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

fenamiphos

finalised: 13 January 2006

SUMMARY

Fenamiphos 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 Netherlands being the designated rapporteur Member State submitted the DAR on fenamiphos in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 27 November 2003. Following a quality check on the DAR, the peer review was initiated on 4 March 2004 by dispatching the DAR for consultation of the Member States and the sole applicant Irvita. 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 27 September 2004. 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 April and May 2005.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 30 November 2005 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 nematicide as proposed by the applicant which comprises application by drip irrigation and "chisel application" (spray application followed by incorporation into the soil) in bell-pepper and tobacco, respectively. The application rates are 10 kg fenamiphos per hectare in bell pepper and 6 kg per hectare in tobacco. Fenamiphos can be used as nematicide and insecticide. It should be noted that during the peer review process the applicant stated that only the use as nematicide will be supported in the EU review programme.

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

The representative formulated product for the evaluation was Nemacur CS 240, a capsule suspension (CS), registered in South Europe.

Adequate methods are available to monitor all compounds given in the respective residue definition except for a method for fenamiphos-sulfone-phenol in ground water and a method for blood and animal tissues.
Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues.
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.

Fenamiphos is rapidly and almost completely absorbed within 24 hours. It is extensively metabolised into fenamiphos-phenols. It has a high acute toxicity (therefore, the following classifications were proposed: T+; R28 "Very toxic if swallowed", T; R24 "Toxic in contact with skin" and T+; R26 "Very toxic by inhalation"). Fenamiphos was irritating to the eye in rabbits (classification Xi; R36 "Irritating to eyes" is proposed). It showed no skin sensitising properties. The relevant short and long term oral no observed adverse effect levels (NOAEL) are 0.083 mg/kg bw/day and 0.56 mg/kg bw/day, respectively. Based on the available *in vitro* and *in vivo* tests, fenamiphos is considered not genotoxic. There was no evidence of treatment related increase in carcinogenicity. In a multi-generation study in rats the relevant NOAEL for parental toxicity was 0.17 mg/kg bw/day, the relevant NOAEL for offspring toxicity was 0.64 mg/kg bw/day, and the relevant reproductive NOAEL was 2.8 mg/kg bw/day. The relevant NOAEL for developmental effects is 0.3 mg/kg bw/day in a teratogenicity study with rabbits. Fenamiphos showed no potential to induce delayed neuropathy after acute or subchronic administration in hens. The NOAEL for acute neurotoxicity is 0.25 mg/kg bw/day based on clinical signs and decreased erythrocyte cholinesterase in the acute dog study. Some metabolites showed high acute toxicity (LD_{50} <25 mg/kg bw). The Acceptable Daily Intake (ADI) and the Acceptable Operator Exposure level (AOEL) are 0.0008 mg/kg bw/day, and the Acute Reference Dose (ARfD) is 0.0025 mg/kg bw (safety factor – SF- 100). Operator, worker and bystander estimated exposure is below the AOEL (<5%).

The behaviour and metabolism of fenamiphos was investigated in a range of crops representing fruity crops, root and tuber crops, leafy crops, oilseeds and pulses as well as different kinds of application. All studies show a similar metabolic pathway in the plants. Fenamiphos is only found directly following application. A short period after treatment, fenamiphos-sulfoxide is the dominant metabolite. In some plants, fenamiphos-sulfone is increasing in time. Therefore, fenamiphos, fenamiphos-sulfoxide and fenamiphos-sulfone form the toxicological relevant residue. Residues of fenamiphos in rotation crops were found in soybean, Swiss chard, beet root, wheat green forage and wheat straw planted up to 8 months after treatment. Fruiting vegetables planted as rotational crops are not tested. It is recommended to prescribe a safety interval for planting or sowing rotational crops of 8

months. Furthermore, it is concluded that the rotational crops investigated are not representative for fruiting vegetables and therefore further data is still required.
Information on fenamiphos fed to ruminants and poultry is present, but is not relevant for the intended uses on sweet pepper and tobacco.
It is concluded that application of fenamiphos on tobacco and sweet pepper following the representative cGAP lead to residue levels on food not giving rise to concern for consumer exposure. However, since there were relevant metabolites found in ground water, a consumer risk assessment was performed, considering the sum of possible intakes of fenamiphos and the metabolites fenamiphos-sulfoxide and fenamiphos-sulfone from drinking water in addition to the intake through diet. The total intakes from diet and drinking were demonstrated to be significantly above the ADI and ARfD of fenamiphos for the considered consumer subgroups.

Fenamiphos is very low or low persistent in soil under aerobic conditions being rapidly oxidized to the major metabolites fenamiphos-sulfoxide and fenamiphos-sulfone. Fenamiphos-sulfoxide is moderate to high persistent in soil and fenamiphos-sulfone low to moderately persistent. Both organophosphate metabolites are hydrolysed to the major metabolites fenamiphos-sulfoxide-phenol and fenamiphos-sulfone-phenol. These metabolites are subsequently transformed to non extractable residues and mineralized to CO_2. Photolysis may contribute to the environmental degradation of fenamiphos.
Bare soil field dissipation in four Southern European locations with fenamiphos formulated as the representative capsule suspension product (Nemacur 240 CS) was investigated in one study. All major metabolites were found in the 0-10 cm layer and fenamiphos-sulfoxide was also found at deeper layers. Experts' meeting agreed that photolysis was not likely to have affected the degradation rate of fenamiphos and its metabolites in the field trials but leaching could not be completely excluded taking onto account the adsorbtion/desorption properties of these compounds.
The data provided after the expert's meeting confirm that the Spanish field trial should not be considered in the assessment of soil compartment and for PEC soil calculations.
Experts' meeting agreed with the RMS not to consider Nemacur 240 CS a slow release formulation.
New PECs soil have been provided by the RMS in the list of end points to take also into account the application rates of the representative uses and the maximum percentage of metabolites found in the laboratory studies, as agreed by the experts' meeting.
According batch adsorption/desorption studies, fenamiphos is low to high mobile whereas fenamiphos-sulfoxide, fenamiphos-sulfone, fenamiphos-sulfoxide-phenol and fenamiphos-sulfone-phenol are medium to very high mobile. No column leaching, field leaching or lysimeter studies are available for fenamiphos.
In sterile buffer solutions (pH 5, 7 and 9) at 20 °C fenamiphos may be considered stable (DT_{50} > 200 d). Aqueous photolysis may contribute to the transformation of fenamiphos into fenamiphos-sulfoxide. Fenamiphos sulfonic acid was detected as a minor metabolite and fenamiphos-phenol-sulfonic acid as a major photolysis metabolite of fenamiphos. This later metabolite shown to be stable to photolysis in water (DT_{50} = 768 d).
The experts' meeting proposed to classify fenamiphos as not ready biodegradable.

In water sediment systems fenamiphos dissipated relatively fast from the water phase but may be highly persistent in the whole system ($DT_{50\ whole\ system}$ = 9.3 – 111 d). Major metabolites in water were fenamiphos-sulfoxide and fenamiphos–sulfoxide-phenol. Fenamiphos-sulfoxide was also a major metabolite in the sediment. Mineralization reached a maximum of 2.4-14.3 % AR at the end of the study (100 d) and bound residues reached maximum amounts of 17.4 - 48 % AR.

For the representative uses of NEMACUR CS 240 (soil treatment with incorporation and drip irrigation) direct emissions to surface water are not expected. However, emissions via run-off and drainage may not be excluded. RMS presented FOCUS $PEC_{SW\ /\ SED}$ (Steps 1 and 2) calculations for fenamiphos, and initial FOCUS $PEC_{SW\ /\ SED}$ (step 1 and 2) for fenamiphos-sulfoxide, fenamiphos-sulfoxide-phenol, fenamiphos-phenol-sulfonic acid, fenamiphos-sulfone and fenamiphos-sulfone-phenol in an addendum that was discussed in the experts meeting. The meeting agreed that further refinement by FOCUS Step 3 should be provided by the applicant taking into consideration EFSA Opinion on the use of FOCUS SW.

For the FOCUS PEC_{GW} presented in the original DAR field dissipation half lives were employed as input parameters. The experts' meeting expressed concerns on the use the field dissipation half lives as degradation parameters for modelling in this case. New FOCUS-PEARL calculations, using normalized laboratory half lives, have been provided by the RMS in the list of end points and the updated addendum for the FOCUS scenarios Piacenza, Porto, Sevilla and Thiva. Potential contamination of ground water under vulnerable situations by fenamiphos metabolites over the triggers of 0.1 µg/L, 0.75µg/L and 10 µg/L may be deduced from these new calculations. Two of the metabolites are relevant. The experts' meeting recognized the difficulty to address potential ground water contamination from protected crop uses with the available scenarios. Since the practices to grow crops under protection are variable among EU a better definition of greenhouse uses is necessary. According to the applicant, NEMACUR CS 240 is used on permanent structures covered with plastic and nets and the crops are planted over the natural soil. The crop is irrigated to satisfy the crop water requirements. With the results of the new $FOCUS_{GW}$ simulations an assessment of the applicability of available FOCUS scenarios for the greenhouse use would be necessary.

Based on the available volatilisation experiment and the calculated atmospheric half life contamination of the air compartment and long range transport through air are not expected.

For the representative uses evaluated the only potentially relevant routes of bird and mammal exposure are via intake of contaminated soil arthropods, earthworms and fish. Since birds and mammals have no access to permanent glasshouses the only route of exposure from the use on bell peppers is via ingestion of contaminated fish. For the use on tobacco fields exposure via contaminated earthworms and soil arthropods is also possible. The initial risk assessment indicated a high risk for fish-eating birds and mammals from both uses and a high risk for earthworm-eating birds and mammals for the use in tobacco fields. Limited field surveys indicate that earthworms are not present in tobacco fields, but this has to be investigated further. The risk assessment for fish-eating birds and mammals needs to be refined based on refined PEC surface water data.

Fenamiphos and the metabolites fenamiphos-sulfoxide and fenamiphos-sulfone are very toxic to fish and aquatic invertebrates. The results from a mesocosm study indicate a potential high risk and the assessment need to be refined based on refined PEC surface water data.
The risk to bees and other non-target arthropods is considered low from the representative uses evaluated, while a risk to earthworms, other soil macro-organism and micro-organism has been identified and needs to be further addressed.
The risk to non-target plants and biological methods of sewage treatment is considered low.

Key words: fenamiphos, peer review, risk assessment, pesticide, nematicide, insecticide

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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. Fenamiphos is one of the 52 substances of the second stage covered by the amended Regulation (EC) No 451/2000 designating the Netherlands as rapporteur Member State.

In accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, the Netherlands submitted the report of its initial evaluation of the dossier on fenamiphos, hereafter referred to as the draft assessment report, to the EFSA on 27 November 2003. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 8(5) of the amended Regulation (EC) No 451/2000 the revised version of the draft assessment report was distributed for consultation on 4 March 2004 to the Member States and the main applicant Irvita 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 27 September 2004 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 at the Federal Office of Consumer Protection and Food Safety at Braunschweig, Germany, in April and May 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 30 November2005 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 12 October 2004)
- 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. 1-3 of 12 December 2005).

Given the importance of the draft assessment report including its addendum (compiled version of December 2005 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

Fenamiphos is the ISO common name for (*RS*)-ethyl 4-methylthio-*m*-tolyl isopropylphosphoramidate (IUPAC).

Fenamiphos belongs to the class of organophosphate nematicides such as cadusafos and ethoprophos and to the class of phosphoramidate insecticides such as fosthietan and phosfolan. Fenamiphos is acting as an inhibitor of the acetylchloinesterase.

The representative formulated product for the evaluation was Nemacur CS 240, a capsule suspension (CS), registered in South Europe.

The evaluated representative uses as nematicide as proposed by the applicant comprises application by drip irrigation and "chisel application" (spray application followed by incorporation into the soil) in bell-pepper and tobacco, respectively. The application rates are 10 kg fenamiphos per hectare in bell pepper and 6 kg per hectare in tobacco. Fenamiphos can be used as insecticide and nematicide. It should be noted that during the peer review process the applicant stated that only the use as nematicide will be supported in the EU review programme.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of fenamiphos as manufactured should not be less than 940 g/kg. It should be noted that the technical material is a racematic mixture. The technical material does not contain any relevant impurity.
At the moment no FAO specification exists.

The content of fenamiphos in the representative formulation is 240 g/L (pure).

The assessment of the data package revealed no particular area of concern. However, analytical methods for enforcement purposes (surface water and animal tissues) are missing or have to be evaluated (for details see below).

The main data regarding the identity of fenamiphos 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 fenamiphos in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material.
Therefore, enough data 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. sum of fenamiphos, fenamiphos-sulfoxide[3] and fenamiphos-sulfone[4] expressed as fenamiphos in food of plant origin; fenamiphos, fenamiphos-sulfoxide and fenamiphos-sulfone in soil; fenamiphos, fenamiphos sulfoxide and fenamiphos sulfone in surface water; fenamiphos in air.
The residue definition for ground water is fenamiphos, fenamiphos-sulfoxide, fenamiphos-sulfone and fenamiphos-sulfone-phenol[5]. At the moment no analytical method is available for the determination of fenamiphos sulfone phenol. Moreover, an analytical method for the determination of fenamiphos in blood and animal tissues (Annex point 4.2.5, Directive 96/46/EC) is missing. Due to the fact that fenamiphos metabolise rapidly and extensively[6], the submitted method for the determination of fenamiphos is not appropriate. Therefore, a suitable analytical method for the determination of residues of fenamiphos in blood and animal origin is required (see also chapter 2.2).

[3] fenamiphos-sulfoxide: (M01), *O*-ethyl-*O*-[4-(methylsulfinyl)-3-methylphenyl]-*N*-methylethyl phophoramidate
[4] fenamiphos-sulfone: (M02), *O*-ethyl-*O*-[4-(methylsulfonyl)-3-methylphenyl]-*N*-methylethyl phophoramidate
[5] fenamiphos-sulfone-phenol: (M03), 3-methyl-4-[methylsulfonyl]phenol
[6] This information was not available at the EPCO expert meeting.

Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues.
The methodology used is HPLC with UV or MS/MS detection and GC with MS detection. None of them is enantio selective.
An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed (see 3.2).

The discussion in the expert meeting (EPCO 25, May, 2005) on identity, physical and chemical properties and analytical methods was limited to the specification of the technical material, analytical methods for enforcement purposes. The clarification with respect to the analytical method for blood, given in the evaluation table (17077/EPCO/BVL/04 rev.1-2) was not discussed in an expert meeting, but the assessment of the RMS is confirmed by EFSA.

A recently submitted study for the determination of fenamiphos phenolsulfonic acid[7] in surface water was not evaluated by the RMS yet, but is not required according to the proposed residue definition for monitoring purposes (see chapter 6). A method for the determination of fenamiphos in animal tissues is required but not submitted.

2. Mammalian toxicology

Fenamiphos was discussed at the EPCO experts' meeting for mammalian toxicology (EPCO 23) in May 2005. The results of cholinesterase measurements in the short and long term studies were discussed during the meeting and considered as acceptable.

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

Absorption and excretion of the radioactivity after administration of radiolabelled fenamiphos were nearly complete and very rapid, 40-80% of the radiolabel being excreted renally within 4 h of treatment. After 48 h, >96% of the recovered radiolabel had been excreted by animals at all doses. Faecal elimination accounted for only 1.5-3.7% of the recovered radiolabel. The small amounts found in the faeces after intravenous administration indicate that a small amount of biliary excretion occurs. There were no indications of accumulation of the parent compound or its metabolites.

Identification of the metabolites covered more than 93% of the total radioactivity. The main groups of metabolites, comprising 80% to 96% of the recovered radioactivity, were the fenamiphos-phenols (fenamiphos phenol, M11[8], fenamiphos sulfoxide phenol, M12[9], fenamiphos sulfone phenol, M13) in different stages of oxidation at the sulphur atom and their respective sulphuric acid conjugates. Metabolites of toxicological relevance were detected in amounts of 0.3 to 1.3% (fenamiphos-

[7] fenamiphos phenolsulfonic acid, M24: 4-hydroxy-2-methylbenzenesulfonic acid
[8] fenamiphos phenol, M11, 3-methyl-4-(methylthio)phenol
[9] fenamiphos sulfoxide phenol, M12, 3-methyl-4-[methylsulfinyl]phenol

sulfoxide, M01) and of 0.4 to 0.7% (des-isopropyl fenamiphos sulfoxide, M07[10]). Parent compound or other oxidised and/or desisopropylated compounds were not detected above the limit of detection.

2.2. ACUTE TOXICITY

The oral LD_{50} of fenamiphos in rats was 6.0 – 6.1 mg/kg bw in males and females respectively. Therefore, fenamiphos is proposed to be labelled **T+; R28 "Very toxic if swallowed"**.

The dermal LD_{50} of fenamiphos in rats was 72 –92 mg/kg bw in males and females respectively. Therefore, fenamiphos is proposed to be labelled **T; R24 "Toxic in contact with skin**".

The LC_{50} inhalation of fenamiphos in rats was 65 – 79 µg/L in males and females respectively. Therefore, fenamiphos is proposed to be labelled **T+; R26 "Very toxic by inhalation**".

For skin irritation of fenamiphos no acceptable study was submitted.

Fenamiphos was irritating to the eye in rabbits. Therefore, fenamiphos is proposed to be labelled: **Xi; R36 "Irritating to eyes**".

In a maximisation test fenamiphos showed no skin sensitising properties.

