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

fenpropimorph

Finalised: 14 April 2008

SUMMARY

Fenpropimorph is one of the 79 substances of the third stage Part A of the review programme covered by Commission Regulation (EC) No 1490/2002[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU-Commission 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 six months a conclusion on the risk assessment to the EU-Commission.

Germany being the designated rapporteur Member State submitted the DAR on fenpropimorph in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 17 March 2005. The peer review was initiated on 11 July 2005 by dispatching the DAR for consultation of the Member States and the sole applicant BASF. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and remaining issues were agreed on during a written procedure in July – September 2006. The identified issues as well as further data made available by the applicant upon request were evaluated in a series of scientific meetings with Member State experts in January and March 2007.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in February-March 2008 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 fungicide as proposed by the notifier which comprises foliar spraying to cereals, sugar beet and sunflower against several agriculturally important phytopathogens. Full details of the GAP can be found in the attached end points.

The representative formulated product for the evaluation was “Corbel”, an emulsifiable concentrate (EC) containing 750 g/L fenpropimorph.

[1] OJ No L 224, 21.08.2002, p. 25, as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19)

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. Adequate methods are available to monitor all compounds given in the respective residue definitions for monitoring for food/feed of plant and animal origin and for environmental matrices.

With regard to the rat metabolism during the toxicological studies, fenpropimorph is rapidly and almost completely absorbed, largely distributed, extensively metabolised and without bioaccumulation in the body. In the acute toxicity studies, the compound was shown to be harmful if swallowed (R22) and irritating to the skin (R38). In the short term studies, the liver was the target organ and the body weight was decreased in all species. A battery of tests for mutagenicity did not demonstrate a genotoxic potential in vivo, and long term studies in rats and mice didn't show carcinogenic effects.
No effects on the reproductive parameters were observed in a multigeneration study in rats, but teratogenic findings in rats and rabbits led to the proposed classification Repro Cat.3 R63 Possible risk of harm to the unborn child. In specific neurotoxicity studies, adverse effects were only observed in the functional observational battery. Changes in serum acetyl cholinesterase activity were not considered as relevant adverse effects. In mechanistic studies, fenpropimorph was shown to induce hepatic drug metabolising enzymes and to inhibit the cholesterol biosynthesis.
The agreed ADI (acceptable daily intake) was 0.003 mg/kg bw/day, the agreed AOEL (acceptable operator exposure level) 0.007 mg/kg bw/day and the agreed ARfD (acute reference dose) 0.03 mg/kg bw. The agreed dermal absorption value was 10%, and the operator exposure assessment is below the AOEL only within the German model with the use of PPE (personal protective equipment).

The plant metabolism of fenpropimorph has been elucidated and appropriate residue definitions can be proposed for monitoring and risk assessment. All representative uses are not supported by appropriate residue data and further data should be submitted. No residues are expected in rotational crops under practical conditions above analytical limit of quantification. Fenpropimorph residues are not altered under processing conditions.
A transfer of residues to livestock consuming treated feedstuffs may result in measurable residue levels in animal commodities.
MRLs are proposed for plant and animal commodities. The resulting consumer exposure has been assessed and found to be below the toxicological reference values. However it should be noted that there is uncertainty related to the isomer ratio the consumer is actually exposed to.

If MRLs need to be raised as a consequence of the results of the required residue trials, the consumer risk assessment should be reconsidered.

In soil under aerobic conditions fenpropimorph exhibits low to very high persistence forming the minor non transient soil metabolites fenpropimorph carboxylic acid (BF-421-2)[2] (accounting for up to 9.7% of applied radioactivity (AR)) which exhibits low persistence and BF-421-7[3] (accounting for up to 9.8%AR) which also exhibited low persistence in the single soil where peer reviewed information was available. Mineralisation of both the phenyl and morpholine rings to carbon dioxide accounted for 33 and 46 % AR respectively after 91 days. The formation of unextractable residues was a significant sink, accounting for 65 and 50 % AR respectively after 91 days. Fenpropimorph is immobile or exhibits slight mobility in soil, fenpropimorph carboxylic acid (BF-421-2) exhibits very high to high mobility in soil. A data gap was identified for information on the soil mobility of BF-421-7. There was no indication that adsorption of fenpropimorph was pH dependent. The adsorption of fenpropimorph carboxylic acid (BF-421-2) is pH dependent, with adsorption decreasing as soil pH increases. The assessment of soil accumulation potential under conditions represented by one of the German field trial sites has not been finalised.

In dark natural sediment water systems fenpropimorph partitioned relatively rapidly to sediment, where it exhibited moderate persistence degrading to the metabolite fenpropimorph carboxylic acid (BF-421-2) which partitioned back to the water accounting for up to 22% AR in water. The terminal metabolite, carbon dioxide, was a small sink in the material balance accounting for a maximum of 6.3-8.5 % AR (mean of the phenyl and morpholine ring radiolabels) at 100 days (study end). Unextracted sediment residues were also a sink representing 20-37 % AR (mean of both radiolabels) at study end. The necessary surface water and sediment exposure assessments were appropriately carried out using the agreed FOCUS scenarios approach for fenpropimorph at steps 1-4, with spray drift mitigation factors being appropriately applied at step 4. Volatilisation short range transport and redeposition of fenpropimorph to surface water using the results of field and wind tunnel experiments were included in the step 4 calculations, due to the potential for volatilisation of fenpropimorph which has a relatively high vapour pressure compared to many active substances. For the metabolite fenpropimorph carboxylic acid (BF-421-2), appropriate FOCUS step 1 calculations were agreed. These values are the basis for the risk assessment discussed in this conclusion.

The potential for groundwater exposure from the applied for intended uses by fenpropimorph and fenpropimorph carboxylic acid (BF-421-2) above the parametric drinking water limit of 0.1 µg/L, was concluded to be low in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios. However for the soil metabolite BF-421-7, a data gap was identified for a groundwater exposure assessment. It was concluded that fenpropimorph is unlikely to be subject to long range atmospheric transport as a consequence of its likely indirect photooxidation intermediated transformation (half life estimated at 2.9 hours).

[2] fenpropimorph carboxylic acid (BF-421-2): 2-methyl-2-(4-{(2*RS*)-3-[cis-2,6-dimethylmorpholin-4-yl]-2-methylpropyl}phenyl)propanoic acid

[3] BF-421-7: (2?)-1-{[(2*RS*)-3-(4-*tert*-butylphenyl)-2-methylpropyl]amino}propan-2-ol (?=unknown stereochemistry)

The acute and short-term risk to birds and the acute risk to mammals were assessed as low in a first tier risk assessment for the representative uses in cereals, sugar beet and sunflower. The long term TER values for insectivorous and herbivorous birds and for herbivorous mammals were below the Annex VI trigger value of 5 for all representative uses. The refined risk assessment was discussed in the expert meeting. A new risk assessment was presented in the not peer-reviewed addendum 4. The long-term trigger of 5 was exceeded for the uses in cereals and sugar beet. The risk assessment presented deviated for skylark from the recommendations in the experts meeting. It was assumed that skylark feeds only on large insects (RUD of 5.1 instead of 29 for small insects) based on data from a PhD theses. This refinement step was not peer-reviewed and without this refinement the TER for skylark would be below the trigger of 5. However it is likely that a certain percentage of the insect prey consist of large insects. The long-term endpoint is based on a NOEC where no effects were observed at the highest tested dose. Therefore it may be possible to agree in a weight of evidence approach that the long-term risk to skylark can be regarded as sufficiently addressed. No accepted risk refinement is available for the use in sunflower. The refined long-term risk assessment for the uses in sugar beet and sunflower based on hare (medium herbivorous mammal) resulted in TERs above the trigger of 5 and were accepted by the experts. The vole (*Microtus arvalis*) was rejected as a focal species for the use in cereals. The risk assessment provided in addendum 4 (not peer-reviewed) was conducted according to the recommendations of the expert meeting (wood mouse, *Apodemus sylvaticus* as a focal species and refinement of PD). The resulting TERs were above the trigger of 5 indicating a low risk. The risk to birds and mammals from secondary poisoning from uptake of contaminated earthworms and fish was assessed as low. Potential endocrine disrupting properties of fenpropimorph were discussed in the meeting. On the basis of the available information it was agreed that endocrine disrupting effects due to aromatase inhibition are unlikely to occur. Overall it is concluded that the risk to birds and mammals is expected to be low for the uses evaluated except for the use in sunflower where the long-term risk to birds needs further refinement.

The long-term toxicity to fish was driving the aquatic risk assessment. In the expert meeting it was agreed to use the NOEC of 1.95 µg a.s./L from an early life stage study (ELS) conducted under a realistic exposure situation. The endpoint (NOEC) of 1.95 µg a.s./L was suggested to be used in the risk assessment in combination with the maximum peak PECsw value. A new risk assessment was presented in the not peer-reviewed addendum 4 from February 2008. The TER calculation presented in the addendum combined no-spray buffer zones with drift reduction nozzles and run-off mitigation to achieve TERs above the trigger of 10. No spray buffer zones of >20 metres alone are not sufficient to achieve a full FOCUS step4 scenario with TERs >10. The risk assessment for aquatic organisms needs to be refined further. The major metabolite in the water-sediment system fenpropimorph carboxylic acid (BF-421-2) is of low acute toxicity to fish, daphnids and algae. The risk from BF 421-2 to aquatic organisms is considered as low.

A short-term impact on sensitive arthropod species is likely to occur in the in-field area after application of fenpropimorph. However given the rapid residue decline in plants it is likely that the treated area is recolonised within a short period of time from unaffected off-crop areas. Therefore it was agreed by the experts that the risk to non-target arthropods is low for the representative uses evaluated.

The acute risk to earthworms was assessed as low. However, the first-tier long-term (reproduction) TERs were <5. A field study with earthworms was made available by the applicant. No effects were observed on abundance and total biomass of earthworms. The observation period in the study was too short to detect potential effects on the reproduction of those earthworm species with long reproductive cycles. However the study gives an indication that the long term risk to earthworms is low. The experts agreed to the assessment of the RMS and considered the risk to earthworms as sufficiently addressed for the representative uses evaluated. However as the soil exposure assessment is not finalised (as the accumulation potential in soil is not finalised), the risk assessment to earthworms cannot be finalised.

Statistical significant effects of 7.4 % to 19.3 % were observed in the litterbag study. The experts considered the effects as relevant and the study was too short to exclude adverse effects on organic matter breakdown. The experts considered a new study in accordance with the latest guidance as necessary.

The risk to bees, soil micro-organisms (subject to finalisation of the soil exposure assessment), non-target plants and biological methods of sewage treatment was assessed as low.

Key words: fenpropimorph, peer review, risk assessment, pesticide, fungicide

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BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000, as amended by Commission Regulation (EC) No 1095/2007 regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Fenpropimorph is one of the 79 substances of the third stage, part A, covered by the Regulation (EC) No 1490/2002 designating Germany as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Germany submitted the report of its initial evaluation of the dossier on fenpropimorph, hereafter referred to as the draft assessment report, to the EFSA on 17 March 2005. 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 11(2) of the Regulation (EC) No 1490/2002 the revised version of the draft assessment report was distributed for consultation on 11 July 2005 to the Member States and the main applicant BASF 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, EFSA and Member States identified and agreed during a written procedure in July – September 2006 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the requested information received from the notifier, a scientific discussion took place in experts' meetings in January and March 2007. 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 during a written procedure with the Member States in February-March 2008 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 11c (1) of the amended Regulation (EC) No 1490/2002, 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 27 September 2006)

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

- the reports of the scientific expert consultation;
- the evaluation table (rev. 2-1 of 13 March 2008).

Given the importance of the draft assessment report including its addendum (compiled version of January 2008 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

Fenpropimorph is the ISO common name for *cis*-4-[(*RS*)-3-(4-*tert*-butylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine (IUPAC).

Fenpropimorph belongs to the class of morpholine fungicides. Fenpropimorph is a systemic fungicide with protective, curative and eradicative effect. It inhibits the formation of appressoria and haustoria and controls mycelial growth and sporulation. Fenpropimorph is used in cereals, sugar beet, sunflower, field bean, leek and Brussels sprout to control a range of fungal diseases.

The representative formulated product for the evaluation was "Corbel", an emulsifiable concentrate (EC) containing 750 g/L fenpropimorph, registered under different trade names in Europe.

The representative uses evaluated comprise foliar spraying against *Erysiphe graminis*, *Puccinia* spp., *Rhynchosporium* sp in cereals (barley, oats, rye, triticale, wheat), up to growth stage of BBCH 25-69, in all EU countries, up to a maximum 2 applications at a maximum individual application rate per spray of 750 g a.s./ha, with an interval of 28 days between applications, and foliar spraying against *Erysiphe betae*, *Uromyces betae*, *Cercospora beticola* in sugar beet, up to growth stage of BBCH 31-49, in all EU countries, at a single application at a maximum application rate of 750 g a.s./ha.
The use in sunflower against *Phomopsis helianthi* as a single application at a maximum application rate of 600 g a.s./ha is no longer supported by the notifier.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of fenpropimorph is 930 g/kg. No FAO specifications exist.

In order to justify the specification of impurities in the technical material and, as based on the data submitted for the preparation of the DAR, the specification of one impurity (114280) was declared as open point, a new analytical profile of 5 new batches of a technical production plant were submitted. The batch data did not support the proposed specification. The RMS performed an equivalence check, however the new data required a tier II assessment for impurity 116453, for which further toxicological data were required. The tier II assessment was not peer reviewed and the equivalence of the new five batch with the original one was not concluded on.
Since clarification is required with respect to the proposed maximum levels and relevance of one impurity in the technical material, the specification for the technical material as a whole should be regarded as provisional for the moment.
Beside the specification the assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of fenpropimorph or the respective formulation.

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

Adequate analytical methods (GC-FID) are available for the determination of fenpropimorph in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material (GC-FID, HPLC-UV).
Sufficient test methods and data relating to physical, chemical and technical properties and analytical methods are available to ensure that quality control measurements of the plant protection product are possible.

Adequate methods are available to monitor all compounds given in the respective residue definitions in food/feed of plant and animal origin and environmental matrices. Since fenpropimorph is not classified as acute toxic or very toxic, analytical methods for the determination of residues of fenpropimorph in body fluids and/or tissues are not needed. However pending on the final classification (see section 2.6) a method for body fluids and/or tissues may be needed.
Several methods are available to monitor residues of fenpropimorph in plant matrices with LOQs of 0.5 mg/kg for barley and oats, 0.2 mg/kg for wheat, rye and triticale and 0.05 mg/kg for sugar beet roots and other products of plant origin.
The extended version of the German modular multi-method DFG S19 is suitable as an enforcement method for the determination of residues of fenpropimorph in different plant materials (validated for dry and water containing matrices) with LOQ of 0.01 mg/kg, in rapeseed down to 0.02 mg/kg.

HPLC-MS/MS methods are available to monitor residues of fenpropimorph and fenpropimorph carboxylic acid[4] (BF-421-2) in food of animal origin (milk, eggs, meat, fat, kidney, liver) with LOQs from 0.01 mg/kg to 0.5 mg/kg.

Adequate methods are available (HPLC-MS/MS) to monitor fenpropimorph in water (drinking water, surface water) with LOQ of 0.1 µg/L and 0.16 µg/L respectively. Several methods are available (GC-MS and HPLC-MS/MS) to determine residues of fenpropimorph in soil with LOQ of 0.01 mg/kg and in air with LOQ of 0.5 µg/m³ (GC-NPD) or alternatively 0.09 µg/m³ (HPLC-MS/MS).

2. Mammalian toxicology

Fenpropimorph was discussed by the experts in mammalian toxicology in January 2007 (PRAPeR 14, Round 3). As a result of this meeting, the toxicological batches could not be concluded as representative of the technical specification (see point 2.8).

EFSA notes that the issue of isomerisation has not been considered in the DAR or by the experts in mammalian toxicology, nothing more can be said about isomers at this stage.

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

Fenpropimorph is rapidly and almost completely absorbed, with a mean maximum plasma concentration reached after 4-8 hours and a half life of 16-24 h. It is distributed into various organs and tissues, with the highest amounts found in the liver and digestive tract, followed by fat and kidneys. It is excreted in approximately the same amounts via urine and faeces (mainly biliary excretion) and it has no accumulating potential.

The parent compound was detected in very low amounts in the metabolism study indicating a complete metabolic breakdown. The metabolic pattern included oxidations, ring opening, breakdown of the dimethylmorpholine moiety, and further conjugations.

2.2. Acute toxicity

Fenpropimorph is harmful after oral administration (rat LD_{50} 1670 mg/kg bw), but has a low acute toxicity after dermal (rat LD_{50} >4000 mg/kg bw) or intraperitoneal (rat LD_{50} 2465 mg/kg bw) administration. Exposure by inhalation gave LC_{50} values between 2.9 and 9.1 mg/L.

Taking all findings of *in vivo* and *in vitro* skin irritation tests into consideration, it has been concluded that fenpropimorph is irritating to the skin. The experts discussed the potential for eye irritation and agreed with ECB's proposal (ATP 29, 2004) that there was insufficient evidence for classification. With regard to the skin sensitisation, the results were negative in two maximisation tests. Based on these results, the proposed classification is **Xn R22 'Harmful if swallowed', Xi R38 Irritating to skin.**

EFSA notes that the classification for acute toxicity by inhalation has not been discussed by the experts. Xn R20 'Harmful by inhalation' has not been adopted by ECB (24th ATP, 1998) but might have been proposed based on a LC_{50} lower than 5 mg/L in one study by inhalation.

[4] fenpropimorph carboxylic acid (BF-421-2): 2-methyl-2-(4-{(2*RS*)-3-[cis-2,6-dimethylmorpholin-4-yl]-2-methylpropyl}phenyl)propanoic acid

2.3. SHORT TERM TOXICITY

The oral short term toxicity of fenpropimorph was investigated in different species (rat: 4-week and 3-month; mouse: 4-week and 6-week; dog: 4-week, 3-month and 1-year). The liver was the target organ with changes in clinical chemistry parameters, increased weight but no histopathological correlate. Decreased body weight and body weight gain was observed in all species, clinical signs appeared in rats and mice, and changes in haematological parameters occurred only in rats (at high doses). The determination of plasma/serum-, erythrocyte- and brain cholinesterase showed that only plasma/serum cholinesterase was reduced and exclusively in rats. However, this finding was not consistent and not considered as relevant to humans (see also point 2.5).

From the rat studies, the relevant NOAEL was 0.7 mg/kg bw/day (3-month study), excluding plasma ChE reduction. From the dog studies, the relevant NOAEL was 0.8 mg/kg bw/day based on a slight liver toxicity (increased hepatic enzymes).

In a 4-week dermal study in rats, no effects were observed up to the highest dose applied, resulting in a NOAEL of 2.0 mg/kg bw/day.

In the 4-week inhalation study in rats, several clinical chemical parameters were altered (increased P.Alk and ALT, decreased cholesterol) and the plasma ChE activity was reduced, resulting in a NOAEL of 0.01 mg/l (2.5 mg/kg bw/d – males, 3.4 mg/kg bw/d – females).

