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CONCLUSION ON PESTICIDE PEER REVIEW

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

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ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State, the United Kingdom, for the pesticide active substance esfenvalerate, are reported. The context of the peer review was that required by Commission Regulation (EU) No 1141/2010 as amended by Commission Implementing Regulation (EU) No 380/2013. The conclusions were reached on the basis of the evaluation of the representative uses of esfenvalerate as an insecticide on cereals, potatoes and oilseed rape. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

KEY WORDS

esfenvalerate, peer review, risk assessment, pesticide, insecticide

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SUMMARY

Commission Regulation (EU) No 1141/2010, as amended by Commission Implementing Regulation (EU) No 380/2013, (hereinafter referred to as 'the Regulation') lays down the procedure for the renewal of the approval of a second group of active substances and establishes the list of those substances. Esfenvalerate is one of the active substances listed in the Regulation.

The rapporteur Member State (RMS) provided its initial evaluation of the dossier on esfenvalerate in the Renewal Assessment Report (RAR), which was received by the EFSA on 30 July 2013. The peer review was initiated on 28 August 2013 by dispatching the RAR for consultation of the Member States and the applicant Sumitomo Chemical Agro Europe S.A.S.

Following consideration of the comments received on the RAR, it was concluded that EFSA should conduct an expert consultation in the areas of mammalian toxicology and ecotoxicology and EFSA should adopt a conclusion on whether esfenvalerate can be expected to meet the conditions provided for in Article 4 of Regulation (EC) No 1107/2009 of the European Parliament and the Council.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of esfenvalerate as an insecticide on cereals, potatoes and oilseed rape, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

A data gap was identified in the area of analytical methods.

In the area of mammalian toxicology, a data gap is identified related to the lack of assessment of the toxicological relevance of impurities in the technical specification. A data gap and a critical area of concern have been concluded based on the fact that the batches tested in the toxicological studies have not been demonstrated as representative of the technical specification.

In the area of residues and consumer exposure data gaps or concerns were not identified.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level for the representative uses, with the notable exception that information is missing regarding the adsorption of the anaerobic soil metabolites CPIA and PBacid and the degradation rate in soil under aerobic conditions of the metabolite CPIA. Consequently, the groundwater exposure assessments for these metabolites could not be finalised, for the representative uses on winter cereals and winter oilseed rape.

In the area of ecotoxicology, a data gap for the aquatic organisms and a critical area of concern was concluded. The risk characterisation of the 2SαR-isomer of fenvalerate for aquatic organisms could not be finalised. A data gap was also concluded to demonstrate the in-field recolonisation of non-target arthropods. Furthermore, a data gap and a critical area of concern were identified in relation to the compliance of the tested batches with the proposed specification.

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BACKGROUND

Commission Regulation (EU) No 1141/2010[3] as amended by Commission Implementing Regulation (EU) No 380/2013[4] (hereinafter referred to as 'the Regulation') lays down the detailed rules for the procedure for the renewal of the approval of a second group of active substances. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant for comments on the initial evaluation in the Renewal Assessment Report (RAR) provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

In accordance with Article 16 of the Regulation, if mandated, EFSA is required to adopt a conclusion on whether the active substance is expected to meet the conditions provided for in Article 4 of Regulation (EC) No 1107/2009 within 6 months from the receipt of the mandate, subject to an extension of upto 9 months where additional information is required to be submitted by the applicant(s) in accordance with Article 16(3).

In accordance with Article 4 of the Regulation the United Kingdom (hereinafter referred to as the 'RMS') received an application from Sumitomo Chemical Agro Europe S.A.S. for the renewal of approval of the active substance esfenvalerate. Complying with Article 11 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on esfenvalerate in the RAR, which was received by the EFSA on 30 July 2013 (United Kingdom, 2013). The peer review was initiated on 29 August 2013 by dispatching the RAR to Member States and the applicant Sumitomo Chemical Agro Europe S.A.S. for consultation and comments. In addition, EFSA conducted a public consultation on the RAR. The comments received were collated by EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant, in accordance with Article 16(3) of the Regulation, were considered in a telephone conference between EFSA, the RMS, and the European Commission on 10 December 2013. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant and EFSA should organise an expert consultation in the areas of mammalian toxicology and ecotoxicology. According to Art. 16(2) of the Regulation COM decided to consult EFSA. The mandate was received on 8 January 2014.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, and the additional information to be submitted by the applicant, were compiled by EFSA in the format of an Evaluation Table.

[3] Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances. OJ L 322,8.12.2011, p. 10-19.

[4] Commission Implementing Regulation (EU) No 380/2013 of 25 April 2013 amending Regulation (EU) No 1141/2010 as regards the submission of the supplementary complete dossier to the Authority, the other Member States and the Commission. OJ L 116, 26.4.2013, p.4

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert consultation where this took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in September – October 2014

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as an insecticide on cereals, potatoes and oilseed rape, as proposed by the applicant. A list of the relevant end points for the active substance, as well as the formulation, is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2014) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the RAR,
- the Reporting Table (10 December 2013),
- the Evaluation Table (17 October 2014),
- the report(s) of the scientific consultation with Member State experts (where relevant),
- the comments received on the assessment of the additional information (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR including its addendum (compiled version of June 2014 containing all individually submitted addenda (United Kingdom, 2014)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated to have regulatory access to the information on which this conclusion report is based.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Esfenvalerate is the ISO common name for (α*S*)-α-cyano-3-phenoxybenzyl (2*S*)-2-(4-chlorophenyl)-3-methylbutyrate (IUPAC).

The representative formulated product for the evaluation was 'Esfenvalerate 5 EC', an emulsifiable concentrate (EC) containing 50 g/L esfenvalerate.

The representative uses evaluated comprise applications by foliar spraying to control a range of insects in spring and winter cereals, potatoes and spring and winter oilseed rape. Full details of the GAPs can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000), SANCO/10597/2003 – rev. 10.1 (European Commission, 2012), and SANCO/825/00 rev. 8.1 (European Commission, 2010).

The minimum purity of esfenvalerate technical material is 830 g/kg. An FAO specification does not exist.

The proposed specification is based on batch data from industrial scale production. Toluene was considered as relevant impurity with no toxicological concern at the level present in the technical material (see section 2). 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 esfenvalerate or the representative formulation. The main data regarding the identity of esfenvalerate and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of esfenvalerate and the respective impurities in the technical material. The representative formulation can be analysed for the total isomers by GC-FID and for the isomer ratio by chiral HPLC. It should be mentioned that CIPAC methods also exist for the determination of esfenvalerate in the technical material and formulations.

The compounds of the residue definition for food and feed of plant origin can be monitored using the multi-residue method DFG S19 with LOQs of 0.01 mg/kg in all commodity groups. The residue definition for food and feed of animal origin was set as fenvalerate (any ratio of constituent isomers including esfenvalerate), however for liver and kidney a separate residue definition was proposed, including also CPIA (see section 3). A GC-ECD method exists for monitoring fenvalerate with a LOQ of 0.01 mg/kg for the total isomers, while CPIA in liver and kidney can be determined by LC-MS/MS with a LOQ of 0.01 mg/kg. It should be mentioned that a data gap has been identified for additional validation data to assess the extraction efficiency used in the animal methods.

Residues of esfenvalerate in soil can be monitored by LC-MS/MS with a LOQ of 0.01 mg/kg or by GC-ECD or GC-MS with LOQs of 0.005 mg/kg. An appropriate GC-ECD method is available for monitoring esfenvalerate in surface water and drinking water with a LOQ of 0.001 µg/L. Esfenvalerate in the air can be determined by GC-ECD with a LOQ of 0.1 µg/m^3. Analytical methods for the determination of esfenvalerate residues in human body fluids are GC-ECD or GC-MS/MS with a LOQ of 0.005 mg/L in blood and for human tissues the methods for food of animal origin are applicable.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000 rev. 10 - final (European Commission, 2003), SANCO/222/2000 rev. 7 (European Commission, 2004) and SANCO/10597/2003 – rev. 10.1 (European Commission, 2012).

In the original dossier, toxicological data for both fenvalerate and esfenvalerate had been assessed and used for the risk assessment for humans (taking into account that esfenvalerate is one of the 4 isomers of fenvalerate, the [2S,αS] isomer). In the renewal dossier, the new studies provided for esfenvalerate constituted a sufficient data package to derive specific reference values for esfenvalerate.

Esfenvalerate was discussed by the experts in mammalian toxicology during the peer review meeting 114 and 118 (May and September 2014). With regard to the technical specification, toluene is a toxicologically relevant impurity, of no concern at the proposed level, and the impurity 2 is not toxicologically relevant. For the impurities 3 to 11, the (non-)toxicological relevance cannot be concluded on the basis of the available assessment (data gap). Based on the lack of analytical data for the batches used in the toxicological studies, they cannot be considered to be representative of the technical specification (critical area of concern).

Esfenvalerate has an oral absorption value of 64%; it is acutely toxic by the oral and inhalation routes and is a skin sensitiser. The harmonised classification[5] is Acute Tox 3 (H301 and H331) and Skin Sens 1 (H317) whereas the peer review proposed Acute Tox 2 (H330) for the acute toxicity by inhalation. It is not a skin or eye irritant, it is of low acute dermal toxicity. In short term studies, the critical effects were clinical signs of neurotoxicity in rats (NOAEL 2.5 mg/kg bw per day) and mice (NOAEL 30.5 mg/kg bw per day), and no adverse effects were observed in dogs up to 5 mg/kg bw per day. It was not shown to be genotoxic *in vitro* or *in vivo*, esfenvalerate is proposed to be classified[6] as Carc. Cat. 2 on the basis of increased incidences of Leydig cell tumours in the 2-year rat study. The NOAEL for systemic toxicity and for carcinogenic effects in rats is 2.3 mg/kg bw per day. In mice, the long term NOAEL is 4.3 mg/kg bw per day and no treatment-related tumours were observed. In the reproductive toxicity studies, no adverse effects were observed on fertility parameters, gestation, reproductive organs and foetal development. From the 2-generation and one-generation studies, an overall parental NOAEL of 2.4 mg/kg bw per day was derived. From the developmental studies (including the pilot studies), parental NOAELs of 3 and 2 mg/kg bw per day were established for rats and rabbits respectively, with a developmental NOAEL of 20 mg/kg bw per day for both species. In the acute neurotoxicity study with rats, a NOAEL of 1.75 mg/kg bw per day was set on the basis of clinical signs of neurotoxicity. The same kind of effects were observed in the 90-day neurotoxicity studies with an overall NOAEL of 3.2 mg/kg bw per day.

The plant metabolite CPIA, being a major metabolite of esfenvalerate in the rat and mouse (up to ~15% of the administered dose), can be considered as being covered by the reference values of esfenvalerate. The metabolite dec-Fen was shown to be not mutagenic in an Ames test. With an acute oral LD_{50} >5000 mg/kg bw and an acute dermal LD_{50} >2000 mg/kg bw, it was not irritant to the rabbit skin and eyes, and not a skin sensitiser in guinea pigs. The metabolite $CONH_2$-Fen was demonstrated to be of low acute oral toxicity (LD_{50} > 2800 mg/kg bw), and was non-mutagenic in a reverse mutation test (Ames test). According to the guidance document on groundwater metabolite relevance, all the potential groundwater metabolites have to be considered toxicologically relevant since it has not been demonstrated that they do not share the carcinogenic properties of the parent.

Data from a literature search and from *in vivo* and *in vitro* assays conducted for US EPA's Endocrine Disruptor Screening Programme (EDSP) (Tier 1 Battery) were provided during the peer review. Esfenvalerate did not exhibit any evidence of endocrine mediated effects in the EDSP's assays, including studies for androgen receptor binding, aromatase, estrogen receptor binding, estrogen receptor transcriptional activation, Hershberger, female pubertal, male pubertal, steroidogenesis and uterotrophic assessment.

[5] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[6] It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

In an article identified during the first expert meeting (Pine, 2008), delayed vaginal opening and hormonal changes were observed in prepubertal female rats. In its evaluation, the RMS noted that the described study had some limitations such as missing investigations of the systemic toxicity. In a second discussion (Peer Review Meeting 118), the experts agreed that these effects were overruled by the studies submitted to US EPA (EDSP battery), where the investigated end points would have been affected by the hormonal changes observed in the Pine study. Additionally, no effect was observed on the time of vaginal opening in the US EPA study (GLP and guideline).

Regarding the interim provisions of Regulation (EC) No. 1107/2009 for the consideration of potential endocrine disrupting properties, esfenvalerate is not classified or proposed to be classified as toxic for the reproduction category 2. With regard to the scientific risk assessment, following the EFSA Scientific Opinion on the hazard assessment of endocrine disruptors (EFSA, 2013), esfenvalerate is unlikely to have endocrine disrupting properties. This conclusion is based on the absence of adverse effects in the US EPA's EDSP assays and in the regulatory studies.

The acceptable daily intake (ADI) is 0.0175 mg/kg bw per day, the acute reference dose (ARfD) is 0.0175 mg/kg bw, both are based on the rat acute neurotoxicity study and applying an uncertainty factor of 100. The acceptable operator exposure level (AOEL) is 0.011 mg/kg bw per day on the basis of the rat acute neurotoxicity study, with an uncertainty factor of 100 and a correction for an oral absorption value of 64%.

The experts agreed that these reference values are also applicable to fenvalerate, taking into account that esfenvalerate appears to be more toxic in rat studies and has a similar level of toxicity to fenvalerate in the mouse studies.

The exposure estimates (provided for dermal absorption values according to both new and old guidance) do not exceed the AOEL for operators, workers, bystanders and residents (with use of personal protective equipment for operators according to the UK POEM).

3. Residues

The assessment in the residue section below is based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999), and the JMPR recommendations on livestock burden calculations stated in the 2004 and 2007 JMPR reports (JMPR, 2004, 2007).

Primary crop metabolism of esfenvalerate and fenvalerate was investigated in three different crop groups following foliar application. Metabolic patterns in the different studies were shown to be similar and the relevant residue for enforcement and risk assessment in all crops supported in the framework of this review could be defined as fenvelerate (any ratio of constituent isomers including esfenvalerate).

Regarding the magnitude of residues in primary crops, the available residues data were considered acceptable to derive MRL proposals and risk assessment values for all the representative uses. Processing studies were not required as the overall chronic exposure did not exceed 10 % of the ADI. Occurrence of esfenvalerate residues in rotational crops was investigated in cereal, root and leafy crops. It was concluded that significant residues in rotational crops would not be expected.

Based on the representative uses significant intakes were calculated for dairy ruminant, meat ruminants and pigs but not for poultry. Metabolism in lactating ruminants was sufficiently investigated and findings can be extrapolated to pig. The relevant residue definition for enforcement in meat, fat, milk and eggs was defined as fenvelerate (any ratio of constituent isomers including esfenvalerate). The same residue definition can apply for the risk assessment related to the consumption of these commodities. Considering liver and kidney the relevant residue definition for risk assessment and enforcement is the sum of fenvelerate (any ratio of constituent isomers including esfenvalerate) and CPIA, expressed as fenvalerate. Feeding studies were available and with the metabolism data the levels of the residues in products of animal origin were calculated. The residues in animal products

may be slightly over estimated, but given that there is a margin of safety in the consumer risk assessment this can be accepted.

Chronic consumer exposure resulting from the MRLs proposed was calculated using revision 2 of the EFSA PRIMo model. Intakes were less than 10% of the ADI and regarding acute exposure the highest intake was for table grapes at 37.4 % of the ARfD.

4. Environmental fate and behaviour

In soil laboratory incubations under aerobic conditions in the dark, esfenvalerate did not epimerise, it exhibited moderate to high persistence, forming the major (>10% applied radioactivity (AR)) metabolite $CONH_2$-Fen (max. 32 % AR, isomer composition unknown), which exhibited low to moderate persistence. Mineralisation of the phenoxyphenyl ring, benzylmethyne and carbonyl 14C radiolabels to carbon dioxide accounted for 21 - 82 % AR after 84-100 days. The formation of unextractable residues (not extracted by methanol, methanol / water, acetone or acetone / methanol) for these radiolabels accounted for 5 – 39 % AR after 84-180 days. In anaerobic soil incubations esfenvalerate exhibited medium persistence (single first order DT_{50} 65 days) forming the major metabolites PBacid (max. 22 % AR, which exhibited very low persistence under aerobic conditions) and CPIA (max. 38 % AR, isomer composition unknown, with a data gap being identified for its aerobic soil degradation rate, see section 7). In a laboratory soil photolysis study the major metabolite Dec-Fen (max 15.3% AR, isomer composition unknown, diastereoisomer ratio available) was formed. Esfenvalerate, $CONH_2$-Fen and Dec-Fen were immobile in soil. Data gaps have been identified for soil mobility information for PBacid and CPIA, as the PBacid information cited by the applicant was ineligible to be considered in an EFSA conclusion, consequently the read across case from PBacid to CPIA also has to be treated as ineligible. Batch adsorption data assessed as reliable in EFSA conclusions for other pyrethroid compounds for PBacid indicate that PBacid exhibits very high to high mobility in soil. It was concluded that the soil adsorption of these compounds is not pH dependent in the range of environmentally relevant pH. In satisfactory field dissipation studies carried out at 11 sites across Europe (spray application to the soil surface on bare soil plots in summer and autumn) esfenvalerate exhibited very low to medium persistence. Sample analyses were only carried out for esfenvalerate and its isomers (epimerisation did not occur) and $CONH_2$-Fen (isomer composition unknown due to the analytical method used). $CONH_2$-Fen concentrations were up to 0.059 mg/kg in the top 5 cm soil layer but the patterns of the levels detected did not allow kinetics of formation and decline to be estimated.

In laboratory incubations in dark aerobic natural sediment water systems, esfenvalerate partitioned to sediment where it exhibits moderate to high persistence, forming the major metabolites PBacid (max. 18 % AR) and CPIA (max. 54 % AR, isomer composition unknown). In the sediment/water study where esfenvalerate was dosed to (mixed with) the sediment, analysis was appropriate to confirm that the 2SαR-isomer isomer accounted for 5.3% of the applied radioactivity which represented 13.7% of the measured esfenvalerate in sediment at 56 days. However in the sediment water study where esfenvalerate was applied to surface water, 32% AR remained in the water phase as constituent isomers of fenvalerate (chiral analysis was not carried out) for the first 2 days. Therefore with the available data, epimerisation to the 2SαR-isomer of fenvalerate, as was measured in neutral and alkaline hydrolysis studies, cannot be excluded to be of significance in natural sediment water systems. Therefore, EFSA has included the 2SαR-isomer of fenvalerate in the residue definition for exposure assessment in surface water. The unextractable sediment fraction (not extracted by acetone or acidified ethyl acetate followed by methanol) was a sink for the benzylphenyl and chlorophenyl ring 14C radiolabels, accounting for 11 – 16 % AR at study end (100-126 days). Mineralisation of these radiolabels accounted for 21-42 % AR at 98-100 days. The rate of decline of esfenvalerate in a laboratory sterile aqueous photolysis experiment was rapid compared to that which occurred in the aerobic sediment water incubations. The major metabolites identified were Dec-Fen (max 37% AR, isomer composition unknown, diastereoisomer ratio available), PA-Fen (max. 11 % AR, isomer composition unknown) and PBacid (max. 18 % AR). Surface water and sediment exposure assessments (Predicted environmental concentrations (PEC) calculations) were carried out for the

metabolites $CONH_2$-Fen, Dec-Fen, CPIA and PA-Fen (as sum of isomers) and PBacid, using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 1.1 of the Steps 1-2 in FOCUS calculator). For the active substance esfenvalerate and the 2SαR-isomer of fenvalerate, appropriate step 3 (FOCUS, 2001) and step 4 calculations were available that represent the sum of these isomers[7]. The step 4 calculations appropriately followed the FOCUS (FOCUS, 2007) guidance, with no-spray drift buffer zones of up to 20 m being implemented (representing a 58 – 93 % spray drift reduction). The SWAN tool (version 1.1.4) was appropriately used to implement these mitigation measures in the simulations.

Groundwater exposure assessments were carried out using FOCUS (FOCUS, 2009) scenarios and the models PEARL 4.4.4[7] for the active substance esfenvalerate and its soil metabolites $CONH_2$-Fen and Dec-Fen. The potential for groundwater exposure from the representative uses by these compounds above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios. For the anaerobic soil metabolites CPIA and PBacid, it has not been demonstrated that it can be excluded that they are formed in groundwater vulnerable situations, for the representative uses on winter cereals and winter oilseed rape, it is not possible to conclude on the potential for groundwater exposure whilst adsorption data eligible to be considered by the peer review for these metabolites are not available. A soil half life for CPIA is not available. A data gap has been identified in section 7 in relation to the missing information on these anaerobic soil metabolites. This is identified as an assessment not finalised (see sections 9.1 and 9.3).

The PEC in soil, surface water, sediment, and groundwater covering the representative uses assessed can be found in Appendix A of this conclusion with the exception that for oilseed rape crops, situations when 4 (north EU spring crops and south EU spring and winter crops) or 6 applications (north EU winter crops) would be made, as would be possible the way that these uses have been defined in the GAP table, should seed weevils require the maximum number of treatments in addition to the maximum number of treatments being made to control the other pests indicated, when present at earlier growth stages. The available exposure assessments only cover 2 and 3 applications respectively. Consequently the available risk characterisations do not cover these situations of a higher number of applications. Therefore a data gap was identified in section 7.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a, 2002b, 2002c), SETAC (2001), and EFSA (2009).

Some aspects of the risk assessment were discussed at the Pesticides Peer Review Meeting 115 (May 2014).

The acute and the long-term risks to **birds** and to **mammals** via dietary exposure were assessed as low for the active substance for all the representative uses with the screening step and/or the first-tier assessment. The risks via consumption of contaminated water and via secondary poisoning were also considered as low.

A number of studies were available on **aquatic organisms** with the active substance, the representative formulated product and the pertinent metabolites. Fish and invertebrates were the most sensitive organisms, but fish showed a higher sensitivity than invertebrates under laboratory exposure regimes. To further investigate the effects of esfenvalerate on this group of organisms under more realistic conditions, several mesocosm studies were carried out. The results of these studies indicated that some aquatic insects were more sensitive than standard species (*Daphnia magna*) tested in laboratory. The mesocosm studies including fish indicated that fish tested under the exposure conditions of these model ecosystems were less sensitive than fish tested under laboratory conditions. Overall, the experts at the Pesticides Peer Review Meeting 115 (May 2014) agreed to used the NOEC

[7] Simulations correctly utilised the agreed Q_{10} of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7

of 0.001 µg a.s./L from mesocosms, based on the most sensitive aquatic insects. The experts also agreed to apply an assessment factor of 2. Therefore, the agreed regulatory acceptable concentration (RAC) was 0.0005 µg a.s./L. This RAC drove the acute and chronic risk assessment for the aquatic environment, i.e. it also covers the risk to fish. Overall, the risk based on standard toxicity endpoints was assessed as low for algae (with FOCUS step 3 PECsw) and Chironomids (with FOCUS step 4 PECsw) for all the representative uses. However, the risk assessment based on RAC of 0.0005 µg a.s./L and FOCUS step 4 PECsw, including mitigations measures comparable with no spray buffer zone of 20 m (representing up to 93% drift mitigation), indicated a high risk to the aquatic environment for all the representative uses. According to the criteria laid down in the aquatic guidance document (European Commission, 2002b), a risk of potential for bioaccumulation in the aquatic food chain was triggered. Further investigation was carried out by the Applicant by mean of simple food web modelling. However, this modelling was considered not suitable to address this issue. Overall, the risk to aquatic organisms, including the bioaccumulation through the food chain should be further addressed (data gap). The risk to aquatic organisms from the metabolites, except 2SαR-isomer of fenvalerate, was assessed as low. The 2SαR-isomer of fenvalerate formed in surface water should be further considered within the data gap identified for esfenvalerate.

