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

fenoxaprop-P

finalised: 29 November 2007

SUMMARY

Fenoxaprop-P 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 a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the EU-Commission.

Austria being the designated rapporteur Member State submitted the DAR on fenoxaprop-P in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 2 May 2005. Following a quality check on the DAR, the peer review was initiated on 22 December 2005 by dispatching the DAR for consultation of the Member States and the sole applicant Bayer CropScience AG. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed on during a written procedure in August – September 2006. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in March 2007.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 14 November 2007 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 herbicide as proposed by the notifier, which comprise foliar spraying to spring and winter-sown varieties of wheat, durum wheat, rye, triticale, spring and winter barley, at rates up to a maximum of 83 g a.s./ha for the control of annual grass weeds, in Northern and Southern Europe, either one application in autumn or one in spring or one application in autumn and one in spring.
The representative formulated product for the evaluation was “Puma S 69EW”, an emulsion oil in water (EW), containing fenoxaprop-P-ethyl as the active substance and mefenpyr-diethyl as safener, registered under different trade names in Europe.

[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)

Adequate 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.

The analytical methods to monitor all compounds given in the respective residue definition for plants are non enantio-selective and are not specific to fenoxaprop-P-ethyl.

Due to a similar toxicological profile in acute, short term, genotoxicity and developmental studies, the long term and reproductive studies performed with fenoxaprop-ethyl were considered sufficiently representative to be used for fenoxaprop-P-ethyl. Fenoxaprop-P-ethyl was rapidly and extensively absorbed, and of low acute toxicity. Nevertheless, the classification with R43 May cause sensitisation by skin contact was proposed. In repeat dose studies, the target organs were the liver and the kidneys. Negative results were obtained in mutagenicity tests, and no evidence of carcinogenic properties was observed in rats, mice or dogs. No effects on the reproductive parameters were noted, but there was some indication of teratogenicity in the rat developmental studies leading to the proposal Toxic to Repr. cat.3, R63?. The acceptable daily intake (ADI) was 0.01 mg/kg bw/day, the acceptable operator exposure level (AOEL) was 0.014 mg/kg bw/day and the acute reference dose (ARfD) was 0.1 mg/kg bw/day, with the use of a safety factor of 100. The estimated operator exposure level is below the AOEL with the use of gloves during mixing/loading and spraying, and coverall during spraying (according to the German model).

The metabolism of fenoxaprop-P-ethyl in cereals is clearly elucidated. Shortly after application the parent compound is hydrolysed to the acid form which is still biologically active. Fenoxaprop-P acid is further degraded by ether cleavage with formation of chlorobenzoxazolone and phenoxypropionic acid moieties, each undergoing conjugation processes. Very early, these moieties represent the major part of the residual content and it is therefore proposed to adopt as residue definition for monitoring and risk assessment the sum of the parent compound and all metabolites containing the chlorobenzoxazolone moiety. The plant residue pattern is covered by the toxicological studies conducted with the parent compound.
Resulting from the early stage of application and of the absence of any translocation potential, residues in grains and straw are expected to be low in mature cereals and supervised residue trials actually demonstrate that they do not exceed analytical limits of quantification (0.02 and 0.05 mg/kg in grains and straw respectively). The MRL in cereals is therefore proposed to be set at the LOQ level. Due to the absence of residues in straw livestock exposure is very low and there is no need to establish a residue definition and MRLs for animal commodities. It must however be noted that if fenoxaprop-P-ethyl is applied later than the latest growth stage of application supported as representative use, significant residues may be present in straw and in this case the transfer of residues to animal products should be reconsidered.
The effect of processing on the residues was not investigated given the low residues in raw grains.
The transfer of soil residues to rotational crops was investigated and concluded to be negligible.

Chronic and acute consumer exposure assessments were conducted and found to be far below the respective toxicological reference values.

In soil under dark aerobic conditions, fenoxaprop-P-ethyl or fenoxaprop-ethyl was rapidly hydrolysed to the active fenoxaprop-P or fenoxaprop. The only major metabolite identified in the route studies was the chlorobenzoxazolone. Also under anaerobic conditions fenoxaprop-P or fenoxaprop was rapidly produced. Under these conditions a major metabolite hydroxy phenoxy propionic acid (HOPP-acid, AE F020686) was identified. Under anaerobic conditions, fenoxaprop-P was moderate persistent, metabolite chlorobenzoxazolone was moderate persistent and anaerobic metabolite hydroxy phenoxy propionic acid was very high persistent under anaerobic conditions. After the experts' meeting, EFSA identified a data gap for the information necessary to address the major anaerobic metabolite HOPP-acid in soil and ground water to address situations were anaerobic conditions are prevalent.

Contribution of photolysis to the degradation of fenoxaprop-ethyl in soil was relevant but limited when compared with degradation under aerobic conditions.

PEC soil for fenoxaprop-P-ethyl, fenoxaprop-P and chlorobenzoxazolone were calculated for the representative use.

From the results of batch soil adsorption / desorption studies fenoxaprop-P-ethyl may be classified as immobile in soil, fenoxaprop-P as medium to low mobile and chlorobenzoxazolone as medium to low mobile.

Hydrolysis of fenoxaprop-P-ethyl at 25 ºC is pH dependent ($DT_{50\ pH\ 4}$ = 2.8 d; $DT_{50\ pH\ 5}$ = 19.2 d; $DT_{50\ pH\ 7}$ = 23.2 d; $DT_{50\ pH\ 9}$ = 0.6 d). Hydrolysis of fenoxaprop-P at 25 ºC is also pH dependent being practically stable at neutral pH ($DT_{50\ pH\ 5}$ = 26.8 d; $DT_{50\ pH\ 7}$ = 182.7 d; $DT_{50\ pH\ 9}$ = 33 d). Main hydrolysis product of fenoxaprop-P is chlrobenzoxazolone (max 37.7 % AR). Chlorobenzoxazolone is hydrolytically stable (DT_{50} > 1 yr).

Aqueous photolysis fenoxaprop-P-ethyl was investigated at 25 ºC in natural surface water (pH 9), and two sterile systems (pH 5 and 6.8). Main photolysis metabolite (not observed in the dark control) was observed at pH 9: AE 0316854 (6-hydroxy-2,3-dyhydro-benzoxazol-2-one, max 27.4 % AR). In the other experiments metabolites found were common to the ones found in the dark control. Half lives calculated assuming 12 h sunshine were between 7.1 d (natural system, pH 9) and 127.8 d (distilled water, pH 6.8). Aqueous photolysis of soil aerobic metabolite chlorobenzoxazolone was also investigated at pH 7 and 25 ºC. A photolysis half life of 1.42 d was observed that could be translated to environmental half lives of 7.4 d to 50.6 d depending on the latitude and season.

Fenoxaprop-P-ethyl and fenoxaprop-P are considered not to be readily biodegradable.

In the two dark aerobic water / sediment systems investigated fenoxaprop-P-ethyl was rapidly hydrolysed to fenoxaprop-P that is subsequently adsorbed to sediment and transformed ($DT_{50\ total\ system}$ = 8.3 – 46.3 d) to HOPP-acid (AE F 096918) and chlorobenzoxazolone (AE F054014). HOPP-acid is subsequently degraded. At the end of the studies (118 199 d), the vast majority of the radioactivity was transformed into unextractable residues (27.4 – 69.1 % AR) and CO_2 (max. 16.9 - 45.9 % AR).

PEC_{SW} were calculated for fenoxaprop-P-ethyl, fenoxaprop-P, chlorobenzoxazolone and HOPP-acid following the FOCUS SW scheme up to Step 2.

For the representative uses proposed none of the calculated concentrations of the potential residue components exceeds the trigger values of 0.1 µg / L.
Long term transport of fenoxaprop-P-ethyl and fenoxaprop-P through the atmosphre is not expected based on their physical and chemical properties.

The risk to birds and mammals, aquatic organisms, bees, other non-target arthropods, soil non-target micro-organisms and biological methods of sewage treatment was assessed as low.
The acute TER values for earthworms were well above the Annex VI trigger for fenoxaprop-P-ethyl and the soil metabolites fenoxaprop-P and chlorobenzoxazolone. No long-term risk assessment was triggered since the DT_{90} in soil is <100 days and the product is applied only once per year. The RMS pointed out that particular attention should be paid to potential long-term effects if fenoxaprop-P-ethyl is applied in regions with lower temperatures where fenoxaprop-P is more persistent. The same applies if fenoxaprop-P-ethyl is used where anaerobic conditions occur. Under anaerobic conditions the metabolites fenoxaprop-P, chlorobenzoxazolone and the HOPP-acid (AE F020686) are assumed to be persistent. The TER for non-target plants in the off-field area was below the trigger of 5 and risk mitigation measures such as a no-spray buffer zone of 5 metres are required.

Key words: Fenoxaprop-P, fenoxaprop-P-ethyl, peer review, risk assessment, pesticide, herbicide

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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, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Fenoxaprop-P is one of the 79 substances of the third stage, part A, covered by the Regulation (EC) No 1490/2002 designating Austria as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Austria submitted the report of its initial evaluation of the dossier on fenoxaprop-P, hereafter referred to as the draft assessment report, to the EFSA on 2 May 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 22 December 2005 to the Member States and the sole applicant Bayer CropScience AG as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives from Member States identified and agreed during a written procedure in 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 information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in expert meetings in 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 with representatives from Member States on 14 November 2007 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 11(4) of the 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 16 October 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 15 November 2007).

Given the importance of the draft assessment report including its addendum (compiled version of August 2007 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

Fenoxaprop-P is the ISO common name for (*R*)-2-[4-(6-chloro-1,3-benzoxazol-2-yloxy)phenoxy]propionic acid or (*R*)-2-[4-(6-chlorobenzoxazol-2-yloxy)phenoxy]propionic acid. However the data submitted in the dossier relate to the variant fenoxaprop-P-ethyl, which is (*R*)-2-[4-(6-chloro-1,3-benzoxazol-2-yloxy)phenoxy]propionate or ethyl (*R*)-2-[4-(6-chlorobenzoxazol-2-yloxy)phenoxy]propionate.

Fenoxaprop-P belongs to the class of aryloxyphenoxypropionic herbicides. It inhibits the lipid biosynthesis of the grasses very rapidly after in vivo application. This effect is based on an efficient inhibition of the enzyme acetyl-CoA carboxylase and thus the de novo synthesis of fatty acids in the plastids of grasses. Fenoxaprop-P is used in post-emergence applications for the selective control of grass weeds in dicotyl crops.
The representative formulated product for the evaluation was "Puma S 69EW", an emulsion oil in water (EW) containing 69 g/l fenoxaprop-P-ethyl as the active substance and 75 g/l mefenpyr-diethyl as safener, registered under different trade names in Europe.

The representative uses evaluated comprise foliar spraying to spring and winter-sown varieties of wheat, durum wheat, rye, triticale, spring and winter barley up to growth stages of BBCH 10-32, to control *Setaria*, *Avena*, *Apera*, *Leptochloa*, *Alopecurus*, *Echinochloa* and other annual grass weeds, in all EU countries, up to maximum 1-2 treatments per year, at a maximum total active substance rate per season of 83 g as/ha either once applied in autumn or spring or one application in autumn and one in spring using 180-400 l/ha water.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of fenoxaprop-P-ethyl is 920 g/kg. No FAO specifications exist.
The data provided in the DAR relate to the variant fenoxaprop-P-ethyl.
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 fenoxaprop-P-ethyl or the respective formulation.
The main data regarding the identity of fenoxaprop-P-ethyl and its physical and chemical properties are given in appendix 1.

Adequate analytical methods are available for the determination of fenoxaprop-P-ethyl, its enantiomeric purity and the impurities (HPLC-UV and GC-FID) in the technical material. A CIPAC method for the determination of chemical and optical purity in the technical material is also available.

As the residue definition for monitoring for plants is sum of fenoxaprop-P-ethyl and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, or alternatively: sum of fenoxaprop-ethyl and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, the available analytical methods are able to monitor only the compounds given in the second residue definition, as they are not enantio-selective. The GC-MSD method is determining fenoxaprop, its esters, salts and metabolites after acetilation as 3-acetyl-6-chloro-2,3-dihydrobenzoxazol-2-one and is neither enantio-selective nor specific to fenoxaprop-P-ethyl.
The multi-residue methods such as DFG S19 or MRM 3 are not suitable for the determination of fenoxaprop-P-ethyl.
Several methods for the determination of fenoxaprop-ethyl and the metabolites fenoxaprop and 6-chloro-2,3-dihydrobenzoxazol-2-one in soil and water exist, however they are not enantio-selective and are not specific to fenoxaprop-P-ethyl. The experts of PRAPeR 16 proposed a data gap for an enforcement method suitable for all soil types/conditions. An LC/MS/MS based enforcement method with a limit of quantification of 0.01 mg/kg was submitted and evaluated in an addendum, however it was not peer reviewed. The method is not enantio-selective and is not specific to fenoxaprop-P-ethyl.
It should be noted that the residue definition is unspecific not only with respect to the racemic mixture fenoxaprop-ethyl but also with respect to other chemicals, as eg. insecticide phosalone, that may potentially be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one upon hydrolysis and give false positive results when determined with these methods.
The methods for residues in air were validated for the determination of fenoxaprop (expressed as fenoxaprop-P) and fenoxaprop-ethyl (expressed as fenoxaprop-P-ethyl) with a limit of quantification of 1 µg/m^3. It should be noted that the method for fenoxaprop would also extract salts of fenoxaprop and being not enantio-selective is not specific to fenoxaprop-P-ethyl.
An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed.

2. Mammalian toxicology

Fenoxaprop-P-ethyl was discussed by the experts in mammalian toxicology in a PRAPeR meeting in March 2007 (PRAPeR 19, round 4). Toxicological data were provided for the active isomer fenoxaprop-P-ethyl but also for the racemic mixture fenoxaprop-ethyl.

Based on the available information (addendum rev.1 to Vol.4, January 2007) two impurities were shown at higher levels in the specification than in the toxicological batches. Considering that they were structurally very similar to the parent and would present a similar or lower toxicity, the experts concluded that the technical specification was covered by the toxicological batches.

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

After oral administration, **fenoxaprop-P-ethyl** was rapidly and extensively absorbed (>80%). Largely distributed, it was mainly concentrated in the kidney, the fatty tissue and the blood, showing a low level of residues after 7 days (max 2% of the applied dose). The metabolism proceeds via hydrolysis of the parent compound to the free acid which may be conjugated and excreted or further degraded by cleavage, and excreted with or without conjugation. The parent compound was found in faeces but not in urine. The main metabolites were the mercapturic acid and the free acid.

ADME studies were also performed with **fenoxaprop-ethyl** and no significant difference in rat metabolism and kinetics was observed between both compounds.

2.2. Acute toxicity

Both **fenoxaprop-P-ethyl** and **fenoxaprop-ethyl** were of low acute toxicity when administered by the oral, dermal or inhalation routes. The oral and dermal LD_{50} were higher than 2000 mg/kg bw/day. The inhalation toxicity studies were not directly comparable since different concentration levels and vehicles were used: the LC_{50} was higher than 1.224 mg/L for fenoxaprop-P-ethyl (highest technically achievable dose) whereas it was higher than 0.475 mg/L for fenoxaprop-ethyl (where one death occurred). Both were slightly irritating to the skin and the eyes but not classified. Fenoxaprop-P-ethyl demonstrated sensitising properties in a maximisation test but was negative in a modified Buehler test where the induction phase was conducted under non-irritating conditions. Fenoxaprop-ethyl did not induce skin sensitisation in a supportive Buehler test with a reduced number of animals. According to these results, the proposed classification for fenoxaprop-P-ethyl is **R43 May cause sensitisation by skin contact**.

2.3. Short term toxicity

The oral short term toxicity of **fenoxaprop-P-ethyl** has been investigated in 28 days and 13 weeks dietary studies in rats, mice and dogs. The target organs were the liver and the kidneys. The rat was the most sensitive species with a NOAEL of 0.7 mg/kg bw/day based on the 13-week study.