2.4. GENOTOXICITY

Fenpropimorph was evaluated for possible mutagenic/genotoxic effects *in vitro* and *in vivo*. Negative results were obtained in the reverse mutation assays in bacteria (Ames test) and in the gene mutation test in Chinese hamster ovary cells (HPRT assay). Equivocal results were obtained in the chromosome aberration test *in vitro* in Chinese hamster V79 cells, but were not confirmed in human lymphocytes. Unscheduled DNA synthesis was assayed in primary rat hepatocytes *in vitro* and the absence of a DNA damaging potential was confirmed in a mitotic recombination assay with Saccharomyces cerevisiae. In two *in vivo* studies (mouse micronucleus test and dominant lethal assay in mice), the absence of a genotoxic potential was confirmed.

2.5. LONG TERM TOXICITY

The chronic toxicity and carcinogenicity of fenpropimorph was investigated in rats and mice. In both species, a decrease in body weight or body weight gain was observed and the liver was the target organ for toxicity, showing an increased weight and histopathological findings (enlargement of centrilobular hepatocytes in rats). Based on these results, the rat NOAEL was 0.3 mg/kg bw/day, and the mouse NOAEL 16.0 mg/kg bw/day.

In the rat study, the brain cholinesterase activity was significantly reduced at all dose levels. However, this was only observed in males, not accompanied by a decreased plasma cholinesterase activity at the low dose levels (including 0.3 mg/kg bw/day) and without any decrease in erythrocyte cholinesterase activity. Therefore the experts concluded that this effect was not relevant for the human risk assessment. In the mouse study, the plasma and brain cholinesterase activities were not

affected, and the reduced erythrocyte cholinesterase activity of the females at the end of the study (at 16 mg/kg bw/day and above) was attributed to a high control value.
An increased incidence of benign liver tumours was observed in mice at the NOAEL, but a shift from malignant to benign liver tumours was observed in the higher dose groups, and the sum of benign and malignant liver tumours did not show any dose related effect. Therefore, this was not considered relevant to humans. The experts concluded that fenpropimorph had no carcinogenic potential.

2.6. REPRODUCTIVE TOXICITY

In a two-generation rat study (2003), fenpropimorph had no adverse effects on reproductive performance or fertility. Therefore the reproductive NOAEL was the highest dose tested i.e. 16 mg/kg bw/day. Parental findings included temporarily decreased food consumption and lower body weight (gain), triggering a systemic NOAEL of 4 mg/kg bw/day. The reduction of serum cholinesterase activity, and the indications of mild liver impairment (clinical chemistry findings, increased liver weight less than 20% without concomitant histopathological observations) were not considered to be adverse effects. The adverse effects in the offspring were limited to a decreased body weight and body weight gain with a NOAEL of 4 mg/kg bw/day.
In a supplementary 2-generation rat study (1981) where only low dose levels have been tested, no effects have been observed up to 2.4 mg/kg bw/day, supporting the results of the more recent study.
A pre-postnatal toxicity test in rats lead to general symptoms in females at all dose levels (decreased food consumption, body weight, body weight gain and serum cholinesterase activity) with effects on litter size and embryo-foetal/postnatal growth. Therefore the resulting maternal and developmental NOAELs were lower than 5 mg/kg bw/day.
In the rat developmental toxicity study, the maternal NOAEL of 10 mg/kg bw/day was based on a decreased body weight gain at 40 mg/kg bw/day. At the high dose (160 mg/kg bw/day), an increased incidence of vaginal bleedings and total litter loss during early embryonic development were observed. The high dose in foetuses induced a reduced foetal weight and length, an increased placental weight, and an increased incidence of cleft palate, resulting in a developmental NOAEL of 40 mg/kg bw/day.
Three rabbit teratology studies were presented in the DAR, from which only one was acceptable and the others supplementary. According to the acceptable study (Marty, 1993), the maternal NOAEL was 15 mg/kg bw/day based on clinical signs and reduced body weight and body weight gain. The same value was agreed for the developmental NOAEL, based on reduced foetal weight and skeletal defects (shortening of long bones, position anomalies of the limbs, cleft palate, fused sternebrae) at 30 mg/kg bw/day. Position anomalies of limbs were observed consistently in all 3 studies, with a large proportion of the affected foetuses also exhibiting reduction of long bones and, in a few cases, cleft palate.
Based on these teratogenic findings in rats (cleft palates) and rabbits (skeletal malformations), the experts agreed to the proposed classification **Repro Cat. 3, R63 Possible risk of harm to the unborn child** in agreement with ECB's decision (ATP 29, April 2004). The proposal Repro Cat. 2, R61? (with a question mark) was also mentioned during the discussion of the list of end points as a concern for ECB.

2.7. NEUROTOXICITY

Fenpropimorph did not cause neurotoxic effects in an acute neurotoxicity study in rats, where the NOAEL for neurotoxicity was 1500 mg/kg bw (highest dose) and the systemic NOAEL 100 mg/kg bw.

In a 90-day rat neurotoxicity study, effects on parameters of a functional observational battery (FOB) were observed, and resulted in a NOAEL for neurotoxicity of 0.7 mg/kg bw/day. It is noted that the observed reduction in serum acetyl cholinesterase activity in females from 0.7 mg/kg bw/day onwards and in males from 7.1 mg/kg bw/day onwards was not considered adverse since it was not accompanied by clinical signs or changes in the brain/erythrocyte cholinesterase activity.

There were no signs of delayed neurotoxicity in hens.

2.8. FURTHER STUDIES

Metabolites

The metabolites BF-421-1[5] and BF-421-10[6] were major metabolites in plants, but also major rat metabolites. Therefore the experts agreed that their toxicity was covered by the reference values of the parent.

Mechanistic studies

A 14-day dietary administration of fenpropimorph in rats resulted in an induction of hepatic drug metabolising enzymes, with a NOAEL of 4 mg/kg bw/day.

In vitro incubations of fenpropimorph with rat, mouse, dog and human liver microsomes showed that fenpropimorph is extensively metabolised to form the main metabolite BF-421-1 in all species. In incubates of liver slices, BF-421-1 is predominantly glucuronided in dogs and mice, but only to a low extent in rats. Furthermore, tests for inhibition of plasma AChE activity demonstrated an inhibitory potential of the hydroxyl-metabolite BF-421-1 (qualitatively comparable to the results in rats *in vivo*). However no further conclusion with respect to the situation in humans can be drawn from this study since both quantitative dose-response relationships and the spectrum of metabolites found in these *in vitro* experiments do only partly reflect the *in vivo* situation.

Other *in vitro* investigations on the plasma cholinesterase inhibition used only surrogate compounds for fenpropimorph and rat metabolites, and supported the assumption that the delayed onset of cholinesterase activity reduction (2-3 days) is due to metabolites and not to fenpropimorph itself.

In a supplementary *in vitro* study with 3T3 fibroblasts, fenpropimorph was shown to inhibit the cholesterol biosynthesis, with an accumulation of polar sterols and a decrease in the cellular activity of hydroxymethylglutaryl CoA reductase.

Impurities

The impurities **116453** and **114280** were present at lower levels in the toxicological batches than in the technical specification. Their toxicological relevance was discussed by the experts based on

[5] BF-421-1: 2-methyl-2-(4-{(2*RS*)-3-[*cis*-2,6-dimethylmorpholin-4-yl]-2-methylpropyl}phenyl)propan-1-ol
[6] BF-421-10: 2,6-dimethylmorpholine

results of mutagenicity studies provided in the revised DAR (January 2007): Ames test negative for the impurity 114820 and *in vitro* micronucleus test negative for the impurity 116453. According to the guidance document SANCO 10597/2003, the experts agreed to require an Ames test with the impurity 116453 (with the new batch or with the impurity itself) as a first step. Pending on the results, further data may be required.

EFSA notes: In the addendum 2 to Volume 4 (February 2007, after the experts' meeting), a revised overview of the toxicological batches (combined with the ecotoxicological batches) and a comparison with the technical specification were provided. In the addendum 3 to Volume 3 (January 2008), the results of an Ames test with the impurity 116453 were provided but not peer-reviewed.

2.9. MEDICAL DATA

The personnel who is handling fenpropimorph in manufacturing, research, and formulation is surveyed by regular medical examinations (not aimed to detect specific symptoms or diseases).

No other poisoning incidents than a few cases of skin irritation are known.

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

ADI

The agreed ADI is 0.003 mg/kg bw/day, based on the 2-year rat study, with the use of a safety factor of 100.

EFSA notes: during the discussions, the experts took into consideration the value set by JMPR (1994) which was also 0.003 mg/kg bw/day, and the value set by UK (2002) in their national registration (0.02 mg/kg bw/day based on a higher NOAEL in the same 2-year rat study).

AOEL

The agreed AOEL is 0.007 mg/kg bw/day, based on the 90-day rat study, with the use of a safety factor of 100.

EFSA notes: during the discussion, the experts took into consideration the value set by UK (2002) in their national registration (0.07 mg/kg bw/day based on the 90-day dog study).

ARfD

Based on the developmental rabbit studies, the agreed ARfD is 0.03 mg/kg bw, with the use of a safety factor of 500 which gives a margin of safety of 1000 with respect to the LOAEL where developmental effects are observed.

EFSA notes: during the discussion, the experts took into consideration the value set by JMPR in 2001 (1 mg/kg bw based on the systemic NOAEL in the rat acute neurotoxicity study). The agreed value of 0.03 was supported by all experts. However, in the addendum 3 of January 2008, the RMS indicated its disagreement about that value.

2.11. DERMAL ABSORPTION

The studies available were not performed with the representative formulation Corbel (based on organic solvents) but with the formulation Mentor (water based) or with fenpropimorph in a

cyclohexanone solution. Therefore the meeting discussed the possible reduction of the default value 100% based on the information presented in the DAR.
Taking into consideration the results with Mentor (3% dermal absorption for the dilution and 0.1% for the concentrate) and with fenpropimorph (40% in the rat in vivo, in vitro ratio rat/human of 15 for both concentrate and dilution), the agreed default value was 10% as reasonable worst case based on expert judgement.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product Corbel is an EC (emulsifiable concentrate) formulation containing 750 g of fenpropimorph/L, solved in cyclohexanone, for use on cereals, sugarbeet and sunflower.

Operator exposure

According to the intended uses submitted by the applicant, the maximum applied dose is 750 g a.i./ha, and the minimum volume 200 L of water/ha. The supported use is of tractor mounted equipment (downward spraying).
The estimated operator exposure for Corbel is below the AOEL with PPE, according to German model (work rate 20 ha/day). According to calculations with UK POEM, (work rate 50 ha/day) even with gloves during mixing/loading and application, the estimated exposure is above the AOEL (see table beneath).

Estimated exposure presented as % of AOEL, according to calculations with the German and UK POEM model. The default for body weight of operator is 70 kg in the German model and 60 kg in the UK-POEM model. The assumed dermal absorption is 10%.

Model	No PPE	With PPE:
German	1364	56.3*
UK POEM	5549	808**

*PPE (personal protective equipment): gloves during mixing/loading (M/L) and application (A), standard protective garment and sturdy footwear during application.
**PPE: gloves during M/L and A

A field study on operator exposure was performed in Germany (April-May 2000) with the representative formulation and the correct application rate. Although there are some weaknesses (e.g. no discrimination between mixing/loading and application) this study was considered acceptable by the experts for the risk assessment.
It should be noted that two operators experienced a distinct higher level of dermal exposure due to less accurate handling of the product (with a significant transfer of active substance from the protective gloves to the inner dosimeters) or due to the use of an unusual application equipment (requiring 29 individual mixing/loading operations for a work rate of 50 ha/day). Nevertheless the meeting agreed to include these values in the final mean exposure level, adjusted for a treated area of 50 ha and 20 ha as well considering the default values of the UK and German models respectively.

In the addendum 3 (January 2008), recalculations were provided for a treated area of 50 ha/day, giving an exposure level of 197% of the AOEL including all the operators.

EFSA notes: it is presumed that adjusting the treated area to 20 ha/day will lead to an exposure level below the AOEL (around 75%).

Worker exposure

A German re-entry model[7] was used to estimate worker exposure during inspection of cereals (2 h/day), with a reduced transfer factor value (proposed in the EUROPOEM). This resulted in a worker exposure of 538% of the AOEL without PPE and 26.8% of the AOEL with PPE.

EFSA notes: The RMS also presented an exposure assessment for a very specific task not belonging to standard growing procedures and consisting of selective hand-picking in some cereals. The resulting estimate was 45.9% of the AOEL with PPE.

Bystander exposure

In view of the application technique, bystanders may be exposed briefly and to relatively low quantities of spray compared to an operator. Using drift estimates derived by Ganzelmeier (1995), the potential exposure would be 7.3% of the systemic AOEL.

3. Residues

Fenpropimorph was discussed by the experts in residues in January 2007 (PRAPeR 15, Round 3). It should be noted that the methods of analysis used in all the residues studies were not stereoselective. Therefore the regulatory dossier provides no information on the behaviour of each individual fenpropimorph enantiomer in plants and domestic animals. Therefore all residues reported as fenpropimorph in section 3 of this conclusion are for the sum of the 2 enantiomers. It is not known if either isomer is differentially metabolised in plants and animals.

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

Plant uptake, distribution and metabolism of fenpropimorph have been investigated in wheat, bananas and sugar beet using labelling either in the morpholine or the phenyl ring. In each crop the metabolic pathway was similar and consists of 2 main routes:

- Oxidation of the tertiary butyl group to alcohol and acid derivatives;
- Oxidative opening and cleavage of the morphol[8]ine ring. The resulting C-fragments are used during assimilation processes for biosynthesis of plant sugars which are stored in grains and fruits.

Generally, these reactions are followed by glucosylation of the produced metabolites.

The residue pattern is dominated by the parent compound which was the most abundant constituent of the residue in cereal hay, straw and grain, bananas as well as in sugar beet leaves and roots. The

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

global amount of identified metabolites is roughly similar to the amount of the parent compound. Some of the metabolites (BF-421-1, BF 421-20 and BF 421-36), mainly present under conjugated form exceeded 10 % of the Total Radioactive Residues, depending on the plant part. These metabolites are structurally related to the parent compound and they result from metabolic pathways which are similar to those observed in rats.

In addition the intact morpholine ring after cleavage (2,6-dimethylmorpholine) was present in foliar plant parts such as sugar beet leaves and cereal hay and straw. The effects of this metabolite, being major in rats, are also sufficiently explored via the toxicological characterisation of the parent compound fenpropimorph.

It can be considered that the submitted information on three crop groups is sufficient to conclude on a residue definition, valid for all plant commodities (including oilseeds) after foliar application of fenpropimorph. The residue definition for monitoring can be restricted to fenpropimorph, acting as an appropriate indicator compound. For risk assessment the expert meeting agreed to include metabolite BF-421-1 (free and conjugated) and 2,6-dimethylmorpholine (BF-421-10) in the definition considering their potential contribution to the toxicological burden (refer to point 2.8).

The expert meeting also agreed that no conversion factor were necessary for sugar beet roots, cereal grains and sunflower seed. In leafy plant parts the contribution of metabolites, and in particular that of metabolite BF-421-1, to the toxicological burden is high, and conversion factors of 5 derived from the metabolism studies should be applied to cereal straw and sugar beet leaves respectively on the basis of the metabolism studies. For application of fenpropimorph on edible leafy crops beyond the scope of this peer review the appropriate determination of conversion factors on the basis of field data should be considered.

The field studies were conducted with analysis of the parent compound only. In cereals a sufficient amount of supervised residue trials is available for a reliable assessment of human and livestock exposures related to the representative use of fenpropimorph on wheat, rye, triticale, barley and oats in Northern Europe as well as on barley and oats in Southern Europe. The information related to wheat, triticale and rye in Southern Europe is however not sufficient. For sunflower, only 4 supervised residue trials were submitted but they were not carried out according to the proposed representative use. The product was applied in a too early growth stage and therefore the residues found at harvest may be an underestimation of the critical use conditions. For sugar beets valid information was provided only for Southern Europe, with the last application at BBCH growth stage 49. Decline curves within 30 days after last application demonstrate that residues in roots are always below the limit of quantification (LOQ). The residue situation in leaves, which may be used as feedstuff, is however not possible to assess correctly as multiple applications were made in nearly all trials. The reliability of the provided residue trials is supported by deep freeze storage stability studies demonstrating that fenpropimorph residues are stable in various matrices (cereal grain and straw, banana peel and pulp, sunflower seed, sugar beet root) for 2 years. In sugar beet leaves and tops a degradation slightly exceeding 30 % was observed after 1 year.

The effects of processing on the nature of fenpropimorph residues were investigated through hydrolysis studies simulating sterilisation, boiling and pasteurisation. Fenpropimorph was proved to be stable under these processing conditions. Processing studies were carried out on wheat, barley and

oats. However as low residue levels were present in raw grains these studies do not form an appropriate basis for establishment of transfer factors to processed commodities. The results confirm the expectation that fenpropimoph is preferentially transferred to bran fraction during the milling process and that no analytically quantifiable residues are to be expected in beer. Four additional processing studies (2 for wheat grains and 2 for barley grains) have been evaluated by the RMS in the addendum of January 7, 2008 but were not peer-reviewed.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

A confined rotational crop study is available carried out with application of fenpropimorph on bare soil at the yearly maximal application rate. Residues identified in rotational crops were the active substance (for plant back intervals of 30 days), metabolite BF-421-1, 2,6-dimethylmorpholine (BF-421-10) as well as sugars. This suggests that the metabolic pathway in rotational crops is similar to that in primary crops. In the edible parts of the investigated succeeding crops (lettuce, radish and wheat), these compounds were individually present at low levels. The highest individual level amounted to 0.056 mg/kg and was assigned to 2,6-dimethylmorpholine (BF-421-10). Given these results, it can be expected that under practical conditions assuming interception of the applied substance by the treated crops, only low residue levels, below analytically quantifiable levels are to be expected in rotational crops. No concern for consumer safety is identified and no restriction is necessary as far as rotational crops are concerned. This needs however to be confirmed when the long term plateau concentration in soil will have been determined (refer to point 4.1.2).

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

The metabolism of fenpropimorph was investigated in lactating goats and laying hens. As in plant, the main routes of degradation in both species consist in oxidative reaction of the tertiary butyl group and oxidative opening and cleavage of the morpholine ring. In addition in hens the resulting fragments of the degradation of the morpholine moiety enter in anabolic pathways such as fatty acids biosynthesis. The main constituents of the residue are the parent compound, as well as its metabolites fenpropimorph carboxylic acid (BF-421-2) and BF 421-3[9], with varying ratios according to tissues. The RMS proposed to define the appropriate residue for monitoring and risk assessment as the sum of parent compound and its metabolite BF 421-2. The non inclusion of metabolite BF 421-3 in the residue definition for risk assessment is of limited impact in term of consumer safety as this metabolite represents less than 25 % of the toxicological burden in animal tissues and has a higher polarity than the parent compound and metabolite BF-421-2.

Livestock is exposed to fenpropimorph residues through consumption of cereal grain and straw, as well as sugar beet and sunflower by-products. Available information regarding residues in cereals grains and straw, sugar beet roots and sunflower seeds were considered for estimating the potential exposure of livestock. Potential residues in sugar beet leaves could not be considered for the time being as appropriate data are lacking.