The acute toxicity to **honeybees** was investigated with the active substance (contact) and the product SUMI-ALPHA 5% EC (oral and contact), considered comparable to the representative formulation. The active substance and the formulated product had a similar toxicity via contact exposure. The data on the formulated product indicated that contact toxicity is higher than the oral toxicity. The first-tier risk assessment based on the oral and contact HQs, indicated a high risk to honeybees. In addition to the semi-field and field studies available for the first approval of esfenvalerate, several new field studies were provided. All these new studies were performed in Germany except one study performed in France. A single application was tested: the study in France was carried out at 15 g a.s./ha; two of the studies in Germany were performed at 25 g a.s./ha and the others at 12.5 g a.s./ha. All these studies were either insufficient or not robust enough to draw a clear conclusion for the representative uses regarding the effects of esfenvalerate in field, particularly regarding the extent and the occurrence of exposure. They showed inconsistent results regarding the increase in mortality but when effects on mortality occurred they were not long-lasting and did not affect the survival of the hive. The studies showed flight activity reduction that lasted for the day of application. Overall, on the basis of the available information, the experts at the Pesticides Peer Review Meeting 115 (May 2014) agreed that the risk to honeybees can be addressed with the application of appropriate mitigation measures aimed at reducing the contact exposure, such as for example the application being timed after bee flight. However, it has to be noted that no studies were available to investigate the effects on bees under these circumstances. It has also to be noted that, since the dossier was submitted and evaluated by the RMS before the adoption of the opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (EFSA, 2012), the higher tier studies available (i.e. the field studies mentioned above) and the risk to bees were not evaluated by considering the recommendations of this opinion. It is further noted that the available assessments refer to honeybees but other pollinators such as wild bees are not covered.

A high in-field and off-field risk to **non-target arthropods** was not excluded with the first tier risk assessments based on the HQs. A high risk was also not excluded based on extended laboratory studies. The available field studies were considered as not suitable for risk assessment or not sufficient to demonstrate a potential for the in-field recovery for some species, while risk mitigation measures comparable to no-spray buffer zone of 5 m were sufficient to address the off-field risk. A data gap was agreed to demonstrate the in-field recolonisation.

The risk was indicated as low for **earthworms**, **soil macro and microorganisms**, **terrestrial non-target plants, organisms in sewage treatment plants**.

With regard to the endocrine disruption potential, as discussed in Section 2, it is unlikely that esfenvalerate is an endocrine disruptor in mammals; however no firm conclusion can be drawn regarding birds and fish (21-day amphibian metamorphosis and 21-day fish assay available).

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

6.1 Soil

Compound (name and/or code)	Persistence	Ecotoxicology
esfenvalerate	Very low to high persistence Single first-order DT_{50} 35-109 days, + 3 soils biphasic kinetics DT_{50} 16.2-19.1 days (DT_{90} 133-273 days, all normalised to 20ºC pF2) European field dissipation studies Single first-order DT_{50} 9.4-36.5 days, biphasic kinetics DT_{50} 0.3-38.8 days (DT_{90} 38.5-259 days)	Low risk for soil organisms
$CONH_2$-Fen (sum of isomers)	low to moderate persistence Biphasic kinetics DT_{50} 1.3-3.7 days (DT_{90} 30.6-105 days, 20ºC 21-40% MWHC)	Low risk for soil organisms
Dec-Fen (sum of isomers)	Data not available. Environmental exposure assessments completed using a DT_{50} of 1000 days.	No data. However, the risk for soil organisms may be considered as low.
PBacid (anaerobic metabolite)	Very low persistence Single first-order DT_{50} 0.288-0.375 days (20ºC 55% MWHC)	No data. However, the risk for soil organisms may be considered as low.
CPIA (sum of isomers, anaerobic metabolite)	Data gap	No data. However, the risk for soil organisms may be considered as low.

6.2 Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
esfenvalerate	Immobile K_{doc} 85700-596200 mL/g	No	Yes	Yes	Yes
$CONH_2$-Fen (sum of isomers)	Immobile K_{Foc} 38532-217658 mL/g	No	Information not available, assessment not triggered	Yes, based on the proposed classification[(a)] as Carc Cat 2 for the parent	Risk assessed as low for higher surface water exposure levels
Dec-Fen (sum of isomers)	Immobile Based on QSAR estimates and an uncertainty factor of 10.	No	Information not available, assessment not triggered	Yes, based on the proposed classification[(a)] as Carc Cat 2 for the parent	Risk assessed as low for higher surface water exposure levels
PBacid (anaerobic metabolite)	Very high to high mobility, based on information in dossiers for other pyrethroids peer reviewed by EFSA. The deltamethrin source of information used by the applicant is not in the dossier and is ineligible as it has not been peer reviewed by EFSA.	Data gap	Information not available, whether assessment is required pending confirmation of the ground water levels.	Yes, based on the proposed classification[(a)] as Carc Cat 2 for the parent, whether consideration is required pending confirmation of the ground water levels.	Conclusion pending confirmation of the ground water levels.

CPIA (sum of isomers, anaerobic metabolite)	Very high to high mobility Based on QSAR estimates and comparison of the QSAR for PBacid Data gap identified due to ineligibility of PBacid data	Data gap	Information not available, whether assessment is required pending confirmation of the ground water levels.	Yes, based on the proposed classification[(a)] as Carc Cat 2 for the parent, whether consideration is required pending confirmation of the ground water levels.	Conclusion pending confirmation of the ground water levels.

(a): It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

6.3 Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
esfenvalerate	High risk to aquatic organisms based on higher tier assessments
2SαR-isomer of fenvalerate	Data gap.
$CONH_2$-Fen (sum of isomers)	Low risk to aquatic organisms
Dec-Fen (sum of isomers)	Low risk to aquatic organisms
PA-Fen (sum of isomers)	Low risk to aquatic organisms
PBacid	Low risk to aquatic organisms
CPIA (sum of isomers)	Low risk to aquatic organisms

6.4 Air

Compound (name and/or code)	Toxicology
esfenvalerate	Acute Tox 2, H330 Fatal if inhaled (rat LC_{50} 0.48 mg/L)[(a)]

(a):It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a list of data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful effects).

- Additional validation data to assess the extraction efficiency of the animal methods (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)

- Assessment of the toxicological relevance of the impurities 3 to 11 (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2)

- A sufficient compliance check of the batches tested in the toxicological and ecotoxicological studies with the proposed specification (relevant for all uses evaluated; submission date proposed by the applicant: unknown; see section 2 and 5)

- Soil adsorption information that was eligible to be considered by the peer review for the metabolites PBacid and CPIA was not available. A soil DegT50 for metabolite CPIA was not available. Consequently reliable groundwater exposure assessments for these anaerobic soil metabolites were not available. (relevant for the representative uses on winter cereals and winter oilseed rape; submission date proposed by the applicant: unknown; see section 4)

- What is known and what is uncertain regarding the possible constituent isomers that make up the compounds CONH2-Fen, Dec-Fen, CPIA and PA-Fen that are included in the residue definitions triggering environmental risk assessment, that retain at least 1 chiral centre was not transparently presented.

- Environmental risk assessments are not available to cover situations when 4 (north EU spring crops and south EU spring and winter crops) or 6 applications (north EU winter crops) would be made to an oilseed rape crop (the available exposure assessments only cover 2 and 3 applications respectively), as would be possible the way that the uses have been defined in the GAP table, should seed weevils require the maximum number of treatments in addition to the maximum number of treatments being made to control the pests indicated, when present at earlier growth stages (relevant for the representative uses evaluated in spring and winter oilseed rape; submission date proposed by the applicant: unknown; see section 4 and 5)

- The risk to aquatic organisms from exposure to the active substance, including the bioaccumulation through the food chain of the active substance should be further addressed. In addition risk characterisation should consider the issue of exposure to the 2SαR-isomer of fenvalerate which may also need to consider bioaccumulation through the food chain (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see sections 4 and 5)

- The in-field recolonisation of non-target arthropods should be further addressed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5)

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

- Mitigation measures comparable to 5 m of no spray buffer zone were needed to manage the off-field risk to non-target arthropods (see section 5).

- Mitigation measures such as evening applications were identified to reduce the honeybees contact exposure (see section 5).

9. Concerns

9.1 Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[8] and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as an issue that could not be finalised where the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation.

1. The aquatic risk assessment for the 2SαR-isomer of fenvalerate could not be finalised.

2. The groundwater exposure assessment for the anaerobic soil metabolites CPIA and PBacid could not be finalised for the representative uses on winter cereals and winter oilseed rape.

9.2 Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of Regulation (EC) No. 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

3. The test material used in the mammalian toxicology and ecotoxicology studies has not been demonstrated to be representative of the technical specification.

4. A high risk to aquatic organisms was identified including when exposure mitigation in line with FOCUS landscape guidance (such as may be achieved by 20m no spray buffer zones) was implemented.

[8] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127-175.

9.3 Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

All columns are grey as the technical material specification proposed was not comparable to the material used in the testing that was used to derive the toxicological and ecotoxicological reference values.

Representative use		Spring cereals	Winter cereals	Potatoes	Spring oilseed rape	Winter oilseed rape
Operator risk	Risk identified					
	Assessment not finalised					
Worker risk	Risk identified					
	Assessment not finalised					
Bystander risk	Risk identified					
	Assessment not finalised					
Consumer risk	Risk identified					
	Assessment not finalised					
Risk to wild non target terrestrial vertebrates	Risk identified					
	Assessment not finalised					
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified					
	Assessment not finalised					
Risk to aquatic organisms	Risk identified	X[4]	X[4]	X[4]	X[4]	X[4]
	Assessment not finalised	X[1]	X[1]	X[1]	X[1]	X[1]
Groundwater exposure active substance	Legal parametric value breached					
	Assessment not finalised					
Groundwater exposure metabolites	Legal parametric value breached[(a)]					
	Parametric value of 10µg/L[(b)] breached					
	Assessment not finalised		X[2]			X[2]
Comments/Remarks						

The superscript numbers in this table relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number see Sections 2 to 6 for further information.

(a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December.

(b): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003.

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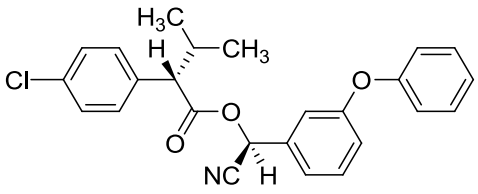
APPENDICES

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

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

Active substance (ISO Common Name) ‡	Esfenvalerate
Function (*e.g.* fungicide)	Insecticide
Rapporteur Member State	United Kingdom
Co-rapporteur Member State	Portugal

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	(α*S*)-α-cyano-3-phenoxybenzyl (2*S*)-2-(4-chlorophenyl)-3-methylbutyrate
Chemical name (CA) ‡	(*S*)-cyano(3-phenoxyphenyl)methyl (α*S*)-4-chloro-α-(1-methylethyl)benzeneacetate
CIPAC No ‡	481
CAS No ‡	66230-04-4
EC No (EINECS or ELINCS) ‡	Not assigned
FAO Specification (including year of publication) ‡	Not applicable
Minimum purity of the active substance as manufactured ‡	830 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Toluene Max. 10 g/kg
Molecular formula ‡	$C_{25}H_{22}ClNO_3$
Molar mass ‡	419.91g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	59.1 to 60.1°C (99.9%)
Boiling point (state purity) ‡	355.97°C (100%)
Temperature of decomposition (state purity)	Decomposition occurred with boiling at 355.97°C (100%)
Appearance (state purity) ‡	White crystalline solid (pure substance, 99.4%) Yellow viscous liquid (technical material, 85.3%)
Vapour pressure (state temperature, state purity) ‡	1.17 x 10^{-9} Pa at 20°C (99.9%) 2.84 x 10^{-9} Pa at 25°C (99.9%)
Henry's law constant ‡	4.92 x 10^{-4} Pa m^3 mol^{-1} at 20°C
Solubility in water (state temperature, state purity and pH) ‡	pH 5: <1 µg/L at 20°C (100%, pH 5.4) pH 7: No effect of pH expected due to no dissociation
	pH 5: <1 µg/L at 20°C (100%, pH 5.4) pH 9: No effect of pH expected due to no dissociation
Solubility in organic solvents ‡ (state temperature, state purity)	All at 20°C, 87.3% n-heptane: 14-20 g/L 1,2-dichloroethane: > 250 g/L methanol: >50 g/L acetone: > 250 g/L *p*-xylene: >250 g/L ethyl acetate: > 250 g/L
Surface tension ‡ (state concentration and temperature, state purity)	Water solubility is too low to require determination of surface tension according to EEC A.5
Partition co-efficient ‡ (state temperature, pH and purity)	log $P_{O/W}$ = 6.24 at 25°C (99.4%, pH not stated)
Dissociation constant (state purity) ‡	Data from UV spectra testing at different pH was evaluated to conclude that esfenvalerate does not exhibit a dissociation constant within the normal pH range. This is consistent with the structure of esfenvalerate which indicates no groups with appreciable acid or base character (100%).
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	UV/VIS, Molar extinction coefficients (ε, L mol^{-1} cm^{-1}) determined at maxima as: Acidic conditions: 277.0 nm = 2242.6 ε, L mol^{-1} cm^{-1} (100%) Neutral conditions: 277.1 nm = 2237.1 ε, L mol^{-1} cm^{-1} (100%) Basic conditions: 223.6 nm = 31353.1 ε, L mol^{-1} cm^{-1} (100%) 305.3 nm = 1247.7 ε, L mol^{-1} cm^{-1} (100%)

Flammability ‡ (state purity)	Experimental aspects of testing for flammability of solid materials are performed according to EC Directive 92/69/EEC A.10. In this instance the TGAI test substance is not a solid and does not fall into this category as it is a liquid. Experimental testing is therefore inappropriate.
Explosive properties ‡ (state purity)	Not classified as explosive (97.8 %)
Oxidising properties ‡ (state purity)	Esfenvalerate is not considered capable of possessing oxidising properties, as whilst it contains oxygen and chlorine atoms, these are bonded to carbon only. The calculated oxygen balance is -219 % This value is outside the region where there may be a potential for the test substance to be considered an oxidiser.

Summary of representative uses evaluated (*esfenvalerate*)*

Crop and/ or situation (a)	Country and/or Region	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Spring cereals (Wheat, Barley, Rye, Triticale, Oat)	NEU	Esfen-valerate 5EC	F	Aphids	EC	50 g/L	Tractor mounted downward sprayer	When pest occurs from BBCH 12-75	1-2	14	0.003-0.005	300-500	0.015	35	
Winter cereals (Wheat, Barley, Rye, Triticale, Oat)	NEU	Esfen-valerate 5EC	F	Aphids	EC	50 g/L	Tractor mounted downward sprayer	When pest occurs from BBCH 12-25 & 40-75	1-3	14	0.003-0.005	300-500	0.015	35	Max 2 applic in spring; Stages: - autumn: BBCH 12-25 - spring: BBCH 40-75
Spring and winter cereals (Wheat, Barley, Rye, Triticale, Oat)	SEU	Esfen-valerate 5EC	F	Aphids	EC	50 g/L	Tractor mounted downward sprayer	When pest occurs from BBCH 12-75	1-2	14	0.0019-0.005	300-800	0.015	28	
Potatoes	N&SEU	Esfen-valerate 5EC	F	Aphids, Colorado Potato beetle	EC	50 g/L	Tractor mounted downward sprayer	When pest occurs from BBCH 12	1-3	14	0.0025-0.015	100-600	0.015	7	

Crop and/ or situation (a)	Country and/or Region	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
								onwards							
Spring OSR	NEU	Esfen-valerate 5EC	F	Stem weevils, Rape beetle	EC	50 g/L	Tractor mounted downward sprayer	When pest occurs from BBCH 31-59	1-2	14	0.00375-0.015	100-400	0.015	42	
Spring OSR	NEU	Esfen-valerate 5EC	F	Seed weevil	EC	50 g/L	Tractor mounted downward sprayer	BBCH 70-79	1-2	14	0.00375-0.015	100-400	0.015	42	
Winter OSR	NEU	Esfen-valerate 5EC	F	Flea beetle, Stem weevil, Rape beetle	EC	50 g/L	Tractor mounted downward sprayer	When pest occurs from BBCH 12-59	1-3	14	0.00375-0.015	100-400	0.015	42	Max 2 applications in Spring
Winter OSR	NEU	Esfen-valerate 5EC	F	Seed weevil	EC	50 g/L	Tractor mounted downward sprayer	BBCH 70-79	1-3	14	0.00375-0.015	100-400	0.015	42	Max 2 applications in Spring
Spring & winter OSR	SEU	Esfen-valerate 5EC	F	Flea beetle, Stem weevil, Rape beetle	EC	50 g/L	Tractor mounted downward sprayer	When pest occurs from BBCH 12-59	1-2	14	0.00375-0.015	100-400	0.015	42	
Spring & winter OSR	SEU	Esfen-valerate 5EC	F	Seed weevil	EC	50 g/L	Tractor mounted downward sprayer	BBCH 70-79	1-2	14	0.00375-0.015	100-400	0.015	42	

(a) For crops, the Codex and EU (or other) classifications should be used; where relevant, the (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type

Crop and/ or situation (a)	Country and/or Region	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	(l)	(m)

use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) e.g. biting and sucking insects, soil borne 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 of equipment used must be indicated

(i) g/kg or g/l

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) Indicate the minimum and maximum number of applications possible under practical conditions of use

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions

Methods of Analysis

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

Technical as (analytical technique)	GC-FID for total isomers Chiral LC-UV for isomer ratios
Impurities in technical as (analytical technique)	GC-FID or titration for impurities
Plant protection product (analytical technique)	GC-FID based on CIPAC 481/TC/M/3.1 for total isomers Chiral LC-UV based on CIPAC 481/TC/M/3.2 for isomer ratios

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Fenvalerate (any ratio of constituent isomers including esfenvalerate)
Food of animal origin		Fenvalerate (any ratio of constituent isomers including esfenvalerate). For liver and kidney a separate residue definition is proposed; Sum of fenvalerate (any ratio of constituent isomers including esfenvalerate) and CPIA expressed as fenvalerate.
Soil		Esfenvalerate
Water	surface	At least esfenvalerate, regarding 2*SαR*-isomer of fenvalerate open
	drinking/ground	Esfenvalerate
Air		Esfenvalerate
Body fluids and tissues		Esfenvalerate

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Multi-residue method DFG S19. GC-ECD for esfenvalerate. LOQ = 0.01 mg/kg for total isomers. Valid for commodities with high water, high acid, high oil/fat and dry.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	GC-ECD for esfenvalerate. LOQ = 0.01 mg/kg for total isomers. LC-MS/MS for CPIA in liver/kidney. LOQ = 0.01 mg/kg. Data gap: extraction eficiency

Soil (analytical technique and LOQ)	LC-MS/MS for esfenvalerate LOQ = 0.01 mg/kg GC/ECD or GC/MS for esfenvalerate. LOQ = 0.005 mg/kg
Water (analytical technique and LOQ)	GC-ECD for esfenvalerate LOQ = 0.001 µg/L (drinking) LOQ = 0.001 µg/L (surface)
Air (analytical technique and LOQ)	GC-ECD for esfenvalerate. LOQ = 0.1µg/m^3
Body fluids and tissues (analytical technique and LOQ)	tissues: see methods for food of animal origin GC-ECD or GC/MS/MS for esfenvalerate in blood. LOQ = 0.005 mg/L

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

	RMS/peer review proposal
Active substance	CLP: Not classified
Formulated product	1999/45/EC: R10: Flammable CLP: GHS02, Warning, flammable cat 3, H226

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	64% (based on urine + carcass)
Distribution ‡	Widely distributed
Potential for accumulation ‡	None
Rate and extent of excretion ‡	94 – 100% excreted after 7 days
Metabolism in animals ‡	More than 20 metabolites, being formed by oxidation of the acid and alcohol parts of the molecule, cleavage of the ester linkage and conversion of the cyano group.
Toxicologically relevant compounds ‡ (animals and plants)	Esfenvalerate
Toxicologically relevant compounds ‡ (environment)	Esfenvalerate

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡ Mouse LD_{50} oral	88.5 mg/kg bw 250 mg/kg bw	Acute Tox. 3 (H301) [9]
Rat LD_{50} dermal ‡ Rabbit LD_{50} dermal	>5000 mg/kg bw > 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	0.48 mg/L (4h, whole body exposure to substance in corn oil mist)	Acute Tox. 2 (H330) [10]
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non-irritant	
Skin sensitisation ‡	Sensitising (M&K method) Not sensitising (in 2 Buehler tests)	Skin Sens. 1B (H317) [1]

[9] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[10] It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Clinical signs of neurotoxicity (rat, mouse) Decreased body weight (rat, mouse), kidney (increased weight, rat), liver (mouse)	
Relevant oral NOAEL ‡	Rat: 2.5 mg/kg bw per day (90-day) Mouse: 30.5 mg/kg bw per day (90-day) Dog: 5 mg/kg bw per day (1 year, highest dose)	
Relevant dermal NOAEL ‡	25 mg/kg bw per day (21-day, rat)	
Relevant inhalation NOAEL ‡	Not relevant	

Genotoxicity ‡ (Annex IIA, point 5.4)

Negative in *in vitro* and *in vivo* studies	

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

Target/critical effect ‡	Increased stomach inflammation (150 ppm); decreased body weight gain and neurological signs (400 ppm) (rats, 104-week) Decreased body weight gain (mice, 18-month)	
Relevant NOAEL ‡	2.3 mg/kg bw per day (rat, 104-week) 4.3 mg/kg bw per day (mouse, 18-month)	
Carcinogenicity ‡	Increased Leydig cell tumours in testes (rats)	Carc. Cat. 2 H351 [11]

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental toxicity: reduction in body weight gain Reproductive toxicity: no adverse effect Offspring's toxicity: decreased body weight	
Relevant parental NOAEL ‡	2.45 mg/kg bw per day	
Relevant reproductive NOAEL ‡	6 mg/kg bw per day	
Relevant offspring NOAEL ‡	2.45 mg/kg bw per day	

[11] It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

Developmental toxicity

Developmental target / critical effect ‡	Maternal toxicity: clinical signs of neurotoxicity Developmental toxicity: no adverse effect	
Relevant maternal NOAEL ‡	3 mg/kg bw per day (rat, pilot study) 2 mg/kg bw per day (rabbit, pilot study)	
Relevant developmental NOAEL ‡	20 mg/kg bw per day (rat, rabbit)	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	Clinical signs of neurotoxicity NOAEL 1.75 mg/kg bw (rat)	
Repeated neurotoxicity ‡	Clinical signs of neurotoxicity (reduced forelimb grip strength, reduced motor activity) NOAEL 3.2 mg/kg bw per day (rat, 13 week)	
Delayed neurotoxicity ‡	Not relevant	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No effect on serum luteinizing hormone and testosterone concentrations (male rats, 26 week oral)
	Inhibitory effect of esfenvalerate on gap junctional intercellular communications *in vitro*, not reproduced *in vivo.*

US EPA's EDSP: Tier 1 Battery	Estrogen receptor transcriptional activation assay: E is not an agonist of human estrogen receptor alpha H295R steroidogenesis assay: E did not induce or inhibit steroid biosynthesis Aromatase inhibition (human recombinant microsomes): E did not inhibit aromatase activity 10-day Hershberger bioassay for detecting androgenic activity: E did not exhibit androgenic or anti-androgenic properties (up to 9 mg/kg bw per day) Pubertal development and thyroid function in juvenile male and female rats: E did not induce effects on pubertal development, reproductive/endocrine organs or hormone levels (up to 9 mg/kg bw per day) 5-day Hershberger and uterotrophic assay: E did not exhibit androgenic, anti-androgenic or estrogenic properties (up to 20 mg/kg bw per day)
Studies performed on metabolites or impurities ‡	Decarboxyfenvalerate (dec-Fen): Rat acute oral LD_{50} > 5000 mg/kg bw Rat acute dermal LD_{50} >2000 mg/kg bw Not skin or eye irritant Not skin sensitiser (limited Buehler test) Ames test: negative
	α-Carbamoyl-3-phenoxybenzyl 2-(4-chlorophenyl)-3-methylbutyrate ($CONH_2$-Fen): Mouse acute oral LD_{50} > 2800 mg/kg bw Ames test negative

Medical data ‡ (Annex IIA, point 5.9)

Skin symptoms and reactions, notably paraesthesia, have been observed as a result of exposure to pyrethroids; poisoning cases including accidental and occupational have also been reported. No reports of adverse effects from exposure to esfenvalerate during manufacture. Vitamin E and benzocaine ameliorated the effects of esfenvalerate-induced paresthesia in rabbits (by dermal exposure). Methocarbamol can mediate the clinical signs elicited by esfenvalerate.