Taking into account the results of the 6-month interim sacrifice of the chronic toxicity study, the experts agreed for an overall short term NOAEL of 2 mg/kg bw/day for rats. Considering the dose

spacing in the different mice studies, they agreed for an overall short term NOAEL of 5.5 mg/kg bw/day, based on the interim sacrifice in the carcinogenicity study. In the dog studies, the short term NOAEL was 15.6 mg/kg bw/day based on the 13-week study with decreased body weight gain and clinical chemistry changes.

In repeat-dose studies by inhalation or dermal administration, effects were also observed in the liver, in the kidney and in the haematological parameters with NOAEL values of 0.015 mg/L/day and 20 mg/kg bw/day.

Studies performed with **fenoxaprop-ethyl** gave similar results in rats. In mice, additional target organs were shown (spleen and adrenals) but the effects levels were generally comparable with fenoxaprop-P-ethyl. The results of the dog studies with fenoxaprop-P-ethyl and fenoxaprop-ethyl showed no consistent pattern of effects.

2.4. GENOTOXICITY

Fenoxaprop-P-ethyl gave negative results in a battery of *in vitro* and *in vivo* genotoxicity tests including gene mutation, chromosome aberration and DNA repair *in vitro* as well as *in vivo* micronucleus assay. The use of different batches (with lower purity of the D-isomer) was considered not to affect the final outcome of the studies since the chemical purity of the two batches (sum of D+L isomers) was nearly the same, and similar genotoxicity tests with **fenoxaprop-ethyl** were also negative (both *in vitro* and *in vivo*). In conclusion, both test substances were considered non genotoxic.

2.5. LONG TERM TOXICITY

No long term study has been provided for fenoxaprop-P-ethyl. However, the chronic/carcinogenicity studies performed with **fenoxaprop-ethyl** have been used as bridging data since the two compounds showed a similar profile in acute and short term studies.

The long term toxicity of fenoxaprop-ethyl has been tested in rats, mice and dogs (2-year studies). Hepatocellular tumours were observed in increased incidences in mice but were shown to be due to a highly species-specific mechanism of peroxisome proliferation. No carcinogenic potential was observed in the other species. The rat NOAEL was 1.6 mg/kg bw/day, the mouse NOAEL was 5.67 mg/kg bw/day and the dog NOAEL was 1.1 mg/kg bw/day based on reduced body and organ weights at the highest dose (4.6 mg/kg bw/day).

2.6. REPRODUCTIVE TOXICITY

Rat multigeneration studies

No multigeneration study has been performed with fenoxaprop-P-ethyl. As the short term and developmental toxicological profiles of fenoxaprop-P-ethyl and fenoxaprop-ethyl were similar with comparable effect levels, it was considered justified to use the multigeneration study with fenoxaprop-ethyl for the evaluation of the reproductive toxicity of fenoxaprop-P-ethyl.

In the available study with **fenoxaprop-ethyl**, no effect on reproduction parameters, fertility or offspring development were observed. Based on organ weight changes (liver and kidney) and clinical

chemistry parameters, in addition to reduced body weight gain in the offspring during lactation, the parental and the offspring NOAELs were 1.42 mg/kg bw/day whereas the reproductive NOAEL was 8.77 mg/kg bw/day.

Teratogenicity/developmental studies

In the developmental rat study with **fenoxaprop-P-ethyl**, the maternal NOAEL was 32 mg/kg bw/day based on decreased body weight gain. In foetuses, weak or non-ossification of at least one cranial bone was increased at 32 and 100 mg/kg bw/day, slightly above the historical control data. Therefore the foetal NOAEL was 10 mg/kg bw/day and the experts agreed to highlight the concern about the developmental effects with the proposal **Toxic to Repr. cat.3, R63?**. In a developmental study with rabbits, the maternal and foetal NOAELs were 32 mg/kg bw/day, while there was no indication of teratogenicity.

The teratogenic potential of **fenoxaprop-ethyl** was studied in rats, rabbits, mice and monkeys, and in a study for embryotoxicity and postnatal development in rats. From the rat studies, a maternal and foetal NOAEL of 32 mg/kg bw/day could be established, in the absence of any teratogenic effect. In the two rabbit studies, the NOAEL for maternal and foetal toxicity was 10 mg/kg bw/day. An evidence of teratogenicity (diaphragmatic hernias) was observed at the high dose (200 mg/kg bw/day) in the first study but was questionable as a single case at the high dose (50 mg/kg bw/day) in the second study. In mice, no foetotoxicity or teratogenicity was observed and the maternal NOAEL was 10 mg/kg bw/day while the foetal NOAEL was 50 mg/kg bw/day. The study with monkeys was of limited validity and no NOAELs were established.

2.7. NEUROTOXICITY

According to the available acute, subchronic and chronic studies, there was no indication of a neurotoxic potential (neither neurobehavioural changes nor any morphological changes in the CNS or in the peripheral nerves).

2.8. FURTHER STUDIES

Drug-metabolizing enzymes were only changed at high dose levels and not consistently, giving only weak indication of an induction of the hepatic drug-metabolizing system. In contrast, catalase activity was clearly increased in mice, pointing to induction of peroxisome proliferation. In rats, elevation of catalase activity was observed at higher doses. In dogs, catalase activity was not determined.

In a study with combined administration, there was no influence of the safener mefenpyr-diethyl on the excretion or metabolism of fenoxaprop-P-ethyl.

A combined administration of fenoxaprop-P-ethyl with the safener mefenpyr-diethyl (ratio 2:1) in a 13-week rat dietary rat study revealed a slight increase in hepatotoxicity, considered as reflecting a change in the sensitivity of the rat strain. The resulting NOAEL was 0.74 + 0.37 mg/kg bw/day (a.s. + safener).

2.9. MEDICAL DATA

No substance-related changes have been indicated by clinical or laboratory examination and no adverse effects on health have been recorded among industrial workers or during experimental agricultural use.

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

With regard to the reference values, the results from long term and reproduction studies conducted with fenoxaprop-ethyl were used for fenoxaprop-P-ethyl due to the similar toxicological profile observed in toxicokinetics, acute/subchronic toxicity, genotoxicity and developmental toxicity for both compounds. Therefore, the agreed **ADI** was 0.01 mg/kg bw/day based on the 2-year dog study supported by the 2-year and multigeneration rat studies, and with the use of a safety factor of 100. The agreed **AOEL** was 0.014 mg/kg bw/day based on the multigeneration study in rats supported by the 2-year dog study, and with the use of a safety factor of 100.

In the initial DAR, the rapporteur Member State considered that an **ARfD** was not necessary. However, the experts agreed to set the ARfD at 0.1 mg/kg bw based on the foetal NOAEL from the rat developmental study with the use of a safety factor of 100.

EFSA notes that these values are applicable to fenoxaprop-P-ethyl and fenoxaprop-ethyl since a similar toxicological profile has been demonstrated and bridging studies with fenoxaprop-ethyl were used to assess the long term and the reproductive toxicity of fenoxaprop-P-ethyl.

2.11. DERMAL ABSORPTION

The *in vivo* study was performed with Puma (representative formulation) while the *in vitro* study was performed with another formulation Cheetah. After comparison, the two formulations were considered sufficiently similar to allow a read-across of dermal absorption results. The agreed dermal absorption values were 1.6% for the concentrate and 36% for the dilution.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product Puma S69EW (oil in water emulsion) contains 69 g fenoxaprop-P-ethyl/L and 71.5 g mefenpyr-diethyl/L, a safener.

EFSA notes: the risk assessment has been conducted for the single active substance fenoxaprop-P-ethyl. The combined exposure and risk assessment for fenoxaprop-P-ethyl and the safener mefenpyr-diethyl have to be taken into account at a member state level since there is no agreed procedure. Consequently the risk assessment for the formulation cannot be concluded for the operators, workers and bystanders.

Operator exposure

The representative use includes a maximum dose of 0.083 kg fenoxaprop-P-ethyl/ha, a minimum volume of 180 L water/ha, and an application by tractor mounted boom sprayers using standard nozzles. The estimated exposures are provided in the table below.

Estimated exposure presented as % of AOEL (0.014 mg/kg bw/day), according to calculations with the German BBA and UK POEM models. The default for body weight of operator is 70 kg in the German model and 60 kg in the UK-POEM model. As worst case, a container size of 1L has been considered in the UK POEM.

Model	Without PPE	With PPE[1]	With PPE[2]
German BBA	131	102	9
UK POEM	901	134	-

PPE[1]: (personal protective equipment): gloves during mixing/loading and spraying

PPE[2]: gloves during mixing/loading and spraying, coverall during spraying

Worker exposure

With a re-entry scenario for crop inspection (Hoernicke et al., 1998), the estimated exposure was 38% of the AOEL. The experts agreed that this was not a realistic scenario since an exposure of 8h was considered whereas the duration of crop inspection is usually shorter.

Bystander exposure

Calculations with an exposure scenario according to Lloyd and Bell (1983) demonstrate that a short exposure of bystanders outside the treatment areas is 2.3% of the AOEL.

3. Residues

Fenoxaprop-P-ethyl was discussed at the PRAPeR experts' meeting for residues (PRAPeR 20) in March 2007.

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

Metabolism studies were conducted in wheat, barley and rice with fenoxaprop-P-ethyl as well as with the racemic substance fenoxaprop-ethyl. The substances were labelled either in the chlorophenyl ring or the dioxyphenyl ring to provide complete information on the degradation profile. Considering the selected mode and time of application, the information provided by these studies covers the supported representative use of fenoxaprop-P-ethyl in cereals.

There is no translocation of residues to newly formed leaves or other plant parts. At harvest, after application of fenoxaprop-P-ethyl at early tillering stage of wheat, total radioactive residues (TRR) in grains and straw were below the limit of quantification (LOQ, 0.004 and 0.011 mg/kg for grains and straw respectively).

Due to the rapid metabolism of the active substance, the metabolic pathway was determined on early growth stage of the cereal plants within 10 days following the application. There is no obvious difference in the metabolic behaviour of the racemic compound and the P-enantiomer. In both cases the active substance is converted in the plant via ester hydrolysis to fenoxaprop or fenoxaprop-P, which is still biologically active. After 7 days only 10 % of the applied active substance remains unchanged on cereal plants. Further metabolism proceeds through cleavage of the ether-linkage

between the benzoxazolone and the phenoxy- moieties of the substance. From 2 to 7 days after application compounds resulting from this cleavage (chlorobenzoxazolone[2] and 2-(4-hydroxyphenoxy)-propionic acid, as free or conjugated forms) appear as major constituent of the residue. The same residue pattern was observed in wheat and rice.

The influence of the safener mefenpyr-diethyl on the metabolism of fenoxaprop-P-ethyl was investigated on barley shoots and it was shown that the metabolic profile was independent of the presence or absence of the safener.

It was also shown that no racemisation either of the parent compound or the free acid occurs during plant metabolism.

The rat metabolism proceeds through the same major steps as plant metabolism and it can be considered that the plant metabolism is covered by the toxicological studies conducted with the parent compound. Considering this, and based on the fact that the parent compound and its free acid form cannot be considered as valid indicator of the residue situation at harvest, the residue definition for monitoring and risk assessment is proposed to include the parent compound and all metabolites containing the chlorobenzoxazolone moiety, expressed as fenoxaprop-P-ethyl.

Considering that the unavailability of an enantio-selective method of analysis may cause problems at management level, EFSA is of the opinion that an optional residue definition for monitoring could be set as the sum of fenoxaprop-ethyl and all metabolites containing the chlorobenzoxazolone moiety, expressed as fenoxaprop-ethyl, considering that toxicological reference values concluded for fenoxaprop-P-ethyl are evenly valid for fenoxaprop-ethyl. This extension of the residue definition does not alter the safety of the consumer.

Twelve supervised residue trials in Northern Europe and 2 in Southern Europe on various cereals (wheat, rye and barley) were conducted with application of fenoxaprop-P-ethyl at growth stage BBCH 29-31, reflecting adequately the supported representative use. In all these trials residues were analysed with a common moiety method of analysis covering all compounds, conjugates included, containing the chlorobenzoxazolone structure. All samples of grains and straw contained residues below the LOQ level (0.02 and 0.05 mg/kg in grains and straw respectively). Additional trials were conducted in the Mediterranean region with application at later growth stages, again with residues in the grain below the LOQ. The data base is therefore sufficient to conclude that residues above the LOQ are not expected in grains.

However these additional trials showed measurable residues in the straw samples (up to 0.89 mg/kg when fenoxaprop-P-ethyl was applied at growth stage BBCH 39). The need for a residue definition in animal products, and of metabolism/feeding studies reflecting the actual residue pattern animals may be exposed to through consumption of straw, should therefore be reconsidered at Member State level in case of authorisation for use at later growth stage than those peer-reviewed.

The reliability of the supervised residue trials is supported by storage stability studies showing that the total amount of residues containing the chlorobenzoxazolone moiety is stable under deep-freeze conditions for at least 14 months.

[2] chlorobenzoxazolone: 6-chloro-2,3-dihydrobenzoxazol-2-one

Studies on the effect of processing on residues are not regarded as necessary because no residue was found above the LOQ in cereal grains and the potential consumer exposure is far below the toxicological reference values.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

The possible uptake of soil residues by rotational crops was investigated by 2 confined rotational crop studies, one with fenoxaprop-P-ethyl, and the other with the racemic compound fenoxaprop-ethyl. TTR in plants, sown 30 days, 120 days and one year after application at normal use rate were below the LOQ for all crops tested (leafy vegetables, root vegetables and cereals). Considering this, field trials in rotational crops are not regarded as necessary and no related label restriction is needed.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

Supervised residue trials show that when fenoxaprop-P-ethyl is applied in cereals up to BBCH growth stage 31, no residues of the parent compound and its metabolites above the LOQ are expected in grains and straw. Therefore livestock exposure is negligible and animal metabolism studies as well as MLRs in animal commodities are not required.

Nevertheless the notifier submitted studies performed in lactating goats and laying hens with the racemic substance fenoxaprop-ethyl. These studies suggest that livestock and rat metabolisms are similar.

In addition to this, a ruminant feeding study was conducted with animals fed with a mixture of the racemic substance fenoxaprop-ethyl and chlorobenzoxazolone. This study shows that up to a dietary burden of 0.2 mg fenoxaprop-ethyl equivalent/kg feed, total residues in edible ruminant commodities are below the LOQ level (0.01 mg/kg).

3.3. CONSUMER RISK ASSESSMENT

No risk for the consumer is expected resulting from the use of fenoxaprop-P-ethyl according to the representative uses supported in cereals.

Chronic exposure

Theoretical Maximum Daily Intake (TMDI) was calculated using the WHO guidelines. The typical European diets for adult consumers and the German diet for the 4-6 year old girl were used. Residue levels in cereal grains were considered to be at the level of the LOQ proposed as MRL (0.02 mg/kg). No exposure from animal commodities was considered as residues are negligible in these commodities. Based on this, the calculated TMDI were below 5 % of the ADI in both considered populations of consumer.

Acute exposure

Considering the toxicological end point used for setting the ARfD, only adult consumers need to be considered in the acute dietary risk assessment. National Estimates of Short Term Intakes (NESTI) were carried out by the RMS on the basis of UK national consumption data for adults. Residues in

cereals were considered to be at the level of the LOQ proposed as MRL. No variability factor needs to be used for cereals. Based on this, calculated NESTIs for adults were below 1 % the ARfD for all cereal commodities.

3.4. PROPOSED MRLS

Based on the submitted supervised residue trials it is proposed to set the MRL for cereals at the LOQ level (0.02* mg/kg).

