CONCLUSION ON PESTICIDE PEER REVIEW

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

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SUMMARY

Bifenthrin is one of the 79 substances of the third stage Part A of the review programme covered by Commission Regulation (EC) No 1490/2002[3] as amended by Commission Regulation (EC) No 1095/2007[4]. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the European Commission a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the designated rapporteur Member State and to provide within six months a conclusion on the risk assessment to the European Commission.

France being the designated rapporteur Member State submitted the DAR on bifenthrin in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 15 December 2005. The peer review was initiated on 1 June 2006 by dispatching the DAR for consultation of the Member States and on 12 May 2006 to the sole applicant FMC Chemicals. Subsequently, the comments received on the DAR were examined and responded by the rapporteur Member State in the reporting table. This table was evaluated by EFSA to identify the remaining issues which were agreed during a written procedure in February 2008. The identified issues as well as further information made available by the applicant upon request were evaluated in a series of scientific meetings with Member State experts in June – July 2008.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in September 2008 leading to the conclusions set out in the EFSA Conclusion finalised on 30 September 2008 (EFSA Scientific Report (2008) 186).

Following the Commission Decision of 30 November 2009 (2009/887/EC)[5] concerning the non-inclusion of bifenthrin in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant FMC Chemicals made a resubmission application for the inclusion of bifenthrin in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008[6]. The resubmission dossier included further data in response to the issues identified in the conclusions leading to the Decision on non-inclusion, as set out in the Review Report (SANCO/125/08) as follows:

- The fate and behaviour in soil and water, due to the possible presence of major soil metabolites, the relevance of which must be determined and, if necessary, further assessed. As a consequence, the risk to groundwater, could not be finalised;

[1] On request from the European Commission, Question No EFSA-Q-2010-01217, issued on 11 May 2011.
[2] Correspondence: pesticides.peerreview@efsa.europa.eu
[3] OJ L 224, 21.08.2002, p. 25, as amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19)
[4] OJ L 246, 21.9.2007, p. 19
[5] OJ L 318, 4.12.2009, p. 41
[6] OJ L 15, 18.01.2008, p. 5

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- The risk to aquatic organisms which, with the exception of invertebrates and algae, does not generate an acceptable use;
- The risk to several species of mammals, non-target arthropods, non-target plants and non-target soil macro-organisms.

and concerns were identified with regard to:

- The risk to consumers, which may be underestimated, given the data gaps identified in the residue section, and the possible impact of the different isomers constituting bifenthrin;
- The potential for contamination of groundwater by the major soil metabolite TFP acid;
- The unacceptable high risk to aquatic vertebrates;
- The long term risk to mammals;
- The risk from secondary poisoning of earthworm-eating mammals;
- The risk from bioaccumulation through the aquatic food chain which is not finalised;
- The risk to non-target arthropods (in-field), non-target plants and non-target soil macro-organisms which remains inconclusive.

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, France, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 6 August 2010.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 10 August 2010. The EFSA collated and forwarded all comments received to the European Commission on 23 September 2010.

In accordance with Article 20, following consideration of the Additional Report and the comments received, the European Commission requested the EFSA to deliver its conclusions on bifenthrin.

The conclusion of the original review was reached on the basis of the evaluation of the representative uses as an insecticide, which comprise of foliar spraying in cereals, grape and pome fruit for the control of a broad range of foliar pests, sucking and biting insects, mites, aphids. Full details of the GAP can be found in Appendix A. The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of bifenthrin as an insecticide on cereals, ornamentals and head cabbage, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

The representative formulated product for the evaluation was ‘Talstar 8 SC’, a suspension concentrate (SC) containing 80 g/l bifenthrin.

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

Adequate methods are available to monitor bifenthrin residues in food/feed of plant and animal origin, in the environmental matrices and in body fluids and tissues.

As for mammalian toxicity, bifenthrin is “Toxic if swallowed” (R25), it is toxic by inhalation (R23 “Toxic by inhalation” proposed). Bifenthrin is a skin sensitiser (R43 “May cause skin sensitisation by skin contact” proposed). It is not a skin or eye irritant.

The main effect observed for repeated exposures is tremor and/or neurotoxic effects. The relevant short-term toxicity NOAEL is 2.5 mg/kg bw/day in dogs whereas for long-term exposures the NOAELs is 4.7 mg/kg bw/day in rats. Bifenthrin did not show any genotoxic potential. Due to the occurrence of bladder leiomyosarcomas/hemangiopericytomas in mice and as their relevance to humans could not be excluded, and the historical control data were not conclusive, R40 (Carc. Cat. 3)

was proposed. In multigeneration studies the relevant maternal NOAEL is 3.0 mg/kg bw/day and the reproductive NOAEL is 5 mg/kg bw/day, based on the occurrence of tremors and marginally lower body weight in the P and F1 generation females during gestation and lactation. Bifenthrin did not show any teratogenic potential (maternal NOAEL>7.4 mg/kg bw/day and developmental NOAEL >2 mg/kg bw/day). Bifenthrin did not show developmental neurotoxicity potential. The ADI is 0.015 mg/kg bw/day based on the 1-year dog study with a SF of 100, supported by the developmental study in rats. The ARfD is 0.03 mg/kg bw based on the 90-day neurotoxicity study with a SF of 100. The AOEL is 0.0075 mg/kg bw/day (SF 100 and correction factor of 50% for limited oral absorption). The operator, worker and bystander exposure showed levels below the AOEL.

In the metabolism studies on apples (fruit crops), cotton seed (pulses and oilseeds) and maize plants (cereals) bifenthrin was found to be the predominant compound of the total residues. No significant cis-trans isomerisation and translocation of residues through the plant were observed. The proposed global residue definition for monitoring and risk assessment in plant commodities is bifenthrin (sum of isomers). Complete residue database were provided to support the representative uses on cereals (wheat, triticale, rye, barley and oat) for both Northern and Southern Europe and to propose MRLs while 4 additional residue trials are required on head cabbage (Northern Europe). The nature of the residues in processed commodities was sufficiently addressed for pasteurisation and baking, brewing and boiling but not for sterilisation. A data gap was identified to require a new hydrolysis study simulating the conditions of sterilisation to determine the nature of the residues in processed commodities. Based on the metabolism studies in ruminants and poultry, the proposed residue definition for monitoring for animal commodities is bifenthrin (sum of isomers). For risk assessment, the residue definition proposals are as follows:

-ruminant liver and kidney: sum of bifenthrin (sum of isomers) and BP-acid, expressed as bifenthrin (conversion factor of 2 for monitoring to risk assessment);

-eggs, poultry liver: sum of bifenthrin (sum of isomers) and hydroxyl-methyl bifenthrin and its fatty acid conjugates, expressed as bifenthrin (conversion factor of 2 for monitoring to risk assessment);

-for milk and all other animal products: bifenthrin (sum of isomers).

The storage time interval of the samples from the residue trials on cereals and head cabbage and of the animal tissues from the feeding studies can be considered as covered by the available storage stability data. Under normal agricultural practices, bifenthrin residue levels in the edible parts of the rotational crops intended for human consumption and as feed items are expected to be below 0.01 and 0.05 mg/kg, respectively. No chronic and acute intake concerns were identified according to EFSA PRIMo rev.2A model. The consumer risk assessment should be regarded as provisional pending the submission of the additional residue trials on head cabbage. The potential for a different degradation of bifenthrin enantiomers in plant and animal commodities was considered as sufficiently addressed since the S/R enantiomeric ratio of the parent bifenthrin was shown to remain unchanged (S/R ratio: 1/1) both in cereals and head cabbage samples from the residue trials and in fat samples from the rat. Based on the available residue datasets an MRL of 0.05 mg/kg is proposed for wheat, triticale and rye grain and a MRL of 0.1 mg/kg is set for barley and oat grain. A provisional MRL of 0.3 mg/kg is proposed for head cabbage. MRLs were also defined for animal matrices.

In soil under aerobic conditions bifenthrin exhibits moderate to high persistence forming the major soil metabolite TFP acid (accounting for up to 11.6% of applied radioactivity (AR)) which exhibits low to moderate persistence and the minor non-transient metabolite 4'-OH bifenthrin (accounting for up to 8.3% AR) which exhibits moderate persistence. Mineralisation of both the cyclopropyl and phenyl rings to carbon dioxide accounted for 30-39% AR after 90 days. The formation of unextractable residues was a sink that accounted for 14-18 % AR after 90 days. Bifenthrin is immobile in soil, 4'-OH bifenthrin is expected to be immobile in soil though there was a data gap identified to confirm this. Metabolite TFP acid exhibited very high to medium mobility. There was no indication that adsorption

of either bifenthrin or 4'-OH bifenthrin was pH dependent, whereas TFP acid exhibited pH dependent adsorption.

In dark natural sediment water systems bifenthrin degraded exhibiting high persistence in sediment to the metabolite 4'-OH bifenthrin in sediment (max. 11.1% AR). The terminal metabolite, CO_2, was a sink in the material balance from both the cyclopropyl and phenyl radiolabels accounting for a maximum of 3-27 % AR at 99 days (study end). Unextracted sediment residues accounted for 6-14 % AR at study end. The necessary surface water and sediment exposure assessments were appropriately carried out using the agreed FOCUS scenarios approach for bifenthrin at steps 1-4, with spray drift and run-off mitigation being applied at step 4 for the applied for representative uses on cereals and head cabbage. For the metabolite TFP acid and additionally for the 4'-OH bifenthrin, appropriate FOCUS step 2 calculations were carried out. These values are the basis for the risk assessment discussed in this conclusion. Regarding the outdoor uses on ornamentals, a data gap was identified for exposure estimations for surface water and sediment.

The potential for groundwater exposure from the representative uses on cereals and head cabbage by bifenthrin, TFP acid and 4'-OH bifenthrin above the parametric drinking water limit of 0.1 µg/L, was concluded to be low in geoclimatic situations that are represented by the relevant FOCUS groundwater scenarios. The potential for groundwater exposure from the uses on ornamentals was accepted to be covered by the estimations available for cereals.

Since bifenthrin and its two metabolites relevant for the environment consist of 2 enantiomers and because only limited information on the behaviour of the enantiomers of bifenthrin in the environment was available, a data gap regarding this issue remained.

Low acute, short-term and long-term risks were indicated with the first-tier risk assessment for birds and a low acute risk was indicated for mammals for the outdoor representative uses. A potential high long-term risk to mammals was identified with the first tier for outdoor representative uses; however, the risk was assessed as low with a subsequent assessment based on the Guidance Document on Birds and Mammals (EFSA, 2009). The risk of bifenthrin to earthworm-eating birds and mammals was assessed as low for the outdoor representative uses, based on PEC_{soil} plateau of 0.027 mg/kg. The risk to fish-eating birds and mammals was considered to be low based on the BCF value for fish of 1709.

Since bifenthrin has a potential for biomagnification i.e. potential for accumulation observed in a metabolism study on rat and estimated biomagnification factor (BAF)>1, a food chain modelling has been carried out. However, the experts at the PRAPeR 87 experts' meeting identified several uncertainties in the model assumptions and parameterization and therefore they concluded that a high risk from biomagnification in the terrestrial food chain cannot be excluded. Therefore the experts agreed to identify a data gap for the applicant to further address this risk.

The risk to birds and mammals for the indoor representative use in ornamentals is low since no exposure is expected.

The first tier risk assessment indicated a potential high acute and long-term risk to fish and aquatic invertebrates. The estimated TER values, based on the FOCUS PECsw step 4 (20-25 m no-spray buffer zones and run-off reduction) and higher tier toxicity end points, were above the Annex VI trigger values indicating a low risk. To fulfil the data gap identified during the PRAPeR 53 to further address the risk from bioaccumulation through the food chain, a biomagnification modelling has been carried out and provided in the Additional Report. This modelling has been discussed at the PRAPeR 87. The experts agreed that a high risk from bioaccumulation through the food chain for aquatic organisms could not be excluded on the basis of the available data. Therefore, a data gap was identified to further address the risk from biomagnification in the aquatic food chain and to address the uncertainties raised.

The experts concluded that a high risk was identified for bifenthrin to bees for all the outdoor representative uses. Risk mitigation measures should be applied to avoid the exposure of bees and

effects from residual toxicity (by considering an appropriate interval between the last application and flowering).

It could be concluded from the available information that there is a high risk to non-target arthropods for in-field and off-field areas within the treated area from the outdoor representative uses. Risk mitigation measures are required to reduce the exposure of non-target arthropods in the off-field areas. A data gap was identified for the applicant to provide further data to address the residual toxicity of bifenthrin to non-target arthropods and the potential for recovery/recolonisation.

The acute and long-term risk of bifenthrin and TFP acid to earthworms was assessed as low.

The risk to soil macro-organisms, micro-organisms, non-target plants and biological methods of sewage treatment was assessed as low for all the representative uses evaluated.

KEY WORDS

bifenthrin, peer review, risk assessment, pesticide, insecticide

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BACKGROUND

Commission Regulation (EC) No 451/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 1490/2002, and by Commission Regulation (EC) No 1095/2007[7], regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the Draft Assessment Reports (DAR) provided by the designated rapporteur Member State (RMS). Bifenthrin is one of the 79 substances of the third stage, part A, covered by the Regulation (EC) No 1490/2002 designating France as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, France submitted the report of its initial evaluation of the dossier on bifenthrin (France, 2005), hereafter referred to as the DAR, received by EFSA on 15 December 2005. Following an administrative evaluation, the DAR was distributed for consultation in accordance with Article 11(2) of the Regulation (EC) No 1490/2002 on 1 June 2006 to the Member States and on 12 May 2006 to the sole applicant FMC Chemicals, as identified by the rapporteur Member State.

The comments received on the DAR were evaluated and addressed by the rapporteur Member State. Based on this evaluation, EFSA identified and agreed with Member States during a written procedure in February 2008 on lacking information to be addressed by the applicant as well as issues for further detailed discussion at expert level.

Taking into account the requested information received from the applicant, a scientific discussion took place in experts' meetings in June – July 2008. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in September 2008 leading to the conclusions set out in the EFSA Conclusion finalised on 30 September 2008 (EFSA, 2008).

Following the Commission Decision of 30 November 2009 (2009/887/EC)[8] concerning the non-inclusion of bifenthrin in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant FMC Chemicals made a resubmission application for the inclusion of bifenthrin in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008[9]. The resubmission dossier included further data in response to the issues identified in the conclusions leading to the Decision on non-inclusion, as set out in the Review Report (SANCO/125/08) (European Commission, 2009a) as follows:

- The fate and behaviour in soil and water, due to the possible presence of major soil metabolites, the relevance of which must be determined and, if necessary, further assessed. As a consequence, the risk to groundwater, could not be finalised;
- The risk to aquatic organisms which, with the exception of invertebrates and algae, does not generate an acceptable use;
- The risk to several species of mammals, non-target arthropods, non-target plants and non-target soil macro-organisms.

and concerns were identified with regard to:

- The risk to consumers, which may be underestimated, given the data gaps identified in the residue section, and the possible impact of the different isomers constituting bifenthrin;
- The potential for contamination of groundwater by the major soil metabolite TFP acid;

[7] OJ L 246, 21.9.2007, p.19
[8] OJ L 318, 4.12.2009, p.41
[9] OJ L 15, 18.01.2008, p.5

- The unacceptable high risk to aquatic vertebrates;
- The long term risk to mammals;
- The risk from secondary poisoning of earthworm-eating mammals;
- The bioaccumulation assessment which is not finalised;
- The risk to non-target arthropods (in-field), non-target plants and non-target soil macro-organisms which remains inconclusive.

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, France, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report (France, 2010). The Additional Report was received by the EFSA on 6 August 2010.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 10 August 2010. The EFSA collated and forwarded all comments received to the European Commission on 23 September 2010. The collated comments were also forwarded to the RMS for compilation 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.

In accordance with Article 20, following consideration of the Additional Report and the comments received, the European Commission decided to further consult the EFSA. By written request, received by the EFSA on 4 November 2010, the European Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on bifenthrin within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were required to be submitted by the applicant in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicant in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the European Commission on 25 October 2010; the applicant was also invited to give its view on the need for additional information. On the basis of the comments received, the applicant's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that EFSA should organise a consultation with Member State experts in the area of ecotoxicology, and that further information should be requested from the applicant in the areas of physical and chemical properties, residues, environmental fate and behaviour and ecotoxicology.

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 were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table 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 April 2011.

The conclusion from the original review was reached on the basis of the evaluation of the representative uses as presented in the DAR, i.e. use as an insecticide, which comprise foliar spraying in cereals, grape and pome fruit for the control of a broad range of foliar pests, sucking and biting insects, mites and aphids. The conclusion of the peer review of the resubmission was reached on the basis of the evaluation of the representative uses of bifenthrin as an insecticide on cereals, ornamentals and head cabbage, 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.

The documentation developed during the resubmission peer review was compiled as a Peer Review Report (EFSA, 2011) comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's Additional Report:

- the comments received
- the Reporting Table (rev. 1-1; 25 October 2010)
- the Evaluation Table (5 May 2011)
- the report of the scientific expert consultation with Member State experts

Given the importance of the Additional Report including its addendum (compiled version of March 2011 containing all individually submitted addenda) (France, 2011) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion. The documents of the Peer Review Report (EFSA, 2008a) and the final addendum (France, 2008) developed and prepared during the course of the initial review process are made publicly available as part of the background documentation to the original conclusion, finalised on 30 September 2008 (EFSA, 2008b).

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Bifenthrin is the ISO common name for 2-methylbiphenyl-3-ylmethyl (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate or 2-methylbiphenyl-3-ylmethyl (1*RS*)-*cis*-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate (IUPAC).

Bifenthrin belongs to the class of pyrethroid ester insecticides, acaricides. It is active by contact, ingestion or inhalation. Bifenthrin acts on the nervous system of insects, disturbing the function of neurons by interaction with the sodium channel, disrupting the normal transmission of nerve impulses causing repetitive firing of the insect's nerve resulting in paralysis and ultimately death. Bifenthrin has a broad spectrum of activity on a wide variety of foliar pests, it is used as an agricultural insecticide on a large variety of crops, including cereals, vegetables, vine grapes and fruits, and also in post-harvest treatment on cereals.

The representative formulated product for the evaluation was 'Talstar 8 SC', a suspension concentrate (SC) containing 80 g/l bifenthrin, registered under different trade names in Europe.

The representative uses evaluated under the resubmission comprise foliar spraying to control sucking and biting insects and aphids in cereals, ornamentals and head cabbage. Full details of the GAP 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. 8.1 (European Commission, 2009b) and SANCO/825/00 rev. 7 (European Commission, 2004a).

The minimum purity of bifenthrin technical material is 930 g/kg. Bifenthrin is a racemate. There is no FAO specification available, only the evaluation report is published.

Technical bifenthrin is manufactured in three different locations having one common specification, the specification of the reference source, identified in the Additional Report. 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 bifenthrin or the respective formulation, however a data gap was identified for a two year shelf-life study for the NPE-free formulation. The main data regarding the identity of bifenthrin and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of bifenthrin in the technical material and in the representative formulation (GC-FID, HPLC-UV) as well as for the determination of the respective impurities in the technical material (HPLC-UV, HPLC-MS and GPC).

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

Adequate GC-ECD and GC-MSD methods are available to monitor residues of bifenthrin in food of plant and animal origin. Residues of bifenthrin in plants can also be monitored with the multi-residue method DFG S19. Residues of bifenthrin in soil and sediment can be monitored by GC-ECD and GC-MSD with LOQs of 0.005 mg/kg. Bifenthrin residues in surface water and air can be determined by GC-MSD with LOQs of 1 ng/l and 0.5 µg/m^3 respectively. Adequate GC-ECD and GC-MSD methods are available to monitor residues of bifenthrin in body fluids and tissues.

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, March 2004 (European Commission, 2004b) and SANCO/10597/2003 rev. 8.1, May 2009 (European Commission, 2009b).

Bifenthrin was discussed in a meeting of experts in July 2008 (PRAPeR 54 subgroup 1). No expert consultation took place during the resubmission procedure.

The PRAPeR 54 meeting considered the information presented by the RMS on impurities present at low levels in the batch used in the key toxicological studies. The meeting noted that 5 impurities in the declared specification were not included in the batches used in the toxicological studies, and one impurity was at a significantly higher level in the declared specification (4.2% as opposed to <0.05%). However, it was noted that aspects of this impurity structure were present in the parent bifenthrin, and were similar to another impurity which was covered in the toxicological batches. The meeting concluded that the batches tested in the mammalian toxicity package were representative of the declared technical specification.

The impurity toluene is considered a relevant impurity in the technical material based on its hazards, with a maximum limit of 5 g/kg.

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

Bifenthrin is partially absorbed when orally administered (50% estimated bioavailability, based on bile cannulated rats showing 50% excretion in the faeces). Fat, skin, liver and lungs contained the highest residue levels. Elimination of the radioactivity was complete within 48 hours (up to 25% and to 88% in urine and faeces, respectively). Bifenthrin showed a potential for accumulation in fat.

Bifenthrin is extensively metabolised, mainly via hydrolysis, oxidation and conjugation.

The non-selectivity of the metabolism of bifenthrin enantiomers has been demonstrated in rats. It has been shown that there is a symmetrical biotransformation/metabolism and elimination of both bifenthrin enantiomers (S and R) without enantiomeric preference.

2.2. Acute toxicity

Bifenthrin is classified as “Toxic if swallowed” with the risk phrase R25 (oral LD_{50} in rats 54.5 mg/kg bw); it is toxic to rat by inhalation (LC_{50} 1.01 mg/L, risk phrase R23 “Toxic by inhalation” proposed). Bifenthrin was found to be a skin sensitiser to guinea-pigs in the maximisation test, and therefore was proposed for classification as R43 “May cause skin sensitisation by skin contact”. It is not a skin or eye irritant.

Acute oral toxicity studies demonstrated that the *R*-enantiomer is more toxic than the *S*-enantiomer.

2.3. Short-term toxicity

The sub-chronic toxicity of bifenthrin was evaluated in rats, dogs and rabbits.

The main effect observed is tremor and/or neurotoxic effects for the 3 tested species. The relevant NOAELs are 2.5 mg/kg bw/day and 1.5 mg/kg bw/day (90-day and 1-year study in dogs, respectively). The relevant NOAEL for repeated dermal administration in rats and rabbits are 50 mg/kg bw/day and 100 mg/kg bw/day, respectively.

2.4. Genotoxicity

In vitro and *in vivo* genotoxicity tests were negative except for the test on mouse lymphoma cells, which was "slightly positive". However, the main part of the data showed that bifenthrin is not genotoxic.

2.5. Long-term toxicity

As well as in short-term toxicity tests the critical effect was represented by tremors (relevant NOAELs 3 mg/kg bw/day in the 2-year study in rats, and 7.6 mg/kg bw/day in the 18-months study in mice). No evidence of carcinogenicity was found in rat.

The carcinogenic potential of bifenthrin in mice was discussed in the PRAPeR 54 meeting. The tumours occurring in mice exposed to bifenthrin were multi-site (urinary bladder, lung, liver, leukaemia) and therefore the carcinogenic potential of bifenthrin could not be excluded in the absence of mechanistic data.

Liver tumours (observed only in males) were not statistically significantly increased, but dose related. Based on the historical controls they were considered unlikely to be treatment related.

Lung tumours were neither dose related nor showing dose trends.

As for bladder tumours, males showed a dose related increase of leiomyosarcomas, statistically significant at high dose in males. A complementary assessment of the key study (Wilborn, 1988 in France, 2005) identified other lesions of the same nature in the controls. A panel of 3 pathologists revised the histology of the lesions classifying them as hemangiopericytoma, rising from the submucosa, instead of leiomyosarcoma. In another position paper from the applicant, the lesions are widely described as SML: submucosal mesenchymal lesions. The relevance of these lesions for humans is questionable.

The historical control data were not reassuring (as they were for other strains and facilities); therefore R40 (Carc. Cat. 3) was proposed. It was noted that the tumours do not have an impact on the risk assessment.

2.6. Reproductive toxicity

In a two generation study in the rat, there was no effect on reproductive performance up to and including the highest dose level. The relevant maternal NOAEL is 60 ppm (3.0 mg/kg bw/day) and the reproductive NOAEL is 5 mg/kg bw/day, based on the occurrence of tremors and marginally lower body weight in the P and F1 generation females during gestation and lactation

Bifenthrin did not show any teratogenic potential (maternal NOAEL >7.4 mg/kg bw/day and developmental NOAEL >2 mg/kg bw/day).

The developmental neurotoxicity potential of bifenthrin was considered during the PRAPeR 54 meeting.

Tremors were observed in the pups that may have been exposed via milk. After discussion in the meeting, R64 “May cause harm to breastfed babies“ was not proposed as tremors occurred after 20 days post birth, when mixed exposure can be assumed. Considering the concentrations in milk (max. day 11 of lactation) the effects should have occurred earlier. The RMS reported about the content of the study and this showed no neuro-developmental toxicity concerns.

