEC_{INI} mg/kg (4th)	0.371	0.371
1	0.346	0.358
2	0.322	0.346
4	0.280	0.323
7	0.226	0.293
14	0.138	0.236
28	0.051	0.162
50	0.011	0.102
100	0.000	0.052

PECsoil for dimethoate on sugar beet, Southern Europe after 1 and 2 applications

		TWA
PEC_{INI} mg/kg (1^{st} appn)	0.640	0.640
1	0.596	0.618
2	0.556	0.597
4	0.482	0.557
7	0.390	0.505
14	0.238	0.406
28	0.088	0.279
50	0.019	0.176
100	0.001	0.090

PECinitial	0.240	TWA
PEC_{INI} mg/kg (2^{nd} appn)	0.317	0.317
1	0.295	0.306
2	0.275	0.295
4	0.239	0.276
7	0.193	0.250
14	0.118	0.201
28	0.044	0.138
50	0.009	0.087
100	0.000	0.045

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

PECsoil for dimethoate on tomato after 2 applications

PECinitial	0.160	TWA
PEC_{INI} mg/kg (2^{nd} appn)	0.215	0.215
1	0.201	0.208
2	0.187	0.201
4	0.162	0.188
7	0.131	0.170
14	0.080	0.137
28	0.030	0.094
50	0.006	0.059
100	0.000	0.030

PECsoil for dimethoate on wheat, Southern Europe after 1 application

		TWA
PEC_{INI} mg/kg (1^{st} appn)	0.160	0.160
1	0.149	0.154
2	0.139	0.149
4	0.121	0.139
7	0.098	0.126
14	0.059	0.102
28	0.022	0.070
50	0.005	0.044
100	0.000	0.023

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

PECsoil for dimethoate on sugar beet, Northern Europe after 2 applications

PECinitial	0.160	TWA
PEC_{INI} mg/kg (2^{nd} appn)	0.171	0.171
1	0.159	0.165
2	0.148	0.159
4	0.129	0.149
7	0.104	0.135
14	0.063	0.108
28	0.024	0.074
50	0.005	0.047
100	0.000	0.024

PECsoil for dimethoate on wheat, Northern Europe after 1 and 2 applications

		TWA
PEC_{INI} mg/kg (1^{st} appn)	0.453	0.453
1	0.422	0.438
2	0.394	0.423
4	0.342	0.395
7	0.276	0.358
14	0.168	0.288
28	0.063	0.197
50	0.013	0.124
100	0.000	0.064

PECinitial	0.136	TWA
PEC_{INI} mg/kg (2^{nd} appn)	0.190	0.190
1	0.177	0.184
2	0.165	0.177
4	0.143	0.166
7	0.116	0.150
14	0.071	0.121
28	0.026	0.083
50	0.006	0.052
100	0.000	0.027

PECsoil Metabolite - omethoate

Method of calculation	Equal distribution in 5cm soil layer, bulk density 1.5 g/cm^3. Omethoate: worst case 1^{st} order field DT_{50} 22.7 days. Assumes peak observed formation 67.7% w/w. Due to uncertainties over metabolite formation and degradation under multiple application regimes, PEC calculation for metabolite based on maximum total dose of parent.
Application rate	See above for dimethoate

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

PECsoil for omethoate following dimethoate use on olives

Days after appl'n	PECsoil (mg/kg)	Time weighted average (mg/kg)
0	0.780	0.780
1	0.756	0.768
2	0.734	0.757
4	0.690	0.734
7	0.630	0.702
14	0.509	0.635
28	0.332	0.524
50	0.169	0.400
100	0.037	0.243

PECsoil for omethoate following dimethoate use on sugar beet in Southern Europe

Days after appl'n	PECsoil (mg/kg)	Time weighted average (mg/kg)
0	0.596	0.596
1	0.578	0.587
2	0.560	0.578
4	0.527	0.561
7	0.481	0.536
14	0.389	0.485
28	0.253	0.400
50	0.129	0.305
100	0.028	0.186

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

PECsoil for omethoate following use of dimethoate on tomato

Days after appl'n	PECsoil (mg/kg)	Time weighted average (mg/kg)
0	0.217	0.217
1	0.210	0.213
2	0.204	0.210
4	0.192	0.204
7	0.175	0.195
14	0.141	0.176
28	0.092	0.146
50	0.047	0.111
100	0.010	0.068

PECsoil for omethoate following use of dimethoate on wheat in Southern Europe

Days after appl'n	PECsoil (mg/kg)	Time weighted average (mg/kg)
0	0.108	0.108
1	0.105	0.106
2	0.102	0.105
4	0.096	0.102
7	0.087	0.097
14	0.070	0.088
28	0.046	0.073
50	0.023	0.055
100	0.005	0.034

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

PECsoil for omethoate following dimethoate use on sugar beet in Northern Europe

Days after appl'n	PECsoil (mg/kg)	Time weighted average (mg/kg)
0	0.169	0.169
1	0.164	0.166
2	0.159	0.164
4	0.150	0.159
7	0.136	0.152
14	0.110	0.137
28	0.072	0.114
50	0.037	0.087
100	0.008	0.053

PECsoil for omethoate following use of dimethoate on wheat in Northern Europe

Days after appl'n	PECsoil (mg/kg)	Time weighted average (mg/kg)
0	0.399	0.399
1	0.387	0.393
2	0.375	0.387
4	0.353	0.376
7	0.322	0.359
14	0.260	0.325
28	0.170	0.268
50	0.087	0.205
100	0.019	0.124