[9] BF 421-3: 2-methyl-2-(4-{(2*RS*)-3-[*cis*-2-methy-6-hydroxymethyl-morpholin-4-yl]-2-methylpropyl}phenyl)propanoic acid

A livestock feeding study in dairy cows was performed with a choice of dosing levels reflecting in an appropriate way the potential animal exposure. The RMS in addendum 3 of January 2008 selected the lowest dose level (2 mg/kg feed corresponding to 0.07 mg/kg bw) as representative for MRL setting. However this level covers the exposure to the parent compound only, and the EFSA considers that exposure to metabolite BF-421-1 should also be taken into consideration as this metabolite is most probably a precursor of metabolite BF-421-2, which is included in the residue definition for monitoring and risk assessment. Therefore the median dosing level (6.5 mg/kg feed corresponding to 0.2 mg/kg bw) would be representative for milk. For beef tissues, both the median and the highest dose level (22 mg/kg feed corresponding to 0.7 mg/kg bw) would need to be considered. The MRLs proposed under point 3.4 are based on this approach. They differ by a 2 fold factor from the RMS proposal in the addendum 3.

For poultry, no feeding study is available. Considering the metabolism data it was concluded that the transfer of residues to poultry products was not of nature to reach quantifiable levels and that a feeding study in laying hens was not necessary.

No specific data are available for pigs. Given the similar metabolic pathway in rats and goats, no pig studies have to be performed. MRLs are proposed to be established on the basis of the lowest dosing level of the cow feeding study, although this level is about 20 times higher the practical critical exposure level. Setting the LOQ for meat and fat of pigs could however be considered at regulatory level.

3.3. CONSUMER RISK ASSESSMENT

Under restriction of the requested field residue data, no risk for the consumer resulting from the use of fenpropimorph according to the representative uses in cereals, sugar beets and sunflower is expected.

Chronic exposure.

The chronic dietary exposure assessment has been based on the International (National) Estimated Daily Intake ((I)NEDI) calculation model of WHO using the WHO typical European diet for adult consumers and the German national diet for 2 to 5 years of age children. Residues in cereals, sugar beet roots and animal products were considered to be at the level of respective proposed MRL. In sunflower seeds the hypothetical residue level of 0.05 mg/kg was used in the absence of valid data based on the assumption that residues on seeds should be low given the application stage of fenpropimorph. Based on these assumptions, the calculated IEDI and the NEDI were about 25 % of the ADI for the European adult and the German child respectively.

Acute exposure.

An ARfD has been allocated to fenpropimorph. As being based on developmental effects, the acute exposure assessment is valid for adult population only. For cereals and sugar beets an acute risk to consumer is not expected. This is due to the low residues of fenpropimorph found in supervised field trials, the high degree of mixing (cereals) and/or further crop processing (production of sugar). NESTI (National Estimated Short Term Intakes) calculations carried out by the RMS according to the UK consumption data demonstrated consumer exposures related to cereal consumption to be below 15 % of the ARfD in the adult population. In case of sunflower seeds, the acute risk assessment was

not performed as residue data do not allow to determine the highest levels of residues to expect under the proposed representative use. A risk is however not expected due to the low consumption and the low residues. Similarly, residues in animal products do not lead to acute exposures of concern.

In addition, the risk assessment was performed disregarding the possible impact of a change of the enantiomer ratio due to plant or livestock metabolism as this was not investigated by the notifier.

3.4. PROPOSED MRLS

Based on the results of supervised residue trials and, where relevant and their analysis according to the statistical methods recommended by the current guidelines following MRLs are proposed to accommodate the representative uses supported by the applicant:

Plant products

Fenpropimorph (mg/kg):

Wheat, rye, triticale	0.1
Barley, oats	0.5
Sunflower seeds	No proposal, due to the lack of appropriate data
Sugar beet roots	0.05*

* Indicates that the MRL is proposed to be set at the level of the limit of quantification of the monitoring method of analysis.

MRLs proposed in wheat, rye and triticale are supported by relevant data for Northern Europe only while MRLs for sugar beet roots are proposed on the basis of data valid for Southern Europe only.

Animal products

Sum of fenpropimorph and BF-421-2, expressed as fenpropimorph (mg/kg):

Ruminant liver	1
Ruminant kidney	0.2
Ruminant meat and fat	0.1
Milk and milk products	0.02
Eggs and poultry products	0.01*
Pig liver	0.5
Pig kidney	0.1
Pig meat and fat	0.05

* Indicates that the MRL is proposed to be set at the level of the limit of quantification of the monitoring method of analysis.

MRL proposals for animal commodities may need to be reconsidered once lacking data on sugar beet leaves will be made available.

4. Environmental fate and behaviour

Fenpropimorph was discussed at the PRAPeR experts' meeting for environmental fate and behaviour PRAPeR 12 in January 2007. It should be noted that the methods of analysis used in all the fate and behaviour studies were not stereoselective. Therefore the regulatory dossier provides no information on the behaviour of each individual fenpropimorph enantiomer in the environment. Therefore all residues reported as fenpropimorph in section 4 of this conclusion are for the sum of the 2 enantiomers. It is not known if either isomer is degraded more quickly than the other in the environmental matrices studied.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

Valid single soil (loamy sand, organic carbon (oc) 2.26%, pH7.3) experiments were carried out under aerobic conditions in the laboratory (20°C 40% maximum water holding capacity (MWHC) in the dark (see addendum 1 of 9 January 2007). The formation of residues not extracted by methanol or methanol:water were a significant sink for the applied phenyl or morpholine ring-^{14}C-radiolabels (65.1% and 49.7% of the applied radiolabel (AR) after 91 days respectively). Mineralisation to carbon dioxide accounted for 32.8% and 45.8 AR after 91 days respectively. The extractable breakdown product fenpropimorph carboxylic acid (BF-421-2) accounted for maxima of 7.8-9.7%AR and was present at >5%AR between days 3 and 27 after dosing. The member state experts agreed that the nature of the residues identified in the aerobic laboratory route of degradation studies as summarised in the DAR were not appropriate, as it had been demonstrated that the harsh extraction methods used had changed the nature of the residues (see addendum 1 of 9 January 2007[10]). It was accepted that 2,6-dimethylmorpholine (BF-421-10) was formed as an artefact of the extraction method used and was not a soil metabolite.

In a radiolabelled (benzylic bridge-^{14}C) cropped (wheat) field dissipation study (sandy loam, organic matter (om) 2.9% , pH 6.2) at a site in Switzerland (see DAR) where application was made to soil constrained in 5.8cm diameter PVC tubes, the extractable breakdown product BF-421-7[11] accounted for a maximum of 9.8%AR at 28 days after dosing. It was present at >5%AR between days 7 (first sampling time) and 84 (last sampling time) after dosing.

Data on anaerobic degradation in soil were available in a study carried out with the morpholine ring-^{14}C-radiolabel indicated that transformation of fenpropimorph was more limited than under aerobic conditions as fenpropimorph accounted for 78 %AR at the end of the study (120 days), with mineralisation being <2%AR unextracted (acetonitrile water followed by acidified acetonitrile extraction) residues < 3.3%AR, metabolites were not identified but no individual resolved component accounted for > 3.5%AR. In a laboratory soil photolysis study, fenpropimorph was moderately

[10] and subsequent addendum 4 of 7 January 2008 where it was confirmed that the full final reports of the studies evaluated in addendum 1 as discussed by the expert meeting have been provided to update the dossier.
[11] BF-421-7: (2?)-1-{[(2*RS*)-3-(4-*tert*-butylphenyl)-2-methylpropyl]amino}propan-2-ol (?=unknown stereochemistry)

degraded (single first order DT50 ca. 45 days 50°N sunlight equivalents 12 hour photoperiods, season not reported) forming primarily residues that were not extracted by methylene chloride water extraction, followed by acidified and basified methylene chloride water extraction. There were extractable breakdown products resolved by chromatography but none accounted for >9.3%AR at any sampling time. Therefore under field conditions photolysis at the soil surface may contribute to the degradation of fenpropimorph, however novel photoproducts requiring a leaching assessment or a risk assessment to non target species would not be expected.

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

The rate of degradation of fenpropimorph was estimated from the results of dark aerobic laboratory soil studies. DT_{50} were: 11.3-123.8 days (single first order non linear regression, 20-22°C 20-60% MWHC, 6 different soils). After normalisation to FOCUS reference conditions[12] (20°C and -10kPa soil moisture content) this range of single first order DT_{50} is 9.5-123.8 days (geometric mean that is appropriate for use in FOCUS modelling 19.6 days). (See addendum 1 of 9 January 2007 for normalised values).

Single first-order DT_{50} values for the minor but > 5 %AR at 2 sampling time degradation product BF-421-2 were estimated from studies where BF-421-2 was applied as test substance to 3 soils and incubated in the laboratory (aerobic dark 20°C 40%MWHC). These single first-order DT_{50} values were calculated to be 4.4-9.4 days. In addition for one of these soils ('Bruch West') a kinetic assessment for BF-421-2 from the experiments (2 different labelling positions, see section 4.1.1) where parent fenpropimorph was dosed was presented. The resulting estimated mean single first order DT_{50} was 4.1 days with the associated mean kinetic formation fraction of 0.486. The appropriate value to use for this metabolite in FOCUS modelling is a geometric mean value after normalisation to FOCUS reference conditions from all 3 soils of 4.9 days (see addendum 1 of 9 January 2007 for the evaluation of this study and all values for BF-421-2 both before and after normalisation).

Field soil dissipation studies (bare soil) were provided from 5 sites in Germany where applications were made between the end of April and the beginning of June. At a 6th trial site in Switzerland on a small plot cropped with wheat (study design as already briefly outlined at 4.1.1), the application was made in June. The studies were evaluated in the DAR with additional information and a new kinetic analysis reported in the addendum 1 of 9 January 2007. Using the residue levels of parent fenpropimorph determined in depth segments of the sampled soil cores (either 0-5cm (Swiss site) 0-10cm (Oberding site) or 0-25cm soil layer other sites), single first order DT_{50} were 8.8-42.8 days at 3 of the trial sites (DT90 29.4-142 days) whilst at the remaining 3 trial sites a first order multi compartment (FOMC) model better described the pattern of decline with DT50/90 which were estimated to be 23.4/285.5 days[13], 50.6 /4481 days[14] (Stetten site) and 9/11705 days[15] (Birkenheide

[12] Using section 2.4.2 of the generic guidance for FOCUS groundwater scenarios, version 1.1 dated April 2002.
[13] α=0.79927 ß=16.967

site). Note the last 2 DT90 values (Stetten and Birkenheide sites) were extrapolated significantly beyond the study durations of 350-369 days and that after initial relatively fast dissipation (to 187 days at Stetten and 61 days at Birkenheide), there was limited further dissipation of fenpropimorph at these two trial sites, indicating that there is the potential for accumulation of fenpropimorph when it is used at the same location in consecutive years.

In the Swiss trial a single first order DT50 of 9.9 days (corresponding kinetic formation fraction not reported but would be around 1) was estimated for the metabolite BF-421-7 (see addendum 1 of 9 January 2007). Ideally further soil DT50 data for BF-421-7 would have been appreciated to reduce the level of uncertainty in the soil mobility / groundwater exposure assessment for this metabolite, though as it is a minor soil metabolite, the experts considered this should not be a formal data gap. It is noted that according to addendum 4 of 7 January 2008 the applicant has carried out an aerobic laboratory soil degradation study (dated May 2007 currently without a GLP compliance statement) where BF-421-7 was dosed to one soil. However the study was made available to the RMS after the meeting of experts, has not been evaluated by the RMS, would need to audited and confirmed to conform to GLP and has not been peer reviewed.

The member state experts discussed whether the degradation rate in soil of fenpropimorph might be pH dependent (faster degradation under very acidic conditions pH<6-7 due to protonation of fenpropimorph making it less adsorbed and more bioavailable for microbial degradation), as postulated in the DAR with further arguments for this possibility being presented in the addendum 1 of 9 January 2007. The experts agreed that considering all the available data (from both the laboratory and field experiments where the lowest pH soil investigated was pH 5.7) there was no consistent evidence that there was faster degradation under acidic soil conditions. They also considered that contrary to the RMS arguments, cations may be more strongly adsorbed to soil than neutral compounds or anions. Consequently it could also have been postulated that under very acidic conditions the protonated fenpropimorph might be less bioavailable. It was agreed that exposure assessments should be completed assuming no effect of pH on fenpropimorph degradation rate.

The pattern of dissipation leading to potential accumulation represented by the Stetten trial site (DT50 50.6 days DT90 4481 days) was used to calculate potential accumulated soil residues in the addendum 4 of 7 January 2008. The RMS calculation and argumentation in addendum 4 regarding the effect of temperature on the pattern of dissipation at this trial site are reasonable and the accumulated PEC of 2.213 mg fenpropimorph/kg dry weight soil (identified as approach b) in addendum 4 and the list of endpoints can be agreed as a conservative approach to calculating soil PEC that represents what happened at this trial site. The EFSA also considers that the accumulated PEC of 1.085 mg fenpropimorph/kg dry weight soil (identified as approach a) in addendum 4 is also reasonable for this trial site but considers it cannot be an agreed EU endpoint as the member state experts have not discussed the approach used. However EFSA considers these calculations do not

[14] α=0.3733 ß=9.4143
[15] α=0.2260 ß=0.4401

cover the potential accumulation that is represented by the Birkenheide trial site. The argumentation presented in addendum 4 (that was not available to the meeting of experts) regarding calculating an accumulated soil PEC using the DT50 from the slow phase of a poor DFOP fit of 636 days for the Birkenheide trial site is not accepted by EFSA and cannot be considered peer reviewed, as the experts at the meeting of experts were not able to agree this fitting procedure (graphs and approach not available to them, note FOCUS kinetics guidance identifies visual fit as an important criteria in accepting that the kinetics selected are appropriate). EFSA considers, contrary to the position of the RMS that looking at the visual fit presented in Figure 8.3-6 of addendum 4, that there is no clear decline observed in the measured data after day 61 (5 samples taken including day 61 and the last at day 369), so the value of 636 days resulting from this fit is not reasonable. Consequently EFSA proposes that the data requirement 4.7 is still not addressed and the applicant still needs to deal with the potential for fenpropimorph soil accumulation under the geoclimatic conditions represented by the Birkenheide trial site. There is therefore the concern that the risk assessment to soil dwelling organisms cannot be finalised, as a plateau soil exposure concentration is not available to cover a realistic worst case for the applied for intended uses in the EU. EFSA also noted that the PEC soil calculations included in appendix 1 used more conservative crop interception factors than would usually be accepted for the applied for intended use on cereals, as 50% crop interception was assumed for all applications. Whilst this is appropriate for the first application in a season, for the second application, the use of a 70% crop interception factor (BBCH 30-39 stem elongation) would have been justified (following FOCUS guidance) considering the minimum application interval that has been specified.

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

The adsorption / desorption of fenpropimorph was investigated in 3 soils in satisfactory batch adsorption experiments. Calculated adsorption $K_f$oc values varied from 2772 to 5943 mL/g, (1/n 0.867 – 1.34). There was no evidence of a correlation of adsorption with pH, though the range of pH in the soils that were investigated was very narrow (pH 7-7.3). The experts agreed that though adsorption measurements were only available for 3 soils (and the data requirements are for measurements in 4 soils) they were content that these data were sufficient to carry out the exposure assessment, but that in line with FOCUS guidance (regarding the situation when less than the minimum data set is available), the lowest adsorption value (2772mL/g, 1/n 0.867) was appropriate for use in leaching modelling.

The adsorption / desorption of BF-421-2 was investigated in five soils in satisfactory guideline batch adsorptions experiments. Calculated adsorption $K_f$oc values were 17.5-68.6 mL/g (1/n 0.851 – 0.955). There was clear evidence of a correlation of adsorption with soil pH of this acidic metabolite (adsorption decreased as pH increased). The experts therefore agreed that a mean adsorption value was inappropriate for input into FOCUS leaching modelling and accepted the conservative approach proposed by the RMS to use the lowest value as modelling input (17.5mL/g, 1/n 0.851). These data were evaluated in the addendum 1 of 9 January 2007

The adsorption / desorption of BF-421-7 was stated by the RMS to have been investigated in 6 soils in a study report that did not have a GLP compliance statement. However the study dated May 2007 was made available to the RMS after the meeting of experts and has not been evaluated by the RMS (see addendum 4 of 7 January 2008). As the meeting of experts agreed that the leaching potential of metabolites of fenpropimorph including BF-421-7 needed to be addressed further, a data gap is therefore identified for an acceptable (GLP) adsorption study on BF-421-7 in at least 3 soils, to support a groundwater leaching assessment for this metabolite.

The meeting of experts agreed that Data requirement 4.1 (see evaluation table) should be maintained as though they had agreed that 2,6-dimethylmorpholine was not a soil metabolite but an extraction artefact (see section 4.1.1) so any specific studies on 2,6-dimethylmorpholine (BF-421-10) would now be redundant, they wanted an assessment of these existing fate studies in particular the 2 lysimeter study reports mentioned, to get a full picture of the leaching potential of fenpropimorph soil metabolites (in particular BF-421-7). These studies were made available to the RMS as stated in addendum 4 of 7 January 2008. An evaluation of these studies was not presented in any addendum, however a statement (dated 07.01.2008) clarifying why these studies contain no pertinent information on the leaching potential of fenpropimorph soil metabolites (in lysimeters, the test substance used was not radiolabelled, analysis was only for fenpropimorph and BF 421-1) was provided by the RMS in the evaluation table. As the evaluation table statement has not been peer reviewed, this data requirement in relation to the evaluation of the pertinence of the lysimeter studies (even if they do not comply with current guidelines) regarding any information that they might contain on the leaching potential of fenpropimorph metabolites remains.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

Fenpropimorph was stable under sterile hydrolysis conditions at 25°C at pH 3, 5, 7 and 9. Fenpropimorph was stable under the conditions of an appropriate laboratory sterile direct aqueous photolysis study.

In dark water-sediment studies (2 systems studied at 20°C in the laboratory, sediment pH 5.4-7.4, water pH 7.8-8.4 sediment oc content 5.3 and 1%) fenpropimorph dissipated primarily by partitioning to the sediment with single first order DT50 of 1.9-3.4 days where it subsequently degraded (whole system non first order DT50 18-54 days, DT90>220d) forming the major metabolite metabolite BF-421-2 that was present in the water phase (max. 17-22 % AR at 29-100 days) and only accounted for a maximum of 5.7%AR in the sediment. The terminal metabolite, CO_2, accounted for only 6.3-8.5 %AR (mean of the phenyl and morpholine ring-^{14}C-radiolabels by 100 days (study end)). Residues not extracted from sediment by acetonitrile and acetonitrile:water were a significant sink representing 20-37%AR (mean of both radiolabels) at study end. The experts discussed the compartment modelling (4 compartments: a.s. water, a.s. sediment, metabolite BF-421-2 in water and elimination compartment, see DAR for complete details) used to generate first order degradation rates for water and sediment for use in FOCUS surface water modelling. The experts noted that whilst what had

been done was not completely in line with FOCUS kinetics recommendations, the approach taken was considered appropriate as it calculated first order degradation rates in the water and sediment compartments separately. They agreed that there was uncertainty in the solution from the model fitted due to the high number of degrees of freedom in the conceptual model. The consensus of the experts was that this uncertainty could be accepted in this case. The agreed endpoints from the study for fenpropimorph appropriate for use in FOCUS modelling are therefore single first order DT50: for water degradation of 6.8 days (geometric mean of 4 and 11.7 days) and sediment 80.5 days (geometric mean of 102 and 63.4 days).