4. Environmental fate and behaviour

Fenoxaprop-P-ethyl was discussed at the PRAPeR experts' meeting for fate and behaviour in the environment (PRAPeR 17) in March 2007.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

Route of degradation of fenoxaprop-P-ethyl was investigated in three separated studies under dark aerobic conditions with the compound ^{14}C labelled at the chlorophenyl ring (2 studies, 4 soils at 20 ºC and 1 soil at 11 and 21 ºC: pH_{CaCl2} 5.2 – 5.8; OM 1.2 – 4.5 %; clay 6.9 - 11.6 %) and the fate of fenoxaprop-ethyl (racemic mixture) with the compound ^{14}C labelled at the dioxyphenyl ring (1 study, 2 soils at 22 ºC: pH_{CaCl2} 6.9 – 7.0; OM 1.6 – 8.11 %; clay 2.1 – 22.4 %). In these studies, fenoxaprop-P-ethyl or fenoxaprop-ethyl was rapidly hydrolysed to the active fenoxaprop-P or fenoxaprop (max. 81.1 % AR after 3 d). The only major metabolite identified in the route studies was the **chlorobenzoxazolone** (AE F054014, max. 19.1 % after 15 d). Unextractable residue was in the range of 34.9 - 70 % AR and mineralization in the range of 9.7 – 32.5 % AR after 100 d in the experiments performed with the compound ^{14}C labelled at the chlorophenyl ring. Unextractable residue was in the range of 28.2 – 32.1 % AR and mineralization in the range of 44.8 – 54.6 % AR after 64 d in the experiments performed with the compound ^{14}C labelled at the dioxyphenyl ring.

During the expert's meeting the need to investigate the degradation of fenoxaprop-P in alkaline soils to determine the possible formation of the metabolite *p*-chloro-*o*-phenolaniline was discussed. This concern was raised by the observation that chlorbenzoxazolone metabolite is rapidly degraded in alkaline soils used to investigate adsorption /desorption in soil, eventually giving rise to subsequent transformation products. Further information on these adsorption /desorption experiments including recoveries were provided by the RMS in an addendum. It was observed that most of the radioactivity resulting form the degradation of the chlorobenzoxazolone metabolite in these studies was unextractable residue. It was concluded by the meeting that this un-extractable residue do not deserves further assessment for potential groundwater contamination (since at any case should be a practically immobile residue) and that a further study was not required since it was considered high unlikely that could result in the identification of new metabolites.

Degradation of fenoxaprop-P-ethyl ^{14}C labelled at the chlorophenyl ring and fenoxaprop-ethyl (racemic mixture) ^{14}C labelled at the dioxyphenyl ring was also investigated under dark anaerobic

conditions at 20 ºC in one soil (pH_{CaCl2} 5.4; OC 2.11 %; clay 8.8 %). Also under anaerobic conditions fenoxaprop-P was rapidly produced (max. 93.9 % after 2 d). Under these conditions a major metabolite **HOPP-acid** (hydroxy phenoxy propionic acid, AE F020686; max. 74.1 % after 120 d) was identified. Unextractable residue amounted for 73.7 % AR after 266 d in the experiment with compound ^{14}C labelled at the chlorophenyl ring and a max. of 14.5 % AR in the experiment with the product ^{14}C labelled at the dioxyphenyl ring. Mineralization was low (CO_2 = 7.8 % AR after 266 d) in the experiment with compound ^{14}C labelled at the chlorophenyl ring but considerably higher for the dioxyphenyl ring moiety (CO_2 = 31.9 % AR after 266 d). After the experts' meeting, EFSA identified a data gap for the information necessary to address the major anaerobic metabolite HOPP-acid in soil and ground water to address situations were anaerobic conditions are prevalent.

Photodegradation was only investigated with the racemic mixture fenoxaprop-ethyl at 25 ºC under filtered xenon lamp light simulating sunlight (at 53 ºN) in one soil (pH_{CaCl2} 7.3; OM 0.45 %; clay 19.5 %).

Contribution of photolysis to the degradation of fenoxaprop-ethyl in soil was relevant but limited when compared with degradation under aerobic conditions. Fenoxaprop (acid) was not detected in this study which may suggest an enhanced degradation of this compound under irradiated conditions. However, this effect is not expected to have a impact on the risk assessment since no new major metabolites are observed.

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

Rate of degradation of fenoxaprop-P-ethyl, fenoxaprop and its major aerobic soil metabolite was investigated in the same studies used to investigate the route of degradation. The data were analyzed with a multicompartmental fitting to SFO kinetics with TOP Fit model. Experts' meeting discussed the adequacy of this multicompartmental fitting. Good agreement between the results of this kinetic analysis and more simplistic approaches was noted. The experts' meeting concluded that the kinetic parameters derived from the multicompartmental analysis were adequate to be used in modelling for risk assessment.

Fenoxaprop-P-ethyl was very low persistent in soil under aerobic conditions ($DT_{50\ lab\ 20\ °C}$ = 0.02 – 0.8 d) and was rapidly converted to fenoxaprop-P that was low to moderately persistent ($DT_{50\ lab\ 20\ °C}$ = 2.2 – 13.3 d). Metabolite chlorobenzoxazolone was also low to moderately persistent in soil under aerobic conditions ($DT_{50\ lab\ 20\ °C}$ = 5 – 14.8 d).

Kinetics of the degradation study under anaerobic conditions was also analyzed with a multicompartmental model using TopFit 2.0. According this analysis fenoxaprop-P-ethyl was very low persistent ($DT_{50\ lab\ anerob.\ 20\ °C}$ = 0.34 d), fenoxaprop-P was moderate persistent ($DT_{50\ lab\ anerob.\ 20\ °C}$ = 36.6 d), metabolite chlorobenzoxazolone was moderate persistent ($DT_{50\ lab\ anerob.\ 20\ °C}$ = 57.5 d) and anaerobic metabolite hydroxy phenoxy propionic acid was very high persistent ($DT_{50\ lab\ anerob.\ 20\ °C}$ > 250 d) under anaerobic conditions.

A number of field studies were provided by the applicant in the original dossier. These studies were considered not acceptable by the RMS. Results of laboratory experiments do not trigger further field dissipation studies.

PEC soil for fenoxaprop-P-ethyl, fenoxaprop-P and chlorobenzoxazolone were calculated for the representative use with worst case laboratory half lives and maximum amount observed in degradation studies corrected for the molecular weight.

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

Batch soil adsorption / desorption studies are available for fenoxaprop-P-ethyl (two studies, 8 soils: pH_{CaCl2} 5.4 – 7.6; OM 0.4 – 4.56 %; clay 11.4 – 65.6 %), fenoxaprop-P (one study, 5 soils: pH_{CaCl2} 4.7 – 7.4; OM 0.92 – 4.5 %; clay 6.0 – 32.2 %) and major soil aerobic metabolite chlorobenzoxazolone (one study, 5 soils: pH_{CaCl2} 4.5 – 6.0; OM 0.92 – 3.56 %; clay 6.8 – 40 %). In these studies fenoxaprop-P-ethyl and the aerobic metabolite chlorobenzoxazolone were instable in neutral and alkaline soil. Fenoxaprop-P-ethyl may be classified as immobile in soil (K_{OC} = 5419 – 26207 mL / g), fenoxaprop-P as medium to low mobile (K_{OC} = 145 – 568 mL / g) and chlorobenzoxazolone as medium to low mobile (K_{OC} = 296 - 537 mL / g). Only values obtained with the parent fenoxaprop-P (Ruppecht, J.K. (1999)) and the parent chlorobenzoxazolone (Allan J.G. (1999)) were considered by the RMS reliable for use in further exposure assessments.

Two column leaching studies are available with formulated fenoxaprop-P-ethyl where fresh and aged residues leaching behaviour was examined are available.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

Hydrolysis of fenoxaprop-P-ethyl, fenoxaprop-P and chlorobenzoxazolone was investigated in three separated studies in aqueous buffer solutions at pH 4, 5, 7 and 9 at 20, 25 40 and 50 ºC. Hydrolysis of fenoxaprop-P-ethyl at 25 ºC is pH dependent ($DT_{50\ pH\ 4}$ = 2.8 d; $DT_{50\ pH\ 5}$ = 19.2 d; $DT_{50\ pH\ 7}$ = 23.2 d; $DT_{50\ pH\ 9}$ = 0.6 d). Under acidic conditions main hydrolysis product is chlorobenzoxazolone whereas in alakaline conditions fenoxaprop-P is also detected. Hydrolysis of fenoxaprop-P at 25 ºC is also pH dependent being practically stable at neutral pH ($DT_{50\ pH\ 5}$ = 26.8 d; $DT_{50\ pH\ 7}$ = 182.7 d; $DT_{50\ pH\ 9}$ = 33 d). Main hydrolysis product of fenoxaprop-P is chlorobenzoxazolone (max 37.7 % AR). Chlorobenzoxazolone is hydrolytically stable (DT_{50} > 1 yr) in the range of pH (4-9) and temperatures (25 – 50 ºC) tested.

Aqueous photolysis fenoxaprop-P-ethyl was investigated at 25 ºC in natural surface water (pH 9), and two sterile systems (pH 5 and 6.8) in SUNSET photoreactors with a filtered xenon lamp and light intensities three times mean intensity at 52 ºN in June. Main photolysis metabolite (not observed in the dark control) was observed at pH 9: AE 0316854 (6-hydroxy-2,3-dyhydro-benzoxazol-2-one, max 27.4 % AR). In the other experiments metabolites found were common to the ones found in the dark control. Half lives calculated assuming 12 h sunshine were between 7.1 d (natural system, pH 9) and 127.8 d (distilled water, pH 6.8). Aqueous photolysis of soil aerobic metabolite chlorobenzoxazolone was also investigated at pH 7 and 25 ºC in a similar experiment. A photolysis half life of 1.42 d was observed that could be translated to environmental half lives of 7.4 d to 50.6 d depending on the

latitude and season. The only major aqueous photolysis metabolite identified was AE 0316854 (max. 32.2 % AR).

No readily biodegradation study is available. Fenoxaprop-P-ethyl and fenoxaprop-P is considered not to be readily biodegradable.

Two dark aerobic water sediment studies are available that investigated the degradation/dissipation of fenoxaprop-P-ethyl ^{14}C labelled either in the chlorophenyl ring or the dioxyphenyl ring in a total of four water / sediment systems (pH $_{water}$ = 6.6 – 8.0; pH $_{sed}$ = 5.1 – 7.9). In all the systems fenoxaprop-P-ethyl was rapidly hydrolysed ($DT_{50\ total\ system}$ = 0.1 – 0.32 d) to **fenoxaprop-P** (max. $_{water}$ = 97.2 % AR) that is subsequently adsorbed to sediment (max. $_{sed}$ = 26.8 %) and transformed (DT50 $_{total\ system}$ = 8.3 – 46.3 d) to **HOPP-acid** (AE F 096918, max $_{water}$ = 22.9 % AR; max. $_{sed.}$ = 3.4 % AR) and chlorobenzoxazolone (AE F054014, max $_{water}$ = 5.0 % AR; max $_{sed}$ = 1.5 % AR). HOPP-acid is subsequently degraded ($DT_{50\ total\ system}$ = 10.7 – 24.6 d). At the end of the studies (118 199 d), the vast majority of the radioactivity was transformed into unextractable residues (27.4 – 69.1 % AR) and CO_2 (max. 16.9 - 45.9 % AR).

A dark anaerobic water-sediment study was also provided in the dossier but has not been used in for the EU risk assessment.

PEC_{SW} were calculated for fenoxaprop-P-ethyl, fenoxaprop-P, chlorobenzoxazolone and HOPP-acid following the FOCUS SW scheme up to Step 2. Geometric mean of soil and total water – sediment systems half lives were used in these calculations.

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

Potential contamination of ground water was assessed by calculation of the 80th percentile annual average predicted concentration of fenoxaprop-P-ethyl, fenoxaprop-P and chlorobenzoxazolone in the leachate at 1m depth on the relevant FOCUS scenarios employing FOCUS PELMO vs. 2.2.2. model. For the representative uses proposed none of the calculated concentrations of the potential residue components exceeds the trigger values of 0.1 µg / L.

4.3. FATE AND BEHAVIOUR IN AIR

A very low vapour pressure was determined for fenoxaprop-P-ethyl, which is expected to be even lower for the acidic form fenoxaprop-P. Based on reaction with OH radicals tropospheric half life of fenoxaprop-P-ethyl was calculated to be 13.4 h and tropospheric half life of fenoxaprop-P was 3.4 h. Long term transport of fenoxaprop-P-ethyl and fenoxaprop-P through the atmosphere is not expected.

5. Ecotoxicology

Fenoxaprop-P-ethyl was discussed at the PRAPeR experts' meeting for ecotoxicology (PRAPeR 18) in March 2007. An assessment of the compliance of the batches used in the ecotox tests with the technical specification was included in the addendum to Vol. 4 of January 2007. The experts agreed to the conclusion of the RMS that the ecotox batches cover the technical specification.

5.1. RISK TO TERRESTRIAL VERTEBRATES

Birds and mammals may be exposed to fenoxaprop-P-ethyl by eating contaminated vegetation, insects, earthworms or vertebrate prey. Additionally the risk from ingestion of contaminated drinking water was considered. Available acute toxicity studies indicate that the formulation may be more toxic than the technical material itself.

The risk to generic species, representing large herbivorous birds, insectivorous birds, small herbivorous mammals as well as insectivorous mammals, was assessed according to SANCO/ 4145/2000 for the use of 0.083 kg/ha fenoxaprop-P-ethyl in cereals. The first tier assessment indicates a low risk to birds and insectivorous mammals. The long-term risk assessment for small herbivorous mammals was refined based on actual residue levels and decline in cereal shoots. The resulting TER value is 5.4 which is above the Annex VI trigger. Hence the risk is considered as low.

In the toxicological evaluation it was concluded that the toxicological profile of the racemat and fenoxaprop-P-ethyl is fully comparable for mammals.

A worst case assessment of exposure via contaminated drinking water was conducted based on ingestion of spray liquid diluted 5 times. The TER values are well above the trigger for both birds and mammals when based on the toxicity endpoint for the fenoxaprop-P-ethyl. The acute TER is >5.6 when based on toxicity of the formulation. Since no mortality was observed at the highest dose tested the risk is considered to be low. Also the risk for secondary poisoning via earthworms or fish is low.

Since the $logP_{ow}$ for fenoxaprop-P-ethyl is >3 a potential for bioaccumulation is indicated. However a rapid conversion to the free acid, with a much lower $logP_{ow}$, takes place in animals. The TER values calculated according to SANCO/4145/2000 are also well above the triggers indicating a low risk.

Three metabolites, free acid fenoxaprop-P, chloro-benzoxalone and M2 were determined at concentrations >10%TRR in cereals. The free acid and chloro-benzoxalone were also identified in poultry and rat metabolism studies and therefore the toxicity is considered to be covered by the studies with fenoxaprop-P-ethyl. M2 is a conjugate and was considered as not relevant.

5.2. RISK TO AQUATIC ORGANISMS

Fenoxaprop-P-ethyl is acutely very toxic to fish, aquatic invertebrates and algae and toxic to *Lemna gibba*. However, for the intended use with an application rate of 83 g/ha in cereals the acute TER values are above the Annex VI trigger based on FOCUS step 2 PEC_{sw}, hence indicating a low risk. Also the long-term risk to aquatic organisms is considered low based on toxicity of the technical material, while the long-term TER for *Daphnia* based on the toxicity of the formulation from a static renewal study is 9. Since the TER value based on the endpoint from a static study meets the trigger (TER=12) no risk mitigation measures are considered necessary.

Fenoxaprop-P-ethyl did not partition into sediment at amounts of >10% in the water/sediment studies. However, a study with *Chironomus riparius* was made available. The TER values indicated a low risk for sediment dwelling arthropods.

The bioconcentration factor for whole fish was determined to 338. The clearance time CT_{50} was determined as 0.4 days and only 1% was present as residue after 14 days of depuration. The risk for bioaccumulation was therefore considered to be low.