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} dimethoate 156 days, O-desmethyl dimethoate 12.2% AR at 30 DAT pH7, 25 °C: DT_{50} dimethoate 68 days, O-desmethyl dimethoate 22.1% AR at 30 DAT pH9, 25 °C: DT_{50} dimethoate 4.4 days, O-desmethyl dimethoate 62.2% AR at 21 DAT, O,O-dimethyl thiophosphoric acid 36.0% AR at 30 DAT

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Photolytic degradation of active substance and relevant metabolites ‡	No significant degradation compared to dark control over 15 day time period. Photolytic half-life estimated as >175 days under study conditions (25°C, xenon arc lamp, equivalent clear sunny day in equatorial regions)
Readily biodegradable (yes/no)	No (OECD 301 D)
Degradation in water/sediment - DT_{50} water ‡ - DT_{90} water ‡ - DT_{50} whole system ‡ - DT_{90} whole system ‡	12.5 – 14.8 days 41.5 – 49.1 days (1st order, r2>0.9, n=2) 13.2 – 17.2 days 43.8 – 57.2 days (1st order, r2>0.9, n=2)
Mineralization	24.5 – 28.0% AR (at study end, 105 DAT)
Non-extractable residues	40.4 – 51.5% AR (at study end, 105 DAT)
Distribution in water / sediment systems (active substance) ‡	Maximum 11.9% AR in sediment at 7 DAT, declining to 0.2 – 0.8% AR at study end (105 DAT)
Distribution in water / sediment systems (metabolites) ‡	Aerobic laboratory sediment/water study at 20 ºC in two systems (natural river water and pond water) Water: Highest individual metabolite O-desmethyl dimethoate, 13.3 – 17.6% AR at 7 – 30 DAT, declining to 0.7 – 1.5% AR at study end Sediment: Highest individual metabolite O-desmethyl dimethoate, 3.6 – 4.6% AR at 7 – 30 DAT, declining to 0.2 – 0.3% AR at study end

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

Parent

Method of calculation	Static water body 30cm deep with 5cm sediment 1st order water phase DT_{50} of 14.8 days
Application rate	See individual tables below for details of dose and spray drift assumptions (note, only tables for PEC values for distances giving acceptable aquatic risk assessments.
Main routes of entry	Spray drift

For other PECsw values, see Section B.8.6 of Volume 3 of dimethoate Draft Assessment Report.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

PECsw for dimethoate on olives, 4 applications, 0.80% drift @ 20m, 720 g/ha for each application, 21 day spray interval.

Days after appl'n	PECsoil (mg/kg)	Time weighted average (mg/kg)
0	3.007	3.007
1	2.869	2.938
2	2.738	2.871
4	2.493	2.742
7	2.167	2.564
14	1.561	2.206
21	1.125	1.914
28	0.810	1.675
42	0.421	1.315

PECsw for dimethoate on sugar beet (Southern Europe), 2 applications, 0.47% drift @ 5m, 600 g/ha for each application, 30 day spray interval.

Days after appl'n	PECsoil (mg/kg)	Time weighted average (mg/kg)
0	1.171	1.171
1	1.117	1.144
2	1.066	1.117
4	0.971	1.068
7	0.843	0.998
14	0.608	0.859
21	0.438	0.745
28	0.315	0.652
42	0.164	0.512

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

PECsw for dimethoate on tomatoes, 2 applications, 1.07% drift @ 10m, 600 g/ha for both applications, 15 day spray interval.

Days after appl'n	PECsoil (mg/kg)	Time weighted average (mg/kg)
0	3.200	3.200
1	3.054	3.126
2	2.914	3.055
4	2.653	2.918
7	2.306	2.728
14	1.661	2.347
21	1.197	2.037
28	0.862	1.783
42	0.448	1.399

PECsw for dimethoate on wheat (Southern Europe), 1 application, 2.77% drift @ 1m, 400 g/ha

Days after appl'n	PECsoil (mg/kg)	Time weighted average (mg/kg)
0	3.693	3.693
1	3.524	3.608
2	3.363	3.526
4	3.062	3.368
7	2.661	3.149
14	1.917	2.709
21	1.381	2.351
28	0.995	2.058
42	0.517	1.615

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

PECsw for dimethoate on sugar beet (Nothern Europe), 2 applications, 2.38% drift @ 1m, 84 g/ha for first application, 400 g/ha for second application, 30 day spray interval.

Days after 2nd appl'n	PECsoil (mg/kg)	Time weighted average (mg/kg)
0	3.337	3.337
1	3.184	3.260
2	3.038	3.185
4	2.767	3.043
7	2.404	2.845
14	1.732	2.447
21	1.248	2.124
28	0.899	1.859
42	0.467	1.459

PECsw for dimethoate on wheat (Northern Europe), 1 application, 0.57% drift @ 5m, 680 g/ha

Days after appl'n	PECsoil (mg/kg)	Time weighted average (mg/kg)
0	1.292	1.292
1	1.233	1.262
2	1.176	1.233
4	1.071	1.178
7	0.931	1.102
14	0.671	0.948
21	0.483	0.822
28	0.348	0.720
42	0.181	0.565

Metabolite - O-desmethyl dimethoate

Method of calculation	See above for PECsw assumptions. O-desmethyl dimethoate: maximum 17.6% AR in dark sediment/water study, DT_{50} not calculable Molecular weight correction factor 0.94
Application rate	Dimethoate on olives, 2.88 kg a.s./ha (4 x 0.72 kg /ha)
Main routes of entry	Via spray drift of dimethoate, 11.01% drift at 3m

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

PEC$_{(sw)}$ (µg / l)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			17.486	