FOCUS surface water modelling was evaluated up to step 4 for fenpropimorph and step 2 for the metabolite BF-421-2 in addendum 1 of 9 January 2009. The meeting of experts agreed the step 1 PEC for metabolite BF-421-2 (which was sufficient to complete the risk assessment and did not require an appropriate water DT50 for this metabolite to be identified), but asked for additional step 4 calculations to show the 90th percentile drift input from single applications in combination with volatilisation / deposition input to be provided (only 2 application 82nd percentile drift values with volatilisation / deposition were presented in addendum 1) They also requested that the effects of spray drift mitigation (no spray buffer zones) without runoff mitigation be presented separately from runoff mitigation+ spray drift mitigation combined. These new calculations were provided in the addendum of 4 of 7 January 2008[16]. Simulations with single applications very often gave the highest PEC in surface water whereas the highest PEC in sediment originated more often from 2 application simulations. As an agreed standard methodology was used for these calculations, EFSA considers these PEC surface water and sediment as presented in the addendum 4 of 7 January 2008 as appropriate for use in risk assessment where drift reduction nozzles were not considered and surface runoff was not mitigated (referred to as step 4b in addendum 4 Table B.8.5-7), as the model parameterisation used and these mitigation measures are those agreed by the meeting of experts[17]. It should be noted that there is uncertainty in the PEC for surface water and sediment presented in addendum of 4 of 7 January 2008 where no spray buffer zones are combined with low drift nozzle reductions as whilst it is accepted that drift reducing nozzles may substantially reduce spray drift, the magnitude of the drift reduction when combined with no spray buffer zones is currently unclear as discussed in the Draft FOCUS Report on Landscape and Mitigation factors in aquatic ecological risk assessment[18] and the PPR Opinion[19] on the report.

[16] With the exception of 50m no spray zone values that can only be found in the original modelling report and appendix 1 to this conclusion.
[17] For parent fenpropimorph the risk mitigation of runoff by up to 90% was accepted as being of demonstrative benefit for national assessments, but there is uncertainty if such reductions can be achieved in the field, so the runoff mitigated PEC in addendum 4 are not considered to be agreed EU endpoints.
[18] Sanco/10422/2005, version 1.0, May 2005
[19] Opinion of the Scientific Panel on Plant protection products and their Residues on a request from EFSA on the Final Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EFSA Journal (2006) 437, 1-30. http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620770123.htm

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

The applied for representative use of Spring/summer applications (March to June) to winter cereals sugar beet and sunflower was simulated using FOCUS PELMO 3.3.2 and FOCUS MACRO using the following input parameters:
either fenpropimorph single first order DT_{50} 124 days, K_{foc} 5152 mL/g, 1/n=0.9 (See DAR)
or fenpropimorph single first order DT_{50} 14.7 days, K_{foc} 2772 mL/g, 1/n=0.867; metabolite BF-421-2 single first order DT_{50} 4.9 days, kinetic formation fraction from fenpropimorph 0.486, K_{foc} 17.5 mL/g, 1/n=0.851 (see addendum 1 dated 9 January 2007).

The results of both these sets of modelling was that both parent fenpropimorph and metabolite BF-421-2 was calculated to be present in leachate leaving the top 1m soil layer at 80th percentile annual average concentrations of <0.001µg/L.

The peer review agreed endpoints that should have been used are:
fenpropimorph single first order DT_{50} 19.6 days, K_{foc} 2772 mL/g, 1/n=0.867 (lowest value as less than the minimum data set is available); metabolite BF-421-2 single first order DT_{50} 4.9 days, kinetic formation fraction from fenpropimorph 0.486, K_{foc} 17.5 mL/g, 1/n=0.851 (lowest value as adsorption is pH dependent). The member state experts discussed the available modelling and concluded that even though simulations with the correct substance input parameters were not available, it could be concluded that the potential for groundwater exposure >0.1µg/L by fenpropimorph and metabolite BF-421-2 was low in relation to the applied for intended uses on the basis of the available simulations.

However the member state experts agreed that a groundwater exposure assessment is triggered for the soil metabolite BF-421-7 (present at >5%AR in all samples taken that covered a period of 77 days in a radiolabelled field study, see section 4.1.1) and that the assessment of potential groundwater contamination cannot be finalised until satisfactory information to address the leaching risk of this metabolite has been evaluated. For BF-421-7 a single agreed soil DT50 with its associated kinetic formation fraction is available (see section 4.1.2) and though a DT50 in a further soil and adsorption measurements have been provided by the applicant (after the meeting of member state experts), these have not been evaluated and cannot be considered peer reviewed (see sections 4.1.2 & 4.1.3). A data gap for these adsorption studies (as already discussed section 4.1.3) and a consequent groundwater exposure assessment for BF-421-7 are therefore appropriate / necessary.

4.3. FATE AND BEHAVIOUR IN AIR

The vapour pressure of fenpropimorph ($3.9x10^{-3}$ Pa at 20°C) means that fenpropimorph would be classified under the national scheme of The Netherlands as slightly volatile, indicating some losses due to volatilisation would be expected with some short range deposition off crop also occurring as indicated in a wind tunnel experiment and a field experiment where the Formulation 'CORBEL' was applied to wheat crops. Re-deposition rates of 0.044-0.056% of applied substance were measured 1m

down wind of the treated areas over the first 24 hours after treatment with this declining to 0.0084% 50m down wind. These re-deposition values were taken into account in FOCUS step 4 surface water and sediment PEC calculations (see section 4.2.1). Calculations using the method of Atkinson for indirect photooxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half life estimated at 2.9 hours (assuming an atmospheric hydroxyl radical concentration of $5x10^5$ radicals cm^{-3}) indicating the proportion of applied fenpropimorph that will volatilise would be unlikely to be subject to long range atmospheric transport.

5. Ecotoxicology

Fenpropimorph was discussed at the PRAPeR experts' meeting for ecotoxicology PRAPeR 13 in January 2007. In the environmental risk assessment it was not considered that fenpropimorph consists of a racemic mixture of two enantiomers. No information was made available on the toxicity of the different isomers or on potential different degradation rates of the isomers in the environment. This adds additional uncertainty to the environmental risk assessment and needs to be addressed further.

5.1. RISK TO TERRESTRIAL VERTEBRATES

The acute and short-term risk to birds and the acute risk to mammals were assessed as low in a first tier risk assessment for the representative uses in cereals, sugar beet and sunflower. The long term TER values for insectivorous and herbivorous birds and for herbivorous mammals were below the Annex VI trigger value of 5 for all representative uses.

The suggested refinements of the long-term risk assessment were discussed in the experts-meeting. The experts agreed using geese (*Anser anser*), grey partridge (*Perdix perdix*), yellowhammer (*Emberiza citronella*) and skylark (*Alauda arvensis*) as focal species for cereals and grey partridge, yellowhammer and skylark for sugar beet. A data gap was suggested for the uses in sunflower since no information was provided to justify a proposal of a focal species in sunflower.

The experts agreed that no robust PT and PD refinement for geese can be derived from the submitted data. For yellowhammer it was suggested in the meeting that a diet consisting of 82% large insects and 12% small insects should be applied for the use in cereals and that a diet of 65% epigaeic insects, 25% soil dwelling insects, 8% cereal grain, 2% small seeds should be applied for the use in sugar beet. For skylark the diet composition of 50% grasses and cereal shoots, 20% weed seeds and 30% arthropods should be used.

A DT_{50} of 6.4 days and mean RUD values were accepted (provide that the residues were measured immediately after application of fenpropimorph. The experts identified and open point for the RMS to check whether the time when the residues were determined are relevant for the exposure of birds.

A new long-term risk assessment was presented in addendum 4 (not peer-reviewed). The long-term trigger of 5 was exceeded for the uses in cereals and sugar beet. The risk assessment presented

deviated for skylark from the recommendations in the experts meeting. It was assumed that skylark feeds only on large insects (RUD of 5.1 instead of 29 for small insects) based on data from a PhD theses. This refinement step was not peer-reviewed and without this refinement the TER for skylark would be below the trigger of 5. However it is likely that a certain percentage of the insect prey consist of large insects. The long-term endpoint is based on a NOEC where no effects were observed at the highest tested dose. Therefore it may be possible to agree in a weight of evidence approach that the long-term risk to skylark can be regarded as sufficiently addressed.

No accepted risk refinement is available for the use in sunflower.

The refined long-term risk assessment for the uses in sugar beet and sunflower based on hare (medium herbivorous mammal) resulted in TERs above the trigger of 5 and were accepted by the experts. The vole (*Microtus arvalis*) was rejected as a focal species for the use in cereals. The risk assessment provided in addendum 4 (not peer-reviewed) was conducted according to the recommendations of the expert meeting (wood mouse, *Apodemus sylvaticus* as a focal species and refinement of PD). The resulting TERs were above the trigger of 5 indicating a low risk.

The risk to birds and mammals from secondary poisoning from uptake of contaminated earthworms and fish was assessed as low.

Potential endocrine disrupting properties of fenpropimorph were discussed in the meeting. On the basis of the available information it was agreed that endocrine disrupting effects due to aromatase inhibition are unlikely to occur

Overall it is concluded that the risk to birds and mammals is expected to be low for the uses evaluated except the use in sunflower where the long-term risk to birds needs further refinement.

5.2. RISK TO AQUATIC ORGANISMS

The toxicity of fenpropimorph to aquatic organisms was similar to fish and daphnids. For the TER calculations the maximum PEC from the FOCUS step 3 worst case scenario was taken. No acute risk was shown for fish, daphnids and algae. PECtwa values were applied for the long-term TER calculation for fish (based on the endpoints of two early life stage studies) and daphnids. The long-term TERs for fish did not meet the Annex VI trigger values and also not for daphnids if the maximum PEC is used. 12 out of 14 FOCUS step 3 scenarios result in chronic TERs for the ELS (early life stage) study below the Annex VI trigger of 10 (flow through ELS study).
The second ELS study was conducted as a static study with sediment and two applications of the a.s. The study duration was only 28 days and therefore no conclusion about long term effects can be drawn from the endpoints from this study. The RMS set a data requirement for the applicant for a new ELS study with a more realistic exposure situation. Such a study was submitted and accepted by the experts in the meeting. The endpoint (NOEC) of 1.95 µg a.s./L was suggested to be used in the risk assessment in combination with the maximum peak PECsw value. A new risk assessment was

presented in the not peer-reviewed addendum 4 from February 2008. The TER calculation presented in the addendum combined no-spray buffer zones with drift reduction nozzles and run-off mitigation to achieve TERs above the trigger of 10. FOCUS step4 PECsw values based on no-spray buffer zones of up to 20 metres were presented in the fate addendum from February 2008. If those PECsw values are compared to the NOEC of 1.95 µg a.s./L it is evident that a no spray buffer zone of 20 metres alone is not sufficient as a risk mitigation measure. No full FOCUS step 4 scenario would result in TERs of >10.

The TER for sediment dwelling organisms was below the trigger of 10 with FOCUSstep1 PECsw values and the endpoint of 125 µg a.s./L (20d-NOEC for Chironomus riparius). Based on the worst case FOCUS step 3 PECsw of 4.795µg a.s./L the TER would be above 10. It should be noted that this calculation does not necessarily always address the risk. As the endpoint was derived from a water spiked test and the substance following GAP is applied twice and partitions rapidly to sediment, there is the potential that the resulting higher PEC concentrations in sediment is not covered by the available water PEC. Therefore the TER should also be calculated based on sediment concentrations. However the concentration in sediment was not measured during the available test. If a "pseudo water concentration" is calculated on the basis of the PECsed (assuming the water volume and sediment mass in the available Chironomus test)[20] and compared to the endpoint then the TER is again above the trigger confirming the low risk to sediment dwelling organisms.

The major metabolite in the water-sediment system fenpropimorph carboxylic acid (BF 421-2) is of very low acute toxicity to fish, daphnids and algae. The risk from BF 421-2 to aquatic organisms is considered as low.

Three bioconcentration studies with two different fish species were submitted. Bioconcentration factors of 942 - 1145 were observed. The depuration was slow (DT_{90} of up to 31 days). The Annex VI trigger value for not readily degradable substances of 100 was exceeded indicating a potential high risk of bioconcentration. However direct long-term effects to fish are considered to be covered by the available early life stage test and the risk to birds and mammals from secondary poisoning from uptake of contaminated fish was assessed as low. Considering that fenpropimorph dissipates rapidly from the water phase (DT_{90} = 6.4 – 11.1 days) the risk from bioaccumulation is assumed to be low.

5.3. RISK TO BEES

The acute oral and dermal toxicity to bees was tested with the technical a.s. and the lead formulation. The toxicity to bees is low and the HQ values for bees are well below the Annex VI trigger of 50. Therefore no risk to bees is expected from the representative uses of fenpropimorph.

[20] Highest pertinent PECsed 16.32µg/kg (R4 stream), pseudo PECsw from this PECsed= (16.32µg/kgx0.237kg)/0.9L=4.21µg/L

5.4. RISK TO OTHER ARTHROPOD SPECIES

Standard laboratory studies with the indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri* were submitted. The in-field HQ trigger of 2 was exceeded for *A. rhopalosiphi* for all uses and for *T. pyri* for the use in cereals. Additional standard laboratory studies were conducted with *Chrysoperla carnea*, *Poecilus cupreus*, *Aleochara bilineata* and *Pardosa sp.* Extended laboratory studies with *A. rhopalosiphi*, *T. pyri*, *C. carnea* and *Pardosa sp.* were also submitted. The risk assessment was discussed in the expert meeting. A short-term impact on sensitive species is likely to occur in the in-field area. However given the rapid residue decline in plants (DT50 of about 6.4 days) it is likely that the treated area is recolonised within a short period of time. It was agreed by the experts that the risk to non-target arthropods is low for the representative uses evaluated.

5.5. RISK TO EARTHWORM

The acute risk to earthworms was assessed as low. The first-tier TERs were <5 indicating a potential high long term risk to earthworms. A field study with earthworms was made available by the applicant. No effects were observed on abundance and total biomass of earthworms. The observation period in the study was too short to observe potential effects on the reproduction of earthworm species with long reproductive cycles. However it gives an indication that the long term risk to earthworms is low. The earthworm field study was re-assessed by the RMS in addendum 1. The experts agreed to the assessment of the RMS and considered that risk to earthworms as sufficiently addressed for the representative uses evaluated. However as the exposure assessment in soil is not finalised (accumulation potential not finalised, see section 4.1.2) the risk assessment cannot be finalised.

5.6. RISK TO OTHER SOIL NON-TARGET ORGANISMS

A litter-bag study was conducted. Statistical significant effects of 7.4 % to 19.3 % were observed in the litter-bag study. The experts considered the effects as relevant and the study as too short to exclude adverse effects on organic matter breakdown. The experts considered a new study in accordance with the latest guidance as necessary. Any new test should take into account the outcome of the outstanding soil accumulation assessment (see section 4.1.2).

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

No effects of >25 % on soil respiration and nitrification were observed up to a 10 fold dose of the application rate for the representative uses. A new study with the metabolite BF 421-2 and soil micro-organisms was evaluated in addendum 1. No effects of >25% were observed. The experts agreed that the risk from the representative uses to soil non-target micro-organisms is low. However as the exposure assessment in soil is not finalised (accumulation potential not finalised, see section 4.1.2) the risk assessment cannot be finalised.

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

The lead formulation was tested with 6 different crop species (*Zea mays, Avena sativa, Allium cepa, Brassica oleracea, Pisum sativum* and *Daucus carota*). The observed effects on mean plant weight and visible damage were less than 50 % after 14 d at an application rate of 2.25 L product/ha. Therefore the risk to non-target flora is considered to be low for the representative uses.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

The toxicity to sewage sludge was tested with technical fenpropimorph. 21 % inhibition of respiration was observed at the highest tested dose of 1000 mg a.s./L. No effects on respiration were at the next lower concentration of 500 mg a.s./L. Therefore the risk to biological methods of sewage treatment is considered to be low.

6. Residue definitions

Soil

Definitions for risk assessment: fenpropimorph and fenpropimorph carboxylic acid (BF-421-2)[21]

Definitions for monitoring: fenpropimorph.

Water

Ground water

Definitions for exposure assessment: fenpropimorph, BF-421-2 and BF-421-7[22]

Definitions for monitoring: At least fenpropimorph. A data gap would need to be addressed before the definition could be finalised.

Surface water

Definitions for risk assessment: water: fenpropimorph and BF-421-2
sediment: fenpropimorph

Definitions for monitoring: fenpropimorph.

Air

Definitions for risk assessment: fenpropimorph

Definitions for monitoring: fenpropimorph.

Food of plant origin

Definitions for risk assessment: sum of fenpropimorph, BF 421-1 and its conjugates, 2,6-dimethylmorpholine, expressed as fenpropimorph

Definitions for monitoring: fenpropimorph

[21] fenpropimorph carboxylic acid (BF-421-2): 2-methyl-2-(4-{(2*RS*)-3-[cis-2,6-dimethylmorpholin-4-yl]-2-methylpropyl}phenyl)propanoic acid

[22] BF-421-7: (2*?*)-1-{[(2*RS*)-3-(4-*tert*-butylphenyl)-2-methylpropyl]amino}propan-2-ol (?=unknown stereochemistry)

Food of animal origin

Definitions for risk assessment: sum of fenpropimorph and BF 421-2, expressed as fenpropimorph

Definitions for monitoring: sum of fenpropimorph and BF 421-2, expressed as fenpropimoph

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

Soil

Compound (name and/or code)	**Persistence**	**Ecotoxicology**
fenpropimorph	Low to very high persistence Single first order DT_{50} 9.5-124 days (20°C, PF2 soil moisture) German and Swiss field trials Single first order DT_{50} 8.8-43 days FOMC DT50 9-51 days (DT90 285-11705 days)	Low acute risk to earthworms. The first-tier long-term TER was below the trigger of 5. From a field study it was concluded that the long-term (reproductive) risk is probably low, however the soil exposure assessment is not finalised, so this risk assessment is not finalised.
BF-421-2	Low persistence Single first order DT_{50} 3.4-8.9 days (20°C, PF2 soil moisture)	Low toxicity and low risk to soil dwelling organisms.

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 activity**
fenpropimorph	slight mobility to immobile K_{foc} 2772-5943mL/g	No	Yes	Yes	Yes

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 activity
BF-421-2	Very high to high mobility K_{foc} 17.5-68.6 mL/g pH dependent	No	No data available. Assessment not required.	No data available. Assessment not required.	No
BF-421-7	Data gap	Data gap	No data available. Assessment may be required.	Limited data available. Assessment may be required.	No data available. Assessment may be required.

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
fenpropimorph	Very toxic to aquatic organisms. A no-spray buffer zone of 20 metres is not sufficient to identify a full FOCUS scenario with TERs >10.
BF-421-2 (water only)	Low toxicity and low risk to aquatic organisms.