Due to the classification as very toxic (Annex point 4.2.5), an analytical method for the determination of fenamiphos/fenamiphos residues in blood and animal tissues, according to Directive 96/46/EC, is needed.

2.3. SHORT TERM TOXICITY

The short term effects of fenamiphos were studied in oral studies in rats (28 and 90 days) and dogs (90 days, 1 and 2 years), in dermal studies in rats (28 days) and rabbit (21 days) and in inhalation studies in rats (5 and 21 days). The main effect observed was inhibition of cholinesterase in plasma erythrocytes and brain.

The relevant oral NOAEL is 0.083 mg/kg bw/day in the 1-year study in the dog; the relevant dermal NOAEL is 2.5 mg/kg bw/day in the 21 day study in the rabbit and the relevant inhalation NOAEL is 3.5 µg/L, the highest dose tested in the 28 day inhalation study in the rat (no effect on brain cholinesterase was observed).

2.4. GENOTOXICITY

Fenamiphos was tested in a number of *in vitro* genotoxicity studies including the bacteria microsome assay (Ames test) for point mutations, the HGPRT assay for forward mutations in cultured Chinese hamster ovarian cells, the unscheduled DNA synthesis assay in rat primary hepatocytes and the sister chromatid exchange assay in Chinese hamster V79 cells. The compound showed positive test results for clastogenicity in the chromosomal aberration assay in human lymphocytes at cytotoxic dose levels. In the first study a positive result was obtained at one single dose without activation. In the second study a positive result was observed only with metabolic activation at a dose level with high cytotoxicity. Independent repeat assays were not submitted. These positive results in human lymphocytes were not confirmed in a mouse lymphoma assay. Fenamiphos was not mutagenic in the *in vivo* dominant lethal test for germ cell chromosomal and dominant gene mutations. Further, two

10 desisopropylfenamiphos-sulfoxide, M07, Ethyl 3-methyl-4-(methylsulfinyl)phosphoramidic acid phenyl ester

micronucleus tests were available. The first (oral) study was not acceptable. The second test in which the test substance was given i.p. was negative.
Based on the available *in vitro* and *in vivo* tests, fenamiphos is considered not genotoxic.

2.5. LONG TERM TOXICITY

One 20-month study in mice and two 2-year studies in rats with fenamiphos were submitted. The main effect of fenamiphos was inhibition of cholinesterase (not measured in the mouse study). At higher doses clinical signs and changes in several organ weights were observed. There was no evidence of treatment related increase in carcinogenicity.
The relevant long term NOAEL is 0.56 mg/kg bw/day based on inhibition of cholinesterase (brain and erythrocytes) and clinical signs at higher doses in the 2-year rat studies.

2.6. REPRODUCTIVE TOXICITY

One acceptable 2-generation reproduction study in rats was submitted.
The relevant NOAEL for parental toxicity was 0.17 mg/kg bw/day, on the basis of decreased body-weight gain in males and inhibition of erythrocyte ChE activity in both males and females.
The relevant NOAEL for offspring toxicity was 0.64 mg/kg bw/day, on the basis of decreased pup body weights during lactation and in addition inhibition of erythrocyte ChE activity.
The relevant NOAEL for reproductive toxicity was 2.8 mg/kg bw/day, based on the absence of reproductive effects at the highest dose tested.
Four studies on embryo/foetal toxicity and teratogenicity of fenamiphos were submitted, two in rats and two in rabbits. Fenamiphos was found to induce no specific developmental toxicity and no teratogenicity at dose levels, which were clearly toxic to dams. An increase in hyoid body variations was an adverse developmental effect at clearly maternal toxic levels (3.0 mg/kg bw/day) in studies in rats. A slightly lower foetal weight and skeletal findings (at a maternal toxic dose of 1 mg/kg bw/day) were the only adverse developmental effects observed in one of two studies in rabbits.
The relevant NOAEL for developmental effects was 0.3 mg/kg bw/day in a teratogenicity study with rabbits. The relevant NOAEL for parental toxicity was 0.1 mg/kg bw/day in a teratogenicity study with rabbits.

2.7. NEUROTOXICITY

In an acute and a semichronic neurotoxicity screening study in rats investigating specific neurotoxicological parameters, no primary neurotoxic effects were found for fenamiphos. All effects observed seemed related to the general cholinergic action of this compound.
Fenamiphos has no potential to induce delayed neuropathy after acute or subchronic administration in hens.
The relevant NOAEL for acute neurotoxicity is 0.25 mg/kg bw/day based on clinical signs and decreased erythrocyte cholinesterase in the acute dog study.
The relevant NOAEL for short term neurotoxicity is 0.61 mg/kg bw/day based on clinical signs and inhibition of brain cholinesterase in the 15 week rat neurotoxicity study.

2.8. FURTHER STUDIES

A number of acute oral toxicity studies with fenamiphos metabolites was submitted. The main metabolites are much less toxic than fenamiphos (e.g. fenamiphos sulfone phenol - M13, LD_{50} 1250 mg/kg bw). However, some metabolites have still very high acute toxicity (LD_{50} <25 mg/kg bw). These are fenamiphos-sulfoxide (M01), fenamiphos-sulfone (M02), des-isopropyl fenamiphos (M06[11]) and des-isopropyl fenamiphos-sulfoxide (M07).

Metabolite M09[12] (des-isopropylamino fenamiphos sulfoxide) is plausibly an intermediate metabolite in the rat metabolism. It is much less toxic than the parent compound (LD_{50} of more than 300 mg/kg bw) and did not induce point mutations in a bacterial test. It is therefore concluded that metabolite M09 is of no toxicological concern.

2.9. MEDICAL DATA

In health checks for production workers in two productions plants only in a few workers over 80% inhibition of whole blood was found. The effect was reversible at the next measurement 3 months later.

No poisoning incidents have been reported and no epidemiological studies have been performed.

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

The experts concluded that dog is the most sensitive species and based the setting of reference values on these results.

ADI

The meeting agreed on an ADI based on the NOAEL of 0.083 for brain cholinesterase inhibition in the 1-year dog study and a safety factor of 100.

The ADI is 0.0008 mg/kg bw/day.

AOEL

The meeting agreed on an ADI based on the NOAEL of 0.083 for brain cholinesterase inhibition in the 1-year dog study and a safety factor of 100. Correction for oral absorption was not considered necessary.

The AOEL is 0.0008 mg/kg bw/day.

[11] des-isopropyl fenamiphos, M06, ethyl 3-methyl-4-(methylthio)phosphoramidic acid phenyl ester

[12] des-isopropylamino fenamiphos sulfoxide, M09, Ethyl 3-methyl-4-(methylsulfinyl)phosphoric acid phenyl ester

ARfD

The meeting agreed on an ARfD based on the NOAEL of 0.25 for clinical signs and erythrocye cholinesterase inhibition in the acute oral dog study and a safety factor of 100.

The ARfD is 0.0025 mg/kg bw.

2.11. DERMAL ABSORPTION

Dermal absorption values for Nemacur CS 240 (a microencapsulated formulation) are based on an *in vitro* study with human skin presented in the Addendum. The results show very low recovery rates suggesting that only 50% of the substance came into contact with the skin.

The experts considered a correction for the low recovery in the study and agreed on the following values: for the EC formulation 6% for the concentrate and 50% for the dilution; for the CS formulation 1 % for the concentrate and 5% for the dilution

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The intended uses for Nemacur CS 240 are:

- In bell peppers by drip irrigation; up to 10 kg a.s./ha (42 L product/ha)
- In tobacco by "Shank-chisel"technique.; 6 kg a.s./ha (25 L product/ha)

Operator exposure

The operator exposure was assessed by modelling, considering a dermal absorption value of 50%. Both UK POEM and German model showed estimated exposure exceeding the AOEL.

The assessment was refined based on new dermal absorption values agreed on during the meeting and estimated exposure still exceeded the AOEL.

Then, operator exposure data were derived from a field study with Nemacur CS 240 applied by drip irrigation in bell peppers. It is assumed that the results can be extrapolated to Shank-chivel application in tobacco. The study was carried out in Spain with 12 operators. Only mixing/loading activities were monitored. Exposure was assessed according to the OECD Guidance Document for the purpose, and the study was in GLP compliance. Therefore, the study can be considered as of good quality and acceptable. PPE was worn during the study (coveralls and nitrile gloves).

Since exposure is almost exclusively due to the preparation of the dilution (mixing and loading), and the dilution is not applied by spraying, a dermal absorption value of 1% determined for the concentrated formulation is used.

Operator exposure (% AOEL) based on the field study.

Application	% AOEL
Bell pepper	2% with PPE (field study)
Tobacco	4% with PPE (field study)

Worker exposure

Since Nemacur CS 240 is applied to the ground by drip irrigation and not sprayed on the plants, the worker exposure is considered negligible.

Bystander exposure

Since Nemacur CS 240 is applied to the ground and not sprayed on the plants, the bystander exposure is considered negligible.

3. Residues

Fenamiphos was discussed at the EPCO experts' meeting for residues (EPCO 24) in May 2005 in Braunschweig (Germany).

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

The behaviour and metabolism of fenamiphos was investigated in tomato, pineapple, carrot, tobacco, cabbage, bean and peanut plants. Application of radio labelled material was performed by stem-injection, soil-treatment, solution uptake, or spraying. All studies show a similar metabolic pathway.

First step is formation of fenamiphos sulfoxide (M01) and fenamiphos sulfone (M02) by oxidation of the sulfur. A minor metabolite, detected at early intervals of several bean plant studies, was identified as des-isopropyl fenamiphos sulfoxide (M07). All the compounds still have the intact organophosphate structure and are moreover considered toxicologically relevant. (see 2.1 and 2.8) Second step is cleavage of the phosphate ester bond, resulting in the formation of the much less toxic compounds fenamiphos sulfoxide phenol (M12), fenamiphos sulfone phenol (M13), and possibly in one case fenamiphos phenol (M11). These compounds are often found as beta-glucoside conjugates. Cleavage of the P-O-ethyl group can lead to incorporation into plant structural elements and release as CO_2.

Fenamiphos was found in tomato fruit, pineapple fruit, tobacco leaves, bean plants, and peanut plant from below 1 %TRR up to 63 %TRR (in bean plant, 2 DAT via solution uptake). Its amount decreases fast and generally disappears 1-3 weeks after treatment, although in tobacco a small amount (1 %TRR) was found at 70 DAT. M01 is the major metabolite, and also marker compound, formed rapidly in amounts varying from 6.5 to 86 %TRR. In most studies its amount is highest at early intervals after treatment (varying from 1 DAT for spray treated pineapple plants to 50 DAT for soil treated tobacco) and decreases afterwards. M02 is a second major metabolite. It is formed more slowly than M01 and is usually found in smaller amounts, varying from 1.2 to 42 %TRR. Because of their toxicity, these three compounds, i.e. fenamiphos, M01 and M02 are considered to be residues of concern. Residues of these metabolites are found in fruit and tobacco at intervals, comparable to the PHI in GAP. Tomato fruit from soil-treated plants at 66 DAT contains 22 %TRR M01 and 6.2 %TRR M02. Pineapple fruit from soil-treated plants at 60 DAT contains 8.1 %TRR M01 and 0.92 %TRR

M02. Tobacco leaves from soil-treated plants (granular formulation) at 70 DAT contain 1.0 %TRR fenamiphos, 6.5 %TRR M01 and 4.6 %TRR M02.
M01 and M02 are transformed into M12 and M13 and the subsequent formation of beta-glucoside conjugates increases their water-solubility. An increase of the total residues in the water fraction with time was observed for tomato, pineapple, cabbage and bean, indicating the formation of glucoside conjugates in those crops.

The application rate for intended use (soil treatment with CS formulation) is 10 kg a.s./ha for sweet pepper plants and 6.0 kg a.s./ha for tobacco. Soil treatment of tomato plants with an application rate of 6.7 kg a.s./ha, resulted in a total residue level in ripe fruit of 0.36 mg/kg at 66 DAT. Soil treatment of pineapple plants with an application rate of 22 kg a.s./ha, resulted in a total residue level in fruit of 0.086 mg/kg at 90 DAT. In tomato and pineapple, total residues were higher in foliage than in fruit. In carrot, total residues are higher in foliage than in roots after soil treatment. Pineapple fruit from soil-treated plants contains very little residues in comparison with fruit from sprayed and stem-injected plants. For bean plants, distribution of residues is not significantly different when treated by stem injection or by solution uptake. However, stem-injected plants seem to contain relatively less fenamiphos and more phenols than solution uptake-treated pants. Metabolites in a stem-injected bean plant are comparable to a soil treated plant. Soil-treated tobacco plants grown indoor and outdoor show no difference in the distribution of residues. However, there seems to be a definite influence of the formulation on residue levels. Tobacco plants treated with a solution of fenamiphos showed a residue level of an order of magnitude higher than tobacco plants treated with a granular formulation at a comparable application rate and PHI. Residue levels of the capsule suspension would be expected to be between the levels determined for these two formulation types.

Fenamiphos is found in several plant metabolism studies but only at short periods after treatment. In addition, two main metabolites of toxicological relevance, fenamiphos sulfoxide (M01) and fenamiphos sulfone (M02) are found. Usually M01 is the predominant metabolite but in some plants, the level of M02 increases with time. This variation of their individual levels with time and type of plant hampers the selection of one as a marker molecule. Metabolite M07 is toxic as well (see 2.8), but its occurrence is very rare.
Therefore the following residue definition of plant products for monitoring and consumer risk assessment is proposed: sum of fenamiphos, fenamiphos sulfoxide (M01), and fenamiphos sulfone (M02), expressed as fenamiphos.

Residues trials were performed conforming to critical GAP on bell peppers and tobacco under glass and in the field, respectively. The submitted trials covered use in Southern Europe. All trials were reported in sufficient detail and were supported by acceptable analytical information. Thus, based on the data an MRL can be proposed for peppers.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

Rotational crop metabolism studies were conducted using soybean, sugar beet, red beet, mustard, Swiss chard, wheat, and oat under confined conditions (greenhouse or shelter). A mostly similar pattern was found as in the primary plant metabolism studies. However, an important difference was the identification of two metabolites that were not identified before. Metabolites M09 and M18[13] were found in Swiss chard, red beet and wheat. M18 is expected to be much less toxic, because of a cleaved phosphate ester bond. However, M09 with an intact organophosphate structure was expected to be toxic. Therefore it was toxicologically tested and considered of no concern. (see 2.8) Thus, there is no need to include M09 it in the plant residue definition.

In the studies high levels of residues of fenamiphos, M01 and M02 (expressed as fenamiphos equivalents) were found: 17 mg/kg in young soybean plants planted 160 DAT; 4.2 mg/kg in Swiss chard planted 30 DAT; 2.2 mg/kg in red beet roots planted 30 DAT; 8.5 mg/kg in wheat green forage planted 30 DAT; 11 mg/kg in wheat straw planted 30 DAT. For wheat planted 269 DAT still residues of 1.3 and 0.64 mg/kg were found for green forage and straw, respectively. In most cases, the used application rate was lower (*ca* 0.7 N) as the recommended rate for tobacco.
One rotational crop residue trial was conducted in the field in the USA using turnip, mustard, spinach, wheat, and sorghum. Most residues were below 0.01 mg/kg for crops planted 120 DAT. However, higher residues were found: 0.75 mg/kg for wheat green forage planted 30 DAT; 0.44 mg/kg for sorghum green forage planted 120 DAT.

Because of the use of those crops as animal feed, such high residues are of concern. Based on the rotational crop residue trial, RMS proposes a waiting period of 8 months. Although soil degradation studies predict that soil residues of the active substance and relevant metabolites were declined by more than 90% at 100 days after treatment, actual rotational crop field studies show significant residues, both, in soil and in plants. The discrepancy between soil residues in the field rotational crop study and the soil degradation study can neither be explained by different release rate of the formulations used nor by the different soil types. Hence the expert meeting on residues agreed on RMS position that the rotational crops studied are not representative for fruiting vegetables, and supported its proposal for a requirement of a rotational crop study in a glasshouse with a fruiting vegetable other than pepper.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

Definition of the residue in animal products is considered not relevant, because fenamiphos is intended for use on sweet pepper and tobacco and these plants are not fed to livestock.
However, studies on the metabolism of fenamiphos in lactating goat and laying hens have been submitted and evaluated in the DAR and in an addendum.

[13] M18: 5-hydroxy-2-(methylsulfonyl)benzenemethanol

3.3. CONSUMER RISK ASSESSMENT

Chronic exposure

A calculation of the TMDI is carried out using the WHO/GEMS Food Standard European diet and the National Dutch diet. Consumption of tobacco is not considered and intake via sweet pepper is based on the MRL proposed by the RMS. Under these conditions, the TMDI covers 1.4% of the ADI (0.0008 mg/kg bw/d) for GEMS Food European diet and 0.5% of the ADI for the Dutch diet for both general population and children. Thus, with the intake by the consumption of sweet pepper there is no chronic risk for the population.

In groundwater the level of 0.1 µg /L is expected to be exceeded by the metabolites M01, M02 and M13 (refer to point 4.2.2). Moreover, two out of the three metabolites, namely M01 and M02 are considered toxicologically relevant (refer to point 2.1). Therefore, a consumer risk assessment was performed, considering the sum of possible intakes of the two metabolites from drinking water in addition to the intake through diet. The estimates are based on the default assumptions laid down in the WHO Guidelines of drinking water quality and on values from FOCUS modelling for the use on tobacco at the intended application rate, in order to reflect the worst case.