Available studies with fish, Daphnia and algae show that the major metabolites in water (fenoxaprop-P and HOPP-acid) and in soil (chlorobenzoxazolone) are less toxic than the parent substance. The TER values based on FOCUS step2 PECsw are well above the Annex VI trigger values of 100 and 10.

5.3. RISK TO BEES

Bees may be exposed to fenoxaprop-P-ethyl by over spraying, by ingestion of contaminated nectar and honey dew and by contact with residues on plants from the use of Puma S 69EW. The HQ values obtained from the first tier oral and contact toxicity studies with fenoxaprop-P-ethyl and the formulated product are clearly below the Annex VI trigger of 50 and hence the risk to bees is considered to be low from the evaluated representative use.

5.4. RISK TO OTHER ARTHROPOD SPECIES

The in-field and off-field risk to non-target arthropods from the use of Puma S 69EW in cereals is considered to be low based on HQ calculations using ER_{50} values from glass plate studies with the two standard species *Aphidius rhopalosiphi* and *Typhlodromus pyri*. In-field HQ values are 1.8 and <1 respectively and hence no off-field risk is expected. No significant effects were observed on *Crysoperla carnea* in a glass plate study. Additional data on three species of ground-dwelling species with a slightly different formulation of fenoxaprop-P-ethyl indicate that no significant effects are expected from the intended use of fenoxaprop-P-ethyl.

5.5. RISK TO EARTHWORMS

Acute toxicity studies are available with fenoxaprop-P-ethyl, the soil metabolites fenoxaprop-P (AE F088406) and chlorobenzoxazolone (AE F054014) and a formulation which was concluded to be comparable to the lead formulation Puma S 69EW. TER values were calculated based on PEC for soil assuming an application rate of 83 g fenoxaprop-P-ethyl/ha, 25% crop interception and incorporation into a 5 cm soil layer with a density of 1.5 g/cm^3. All TER values are far above the Annex VI trigger of 10 indicating a low risk. No chronic studies are required since TER acute >10, only one application is intended and DT_{90} in soil is <100 days. However, the RMS points out that particular attention chould be payed to possible long term effects if fenoxaprop-P-ethyl is applied in colder regions as at lower temperatures fenoxaprop-P may be persistent. The same applies if fenoxaprop-P-ethyl is used where anaerobic conditions occure (e.g. autumn application). Under anaerobic conditions the

metabolites fenoxaprop-P, chlorobenzoxazolone and the HOPP-acid (AE F020686) seem to be persistent.

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

Studies on other soil non-target macro-organisms and organic matter breakdown are not triggered in case of fenoxaprop-P-ethyl and its major metabolites. Low risk is indicated with regard to earthworms and non-target arthropods and the parent compound as well as its soil metabolites are not persistent under standard conditions (aerobic, 20° C).

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The effects on soil respiration and nitrification were tested with fenoxaprop-P-ethyl and a formulation which was concluded to be comparable to the lead formulation Puma S 69EW. No deviation >25% from the control was observed and hence the risk is considered low. Since fenoxaprop-ethyl and fenoxaprop-P are rapidly degraded it was considered likely that the effects from the metabolite chlorobenzoxazolone were covered by the available studies.

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

Effects on vegetative vigour and seedling emergence and growth were tested with the lead formulation Puma S 69EW. The most sensitive of the species and parameters tested was corn biomass (*Zea mays*) determined in the vegetative vigour test. Based on this a TER of 3.5 was calculated for a distance of 1 m (2.77% drift) from the treated field. Thus risk mitigation measures like 5 m buffer zones or drift reducing nozzles are required to protect off-field non-target plants.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

Data from a test with fenoxaprop-P-ethyl on effects on activated sludge respiration rate are available. The EC50 was > 1000 mg fenoxaprop-p-ethyl/L. It is not expected that fenoxaprop-P-ethyl would reach sewage treatment plants in amounts exceeding 1000 mg fenoxaprop-P-ethyl/L if applied according to the GAP.

6. Residue definitions

Soil

Definitions for risk assessment: fenoxaprop-P-ethyl, fenoxaprop-P, chlorobenzoxazolone and HOPP-acid (when anaerobic conditions are prevalent).

Definitions for monitoring: fenoxaprop-P or alternatively fenoxaprop (unspecific) expressed as fenoxaprop-P ethyl.

However, the methods submitted but not peer reviewed only allow monitoring according to the following residue definition: sum of fenoxaprop-P-ethyl, fenoxaprop-ethyl, fenoxaprop-P, fenoxaprop and all metabolites which may be converted to 6-chloro-benzoxazolone, expressed as fenoxaprop-P-

ethyl. Risk managers should be alerted that this residue definition is unspecific not only with respect to the racemic mixture fenoxaprop-ethyl but also with respect to other chemicals as insecticide phosalone that may potentially contaminate the sample.

Water

Ground water

Definitions for exposure assessment: fenoxaprop-P-ethyl, fenoxaprop-P, chlorobenzoxazolone and HOPP-acid (when anaerobic conditions are prevalent).

Definitions for monitoring: fenoxaprop-P or alternatively fenoxaprop (unspecific) expressed as fenoxaprop-P ethyl.

However, the methods available only allow monitoring according to the following residue definition: sum of fenoxaprop-P-ethyl, fenoxaprop-ethyl, fenoxaprop-P, fenoxaprop and all metabolites which may be converted to 6-chlorobenzoxazolone, expressed as fenoxaprop-P-ethyl. Risk managers should be alerted that this residue definition is unspecific not only with respect to the racemic mixture fenoxaprop-ethyl but also with respect to other chemicals, as e.g. insecticide phosalone, that may potentially be converted to 6-chlorobenzoxazolone upon hydrolysis.

Surface water

Definitions for risk assessment: fenoxaprop-P-ethyl, fenoxaprop-P, chlorobenzoxazolone (from soil) and HOPP-acid.

Definitions for monitoring: fenoxaprop-P or alternatively fenoxaprop (unspecific) expressed as fenoxaprop-P ethyl.

However, the methods available only allow monitoring according to the following residue definition: sum of fenoxaprop-P-ethyl, fenoxaprop-ethyl, fenoxaprop-P, fenoxaprop and all metabolites which may be converted to 6-chlorobenzoxazolone, expressed as fenoxaprop-P-ethyl. Risk managers should be alerted that this residue definition is unspecific not only with respect to the racemic mixture fenoxaprop-ethyl but also with respect to other chemicals, as e.g. insecticide phosalone, that may potentially be converted to 6-chlorobenzoxazolone upon hydrolysis.

Air

Definitions for risk assessment: fenoxaprop-P-ethyl, fenoxaprop-P

Definitions for monitoring: fenoxaprop-P or alternatively fenoxaprop (unspecific) expressed as fenoxaprop-P ethyl.

However, the methods available only allow monitoring according the following residue definition: sum of fenoxaprop-P-ethyl, fenoxaprop-ethyl, fenoxaprop-P, fenoxaprop and all metabolites which may be converted to 6-chlorobenzoxazolone, expressed as fenoxaprop-P-ethyl. Risk managers should be alerted that this residue definition is unspecific not only with respect to the racemic mixture

fenoxaprop-ethyl but also with respect to other chemicals, as e.g. insecticide phosalone, that may potentially be converted to 6-chlorobenzoxazolone upon hydrolysis.

Food of plant origin

Definitions for risk assessment: Sum of fenoxaprop-P-ethyl and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-P-ethyl.

Definitions for monitoring: Sum of fenoxaprop-P-ethyl and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-P-ethyl.
or alternatively: Sum of fenoxaprop-ethyl and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-ethyl.

Food of animal origin

Definitions for risk assessment: not required.

Definitions for monitoring: not required.

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

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Fenoxaprop-P-ethyl	Very low persistent ($DT_{50\ lab\ 20\ °C}$ = 0.02 – 0.8 d)	Low acute toxicity and low risk to earthworms
Fenoxaprop-P	Low to moderately persistent ($DT_{50\ lab\ 20\ °C}$ = 2.2 – 13.3 d)	Low acute toxicity and low risk to earthworms
Chlorobenzoxazolone	Low to moderately persistent ($DT_{50\ lab\ 20\ °C}$ = 5 – 14.8 d)	Low acute toxicity and low risk to earthworms
HOPP-acid (major metabolite under anaerobic conditions)	No data available. Data gap identified to address situations where anaerobic conditions are prevalent.	No data available. Data gap identified to address situations where anaerobic conditions are prevalent.

Ground water

Compound (name and/or code)	**Mobility in soil**	> 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological relevance
Fenoxaprop-P-ethyl	immobile in soil (K_{OC} = 5419 – 26207 mL / g)	FOCUS GW: No	Yes	Yes	Very toxic to aquatic organisms
Fenoxaprop-P	medium to low mobile (K_{OC} = 145 – 568 mL / g)	FOCUS GW: No	No information provided	No data available, not required	Toxic to aquatic organisms. (Less toxic to aquatic organisms compared to fenoxaprop-P-ethyl)

Compound (name and/or code)	**Mobility in soil**	> 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological relevance
Chlorobenzoxazolone	medium to low mobile (K_{OC} = 296 – 537 mL / g)	FOCUS GW: No	No information provided	No data available, not required	Toxic to aquatic organisms. (Less toxic to aquatic organisms compared to fenoxaprop-P-ethyl)
HOPP-acid (major soil metabolite under anaerobic conditions)	No data available. Data gap identified to address situations were anaerobic conditions are prevalent.	No data available. Data gap identified to address situations where anaerobic conditions are prevalent.	No data available. Data gap identified to address situations where anaerobic conditions are prevalent.	No data available. Data gap identified to address situations where anaerobic conditions are prevalent.	Toxic to aquatic organisms. (Less toxic to aquatic organisms compared to fenoxaprop-P-ethyl)

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Fenoxaprop-P-ethyl (water and sediment)	Very toxic to aquatic organisms. The risk to aquatic organisms was assessed as low.
Fenoxaprop-P (water and sediment)	Toxic to aquatic organisms. The risk to aquatic organisms was assessed as low.
chlorobenzoxazolone (water and sediment, from soil)	Toxic to aquatic organisms. The risk to aquatic organisms was assessed as low.
HOPP-acid (water only)	Toxic to aquatic organisms. The risk to aquatic organisms was assessed as low.

Air

Compound (name and/or code)	Toxicology
Fenoxaprop-P-ethyl	Not acutely toxic by inhalation (rat LC_{50} > 1.224 mg/l air, highest technically achievable)
Fenoxaprop-P	No data available

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

- Data gap for a method to monitor all compounds given in the respective residue definition in soil which can be used for all soil types (relevant for all representative uses evaluated; submission date proposed by the notifier: submitted, evaluated in Addendum to vol. 3, not peer reviewed, refer to chapter 1)
- Data gap for the information necessary to address the major anaerobic metabolite HOPP-acid in soil and ground water to address situations were anaerobic conditions are prevalent (relevant for all representative uses when anaerobic conditions are expected; data gap identified by EFSA after the experts' meeting, no date of submission has been proposed by the notifier, refer to chapters 4 and possibly to 2 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 comprises foliar spraying to spring and winter-sown varieties of wheat, durum wheat, rye, triticale, spring and winter barley up to growth stages of BBCH 10-32, to control *Setaria*, *Avena*, *Apera*, *Leptochloa*, *Alopecurus*, *Echinochloa* and other annual grass weeds, in all EU countries, up to maximum 1-2 treatments per year, at a maximum total active substance rate per season of 83 g as/ha either once applied in autumn or spring or one application in autumn and one in spring.

The representative formulated product for the evaluation was "Puma S 69EW", an emulsion oil in water (EW) containing 69 g/l fenoxaprop-P-ethyl as the active substance and 75 g/l mefenpyr-diethyl as safener, registered under different trade names in Europe.

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.

Analytical methods are available to monitor all compounds given in the residue definition for plants, however the methods are not specific to fenoxaprop-P-ethyl.

Due to a similar toxicological profile in acute, short term, genotoxicity and developmental studies, the long term and reproductive studies performed with fenoxaprop-ethyl were considered sufficiently representative to be used for fenoxaprop-P-ethyl. Fenoxaprop-P-ethyl was rapidly and extensively absorbed, and of low acute toxicity. Nevertheless, the classification with **R43** May cause sensitisation by skin contact was proposed. In repeat dose studies, the target organs were the liver and the kidneys. Negative results were obtained in mutagenicity tests, and no evidence of carcinogenic properties was

observed in rats, mice or dogs. No effect on reproductive parameters, fertility or offspring development were noted, but there was some indication of teratogenicity in the rat studies leading to the proposal **Toxic to Repr. cat.3, R63?.** The acceptable daily intake (ADI) was 0.01 mg/kg bw/day, the acceptable operator exposure level (AOEL) was 0.014 mg/kg bw/day and the acute reference dose (ARfD) was 0.1 mg/kg bw/day, with the use of a safety factor of 100. The estimated operator exposure level is below the AOEL with the use of gloves during mixing, loading and spraying, and of coverall during spraying (according to the German model).

The metabolism of fenoxaprop-P-ethyl in cereals is clearly elucidated. Shortly after application the parent compound is hydrolysed to the acid form which is still biologically active. Fenoxaprop-P acid is further degraded by ether cleavage with formation of chlorobenzoxazolone and phenoxypropionic acid moieties, each undergoing conjugation processes. Very early, these moieties represent the major part of the residual content and it is therefore proposed to adopt as residue definition for monitoring and risk assessment the sum of the parent compound and all metabolites containing the chlorobenzoxazolone moiety. The plant residue pattern is covered by the toxicological studies conducted with the parent compound.
Resulting from the early stage of application and of the absence of any translocation potential, residues in grains and straw are expected to be low in mature cereals and supervised residue trials actually demonstrate that they do not exceed analytical limits of quantification (0.02 and 0.05 mg/kg in grains and straw respectively). The MRL in cereals is therefore proposed to be set at the LOQ level. Due to the absence of residues in straw livestock exposure is very low and there is no need to establish a residue definition and MRLs for animal commodities. It must however be noted that if fenoxaprop-P-ethyl is applied later than the latest growth stage of application supported as representative use, significant residues may be present in straw and in this case the transfer of residues to animal products should be reconsidered.
The effect of processing on the residues was not investigated given the low residues in raw grains.
The transfer of soil residues to rotational crops was investigated and concluded to be negligible.
Chronic and acute consumer exposure assessments were conducted and found to be far below the respective toxicological reference values.

In soil under dark aerobic conditions, fenoxaprop-P-ethyl or fenoxaprop-ethyl was rapidly hydrolysed ($DT_{50\ lab\ 20\ °C}$ = 0.02 – 0.8 d) to the active fenoxaprop-P or fenoxaprop (max. 81.1 % AR after 3 d; $DT_{50\ lab\ 20\ °C}$ = 2.2 – 13.3 d). The only major metabolite identified in the route studies was the chlorobenzoxazolone (AE F054014, max. 19.1 % after 15 d; $DT_{50\ lab\ 20\ °C}$ = 5 – 14.8 d). Also under anaerobic conditions fenoxaprop-P or fenoxaprop was rapidly produced (max. 93.9 % after 2 d). Under these conditions a major metabolite hydroxy phenoxy propionic acid (HOPP-acid, AE F020686; max. 74.1 % after 120 d) was identified. Fenoxaprop-P was moderate persistent ($DT_{50\ lab\ anerob.\ 20\ °C}$ = 36.6 d), metabolite chlorobenzoxazolone was moderate persistent ($DT_{50\ lab\ anerob.\ 20\ °C}$ = 57.5 d) and anaerobic metabolite hydroxy phenoxy propionic acid was very high persistent ($DT_{50\ lab\ anerob.\ 20\ °C}$ > 250 d) under anaerobic conditions. After the experts' meeting, EFSA identified a data gap for the

information necessary to address the major anaerobic metabolite HOPP-acid in soil and ground water to address situations were anaerobic conditions are prevalent.