Metabolite - O,O-dimethyl thiophosphoric acid

Method of calculation	See above for PECsw assumptions. O,O-dimethyl thiophosphoric acid: maximum 36.0% AR in sterile dark hydrolysis study, DT_{50} not calculable Molecular weight correction factor 0.62
Application rate	Dimethoate on olives, 2.88 kg a.s./ha (4 x 0.72 kg /ha)
Main routes of entry	Via spray drift of dimethoate, 11.01% drift at 3m

PEC$_{(sw)}$ (µg / l)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			23.591	

PEC (sediment)

Parent

Method of calculation	Sediment dwellers toxicity end-point is expressed in terms of a nominal water concentration rather than a sediment concentration, and thus an accumulated PECsw has been calculated for multiple applications which assumes no degradation between applications. This conservative approach allows for uncertainty about the accumulation of dimethoate in sediment under multiple application GAPs. PEC values for distances giving acceptable aquatic risk assessments are given. See section B.8.6 of Volume 3 of Draft Assessment Report for other PEC values. A maximum PECsed based on 5cm depth sediment, 1.3 g/cm3 bulk density, max. total dose 2880 g a.s./ha, 11.01 % drift at 3m 11.9% AR in sediment at 7 DAT and 0.8% AR in sediment at 105 DAT in sediment/water study
Application rate	See above for application rates

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Olives, 20m – 7.680 µg/L
Sugar beet, Southern Europe 1m – 9.520 µg/L
Tomato 10m – 4.280 µg/L
Wheat, Southern Europe 1m – one application only, thus not applicable
Sugar beet, Northern Europe 1m – 3.840 µg/L
Wheat, Northern Europe 1m – 8.092 µg/L

PEC$_{(sed)}$ (µg / kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial (7 DAT)			58.051 µg/kg	
Short term				
Long term (105 DAT)			3.903 µg/kg	

Metabolite

Method of calculation	No significant metabolites in sediment, thus no calculation made.
Application rate	Not relevant

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

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	FOCUS-PELMO 2.2.2 modelling with prescribed FOCUS scenarios for the notified GAPs except glasshouse lettuce (not modelled). Olives not specified in FOCUSgw, thus citrus considered to be acceptable in its stead.
Application rate	See GAP and application dates table below. Input parameters for dimethoate and omethoate given below.

PEC$_{(gw)}$

Maximum concentration	No data available
Average annual concentration (Results quoted for modelling with FOCUS gw scenarios, according to FOCUS guidance)	Not relevant

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

GAP information

Crop	Number of appli-cations	Growth stage [BBCH]	Minimum Interval between applications	Application rate per treatment (kg as/ha)	Deposition (%)	deposition per treatment (kg as/ha)
Southern Europe						
Olives	4	-	30	0.72	30	0.22
Sugar beet	2	16-18/ 35-43	30	0.6	80/ 50	0.48/ 0.18
Tomatoes	2	69-81	15	0.6	20/ 20	0.12/ 0.12
Wheat	1	69	-	0.4	30	0.12
Northern Europe						
Sugar beet	2	16-18/ 35-43	30	0.084/ 0.4	80/ 30	0.07/ 0.12
wheat	2	23-30/ 69	30	0.68 / 0.34	50/ 30	0.34/ 0.1

Application dates specified in FOCUS-PELMO 2.2.2

Location	Date of 1st application	Date of 2nd application	Date of 3rd application	Date of 4th application	Date of harvest
Olives					
Piacenza	16/9	7/10	28/10	18/11	15/12
Porto	16/9	7/10	28/10	18/11	15/12
Sevilla	16/9	7/10	28/10	18/11	15/12
Thiva	31/8	21/9	12/10	02/11	30/11
Sugar beet in Southern Europe					
Piacenza	15/07	15/08	-	-	15/09
Porto	01/06	01/07	-	-	01/08
Sevilla	01/05	01/06	-	-	01/07
Thiva	30/07	30/08	-	-	30/09
Tomatoes in Southern Europe					
Piacenza	20/07	04/08	-	-	25/08
Porto	26/07	10/08	-	-	31/08
Sevilla	26/05	10/06	-	-	01/07
Thiva	05/08	20/08	-	-	10/09

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Location	Date of 1st application	Date of 2nd application	Date of 3rd application	Date of 4th application	Date of harvest
Wheat (= winter cereals scenario) in Southern Europe					
Piacenza	03/06	-	-	-	01/07
Porto	02/06	-	-	-	30/06
Sevilla	03/05	-	-	-	31/05
Thiva	02/06	-	-	-	30/06
Sugar beet in Northern Europe					
Chateaudun	25/05	25/06			15/10
Hamburg	18/05	18/06			08/10
Jokioinen	25/05	25/06			15/10
Kremsmunster	20/05	20/06			10/10
Okehampton	05/06	05/07			25/10
Wheat (= winter cereals scenario) in Northern Europe					
Chateaudun	01/03	01/07			15/07
Hamburg	25/03	25/07			10/08
Jokioinen	30/03	30/07			15/08
Kremsmunster	25/03	25/07			10/08
Okehampton	15/03	15/07			01/08

Input parameters, dimethoate and omethoate

Parameters	Unit	Dimethoate	Remarks	Omethoate	Remarks
Molecular weight	[g/mol]	229.3		213.2	-
Solubility in water	[mg/L]	39.8[1]	at 20°C	nr	-
Vapour pressure	[Pa]	2.46×10^{-4}	at 25°C	nr	-
pKa-value	[-]	20	Dimethoate does not dissociate	20	no dissociation