For the considered consumer subgroups of infants, toddlers and adults the estimated intakes from drinking water are 0.00656 mg/kg bw/day, 0.00437 mg/kg bw/day and 0.00146 mg/kg bw/day, respectively corresponding to *ca* 820%, 546% and 182% of the ADI of fenamiphos, respectively. Hence, the total intake from diet and drinking water **is significantly above the ADI** for all considered consumer subgroups.

Acute exposure

A calculation of the NESTI is carried out using the National Dutch diet and the National UK diet. Consumption of tobacco is not considered and intake via sweet pepper is based on the HR proposed by the RMS and on the LP consumption. Under these conditions, the NESTI covers 11% of the ARfD (0.0025 mg/kg bw) for the Dutch diet for both, general population and children. With the UK diet, the maximum NESTI covers 8.6% of the ARfD for adults and 26% of the ARfD for toddlers. Thus, no acute risk for the consumer is expected from the consumption of sweet pepper.

Based on the estimated intakes of relevant compounds through drinking water (see above) the acute risk assessment showed an **exceedance of the ARfD** for toddlers and infants (175% and 262% ARfD, respectively), even though the applied daily consumption figures might rather reflect a mean consumption than a high consumption that is normally used for acute intake and risk assessment.

3.4. PROPOSED MRLS

MRL proposals were derived according to the proposed residue definition for plants and after evaluation of provided residue trials with sweet pepper in greenhouse.

Sweet pepper	0.05 mg/kg

For tobacco usually no MRL will be set in Europe, however, RMS proposed a tolerance of 0.5* mg/kg for green tobacco leaves for export purposes.
Fenamiphos is an old active substance, for which Codex Alimentarius Commission (CAC) MRLs have been established in the past, including for sweet pepper (0.5 mg/kg). Since for most of the MRLs the ARfD is exceeded, a re-evaluation of the CAC-MRLs is ongoing. None of the CAC-MRLs are proposed as EU-MRLs.

4. Environmental fate and behaviour

Fenamiphos was discussed in experts' meeting on fate and behaviour in the environment EPCO 21 (April 2005). The addendum of March 2005 was discussed in this experts' meeting. As a general issue, experts' meeting agreed on the need of a harmonized approach to address protected crop uses at EU level. The need of a better definition of the types of protected crops and specific $FOCUS_{GW}$ scenarios for glasshouses was highlighted.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

Route and rate of degradation of fenamiphos under dark aerobic conditions at 16 °C, 20 °C, 22 °C and 28 °C (tropical soils only, data not used in the EU risk assessment) was investigated in two separated studies with eleven (16 °C, 22 °C, 28 °C; EU, USA, Canada, Japan, Brazil) and four soils (20 °C; Germany) respectively. The sixteen soils covered a range of pH (5.8 – 8.0), organic matter content (0.65 % - 11.1 %) water content (eleven soils: 11.7 % - 59.8 % MWHC; four soils: 27.6 – 63.1% MWHC) and soil textures. In the first study (eleven soils) water soil content was adjusted to 75 % MWHC. No adjustment of soil moisture during incubation was done in the second study. Application rates were of 7.7 mg a.s. / kg soil (equivalent to 5.8 kg a.s. /ha) for the first study and of 0.67 mg a.s. / kg soil (equivalent to 0.5 kg/ha) in the second one.
Fenamiphos was initially oxidized to **fenamiphos sulfoxide** (M01: max. 79.1 % AR after 30 d at 16 °C) and subsequently to **fenamiphos sulfone** (M02: max. 24.9 % AR after 4 d at 20 °C). Both organophosphate metabolites are hydrolysed to the corresponding **fenamiphos sulfoxide phenol** (M12: max. 11.1 % AR after 50 d at 22 °C) and **fenamiphos sulfone phenol** (M13: max. 24.7 % AR after 90 d at 22 °C).
In the first study, mineralization after 90 d ranged form 1.1 % AR to 39 % AR at 22 °C and from 0.4 % AR to 23 % AR at 16 °C. Non extractable residues reached values of 19 % AR to 69 % AR at 22 °C and from 9.1 % AR to 46 % AR at 16 °C.
In the second study, mineralization after 120 d ranged from 23 % AR to 52 % AR. Non extractable residue reached values of 16 % AR to 36 % AR.
An anaerobic soil biodegradation study is available in which fenamiphos was applied at 13.3 mg a.s. /kg soil (equivalent to 10 kg a.s /ha). Only fenamiphos sulfoxide exceeded the 10 % AR under these conditions.

Soil photolysis was studied in a sandy loam soil under artificial light (λ > 300 nm). According the results of this study, photolysis may contribute to the environmental degradation of fenamiphos.

A field dissipation study in four locations in Southern Europe (France, Spain and two locations in Italy) is available. Fenamiphos was formulated as the representative capsule suspension product (Nemacur 240 CS). All major metabolites were found in the 0-10 cm layer. Fenamiphos-sulfoxide was also consistently found at deeper layers.

From the information provided by the notifier it was not clear if the Nemacur 240 CS formulation should be considered a slow release formulation. RMS, taking into account the early appearance of metabolites in the earthworm study, considered that this product should not be classified as a slow release formulation. This issue was discussed during the experts meeting that agreed not to consider Nemacur 240 CS a slow release formulation.

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

The same laboratory studies used to establish the route of degradation were employed to determine the rate of degradation of fenamiphos and its metabolites under aerobic conditions. First study (11 soils) was not useful to obtain reliable half lives of fenamiphos due to the fact that at the first sampling date (15 d) more than 90 % fenamiphos has already been transformed. On the second study (four soils) fenamiphos shows to be very low or low persistent ($DT_{50\ lab\ 20\ °C}$ = 0.4 – 1.4 d). Fenamiphos-sulfoxide is moderate to high persistent in soil (data from both studies: $DT_{50\ lab}$ = 25 – 109 d), fenamiphos-sulfone low to moderately persistent (data from both studies: $DT_{50\ lab}$ = 6 – 60 d), fenamiphos-sulfoxide-phenol moderately persistent (only one determination from first study: $DT_{50\ lab}$ = 14 d) and fenamiphos-sulfone phenol moderately to medium persistent (data from both studies: $DT_{50\ lab}$ = 10 – 79 d). Experts' meeting agreed that the degradation rate of fenamiphos and its metabolites was not significantly depended on the application rate (within the range of available data approx. 0.5 – 6 Kg / ha).

In the field study dissipation half lives were estimated by multiple fit, taking into account simultaneous formation and dissipation of metabolites. Field trials were performed on bare soil and the meeting discussed potential contribution of photolysis. The experts' meeting concluded that photolysis was not likely to have affected the degradation rate of fenamiphos and its metabolites in the field trials but leaching could not be completely excluded taking onto account the adsorption/desorption properties of these compounds.

Reliability of the dissipation half lives obtained in the trial performed in Spain was discussed in the experts' meeting. RMS was required to provide further information on the location of the residue trial to support its exclusion from the assessment based in abnormally dry climatic conditions. After the meeting, further information on the weather average data and weather during the trial was provided by the applicant and was made available to the experts of the meeting. Spain commented on these new data confirming that the soil was abnormally dry and pointing out other differences with respect to the other field trials. RMS therefore confirms that the Spanish field trial should not be considered in the assessment of soil compartment and that PEC soil should be based on dissipation half lives from the other trials.

PEC soil presented in the DAR were calculated based on average field dissipation half lives. Experts' meeting noted that this is not the standard procedure for PEC soil calculation since worst case half lives should be used. However, since risk assessment is mainly based on initial PEC, only initial PEC soil values are reported in the list of end points [14]. New PEC soil have been provided by the RMS in the list of end points to take also into account the application rates proposed in the GAP table and the maximum percentage of metabolites found in the laboratory studies as agreed by the experts' meeting. EFSA transferred these values to the updated addendum for transparency.

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

Batch adsorption/desorption studies are available for fenamiphos (four soils) and its metabolites fenamiphos-sulfoxide (two + four soils) and fenamiphos-sulfone (two + four soils). Also adsorption/ desorption of fenamiphos, fenamiphos-sulfoxide-phenol and fenamiphos-sulfone-phenol was investigated in the eleven soils employed in the first aerobic degradation study in soil. According these studies, fenamiphos is low to high mobile (Koc = 76 – 1432 L/kg) whereas fenamiphos-sulfoxide, fenamiphos-sulfone, fenamiphos-sulfoxide-phenol and fenamiphos-sulfone-phenol are medium to very high mobile (fenamiphos-sulfoxide: Koc = 44.8 – 225 L/kg; fenamiphos-sulfone: Koc = 52.4 – 311 L/kg; fenamiphos-sulfoxide-phenol: Koc = 12.5-166 L/kg; fenamiphos-sulfone-phenol: Koc = 31-207 L/kg). Due to the fast degradation of fenamiphos the values for this substance should be considered only as indicative.

No column leaching, field leaching or lysimeter studies are available for fenamiphos.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

In sterile buffer solutions at 20 °C fenamiphos may be considered stable at pH 5, 7 and 9 (DT_{50} > 200 d). Hydrolysis of fenamiphos, fenamiphos-sulfoxide and fenamiphos sulfone has only been tested at pH 4. Under these conditions, hydrolysis half life of fenamiphos is still above 200 d and above 120 d for its metabolites.

Two aqueous photodegradation studies were performed with fenamiphos, one with fenamiphos-sulfoxide and one with fenamiphos-phenol sulfonic acid. Aqueous photolysis may contribute to the transformation of fenamiphos into fenamiphos-sulfoxide. Fenamiphos sulfonic acid was detected as a minor metabolite and **fenamiphos-phenol-sulfonic acid**[15] (max. 18.6 %) as a major photolysis metabolite of fenamiphos. This later metabolite shown to be stable to photolysis in water (DT_{50} = 768 d).

No information on the ready biodegradability of fenamiphos has been provided. The experts' meeting proposed to classify it as not ready biodegradable and candidate to R53.

[14] In fact 21d TWA-PEC_S for fenamiphos equal to 0.494 mg/kg is used in the risk assessment of terrestrial vertebrates. The actual value 21d TWA-PEC_S using worst case field half life (DT_{50} = 2.2 d) would be equal to 0.704 mg/kg; the use of this value will not change the outcome for the terrestrial vertebrates risk assessment.

[15] **fenamiphos-phenol-sulfonic acid:** 2-methyl-benzosulfonic acid (or *o*-toluensulfonic acid)

Degradation in water sediment was tested in one study with two systems; one with a sandy sediment and the other with a loam sediment. Fenamiphos dissipated relatively fast from the water phase ($DT_{50water}$ = 3.6-7.9 d) but, depending on the nature of the sediment, may be highly persistent in the whole system ($DT_{50\ whole\ system}$ = 9.3 – 111 d). Major metabolites in water were fenamiphos-sulfoxide (loam system: max. 13.8 % after 100 d) and fenamiphos–sulfoxide-phenol (sand system: max. 10.8 % AR after 20 d). Fenamiphos-sulfoxide was also a major metabolite in the sediment (loam system: max 16.8 % after 100 d). Mineralization reached a maximum of 14.3 % AR (sand system) and 2.4 % (loam system) at the end of the study (100 d) and bound residues reached maximum amounts of 48 % AR (sand system after 58 d) and 17. 4 % AR (loam system after 100 d).

For the representative uses of NEMACUR CS 240 (soil treatment with incorporation and drip irrigation) direct emissions to surface water are not expected. However, emissions via run –off and drainage may not be excluded. RMS presented FOCUS $PEC_{SW/SED}$ calculations for fenamiphos, fenamiphos-sulfoxide (initial $PEC_{SW/SED}$), fenamiphos-sulfoxide-phenol (initial PEC_{SW}), fenamiphos-phenol-sulfonic acid (initial $PEC_{SW/SED}$), fenamiphos-sulfone (initial $PEC_{SW/SED}$) and fenamiphos-sulfone –phenol (initial $PEC_{SW/SED}$) based on Steps 1 and 2 in an addendum that was discussed in the experts' meeting. The meeting agreed that further refinement by FOCUS Step 3 should be provided by the applicant taking into consideration EFSA's PPR Opinion on the use of FOCUS SW[16].

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

Potential for ground water contamination is assessed based on the calculation of PEC_{GW} with FOCUS GW modelling and scenarios tools. Calculations presented in the original DAR, field dissipation DT_{50} were employed as input parameters. Experts' meeting expressed concerns on the use of the field dissipation half lives as degradation parameters for modelling in this case. New FOCUS-PEARL calculations, using normalized laboratory half lives, have been provided by the RMS in the list of end points and the updated addendum for the FOCUS scenarios Piacenza, Porto, Sevilla and Thiva. The trigger of 0.1 µg/L is exceeded by fenamiphos-sulfoxide (tobacco: 3 of 4 scenarios, bell pepper: 4 of 4 scenarios), fenamiphos-sulfone (tobacco and bell pepper: 2 of 4 scenarios) and fenamiphos-sulfone-phenol (tobacco: 3 of 4 scenarios, bell pepper: 4 of 4 scenarios). The trigger of 0.75 µg /L is exceeded by fenamiphos-sulfoxide (tobacco: 3 of 4 scenarios, bell pepper: 3 of 4 scenarios), fenamiphos-sulfone (tobacco: 1 of 4 scenarios, bell pepper: 2 of 4 scenarios) and fenamiphos-sulfone-phenol (bell pepper: 2 of 4 scenarios). Finally the trigger of 10 µg/L is only exceeded by fenamiphos-sulfoxide (tobacco: 1 of 4 scenarios, bell pepper: 2 of 4 scenarios). Fenamiphos-sulfoxide and fenamiphos-sulfone have been considered toxicologically relevant (see 2.8). The experts' meeting recognized the difficulty to address potential ground water contamination from protected crop uses with the available scenarios. Since the practices to grow crops under protection are variable among EU a better definition of greenhouse uses is necessary. According to the applicant, NEMACUR CS 240 is used

[16] Opinion of the Scientific Panel on plant health, Plant protection products and their Residues on a request of EFSA on the appropriateness of using the current FOCUS water scenarios for estimating exposure for risk assessment in aquatic ecotoxicology in the context of the Council Directive 91/414/EEC. *The EFSA Journal (2004) 145, 1-31.*

on permanent structures covered with plastic and nets and the crops are planted over the natural soil. Crop is irrigated to satisfy the crop water requirements. The experts' meeting did not specifically discuss the relevance of available $FOCUS_{GW}$ scenarios to this particular case because initial calculations in the DAR did not show potential for contamination above the triggers. With the results of the new $FOCUS_{GW}$ simulations, an assessment of the applicability of available FOCUS scenarios (with soil temperatures and precipitation pertinent to outdoor conditions) to the greenhouse is necessary. The available modelling for the greenhouse use probably overestimates leaching potential if the crop is grown under permanent protection. Therefore, a data gap is identified for the intended use on protected bell pepper.

4.3. FATE AND BEHAVIOUR IN AIR

Fenamiphos has a vapour pressure of $1.2 \cdot 10^{-4}$ Pa at 20 °C, and a calculated Henry's law constant of $9.1 \cdot 10^{-5}$ $Pa \cdot m^3 \cdot mol^{-1}$. Based on the available volatilisation experiment, it is considered that significant volatilisation of fenamiphos from soil is unlikely to occur. The gas phase oxidation half-life of fenamiphos and its metabolites fenamiphos-sulfoxide and fenamiphos-sulfone, was estimated to be 1.7, 1.0 and 1.9 hours, respectively.

5. Ecotoxicology

Fenamiphos was discussed at the EPCO experts' meeting for ecotoxicology (EPCO 22) in April 2005.

5.1. RISK TO TERRESTRIAL VERTEBRATES

Acute, short- and long-term toxicity studies are available to assess the risk to birds and mammals. However, since the representative use evaluated for fenamiphos is for the product NEMACUR CS 240 which is to be applied either via drip irrigation to bell peppers in permanent glasshouses or as a chank chisel applied at 10 cm depth in tobacco fields, direct exposure of birds and mammals is not assumed. Fenamiphos is systemic and there is a potential for tobacco foliage to contain residues. However, tobacco belongs to the solanaceae, which are assumed to be unpalatable for most birds and mammals. Hence, any exposure of herbivorous birds and mammals is unlikely. Therefore, the acute and short-term risks to birds and mammals are expected to be negligible. However, as a confirmatory data requirement the applicant has to present data/information on avoidance/paltibility of solanacea as food source for herbivorous birds. The only potentially relevant routes of exposure are via contaminated soil arthropods, earthworms and fish. The long-term risks for earthworm- and fish-eating birds and mammals were assessed according to SANCO/4145/2000 based on a single application of 6 kg a.s./ha in tobacco fields. The resulting TER values are 0.1 and 0.13 for earthworm-eating birds and mammals respectively. For fish-eating birds the TER values are 0.53 (bell peppers) and 0.87 (tobacco), and for fish-eating mammals 1.4 (bell peppers) and 2.3 (tobacco). All TER values are below the Annex VI trigger indicating a high risk.

A field survey of earthworm populations in tobacco fields in Italy is available and no earthworms were found in the three sampled fields. At the experts' meeting it was discussed whether the absence of earthworms was caused by the soil management regime in tobacco fields, by repellent tobacco plants or by earlier application of pesticides. The applicant has proposed to conduct additional more extensive surveys in each Member State to support national re-registration, but a data requirement was agreed for the applicant to present a field study with the shank-chisel application of fenamiphos to grassland or other uses were earthworms are present in order to show that fenamiphos is not the reason for the absence of earthworms.