Summary (Annex IIA, point 5.10)	Value (mg/kg bw (per day))	Study	Uncertainty factor
ADI ‡	0.0175	Acute neurotoxicity in rats	100
AOEL ‡	0.011	Acute neurotoxicity in rats	100 (+ correction for 64% oral absorption)
ARfD ‡	0.0175	Acute neurotoxicity in rats	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (Esfenvalerate 5EC, 50 g/L)	3% for the concentrate and 13% for the diluted formulation (*in vitro* human). [4% for the concentrate and 21% for the diluted formulation (*in vitro* human considering significant variation, as recommended in the new guidance)]

Exposure scenarios (Annex IIIA, point 7.2)

Operators

Scenario	PPE	% AOEL
Dermal absorption: concentrate 3%, dilution 13%		
German model, boom sprayer	None	13
UK POEM, boom sprayer	None	158
UK POEM, boom sprayer	Gloves during mixing/loading	128
UK POEM, boom sprayer	Gloves during mixing/loading and application	24
Dermal absorption: concentrate 4%, dilution 21%		
German model, boom sprayer	None	20
UK POEM, boom sprayer	None	245
UK POEM, boom sprayer	Gloves during mixing/loading	204
UK POEM, boom sprayer	Gloves during mixing/loading and application	37

Workers	Dermal absorption: 3% for the concentrate and 13% for the dilution Crop inspection/scouting of field crops, no PPE: 27% AOEL.
	Dermal absorption: 4% for the concentrate and 21% for the dilution Crop inspection/scouting of field crops, no PPE: 43% AOEL.

Bystanders and residents	Dermal absorption: 3% for the concentrate and 13% for the dilution **UK Approach** Exposure to vapour: 6% AOEL Exposure to drift : <1% AOEL Exposure to fallout : <1% AOEL **German Approach** Bystander exposure: - adult : <1% AOEL - child : <1% AOEL Resident exposure: - adult : 3% AOEL - child : 5% AOEL
	Dermal absorption: 4% for the concentrate and 21% for the dilution **UK Approach** Exposure to vapour : 6% AOEL Exposure to drift : <1% AOEL Exposure to fallout : <1% AOEL **German Approach** Bystander exposure: - adult : <1% AOEL - child : <1% AOEL Resident exposure: - adult : 3% AOEL - child : 5% AOEL

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

Substance:	Esfenvalerate
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]12 :	Acute Tox. 3; H301 Toxic if swallowed Skin Sens. 1; H317 May cause an allergic skin reaction Acute Tox. 3; H331 Toxic if inhaled
Peer review proposal[13] for harmonised classification according to Regulation (EC) No 1272/2008:	Acute Tox. 3, H301 Toxic if swallowed Acute Tox. 2, H330 Fatal if inhaled Skin Sens. 1B, H317 May cause an allergic skin reaction Carc. Cat.2, H351 Suspected of causing cancer

[12] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[13] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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

Plant groups covered	Cabbage, kidney bean, apple, lettuce, tomato and soybean
Rotational crops	Investigated in cereal, root and leaf crops. Limited uptake of residues from soil.
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	The nature of residue data not required due to physical chemical properties of esfenvalerate. Very low water solubility (<1µg/L at 20°C) and generally resistant or stable to hydrolysis. OECD guideline 507 states that on the basis of the water solubility of the active ingredient, no model hydrolysis studies are necessary for substances with a water solubility of <0.01 mg/L.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable.
Plant residue definition for monitoring	Fenvalerate (any ratio of constituent isomers including esfenvalerate)
Plant residue definition for risk assessment	Fenvalerate (any ratio of constituent isomers including esfenvalerate)
Conversion factor (monitoring to risk assessment)	None

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

Animals covered	Lactating cattle, laying hens
Time needed to reach a plateau concentration in milk and eggs	Milk 3 to 7 days Eggs 7 days
Animal residue definition for monitoring	Fenvalerate (any ratio of constituent isomers including esfenvalerate) For liver and kidney a separate residue definition is proposed; Fenvalerate (any ratio of constituent isomers including esfenvalerate) and CPIA expressed as fenvalerate.
Animal residue definition for risk assessment	Fenvalerate (any ratio of constituent isomers including esfenvalerate) For liver and kidney a separate residue definition is proposed; Fenvalerate (any ratio of constituent isomers including esfenvalerate) and CPIA expressed as fenvalerate.

Conversion factor (monitoring to risk assessment)	None.
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Yes

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

Not applicable

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

Esfenvalerate: At least 36 months under frozen storage for commodities with high water, high acid, high oil, dry and eggs, meat and soil.

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes Maximum dietary burden 0.831 mg/kg diet beef cattle for proposed uses Maximum dietary burden 0.407 mg/kg diet dairy cattle for proposed uses	No	No
Potential for accumulation (yes/no):	Yes	Yes	Yes
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Yes	Yes	No
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	Estimated 0.0019 mg/kg (0.0027 mg/kg) fenvalerate (including SS isomer esfenvalerate) for supported uses	Estimated <0.01 mg/kg fenvalerate (including SS isomer esfenvalerate) for supported	Estimated <0.01 mg/kg fenvalerate (including SS isomer esfenvalerat

		uses	e) for supported uses
Liver	Estimated 0.02* (0.02*) mg/kg fenvalerate (including SS isomer esfenvalerate) for supported uses	Estimated <0.01 mg/kg fenvalerate (including SS isomer esfenvalerate) for supported uses	Estimated <0.01 mg/kg fenvalerate (including SS isomer esfenvalerate) for supported uses
Kidney	Estimated 0.02* mg/kg (0.02* mg/kg) fenvalerate (including SS isomer esfenvalerate) for supported uses	Estimated <0.01 mg/kg fenvalerate (including SS isomer esfenvalerate) for supported uses	Estimated <0.01 mg/kg fenvalerate (including SS isomer esfenvalerate) for supported uses
Fat	Estimated 0.1 mg/kg fenvalerate (including SS isomer esfenvalerate) for supported uses	Estimated <0.01 mg/kg fenvalerate (including SS isomer esfenvalerate) for supported uses	Estimated <0.01 mg/kg fenvalerate (including SS isomer esfenvalerate) for supported uses
Milk	Estimated <0.01mg/kg fenvalerate (including SS isomer esfenvalerate) for supported uses		
Eggs		Estimated <0.01mg/kg fenvalerate (including SS isomer esfenvalerate) for supported uses	

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)
Potato	NEU	4 x <0.01	New MRL proposed at LOQ	0.01*	0.01	0.01
	SEU	8 x <0.01	New MRL proposed at LOQ	0.01*	0.01	0.01
Oilseed rape	NEU	3 x <0.01; 0.01	Insufficient number of residue trials	-	-	-
Oilseed rape	SEU	4 x <0.01	New MRL proposed at LOQ	0.01*	0.01	0.01
Wheat (including rye and triticale)	NEU	6 x <0.01, 0.01, 0.02	New MRL proposed	0.03	0.02	0.01
Wheat (including rye and triticale)	SEU	6 x <0.01, 0.01, 0.02	New MRL proposed	0.03	0.01	0.01
Barley (including oats)	NEU	0.07, 0.05, 0.04, 0.07, 0.08, 0.06, 0.08, 0.11	New MRL proposed	0.3	0.11	0.07
Barley (including oats)	SEU	0.2, 0.05, 0.05, 0.07, 0.23, 0.02, 0.05, 0.06	New MRL proposed	0.4	0.23	0.055

(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

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

ADI	0.0175 mg/kg bw per day
TMDI (% ADI) according to WHO European diet	With the current EFSA model the chronic risk assessment ranges from 1 to 8.6 % of the ADI. The diet with the highest TMDI is "DE children" with 8.4 % of the ADI. The second diet with the highest TMDI is WHO Cluster diet B.
TMDI (% ADI) according to national (to be specified) diets	Not required
IEDI (WHO European Diet) (% ADI)	Not required. TMDI <10 % ADI
NEDI (specify diet) (% ADI)	Not required TMDI <10 % ADI
Factors included in IEDI and NEDI	Not required
ARfD	0.0175 mg/kg bw
IESTI (% ARfD)	The highest estimate short-term intake (IESTI) is for the consumption of table grapes and represents 37. 4% of the ARfD.
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not required
Factors included in IESTI and NESTI	Not required

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	
Barley (beer processing)	2	Estimate 0.06 to beer (residues <LOQ)		
Barley (pot barley)	2	0.06 to pot barley		

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

Products of Plant Origin: Potato: 0.01* mg/kg Oilseed rape: 0.01* mg/kg Wheat grain: 0.03 mg/kg (including rye and triticale) Barley grain: 0.4 mg/kg (includes oats)
Products of Animal Origin: Liver (Swine, bovine, poultry) : 0.02* mg/kg Kidney (Swine, bovine): 0.02 * mg/kg Eggs : 0.01* mg/kg Fat (Poultry): 0.01* mg/kg Fat (Swine): 0.02 mg/kg Fat (Bovine): 0.1 mg/kg Milk: 0.01* mg/kg Meat (Bovine): 0.03 mg/kg Meat (Swine): 0.02 mg/kg Meat (poultry): 0.01* mg/kg

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

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

Mineralization after 100 days ‡	21.5 – 47.1% after 90 d, [^{14}C-phenoxyphenyl]-label (n^{14}= 5) 56.8-58.3% after 84 d, [^{14}C- benzylmethyne]-label (n= 2) 58.3-82.4% after 100 d, [^{14}C- carbonyl]-label (n= 3)
Non-extractable residues after 100 days ‡	27.5 – 39.1%% after 180 d, [^{14}C-phenoxyphenyl]-label (n= 5) 16.2 – 26.9% after 84 d, [^{14}C- benzylmethyne]-label (n= 2) 5.30% after 100 d, [^{14}C-carbonyl]-label (n= 3)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	$CONH_2$-Fen - *32* % at *365* d (n= *1*)

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

Anaerobic degradation ‡

Mineralization after 100 days	*37.2*-39.6% after *141* d, [^{14}C-Phenoxyphenyl]-label (n= 1) *36.0-36.7*% after *141* d, [^{14}C-Chlorophenyl]-label (n= 1)
Non-extractable residues after 100 days	*20.3-20.6* % after 141 d, [^{14}C-Phenoxyphenyl]-label (n= 1) *14.6-14.8* % after *141* d, [^{14}C-Chlorophenyl]-label (n= 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	PBacid – *16.3-27.1* % (mean 21.7%) at 111 d (n= 1) (Phenoxyphenyl) CPIA – *31.8*-44.4 % (mean 38.1) at *111* d (n= 1) (chlorophenyl)

Soil photolysis ‡

Parent	Esfenvalerate: photolysis is unlikely to be a significant route of dissipation in the field compared with biotic degradation in the absence of light
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Dec-fen (A+B) – *15.3* % at *31* d [^{14}C-Phenoxyphenyl]-label (n= 1) $CONH_2$-Fen - 53.7 - 60.9% [^{14}C-Chlorophenyl]-label (n= 2)

[14] n corresponds to the number of soils.

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	X[15]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	χ^2 error (%)	Method of calculation
Sandy silt loam		7.2	25°C / 80% of 33 kPa	72.2 / 240.0	78.2	3.6	SFO
Loam		6.9	25°C / 40%	27.1 / 89.9	43.5	3.5	SFO
Sandy clay loam		6.4	25°C / 40%	67.7 / 225.0	108.7	3.5	SFO
Sandy loam		7.1	15°C / 75% of 33 kPa	65.3 / 216.8	35.3	8.3	SFO
Sandy loam		7.0	15°C / 75% of 33 kPa	30.8/ 438.8 249 [b] k1: 0.0406 k2: 0.00278 g: 0.662	155.0 [b]	1.77	DFOP
Sandy loam (Noichi soil)		7.0	15°C / 75% of 33 kPa	176 / 585[a]	99.3	1.687	SFO
Loamy sand		5.6	15°C / 75% of 33 kPa	73.6	45.8	6.5	SFO
Sand		5.9	20°C / 50%	52.6	52.6	4.2	SFO
Sand		5.9	20°C / 80%	36.5	36.5	4.0	SFO
Loamy sand		5.8	20°C / 50%	18.3/ 178.1 114.9 [b] k1: 0.05951 k2: 0.00603 g: 0.707	114.9 [b]	1.2	DFOP
Loamy sand		5.8	20°C / 80%	16.2/ 132.7 91.7 [b] k1: 0.0638 k2: 0.00756 g: 0.728	91.7 [b]	0.6	DFOP
Sandy loam		5.3	20°C / 50%	40.6 / 135	40.6	0.6	SFO
Geometric mean					66.6[c]		

[a] DT50 extrapolated beyond study end
[b] slow phase DFOP DT_{50}
[c] 64.2 days used in modelling (Noichi soil excluded by applicant)

[15] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

$CONH_2$-fenvalerate	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa *	χ^2 error (%)	Method of calculation
Sandy loam		7.1	20°C/21.7 %	3.7 / 81.9 α:0.5816 β: 1.5938	1	21.0	5.9	FOMC
Loam		7.3	20°C/35.5 %	1.3 / 30.6 α:0.5673 β: 0.5367	1	8.5	2.6	FOMC
Silt loam		5.9	20°C/40.5 %	3.5 / 104.6 α:0.5172 β: 1.234	1	28.8	1.8	FOMC
Geometric mean						17.3		

* DT90/3.322

PBacid	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (hours)	f. f. k_{dp}/k_f	DT_{50} (hours) 20°C pF2/10kPa *	χ^2 error (%)	Method of calculation
Sandy loam		5.1	20°C/55%	6.9 / 23	n/a	6.9	4.6	SFO
Silt Loam		6.5	20°C/55%	9.0 / 30	n/a	9.0	2.5	SFO
Clay loam		7.3	20°C/55%	7.0 / 23	n/a	7.0	0.9	SFO
Geometric mean				7.6		7.6 (0.32 d)		7.6

* study performed at pF2 or higher

Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	χ^2 error (%)	DT_{50} (d) Norm.	Method of calculation
Clay loam	Germany		-	-	34.5	114.5	15.2	-	SFO
Loamy sand	Germany		-	-	9.4	31.3	0.76	-	SFO
Sandy silt loam	UK		-	-	21.2 α:1.2654 β: 29.0135	150.0	10.8	-	FOMC

Field studies ‡

Clay	UK		-	-	18.4 k1: 0.1642 k2: 0.00651 g: 0.462	258.7	15.6	-	DFOP
Sandy silt loam	UK		-	-	8.3 k1: 0.5293 k2: 0.00816 g: 0.471	204.3	10.2	-	DFOP
Clay	UK		-	-	38.8 α:1.725 β: 78.498	219.8	31.7	-	FOMC
Silt loam	Germany		6.0		36.5	121.3	25.9	-	SFO
Sandy loam	France		6.7		19.2	63.9	16.4	-	SFO
Loam	Italy		5.3		0.3 k1: 5.132 k2: 0.0341 g: 0.920	38.5	9.9	-	DFOP
Silt Loam	South France		5.4	-	12.5 k1: 0.144 k2: 0.022 g: 0.44	78.5	14.9	-	DFOP
Silt clay Loam	South France		7.5	-	12.0 α: 1.570 β: 24.220	96.8	8.4		FOMC
Geometric mean/median					-	-	-	-	

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	No accumulation

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	X[16]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	χ^2 error (%)	Method of calculation
Sandy loam		7.2	20 °C / 70 %	64.8 / 215.4	64.8	10.2	SFO
Geometric mean/median							

[16] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent: esfenvalerate							
Soil Type	OC %	Soil pH*	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n**
Silt loam	0.2	7.0	750	375000	-	-	-
Sandy clay loam	0.5	8.1	700	140000	-	-	-
Sandy loam	0.7	8.5	600	85700	-	-	-
Loam	1.2	5.2	1700	141700	-	-	
Silty clay loam	2.6	4.8	15500	596200	-	-	-
Loamy sand	3.0	4.8	5200	171700	-	-	-
Arithmetic mean				251700	-	-	-
pH dependence, Yes or No			No				

* it is not stated in the study whether soil pH was measured in water or $CaCl^2$
** a default 1/n of 0.9 was used in modelling

Metabolite 1: $CONH_2$-fenvalerate							
Soil Type	OC %	Soil pH ($CaCl_2$)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Silt loam	2.7	6.1	-	-	2449	90707	1.09
Loam/silt loam	3.9	5.0	-	-	1503	38532	1.02
Loamy sand	0.8	4.2	-	-	1741	217658	1.12
Arithmetic mean						115632	1.08
pH dependence (yes or no)			No				

Metabolite 2: Dec-Fen							
Soil Type: n/a, HPLC method	OC %	Soil pH ($CaCl_2$)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Dec_Fen A	-	-	-	363000	-	-	-
Dec-Fen B	-	-	-	331000	-	-	-
Arithmetic mean					-	-	-
pH dependence (yes or no)			No				

Due to uncertainty / extrapolation in the HPLC estimation method groundwater simulations used 30000 mL/g

PBacid							
Soil Type	OC %	Soil pH ($CaCl_2$)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Data gap							

Arithmetic mean							
pH dependence (yes or no)			No				

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

Column leaching ‡	Data not available, not required
	Leachate: Data not available, not required
Aged residues leaching ‡	Data not available, not required
	Analysis of soil residues post ageing Data not available, not required
	Leachate: Data not available, not required.
Lysimeter/ field leaching studies ‡	Data not available, not required

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 38.8 d; DT_{90}: 219.8 d Kinetics: FOMC (alpha = 1.725; beta = 78.498) Field or Lab: representative worst case from field studies.
Application data	Crop: potatoes Depth of soil layer: 5 cm. Soil bulk density: 1.5 g/cm^3 % plant interception: 1st application 15%, 2nd and 3rd applications, 50%. Number of applications: *3* Interval (d): 14 Application rate(s): 15 g as/ha

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	x		0.0276	
Short term 24h	x	x	0.0271	0.0273
2d	x	x	0.0266	0.0271
4d	x	x	0.0256	0.0266
Long term 7d	x	x	0.0243	0.0259
28d	x	x	0.0174	0.0224
50d	x	x	0.013	0.0206
100d	x	x	0.0078	0.0169
Plateau concentration	Not calculated			

Parent Method of calculation	DT_{50} (d): 18.4 d; DT_{90}: 258.7 d Kinetics: DFOP (k_1 0.1642 d^{-1}, k_2 0.00651 d^{-1}, g 0.462) Field or Lab: representative worst case from field studies.