[1] The correct input parameters to be used is 39800 mg/L (refer to the physical-chemical properties section). However, in the evaluated PELMO modelling the direct input parameter for the Henry's Law constant (1.42×10^{-6} Pa m^3 mol^{-1}) was used. Therefore, as the solubility input parameter of 39.8 mg/L was not taken into consideration, the modelling is considered valid.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Parameters	Unit	Dimethoate	Remarks	Omethoate	Remarks
Reference pH value at which Koc value was determined	[-]	6.7		7	FOCUS, 2000
Henry coefficient	[Pa m³ mol^{-1}]	1.42 x 10^{-6}		nr	-
Diffusion coefficient air	[cm²/s]	0.05	FOCUS (2000) default	nr	-
Volatilisation depth	[cm]	0.1	FOCUS (2000) default	nr	-
DT_{50}	[d]	2.6		2.8	Wagner, 1975
Formation fraction		-		1.0	
Reference temperature	[°C]	20	FOCUS (2000)	20	FOCUS, 2000
Reference soil moisture	[kPa]	10	FOCUS (2000)	10	FOCUS, 2000
Q10-factor	[-]	2.2	FOCUS (2000)	2.2	FOCUS, 2000
Koc-value	[mL/g]	30.1	Annex II, 7.1.2	41.3	Bachlechner, 1988
Exponent of the Freundlich isotherm	[-]	1.019	FOCUS (2000)	1.0	FOCUS, 2000

nr = not required by PELMO

PEC(gw) - FOCUS modelling results, 80th percentile concentrations

Scenario	Southern Europe (dimethoate µg/L : omethoate µg/L)			
	Olives	Sugar beets)	Tomatoes	Wheat
Piacenza	0.148 : 0.412	0.001 : 0.003	0.000 : 0.000	0.000 : 0.000
Porto	0.000 : 0.000	0.000 : 0.000	0.000 : 0.000	0.000 : 0.000
Sevilla	0.009 : 0.014	0.000 : 0.000	0.000 : 0.000	0.000 : 0.000
Thiva	0.009 : 0.038	0.000 : 0.000	0.000 : 0.000	0.000 : 0.000

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

	Northern Europe (dimethoate µg/L : omethoate µg/L)	
	Sugar beets	Wheat
Châteaudun	0.000 : 0.000	0.000 : 0.000
Hamburg	0.000 : 0.000	0.000 : 0.000
Jokioinen	0.000 : 0.000	0.000 : 0.000
Kremsmünster	0.000 : 0.000	0.000 : 0.000
Okehampton	0.000 : 0.000	0.000 : 0.000

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

Direct photolysis in air ‡	Not studied – no data requested
Quantum yield of direct phototransformation	Not provided, estimated to be close to zero.
Photochemical oxidative degradation in air ‡	DT_{50} of 1.6 hours (OH radical concentration 6 x 10^5 molecules/cm^3 with 12 hours irradiation) according to Atkinson method of calculation
Volatilization ‡	from plant surfaces: 13.1 – 13.8% AR after 24 hours from soil: 1.3% AR after 24 hours
	Henry's Law Constant 1.42 x 10^{-6} Pa.m^3/mol Henry's Law Coefficient 5.8 x 10^{-10}

PEC (air)

Method of calculation	Expert judgement, based on vapour pressure, dimensionless Henry's Law coefficient, information on volatilisation from plants and soil and Atkinson calculation

$PEC_{(a)}$

Maximum concentration	Negligible

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment for risk assessment and monitoring purposes	Soil: active substance dimethoate, omethoate. Surface water: active substance dimethoate, O-desmethyl dimethoate, O,O-dimethyl thiophosphoric acid Sediment: active substance dimethoate. Groundwater: active substance dimethoate, omethoate. Air: dimethoate, omethoate[10]

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

Soil (indicate location and type of study)	None submitted
Surface water (indicate location and type of study)	Four studies covering a wide range of European situations. Highest concentration in a UK stream fed by field drainage, 3µg/L
Ground water (indicate location and type of study)	Netherlands and UK, highest concentration in Netherlands, 0.06µg/L
Air (indicate location and type of study)	None submitted

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	Candidate for R 53 (may cause long-term adverse effects in the aquatic environment)

[10] The inclusion of the metabolite omethoate in the definition for air is precautionary since Omethoate has been withdrawn from List 2 as an active substance and is not included on Annex I.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.6: Effects on non-target Species

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

Acute toxicity to mammals ‡	Dimethoate: Mouse LD_{50} (oral) 160 mg a.s. /kg bw Omethoate: Rat LD_{50} (oral) 22 mg metabolite /kg bw
Reproductive toxicity to mammals ‡	Dimethoate: Rat NOEC 15 ppm a.s. in diet (1.2 mg a.s. /kg bw /day) Omethoate: Rat NOEC 3 ppm metabolite in diet (0.2 mg metabolite /kg bw /day)
Acute toxicity to birds ‡	*Colinus virginianus* (Bobwhite quail). Dimethoate: LD_{50} (oral) 10.5 mg a.s. / kg bw, NOEL 5 mg a.s. / kg bw Omethoate: LD_{50} (oral) 9.9 mg metabolite / kg bw, NOEL 1.0 mg metabolite / kg bw *Phasianus colchicus* (Ring-necked pheasant). Dimethoate: LD_{50} (oral) 14.1 mg a.s. / kg bw, NOEL 10 mg a.s. / kg bw Omethoate: LD_{50} (oral) 29 mg a.s. / kg bw, NOEL 2.5 mg a.s. / kg bw
Dietary toxicity to birds ‡	*Colinus virginianus* (Bobwhite quail): Dimethoate: 5 day LC_{50} (oral) 154 ppm a.s. in diet (14.8 mg a.s. /kg bw /day), NOEC 36 ppm a.s. in diet. *Phasianus colchicus* (Ring-necked pheasant): Dimethoate: 5 day LC_{50} (oral) 396 ppm a.s. in diet (41.9 mg a.s. /kg bw /day), NOEC 150 ppm a.s. in diet
Reproductive toxicity to birds ‡	*Colinus virginianus* (Bobwhite quail):: Dimethoate: NOEC 10.1 ppm a.s. in diet (1.0 mg a.s. / kg bw / day) *Anas platyrhynchos* (Mallard duck): Dimethoate: NOEC 35.4 ppm a.s. in diet (5.8 mg a.s. / kg bw / day)