Air

Compound (name and/or code)	**Toxicology**
fenpropimorph	Low acute toxicity by inhalation in rats ($2.9<LC_{50}<9.1$ mg/L) 4-week NOAEL by inhalation in rats = 0.01 mg/L

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

- A revised technical specification is required. (relevant for all representative uses evaluated, date of submission unknown, data gap identified by RMS in addendum 2 to Volume 4, February 2007 and confirmed by expert meeting, March 2007; refer to chapter 1)
- Ames test with the impurity 116453 or with a new representative batch (relevant for all representative uses evaluated, data gap identified in the PRAPeR meeting 14, study provided to the RMS and evaluated in the addendum 3 to Volume 3 of January 2008 but not peer reviewed; refer to point 2.8)
- Supervised residue trials in wheat, rye and triticale in Southern Europe (relevant for representative uses in wheat, rye and triticale in Southern Europe; No submission date proposed by the notifier; refer to point 3.1.1)
- Supervised residue trials in sunflower in Southern and Northern Europe (relevant for representative uses in sunflower in Southern and Northern Europe; No submission date proposed by the notifier; refer to point 3.1.1)
- Supervised residue trials in sugar beets in Northern Europe (relevant for representative uses in sugar beets in Northern Europe; No submission date proposed by the notifier; refer to point 3.1.1)
- Supervised residue trials in sugar beets with analysis of leaves (relevant for representative uses in sugar beets in Southern and Northern Europe; No submission date proposed by the notifier; refer to point 3.1.1)
- Impact of different isomer ratios on the consumer risk assessment of fenpropimorph is to be addressed (relevant for all applied for all representative uses evaluated; requirement identified by EFSA after the expert meeting: submission date by the notifier unknown; refer to point 3.3)
- Potential for fenpropimorph soil accumulation under the geoclimatic conditions represented by the Birkenheide trial site needs to be addressed, with a plateau soil concentration predicted and a consequent risk assessment to soil dwelling organisms provided (relevant for all representative uses evaluated; requirement identified by the meeting of fate and behaviour experts: submission date by the notifier unknown; refer to point 4.1.2 and 5.5 to 5.7).
- A guideline adsorption / desorption study on metabolite BF-421-7 investigating adsorption on at least 3 soils (relevant for all representative uses evaluated; requirement identified by the meeting of fate and behaviour experts; submission date proposed by the notifier unknown, a non GLP study report is available to the RMS that has not been evaluated; refer to point 4.1.3)
- The available lysimeter studies where fenpropimorph was dosed (relevant for all representative uses evaluated; requirement identified by member state comments on the DAR, data provided by the notifier to the RMS but the data have not been evaluated, however a not peer reviewed statement from the RMS indicates that no pertinent information on the leaching of fenpropimorph metabolites is available in these studies; refer to point 4.1.3)
- A groundwater exposure assessment for the soil metabolite BF-421-7 (relevant for all representative uses evaluated; requirement identified by the meeting of fate and behaviour

experts, a soil degradation rate experiment and groundwater modelling was provided by the notifier to the RMS but the data have not been evaluated by the RMS; refer to point 4.2.2)

- The long-term risk assessment for birds needs to be refined (relevant for the use in sunflower; data gap identified at the experts meeting on ecotoxicology (PRAPeR 13) in January 2007; no submission date proposed; refer to point 5.1)
- A new litter-bag study in accordance to the latest guidance (relevant for all representative uses; data gap identified at the experts meeting on ecotoxicology (PRAPeR 13) in January 2007; no submission date proposed; refer to point 5.6)
- fenpropimorph consists of 2 isomers (enantiomers). This needs to be taken into account in the environmental risk assessment. Information on the toxicity and/or on the degradation of the 2 isomers in the environment is needed. (relevant for all representative uses evaluated; issue identified after the expert meeting by EFSA; no submission date proposed by the applicant; refer to sections 4 and 5)

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as proposed by the applicant which comprise foliar spraying against *Erysiphe graminis*, *Puccinia* spp., *Rhynchosporium* sp in cereals (barley, oats, rye, triticale, wheat), up to growth stage of BBCH 25-69, in all EU countries, up to a maximum 2 applications at a maximum individual application rate per spray of 750 g a.s./ha, with an interval of 28 days between applications, and foliar spraying against *Erysiphe betae*, *Uromyces betae*, *Cercospora beticola* in sugarbeet, up to growth stage of BBCH 31-49, in all EU countries, at a single application at a maximum application rate of 750 g a.s./ha.
The use in sunflower against *Phomopsis helianthi* as a single application at a maximum application rate of 600 g a.s./ha is no longer supported by the notifier.

The representative formulated product for the evaluation was “Corbel”, an emulsifiable concentrate (EC) containing 750 g/L fenpropimorph, registered under different trade names in Europe.

Adequate analytical methods are available to monitor all compounds given in the respective residue definitions in food/feed of plant and animal origin and environmental matrices.
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 products are possible.

With regard to the rat metabolism during the toxicological studies, fenpropimorph is rapidly and almost completely absorbed, largely distributed, extensively metabolised and without bioaccumulation in the body. In the acute toxicity studies, it was shown to be harmful if swallowed and irritating to the skin. In the short term studies, the liver was the target organ and the body weight

was decreased in all species. A battery of tests for mutagenicity did not demonstrate a genotoxic potential in vivo, and long term studies in rats and mice didn't show carcinogenic effects.
No effects on the reproductive parameters were observed in a multigeneration study in rats, but teratogenic findings in rats and rabbits led to the proposed classification **Repro Cat.3 R63 Possible risk of harm to the unborn child**. In specific neurotoxicity studies, adverse effects were only observed in the functional observational battery. Changes in serum acetyl cholinesterase activity were not considered as relevant adverse effects. In mechanistic studies, fenpropimorph was shown to induce hepatic drug metabolising enzymes and to inhibit the cholesterol biosynthesis.
It was agreed that the toxicity of the main plant metabolite BF 421-1 was covered by the reference values of fenpropimorph. The toxicological batches could not be concluded as representative of the technical specification due to impurities in lower levels. An additional test was required in order to establish the toxicological relevance of one of these impurities.
The agreed **ADI** (**acceptable daily intake**) was 0.003 mg/kg bw/day, the agreed **AOEL** (**acceptable operator exposure level**) 0.007 mg/kg bw/day and the agreed **ARfD** (**acute reference dose**) 0.03 mg/kg bw. The agreed dermal absorption value was 10%, and the operator exposure assessment is 27% of the AOEL within the German model with the use of PPE (personal protective equipment). An acceptable field study showed exposure level of the same order of magnitude. The estimated worker exposure during inspection of cereals was 46% of the AOEL with the use of PPE, and the potential exposure of bystanders was less than 10% of the AOEL.

The plant metabolism of fenpropimorph has been elucidated and appropriate residue definitions can be proposed for monitoring and risk assessment. All representative uses are not supported by appropriate residue data and further data should be submitted. No residues are expected in rotational crops under practical conditions above analytical limit of quantification. Fenpropimorph residues are not altered under processing conditions.
A transfer of residues to livestock consuming treated feedstuffs may result in measurable residue levels in animal commodities.
MRLs are proposed for plant and animal commodities. The resulting consumer exposure has been assessed and found to be below the toxicological reference values. If MRLs need to be raised as a consequence of the results of the required residue trials, the consumer risk assessment should be reconsidered. However it should be noted that there is uncertainty related to the isomer ratio the consumer is actually exposed to.

The information available on the fate and behaviour in the environment is sufficient to carry out an appropriate environmental exposure assessment at the EU level with the notable exception that the assessment of the potential for fenpropimorph to accumulate in soil cannot be finalised under geoclimatic conditions represented by a German field dissipation study and that the potential for groundwater exposure by soil metabolite BF-421-7 above the parametric drinking water limit of 0.1 µg/L has not been concluded. For the applied for intended uses, the potential for groundwater

exposure by fenpropimorph and the soil metabolite BF-421-2 above the parametric drinking water limit of 0.1 µg/L, is low.

A potential high long-term risk to birds and mammals was indicated in the first-tier risk assessment. A new long-term risk assessment in line with the recommendations of he expert meeting was presented in the not peer-reviewed addendum 4. The long-term trigger of 5 was exceeded for the uses in cereals and sugar beet. The risk assessment presented deviated for skylark from the recommendations in the experts meeting. It was assumed that skylark feeds only on large insects (RUD of 5.1 instead of 29 for small insects) based on data from a PhD theses. This refinement step was not peer-reviewed and without this refinement the TER for skylark would be below the trigger of 5. However it is likely that a certain percentage of the insect prey consist of large insects. The long-term endpoint is based on a NOEC where no effects were observed at the highest tested dose. Therefore it may be possible to agree in a weight of evidence approach that the long-term risk to skylark can be regarded as sufficiently addressed. No accepted risk refinement is available for the use in sunflower. The refined long-term risk assessment for the uses in sugar beet and sunflower based on hare (medium herbivorous mammal) resulted in TERs above the trigger of 5 and were accepted by the experts. The risk assessment provided in addendum 4 (not peer-reviewed) was conducted according to the recommendations of the expert meeting for wood mouse, *Apodemus sylvaticus* as a focal species and refinement of PD. The resulting TERs were above the trigger of 5 indicating a low risk. The risk to birds and mammals from secondary poisoning was assessed as low. Potential endocrine disrupting properties of fenpropimorph were discussed in the meeting. On the basis of the available information it was agreed that endocrine disrupting effects due to aromatase inhibition are unlikely to occur. Overall it is concluded that the risk to birds and mammals is expected to be low for the uses evaluated except for the use in sunflower where the long-term risk to birds needs further refinement.
The long-term toxicity to fish was driving the aquatic risk assessment. In the expert meeting it was agreed to use the NOEC of 1.95 µg a.s./L from an early life stage study (ELS) together with the maximum peak PECsw values. No spray buffer zones of 20 metres alone are not sufficient to achieve TERs of >10. A short-term impact on sensitive arthropod species is likely to occur in the in-field area after application of fenpropimorph. However given the rapid residue decline in plants it is likely that the treated area is recolonised within a short period of time from unaffected off-crop areas. The acute risk to earthworms was assessed as low. However the first-tier long-term (reproduction) TERs were below 5. A field study with earthworms was made available by the applicant. No effects were observed on abundance and total biomass of earthworms. The observation period in the study was too short to detect potential effects on the reproduction of those earthworm species with long reproductive cycles. However the study gives an indication that the long term risk to earthworms is low. The experts agreed to the assessment of the RMS and considered the risk to earthworms as sufficiently addressed for the representative uses evaluated. Statistical significant effects of 7.4 % to 19.3 % were observed in the litterbag study. The experts considered the effects as relevant and the study was too short to exclude adverse effects on organic matter breakdown. The experts considered a new study in accordance with the latest guidance as necessary.

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

- Use of personal protective equipment by the operators and re-entry workers in order to have an exposure level below the AOEL (refer to point 2.12).
- Substantial risk mitigation measures are required to protect the aquatic environment. A 20m no-spray buffer zone alone is not sufficient to achieve a full FOCUSstep4 scenario with TERs >10.

Critical areas of concern

- The technical material specification is currently not supported.
- As the assessment of the potential for fenpropimorph to accumulate in soil cannot be finalised, the risk to soil dwelling organisms cannot be finalised.
- The groundwater exposure assessments for the metabolite BF-421-7 has not been finalised.
- The long-term risk to birds needs to be refined for the use in sunflower.
- Prolonged adverse effects on organic matter breakdown cannot be excluded.
- A high risk to aquatic organisms. No spray buffer zones of 20 metres alone are not sufficient to identify a full FOCUS step 4 scenario with TERs above the trigger of 10.

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

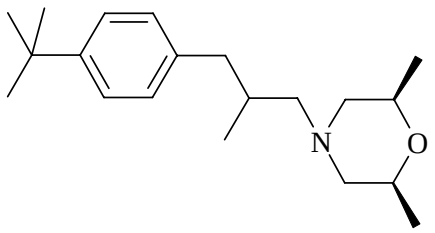
(Abbreviations used in this list are explained in appendix 2)

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

Active substance (ISO Common Name) ‡	fenpropimorph
Function (*e.g.* fungicide)	fungicide

Rapporteur Member State	Federal Republic of Germany
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	(*RS*)-*cis*-4-[3-(4-*tert*-butylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine
Chemical name (CA) ‡	*cis*-4-[3-[4-(1,1-dimethylethyl)phenyl-2-methylpropyl]-2,6-dimethylmorpholine
CIPAC No ‡	427
CAS No ‡	67564-91-4
EC No (EINECS or ELINCS) ‡	266-719-9
FAO Specification (including year of publication) ‡	-
Minimum purity of the active substance as manufactured ‡	930 g/kg Racemate (*RS*)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	none
Molecular formula ‡	$C_{20}H_{33}NO$
Molecular mass ‡	303.5 g/mol
Structural formula ‡	

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

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	-47 C – -41 °C (99.6 %)
Boiling point (state purity) ‡	Decompositon before boiling
Temperature of decomposition (state purity)	> 310 °C (99.6 %)
Appearance (state purity) ‡	colourless liquid (99.6 % and 93.0 %)
Vapour pressure (state temperature, state purity) ‡	$3.9 * 10^{-3}$ Pa at 20 °C (98.9 %) $7.0 * 10^{-3}$ Pa at 25 °C (98.9 %)
Henry's law constant ‡	$2.74 * 10^{-4}$ kPa m^3 mol^{-1}
Solubility in water (state temperature, state purity and pH) ‡	4.32 (99.2 %) mg/L at 20 °C (pH 6, deionised water)
	3.56 mg/L at 20 °C (pH 10.2) (99.2 %)
	7.3 g/L at 20 °C (pH 4.4) (99.2 %)
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20 °C in g/L (99.6 %) *n*-Heptane > 7254 g/L Toluene > 7646 g/L Dichloromethane > 7742 g/L Methanol > 7892 g/L Acetone > 7604 g/L Ethyl acetate > 7780 g/L Acetonitrile > 7727 g/L Octanol > 7705 g/L 2-Propanol > 8167 g/L
Surface tension ‡ (state concentration and temperature, state purity)	49.0 mN/m at 20 °C (0.5 %) (93.0 %) 48.9 mN/m at 20 °C (2.0 %) (93.0 %)
Partition co-efficient ‡ (state temperature, pH and purity)	$\log P_{O/W}$ = 2.10 (pH 1) (calculation)
	$\log P_{O/W}$ = 2.22 (pH 4) (calculation)
	$\log P_{O/W}$ = 4.50 (pH 7) (calculation)
	$\log P_{O/W}$ = 5.18 (pH 9) (calculation)
Dissociation constant (state purity) ‡	pK_a: 6.98 (corresponding acid, 20 °C) (99.4 %) pK_a: 6.81 (corresponding acid, 25 °C) (99.4 %)

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

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	methanol solution (99.6 %): λ_{max} (nm); ε ($L.mol^{-1}.cm^{-1}$) 203 1.1×10^4 219 1.1×10^4 242 2.1×10^2 264 4.2×10^2 270 3.2×10^2 272 4.2×10^2 at λ > 290 nm: no absorption
Flammability ‡ (state purity)	Flammability: No test performed because the substance is a liquid. Auto-Flammability: 265 °C (96.6 %) Flashpoint: 157 °C (93.0 %)
Explosive properties ‡ (state purity)	Not explosive.
Oxidising properties ‡ (state purity)	Not oxidising.

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

Summary of representative uses evaluated (*fenpropimorph*)*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		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		
Cereals (barley, oats, rye, triticale, wheat)	Northern and Southern Europe	Corbel (Corbel BASF, Forbel, Funbas 750 BASF)	F	*Erysiphe graminis*, *Puccinia* spp., *Rhynchosporium* sp.	EC	750	SP [1)]	25-69	1-2	28	0.1875 – 0.375	200 – 400	0.75	F [2)]	[1]
Sugarbeet (*Beta vulgaris*)	Northern Europe	Corbel	F	*Erysiphe betae*, *Uromyces betae*, *Cercospora beticola*	EC	750	SP [1)]	31-49	1	n.a.	0.1875 – 0.375	200 - 400	0.75	35	[1] Missing residue trials (sugar beets)
	Southern Europe	Corbel	F	*Erysiphe betae*, *Uromyces betae*, *Cercospora beticola*	EC	750	SP [1)]	31-49	1	n.a.	0.1875 – 0.375	200 - 400	0.75	7 - 14	[1] Missing residue trials (sugar beets)
Sunflower (*Helianthus annuus*)	France, Italy, Greece, Portugal, Spain	Corbel	F	*Phomopsis helianthi*	EC	750	SP [1)]	30-61	1	n.a.	0.15 – 0.30	200 - 400	0.60	F [2)]	[1] [2] Use no longer supported by notifier

[1] The risk to soil functioning needs to be addressed further (new litter-bag study), high risk to aquatic organisms (20 metres no-spray buffer zones are not sufficient to achieve TERs >10 in at least one full FOCUS step 4 scenario), the risk assessment to soil dwelling organisms cannot be finalised because the assessment of accumulation potential in soil is not finalised, the exposure assessment to groundwater from metabolite BF-421-7 is not finalised.
[2] The long-term risk to birds needs refinement.

Remarks:
(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)
(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)
(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
(k) The minimum and maximum number of application possible under practical conditions of use must be provided

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

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions
1) SP: spraying
2) F: PHI is covered by the application conditions such as growth stages

‡ Endpoint identified by the 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 (analytical technique)	GC-FID
Impurities in technical as (analytical technique)	GC-FID HPLC-UV
Plant protection product (analytical technique)	GC-FID

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Fenpropimorph
Food of animal origin		Sum of fenpropimorph and fenpropimorph carboxylic acid (BF 421-2) expressed as fenpropimorph
Soil		Fenpropimorph
Water	surface	Fenpropimorph
	drinking/ground	Fenpropimorph
Air		Fenpropimorph

Monitoring/enforcement methods

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	GC-MS	LOQ = 0.01 mg/kg (tomato, lemon, wheat, barley) LOQ = 0.02 mg/kg (rape seed)
	LC-MS/MS	LOQ = 0.05 mg/kg (wheat, orange, sunflower seed)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	LC-MS/MS	LOQ = 0.005 mg/kg (muscle, liver, kidney, fat, egg) LOQ = 0.001 mg/L (milk)
Soil (principle of method and LOQ)	LC-MS/MS	LOQ = 0.01 mg/kg
Water (principle of method and LOQ)	GC-PND	LOQ = 0.05 µg/L (tap water and surface water)
	GC-MS	LOQ = 0.05 µg/L (tap water and surface water)
Air (principle of method and LOQ)	GC-PND	LOQ = 0.5 µg/m^3
	LC-MS/MS	LOQ = 0.09 µg/m^3
Body fluids and tissues (principle of method and LOQ)	no method submitted fenpropimorph is not classified as toxic or highly toxic (pending on the final classification a method may be required)	

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

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	none

‡ Endpoint identified by the 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 (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	rapid and complete absorption (based on urinary and assumed biliary excretion, after low dose application)
Distribution ‡	highest residues in liver and fat
Potential for accumulation ‡	no accumulating potential
Rate and extent of excretion ‡	fast and nearly complete excretion within 96 h (30 %-52 % in urine, 40 %-55 % in faeces, in bile cannulated animals up to 80 % in bile)
Metabolism in animals ‡	completely metabolised, oxydation of side chain and methyl groups, ring opening, breakdown of morpholine moiety, conjugation
Toxicologically relevant compounds ‡ (animals and plants)	parent compound metabolite BF 421-1
Toxicologically relevant compounds ‡ (environment)	parent compound

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	1670 mg/kg bw	R22
Rat LD_{50} dermal ‡	> 4000 mg/kg bw	
Rat LC_{50} inhalation ‡	2.9 < LC_{50} < 9.1 mg/L (4h, nose only, aerosol)	
Skin irritation ‡	irritant	R38
Eye irritation ‡	non irritant	
Skin sensitisation ‡	not a skin sensitiser (M & K test)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	body weight gain ↓, liver weight ↑	
Relevant oral NOAEL ‡	rat, 90-day: 0.7 mg/kg bw/d	
Relevant dermal NOAEL ‡	rat, 28-day: 2 mg/kg bw/d (highest dose group)	
Relevant inhalation NOAEL ‡	rat, 28-day: 0.01 mg/L	

Genotoxicity ‡ (Annex IIA, point 5.4)

• unlikely to be genotoxic	

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

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

Target/critical effect ‡	body weight gain ↓, liver weight ↑, histopathology liver	
Relevant NOAEL ‡	rat, 2-yr: 0.3 mg/kg bw/d mouse, 95-week: 16 mg/kg bw/d	
Carcinogenicity ‡	no evidence of carcinogenicity	

Reproductive toxicity (Annex IIA, point 5.6)
Reproduction toxicity

Reproduction target / critical effect ‡	parental: decreased body weight and food intake no adverse effects on reproductive performance or fertility offspring: reduced body weight	
Relevant parental NOAEL ‡	4 mg/kg bw/d	
Relevant reproductive NOAEL ‡	16 mg/kg bw/d	
Relevant offspring NOAEL ‡	4 mg/kg bw/d	

Developmental toxicity

Developmental target / critical effect ‡	increased incidence of malformations in rats (cleft palates) and rabbits (skeleton malformations) at maternal toxic doses	R63 (R61?)
Relevant maternal NOAEL ‡	rat: 10 mg/kg bw/d rabbit: 12 mg/kg bw/d	
Relevant developmental NOAEL ‡	rabbit: 15 mg/kg bw/d rat: 40 mg/kg bw/d	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	NOAEL 1500 mg/kg bw (highest dose tested)	
Repeated neurotoxicity ‡	NOAEL 0.7 mg/kg bw/d (effects on FOB, 90-day study in rats)	
Delayed neurotoxicity ‡	No signs of delayed neurotoxicity in domestic hens	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies	Induction of hepatic drug metabolising enzymes in a 14 day dietary study in rats; NOAEL: 4 mg/kg bw/d.
Studies performed on metabolites or impurities ‡	Impurity 116453: negative in an in vitro study for chromosome aberrations. Impurity 114280: negative in the Ames test

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

Medical data ‡ (Annex IIA, point 5.9)

Few cases of skin irritation were reported.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.003 mg/kg bw/d	Rat, 2-yr	100
AOEL ‡	0.007 mg/kg bw/d	Rat, 90 day	100
ARfD ‡	0.03 mg/kg bw	Rabbit, developmental	500 *

* usual safety factor of 100 with an additional safety factor of 5 which gives a margin of safety of 1000 with respect to teratogenic effects.