Contribution of photolysis to the degradation of fenoxaprop-ethyl in soil was relevant but limited when compared with degradation under aerobic conditions.

PEC soil for fenoxaprop-P-ethyl, fenoxaprop-P and chlorobenzoxazolone were calculated for the representative use.

From the results of batch soil adsorption / desorption studies fenoxaprop-P-ethyl may be classified as immobile in soil (K_{OC} = 5419 – 26207 mL / g), fenoxaprop-P as medium to low mobile (K_{OC} = 145 – 568 mL / g) and chlorobenzoxazolone as medium to low mobile (K_{OC} = 296 to 537 mL / g).

Hydrolysis of fenoxaprop-P-ethyl at 25 ºC is pH dependent ($DT_{50\ pH\ 4}$ = 2.8 d; $DT_{50\ pH\ 5}$ = 19.2 d; $DT_{50\ pH\ 7}$ = 23.2 d; $DT_{50\ pH\ 9}$ = 0.6 d). Under acidic conditions main hydrolysis product is chlorobenzoxazolone whereas in alkaline conditions fenoxaprop-P is also detected. Hydrolysis of fenoxaprop-P at 25 ºC is also pH dependent being practically stable at neutral pH ($DT_{50\ pH\ 5}$ = 26.8 d; $DT_{50\ pH\ 7}$ = 182.7 d; $DT_{50\ pH\ 9}$ = 33 d). Main hydrolysis product of fenoxaprop-P is chlrobenzoxazolone (max 37.7 % AR). Chlorobenzoxazolone is hydrolytically stable (DT_{50} > 1 yr) in the range of pH (4-9) and temperatures (25 – 50 ºC) tested.

Aqueous photolysis fenoxaprop-P-ethyl was investigated at 25 ºC in natural surface water (pH 9), and two sterile systems (pH 5 and 6.8). Main photolysis metabolite (not observed in the dark control) was observed at pH 9: AE 0316854 (6-hydroxy-2,3-dyhydro-benzoxazol-2-one, max 27.4 % AR). In the other experiments metabolites found were common to the ones found in the dark control. Half lives calculated assuming 12 h sunshine were between 7.1 d (natural system, pH 9) and 127.8 d (distilled water, pH 6.8). Aqueous photolysis of soil aerobic metabolite chlorobenzoxazolone was also investigated at pH 7 and 25 ºC. A photolysis half life of 1.42 d was observed that could be translated to environmental half lives of 7.4 d to 50.6 d depending on the latitude and season.

No readily biodegradation study is available. Fenoxaprop-P-ethyl and fenoxaprop-P are considered not to be readily biodegradable.

In the two dark aerobic water / sediment systems investigated fenoxaprop-P-ethyl was rapidly hydrolysed ($DT_{50\ total\ system}$ = 0.1 – 0.32 d) to fenoxaprop-P (max. $_{water}$ = 97.2 % AR) that is subsequently adsorbed to sediment (max. $_{sed}$ = 26.8 %) and transformed (DT50 $_{total\ system}$ = 8.3 – 46.3 d) to HOPP-acid (AE F 096918, max $_{water}$ = 22.9 % AR; max. $_{sed.}$ = 3.4 % AR) and chlorobenzoxazolone (AE F054014, max.$_{water}$ = 5.0 % AR; max $_{sed}$ = 1.5 % AR). HOPP-acid is subsequently degraded ($DT_{50\ total\ system}$ = 10.7 – 24.6 d). At the end of the studies (118 199 d), the vast majority of the radioactivity was transformed into unextractable residues (27.4 – 69.1 % AR) and CO_2 (max. 16.9 - 45.9 % AR).

PEC_{SW} were calculated for fenoxaprop-P-ethyl, fenoxaprop-P, chlorobenzoxazolone and HOPP-acid following the FOCUS SW scheme up to Step 2. Geometric mean of soil and total water – sediment systems half lives were used in these calculations.

Potential contamination of ground water was assessed by calculation of the 80th percentile annual average predicted concentration of fenoxaprop-P-ethyl, fenoxaprop-P and cholobenzoxazolone in the leachate at 1m depth on the relevant FOCUS scenarios employing FOCUS PELMO vs. 2.2.2. model.

For the representative uses proposed none of the calculated concentrations of the potential residue components exceeds the trigger values of 0.1 µg / L.
Long term transport of fenoxaprop-P-ethyl and fenoxaprop-P through the atmosphere is not expected based on their physical and chemical properties.

The risk to birds and mammals, aquatic organisms, bees, other non-target arthropods, soil non-target micro-organisms and biological methods of sewage treatment was assessed as low.
The acute TER values for earthworms were well above the Annex VI trigger for fenoxaprop-P-ethyl and the soil metabolites fenoxaprop-P and chlorobenzoxazolone. No long-term risk assessment was triggered since the DT_{90} in soil is <100 days and the product is applied only once per year. The RMS pointed out that particular attention should be paid to potential long-term effects if fenoxaprop-P-ethyl is applied in regions with lower temperatures where fenoxaprop-P is more persistent. The same applies if fenoxaprop-P-ethyl is used where anaerobic conditions occur. Under anaerobic conditions the metabolites fenoxaprop-P, chlorobenzoxazolone and the HOPP-acid (AE F020686) are assumed to be persistent. The TER for non-target plants in the off-field area was below the trigger of 5 and risk mitigation measures such as a no-spray buffer zone of 5 metres are required.

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

- The use of PPE (personal protective equipment) is required to have an operator exposure estimate below the AOEL.
- Risk mitigation measures comparable to an in-field no spray buffer zone of 5 metres are required to protect non-target plants in the off-field area.

Critical areas of concern

- The operator/worker/bystander exposure assessment for the safener mefenpyr-diethyl and the risk assessment for the formulation (fenoxaprop-P-ethyl + mefenpyr-diethyl) could not be concluded and are to be considered at Member State level.

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

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

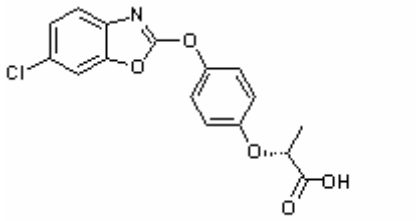
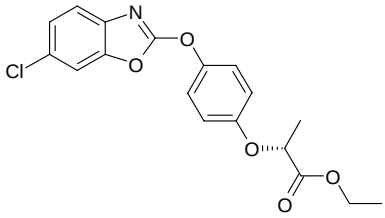
Appendix 1.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Fenoxaprop-P (accepted ISO common name) **Fenoxaprop-P-ethyl** (unless otherwise stated the data relate to the variant)
Function (e.g. fungicide)	Herbicide
Rapporteur Member State	Austria
Co-rapporteur Member State	None

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Fenoxaprop-P: (R)-2[4-[(6-chloro-2-benzoxazolyl)oxy]-phenoxy]-propanoic acid Fenoxaprop-P-ethyl: (variant) ethyl (R)-2[4-[(6-chloro-2-benzoxazolyl)oxy]-phenoxy]-propanoate
Chemical name (CA) ‡	Fenoxaprop-P: (R)-2{4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy} propanoic acid Fenoxaprop-P-ethyl: (variant) ethyl (R)-2{4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy} propanoate
CIPAC No ‡	Fenoxaprop-P: 484 Fenoxaprop-P-ethyl: (variant) 484.202
CAS No ‡	Fenoxaprop-P: 113158-40-0 Fenoxaprop-P-ethyl: (variant) 71283-80-2
EC No (EINECS or ELINCS) ‡	Not allocated
FAO Specification (including year of publication) ‡	No FAO Specification available at the time of evaluation
Minimum purity of the active substance as manufactured ‡	920 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	There are no impurities of toxicological or environmental concern

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

Molecular formula ‡	Fenoxaprop-P: $C_{16}H_{12}ClNO_5$ Fenoxaprop-P-ethyl: (variant) $C_{18}H_{16}ClNO_5$
Molecular mass ‡	Fenoxaprop-P: 333.7 g/mol Fenoxaprop-P-ethyl: (variant) 361.8 g/mol
Structural formula ‡	Fenoxaprop-P:  Fenoxaprop-P-ethyl: (variant) 

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

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	86.5 °C (99.5% w/w)
Boiling point (state purity) ‡	Not applicable
Temperature of decomposition (state purity)	> 260 °C (≈ 93.0% w/w)
Appearance (state purity) ‡	Pure material: white solid (98.7% w/w) Technical material: yellowish flakes (96.3% w/w)
Vapour pressure (state temperature, state purity) ‡	5.3 x 10^{-7} Pa at 20 °C (98.7% w/w)
Henry's law constant ‡	2.739 x 10^{-4} Pa▪m^3▪mol^{-1} at 20°C (98.7% w/w)
Solubility in water (state temperature, state purity and pH) ‡	0.7 mg/L at 20 °C (bidistilled water pH 5.8) (98.7% w/w)
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20 °C in g/L (89.8% w/w) n-hexane 7.0 acetone >400 toluene >480 dichloromethane >400 methanol 43.1 isopropanol 14.2 ethyl acetate >380 polyethylene glycol 18.2 dimethylsulfoxide >500
Surface tension ‡ (state concentration and temperature, state purity)	Not applicable as the water solubility is <1.0 mg/L
Partition co-efficient ‡ (state temperature, pH and purity)	4.58 at 30 °C (98.4% w/w) (water/methanol 70:30 v/v) unbuffered solution
	relevant metabolites: Hoe 053022 (Fenoxaprop) (98.1% w/w) 1.81 (pH = 5) 0.46 (pH = 7 0.24 (pH = 9) AE F054014 (6-chloro-2,3-dihydro-benzoxazol-2-one) 1.9 (99.8% (w/w)
Dissociation constant (state purity) ‡	pKa = - 0.18 ± 0.30 (calculation)
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	9.785 mg as/L in acetonitrile (99.5% w/w) λ_{max} [nm] ε_{max} [L•mol^{-1}•cm^{-1}] 239 22862 278 7980 291 1488
Flammability ‡ (state purity)	Not highly flammable (96.3% w/w)
Explosive properties ‡ (state purity)	Not explosive (96.3% w/w)
Oxidising properties ‡ (state purity)	Fenoxaprop-P-ethyl is not considered to have oxidising properties (statement)

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

Summary of representative uses evaluated *

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL min – max (l)	water L/ha min – max	g as/ha min – max (l)		
Cereals wheat (s+w) durum wheat rye, w.-rye triticale barley (s+w)	all EU Member States	Puma S 69EW	F	grassy weed species	EW	69 g/L Fenoxaprop-P-ethyl	ground-boom sprayers	BBCH: 10-32	1 - 2[1])		3.8-42	180-400	15 - 83	is covered by the normal vegetation period between last application and harvest	

[1]) either one application in autumn or one in spring or one application in autumn and one in spring (max. 83 g as/ha in one season)

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF 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 plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(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) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

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

Appendix 1.2: Methods of Analysis

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

Technical as (analytical technique)	HPLC-UV [also CIPAC]
Impurities in technical as (analytical technique)	HPLC-UV GC-FID
Plant protection product (analytical technique)	HPLC-UV [also CIPAC]

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	Sum of fenoxaprop-P-ethyl and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-P-ethyl. or alternatively: Sum of fenoxaprop-ethyl and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-ethyl.
Food of animal origin	Not necessary
Soil	Definitions for risk assessment: fenoxaprop-P-ethyl, fenoxaprop-P, chlorobenzoxazolone and HOPP-acid (when anaerobic conditions are prevalent). Definitions for monitoring: fenoxaprop-P or alternatively fenoxaprop (unspecific) expressed as fenoxaprop-P ethyl. However, the methods submitted but not peer reviewed only allow monitoring according the following residue definition: sum of fenoxaprop-P-ethyl, fenoxaprop-ethy, fenoxaprop-P, fenoxaprop and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-P-ethyl. Risk managers should be alerted that this residue definition is unspecific not only with respect to the racemic mixture fenoxaprop-ethyl but also with respect to other chemicals as insecticide phosalone that may potentially contaminate the sample.
Water surface	Definitions for risk assessment: fenoxaprop-P-ethyl, fenoxaprop-P, chlorobenzoxazolone (from soil) and HOPP-acid. Definitions for monitoring: fenoxaprop-P or alternatively fenoxaprop (unspecific) expressed as fenoxaprop-P ethyl. However, the methods available only allow to monitor according the following residue definition: sum of fenoxaprop-P-ethyl, fenoxaprop-ethy, fenoxaprop-P, fenoxaprop and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-P-ethyl. Risk managers should be alerted that this residue definition is unspecific not only with

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

	respect to the racemic mixture fenoxaprop-ethyl but also with respect to other chemicals, as eg. insecticide phosalone, that may potentially be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one upon hydrolysis.
drinking/ground	Definitions for exposure assessment: fenoxaprop-P-ethyl, fenoxaprop-P, chlorobenzoxazolone and HOPP-acid (when anaerobic conditions are prevalent). Definitions for monitoring: fenoxaprop-P or alternatively fenoxaprop (unspecific) expressed as fenoxaprop-P ethyl. However, the methods available only allow to monitor according the following resiudue definition: sum of fenoxaprop-P-ethyl, fenoxaprop-ethy, fenoxaprop-P, fenoxaprop and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-P-ethyl. Risk managers should be alerted that this residue definition is unspecific not only with respect to the racemic mixture fenoxaprop-ethyl but also with respect to other chemicals, as eg. insecticide phosalone, that may potentially be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one upon hydrolysis.
Air	Definitions for risk assessment: fenoxaprop-P-ethyl, fenoxaprop-P Definitions for monitoring: fenoxaprop-P or alternatively fenoxaprop (unspecific) expressed as fenoxaprop-P ethyl

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	GC-MS, non enantio-selective, non specific for fenoxaprop-P-ethyl LOQ: AE F46360 [1] 0.01 mg/kg (grain) AE F054014 [2] 0.01 mg/kg (grain) AE F088406 [3] 0.01 mg/kg (grain)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	No analytical method is required as no MRLs and no residue definition for food of animal origin is proposed
Soil (analytical technique and LOQ)	*Open* (a not peer reviewed HPLC-MS/MS method, non enantio-selective, non specific for fenoxaprop-P-ethyl)
Water (analytical technique and LOQ)	HPLC-UV, non enantio-selective, non specific for fenoxaprop-P-ethyl drinking water: LOQ: AE F46360 [1] 0.1 µg/L AE F054014 [2] 0.1 µg/L AE F088406 [3] 0.1 µg/L surface water: LOQ: AE F46360 [1] 1.0 µg/L AE F054014 [2] 1.0 µg/L AE F088406 [3] 1.0 µg/L

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

Air (analytical technique and LOQ)	HPLC-UV, non enantio-selective, non specific for fenoxaprop-P-ethyl		
	LOQ:	AE F46360 [1]	1.0 µg/m^3
		AE F088406 [3]	1.0 µg/m^3
Body fluids and tissues (analytical technique and LOQ)	No analytical method is required as Fenoxaprop-P-ethyl is not classified as toxic or very toxic		

[1] AE F046360 Fenoxaprop-P-ethyl
[2] AE F054014 6-chloro-2,3-dihydrobenzoxazol-2-one
[3] AE F088406 Fenoxaprop-P (free acid)

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

	RMS/peer review proposal
Active substance	None

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

Appendix 1.3: Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Rapid (Cmax <8hrs) and almost completely absorbed (>90%) after oral low dose application in rats, based on urinary and faecal (assumed biliary) excretion after oral and i.v. application
Distribution ‡	Widely distributed, highest concentrations in kidneys, blood, fatty tissues and liver; total amount after 7 days: 0.7-2%
Potential for accumulation ‡	No potential for accumulation
Rate and extent of excretion ‡	> 75% excreted within 48 hours; males generally excrete lower amounts of radioactivity via urine (35 - 65%) than via faeces (43 - 54%)
Metabolism in animals ‡	Extensively metabolised via hydrolysis into free acid and conjugation
Toxicologically relevant compounds ‡ (animals and plants)	Parent compound
Toxicologically relevant compounds ‡ (environment)	Parent compound