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

Crop use & vertebrate category	Time scale	TER	Annex VI trigger
Wheat (S. Europe): 1 x 0.4 kg a.s./ha			
Insectivorous bird (10 g bw)	Acute	0.49	10
	Short-term dietary	1.23	10
	Long-term dietary	0.08	5

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Crop use & vertebrate category	Time scale	TER	Annex VI trigger
Large herbivorous bird (3000 g bw)	Acute Short-term dietary Long-term dietary	0.42 1.11 0.14	10 10 5
Small insectivorous mammal (10 g bw)	Acute Long-term dietary	45.33 0.93	10 5
Small herbivorous mammal (25 g bw)	Acute Long-term dietary	2.03 0.05	10 5
Wheat (N. Europe): 1 x 0.68 + 1 x 0.34 kg a.s./ha			
Insectivorous bird (10 g bw)	Acute Short-term dietary Long-term dietary	0.29 0.72 0.05	10 10 5
Large herbivorous bird (3000 g bw)	Acute Short-term dietary Long-term dietary	0.25 0.65 0.08	10 10 5
Small insectivorous mammal (10 g bw)	Acute Long-term dietary	26.67 0.53	10 5
Small herbivorous mammal (25 g bw)	Acute Long-term dietary	1.19 0.03	10 5
Olives (S. Europe): 4 x 0.72 kg a.s./ha, 20 day interval.			
Insectivorous bird (10 g bw)	Acute Short-term dietary Long-term dietary	0.27 0.68 0.05	10 10 5
Small herbivorous mammal (25 g bw)	Acute Long-term dietary	1.13 0.03	10 5
Sugar beet (S. Europe): 2 x 0.6 kg a.s./ha, 30 day interval.			
Insectivorous bird (10 g bw)	Acute Short-term dietary Long-term dietary	0.32 0.82 0.06	10 10 5
Medium herbivorous bird (300 g bw)	Acute Short-term dietary Long-term dietary	0.26 0.81 0.10	10 10 5
Medium herbivorous mammal (3000 g bw)	Acute Long-term dietary	10.94 0.34	10 5

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Crop use & vertebrate category	Time scale	TER	Annex VI trigger
Sugar beet (N. Europe): 1 x 0.084 + 1 x 0.4 kg a.s./ha ##			
Insectivorous bird (10 g bw)	Acute Short-term dietary Long-term dietary	0.48 1.23 0.08	10 10 5
Medium herbivorous bird (300 g bw)	Acute Short-term dietary Long-term dietary	0.40 1.22 0.16	10 10 5
Medium herbivorous mammal (3000 g bw)	Acute Long-term dietary	16.43 0.51	10 5
Tomato (S. Europe): 2 x 0.6 kg a.s./ha, 15 day interval.			
Insectivorous bird (10 g bw)	Acute Short-term dietary Long-term dietary	0.32 0.82 0.06	10 10 5
Small insectivorous mammal (10 g bw)	Acute Long-term dietary	30.25 0.62	10 5

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
Laboratory tests ‡				
‡*Oncorhyncus mykiss*	a.s.	Acute	96h LC_{50}	30.2 mg a.s./L
‡*Daphnia magna*	a.s.	Acute	48h EC_{50}	2.0 mg a.s./ L
‡*Selenastrum capricornutum*	a.s.	Acute	72h EbC50	90.4 mg a.s./L
‡*Lepomis machrochirus*	Formulation1	Acute	96h LC_{50}	17.6 mg a.s./L
‡*Daphnia magna*	Formulation1	Acute	48h EC_{50}	2.2 mg a.s./L
‡*Selenastrum capricornutum*	Formulation1	Acute	72h EbC50	93.3 mg a.s./L
‡*Oncorhyncus mykiss*	O-desmethyl dimethoate	Acute	96h LC_{50}	>100 mg/L

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
‡*Daphnia magna*	O,O-dimethyl thiophosphoric acid	Acute	48h EC_{50}	70.5 mg/L
‡*Oncorhyncus mykiss*	O,O-dimethyl phosphoric acid	Acute	96h LC_{50}	>1000 mg/L
‡*Daphnia magna*	O,O-dimethyl phosphoric acid	Acute	48h EC_{50}	> 1000 mg/L
‡*Oncorhyncus mykiss*	a.s.	Chronic	21-day juvenile NOEC	0.4 mg a.s./L
Oncorhyncus mykiss	Formulation1	Chronic	21-day juvenile NOEC	0.29 mg a.s./L
‡*Oncorhyncus mykiss*	a.s.	Chronic	96-day ELS NOEC	1.5 mg a.s./L
‡*Daphnia magna*	a.s.	Chronic	21-day NOEC	0.04 mg a.s./L
Daphnia magna	Formulation1	Chronic	21-day NOEC	0.024 mg a.s./L
‡*Chironomus riparius*	a.s.	Chronic (spiked water)	28-day EC05	0.08 mg a.s./L

[1] 'Roxion' (400 g a.s./L EC formulation)

Microcosm or mesocosm tests
No studies presented.