For fish-eating birds and mammals the assessment was based on PEC_{sw} from FOCUS step 2 calculations on drainage and runoff (see 4.2.1). Since a high risk was identified the assessment needs to be refined before a definite conclusion on the risk to these groups of organisms can be drawn.

A further data requirement was agreed in the experts' meeting for the applicant to present a refined risk assessment for birds and mammals eating soil arthropods.

The three major soil metabolites, fenamiphos-sulfoxide, fenamiphos-sulfone and fenamiphos-sulfone-phenol could theoretically be toxic to earthworm-eating birds. Data on chronic toxicity are not available but results from acute studies indicate that the two former are of equal toxicity to birds as the parent compound. However, modelling results indicate that the log K_{ow} values are <3 and further consideration was not considered necessary in the experts'meeting.

5.2. RISK TO AQUATIC ORGANISMS

Fenamiphos is very toxic to fish and aquatic invertebrates. The LC_{50} for fish is 9.3 µg/L and the NOEC from an early life stage study is 3.8 µg/L. No acute study with Daphnia is available and a data requirement for the applicant was set at the experts' meeting to present a full data package for aquatic organisms also including toxicity studies with fish for the metabolites in case that surface water can be contaminated. The NOEC for *Daphnia* from a long-term study is 0.12 µg/L. Algae are less sensitive. Also the metabolites fenamiphos-sulfoxide and fenamiphos-sulfone are very toxic to *Daphnia*, while fenamiphos-sulfoxide-phenol and fenamiphos-sulfone-phenol are non toxic.

Since no exposure of surface water is expected from drift from the uses evaluated, the first tier risk assessment is based on drainage and run-off PEC_{sw} values calculated with FOCUS step 2. The acute TER values for fenamiphos are 0.25 and 0.42 for fish for the use in greenhouses and tobacco fields respectively. The chronic TER values are 0.10 (greenhouse) and 0.17 (tobacco) for fish, and 0.003 (greenhouse) and 0.005 (tobacco) for *Daphnia*. All available first tier TER values for fish and *Daphnia* thus indicate a high risk. For algae the risk is considered to be low.

Fenamiphos does not partition to sediment in significant amount but the metabolite fenamiphos-sulfoxide was found at percentages of 16.8% at 100 days in the water/sediment study. A reproduction study with *Chironomus riparius* is available and the TER values based on the NOEC from this study

are 11.6 for greenhouse use and 19.1 for field tobacco. Since the Annex VI trigger is met, the risk to sediment dwelling organism is considered to be low.

A higher tier mesocosm study is available to refine the assessment for fish and invertebrates. Based on the EAC value of 3.5 µg/L from this study, TER values of 0.10 for greenhouse use and 0.16 for field use on tobacco were obtained. Since these values are far below the trigger of 3 proposed by the RMS, a potential high risk to the aquatic environment is concluded and the assessment need to be refined based on FOCUS step 3 modelling data for surface water. The mesocosm study was performed at very high temperature conditions. This may be representative for southern EU for which the representative use is evaluated, but not for northern EU.

A bioconcentration factor of 110 L/kg wwt was determined for fenamiphos. Since there is no information on readily biodegradability a trigger value of 100 is used. Since the long-term risk to fish is high and the risk to fish-eating birds and mammals also is high (see 5.1) the conclusion is that there is a high risk from bioaccumulation. No data on bioconcentaration are available for the metabolites. However, modelling results indicate that the log K_{ow} values are <3 and further consideration is not necessary.

5.3. RISK TO BEES

Acute oral and contact toxicity studies with bees and two field tests on the effects of greenhouse soil treatment with NEMACUR CS 240 (4.8 – 10 kg a.s./ha) on bumblebee pollination activity and hive condition are available. The field tests did not show any deleterious effects and therefore the risk to bees from use on bell peppers in greenhouses is considered low. Tobacco is a self-pollinating crop and is not considered a 'bee-relevant' crop plant in Europe. The risk to bees from the use of fenamiphos in tobacco fields is considered low.

5.4. RISK TO OTHER ARTHROPOD SPECIES

Glass plate studies and extended laboratory studies on toxicity of NEMACUR CS 240 are available for the two standard species *Aphidius rhopalosiphi* and *Typhlodromus pyri*. Additional extended laboratory studies are available with the foliar dwelling species *Crysoperla carnea* and the ground dwelling species *Poecilus cupreus*. The LR_{50} values derived from the extended laboratory studies are 13.8 g a.s./ha (*T .pyri*), 14.1 g a.s./ha (*A. rhopalosiphi*), 33.3 g a.s./ha *(C. carnea*) and 219 g a.s./ha *(P. cupreus*) indicating a high risk to non-target arthropods from application rates of 6-10 kg a.s./ha. However, NEMACUR CS 240 is to be applied via drip irrigation or by shank-chisel application at 10 cm depth and therefore direct exposure of leaf dwelling arthropods is negligible.

The LR_{50} for *P. cupreus* of 219 g a.s./ha was obtained in a test on natural soil and since this value is much lower than the application rate for soil treatment with NEMACUR CS 240 an effect on beetles is expected. Further extended laboratory studies with *P. cupreus* are available where chank chisel and drip irrigation was simulated at application rates of 6 and 10 kg a.s./ha respectively. From these

studies it is concluded that no harmful effects to surface active soil arthropods will occur if the product is applied according to the proposed GAP.

The risk from the four soil metabolites to soil dwelling arthropods is considered low since exposure will be limited due to the way of application, and based on the available data for the soil insect species *Folsomia candida* which show that the metabolites are about one order of magnitude less toxic than the parent compound.

5.5. RISK TO EARTHWORMS

Studies on the acute toxicity to earthworms from fenamiphos, the formulated product and the four soil metabolites are available. Effects on survival were only found in the test with the technical substance. Since the highest test concentration used with the formulation was lower than the LC_{50} for the technical material it is not known whether the product is of comparable toxicity to the active substance alone. Results from a chronic test where Fenamiphos 400 EC was applied to soil surface indicate that reproduction is a far more sensitive parameter (NOEC 6 kg a.s./ha). This is confirmed by the results of a field study with the formulation NEMACUR 400 EC, sprayed at rates of 10 and 40 kg a.s./ha, where significant reduction in abundance and biomass of epilobous worms were observed 6 weeks after application. The effect was still present after 6 months. Even if recovery seemed to have taken place within one year, the study is not conclusive due to the difference in application method compared to the proposed GAP.

The applicant has stated that due to soil fumigation in glasshouses there are unlikely to be significant populations of earthworms, and that the inside of the greenhouses are not a continuum with the field environment. At the experts' meeting it was agreed that a risk assessment for earthworms shall be conducted at Member State level for the use in glasshouses if earthworms are expected in the soil.

A field survey of earthworm populations in tobacco fields in Italy is available and no earthworms were found in the three sampled fields. At the experts' meeting it was discussed whether the absence of earthworms was caused by the soil management regime in tobacco fields, by repellent tobacco plants or by earlier application of pesticides. The applicant has proposed to conduct additional more extensive surveys in each Member State to support national re-registration, but a data requirement was agreed for the applicant to present a field study with the shank-chisel application of fenamiphos to grassland, or other uses where earthworms are present, in order to show that fenamiphos is not the reason for the absence of earthworms and that recovery is possible within an acceptable time frame.

For the soil metabolites all acute TER values are >10 indicating a low risk, and since the DT_{90} values for the metabolites are <100 days no further studies are required.

5.6. RISK TO OTHER SOIL NON-TARGET ORGANISMS

Fenamiphos is toxic to *Folsomia candida* and *Hypoaspis aculeifer* in laboratory studies. TER values calculated based on initial soil PECs for the evaluated uses are far below the Annex VI trigger of 5.

TER for *F. candida* are 0.012 and 0.04, and TER for *H. aculeifer* are ≥0.17 and ≥0.57 for bell peppers and tobacco respectively. Also the TER values for the metabolite fenamiphos-sulfoxide are below the trigger for both uses. For fenamiphos-sulfone the TER value is below the trigger for the use on bell peppers. For the other two soil metabolites, fenamiphos-sulfoxide phenol and fenamiphos- sulfone-phenol the risk is considered low for both uses.

As for earthworms it is proposed that the risk to soil macro-organisms is assessed at Member State level for the use in glasshouses.

For the use on tobacco fields it was agreed in the experts' meeting that the risk to other soil non-target macro-organisms has to be addressed with a field study. The two species mentioned above should be taken into account and recovery or potential for recovery has to be shown.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The effects of fenamiphos on soil carbon and nitrogen conversion were tested. The effects on respiration and mineralization of a dose equal to the highest soil PEC was transient over a period of 28 days. A significant effect of >25% on nitrification remained until 56 days (end of study) after application. Hence the Annex VI trigger was not met indicating a high risk. Further studies are thus needed to address the risk to soil micro-organisms.

For three of the soil metabolites (fenamiphos-sulfoxide, fenamiphos-sulfone and fenamiphos-sulfoxide-phenol) studies are available that show a transient effect on soil nitrification, thus not indicating an adverse effect. For fenamiphos-sulfone-phenol no studies are available and the experts' meeting asked for further information. However, the structure is similar to fenamiphos-sulfoxide-phenol and this metabolite was considered by the RMS as probably present in the studies with the parent compound and fenamiphos-sulfone.

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

The toxicity of fenamiphos to 6 dicotelydon and 5 monocotelydon plants was low in initial screening tests with pre-emergence application of up to 15 kg a.s./ha. Since no exposure of off-crop plants is expected from the evaluated uses the risk to non-target plants is considered negligible.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

Data from a test with activated sludge are available and indicate that the risk to biological methods of sewage treatment plants is low.

6. Residue definitions

Soil

Definitions for risk assessment: fenamiphos, fenamiphos-sulfoxide,[17] fenamiphos-sulfone,[18] fenamiphos-sulfoxide-phenol,[19] fenamiphos-sulfone-phenol[20]

Definitions for monitoring: fenamiphos, fenamiphos-sulfoxide, fenamiphos-sulfone

Water

Ground water

Definitions for exposure assessment: fenamiphos, fenamiphos-sulfoxide, fenamiphos-sulfone, fenamiphos-sulfoxide-phenol, fenamiphos-sulfone-phenol

Definitions for monitoring: fenamiphos, fenamiphos-sulfoxide, fenamiphos-sulfone, fenamiphos-sulfone-phenol (due to the lack of toxicological data)

Surface water

Definitions for risk assessment: fenamiphos, fenamiphos-sulphoxide, fenamiphos-sulphoxide-phenol, fenamiphos-sulphonic-acid (aqueous photolysis metabolite).

Definitions for monitoring: fenamiphos, fenamiphos-sulfoxide, fenamiphos-sulfone

Air

Definitions for risk assessment: fenamiphos.

Definitions for monitoring: fenamiphos.

Food of plant origin

Definitions for risk assessment: fenamiphos, fenamiphos sulfoxide and fenamiphos sulfone, expressed as fenamiphos

Definitions for monitoring: fenamiphos, fenamiphos sulfoxide and fenamiphos sulfone expressed as fenamiphos

Food of animal origin

Definitions for risk assessment: not proposed, not relevant for representative uses

Definitions for monitoring: not proposed, not relevant for representative uses

[17] fenamiphos-sulfoxide: *O*-ethyl-*O*-[4-(methylsulfinyl)-3-methylphenyl]-*N*-methylethyl phophoramidate
[18] fenamiphos-sulfone: *O*-ethyl-*O*-[4-(methylsulfonyl)-3-methylphenyl]-*N*-methylethyl phophoramidate
[19] fenamiphos-sulfoxide-phenol: 3-methyl-4-[methylsulfinyl]phenol
[20] fenamiphos-sulfone-phenol: 3-methyl-4-[methylsulfonyl]phenol

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

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Fenamiphos	very low to low persistent ($DT_{50\ lab\ 20\ °C}$ = 0.4 – 1.4 d).	See sections 5.1, 5.5 and 5.6
fenamiphos-sulfoxide	moderate to high persistent ($DT_{50\ lab}$ = 25 – 109 d),	The risk to earthworms is low, a high risk was identified for other soil macro-organisms for both uses, the risk to soil micro-organisms is low
fenamiphos-sulfone	low to moderately persistent ($DT_{50\ lab}$ = 6 – 60 d),	The risk to earthworms is low, a risk was identified for other soil macro-organisms for the use on bell peppers, the risk to soil micro-organisms is low
fenamiphos-sulfoxide-phenol	moderately persistent ($DT_{50\ lab}$ = 14 d)	The risk to earthworms, other soil macro-organisms and micro-organisms is low
fenamiphos-sulfone-phenol	moderately to medium persistent ($DT_{50\ lab}$ = 10 – 79 d)	The risk to earthworms, other soil macro-organisms and micro-organisms is low

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 activity	Ecotoxicological relevance
Fenamiphos	low to high mobile (Koc = 76 – 1432 L/kg)	FOCUS gw: trigger not exceeded for any scenario	Yes	Yes	Yes Very toxic to fish (EC_{50}=0.0093 mg/L)
fenamiphos-sulfoxide	medium to very high mobile Koc = 44.8 – 225 L/kg	FOCUS gw: triggers of 0.1 µg /L, 0.75 µg/L and 10 µg/L exceeded in at least one scenario	Yes*	Yes, very high acute toxicity (LD_{50} 10 mg/kg bw)	Yes Very toxic to *Daphnia* (EC_{50}=0.015 mg/L)
fenamiphos-sulfone	medium to very high mobile Koc = 52.4 – 311 L/kg	FOCUS gw: triggers of 0.1 µg /L and 0.75 µg/L exceeded in at least one scenario	Yes	Yes, very high acute toxicity (LD_{50} 2.4 mg/kg bw)	Yes Very toxic to *Daphnia* (EC_{50}=0.0035 mg/L)
fenamiphos-sulfoxide-phenol	medium to very high mobile Koc = 12.5-166 L/kg	FOCUS gw: triggers not exceeded for any scenario	No assessment necessary	No data available, no assessment necessary	No exposure. No assessment needed.
fenamiphos-sulfone-phenol	medium to very high mobile Koc = 31-207 L/kg	FOCUS gw: triggers of 0.1 µg /L and 0.75 µg/L exceeded in at least one scenario	No data available	Not acutely toxic (LD_{50} 1250 mg/kg bw)	Not relevant

* Assumption based on high toxicological and ecotoxicological activity.

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Fenamiphos (water and sediment)	See section5.2
fenamiphos-sulfoxide(water and sediment)	Very toxic to aquatic invertebrates (EC_{50}=0.015 mg/L for *Daphnia magna*)
fenamiphos-sulfoxide-phenol (only water)	Non toxic to fish and aquatic invertebrates
fenamiphos-sulfonic-acid (aqueous photolysis metabolite)	No laboratory studies available but metabolite probably present in microcosm study

Air

Compound (name and/or code)	Toxicology
fenamiphos	Very toxic by inhalation

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

- An analytical method for the determination of residues of fenamiphos in blood and animal tissues to cover the requirement of Directive 96/46/EC for substance classified as very toxic (Annex point 4.2.5) (date of submission unknown, data gap identified by the expert meeting and subsequently amended by EFSA; refer to chapter 1).
- Analytical method for the determination fenamiphos-sulfone-phenol in ground water (date of submission unknown, data gap identified after the expert meeting, refer to chapter 1 and 6)
- A rotational crop study with fruiting vegetables grown in greenhouses, since fruiting vegetables were not investigated and it is concluded from other crops that residues in succeeding crops can not be excluded (date of submission unknown, data gap identified by the experts' meeting for residues; refer to point 3.1.2).
- Further refinement of PECsw and PECsed by FOCUS Step 3 should be provided taking into consideration the EFSA Opinion on the use of FOCUS SW[21] (relevant for all representative uses evaluated; submission date proposed by the notifier: FOCUS step 3 already provided by June 2005; refer to point 4.2).
- An assessment of the applicability of available FOCUS scenarios (that use soil temperatures and precipitation pertinent to outdoor conditions) to the greenhouse by the applicant is necessary. Depending on the outcome a further groundwater exposure assessment for protected uses may be necessary (data gap identified by EFSA after the expert meeting; refer to point 4.2.2).
- The risk to fish-eating birds and mammals need to be further addressed based on refined PECsw data (relevant for both representative uses evaluated; no submission date proposed by the notifier; refer to point 5.1).
- The risk to birds and mammals eating soil arthropods need to be further addressed (relevant for the use in tobacco fields; no submission date proposed by the notifier; refer to point 5.1).
- A confirmatory data requirement was set for the applicant to present data/information on the avoidance/palatability of solanacea as food source for herbivorous birds.
- An acute toxicity study with Daphnia (relevant for both representative uses evaluated; no submission date proposed by the notifier; refer to point 5.2).
- Acute toxicity studies with fish for the metabolites fenamiphos-sulfoxide and fenamiphos-sulfone in case surface water can be contaminated (relevant for both representative uses evaluated; no submission date proposed by the notifier; refer to point 5.2).
- The risk to the aquatic environment needs to be further addressed based on refined PECsw data (relevant for both representative uses evaluated; no submission date proposed by the notifier; refer to point 5.2).
- An earthworm field study is required in order to show that fenamiphos is not the reason for the absence of earthworms in tobacco fields and that recovery is possible within an acceptable time

[21] Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from EFSA on the appropriateness of using the current FOCUS surface water scenarios for estimating exposure for risk assessment in aquatic ecotoxicology in the context of Council Directive 91/414/EEC, The EFSA Journal (2004) 145, 1-31.

frame (relevant for the use in tobacco fields (relevance for glasshouse use decided on MS level); no submission date proposed by the notifier; refer to point 5.5).