2.7. Neurotoxicity

Bifenthrin was tested in acute and delayed neurotoxicity studies and was not considered to be a delayed neurotoxin when administered to adult hens. In another acute neurotoxicity study in rat with

undiluted bifenthrin, the NOAEL was 35 mg/kg bw/day. When tested in a sub-chronic neurotoxicity test in rats (90-day study) a NOAEL of 2.9 mg/kg bw/day was established.

2.8. Further studies

No specific data are available on the metabolites.

During the PRAPeR 54 meeting, the experts of the meeting on residues (running in parallel) sent a question about the relevance of BP-acid (proposed for residue definition for animal products) and OH-methyl bifenthrin (residues in egg yolk), whether they were covered by toxicity data. The experts in the tox meeting noted that BP-acid was a product in the rat metabolism.

Overall, the experts agreed that the metabolite does not give cause for concern as it occurs as an intermediate in the rat metabolic pathway and should therefore be of lower toxicity than the parent and would be covered by the ADI for bifenthrin.

OH-methyl bifenthrin and fatty acid ester conjugates are also present in egg yolk, but the experts agreed that these are detoxification products in rat metabolism and would also be covered by the tox profile of the parent.

In conclusion, both metabolites were considered to be less toxic than the parent. The PRAPeR 54 meeting agreed that if reference values are needed to perform consumers' risk assessment (e.g. in case of significant amount of metabolites in crops), the reference values of bifenthrin are applicable, as specific toxicological information on the metabolites is missing.

2.9. Medical data

Health surveillance programmes conducted in the applicant's company did not show any unexplained or significant changes from the baseline or values falling outside the reference ranges for employees working in the unit, nor have employees experienced harmful effects as a result of their work in the production unit. Further, industrial hygiene monitoring in the area where bifenthrin is handled demonstrated that airborne levels of the product are generally less than the analytical detection limit.

Following accidental exposures the predominant finding was dermal sensations of burning/tingling, which mostly resolved within 24 hours. The second most common complaint was eye irritation.

2.10. Acceptable daily intake (ADI), acceptable operator exposure level (AOEL) and acute reference dose (ARfD)

The ADI, ARfD and AOEL for bifenthrin were agreed during the PRAPeR 54 meeting of experts.

ADI

The meeting agreed the ADI should be 0.015 mg/kg bw/day based on the 1-yr dog with a SF of 100, supported by the developmental study in rats.

ARfD

The meeting agreed an ARfD was triggered. The RMS suggested 0.03 mg/kg bw based on the 90-day neurotoxicity study with a SF of 100. This was agreed by the experts.

AOEL

It was agreed the AOEL should be based on the 1-yr dog study, giving an AOEL of 0.0075 mg/kg bw/day (SF 100 and correction factor of 50% for limited oral absorption).

Bifenthrin is a racemate. It can be assumed that toxicological batches are performed with the racemic mixture and that the reference values (ADI, AOEL and ARfD) are based on the racemic mixture.

2.11. Dermal absorption

An *in vivo* study in rat dosed with FMC 54800 showed that the amount of bifenthrin eliminated in the urine and faeces was less than 1% of the dose applied, even after 24 hours of exposure. The amount absorbed (including the amount in the skin) was 55.14% after 10 hours and 69.1% after 24 hours.

A second *in vivo* study in rats dermally dosed with Capture 2 EC gave a better representation of the dermal absorption of bifenthrin. After 10 hours, 0.85% of the dose was found in the carcass, 0.43% in the urine and none in the faeces. These values added to the skin value of 16.55% indicated a total of 17.83% absorbed or remaining in the skin 10 hours after application (value used by the RMS for predicting the operator exposure). The PRAPeR 54 meeting agreed to use the proposed dermal absorption of 17.83% (rounded to 18%) for the concentrate and dilution.

During the resubmission, a new *in vitro* human study with the representative formulation 'Talstar 8 SC' was submitted. The study was considered acceptable. Based on this study the dermal absorption values to be used in the exposure to operators, workers and bystander are 3% for the concentrate and 35% for the aqueous dilution.

2.12. Exposure to operators, workers and bystanders

The representative formulation of bifenthrin is 'Talstar 8 SC' to be applied on cereals, head cabbage and ornamentals (indoor and outdoor) at application rates of 0.0076-0.010 kg a.s/ha.

Operator exposure

From the representative uses, two main scenarios are considered: field crops and glasshouse application. The worst-case exposure conditions for each of the two scenarios are represented by cereals for field crops when the preparation is applied by tractor-mounted equipment and by ornamentals when the preparation is applied by hand-held application. Only these representative (worst-case) scenarios are considered in the risk assessment. Results are summarised in the following table.

Table 2.12-1: Operator exposure estimates to 'Talstar 8 SC' according to the representative uses.

Crop	Model	Systemic exposure (mg/kg bw/day)		% of systemic AOEL	
		No PPE	PPE*	No PPE	PPE*
Cereals	UK POEM	0.0190	0.0027	253.7	36.2
	German	0.00225	0.00167	30	22.3
Ornamentals (Outdoor and indoor)	UK POEM	0.0227	0.0063	303.2	84.7
	German	0.0029	0.0015	39.3	20.7
Ornamentals (Indoor)	Dutch	0.71	0.071	135	13.5

*PPE (Personal Protective Equipment): Gloves during mixing, loading and application for the UK POEM and German Model; and gloves and coverall during mixing, loading and application for the Dutch Model.

According to operator exposure estimates no PPE is needed according to the German Model (cereals, head cabbage and ornamental outdoors). PPE (gloves during mixing and loading and application) is needed according to the UK POEM Model (cereals, head cabbage and ornamental outdoors). PPE (gloves and coverall) is needed according to the Dutch Model (ornamental indoors).

Worker exposure

Worker exposure has been estimated according to the EUROPOEM. The total systemic exposure for workers re-entering treated areas after application on cereals (worst-case scenario compared to head cabbage) to perform activities such as scouting is 0.0009 mg/kg bw/day without the use of PPE (11.7% of the AOEL). The total systemic exposure for workers re-entering treated areas after application on ornamentals to perform activities such as cut, sort, bundle or carry is 0.0197 mg/kg bw/day without the use of PPE (263.1% of the AOEL) and 0.0021 mg/kg bw/day with PPE (coverall; 27.9% of the AOEL). It is noted that the assessment made by the RMS (France, 2010) for ornamentals has been based on the indoor application; however it can be considered as representative of the outdoor application.

Bifenthrin is a racemate. Acute oral toxicity studies demonstrated that the R-enantiomer is more toxic than the S-enantiomer (see section 2.2). Although the differences in toxicity with regard to the potential impact on worker exposure risk assessment have not been addressed, assuming a worst-case scenario where all the toxicity of the bifenthrin is due to the R-enantiomer (i.e. AOEL = 0.00375 mg/kg bw/d) and workers are exposed only to the R-enantiomer, worker exposure would be below the AOEL of 0.00375 mg/kg bw/day for cereals and cabbages without the use of PPE and for ornamentals (indoor and outdoor) with the use of PPE.

Bystander exposure

Bystander exposure has been estimated according to the EUROPOEM for ornamentals-outdoors. The total systemic exposure is 0.000128 mg/kg bw/day (1.7% of the AOEL). Ornamentals-outdoors is considered a worst-case scenario for field crops.

For indoor uses no bystander exposure is expected since they should not be allowed in greenhouses.

3. Residues

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

Bifenthrin was discussed at the PRAPeR Expert Meeting 55 for residues in July 2008. The assessment for the original representative uses on pome fruit and grapes was not updated as these uses were no longer supported by the applicant in his resubmission application. Therefore data gaps related to the uses on pome fruit and grapes were not considered in this conclusion. In the framework of the resubmission application, the representative uses were on cereals (wheat, barley, oat, triticale and rye), head cabbage and ornamentals.

Bifenthrin is a mixture of two optical isomers (*Z*)-(*1R*)-*cis*-acid and (*Z*)-(*1S*)-*cis*-acid (enantiomers). The analytical methods used in the reported studies were not stereoselective and therefore the residues reported in this conclusion are expressed as the sum of the two enantiomers.

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

The metabolism of bifenthrin was investigated in apples (fruit crops), cotton seed (oilseeds and pulses) and maize plants (cereals) using ^{14}C-bifenthrin labelled on the phenyl ring and on the cyclopropyl moiety (also referenced as Alcohol ^{14}C-bifenthrin and Acid ^{14}C-bifenthrin, respectively). In apples, following foliar treatment, the major part of the total residues remained on the peel for the 2 labelling forms (84.5%-92.8% TRR). In peel and pulp, bifenthrin was the predominant compound of the total residues and accounted for up to 91% TRR and 12.4% TRR, respectively. In mature treated cotton leaves, the parent compound was also identified as the predominant component of the total residues (up to 64.6% TRR for both the 2 labelling forms) while the metabolites BP-acid, BP-alcohol and TFP acid were detected in negligible amounts (<1% TRR). The same metabolic profile was observed in cotton leaves following soil treatment. In addition, the metabolite 4'-OH bifenthrin was also recovered

(up to 7% TRR). Low levels of total residues (below the LOQ) were found in cotton seed at maturity and no investigation to identify the metabolites was therefore attempted. Following foliar application on young maize plants, the total radioactive residues in mature grain accounted for up to 0.069 mg/kg for both the 2 labelling forms and no further metabolite identification was investigated. The total radioactive residues in treated leaves decreased from 29.5 mg/kg to 20.5 mg/kg within 30 days after treatment, indicating that the parent compound had a limited systemicity. Bifenthrin constituted the main constituent of the total residues in maize leaves, up to 68% TRR for both the 2 labelling forms, while minor metabolites such as BP-acid, BP-alcohol, BP-aldehyde and TFP acid occurred at negligible levels (<1% TRR), except 4'-OH-bifenthrin (12% TRR). It must be highlighted that the levels of recovered residues were similar both in the control and treated maize grain and plant parts (silage, stalks/leaves and husk) samples after foliar and soil application and corresponded to the background radiation level. Nevertheless, the meeting of experts considered this study as acceptable. Overall and based on these metabolism studies, two main metabolic pathways have been depicted in plants:

- hydroxylation of the terminal phenyl ring leading to 4'-OH bifenthrin;
- hydrolytic cleavage of the ester linkage of the parent molecule yielding the metabolites TFP-acid and BP-alcohol, the latter being progressively oxidised to BP-aldehyde and BP-acid with further conjugation to plant materials.

The metabolites found in plants were also observed in rat metabolism. No significant *cis*- to *trans*-isomerisation and translocation of residues through the plant were observed in the course of the metabolism studies.

As unchanged bifenthrin was shown to be the predominant component of the residues in the three categories of crops, the global residue definition for monitoring and risk assessment in plant commodities is proposed as bifenthrin (sum of isomers).

The residue database provided on cereals (wheat, barley, triticale and oat) included the residue trials provided in the original DAR and the additional trials that were provided after the submission of the DAR to EFSA (April 2007) but that could not be considered in the course of the first peer review process as laid down in Commission Regulations (EC) No.1490/2002 and No.1095/2007.

A complete residue database on wheat covering both Northern and Southern Europe and also 2 trials on triticale (Northern Europe) were considered as acceptable to propose an MRL of 0.05 mg/kg on wheat with possible extrapolation to triticale and rye. A complete residue database on barley for both Northern and Southern Europe and 2 additional residue trials on oat (Northern Europe) were considered as acceptable to propose an MRL of 0.1 mg/kg on barley with possible extrapolation to oat. A provisional MRL of 0.3 mg/kg was proposed on head cabbage, based on 4 Northern trials and a data gap was identified for 4 additional trials, as head cabbage is a major crop in that zone. In order to address the potential of a different degradation of bifenthrin enantiomers in plant commodities, samples of the residue trials on cereals and head cabbage were analysed for the residues of *cis-Z-R,R*-bifenthrin and *cis-Z-S,S*-bifenthrin using an enantiospecific analytical method. The *S/R* enantiomeric ratio of the parent bifenthrin was shown to remain constant (*c.a.* 1/1) in the samples of wheat straw, barley grain and straw and in head cabbage indicating no preferential differential degradation of bifenthrin isomers in those matrices.

Storage stability studies demonstrated that bifenthrin residues are stable for 49 months in apples, maize silage and maize stover, for 34 months in maize grain, for 24 months in cotton seed, for 6 months in potato tuber and its processed parts and for 15 months in dry pea seeds. The storage time intervals of the samples from the residue trials on cereals and head cabbage can be considered as covered by the available storage stability data.

A new standard hydrolysis study, to address the nature of the residues in processed products, was reported in the Additional Report of July 2010 as the initial study evaluated in the DAR of 2005 was considered not acceptable. Bifenthrin was found to be stable under pasteurisation and baking

conditions. Under sterilisation, the average recovery decreased from 102% at time 0 to 60% of the applied radioactivity after 20 minutes, the residual radioactivity being composed of the parent compound only. The applicant argued that this important loss of radioactivity was due to the volatilisation of the labelled bifenthrin test substance during processing at the elevated temperature of 120°C. EFSA is of the opinion that the nature of the residues in sterilised commodities was not sufficiently addressed and a data gap was identified to require a new hydrolysis study simulating the conditions of sterilisation to determine the nature of the residues in processed commodities.

No studies on the effect of processing on the level of residues are required for cereals as no significant residues occurred in cereal grain (below 0.1 mg/kg). Also no processing data are required on head cabbage since the TMDI is less than 10% of the ADI. This should be reconsidered pending the outcome of the requested additional residue trials on head cabbage, the outcome of the hydrolysis study simulating sterilisation and the amendment of the consumer risk assessment.

3.1.2. Succeeding and rotational crops

A confined rotational crop study was conducted using ^{14}C-bifenthrin labelled respectively on the phenyl ring and the cyclopropyl moiety, at an excessive application rate of 560 g a.s./ha (28N, 37N and 56N for cereals, head cabbage and ornamentals, respectively). Lettuce, sugar beet and wheat were planted after 30, 60 and 120 days of soil ageing, wheat also after 7 and 12 months. At the normal agricultural practices, bifenthrin residue levels in the edible parts of the rotational crops intended for human consumption and as feed items are expected to be below 0.01 and 0.05 mg/kg, respectively. The metabolite pattern was determined in wheat straw only and was found to be similar to the metabolism observed in the primary crops.

3.2. Nature and magnitude of residues in livestock

The metabolism of bifenthrin has been studied in ruminants and poultry using ^{14}C-bifenthrin labelled on the phenyl ring and the cyclopropyl moiety, respectively.

After dosing lactating goats at a dose rate of 2.3 mg/kg b.w./day (55N-beef; 85N-dairy cattle) over 7 days, most of the applied radioactivity was recovered in faeces and urine (95%), while less than 1.3% and 2.2% were recovered in milk and tissues, respectively. The radioactive residues in milk reached a plateau after 4 days at an average concentration of approximately 0.9 mg^{14}C bifenthrin equiv./kg (max. 1.5 mg/kg). In tissues, the highest residue concentrations were found in liver (3.9 mg/kg) and in fat (2.8 mg/kg). While bifenthrin was the predominant compound of the total residues in milk (82.4% TRR), muscle (87.7% TRR) and fat (80.2% TRR) along with the minor metabolite OH-methyl-bifenthrin (up to 5% TRR in muscle), the metabolism was more extensive in kidney and liver where bifenthrin accounted for 21.5% and 44% TRR while the predominant metabolite observed in those matrices was the BP-acid (up to 35% and 28.5% TRR, respectively). The TFP acid metabolite was recovered to a minor extent in kidney and liver (4.3% and 1.7% TRR, respectively). Hydrolysis of the lipid conjugates from milk, fat, kidney and liver released non-negligible amounts of BP-alcohol in milk, fat and liver and BP-acid in kidney and liver.

For laying hens dosed with bifenthrin at 2 mg/kg b.w./day for 10 days (>300N), the recovered radioactivity accounted for 90% of the applied dose in excreta with less than 0.8% and 0.4% of the total dose in egg yolk and tissues, respectively. The total radioactive residues in egg yolk reached a plateau after 7/8 days corresponding to a maximum concentration of 3.3 mg^{14}C bifenthrin equiv./kg with lower levels of radioactivity in egg white (0.02-0.05 mg/kg). In tissues, the highest total residues were found in liver and fat (1.9 and 2.1 mg/kg, respectively). The major compound of the radioactive residues identified in fat and muscle was bifenthrin (up to 53% TRR for both the labelling forms) with non-negligible amounts of the fatty acid conjugates of OH-methyl bifenthrin in fat (up to 21.8% TRR). In egg yolk similar levels of bifenthrin (up to 44% TRR) and of both unconjugated OH-methyl bifenthrin and its fatty acid conjugates (around 40% TRR) were identified. In liver, besides the predominant metabolite OH-methyl bifenthrin, free and under its fatty acid conjugated form (together

up 47% TRR for both the 2 labellings), the TFP acid metabolite was also detected at a non-negligible level (24.5% TRR).

The major route of degradation of bifenthrin in ruminants consisted of hydrolysis of the ester linkage with a preferential formation of the metabolite BP-acid observed mainly in liver and kidney while in poultry a preferential hydroxylation of the 2-methyl carbon of the cyclopropane ring occurred to form the hydroxyl-methyl bifenthrin followed by fatty acids conjugation.

The residue definition for animal commodities was intensively discussed during the PRAPeR 55 expert meeting. For monitoring, the residue definition was limited to bifenthrin (sum of isomers), as it was shown that the parent compound accounted for a major part of the radioactivity in most of the ruminant and poultry matrices (17% to 78% TRR, except poultry liver; 2-4% TRR). For risk assessment, and based on the metabolism studies, the following residue definitions and conversion factors were proposed:

- Ruminant liver and kidney: sum of bifenthrin (sum of isomers) and BP-acid expressed as bifenthrin (conversion factor of 2 for monitoring to risk assessment);
- Eggs, poultry liver: sum of bifenthrin (sum of isomers) and hydroxyl-methyl bifenthrin and its fatty acid conjugates, expressed as bifenthrin (conversion factor of 2 for monitoring to risk assessment);
- For milk and all other animal products: bifenthrin (sum of isomers).

Although the meeting of experts agreed on these definitions, EFSA is of the opinion that the definitions for risk assessment were established in a conservative way, since it was finally concluded that the hydroxyl-methyl bifenthrin and BP-acid metabolites should be considered as less toxic than the parent (see section 2.8). Furthermore, in the feeding studies, the metabolite BP-acid was not detected in goat liver and kidney at the 5N feeding dose level and the hydroxyl-methyl bifenthrin was never detected in eggs, even at the highest feeding dose level (2.5N).

The storage stability data for bifenthrin and its metabolites in animal matrices were reported in the revised Additional Reports (July and September 2010). The bifenthrin residues were shown to be stable under frozen storage conditions in cow fat, muscle, liver, milk and poultry eggs for 36 months while the residues of BP-acid were stable in cow liver, muscle and fat for at least 24 months. The storage time interval of the tissues, milk and egg samples from the cow and poultry feeding studies was covered by the available storage stability data. No standard storage stability data were provided for the relevant metabolite fatty acids conjugates of hydroxyl-methyl bifenthrin in eggs. Nevertheless, based on the storage stability data on egg samples from the poultry metabolism studies reported in Addendum 1 to the Additional Report to the DAR (January 2011), EFSA is of the opinion that there is sufficient evidence that no significant degradation of the fatty acids conjugates of the hydroxyl-methyl bifenthrin metabolite may occur in egg yolk during the storage time period of the samples analysed for this metabolite in the feeding study (36-38 days). No further data are required to address the storage stability of this metabolite in egg yolks.

The livestock dietary burden calculation was amended in the Additional Report (September 2010) and was performed considering the STMR value for cereal grain and the HR value for straw and head cabbage. The maximum feed intake exceeded the trigger value of 0.1 mg/kg DM/day for dairy/beef cattle and pigs but not for poultry. Feeding studies on dairy cattle and poultry were performed using unlabelled bifenthrin. For dairy cattle, the samples of milk and tissues were analysed for parent and for the metabolites BP-alcohol and BP-acid. At the lowest feeding level investigated of 5 mg/kg DM diet corresponding to *c.a.* 7 and 5 times the estimated animal burden respectively for dairy cattle and beef cattle, the highest bifenthrin residue levels accounted for 0.02 mg/kg in liver, 0.1 mg/kg in kidney, 0.07 mg/kg in muscle, 1.82 mg/kg in peritoneal fat while the mean bifenthrin residue levels in whole milk and milk fat accounted for 0.12 mg/kg and 0.91 mg/kg, respectively. No metabolite was detected except BP-alcohol in peritoneal fat (0.11 mg/kg). For poultry, eggs were analysed for bifenthrin and hydroxyl-methyl bifenthrin after the release of the fat soluble conjugates. Tissues were analysed for bifenthrin, BP-alcohol and TFP acid. No residues of the parent or of any metabolite were detected

above the LOQ of the analytical method in eggs and poultry tissues at the highest feeding level of 0.25 mg/kg DM diet, corresponding to *c.a.* 2.5 times the estimated dietary burden. MRLs for milk, eggs and animal matrices were derived from these studies. It should be noted that the livestock dietary burden calculation and the MRL proposals for animal products will have to be revised according to the outcome of the requested additional residue trials on head cabbage.

The *S/R* enantiomeric ratio of the parent bifenthrin was shown to remain unchanged (*c.a.* 1/1) in samples of plasma, fat and faecal extracts from rats indicating no preferential enantiomeric absorption or metabolism of bifenthrin isomers in rat fat. EFSA considers that no further information is required on the *S/R* enantiomeric ratio of bifenthrin in the other animal tissues.

3.3. Consumer risk assessment

No chronic intake concern was identified according to EFSA PRIMo rev.2A model considering the MRLs proposals for plants and animals matrices and the conversion factors for monitoring to risk assessment set for ruminant liver and kidney and poultry eggs and liver (TMDI: 7% ADI). The acute exposure estimate did no indicate any concern (IESTI: 40% ARfD) considering the STMR value for cereal grain, the HR values for head cabbage and animal commodities and also the conversion factors for monitoring to risk assessment. The potential for a different degradation of bifenthrin enantiomers in plant and animal commodities was considered as sufficiently addressed since the *S/R* enantiomeric ratio of the parent bifenthrin was shown to remain unchanged (*S/R* ratio: 1/1) both in cereals and head cabbage samples from the residue trials and in fat samples from the rat. It should be noted that the consumer risk assessment has to be regarded as provisional pending the outcome of the required additional residue trials on head cabbage.

3.4. Proposed MRLs

Complete residue datasets were provided to propose an MRL of 0.05 mg/kg for wheat, triticale and rye grain and an MRL of 0.1 mg/kg for barley and oat grain. Insufficient residue trials were provided for the major crop head cabbage (Northern Europe). 4 additional residue trials are required to confirm the provisional MRL proposal of 0.3 mg/kg. MRLs were also proposed for animal matrices.

4. Environmental fate and behaviour

Bifenthrin was discussed at the PRAPeR experts' meeting for environmental fate and behaviour PRAPeR 52 in June/July 2008. It should be noted that the methods of analysis used in the majority of the fate and behaviour studies were not stereoselective. All residues reported as bifenthrin or the two metabolites in this conclusion are for the sum of the 2 enantiomers. Limited information on the behaviour of each individual bifenthrin enantiomer in the environment was available in the regulatory dossier, but no data were provided for the enantiomers of the metabolites TFP acid and 4'-OH bifenthrin. The information for bifenthrin provides indications that the more active *R*-enantiomer degraded more quickly than the *S*-enantiomer, in some, but not all soils. There were also indications that in water systems, significant enantioselective degradation would not be expected. These conclusions are however based on a limited data set. Therefore a data gap regarding this issue remains.

4.1. Fate and behaviour in soil

4.1.1. Route of degradation in soil

A soil experiment on a silt loam soil (pH 6.5, 4.3% organic matter (OM)) was carried out under aerobic conditions in the laboratory (25°C, 63% of 1/3 bar (pF2.5) moisture holding capacity (MHC)) in the dark. The formation of residues not extracted by acetonitrile/water were a sink with the cyclopropyl-1-^{14}C-radiolabel accounting for 13.8% of the applied radioactivity (AR) and the phenyl ring ^{14}C-radiolabel accounting for 18.4% AR after 90 days. Mineralisation to carbon dioxide of these radiolabels accounted for 39% AR and 30% AR after 90 days respectively. No extracted resolved radiolabelled chromatographic fraction except that ascribed to bifenthrin accounted for more than 3.8 % AR at any sampling time. It should be noted that as these incubations appear to have been carried

with a soil moisture content below field capacity (pF2), microbial breakdown would not have been optimised as is the intent in a route of degradation study. If a guideline study had been available with soil moisture maintained at field capacity, levels of breakdown products might have been higher. In this study the identified metabolites TFP acid, 4'-OH bifenthrin, BP-acid and BP-alcohol accounted for maxima of 0.8, 3.8, 0.7 and 0.4 % AR respectively. In a number of additional 25°C dark aerobic laboratory incubations in 3 different soils, where sampling intervals were few and soil moisture incubation conditions were not always clear (but were at least initially probably 65% of 1/3 bar MHC) the metabolite TFP acid was present at up to 3.7% AR at 180 days whilst 4'-OH bifenthrin was present at up to 8.2% AR at 120 days. In these studies on three soils the formation of residues not extracted by acetonitrile/water and mineralisation to carbon dioxide of the cyclopropyl-1-^{14}C-radiolabel and the phenyl ring ^{14}C-radiolabel radiolabels were broadly comparable to those noted above for the silt loam soil.