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

Application rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
0.4	Wheat (S)	*O mykiss*	acute	1m	8184	100
		*L machrochirus**	acute	1m	4770	100
		D magna	acute	1m	542	100
		*D magna**	acute	1m	592	100
		S capricornutum	acute	1m	24498	10
		*S capricornutum**	acute	1m	25284	10
		O mykiss	Chronic	1m	406	10
		D magna	Chronic	1m	10.8	10

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Application rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
0.68/0.34	Wheat (N)	*O mykiss*	acute	1m	4817	100
		*L machrochirus**	acute	1m	2807	100
		D magna	acute	1m	319	100
		*D magna**	acute	1m	350	100
		S capricornutum	acute	1m	14418	10
		*S capricornutum**	acute	1m	14880	10
		O mykiss	Chronic	1m	239	10
		D magna	Chronic	1m	**6.4**	10
		D magna	Chronic	5m	31	10
0.72 x 4	Olives (S)	*O mykiss*	acute	3m	730	100
		*L machrochirus**	acute	3m	425	100
		D magna	acute	3m	**48.3**	100
		*D magna**	acute	3m	**53.3**	100
		D magna	acute	5m	**88.1**	100
		*D magna**	acute	5m	**96.9**	100
		D magna	acute	10m	199	100
		*D magna**	acute	10m	218	100
		S capricornutum	acute	3m	2185	10
		*S capricornutum**	acute	3m	2259	10
		O mykiss	Chronic	3m	36.6	10
		D magna	Chronic	3m	**0.97**	10
		D magna	Chronic	5m	**1.8**	10
		D magna	Chronic	10m	**4.0**	10
		D magna	Chronic	15m	**7.7**	10
		D magna	Chronic	20m	13.3	10

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Application rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
0.6 x 2	Sugar beet (S)	*O mykiss*	acute	1m	5093	100
		*L machrochirus**	acute	1m	2983	100
		D magna	acute	1m	337	100
		*D magna**	acute	1m	372	100
		S capricornutum	acute	1m	15244	10
		*S capricornutum**	acute	1m	15814	10
		O mykiss	Chronic	1m	253	10
		D magna	Chronic	1m	**6.7**	10
		D magna	Chronic	5m	34.2	10
0.084/0.04	Sugar beet (N)	*O mykiss*	acute	1m	9042	100
		*L machrochirus**	acute	1m	5269	100
		D magna	acute	1m	599	100
		*D magna**	acute	1m	659	100
		S capricornutum	acute	1m	27066	10
		*S capricornutum**	acute	1m	27934	10
		O mykiss	Chronic	1m	449	10
		D magna	Chronic	1m	12.0	10
0.6 x 2	Tomatoes	*O mykiss*	acute	3m	1397	100
		*L machrochirus**	acute	1m	815	100
		D magna	acute	3m	**92.5**	100
		D magna	acute	5m	228	100
		*D magna**	acute	3m	101.8	100
		S capricornutum	acute	3m	4181	10
		*S capricornutum**	acute	3m	4319	10
		O mykiss	Chronic	3m	69.4	10
		D magna	Chronic	3m	**1.8**	10
		D magna	Chronic	5m	**4.2**	10
		D magna	Chronic	10m	12.5	10

* Formulation toxicity (TERs based on active substance equivalents)

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Bioconcentration

Bioconcentration factor (BCF) ‡	Log Pow 0.7: therefore study not required.
Annex VI Trigger:for the bioconcentration factor	Not required.
Clearance time (CT_{50}) (CT_{90})	Not required.
Level of residues (%) in organisms after the 14 day depuration phase	Not required.

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

Acute oral toxicity ‡	Technical dimethoate 0.1 µg/bee (lowest value stated in OECD Guideline 213 for this toxic reference material)
Acute contact toxicity ‡	Technical dimethoate 0.1 µg/bee (lowest value stated in OECD Guideline 214 for this toxic reference material)

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

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
400	Wheat (S)	Oral/contact	4000	50
340[1]	Wheat (N)	Oral/contact	3400	50
720	Olives	Oral/contact	7200	50
600	Sugar Beet (S)	Oral/contact	6000	50
400	Sugar Beet (N)	Oral/contact	4000	50
600	Tomatoes	Oral/contact	6000	50
340	Lettuce (G)	No relevant exposure	NA	NA

(S) Southern Europe, (N) Northern Europe, (G) Glasshouse
[1] late season application rate which is considered more relevant for risk assessment

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Field or semi-field tests
High mortality in bees exposed to residues aged for up to 120 hrs on detached apple leaves previously treated with Dimethoate 40% EC at 720 g a.s./ha. No significant adverse impacts (i.e. <20% mortality) following continuous exposure for 24 h to 12 day old aged residues on apple leaves in same study. After continuous exposure for 48 hours, mortality was 35% when exposed to 12 day old residues and 10% when exposed to 14 day old residues. High mortality in bees exposed for 24 hrs to flowering oilseed rape treated the previous day with Dimethoate 40% EC at 890 g a.s./ha. Mortality in bees fed on nectar from glasshouse grown Bluebell and oilseed rape treated previously with 0.1 and 0.2 % dimethoate solutions. Evidence of a weak repellency effect in apple orchards, but results are difficult to relate to supported uses due to differential attractiveness of crops and the presence in the trials of high proportions of untreated trees. Mortality and subsequent loss of hive condition in tunnel test following application of Dimethoate 40% EC at 400 and 500 g a.s/ha whilst bees were actively foraging on artificial aphid honeydew in cereals. Field studies indicate high risk to bees present at time of application and for short periods after treatments. MS's to consider appropriate risk mitigation measures, which will vary according to rate of application and attractiveness of the crop.