Application data	Crop: potatoes Depth of soil layer: 5 cm. Soil bulk density: 1.5 g/cm^3 % plant interception: 1st application 15%, 2nd and 3rd applications, 50%. Number of applications: *3* Interval (d): 14 Application rate(s): 15 g as/ha

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	x		0.0231	
Short term 24h	x	x	0.0222	0.0226
2d	x	x	0.0214	0.0222
4d	x	x	0.0201	0.0215
Long term 7d	x	x	0.0243	0.0206
28d	x	x	0.0174	0.0176
50d	x	x	0.013	0.0165
100d	x	x	0.0078	0.0145
Plateau concentration	Not calculated			

Metabolite $CONH_2$-fen Method of calculation	Molecular weight relative to the parent: 437.9/419.9 DT_{50} (d): Instant formation of metabolite from parent assumed Kinetics: not applicable Field or Lab: representative worst case from lab studies.
Application data	Application rate assumed: 27.75 g as/ha (assumed Met I is formed at a maximum of 60.9 % of the applied dose, taking into account difference in mol.wt., crop interception and maximum formation in lab study)

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			0.023	
Short term 24h				
2d				
4d				
Long term 7d				
28d				
50d				
100d				
Plateau concentration	Not calculated			

Metabolite CPIA Method of calculation	Molecular weight relative to the parent: 212.7/419.9 DT_{50} (d): Instant formation of metabolite from parent assumed Kinetics: not applicable Field or Lab: representative worst case from lab studies.
Application data	Application rate assumed: 27.75 g as/ha (assumed CPIA is formed at a maximum of 38.1 % of the applied dose, taking into account difference in mol.wt., crop interception and maximum formation in lab study)

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			0.007	
Short term 24h				
2d				

4d				
Long term 7d				
28d				
50d				
100d				
Plateau concentration	Not calculated			

Metabolite PBacid Method of calculation	Molecular weight relative to the parent: 214.2/419.9 DT_{50} (d): Instant formation of metabolite from parent assumed Kinetics: not applicable Field or Lab: representative worst case from lab studies.
Application data	Application rate assumed: 27.75 g as/ha (assumed Met I is formed at a maximum of 21.7 % of the applied dose, taking into account difference in mol.wt., crop interception and maximum formation in lab study)

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			0.004	
Short term 24h				
2d				
4d				
Long term 7d				
28d				
50d				
100d				
Plateau concentration	Not calculated			

Metabolite Dec-Fen Method of calculation	Molecular weight relative to the parent: 375.9/419.9 DT_{50} (d): Instant formation of metabolite from parent assumed Kinetics: not applicable Field or Lab: representative worst case from lab studies.
Application data	Application rate assumed: 27.75 g as/ha (assumed Met I is formed at a maximum of 15.3 % of the applied dose, taking into account difference in mol.wt., crop interception and maximum formation

			in lab study)	
PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			0.005	
Short term 24h				
2d				
4d				
Long term 7d				
28d				
50d				
100d				
Plateau concentration	Not calculated			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 4: Stable
	pH 7: 427.7 d at 20 °C (1^{st} order) PBald: 36.5%AR (25 d at 40°C) (phenoxyphenyl) CPIA: 41.6% (29 d at 40°C) (chlorophenyl)
	pH 9: 5.3 d at 20 °C (1^{st} order) PBald: 90.9%AR (32 d at 25°C) (phenoxyphenyl) CPIA: 93.5% (25 d at 25°C) (chlorophenyl) CPIA-Carboxamide: 10.6 %AR (32 d at 25°C) (chlorophenyl)
Photolytic degradation of active substance and metabolites above 10 % ‡	DT_{50} : 2 d Xenon lamp, 50°N; DT_{50} 2.0 days equivalent to UK/US summer sunlight Dec-fen A: 23.4% AR (7 d) Dec-fen B: 14.3% AR (3 d) PA-fen: 11.5% AR (3 d) PBacid: 17.8% AR (14 d)
Quantum yield of direct phototransformation in water at □ > 290 nm	0.016 mol Einstein $^{-1}$
Readily biodegradable ‡ (yes/no)	Substance considered not ready biodegradable.

Degradation in water / sediment

Parent	Distribution (eg max in water 20-30 % at time zero 2.7 – 3.4% after 100 d. Max. sed 61-73% at time 0, 26-27 % after 100 d)										
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys at study temp	DT_{50}-DT_{90} whole sys normalised to 20°C	$\chi 2$ error (%)	DT_{50}/DT_{90} water	St. (r^2)	DT_{50}./ DT_{90} sed	St. (r^2)	Method of calculation
Millstream system	7.89	7.6	10	65.3 / 217	25.3	5.4	-		-	-	SFO
System B	7.74	7.3	10	79.3 / 263	30.7	6.7	-		-	-	SFO
Pond (substance applied to sediment prior to flooding)	6.9	4.4	25	65.7 / 252.2* k1: 0.3688 k2: 0.00863 g: 0.118	129 (normalised k2 value)	0.6	-		-	-	DFOP
River (substance applied to sediment prior to flooding)	7.9	5.9	25	40.3 / 181.8 k1: 0.1059 k2: 0.0113 g: 0.2149	98.5 (normalised k2 value)	1.7	-		-	-	DFOP
Geometric mean					56.0				-		

*Note for triggering purposes (POP, PBT and vPvB) the longest SFO whole system value estimated by DT90/3.32 is 75.96 days at 25°C equivalent to 119.1 days at at 20°C, which is just below the PBT trigger for sediment of 120 days, when 20°C is accepted as being 'appropriate conditions'

Metabolites

Properties	**PBacid**	**CPIA**
Molecular Weight (g/mol)	214.2	212.7
Aqueous Solubility (mg/L)	1 (default)	1 (default)
Max. formation in water/sediment (%)	18	53.8
Water DT_{50} (Lab) (days) at 20ºC	1000 (default)	1000 (default)
Sediment DT_{50} (Lab) (days) at 20ºC	1000 (default)	1000 (default)

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after 98-100 d.	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after 100-126d (end of the study)
10°C Millstream system	7.89	7.6	2.26 %-chlorophenyl	1.33 %-chlorophenyl	1.33 %-chlorophenyl
10°C System B	7.74	7.3	1.15 %-chlorophenyl	3.65 %-chlorophenyl	3.65 %-chlorophenyl
25°C Pond (substance applied to sediment prior to flooding)	6.9	4.4	21 %-chlorophenyl 34.4 %-benzylphenyl	14.9 %-chlorophenyl 16.1 %-benzylphenyl after 98 days	14.9 %-chlorophenyl 13.3 %-benzylphenyl
25°C River (substance applied to sediment prior to flooding)	7.9	5.9	29.2 %-chlorophenyl 42.2 %-benzylphenyl	15.6 %-chlorophenyl 13.4 %-benzylphenyl after 98 days	15.6 %-chlorophenyl 10.8 %-benzylphenyl

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

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: Step 1 and 2 not calculated Molecular weight (g/mol): Water solubility (mg/L): K_{OC}/K_{OM} (L/kg): DT_{50} soil (d): *x* days (Lab or field. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): (representative worst case from sediment water studies) DT_{50} water (d): DT_{50} sediment (d): Crop interception (%):
Parameters used in FOCUSsw step 3 (if performed)	Molecular weight (g/mol): 419.9 Water solubility (mg/L): 0.001 (20°C) DT_{50} soil (d): 64.2 days (Lab. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 56 (geometric mean from sediment water studies) DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Version control no.'s of FOCUS software: SWASH v3.1, PRZM v1.5.6, MACRO v4.4.2,

	TOXSWA v3.3.1 Vapour pressure: 1.17 x 10^{-9} at 20ºC K_{OC}/K_{OM} (L/kg): 251700/146000 1/n: 0.9 (Freundlich exponent general or for soil ,susp. solids or sediment respectively)
Application rate	Crop: winter oilseed rape, winter cereals, potatoes Crop interception: Number of applications: 3 Interval (d): 14 Application rate(s): 15 g as/ha Application window: 30 days

FOCUS STEP 1 and 2 not performed

FOCUS STEP 3

Crop	Water-body	Application dates	Maximum PECsw (µg/l)	Maximum PECsed (µg/kg)
Winter OSR 3 x 15 g as/ha	D2 Ditch	12 Mar, 1 Apr, 7 May	0.0467	0.740
	D2 Stream	12 Mar, 1 Apr, 7 May	0.0404	0.468
	D3 Ditch	29 Feb, 16 Mar, 4 Apr	0.0454	0.471
	D4 Pond	1 Mar, 19 Mar, 18 Apr	0.00174	0.118
	D4 Stream	1 Mar, 19 Mar, 18 Apr	0.0363	0.0662
	D5 Pond	7 Mar, 8 Apr, 22 Apr	0.00187	0.115
	D5 Stream	7 Mar, 8 Apr, 22 Apr	0.0397	0.0946
	R1 Pond	17 Mar, 7 Apr, 26 Apr	0.00183	0.121
	R1 Stream	17 Mar, 7 Apr, 26 Apr	0.0292	0.593
	R3 Stream	1 Mar, 28 Mar, 11 Apr	0.0416	0.265

Crop	Water-body	Application dates	Maximum PECsw (µg/l)	Maximum PECsed (µg/kg)
Winter OSR respective single application	D2 Ditch	12 Mar	**0.0634**	0.598
	D2 Stream	12 Mar	0.0562	0.532
	D3 Ditch	29 Feb	0.0625	0.403
	D4 Pond	1 Mar	0.00189	0.0586
	D4 Stream	1 Mar	0.0506	0.0921
	D5 Pond	7 Mar	0.00189	0.0568
	D5 Stream	7 Mar	0.0493	0.0417

	R1 Pond	17 Mar	0.00189	0.0575
	R1 Stream	17 Mar	0.0408	0.241
	R3 Stream	1 Mar	0.0577	0.234

Crop	Water-body	Application dates	Maximum PECsw (µg/l)	Maximum PECsed (µg/kg)
Spring OSR 2 x 15 g as/ha	D1 Ditch	17 June, 2 July	0.0600	1.006
	D1 Stream	17 June, 2 July	0.0477	0.437
	D3 Ditch	23 June, 8 July	0.0557	0.628
	D4 Pond	1 June, 4 July	0.00179	0.0832
	D4 Stream	1 June, 4 July	0.0463	0.207
	D5 Pond	9 June, 19 July	0.00176	0.0804
	D5 Stream	9 June, 19 July	0.0502	0.270
	R1 Pond	1 June, 29 June	0.00181	0.0956
	R1 Stream	1 June, 29 June	0.0351	0.982

Crop	Water-body	Application dates	Maximum PECsw (µg/l)	Maximum PECsed (µg/kg)
Spring OSR respective single application	D1 Ditch	17 June	**0.0634**	0.600
	D1 Stream	17 June	0.0552	0.384
	D3 Ditch	23 June	0.0629	0.462
	D4 Pond	1 June	0.00189	0.0545
	D4 Stream	1 June	0.0517	0.119
	D5 Pond	9 June	0.00189	0.0544
	D5 Stream	9 June	0.0583	0.284
	R1 Pond	1 June	0.00189	0.0582
	R1 Stream	1 June	0.0408	0.507

Crop	Water-body	Application dates	Maximum PECsw (µg/l)	Maximum PECsed (µg/kg)
Winter cereals 3 x 15 g as/ha	D1 Ditch	7 Mar, 29 Mar, 25 Apr	0.046	0.599
	D1 Stream	7 Mar, 29 Mar, 25 Apr	0.0383	0.149
	D2 Ditch	12 Mar, 1 Apr, 7 May	0.0465	0.704
	D2 Stream	12 Mar, 1 Apr, 7 May	0.0404	0.462
	D3 Ditch	29 Feb, 16 Mar, 4 Apr	0.0453	0.455
	D4 Pond	1 Mar, 19 Mar, 18 Apr	0.00174	0.118
	D4 Stream	1 Mar, 19 Mar, 18 Apr	0.0362	0.0649
	D5 Pond	7 Mar, 8 Apr, 22 Apr	0.00187	0.115
	D5 Stream	7 Mar, 8 Apr, 22 Apr	0.0392	0.0807
	D6 Ditch	5 Mar, 9 Apr, 23 Apr	0.0494	0.880
	R1 Pond	17 Mar, 7 Apr, 26 Apr	0.00183	0.126
	R1 Stream	17 Mar, 7 Apr, 26 Apr	0.0292	1.026
	R3 Stream	1 Mar, 28 Mar, 11 Apr	0.0417	0.401
	R4 Stream	5 Mar, 4 May, 27 May	0.0293	1.553

Crop	Water-body	Application dates	Maximum PECsw (µg/l)	Maximum PECsed (µg/kg)
Winter cereals respective single	D1 Ditch	7 Mar	0.0623	0.374
	D1 Stream	7 Mar	0.0418	0.0263
	D2 Ditch	12 Mar	**0.0634**	0.597
	D2 Stream	12 Mar	0.0554	0.525

application	D3 Ditch	29 Feb	0.0624	0.385
	D4 Pond	1 Mar	0.00189	0.0585
	D4 Stream	1 Mar	0.0505	0.0903
	D5 Pond	7 Mar	0.00189	0.0566
	D5 Stream	7 Mar	0.0488	0.0391
	D6 Ditch	5 Mar	0.0625	0.423
	R1 Pond	17 Mar	0.00189	0.0576
	R1 Stream	17 Mar	0.0408	0.401
	R3 Stream	1 Mar	0.0578	0.238
	R4 Stream	5 Mar	0.0406	0.777

Crop	Water-body	Application dates	Maximum PECsw (µg/l)	Maximum PECsed (µg/kg)
Potatoes 3 x 15 g as/ha	D3 Ditch	14 May, 14 Jun, 8 Jul	0.0370	0.338
	D4 Pond	17 May, 31 May, 21 June	0.00173	0.104
	D4 Stream	17 May, 31 May, 21 June	0.0306	0.0455
	D6 Ditch (1)	17 May, 4 Jun, 23 Jun	0.0373	0.388
	D6 Ditch (2)	1 Aug, 23 Aug, 6 Sept	0.0373	0.333
	R1 Pond	13 Jun, 5 Jul, 20 Jul	0.00178	0.125
	R1 Stream	13 Jun, 5 Jul, 20 Jul	0.0252	2.296
	R2 Stream	20 May, 3 Jun, 25 Jun	0.0341	5.902
	R3 Stream	18 May, 1 Jun, 18 Jun	0.0360	0.920

Crop	Water-body	Application dates	Maximum PECsw (µg/l)	Maximum PECsed (µg/kg)
Potatoes respective single application	D3 Ditch	14 May	0.0514	0.344
	D4 Pond	17 May	0.00183	0.0534
	D4 Stream	17 May	0.0427	0.0635
	D6 Ditch (1)	17 May	0.0514	0.336
	D6 Ditch (2)	1 Aug	**0.0519**	0.458
	R1 Pond	13 Jun	0.00183	0.0561
	R1 Stream	13 Jun	0.0352	0.898
	R2 Stream	20 May	0.0477	1.090
	R3 Stream	18 May	0.0501	0.367

FOCUS STEP 4 single application to winter oilseed rape, spring Oilseed rape, winter cereals or potatoes – 20m Buffer zone

Crop	Water-body	Application dates	Maximum PECsw (µg/l)	Maximum PECsed (µg/kg)
Winter OSR single application	D2 Ditch	12 Mar	0.00437	0.0457
	D2 Stream	12 Mar	0.00520	0.0540
	D3 Ditch	29 Feb	0.00431	0.0308
	D4 Pond	1 Mar	0.000774	0.0250
	D4 Stream	1 Mar	0.00468	0.00868
	D5 Pond	7 Mar	0.000774	0.0242
	D5 Stream	7 Mar	0.00455	0.00390
	R1 Pond	17 Mar	0.000774	0.0261
	R1 Stream	17 Mar	0.00376	0.235
	R3 Stream	1 Mar	**0.00534**	0.0891

Crop	Water-body	Application dates	Maximum PECsw (µg/l)	Maximum PECsed (µg/kg)
Spring OSR single application	D1 Ditch	17 June	0.00437	0.0457
	D1 Stream	17 June	0.00510	0.0389
	D3 Ditch	23 June	0.00433	0.0356
	D4 Pond	1 June	0.000775	0.0233
	D4 Stream	1 June	0.00478	0.0113
	D5 Pond	9 June	0.000775	0.0232
	D5 Stream	9 June	**0.00539**	0.0280
	R1 Pond	1 June	0.000774	0.0302
	R1 Stream	1 June	0.00377	0.506

Crop	Water-body	Application dates	Maximum PECsw (µg/l)	Maximum PECsed (µg/kg)
Winter cereals single application	D1 Ditch	7 Mar	0.00429	0.0284
	D1 Stream	7 Mar	0.00386	0.00244
	D2 Ditch	12 Mar	0.00437	0.0456
	D2 Stream	12 Mar	0.00512	0.0532
	D3 Ditch	29 Feb	0.00430	0.0293
	D4 Pond	1 Mar	0.000774	0.0249
	D4 Stream	1 Mar	0.00467	0.00851
	D5 Pond	7 Mar	0.000774	0.0241
	D5 Stream	7 Mar	0.00450	0.00365
	D6 Ditch	5 Mar	0.00431	0.0324
	R1 Pond	17 Mar	0.000774	0.0286
	R1 Stream	17 Mar	0.00376	0.399
	R3 Stream	1 Mar	**0.00534**	0.148
	R4 Stream	5 Mar	0.00375	0.776

Crop	Water-body	Application dates	Maximum PECsw (µg/l)	Maximum PECsed (µg/kg)
Potatoes respective single application	D3 Ditch	14 May	0.00431	0.0319
	D4 Pond	17 May	0.000774	0.0235
	D4 Stream	17 May	0.00457	0.00692
	D6 Ditch (1)	17 May	0.00431	0.0311
	D6 Ditch (2)	1 Aug	0.00435	0.0423
	R1 Pond	13 Jun	0.000775	0.0397
	R1 Stream	13 Jun	0.00376	0.897
	R2 Stream	20 May	0.00511	1.090
	R3 Stream	18 May	**0.00537**	0.365

Two additional soil metabolites (PBacid and CPIA), have been considered to require further assessment in water. The PECsw have been updated based on the maximum percentages present in anaerobic soil (PBacid: 21.7%, CPIA: 38.1%).

Metabolite PBacid Parameters used in FOCUSsw step 1 and 2	Molecular weight: 214.2 Water solubility (mg/L): 1 (default) Soil or water metabolite: Koc (L/kg): 10 (default) DT_{50} soil (d): 1000 DT_{50} water/sediment system (d): (representative worst case from sediment water studies) DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Crop interception (%): Maximum occurrence observed (% molar basis with respect to the parent) Soil: 21.7 (max in anaerobic soil study) Water: 53.8* (overall water/sediment system) Sediment: 53.8*(overall water/sediment system) *In future calculations the correct value to use would be 18%
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Crop: winter wheat Number of applications: 3 Interval (d): 14 Application rate(s): 15 g as/ha Depth of water body: 30 cm Application window: 30 d

	Crop: oilseed rape Number of applications: 3 Interval (d): 14 Application rate(s): 15 g as/ha Depth of water body: 30 cm Application window: 30 d
	Crop: potatoes Number of applications: 3 Interval (d): 14 Application rate(s): 15 g as/ha Depth of water body: 30 cm Application window: 30 d
Main routes of entry	Spraydrift

Winter cereals

	3 x 15 g a.s./ha				Respective single application			
	PECsw (µg/L)		PECsed (µg/kg dry sediment)		PECsw (µg/L)		PECsed (µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.4861	---	0.0485	---	0.1736	---	0.0173	---
1	0.4855	0.4858	0.0485	0.0485	0.1733	0.1735	0.0173	0.0173
2	0.4851	0.4855	0.0485	0.0485	0.1732	0.1734	0.0173	0.0173
4	0.4844	0.4852	0.0484	0.0485	0.1729	0.1732	0.0173	0.0173
7	0.4834	0.4846	0.0483	0.0484	0.1726	0.173	0.0172	0.0173
14	0.4811	0.4835	0.0481	0.0483	0.1718	0.1726	0.0172	0.0172
21	0.4788	0.4823	0.0478	0.0482	0.1709	0.1722	0.0171	0.0172
28	0.4765	0.4811	0.0476	0.0481	0.1701	0.1718	0.017	0.0172
42	0.4719	0.4788	0.0472	0.0478	0.1685	0.1709	0.0168	0.0171
50	0.4692	0.4775	0.0469	0.0477	0.1675	0.1705	0.0167	0.017
100	0.4533	0.4693	0.0453	0.0469	0.1618	0.1676	0.0162	0.0167

Oilseed rape

	3 x 15 g a.s./ha				Respective single application			
	PECsw (µg/L)		PECsed (µg/kg dry sediment)		PECsw (µg/L)		PECsed (µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.3243	---	0.0324	---	0.1191	---	0.0119	---

1	0.3237	0.3240	0.0324	0.0324	0.1189	0.1190	0.0119	0.0119
2	0.3235	0.3238	0.0323	0.0324	0.1188	0.1189	0.0119	0.0119
4	0.3231	0.3236	0.0323	0.0323	0.1186	0.1188	0.0119	0.0119
7	0.3224	0.3232	0.0322	0.0323	0.1184	0.1187	0.0118	0.0119
14	0.3208	0.3224	0.0321	0.0322	0.1178	0.1184	0.0118	0.0118
21	0.3193	0.3216	0.0319	0.0321	0.1172	0.1181	0.0117	0.0118
28	0.3177	0.3208	0.0318	0.0321	0.1167	0.1178	0.0117	0.0118
42	0.3147	0.3193	0.0314	0.0319	0.1155	0.1172	0.0115	0.0117
50	0.3129	0.3184	0.0313	0.0318	0.1149	0.1169	0.0115	0.0117
100	0.3023	0.3130	0.0302	0.0313	0.1110	0.1149	0.0111	0.0115

Potatoes

	3 x 15 g a.s./ha				Respective single application			
	PECsw (µg/L)		PECsed (µg/kg dry sediment)		PECsw (µg/L)		PECsed (µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.4052	---	0.0405	---	0.1464	---	0.0146	---
1	0.4046	0.4049	0.0404	0.0404	0.1461	0.1462	0.0146	0.0146
2	0.4043	0.4047	0.0404	0.0404	0.1460	0.1461	0.0146	0.0146
4	0.4038	0.4044	0.0403	0.0404	0.1458	0.1460	0.0146	0.0146
7	0.4029	0.4039	0.0403	0.0404	0.1455	0.1459	0.0145	0.0146
14	0.4010	0.4029	0.0401	0.0403	0.1448	0.1455	0.0145	0.0145
21	0.3990	0.4020	0.0399	0.0402	0.1441	0.1451	0.0144	0.0145
28	0.3971	0.4010	0.0397	0.0401	0.1434	0.1448	0.0143	0.0145
42	0.3933	0.3990	0.0393	0.0399	0.1420	0.1441	0.0142	0.0144
50	0.3911	0.3979	0.0391	0.0398	0.1412	0.1437	0.0141	0.0144
100	0.3778	0.3912	0.0377	0.0391	0.1364	0.1412	0.0136	0.0141

Metabolite CPIA Parameters used in FOCUSsw step 1 and 2	Molecular weight: 212.7 Water solubility (mg/L): 1 (default) Soil or water metabolite: Koc (L/kg): 10 (default) DT_{50} soil (d): 1000 DT50 water/sediment system (d): (representative worst case from sediment water studies) DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Crop interception (%): Maximum occurrence observed (% molar basis with respect to the parent) Soil: 38.1 (max in anaerobic soil study) Water: 53.8 (overall water/sediment system) Sediment: 53.8 (overall water/sediment system)
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Crop: wheat Number of applications: *3* Interval (d): *14* Application rate(s): *15* g as/ha Depth of water body: *30* cm Application window: 30 d
	Crop: oilseed rape Number of applications: *3* Interval (d): *14* Application rate(s): *15* g as/ha Depth of water body: *30* cm Application window: 30 d
	Crop: potatoes Number of applications: *3* Interval (d): *14* Application rate(s): *15* g as/ha Depth of water body: *30* cm Application window: 30 d
Main routes of entry	Spraydrift

Winter cereals

	3 x 15 g a.s./ha				Respective single application			
	PECsw (µg/L)		PECsed (µg/kg dry sediment)		PECsw (µg/L)		PECsed (µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.7864	---	0.0785	---	0.2746	---	0.0274	---