Dermal absorption ‡ (Annex IIIA, point 7.3)

Corbel EC: 10 % (default value, based on expert judgement)

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Exposure estimates (% of AOEL) with German model: 1364 % without PPE; 56.3 % with gloves during mix/load and appl., and garment during appl. Field study: 197 %, without gloves during application, for a treated area of 50 ha/day
Workers	During inspection of cereals: 538 % of AOEL without PPE, 26.8 % of AOEL with PPE
Bystanders	7.3 % of AOEL

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	Xn, R22-38-63 (R61 ?) Repr. Cat. 3 (Cat 2 ?)

‡ Endpoint identified by the 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	Wheat, banana, sugar beets
Rotational crops	Lettuce, radish, wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes, but the main metabolite in rotational crops was dimethylmorpholine while in primary crops the parent compound fenpropimorph was the main residue. Dimethylmorpholine could be detected in some wheat and sugar beet matrices as well and is toxicologically covered by fenpropimorph.
Processed commodities	Simulation of industrial processing or household preparation (pasteurisation; baking, brewing and boiling; sterilisation)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes. Fenpropimorph is the only relevant residue.
Plant residue definition for monitoring	Fenpropimorph
Plant residue definition for risk assessment	Sum of fenpropimorph, metabolite BF 421-1 (free and conjugated) and 2,6-dimethylmorpholine, expressed as fenpropimorph
Conversion factor (monitoring to risk assessment)	None for commodities for human consumption considered under the representative use. 5 for cereal straw and sugar beet leaves

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

Animals covered	Lactating goats, laying hens
Time needed to reach a plateau concentration in milk and eggs	A plateau concentration was reached after 3 days in milk and after 6 days in eggs.
Animal residue definition for monitoring	Sum of fenpropimorph and fenpropimorph carboxylic acid, expressed as fenpropimorph
Animal residue definition for risk assessment	Sum of fenpropimorph and fenpropimorph carboxylic acid, expressed as fenpropimorph
Conversion factor (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Higher residues of fenpropimorph and fenpropimorph carboxylic acid in fat than in muscle in metabolism studies and the partition coefficient (log $P_{O/W}$) for fenpropimorph of 4.1 (pH 7) indicate the fat solubility of both compounds.

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

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

The total residues in edible parts of succeeding crops were low and declined continuously with subsequent plant back intervals. Residues of fenpropimorph could only be detected in samples of 30 days plant back interval. The main metabolite in rotational crops was dimethylmorpholin with relatively high residues in lettuce and radish leaf (0.056-0.102 mg/kg) and also in wheat straw (0.579 mg/kg). A new rat metabolism study showed that dimethylmorpholine can be considered to be toxicologically sufficient explored via the toxicological characterisation of the parent compound fenpropimorph.

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

The storage stability of fenpropimorph in wheat matrices (green plant, straw and grain) is guaranteed for at least 2 years. In banana pulp and peel, sunflower seed, sugar beet leaves and roots a more or less degradation of fenpropimorph was determined. After 2 years the degradation values are 17, 23, 24, 36 and 22 % for banana pulp, banana peel, sunflower seed, sugar beet leaves and sugar beet roots, respectively.

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)*	yes dairy cattle: 5.2 mg/kg feed beef cattle: 10.2 mg/kg feed	yes 0.28 mg/kg feed	yes 0.27 mg/kg feed
Potential for accumulation (yes/no):	no	no	n.a.
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	yes	no	n.a.
	Feeding studies (6.5 and 21.7 mg/kg feed) Residue levels in matrices for feeding level of 6.5 and 21.7 mg/kg feed respectively		
Muscle	0.04 & 0.14	n.a.	n.a.
Liver	0.77 & 2.89	n.a.	n.a.
Kidney	0.15 & 0.48	n.a.	n.a.
Fat	0.05 & 0.18	n.a.	n.a.
Milk	0.013-0.019 & 0.041-0.053		
Eggs		n.a.	

* The intake calculations are preliminary because there are no residue data for sugar beet tops and not enough data for sunflower seed.

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

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Wheat and rye (grains)	Northern Europe field use	<0.05 (15), 0.05 (2), 0.06 (3), 0.07, 0.08 (2), 0.09 mg/kg	Calculation of MRL for wheat, rye and triticale is based on residue data from Northern Europe.	0.1 mg/kg	0.09 mg/kg	0.05 mg/kg
	Southern Europe field use	<0.01, 0.02 mg/kg	Only two trials on wheat in Southern Europe correspond to the critical GAP. Similar to the barley/oats group it seems that residue levels in wheat from N-EU are higher than in wheat from S-EU, but two trials are not sufficient to be sure of this assumption. Thus, at least 2 additional trials are required.			
Wheat and rye (straw)	Northern Europe field use	0.05, 0.08, 0.1, 0.17, 0.19 (2), , 0.29, 0.42, 0.48, 0.74, 0.95, 1.1 (2), 1.3, 1.4, , 1.6, 2.1, 2.7, 2.9, 3.3, 3.6 (2), 3.8, 4.3 mg/kg			1.1 mg(kg	4.3 mg/kg
	Southern Europe field use	0.1, 0.2 mg/kg				
Barley and oats (grains)	Northern Europe	<0.05, 0.05, 0.06, 0.09, 0.1, 0.11,	Calculation of MRL for barley	0.5 mg/kg	0.27 mg/kg	0.13 mg/kg

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

	field use	0.13 (3), 0.16, 0.22, 0.24, 0.27, mg/kg	and oats is based on residue data from Northern Europe.			
	Southern Europe field use	0.01, 0.03, <0.05 (2), 0.07 (2) mg/kg			0.07	0.05
Barley and oats (straw)	Northern Europe field use	0.53, 0.61, 0.66, 0.68, 0.69, 0.76, 1.3 (2), 1.7 (2), 2.2, 2.5, 3.3, 3.9 mg/kg			1.3	3.9
	Southern Europe field use	<0.05 (2), 0.05, 0.08, 0.14, 0.37 mg/kg			0.37	0.065
Sunflower seed	Northern Europe field use	<0.05 (2) mg/kg	Not sufficient data for deriving MRL proposal for sunflower seed. Six further supervised residue trials are required for Southern Europe and two further trials for Northern Europe. In the Evaluation table the notifier has announced not to perform additional residue trials for sunflower. Thus, no MRL proposal for fenpropimorph in sunflower seed can be made.			
	Southern Europe field use	<0.05, 0.05 mg/kg				
Sugar beet roots	Southern Europe field use	<0.05 (6)		0.05* mg/kg	0.05	0.05
Sugar beet leaves	Northern and Southern Europe		Residue data on sugar beets do not correspond to the critical GAP. For Southern and Northern Europe each 4 additional trials are required. In the Evaluation table the notifier has announced			

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

			not to perform additional residue trials for sugar beets, but sugar beet leaves are still used as a regular feeding stuff. Thus, the requirement of new trials persist.			

(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 representative use
(c) Highest residue

‡ Endpoint identified by the 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	0.003mg/kg bw
TMDI (% ADI) according to WHO European diet	43%
TMDI (% ADI) according to national diets ("new" German model)	36% using the new German consumption data for toddlers of 2 to < 5 years of age
IEDI (WHO European Diet) (% ADI)	26%
NEDI ("old" and "new" German model) (% ADI)	25% using the new German model
Factors included in IEDI and NEDI	Conversion factor of 2 for ruminant products
ARfD	0.03 mg/kg bw
NESTI (% ARfD) according to UK consumption data	For cereals, sugar beets and animal matrices an acute risk is not expected. For sunflower seed the acute dietary risk assessment was not conducted because there are not enough data. Cereals: 14% for adults Sugar beets: 3.7 % for adults Ruminant liver: 9 % for adults
Factors included in IESTI and NESTI	None

Note that the results provided in this table rely on available residue data. As further residue trials are requested to support certain representative uses, the consumer exposure assessment may need to be reconsidered when these data will be available.

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

New processing trials on wheat and barley were required, so the calculation of processing factors is preliminary.

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Data have been submitted showing that fenpropimorph is preferably transferred to the bran fraction during the milling process and that no residue in beer above the LOQ is expected. Nevertheless due to the low residue level in the raw commodities the deriving of reliable processing factors is not possible				

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

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

Fenpropimorph :	
Barley and oats[1)]	0.5 mg/kg
Wheat, rye and triticale[1)]	0.1 mg/kg
Sugar beet roots	0.05* mg/kg
Sunflower seed	No proposal as appropriate data are not sufficient
Sum of fenpropimoph and BF 421-2, expressed as fenpropimorph:	
Ruminant liver	1 mg/kg
Ruminant kidney	0.2 mg/kg
Ruminant meat and fat	0.1 mg/kg
Milk and milk products	0.02 mg/kg
Eggs and all edible tissues of poultry	0.01* mg/kg
Pig liver	0.5 mg/kg
Pig kidney	0.1 mg/kg
Pig meat and fat	0.05 mg/kg

[1)] Because for cereals not sufficient residue data were presented for Southern-Europe, the MRL proposals for cereals are based on the residue data for Northern Europe only.
When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

‡ Endpoint identified by the 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)

Mineralisation after 100 days ‡	morpholine ^{14}C-labelled Loamy sand , Bruch West, Germany 45.8 % after 91 d; 49.4 % after 119 d phenyl ^{14}C-labelled Loamy sand , Bruch West, Germany 32.8 % after 91 d; 36.0 % after 119
Non-extractable residues after 100 days ‡	morpholine ^{14}C-labelled 33.6 % after 91 d; 37.0 % after 119 d phenyl ^{14}C-labelled 55.6 % after 91 d; 50.5 % after 119 d
Relevant metabolites - name and/or code, % of applied (range and maximum) ‡	**BF 421-2** morpholine ^{14}C-labelled ≥ 5 % DAT 3-22; max. 7.8 % at DAT 10-14 phenyl ^{14}C-labelled ≥ 5 % DAT 3-27; max. 9.7 % at DAT 14 **BF 421-7** Observed in field study with ^{14}C-labelled fenpropimorph ≥ 5 % DAT 1-12; max. 9.8 % at 4 days after treatment

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

Anaerobic degradation ‡	Recoveries in % of total applied radioactivity (TAR): active substance 77.8 % after 61 days active substance 78.2 % after 120 days (study end) metabolites: max. 4.8 % after 90 days mineralisation: 1.66 % after 120 d bound residues: 3.3 % day 0 and 2.5 % day 120
Soil photolysis ‡	Investigated: Phenylring ^{14}C-labelled fenpropimorph Loamy sand, light/dark cycle Recoveries in % of total applied radioactivity: active substance 78.7 % after 8 days 63.3 % after 16 days 51 % after 30 days (study end) essentially stable to photolysis

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

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

Method of calculation	Lab. DT_{50} aerob: ModelMaker 3.0.4 1st order kinetics Lab. DT_{90} aerob: ModelMaker 3.0.4 1st order kinetics Field DT_{50} aerob: ModelMaker 3.0.4 'best fit' according to FOCUS Kinetics
Laboratory studies (range or median, with n value, with r^2 value) ‡	**Fenpropimorph** DT_{50lab} (20 °C, aerobic): standardised to pF2, -10kPa, with Q10 2.2, Walker-equation exponent 0.7: geom. mean DT_{50lab}: 19.6 d n = 6, (9.5; 10.8; 14.0; 16.7; 19.2; 123.8) **BF 421-2** geom. mean DT_{50lab}: 4.9 d n = 3, (3.4; 3.8; 8.9 d)
	DT_{90lab} (20 °C, aerobic): measured at 20 °C and 40 % MWC geom. mean DT_{90lab}: 59.1 d n = 5, (41.4; 49.5; 60.1; 72.4; 81.1 d – 411.2 d excluded as outlier)
	DT_{50lab} (10 °C, aerobic): Calculated by RMS with Q10 2.2 from above-quoted DT_{50lab} 20 °C) geom. mean DT_{50lab}: 32.4 d n = 5, (23.8; 26.4; 36.7; 36.7; 42.2 d)
	DT_{50lab} (20 °C, anaerobic): > 120 d taken from raw data of the study
	degradation in the saturated zone: not relevant

Field studies (state location, range or median with n value) DT_{50f}	Fenpropimorph State / Location / DT_{50f} / Fit / r^2 Germany / Oberding / 8.8 / SFO / 0.9997 Brockhausen / 23.4 / FOMC[23] / 0.9822 Birkenheide / 9.0 / FOMC[24] / 0.9655 Hoheneggelsen / 18.1 / SFO / 0.9895 Stetten / 50.6 / FOMC[25] / 0.9803 Schweiz / Dielsdorf / 42.8 / SFO / 0.985 BF-421-7 Schweiz / Dielsdorf / 9.9 / SFO / 0.985
DT_{90f}	State / Location / DT_{90f} / Fit / r^2 Germany / Oberding / 29.4 / SFO / 0.9997 Brockhausen / 286 / FOMC / 0.9822 Birkenheide / 11703* / FOMC / 0.9655 Hoheneggelsen / 60.1 / SFO / 0.9895 Stetten / 4484* / FOMC / 0.9803 Schweiz / Dielsdorf / 142.2 / SFO / 0.985 BF-421-7 Schweiz Dielsdorf / 33 / SFO / 0.985 * = not reached during 2 × study duration

[23] α=0.79927 ß=16.967
[24] α=0.2260 ß=0.4401
[25] α=0.3733 ß=9.4143

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

Soil accumulation and plateau concentration ‡	Approach b) Calculation based on degradation data from Stetten field dissipation study: FOMC; DT_{90f} = 4480 d M_0 = 0.3311; alpha = 0.3733; beta = 9.4143 Pseudo-SFO DT_{50} = FOMC DT_{90} / 3.32 = 1350 d background (20 cm): 1.213 mg/kg after 15 yr PECsoil,accu (5 cm) = 2.213 mg/kg

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡	**Fenpropimorph** High adsorption $C_{org.}$ dependent: pH K_f (mL/g) 1/n K_{oc} (mL/g) Loam 7.3 34.47 1.340 5943 (C_{org} 0.58 %; 13 CEC (mVal/100 g dry soil) Loamy sand 7.2 73.73 0.867 2772 (C_{org} 2.66 %; 10 CEC (mVal/100 g dry soil) Sand 7.0 22.60 0.949 4432 (C_{org} 0.51 %; 3.7 CEC (mVal/100 g dry soil) Worst case K_{Foc} 2772 L/kg with 1/n = 0.867 to be used for FOCUS modelling. **BF 421-2** pH K_f (mL/g) 1/n K_{foc} (mL/g) LUFA 2.2 5.6 1.45 0.882 68.6 (C_{org} 2.12 %; 10.6 CEC (mVal/100 g dry soil) Birnbaum 6.1 0.443 0.955 55.4 (C_{org} 0.8 %; 13.0 CEC (mVal/100 g dry soil) Sora 6.4 0.883 0.890 46.2 (C_{org} 1.91 %; 16.6 CEC (mVal/100 g dry soil) Bruch West 7.4 0.403 0.851 17.5 (C_{org} 2.3 %; 20.9 CEC (mVal/100 g dry soil) LUFA 3A 7.5 0.833 0.835 29.9 (C_{org} 2.79 %; 21.4 CEC (mVal/100 g dry soil) **BF 421-7 (non-GLP study)** Data gap identified.
K_d ‡ pH dependence (yes / no) (if yes type of dependence) ‡	Fenpropimorph: no BF 421-2: yes, lowest value was selected for use in FOCUS modelling

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

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

Column leaching ‡	Not submitted, not required
Aged residues leaching ‡	30 day ageing in the dark, 25 °C, 40 % WHC, 1 mg as/kg No radioactivity in the leachates from - sandy loam (2.31 % C_{org}; CEC 2.39 mVal/100 g dry soil; pH 5.8; MWC 44 g H_2O/100 g dry soil) and - loamy sand (0.89 % C_{org}; CEC 8.5 mVal/100 g dry soil; pH 6.8; MWC 30 g H_2O/100 g dry soil) 85 % of applied radioactivity in the first soil segments. 30 day ageing in the dark (25 °C, 40 % WHC), 5.6 mg as as/kg. No radioactivity in the leachate from the soil (2.66 % C_{org}; CEC 10 mVal/100 g dry soil; pH 6.1) 92 % of applied radioactivity in the first 2 soil segments.
Lysimeter/ field leaching studies ‡	not required, high K_{oc} value, no risk for displacement into deeper soil layers and groundwater. In agreement with FOCUS groundwater calculations.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation	Calculation based on degradation data from Stetten field dissipation study (worst case): FOMC; DT_{50f} = 50.6 d M_0 = 0.3311; alpha = 0.3733; beta = 9.4143 , 5 cm soil layer, 1.5 kg/L bulk density, with interception (FOCUS) for cereal scenario f = 0.5
Application rate	annual rate 1500 g active substance /ha

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	1.000			
Short term 24h	0.963	0.981	--	--
2d	0.931	0.964		
3d	0.902	0.948		
4d	0.876	0.933		
Long term 7d	0.813	0.894	--	--
14d	0.712	0.826		
21d	0.645	0.776		
28d	0.597	0.737		
42d	0.531	0.679		
100d	0.400	0.549		