- A field study is required to address the risk to other non-target soil macro-organisms (relevant for the use in tobacco fields (relevance for glasshouse use decided on MS level); no submission date proposed by the notifier; refer to point 5.6)
- The risk to soil micro-organisms needs to be further addressed (relevant for both representative uses evaluated; no submission date proposed by the notifier; refer to point 5.7)

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as nematicide as proposed by the applicant which comprises application by drip irrigation and "chisel application" (spray application followed by incorporation into the soil) in bell-pepper and tobacco, respectively. The application rates are 10 kg fenamiphos per hectare in bell pepper and 6 kg per hectare in tobacco. Fenamiphos can be used as nematicide and insecticide. It should be noted that during the peer review process the applicant stated that only the use as nematicide will be supported in the EU review programme.

The representative formulated product for the evaluation was Nemacur CS 240, a capsule suspension (CS), registered in South Europe.

Adequate methods are available to monitor all compounds given in the respective residue definition except for a method for fenamiphos-sulfone-phenol in ground water and a method for blood and animal tissues.

Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues.

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.

Fenamiphos has a high acute toxicity therefore, the following classifications were proposed: T+; R28 “Very toxic if swallowed”, T; R24 “Toxic in contact with skin” and T+; R26 “Very toxic by inhalation”. Fenamiphos is proposed to be labelled: Xi; R36 “Irritating to eyes”. It showed no skin sensitising properties. The relevant short term oral NOAEL is 0.083 mg/kg bw/day from the 1-year study in the dog. The relevant long term NOAEL is 0.56 mg/kg bw/day in the 2-year rat studies. Fenamiphos is considered not genotoxic and not carcinogenic. Overall, no reproductive or developmental toxic potential. Fenamiphos showed no potential to induce delayed neuropathy after acute or subchronic administration in hens. The NOAEL for acute neurotoxicity is 0.25 mg/kg bw/day. Some metabolites showed high acute toxicity (LD_{50} <25 mg/kg bw). The Acceptable Daily Intake (ADI) and the Acceptable Operator Exposure level (AOEL) are 0.0008 mg/kg bw/day, and the Acute Reference Dose ARfD is 0.0025 mg/kg bw (safety factor – SF- 100).

The behaviour and metabolism of fenamiphos was investigated in a range of crops representing fruity crops, root and tuber crops, leafy crops, oilseeds and pulses as well as different kinds of application. All studies show a similar metabolic pathway in the plants. Fenamiphos is only found directly following application. A short period after treatment, fenamiphos-sulfoxide is the dominant metabolite. In some plants, fenamiphos-sulfone is increasing in time. Therefore, fenamiphos, fenamiphos-sulfoxide and fenamiphos-sulfone form the toxicological relevant residue. Residues of fenamiphos in rotation crops were found in soybean, Swiss chard, beet root, wheat green forage and wheat straw planted up to 8 months after treatment. Fruiting vegetables planted as rotational crops are not tested. It is recommended to prescribe a safety interval for planting or sowing rotational crops of 8 months. Furthermore, it is concluded that the rotational crops investigated are not representative for fruiting vegetables and therefore further data is still required.
Information on fenamiphos fed to ruminants and poultry is present, but is not relevant for the intended uses on sweet pepper and tobacco.
It is concluded that application of fenamiphos on tobacco and sweet pepper following the representative cGAP lead to residue levels on food not giving rise to concern for consumer exposure. However, since there were relevant metabolites found in ground water, a consumer risk assessment was performed, considering the sum of possible intakes of fenamiphos and the metabolites fenamiphos-sulfoxide and fenamiphos-sulfone from drinking water in addition to the intake through diet. The total intakes from diet and drinking were demonstrated to be significantly above the ADI and ARfD of fenamiphos for the considered consumer subgroups.

Fenamiphos is very low or low persistent ($DT_{50\ lab\ 20\ °C}$ = 0.4 – 1.4 d) in soil under aerobic conditions being rapidly oxidized to the major metabolites fenamiphos-sulfoxide and fenamiphos-sulfone. Fenamiphos-sulfoxide is moderate to high persistent in soil ($DT_{50\ lab}$ = 25 – 109 d) and fenamiphos-sulfone low to moderately persistent ($DT_{50\ lab}$ = 6 – 60 d). Both organophosphate metabolites are hydrolysed to the major metabolites fenamiphos-sulfoxide-phenol ($DT_{50\ lab}$ = 14 d) and fenamiphos-sulfone-phenol ($DT_{50\ lab}$ = 10 – 79 d). At the end of the available studies (90-120 d), mineralization ranged form 0.4 to 52 % AR and non-extractable residues reached values of 16 to 69 % AR. Under anaerobic conditions, only fenamiphos sulfoxide was found to exceed 10 % AR.
According to the available study, photolysis may contribute to the environmental degradation of fenamiphos.
A bare soil field dissipation study in four locations in Southern Europe (France, Spain and two locations in Italy) is available. Fenamiphos was formulated as the representative capsule suspension product (Nemacur 240 CS). All major metabolites were found in the 0-10 cm layer and fenamiphos-sulfoxide was also consistently found at deeper layers. Experts' meeting agreed that photolysis was not likely to have affected the degradation rate of fenamiphos and its metabolites in the field trials but leaching could not be completely excluded taking onto account the adsorption/desorption properties of these compounds.
Reliability of the dissipation half lives obtained in the trial performed in Spain (excluded from the assessment based in abnormal dry climatic conditions) was discussed in the experts' meeting. Further

information provided by the applicant after the meeting has been examined by the RMS the Spanish experts and EFSA. This new information confirms that the Spanish field trial should not be considered in the assessment of soil compartment and for PEC soil calculation.

From the information provided by the notifier it was not clear if the Nemacur 240 CS formulation should be considered a slow release formulation. However, experts' meeting agreed with the RMS not to consider Nemacur 240 CS a slow release formulation.

New PEC soil have been provided by the RMS in the list of end points to take also into account the application rates proposed in the GAPs table and the maximum percentage of metabolites found in the laboratory studies as agreed by the experts' meeting. EFSA transferred these values to the updated addendum for transparency.

According batch adsorption/desorption studies, fenamiphos is low to high mobile (Koc = 76 – 1432 L/kg) whereas fenamiphos-sulfoxide, fenamiphos-sulfone, fenamiphos-sulfoxide-phenol and fenamiphos-sulfone-phenol are medium to very high mobile (fenamiphos-sulfoxide: Koc = 44.8 – 225 L/kg; fenamiphos-sulfone: Koc = 52.4 – 311 L/kg; fenamiphos-sulfoxide-phenol: Koc = 12.5-166 L/kg; fenamiphos-sulfone-phenol: Koc = 31-207 L/kg). Due to the fast degradation of fenamiphos the values for this substance should be considered only as indicative.

No column leaching, field leaching or lysimeter studies are available for fenamiphos.

In sterile buffer solutions (pH 5, 7 and 9) at 20 °C fenamiphos may be considered stable (DT_{50} > 200 d). Hydrolysis of fenamiphos, fenamiphos-sulfoxide and fenamiphos sulfone has also been tested at pH 4. Under these conditions, hydrolysis half life of fenamiphos is still above 200 d and above 120 d for its metabolites.

Aqueous photolysis may contribute to the transformation of fenamiphos into fenamiphos-sulfoxide. Fenamiphos-sulfonic-acid was detected as a minor metabolite and fenamiphos-phenol-sulfonic acid as a major photolysis metabolite of fenamiphos. This later metabolite shown to be stable to photolysis in water (DT_{50} = 768 d).

Experts' meeting proposed to classify fenamiphos as not ready biodegradable.

In water sediment systems fenamiphos dissipated relatively fast from the water phase ($DT_{50water}$ = 3.6-7.9 d) but may be highly persistent in the whole system ($DT_{50\ whole\ system}$ = 9.3 – 111 d). Major metabolites in water were fenamiphos-sulfoxide and fenamiphos–sulfoxide-phenol. Fenamiphos-sulfoxide was also a major metabolite in the sediment. Mineralization reached a maximum of 2.4-14.3 % AR at the end of the study (100 d) and bound residues reached maximum amounts of 17.4 - 48 % AR.

For the representative uses of NEMACUR CS 240 (soil treatment with incorporation and drip irrigation) direct emissions to surface water are not expected. However, emissions via run-off and drainage may not be excluded. RMS presented FOCUS $PEC_{SW\ /\ SED}$ (Steps 1 and 2) calculations for fenamiphos, and initial FOCUS $PEC_{SW\ /\ SED}$ (Steps 1 and 2) for fenamiphos-sulfoxide, fenamiphos-sulfoxide-phenol, fenamiphos-phenol-sulfonic acid, fenamiphos-sulfone and fenamiphos-sulfone-phenol in an addendum that was discussed in the experts meeting. The meeting agreed that further refinement by FOCUS Step 3 should be provided by the applicant taking into consideration EFSA Opinion on the use of FOCUS SW.

For the FOCUS PEC_{GW} presented in the original DAR field dissipation half lives were employed as input parameters. Experts' meeting expressed concerns on the use the field dissipation half lives as degradation parameters for modelling in this case. New FOCUS-PEARL calculations, using normalised laboratory half lives, have been provided by the RMS in the list of end points and the updated addendum for the FOCUS scenarios Piacenza, Porto, Sevilla and Thiva. Potential contamination of ground water under vulnerable situations by fenamiphos metabolites over the triggers of 0.1 µg/L, 0.75µg/L and 10 µg/L may be deduced from these new calculations. Experts' meeting recognized the difficulty to address potential ground water contamination from protected crop uses with the available scenarios. Since the practices to grow crops under protection are variable among EU a better definition of greenhouse uses is necessary. According to the applicant, NEMACUR CS 240 is used on permanent structures covered with plastic and nets and the crops are planted over the natural soil. Crop is irrigated to satisfy the crop water requirements. Experts' meeting did not specifically discuss the relevance of available $FOCUS_{GW}$ scenarios to this particular case because initial calculations in the DAR did not show potential for contamination above the triggers. With the results of the new $FOCUS_{GW}$ simulations, an assessment of the applicability of available FOCUS scenarios for the greenhouse use would be necessary.
Based on the available volatilisation experiment and the calculated atmospheric half life contamination of the air compartment and long range transport through air are not expected.

For the representative uses evaluated the only potentially relevant routes of bird and mammal exposure are via intake of contaminated soil arthropods, earthworms and fish. Since birds and mammals have no access to permanent glasshouses the only route of exposure from the use on bell peppers is via ingestion of contaminated fish. For the use on tobacco fields exposure via contaminated earthworms and soil arthropods is also possible. The initial risk assessment indicated a high risk for fish-eating birds and mammals from both uses and a high risk for earthworm-eating birds and mammals for the use in tobacco fields. Limited field surveys indicate that earthworms are not present in tobacco fields, but this has to be investigated further. The risk assessment for fish-eating birds and mammals needs to be refined based on refined PEC surface water data.

Fenamiphos and the metabolites fenamiphos-sulfoxide and fenamiphos-sulfone are very toxic to fish and aquatic invertebrates. The results from a mesocosm study indicate a potential high risk and the assessment needs to be refined based on refined PEC surface water data.

The risk to bees and other non-target arthropods is considered low from the representative uses evaluated, while a risk to earthworms, other soil macro-organism and micro-organism has been identified and needs to be further addressed.

The risk to non-target plants and biological methods of sewage treatment is considered low.

Particular conditions proposed to be taken into account to manage the risk(s) identified

- The use of fenamiphos on bell peppers should be restricted to those greenhouses which consist of permanent structures to protect terrestrial vertebrates.
- For the use in glasshouses the risk to earthworms and other soil organisms should be considered at Member State level.
- A waiting period before replanting or sowing of 8 months is advised for uses in the field (refer to 3.1.2)

Critical areas of concern

- Fenamiphos is very toxic by oral, dermal and respiratory route.
- For uses under glass residues in succeeding crops are possible, which are likely to be composed of compounds of high toxicity. No plant back interval for glasshouse applications can be fixed on the basis of the currently available information.
- A high potential for ground water contamination by the metabolites of fenamiphos (fenamiphos-sulfoxide (M01), fenamiphos-sulfone (M02), fenamiphos-sulfone-phenol (M13)) when used in field is identified. Pertinence of the available FOCUS modelling with standard FOCUS scenarios to greenhouse uses needs to be assessed, taking into account the kind of structures, the practices employed and the resulting soil temperatures and precipitation / irrigation regime.
- Metabolites M01 and M02, found in groundwater, show very high acute toxicity (LD_{50}<10 mg/kg bw) and should be considered as relevant. A consumer risk assessment indicates possible intakes above the ADI and acute reference dose.
- A high potential risk to fish-eating birds and mammals was identified based on FOCUS step 2 surface water PEC values for both representative uses.
- A high potential risk to fish and aquatic invertebrates was identified based on FOCUS step 2 surface water PEC values for both representative uses.
- A high risk to earthworms and other soil macro-organisms for the use in tobacco.
- A high risk to soil non-target micro-organisms for the use in tobacco.

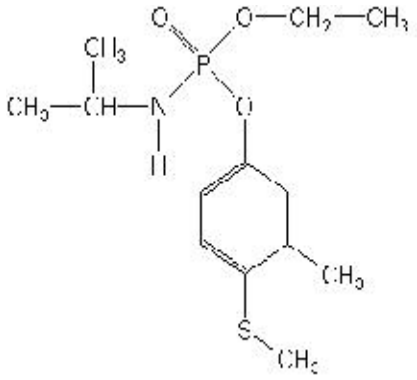
APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

(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) ‡	Fenamiphos
Function (e.g. fungicide)	Nematicide, insecticide
Rapporteur Member State	The Netherlands
Co-rapporteur Member State	None

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	(*RS*)-ethyl 4-methylthio-m-tolyl isopropylphosphoramidate
Chemical name (CA) ‡	ethyl 3-methyl-4-(methylthio)phenyl (1-methylethyl)phosphoramidate
CIPAC No ‡	692
CAS No ‡	22224-92-6
EEC No (EINECS or ELINCS) ‡	244-848-1
FAO Specification ‡ (including year of publication)	No FAO specification established
Minimum purity of the active substance as manufactured ‡ (g/kg)	940 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	None
Molecular formula ‡	$C_{13}H_{22}NO_3PS$
Molecular mass ‡	303.4
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) ‡	43-49 °C (99.5%)
Boiling point (state purity) ‡	Not available (thermal decomposition)
Temperature of decomposition	200 °C (99.6%)
Appearance (state purity) ‡	Not available
Relative density (state purity) ‡	1.191 at 23 °C (99.5%)
Surface tension	47.2 mN/m at 20°C (99.5%)
Vapour pressure (in Pa, state temperature) ‡	1.2 x 10-4 Pa at 20°C 2.3 x 10-4 Pa at 25°C extrapolated from measurements at higher temperature (54 and 106°C) (99.6%).
Henry's law constant (Pa m^3 mol^{-1}) ‡	9.9 x 10-5 Pa m3mol-
Solubility in water ‡ (g/l or mg/l, state temperature)	Purity 99.5%: 368 mg/L at 20 °C in Milli-Q water 356 mg/L at 20 °C in buffer of pH 4 345 mg/L at 20 °C in buffer of pH 7 344 mg/L at 20 °C in buffer of pH 9
Solubility in organic solvents ‡ (in g/l or mg/l, state temperature)	*n*-hexane 27 g/L at 20°C xylene >250 g/L at 20°C dichloromethane >250 g/L at 20°C 2-propanol >250 g/L at 20°C polyethyleneglycol >250 g/L at 20°C 1-octanol >250 g/L at 20°C acetone >250 g/L at 20°C ethylacetate >250 g/L at 20°C acetonitrile >250 g/L at 20°C dimethylsulfoxide >250 g/L at 20°C
Partition co-efficient (log POW) ‡ (state pH and temperature)	Fenamiphos: as fenamiphos is surface active the determination method is les reliable. Therefore more results are given here. based on determination: 3.3 (Log P_{ow} = 3.30 at 20°C (99.6%)) based on calculation on solubility in water and octanol: = 2.8 Based on estimation: 3.29 (EPIWIN v. 3.10) On this basis a log P_{ow} = 3.30 is accepted

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

	Fenamiphos-sulfoxide: 1.13 (estimated with EPIWIN v.3.10) fenamiphos-sulfone: 1.26 (estimated with EPIWIN v.3.10) fenamiphos-sulfoxide-phenol 1.85 (estimated with EPIWIN v.3.10) fenamiphos-sulfone-phenol 0.63 (estimated with EPIWIN v.3.10)
Hydrolytic stability (DT50) ‡ (state pH and temperature)	99.3% radio chem. Pure: Half life at 25 °C: at pH 5 245 days at pH 7 301 days at pH 9 235 days
Dissociation constant ‡	No basic or acidic properties
UV/VIS absorption (max.) ‡ (if absorption > 290 nm state ε at wavelength)	UV-spectrum, solution in acetonitrile ε L/(molxcm) @ 201nm = 24.3×10^3 ε L/(molxcm) @ 251nm = 11.4×10^3 ε L/(molxcm) @ 287nm = 1.4×10^3
Photostability (DT_{50}) ‡ (aqueous, sunlight, state pH)	DT_{50} a.s. in sterile buffer pH 7, 27-28 °C, irradiation with mercury lamp: 3.6 hours; metabolites >5% nemacur sulfonic acid (max. 6.1% at end), nemacur phenol sulfonic acid (max. 18.6% at end), nemacur sulfoxide (max. 17.3% at end). Environmental half life: 2.6, 3.7, 6.2 and 12 days (summer, 30, 40, 50 and 60°N respectively, clouds not considered); 7.1 days (June, 50°N, clouds taken into consideration).
Quantum yield of direct phototransformation in water at Σ > 290 nm ‡	The quantum yield was calculated to be Φ = 0.232 (99.5%)
Flammability ‡	Not highly flammable, not undergoing spontaneous combustion
Explosive properties ‡	Not explosive
Oxidising properties	No oxidizing properties

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

List of representative uses evaluated*

Crop and / or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (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		
Bell pepper (CPSAN)	Southern Europe	Nemacur CS 240	G	nematodes	CS	240	apply by drip irrigation	No later than BBCH 61	1	-	n.a.	n.a.	10	60	[1] [2] Application only on soil grown peppers
Tobacco, Virginian (NIOTA)	Southern Europe	Nemacur CS 240	F	nematodes	CS	240	Shank-chisel	at trans-planting	1	n.a.	1.2 - 5	120 - 500	6.0	80	[1] [2] [3] Waiting period for succeeding crops: 8 months

[1] The assessment has revealed data gaps in section 4 (groundwater exposure estimates) and section 5.
[2] The risk assessment has revealed a risk (exceedence of relevant thresholds) in section 5
[3] The groundwater exposure assessment in section 4 indicates unacceptable concentrations of relevant metabolites. A consumer risk assessment for these metabolite concentrations in section 3 identifies intakes as a result of water consumption above the ADI and acute reference dose.