1	0.7855	0.7859	0.0785	0.0785	0.2742	0.2744	0.0274	0.0274
2	0.7849	0.7856	0.0784	0.0785	0.2740	0.2743	0.0274	0.0274
4	0.7838	0.7850	0.0783	0.0784	0.2736	0.2740	0.0273	0.0274
7	0.7822	0.7841	0.0782	0.0784	0.2731	0.2738	0.0273	0.0274
14	0.7784	0.7822	0.0778	0.0782	0.2718	0.2731	0.0272	0.0273
21	0.7747	0.7803	0.0774	0.0780	0.2704	0.2724	0.0270	0.0272
28	0.7709	0.7784	0.0770	0.0778	0.2691	0.2718	0.0269	0.0272
42	0.7635	0.7747	0.0763	0.0774	0.2665	0.2705	0.0266	0.0270
50	0.7592	0.7726	0.0759	0.0772	0.2651	0.2697	0.0265	0.0270
100	0.7334	0.7594	0.0733	0.0759	0.2560	0.2651	0.0256	0.0265

Oilseed rape

	3 x 15 g a.s./ha				Respective single application			
	PECsw (µg/L)		PECsed (µg/kg dry sediment)		PECsw (µg/L)		PECsed (µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.5042	---	0.0504	---	0.1796	---	0.0179	---
1	0.5035	0.5039	0.0503	0.0503	0.1793	0.1795	0.0179	0.0179
2	0.5032	0.5036	0.0503	0.0503	0.1792	0.1794	0.0179	0.0179
4	0.5025	0.5032	0.0502	0.0503	0.1789	0.1792	0.0179	0.0179
7	0.5014	0.5027	0.0501	0.0502	0.1786	0.1790	0.0178	0.0179
14	0.4990	0.5014	0.0499	0.0501	0.1777	0.1786	0.0178	0.0178
21	0.4966	0.5002	0.0496	0.0500	0.1769	0.1781	0.0177	0.0178
28	0.4942	0.4990	0.0494	0.0499	0.1760	0.1777	0.0176	0.0178
42	0.4894	0.4966	0.0489	0.0496	0.1743	0.1769	0.0174	0.0177
50	0.4867	0.4952	0.0486	0.0495	0.1733	0.1764	0.0173	0.0176
100	0.4701	0.4868	0.0470	0.0486	0.1674	0.1734	0.0167	0.0173

Potatoes

	3 x 15 g a.s./ha		Respective single application	
	PECsw (µg/L)	PECsed (µg/kg dry	PECsw (µg/L)	PECsed (µg/kg dry

			sediment)				sediment)	
Time (d)	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.6453	---	0.0644	---	0.2271	---	0.0227	---
1	0.6445	0.6449	0.0644	0.0644	0.2268	0.2269	0.0227	0.0227
2	0.6440	0.6446	0.0644	0.0644	0.2266	0.2268	0.0226	0.0227
4	0.6432	0.6441	0.0643	0.0644	0.2263	0.2266	0.0226	0.0226
7	0.6418	0.6434	0.0641	0.0643	0.2258	0.2264	0.0226	0.0226
14	0.6387	0.6418	0.0638	0.0641	0.2247	0.2258	0.0225	0.0226
21	0.6356	0.6403	0.0635	0.0640	0.2236	0.2253	0.0223	0.0225
28	0.6325	0.6387	0.0632	0.0638	0.2226	0.2247	0.0222	0.0225
42	0.6264	0.6356	0.0626	0.0635	0.2204	0.2237	0.0220	0.0223
50	0.6230	0.6339	0.0623	0.0633	0.2192	0.2230	0.0219	0.0223
100	0.6018	0.6231	0.0601	0.0623	0.2117	0.2192	0.0212	0.0219

Metabolite Dec-Fen

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 375.9

Water solubility (mg/L): 1 (default)

Soil or water metabolite:

Koc (L/kg): 10 (default)

DT_{50} soil (d): 300 (default)

DT50 water/sediment system (d): (representative worst case from sediment water studies)

DT_{50} water (d): 1000

DT_{50} sediment (d): 1000

Crop interception (%):

Maximum occurrence observed (% molar basis with respect to the parent)

Soil: 15.3

Water: 40 (overall water/sediment system)

Sediment: 40 (overall water/sediment system)

Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure: 0 Kom/Koc: 10 1/n: 1 (Freundlich exponent general or for soil ,susp. solids or sediment respectively) Metabolite kinetically generated in simulation (yes/no): Formation fraction in soil (k_{dp}/k_f): (If formation degradation of metabolite is kinetically simulated by PRZM)
Application rate	Crop: wheat Number of applications: 3 Interval (d): 14 Application rate(s): 15 g as/ha Depth of water body: 30 cm Application window: 30 d
	Crop: oilseed rape Number of applications: 3 Interval (d): 14 Application rate(s): 15 g as/ha Depth of water body: 30 cm Application window: 30 d
	Crop: potatoes Number of applications: 3 Interval (d): 14 Application rate(s): 15 g as/ha Depth of water body: 30 cm Application window: 30 d
Main routes of entry	Spraydrift

Winter cereals

	3 x 15 g a.s./ha				Respective single application			
	PECsw (µg/L)		PECsed (µg/kg dry sediment)		PECsw (µg/L)		PECsed (µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.6070	---	0.0606	---	0.2173	---	0.0217	---
1	0.6061	0.6066	0.0606	0.0606	0.2170	0.2171	0.0217	0.0217
2	0.6057	0.6063	0.0605	0.0606	0.2168	0.2170	0.0217	0.0217
4	0.6049	0.6058	0.0604	0.0605	0.2165	0.2168	0.0216	0.0217
7	0.6036	0.6051	0.0603	0.0605	0.2161	0.2166	0.0216	0.021

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14	0.6007	0.6036	0.0600	0.0603	0.2150	0.2161	0.0215	0.0216
21	0.5978	0.6022	0.0597	0.0602	0.2140	0.2155	0.0214	0.0215
28	0.5949	0.6007	0.0594	0.0600	0.2129	0.2150	0.0213	0.0215
42	0.5892	0.5978	0.0589	0.0597	0.2109	0.2140	0.0211	0.0214
50	0.5859	0.5962	0.0585	0.0596	0.2097	0.2134	0.0210	0.0213
100	0.5659	0.5860	0.0566	0.0586	0.2026	0.2097	0.0202	0.0210

Oilseed rape

	3 x 15 g a.s./ha				Respective single application			
	PECsw (µg/L)		PECsed (µg/kg dry sediment)		PECsw (µg/L)		PECsed (µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.4068	---	0.0406	---	0.1499	---	0.0150	---
1	0.4060	0.4064	0.0406	0.0406	0.1496	0.1498	0.0149	0.0150
2	0.4058	0.4062	0.0405	0.0406	0.1495	0.1497	0.0149	0.0149
4	0.4052	0.4058	0.0405	0.0405	0.1493	0.1495	0.0149	0.0149
7	0.4044	0.4054	0.0404	0.0405	0.1490	0.1494	0.0149	0.0149
14	0.4024	0.4044	0.0402	0.0404	0.1483	0.1490	0.0148	0.0149
21	0.4004	0.4034	0.0400	0.0403	0.1475	0.1486	0.0147	0.0149
28	0.3985	0.4024	0.0398	0.0402	0.1468	0.1483	0.0147	0.0148
42	0.3947	0.4005	0.0394	0.0400	0.1454	0.1476	0.0145	0.0147
50	0.3925	0.3994	0.0392	0.0399	0.1446	0.1471	0.0145	0.0147
100	0.3791	0.3926	0.0379	0.0392	0.1397	0.1446	0.0140	0.0145

Potatoes

	3 x 15 g a.s./ha				Respective single application			
	PECsw (µg/L)		PECsed (µg/kg dry sediment)		PECsw (µg/L)		PECsed (µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.5069	---	0.0506	---	0.1836	---	0.0183	---
1	0.5061	0.5065	0.0506	0.0506	0.1833	0.1834	0.0183	0.0183
2	0.5057	0.5062	0.0505	0.0506	0.1832	0.1833	0.0183	0.0183
4	0.5050	0.5058	0.0505	0.0505	0.1829	0.1832	0.0183	0.0183
7	0.5040	0.5052	0.0504	0.0505	0.1825	0.1830	0.0182	0.0183
14	0.5015	0.5040	0.0501	0.0504	0.1816	0.1825	0.0182	0.0182
21	0.4991	0.5028	0.0499	0.0502	0.1808	0.1821	0.0181	0.0182
28	0.4967	0.5016	0.0496	0.0501	0.1799	0.1816	0.0180	0.0182
42	0.4919	0.4991	0.0492	0.0499	0.1781	0.1808	0.0178	0.0181
50	0.4892	0.4978	0.0489	0.0497	0.1772	0.1803	0.0177	0.0180
100	0.4725	0.4893	0.0472	0.0489	0.1711	0.1772	0.0171	0.0177

Metabolite $CONH_2$-Fen Parameters used in FOCUSsw step 1 and 2	Molecular weight: 437.9 Water solubility (mg/L): 1 (default) Soil or water metabolite: Koc (L/kg): 115632 DT_{50} soil (d): *17.3* DT50 water/sediment system (d): (representative worst case from sediment water studies) DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Crop interception (%): Maximum occurrence observed (% molar basis with respect to the parent) Soil: 60.9% formation used in Step 1-2 calculations Water: 0.0001 (overall water/sediment system) Sediment: 0.0001 (overall water/sediment system)
Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure: 0 Kom/Koc: 10 1/n: 1 (Freundlich exponent general or for soil ,susp. solids or sediment respectively) Metabolite kinetically generated in simulation (yes/no): Formation fraction in soil (k_{dp}/k_f): (If formation degradation of metabolite is kinetically simulated by PRZM)
Application rate	Crop: wheat Number of applications: *3* Interval (d): *14* Application rate(s): *15* g as/ha Depth of water body: *30* cm Application window: 30 d
	Crop: oilseed rape Number of applications: *3* Interval (d): *14* Application rate(s): *15* g as/ha Depth of water body: *30* cm Application window: 30 d
	Crop: potatoes Number of applications: *3* Interval (d): *14* Application rate(s): *15* g as/ha Depth of water body: *30* cm Application window: 30 d
Main routes of entry	Spraydrift

Winter cereals

	3 x 15 g a.s./ha				Respective single application			
	PECsw (µg/L)		PECsed (µg/kg dry sediment)		PECsw (µg/L)		PECsed (µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.0083	---	9.5571	---	0.0044	---	5.0397	---
1	0.0083	0.0083	9.5505	9.5538	0.0044	0.0044	5.0362	5.0380
2	0.0083	0.0083	9.5439	9.5505	0.0044	0.0044	5.0328	5.0362
4	0.0082	0.0083	9.5307	9.5439	0.0043	0.0044	5.0258	5.0328
7	0.0082	0.0082	9.5109	9.5340	0.0043	0.0043	5.0153	5.0275
14	0.0082	0.0082	9.4648	9.5109	0.0043	0.0043	4.9911	5.0154
21	0.0081	0.0082	9.4190	9.4879	0.0043	0.0043	4.9669	5.0032
28	0.0081	0.0082	9.3734	9.4650	0.0043	0.0043	4.9429	4.9911
42	0.0080	0.0081	9.2829	9.4193	0.0042	0.0043	4.8951	4.9671
50	0.0080	0.0081	9.2316	9.3934	0.0042	0.0043	4.8681	4.9534
100	0.0077	0.0080	8.9171	9.2334	0.0041	0.0042	4.7022	4.8690

Oilseed rape

	3 x 15 g a.s./ha				Respective single application			
	PECsw (µg/L)		PECsed (µg/kg dry sediment)		PECsw (µg/L)		PECsed (µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.0050	---	5.7343	---	0.0026	---	3.0238	---
1	0.0050	0.0050	5.7303	5.7323	0.0026	0.0026	3.0217	3.0228
2	0.0050	0.0050	5.7263	5.7303	0.0026	0.0026	3.0197	3.0217
4	0.0049	0.0050	5.7184	5.7263	0.0026	0.0026	3.0155	3.0197
7	0.0049	0.0049	5.7065	5.7204	0.0026	0.0026	3.0092	3.0165
14	0.0049	0.0049	5.6789	5.7065	0.0026	0.0026	2.9946	3.0092
21	0.0049	0.0049	5.6514	5.6927	0.0026	0.0026	2.9801	3.0019
28	0.0049	0.0049	5.6241	5.6790	0.0026	0.0026	2.9657	2.9947
42	0.0048	0.0049	5.5697	5.6516	0.0025	0.0026	2.9371	2.9802
50	0.0048	0.0049	5.5389	5.6360	0.0025	0.0026	2.9208	2.9720
100	0.0046	0.0048	5.3503	5.5401	0.0024	0.0025	2.8213	2.9214

Potatoes

	3 x 15 g a.s./ha				Respective single application			
	PECsw (µg/L)		PECsed (µg/kg dry sediment)		PECsw (µg/L)		PECsed (µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.0066	---	7.6457	---	0.0035	---	4.0318	---
1	0.0066	0.0066	7.6404	7.6430	0.0035	0.0035	4.0290	4.0304
2	0.0066	0.0066	7.6351	7.6404	0.0035	0.0035	4.0262	4.0290
4	0.0066	0.0066	7.6245	7.6351	0.0035	0.0035	4.0206	4.0262
7	0.0066	0.0066	7.6087	7.6272	0.0035	0.0035	4.0123	4.0220
14	0.0065	0.0066	7.5719	7.6087	0.0035	0.0035	3.9929	4.0123
21	0.0065	0.0066	7.5352	7.5903	0.0034	0.0035	3.9735	4.0026
28	0.0065	0.0065	7.4987	7.5720	0.0034	0.0035	3.9543	3.9929
42	0.0064	0.0065	7.4263	7.5355	0.0034	0.0034	3.9161	3.9737
50	0.0064	0.0065	7.3853	7.5147	0.0034	0.0034	3.8945	3.9627
100	0.0062	0.0064	7.1337	7.3867	0.0033	0.0034	3.7618	3.8952

Metabolite PA-Fen

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 393.9

Water solubility (mg/L): 1 (default)

Soil or water metabolite:

Koc (L/kg): 10 (default)

DT_{50} soil (d): not required

DT50 water/sediment system (d): (representative worst case from sediment water studies)

DT_{50} water (d): 11.5

DT_{50} sediment (d): 11.5

Crop interception (%):

Maximum occurrence observed (% molar basis with respect to the parent)

Soil: 5% (worst case assumption)

Water: 11.5% (overall water/sediment system)

Sediment: 11.5% (overall water/sediment system)

Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure: 0 Kom/Koc: 10 1/n: 1 (Freundlich exponent general or for soil ,susp. solids or sediment respectively) Metabolite kinetically generated in simulation (yes/no): Formation fraction in soil (k_{dp}/k_f): (If formation degradation of metabolite is kinetically simulated by PRZM)
Application rate	Crop: wheat Number of applications: 3 Interval (d): 14 Application rate(s): 15 g as/ha Depth of water body: 30 cm Application window: 30 d
	Crop: oilseed rape Number of applications: 3 Interval (d): 14 Application rate(s): 15 g as/ha Depth of water body: 30 cm Application window: 30 d
	Crop: potatoes Number of applications: 3 Interval (d): 14 Application rate(s): 15 g as/ha Depth of water body: 30 cm Application window: 30 d
Main routes of entry	Spraydrift

Winter cereals

	3 x 15 g a.s./ha				Respective single application			
	PECsw (µg/L)		PECsed (µg/kg dry sediment)		PECsw (µg/L)		PECsed (µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.2035	---	0.0203	---	0.0724	---	0.0072	---
1	0.2032	0.2034	0.0203	0.0203	0.0723	0.0724	0.0072	0.0072
2	0.2031	0.2032	0.0203	0.0203	0.0722	0.0723	0.0072	0.0072
4	0.2028	0.2031	0.0203	0.0203	0.0721	0.0723	0.0072	0.0072
7	0.2024	0.2029	0.0202	0.0203	0.0720	0.0722	0.0072	0.0072
14	0.2014	0.2024	0.0201	0.0202	0.0716	0.0720	0.0072	0.0072
21	0.2004	0.2019	0.0200	0.0202	0.0713	0.0718	0.0071	0.0072
28	0.1994	0.2014	0.0199	0.0201	0.0710	0.0716	0.0071	0.0072
42	0.1975	0.2004	0.0197	0.0200	0.0703	0.0713	0.0070	0.0071
50	0.1964	0.1999	0.0196	0.0200	0.0699	0.0711	0.0070	0.0071
100	0.1897	0.1965	0.0190	0.0196	0.0675	0.0699	0.0067	0.0070

Oilseed rape

	3 x 15 g a.s./ha				Respective single application			
	PECsw (µg/L)		PECsed (µg/kg dry sediment)		PECsw (µg/L)		PECsed (µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.1349	---	0.0135	---	0.0493	---	0.0049	---
1	0.1347	0.1348	0.0135	0.0135	0.0492	0.0493	0.0049	0.0049
2	0.1346	0.1347	0.0134	0.0135	0.0492	0.0492	0.0049	0.0049
4	0.1344	0.1346	0.0134	0.0134	0.0491	0.0492	0.0049	0.0049
7	0.1341	0.1345	0.0134	0.0134	0.0490	0.0491	0.0049	0.0049
14	0.1335	0.1341	0.0133	0.0134	0.0488	0.0490	0.0049	0.0049
21	0.1328	0.1338	0.0133	0.0134	0.0486	0.0489	0.0049	0.0049
28	0.1322	0.1335	0.0132	0.0133	0.0483	0.0488	0.0048	0.0049
42	0.1309	0.1328	0.0131	0.0133	0.0479	0.0486	0.0048	0.0049
50	0.1302	0.1325	0.0130	0.0132	0.0476	0.0484	0.0048	0.0048
100	0.1258	0.1302	0.0126	0.0130	0.0460	0.0476	0.0046	0.0048

Potatoes

	3 x 15 g a.s./ha				Respective single application			
	PECsw (µg/L)		PECsed (µg/kg dry sediment)		PECsw (µg/L)		PECsed (µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.1692	---	0.0169	---	0.0609	---	0.0061	---
1	0.1689	0.1691	0.0169	0.0169	0.0608	0.0608	0.0061	0.0061
2	0.1688	0.1690	0.0169	0.0169	0.0607	0.0608	0.0061	0.0061
4	0.1686	0.1688	0.0168	0.0169	0.0606	0.0607	0.0061	0.0061
7	0.1682	0.1687	0.0168	0.0169	0.0605	0.0607	0.0060	0.0061
14	0.1674	0.1683	0.0167	0.0168	0.0602	0.0605	0.0060	0.0060
21	0.1666	0.1678	0.0167	0.0168	0.0599	0.0604	0.0060	0.0060
28	0.1658	0.1674	0.0166	0.0167	0.0596	0.0602	0.0060	0.0060
42	0.1642	0.1666	0.0164	0.0167	0.0591	0.0599	0.0059	0.0060
50	0.1633	0.1662	0.0163	0.0166	0.0587	0.0598	0.0059	0.0060
100	0.1577	0.1633	0.0158	0.0163	0.0567	0.0587	0.0057	0.0059

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: FOCUS PEARL v 4.4.4 (with version control no.(s)) Scenarios (list of names): Crop: Winter OSR – Châteaudun, Hamburg, Kremsmünster, Okehampton, Piacenza, and Porto Winter Cereals – Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla and Thiva Potatoes – Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla and Thiva Geometric mean parent DT_{50lab} 64.2 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58). K_{OC}: parent, arithmetic mean 251700, $^1/_n$= 0.9. Metabolites: all above information required for each metabolite. $CONH_2$-fenvalerate Geometric mean parent DT_{50lab} 17.3 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58). K_{OC}: arithmetic mean 115632, $^1/_n$= 1.08 Dec-Fen Geometric mean parent DT_{50lab} 1000 d (FOCUS default). K_{OC}: 30000, $^1/_n$= 1 For field and lysimeter studies Location: UK, N/A Study type (e.g.lysimeter, field): lysimeter Soil properties: pH = , OC= , MWHC = Dates of application : Crop : /Interception estimated: Number of applications: x years, x applications year Duration. Average annual rainfall (mm): x mm Average annual leachate volume (mm): x mm
Application rate	Application rate: 15 g/ha. No. of applications: 3 Time of application (month or season): spring

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

	Scenario	Parent (µg/L)	Metabolite (µg/L)			
			$CONH_2$-fenvalerate	Dec-Fen	PBacid anaerobic metabolite Data gap	CPIA anaerobic metabolite Data gap
FOCUS PEARL v 4.4.4/winter oilseed rape	Châteaudun	<0.001	<0.001	0.0000		
	Hamburg	<0.001	<0.001	0.0000		
	Kremsmünster	<0.001	<0.001	0.0000		
	Okehampton	<0.001	<0.001	0.0000		
	Piacenza	<0.001	<0.001	0.0000		
	Porto	<0.001	<0.001	0.0000		
	-	-	-		-	
	-	-	-		-	
	-	-	-		-	

	Scenario	Parent (µg/L)	Metabolite (µg/L)			
			$CONH_2$-fenvalerate	Dec-Fen	PBacid anaerobic metabolite Data gap	CPIA anaerobic metabolite Data gap
FOCUS PEARL v 4.4.4/winter cereals	Châteaudun	<0.001	<0.001	0.0000		
	Hamburg	<0.001	<0.001	0.0000		
	Jokioinen	<0.001	<0.001	0.0000		
	Kremsmünster	<0.001	<0.001	0.0000		
	Okehampton	<0.001	<0.001	0.0000		
	Piacenza	<0.001	<0.001	0.0000		
	Porto	<0.001	<0.001	0.0000		
	Sevilla	<0.001	<0.001	0.0000		
	Thiva	<0.001	<0.001	0.0000		

	Scenario	Parent (µg/L)	Metabolite (µg/L)			
			$CONH_2$-fenvalerate	Dec-Fen	PBacid anaerobic metabolite Data gap	CPIA anaerobic metabolite Data gap
FOCUS PEARL v 4.4.4/potatoes	Châteaudun	<0.001	<0.001	0.0000		
	Hamburg	<0.001	<0.001	0.0000		
	Jokioinen	<0.001	<0.001	0.0000		
	Kremsmünster	<0.001	<0.001	0.0000		
	Okehampton	<0.001	<0.001	0.0000		
	Piacenza	<0.001	<0.001	0.0000		
	Porto	<0.001	<0.001	0.0000		
	Sevilla	<0.001	<0.001	0.0000		
	Thiva	<0.001	<0.001	0.0000		

$PEC_{(gw)}$ From lysimeter / field studies: Data not available, not required

Parent	1st year	2nd year	3rd year
Annual average (µg/L)			

Metabolite X	1st year	2nd year	3rd year
Annual average (µg/L)			

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 [@]Latitude: ..... Season: ..... DT_{50} .....
Quantum yield of direct phototransformation	active substance:
Photochemical oxidative degradation in air ‡	DT_{50} of 0.48 days derived by the Atkinson model (version 1.91). OH (12 h) concentration assumed = 1.5E6 OH/cm^3
Volatilisation ‡	from plant surfaces (BBA guideline): data not available, not required
	from soil surfaces (BBA guideline): data not available, not required
Metabolites	None

PEC (air)

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

$PEC_{(a)}$

Maximum concentration	e.g. negligible

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.	Soil: esfenvalerate, $CONH_2$-Fen, Dec-Fen, CPIA, PBacid Surface Water: esfenvalerate, 2SαR-isomer of fenvalerate, $CONH_2$-Fen, Dec-Fen, CPIA, PBacid, PA-Fen Sediment: esfenvalerate, CPIA Ground water: esfenvalerate, $CONH_2$-Fen, Dec-Fen, CPIA, PBacid Air: none

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

Soil (indicate location and type of study)	None available
Surface water (indicate location and type of study)	None available

[@] If direct photolysis data is provided, information on the latitude etc. should be included.