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 3150 mg/kg bw (♂ + ♀)	
Rat LD_{50} dermal ‡	> 2000 mg/kg bw (♂ + ♀)	
Rat LC_{50} inhalation ‡	> 1.224 mg/L air (♂ + ♀) (aerosol, 4 hours, nose only, technically highest administrable dose)	
Skin irritation ‡	Slightly irritating (classification not required)	
Eye irritation ‡	Slightly irritating (classification not required)	
Skin sensitisation ‡	Sensitizer to the skin (Magnusson & Kligman)	**R 43**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Liver, kidneys (rat, mouse, to a weaker extent also dog)	
Relevant oral NOAEL ‡	Rat: overall 2 mg/kg bw/d (13 wk + 6 mo interim) Mouse: overall 5.5 mg/kg bw/d (13 wk + 12 mo interim) Dog: 15.6 mg/kg bw/d (13 wk)	
Relevant dermal NOAEL ‡	20 mg/kg bw/d (rats, 21 appl. within 30d)	

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

Relevant inhalation NOAEL ‡	0.015 mg/L air (rats, 28 exposures 6h/day within 40 days, nose only)	

Genotoxicity ‡ (Annex IIA, point 5.4)

……..	No genotoxic potential	

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

Target/critical effect ‡	Studies performed with the racemic fenoxaprop-ethyl, data bridged for the a.s. fenoxprop-P-ethyl Liver, kidneys (rat, mouse) Decreased body weight gain (dog)	
Relevant NOAEL ‡	2 year study, rat: 1.6 mg/kg bw/d 2 year study, mouse: 5.7 mg/kg bw/d 2 year study, dog: 1 mg/kg bw/d	
Carcinogenicity ‡	Liver adenomas and carcinomas in NMRI mice: non-genotoxic mechanism in rodents (peroxisome proliferation) Unlikely to pose a carcinogenic risk to humans. No tumors found in rats and dogs	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Study performed with the racemic fenoxaprop-ethyl, data bridged for the a.s. fenoxprop-P-ethyl Parental: organ weight changes of liver, kidneys Reproduction: no effects on reproduction Offspring: reduced body weight during lactation; organ weight changes of liver, kidneys	
Relevant parental NOAEL ‡	1.4 mg/kg bw/d	
Relevant reproductive NOAEL ‡	8.8 mg/kg bw/d	
Relevant offspring NOAEL ‡	1.4 mg/kg bw/d	

Developmental toxicity

Developmental target / critical effect ‡	Maternal toxicity: decreased food consumption and body weight gain (rat and rabbit), reduced placental weight (rat only) Fetal toxicity: delayed ossification particularly in cranial bones (rat); increased incidence of a	

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

	13th rib (rabbit)	
Relevant maternal NOAEL ‡	Rat and rabbit 32 mg/kg bw/d	
Relevant developmental NOAEL ‡	Rat 10 mg/kg bw/d Rabbit 32 mg/kg bw/d	**R63?**

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data, no concern from other studies	
Repeated neurotoxicity ‡	No data, no concern from other studies	
Delayed neurotoxicity ‡	No data, no concern from other studies	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Increased catalase activity (liver) in mice (80 ppm onwards) after short term repeated dose indicating peroxisome proliferation Combined repeated dose toxicity study with the active substance and the safener mefenpyr-diethyl: no change of the toxicological profile of fenoxaprop-P-ethyl
Studies performed on metabolites or impurities ‡	No data available – not required

Medical data ‡ (Annex IIA, point 5.9)

……..	No evidence of adverse effects to industrial workers and after agricultural use reported

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.01 mg/kg bw/d	2 year feeding study in dogs supported by the multigeneration study in rats	100
AOEL ‡	0.014 mg/kg bw/d	Multigeneration study in rats	100
ARfD ‡	0.1 mg/kg bw	Developmental study in rats	100

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

Dermal absorption ‡ (Annex IIIA, point 7.3)

Representative formulation: PUMA S 69EW	Concentrate: 1.6 %; Dilution: 36 % rat *in vivo* with Puma S 69EW + comparative rat / human *in vitro* study with Cheetah super

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Tractor field application: BBA model: 131 % of AOEL without PPE 9 % of AOEL with PPE POEM model: 901 % of AOEL without PPE 134 % of AOEL with PPE
Workers	According to Hoernicke et al., 1998: 38 % of AOEL without PPE
Bystanders	According to Lloyd and Bell, 1983: 2.3 % of AOEL

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

	RMS/peer review proposal
Substance (name)	R43 May cause sensitsation by skin contact Toxic to Repr. cat.3, R 63? Possibile risk of harm to the unborn child

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

Appendix 1.4: Residues

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

Plant groups covered	Cereals (wheat, barley, rice) post emergence
Rotational crops	Leafy vegetables (spinach, lettuce) root vegetables (little radish, carrots, red beets), cereals (wheat and buckwheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Expected to be similar considering the residue pattern in soil. Nevertheless residues in rotational crops were not identified due to their extremely low levels.
Processed commodities	Not relevant
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not relevant
Plant residue definition for monitoring	Sum of fenoxaprop-P-ethyl and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-P-ethyl or alternatively: Sum of fenoxaprop-ethyl and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-ethyl.
Plant residue definition for risk assessment	Sum of fenoxaprop-P-ethyl and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-P-ethyl
Conversion factor (monitoring to risk assessment)	None

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

Animals covered	Not required. Studies on lactating goat and laying hens available.
Time needed to reach a plateau concentration in milk and eggs	Not reached throughout the duration of the metabolism studies (3 days-lactating goat, 5 days-laying hens)
Animal residue definition for monitoring	Not necessary
Animal residue definition for risk assessment	Not necessary
Conversion factor (monitoring to risk assessment)	Not necessary
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Fenoxaprop-P-ethyl: yes, Log P_{ow}= 4.58 Metabolites: AE F088406: no data submitted AE F053022: no (Log P_{ow}= 0.46, pH 7) AE F054014: no (Log P_{ow}= 1.9)

‡ Endpoints identified by 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)

……..	Rotational crop study using radiolabelled material : No significant residues to be expected

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

……..	Stable for 14 months (barley grain and straw) Stable for 24 months (wheat grain)

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)	No	No	No
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No	No	No
	Feeding studies Residue levels in matrices : Mean (max) mg/kg		
Muscle	Not relevant	Not relevant	Not relevant
Liver	Not relevant	Not relevant	Not relevant
Kidney	Not relevant	Not relevant	Not relevant
Fat	Not relevant	Not relevant	Not relevant
Milk	Not relevant		
Eggs		Not relevant	

‡ Endpoints identified by 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, Rye, Barley	Northern	12x < 0.02 *) 12x < 0.05 *)	Grain Straw	0.02* -	< 0.02 < 0.05	< 0.02 < 0.05
Wheat, Barley	Mediterranean	2x < 0.02 *) 2x < 0.05 *)	Grain Straw	0.02* -	< 0.02 < 0.05	< 0.02 < 0.05

* LOQ

(a) Numbers of trials in which particular residue levels were reported e.g. 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue i.e. the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

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

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

ADI	0.01 mg/kg bw/day
TMDI (% ADI) according to WHO European diet	TMDI = 1% ADI (adult of 60 kg bw)
TMDI (% ADI) according to national (to be specified) diets	German diet: TMDI = 4% ADI (girl of 13,5 kg bw)
IEDI (WHO European Diet) (% ADI)	Not necessary
NEDI (specify diet) (% ADI)	Not necessary
Factors included in IEDI and NEDI	Not necessary
ARfD	0.1 mg/kg bw/day
IESTI (% ARfD)	Only NESTI calculations were conducted
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Cereals (oat, barley, wheat, rye) : < 1% ARfD for each crop (Adults (UK model))
Factors included in IESTI and NESTI	Not necessary

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Not relevant				

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

Cereals (wheat, durum wheat, rye, barley, triticale)	0.02* mg/kg

* LOQ

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

Appendix 1.5: Fate and Behaviour in the Environment

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

Mineralization after 100 days ‡	9.7-32.5 % after 100 d, [^{14}C-chlorophenyl]-label (n[3]= 4) 45-55 % after 64 d, [^{14}C-dioxyphenyl]-label racemic mixture (n= 2)
Non-extractable residues after 100 days ‡	49-70 % after 100 d, [^{14}C-chlorophenyl]-label (n[4]= 4) 28-32 % after 64 d, [^{14}C-dioxyphenyl]-label racemic mixture (n= 2)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	*Chlorophenyl label (4 soils)*: Fenoxaprop-P (AE F088406): 42% AR (day 1) – 81% AR (day 3) Chlorobenzoxazolone (AE F05014): 6% (day 3) – 19% AR (day 15) *Dioxiphenyl label (2 soils; 50:50 racemic mixture)*: Fenoxaprop (AE F053022): 44% (day 4) – 63% AR (day 1)

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

Anaerobic degradation ‡

Mineralization after 100 days	*4.2* % after *90* d, [^{14}C-chlorophenyl]-label (n=1) *7.8* % after *120* d, [^{14}C-dioxyphenyl]-label racemic mixture (n= *1*)
Non-extractable residues after 100 days	*76.4* % after *120* d, [^{14}C- chlorophenyl]-label (n= *1*) *11.0* % after *120* d, [^{14}C- dioxyphenyl]-label (n= *1*)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	*Chlorophenyl label (1 soil):* Fenoxaprop-P (AE F088406): Max. 94% AR after 2 days *Dioxiphenyl label (1 soil; 50:50 racemic mixture)*: Fenoxaprop (AE F053022): Max. 96% AR after 1 day HOPP-acid (AE F020686): Max. 74% AR after 120 days

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Compared to microbial degradation photolytic degradation of Fenoxaprop-ethyl is of minor importance.

[3] n corresponds to the number of soils.
[4] n corresponds to the number of soils.

‡ Endpoints identified by 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)

Laboratory studies ‡

Fenoxaprop-P-ethyl	Aerobic conditions						
Soil type	Label position	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d) Simple 1st order	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam SL V	Chloro-phenyl	5.6	20° C / 40 %	0.33 / 1.1	0.3	0.817	TopFit 2.0 (multi compartment model) Correction according to FOCUS
Loamy sand LS 2.2	"	5.8	20° C / 40 %	0.35 / 1.1	0.3	0.946	
Sandy loam SL S (US)	"	5.2	20° C / 40 %	0.73 / 2.4	0.6	0.953	
Silt loam SL 2 (US)	"	5.2	20° C / 40 %	0.51 / 1.7	0.4	0.957	
Sandy loam SL V 1)	"	5.8	21° C / 40 %	0.65 / 2.1	0.5	0.953	
Silt loam SL 2	Dioxy-phenyl *	6.9	22° C / 40 %	0.72 / 2.4	0.6	0.955	
Silty sand SS 2	"	7.0	22° C / 40 %	0.32 / 1.1	0.4	0.975	
Geometric mean / Arithmetic mean					0.43 / 0.45		
Sandy loam SL V 1)	Chloro-phenyl	5.8	11° C / 40 %	0.74 / 2.5	Not corrected value: 0.02 (not reliable)	0.821	TopFit 2.0 (multi compartment model)

* *racemic mixture (fenoxaprop-ethyl)*

[1]) identical soils

Fenoxaprop-P	Aerobic conditions							
Soil type	Label position	pH	t °C / % MWHC	DT_{50}/ DT_{90} (d) Simple 1st order	Formation rate (%)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam SL V	Chloro-phenyl	5.6	20° C / 40 %	5.0 / 16.7	96.7	3.7	0.817	TopFit 2.0 (multi compartment model) Correction according to FOCUS
Loamy sand LS 2.2	"	5.8	20° C / 40 %	14.3 / 47.7	97.2	12.8	0.946	
Sandy loam SL S (US)	"	5.2	20° C / 40 %	6.7 / 22.2	83.7	2.9	0.953	
Silt loam SL 2 (US)	"	5.2	20° C / 40 %	4.0 / 13.2	80.3	1.7	0.957	
Sandy loam SL V 1)	"	5.8	21° C / 40 %	20 / 67	93.5	26.7	0.953	

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

Fenoxaprop-P	Aerobic conditions							
Soil type	Label position	pH	t °C / % MWHC	DT_{50}/ DT_{90} (d) Simple 1st order	Formation rate (%)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Silt loam SL 2	Dioxy-phenyl *	6.9	22° C / 40 %	10.3 / 34.2	-	5.9	0.915	
Silty sand SS 2	"	7.0	22° C / 40 %	7.9 / 26.3	-	14.9	0.881	
Arithmetic mean					90.3	7.23 / 10.3		
Sandy loam SL V 1)	Chloro-phenyl	5.8	11° C / 40 %	88.7 / 295	95.1	Not corrected value: 76.2	0.821	TopFit 2.0 (multi compartment model)
			10° C:		Arrhenius equation			
Sandy loam SL V			factor 2.2	11 / 36.7				
lamy sand LS 2.2			"	31.5 / 105				
sandy loam SL S			"	14.7 / 49				
Silt loam SL 2			"	8.8 / 29				
Sandy loam SL V			"	44 / 147				
Silt loam SL 2			factor 2.6	26.8 / 88.9				
Silty sand SS 2			"	20.5 / 68.3				

* *racemic mixture (fenoxaprop)*

[1]) identical soils

Chloro-benzoxazolone	Aerobic conditions							
Soil type	Label position	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d) Simple 1st order	Formation rate (%)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam SL V	Chloro-phenyl	5.6	20° C / 40 %	-	3.3* 10.4§	5.8	0.817	TopFit 2.0 (multi compartment model)
Loamy sand LS 2.2	"	5.8	20° C / 40 %	7.7 / 25.6	2.8* 70.6§	4.8	0.946	
Sandy loam SL S (US)	"	5.2	20° C / 40 %	8.5 / 28.3	16.3* 0§	7.0	0.953	Correction according to FOCUS
Silt loam SL 2 (US)	"	5.2	20° C / 40 %	18.0 / 59.9	19.7* 0§	10.1	0.957	
Sandy loam SL V 1)	"	5.8	21° C / 40 %	62 / 207 (unacceptable correlation)	6.5* 0§	12.1	0.953	

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

Chloro-benzoxazolone	Aerobic conditions							
Soil type	Label position	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d) Simple 1st order	Formation rate (%)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Arithmetic mean					9.7 70.6#			
Sandy loam SL V 1)	Chloro-phenyl	5.8	11° C / 40 %	27.7 / 92 (unacceptable correlation)	4.9* 45§	Not corrected value: 14.4	0.821	TopFit 2.0 (multi compartment model)

1) identical soils
* from fenoxaprop-P-ethyl
§ from fenoxaprop-P
# used for risk assessment (worst case)

Field studies ‡

Not considered valid, not essential

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	Not required

Laboratory studies ‡

Fenoxaprop-P-ethyl	Anaerobic conditions						
Soil type	Label position	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d) one compartment decay MicroCal Origin (vs. 3.5)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Loamy sand Speyer 2.2	Chloro-phenyl	5.4	20° C / flooded	0.4 / 1.2	0.34 / 1.1	0.9990	TopFit 2.0 (multi compartment model)
"	Dioxy-phenyl *	"	"	Calculation not possible	0.28 / 0.9	0.9999	

* racemic mixture (fenoxaprop-ethyl)

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

Fenoxaprop-P	Anaerobic conditions						
Soil type	Label position	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d) 1st order, one compartment decay MicroCal Origin (vs. 3.5)	DT_{50}/ DT_{90} (d) single 1st order	St. (r^2)	Method of calculation
Loamy sand Speyer 2.2	Chloro-phenyl	5.4	20° C / flooded	33.9 / 112.5	36.6 / 122	0.997 1	TopFit 2.0 (multi compartment model)
"	Dioxy-phenyl *	"	"	26.7 / 88.6	24.0 / 80	0.986 9	