‡ 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
			(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
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)		
	(c)	*e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds		
	(d)	*e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(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)	GC-FID with internal standard
Impurities in technical as (principle of method)	GC-FID with internal standard Water with Karl Fischer titration
Plant protection product (principle of method)	GC-FID with internal standard

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	HPLC-MS/MS method 00564 Residues of fenamiphos, fenamiphos sulfoxide and fenamiphos sulfone are measured together as fenamiphos sulfone, expressed as parent. LOQ 0.02 mg/kg (parent eq) for commodities with high water content (tomato) and fruits with high acid content (orange, kiwi). LOQ 0.02 mg/kg (parent eq) for commodities with high fat content (olive) for modified method 00564/M001. LOQ 0.02 mg/kg (parent eq) for field pea; LOQ 0.5 mg/kg (parent eq) for tobacco (green and dried)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	No data available, data not required
Soil (principle of method and LOQ)	Soil is extracted with acetonitrile/water (4:1) twice, and evaporated to dryness. After dilution with water (containing 1% MeOH) a) filtered and analysed for fenamiphos, fenamiphos-sulfoxide and fenamiphos-sulfone by LC/MS-MS b) passed through a cartridge b.1) the aliquot is analysed for fenamiphos-phenol-sulfonic acid. After elution of the analytes with ACN, evaporated to dryness, diluted in water and after filtration analysed by HPLC for fenamiphos-sulfoxide-phenol and fenamiphos-sulfone-phenol. b.2) the aqueous eluate is collected, evaporated to dryness, and after filtration, analysed by HPLC for fenamiphos-phenol-sulfonic acid. The limit of quantification is 0.01 mg/kg for fenamiphos, fenamiphos-sulfoxide, fenamiphos-sulfone, fenamiphos-sulfoxide-phenol, fenamiphos-sulfone-phenol and fenamiphos-phenol-sulfonic acid.

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

Water (principle of method and LOQ)	Fenamiphos, fenamiphos-sulfoxide and fenamiphos-sulfone can be determined in water by direct injection of an aliquot onto an HPLC-MS/MS system. The limit of quantification for all compounds is 0.01 µg/L. *A method for fenamiphos-sulfone-phenol is required.*
Air (principle of method and LOQ)	Fenamiphos, fenamiphos-sulfoxide and fenamiphos-sulfone can be determined in air by sampling air through a Tenax adsorption tube. The adsorbed compound is extracted by acetonitrile and determined by liquid chromatographic separation using UV detection. The method is valid for the determination of residues of fenamiphos in air at a level of 0.5 µg/m^3. The linearity of the method was validated to an upper concentration of 50 µg/m^3 for fenamiphos-sulfoxide and fenamiphos-sulfone, and to an upper concentration of 52 µg/m^3 for fenamiphos.
Body fluids and tissues (principle of method and LOQ)	*An analytical method is required (fenamiphos is an inappropriate target analyte)*

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	No classification required on basis physical and chemical data

‡ 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 absorbed, almost complete within 24h
Distribution ‡	Widely distributed, but not in compact bone structures, the spinal marrow and the brain, indicating minimal ability to cross the blood-brain barrier
Potential for accumulation ‡	No potential for accumulation
Rate and extent of excretion ‡	40-80% was excreted renally within 4 h of treatment, after 48h >96% was excreted. Faecal excretion was 1.5(i.v.) -3.7 (oral)%.
Metabolism in animals ‡	Fenamiphos was metabolised to fenamiphos-phenols (methylthiometacresol-derivatives) in different stages of oxidation at the sulphur atom and their respective sulphuric acid conjugates.
Toxicologically significant compounds ‡ (animals, plants and environment)	Parent compound and its metabolites fenamiphos-sulfoxide (M01), fenamiphos-sulfone (M02), des-isopropyl fenamiphos (M06), des-isopropylfenamiphos-sulfoxide (M07), and des-isopropyl fenamiphos sulfone (M08).

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	6.0-6.1 mg/kg bw,	**R28**
Rat LD_{50} dermal ‡	72-92 mg/kg bw,	**R24**
Rat LC_{50} inhalation ‡	65-79 µg/L/ 4h (aerosol),	**R26**
Skin irritation ‡	Study not acceptable. Not required since the acute dermal toxicity is high and no skin effects were found in two repeated dose dermal studies	
Eye irritation ‡	Irritating,	**R36**
Skin sensitization ‡ (test method used and result)	Non sensitiser (Maximisation test)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Inhibition brain ChE activity
Lowest relevant oral NOAEL / NOEL ‡	0.083 mg/kg bw/day, 1 year study in dog
Lowest relevant dermal NOAEL / NOEL ‡	2.5 mg/kg bw/day, 21-day dermal study in rabbit
Lowest relevant inhalation NOAEL / NOEL ‡	3.5 µg/L, 28 days inhalation study in rats

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

Genotoxicity ‡ (Annex IIA, point 5.4)

…….	Indication of clastogenic effects in vitro (human lymphocytes) at cytotoxic dose levels. Overall, fenamiphos is considered not genotoxic.

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

Target/critical effect ‡	Inhibition erythrocyte ChE activity
Lowest relevant NOAEL / NOEL ‡	0.56 mg/kg bw/day, 2-year study in rats
Carcinogenicity ‡	No carcinogenic potential

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	No effects on fertility at highest dose tested, decreased bw gain of the pups at parental toxic dose
Lowest relevant reproductive NOAEL / NOEL ‡	Parental: 0.17 mg/kg bw/day Offspring: 0,64 mg/kg bw/day Reproductive: 2,8 mg/kg bw/day
Developmental target / critical effect ‡	Decrease of foetal weight and skeletal variations at 1 mg/kg bw/day.
Lowest relevant developmental NOAEL / NOEL ‡	Parental NOAEL:0.1 mg/kg bw/day (rabbit) Developmental 0.3 mg/kg bw/day (rabbit)

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

Acute neurotoxicity NOAEL	0.25 mg/kg bw, acute neurotoxicity dog
Semi-chronic neurotoxicity NOAEL	0.61 mg/kg bw, based on clinical signs and marginal brain cholinesterase inhibition at tha highest dose tested (15-week neurotoxicity study in rats)

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

Other toxicological studies ‡ (Annex IIA, point 5.8)

Acute toxicity metabolites	The main fenamiphos metabolites are formed by ester cleavage and are much less toxic than the parent compound (LD_{50} > 1000 mg/kg bw, e.g. M13). Also des-isopropylamino fenamiphos sulfoxide (M09) is less toxic (LD_{50} > 300 mg/kg bw). Metabolites with still very high acute toxicity (LD_{50} <25 mg/kg bw) fenamiphos-sulphoxide (M01), fenamiphos-sulphone (M02), des-isopropyl fenamiphos (M06), and des-isopropyl fenamiphos-sulphoxide (M07).

Medical data ‡ (Annex IIA, point 5.9)

……	No adverse effects reported on employees

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.0008 mg/kg bw/day	overall NOAEL from the 1 year cholinesterase study in dogs	100
AOEL (semi chronic, internal, ECCO)	0.0008 mg/kg bw/day	overall NOAEL from the 1 year cholinesterase study in dogs	100
ARfD ‡ (acute reference dose)	0.0025 mg/kg bw	acute oral neurotoxicity in dogs	100

Dermal absorption (Annex IIIA, point 7.3)

Nemacur 240 CS	Fenamiphos: 50% based on an *in vitro* dermal penetration study with human and rat skin undiluted 240 CS formulation: 1 % absorption 240 CS formulation dissolved in water (in-use application rate): 5 % absorption

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

Acceptable exposure scenarios (including method of calculation)

Operator	Below the AOEL for use in bell pepper cultivation with PPE (2% of AOEL), based on field study. Below the AOEL for use in tobacco cultivation with PPE (4-14% of ALOEL), based on field study.
Workers	Negligible
Bystanders	Negligible

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data	T+,	Very toxic;
	Xi,	Irritant
	R24,	Toxic in contact with skin
	R26,	Very toxic by inhalation
	R28,	Very toxic if swallowed
	R36,	Irritating to eyes

‡ 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	Fruit (tomato, pineapple) root vegetables (carrot) leafy crops (tobacco, cabbage) pulses and oilseeds (bean)
Rotational crops	Leafy vegetable (spinach) root vegetable (turnip) pulses and oilseeds (immature mustard) cereal (wheat, sorghum)
Plant residue definition for monitoring	Sum of fenamiphos, fenamiphos sulfoxide (M01) and fenamiphos sulfone (M02), expressed as fenamiphos
Plant residue definition for risk assessment	Sum of fenamiphos, fenamiphos sulfoxide (M01) and fenamiphos sulfone (M02), expressed as fenamiphos
Conversion factor (monitoring to risk assessment)	1

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

Animals covered	Not required for representative uses
Animal residue definition for monitoring	Not required for representative uses
Animal residue definition for risk assessment	Not required for representative uses
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Not required for representative uses
Fat soluble residue: (yes/no)	No

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

……..	Residues present in field, proposed waiting period of 8 months; succeeding crop study for glasshouse application requested.

‡ 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)

water containing plant materials (asparagus)	24 months at <-5°C
oil containing plant materials (cottonseed)	24 months at <-5°C
protein containing plant materials	No data available, data not required
starch containing plant materials	No data available, data not required

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

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: no	Poultry: no	Pig: no
Muscle	No data required, not applicable		
Liver	No data required, not applicable		
Kidney	No data required, not applicable		
Fat	No data required, not applicable		
Milk	No data required, not applicable		
Eggs	No data required, not applicable		

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

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a) (mg/kg parent eq)	Comments: used application	MRL (mg/kg parent eq)	STMR (b) (mg/kg parent eq)
sweet pepper	Southern Europe (glasshouse)	7x <0.02, 0.022	single glasshouse irrigation application; before BBCH 61; 10 kg a.s./ha; PHI 60-62d.	0.05	0.02*
tobacco green leaves	Southern Europe (field)	4x <0.5	single field application in irrigation water (according to critical GAP) (shank-shivel application); before BBCH 15, 6.0 kg a.s./ha; PHI 80d.	n/a	0.5*

* LOQ
(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

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

ADI	0.0008 mg/kg bw/d
TMDI (European Diet) (% ADI)	2.9% [22]
NEDI (% ADI)	Not required
Factors included in NEDI	N/a
ARfD	0.0025 mg/kg bw
Acute exposure (% ARfD)	11% (NL general, NL children); max 8.6% (UK adults); max 26% (UK toddlers)[23]

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

Crop/processed crop	Number of studies	Processing factor	% Transference *
green tobacco leaves/dried tobacco leaves	1	3.3 (2.0-5.2)	not available
green tobacco leaves/cured tobacco leaves	2	3.7 (0.63-9.7)	not available
cured tobacco leaves/smoke	1	residues in smoke not detected	not available

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

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

sweet pepper	0.05 mg/kg

[22] intake of fenamiphos, fenamiphos sulfoxide and fenamiphos sulfone through drinking water not included; estimated ***ca* 182% ADI** of fenamiphos for adults and ***ca* 546% ADI** for toddlers, based on FOCUS modelling for tobacco

[23] intake of fenamiphos, fenamiphos sulfoxide and fenamiphos sulfone through drinking water not included; estimated ***ca* 58% ARfD** of fenamiphos for adults and ***ca* 175% ARfD** for toddlers, based on FOCUS modelling for tobacco

‡ 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 ‡	1.1-39% after 90 days at 22 ºC 0.4-23% after 90 days at 16 ºC 23-52% after 120 days at 20 ºC
Non-extractable residues after 100 days ‡	69% after 90 days at 22 ºC 46% after 90 days at 16 ºC 36% after 120 days at 20º C
Relevant metabolites - name and/or code, % of applied ‡ (range and maximum)	Fenamiphos-sulfoxide: 79.1% (16 ºC); 65.4% (20 ºC) fenamiphos-sulfone: 22.8% (16 ºC); 24.9% (20 ºC) fenamiphos-sulfoxide-phenol: 11.1% (22 ºC); 4.0% (20 ºC); fenamiphos-sulfone-phenol: 24.7% (22 ºC); 23.7% (20 ºC)

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

Anaerobic degradation ‡	Non-extractable residue: maximum 27% after 60 days mineralisation: 1.1% of AR on day 60 fenamiphos-sulfoxide: 46.5% of AR in soil
Soil photolysis ‡	Non-extractable residue: maximum 5.2% of AR in irradiated samples after 48 hours mineralisation: not measured fenamiphos-sulfoxide: 8.3% after 4 hours in dark control, 63.7% after 6 hours in irradiated samples. fenamiphos-sulfone: 0.8% after 12 hours in dark control, 6.6% after 24 hours in irradiated samples.

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

Method of calculation	Non-linear regression of first-order kinetics
Laboratory studies ‡ (range or median, with n value, with r^2 value)	**Fenamiphos** $DT_{50, lab}$ (20°C, aerobic): 0.4-1.4 d (n=4, r^2 = 0.958-0.992; average 0.85 days) **fenamiphos-sulfoxide** $DT_{50, lab}$ (20°C, aerobic): 25-109 days (n=13, r^2 0.852-0.998 ; average 53 days) **fenamiphos-sulfone** $DT_{50, lab}$ (20°C, aerobic): 6-60 days (n=9, r2 0.839-0.98; average 38 days) **fenamiphos-sulfoxide-phenol** $DT_{50, lab}$ (20°C, aerobic): 14 days (n=1, r^2 0.68) **fenamiphos-sulfone-phenol**

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

	$DT_{50, lab}$ (20°C, aerobic): 10-79 days (n=4, r^2 0.84-0.99; average 40 days)
	$DT_{90, lab}$ (20°C, aerobic): calculated as DT_{50}·3.3 **fenamiphos** 1.3-4.6 days fenamiphos-sulfoxide 83-360 days fenamiphos-sulfone 20-198 days fenamiphos-sulfoxide-phenol 46.2 days fenamiphos-sulfone-phenol 33-261 days
	$DT_{50, lab}$ (10°C, aerobic): not available
	$DT_{50, lab}$ (20°C, anaerobic): 82.4 days
Method of calculation (field)	Multiple fit using the Berkely-Madonna software program, taking account of simultaneous formation and degradation of metabolites
Field studies ‡ (state location, range or median with n value)	$DT_{50, field}$: Southern France (1 trial) and Italy (2 trials) **fenamiphos** 1.5-2.2 days (n=3, average 1.8 days) r^2: 0.999; 0.939; 0.996 **fenamiphos-sulfoxide** 9.4-14.1 days (n=3, average 11.5 days) r^2: 0.989; 0.977; 0.958 **fenamiphos-sulfone** 1.7-7.2 days (n=3, average 4.2 days) r^2: 0.846; 0.830; 0.924 **fenamiphos-sulfoxide-phenol** 6.0 and 9.5 days (average 7.8 days) r^2: 0.947; 0.961 fenamiphos-sulfone-phenol 5.6 days r^2: 0.841

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

	$DT_{90, field}$: calculated as DT_{50}·3.3 **fenamiphos** 5.0-7.3 days fenamiphos-sulfoxide 31-47 days fenamiphos-sulfone 5.6-24 days fenamiphos-sulfoxide-phenol 20 and 31 days fenamiphos-sulfone-phenol 18 days
Soil accumulation and plateau concentration ‡	Not available