Ground water (indicate location and type of study)	None available
Air (indicate location and type of study)	None available

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

Not readily biodegradable.

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 ‡				
Colinus virginianus	a.s.	Acute LD_{50}	1312	-
Anas platyrhynchos	a.s.	Acute LD_{50}	-	-
Colinus virginianus	fenvalerate	NOEC	-	125
Anas platyrhynchos	fenvalerate	NOEC	-	125
Colinus virginianus	a.s.	NOEC	18.7	250
Mammals ‡				
Rat	a.s.	Acute	88.5	--
Rat	a.s.	Chronic	1.75	--
Additional higher tier studies ‡				

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

Crop and application rate

Indicator species/Category[2]	Time scale	DDD	TER[1]	Annex VI Trigger[3]
Screening (Birds)				
Small omnivorous bird	Acute	3.1	423	10
--	Short-term	--	--	10
Small omnivorous bird	Long-term	0.8	23.4	5
Higher tier refinement (Birds) Not required				
Screening (Mammals)				
Small herbivorous mammals	Acute	2.3	38.5	10
Small herbivorous mammals	Long-term	0.58	**3.0**	5
Tier 1 (Mammals) Cereals, 2 x 15 g a.s./ha				
Small insectivorous mammal BBCH 10-19	Long-term	0.05	35	5
Small insectivorous mammal BBCH>20	Long-term	0.02	87.5	5
Small herbivorous mammal BBCH>40	Long-term	0.24	7.29	5
Small omnivorous mammal BBCH 10-29	Long-term	0.09	19.44	5
Small omnivorous mammal BBCH 30-39	Long-term	0.04	43.75	5
Small omnivorous mammal BBCH >40	Long-term	0.03	58.33	5

Indicator species/Category[2]	Time scale	DDD	TER[1]	Annex VI Trigger[3]
Tier 1 (Mammals) Potatoes, 3 x 15 g a.s./ha				
Small insectivorous mammal BBCH 10-19	Long-term	0.05	35	5
Small insectivorous mammal BBCH >20	Long-term	0.02	87.5	5
Small herbivorous mammal BBCH >40	Long-term	0.26	6.73	5
Large herbivorous mammal BBCH 10-40	Long-term	0.17	10.29	5
Large herbivorous mammal BBCH >40	Long-term	0.05	35	5
Small omnivorous mammal BBCH 10-39	Long-term	0.08	21.9	5
Small omnivorous mammal BBCH >40	Long-term	0.03	58.33	5
Tier 1 (Mammals) OSR, 2 x 15 g a.s./ha				
Small insectivorous mammal BBCH 10-19	Long-term	0.05	35	5
Small insectivorous mammal BBCH >20	Long-term	0.02	87.5	5
Small herbivorous mammal BBCH >40	Long-term	0.2	8.75	5
Large herbivorous mammal All season	Long-term	0.16	10.94	5
Small omnivorous mammal BBCH 10-29	Long-term	0.09	19.44	5
Small omnivorous mammal BBCH 30-39	Long-term	0.03	58.33	5
Small omnivorous mammal BBCH >40	Long-term	0.02	87.5	5

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (µg/L)
Laboratory tests ‡				
Fish				
Oncorhynchus mykiss	a.s.	96 hr (flow-through)	Mortality, LC_{50}	0.1_{nom}
Oncorhynchus mykiss	a.s.	21 d (static)	NOEC	0.001_{nom}
Oncorhynchus mykiss	Esfenvalerate 5 EC	96 hr (flow-through)	Mortality, EC_{50}	4.5_{nom} (0.302 µg a.s./L)
Oncorhynchus mykiss	Esfenvalerate 5 EC	21 d (static)	NOEC	0.18_{nom} (0.012 µg a.s./L)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (µg/L)
Oncorhynchus mykiss	3-Phenoxy benzoic acid	96 hr (static)	Mortality, LC_{50}	14300_{mm}
Oncorhynchus mykiss	Dec-Fen	96 hr (static)	Mortality, LC_{50}	$>990_{mm}$
Oncorhynchus mykiss	$CONH_2$-Fen	96 hr (static)	Mortality, LC_{50}	110_{mm}
Oncorhynchus mykiss	PA-Fen	96 hr (static)	Mortality, LC_{50}	$>703_{mm}$
Aquatic invertebrate				
Daphnia magna	2SαR-isomer of fenvalerate	48 hr (static)	Immobility, EC_{50}	0.21_{mm}
Daphnia magna	a.s.	48 hr (static)	Immobility, EC_{50}	27
Daphnia magna	a.s.	21 d (semi-static)	NOEC	0.052_{nom}
Daphnia magna	Esfenvalerate 5 EC	48 hr (static)	Immobility, EC_{50}	3.4_{mm} (**0.228 µg a.s./L**)
Daphnia magna	Esfenvalerate 5 EC	21 d (static)	Reproduction, NOEC	0.056_{nom} (**0.0038 µg a.s./L**)
Daphnia magna	(+)CPIA	48 hr (static)	Immobility, EC_{50}	74000_{nom}
Daphnia magna	3-Phenoxy benzoic acid	48 hr (static)	Immobility, EC_{50}	35400_{nom}
Daphnia magna	Dec-fen	48 hr (static)	Immobility, EC_{50}	$>860_{mm}$
Daphnia magna	$CONH_2$-Fen	48hr (static)	Immobility, EC_{50}	$>870_{mm}$
Daphnia magna	PA-Fen	48hr (static)	Immobility, EC_{50}	$>382_{mm}$
Sediment dwelling organisms				
Chironomus riparius	a.s.	28 day spiked water study	NOEC Emergence, NOEC Development	0.16_{nom} $>320_{nom}$
Algae				
Pseudokirchneriella subcapitata	a.s.	96 h (static) 24-48 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	**6.5_{nom}** 10.0_{nom}
Scenedesmus subspicatus	Esfenvalerate 5 EC	72 hr (static) 24-48 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	135_{nom} (9.0 µg a.s./L) 215_{nom} (14.4 µg a.s./L)
Pseudokirchneriella subcapitata	3-Phenoxy benzoic acid	72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	$>33790_{mm}$ 51920_{mm}

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (µg/L)
Pseudokirchneriella subcapitata	(+)CPIA	72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	64600_{nom} $>100000_{nom}$
Pseudokirchneriella subcapitata	Dec-Fen	72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	$>240_{mm}$ $>240_{mm}$
Pseudokirchneriella subcapitata	$CONH_2$-Fen	72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	$>150_{mm}$ $>150_{mm}$
Pseudokirchneriella subcapitata	PA-Fen	72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	$>421_{mm}$ $>421_{mm}$
Pseudokirchneriella subcapitata	3-Phenoxy benzoic acid	72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	$>33790_{mm}$ 51920_{mm}
Higher plant: not required				
Microcosm or mesocosm tests				
Aquatic invertebrates: NOECpopulation of 0.001 µg a.s./L and an uncertainty factor of 2, giving a regulatory acceptable concentration of 0.0005 µg a.s./L. **Fish** Acute LC_{50} of 0.55 µg a.s./L and an assessment factor of 100, resulting in a regulatory acceptable concentration of 0.0055 Chronic toxicity data used in weight of evidence/qualitative risk assessment to show that chronic risk to fish was not worse than risk to aquatic invertebrates and that risk assessment using the refined aquatic invertebrate toxicity endpoint will cover the chronic risk to fish.					
Endocrine disruption assays					
Xenopus laevis	a.s.	21 day amphibian metamorphosis assay	NOEC	0.0397	Fort, D.J. (2012)
Pimephales promelas	a.s.	21 day fish assay	NOEC	0.231	Dinehart, S. (2012)

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

FOCUS Step1

FOCUS Step 1 and step 2

Please refer to the Environmental fate section. No PECsw were presented for the FOCUS step 1 or 2 for the active substance and therefore the risk assessment starts at FOCUS step 3.

Refined aquatic risk assessment using higher tier FOCUS modelling

FOCUS Step 3

FOCUS Step 3 (based on worst-case PECsw, *i.e.* single application of esfenvalerate at 15 g a.s./ha to winter OSR; spring application)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.	D2	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.0634	**1.58**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0562	**1.78**	100
a.s.	D3	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.0625	**1.6**	100
a.s.	D4	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.00189	**52.91**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0506	**1.98**	100
a.s.	D5	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.00189	**52.91**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0493	**2.03**	100
a.s.	R1	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.00189	**52.91**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0408	**2.45**	100
a.s.	R3	stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0577	**1.73**	100
a.s.	D2	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.0634	**0.02**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.0562	**0.02**	10
a.s.	D3	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.0625	**0.02**	10
a.s.	D4	pond	*Oncorhynchus mykiss*	21 day	0.001	0.00189	**0.53**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.0506	**0.02**	10
a.s.	D5	pond	*Oncorhynchus mykiss*	21 day	0.001	0.00189	**0.53**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.0493	**0.02**	10
a.s.	R1	pond	*Oncorhynchus mykiss*	21 day	0.001	0.00189	**0.53**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.0408	**0.02**	10
a.s.	R3	stream	*Oncorhynchus mykiss*	21 day	0.001	0.0577	**0.02**	10
a.s.	D2	ditch	*Daphnia magna*	48 hour	0.21	0.0634	**3.31**	100

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.0562	**3.74**	100
a.s.	D3	ditch	*Daphnia magna*	48 hour	0.21	0.0625	**3.36**	100
a.s.	D4	pond	*Daphnia magna*	48 hour	0.21	0.00189	111.11	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.0506	**4.15**	100
a.s.	D5	pond	*Daphnia magna*	48 hour	0.21	0.00189	111.11	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.0493	**4.26**	100
a.s.	R1	pond	*Daphnia magna*	48 hour	0.21	0.00189	111.11	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.0408	**5.15**	100
a.s.	R3	stream	*Daphnia magna*	48 hour	0.21	0.0577	**3.64**	100
a.s./ Esfenvalerate 5 EC	D2	ditch	*Daphnia magna*	21 day	0.052/ 0.0038	0.0634	**0.82/ 0.06**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0562	**0.93/ 0.07**	10
a.s./ Esfenvalerate 5 EC	D3	ditch	*Daphnia magna*	21 day	0.052/ 0.0038	0.0625	**0.83/ 0.06**	10
a.s./ Esfenvalerate 5 EC	D4	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.00189	27.51/ **2.01**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0506	**1.03/ 0.08**	10
a.s./ Esfenvalerate 5 EC	D5	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.00189	27.51/ **2.01**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0493	**1.05/ 0.08**	10
a.s./ Esfenvalerate 5 EC	R1	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.00189	27.51/ **2.01**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0408	**1.27/ 0.09**	10
a.s./ Esfenvalerate 5 EC	R3	stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0577	**0.9/ 0.07**	10

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.	D2	ditch	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0634	102.52	10
a.s.		stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0562	115.66	10
a.s.	D3	ditch	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0625	104	10
a.s.	D4	pond	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.00189	3439.15	10
a.s.		stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0506	128.46	10
a.s.	D5	pond	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.00189	3439.15	10
a.s.		stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0493	131.85	10
a.s.	R1	pond	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.00189	3439.15	10
a.s.		stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0408	159.31	10
a.s.	R3	stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0577	112.65	10
a.s.	D2	ditch	*Chironomus riparius*	28 day	0.16	0.0634	**2.52**	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.0562	**2.85**	10
a.s.	D3	ditch	*Chironomus riparius*	28 day	0.16	0.0625	**2.56**	10
a.s.	D4	pond	*Chironomus riparius*	28 day	0.16	0.00189	84.66	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.0506	**3.16**	10
a.s.	D5	pond	*Chironomus riparius*	28 day	0.16	0.00189	84.66	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.0493	**3.25**	10
a.s.	R1	pond	*Chironomus riparius*	28 day	0.16	0.00189	84.66	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.0408	**3.92**	10
a.s.	R3	stream	*Chironomus riparius*	28 day	0.16	0.0577	**2.77**	10

The TERs highlighted in bold do not exceed the Annex VI trigger values.

FOCUS Step 3 (based on worst-case PECsw, *i.e.*single application of esfenvalerate 15 g a.s./ha to spring OSR, spring application)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.	D1	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.0634	**1.58**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0552	**1.81**	100
a.s.	D3	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.0629	**1.59**	100
a.s.	D4	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.00189	**52.91**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0517	**1.93**	100
a.s.	D5	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.00189	**52.91**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0583	**1.72**	100
a.s.	R1	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.00189	**52.91**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0408	**2.45**	100
a.s.	D1	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.0634	**0.02**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.0552	**0.02**	10
a.s.	D3	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.0629	**0.02**	10
a.s.	D4	pond	*Oncorhynchus mykiss*	21 day	0.001	0.00189	**0.53**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.0517	**0.02**	10
a.s.	D5	pond	*Oncorhynchus mykiss*	21 day	0.001	0.00189	**0.53**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.0583	**0.02**	10
a.s.	R1	pond	*Oncorhynchus mykiss*	21 day	0.001	0.00189	**0.53**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.0408	**0.02**	10
a.s.	D1	ditch	*Daphnia magna*	48 hour	0.21	0.0634	**3.31**	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.0552	**3.8**	100
a.s.	D3	ditch	*Daphnia magna*	48 hour	0.21	0.0629	**3.34**	100
a.s.	D4	pond	*Daphnia magna*	48 hour	0.21	0.00189	111.11	100

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.0517	**4.06**	100
a.s.	D5	pond	*Daphnia magna*	48 hour	0.21	0.00189	111.11	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.0583	**3.6**	100
a.s.	R1	pond	*Daphnia magna*	48 hour	0.21	0.00189	111.11	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.0408	**5.15**	100
a.s./ Esfenvalerate 5 EC	D1	ditch	*Daphnia magna*	21 day	0.052/ 0.0038	0.0634	**0.82/ 0.06**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0552	**0.94/ 0.07**	10
a.s./ Esfenvalerate 5 EC	D3	ditch	*Daphnia magna*	21 day	0.052/ 0.0038	0.0629	**0.83/ 0.06**	10
a.s./ Esfenvalerate 5 EC	D4	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.00189	27.51/ **2.01**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0517	**1.01/ 0.07**	10
a.s./ Esfenvalerate 5 EC	D5	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.00189	27.51/ **2.01**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0583	**0.89/ 0.07**	10
a.s./ Esfenvalerate 5 EC	R1	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.00189	27.51/ **2.01**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0408	**1.27/ 0.09**	10
a.s.	D1	ditch	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0634	102.52	10
a.s.		stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0552	117.75	10
a.s.	D3	ditch	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0629	103.34	10
a.s.	D4	pond	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.00189	3439.15	10

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.		stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0517	125.73	10
a.s.	D5	pond	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.00189	3439.15	10
a.s.		stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0583	111.49	10
a.s.	R1	pond	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.00189	3439.15	10
a.s.		stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0408	159.31	10
a.s.	D1	ditch	*Chironomus riparius*	28 day	0.16	0.0634	**2.52**	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.0552	**2.9**	10
a.s.	D3	ditch	*Chironomus riparius*	28 day	0.16	0.0629	**2.54**	10
a.s.	D4	pond	*Chironomus riparius*	28 day	0.16	0.00189	84.66	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.0517	**3.09**	10
a.s.	D5	pond	*Chironomus riparius*	28 day	0.16	0.00189	84.66	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.0583	**2.74**	10
a.s.	R1	pond	*Chironomus riparius*	28 day	0.16	0.00189	84.66	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.0408	**3.92**	10

The TERs highlighted in bold do not exceed the Annex VI trigger values.

FOCUS Step 3 (based on worst-case PECsw, *i.e.*single application of esfenvalerate to winter cereals at 15 g a.s./ha, spring application)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.	D1	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.0623	**1.61**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0418	**2.39**	100
a.s.	D2	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.0634	**1.58**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0554	**1.81**	100
a.s.	D3	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.0624	**1.6**	100
a.s.	D4	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.00189	**52.91**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0505	**1.98**	100
a.s.	D5	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.00189	**52.91**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0488	**2.05**	100
a.s.	D6	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.0625	**1.6**	100
a.s.	R1	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.00189	**52.91**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0408	**2.45**	100
a.s.	R3	stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0578	**1.73**	100
a.s.	R4	stream	Oncorhynchus mykiss	96 hour	0.1	0.0406	**2.46**	10
a.s.	D1	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.0623	**0.02**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.0418	**0.02**	10
a.s.	D2	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.0634	**0.02**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.0554	**0.02**	10
a.s.	D3	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.0624	**0.02**	10
a.s.	D4	pond	*Oncorhynchus mykiss*	21 day	0.001	0.00189	**0.53**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.0505	**0.02**	10
a.s.	D5	pond	*Oncorhynchus mykiss*	21 day	0.001	0.00189	**0.53**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.0488	**0.02**	10
a.s.	D6	ditch	*Oncorhynch*	21 day	0.001	0.0625	**0.02**	10

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
			us mykiss					
a.s.	R1	pond	*Oncorhynchus mykiss*	21 day	0.001	0.00189	**0.53**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.0408	**0.02**	10
a.s.	R3	stream	*Oncorhynchus mykiss*	21 day	0.001	0.0578	**0.02**	10
a.s.	R4	stream	*Oncorhynchus mykiss*	21 day	0.001	0.0406	**0.02**	10
a.s.	D1	ditch	*Daphnia magna*	48 hour	0.21	0.0623	**3.37**	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.0418	**5.02**	100
a.s.	D2	ditch	*Daphnia magna*	48 hour	0.21	0.0634	**3.31**	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.0554	**3.79**	100
a.s.	D3	ditch	*Daphnia magna*	48 hour	0.21	0.0623	**3.37**	100
a.s.	D4	pond	*Daphnia magna*	48 hour	0.21	0.00189	111.11	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.0505	**4.16**	100
a.s.	D5	pond	*Daphnia magna*	48 hour	0.21	0.00189	111.11	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.0488	**4.3**	100
a.s.	D6	ditch	*Daphnia magna*	48 hour	0.21	0.0625	**3.36**	100
a.s.	R1	pond	*Daphnia magna*	48 hour	0.21	0.00189	111.11	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.0408	**5.15**	100
a.s.	R3	stream	*Daphnia magna*	48 hour	0.21	0.0578	**3.63**	100
a.s.	R4	stream	*Daphnia magna*	48 hour	0.21	0.0406	**5.17**	100
a.s./ Esfenvalerate 5 EC	D1	ditch	*Daphnia magna*	21 day	0.052/ 0.0038	0.0623	**0.83/ 0.06**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0418	**1.24/ 0.09**	10
a.s.	D2	ditch	*Daphnia magna*	21 day	0.052/ 0.0038	0.0634	**0.82/ 0.06**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0554	**0.94/ 0.07**	10
a.s./ Esfenvalerat	D3	ditch	*Daphnia magna*	21 day	0.052/ 0.0038	0.0624	**0.83/ 0.06**	10

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
e 5 EC								
a.s./ Esfenvalerate 5 EC	D4	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.00189	27.51/ **2.01**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0505	**1.03/ 0.08**	10
a.s./ Esfenvalerate 5 EC	D5	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.00189	27.51/ **2.01**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0488	**1.07/ 0.08**	10
a.s./ Esfenvalerate 5 EC	D6	ditch	*Daphnia magna*	21 day	0.052/ 0.0038	0.0625	**0.83/ 0.06**	10
a.s./ Esfenvalerate 5 EC	R1	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.00189	27.51/ **2.01**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0408	**1.27/ 0.09**	10
a.s./ Esfenvalerate 5 EC	R3	stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0578	**0.9/ 0.07**	10
a.s./ Esfenvalerate 5 EC	R4	stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0406	**1.28/ 0.09**	10
a.s.	D1	ditch	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0623	104.33	10
a.s.		stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0418	155.5	10
a.s.	D2	ditch	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0634	102.52	10
a.s.		stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0554	117.33	10
a.s.	D3	ditch	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0624	104.17	10
a.s.	D4	pond	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.00189	3439.15	10
a.s.		stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0505	128.71	10

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.	D5	pond	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.00189	3439.15	10
a.s.		stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0488	133.2	10
a.s.	D6	ditch	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0625	104	10
a.s.	R1	pond	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.00189	3439.15	10
a.s.		stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0408	159.31	10
a.s.	R3	stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0578	112.46	10
a.s.	R4	stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0406	160.1	10
a.s.	D1	ditch	*Chironomus riparius*	28 day	0.16	0.0623	**2.57**	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.0418	**3.83**	10
a.s.	D2	ditch	*Chironomus riparius*	28 day	0.16	0.0634	**2.52**	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.0554	**2.89**	10
a.s.	D3	ditch	*Chironomus riparius*	28 day	0.16	0.0624	**2.56**	10
a.s.	D4	pond	*Chironomus riparius*	28 day	0.16	0.00189	84.66	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.0505	**3.17**	10
a.s.	D5	pond	*Chironomus riparius*	28 day	0.16	0.00189	84.66	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.0488	**3.28**	10
a.s.	D6	ditch	*Chironomus riparius*	28 day	0.16	0.0625	**2.56**	10
a.s.	R1	pond	*Chironomus riparius*	28 day	0.16	0.00189	84.66	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.0408	**3.92**	10
a.s.	R3	stream	*Chironomus riparius*	28 day	0.16	0.0578	**2.77**	10
a.s.	R4	stream	*Chironomus riparius*	28 day	0.16	0.0406	**3.94**	10

The TERs highlighted in bold do not exceed the Annex VI trigger values.