In radiolabelled field soil residue samples taken in a rotational crop study (seasonally open glasshouse, semi-field experiment in North America) TFP acid was present at up to 11.6% AR after 120 days, so the peer review agreed that this must be considered a major (>10% AR) metabolite following regulatory practice. In these experiments 4'-OH bifenthrin accounted for 6% AR at 65 days, 8.3% AR at 103 days and 5.1% AR at 181 days so the peer review classified this metabolite as a non-transient metabolite occurring at >5% AR and consequently a groundwater exposure assessment was triggered for it. Comparable (numerically slightly lower) values for these 2 metabolites were also found in soil samples in another confined rotational crop study (Bixler, 1986 in France, 2008).

An anaerobic soil experiment was carried out on a loamy sand soil (pH 5.8, 2.9% OM) in the laboratory at 20°C in the dark. Under the anaerobic incubation, no significant decline of bifenthrin was observed. The identified metabolites 4'-OH bifhentrin and TFP acid, were detected at a maximum of 4.4 and 4.1% of AR, respectively in the anaerobic phase of the study. The formation of the other metabolites did not exceed 3.4% AR under anaerobic condition. Mineralisation and non-extractable residues reached about 5 % AR and 3 % AR, respectively. In a laboratory soil photolysis study, no novel photodegradation products were identified. The identified products accounted for a maximum of 3.8% AR, with the *trans*-isomer of bifenthrin accounting for a maximum of 3.1% AR.

4.1.2. Persistence of the active substance and their metabolites, degradation or reaction products

The rate of degradation of bifenthrin was estimated from the results of the laboratory studies described in 4.1.1 above and laboratory experiments on 2 additional soils at 22°C and 40% maximum water holing capacity (MWHC). New kinetic analyses considering the recommendations of the FOCUS kinetics document (FOCUS, 2006) were conducted in the resubmission peer review. DT_{50} values were between 67-174 days (non-linear single first order regression). After normalisation to FOCUS reference conditions[10] (20°C and -10kPa soil moisture content) the range of single first order DT_{50} was 54-174 days (geomean DT_{50}: 102.2 days).

Regarding the soil metabolites 4'-OH bifenthrin and TFP acid, the existing data were amended with additional soil experiments (at 20°C and 45% MWHC) for the resubmission application, resulting in sufficient data sets of three or four soil DT_{50} values. DT_{50} values for 4'-OH bifenthrin were between 9.1-22.2 days (non-linear single first order) and between 3.3-16.1 days (non-linear single first order) for TFP acid. After normalisation[10], these ranges of DT_{50} values became 10.8-22.2 days and 3.2-25.3 days, respectively. It is noted that in case of a single soil incubation of TFP acid, the best-fit degradation kinetics was found to be hockey-stick (non-normalized DT_{50} 2.3 days, DT_{90} 16 days), however since the SFO fit was found to be acceptable, this SFO DT_{50} was considered to be used for modelling in the further assessments. Kinetic formation fractions from one single silt loam soil could be derived. These were 0.05 for TFP acid and 0.43 for 4'-OH bifenthrin.

[10] Using section 2.4.2 of the generic guidance for FOCUS groundwater scenarios, version 1.1 dated April 2002, assuming a Q10 of 2.58 and Walker equation coefficient 0.7 (FOCUS, 2000).

In the PRAPeR 52 meeting, the Member State experts discussed the dataset of field dissipation studies and the kinetics of decline appropriate for the reliable field trials. They agreed that the DT_{50} and DT_{90} for the trials before and after normalisation to FOCUS reference conditions as set out in the Final Addendum to the DAR (France, 2008) were the appropriate values from these trials. However, they considered that the results from the semi-field experiments should be excluded from the dataset of DT values as they did not originate from guideline field dissipation experiments. In particular the fact that soil had been placed in steel troughs meant the results were unlikely to be comparable to experiments that closer resemble guideline studies. The experts agreed that using the experimental results from the available field dissipation experiments carried out in France and Italy it was not possible to estimate reasonable DT values in these experiments as the range of data was too wide. However, in the resubmission procedure some errors were disclosed, so the derivations of degradation parameters with the subsequent normalization procedures were redone. The range of the actual DT_{50} values from the reliable field dissipation studies were between 15-199 days, while the DT_{90} values were between 221-965 days. The kinetics used for the derivation of these degradation parameters were either SFO or biphasic (DFOP or FOMC). The kinetics used for the individual field trials with the necessary further details are reported in Appendix A. After a time step normalisation to reference soil temperature and soil moisture conditions, following the FOCUS recommendations[11], the DT_{50} values ranged between 11 - 103 days and the DT_{90} values ranged between 135 - 496 days. Again, the kinetics used for the derivation of these parameters were either SFO or biphasic (DFOP).

For bifenthrin, the longest not normalised soil DT_{50} of 199 days (SFO) was used in the PEC soil calculations including calculations for accumulation of bifentrin in soil. Regarding the soil metabolites, PECs were calculated considering the molecular weights and the maximum observed formations in the field trials.

4.1.3. Mobility in soil of the active substance and their metabolites, degradation or reaction products

The adsorption / desorption of bifenthrin was investigated in 4 soils in satisfactory batch adsorption experiments. Calculated adsorption K_{oc} values (only a single concentration was investigated) varied from 130526 to 301611 mL/g, (arithmetic mean 236610 mL/g). There was no evidence of a correlation of adsorption with pH.

The adsorption/desorption of TFP acid was investigated in 5 soils in satisfactory batch adsorption experiments. Calculated adsorption K_{foc} values varied from 13.5 to 415 mL/g. The adsorption was found to correlate with pH, sorption decreasing with increasing soil pH. Consequently, a worst case K_{foc} value of 13.5 mL/g with the associated 1/n value of 0.955 (measured at pH 7.3) was used in the subsequent modelling.

The adsorption of 4'-OH bifenthrin was estimated using the PCKOCWIN quantitative structure activity relationship (QSAR) calculation software. This software provided a value of 5230000 mL/g. Subsequently the applicant considered that as 4'-OH bifenthrin was structurally similar to parent bifenthrin, comparable adsorption might be expected. They therefore proposed that in groundwater leaching assessments the lowest value measured for bifenthrin could be used in modelling simulations. The Member State experts agreed that for the relatively low application rates being requested as the representative uses and the low persistence indicated for this metabolite (single first order DT_{50} 11-22 days) exceptionally they were content to consider groundwater modelling using the adsorption value of 130526 mL/g to finalise the EU level assessment. However, the Member State experts confirmed that a data gap for experimental data was appropriate to have reliable information with less uncertainty available for any future assessments that might be required.

In the resubmission application the adsorption of 4'-OH bifenthrin was assessed using the HPLC method (OECD 121). The results of this study indicated that 4'-OH bifenthrin is immobile. However,

[11] The normalisation was done assuming a Q10 of 2.2 (for the US studies) or Q10 of 2.58 (for the EU studies) and Walker equation coefficient of 0.7.

according to the opinion of the Scientific Committee on plants (SCP, 2002) the HPLC method is not recommended to be used for estimation of the adsorption potential for such a compound like 4'-OH bifenthrin. Consequently, these experimental data did not fulfil the data gap agreed by the Member State experts.

4.2. Fate and behaviour in water

4.2.1. Surface water and sediment

Bifenthrin was stable under sterile aqueous hydrolysis conditions at 25°C at pH 5, 7 and 9. In a laboratory artificial light study where the aqueous photolysis of bifenthrin was investigated under sterile conditions at pH 7, a rate of degradation (single first order DT_{50}) between 15-18 days equated to summer sunlight at 40°N was determined. Beside the isomerism of bifenthrin, one major metabolite, BP-alcohol (maximum occurrence 19%) was formed. This metabolite is however not expected to be found in significant amounts in natural aquatic systems due to the high adsorption potential and the rapid partitioning of the parent bifenthrin to the sediment.

A ready biodegradability test indicated that bifenthrin is 'not readily biodegradable' using the criteria defined by the test.

In water-sediment studies (2 systems studied at 20°C in the laboratory, sediment pH 7.1-7.9, water pH 7.7-7.8) bifenthrin dissipated from the water partitioning to sediment. Degradation in sediment subsequently occurred with single first order whole system DT_{50} being calculated as 278 (4.8% OC sediment system, geomean of experiments with two radiolabels) and 93 days (0.7% OC sediment system, geomean of experiments with two radiolabels) (overall geomean value 161 days). The only major (>10%AR) metabolite except carbon dioxide present at any sampling time was 4'-OH bifenthrin which accounted for up to 11.1% AR at study end (99 days) in sediment. The minor breakdown products identified were: BP alcohol and TFP acid. The formation of residues not extracted by acetonitrile/water were a sink with the cyclopropyl-1-^{14}C-radiolabel accounting for 6.2 to 9.6 % AR and the phenyl ring ^{14}C-radiolabel accounting for 10-14.2 % AR after 99 days. Mineralisation to carbon dioxide of these radiolabels accounted for 6.9-12.1 % AR and 3.5-27.3 % AR after 99 days respectively. The peer review concluded that for bifenthrin water and sediment DT_{50} of 1000 days (default) and 161 days (geomean of whole system values) respectively were acceptable for use as FOCUSsw scenario calculation input at steps 3 and 4.

For the representative uses in cereals and head cabbage, the necessary surface water and sediment exposure assessments (PEC) were carried out for bifenthrin as well as for the metabolites 4'-OH bifenthrin and TFP acid using the FOCUS (FOCUS, 2001) step 1 and step 2 approaches. For bifenthrin FOCUS step 3 and step 4 calculations were also carried out. The mitigation measures implemented at FOCUS step 4 level included no-spray buffer zones of 20 m or 25 m combined with a maximum of 90% runoff mitigation for the run-off scenarios. Additionally, for the representative uses in cereals, taking into consideration that bifenthrin is persistent in water sediment systems, PECsed values considering the accumulation potential of bifenthrin were calculated at step 4 level (20 m no-spray buffer zone + runoff mitigation). These values were lower than the standard step 3 results that were sufficient to demonstrate low risk to sediment-dwellers. The representative use for ornamentals comprised both indoor and outdoor applications. For indoor use the PECsw calculations were based on a simple assumption that 0.1% of the active substance reaches a receiving static water body of 30 cm depth. For outdoor use the peer review concluded that no reliable estimations for the exposure were available. Consequently, a data gap was identified for $PEC_{SW/SED}$ calculations for outdoor use in ornamentals.

4.2.2. Potential for ground water contamination of the active substance, their metabolites, degradation or reaction products

The representative uses in spring and winter planted cereals and cabbage were simulated using FOCUS PELMO 3.3.2 and PEARL 3.3.3 for the active substance bifenthrin and the metabolites 4'-OH

bifenthrin and TFP-acid[12]. Detailed information about the model parameterisation is provided in Appendix A. Regarding the use in ornamentals, the peer review agreed that the estimation for the potential of groundwater contamination was covered by the calculations available for cereals.

The parent bifenthrin and the metabolite 4'-OH bifenthrin were calculated to be present in the leachate leaving the top 1 m soil layer at 80th percentile annual average concentrations of <0.001µg/L. Also, the predicted concentrations for the metabolite TFP-acid leaving the top 1 m soil layer were below the parametric drinking water limit of 0.1 µg/L for all the modelled scenarios (PECgw ≤ 0.007 µg/L).

4.3. Fate and behaviour in air

The vapour pressure of bifenthrin (1.78×10^{-5} Pa at 20°C) means that bifenthrin would be classified under the national scheme of The Netherlands as very slightly volatile, indicating that significant losses due to volatilisation would not be expected. Based on the results of a laboratory climate chamber experiment where a bifenthrin EC formulation was applied to loam soil (1.1% OC, initially at 75% field capacity moisture levels) it was estimated that 1.97 % of the radioactivity from the radioactive bifenthrin applied was lost to the air compartment in 39 hours at 40°C. This measured loss was lower at 25°C (0.3% AR). Calculations using the method of Atkinson for indirect photo oxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half-life estimated at 8.7 hours (assuming an atmospheric hydroxyl radical concentration of 1.5×10^{6} radicals cm^{-3}) indicating that the expected small proportion of bifenthrin that does reach the upper atmosphere would be unlikely to be subject to long-range atmospheric transport.

5. Ecotoxicology

Bifenthrin was discussed at the PRAPeR 53 meeting in July 2008 on the basis of the DAR and the Addendum 2 Vol 3 B.9.

Additionally, bifenthrin was discussed at the PRAPeR 87 meeting in March 2011 on the basis of the Additional Report from July 2010 and the Addendum from January 2011.

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

Bifenthrin has 2 isomers and the *R*-form is more toxic than the *S*-form. However, the current risk assessment carried out for the sum of isomers can be considered as sufficiently conservative for the aquatic environment. Indeed, no enantioselective degradation was observed in water sediment systems. Furthermore, the more toxic isomer was shown to degrade slightly quicker than the less toxic isomer in some soils. Although the data set was considered limited by the fate section (see data gap in section 4), for soil organisms, assuming the worst-case situation where all toxicity would be attributed to the more toxic isomer (i.e. by dividing the toxicity end points by 2), the risk would still be indicated as low.

5.1. Risk to terrestrial vertebrates

The acute oral and dietary short-term LD_{50}/NOED for birds were 1800 mg a.s./kg bw/day and 104.5 mg a.s./kg bw/day respectively. The long-term reproductive endpoint NOED was 6.63 mg a.s./kg bw/d. The short-term risk calculations were based on the $NOED_{mortality}$ of 104.5 mg a.s./kg bw/day derived in the study with Mallard ducks. The NOED was chosen since food avoidance was observed and therefore the LC_{50} was considered unreliable. This approach leads to a more conservative assessment. No signs of toxicity that would affect bird behaviour were observed in the acute oral or short-term dietary studies below the $NOED_{mortality}$ of 104.5 mg/kg bw/day, and no effects on reproduction were observed at the highest dose of 75 mg a.s./kg feed tested in the reproduction study.

[12] Simulations correctly utilised the agreed Q10 of 2.58 (EFSA, 2007), Walker equation coefficient of 0.7 and were in accordance with the pertinent EFSA opinion (EFSA, 2004).

The acute, short-term and long-term risk to birds was assessed as low for all the outdoor representative uses.

The lowest acute endpoint for mammals was observed in a test with mouse (LD_{50}= 42.5 mg a.s./kg bw/d). The first tier acute risk assessment resulted in a TER value above the Annex VI trigger value suggesting that the acute risk to mammals was low for the outdoor representative uses.

The NOEL/NOAEL endpoints for mammals were discussed by the experts in the PRAPeR 53 meeting. The experts suggested using the NOAEL of 3 mg a.s./kg bw/day derived form the 2-year oral toxicity study in rats. It was based on tremors and a slight decrease in the body weight. The first tier long-term risk assessment resulted in a TER_{lt} value of 3.9 for herbivorous mammals, for the use in cereals, indicating a potential high risk; however, the risk was assessed as low with a subsequent assessment based on the EFSA (2009), which was provided in the Additional Report.

As bifenthrin has a log P_{ow} of 6.6, the risk from secondary poisoning was considered. The risk assessment for earthworm-eating birds and mammals resulted in TER value above the Annex VI trigger for all the outdoor representative uses based on PEC_{soil} plateau of 0.027 mg/kg. The risk to fish-eating birds and mammals was considered to be low based on the BCF value for fish of 1709 and the highest PEC_{sw} value.

Since bifenthrin has a potential for biomagnification i.e. potential for accumulation observed in a metabolism study on rat and estimated biomagnification factor (BAF)>1, a food chain modelling was carried out following a stepwise approach. Firstly, TERs for different trophic level organisms were estimated based on the guidance document (European Commission, 2002c). Since some TERs were below the Annex VI trigger of 5 for top predators (birds and mammals), a subsequent modelling refinement was carried out. In this refinement the biotransformation process was included by taking into account the uptake efficiency and the biotransformation rate constants. Two species were used as representative of the terrestrial food chain: the shrew (family *Soricidae*) and the little Owl (*Athene noctua*). This refined modelling was discussed at the PRAPeR 87 experts' meeting. The experts identified several uncertainties in the model assumptions and parameterization and therefore they concluded that a high risk from biomagnification in the terrestrial food chain could not be excluded on the basis of the available data. Therefore the experts agreed to identify a data gap to further address this risk for the outdoor representative uses.

The risk to birds and mammals from intake of contaminated water from axil water or puddles was considered to be low for cabbage and cereals, respectively.

In conclusion, for the outdoor uses the acute, short-term and long-term risk to birds and the acute and long-term risk to mammals via dietary exposure were assessed as low. The risk to earthworm-eating birds and mammals and to fish-eating birds and mammals was considered low. However, a high risk from biomagnification in the terrestrial food chain could not be excluded for the outdoor uses. Therefore the experts agreed to identify a data gap for the applicant to further address this risk for the outdoor uses.

The risk to birds and mammals for the indoor representative use in ornamentals could be considered as low as no exposure is expected.

5.2. Risk to aquatic organisms

Based on the available acute toxicity data, bifenthrin was proposed to be classified as very toxic to aquatic organisms. LC_{50} for fish and EC_{50} for Daphnids were 0.10 and 0.11 µg a.s./L, respectively. With regard to chronic toxicity, aquatic invertebrates are more sensitive than fish. The NOEC for reproductive effects is 0.95 ng a.s./L for *Daphnia magna*. The first tier risk assessment indicated a high acute and long-term risk to fish, aquatic invertebrates and sediment-dwelling organisms for both cereal and cabbage uses. However, a low risk was identified for algae at FOCUS Step1. The TER

calculations based on PEC_{sw} step 3 did not meet the Annex VI criteria for fish and aquatic invertebrates (cereals and cabbage use) and sediment-dwelling organisms (only cabbage use).

To further address the risk, TER calculations were provided based on the FOCUS PEC_{sw} step 4 (20-25 m no-spray buffer zones and run-off reduction). Refined toxicity endpoints were also considered for the risk assessment to fish and aquatic invertebrates. In particular, for the refinement of the acute endpoint for fish, a species sensitivity distribution analysis (SSD) was carried out on the basis of 6 new acute toxicity studies. A median HC_5 of 0.072 µg a.s./L was derived which was used in the risk assessment along with an assessment factor of 10. For the refinement of the chronic risk the NOEC of 0.04 µg a.s./L from a full life cycle was considered more appropriate since it covers both embryonic and larval stage effects.

The higher tier acute risk assessment for fish resulted in a TER_a>10 based on initial FOCUS PEC_{sw} Step 4 with 20 m no-spray buffer zone and of run-off reduction in cereals and cabbage, in all scenarios.

The higher tier chronic risk assessment for fish resulted in a TER_{lt} above the Annex VI trigger of 10 based on initial FOCUS PEC_{sw} Step 4 with 20-25 m no-spray buffer zones and run-off reduction in cereals and cabbage, in all scenarios, except D5-stream for the cereals use.

Two higher tier studies, one pond study from a cotton field in Alabama and one mesocosm study performed in Austria, were available to refine the assessment for invertebrates. Since no recovery was observed in the pond study, a NOEC could not be derived but was stated to be lower than the measured concentration in the study: 6-18 ng a.s/L in the water column and 52-60 µg a.s./kg in the sediment. From the mesocosm study the RMS concluded that a NOEAEC of 0.015 µg a.s./L could be derived and should be used in the risk assessment. This value was considered to cover the most sensitive species (gammarids, copepods and chaoboridae). In response to the NOEAEC suggested by the RMS, a position paper was provided by the applicant. In this position paper an NOEAEC of 0.037 µg a.s./L was proposed, based on arguments that direct effects on zooplankton were recovered within 42 days (i.e.class 2 effects). Recovery longer that 42 days (up to 70 days after last application) was only required for species affected by indirect effects. The NOEC for *Gammarus fossarum*, exposed to bifenthrin in single-species toxicity tests was a factor of 3.9 higher (less toxic) than the proposed NOEAEC of 0.037 µg a.s./L. The HC_5 value derived from single-species toxicity data for arthropods was 0.017 µg/L and supported the NOEAEC derived from the mesocosm study. The RMS clarified their selection of NOEAEC= 0.015 µg a.s /L (Addendum 2 of June 2008). The pertinent points of the RMS were that some of the effects (i.e. on *Keratella quadrata*, on open water invertebrate community, on community emerging insects) at 0.037 µg a.s./L may require 84 days after the treatment to recover. The recovery time should be considered in the same time window as direct effects to decide for acceptable effects. The endpoint from the laboratory study with *Gammarus fossarum* was considered to be not valid due to exposure uncertainties. The HC_5 value was not considered to take into account indirect effects and could not be directly compared to a NOEAEC from the mesocosm study. For these reasons the RMS considered that the use of NOEAEC= 0.015 µg a.s./L, was the most appropriate regulatory endpoint. The Member State experts at the PRAPeR 53 discussed the endpoint. It was unclear to the experts if the HC_5 of 0.017 µg/L presented in the review by Blake (2007) was the minimum ($HC_5^{0.05}$) or the mean value. In case it was a $HC_5^{0.05}$ value, the experts considered it to be a protective endpoint for the class 2 effects from the mesocosm. The experts considered that further details should be required to explain the NOEAEC of 0.015 µg a.s./L in addition to further information on the derivation of the HC_5 value. EFSA noted that no further information was provided after the meeting of experts. During the written commenting one Member State commented that such information was important and may influence the endpoint determined from the mesocosm study and the assessment factor used. On the basis of the available information, it was concluded that the NOEAEC of = 0.015 µg a.s./L should be used with an assessment factor of 3, as proposed by RMS. The assessment factor of 3 should cover variation in potential for recovery depending on the nature of the ecosystem. The higher tier risk assessment resulted in a TER_{lt}>3 based on the NOEAEC from the

mesocosm and initial FOCUS PEC_{sw} Step 4 with 20 m no-spray buffer zone and run-off reduction in cereals and cabbage, in all scenarios.

For the use in cabbage, the higher tier risk assessment for sediment-dwelling organisms resulted in a TER_a>10 based on initial FOCUS PEC_{sw} Step 4 with 20 m no-spray buffer zone and run-off reduction, in all scenarios. Although the potential accumulation in sediment was not taken into account in this risk assessment, the TER calculations were well above the trigger to cover this issue. One major metabolite, 4'-OH bifenthrin, was detected in sediment. The toxic effects of this metabolite are considered to be covered by the mesocosm study. However, the risk assessment for aquatic organisms was provided and a low risk was indicated with FOCUS step 1 & 2.

Since no TERs have been provided for the outdoor use in ornamentals it was not possible to finalise the risk and a data gap was identified.

A low risk has been indicated for the indoor use in ornamentals based on PECsw of 0.003 µg a.s./L estimated with the "Dutch approach".

Due to the $logP_{ow}$ of 6.6 for bifenthrin the potential to bioconcentrate was considered to be high. Available laboratory studies gave BCFs in the range of 1030 to 30000. All values represent overall radioactivity and include metabolites and breakdown products of bifenthrin. The bio-concentration of bifenthrin is not fully described by the available data. The plateau was not reached in two of the four studies and accumulated residues were not characterised. Although studies in the presence of sediment showed that rapid partitioning to sediment decreased the bioavailability of bifenthrin from the water phase, bioaccumulation via the food chain may occur. This is also indicated by high bifenthrin residues in fish from the pond study. The experts agreed to propose a new open point to the RMS to submit a transparent evaluation of bioaccumulation studies. The RMS submitted this new assessment of the BCF studies in the evaluation table rev. 2 (04.08.2008). The outcome of this assessment did not change that proposed in the DAR. The RMS considered that "despite that several studies were available the question of the bioaccumulation of the bifenthrin is not solved. Indeed the phenomenon seems to depend on the species, the life stage and the exposure. It would be useful to have more information". EFSA agreed that the potential for bifenthrin to accumulate in aquatic organisms needed to be further addressed, so a data gap was identified. The RMS informed the experts that a new bioaccumulation study was submitted by the applicant and assessed by the RMS though in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies as laid down in Commission Regulation (EC) No. 1095/2007 the results of this study could not be considered in the first peer review.