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

Metabolite

Method of calculation	SFO, DT_{50} = 9.4 d--
Application rate	based on $PEC_{(s)}$ of fenpropimorph 9.7 % formation in metabolism study correction for molar mass (333.5/303.5 = 1.099)

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.107			
Short term 24h	0.099	0.103	-	-
2d	0.092	0.099		
3d	0.085	0.096		
4d	0.079	0.092		
Long term 7d	0.064	0.083	-	-
14d	0.038	0.066		
21d	0.023	0.054		
28d	0.014	0.045		
42d	0.005	0.033		
50d	0.003	0.028		
100d	0.000	0.014		
365d	0.000	0.004		

‡ Endpoint identified by the 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) ‡	pH 3, 5, 7 and 9 (25 °C): stable
Photolytic degradation of active substance and relevant metabolites ‡	stable, no UV adsorption above 290 nm
Readily biodegradable (yes/no) ‡	No data submitted, none required
Dissipation in water/sediment - DT_{50} water ‡ - DT_{90} water ‡ - DT_{50} whole system ‡ - DT_{90} whole system ‡	Fenpropimorph as: (ModelMaker 3.0.4) system A / system B $DT_{50,water}$ 3.4 d / 1.9 d $DT_{90,water}$ 11.1 d / 6.4 d $DT_{50,system}$ 54 d / 18 d $DT_{90,system}$ > 2 x study duration (>200 d) BAS 421-2 metabolite: system A / system B $DT_{50,water}$ - / 38.7 d $DT_{90,water}$ > 2 times study duration (>200 d) $DT_{50,system}$ no data given / no data given $DT_{90,system}$ no data given / no data given
- DT_{50} (only degradation) ‡	Fenpropimorph as (ModelMaker 4.0): system A / system B / geom.. mean $DT_{50,water\ degradation}$ 11.7 d / 4.0 d / 6.8 d $DT_{50,sediment\ degradation}$ 102.2 d / 63.4 d / 80.5 d BAS 421-2 metabolite (ModelMaker 4.0): system A / system B / geom.. mean $DT_{50,water\ degradation}$ 555 d / 31.9 d / 133 d
Mineralisation	water/sediment, 2 systems after 100 days (study end): System A 6.3 % and system B 8.5 % (mean of phenyl and morpholine radiolabel)
Non-extractable residues	water/sediment, 2 systems after 100 days (study end): System A 20.0 % and system B 36.8 % (mean of phenyl and morpholine radiolabel)
Distribution in water / sediment systems (active substance) ‡	BAS 421 F in % total applied radioactivity (as phenyl- and morpholine-^{14}C label)

days after application	(A) **water**	(B)	(A) **sediment**	(B)
0	70.1	73.5	13.2	11.5
0.25	73.5	68.9	9.3	11.7
1	60.1	48.6	20.9	28.8
2	43.4	36.1	30.0	33.3
7	19.8	9.1	46.9	44.8
14	7.6	4.5	48.2	44.6
29	4.5	2.0	46.2	32.0
63	3.0	0.7	34.7	25.7
100	2.7	1.0	28.2	27.4

Distribution in water / sediment systems (metabolites) ‡

BAS 421-2 in % total applied radioactivity (as phenyl- and morpholine-^{14}C label)

days after application	(A) **water**	(B)	(A) **sediment**	(B)
0	0	0	0	0
0.25	0	0	0	0

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

	1	0	0	0	0
	2	0	0	0	0
	7	1.7	7.5	0	0
	14	6.5	10.9	0	0
	29	9.3	16.9	0.2	4.3
	63	20.5	14.0	4.1	5.2
	100	22.6	8.6	7.7	5.7

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

Parent

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: … Molecular weight (g/mol): 303.5 Water solubility (mg/L): 4 K_{OC}/K_{OM} (L/kg): 2772 (worst case of 3 soils) DT_{50} soil (d): Steps 1&2 – 14.7 d (geomean lab.); Steps 3&4 – 19.6 d (revised geomean lab.) DT_{50} water/sediment system (d): 1000 d (conservative assumption) DT_{50} water (d): 6.8 d DT_{50} sediment (d): 80.5 d Crop interception (%): 50
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: FOCUS-PRZM shell version 2.6, FOCUS-MACRO shell version 4.4.2 and FOCUS-TOXSWA shell version 2.5 Vapour pressure: 0.0035 Pa (20 °C) Kom/Koc: 2772 (worst case of 3 soils) 1/n: 0.9
Application rate	Crop: cereals Crop interception: 50 % Number of applications: 2 Interval (d): 28 d Application rate(s): 750 g as/ha Application window: BBCH 25-69

‡ Endpoint identified by the 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)	
		Actual	TWA	Actual	TWA
	0 h	120.27		2950	
	24 h	109.34	114.80	3030	2990
	2 d	109.26	112.05	3030	3010
	4 d	109.11	110.62	3020	3020
	7 d	108.88	109.92	3020	3020
	14 d	108.35	109.27	3000	3020
	21 d	107.83	108.88	2990	3010
	28 d	107.31	108.55	2970	3000
	42 d	106.27	107.96	2950	2990
	50 d	105.68	107.65	2930	2980
	100 d	102.08	105.76	2830	2930

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	7.50	---	195.6	---
	24 h	6.43	6.96	190.3	192.9
	2 d	6.25	6.65	185.1	190.3
	4 d	5.91	6.37	175.1	185.2
	7 d	5.44	6.07	161.1	177.8
	14 d	4.48	5.51	132.6	162.1
	21 d	3.69	5.03	109.2	148.2
	28 d	3.04	4.61	89.9	136.0
	42 d	2.06	3.91	60.9	115.5
	50 d	1.65	3.58	48.8	105.8
	100 d	0.41	2.24	12.2	66.1
Southern EU Application period March-May	0 h	13.08	---	349.3	---
	24 h	11.47	12.28	349.1	349.2
	2 d	11.16	11.80	339.6	346.8
	4 d	10.56	11.33	321.2	338.6
	7 d	9.71	10.81	295.6	325.6
	14 d	8.00	9.82	243.3	297.1
	21 d	6.58	8.97	200.4	271.8

‡ Endpoint identified by the 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)	
		Actual	TWA	Actual	TWA
	28 d	5.42	8.22	165.0	249.4
	42 d	3.68	6.98	111.8	211.8
	50 d	2.94	6.39	89.6	194.0
	100 d	0.73	3.99	22.3	121.2

Only PECglobal,max values are provided for Step 3 as other values are not relevant for the risk assessment using the most sensitive ecotoxicological endpoint. Typically, entries in surface water bodies are higher when 1 application is assumed with a 90th percentile instead of 2 individual applications with a 82nd percentile each and full dissipation from the water column in the time between applications. However, for some runoff scenarios, PECglobal,max values derived from twofold application are higher than from single application this happens more often for PECsed. In the table, the respective highest PECglobal,max are listed. Due to the relatively high volatility of fenpropimorph, Step 4a values considering also volatilisation and deposition are documented.

FOCUS STEP 3 Scenario and step 4a (actual +volatilisation / deposition)	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Step 3 Actual	Step 4a Actual + volatilisation/ deposition	Step 3 Actual	Step 4a Actual + volatilisation/ deposition
D1	Ditch	0 h	4.795*	4.795*	11.635*	11.951*
D1	Stream	0 h	4.192*	4.193*	2.428*	2.5*
D2	Ditch	0 h	4.794*	4.794*	12.081*	12.411*
D2	Stream	0 h	4.187*	4.189*	2.507*	2.592*
D3	Ditch	0 h	4.725*	4.725*	2.968**	3.060**
D4	Pond	0 h	0.163*	0.172*	0.974**	1.263**
D4	Stream	0 h	3.859*	3.879*	0.254*	0.258*
D5	Pond	0 h	0.163*	0.171*	0.891**	1.156**
D5	Stream	0 h	3.433*	3.439*	0.113**	0.115**
D6	Ditch	0 h	4.674*	4.674*	7.310**	7.548**
R1	Pond	0 h	0.218**	0.227**	1.540**	1.627**
R1	Stream	0 h	3.119*	3.134*	10.779**	10.790**
R3	Stream	0 h	4.382*	4.391*	4.096*	4.105*
R4	Stream	0 h	4.004**	4.004**	16.314**	16.324**

* considering single application (with 90th drift percentile)
** considering twofold application (with 82nd drift percentile each)

Step 4b PEC global max for each scenario including volatilisation / deposition with risk mitigation of just no spray buffer zones at 10m, 20m or 50m (note no spray buffer distances

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

of 5m and 15m would also be agreed EU endpoints and can be found in tables B.8.5-9, B.8.5-36, B.8.5-23 and B.8.5-49 in addendum 4 of 9 January 2008)

FOCUS STEP 4a Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)			PEC_{SED} (µg/kg)		
			Actual 10m no spray buffer	Actual 20m no spray buffer	Actual 50m no spray buffer	Actual 10m no spray buffer	Actual 20m no spray buffer	Actual 50m no spray buffer
D1	Ditch	0 h	0.689*	0.359*	0.151*	1.890*	1.021*	0.448*
D1	Stream	0 h	0.812*	0.422*	0.175*	0.506*	0.269*	0.116*
D2	Ditch	0 h	0.688*	0.359*	0.151*	1.968*	1.064*	0.468*
D2	Stream	0 h	0.811*	0.422*	0.175*	0.528*	0.283*	0.123*
D3	Ditch	0 h	0.678*	0.352*	0.146*	0.451**	0.238**	0.103**
D4	Pond	0 h	0.103*	0.069*	0.036*	0.715**	0.481**	0.258**
D4	Stream	0 h	0.755*	0.393*	0.164*	0.051*	0.027*	0.012*
D5	Pond	0 h	0.106**	0.070**	0.037**	0.654**	0.440**	0.236**
D5	Stream	0 h	0.667*	0.347*	0.144*	0.022**	0.012**	0.005**
D6	Ditch	0 h	0.671*	0.349*	0.144*	1.135**	0.604**	0.262**
R1	Pond	0 h	0.199**	0.186**	0.174**	1.352**	1.224**	1.104**
R1	Stream	0 h	1.612**	1.612**	1.612**	10.582**	10.558**	10.543**
R3	Stream	0 h	1.652**	1.652**	1.652**	3.901*	3.875*	3.858*
R4	Stream	0 h	4.004**	4.004**	4.004**	16.127**	16.104**	16.090**

* considering single application (with 90th drift percentile)
** considering twofold application (with 82nd drift percentile each)

For other Step 4 calculations including additional risk mitigation measures see tables in Addendum 4. Note only no spray drift buffer zone reductions including volatilisation / redeposition input are considered to be agreed EU endpoints.

Metabolite BF-421-2 Parameters used in FOCUSsw step 1	Version control no. of FOCUS calculator: 1.1 Molecular weight (g/mol): 333.5 Water solubility (mg/L): 9300 K_{OC} (L/kg): 17.5 (worst case due to pH dependence) DT_{50} soil (d): 4.9 DT_{50} water/sediment system (d): 1000 d (conservative assumption)

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

	Max occurrence in water+sediment 30.3%Max occurrence in soil 9.7%
Application rate	Crop: cereals Lumped total dose application1500 g as/ha

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	56.67		Not presented not required	

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

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	FOCUS-PELMO 3.3.2 and FOCUS-Macro 3.3.1 Input parameters **Fenpropimorph** DT50 = 124 d (laboratory, worst case) $K_{f,oc}$ = 2772 mL/g (worst case) 1/n = 0.867 **BF 421-2** DT50 = 4.9 d (laboratory, geom. mean) $K_{f,oc}$ = 17.5 mL/g (worst case due to pH-dependency) 1/n = 0.851 **BF 421-7** Data gap
Application rate	2 x 750 g as/ha with an interval of 28 days
$PEC_{(gw)}$	
Maximum concentration	< 0.001 µg/L for fenpropimorph, BF 421-2
Average annual concentration (Results quoted for modelling with FOCUS gw scenarios, according to FOCUS guidance)	< 0.001 µg/L for all scenarios for fenpropimorph and BF 421-2

PEC(gw) - FOCUS modelling results

Model /Crop	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			BF 421-2 (µg/L)	2	3
	winter cereals FOCUS-PELMO 3.3.2 and FOCUS-MACRO 3.3.1	< 0.001	< 0.001		-

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

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

Direct photolysis in air ‡	no calculation performed, not studies. not required
Quantum yield of direct phototransformation	Absorption coefficient : < 10 L * mol^{-1} * cm^{-1}
Photochemical oxidative degradation in air ‡	DT_{50} ..2.9 hours. (calculation according to Atkinson 1987, OH radical concentration 5 ×10^5 cm^{-3}))
Volatilisation ‡	from plant surfaces: ‡ 61 % 24 h after application. Laboratory study, formulation application rate 750 g as/ha, plants: bush beans; soil: 83 % sand, 7 % silt; 10 % clay; C_{org} 0.5 %, pH 5.8 %, MWC 24 g/100 g dry soil. Facility: volatilisation chamber, air flow 195 - 222 L/h, 20 - 22 °C, wind speed 1 m/s. Study in wind tunnel system Application of nominal 750 g as/ha on winter wheat (BBCH 51), sampling in water containers downwind of application area Concentration of fenpropimorph in the water samples 24 h after application. Distance (m) % of applied 1 0.044 3 0.019 5 0.011 10 0.054 15 0.026 20 0.026 Field study Application of nominal 750 g as/ha on summer wheat (BBCH 37), sampling in water containers downwind of application area Deposition amounts of fenpropimorph fitted according to Gustafson & Holden for distances between 0 m and 50 m Distance (m) % of applied 0 0.0850 1 0.0561 3 0.0373 5 0.0294 10 0.0206 15 0.0165 20 0.0141 50 0.0084
	from soil: ‡ 27 % 24 h after application

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

PEC (air)

Method of calculation	not performed

PEC$_{(a)}$	
Maximum concentration	not required

Definition of the Residue (Annex IIA, point 7.3)

Residues requiring risk assessment / groundwater exposure assessment	Residues requiring risk assessment / groundwater exposure assessment Soil: Fenpropimorph and BF 421-2 Ground water: Fenpropimorph BF 421-2 and BF 421-7 Surface water: Fenpropimorph and BF 421-2 Sediment: Fenpropimorph Air: Fenpropimorph (default)

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

Soil (indicate location and type of study)	not available
Surface water (indicate location and type of study)	not available
Ground water (indicate location and type of study)	Germany, groundwater monitoring programme fenpropimorph 1999 - 2002 number of samples: 784 number of samples > LOQ: 4 Lower Saxony 2002 n = 1 > LOQ ≤ 0.1 µg/L n = 3 > 0.1 ≤ 1.0 µg/L
Air (indicate location and type of study)	not available

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	Candidate for R 53

‡ Endpoint identified by the 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 ‡	rat LD_{50} = 2230 mg as/kg bw
Long-term toxicity to mammals ‡	rat NOAEDD = 16 mg as/kg bw/d (24 months reproduction)
Acute toxicity to birds ‡	*Colinus virginianus* LD_{50} = > 2000 mg as/kg bw
Dietary toxicity to birds ‡	*Colinus virginianus* LDD_{50} = > 881 mg as/kg bw/d > 5000 mg as/kg diet
Reproductive toxicity to birds ‡	*Colinus virginianus* NOEDD = > 30.3 mg as/kg bw/d

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

Cereals, 2 x 750 g as/ha

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Large herbivore	Acute	56.2	> 36	10
Insectivore	Acute	40.6	> 49	10
Large herbivore	Short-term	26.3	> 33	10
Insectivore	Short-term	22.6	> 39	10
Large herbivore	Long-term	14.0	2.2	5
Insectivore	Long-term	22.6	1.3	5
Higher tier refinement (Birds)				
Greylag goose (*Anser anser*) measured RUD and DT50 for green plant matter	Long-term	2.5	12.3	5
Grey partridge (*Perdix perdix*) mixed diet (31 % grasses and cereal shoots, 31 % non-grass herbs, 34 % weed seeds, 4 % arthropods) measured RUD and DT50 for green plant matter	Long-term	2.2	14.1	5
Yellowhammer (*Emberiza citrinella*) – insectivorous diet arthropod RUD for 89 % large/11 % small arthropods	Long-term	4.5	6.8	5
Yellowhammerr (*Emberiza citrinella*) – mixed diet mixed diet (65 % epigaeic insects, 25 % soil-inhabiting insects, 10 % weed seeds)	Long-term	3.6	8.4	5

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

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
skylark (*Alauda arvensis*) mixed diet (50 %grasses and cereal shoots, 30 % weed seeds; ~~20 % large arthropods)*~~ measured RUD and DT50 for green plant matter	Long-term	~~4.3~~	~~7.1~~	5
Tier 1 (Mammals)				
Small herbivore	Acute	177.6	12.6	10
Insectivore	Acute	6.6	337	10
Small herbivore	Long-term	47.9	0.3	5
Insectivore	Long-term	2.4	6.6	5
Higher tier refinement (Mammals)				
Wood mouse (*Apodemus sylvaticus*) May-July diet (11 % green plant matter, 51.7 % weed seeds, 21 % arthropods, 16.3 % earthworms) measured RUD and DT50 for green plant matter	Long-term	1.37	11.8	5
Wood mouse (*Apodemus sylvaticus*) March-June diet (17.8 % green plant matter, 31.5 % weed seeds, 26.3 % arthropods, 24.5 % earthworms) measured RUD and DT50 for green plant matter	Long-term	1.35	11.9	5

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

Sugar beet, 1 x 750 g as/ha

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Medium herbivore	Acute	49.6	> 40	10
Insectivore	Acute	40.6	> 49	10
Medium herbivore	Short-term	22.8	> 39	10
Insectivore	Short-term	22.6	> 39	10
Medium herbivore	Long-term	12.1	2.5	5

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

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Insectivore	Long-term	22.6	1.3	5
Higher tier refinement (Birds)				
Grey partridge (*Perdix perdix*) mixed diet (31 % grasses and cereal shoots, 31 % non-grass herbs, 34 % weed seeds, 4 % arthropods) measured RUD and DT50 for green plant matter	Long-term	1.9	15.7	5
Yellowhammer (*Emberiza citrinella*) – insectivorous diet arthropod RUD for 89 % large/11 % small arthropods	Long-term	4.5	6.8	5
Yellowhammerr (*Emberiza citrinella*) – mixed diet mixed diet (65 % epigaeic insects, 25 % soil-inhabiting insects, 10 % weed seeds)	Long-term	3.5	8.8	5
skylark (*Alauda arvensis*) mixed diet (50 % non-grass herbs, 30 % weed seeds; ~~20 % large arthropods~~* measured RUD and DT50 for green plant matter	Long-term	~~3.7~~	~~8.3~~	5
Tier 1 (Mammals)				
Medium herbivore	Acute	18.3	122	10
Medium herbivore	Long-term	4.5	3.6	5
Higher tier refinement (Mammals)				
Hare (*Lepus europaeus*) measured RUD and DT50 for green plant matter	Long-term	0.6	29	5

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.
*Suggested refinement (only large insect prey) was not discussed and agreed in the experts meeting.