FOCUS Step 3 (based on worst-case PECsw, *i.e.*single application of esfenvalerate to potatoes at 15 g a.s./ha, spring application)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.	D3	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.0514	**1.95**	100
a.s.	D4	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.00183	**54.64**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0427	**2.34**	100
a.s.	D6	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.0514	**1.95**	100
a.s.	D6	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.0519	**1.93**	100
a.s.	R1	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.00183	**54.64**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0352	**2.84**	100
a.s.	R2	stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0477	**2.1**	100
a.s.	R3	stream	*Oncorhynchus mykiss*	96 hour	0.1	0.0501	**2.0**	100
a.s.	D3	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.0514	**0.02**	10
a.s.	D4	pond	*Oncorhynchus mykiss*	21 day	0.001	0.00183	**0.55**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.0427	**0.02**	10
a.s.	D6	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.0514	**0.02**	10
a.s.	D6	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.0519	**0.02**	10
a.s.	R1	pond	*Oncorhynchus mykiss*	21 day	0.001	0.00183	**0.55**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.0352	**0.03**	10
a.s.	R2	stream	*Oncorhynchus mykiss*	21 day	0.001	0.0477	**0.02**	10
a.s.	R3	stream	*Oncorhynchus mykiss*	21 day	0.001	0.0501	**0.02**	10
a.s.	D3	ditch	*Daphnia magna*	48 hour	0.21	0.0514	**4.09**	100
a.s.	D4	pond	*Daphnia magna*	48 hour	0.21	0.00183	114.75	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.0427	**4.92**	100
a.s.	D6	ditch	*Daphnia magna*	48 hour	0.21	0.0514	**4.09**	100
a.s.	D6	ditch	*Daphnia magna*	48 hour	0.21	0.0519	**4.05**	100

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.	R1	pond	*Daphnia magna*	48 hour	0.21	0.00183	114.75	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.0352	**5.97**	100
a.s.	R2	stream	*Daphnia magna*	48 hour	0.21	0.0477	**4.4**	100
a.s.	R3	stream	*Daphnia magna*	48 hour	0.21	0.0501	**4.19**	100
a.s./ Esfenvalerate 5 EC	D3	ditch	*Daphnia magna*	21 day	0.052/ 0.0038	0.0514	**1.01/ 0.07**	10
a.s./ Esfenvalerate 5 EC	D4	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.00183	28.42/ **2.08**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0427	**1.22/ 0.09**	10
a.s./ Esfenvalerate 5 EC	D6	ditch	*Daphnia magna*	21 day	0.052/ 0.0038	0.0519	**1.00/ 0.07**	10
a.s./ Esfenvalerate 5 EC	R1	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.00183	28.42/ **2.08**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0352	**1.48/ 0.11**	10
a.s./ Esfenvalerate 5 EC	R2	stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0477	**1.09/ 0.08**	10
a.s./ Esfenvalerate 5 EC	R3	stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.0501	**1.04/ 0.08**	10
a.s.	D3	ditch	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0514	126.46	10
a.s.	D4	pond	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.00183	3551.91	10
a.s.		stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0427	152.22	10
a.s.	D6	ditch	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0514	126.46	10
a.s.	D6	ditch	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0519	125.24	10
a.s.	R1	pond	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.00183	3551.91	10

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.		stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0352	184.66	10
a.s.	R2	stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0477	136.27	10
a.s.	R3	stream	*Pseudokirchneriella subcapitata*	72 hour	6.5	0.0501	129.74	10
a.s.	D3	ditch	*Chironomus riparius*	28 day	0.16	0.0514	**3.11**	10
a.s.	D4	pond	*Chironomus riparius*	28 day	0.16	0.00183	87.43	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.0427	**3.75**	10
a.s.	D6	ditch	*Chironomus riparius*	28 day	0.16	0.0514	**3.11**	10
a.s.	D6	ditch	*Chironomus riparius*	28 day	0.16	0.0519	**3.08**	10
a.s.	R1	pond	*Chironomus riparius*	28 day	0.16	0.00183	87.43	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.0352	**4.55**	10
a.s.	R2	stream	*Chironomus riparius*	28 day	0.16	0.0477	**3.35**	10
a.s.	R3	stream	*Chironomus riparius*	28 day	0.16	0.0501	**3.19**	10

The TERs highlighted in bold do not exceed the Annex VI trigger values.

FOCUS Step 4

FOCUS Step 4 (based on worst-case PECsw, *i.e.*single application of esfenvalerate to winter OSR at 15 g a.s./ha, spring application)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.	D2	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.00437	**22.88**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00520	**19.23**	100
a.s.	D3	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.00431	**23.2**	100
a.s.	D4	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.000774	129.2	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00468	**21.37**	100
a.s.	D5	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.000774	129.2	100

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00455	**21.98**	100
a.s.	R1	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.000774	129.2	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00376	**26.6**	100
a.s.	R3	stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00534	**18.73**	100
a.s.	D2	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.00437	**0.23**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.00520	**0.19**	10
a.s.	D3	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.00431	**0.23**	10
a.s.	D4	pond	*Oncorhynchus mykiss*	21 day	0.001	0.000774	**1.29**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.00468	**0.21**	10
a.s.	D5	pond	*Oncorhynchus mykiss*	21 day	0.001	0.000774	**1.29**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.00455	**0.22**	10
a.s.	R1	pond	*Oncorhynchus mykiss*	21 day	0.001	0.000774	**1.29**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.00376	**0.27**	10
a.s.	R3	stream	*Oncorhynchus mykiss*	21 day	0.001	0.00534	**0.19**	10
a.s.	D2	ditch	*Daphnia magna*	48 hour	0.21	0.00437	**48.05**	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.00520	**40.38**	100
a.s.	D3	ditch	*Daphnia magna*	48 hour	0.21	0.00431	**48.72**	100
a.s.	D4	pond	*Daphnia magna*	48 hour	0.21	0.000774	271.32	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.00468	**44.87**	100
a.s.	D5	pond	*Daphnia magna*	48 hour	0.21	0.000774	271.32	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.00455	**46.15**	100
a.s.	R1	pond	*Daphnia magna*	48 hour	0.21	0.000774	271.32	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.00376	**55.85**	100
a.s.	R3	stream	*Daphnia magna*	48 hour	0.21	0.00534	**39.33**	100

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s./ Esfenvalerate 5 EC	D2	ditch	*Daphnia magna*	21 day	0.052/ 0.0038	0.00437	11.9/ **0.87**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.00520	10.0/ **0.73**	10
a.s./ Esfenvalerate 5 EC	D3	ditch	*Daphnia magna*	21 day	0.052/ 0.0038	0.00431	12.06/ **0.88**	10
a.s./ Esfenvalerate 5 EC	D4	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.000774	67.18/ **4.91**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.00468	11.11/ **0.81**	10
a.s./ Esfenvalerate 5 EC	D5	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.000774	67.18/ **4.91**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.00455	11.43/ **0.84**	10
a.s./ Esfenvalerate 5 EC	R1	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.000774	67.18/ **4.91**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.00376	13.83/ **1.01**	10
a.s./ Esfenvalerate 5 EC	R3	stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.00534	**9.74/ 0.71**	10
a.s.	D2	ditch	*Chironomus riparius*	28 day	0.16	0.00437	36.61	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.00520	30.77	10
a.s.	D3	ditch	*Chironomus riparius*	28 day	0.16	0.00431	37.12	10
a.s.	D4	pond	*Chironomus riparius*	28 day	0.16	0.000774	206.72	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.00468	34.19	10
a.s.	D5	pond	*Chironomus riparius*	28 day	0.16	0.000774	206.72	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.00455	35.16	10
a.s.	R1	pond	*Chironomus riparius*	28 day	0.16	0.000774	206.72	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.00376	42.55	10
a.s.	R3	stream	*Chironomus riparius*	28 day	0.16	0.00534	29.96	10

The TERs highlighted in bold do not exceed the Annex VI trigger values.

FOCUS Step 4 (based on worst-case PECsw, *i.e.*single application of esfenvalerate to spring OSR at 15 g a.s./ha, spring application)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.	D1	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.00437	**22.88**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00510	**19.61**	100
a.s.	D3	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.00433	**23.09**	100
a.s.	D4	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.000775	129.03	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00478	**20.92**	100
a.s.	D5	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.000775	129.03	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00539	**18.55**	100
a.s.	R1	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.000774	129.2	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00377	**26.53**	100
a.s.	D1	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.00437	**0.23**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.00510	**0.2**	10
a.s.	D3	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.00433	**0.23**	10
a.s.	D4	pond	*Oncorhynchus mykiss*	21 day	0.001	0.000775	**1.29**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.00478	**0.21**	10
a.s.	D5	pond	*Oncorhynchus mykiss*	21 day	0.001	0.000775	**1.29**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.00539	**0.19**	10
a.s.	R1	pond	*Oncorhynchus mykiss*	21 day	0.001	0.000774	**1.29**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.00377	**0.27**	10
a.s.	D1	ditch	*Daphnia magna*	48 hour	0.21	0.00437	**48.05**	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.00510	**41.18**	100
a.s.	D3	ditch	*Daphnia magna*	48 hour	0.21	0.00433	**48.5**	100
a.s.	D4	pond	*Daphnia magna*	48 hour	0.21	0.000775	270.97	100

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.00478	**43.93**	100
a.s.	D5	pond	*Daphnia magna*	48 hour	0.21	0.00077 5	270.97	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.00539	**38.96**	100
a.s.	R1	pond	*Daphnia magna*	48 hour	0.21	0.00077 4	271.32	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.00377	**55.7**	100
a.s./ Esfenvalerate 5 EC	D1	ditch	*Daphnia magna*	21 day	0.052	0.00437	11.9/ **0.87**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052	0.00510	10.2/ **0.75**	10
a.s./ Esfenvalerate 5 EC	D3	ditch	*Daphnia magna*	21 day	0.052	0.00433	12.01/ **0.88**	10
a.s./ Esfenvalerate 5 EC	D4	pond	*Daphnia magna*	21 day	0.052	0.00077 5	67.1/ **4.91**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052	0.00478	10.88/ **0.79**	10
a.s./ Esfenvalerate 5 EC	D5	pond	*Daphnia magna*	21 day	0.052	0.00077 5	67.1/ **4.91**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052	0.00539	**9.65/ 0.71**	10
a.s./ Esfenvalerate 5 EC	R1	pond	*Daphnia magna*	21 day	0.052	0.00077 4	67.18/ **4.91**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052	0.00377	13.79/ **1.01**	10
a.s.	D1	ditch	*Chironomus riparius*	28 day	0.16	0.00437	36.61	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.00510	31.37	10
a.s.	D3	ditch	*Chironomus riparius*	28 day	0.16	0.00433	36.95	10
a.s.	D4	pond	*Chironomus riparius*	28 day	0.16	0.00077 5	206.45	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.00478	33.47	10
a.s.	D5	pond	*Chironomus riparius*	28 day	0.16	0.00077 5	206.45	10

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.00539	29.68	10
a.s.	R1	pond	*Chironomus riparius*	28 day	0.16	0.000774	206.72	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.00377	42.44	10

The TERs highlighted in bold do not exceed the Annex VI trigger values.

FOCUS Step 4 (based on worst-case PECsw, *i.e.*single applications of esfenvalerate to winter cereals at 15 g a.s./ha, spring application)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.	D1	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.00429	**23.31**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00386	**25.91**	100
a.s.	D2	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.00437	**22.88**	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00512	**19.53**	100
a.s.	D3	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.00430	**23.26**	100
a.s.	D4	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.000774	129.2	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00467	**21.41**	100
a.s.	D5	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.000774	129.2	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00450	**22.22**	100
a.s.	D6	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.00431	**23.2**	100
a.s.	R1	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.000774	129.2	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00376	**26.6**	100
a.s.	R3	stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00534	**18.73**	100
a.s.	R4	stream	Oncorhynchus mykiss	96 hour	0.1	0.00375	26.67	10
a.s.	D1	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.00429	**0.23**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.00386	**0.26**	10
a.s.	D2	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.00437	**0.23**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.00512	**0.2**	10
a.s.	D3	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.00430	**0.23**	10
a.s.	D4	pond	*Oncorhynchus mykiss*	21 day	0.001	0.000774	**1.29**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.00467	**0.21**	10
a.s.	D5	pond	*Oncorhynchus mykiss*	21 day	0.001	0.000774	**1.29**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.00450	**0.22**	10
a.s.	D6	ditch	*Oncorhynch*	21 day	0.001	0.00431	**0.23**	10

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
			us mykiss					
a.s.	R1	pond	*Oncorhynchus mykiss*	21 day	0.001	0.000774	**1.29**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.00376	**0.27**	10
a.s.	R3	stream	*Oncorhynchus mykiss*	21 day	0.001	0.00534	**0.19**	10
a.s.	R4	stream	*Oncorhynchus mykiss*	21 day	0.001	0.00375	**0.27**	10
a.s.	D1	ditch	*Daphnia magna*	48 hour	0.21	0.00429	**48.95**	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.00386	**54.4**	100
a.s.	D2	ditch	*Daphnia magna*	48 hour	0.21	0.00437	**48.05**	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.00512	**41.02**	100
a.s.	D3	ditch	*Daphnia magna*	48 hour	0.21	0.00430	**48.84**	100
a.s.	D4	pond	*Daphnia magna*	48 hour	0.21	0.000774	271.32	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.00467	**44.97**	100
a.s.	D5	pond	*Daphnia magna*	48 hour	0.21	0.000774	271.32	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.00450	**46.67**	100
a.s.	D6	ditch	*Daphnia magna*	48 hour	0.21	0.00431	**48.72**	100
a.s.	R1	pond	*Daphnia magna*	48 hour	0.21	0.000774	271.32	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.00376	**55.85**	100
a.s.	R3	stream	*Daphnia magna*	48 hour	0.21	0.00534	**39.33**	100
a.s.	R4	stream	*Daphnia magna*	48 hour	0.21	0.00375	**56.00**	100
a.s./ Esfenvalerate 5 EC	D1	ditch	*Daphnia magna*	21 day	0.052	0.00429	12.12/ **0.89**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052	0.00386	13.47/ **0.98**	10
a.s./ Esfenvalerate 5 EC	D2	ditch	*Daphnia magna*	21 day	0.052/ 0.0038	0.00437	11.9/ **0.87**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.00512	10.16/ **0.74**	10
a.s./	D3	ditch	*Daphnia*	21 day	0.052/	0.00430	12.09/	10

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
Esfenvalerate 5 EC			*magna*		0.0038		**0.88**	
a.s./ Esfenvalerate 5 EC	D4	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.000774	67.18/ **4.91**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.00467	11.13/ **0.81**	10
a.s./ Esfenvalerate 5 EC	D5	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.000774	67.18/ **4.91**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.00450	11.56/ **0.84**	10
a.s./ Esfenvalerate 5 EC	D6	ditch	*Daphnia magna*	21 day	0.052/ 0.0038	0.00431	12.06/ **0.88**	10
a.s./ Esfenvalerate 5 EC	R1	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.000774	67.18/ **4.91**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.00376	13.83/ **1.01**	10
a.s./ Esfenvalerate 5 EC	R3	stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.00534	**9.74/ 0.71**	10
a.s./ Esfenvalerate 5 EC	R4	stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.00375	13.87/ **1.01**	10
a.s.	D1	ditch	*Chironomus riparius*	28 day	0.16	0.00429	37.3	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.00386	41.45	10
a.s.	D2	ditch	*Chironomus riparius*	28 day	0.16	0.00437	36.61	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.00512	31.25	10
a.s.	D3	ditch	*Chironomus riparius*	28 day	0.16	0.00430	37.21	10
a.s.	D4	pond	*Chironomus riparius*	28 day	0.16	0.000774	206.72	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.00467	34.26	10
a.s.	D5	pond	*Chironomus riparius*	28 day	0.16	0.000774	206.72	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.00450	35.56	10
a.s.	D6	ditch	*Chironomus riparius*	28 day	0.16	0.00431	37.12	10

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.	R1	pond	*Chironomus riparius*	28 day	0.16	0.000774	206.72	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.00376	42.55	10
a.s.	R3	stream	*Chironomus riparius*	28 day	0.16	0.00534	29.96	10
a.s.	R4	stream	*Chironomus riparius*	28 day	0.16	0.00375	42.67	10

The TERs highlighted in bold do not exceed the Annex VI trigger values.

FOCUS Step 4 (based on worst-case PECsw, *i.e.*single applications of esfenvalerate to potatoes at 15 g a.s./ha, spring application)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.	D3	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.00431	**23.2**	100
a.s.	D4	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.000774	129.2	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00457	**21.88**	100
a.s.	D6	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.00431	**23.2**	100
a.s.	D6	ditch	*Oncorhynchus mykiss*	96 hour	0.1	0.00435	**22.99**	100
a.s.	R1	pond	*Oncorhynchus mykiss*	96 hour	0.1	0.000775	129.03	100
a.s.		stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00376	**26.6**	100
a.s.	R2	stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00511	**19.57**	100
a.s.	R3	stream	*Oncorhynchus mykiss*	96 hour	0.1	0.00537	**18.62**	100
a.s.	D3	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.00431	**0.23**	10
a.s.	D4	pond	*Oncorhynchus mykiss*	21 day	0.001	0.000774	**1.29**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.00457	**0.22**	10
a.s.	D6	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.00431	**0.23**	10
a.s.	D6	ditch	*Oncorhynchus mykiss*	21 day	0.001	0.00435	**0.23**	10
a.s.	R1	pond	*Oncorhynchus mykiss*	21 day	0.001	0.000775	**1.29**	10
a.s.		stream	*Oncorhynchus mykiss*	21 day	0.001	0.00376	**0.27**	10
a.s.	R2	stream	*Oncorhynch*	21 day	0.001	0.00511	**0.2**	10

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
			us mykiss					
a.s.	R3	stream	*Oncorhynchus mykiss*	21 day	0.001	0.00537	**0.19**	10
a.s.	D3	ditch	*Daphnia magna*	48 hour	0.21	0.00431	**48.72**	100
a.s.	D4	pond	*Daphnia magna*	48 hour	0.21	0.000774	271.32	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.00457	**45.95**	100
a.s.	D6	ditch	*Daphnia magna*	48 hour	0.21	0.00431	**48.72**	100
a.s.	D6	ditch	*Daphnia magna*	48 hour	0.21	0.00435	**48.28**	100
a.s.	R1	pond	*Daphnia magna*	48 hour	0.21	0.000775	270.97	100
a.s.		stream	*Daphnia magna*	48 hour	0.21	0.00376	**55.85**	100
a.s.	R2	stream	*Daphnia magna*	48 hour	0.21	0.00511	**41.1**	100
a.s.	R3	stream	*Daphnia magna*	48 hour	0.21	0.00537	**39.11**	100
a.s./ Esfenvalerate 5 EC	D3	ditch	*Daphnia magna*	21 day	0.052/ 0.0038	0.00431	12.06/ **0.88**	10
a.s./ Esfenvalerate 5 EC	D4	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.000774	67.18/ **4.91**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.00457	11.38/ **0.83**	10
a.s./ Esfenvalerate 5 EC	D6	ditch	*Daphnia magna*	21 day	0.052/ 0.0038	0.00431	12.06/ **0.88**	10
a.s./ Esfenvalerate 5 EC	D6	ditch	*Daphnia magna*	21 day	0.052/ 0.0038	0.00435	11.95/ **0.87**	10
a.s./ Esfenvalerate 5 EC	R1	pond	*Daphnia magna*	21 day	0.052/ 0.0038	0.000775	67.1/ **4.90**	10
a.s./ Esfenvalerate 5 EC		stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.00376	13.83/ **1.01**	10
a.s./ Esfenvalerate 5 EC	R2	stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.00511	10.18/ **0.74**	10
a.s./ Esfenvalerate 5 EC	R3	stream	*Daphnia magna*	21 day	0.052/ 0.0038	0.00537	**9.68/ 0.71**	10
a.s.	D3	ditch	*Chironomus riparius*	28 day	0.16	0.00431	37.12	10

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC_{sw} [µg L^{-1}]	TER	Annex VI trigger
a.s.	D4	pond	*Chironomus riparius*	28 day	0.16	0.000774	206.72	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.00457	35.01	10
a.s.	D6	ditch	*Chironomus riparius*	28 day	0.16	0.00431	37.12	10
a.s.	D6	ditch	*Chironomus riparius*	28 day	0.16	0.00435	36.78	10
a.s.	R1	pond	*Chironomus riparius*	28 day	0.16	0.000775	206.45	10
a.s.		stream	*Chironomus riparius*	28 day	0.16	0.00376	42.55	10
a.s.	R2	stream	*Chironomus riparius*	28 day	0.16	0.00511	31.31	10
a.s.	R3	stream	*Chironomus riparius*	28 day	0.16	0.00537	29.8	10

The TERs highlighted in bold do not exceed the Annex VI trigger values.

Refinement of the risk to aquatic invertebrates

Revised FOCUS step 4 using the aquatic invertebrate RAC (based on single application of esfenvalerate to winter OSR (spring application)

Test substance	Scenario	Water body type	Test organism	Time scale	Buffer zone	PEC_{sw} [µg L^{-1}]	RAC (µg a.s./L)
a.s.	D2	ditch	Aquatic invertebrate	127 days	20m	**0.00437**	0.0005
a.s.		stream	Aquatic invertebrate	127 days	20m	**0.00520**	0.0005
a.s.	D3	ditch	Aquatic invertebrate	127 days	20m	**0.00431**	0.0005
a.s.	D4	stream	Aquatic invertebrate	127 days	20m	**0.00468**	0.0005
		pond	Aquatic invertebrate	127 days	20m	**0.000774**	0.0005
a.s.	D5	stream	Aquatic invertebrate	127 days	20m	**0.00455**	0.0005
		pond	Aquatic invertebrate	127 days	20m	**0.000774**	0.0005
a.s.	R1	stream	Aquatic invertebrate	127 days	20m	**0.00376**	0.0005
		pond	Aquatic invertebrate	127 days	20m	**0.000774**	0.0005
a.s.	R3	stream	Aquatic invertebrate	127 days	20m	**0.00534**	0.0005

The PECsw exceeds the RAC for aquatic invertebrates for all 6 FOCUS step 4 scenarios for all relevant water body types (highlighted in bold) and therefore low risk for these scenarios has not been demonstrated.

Revised FOCUS step 4 using the aquatic invertebrate RAC (based on single applications of esfenvalerate to spring OSR; spring application)

Test substance	Scenario	Water body type	Test organism	Time scale	Buffer zone	PEC_{sw} [µg L^{-1}]	RAC (µg a.s./L)
a.s.	D2	ditch	*Aquatic invertebrate*	127 days	20m	**0.00437**	0.0005
a.s.		stream	*Aquatic invertebrate*	127 days	20m	**0.00510**	0.0005
a.s.	D3	ditch	*Aquatic invertebrate*	127 days	20m	**0.00433**	0.0005
a.s.	D4	stream	*Aquatic invertebrate*	127 days	20m	**0.00478**	0.0005
		pond	Aquatic invertebrate	127 days	20m	**0.000775**	0.0005
a.s.	D5	stream	*Aquatic invertebrate*	127 days	20m	**0.00539**	0.0005
		pond	Aquatic invertebrate	127 days	20m	**0.000775**	0.0005
a.s.	R1	stream	*Aquatic invertebrate*	127 days	20m	**0.00377**	0.0005
		pond	Aquatic invertebrate	127 days	20m	**0.000774**	0.0005

The PECsw exceeds the RAC for aquatic invertebrates for all 5 FOCUS step 4 scenarios for all relevant water body types (highlighted in bold) and therefore low risk for these scenarios has not been demonstrated.