The appropriateness of the originally submitted bioaccumulation studies on fish has been re-evaluated in the Additional Report. Out of 4 studies, only 2 have been considered reliable. In particular the 2 studies giving higher BCF values have been considered weak and flawed regarding the setting of BCF values. Therefore, during the PRAPeR 87 experts' meeting a BCF value of 1709 was recommended as the more ecologically relevant one.

To fulfil the data gap identified during the PRAPeR 53 meeting for further risk assessment from bioaccumulation through the food chain, a biomagnification modelling has been carried out and provided in the Additional Report. In this refinement, the biotransformation process was included by taking into account the uptake efficiency for different trophic level organisms and the biotransformation rate constants. This modelling has been discussed at the PRAPeR 87 experts' meeting. Firstly, the experts expressed concern regarding the BCF values used in the modelling and further clarification on this was requested. It was noted that choosing the 'correct' BCF is not possible as it depends on many variable factors. It was highlighted that, preferably, BCF normalised with respect to the lipid content of the organisms should be used for biomagnification modelling purposes. Secondly, it was noted that the PEC values used in the bioaccumulation risk assessment are highly refined, i.e. FOCUS step 4 including 20-25 m buffer zones. The use of PNEC values was considered more appropriate. Finally, uncertainties were highlighted regarding some assumptions and

parameterisation like the choice of feeding preferences and the derivation of rate constants. In conclusion, the experts agreed that a high risk from bioaccumulation through the food chain for aquatic organisms could not be excluded on the basis of the available data. Therefore, a data gap was identified to further address the risk from biomagnification in the aquatic food chain and to address the uncertainties raised during the PRAPeR 87 experts' meeting.

Since aquatic organisms were expected to be exposed to the TFP acid metabolite, to fulfil the data gap identified during the previous peer review, acute toxicity studies on fish, invertebrates, and algae with the TFP acid were provided. The risk was assessed as low with FOCUS step1.

5.3. Risk to bees

Bifenthrin was highly toxic to bees. The LD_{50} from oral and contact tests with 'Talstar 8 SC' were 0.01 and 0.0016 µg a.s./bee, respectively. Hazard quotients were calculated to be in the range of 2000 to 12500 for cereals. A total of 11 different studies using different formulations of bifenthrin under more realistic conditions were available to refine the risk assessment. It was assumed that the high toxicity of bifenthrin itself drives the toxicity of the formulation and all formulations were considered to be "comparable". The tests were run in attractive crops like alfalfa or *Phacelia tanecetifolia*. None of these studies included more than one application, although some were carried out at a dose rate 10 g a.s./ha. From the studies it could be concluded that bifenthrin may exert some residual toxicity lasting from 1 to 5 days even at the lowest application rate.

The experts at the PRAPeR 53 meeting concluded that a high risk to bees could not be excluded for bifenthrin and appropriate mitigation measures should be applied (SPe safety phrase).

The issue was further considered at the PRAPeR 87 meeting. It was recommended that when setting risk mitigation measures, Member States should consider an appropriate interval between last application and flowering to avoid effects from residual toxicity. Furthermore, it was concluded that no new data (in particular a new bee brood test) are necessary, Indeed, with the application of appropriate mitigation measures, no treatments during flowering should be performed, and since the substance is not systemic, there will be no exposure of the larvae from contaminated pollen or nectar brought back to the hive. In addition, the effects on the brood are covered by the available tunnel and field studies. Since the recommendation of the experts' meeting is to implement risk mitigation measures to avoid exposure of the adults, there should not be any exposure of the larvae.

5.4. Risk to other arthropod species

The insecticidal activity of bifenthrin was confirmed in laboratory studies where 100% mortality was observed for *Aphidius rhopalosiphi, Typhlodromus pyri* and *Chrysoperla carnea,* and 90% mortality for *Poecilius cupreus* at 60 g a.s./ha. Also 7.5 g a.s./ha caused 100% mortality of *A. rhopalosiphi* in a glass plate test. Dose response tests conducted as extended laboratory tests on natural substrate are available with *A. rhopalosiphi, T. pyri, C. carnea* and *Coccinella septempunctata* from which LR_{50} values could be derived. The LR_{50} for *A. rhopalosiphi, T. pyri* were 8.145 and 0.113 g a.s./ha, respectively. The LR_{50} for *A. rhopalosiphi* and *T. pyri* were used to calculate hazard quotients (HQ) for in-field and off-field rates at different distances from the treated field. Off-field HQ values for the more sensitive *T. pyri* were 0.43 with 5 m in-field no-spray buffer zone in cereals.

The LR_{50} derived for *C. septempunctata* was even lower than the one for *T. pyri* (0.084 g a.s./ha compared to 0.113 g a.s./ha). The experts at the meeting agreed with the use of the LR_{50} = 0.084 g a.s./ha as the endpoint for the *C. septempunctata* .

Two aged residue studies, one with *A. rhopalosiphi* and one with *C. septempunctata,* demonstrated severe residual toxicity of the bifenthrin based on the lethal effects of insects exposed to the in-field rate with a complete reduction of residual toxicity observed after 42 day for both species. A complete reduction of lethal effects was observed after 14 days for the parasitoid and 21 days for the ladybird.

Three field studies, two in orchards and one in cereal were available in the DAR. The two studies in orchards were performed at rates ranging from 20 to 50 g a.s./ha, and the cereals field studies with low application rates of 7.5 and 5 g a.s./ha. The results from all the field studies indicated impact on some populations and did not allow determination of time needed for recovery.

It was concluded from the available information that there was a high risk to non-target arthropods within the treated area from the use in cereals. Risk mitigation measures are required to protect non-target arthropods in the off-field areas. An in-field no-spray buffer zone of 5 m, is required for cereals. No risk assessment has been provided for the other outdoor representative uses (i.e. cabbage and ornamentals); however it could be considered as covered by the risk assessment on cereals.

Following the data gap identified at the PRAPeR 53 for the applicant to refine the in-field risk to non-target arthropods, no new data have been provided in the Additional Report, except a study on *Poecilus cupreus*. However, the applicant advised that new aged-residue studies and a state of the art field study are available to address the issue of residual toxicity and the potential for recovery and recolonisation. Since these studies could not be taken into consideration within the resubmission peer review for procedural reasons, a data gap is identified

5.5. Risk to earthworms

The acute toxicity of bifenthrin and the formulation 'Talstar 8 SC' to earthworms was low. The NOEC for reproductive effects was determined as 2.13 mg a.s./kg soil, corrected to 1.065 mg a.s./kg soil because log P_{ow}>2. TER values were calculated using the soil maximum PEC_{soil} plateau of 27 µg /kg soil and were above the Annex VI triggers indicating a low acute and chronic risk of bifenthrin to earthworms. The metabolite of bifenthrin, TFP acid was identified as a major soil metabolite. There were no ecotox data available for this metabolite; however the RMS proposed to use a general approach considering that the toxicity of the metabolite was 10 times higher than bifenthrin. This approach was agreed by the experts. The TER_a values estimated based on the initial PEC_{soil} values were above the Annex VI trigger value. The experts in the PRAPeR 53 meeting agreed that a chronic risk assessment was not necessary for the metabolite, due to its low persistence. EFSA noted after the meeting that there could be long-term exposure even though the soil half-life is short as the degradation rate of the precursor bifenthrin is very slow. Therefore, the reasoning was not scientifically correct and a data gap for the applicant to address the chronic risk to earthworms for this metabolite was identified.

The chronic toxicity of the metabolites TFP acid and 4'-OH bifenthrin was investigated in reproduction toxicity studies. The resulting endpoints were NOEC=17.8 mg/kg and NOEC 178 mg/kg for TFP acid and 4'-OH bifenthrin, respectively. It is noted that 4'-OH bifenthrin was not a major metabolite in soil. The risk was assessed as low.

5.6. Risk to other soil non-target macro-organisms

A litterbag study was submitted by the applicant during the evaluation period of the RMS and prior to the submission of the DAR to EFSA but its assessment was erroneously omitted from the DAR. A summary and an assessment of this study were presented by the RMS in Addendum 2 (France, 2008), and was considered by the PRAPeR 53 meeting of experts. This study shows no effects of bifenthrin on the litter decomposition. However, the experts at the PRAPeR 53 meeting agreed that the litter bag study did not cover the risk for the macro-organisms in the case of pyrethroid compounds. However, since the long-term risk for earthworms was indicated as low, no further data are needed.

5.7. Risk to soil non-target micro-organisms

The formulation 'Talstar 8 SC' had no effects >25% after 28 days on soil respiration or nitrogen turnover following treatment corresponding to 100 g a.s./ha. The tested concentration is above the plateau concentration and the risk to soil micro-organisms is therefore considered to be low.

5.8. Risk to other non-target organisms (flora and fauna)

Though a study of the effects of bifenthrin on non-target plants was submitted and assessed by the RMS in addendum 2 Vol 3 (B.9), it was not possible to consider this assessment in the first peer review in view of the restrictions on the acceptance of new studies under Commission Regulation (EC) No1490/2002 as amended by Commission Regulation (EC) No 1095/2007. Consequently a data gap was identified for the submission of a risk assessment to non-target plants.

Data were provided in the Additional Report. On the basis of these data, the risk to non-target terrestrial plants was indicated as low.

5.9. Risk to biological methods of sewage treatment

No inhibitory effect of bifenthrin to respiration rates of activated sludge was observed up to suspended concentrations of >1900 mg/L. It is unlikely that bifenthrin should reach sewage treatment facilities via waste water channels. The risk to biological methods of sewage treatments plants is considered to be low.

6. Residue definitions

6.1. Soil

Definitions for risk assessment: sum of isomers of bifenthrin and sum of isomers of TFP acid

Definitions for monitoring: sum of isomers of bifenthrin

6.2. Water

Ground water

Definitions for exposure assessment: sum of isomers of bifenthrin, sum of isomers of TFP acid and sum of isomers of 4'-OH bifenthrin

Definitions for monitoring: sum of isomers of bifenthrin

Surface water

Definitions for risk assessment:

water: sum of isomers of bifenthrin and sum of isomers of TFP acid
Sediment: sum of isomers of bifenthrin and sum of isomers 4'-OH bifenthrin

Definitions for monitoring: sum of isomers of bifenthrin.

6.3. Air

Definitions for risk assessment: sum of isomers of bifenthrin

Definitions for monitoring: sum of isomers of bifenthrin

6.4. Food of plant origin

Definitions for risk assessment: bifenthrin (sum of isomers)

Definitions for monitoring: bifenthrin (sum of isomers)

6.5. Food of animal origin

Definitions for risk assessment:
- Ruminant liver and kidney: sum of bifenthrin (sum of isomers) and BP-acid, expressed as bifenthrin (conversion factor of 2 for monitoring to risk assessment);
- Eggs, poultry liver: sum of bifenthrin (sum of isomers) and hydroxyl-methyl bifenthrin and its fatty acid conjugates, expressed

	as bifenthrin (conversion factor of 2 for monitoring to risk assessment); - Milk and other animal products: bifenthrin (sum of isomers).
Definitions for monitoring:	bifenthrin (sum of isomers)

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

7.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Sum of isomers of bifenthrin	Moderate to high persistence[a] Laboratory studies: single first order DT_{50} 54 - 174 days (20°C, -10kPa soil moisture) Field studies: single first order DT_{50} 67-199 days, biphasic (DFOP, FOMC) DT_{90} 222-965 days (non-normalised values)	The LC_{50corr} > 8 mg a.s./kg soil. The risk was identified as low.
Sum of isomers of TFP acid	Low to moderate persistence Single first order DT_{50} 3.2 – 25.3 days (20°C, -10kPa soil moisture)[b]	The risk was identified as low

(a): classification based on the laboratory data

(b): In a single soil incubation, the best-fit degradation kinetics was found to be hockey-stick, however the SFO fit was found to be acceptable. The non-normalized HS DT_{50} in this soil was 2.3 days and the DT_{90} 16 days, while the SFO DT_{50} was 3.3 days (DT_{90} 11 days). These indicated low persistence in this soil.

7.2. 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
Sum of isomers of bifenthrin	Immobile K_{oc} 130526-301611 mL/g	No	Yes	Yes	Yes

Sum of isomers of TFP acid	Very high to medium K_{foc} 14 - 415 mL/g	No	No information available	No data available assessment not triggered.	Assessed as low
Sum of isomers of 4'-OH bifenthrin	Data gap but expected to be immobile[a]	No[b]	No data available assessment not triggered	No data available assessment not triggered	Assessed as low

(a): QSAR estimations, results from an HPLC experiment, moreover similarity in the chemical structure to the parent indicated that this metabolite might be classified as immobile
(b): A data gap was identified for determination of the mobility, FOCUS modelling used the lowest K_{oc} value of the parent as agreed in PRAPeR 52

7.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
Sum of isomers of bifenthrin	A potential high risk was identified for all the aquatic organisms in the first tier assessment. The risk was indicated low with higher tier toxicity endpoints and FOCUS step 4 PECsw, providing the use of 20-25 m no-spray buffer zones and 80% run-off reduction
Sum of isomers of TFP acid (water only)	A low risk was identified for aquatic organisms.
Sum of isomers of 4'-OH bifenthrin (sediment only)	A low risk was identified for aquatic organisms.

7.4. Air

Compound (name and/or code)	**Toxicology**
Sum of isomers of bifenthrin	Toxic by inhalation (R23 proposed, based on LC_{50} 1.01 mg/L)

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

- A 2 years shelf-life study for the NPE-free formulation (relevant for all representative uses evaluated, data gap identified by the RMS confirmed by the PRAPeR 51 meeting (June 2008), date of submission unknown; refer to chapter 1).
- 4 additional residue trials on head cabbage (Northern Europe) (relevant for head cabbage use, data gap identified by EFSA; submission date proposed by the applicant: unknown; refer to chapter 3.1.1).
- A new hydrolysis study representative of the sterilisation conditions is required to address the nature of the residues in processed commodities (relevant for head cabbage use, data gap identified by EFSA; submission date proposed by the applicant: unknown; refer to chapter 3.1.1).
- Soil adsorption measurements following recommendations contained in SCP opinion SCP/KOC/002-Final (adopted on 18 July 2002) in at least three different soils for the soil metabolite 4'-OH bifenthrin (relevant for all representative uses evaluated; submission date proposed by the applicant: according to the applicant a study is ongoing; refer to chapter 4.1.3).
- PECsw/sed calculations for outdoor use in ornamentals and the subsequent risk assessment for the aquatic organisms (relevant for use in ornamentals; submission date proposed by the applicant: unknown; refer to sections 4 and 5).
- Bifenthrin and its metabolites TFP acid and 4'-OH bifenthrin consist of 2 isomers. This needs to be taken into account in the environmental risk assessment. Information on the degradation of the 2 isomers in soil is needed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; refer to section 4).
- The risk of bioaccumulation through the terrestrial food chain needs to be addressed further (relevant for all the outdoor representative uses evaluated; submission date proposed by the applicant: unknown; data gap was identified during the PRAPeR 87 meeting; refer to chapter 5.1).
- The risk of bioaccumulation through the aquatic food chain needs to be addressed further (relevant for all the representative uses evaluated; submission date proposed by the applicant: unknown; data gap was identified during the PRAPeR 87 meeting; refer to chapter 5.2).
- Data to further address the residual toxicity of bifenthrin on non-target arthropods and to address the potential for recolonisation should be provided (relevant for all outdoor representative uses evaluated; submission date proposed by the applicant: aged residue and field study are available but were not submitted in the Additional Report; refer to chapter 5.4).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as insecticide as proposed by the applicant, which comprise foliar spraying to control sucking and biting insects and aphids in cereals, ornamentals and head cabbage.

The representative formulated product for the evaluation is ‘Talstar 8 SC’, a suspension concentrate (SC) containing 80 g/l bifenthrin, registered under different trade names in Europe.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection products are possible.

Adequate methods are available to monitor bifenthrin residues in food/feed of plant and animal origin, in the environmental matrices and in body fluids and tissues.

As for mammalian toxicity, bifenthrin is "Toxic if swallowed" (R25), it is toxic by inhalation (R23 "Toxic by inhalation" proposed). Bifenthrin is a skin sensitiser (R43 "May cause skin sensitisation by skin contact" proposed). It is not a skin or eye irritant.

The main effect observed for repeated exposures is tremor and/or neurotoxic effects. The relevant short-term toxicity NOAEL is 2.5 mg/kg bw/day in dogs whereas for long-term exposures the NOAELs is 4.7 mg/kg bw/day in rats. Bifenthrin did not show any genotoxic potential. Due to the occurrence of bladder leiomyosarcomas/hemangiopericytomas in mice, as their relevance to humans could not be excluded and since the historical control data were not conclusive, R40 (Carc. Cat. 3) was proposed. In multigeneration studies the relevant maternal NOAEL is 3.0 mg/kg/day and the reproductive NOAEL is 5 mg/kg bw/day, based on the occurrence of tremors and marginally lower body weight in the P and F1 generation females during gestation and lactation. Bifenthrin did not show any teratogenic potential (maternal NOAEL>7.4 mg/kg bw/day and developmental NOAEL >2 mg/kg bw/day). Bifenthrin did not show developmental neurotoxicity potential. The ADI is 0.015 mg/kg bw/day based on the 1-year dog study with a SF of 100, supported by the developmental study in rats. The ARfD is 0.03 mg/kg bw based on the 90-day neurotoxicity study with a SF of 100. The AOEL is 0.0075 mg/kg bw/day (SF 100 and correction factor of 50% for limited oral absorption). The operator, worker and bystander exposure showed levels below the AOEL.

In the metabolism studies on apples (fruit crops), cotton seed (pulses and oilseeds) and maize plants (cereals) bifenthrin was found to be the predominant compound of the total residues. No significant cis-trans isomerisation and translocation of residues through the plant were observed. The proposed global residue definition for monitoring and risk assessment in plant commodities is bifenthrin (sum of isomers). Complete residue database were provided to support the representative uses on cereals (wheat, triticale, rye, barley and oat) for both Northern and Southern Europe and to propose MRLs while 4 additional residue trials are required on head cabbage (Northern Europe). The nature of the residues in processed commodities was sufficiently addressed for pasteurisation and baking, brewing and boiling but not for sterilisation. A data gap was identified to require a new hydrolysis study simulating the conditions of sterilisation to determine the nature of the residues in processed commodities. Based on the metabolism studies in ruminants and poultry, the proposed residue definition for monitoring for animal commodities is bifenthrin (sum of isomers). For risk assessment, the residue definition proposals are as follows:

-ruminant liver and kidney: sum of bifenthrin (sum of isomers) and BP-acid, expressed as bifenthrin (conversion factor of 2 for monitoring to risk assessment);

-eggs, poultry liver: sum of bifenthrin (sum of isomers) and hydroxyl-methyl bifenthrin and its fatty acid conjugates, expressed as bifenthrin (conversion factor of 2 for monitoring to risk assessment);

-for milk and all other animal products: bifenthrin (sum of isomers).

The storage time interval of the samples from the residue trials on cereals and head cabbage and of the animal tissues from the feeding studies can be considered as covered by the available storage stability data. Under normal agricultural practices, bifenthrin residue levels in the edible parts of the rotational crops intended for human consumption and as feed items are expected to be below 0.01 and 0.05 mg/kg, respectively.

No chronic and acute intake concerns were identified according to the EFSA PRIMo rev.2A model. The consumer risk assessment should be regarded as provisional pending the submission of the

additional residue trials on head cabbage. The potential for a different degradation of bifenthrin enantiomers in plant and animal commodities was considered as sufficiently addressed since the S/R enantiomeric ratio of the parent bifenthrin was shown to remain unchanged (S/R ratio: 1/1) both in cereals and head cabbage samples from the residue trials and in fat samples from the rat.

Based on the available residue datasets an MRL of 0.05 mg/kg is proposed for wheat, triticale and rye grain and an MRL of 0.1 mg/kg is set for barley and oat grain. A provisional MRL of 0.3 mg/kg is proposed for head cabbage. MRLs were also defined for animal matrices.

The peer reviewed information available on the fate and behaviour in the environment is essentially sufficient to carry out an appropriate environmental exposure assessment at the EU level, however more information is necessary regarding the behaviour of the enantiomers of bifenthrin and its metabolites in the environment. A satisfactory bath adsorption/desorption study for the soil metabolite 4'-OH bifenthrin is still missing. Once these data are available, the groundwater exposure assessments might need to be updated. Satisfactory exposure assessments for surface water and sediment are not available for the representative use on ornamentals (outdoor use).

For the representative use on cereals, the potential for groundwater exposure by bifenthrin and its soil metabolites TFP acid and 4'-OH bifenthrin above the parametric drinking water limit of 0.1 µg/L is low.

Low acute, short-term and long-term risks were indicated with the first tier risk assessment for birds and a low acute risk was indicated for mammals for the outdoor representative uses. A potential high long-term risk to mammals was identified with the first tier for outdoor representative uses; however, the risk was assessed as low with a subsequent assessment based on the Guidance Document on Birds and Mammals (EFSA, 2009). The risk of bifenthrin to earthworm-eating birds and mammals was assessed as low for the outdoor representative uses, based on PEC_{soil} plateau of 0.027 mg/kg. The risk to fish-eating birds and mammals was considered to be low based on the BCF value for fish of 1709.

Since bifenthrin has a potential for biomagnification i.e. potential for accumulation observed in a metabolism study on rat and estimated biomagnification factor (BAF)>1, a food chain modelling has been carried out. However, the experts at the PRAPeR 87 experts' meeting identified several uncertainties in the model assumptions and parameterization and therefore they concluded that a high risk from biomagnification in the terrestrial food chain cannot be excluded. Therefore the experts agreed to identify a data gap for the applicant to further address this risk.

The risk to birds and mammals for the indoor representative use in ornamentals is low since no exposure is expected.

The first tier risk assessment indicated a potential high acute and long-term risk to fish and aquatic invertebrates. The estimated TER values, based on the FOCUS PECsw step 4 (20-25 m no-spray buffer zones and run-off reduction) and higher tier toxicity end points, were above the Annex VI trigger values indicating a low risk. To fulfil the data gap identified during the PRAPeR 53 to further address the risk from bioaccumulation through the food chain, a biomagnification modelling has been carried out and provided in the Additional Report. This modelling has been discussed at the PRAPeR 87. The experts agreed that a high risk from bioaccumulation through the food chain for aquatic organisms could not be excluded on the basis of the available data. Therefore, a data gap was identified to further address the risk from biomagnification in the aquatic food chain and to address the uncertainties raised.

The experts concluded that a high risk was identified for bifenthrin to bees for all the outdoor representative uses. Risk mitigation measures should be applied to avoid the exposure of bees.

It could be concluded from the available information that there is a high risk to non-target arthropods for in-field and off-field areas within the treated area from the outdoor representative uses. Risk mitigation measures are required to reduce the exposure of non-target arthropods in the off-field areas.

A data gap was identified for the applicant to provide further data to address the residual toxicity of bifenthrin to non-target arthropods and the potential for recovery/recolonisation.

The acute and long-term risk of bifenthrin and TFP acid to earthworms was assessed as low.

The risk to soil macro-organisms, micro-organisms, non-target plants and biological methods of sewage treatment was assessed as low for all the applied for representative uses evaluated.

Persistent organic pollutant screening criteria (Stockholm Convention)

At the request of the Member States, EFSA has made a comparison of the agreed endpoints from the available reliable studies for bifenthrin against the persistent organic pollutant (POP) screening criteria as set out in Annex D of the Stockholm Convention RS 0.814.03.

Persistence:

Half-life in water is greater than 2 months (EFSA interprets as 60.8 days) or

Half-life in soil or sediment is greater than 6 months (EFSA interprets as 182.5 days)

Due to low water solubility and high partitioning potential to sediment it can be concluded that the half-life in water of bifenthrin is less than 2 months, with the possible exception of water environments where significant amounts of suspended solids are present.

If half-life is interpreted to mean a single first order pattern of decline for the extractable bifenthrin residue (i.e. the shape of a radioactive decay curve, which was the original use of this term and is the definition given to half-life by the FOCUS kinetics working group) then at field soil dissipation trial sites, 3 of the 8 experiments available have half-lives longer than 6 months (in 5 of the 8 experiments the pattern of decline was not single first order, but a half life can be estimated by dividing the estimated DT_{90} by 3.32).

If half-life is interpreted to simply mean the time taken for half the initial bifenthrin concentration to be present in extracted samples, then only 1 of these 8 experiments has a half-life longer than 6 months.

The half-life (single first order decline) estimated in 20°C laboratory sediment water studies (2 systems studied) where bifenthrin was located primarily in the sediment was less than 6 months in a system where the sediment organic carbon content was 0.7 % but was longer than 6 months in the system where sediment organic carbon content was 4.8 %.

In conclusion, the available evidence indicates that depending on environmental conditions, the half-life of bifenthrin in soil and sediment (either when more strictly defined as a single first order DT_{50}, or just defined as any kind of DT_{50}) can be greater than 6 months.