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡ K_d ‡ pH dependence ‡ (yes / no) (if yes type of dependence)	**fenamiphos** K_F: 0.7-23.3 L/kg (n=19) corresponding K_{om} values: 44.8-842 L/kg (average 173 L/kg) corresponding K_{oc} values: 76-1432 L/kg all K_{om} values are considered to be indicative **fenamiphos-sulfoxide** K_F : 0.71-3.60 L/kg (n=3) corresponding K_{om} values: 26.4-133 L/kg (average 66 L/kg) corresponding K_{oc} values: 44.8-225 L/kg **fenamiphos-sulfone** K_F : 0.33-4.98 L/kg (n=5) corresponding K_{om} values: 30.8-183 L/kg (average 71 L/kg) corresponding K_{oc} values: 52.4-311 L/kg **fenamiphos-sulfoxide-phenol** K_F : 0.154-7.884 (n=16) corresponding K_{om} values: 7.35-98 L/kg (average 44 L/kg) corresponding K_{oc} values: 12.5-166 L/kg **fenamiphos-sulfone-phenol** K_F : 1.09-9.835 (n=16) corresponding K_{om} values: 18.2-122 L/kg (average 60 L/kg) corresponding K_{oc} values: 31-207 L/kg

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

Column leaching ‡	Not available
Aged residues leaching ‡	Not available

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

Lysimeter/ field leaching studie ‡	Not available

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation	$PEC_S(t) = \sum_{i=1}^{n} PEC_{S,\ init,\ i} \bullet e^{-k(t-t_i)}$ first order exponential decay, with average $DT_{50,field}$ 100% of dosage reaching soil bell pepper in glasshouse: 5 cm soil depth tobacco in field: 10 cm soil depth soil density 1.5 kg/L **fenamiphos** $DT_{50,field}$ 1.8 days **fenamiphos-sulfoxide** max. 79.1% of AR relative molar mass: 1.05 $DT_{50,field}$ 11.5 days **fenamiphos-sulfone** max. 24.9% of AR relative molar mass: 1.11 $DT_{50,field}$ 4.2 days **fenamiphos-sulfoxide-phenol** max. 11.1% of AR relative molar mass: 0.56 $DT_{50,field}$ 7.8 days **fenamiphos-sulfone-phenol** max. 24.7% of AR relative molar mass: 0.62 $DT_{50,field}$ 5.6 days
Application rate	tobacco: 6.0 kg as/ha bell pepper: 10 kg as/ha metabolites: application rate of fenamiphos, corrected for formation rate and relative molar mass

PEC_S (mg/kg) fenamiphos

Days after last application	field application (tobacco)		glasshouse application (bell pepper)	
	Single application actual	time weighted average	Single application actual	time weighted average
0	4.00	-	13.33	-

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

PEC_S (mg/kg) fenamiphos-sulfoxide

Days after last application	field application (tobacco)		glasshouse application (bell pepper)	
	Single application actual	time weighted average	Single application actual	time weighted average
0	3.32	-	6.64	-

PEC_S (mg/kg) fenamiphos-sulfone

Days after last application	field application (tobacco)		glasshouse application (bell pepper)	
	Single application actual	time weighted average	Single application actual	time weighted average
0	1.11	-	3.68	-

PEC_S (mg/kg) fenamiphos-sulfoxide-phenol

Days after last application	field application (tobacco)		glasshouse application (bell pepper)	
	Single application actual	time weighted average	Single application actual	time weighted average
0	0.25	-	0.83	-

PEC_S (mg/kg) fenamiphos-sulfone-phenol

Days after last application	field application (tobacco)		glasshouse application (bell pepper)	
	Single application actual	time weighted average	Single application actual	time weighted average
0	0.61	-	2.04	-

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

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)	**Fenamiphos** pH 5 (20 ºC): DT_{50} 252 days pH 7 (20 ºC): DT_{50} 304 days pH 9 (20 ºC): DT_{50} 236 days no metabolites >10% of AR pH 4 (24.5 ºC): DT_{50} 205 days metabolites >10% of AR fenamiphos-sulfoxide 14.9% on day 30 **fenamiphos-sulfoxide (applied as parent)** pH 4 (24.5 ºC): DT_{50} 151 days 1 unidentified metabolite >10% of AR: 11.1% **fenamiphos-sulfone (applied as parent)** pH 4 (24.5 ºC): DT_{50} 134 days 1 unidentified metabolite >10% of AR: 10.8% As both unidentified metabolites are also identified in the water-sediment study that lasted 100 days, further information from a prolonged hydrolysis study is not considered necessary.
Photolytic degradation of active substance and relevant metabolites ‡	**Fenamiphos** water, pH 7, artificial light, >300 nm, constant irradiation, 27-28 ºC, DT_{50} 3.6 hours. metabolites >10% of AR: fenamiphos-sulfoxide: 17.3% (after 24 hours) fenamiphos-phenol-sulfonic acid: 18.6% (after 24 hours) water, artificial light, 295-490 nm, 25 ºC, DT_{50} range 2.6 to >1 year, quantum yield 0.232 moles/einstein **fenamiphos-sulfoxide** phosphate buffer, pH 7, artificial light, 295-400 nm, 25 ºC, DT_{50} 48 days. No major metabolites formed. **fenamiphos-phenol-sulfonic acid** phosphate buffer, pH 7, artificial light, 295-400 nm, 25 ºC, DT_{50} 768 days. No major metabolites formed.
Readily biodegradable (yes/no)	No information available in absence of information considered 'not readily biodegradable.'
Degradation in water/sediment (range or median, with n value, with r^2 value, state temperature)	$DT_{50,\ water}$ (aerobic; 20 ºC) **fenamiphos** sand: DT_{50} 3.6 days major metabolites: FOX: 10.6% of AR after 2 days FOXP: 10.8% of AR after 20 days DT_{50} 7.9 days in loam major metabolites: FOX: 13.8% of AR after 100 days

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

	$DT_{50, sediment}$: (aerobic; 20 ºC) **fenamiphos** sand: could not be determined due to constant levels of fenamiphos from day 20 to the end of the study (day 100) loam: could not be determined; levels of fenamiphos increased until day 58, decrease only measured at two time-points major metabolites: sand: no major metabolites loam: fenamiphos-sulfoxide; 16.8% day 100
	$DT_{50, whole system}$ (aerobic; 20 ºC): **fenamiphos** sand: DT_{50} 9.3 days loam: DT_{50} 111 days
Mineralization	Sand: 14.3% of AR after 100 days, loam: 2.4% of AR after 100 days
Non-extractable residues	Sand: 48.8% of AR after 58 days, loam: 17.4% of AR after 100 days
Distribution in water / sediment systems (active substance) ‡	In both sand and soil fenamiphos in the supernatant the decrease of fenamiphos was >70% in the first 20 days and the increase in the sediment in the loam system reached a maximum of 62.3% on day 58, and in the sand system 31.3% of AR on day 8.
Distribution in water / sediment systems (metabolites) ‡	Metabolites >10% of AR in water phase: sand: fenamiphos-sulfoxide 10.6% on day 2 sand: fenamiphos-sulfoxide-phenol 10.8% on day 20 loam: fenamiphos-sulfoxide 13.8% on day 100 in sediment: sand: no major metabolites formed loam: fenamiphos-sulfoxide 16.8% on day 100

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

Parent Parametres used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 303.4 Water solubility (mg/L): 368 Kom (L/kg): 173 DT_{50} soil (d): 0.85 days (mean lab) DT_{50} water/sediment system (d): 60.2 (mean of both systems) DT_{50} water (d): 5.8 (mean of both systems) DT_{50} sediment (d): 1000 (worst case because value

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

could not be determined) Crop interception (%): no interception No drift including drainage/runoff

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
Southern EU (Mar.-May) tobacco 6 kg fenamiphos/ha		Actual	TWA	Actual	TWA
	0	1430	-	4270	-
	1d	1410	1420	4220	4240
	2d	1400	1410	4170	4220
	4d	1370	1400	4080	4170
	7d	1320	1370	3940	4100
	14d	1220	1320	3630	3940
	21d	1120	1270	3350	3790
	28d	1040	1220	3090	3650
	42d	882	1130	2630	3380
	50d	804	1090	2400	3240
	100d	452	850	1350	2530

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
Southern EU (Mar. –May) tobacco 6 kg fenamiphos/ha		Actual	TWA	Actual	TWA
	0	21.93	-	65.41	-
	1	19.46	20.70	65.37	65.39
	2	17.89	19.69	60.09	64.06
	4	15.12	18.08	50.77	59.69
	7	11.74	16.06	39.43	53.35
	14	6.51	12.47	21.86	41.58
	21	3.61	9.95	12.12	33.23
	28	2.00	8.15	6.72	27.21
	42	0.62	5.82	2.07	19.46
	50	0.31	4.96	1.05	16.59
	100	0.005	2.52	0.016	8.42

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

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
bell pepper 10 kg fenamiphos/ha		Actual	TWA	Actual	TWA
	0	2380	-	7110	-
	1d	2360	2370	7030	7070
	2d	2330	2360	6950	7030
	4d	2280	2330	6790	6950
	7d	2200	2290	6560	6830
	14d	2030	2200	6050	6570
	21d	1870	2120	5590	6320
	28d	1730	2040	5150	6080
	42d	1470	1890	4390	5640
	50d	1340	1810	4000	5410
	100d	754	1420	2250	4220

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU (Mar. –May) bell pepper 10 kg fenamiphos/ha	0	36.55	-	109.02	-
	1	32.44	34.49	108.94	108.98
	2	29.82	32.81	100.14	106.76
	4	25.19	30.13	84.61	99.49
	7	19.57	26.76	65.72	88.91
	14	10.85	20.78	36.44	69.30
	21	6.02	16.59	20.21	55.38
	28	3.34	13.58	11.20	45.35
	42	1.03	9.70	3.45	32.43
	50	0.52	8.27	1.76	27.64
	100	0.008	4.20	0.026	14.03

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

Fenamiphos-sulfoxide Parametres used in FOCUSsw step 1 and 2	Because no DT_{50} in water, sediment and or system only initial concentrations for fenamiphos-sulfoxide are calculated with the use of the maximum percentage of 13.8% in water and 16.8% in sediment and a relative molar mass of 1.05.

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

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
tobacco		Actual	TWA	Actual	TWA
6 kg fenamiphos/ha	0	207	-	753	-

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
Southern EU		Actual	TWA	Actual	TWA
(Mar. –May) tobacco 6 kg fenamiphos/ha	0	3.18	-	11.54	-

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
bell pepper		Actual	TWA	Actual	TWA
10 kg fenamiphos/ha	0	344	-	1255	-

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU (Mar. –May) bell pepper 10 kg fenamiphos/ha	0	5.29	-	19.24	-

PEC sw and PEC sed

Fenamiphos-sulfoxide-phenol Parametres used in FOCUSsw step 1 and 2	Because no DT_{50} in water, sediment and or system only initial concentrations in water for fenamiphos-sulfoxide-phenol are calculated with the use of the maximum percentage of 10.8% in water and a relative molar mass of 0.56.

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

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)			
tobacco 6 kg fenamiphos/ha		Actual	TWA		
	0	86.5	-		

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)			
Southern EU (Mar. –May) tobacco 6 kg fenamiphos/ha		Actual	TWA		
	0	1.33	-		

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)			
bell pepper 10 kg fenamiphos/ha		Actual	TWA		
	0	144	-		

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)			
Southern EU (Mar. –May) bell pepper 10 kg fenamiphos/ha		Actual	TWA		
	0	2.21	-		

PEC sw and PEC sed

Fenamiphos-phenol-sulfonic acid Parametres used in FOCUSsw step 1 and 2	Because no DT_{50} in water, sediment and or system only initial concentrations for fenamiphos-phenol-sulfonic acid are calculated with the use of the maximum percentage of 18.6% in photolytic degradation study and a relative molar mass of 0.57.

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
tobacco 6 kg fenamiphos/ha		Actual	TWA	Actual	TWA
	0	152	-	453	-

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

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
Southern EU		Actual	TWA	Actual	TWA
(Mar. –May) tobacco 6 kg fenamiphos/ha	0	2.33	-	6.94	-

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
bell pepper		Actual	TWA	Actual	TWA
10 kg fenamiphos/ha	0	253	-	754	-

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
Southern EU		Actual	TWA	Actual	TWA
(Mar. –May) bell pepper 10 kg fenamiphos/ha	0	3.88	-	20.28	-

PEC sw and PEC sed

Fenamiphos-sulfone Parametres used in FOCUSsw step 1 and 2	Because no DT_{50} in water, sediment and or system only initial concentrations for fenamiphos-sulfone are calculated with the use of the maximum percentage of 24.9% in soil and a relative molar mass of 1.11. Crop interception (%): no interception No drift including drainage/runoff

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
tobacco		Actual	TWA	Actual	TWA
6 kg fenamiphos/ha	0	475	-	584	-

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

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
Southern EU (Mar. –May) tobacco 6 kg fenamiphos/ha		Actual	TWA	Actual	TWA
	0	7.28	-	8.95	-

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
bell pepper 10 kg fenamiphos/ha		Actual	TWA	Actual	TWA
	0	792	-	974	-

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
Southern EU (Mar. –May) bell pepper 10 kg fenamiphos/ha		Actual	TWA	Actual	TWA
	0	12.14	-	14.92	-

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

Fenamiphos-sulfone-phenol Parametres used in FOCUSsw step 1 and 2	Because no DT_{50} in water, sediment and or system only initial concentrations for fenamiphos-sulfone-phenol are calculated with the use of the maximum percentage of 24.7% in soil and a relative molar mass of 0.56. Crop interception (%): no interception No drift including drainage/runoff

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
tobacco 6 kg fenamiphos/ha		Actual	TWA	Actual	TWA
	0	238	-	292	-

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

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
Southern EU		Actual	TWA	Actual	TWA
(Mar. –May) tobacco 6 kg fenamiphos/ha	0	3.64	-	4.48	-

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
bell pepper		Actual	TWA	Actual	TWA
10 kg fenamiphos/ha	0	396	-	487	-

FOCUS STEP 2 Scenario	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
Southern EU		Actual	TWA	Actual	TWA
(Mar. –May) bell pepper 10 kg fenamiphos/ha	0	6.07	-	7.46	-

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

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	PEARL with four FOCUS-scenarios for Southern-Europe; 100% reaching the soil. Normalised laboratory DT_{50} values to 20 °C and pF 2 and average K_{OM} from adsorption studies are used: **fenamiphos** DT_{50}: 0.85 days K_{om}: 173 L/kg; 1/n: 0.9 **fenamiphos-sulfoxide** DT_{50}: 53 days K_{om}: 65.9 L/kg; 1/n: 0.9 max. 79.1% of AR relative molar mass: 1.05 **fenamiphos-sulfone** DT_{50}: 38 days K_{om}: 71.3 L/kg; 1/n: 0.9 max. 24.9% of AR relative molar mass: 1.11 **fenamiphos-sulfoxide-phenol** DT_{50}: 14 days K_{om}: 44.1 L/kg; 1/n: 0.9 max. 11.1% of AR

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

	relative molar mass: 0.56 **fenamiphos-sulfone-phenol** DT_{50}: 40 days K_{om}: 60.2 L/kg; 1/n: 0.9 max. 24.7% of AR relative molar mass: 0.62
Application rate	tobacco: 6.0 kg as/ha, incorporation 10 cm depth bell pepper: 10 kg as/ha, application to soil surface (results not reported here, see conclusion and addendum to the DAR)

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

	Scenario	fenamiphos	fenamiphos-sulfoxide	fenamiphos-sulfone	fenamiphos-sulfoxide-phenol	fenamiphos-sulfone-phenol
PEARL/Tobacco, field with incorporation	Piacenza	< 0.001	40.45	3.26	0.025	0.655
	Porto	< 0.001	0.081	< 0.001	< 0.001	0.092
	Sevilla	< 0.001	2.39	0.035	< 0.001	0.374
	Thiva	< 0.001	5.90	0.124	< 0.001	0.346

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

Direct photolysis in air ‡	Not available
Quantum yield of direct phototransformation	The quantum yield was calculated to be Φ = 0.232 (99.5%)
Photochemical oxidative degradation in air ‡	DT_{50}: The gas phase oxidation half-life of fenamiphos and its metabolites fenamiphos-sulfoxide and fenamiphos-sulfone, was estimated to be 1.7, 1.0 and 1.9 hours, respectively (Atkinson calculation).
Volatilization ‡	From plant surfaces: Not available from soil: Not available

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

PEC (air)

Method of calculation	Fenamiphos has a vapour pressure of $1.2 \cdot 10^{-4}$ Pa at 20 °C, and a calculated Henry's law constant of $9.1 \cdot 10^{-5}$ $Pa \cdot m^3 \cdot mol^{-1}$. Based on the volatilisation experiment, it is considered that significant volatilisation of fenamiphos from soil is unlikely to occur. The gas phase oxidation half-life of fenamiphos and its metabolites fenamiphos-sulfoxide and fenamiphos-sulfone, was estimated to be 1.7, 1.0 and 1.9 hours, respectively. Should fenamiphos or metabolites volatilise, then the compounds will degrade quickly

$PEC_{(a)}$

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	**Soil** **Definitions for risk assessment:** fenamiphos, fenamiphos-sulfoxide, fenamiphos-sulfone, fenamiphos-sulfoxide-phenol,fenamiphos-sulfone-phenol **Definitions for monitoring:** fenamiphos, fenamiphos-sulfoxide, fenamiphos-sulfone **Water** **Ground water** **Definitions for exposure assessment:** fenamiphos, fenamiphos-sulfoxide, fenamiphos-sulfone, fenamiphos-sulfoxide-phenol, fenamiphos-sulfone-phenol **Definitions for monitoring:** fenamiphos, fenamiphos-sulfoxide, fenamiphos-sulfone, fenamiphos-sulfone-phenol (due to the lack of toxicological data) **Surface water** **Definitions for risk assessment:** fenamiphos, fenamiphos-sulphoxide, fenamiphos-sulphoxide-phenol, fenamiphos-sulphonic-acid (aqueous photolysis metabolite). **Definitions for monitoring:** fenamiphos, fenamiphos-sulfoxide, fenamiphos-sulfone **Air** **Definitions for risk assessment and monitoring:** fenamiphos.