* racemic mixture (fenoxaprop)

HOPP-acid	Anaerobic conditions						
Soil type	Label position	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d) 1st order, one compartment decay MicroCal Origin (vs. 3.5)	DT_{50}/ DT_{90} (d) single 1st order	St. (r^2)	Method of calculation
Loamy sand Speyer 2.2	Dioxy-phenyl *	5.4	20° C / flooded	Calculation not possible	>250 (uncertain value due to late occurence	0.9722	TopFit 2.0 (multi compartment model)

* racemic mixture

Phenolic metabolite (AE F040356)	Anaerobic conditions						
Soil type	Label position	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d) 1st order, one compartment decay MicroCal Origin (vs. 3.5)	DT_{50}/ DT_{90} (d) single 1st order	St. (r^2)	Method of calculation
Loamy sand Speyer 2.2	Chloro-phenyl	5.4	20° C / flooded	Minor metabolite, not calculated	6.6 / 21.9	0.5552	TopFit 2.0 (multi compartment model)
"	Dioxy-phenyl	"	"	- (not identified)	-	-	

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

Chloro-benzoxazolone	Anaerobic conditions						
Soil type	Label position	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d) 1st order, one compartment decay MicroCal Origin (vs. 3.5)	DT_{50}/ DT_{90} (d) single 1st order	St. (r^2)	Method of calculation
Loamy sand Speyer 2.2	Chloro-phenyl	5.4	20° C / flooded	Minor metabolite, not calculated	57.5 / 191	0.9007	TopFit 2.0 (multi compartment model)

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OM %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Silty loam SL 2	1.06	5.4	104	16 774	due to rapid hydrolysis only single concentration calculation possible		unreliable
Sandy loam SL S	1.51	6.3	57	6 404			
Sandy loam SL V	2.17	5.9	82	6 406			
Loamy sand LS 2.2	4.53	5.8	149	5 602			
Clay	0.4	7.6	12.8	5 419			
Silty clay loam	1.4	6.5	212	26 207			
Sandy loam	4.4	6.4	443	17 352			
Clay loam	4.56	6.8	176	6 667			
Arithmetic mean			154	11 354			
pH dependence, Yes or No			No				

Fenoxaprop-P ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam	2.64	7.3			8.76	332	0.733
Sand	0.53	4.7			3.01	568	0.782
Silty clay loam	1.67	7.1			3.05	182	0.823
Sand	0.81	6.4			1.17	145	0.880
Clay loam	1.99	7.4			3.67	184	0.719
Arithmetic mean					3.9	282	0.787
pH dependence (yes or no)			No. May be less mobile in very acidic soils (pH <5)				

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

Chlorobenzoxazolone ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loamy sand	0.53	4.7			2.85	537	0.765
Sandy clay loam	1.84	5.4			5.45	296	0.826
Silty loam	1.52	5.4			6.51	429	0.816
Sandy loam	2.07	4.5			6.47	312	0.859
Loamy sand	1.95	6.0			7.02	360	0.826
Arithmetic mean					5.7	387	0.82
pH dependence (yes or no)			No predictions of the sorption behaviour in neutral or alkaline soils can be done since chlorobenzoxazolone was not stable under neutral or alkaline conditions.				

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

Column leaching ‡	Eluation (mm): 200 mm Time period (d): 2 d
	Leachate: 0.29 %, 0.08 % and 0.12 % radioactivity in leachate
Aged residues leaching ‡	Aged for (d): 2 d, 16 days and 30 days Time period (d): 2 d Eluation (mm): 200 mm
	Analysis of soil residues post ageing (soil residues pre-leaching): Ageing period - 2 d: Majority was fenoxaprop-P. Fenoxaprop-P-ethyl, chlorobenzoxazolone and phenolic metabolite in small amounts. - 16 d: Fenoxaprop-P 44.2 %, chlorobenzoxazolone 4.5 % - 30 d: Fenoxaprop-P-ethyl 2.4 %, Fenoxaprop-P 20.3 %, chlorobenzoxazolone 4.0 %
	Leachate: % total radioactivity in leachate Ageing period - 2 d: 1.9 % AR - 16 d: 3.6 % AR - 30 d: 2.3 % AR Fenoxaprop-P-ethyl, fenoxaprop-P or chlorobenzoxazolone were not detected in the leachates
Lysimeter/ field leaching studies ‡	Not submitted, not required

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

PEC (soil) (Annex IIIA, point 9.1.3)

Fenoxaprop-P-ethyl Method of calculation	Only PECinitial was used as basis for risk assessment
Application data	Crop: cereals Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 25 % plant interception Number of applications: 1 Application rate: 100 g as/ha

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.100		-	
Plateau concentration	Not applicable			

Fenoxaprop-P Method of calculation	Molecular weight relative to the fenoxaprop-P-ethyl: 0.92 Only PECinitial was used as basis for risk assessment
Application data	Application rate assumed: 74.8 g /ha (assumed fenoxaprop-P is formed at a maximum of 81.1 % of the applied dose)

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.075		-	
Plateau concentration	Not applicable			

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

Chlorobenzoxazolone Method of calculation	Molecular weight relative to the fenoxaprop-P-ethyl: 0.47 Only PECinitial was used as basis for risk assessment
Application data	Application rate assumed: 8.95 g /ha (assumed chlorobenzoxazolone is formed at a maximum of 19.1 % of the applied dose)

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.0090		-	
Plateau concentration	Not applicable			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 4: 2.8 d at 25 °C pH 5: 19.2 d at 25 °C pH 7: 23.2 d at 25 °C pH 9: 0.69 d at 25 °C **Fenoxaprop-P (AE F088406)** pH 5: 43.1 d at 20 °C pH 7: 320 d at 20 °C pH 9: 66.2 d at 20 °C **Chlorobenzoxazolone (AE F054014)** pH 4 – 9: stable at 20 °C
Photolytic degradation of active substance and metabolites above 10 % ‡	pH 5 (sterile buffer): 57.5 d pH 6.8 (distilled water): 104.7 d pH 9 (natural surface water): 7.2 d[5] **Chlorobenzoxazolone (AE F054014)** pH 7: 10.4 d (spring), 7.8 d (summer), 15.4 d (fall)
Quantum yield of direct phototransformation in water at Σ > 290 nm	$\Phi = 5.11 \times 10^{-6}$ (sterile buffer) $\Phi = 2.88 \times 10^{-6}$ (distilled water) **Chlorobenzoxazolone (AE F054014)** $\Phi = 5.65 \times 10^{-3}$.
Readily biodegradable ‡ (yes/no)	No data submitted, substance considered not ready biodegradable.

[5] Water dissolved photosensitizers (indirect photolysis) in combination with alkaline conditions (hydrolysis) resulted in rapid degradation

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

Degradation in water / sediment

Fenoxaprop-P-ethyl (^{14}C-chlorophenyl labelled	Distribution (max in water 50.3 % after 2 h, max. sed 3.6 % after 2 h)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
S1 (sand)	7.3	7.9	20	0.1 – 0.4 d	0.988	0.1 – 0.3 d	0.983	not calculated		1st order
S2 (silt loam)	6.8	5.1	20	0.1 – 0.3 d	0.979	0.1 – 0.3 d	0.976	not calculated		1st order
Fenoxaprop-P-ethyl ^{14}C-dioxyhenyl labelled	Distribution (max in water 81.4 % after 2 h. Max. sed : not detected)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
S1 (loamy sand)	6.6	5.8	20	0.16 – 0.54 d	0.984	not calculated		not calculated		1st order
S2 (clay)	8.0	7.7	20	0.29 – 0.96 d	0.990	not calculated		not calculated		1st order
Geometric mean (DT_{50})				0.16		not calculated		not calculated		

Fenoxaprop-P (AE F088406) a.s. (^{14}C-chlorophenyl labelled	Distribution (max in water 97.7% after 1 d, max. sed 26.8 % after 7 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
S1 (sand)	7.3	7.9	20	13 – 43.3 d	0.993	6.6 – 31.9 d	0.990	not calculated		1st order
S2 (silt loam)	6.8	5.1	20	6.9 – 22.8 d	0.990	3.3 – 11.1 d	0.959	not calculated		1st order

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

Fenoxaprop-P (AE F088406) a.s. ^{14}C-dioxyhenyl labelled	Distribution (max in water 81.4 % after 2 h. Max. sed: not detected)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
S1 (loamy sand)	6.6	5.8	20	40 – 133 d	0.988	34 – 133 d	0.988	not calculated		1st order
S2 (clay)	8.0	7.7	20	39 – 129 d	0.980	35 – 116 d	0.981	not calculated		1st order
Geometric mean (DT_{50})				13 d						

HOPP-acid (AE F096918) ^{14}C-dioxyhenyl labelled	Distribution (max in water 22.9 % after 62 d. Max. sed: 3.4 % after 62 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
S1 (loamy sand)	6.6	5.8	20	not calculated						
S2 (clay)	8.0	7.7	20	not calculated						

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
S1 (sand)	7.3	7.9	27.6 % after 199 d (= study end)	75 % after 59 d	54.9 % (study end
S2 (silt loam)	6.8	5.1	17.6 % after 120 d 16.9 % (study end)	75.3 % after 155 d	69.1 % (study end)
S1 (loamy sand)	6.6	5.8	45.9 % after 118 d (= study end)	33.5 % after 118 d	33.5 % (study end)
S2 (clay)	8.0	7.7	46.5 % after 90 d 27.4 % (study end)	28.7 % after 47 d	27.3 % (study end)

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

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

Fenoxaprop-P-ethyl Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: Molecular weight (g/mol): 361.8 Water solubility (mg/L): 0.7 K_{OC}/K_{OM} (L/kg): 6000 DT_{50} soil (d): 0.51days (Lab data in accordance with FOCUS SFO) DT_{50} water/sediment system (d): 0.16 (geometric mean) Crop interception (%): 25 %
Application rate	Crop: cereals Crop interception: 25 % Number of applications: 1 Interval (d): - Application rate(s): 83g as/ha Application window: autumn

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	3.84		184.44	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU (worst case)	0 h	0.763		0.304	

Fenoxaprop-P (AE F088406) Parameters used in FOCUSsw step 1 and 2	Molecular weight: 333.74 Water solubility (mg/L): 6100 Soil and water metabolite: Koc/Kom (L/kg): 246.8 DT_{50} soil (d): 7.1 days (Lab data. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 13 d (geometric mean) Crop interception (%): 25 Maximum occurrence observed (% molar basis with respect to the parent) Water and sediment: 97.2

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

Application rate	Crop: cereals Crop interception: 25 % Number of applications: 1 Interval (d): - Application rate(s): 83g as/ha Application window: autumn
Main routes of entry	Spray drift

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	16.26		38.43	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU (worst case)	4 d	4.45		10.572	

Chlorobenzoxazolone (AE F054014) Parameters used in FOCUSsw step 1 and 2	Molecular weight: 169.57 Water solubility (mg/L): 5 - 10 Soil and water metabolite: Koc/Kom (L/kg): 371.8 DT_{50} soil (d): 9.2 days (Lab data. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 2.3 d (geometric mean) Crop interception (%): 25 Maximum occurrence observed (% molar basis with respect to the parent) Soil: 19.1 % Water and sediment: 8 %
Application rate	Crop: cereals Crop interception: 25 % Number of applications: 1 Interval (d): - Application rate(s): 83g as/ha Application window: autumn
Main routes of entry	Run off, drainage

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

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	1.68		6.16	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU (worst case)	4 d	0.466		1.724	

HOPP-acid (AE F096918)	
Parameters used in FOCUSsw step 1 and 2	Molecular weight: 182.19 Water solubility (mg/L): 42110 Water metabolite: Koc/Kom (L/kg): 29.41 DT_{50} soil (d): not applicable DT_{50} water/sediment system (d): 16.2 d (geometric mean) Crop interception (%): 25 Maximum occurrence observed (% molar basis with respect to the parent) Water and sediment: 26.3
Application rate	Crop: cereals Crop interception: 25 % Number of applications: 1 Interval (d): - Application rate(s): 83g as/ha Application window: autumn
Main routes of entry	Spray drift

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	0.101		0.027	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU (worst case)	4 d	0.101		0.018	

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

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

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)	FOCUS PELMO 2.2.2 systemic compound: plant uptake factor 0.5; Fenoxaprop-P-ethyl: K_{OC}: 6000 1/n: 1.0 DT_{50}: 0.45 d Fenoxaprop-P: K_{OC}: 247 1/n: 0.787 DT_{50}: 10.3 d Chlorobenzoxazolone: K_{OC}: 372 1/n: 0.82 DT_{50}: 7.5 d Relative formation rates for Fenoxaprop-P and chlorobenzoxazolone from the parent compound were 90.3 % and 9.7 %, respectively.
Application rate	Application rate: 100 g/ha No. of applications: 1 25 % plant interception Time of application (month or season): autumn

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

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Fenoxaprop-P	Chlorobenzoxazolone	3
PELMO 2.2.2 /Winter cereals	Chateaudun	<0.001	<0.001	<0.001	
	Hamburg	<0.001	<0.001	<0.001	
	Jokioinen	<0.001	<0.001	<0.001	
	Kremsmunster	<0.001	<0.001	<0.001	
	Okehampton	<0.001	<0.001	<0.001	
	Piacenza	<0.001	<0.001	<0.001	
	Porto	<0.001	<0.001	<0.001	
	Sevilla	<0.001	<0.001	<0.001	
	Thiva	<0.001	<0.001	<0.001	

$PEC_{(gw)}$ From lysimeter / field studies

Parent / metabolite	1st year	2nd year	3rd year
Not available, not required			

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

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	suntest II: $\Phi = 5.47 \times 10^{-6}$

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

	suntest III: $\Phi = 4.75 \times 10^{-6}$
Photochemical oxidative degradation in air ‡	Fenoxaprop-P-ethyl: 0.6 d Fenoxaprop-P: 0.3 d
Volatilisation ‡	From plant surfaces: no data; no significant volatilisation expected (vapour pressure at 20° C: 5.3 x 10-7 Pa)
	from soil: no data; no significant volatilisation expected
Metabolites	No data available, no data required

PEC (air)

Method of calculation	Expert judgement

$PEC_{(a)}$

Maximum concentration	Due to the short half-life of Fenoxaprop-P-ethyl and its free acid in the air and due to its low tendency for volatilisation (vapour presssure: 5.3×10^{-7} Pa, Henry constant: 2.7×10^{-4} Pa▪m³▪mol^{-1}, 20°C) no significant residues are expected in the atmosphere.