Bioaccumulation potential:

Evidence that the bioconcentration factor or bioaccumulation factor in aquatic species is greater than 5000. Based on a re-evaluation of the available bioaccumulation studies on fish, the more reliable and relevant BCF is 1709.

Relevant studies are available on 3 different fish species. Bioconcentration factors (BCF) were greater than 5000 in two of these three species (*Pimephales promelas* and *Lepomi Macrochirus* where a plateau was not reached*) (*BCF was <5000 in *Cyprinus carpio).* On the basis of the re-evaluation provided in the additional report, the studies on *Pimephales promelas* and *Lepomi Macrochirus* were considered not reliable because weak and flawed.

Monitoring data in biota indicating a bioaccumulation potential: No data included in the applicant's dossier.

Potential for long-range environmental transport:

Measured levels in locations distant from the sources of release that are of potential concern: No data included in the applicant's dossier.

Monitoring data showing long-range environmental transport: No data included in the applicant's dossier.

Environmental fate properties and/or modelling results that demonstrate that the chemical has the potential for long-range environmental transport through air, water or migratory species, with potential for transfer to a receiving environment in locations distant from the sources of release. For a chemical that migrates significantly through the air, its half-life in air should be greater than 2 days: No data included in the applicant's dossier regarding water or migratory species. The QSAR estimated atmospheric half-life for bifenthrin is below 2 days when assuming an atmospheric OH radical concentration of $1.5x10^6$radicals/cm^3.

Adverse effects:

Evidence of adverse effects to human health or to the environment that justifies consideration of this chemical within the scope of this convention, or toxicity or ecotoxicity data that indicate potential for damage to human health or the environment.

As an efficacious insecticide, ecotoxicity data in the dossier confirm there is potential for damage to the environment. Risks to aquatic organisms and non target arthropods need to be mitigated with classification proposed as "Very toxic to aquatic organisms, may cause long-term effects in the aquatic environment" (R50/53). With regard to mammals, bifenthrin is "Toxic if swallowed" (R25), it is toxic by inhalation (R23 "Toxic by inhalation" proposed) and is a skin sensitiser (R43 "May cause skin sensitisation by skin contact" proposed). The main effects observed for repeated exposures are tremor and/or neurotoxic effects.

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- According to operator exposure estimates no PPE is needed according to the German Model (cereals, head cabbage and ornamental outdoors). PPE (gloves during mixing and loading and application) is needed according to the UK POEM Model (cereals, head cabbage and ornamental outdoors). PPE (gloves and coverall) is needed according to the Dutch Model (ornamental indoors).

- PPE (coverall) is needed for workers re-entering treated areas after application to ornamentals.

- No-spray buffer zones of 20-25 m and run-off reduction are required to protect aquatic organisms for the uses in cereals and cabbage.

- The experts at the PRAPeR 53 meeting concluded that a high risk was identified for bifenthrin to bees for outdoor uses and that it is necessary to manage the risk to bees by using appropriate mitigation measures. In the PRAPeR 87 meeting it was pointed out that when setting risk mitigation measures, Member States should consider an appropriate interval between the last application and flowering to avoid effects from residual toxicity.

- No-spray buffer zone of 5 m is required to protect non-target arthropods in the off- field treated areas for the use in cereals, cabbage and ornamentals.

ISSUES THAT COULD NOT BE FINALISED

- Exposure and risk assessment for the aquatic organisms for the outdoor use of bifenthrin in ornamentals could not be finalized. It is likely that higher PECsw values than the ones calculated for the cereal use would be expected for ornamentals higher than 50 cm.

- A high risk from bioaccumulation through the terrestrial food chain could not be excluded for all the outdoor uses.

CRITICAL AREAS OF CONCERN

- A high risk from bioaccumulation through the aquatic food chain could not be excluded for all the representative uses.

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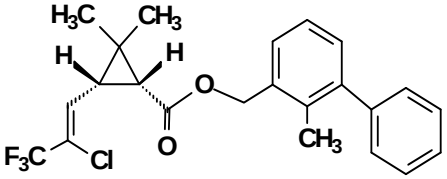
APPENDICES

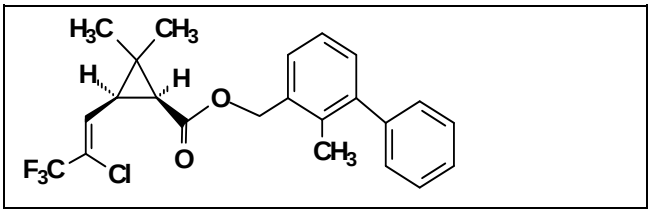
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

Active substance (ISO Common Name) ‡	Bifenthrin
Function (*e.g.* fungicide)	Insecticide
Rapporteur Member State	France
Co-rapporteur Member State	

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	2-methylbiphenyl-3-ylmethyl (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate or 2-methylbiphenyl-3-ylmethyl (1*RS*)-*cis*-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate
Chemical name (CA) ‡	(2-methyl[1,1′-biphenyl]-3-yl)methyl (1*R*,3*R*)-*rel*-3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate
CIPAC No ‡	415
CAS No ‡	82657-04-3
EC No (EINECS or ELINCS) ‡	-
FAO Specification (including year of publication) ‡	Evaluation report published, the publication of the specification is waiting the publication of the AOAC method for the a.s. determination
Minimum purity of the active substance as manufactured ‡	930 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	toluene, max. 5 g/kg
Molecular formula ‡	$C_{23}H_{22}ClF_3O_2$
Molecular mass ‡	422.88 g/mol
Structural formula ‡	



Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	79.6°C (98.6%)
Boiling point (state purity) ‡	Ebullition of decomposed product: 291.3°C (98.6%)
Temperature of decomposition (state purity)	280°C (98.6%)
Appearance (state purity) ‡	fine white solid (98.8%) waxy beige solid (94.93%)
Vapour pressure (state temperature, state purity) ‡	1.78 x 10^{-5} Pa at 20°C (98.8%)
Henry's law constant ‡	7.739 x 10^{-5} Pa x m^3/mol
Solubility in water (state temperature, state purity and pH) ‡	< 0.001 mg/l at 20°C, pH 5(97.8%) < 0.001 mg/l at 20°C, pH 7(97.8%) 0.00376 mg/l at 20°C, pH 9 (97.8%)
Solubility in organic solvents ‡ (state temperature, state purity)	methanol = 48.0 g/l at 20°C xylene= 556.3 g/l at 20°C acetone = 735.7 g/l at 20°C heptane = 144.5 g/l at 20°C ethyl acetate = 579.8 g/l at 20°C 1,2-dichloroethane = 743.2 g/l at 20°C
Surface tension ‡ (state concentration and temperature, state purity)	No data provided due to non solubility in water
Partition co-efficient ‡ (state temperature, pH and purity)	Log $P_{O/W}$ = 6.6 (comparative HPLC method)
Dissociation constant (state purity) ‡	No dissociation
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	λ_{max}= 250 nm; ε = 3282.9 $l.mol^{-1}.cm^{-1}$ in neutral, acidic and basic solution at λ ≥ 290 nm: The tail of the peak at 250 nm results in significant absorption in the range 290 to ca. 300nm.
Flammability ‡ (state purity)	No highly flammable, Flash point higher than 110°C (94.93%)
Explosive properties ‡ (state purity)	No explosive properties (94.93%)
Oxidising properties ‡ (state purity)	No oxidizing properties (94.93%)

Summary of representative uses evaluated (Bifenthrin)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	GS & 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		
Wheat, barley, oats, triticale & rye	EU N & S	Talstar 8 SC	F	Sucking and biting insects Virus vectors (aphids)	SC	80 g/L	Spraying	Acc. to official warnings	1-2	14 days	0.0025-0.0066	150-400	0.008-0.010	35 d	[2][3]
Ornamentals	EU S	Talstar 8 SC	F & G	Sucking and biting insects Virus vectors (aphids)	SC	80 g/L	Spraying		1	-	0.002	500	0.010	-	[1] [2] [3]
Head cabbage	EU N	Talstar 8 SC	F	Sucking and biting insects Virus vectors (aphids)	SC	80 g/L	Spraying	BBCH 43-49	2	7-14 days	0.00152-0.0038	200-500	0.0076	7d	[2] [3]

[1] Exposure and risk assessment for the aquatic organisms for outdoor use of bifenthrin in ornamentals could not be finalized
[2] A high risk from the bioaccumulation through the terrestrial food chain could not be excluded for all the outdoor uses
[3] A high risk from the bioaccumulation through the aquatic food chain could not be excluded for all the representative uses

a. for crops, the EU and Codex Classifications (both) should be used; where relevant, the use situation should be described
b. outdoor or field use (F), glasshouse application (G) or indoor application (I)
c. *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
d. *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (G)
e. IFAP codes – GIFAP technical monograph no. 2, 1989
f. all abreviations used must be explained
g. method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
h. kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants – type of equipment used must be indicated
i. g/kg or g/l
j. growth stage at last treatment (BBCH Monograph, growth stages plants, 1997, Blackwell, ISBN 3-8263-3152-4, including relevant, information on season at time of application
k. the minimum and maximum number of application possible under pratical conditions of used must be provided
l. PHI – minimum pre-harvest interval
m. remarks may include: extend of use/economic importance/restrictions

Methods of Analysis

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

Technical as (analytical technique)	HPLC-UV, GC-FID
Impurities in technical as (analytical technique)	HPLC-UV, HPLC-MS and GPC
Plant protection product (analytical technique)	HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Bifenthrin (sum of isomers)
Food of animal origin		Bifenthrin (sum of isomers)
Soil		Bifenthrin (sum of isomers)
Water	surface	Bifenthrin (sum of isomers)
	drinking/ground	Bifenthrin (sum of isomers)
Air		Bifenthrin (sum of isomers)
Body fluids and tissues		Bifenthrin (sum of isomers)

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	*Bifenthrin* GC-ECD and GC-MSD LOQ: 0.01 mg/kg for oil seed rape, cereals and apple. ILV: seed rape, apple and winter wheat. high water content commodities: DFG S19 LOQ: 0.03mg/kg
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	*Bifenthrin* GC-ECD and GC-MSD (3 ions) LOQ: 0.05 mg/kg for muscle LOQ: 0.01 mg/kg for egg, fat, liver, kidney and milk ILV submitted for muscle, egg, fat, liver, kidney and milk.
Soil (analytical technique and LOQ)	*Bifenthrin* GC-ECD and GC-MSD LOQ: 0.005 mg/kg for soil and sediment Chiral GC-MSD LOQ: 0.01 mg/kg for both enantiomers
Water (analytical technique and LOQ)	*Bifenthrin* GC-MSD (3 ions) LOQ = 1 ng/L for surface water
Air (analytical technique and LOQ)	*Bifenthrin* GC-MSD (3 ions) LOQ = 0.5 µg/m^3 for air.
Body fluids and tissues (analytical technique and LOQ)	*Bifenthrin* GC-ECD and GC-MSD (3 ions) LOQ: 0.01 mg/L in blood

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

	RMS/peer review proposal
Active substance	none

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	50% absorption via oral route in rat in 4-6 hours
Distribution ‡	Fat and skin mainly (3% of the dose remains in tissues)
Potential for accumulation ‡	Potential for accumulation in fat, terminal half-life of up to 51 days.
Rate and extent of excretion ‡	Elimination complete within 48 hours urine (13-25%) and faeces (63-88%), 3% remained in tissues and organs
Metabolism in animals ‡	Via hydrolysis, oxidation and conjugation. No preferential enantiomeric absorption, biotransformation or elimination of bifenthrin S-and R-enantiomers
Toxicologically relevant compounds ‡ (animals and plants)	No main metabolites, all less than 10% Bifenthrin
Toxicologically relevant compounds ‡ (environment)	Bifenthrin

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	LD_{50}: 54.5 mg/kg (diluted in corn oil) 186.1 mg/kg (undiluted)	R25
Rat LD_{50} dermal ‡	>2000 mg/kg	-
Rat LC_{50} inhalation ‡	1.01 mg/l/4h (CI:066-1.1)	R23
Skin irritation ‡	Non irritant	-
Eye irritation ‡	Non irritant	-
Skin sensitisation ‡	Sensitiser (M&K) Not sensitising (Buehler)	R43

Short-term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Neurotoxic effect: tremors; reduction in tail latency; staggered gait and exaggerated hindlimb flexion	
Relevant oral NOAEL ‡	NOAEL: 2.5 mg/kg/day (90-day dog) NOAEL: 1.5 mg/kg/day (1-year dog)	
Relevant dermal NOAEL ‡	NOAEL: 50 mg/kg/day (rat) NOAEL: 100 mg/kg/day (rabbits)	
Relevant inhalation NOAEL ‡	-	

Genotoxicity ‡ (Annex IIA, point 5.4)

Negative	

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

Target/critical effect ‡	Nervous system: Tremors	
Relevant NOAEL ‡	• 2-yr rat: NOAEL: 4.7 mg/kg bw/d for males and 3 mg/kg bw/d for females • 18-m mice: NOAEL: males: 7.6 mg/kg bw/d & females:37 mg/kg bw/d	
Carcinogenicity ‡	Bladder tumors in male mice (statistically significant at 92 mg/kg bw/d)	Carc. Cat 3, R40

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Tremor and marginally lower body weight in the P and F_1 generation females during gestation and lactation	
Relevant parental NOAEL ‡	3.0 mg/kg bw/d	
Relevant reproductive NOAEL ‡	5 mg/kg bw/d	
Relevant offspring NOAEL ‡	5 mg/kg bw/d	

Developmental toxicity

Developmental target / critical effect ‡	No teratogenic effect observed	
Relevant maternal NOAEL ‡	> 7.4 mg/kg bw/d	
Relevant developmental NOAEL ‡	> 2 mg/kg bw/d	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	NOAEL: 35 mg/kg bw/d	
Repeated neurotoxicity ‡	NOAEL: 2.9 mg/kg bw/d males; 3.7 mg/kg bw/d females	
Delayed neurotoxicity ‡	LD50 oral: > 5000 mg/kg No clinical signs of neurotoxicity at 5000 mg/kg followed by a repeat dose after 21 days using the tilting-plane test - rat : no delayed neurological effects at 30 mg/kg	

Other toxicological studies (Annex IIA, point 5.8)

Acute toxicity and peak effect range finding acute neurotoxicity study onBifenthrin ismomeres	LD_{50} of Z,R,R-Bifenthrin: 20 mg/kg for males and 14 mg/kg for females LD_{50} of cis-Z,S,S-Bifenthrin: > 5000 mg/kg for males and females.
Studies performed on metabolites or impurities ‡	see Annex C
Acute Intraperitoneal Toxicity in Rats	LD_{50} = 798.5 (516.1 – 1080.8) mg/kg

Developmental neurotoxicity in rats	Tremors/convulsions. Maternal neurotoxicity NOAEL : 3.6 mg/kg bw/d during gestation, 8.3 mg/kg bw/d during lactation Offspring neurotoxicity: at same dietary levels, during gestation.

Medical data ‡ (Annex IIA, point 5.9)

FMC Corporation Emergency calls (2002) : 58 calls involving formulations containing bifenthrin 31 on Skin irritation/pain including burning/tingling 7 on Eye irritation/pain and/or redness 4 on Nasal irritation/stuffy nose Medical surveillance in manufacturing plant : No unexplained/significant changes from the baseline noted for employees working in the synthetic pyrethroids business unit for 14 years

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.015 mg/kg bw/d	1-year dog (supported by development studies)	100
AOEL ‡	0.0075 mg/kg bw/d	1-year dog	100 absorption 50 %
ARfD ‡	0.03 mg/kg bw	90-day neurotoxicity rat	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (e.g. name 50 % EC)	Talstar 8 SC *In vitro*, human/ rat: 3% concentrate; 35% diluted

Exposure scenarios (Annex IIIA, point 7.2)

Operator	German model – Field crops (Cereals as worst-case compared to cabbage)– 30% of AOEL without PPE – Ornamentals (outdoor)– 39.3% of AOEL without PPE UK POEM – – Field crops (Cereals as worst-case compared to cabbage) – 253.7 % of AOEL without PPE, 36% with gloves for mix/load and application Ornamentals (outdoor) – 303.2% of AOEL without PPE, 84.7 % with gloves for mix/load and application Dutch model – Ornamentals (greenhouse): 135% of

	AOEL without PPE, 13.5% with gloves and coverall (default PPE)
Workers	Crop inspection in field crops (Cereals as worst-case compared to cabbage): 11.7 % of AOEL without PPE. Cut, sort, bundle or carry on (ornamentals (indoor and outdoor): - No PPE: 263.1% of AOEL - Coverall: 27.9 % of AOEL
Bystanders	Field crops (ornamentals-outdoors as worst-case compared to cereals and head cabbage): 1.7% of AOEL No bystander exposure is foreseen in ornamentals-greenhouse.

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

	Peer review proposal
Substance classified (Bifenthrin)	- Based on Directive 67/548/EEC criteria: T, R40 (Carc cat3), R23, R25, R43 - Based on CLP criteria: Carc.2 – H351, Acute Tox. 3 – H331, Acute Tox. 3 – H301, Skin Sens. 1 – H317

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

Plant groups covered	-Maize (cereals) – Foliar and soil treatments -Cotton (pulses and oilseeds) – Foliar and soil treatments -Apple (fruit crops) – Foliar treatment
Rotational crops	Lettuce, sugar beet, wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	-Bifenthrin is stable under pasteurisation and baking/ brewing/boiling. -The nature of the residues in sterilised commodities is not sufficiently addressed. Data gap: a new hydrolysis study simulating the conditions of sterilisation is required.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	-Pasteurisation/baking, brewing and boiling: Yes. -Sterilisation: pending the outcome of the new data required.
Plant residue definition for monitoring	Bifenthrin (sum of isomers)
Plant residue definition for risk assessment	Bifenthrin (sum of isomers)
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	Ruminants and poultry
Time needed to reach a plateau concentration in milk and eggs	4days in milk, 7/8 days in egg yolk
Animal residue definition for monitoring	Bifenthrin (sum of isomers)
Animal residue definition for risk assessment	-Ruminant liver and kidney: sum of bifenthrin (sum of isomers) and BP-acid, expressed as bifenthrin. -Eggs, poultry liver: sum bifenthrin (sum of isomers) and hydroxyl-methyl bifenthrin and its fatty acid conjugates, expressed as bifenthrin; -Milk and all other animal products: bifenthrin (sum of isomers).
Conversion factor (monitoring to risk assessment)	2 for eggs and poultry liver, ruminant liver and kidney
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)

Under normal agricultural practices, bifenthrin residue levels in the edible parts of the rotational crops intended for human consumption and as feed items are expected to be below 0.01 and 0.05 mg/kg, respectively.

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

Bifenthrin parent is stable under frozen conditions (-18°C):
- 49 months in apples, maize silage and maize stover,
- 34 months in maize grain,
- 24 months in cotton seed,
- 6 months in potato tuber and processed parts,
- 15 months in dry peas,
- 36 months in lettuce, pecan,
- 36 months in cow fat, cow muscle, cow liver, cow milk,
- 36 months in poultry eggs.

BP acid is stable under frozen conditions (-18°C):
- at least 24 months in cow muscle, liver and fat

Fatty acids conjugates of hydroxy methyl bifenthrin:

-Stable during the storage time period of the egg yolk samples analysed for this metabolite in the feeding study (36-38 days) (-20°C).

The storage time interval of the samples of the residue trials and of tissues of the feeding studies are covered by the available storage stability data.

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[1] 0.99 (beef) 0.75 (dairy)	Yes[1] 0.10	Yes[1] 0.27
Potential for accumulation (yes/no):	Not excluded[2]	Not excluded[2]	N/A
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Yes	Yes (in egg yolk only)	N/A
	Cattle feeding studies (feeding rates: 5, 15 and 50 mg/kg nominal diet/day) Poultry feeding studies (feeding rates: 0.0025, 0.025 and 0.25 mg/kg DM diet/day) Residue levels in matrices : Mean (max) mg/kg		
Muscle	0.07[3]	<LOQ[4]	N/A
Liver	0.02[3]	<LOQ[4]	
Kidney	0.1[3]	<LOQ[4]	
Fat	1.82[3]	<LOQ[4]	
Milk	0.12[3]		
Eggs		<LOQ[4]	

[1]: The dietary intake will be revised according to the outcome of the requested additional residue trials on head cabbage.
[2]: Not excluded considering the fat solubility of bifenthrin, the highest residue levels recovered in fat and the potential for accumulation in fat of the rat.

(3): Highest residue levels of bifenthrin recovered in animal tissues and milk at the feeding dose level of 5 mg/kg DM diet/day (7N and 5N for dairy and beef cattle, respectively).
(4): Residue levels of bifenthrin in poultry matrices and eggs at the feeding dose level of 0.25 mg/kg DM diet/day (2.5N) – LOQ (eggs): 0.01 mg/kg; LOQ (muscle): 0.02 mg/kg; LOQ (fat, liver): 0.05 mg/kg.
N/A: Not applicable.

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Wheat	North of EU	Grain: 14x<0.01 mg/kg Straw: 0.1-0.13-0.14-0.17-0.17-0.2-0.2-0.2-0.24-0.24-0.35-0.51-0.55-0.7 mg/kg		0.05 mg/kg	0.01	0.01
	South of EU	Grain: 9x<0.01-0.02 mg/kg Straw: 0.11-0.11-0.15-0.17-0.17-0.27-0.28-0.3-0.32-0.43 mg/kg			0.02	0.01
Barley	North of EU	Grain: 4x<0.01-0.012-0.015-0.02-0.02-0.02-0.023-0.03-0.03-0.03-0.04 mg/kg Straw: 0.08-0.08-0.1-0.1-0.11-0.17-0.17-0.19-0.19-0.19-0.21-0.24-0.3-0.33 mg/kg		0.1 mg/kg	0.04	0.02
	South of EU	Grain: 3x0.01-5x0.02-0.04-0.07 mg/kg Straw:0.09-0.11-0.21-0.23-0.23-0.26-0.27-0.35-0.43-0.47 mg/kg			0.07	0.02
Triticale	North of EU	Grain: <0.01-<0.01 mg/kg Straw: 0.069-0.145 mg/kg	Extrapolation from wheat residue database.	0.05 mg/kg	-	-
	South of EU	No data				
Rye	North/South of EU	No data	Extrapolation from wheat residue database.	0.05 mg/kg	-	-
Oat	North of EU	Grain: <0.01-<0.01 mg/kg	Extrapolation from barley residue	0.1 mg/kg	-	-

		Straw: 0.059-0.074 mg/kg	database.			
	South of EU	No data				
Head cabbage	North of EU	<0.01-<0.01-0.03-0.23 mg/kg	4 additional residue trials are required to complete the database.	0.3 mg/kg (provisional)	0.23	-

(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	0.015 mg bw/kg/d
TMDI (% ADI) according EFSA PRIMo rev.2A model	7.1% (NL child)(1)
ARfD	0.03 mg/kg bw
IESTI (% ARfD) according EFSA PRIMo rev.2A model	40.4 % (head cabbage, children) (1) 24.3% (head cabbage, adult) (1)

(1): The consumer risk assessment has to be regarded as provisional pending the outcome of the required 4 additional residue trials on head cabbage and the outcome of the hydrolysis study simulating sterilisation.

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	
Cereals	Not required			
Head cabbage	Not required – This conclusion should be revised pending the outcome of the requested additional residue trials, the hydrolysis study simulating sterilisation and also the amendment of the consumer risk assessment.			