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

Soil (indicate location and type of study)	Adequate monitoring data not available
Surface water (indicate location and type of study)	Adequate monitoring data not available
Ground water (indicate location and type of study)	Adequate monitoring data not available
Air (indicate location and type of study)	Adequate monitoring data not available

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	Candidate for R53.

‡ 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	LD_{50} 6.0 mg/kg bw (male rats)
Long-term toxicity to mammals	NOAEL 0.3 mg/kg bw.d (teratogenicity, rabbit)
Acute toxicity to birds	Fenamiphos: 0.8 mg/kg bw (*C. virginianus*, male) fenamiphos-sulfoxide: 1.5 mg/kg bw (*Anas plathyrhynchos*, male and female) fenamiphos-sulfone: 1.1 mg/kg bw (bw (*Anas plathyrhynchos*, male)
Dietary toxicity to birds	43 mg/kg fd (*C. virginianus*) 6.0 mg/kg bw·d (*C. virginianus*)
Reproductive toxicity to birds	2.2 mg/kg fd (*C. virginianus*, male and female) 0.20 mg/kg bw·d (*C. virginianus*, male and female)

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

Field application: exposure via earthworms and fish; greenhouse application: exposure via fish
BCFworm 3.3 kgwwt soil/kgwwt worm; BCFfish: 110 L/kg wwt
21-days TWA PECS 0.494 mg/kg dwt soil; 21 days TWA PECsw 16.59 µg/L for bell peppers and 9,95 µg/L for tobacco

species	Formulation	Route of exposure	Time scale	Toxicity endpoint	ETE	TER	Annex VI trigger
birds	Nemacur 240 SC	earthworms	long-term	NOEC 0.2 mg/kg bw/d	Tobacco: 1.8 mg/kg bw/day Bell peppers: no exposure expected	0.1	5
birds	Nemacur 240 SC	fish	long-term	NOEC 0.2 mg/kg bw/d	Tobacco: 0.23 mg/kg bw/day Bell peppers: 0.38 mg/kg bw/day	0.87 0.53	5 5
mammals	Nemacur 240 SC	earthworms	long-term	NOEC 0.3 mg/kg bw/d	Tobacco: 2.28 mg/kg bw/day Bell peppers: no exposure expected	0.13	5
mammals	Nemacur 240 SC	fish	long-term	NOEC 0.3 mg/kg bw/d	Tobacco: 0.13 mg/kg bw/day Bell peppers: 0.22 mg/kg bw/day	2.3 1.4	5 5

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

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

Species	Test substance	Time-scale	Endpoint	Toxicity (mg as/L)
Laboratory tests				
fish (*L. macrochirus*)	fenamiphos	acute	LC_{50}	0.0093
fish (*O. mykiss*)	fenamiphos	long-term	ELS, NOEC	0.0038
invertebrates (*D. magna*)	fenamiphos	long-term	growth F1, NOEC	0.00012
invertebrates (*C. riparius*)	fenamiphos	long-term	emergence rate, NOEC	0.01[1]
algae (*S. subspicatus)*	fenamiphos	long-term	biomass, E_bC_{50}	3.8
invertebrates (*D. magna*)	fenamiphos-sulfoxide	acute	EC_{50}	0.015
algae (*S. subspicatus*)	fenamiphos-sulfoxide	long-term	growth rate E_rC_{50} biomass, E_bC_{50}	>100
Invertebrates (*C. riparius*)	fenamiphos-sulfoxide	long-term	emergence rate, NOEC	0.058
invertebrates (*D. magna*)	fenamiphos-sulfone	acute	EC_{50}	0.0035
algae (*S. subspicatus*)	fenamiphos-sulfone	long-term	biomass, E_bC_{50}	25
fish (*L. macrochirus; O. mykiss*)	fenamiphos-sulfoxide-phenol	acute	LC_{50}	>100
invertebrates (*D. magna*)	fenamiphos-sulfoxide-phenol	acute	EC_{50}	94
fish (*L. macrochirus; O. mykiss*)	fenamiphos-sulfone-phenol	acute	LC_{50}	>100
invertebrates (*D. magna*)	fenamiphos-sulfone-phenol	acute	EC_{50}	18.2

Microcosm or mesocosm tests
EAC 3.5 µg/L[1] after two applications of Nemacur® in aquatic mesocosms

1: nominal initial concentration in water phase

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

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

Toxicity-exposure ratios of fenamiphos after application of Nemacur CS 240 on bell peppers in greenhouses and tobacco full field

Substance	Type of application	Highest initial PEC_{sw} [µg/L]	Species	L/EC_{50} [µg as/L]	TER	Annex VI trigger
fenamiphos	greenhouse	36.55	*Scenedesmus subspicatus*	3500	95.8	10
			Daphnia magna	-	-	100
			Lepomis macrochirus	9.3	**0.25**	100
	full field	21.93	*Scenedesmus subspicatus*	3500	160	10
			Daphnia magna	-	-	100
			Lepomis macrochirus	9.3	**0.42**	100

Acute toxicity-exposure ratios of fenamiphos-sulfoxide after application of Nemacur CS 240 on bell peppers in greenhouses and tobacco full field

Substance	Type of application	Highest initial PEC_{sw} [µg/L]	Species	L/EC_{50} [µg as/L]	TER	Annex VI trigger
Fenamiphos -sulfoxide	greenhouse	5.29	*Scendesmus subspicatus*	> 100000	> 20000	10
			Daphnia magna	15	**2.8**	100
			fish	-	-	100
	full field	3.18	*Scendesmus subspicatus*	>100000	>33000	10
			Daphnia magna	15	**4.7**	100
			fish	-	-	100

Acute toxicity-exposure ratios of fenamiphos-sulfone after application of Nemacur CS 240 on bell peppers in greenhouses and tobacco full field

Substance	Type of application	Highest initial PEC_{sw} [µg/L]	Species	L/EC_{50} [µg as/L]	TER	Annex VI trigger
Fenamiphos-sulfone	greenhouse	7.28	*Scendesmus subspicatus*	25000	3434	10
			Daphnia magna	3.5	**0.48**	100
	full field	12.14	*Scendesmus subspicatus*	25000	2059	10
			Daphnia magna	3.5	**0.29**	100

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

Chronic toxicity-exposure ratios of fenamiphos after application of Nemacur CS 240 on bell peppers in greenhouses and tobacco full field

Substance	Type of application	Highest initial PEC_{sw} [µg/L]	Species	L/EC_{50} [µg as/L]	TER	Annex VI trigger
Fenamiphos	greenhouse	36.55	*Daphnia magna*	0.12	**0.003**	10
			Oncorhynchus mykiss	3.8	**0.10**	10
	full field	21.93	*Daphnia magna*	0.12	**0.005**	10
			Oncorhynchus mykiss	3.8	**0.17**	10

Chronic toxicity-exposure ratios of fenamiphos after application of Nemacur CS 240 on bell peppers in greenhouses and tobacco full field using PECtwa values

Substance	Type of application	PECtwa [µg/L]	Species	L/EC_{50} [µg as/L]	TER	Annex VI trigger
Fenamiphos	greenhouse	16.59 (21 days)	*Daphnia magna*	0.12	**0.007**	10
		8.27 (50 days)	*Oncorhynchus mykiss*	3.8	**0.45**	10
	full field	9.95 (21 days)	*Daphnia magna*	0.12	**0.012**	10
		4.96 (50 days)	*Oncorhynchus mykiss*	3.8	**0.77**	10

Toxicity-exposure ratios of fenamiphos after application of Nemacur CS 240 on bell peppers in greenhouses and tobacco full field, using an EAC-value from a mesocosm study

Substance	Type of application	PECtwa [µg/L]	Species	EAC [µg as/L]	TER	Proposed trigger
Fenamiphos	greenhouse	36.55	Aquatic community	3.5	0.10	3
	full field	21.93	Aquatic community	3.5	0.16	3

Toxicity/exposure ratios for sediment dwelling organisms (Annex IIIA, point 10.2)

Toxicity-exposure ratios of fenamiphos-sulfoxide for *Chironomus riparius* after application of Nemacur CS 240 on bell peppers in greenhouses and tobacco full field

Substance	Type of application	PECtwa [µg/L]	Species	NOEC [µg as/L]	TER	Annex VI trigger
Fenamiphos-sulfoxide	greenhouse	5.29	*Chironomus riparius*	58	11.0	10
	full field	3.18	*Chironomus riparius*	58	18.2	10

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

Bioconcentration

Bioconcentration factor (BCF) ‡	110 L/kg wwt
Annex VI Trigger:for the bioconcentration factor	100 (no information on *ready biodegradability*)
Clearance time	CT_{50}: 0.22 d CT_{90}:
Level of residues (%) in organisms after the 14 day depuration phase	>95%, >98% and >99% depuration in fillet, whole fish and viscera respectively

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

Acute oral toxicity ‡	0.45 µg/bee
Acute contact toxicity ‡	0.28 µg/bee

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

not applicable: direct exposure not expected

Field or semi-field tests: two field tests with NEMACUR CS 240 on the effects of greenhouse soil treatment on bumblebee pollination activity and hive condition (dosages 4.8 – 10 kg as/ha): not showing any deleterious effect. Fenamiphos has systemic activity but from the two available field tests it is clear that there are no deleterious effects from this activity.

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

Species	Stage	Test Substance	Substrate	Dose (g as/ha)	Endpoint	Adverse effect* (%)	Annex VI Trigger
Laboratory tests (glass plate)							
T. pyri	protonymphs	CS 240	glass	0.25-4.0	LR_{50}	1.70	
				0.25	mortality fecundity	6 1	30
				0.50	mortality fecundity	4 15 (n.s.)	30
				1.0	mortality fecundity	20 23 (n.s.)	30
				2.0	mortality	55	30
				4.0	mortality	97	30

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

Species	Stage	Test Substance	Substrate	Dose (g as/ha)	Endpoint	Adverse effect* (%)	Annex VI Trigger
A. rhopalosiphi	adults	CS 240	glass	0.023-0.928	LR_{50}	0.175	
				0.023	mortality	0	30
				mortality	mortality	7	30
				0.146	mortality	25	30
				0.371	mortality	100	30
				0.928	mortality	100	30
Extended laboratory tests							
T. pyri	protonymphs	CS 240	leaves	1.0-33.6	LR_{50}	13.8	
				1.0	mortality	3.7	50
				2.6	mortality	- 12.2	50
				6.2	mortality	7.3	50
				14.2	mortality	46.3	50
				33.6	mortality	97.6	50
A. rhopalosiphi	adults	CS 240	leaves	1.0-33.6	LR_{50}	14.1	
				1.0	mortality	5	50
				2.6	mortality	5	50
				6.2	mortality	10	50
				14.2	mortality	45	50
				33.6	mortality	97.5	50
C. carnea	adults	CS 240	leaves	5.4-108.4	LR_{50}	33.3	
				5.4	mortality reproduction	- 2.08 + 10	50
				10.8	mortality reproduction	2.08 + 22	50
				23.8	mortality reproduction	20.83 + 38	50
				51.6	mortality reproduction	81.25 + 84	50
				108.4	mortality	100	50
P. cupreus	adults	CS 240	direct spray natural	52-516	LR_{50}	219	
				52	mortality	0	50

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

Species	Stage	Test Substance	Substrate	Dose (g as/ha)	Endpoint	Adverse effect* (%)	Annex VI Trigger
			soil		food con-sumption	1	
				90	mortality food con-sumption	0 9	50
				163	mortality food con-sumption	23 + 11	50
				284	mortality food con-sumption	77 27	50
				516	mortality food con-sumption	93 36	50
P. cupreus	adults	CS 240	spray on natural soil	6000	mortality food consumptio n	98 71	50
P. cupreus	adults	CS 240	Injection in natural soil	6000	mortality food consumptio n	0 0	50
P. cupreus	adults	CS 240	spray on natural soil	10000	mortality food con-sumption	100 100	50
P. cupreus	adults	CS 240	drip-irriga-tion on natural soil	10000	mortality food con-sumption	2.13 0	50

Field or semi-field tests
no information available

* Adverse effect means:
x % effect on mortality = x % increase of mortality compared to control
y % effect on a sublethal parameter = y % decrease of sublethal parameter compared to control
When effects are beneficial / favourable for the test organisms, a + sign is used for the sublethal effectpercentages (i.e. increase compared to control) and a – sign for mortality effectspercentages (i.e. decrease compared to control).

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

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

Acute toxicity ‡	**Fenamiphos** LC_{50} 888 mg/kg (10% OM), equivalent to 444 mg/kg for a soil with the standard average organic matter content (5.0%), which is used for risk assessment **NEMACUR CS 240** LC_{50} >238 mg as/kg at 10% OM (equivalent to >119 mg as/kg at 5% OM) **fenamiphos-sulfoxide** LC_{50} >1000 mg/kg **fenamiphos-sulfone** LC_{50} >1000 mg/kg **fenamiphos-sulfoxide-phenol** LC_{50} >1000 mg/kg **fenamiphos-sulfone-phenol** LC_{50} >1000 mg/kg
Reproductive toxicity ‡	**Fenamiphos 400 EC** NOEC < 6 kg as/ha fenamiphos + fenamiphos sulfoxide + fenamiphos sulfone NOEC 0.12 + 0.17 + 0.2 mg/kg soil
Field study	Effects on earthworm populations after application of Nemacur 400 EC at 10 and 40 kg as/ha (spray application). Recovery observed within a year after application at a dose of 10 kg as/ha, not at 40 kg as/ha. Earthworm population field survey in tobacco fields in Italy (3 fields): no earthworms sampled.

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

acute: LC_{50} 888 mg/kg, equal to 444 mg/kg for soil with 5% OM
chronic: NOEC < 6 kg as/ha

Application rate (kg as/ha)	Crop	Time scale	PEC_S	TER	Annex VI Trigger
10 (irrigation)	bell pepper	acute	13.33	34.7	10
6.0 (soil treatment)	tobacco	acute	4.00	111	10
10 (irrigation)	bell pepper	chronic	10 kg as/ha	**<0.6**	5
6.0 (soil treatment)	tobacco	chronic	6 kg as/ha	**<1.0**	5

Effects on other soil macro- organisms (Annex IIA, point 8.6)

Mortality	**NEMACUR CS 240** *H. aculeifer*

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

	NOEC survival = 1.33 mg as/kg at 0.9% OM (equivalent to = 2.29 mg as/kg in standard soil with 5% OM)
Reproductive toxicity	**NEMACUR CS 240** *F. candida* NOEC reproduction 0.313 mg as/kg at 10% OM (equivalent to 0.157 mg as/kg in standard soil with 5% OM) **fenamiphos-sulfoxide** *F. candida* NOEC reproduction 2.0 mg/kg at 10% OM **fenamiphos-sulfone** *F. candida* NOEC reproduction 3.75 mg/kg at 10% OM **fenamiphos-sulfoxide-phenol** *F. candida* NOEC reproduction 10 mg/kg at 10% OM **fenamiphos-sulfone-phenol** *F. candida* NOEC reproduction 10 mg/kg at 10% OM

Toxicity/exposure ratios for other soil macro-organisms (Annex IIIA, point 10.6)

Application rate (kg as/ha)	Crop	Time scale	PEC_S		TER	Annex VI Trigger
fenamiphos						
10 (irrigation)	bell pepper	chronic	13.33	*F .candida* *H. aculeifer*	**0.012** **≥0.17**	5 5
6.0 (soil treatment)	tobacco	chronic	4.0	*F. candida* *H. aculeifer*	**0.04** **≥0.57**	5 5
fenamiphos-sulfoxide						
10 (irrigation) (a.s.)	bell pepper	chronic	6.64	*F. candida*	**0.30**	5
6.0 (soil treatment) (a.s.)	tobacco	chronic	3.32	*F. candida*	**0.60**	5
fenamiphos-sulfone						
10 (irrigation) (a.s.)	bell pepper	chronic	3.68	*F. candida*	**1.09**	5
6.0 (soil treatment) (a.s.)	tobacco	chronic	1.11	*F. candida*	**3.37**	5
fenamiphos-sulfoxide-phenol						

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

Application rate (kg as/ha)	Crop	Time scale	PEC_S		TER	Annex VI Trigger
10 (irrigation) (a.s.)	bell pepper	chronic	0.83	*F. candida*	12.0	5
6.0 (soil treatment) (a.s.)	tobacco	chronic	0.25	*F. candida*	40	5
fenamiphos-sulfone-phenol						
10 (irrigation) (a.s.)	bell pepper	chronic	2.04	*F. candida*	4.9	5
6.0 (soil treatment) (a.s.)	tobacco	chronic	0.61	*F. candida*	16.4	5

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

fenamiphos	Nitrogen mineralisation	>25% after 56 days at 13.3 and 133 mg/kg
fenamiphos	Carbon mineralisation	<25% after 28 days at 13.3 and 133 mg/kg
fenamiphos-sulfoxide	Nitrogen mineralisation	<25% after 56 days at 70 mg/kg
fenamiphos-sulfone	Nitrogen mineralisation	<25% after 56 days at 74 mg/kg
fenamiphos-sulfoxide-phenol	Nitrogen mineralisation	<25% after 42 days at 37 mg/kg

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	N,	Harmful to the environment
	R50/53	Very toxic to the environment, 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
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year