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

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint Effect	Annex VI Trigger
Laboratory tests ‡					
Aphidius rhopalo-siphi (aphid parasitoid)	Adult (48 hour exposure to glass plate deposit)	'Dimethoate 400g/L EC' ≡ 'Danidim Dimethoate'	0.01-0.018 g a.s. /ha	**% mortality** g a.s./ha = 40.2%* 0.02 g a.s./ha = 48.4% 0.04 g a.s./ha = 97.3%* 0.08 g a.s./ha =100%* 0.18 g a.s./ha = 100%* Untreated = 8% LR_{50} (95% CL) 0.014 g a.s./ha (0.012 - 0.017) (≡ 0.34 mL form^{n}/ha) **Reproductive capacity** Control = 11.9 mummies/female[3]. No significant effect on reproductive capacity at 0.01 g (0.67 relative to control). Reproductive capacity not determined at higher test concns. due to high adult mortality	30% effects at proposed maximum individual dose

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint Effect	Annex VI Trigger
Typhlodromus pyri (predatory mite)	Adult (48 hour exposure to glass plate deposit)	'Dimethoate 400g/L EC' ≡ 'Danidim Dimethoate'	0.13-13.36 g a.s./ha	**% mortality** 0.13 g a.s./ha = 0% 0.42 g a.s./ha = 6.3% 1.34 g a.s./ha = 28.1%* 4.18 g a.s./ha =76.0%* 13.36 g a.s./ha = 94.8%* Untreated = 4% LR_{50} (95% CL) 2.24 g a.s./ha (1.88 – 2.66) (Equivalent to 5.36 mL form^{n}./ha) **Reproductive capacity** Control 9.1 offspring/female[4]. Reproductive capacity relative to control 0.95, 0.77, 0.69*, at 0.13, 0.42 and 1.34 g a.s./ha. Reproductive capacity not determined at higher test concentrations due to high adult mortality	30% effects at proposed maximum individual dose
Aphidius rhopalosiphi (aphid parasitoid)	Adult female (48 hour exposure to foliar deposit)	'Dimethoate 400g/L EC' ≡ 'Danidim Dimethoate'	1.5-748 g a.s. /ha	**% mortality** Exposure to 0 day old residues: 3.6 mL product /ha: **78%***** 27-1800 mL product /ha: **100%***** Water control: 0% Exposure to 7 day old residues: 3.6 mL product /ha: **52%** *** 27 mL product /ha: **80%** *** 900-1800 mL product /ha: **94-100%** *** Water control: 4% Exposure to 14 day old residues: 3.6 mL product /ha: 2% ns 27 mL product /ha: 4% ns 900 mL product /ha: 6% ns 1500-1800 mL product /ha: **96-100%** *** Water control: 6% Exposure to 21 day old residues: 900 mL product /ha: 12% ns 1500 mL product /ha: 18% ns 1800 mL product /ha: 14% ns Water control: 8% **No. parasitised aphids /female)**	30% effects at proposed maximum individual dose

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint Effect	Annex VI Trigger
				Exposure to 14 day old residues: 3.6 mL product /ha: 23 ns 27 mLproduct /ha: 20 ns 900 mL product /ha: 16 ns Water control: 18 Exposure to 21 day old residues: 900 mL product /ha: 22 ns 1500 mL product /ha: 23 ns 1800 mL product /ha: 26 ns Water control: 31	
Chryso-perla carnea (lacewing)	Larvae (48 hour exposure to foliar deposit)	'Dimethoate 400g/L EC' ≡ 'Danidim Dimethoate'	1.5-748 g a.s. /ha	**% corrected mortality** Larval exposure to 0 day old residues: 3.6 mL product /ha: 3% ns 900 mL product /ha: **92%** *** 1800 mL product /ha: **100%** *** Larval exposure to 7 day old residues: 900 mL product /ha: **39%** *** 1800 mL product /ha: **67%** *** Larval exposure to 14 day old residues: 900 mL product /ha: 6% ns 1800 mL product /ha: **39%** *** Larval exposure to 21 day old residues: 1800 mL product /ha: 0% **Eggs/female/day & % egg viability)** Larval exposure to 0 day old residues: 3.6 mL product /ha: 30 ns; 90%. Control: 31; 91% Larval exposure to 14 day old residues: 900 mL product /ha: 35 ns; 87% Control: 28; 87% Larval exposure to 21 day old residues: 1800 mL product /ha: 36 ns; 89% Control: 35; 89%	30% effects at proposed maximum individual dose

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint Effect	Annex VI Trigger
Aphidius rhopalo-siphi (aphid parasitoid)	Adult female (48h exposure to foliar deposit) Ext. lab. study.	'BAS 152 59 I', an EC (404.2 g/L dimethoate)	0.75-12.0 g a.s. /ha	'BAS 152 59 I' LR50 = 7.68 mL/ha (= 3.07 g dimethoate/ha) (a <50% effect on mortality and fecundity were apparent ≤ 1.5 g dimethoate/ha).	ESCORT II <50%

* Statistically significant difference from the control

Field or semi-field tests

Details were submitted for a large number of cereal field trials examining the effects on non-target arthropod populations of a single spray of 340-500g dimethoate/ha, made mostly in the spring or early summer, with a few trials including autumn application. Use at these rates resulted in high initial levels of mortality of a broad range of non-target arthropods, with recovery or partial recovery of the vast majority of groups within 4-7 weeks. Lack of prey sometimes accounted for incomplete in-crop recovery of predator numbers. Ground dwelling predators (e.g. carabids) showed a variable recovery rate in the reported trials, with re-establishment times of between 7 days and 6 months.

Details from cereal and apple orchard field trials using low doses of dimethoate indicate no effects on non-target arthropods from respective use rates of 1.44 g and 10.8 g a.s./ha.