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

Plant commodities	
Barley and oat grain	0.1 mg/kg
Wheat, triticale and rye grain	0.05mg/kg
Head cabbage	0.3 mg/kg (provisional)
Commodities of animal origin ([1])	
Ruminant fat	0.5 mg/kg fat
Ruminant meat	0.05* mg/kg
Ruminant kidney	0.02 mg/kg
Ruminant liver	0.01*mg/kg
Milk and whole cream cow's milk	0.02 mg/kg
Poultry meat	0.05*mg/kg
Poultry liver	0.01*mg/kg
Poultry fat	0.01*mg/kg
Egg	0.01* mg/kg

(1): Pending the outcome of the requested additional residue trials on head cabbage, the livestock dietary burden will have to be recalculated and the MRLs for animal matrices potentially revised.
*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 ‡	Metabolism study in 1 soil (25°C): 39 % after 90 d, [^{14}C-cyclopropyl]-label (n[13]= 1) 49.7 % after 126 d, [^{14}C-cyclopropyl]-label (n= 1) 30 % after 90 d, [^{14}C-phenyl]-label (n= 1) 36.2 % after 126 d, [^{14}C-phenyl]-label (n= 1) Metabolism study in 3 soils (25°C): 13.4-36.9 % after 120 d, [^{14}C-cyclopropyl]-label (n= 3) 15.6-28.8 % after 120 d, [^{14}C-phenyl]-label (n= 3)
Non-extractable residues after 100 days ‡	Metabolism study in 1 soil (25°C): 13.8 % after 90 d, [^{14}C-cyclopropyl]-label (n= 1) 14.1 % after 126 d, [^{14}C-cyclopropyl]-label (n= 1) 18.4 % after 90 d, [^{14}C-phenyl]-label (n= 1) 18.6 % after 126 d, [^{14}C-phenyl]-label (n= 1) Metabolism study in 3 soils (25°C): 21.6-23.9 % after 120 d, [^{14}C-cyclopropyl]-label (n= 3) 13.9-24.9 % after 120 d, [^{14}C-phenyl]-label (n= 3)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	*Lab studies*: TFP acid: 3.7% AR at 180 days 4'-OH bifenthrin : max 8.2% AR at 120 d *Field studies*: TFP acid: major metabolite (max 11.6% AR at 120 d) 4'-OH bifenthrin: non-transient minor metabolite (max 8.3% AR at 103 d)

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

Anaerobic degradation :

Mineralization after 100 days	3.7 % after 120 d, [^{14}C-cyclopropyl]-label (n= 1) 4.6 % after 120 d, [^{14}C-phenyl]-label (n= 1) Note: these figures include all the volatile radioactivity
Non-extractable residues after 100 days	2.1 % after 120 d, [^{14}C-cyclopropyl]-label (n= 1) 3.1 % after 120 d, [^{14}C-phenyl]-label (n= 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	-

Soil photolysis ‡	Location : Princeton, New Jersey (40°N) Light intensity : natural sunlight Period : July - August 75.5% AR remains as Bifenthrin [^{14}C-phenyl]-label after 30 days 80.4% AR remains as Bifenthrin [^{14}C- cyclopropyl]-label after 30 days

[13] n corresponds to the number of soils.

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	None.

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

Laboratory studies ‡

Bifenthrin	Aerobic conditions						
Soil type		pH*	t. °C / % moisture content	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (χ^2)	Method of calculation
Silt loam		6.5	25°C / 63 % FC	76.3/253.4	119.7	3.1	Non linear SFO
Silty clay loam		7.5	25°C / 65% FC	94.6/314.4	102.0	8.1	Non linear SFO
Sandy loam		7.0	25°C / 65% FC	84.5/280.8	83.1	11.1	Non linear SFO
Silt loam		7.1	25°C / 65% FC	173.8/577.2	173.7	5.6	Non linear SFO
Loamy sand		6.0	22°C / 40% MWHC	129.5/430.3	119.3	10.9	Non linear SFO
Sandy loam		6.2	22°C / 40% MWHC	67.1/223.0	54.2	9.7	Non linear SFO
Geometric mean			-	-	102.2	-	Non linear SFO

* Methods of measurement were not specified

Note: the normalization was done with a Q10 of 2.58

4'-OH bifenthrin	Aerobic conditions							
Soil type		pH	t. °C / % moisture content	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (χ^2)	Method of calculation
Silt loam		6.5*	25°C / 63% FC	9.1/30.3	0.43	14.3	9.1	Non linear SFO
Clay		6.9 (H_2O)	20°C / 45% MWHC	11.3/37.5	-**	10.8	8.2	Non linear SFO
Loamy sand		5.0 (H_2O)	20°C / 45% MWHC	22.2/73.8	-**	22.2	7.4	Non linear SFO
Geometric mean			-			15.1		

* Method of measurement not specified

** Study conducted on 4'-OH bifenthrin

Note: the normalization was done with a Q10 of 2.58

TFP acid	Aerobic conditions							
Soil type		pH	t. °C / % moisture content	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (χ^2)	Method of calculation
Silt loam		6.5*	25 / 63% FC	16.1/53.3	0.05	25.3	11.4	Non linear SFO

TFP acid	Aerobic conditions							
Soil type		pH	t. °C / % moisture content	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (χ^2)	Method of calculation
Loamy sand		5.0 (H_2O)	20 / 45% MWHC	10.2/34.0	-**	12.2	9.7	Non linear SFO
Silt loam		6.4 (H_2O)	20 / 45% MWHC	6.6/21.8	-**	6.6	9.4	Non linear SFO
Clay/clay loam		7.6 (H_2O)	20 / 45% MWHC	2.3/16.0 3.3/11.0	-**	- 3.2	2.6 15.0	HS *** Non linear SFO***
Geometric mean			-			9.0		

* Method of measurement not specified
** Study conducted on TFP acid
*** HS is the best-fit kinetic, but SFO is retained for modelling.
Note: the normalization was done with a Q10 of 2.58

Field studies - actual values

Bifenthrin	Aerobic conditions							
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).		pH**	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	Method of calculation
Loamy sand (bare)	GA (USA)		4.5	30.5	16.6	962.7*	14.8	DFOP k_1=0.0794 d^{-1} k_2=0.0012 d^{-1} g=0.6274
Loam (bare)	IL (USA)		6.3	30.5	39.3	442.2	19.2	DFOP k_1=0.0466 d-1 k_2=0.0035 d-1 g=0.5214
Silt loam (bare)	AR (USA)		6.4	30.5	128.4	426.5*	19.2	Non linear SFO
Silty clay loam (cropped)	CA (USA)		7.2	30.5	56.5	965.1*	9.3	DFOP k_1=0.6973 d^{-1} k_2=0.0018 d^{-1} g=0.4474
Silt loam (cropped)	Netherlands		7.3	20	14.6	221.7	5.4	DFOP k_1=0.0218 d^{-1} k_2=0.0218 d^{-1} g=0.5856
Silt loam (cropped)	Netherlands		6.9	20	66.5	221.0	9.1	Non linear SFO
Silt loam (bare)	Germany		7.2 (H_2O)	15	198.7	660*	19.9	Non linear SFO
Loam (bare)	Italy		8.8 (H_2O)	30	48.3	482.0	18.4	FOMC α=0.9199 β=42.9557
Geometric mean					-	-	-	

* Exceeds study duration

** Method of measurement not specified

Field studies - normalised values

Bifenthrin	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).		pH***	Depth (cm)	DT_{50} (d) Norm**	DT_{90}(d) Norm**	St. (χ^2)	DT_{50} (d) Model.	Method of calculation
Loamy sand (bare)	GA (USA)		4.5	30.5	13.9	496.11	14.8	266.6*	DFOP k_1=0.1055 day^{-1}, k_2=0.0026 day^{-1}, g=0.6320
Silt loam (bare)	AR (USA)		6.4	30.5	79.7	264.8	15.7	79.7	Non linear SFO
Loam (bare)	IL (USA)		6.3	30.5	71.9	238.8	16.2	71.9	Non linear SFO
Silty clay loam (cropped)	CA (USA)		7.2	30.5	102.5	340.4	21.3	102.5	Non linear SFO
Silt loam (cropped)	Netherlands		7.3	20	10.9	135.3	7.7	62.4*	DFOP k_1=0.1557 day^{-1}, k_2=0.0111 day^{-1}, g=0.5493
Silt loam (cropped)	Netherlands		6.9	20	46.0	152.9	8.6	46.0	Non linear SFO
Silt loam (bare)	Germany		7.2 (H_2O)	15	89.6	297.5	21.4	89.6	Non linear SFO
Loam (bare)	Italy		8.8 (H_2O)	30	79.9	265.4	17.1	79.9	Non linear SFO
Geometric mean					-	-	-	86.8**	

* calculated from the slow phase of the DFOP kinetics

** DT_{50} values from field studies conducted in USA were normalised with a Q10 of 2.2. DT_{50} values from field studies conducted in Europe were normalised with a Q10 of 2.58. This is not best practice. The same Q10 (ideally 2.58) should have been used to normalise all the trials, before calculating this geomean.

*** Method of measurement not specified (except for the last two soils)

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	No accumulation study. For the worst-case use on cereals a plateau concentration of 0.027 mg/kg (5 cm) after 5 years is calculated.

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type		pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Loamy sand		5.8 (H_2O)	20°C / flooded	> 1000	-	-	Non linear SFO
Geometric mean/median			-	-	-	-	-

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Bifenthrin ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Silty clay loam	1.34	7.5	3688	275 224	-	-	-
Silt loam	1.80	7.1	5429	301 611	-	-	-
Sandy loam	1.74	7.0	4160	239 080	-	-	-
Fine sand	0.76	6.2	992	130 526	-	-	-
Arithmetic mean				236 610	-	-	-
pH dependence, Yes or No			No				

4'OH bifenthrin: Data gap for experimental data; however, the worst case Koc for parent was agreed as appropriate for use in the EU level exposure assessment for the representative use assessed at the EU level.

TFP acid :							
Soil Type	OC %	Soil pH ($CaCl_2$)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam	28.7	3.1	-	-	108	376	0.979
Loamy clay	4.8	7.3	-	-	0.647	13.5	0.955
Sand	1.1	4.0	-	-	4.57	415	0.948
Sandy silt loam	3.3	5.1	-	-	6.64	201	0.948
Sandy loam	2.3	7.2	-	-	0.319	13.9	0.814
Arithmetic mean/median					Not relevant	Not relevant	Not relevant
pH dependence (yes or no)			Yes				

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

Column leaching ‡	Elution during 2 d, 3 soils
	Leachate: 2-3 % of applied concentration in leachate
Thin layer chromatography	Rf = 0.03-0.30, 4 soils
Aged residues leaching ‡	Aged for (d): 120 and 180 d Elution : 250 ml
	Analysis of soil residues post ageing (soil residues pre-leaching): 43.9 % (120 days), 33 % (180 days) active substance
	Leachate: 4.2 % (120 days), 2.6 % (180 days) of Bifenthrin in leachate
Lysimeter/ field leaching studies ‡	No study submitted, not required.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent	DT_{50} (d): 199 days
Method of calculation	Kinetics: non-linear SFO Field or Lab: worst case from field studies.
Application data	The worst-case is the use on cereals: Crop: cereals Depth of soil layer: 5 cm. Soil bulk density: 1.5 g/cm^3 % plant interception: 25 Number of applications: 2 Interval (d): 14 Application rate(s): 10 g as/ha

$PEC_{(s)}$ (µg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual (without accumulation over a number of years)	Multiple application Time weighted average (without accumulation over a number of years)
Initial	-		19.5	
Short term 24h	-	-	19.5	19.5
2d	-	-	19.4	19.5
4d	-	-	19.3	19.4
Long term 7d	-	-	19.1	19.3
28d	-	-	17.7	18.6
50d	-	-	16.4	17.9
100d	-	-	13.8	16.5
Plateau concentration	27 µg/kg after 5 years (calculated in 5 cm)			

4'-OH bifenthrin	Molecular weight relative to the parent: 438.9/422.9
Method of calculation	
Application data	Application rate: 20 g/ha (the 2 applications are gathered in one) Max. occurrence in soil: 8.3 %
PECmax (t=0)	1.7 µg/kg

TFP-acid	Molecular weight relative to the parent: 242.5/422.9
Method of calculation	
Application data	Application rate: 20 g/ha (the 2 applications are gathered in one)

	Max. occurrence in soil: 11.6%
PECmax (t=0)	1.3 µg/kg

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 4: 20 mn at 100 °C : 51 % hydrolysed
	pH 5: 22 days at 25 °C : no hydrolysis pH 5: 1 h at 100 °C : 69 % hydrolysed
	pH 7: 22 days at 25 °C : no hydrolysis
	pH 9: 22 days at 25 °C : no hydrolysis
Photolytic degradation of active substance and metabolites above 10 % ‡	Continuous irradiation (Xenon lamp, >290 nm) during 262 hours (equivalent to 32 days of natural sunlight at Boulder, Colorado, 40°N in summer) DT_{50} : 15.3 days (cyclopropyl label) -18.4 days (phenyl label) Bifenthrin alcohol: 19 % AR (7 d)
Quantum yield of direct phototransformation in water at Σ > 290 nm	0.0107
Readily biodegradable ‡ (yes/no)	No

Degradation in water / sediment

Bifenthrin	Distribution (eg max in water 27.3-81.5 % after 0 d. Max. sed 87.5 - 95.3 % (14 days))									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50} whole sys.	St. (χ^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Silt loam , cyclopropyl label	7.7	7.9	-	323.5	3.3	-	-	-	-	Non linear SFO
Silt loam , phenyl label	7.7	7.9	-	239.5	2.4	-	-	-	-	Non linear SFO
Sand, cyclopropyl label	7.8	7.1	-	102.7	2.6	-	-	-	-	Non linear SFO
Sand, phenyl label	7.8	7.1	-	84.6	2.2	-	-	-	-	Non linear SFO
Geometric mean				161.1		-		-		

4'-OH bifenthrin	Distribution (eg max in water 1.9-5.4% after 0 d. Max. sed 4.4-11.1 % after 99 d) DT_{50} not provided									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
Silt loam	7.7	7.9	-	-	-	-	-	-	-	-
Sand	7.8	7.1	-	-	-	-	-	-	-	-
Geometric mean/median			-	-		-		-		-

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Silt loam	7.7	7.9	3.5-6.9 % after 99d	6.2-10% after 99 days	-
Sand	7.8	7.1	12.1-27.3% after 99d	9.6-14.2% after 99 days	-

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

Bifenthrin – indoor applications Method of calculation	The initial concentration in surface water is calculated considering a deposition rate of 0.1% (based on the Dutch model) in a static water body of 30 cm depth.
Application rate	Crop: ornamentals, indoor application Number of applications: 1 Application rate(s): 10 g as/ha
Maximum PECsw (µg/L)	0.003

Bifenthrin – outdoor applications Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 1.1 Molecular weight (g/mol): 422.9 Water solubility (mg/L): 0.0025[14] K_{OC} (L/kg): 236610 DT_{50} soil (d): 102.9[15] days (geomean, lab SFO, 20°C, pF2) DT_{50} water/sediment system (d): 161.1 DT_{50} water (d): 161.1[16] DT_{50} sediment (d): 1000[17] Crop interception (%): minimal crop canopy Application window : March-May for spring cereals and cabbages (early) June-September for cabbages (late) October-February for winter cereals
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: SWASH 2.1 Vapour pressure: 2.4 10^{-5} Pa[18] Water solubility (mg/L): 0.0025[14] Koc: 236610 L/kg 1/n: 1 DT_{50} soil (d): 102.9 days[19] (Geomean from lab.,

[14] This value was used in PECsw calculations but the correct one is <0.001 mg/L. Nevertheless, it is not expected to have a significant impact on the results.
[15] This value was used in PECsw calculations, but the nearly correct one is 87 days (geomean of field data; but for some sites the Q10 used for normalisation was wrong). Nevertheless, it is not expected to have a significant impact on the results.
[16] the default of 1000 d should have been used (as agreed in PRAPeR 52)
[17] The geomean of 161.1 days for total system should have been used (as agreed in PRAPeR 52)
[18] This value was used in PECsw calculations but the correct one is 1.78 10^{-5} Pa. Nevertheless, it is not expected to have a significant impact on the results.

	normalised with a Q10 of 2.58) DT_{50} water (d): 161.1[20] DT_{50} sediment (d): 1000[21]
FOCUS step 4	Version control no.'s : SWAN 1.1.4 Input parameters of step 3 combined with following mitigation measures if required: - 20 m non treated area + run-off mitigation (80% for water load and 90% for sediment load) - 25 m non treated area + run-off mitigation (80% for water load and 90% for sediment load)
Application rate	Crop: spring & winter cereals Number of applications: 2 Interval (d): 14 Application rate(s): 10 g as/ha Application window: 14 days post emergence as the earliest date
	Crop: head cabbage Number of applications: 2 Interval (d): 7 Application rate(s): 7.6 g as/ha Application window: 7 days post emergence as the earliest date

Use: Cereals

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Cereals	0 h	0.2		51.02	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Winter cereals, northern EU	0 h	0.08		18.58	
Winter cereals, southern EU	0 h	0.08		15.10	
Spring cereals, northern EU	0 h	0.08		8.15	
Spring cereals, southern EU	0 h	0.08		15.10	

[19] This value was used in PECsw calculations, but the nearly correct one is 87 days (geomean of field data; but for some sites the Q10 used for normalisation was wrong). Nevertheless, it is not expected to have a significant impact on the results.
[20] the default of 1000 d should have been used (as agreed in PRAPeR 52)
[21] The geomean of 161.1 days for total system should have been used (as agreed in PRAPeR 52)

FOCUS STEP 3 Scenario Winter cereals	Water body	Day after overall maximum	Single application		2 applications	
			PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual	PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual
D1	Ditch	0 h	0.0541	0.3200	0.0513	0.5530
D1	Stream	0 h	0.0473	0.2140	0.0410	0.2370
D2	Ditch	0 h	0.0537	0.2570	0.0469	0.2540
D2	Stream	0 h	0.0419	0.0478	0.0363	0.0414
D3	Ditch	0 h	0.0533	0.2100	0.0467	0.2330
D4	Pond	0 h	0.0019	0.0281	0.0018	0.0465
D4	Stream	0 h	0.0463	0.1420	0.0400	0.1370
D5	Pond	0 h	0.0019	0.0281	0.0018	0.0450
D5	Stream	0 h	0.0499	0.1680	0.0432	0.1650
D6	Ditch	0 h	0.0525	0.1550	0.0459	0.1580
R1	Pond	0 h	0.0019	0.0355	0.0018	0.0635
R1	Stream	0 h	0.0352	0.2810	0.0304	0.5740
R3	Stream	0 h	0.0493	0.1500	0.0431	0.2180
R4	Stream	0 h	0.0349	0.3020	0.0302	0.5880

FOCUS STEP 3 Scenario Spring cereals	Water body	Day after overall maximum	Single application		2 applications	
			PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual	PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual
D1	Ditch	0 h	0.0541	0.2970	0.0500	0.4550
D1	Stream	0 h	0.0473	0.2100	0.0410	0.2250
D3	Ditch	0 h	0.0535	0.2270	0.0469	0.2570
D4	Pond	0 h	0.0019	0.0245	0.0018	0.0379
D4	Stream	0 h	0.0443	0.0794	0.0394	0.1020
D5	Pond	0 h	0.0018	0.0271	0.0019	0.0435
D5	Stream	0 h	0.0419	0.0301	0.0397	0.0523
R4	Stream	0 h	0.0354	0.4280	0.0306	0.8160

FOCUS Step 4 for winter cereals: 20m buffer zone (drift + run-off mitigation)

FOCUS STEP 4 Scenario Winter cereals	Water body	Day after overall maximum	Single application		2 applications	
			PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual	PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual
D1	Ditch	0 h	0.0039	0.0233	0.0037	0.0394
D1	Stream	0 h	0.0047	0.0212	0.0039	0.0223
D2	Ditch	0 h	0.0039	0.0187	0.0033	0.0181
D2	Stream	0 h	0.0042	0.0047	0.0034	0.0039
D3	Ditch	0 h	0.0039	0.0153	0.0033	0.0166

FOCUS STEP 4 Scenario Winter cereals	Water body	Day after overall maximum	Single application		2 applications	
			PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual	PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual
D4	Pond	0 h	0.0008	0.0115	0.0007	0.0182
D4	Stream	0 h	0.0046	0.0141	0.0038	0.0129
D5	Pond	0 h	0.0008	0.0115	0.0007	0.0176
D5	Stream	0 h	0.0049	0.0167	0.0041	0.0156
D6	Ditch	0 h	0.0038	0.0113	0.0033	0.0113
R1	Pond	0 h	0.0008	0.0123	0.0007	0.0199
R1	Stream	0 h	0.0035	0.0287	0.0029	0.0587
R3	Stream	0 h	0.0049	0.0149	0.0041	0.0226
R4	Stream	0 h	0.0035	0.0316	0.0029	0.0614

FOCUS Step 4 for spring cereals: 20m buffer zone (drift + run-off mitigation)

FOCUS STEP 4 Scenario Spring cereals	Water body	Day after overall maximum	Single application		2 applications	
			PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual	PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual
D1	Ditch	0 h	0.0039	0.0216	0.0036	0.0325
D1	Stream	0 h	0.0047	0.0208	0.0039	0.0212
D3	Ditch	0 h	0.0039	0.0165	0.0033	0.0183
D4	Pond	0 h	0.0008	0.0101	0.0007	0.0148
D4	Stream	0 h	0.0044	0.0079	0.0037	0.0097
D5	Pond	0 h	0.0008	0.0111	0.0007	0.0170
D5	Stream	0 h	0.0042	0.0030	0.0037	0.0049
R4	Stream	0 h	0.0035	0.0433	0.0029	0.0827

FOCUS Step 4 for winter cereals: 25m buffer zone (drift + run-off mitigation)

FOCUS STEP 4 Scenario Winter cereals	Water body	Day after overall maximum	Single application		2 applications	
			PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual	PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual
D1	Ditch	0 h	0.0034	0.0200	-	-
D1	Stream	0 h	0.0039	0.0175	-	-
D2	Ditch	0 h	0.0033	0.0160	-	-
D2	Stream	0 h	0.0034	0.0039	-	-
D3	Ditch	0 h	0.0033	0.0131	-	-
D4	Pond	0 h	0.0007	0.0102	-	-
D4	Stream	0 h	0.0038	0.0116	-	-
D5	Pond	0 h	0.0007	0.0102	-	-
D5	Stream	0 h	0.0041	0.0137	-	-
D6	Ditch	0 h	0.0033	0.0097	-	-

FOCUS STEP 4 Scenario Winter cereals	Water body	Day after overall maximum	Single application		2 applications	
			PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual	PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual
R1	Pond	0 h	0.0007	0.0111	-	-
R1	Stream	0 h	0.0029	0.0286	-	-
R3	Stream	0 h	0.0040	0.0124	-	-
R4	Stream	0 h	0.0029	0.0315	-	-

Only PECsw for 1 application were provided since it was the worst-case

FOCUS Step 4 for spring cereals: 25m buffer zone (drift + run-off mitigation)

FOCUS STEP 4 Scenario Spring cereals	Water body	Day after overall maximum	Single application		2 applications	
			PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual	PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual
D1	Ditch	0 h	0.0034	0.0185	-	-
D1	Stream	0 h	0.0039	0.0171	-	-
D3	Ditch	0 h	0.0033	0.0142	-	-
D4	Pond	0 h	0.0007	0.0090	-	-
D4	Stream	0 h	0.0036	0.0065	-	-
D5	Pond	0 h	0.0007	0.0099	-	-
D5	Stream	0 h	0.0034	0.0025	-	-
R4	Stream	0 h	0.0029	0.0433	-	-

Only PECsw for 1 application were provided since it was the worst-case

Maximum accumulated Step 4 PEC_{sed} of bifenthrin following repeated application to spring and winter cereals at 2 x 10 g/ha over 5 years (20 m buffer zone; drift + run-off mitigation)

Scenario	Spring cereals	Winter cereals
D1 ditch	0.0467	0.0528
D1 stream	0.0246	0.0257
D2 ditch	-	0.0225
D2 stream	-	0.0040
D3 ditch	0.0215	0.0191
D4 pond	0.0250	0.0343
D4 stream	0.0102	0.0141
D5 pond	0.0274	0.0309
D5 stream	0.0051	0.0171
D6 ditch	-	0.0122
R1 pond	-	0.0445
R1 stream	-	0.2200
R3 stream	-	0.0782
R4 stream	0.2950	0.2070

Use: Head cabbage

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Cabbages	0 h	0.15		38.77	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Cabbages, northern EU Early	0 h	0.06		6.32	
Cabbages, southern EU Early	0 h	0.06		11.72	
Cabbages, northern EU Late	0 h	0.06		6.32	
Cabbages, southern EU Late	0 h	0.06		9.02	

FOCUS STEP 3 Scenario Cabbages - Early	Water body	Day after overall maximum	Single application		2 applications	
			PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual	PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual
D3	Ditch	0 h	0.0407	0.1670	0.0357	0.2000
D4	Pond	0 h	0.0014	0.0198	0.0015	0.0308
D4	Stream	0 h	0.0324	0.0414	0.0280	0.0358
D6	Ditch	0 h	0.0399	0.1110	0.0350	0.1240
R1	Pond	0 h	0.0014	0.0559	0.0015	0.0952
R1	Stream	0 h	0.0268	1.2840	0.0232	2.2100
R2	Stream	0 h	0.0354	0.8680	0.0306	1.6550
R3	Stream	0 h	0.0376	0.4890	0.0326	0.8580
R4	Stream	0 h	0.0268	0.7870	0.0232	1.3290

FOCUS STEP 3 Scenario Cabbages - Late	Water body	Day after overall maximum	Single application		2 applications	
			PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual	PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual
D3	Ditch	0 h	0.0405	0.1540	0.0355	0.1650
R1	Pond	0 h	0.0014	0.0481	0.0014	0.0770

FOCUS STEP 3 Scenario Cabbages - Late	Water body	Day after overall maximum	Single application		2 applications	
			PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual	PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual
R1	Stream	0 h	0.0269	1.0450	0.0233	1.6460
R2	Stream	0 h	0.0360	2.7380	0.0312	4.9460
R3	Stream	0 h	0.0378	0.1630	0.0328	0.3000
R4	Stream	0 h	0.0266	0.2760	0.0231	0.5280

FOCUS Step 4 for cabbages (Early): 20m buffer zone (drift + run-off mitigation)

FOCUS STEP 4 Scenario Cabbages - Early	Water body	Day after overall maximum	Single application		2 applications	
			PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual	PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual
D3	Ditch	0 h	0.0031	0.0125	0.0025	0.0140
D4	Pond	0 h	0.0006	0.0083	0.0005	0.0113
D4	Stream	0 h	0.0032	0.0041	0.0027	0.0035
D6	Ditch	0 h	0.0030	0.0083	0.0025	0.0087
R1	Pond	0 h	0.0006	0.0088	0.0005	0.0140
R1	Stream	0 h	0.0027	0.1290	0.0023	0.2210
R2	Stream	0 h	0.0035	0.0869	0.0030	0.1660
R3	Stream	0 h	0.0038	0.0493	0.0032	0.0864
R4	Stream	0 h	0.0027	0.0794	0.0023	0.1340

FOCUS Step 4 for cabbages (Late): 20m buffer zone (drift + run-off mitigation)

FOCUS STEP 4 Scenario Cabbages - Late	Water body	Day after overall maximum	Single application		2 applications	
			PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual	PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual
D3	Ditch	0 h	0.0030	0.0116	0.0025	0.0116
R1	Pond	0 h	0.0006	0.0082	0.0005	0.0122
R1	Stream	0 h	0.0027	0.1050	0.0023	0.1650
R2	Stream	0 h	0.0036	0.2740	0.0030	0.4950
R3	Stream	0 h	0.0038	0.0166	0.0032	0.0306
R4	Stream	0 h	0.0027	0.0281	0.0023	0.0539

Metabolite 4'OH bifenthrin Parameters used in FOCUSsw step 1 and 2	Molecular weight: 438.9 Soil or water metabolite: soil and sediment Koc/Kom (L/kg): 130526 (worst-case of bifenthrin) DT_{50} soil (d): 15.9 days[22] (Geomean from lab., normalised with a Q10 of 2.58) DT_{50} water/sediment system (d): 1000 (default value) DT_{50} water (d): 1000 (default value) DT_{50} sediment (d): 1000 (default value) Maximum occurrence observed (% molar basis with respect to the parent) Soil: 8.3 % Water sediment system: 11.1%:
Application rate	Crop: winter and spring cereals Number of applications: 2 Interval (d): 14 Application rate(s): 10 g as/ha Application window: - March-May for spring cereals - October-February for winter cereals
	Crop: cabbages Number of applications: 2 Interval (d): 7 Application rate(s): 7.6 g as/ha Application window : March-May for cabbages (early) June-September for cabbages (late) Crop interception (%): minimal crop canopy
Main routes of entry	Drift

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Cereals	0h	0.02		4.44	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Winter cereals, northern EU	0 h	0.01		1.18	
Winter cereals, southern EU	0 h	0.01		0.97	

[22] This value was used in PECsw calculations but the correct one is 15.1 days. Nevertheless, it is not expected to have a significant impact on the results.