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

Sunflowers, 1 x 600 g as/ha

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Medium herbivore	Acute	39.7	> 50	10
Insectivore	Acute	32.4	> 62	10
Medium herbivore	Short-term	18.2	> 48	10
Insectivore	Short-term	18.1	> 49	10
Medium herbivore	Long-term	9.7	3.1	5
Insectivore	Long-term	18.1	1.7	5
Higher tier refinement (Birds)				
No focal species identified	Long-term	-/-	-/-	5
Tier 1 (Mammals)				
Medium herbivore	Acute	14.6	153	10
Medium herbivore	Long-term	3.6	4.5	5
Higher tier refinement (Mammals)				
Hare (*Lepus europaeus*) measured RUD and DT50 for green plant matter	Long-term	1.2	14	5

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

‡ Endpoints identified by the 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) ‡

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L) *
Laboratory tests				
Pseudokirchneriella subcapitata	fenpropimorph	72 h acute	E_bC_{50} biomass E_rC_{50} growth rate NOEC biomass NOEC growth rate	0.327 > 1 0.005 0.058
Daphnia magna	fenpropimorph	48 h acute	EC_{50} immobilisation	2.24
Lepomis macrochirus	fenpropimorph	96 h acute	LC_{50}	2.30
Oncorhynchus mykiss	fenpropimorph	21 d	NOEC behaviour NOEC mortality, young fish	0.1 1.1
Oncorhynchus mykiss	fenpropimorph	94 d	NOEC early life stage	0.00016
Chironomus riparius	fenpropimorph	20 d	NOEC (nominal initial)	0.13
Pseudokirchneriella subcapitata	metabolite BAS 421-2	72 h	EC_{50} biomass NOEC biomass	> 100 25
Daphnia magna	metabolite BAS 421-2	48 h	EC_{50} immobilisation	> 100
Oncorhynchus mykiss	metabolite BAS 421-2	96 h	LC_{50}	> 100
Scenedesmus subspicatus	product RO 14-3169/002	72 h	EC_{50} biomass EC_{50} growth rate NOEC biomass and growth rate based on measured conc. at test end	0.17 (0.13 as) 0.28 (0.21 as) 0.058 (0.044 as)
Daphnia magna	product RO 14-3169/002	48 h	EC_{50} immobilisation	1.5 (1.13 as)
Daphnia magna	product RO 14-3169/002	21 d	NOEC reproduction	0.032 (0.024 as)
Oncorhynchus mykiss	product RO 14-3169/002	96 h	LC_{50}	2.20 (1.65 as)
Oncorhynchus mykiss	product RO 14-3169/002	28 d	NOEC mortality, young fish NOEC other symptoms	0.18 (0.14 as) 0.056 (0.042 as)
Oncorhynchus mykiss	product BAS 421 12 F	49 d	NOEC early life stage (growth young fish)	0.0026 (0.00195 as)

* nominal concentrations, confirmed by chemical analyses

Microcosm or mesocosm tests
not required

‡ Endpoints identified by the 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)

FOCUS Step1

Cereals, 2 ×750 g as/ha

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i (mg/L)	PEC_{twa} (mg/L)	TER	Annex VI Trigger[1]
a.s.	Fish	1.650 (test with product)	Acute	0.12027	-/-	**13.7**	100
a.s.	Fish	0.00195 (test with product)	ELS (49 d)	0.12027	-/-	**0.02**	10
a.s.	Aquatic invertebrates	1.130 (test with product)	Acute	0.12027	-/-	**9.4**	100
a.s.	Aquatic invertebrates	0.024 (test with product)	Chronic (21 d)	-/-	0.10888 (twa 21 d)	**0.2**	10
a.s.	Algae	0.013 (test with product)	Chronic	0.12027		**0.1**	10
a.s.	Higher plants[2]	-/-	Chronic				10
a.s.	Sediment-dwelling[3] organisms	0.125	Chronic	0.12027 (PEC_{sw})		**1.0**	10

[1]If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
[2] only required for herbicides
[3]consider the need for PEC_{sw} and PEC_{sed} and indicate which has been used

FOCUS Step 2

Cereals, 2 ×750 g as/ha
for SE: application March-May

Test substance	N/S[1]	Organism[2]	Toxicity end point (mg/L)	Time scale	PEC[3] (mg/L)	TER	Annex VI Trigger[4]
a.s.	N	Fish	0.00195 (test with product)	ELS (49 d)	0.00750	**0.26**	10
a.s.	S	Fish	0.00195 (test with product)	ELS (49 d)	0.01308	**0.15**	10

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

[1] indicate whether Northern of Southern
[2] include critical groups which fail at Step 1.
[3] indicate whether maximum or twa values have been used.
[4] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

Cereals, 2 ×750 g as/ha

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (µg/L)	PEC[4] (µg/L)	TER	Annex VI trigger[5]
a.s.	D1	Ditch	*O. mykiss* ELS test	49 d	1.95 (test with product)	4.795*	0.4	10
	D1	Stream				4.193*	0.5	
	D2	Ditch				4.794*	0.4	
	D2	Stream				4.189*	0.5	
	D3	Ditch				4.725*	0.4	
	D4	Pond				0.172*	11.3	
	D4	Stream				3.879*	0.5	
	D5	Pond				0.171*	11.4	
	D5	Stream				3.439*	0.6	
	D6	Ditch				4.674*	0.4	
	R1	Pond				0.227**	8.6	
	R1	Stream				3.134*	0.6	
	R3	Stream				4.391*	0.4	
	R4	Stream				4.004**	0.5	

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 2.
[4] indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used
[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
* considering single application (with 90th drift percentile)
** considering twofold application (with 82nd drift percentile each)

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

FOCUS Step 4

Cereals, 2 ×750 g as/ha
Consideration of volatilisation/deposition

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (µg/L)	PEC[4] (µg/L)	TER	Annex VI trigger[5]
a.s.	D1	Ditch	*O. mykiss* ELS test	49 d	1.95 (test with product)	4.795*	0.4	10
	D1	Stream				4.193*	0.5	
	D2	Ditch				4.794*	0.4	
	D2	Stream				4.189*	0.5	
	D3	Ditch				4.725*	0.4	
	D4	Pond				0.172*	11.3	
	D4	Stream				3.879*	0.5	
	D5	Pond				0.171*	11.4	
	D5	Stream				3.439*	0.6	
	D6	Ditch				4.674*	0.4	
	R1	Pond				0.227**	8.6	
	R1	Stream				3.134*	0.6	
	R3	Stream				4.391*	0.4	
	R4	Stream				4.004**	0.5	

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 2.
[4] indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used
[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
* considering single application (with 90th drift percentile)
** considering twofold application (with 82nd drift percentile each)

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

Note only no spray drift buffer zone reductions including volatilisation / redeposition input are considered to be agreed EU endpoints. For other Step 4 calculations including additional risk mitigation measures see tables in Addendum 4.

Bioconcentration

Bioconcentration factor (BCF) ‡	study 1: BCF_{SS}, mean (plateau): 1096 (phenyl label) study 2: BCF_{SS}, mean (plateau): 942 (morpholine label) study 3: BCF_{SS}, mean (plateau): 968 - 1145 based on % TAR BCF_k: 1169 – 1220 based on % TAR BCF_{SS}, mean (plateau): 421- 605 based on % parent
Annex VI Trigger for the bioconcentration factor	100
Clearance time (CT_{50})	study 1: 4.8 days study 2: 5.9 days study 3: 1.7 – 2.8 days
(CT_{90})	study 1 and 2: - study 3: 15.5 – 31 days
Level of residues (%) in organisms after the 14 day depuration phase	study 1: - study 2: 25.6 and 32 % after 14 days study 3: 10.7 and 14.1 % after 16 days, 3.3 and 5.3 % after 56 days

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

Acute oral toxicity ‡	LD_{50} > 95.6 µg as/bee (active substance) LD_{50} > 79.5 µg/bee (formulation BAS 421 12 F)
Acute contact toxicity ‡	LD_{50} > 100 µg as/bee (active substance) LD_{50} > 100 µg/bee (formulation BAS 421 12 F)

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

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests (active substance)				
0.75	cereals, sugar beet	contact (48 h)	< 7.5	50
0.75	cereals, sugar beet	oral (48 h)	< 7.9	50
Laboratory tests (formulation BAS 421 12 F))				
0.75	cereals, sugar beet	contact (48 h)	7.5	50
0.75	cereals, sugar beet	oral (48 h)	< 9.5	50

Field or semi-field tests not required

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

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

Species	Stage	Test substance	Dose (kg as/ha)	Endpoint	Effect	Trigger
Laboratory tests with inert substrate						
Aphidius rhopalosiphi	adults	formulation BAS 421 12 F		mortality	LR_{50} 25.7 g as/ha	30 % *
			0.0075	reproduction	44 %	
Typhlodromus pyri	proto-nymphs	formulation BAS 421 12 F		mortality	LR_{50} 468 g as/ha	30 % *
			0.35	reproduction	22 %	
Chrysoperla carnea	larvae	formulation BAS 421 12 F	0.037	mortality / reproduction	10.4 % / -3 %	50 % **
			1.49		68.8 % / -1 %	
					LR_{50} > 37 < 1488 g as/ha	
Poecilus cupreus	4 weeks old	formulation BAS 421 12 F	1.49	mortality / feeding capacity	3.3 % / 2.7 %	30 % *
Aleochara bilineata	4 weeks old	formulation BAS 421 12 F	1.49	reproduction	- 1.7 %	30 % *
Pardosa spec.	adult	formulation BAS 421 12 F	1.49	mortality / feeding capacity	56 % / 68 %	30 % *
Extended laboratory tests with natural substrate						
Aphidius rhopalosiphi	adults	formulation BAS 421 12 F (sprayed on plants)	1.49	mortality	0 %	50 % **
			0.74	reproduction	10 %	
			1.49	reproduction	40 %	
Typhlodromus pyri	proto-nymphs	formulation BAS 421 12 F (sprayed on detached leaves)	0.037	mortality / reproduction	20 % / 10 %	50 % **
			0.74		39 % / 20 %	
			1.49		92 % / -	
Typhlodromus pyri	proto-nymphs	formulation BAS 421 12 F (sprayed on potted bean plants)	1.49	mortality / reproduction	14.1 % / 12.4 %	50 % **
			0.74		0 % / 1 %	
Chrysoperla carnea	larvae	formulation BAS 421 12 F (sprayed on plants)	1.38 (max. dose)	mortality / reproduction/ hatching rate	4 % / 10 % / 4 %	50 % **
Chrysoperla carnea	larvae	formulation BAS 421 12 F (sprayed on plants)	2 × 0.73 (max. dose)	mortality / reproduction / hatching rate	7 % / 25 % / 15 %	50 % **
Pardosa spec.	adult	formulation BAS 421 12 F (sprayed on soil)	1.49	mortality / feeding capacity	21 % / 9 %	50 % *

* Trigger according to Annex VI 91/414/EEC ** Trigger at field rate according to Sanco/10329/2002

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

Hazard quotients for other arthropod species: in-field and off-field scenario

Cereals, 2 x 750 g as/ha

Test substance	Species	Effect (LR_{50} g product/ha)	HQ in-field	HQ off-field[1]	Trigger
product BAS 421 12 F	*Typhlodromus pyri*	629	2.7	1 m: 0.1	2
product BAS 421 12 F	*Aphidius rhopalosiphi*	34.3	49.6	1 m: 1.2	2

[1] indicate distance assumed to calculate the drift rate

Sugar beet, 1 x 750 g as/ha

Test substance	Species	Effect (LR_{50} g product/ha)	HQ in-field	HQ off-field[1]	Trigger
product BAS 421 12 F	*Typhlodromus pyri*	629	1.6	1 m: < 0.1	2
product BAS 421 12 F	*Aphidius rhopalosiphi*	34.3	29.2	1 m: 0.8	2

Sunflower, 1 x 600 g as/ha

Test substance	Species	Effect (LR_{50} g product/ha)	HQ in-field	HQ off-field[1]	Trigger
product BAS 421 12 F	*Typhlodromus pyri*	629	1.3	1 m: < 0.1	2
product BAS 421 12 F	*Aphidius rhopalosiphi*	34.3	23.3	1 m: 0.6	2

Toxicity/exposure ratios for arthropod species: off-crop scenario (most sensitive species of each group)

TER concept

Species	Crop	AR (L/ha)	MAF	drift	vdf	E/LR50 (L/ha)	TER	Trigger
Aphidius rhopalosiphi	cereals	1.0	1,7	1 m: 2.38 %	5	> 2.0	247	5
	sugarbeet	1.0	1	1 m: 2.77 %			361	
	sunflowers	0.8		1 m: 2.77 %			451	
Typhlodromus pyri	cereals	1.0	1,7	1 m: 2.38 %	1	> 2.0a	49	5
	sugarbeet	1.0	1	1 m: 2.77 %			72	
	sunflowers	0.8		1 m: 2.77 %			90	

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

Field or semi-field tests
No field tests were triggered on basis of the intended field uses and data available

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point[1]
Earthworms			
Eisenia fetida	a.s. ‡	Acute 14 days	LC_{50} > 1000 mg as/kg soil dw corrected for f_{oc} : > 500 mg as/kg soil dw
Eisenia fetida	Preparation	Chronic	NOEC = 4 L/ha = 9.92 mg as/kg soil dw corrected for f_{oc}: 4.96 mg as/kg soil dw
Eisenia fetida	Metabolite BF 421-2	Acute	LC_{50} > 1000 mg as/kg soil dw
Field study	Preparation	Chronic	no significant effects on abundance and biomass after 134 days (determination only once at study end) 2.85 mg as/kg
Other soil macro-organisms – not required			
Soil micro-organisms			
Nitrogen mineralisation	a.s. ‡	in loamy sand and sandy loam:	no effect up to 1.0 L or 10 L product/ha (0.75 kg or 7.5 kg as/ha = 1.33 µL or 13.3 µL formulation/kg soil dw)
	Metabolite BF 421-2	in loamy sand:	no effect up to 0.222 mg/kg soil dw or 2.216 mg/kg soil dw
Carbon mineralisation	a.s. ‡	in loamy sand and sandy loam:	no effect up to 1.0 L or 10 L product/ha (0.75 kg or 7.5 kg as/ha = 1.33 µL or 13.3 µL formulation/kg soil dw)
	Metabolite BF 421-2	in loamy sand:	no effect up to 0.222 mg/kg soil dw or 2.216 mg/kg soil dw

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

Test organism	Test substance	Time scale	End point[1]
Field studies[2]			
Decomposition of organic matter (litter bag test)‡ no effects at 2.85 mg as/kg (-7.4 - -11.4 % compared to control). soil: loamy sand soil (48 % sand, C_{org}3.16 %, nitrate N 3.8 mg/kg dry soil, pH 7.9, mean microbial biomass 32.7 mg carbon/100g dry soil. climate during application (29 May and 1 June 01): mean soil T: 24 - 25.1 °C ; 17.1 - 18.8 mean air T: 30 °C; 16 - 21 °C relative humidity: 47 - 48 %; 50 - 61 %			

[1] indicate where end point has been corrected due to log Pow >2.0 (e.g. LC_{50corr})
[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

Toxicity/exposure ratios for soil organisms

Cereals, 2 × 750 g as/ha (50 % interception)

Test organism	Test substance	Time scale	Soil PEC[2] plateau*	TER	Trigger
Earthworms					
Eisenia fetida	a.s. ‡	Acute	b) 2.213	b) > 226	10
Eisenia fetida	Preparation	Chronic	b) 2.213	b) 2.2	5
Eisenia fetida	Metabolite BF 421-2	Acute	0.107	> 9345	10

[1] to be completed where first Tier triggers are breached
[2] indicate which PEC soil was used (e.g. plateau PEC)
* b) pseudo-SFO DT50 from FOMC kinetics,

Sugar beet, 1 × 750 g as/ha (70 % interception)
Acute risk and risk from metabolites covered by assessment for cereals

Test organism	Test substance	Time scale	Soil PEC[2] plateau*	TER	Trigger
Earthworms					
Eisenia fetida	Preparation	Chronic	b) 0,664	b) 7,5	5

[1] to be completed where first Tier triggers are breached
[2] indicate which PEC soil was used (e.g. plateau PEC)
* b) pseudo-SFO DT50 from FOMC kinetics

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

Sunflower, 1 × 600 g as/ha (50 % interception)
Acute risk and risk from metabolites covered by assessment for cereals

Test organism	Test substance	Time scale	Soil PEC[2] plateau*	TER	Trigger
Earthworms					
Eisenia fetida	Preparation	Chronic	b) 0,885	b) 5,6	5

[1] to be completed where first Tier triggers are breached
[2] indicate which PEC soil was used (e.g. plateau PEC)
* b) pseudo-SFO DT50 from FOMC kinetics

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

Species	Parameter	Test Substance	Dose (kg as/ha)	Effect	Trigger *
Limit test, vegetative vigour test, 14 days					
Zea mays	mean plant weight	formulation BAS 421 12 F	1.688	27.6 % reduction**	50 %
Avena sativa				2.9 % reduction n.s.	
Allium cepa				3.5 % reduction n.s.	
Brassica oleracea				23.9 % reduction n.s.	
Pisum sativum				2.2 % reduction n.s.	
Daucus carota				26.0 % reduction n.s.	
Zea mays	visible damage	formulation BAS 421 12 F	1.688	36.3 % n.s.	50 %
Avena sativa				6.3 % n.s.	
Allium cepa				no effect	
Brassica oleracea				25.0 % n.s.	
Pisum sativum				21.3 % n.s.	
Daucus carota				16.3 % n.s.	

* Trigger at field rate according to Sanco/10329/2002
** significant different from control (Dunnett-test, p<0.05), n.s. not significant different from control

Impact on water treatment procedures (Annex IIA, point 8.7)

Oxygen consumption by activated sludge ‡	1000 mg as/L (nominal) highest test conc.: > 20 % inhibition of respiration. EC_{20} respiration: 960 mg as/L.

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

Definition of the Residue

Relevant to the environment	Soil: Fenpropimorph Ground water: At least Fenpropimorph but cannot be finalised Surface water: Fenpropimorph Sediment: Fenpropimorph Air: Fenpropimorph (default)

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	R 51/53, N, dangerous for the environment

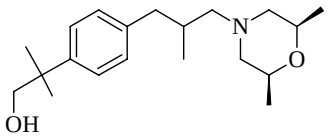
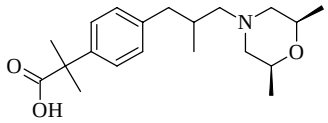
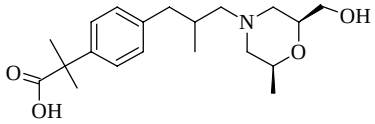
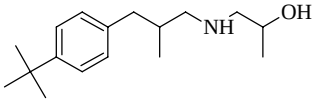
‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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
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
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

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
BF 421-1	2-methyl-2-(4-{(2*RS*)-3-[*cis*-2,6-dimethylmorpholin-4-yl]-2-methylpropyl}phenyl)propan-1-ol	
BF-421-2 fenpropimorph carboxylic acid	2-methyl-2-(4-{(2*RS*)-3-[*cis*-2,6-dimethylmorpholin-4-yl]-2-methylpropyl}phenyl)propanoic acid	
BF 421-3	2-methyl-2-(4-{(2*RS*)-3-[*cis*-2-methy-6-hydroxymethyl-morpholin-4-yl]-2-methylpropyl}phenyl)propanoic acid	
BF-421-7	(2*?*)-1-{[(2*RS*)-3-(4-*tert*-butylphenyl)-2-methylpropyl]amino}propan-2-ol (?=unstated stereochemistry)	
BF 421-10	2,6-dimethylmorpholine