NTA buffer zones

Crop	Application rate (g a.s./ha)	No effect off-field drift (% application rate)	Acceptable drift distance (m) (acceptable drift % application rate) no.applications =1(MAF)	Acceptable drift distance (m) (acceptable drift % application rate) no.applications=GAP
Wheat (F/SEU)	400	0.36[1] 2.70[2]	10 (0.29) 5 (0.57)	10 (0.29) 5 (0.57)
Wheat (F/NEU)	680	0.21[1] 1.59[2]	15 (0.20) 5 (0.57)	15 (0.16) 5 (0.57)
Olives (F/SEU)	720	0.20[1] 1.50[2]	75 (0.11) 20 (1.09)	40 (0.20) 15 (1.28)
Sugar beet (F/SEU)	600	0.24[1] 1.80[2]	15 (0.20) 5 (0.57)	10 (0.24) 5 (0.47)
Sugar beet (F/NEU)	400	0.36[1] 2.70[2]	10 (0.29) 5 (0.57)	10 (0.24) 1 (2.38)

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Crop	Application rate (g a.s./ha)	No effect off-field drift (% application rate)	Acceptable drift distance (m) (acceptable drift % application rate) no.applications =1(MAF)	Acceptable drift distance (m) (acceptable drift % application rate) no.applications=GAP
Tomatoes (F/SEU)	600	0.24[1] 1.80[2]	30 (0.22) 10 (1.23)	30 (0.19) 10 (1.07)
Lettuce (G/NEU)	340	nr	nr	nr

based on cereal [1] and apple orchard[2] field study no effect levels

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

Acute toxicity ‡	Technical dimethoate 14 day LC_{50} 31 mg a.s./kg O,O-dimethyl phosphoric acid 14 day LC_{50} >1000 mg/kg[2] O,O-dimethyl-tiophosphoric acid 14 day LC_{50} >1000 mg/kg[2] 'Dimethoate 40% EC' 14 day LC_{50} 84.5 mg a.s./kg 'Folimat' (50% omethoate) 14-day LC_{50} 23 mg omethoate/kg[1]
Reproductive toxicity ‡	Technical dimethoate 56 day NOEC 2.87 mg a.s.kg 'Dimethoate 40% EC' 56 day NOECs: <5.2 mg a.s./kg in standard OECD artificial soil 5.2 mg a.s./kg in 50:50 mix artificial/sandy loam soil

[1] The Rapporteur notes the apparent 2.7 fold increase in acute toxicity of dimethoate in the active substance study compared to the formulated product endpoint when expressed in terms of active substance and therefore proposes to apply a similar factor to the Folimat toxicity endpoint since exposure to omethoate will be to the metabolite and not to the formulated product.
[2] Metabolites are not major or of ecological relevance in soil.

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

Application rate (kg as/ha)	Crop	Time-scale	TER	Annex VI Trigger
Dimethoate				
0.6	Sugar Beet[1]	Acute	48.4[1]	10
0.6	Sugar Beet[1]	Chronic	**4.5**[4]	5
0.68	Wheat (N Europe)[5]	Chronic	6.33[4]	5
0.6	Sugar Beet[1]	Chronic	8.1[6]	5

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Application rate (kg as/ha)	Crop	Time-scale	TER	Annex VI Trigger
Omethoate				
0.72	Olives[2]	Acute	10.9[2,3]	10
	Olives (the only use for which a chronic risk assessment might be required (i.e > 3 applications))	Chronic	Due to absence of a chronic study this cannot be assessed. Will only be required if omethoate is confirmed as a major soil metabolite	5

[1] Taking into account the application rate, crop interception, number of applications and the proposed spray interval, this use represents the worst case PECini (0.64 mg a.s./kg) for risk assessment
[2] For the soil metabolite omethoate, the worst case PECini (0.78 mg/kg) is based on a worst case assumption of 4 applications each of 0.72 kg dimethoate/ha, with no degredation, on Olives
[3] based on a predicted LC50 of 8.5 mg omethoate/kg soil (see annotation 1 in previous table)
[4] based on repro. NOEC of 2.87 mg a.s./kg soil from technical dimethoate study.
[5] based on the application rate, number of applications and crop interception, this use represents the second highest PEC for use in chronic risk assessment.
[6] refined risk assessment using reproductive NOEC of 5.2 mg/kg soil from a OECD 207 test conducted using a more natural soil.

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

Nitrogen mineralization ‡	Technical dimethoate <25% up to 8.0 mg a.s./kg O,O-dimethyl phosphoric acid <25% up to 9.07 mg/kg O,O-dimethyl thiophosphoric acid <25% up to 9.07 mg/kg 'Dimethoate 40% EC' <25% up to 12 kg a.s./ha 'Folimat' (97.1% omethoate) <25% up to 13.33 mg omethoate/kg
Carbon mineralization ‡	Technical dimethoate <25% up to 8.0 mg a.s./kg O,O-dimethyl phosphoric acid <25% up to 9.07 mg/kg O,O-dimethyl thiophosphoric acid <25% up to 9.07 mg/kg 'Dimethoate 40% EC' <25% up to 12 kg a.s./ha 'Folimat' (51.1% omethoate) <25% up to 33 mg omethoate/kg

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Effects on non-target organisms (flora and fauna) (Annex IIA, point 8.6)

Non target plants ‡	Results of OECD 208 post-emergence growth test conducted with a 40% EC formulation presented. Phytotoxic symptoms <25% in 6 different crop species (4 dicots + 2 monocots) at 1800 g a.s./ha.
Other non target fauna ‡	No summary of biological screening studies presented.

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	N;	Harmful
	R51/53	Toxic to the aquatic organisms, may cause long-term adverse effects in the aquatic environment.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

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
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
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year