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Spring cereals, northern EU	0 h	0.01		0.55	
Spring cereals, southern EU	0 h	0.01		0.97	

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Cabbages	0h	0.02		3.37	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Cabbages, northern EU Early	0 h	0.01		0.46	
Cabbages, southern EU Early	0 h	0.01		0.82	
Cabbages, northern EU Late	0 h	0.01		0.46	
Cabbages, southern EU Late	0 h	0.01		0.64	

Metabolite TFP-acid Parameters used in FOCUSsw step 1 and 2	Molecular weight: 242.5 Soil or water metabolite: soil and water Koc/Kom (L/kg): 13.6 (worst-case) DT_{50} soil (d): 6.0 days[23] (Geomean from lab., normalised with a Q10 of 2.58) DT_{50} water/sediment system (d): 1000 (default value) DT_{50} water (d): 1000 (default value) DT_{50} sediment (d): 1000 (default value) Maximum occurrence observed (% molar basis with respect to the parent) Soil: 11.6 % Water sediment system: 1.5%:
Application rate	Crop: winter and spring cereals Number of applications: 2 Interval (d): 14 Application rate(s): 10 g as/ha Application window: - March-May for spring cereals - October-February for winter cereals
	Crop: cabbages Number of applications: 2 Interval (d): 7 Application rate(s): 7.6 g as/ha Application window : March-May for cabbages (early) June-September for cabbages (late) Crop interception (%): minimal crop canopy
Main routes of entry	Run-off / drainage

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Cereals	0h	0.44		0.06	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Winter cereals, northern EU	0 h	0.06		0.01	
Winter cereals, southern EU	0 h	0.05		0.01	

[23] This value was used in PECsw calculations but the correct one is 9.0 days. Nevertheless, it is not expected to have a significant impact on the results.

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Spring cereals, northern EU	0 h	0.03		0.00	
Spring cereals, southern EU	0 h	0.05		0.01	

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Cabbages	0h	0.33		0.05	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Cabbages, northern EU Early	0 h	0.02		0.00	
Cabbages, southern EU Early	0 h	0.05		0.01	
Cabbages, northern EU Late	0 h	0.02		0.00	
Cabbages, southern EU Late	0 h	0.03		0.00	

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Modelling using FOCUS models with appropriate FOCUSgw scenarios, according to FOCUS guidance. Models used: FOCUS PELMO 3.3.2 and FOCUS PEARL 3.3.3 Scenarios: all the 9 EU scenarios for winter cereals, the representative 6 EU scenarios for spring cereals, the representative 7 EU scenarios for head cabbage Crops: winter and spring cereals, cabbage
	Bifenthrin: Molecular weight (g/mol): 422.9 Water solubility (mg/L): 1.4 10^{-5} [24] Vapour pressure (Pa): 2.4 10^{-5} [25] Geometric mean parent DT_{50lab} 102.9 d[26] (Geomean from lab., normalised with a Q10 of 2.58) K_{OC}: parent, arithmetic mean 236610, $^1/_n$= 1 Crop uptake: 0
	Metabolite 4'OH bifenthrin Molecular weight (g/mol): 438.9 Water solubility (mg/L): 1.4 10^{-5} (same as Bifenthrin) Vapour pressure (Pa): 0 (worst-case) DT_{50lab}: 15.9 d[27] (Geomean from lab., normalised with a Q10 of 2.58) K_{OC}: 130526 (worst-case from the parent), $^1/_n$= 1 Formation fraction from the parent: 0.5 Crop uptake: 0
	Metabolite TFP acid Molecular weight (g/mol): 242.5 Water solubility (mg/L): 100 (worst-case) Vapour pressure (Pa): 0 (worst-case) DT_{50lab} : 6.0 d[28] (Geomean from lab., normalised with a Q10 of 2.58) K_{OC} : 13.6 (worst-case), $^1/_n$= 0.955 Formation fraction from the parent: 0.5 Crop uptake: 0.5[29]

[24] This value was used in but the correct one is <0.001 mg/L
[25] This value was used but the correct one is 1.78 10^{-5} Pa
[26] This value was used in calculations, but the nearly correct one is 87 days (geomean of field data; but for some sites the Q10 used for normalisation was wrong). Nevertheless, it is not expected to have a significant impact on the results.
[27] This value was used in PECgw calculations but the correct one is 15.1 days. Nevertheless, it is not expected to have a significant impact on the results.
[28] This value was used in PECgw calculations but the correct one is 9.0 days. Nevertheless, it is not expected to have a significant impact on the results.
[29] This value was used in PECgw calculations but the correct one is 0 since no data is available. Nevertheless, it is not expected to have a significant impact on the results in this case.

Application rate	Crop: winter & spring cereals Application rate: 10 g/ha. Crop interception: 25% No. of applications: 2 Time of application (month or season): 14 days after emergence
	Crop: head cabbage Application rate: 7.6 g/ha. Crop interception: 25% No. of applications: 2 Time of application (month or season): 7 days after emergence

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

	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			4'-OH bifenthrin	TFP acid
PELMO – Winter cereals	Chateaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001
	Kremsmunster	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001

	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			4'-OH bifenthrin	TFP acid
PEARL – Winter cereals	Chateaudun	< 0.001	< 0.001	0.001
	Hamburg	< 0.001	< 0.001	0.007
	Jokioinen	< 0.001	< 0.001	0.007
	Kremsmunster	< 0.001	< 0.001	0.002
	Okehampton	< 0.001	< 0.001	0.007
	Piacenza	< 0.001	< 0.001	0.003
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001

	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			4'-OH bifenthrin	TFP acid
PELMO – Spring cereals	Chateaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001
	Kremsmunster	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001

	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			4'-OH bifenthrin	TFP acid
PEARL – Spring cereals	Chateaudun	< 0.001	< 0.001	0.001
	Hamburg	< 0.001	< 0.001	0.007
	Jokioinen	< 0.001	< 0.001	0.007
	Kremsmunster	< 0.001	< 0.001	0.002
	Okehampton	< 0.001	< 0.001	0.006
	Porto	< 0.001	< 0.001	0.001

	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			4'-OH bifenthrin	TFP acid
PELMO – Cabbage	Chateaudun (Early)	< 0.001	< 0.001	< 0.001
	Chateaudun (Late)	< 0.001	< 0.001	< 0.001
	Hamburg (Early)	< 0.001	< 0.001	< 0.001
	Hamburg (Late)	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001
	Kremsmunster (Early)	< 0.001	< 0.001	< 0.001
	Kremsmunster (Late)	< 0.001	< 0.001	< 0.001
	Porto (Early)	< 0.001	< 0.001	< 0.001
	Porto (Late)	< 0.001	< 0.001	< 0.001
	Sevilla (Early)	< 0.001	< 0.001	< 0.001
	Sevilla (Late)	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001

	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			4'-OH bifenthrin	TFP acid
PEARL – Cabbage	Chateaudun (Early)	< 0.001	< 0.001	0.001
	Chateaudun (Late)	< 0.001	< 0.001	0.002
	Hamburg (Early)	< 0.001	< 0.001	0.006
	Hamburg (Late)	< 0.001	< 0.001	0.007
	Jokioinen	< 0.001	< 0.001	0.006
	Kremsmunster (Early)	< 0.001	< 0.001	0.002
	Kremsmunster (Late)	< 0.001	< 0.001	0.003
	Porto (Early)	< 0.001	< 0.001	< 0.001
	Porto (Late)	< 0.001	< 0.001	0.001
	Sevilla (Early)	< 0.001	< 0.001	< 0.001
	Sevilla (Late)	< 0.001	< 0.001	0.001
	Thiva	< 0.001	< 0.001	0.001

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

Direct photolysis in air ‡	No data, not required
Quantum yield of direct phototransformation	0.0107 (determined in aqueous solution)
Photochemical oxidative degradation in air ‡	DT_{50} = 8.7 h derived by the Atkinson model, assuming a OH mean concentration of 1.5 x 10^6/cm^3 and 12 hours of daylight
Volatilisation ‡	Volatilisation from soil surfaces: max. 1.97% AR (40°C, 75% MC, air flow 16.7 m/min for 39h). Increases with soil moisture, soil temperature and air flow. Max. rate 40°C: 1.48 10^{-4} µg/cm^2/h (0.32%/d)
Metabolites	None

PEC (air)

Method of calculation	Concluded by expert judgement based on the vapour pressure of 1.78 10^{-5} Pa, the Henry's Law Constant of 7.74 10^{-5} Pa.m^3/mol and the available studies on volatilisation.

$PEC_{(a)}$

Maximum concentration	negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which a groundwater exposure assessment is triggered.	Soil: Bifenthrin (constituent isomers), isomers of TFP acid Surface Water: Bifenthrin (constituent isomers), isomers of TFP acid Sediment: Bifenthrin (constituent isomers), isomers of 4'-OH Bifenthrin Ground water: Bifenthrin (constituent isomers), isomers of TFP acid, isomers of 4'-OH Bifenthrin Air: Bifenthrin (constituent isomers)

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

Soil (indicate location and type of study)	USA, pond and field study after 10 weekly aerial applications
Surface water (indicate location and type of study)	USA, pond and field study after 10 weekly aerial applications
Ground water (indicate location and type of study)	N/A
Air (indicate location and type of study)	N/A

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

Candidate for R53

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)	End point (mg/kg feed)
Birds ‡				
Bobwhite quail	a.s.	Acute	LD_{50} = 1800 #	
Mallard duck	a.s.	Acute	LD_{50} > 2150	
Bobwhite quail	a.s.	Short-term	LD_{50} = 569 per day	LC_{50} = 4450
Mallard duck	a.s.	Short-term	NOED = 104.5 per day #	NOEC = 312
Mallard duck	a.s.	Long-term	NOED = 12.1 per day	NOEC = 75
Bobwhite quail	a.s.	Long-term	NOED = 6.63 per day #	NOEC = 75
Mammals ‡				
mouse	a.s.	Acute	LD_{50} = 42.5 #	
rat	a.s.	Reproductive	NOAEL = 3 per day #	

: Toxicity values used in TER calculations.

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

Cereals, 2 x 0.01 kg a.s./ha, 14 days interval

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Large herbivorous bird – 3000 g	Acute	0.75	2401	10
	Short-term	0.46	227	10
	Long-term	0.24	27.3	5
Insectivorous bird – 10 g	Acute	0.54	3328	10
	Short-term	0.30	346	10
	Long-term	0.30	22	5
Bird (puddle water)	Acute	0.0000013	1388876087	10
Tier 1 (Mammals)				
Small herbivorous mammal – 25 g	Acute	2.37	18	10
	Long-term	0.77	**3.9**	5
Small herbivore Vole	Long-term	0.16	18.8*	5
Large herbivore Lagomorph	Long-term	0.17	17.6*	5
Small omnivore mouse	Long-term	0.06	50*	5
Insectivorous mammal – 10 g	Acute	0.09	482	10
	Long-term	0.03	93	5
Mammal (puddle water)	Acute	0.0000007	62853073	10

*risk assessment based on EFSA (2009)

Cabbage (i.e Leafy crops), 2 x 0.0076 kg a.s./ha, 7 days interval

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Medium herbivorous bird – 300 g	Acute	0.70	2559	10
	Short-term	0.37	280	10
	Long-term	0.20	34	5
Insectivorous bird – 10 g	Acute	0.41	4379	10
	Short-term	0.23	456	10
	Long-term	0.23	29	5
Bird (axil water)	Acute	3.50	515	10
Tier 1 (Mammals)				
Medium herbivorous mammal – 3000 g	Acute	0.26	164	10
	Long-term	0.07	41	5

Ornamentals (outdoor), 1 x 0.010 kg a.s./ha
Risk assessment for birds and mammals is covered by the assessment for cereal and cabbage use.

Risk from secondary poisoning

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Birds				
Earthworm-eating bird	Long-term	0.26	25.5	5
Fish-eating bird	Long-term	0.07*	95	5
Mammals				
Earthworm-eating mammal	Long-term	0.32	9.4	5
Fish-eating mammal	Long-term	0.044*	151	5

*ETE calculations based on BCF of 1709 and Step 1 PECsw values

Risk from bioaccumulation through the terrestrial food chain
A high risk from bioaccumulation through the terrestrial food chain was not excluded and a data gap for further assessment was identified for outdoor uses

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 (µg/L)
Laboratory tests ‡				
Fish				
S. gairdneri	a.s.	120 hr (flow-through)	LC_{50}	0.10 (nom)
L. macrochirus	a.s.	144 hr (flow-through)	LC_{50}	0.30 (nom)
L. macrochirus	a.s.	96 hr (flow-through)	LC_{50}	0.26 (mm)

Group	Test substance	Time-scale (Test type)	End point	Toxicity (µg/L)
S. gairdneri	a.s.	96 hr (flow-through)	LC_{50}	0.10 (mm)
P. pomelas	a.s.	96 hr (flow-through)	LC_{50}	0.21 (mm)
L. macrochirus	a.s.	96 hr (semi-static)	LC_{50}	0.269 (mm)
O. mykiss	a.s.	96 hr (semi-static)	LC_{50}	0.256 (mm)
O. mykiss	a.s.	96 hr (semi-static based on FOCUS model scenario)	LC_{50}	1.113 (mm)
B. rerio	a.s.	96 hr (semi-static)	LC_{50}	1.965 (mm)
O. latipes	a.s.	96 hr (semi-static)	LC_{50}	1.77 (mm)
C. carpio	a.s.	96 hr (semi-static)	LC_{50}	0.635 (mm)
P. pomelas	a.s.	96 hr (semi-static)	LC_{50}	0.234 (mm)
S. gairdneri	a.s.	30 d (flow-through)	NOEC*	0.012 (mm)
P. pomelas	a.s.	21 d (flow-through with pound soil)	NOEC**	1.86 (mm)
P. pomelas	a.s.	FLC (flow-through)	NOEC 368 d	0.040 (mm)***
O. mykiss	TFP-acid	96 hr (flow-through)	LC_{50}	24.5 mg/L
O. mykiss	4'-OH bifenthrin	96 hr (flow-through)	LC_{50}	3.9 µg/L
O. mykiss	TALSTAR 8SC	96 hr (semi-static)	LC_{50}	30 µg a.s./L (nom) 380 µg product/L
O. mykiss	TALSTAR 10EC	192 hr (static with sediment)	LC_{50}	5.49 µg a.s./L (nom) 54.9 µg product/L
SSD (species sensitivity distribution)	a.s.	acute	HC_5	0.072 µg a.s./L

* study not fully valid to address effects on the embryonic stage; NOEC valid for effects on the larval stage.
**established on effects on the survival only.
***used for the refinement of chronic risk since it covers both embryonic and larval stage effects.

Aquatic invertebrate				
D. magna	a.s.	48 hr (flow-through, with laboratory soil)	EC_{50}	<0.1 mg/kg (water and soil mixed) >0.5 mg/kg (unmixed) (nom)
D. magna	a.s.	48 hr (flow-through with pound soil)	EC_{50}	<0.5 mg/kg (water and soil mixed) >0.5 mg/kg (unmixed) (nom)
D. magna	a.s.	48 hr (flow-through)	EC_{50}	1.6 (nom)
D. magna	a.s.	48 hr (flow-through)	EC_{50}	0.11 (mm)
D. magna	a.s.	48 hr (static)	EC_{50}	0.37 (mm)

C. dubia	a.s.	24 hr (static)	EC_{50}	0.31 (mm)
T. platyurus	a.s.	24 hr (static)	EC_{50}	5.7 (mm)
Hexagenia sp	a.s.	48 hr (static)	EC_{50}	0.39 (mm)
Caddis fly	a.s.	48 hr (static)	EC_{50}	0.12 (mm)
G. pulex	a.s.	48 hr (static)	EC_{50}	0.11 (mm)
D. magna	a.s.	21 d (flow-through with pound soil)	NOEC	<0.24 (mm)
A. aquaticus	a.s.	21 d (flow-through with pound soil)	NOEC*	<0.30 (mm)
Corbicula	a.s.	21 d (flow-through with pound soil)	NOEC**	2.58 (mm)
D. magna	a.s.	21 d (flow-through)	NOEC	0.00095 (mm)
D. magna	a.s.	21 d (flow-through)	NOEC	0.0013 (mm)
M. bahia	a.s.	28 d (flow-through)	NOEC	0.0012 (mm)
D. magna	TFP-acid	48 hr (static)	EC_{50} NOEC	nd 20 mg/L
D. magna	4'-OH bifenthrin	48 hr (static)	EC_{50}	1.215 µg/L
D. magna	TALSTAR 8SC	48 hr (static)	EC_{50}	5.7 µg a.s./L (nom) 72 µg product/L

*Established on effects on the survival only.

Sediment dwelling organisms				
C. riparius	a.s.	28 d	NOEC	0.32 (nom)
C. riparius	a.s.	28 d	NOEC	40 µg a.s./kg sed (nom)
C. riparius	4'-OH bifenthrin	28 d	NOEC	1581 µg/kg sed

Algae				
P. subcapitata	TFP-acid	72 h	E_yC_{50} E_rC_{50}	0.822 mg/L 4.543 mg/L
P. subcapitata	4'-OH bifenthrin	72 h	E_yC_{50} E_rC_{50}	> 461.2 µg/L
D. subspicatus	TALSTAR 8SC	72 h	Biomass: E_bC_{50} Growth rate: E_rC_{50}	> 8 mg a.s./L (nom) > 100 mg product/L > 8 mg a.s./L (nom) > 100 mg product/L

Microcosm or mesocosm tests
1. Pond study performed in a cotton field in Alabama (USA). This study investigated the effects of aerial applications (10 applications) at a distance of 5 meters from a pond on the indigenous populations (including fish). Bifenthrin concentrations were checked both in the water column and the sediment. The study showed strong effects (elimination) of calanoid copepods without recovery throughout the study (more than one year), strong effect on Caenis without recovery throughout the study (more than one year) and strong effect on chaoboridae with recovery after one year. Since no recovery was observed in some taxa, no NOEC could be determined from this study. It could simply be stated that the **NOEC could be lower than the measured concentrations in this study, being: 6-18 ng a.s./L in the water column and 52-60 µg a.s./kg in the sediment.** In addition, the study showed residue concentrations (Bifenthrin) in fish ranging from several µg/kg to several hundred µg/kg, with low decrease post application (from one month after the last application to more than one year), indicating various biological bio-concentration patterns among fish species. 2. Mesocosm study performed in Austria (Bay of Fussach, lake Constance). The study reproduced two applications at 14 days interval and tested concentrations ranging from 0.001 to 0.935 µg a.s./L. The study lead to a **NOEAEC of 0.015 µg a.s./L** [#] which covers the most sensitive invertebrate species (Gammarids, copepods and chaoboridae).

[#] : Toxicity values used in TER calculations.