Revised FOCUS step 4 using the aquatic invertebrate RAC (based on single applications of esfenvalerate to winter cereals; spring application)

Test substance	Scenario	Water body type	Test organism	Time scale	Buffer zone	PEC_{sw} [µg L^{-1}]	RAC (µg a.s./L)
a.s.	D1	ditch	Aquatic invertebrate	127 days	20m	**0.00429**	0.0005
a.s.		stream	Aquatic invertebrate	127 days	20m	**0.00386**	0.0005
a.s.	D2	ditch	Aquatic invertebrate	127 days	20m	**0.00437**	0.0005
a.s.		stream	Aquatic invertebrate	127 days	20m	**0.00512**	0.0005
a.s.	D3	ditch	Aquatic invertebrate	127 days	20m	**0.00430**	0.0005
a.s.	D4	stream	Aquatic invertebrate	127 days	20m	**0.00467**	0.0005
		pond	Aquatic invertebrate	127 days	20m	**0.000774**	0.0005
a.s.	D5	stream	Aquatic invertebrate	127 days	20m	**0.00450**	0.0005
		pond	Aquatic invertebrate	127 days	20m	**0.000774**	0.0005
a.s.	D6	Ditch	Aquatic invertebrate	127 days	20m	**0.00431**	0.0005

Test substance	Scenario	Water body type	Test organism	Time scale	Buffer zone	PEC_{sw} [µg L^{-1}]	RAC (µg a.s./L)
a.s.	R1	stream	Aquatic invertebrate	127 days	20m	**0.00376**	0.0005
		pond	Aquatic invertebrate	127 days	20m	**0.000774**	0.0005
a.s.	R3	stream	Aquatic invertebrate	127 days	20m	**0.00534**	0.0005
a.s.	R4	Stream	Aquatic invertebrate	127 days	20m	**0.00375**	0.0005

The PECsw exceeds the RAC for aquatic invertebrates for all 9 FOCUS step 4 scenarios for all relevant water body types (highlighted in bold) and therefore a low risk for these scenarios has not been demonstrated.

Revised FOCUS step 4 using the aquatic invertebrate RAC (based on single applications of esfenvalerate to potatoes; spring application)

Test substance	Scenario	Water body type	Test organism	Time scale	Buffer zone	PEC_{sw} [µg L^{-1}]	RAC (µg a.s./L)
a.s.	D3	ditch	Aquatic invertebrate	127 days	20m	**0.00431**	0.0005
a.s.	D4	stream	Aquatic invertebrate	127 days	20m	**0.00457**	0.0005
		pond	Aquatic invertebrate	127 days	20m	**0.000774**	0.0005
a.s.	D6	ditch	Aquatic invertebrate	127 days	20m	**0.00431**	0.0005
a.s.	D6	ditch	Aquatic invertebrate	127 days	20m	**0.00435**	0.0005
a.s.	R1	stream	Aquatic invertebrate	127 days	20m	**0.00376**	0.0005
		pond	Aquatic invertebrate	127 days	20m	**0.000775**	0.0005
a.s.	R2	stream	Aquatic invertebrate	127 days	20m	**0.00511**	0.0005
a.s.	R3	stream	Aquatic invertebrate	127 days	20m	**0.00537**	0.0005

The PECsw exceeds the RAC for aquatic invertebrates for all 7 FOCUS step 4 scenarios for all relevant water body types (highlighted in bold) and therefore a low risk for these scenarios has not been demonstrated.

METABOLITES

Aquatic risk assessment for metabolites at FOCUS Step 2

Test substance	Organism	Time scale	Toxicity end point (µg/L)	$PEC_{sw,max}$ [µg L^{-1}]	TER	Annex VI Trigger
(+)CPIA	*Daphnia magna*	48 hr	74 000	0.1736	426267	100
(+)CPIA	*Pseudokirchneriella subcapitata*	72 hr	64 600	0.1736	372120	10
3-Phenoxy benzoic acid	*Oncorhynchus mykiss*	96 hr	14 300	0.1748	81808	100
3-Phenoxy benzoic acid	*Daphnia magna*	48 hr	35 400	0.1748	202517	100
3-Phenoxy benzoic acid	*Pseudokirchneriella subcapitata*	72 hr	33 790	0.1748	193249	10
Dec-Fen	*Oncorhynchus mykiss*	96 hr	>990	0.2055	4818	100
Dec-Fen	*Daphnia magna*	48 hr	>860	0.2055	4185	100
Dec-Fen	*Pseudokirchneriella subcapitata*	72 hr	>240	0.2055	1168	10
$CONH_2$-Fen	*Oncorhynchus mykiss*	96 hr	110	0.0083	13253	100
$CONH_2$-Fen	*Daphnia magna*	48 hr	>870	0.0083	104819	100
$CONH_2$-Fen	*Pseudokirchneriella subcapitata*	72 hr	>150	0.0083	18072	10
PA-Fen	*Oncorhynchus mykiss*	96 hr	>703	0.1736	4050	100
PA-Fen	*Daphnia magna*	48 hr	>382	0.1736	2201	100
PA-Fen	*Pseudokirchneriella subcapitata*	72 hr	>421	0.1736	2425	10

[1]Toxicity

Bioconcentration						
	Active substance	**(+) CPIA**	**3-Phenoxy benzoic acid**	**Dec-Fen**	**$CONH_2$-Fen**	**PA-Fen**
$LogP_{OW}$	6.24	NA	NA	NA	NA	NA
Bioconcentration factor (BCF)	3110	NA	NA	NA	NA	NA
Annex VI trigger for the bioconcentration factor	1000	NA	NA	NA	NA	NA
Clearance time (days) (CT_{50})	7.9	NA	NA	NA	NA	NA
(CT_{90})		NA	NA	NA	NA	NA
Level and nature of residues (%) in organisms after the 14 day depuration phase	69.3	NA	NA	NA	NA	NA

NA - not available

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. ‡		0.06 µg a.s./bee

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
SUMI-ALPHA 5 % EC	0.21 µg a.s./bee	0.07 µg a.s./bee
Field or semi-field tests Cage tests, tunnel cage tests and a field trial on oil seed rape were conducted in addition to nine new trials conducted on *Phacelia* or OSR. No consistent, treatment-related effects were evident on mortality or bee brood. On the basis of the information provided, it is not considered that applications of esfenvalerate are likely to cause adverse effects on honey bees at rates of 15 g a.s./ha.		

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

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	250	50
a.s.	oral	No data	50
SUMI-ALPHA 5 % EC	Contact	**214**	50
SUMI-ALPHA 5 % EC	oral	**71**	50
Esfenvalerate is acutely toxic to honey bees and as a result of the previous review of esfenvalerate and detailed consideration by the SCP it was concluded that providing risk mitigation measures were taken then applications of up to 30 g a.s./ha would not pose an unacceptable risk to honey bees. The Notifier has carried out several field studies to determine the effects of esfenvalerate at 12.5 g a.s./ha and one at 15 g a.s./ha (the proposed GAP). On the basis of the data submitted, it is possible to conclude that applications of the formulation results in a decrease in flight activity that lasts for the day of application. Under some situations, the decrease in flight activity with bees returning to the hive or seeking forage elsewhere appears to be sufficient to prevent an increase in mortality, whereas in certain situations an increase in mortality does occur. The increase in mortality is inconsistent and not prolonged and did not appear to affect survival of the hive for the duration of the study. Sub-lethal effects, for example excessive cleaning or 'hanging on flowers' was noted, again this does not appear to be consistent or lead to higher mortalities. On the basis of the above information, it is not considered that applications of esfenvalerate are likely to cause adverse effects on honey bees foraging crops at the time of application. Data did not indicate that the proposed use should cause adverse effects on bee brood.			

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 product/ha)
Typhlodromus pyri	*Esfenvalerate 5 EC*	Mortality LR_{50}	0.256
Aphidius rhopalosiphi		Mortality	No data

Crop and application rate: Three applications to potato (3 x 0.3 L product/ha)

Test substance	Species	Effect (LR_{50} g product/ha)	HQ in-field	HQ off-field (1 m)	Trigger
Esfenvalerate 5 EC	*Typhlodromus pyri*	0.256	**2695**	**54.3**	2
	Aphidius rhopalosiphi	--	**>2**	**> 2**	2

[1] indicate distance assumed to calculate the drift rate

Crop and application rate Two applications to potato, cereals or OSR (2 x 0.3 L product/ha)

Test substance	Species	Effect (LR_{50} g product/ha)	HQ in-field	HQ off-field (1 m)	Trigger
Esfenvalerate 5 EC	*Typhlodromus pyri*	0.256	**1992**	**47.7**	2
	Aphidius rhopalosiphi	--	**>2**	**>2**	2

Crop and application rate: One application to potato, cereals or OSR (1 x 0.3 L product/ha)

Test substance	Species	Effect (LR_{50} g product/ha)	HQ in-field	HQ off-field(1 m)	Trigger
Esfenvalerate 5 EC	*Typhlodromus pyri*	0.256	**1172**	**32.8**	2
	Aphidius rhopalosiphi	--	**>2**	**>2**	2

Further laboratory and extended laboratory studies (Esfenvalerate 50 g/l EC) ‡

Species	**Life stage**	**Test substance, substrate and duration**	**End point (g a.s/ha)**	**PER in-field (g a.s/ha)**	**PER off-field (g a.s/ha)**	**% effect in-field**	**% effect off-field**	**Trigger value**
Coccinella septempunctata	Larvae	Residues on glass plates 48 h	LR_{50} 0.291 ER_{50}: 0.167	34.5 25.5 15	0.35 0.3 0.21	**>50** **>50**	**>50** **>50**	50 %
Typhlodromus pyri	<24 hours old protonymphs	Leaf discs from bean plants (2D) 14 day study	LR_{50}: >0.084 ER_{50}: >0.084	34.5 25.5 15	0.35 0.3 0.21	**>50** **>50**	**>50** **>50**	50 %
A. rhopalosiphi	Adults parasitic wasps	Aged residues on excised bean leaves 0, or 7 DAT. 14 day study (3D)	Mortality >34.5 on 0 DAT Fecundity >34.5 on 0 DAT	34.5 25.5 15	3.47 3.03 0.35	<50 <50	<50 <50	50 %
T. pyri	protonymphs	Aged residues on excised bean leaves 0, 7 or 16 DAT. 14 day study	Mortality >1.5 on 16 DAT Fecundity >1.5 on 16 DAT	34.5 25.5 15	3.47 3.03 2.08	**>50** **>50**	**>50** **>50**	50 %

Species	Life stage	Test substance, substrate and duration	End point (g a.s/ha)	PER in-field (g a.s/ha)	PER off-field (g a.s/ha)	% effect in-field	% effect off-field	Trigger value
Pardosa spp	Adult	Aged residue study on soil 0, 7, 14, 21 and 35 DAT. Exposed for 14-21 days	Mortality 42 on 7 DAT Feeding > 4.2 on 7 DAT	34.5 25.5 15	0.35 0.3 0.21	**>50** **>50**	**<50** **<50**	50%

Crop scenario	Species	Study type	Application rate (g a.s./ha)	MAF	Spray drift	Correction factor	Vegetation distribution factor	PER (g a.s./ha)
Three applications to potato (3 x 15 g a.s./ha)	*A. rhopalosiphi*	3D	15.0	2.3	0.41*	5	1	0.71
	T. pyri	3D	15.0	2.3	0.41*	5	1	0.71
	Pardosa spp	2D	15.0	2.3	0.41*	5	10	0.07
Two applications to potato, cereals or OSR (2 x 15 g a.s./ha)	*A. rhopalosiphi*	3D	15.0	1.7	0.47*	5	1	0.60
	T. pyri	3D	15.0	1.7	0.47*	5	1	0.60
	Pardosa spp	2D	15.0	1.7	0.47*	5	10	0.06
One application to potato, cereals or OSR (1 x 15 g a.s./ha)	*A. rhopalosiphi*	3D	15.0	1.0	0.57*	5	1	0.43
	T. pyri	3D	15.0	1.0	0.57*	5	1	0.43
	Pardosa spp	2D	15.0	1.0	0.57*	5	10	0.04

* Spray drift rate includes 5 m no spray buffer zone.

Crop scenario	Species	Test substance	Toxicity (g a.s./ha)	$PER_{on-field}$ (g a.s./ha)	$PER_{off-field}$ (g a.s./ha)	Effect (%)		Trigger value (%)
						In-field	Off field	
Three applications to potato (3 x 15 g a.s./ha)	*A. rhopalosiphi*	Esfenvalerate 50 g/L EC	Lethal >34.5 Fecundity >34.5	-	0.71	-	<50	≥<50
	T. pyri		Lethal >1.5 Fecundity >1.5	-	0.71	-	<50	≥<50
	Pardosa spp		Lethal 42.0 Feeding4.2	-	0.07	-	<50	≥<50
Two applications to potato, cereals or OSR (2 x 15 g a.s./ha)	*A. rhopalosiphi*	Esfenvalerate 50 g/L EC	Lethal >34.5 Fecundity >34.5	-	0.60	-	<50	≥<50
	T. pyri		Lethal >1.5 Fecundity >1.5	-	0.60	-	<50	≥<50
	Pardosa spp		Lethal 42.0 Feeding4.2	-	0.06	-	<50	≥<50
One application to potato, cereals or OSR (1 x 15 g a.s./ha0	*A. rhopalosiphi*	Esfenvalerate 50 g/L EC	Lethal >34.5 Fecundity >34.5	-	0.43	-	<50	≥<50
	T. pyri		Lethal >1.5 Fecundity >1.5	-	0.43	-	<50	≥<50
	Pardosa spp		Lethal 42.0 Feeding 4.2	-	0.04	-	<50	≥<50

Field or semi-field tests

Crops/ Situations	Maximum individual dose (kg a.s./ha)	Maximum total dose (kg a.s./ha)	Maximum number of treatments	Growth stage of applications	Recovery
Cereals (Jepson, 1990)	0.005	0.005	1	BBCH 68-73, June UK	Inconclusive results owing to wide variability in the control group
Cereals (Vindall & Mead-Brigg, 1999)	0.0075 & 0.015	0.03	2; 20 day spray interval	BBCH 69-77 June/July; UK	At 7.5 g a.s./ha, recovery of Carabidae, Staphylinidae, Lycosidae, Diptera & Hymenoptera species was evident by day 19. Linyphiidae, Aphidius and Coccinellidae decreased at day 19. At 15 g a.s./ha, reduction in *Aphidius*, *Coccinellidae Lycosidae*, and *Linyphiidae* species at 20 days DAT; no evidence of recolonisation.

According to the ESCORT II guidelines recolonisation should be evident within a year for the in-crop scenario. The RMS has given the applicant's data careful consideration, but has concluded that definitive evidence of recolonisation for the in-crop scenario has not been demonstrated. The RMS concludes that outstanding issues still exist with regard to in-crop recolonisation and therefore Member States should pay special attention to non-target arthropods during national registration

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

Test organism	Test substance	Time scale	End point[1]
Earthworms			
Eisenia fetida	a.s.	Acute 14 days	No data
Eisenia fetida	a.s.	Chronic 8 weeks	No data
Eisenia fetida	Esfenvalerate 5% EC	Acute LC_{50} LC_{50orr}	10.6 mg a.s./kg d.w. soil 5.3 mg a.s./kg d.w. soil
Eisenia fetida	Esfenvalerate 5% EC	Chronic NOEC $NOEC_{corr}$	1.1 mg a.s./kg d.w. Soil 0.55 mg a.s./kg d.w. Soil
Eisenia fetida	$CONH_2$-Fen	Acute LC_{50}	>969 mg metabolite/kg soil dw
Other soil macro-organisms			
Hypoaspis aculeifer	Esfenvalerate	Sublethal 14 d	EC_{50} (14 d) 14.5 mg a.s./kg dry soil $NOEC_{mortality}$ = 15.98 mg a.s./kg dry soil $NOEC_{reproduction}$ = 2.0 mg a.s./kg dry soil

Test organism	Test substance	Time scale	End point[1]
Collembola			
Folsomia candida	Esfenvalerate	Sublethal 28 d	EC_{50} (28 d) = >6.4 mg a.s./kg dry soil NOEC (28 d) = 0.4 mg a.s./kg dry soil
Soil micro-organisms			
Nitrogen transformation	Esfenvalerate	28 d	< 25 % effect at 0.08 mg a.s./kg soil dw and 0.4 mg a.s./kg soil dw
Carbon transformation	Esfenvalerate	28 d	< 25 % effect at 0.08 mg a.s./kg soil dw and 0.4 mg a.s./kg soil dw
Field studies: not required			

Toxicity/exposure ratios for soil organisms

Based on worse case scenario of 3 applications to potatoes at 15 g a.s./ha and relevant to all crop GAPs

Test organism	Test substance	Time scale	Soil PEC (mg/kg d.w. Soil)	TER	Trigger
Earthworms					
Eisenia fetida	Esfenvalerate 5% EC	Acute	0.028	190	10
Eisenia fetida	Esfenvalerate 5% EC	Long-term	0.028	19.6	5
Eisenia fetida	$CONH_2$-Fen	Acute	0.023	42	10
Other soil macro-organisms					
Folsomia candida	Esfenvalerate	Long-term	0.028	14	5
Hypoaspis aculeifer	Esfenvalerate	Long-term	0.028	71	5

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

A first tier risk assessment was carried out using the endpoints from the evaluated vegetative vigour study. The exposure was calculated using an application rate of 0.33 L 'Esfenvalerate 5 EC'/ ha and the standard drift value at 1 m for one application, i.e. 2.77 %, as is recommended by the SANCO Terrestrial Guidance Document.

Laboratory dose response tests

Most sensitive species	**Test substance**	**ER_{50} (g/ha) vegetative vigour**	**ER_{50} (g/ha) emergence**	**Exposure (g product/ha)**	**TER**	**Trigger**
Soybean	'Esfenvalerate 5 EC'	> 0.6	--	0.009	36.7	5

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

None required

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

Test type/organism	end point
Activated sludge	3 hour EC_{50} > 1000 mg esfenvalerate/L

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

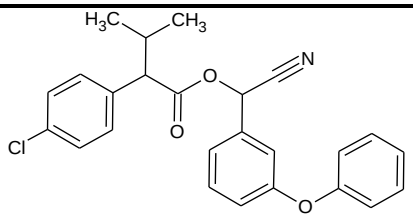
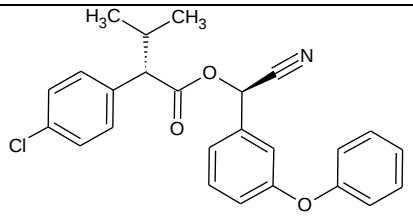
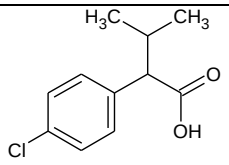
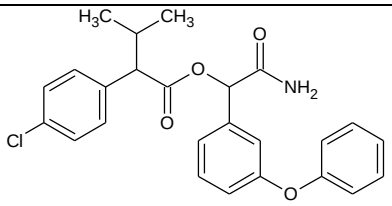
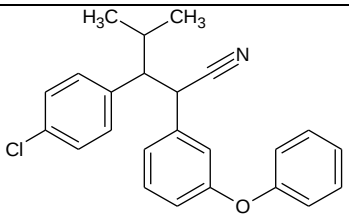
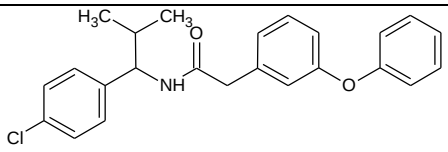
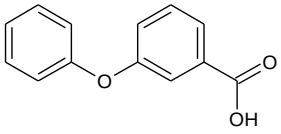
Compartment	
soil	Parent: Esfenvalerate
water	Parent: Esfenvalerate Metabolites:2SαR-isomer of fenvalerate
sediment	Esfenvalerate; 2SαR-isomer of fenvalerate
groundwater	Esfenvalerate

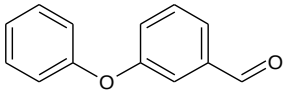
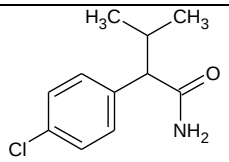
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)*

	RMS/peer review proposal
Active substance	H400/H410 Acute category 1, LC_{50} *Oncorhynchus mykiss* = 0.0001 mg a.s./L *i.e.* is below < 1 mg/L (see table B.9.2.57, section B.9.2.5). Chronic category 1, not readily biodegradable, BCF = 3110, logPow =6.24. The NOEC for *Oncorhynchus mykiss* was 0.000001 mg a.s./L i.e. < 0.1 mg/L (see table B.9.2.57, section B.9.2.5) (see section B.8.4.3).

* It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name/SMILES notation**	Structural formula**
fenvalerate	(α*RS*)-α-cyano-3-phenoxybenzyl (2*RS*)-2-(4-chlorophenyl)-3-methylbutyrate Clc1ccc(cc1)C(C(C)C)C(=O)OC(C#N)c3cccc(Oc2ccccc2)c3	
2SαR-isomer of fenvalerate (Aβ isomer)	(α*R*)-α-cyano-3-phenoxybenzyl (2*S*)-2-(4-chlorophenyl)-3-methylbutyrate Clc1ccc(cc1)[C@H](C(C)C)C(=O)O[C@@H](C#N)c3cccc(Oc2ccccc2)c3	
CPIA	(2*RS*)-2-(4-chlorophenyl)-3-methylbutanoic acid Clc1ccc(cc1)C(C(C)C)C(=O)O	
CONH$_2$-Fen	(1*RS*)-2-amino-2-oxo-1-(3-phenoxyphenyl)ethyl (2*RS*)-2-(4-chlorophenyl)-3-methylbutanoate Clc1ccc(cc1)C(C(C)C)C(=O)OC(c3cccc(Oc2ccccc2)c3)C(N)=O	
Dec-Fen	(2*RS*,3*RS*)-3-(4-chlorophenyl)-4-methyl-2-(3-phenoxyphenyl)pentanenitrile Clc1ccc(cc1)C(C(C)C)C(C#N)c3cccc(Oc2ccccc2)c3	
PA-Fen	*N*-[(1*RS*)-1-(4-chlorophenyl)-2-methylpropyl]-2-(3-phenoxyphenyl)acetamide Clc1ccc(cc1)C(NC(=O)Cc3cccc(Oc2ccccc2)c3)C(C)C	
PBacid	3-phenoxybenzoic acid O=C(O)c2cc(Oc1ccccc1)ccc2	

PBald	3-phenoxybenzaldehyde O=Cc2cc(Oc1ccccc1)ccc2	
CPIA-carboxamide	2-(4-chlorophenyl)-3-methylbutanamide Clc1ccc(cc1)C(C(C)C)C(N)=O	

* The metabolite name in bold is the name used in the conclusion.
** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DFG	Deutshe Forschungsgemeinschaft method
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC	emulsifiable concentrate
EC_{50}	effective concentration
ECHA	European Chemicals Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
FIR	Food intake rate
FOB	functional observation battery

FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography – mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre (also used for mean measured concentrations)
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet

MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen phosphorous detector
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
REACH	Registration, Evaluation, Authorisation of Chemicals Ragulation
RPE	respiratory protective equipment
RUD	residue per unit dose
SD	standard deviation
SFO	single first-order
SMILES	simplified molecular-input line-entry system
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell

WG	water dispersible granule
WHO	World Health Organization
wk	week
yr	year