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: Fenoxaprop-P-ethyl, Fenoxaprop-P, chlorobenzoxazolone and HOPP-acid (when anaerobic conditions are prevalent). Surface Water: Fenoxaprop-P-ethyl, Fenoxaprop-P, HOPP-acid, chlorobenzoxazolone (from soil) Sediment: Fenoxaprop-P-ethyl, Fenoxaprop-P, chlorobenzoxazolone (from soil) Ground water: Fenoxaprop-P-ethyl, Fenoxaprop-P, chlorobenzoxazolone and HOPP-acid (when anaerobic conditions are prevalent). Air: Fenoxaprop-P-ethyl, Fenoxaprop-P

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

Soil (indicate location and type of study)	-
Surface water (indicate location and type of study)	-
Ground water (indicate location and type of study)	-
Air (indicate location and type of study)	-

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

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Candidate for R53

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

Appendix 1.6: Effects on non-target Species

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Japanese Quail	a.s.	Acute	~ 2000	-
Japanese Quail	EW14 formulation	Acute	> 2000 mg prod.	-
Japanese Quail	a.s.	Short-term	> 401	> 5000
Bobwhite Quail	a.s.	Long-term	30.8	400
Mammals ‡				
rat	a.s.	Acute	> 3150	-
rat	Puma S 69EW	Acute	> 4000 mg prod.	-
rat	a.s.	Long-term	9 – 36 (2-gen.) 10 (develop.)*	180 /
Additional higher tier studies ‡				
None				

* this value has been used for risk assessment

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

cereals (early or late) 83 g a.s./ha

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
large herbivorous bird	Acute	5.2	386 / > 27*	10
insectivorous bird		4.5	446 / > 32*	10
large herbivorous bird	Short-term	2.8	> 144	10
insectivorous bird		2.5	> 160	10
large herbivorous bird	Long-term	1.5	20.9	5
insectivorous bird		2.5	12.3	5
Tier 1 (Mammals)				
small herbivorous mammal	Acute	16	> 192 / > 16*	10
insectivorous mammal		0.7	> 4303 / > 383*	10
small herbivorous mammal	Long-term	4.7	2.2	5
insectivorous mammal		0.3	37.5	5

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

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Higher tier refinement (Mammals)				
small herbivorous mammal	Long-term	1.9	5.4 [1]	5

* a.s. / product including safener
[1] actual residues and decline considered

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 (Test type)	End point	Toxicity (mg/L)
Laboratory tests ‡				
Fish				
Lepomis macrochirus	Fenoxaprop-P-ethyl	96 hr (flow-through)	Mortality, EC_{50}	0.19_{mm}
Oncorhynchus mykiss	Fenoxaprop-P-ethyl	91 d (ELS, flow-through)	Mortality, NOEC	0.036_{nom}
Cyprinus carpio	Preparation "Puma S 69EW"	96 hr (static)	Mortality, EC_{50}	3.8 $_{nom}$ (0.27 mg a.s./L)
Oncorhynchus mykiss	AE F088406	96 hr (static)	Mortality, EC_{50}	$> 72.2_{mm}$
Oncorhynchus mykiss	AE F088406	28 d (flow-through)	Mortality, Growth NOEC	≥ 3.2 $_{nom}$
Oncorhynchus mykiss	AE F054014	96 hr (static)	Mortality, EC_{50}	$> 9.22_{mm}$
Oncorhynchus mykiss	AE F096918	96 hr (static)	Mortality, EC_{50}	353 $_{nom}$
Oncorhynchus mykiss	AE F096918	28 d (flow-through)	Mortality, Growth NOEC	≥ 32 $_{nom}$
Aquatic invertebrate				
Daphnia magna	Fenoxaprop-P-ethyl	48 h (static renewal)	Mortality, EC_{50}	$> 1.06_{mm}$
Daphnia magna	Fenoxaprop-P-ethyl	21 d (static renewal)	Reproduction, NOEC	0.22_{mm}
Daphnia magna	Preparation "Puma S 69EW"	48 h (static)	Mortality, EC_{50}	7.0 $_{nom}$ (0.5 mg a.s./L)
Daphnia magna	Preparation "Puma S 69EW"	21 d (static renewal)[2]	Reproduction, NOEC	0.0071 mg a.s./L $_{nom}$
Daphnia magna	Preparation "Puma S 69EW"	21 d (static renewal)[3]	Reproduction, NOEC	0.00925 mg a.s./L $_{nom}$
Daphnia magna	AE F088406	48 h (static)	Mortality, EC_{50}	126 $_{nom}$

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Daphnia magna	AE F088406	21 d (static renewal)	Reproduction, NOEC	1.0
Daphnia magna	AE F054014	48 h (static)	Mortality, EC_{50}	6.6
Daphnia magna	AE F096918	48 h (static)	Mortality, EC_{50}	> 200
Daphnia magna	AE F096918	21 d (static renewal)	Reproduction, NOEC	3.2
Sediment dwelling organisms				
Chironomus riparius	Fenoxaprop-P-ethyl	28 d (static)	Emergence, NOEC	0.2
Algae				
Scenedesmus subspicatus	Fenoxaprop-P-ethyl	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.54 0.66
Pseudokirchneriella subcapitata	Preparation "Puma S 69EW"	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	9.66 (0.69 mg a.s./L) 4.72 (0.34 mg a.s./L)
Pseudokirchneriella subcapitata	AE F088406	72 h (static)	Biomass: E_bC_{50}	35.0_m
Pseudokirchneriella subcapitata	AE F054014	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	8.0 9.9
Pseudokirchneriella subcapitata	AE F096918	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	9.6 53.4
Higher plant				
Lemna gibba	Fenoxaprop-P-ethyl	14 d (static)	Fronds, EC_{50}	≥ 2.76
Microcosm or mesocosm tests				
No study submitted, not required				

[1] based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$).
[2] Renewal of test media: 3 x the week
[3] Renewal of test media: 1 x after 10 days to simulate more realistic exposure conditions

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

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

FOCUS Step1

Cereals (1 x 83 g/ha)

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i	PEC_{twa}	TER	Annex VI Trigger
Fenoxaprop-P-ethyl	Fish	0.19	Acute	0.00384		**49**	100
Fenoxaprop-P-ethyl	Fish	0.036	Chronic	0.00384		**9.4**	10
Fenoxaprop-P-ethyl	Aquatic invertebrates	> 1.06	Acute	0.00384		>276	100
Fenoxaprop-P-ethyl	Aquatic invertebrates	0.220	Chronic	0.00384		57	10
Fenoxaprop-P-ethyl	Algae	0.54	Chronic	0.00384		135	10
Fenoxaprop-P-ethyl	Higher plants	> 2.76	Chronic	0.00384		>719	10
Fenoxaprop-P-ethyl	Sediment-dwelling organisms	0.2	Chronic	0.00384		52	10
AE F088406	Fish	> 72.2	Acute	0.0163		>4440	100
AE F088406	Fish	≥ 3.2	Chronic	0.0163		>197	10
AE F088406	Aquatic invertebrates	126	Acute	0.0163		7749	100
AE F088406	Aquatic invertebrates	1.0	Chronic	0.0163		62	10
AE F088406	Algae	34.2	Chronic	0.0163		197	10
AE F054014	Fish	> 9.22	Acute	0.00168		>5488	100
AE F054014	Aquatic invertebrates	6.6	Acute	0.00168		3929	100
AE F054014	Algae	8.0	Chronic	0.00168		4762	10
AE F096918	Fish	353	Acute	0.000101		$3.5x10^5$	100
AE F096918	Fish	> 32	Chronic	0.000101		>316832	10
AE F096918	Aquatic invertebrates	> 200	Acute	0.000101		$>1.98x10^5$	100
AE F096918	Aquatic invertebrates	3.2	Chronic	0.000101		31683	10
AE F096918	Algae	9.6	Chronic	0.000101		95050	10
Puma S 69EW	Fish	0.27	Acute	0.00384		**70**	100

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

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i	PEC_{twa}	TER	Annex VI Trigger
Puma S 69EW	Aquatic invertebrates	0.5	Acute	0.00384		130	100
Puma S 69EW	Aquatic invertebrates	0.0071	Chronic	0.00384		**1.9**	10
Puma S 69EW	Aquatic invertebrates	0.00925	Chronic	0.00384	**2.4**	10	
Puma S 69EW	Algae	0.34	Chronic	0.00384	88	10	

FOCUS Step 2

Cereals (1 x 83 g/ha)

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i	TER	Annex VI Trigger
Fenoxaprop-P-ethyl	Fish	0.19	Acute	0.000763	249	100
Fenoxaprop-P-ethyl	Fish	0.036	Chronic	0.000763	47	10
Fenoxaprop-P-ethyl	Aquatic invertebrates	> 1.06	Acute	0.000763	>1389	100
Fenoxaprop-P-ethyl	Aquatic invertebrates	0.220	Chronic	0.000763	288	10
Fenoxaprop-P-ethyl	Algae	0.54	Chronic	0.000763	628	10
Fenoxaprop-P-ethyl	Higher plants	> 2.76	Chronic	0.000763	>3617	10
Fenoxaprop-P-ethyl	Sediment-dwelling organisms	0.2	Chronic	0.000763	262	10
AE F088406	Fish	> 72.2	Acute	0.00445	>16225	100
AE F088406	Fish	≥ 3.2	Chronic	0.00445	719	10
AE F088406	Aquatic invertebrates	126	Acute	0.00445	28315	100
AE F088406	Aquatic invertebrates	1.0	Chronic	0.00445	225	10
AE F088406	Algae	34.2	Chronic	0.00445	7685	10
AE F054014	Fish	> 9.22	Acute	0.000466	>19785	100
AE F054014	Aquatic invertebrates	6.6	Acute	0.000466	14163	100
AE F054014	Algae	8.0	Chronic	0.000466	17167	10
AE F096918	Fish	353	Acute	0.000101	$3.5x10^5$	100
AE F096918	Fish	> 32	Chronic	0.000101	>316832	10
AE F096918	Aquatic invertebrates	> 200	Acute	0.000101	$>1.98x10^5$	100
AE F096918	Aquatic invertebrates	3.2	Chronic	0.000101	31683	10

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

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i	TER	Annex VI Trigger
AE F096918	Algae	9.6	Chronic	0.000101	95050	10
Puma S 69EW	Fish	0.27	Acute	0.000763	354	100
Puma S 69EW	Aquatic invertebrates	0.5	Acute	0.000763	655	100
Puma S 69EW	Aquatic invertebrates	0.0071	Chronic	0.000763	**9**	10
Puma S 69EW	Aquatic invertebrates	0.00925	Chronic	0.000763	12	10
Puma S 69EW	Algae	0.34	Chronic	0.000763	442	10

Bioconcentration				
	Fenoxaprop-P-ethyl	AE F088406	AE F054014	AE F096918
$logP_{O/W}$	4.58	no data	1.9	no data
Bioconcentration factor (BCF) ‡	338 (whole fish)			
Annex VI Trigger for the bioconcentration factor	100			
Clearance time (days) (CT_{50})	0.4 d			
(CT_{90})				
Level and nature of residues (%) in organisms after the 14 day depuration phase	1 %			

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s. ‡	> 199	> 200
Preparation Puma S 69EW	23.2 a.s.	> 36.4 a.s.
Field or semi-field tests		
Not required		

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

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

cereals 83 g a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	< 0.4	50
a.s.	oral	< 0.4	50
Puma S 69EW	Contact	3.4	50
Puma S 69EW	oral	< 2.3	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha)
Typhlodromus pyri ‡	Puma S 69EW	Mortality	> 82.2 a.s.
Aphidius rhopalosiphi ‡	Puma S 69EW	Mortality	46.4 a.s.

cereals 83 g a.s/ha

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
Puma S 69EW	*Typhlodromus pyri*	> 82.2	< 1	< 0.03	2
Puma S 69EW	*Aphidius rhopalosiphi*	46.4	1.8	0.05	2

[1] 1 m distance

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
Chrysoperla carnea	larvae - adult	Puma S 69EW, glassplate	82 a.s. initial	mortality fecundity	9.5 no effect	50 %

Field or semi-field tests
Not required

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

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
Earthworms			
	a.s. ‡	Acute 14 days	$LC_{50corr.}$ > 500 mg a.s./kg d.w.soil
	a.s. ‡	Chronic 8 weeks	not required
	Hoe 046360 24 EW14 A203	Acute	LC_{50} 240 mg product/kg d.w.soil
	Preparation	Chronic	not required
	Fenoxaprop-P	Acute	LC_{50} > 1000 mg a.s./kg d.w.soil
	Chlorobenzoxazolone	Acute	560 < LC_{50} < 1000 mg a.s./kg d.w.soil
Other soil macro-organisms			
Not required			
Soil micro-organisms			
Nitrogen mineralisation	a.s. ‡		< 22 % effect at day 0 - 56 at 0.133 mg a.s./kg d.w.soil (100 mg a.s/ha)
Carbon mineralisation	a.s. ‡		< 4 % effect at day 0 - 28 at 0.133 mg a.s./kg d.w.soil (100 mg a.s/ha)
Field studies			
Not required			

Toxicity/exposure ratios for soil organisms

cereals 100 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
	a.s. ‡	Acute	0.100	$TER_{corr.}$ > 5000	10
	a.s. ‡	Chronic	-	-	5
	Preparation	Acute	1.410	$TER_{corr.}$ 85	10
	Fenoxaprop-P	Acute	0.075	> 13333	10
	Chlorobenzoxazolone	Acute	0.009	> 62222	10

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

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha) vegetative vigour	ER_{50} (g/ha) emergence	Exposure $(g/ha)^2$	TER	Trigger
Zea mais	Puma S 69EW	8.14 a.s.		0.47 a.s.	17.3	5

Additional studies (e.g. semi-field or field studies)

Not required

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	Endpoint
Activated sludge	EC_{50} > 1000 mg a.s./L
Pseudomonas sp	/

Ecotoxicologically relevant compounds

Compartment	
soil	Fenoxaprop-P-ethyl
water	Fenoxaprop-P-ethyl
sediment	Fenoxaprop-P-ethyl
groundwater	-
Remark	Residue definition for monitoring: Fenoxaprop-ethyl and the sum of all compounds those give 6-chloro-2,3-dihydrobenzoxazol-2-one (AE F054014) metabolites, expressed as fenoxaprop-P-ethyl

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

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal	
Active substance	N,	harmful
	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effect in the aquatic environment

	RMS/peer review proposal	
Preparation	N,	harmful
	R51/53	Toxic to aquatic organisms, may cause long-term adverse effect in the aquatic environment

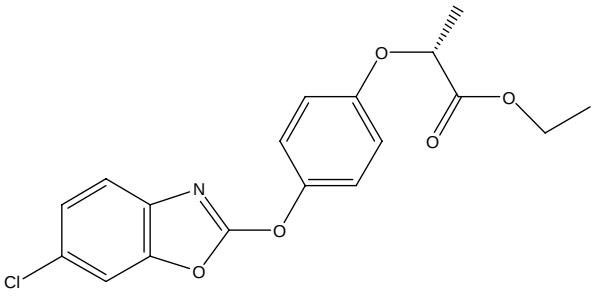
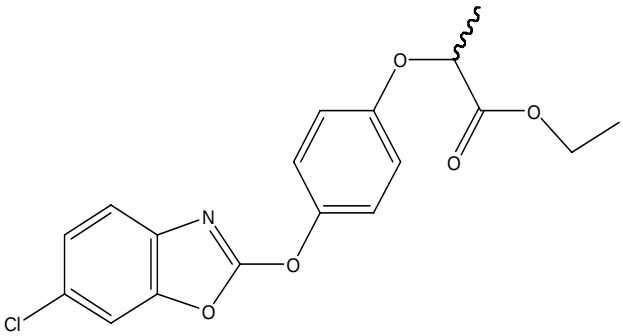
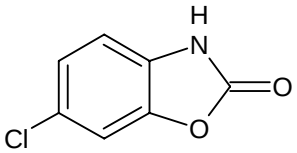
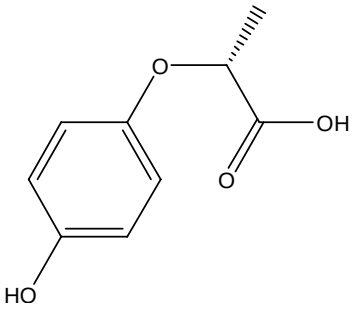
‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry

LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
Fenoxaprop-P AE F088406	(D+)-2-[4-(6-chloro-2-benzoxazolyloxy)-phenoxy]-propanoic acid	
Fenoxaprop AE F053022	(*RS*)-2-[4-(6-chloro-2-benzoxazolyloxy)-phenoxy]-propanoic acid	
Chlorobenzoxazolone AE F05014	6-chloro-2,3-dihydrobenzoxazol-2-one [6-chloro-1,3-benzoxazol-2(3*H*)-one]	
HOPP-acid AE F096918	(D+)-2-(4-hydroxyphenoxy)-propionic acid	
HOPP-acid AE F020686	(*RS*)-2-(4-hydroxyphenoxy)-propionic acid