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

FOCUS Step1

2 x 10 g a.s./ha (cereals)

Test substance	Organism	Toxicity end point (µg/L)	Time scale	PEC_i (µg/L)	TER	Annex VI Trigger
a.s.	Fish	0.10	Acute	0.2	**0.5**	100
a.s.	Fish	0.012	Chronic	0.2	**0.06**	10
a.s.	Aquatic invertebrates	0.11	Acute	0.2	**0.55**	100
a.s.	Aquatic invertebrates	0.00095	Chronic	0.2	**0.00475**	10
Formulation	Algae	8000	Chronic	0.2	4000	10
a.s.	Sediment-dwelling organisms	0.32 40 µg/kg	Chronic	0.2 51.02 µg/kg	**1.6** **0.78**	10
TFP-acid	Fish	24.5 mg/L	Acute	0.44	55 682	100
TFP-acid	Aquatic invertebrates	20 mg/L	Acute	0.44	45 454	100
TFP-acid	Algae	0.822 mg/L	Acute	0.44	1868	10
4'-OH bifenthrin	Fish	3.9	Acute	0.02	195	100
4'-OH bifenthrin	Aquatic invertebrates	1.215	Acute	0.02	**61**	100
4'-OH bifenthrin	Algae	> 461.2	Acute	0.02	> 23 060	10
4'-OH bifenthrin	Sediment-dwelling organisms	1581 µg/kg	Chronic	4.44 µg/kg	356	10

2 x 7.6 g a.s./ha (cabbage)

Test substance	Organism	Toxicity end point (µg/L)	Time scale	PEC_i (µg/L)	TER	Annex VI Trigger
a.s.	Fish	0.10	Acute	0.15	**0.67**	100

Test substance	Organism	Toxicity end point (µg/L)	Time scale	PEC_i (µg/L)	TER	Annex VI Trigger
a.s.	Fish	0.012	Chronic	0.15	**0.08**	10
a.s.	Aquatic invertebrates	0.11	Acute	0.15	**0.73**	100
a.s.	Aquatic invertebrates	0.00095	Chronic	0.15	**0.0063**	10
Formulation	Algae	8000	Chronic	0.15	53333	10
a.s.	Sediment-dwelling organisms	0.32 40 µg/kg	Chronic	0.15 38.77 µg/kg	**2.13** **1.03**	10

1 x 10 g a.s./ha (ornamentals indoor)

Test substance	Organism	Toxicity end point (µg/L)	Time scale	PEC_i (µg/L)	TER	Annex VI Trigger
a.s.	Fish	0.10	Acute	0.003	**33.3**	100
a.s.	Fish	0.012	Chronic	0.003	**4**	10
a.s.	Aquatic invertebrates	0.11	Acute	0.003	**36.7**	100
a.s.	Aquatic invertebrates	0.00095	Chronic	0.003	**0.32**	10
Formulation	Algae	8000	Chronic	0.003	266666	10
a.s.	Sediment-dwelling organisms	0.32 40 µg/kg	Chronic	0.003 -	106.67 -	10

FOCUS Step 2

2 x 10 g a.s./ha (cereals), Northern Europe and Southern Europe

Test substance	N/S	Organism	Toxicity end point (µg/L)	Time scale	PEC (µg/L)	TER	Annex VI Trigger
a.s.	N and S	Fish	0.10	Acute	0.08	**1.25**	100
a.s.	N and S	Fish	0.012	Chronic	0.08	**0.15**	10
a.s.	N and S	Aquatic invertebrates	0.11	Acute	0.08	**1.375**	100
a.s.	N and S	Aquatic invertebrates	0.00095	Chronic	0.08	**0.0119**	10
a.s.	N and S	Sediment-dwelling organisms	0.32 40 µg/kg	Chronic	0.08 18.58 µg/kg	**4** **2.15**	10
4'-OH bifenthrin	N and S	Aquatic invertebrates	1.215	Acute	0.01	122	100

1 x 7.6 g a.s./ha (cabbage), Northern Europe and Southern Europe

Test substance	N/S	Organism	Toxicity end point (µg/L)	Time scale	PEC (µg/L)	TER	Annex VI Trigger

Test substance	N/S	Organism	Toxicity end point (µg/L)	Time scale	PEC (µg/L)	TER	Annex VI Trigger
a.s.	N and S	Fish	0.10	Acute	0.06	**1.67**	100
a.s.	N and S	Fish	0.012	Chronic	0.06	**0.2**	10
a.s.	N and S	Aquatic invertebrates	0.11	Acute	0.06	**1.83**	100
a.s.	N and S	Aquatic invertebrates	0.00095	Chronic	0.06	**0.02**	10
a.s.	N and S	Sediment-dwelling organisms	0.32 40 µg/kg	Chronic	0.06 11.72 µg/kg	**5.33** **3.4**	10

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

2 x 10 g a.s./ha (Cereals)

Scenario	Water body type	Test organism	Toxicity end point (µg/L)	Time scale	PEC (µg/L)	TER	Annex VI trigger
D1	ditch	fish	0.10	Acute	0.0541	**1.85**	100
D1	ditch	fish	0.012	Chronic	0.0541	**0.22**	10
D1	ditch	Invertebrates	0.11	Acute	0.0541	**2.03**	100
D1	ditch	Invertebrates	0.00095	Chronic	0.0541	**0.017**	10
R4	stream	Sediment-dwelling organisms	0.32 40 µg/kg	Chronic	0.0541 0.8160 µg/kg	**5.91** 49	10

1 x 7.6 g a.s./ha (Cabbage)

Scenario	Water body type	Test organism	Toxicity end point (µg/L)	Time scale	PEC (µg/L)	TER	Annex VI trigger
D3	ditch	fish	0.10	Acute	0.0407	**2.46**	100
D3	ditch	fish	0.012	Chronic	0.0407	**0.29**	10
D3	ditch	Invertebrates	0.11	Acute	0.0407	**2.7**	100
D3	ditch	Invertebrates	0.00095	Chronic	0.0407	**0.023**	10
R2	stream	Sediment-dwelling organisms	0.32 40 µg/kg	Chronic	0.0407 4.95 µg/kg	**7.86** **8.1**	10

FOCUS Step 4 (with refined toxicity endpoints, 20-25 m no-spray buffer zones +run-off reduction)

1 x 10 g a.s./ha (cereals)

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	Buffer zone distance	PEC (µg/L)	TER	Trigger

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	Buffer zone distance	PEC (µg/L)	TER	Trigger
D1	ditch	fish	acute	0.072	20 m	0.0039	18.7	10
D1	stream	fish	acute	0.072	20 m	0.0047	15.3	10
D2	ditch	fish	acute	0.072	20 m	0.0039	18.5	10
D2	stream	fish	acute	0.072	20 m	0.0042	17.1	10
D3	ditch	fish	acute	0.072	20 m	0.0039	18.5	10
D4	pond	fish	acute	0.072	20 m	0.0008	90	10
D4	stream	fish	acute	0.072	20 m	0.0046	15.6	10
D5	pond	fish	acute	0.072	20 m	0.0008	90	10
D5	stream	fish	acute	0.072	20 m	0.0049	14.7	10
D6	ditch	fish	acute	0.072	20 m	0.0038	18.9	10
R1	pond	fish	acute	0.072	20 m	0.0008	90	10
R1	stream	fish	acute	0.072	20 m	0.0035	20.6	10
R3	stream	fish	acute	0.072	20 m	0.0049	14.7	10
R4	stream	fish	acute	0.072	20 m	0.0035	20.6	10
D1	ditch	fish	chronic	0.04	20 m	0.0039	10.3	10
D1	stream	fish	chronic	0.04	20 m	0.0047	**8.5**	10
					25 m	0.0039	10.3	
D2	ditch	fish	chronic	0.04	20 m	0.0039	10.2	10
D2	stream	fish	chronic	0.04	20 m	0.0042	**9.5**	10
					25 m	0.0034	11.8	
D3	ditch	fish	chronic	0.04	20 m	0.0039	10.2	10
D4	pond	fish	chronic	0.04	20 m	0.0008	50	10
D4	stream	fish	chronic	0.04	20 m	0.0046	**8.7**	10
					25 m	0.0038	10.5	
D5	pond	fish	chronic	0.04	20 m	0.0008	50	10
D5	stream	fish	chronic	0.04	20 m	0.0049	**8.2**	10
					25 m	0.0041	**9.8**	
D6	ditch	fish	chronic	0.04	20 m	0.0038	10.5	10
R1	pond	fish	chronic	0.04	20 m	0.0008	50	10
R1	stream	fish	chronic	0.04	20 m	0.0035	11.4	10
R3	stream	fish	chronic	0.04	20 m	0.0049	**8.2**	10
					25 m	0.0040	10	
R4	stream	fish	chronic	0.04	20 m	0.0035	11.4	10
D1	ditch	invertebrates	chronic	0.015	20 m	0.0039	3.8	3
D1	stream	invertebrates	chronic	0.015	20 m	0.0047	3.2	3

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	Buffer zone distance	PEC (µg/L)	TER	Trigger
D2	ditch	invertebrates	chronic	0.015	20 m	0.0039	3.8	3
D2	stream	invertebrates	chronic	0.015	20 m	0.0042	3.6	3
D3	ditch	invertebrates	chronic	0.015	20 m	0.0039	3.8	3
D4	pond	invertebrates	chronic	0.015	20 m	0.0008	18.7	3
D4	stream	invertebrates	chronic	0.015	20 m	0.0046	3.3	3
D5	pond	invertebrates	chronic	0.015	20 m	0.0008	18.7	3
D5	stream	invertebrates	chronic	0.015	20 m	0.0049	3.1	3
D6	ditch	invertebrates	chronic	0.015	20 m	0.0038	3.9	3
R1	pond	invertebrates	chronic	0.015	20 m	0.0008	18.7	3
R1	stream	invertebrates	chronic	0.015	20 m	0.0035	4.3	3
R3	stream	invertebrates	chronic	0.015	20 m	0.0049	3.1	3
R4	stream	invertebrates	chronic	0.015	20 m	0.0035	4.3	3

1 x 7.6 g a.s./ha (cabbage)

Scenario	Water body type	Test organism	Time scale	Toxicity end point	Buffer zone distance	PEC (µg/L)	TER	Trigger
D3	ditch	fish	acute	0.072	20 m	0.0031	23.2	10
D4	pond	fish	acute	0.072	20 m	0.0006	120	10
D4	stream	fish	acute	0.072	20 m	0.0032	22.5	10
D6	ditch	fish	acute	0.072	20 m	0.0030	24	10
R1	pond	fish	acute	0.072	20 m	0.0006	120	10
R1	stream	fish	acute	0.072	20 m	0.0027	26.7	10
R2	stream	fish	acute	0.072	20 m	0.0036	20	10
R3	stream	fish	acute	0.072	20 m	0.0038	18.9	10
R4	stream	fish	acute	0.072	20 m	0.0027	26.7	10
D3	ditch	fish	chronic	0.04	20 m	0.0031	12.9	10
D4	pond	fish	chronic	0.04	20 m	0.0006	67	10
D4	stream	fish	chronic	0.04	20 m	0.0032	12.5	10
D6	ditch	fish	chronic	0.04	20 m	0.0030	13.3	10
R1	pond	fish	chronic	0.04	20 m	0.0006	67	10
R1	stream	fish	chronic	0.04	20 m	0.0027	14.8	10
R2	stream	fish	chronic	0.04	20 m	0.0036	11.1	10
R3	stream	fish	chronic	0.04	20 m	0.0038	10.5	10
R4	stream	fish	chronic	0.04	20 m	0.0027	14.8	10

Scenario	Water body type	Test organism	Time scale	Toxicity end point	Buffer zone distance	PEC (µg/L)	TER	Trigger
D3	ditch	invertebrates	chronic	0.015	20 m	0.0031	4.8	3
D4	pond	invertebrates	chronic	0.015	20 m	0.0006	25	3
D4	stream	invertebrates	chronic	0.015	20 m	0.0032	4.7	3
D6	ditch	invertebrates	chronic	0.015	20 m	0.0030	5	3
R1	pond	invertebrates	chronic	0.015	20 m	0.0006	25	3
R1	stream	invertebrates	chronic	0.015	20 m	0.0027	5.5	3
R2	stream	invertebrates	chronic	0.015	20 m	0.0036	4.2	3
R3	stream	invertebrates	chronic	0.015	20 m	0.0038	3.9	3
R4	stream	invertebrates	chronic	0.015	20 m	0.0027	5.5	3
D3	ditch	Sediment dwelling organisms	chronic	40 µg/kg	20 m	0.0140	2857	10
D4	pond	Sediment dwelling organisms	chronic	40 µg/kg	20 m	0.0113	3540	10
D4	stream	Sediment dwelling organisms	chronic	40 µg/kg	20 m	0.0041	9756	10
D6	ditch	Sediment dwelling organisms	chronic	40 µg/kg	20 m	0.0087	4598	10
R1	pond	Sediment dwelling organisms	chronic	40 µg/kg	20 m	0.0140	2857	10
R1	stream	Sediment dwelling organisms	chronic	40 µg/kg	20 m	0.2210	181	10
R2	stream	Sediment dwelling organisms	chronic	40 µg/kg	20 m	0.4950	81	10
R3	stream	Sediment dwelling organisms	chronic	40 µg/kg	20 m	0.0864	463	10
R4	stream	Sediment dwelling organisms	chronic	40 µg/kg	20 m	0.1340	298	10

1 x 10 g a.s./ha (ornamentals indoor)

Scenario	Water body type	Test organism	Time scale	Toxicity end point	PEC (µg/L)	TER	Trigger
"Dutch calculations"		fish	acute	0.072	0.003	24	10

Scenario	Water body type	Test organism	Time scale	Toxicity end point	PEC (µg/L)	TER	Trigger
"Dutch calculations"		fish	chronic	0.04	0.003	13.3	10
"Dutch calculations"		invertebrates	chronic	0.015	0.003	5	3

1 x 10 g a.s./ha (ornamentals outdoor)
DATA GAP (see fate section)

Risk from bioaccumulation through the aquatic food chain
A high risk from bioaccumulation through the aquatic food chain was not excluded and a data gap for further assessment was identified for all representative uses

Bioconcentration	
	Active substance
$logP_{O/W}$	6.6
Bioconcentration factor (BCF) ‡	**1709**
Annex VI Trigger for the bioconcentration factor	1000
Clearance time (days) (CT_{50})	22 - 28
Level and nature of residues (%) in organisms after the 14 day depuration phase	See studies

Other studies

Group	Time scale	Stage	BCF	Clearance time
Fish (*P. promelas*)	357 days	Parents Fertilized embryos Live embryos Larvae	21 000-30 000* 1300-4700* 790-10 000* 6000*	No depuration phase
Fish (*L. Macrochirus*)	42 days	Adults	2140 (muscle)* 8720 (viscera)* 6090 (whole body)* 11750 (k1/k2)*	CT_{50} 21-42 days
Fish (*L. Macrochirus*)	60 days		1100-1414 1709 (whole fish)	CT_{50} 22-28 days
Fish (*C. carpio*)	70 days	Adults	1030-1330	CT_{50} 6-11 days
Fish (*P. promelas*)	21 days	Adults	45-63**	No depuration phase
Invertebrate (*D. magna*)	21 days	Adults	270-440**	No depuration phase
Invertebrate (*A. aquaticus*)	21 days	Adults	71-82**	No depuration phase
Invertebrate (*Corbicula*)	21 days	Adults	41-74 (92-140 when exposed to soil)**	No depuration phase

*: plateau not reached.
**: presence of soil in the test media

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

Test substance	Acute oral toxicity (LD_{50} µg a.s./bee)	Acute contact toxicity (LD_{50} µg a.s./bee or % effect)
a.s. ‡	0.1	100 % at 50 ppm*
TALSTAR 8SC	0.01 #	0.0016 #

* : values reported as indicative

: toxicity values used in HQ calculations.

Field or semi-field tests

Test type	Parameter**	Measured as	Crop and dose (active substance)	Value (active substance)	Reference
Residue test					
CAPTURE 2 EC	Mortality	% effect	Cotton 67 g/ha	Residual effects > control for 2 to 5 days	Waller *et al*., 1988
Cage test					
TALSTAR 8FL	Mortality	% effects	*Phacelia tanecetifolia*, 9.75 g/ha	Lethal effect for 5 days when applied during bee flight no effect when applied after bee flight (evening)	Tornier, 1993
Field test					
CAPTURE 2EC BRIGADE 10WP	Mortality Foraging Residual toxicity	% effect or nb visiting bees /count	Alfalfa, 57, 112 and 224 g /ha	Effects > control when applied during bee flight and for more than 5 days, no repellent effect	Atkins and Kellum, 1986
TALSTAR 10EC	Mortality	LD_{50} 48 h oral and contact Mortality in treated fields	*Phacelia tanecetifolia*, 50 g/ha	LD_{50} oral = 0.12 µg/bee LD_{50} oral multiple contacts = 0.00067 µg/bee LD_{50} contact = 0.044 µg/bee LD_{50} treated surface = 0.0058 µg/bee No lethal effect nor reduced visits of treated plants in the field	Illarionov, 1991
TALSTAR 8SC	Mortality Flight intensity Brood development	Nb dead bees	*Phacelia tanecetifolia*, 10 g/ha	No lethal effect Effects on flight intensity or brood development not highlighted due to fluctuations	Schur, 2002
TALSTAR 8SC + CARAMBA (metconazol)	Mortality Flight intensity Brood development	Nb dead bees	*Phacelia tanecetifolia*, 10 g/ha	No lethal effect No effect on flight intensity Effects on brood development not highlighted due to fluctuations	Kling, 2003
TALSTAR 8SC + FOLICUR (tebuconazol)	Mortality Flight intensity Brood development	Nb dead bees	*Phacelia tanecetifolia*, 10 g/ha	No lethal effect Effect on flight intensity restrained to immediate time after application Effects on brood development not	Schur, 2003

Test type	Parameter**	Measured as	Crop and dose (active substance)	Value (active substance)	Reference
				highlighted due to fluctuations	
CAPTURE 2EC	Mortality Foraging Residual toxicity	% effect or nb visiting bees /count	Alfalfa, 22.5, 45 and 90 g /ha	Mortality of 79.80-100% when applied at flyover, no lethal effects from fumigation Residual toxicity up to 6 days, reduced toxicity after 12 days Reduced foraging at all dose rates on the day of treatment	Atkins and Kellum, 1986
Tunnel test					
TALSTAR 10EC	Mortality Foraging	Nb dead bees or nb of bees/m^2	Wheat (15 g/ha and mustard (15 or 30 g/ha)	Mortality at one day post treatment No repellent effect	Gaulliard, 1985
TALSTAR FLO	Mortality Foraging Hive parameters	Nb dead bees or nb of bees/m^2	*Phacelia tanecetifolia*, 50 g/ha	Mortality at one day post treatment Repellent effect within the first 30 min post-treatment No effect on the hive in two out of three trials	Gaulliard, 1986
TALSTAR FLO	Mortality Foraging	Nb dead bees or nb of bees/m^2	*Phacelia tanecetifolia*, 15 g/ha	Mortality at one day post treatment Repellent effect within the first 5 hours post-treatment in one out of two trial	Tisseur, 1988

** : assessed in adults unless specifically indicated

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

2 x 10 g a.s./ha (cereals)

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	**12500**	50
a.s.	oral	**2000**	50

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

Laboratory tests

Species	Life stage	Test Substance	Dose (g/ha)	Effect	Trigger value
Aphidius rhopalosiphi‡	(adults)	a.s.	60 g a.s./ha	**100%** mortality	50 %
Aphidius rhopalosiphi‡	(adults) (mummies)‡	TALSTAR FLO	7.5 g a.s./ha	**100%** mortality in adults exposed on glass and maize leaves No effect on emergence or survival of directly sprayed mummies	50 %

Species	Life stage	Test Substance	Dose (g/ha)	Effect	Trigger value
Poecilus cupreus‡	(adults)‡	a.s.	60 g a.s./ha	**90%** mortality	50 %
Typhlodromus pyri	(protonymphs)	a.s.	60 g a.s./ha	**100%** mortality	50 %
Chrysoperla carnea	(larvae)	a.s.	60 g a.s./ha	**100%** mortality	50 %
Episyrphus balteatus	(larvae)	TALSTAR FLO	7.5g a.s./ha	16.8% mortality in immature stages **61%** effect on fertility assessed from viable eggs/female	50 %

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance	Dose	Effect
Aphidius rhopalosiphi	(adults)	TALSTAR 8SC	Dose response test	LR_{50} = 8.145 g a.s./ha [#] NOED = 0.769 g a.s./ha (lethal effects)
Aphidius rhopalosiphi	(adults)	TALSTAR 8SC, aged residue test	2 x 50 g a.s./ha 2 x 6.1 g a.s./ha 2 x 1.6 g a.s./ha	Lethal effects of -5.7% (corr.) after 28 days at the in crop rate, Lethal effects of -2.6% (corr.) after 14 days at the off crop rate
Typhlodromus pyri	(protonymphs)	TALSTAR 8SC	Dose response test	LR_{50} = 0.113 g a.s./ha [#] NOED = 0.009 g a.s./ha (lethal effects)
Poecilus cupreus	(adults)	TALSTAR 8SC	80 g a.s./ha	0% mortality 3% reduction food consumption
Chrysoperla carnea	(larvae)	TALSTAR 8SC	Dose response test	LR_{50} = 5.132 g a.s./ha NOED = 2.279 g a.s./ha (lethal effects)
Coccinella septempunctata	(larvae)	TALSTAR 8SC	Dose response test	LR_{50} = 0.084 g a.s./ha NOED = 0.03 g a.s./ha (lethal effects)
Coccinella septempunctata	(larvae)	TALSTAR 8SC, aged residue test	2 x 50 g a.s./ha 2 x 7.87 g a.s./ha	Lethal effects of 40% (corr.) after 27 days at the in crop rate, Lethal effects of 23.4% (corr.) after 14 days at the off crop rate

[#] : toxicity values used in HQ calculations.

Field tests

Species	Test substance	Dose	Effect
Orchard fauna in Spain and France	TALSTAR FLO	20, 30 or 50 g a.s./ha	Effects on all groups of predators, full recovery not observed 10 days after treatment 3 or 31 days after treatment 2 in the most sensitive groups

Species	Test substance	Dose	Effect
Orchard fauna in France	TALSTAR FLO	30 g a.s./ha	Effects on all groups of predators, no selectivity demonstrated, and no treatment related effect after 33-40 days after treatment.
Wheat fauna in France	TALSTAR FLO	7.5 and 5 g a.s./ha	Conclusions possible only for micro hymenoptera and lacewings. Effects observed on the lacewings, reversible but full recovery not observed during the study

Hazard quotients for non-target arthropods

2 x 10 g a.s./ha (cereals)

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field*	Trigger
a.s.	*Aphidius rhopalosiphi*	8.145	**2.08**	0.03 (1m)	2
a.s.	*Typhlodromus pyri*	0.113	**150.4**	**2.07** (1m) 0.43 (5m)	2

* : Rautman et al. (2001) drift values.

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	End point $_{corr}$ [1]
Earthworms				
Eisenia fetida	a.s. ‡	Acute 14 d	LC_{50} > 16 mg a.s./kg d.w.soil	LC_{50} > 8 mg a.s./kg d.w.soil [#]
Eisenia fetida	TFP acid	Chronic 56 d	NOEC = 17.8 mg/ kg d.w.soil	-
Eisenia fetida	4'-OH bifenthrin	Chronic 56 d	NOEC = 178 mg/ kg d.w.soil	-
Eisenia fetida	TALSTAR 8SC	Acute 14 d	LC_{50} > 78 mg a.s./kg d.w.soil	LC_{50} > 39 mg a.s./kg d.w.soil [#]
Eisenia fetida	TALSTAR 8SC	Chronic 56 d	NOEC = 2.13 mg a.s./kg d.w.soil	NOEC = 1.065 mg a.s./kg d.w.soil [#]

[1] toxicity values are divided by 2 when log P_{ow} > 2.

[#] : values used in TER calculations.

Soil micro-organisms			
Nitrogen mineralisation	TALSTAR 8SC ‡		< 25 % effect up to 0.128 mg a.s./kg d.w.soil
Carbon mineralisation	TALSTAR 8SC ‡		< 25 % effect up to 0.128 mg a.s./kg d.w.soil

Toxicity/exposure ratios for soil organisms

Cereals: 2 x 10 g a.s./ha, no interception

Test organism	Test substance	Time scale	PECplateau (µg/kg)	TER	Trigger
Earthworms					
Eisenia fetida	a.s. ‡	Acute	27	> 296	10
Eisenia fetida	TFP-acid	Acute	1.3	>471*	10
Eisenia fetida	4'-OH bifenthrin	Acute	1.7	>615*	10
Eisenia fetida	TFP-acid	Chronic	1.3	13692	5
Eisenia fetida	4'-OH bifenthrin	Chronic	1.7	104706	5
Eisenia fetida	TALSTAR 8SC	Acute	27	> 1444	10
Eisenia fetida	TALSTAR 8SC	Chronic	27	39	5

*estimated assuming the metabolites are 10 times acutely more toxic than the parent

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

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha) growth	ER_{50} (g/ha) emergence	Exposure (g/ha)	TER	Trigger
Allium cepa	TALSTAR 8SC	> 60 a.s.	> 60 a.s.	High (1 m) : 0.277	> 217	5

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

Test type/organism	end point
Activated sludge	Bifenthrin : EC_{50} 3h > 1900 mg a.s./L

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

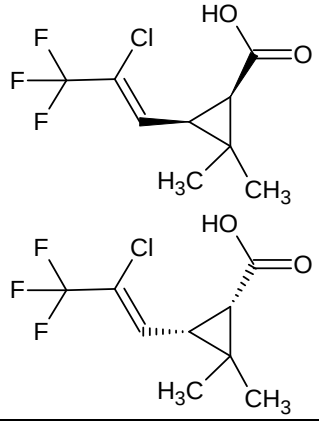
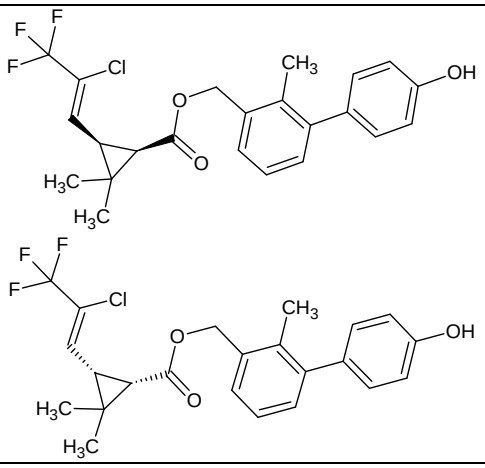
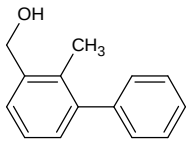
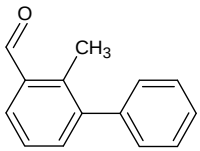
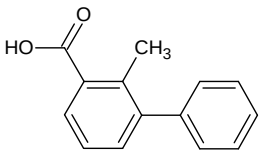
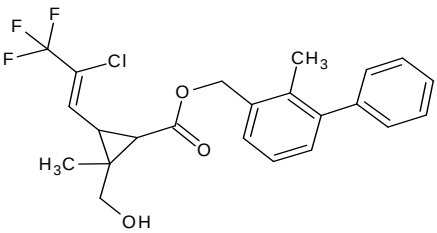
Compartment	
soil	Bifenthrin (sum of isomers)
water	Bifenthrin (sum of isomers)
sediment	Bifenthrin (sum of isomers)

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

	RMS/peer review proposal
Active substance	N R50/53

	RMS/peer review proposal
Preparation	N R50/53

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name*	Structural formula*
TFP acid	(1*RS*,3*RS*)-3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylic acid	
4'-OH bifenthrin	(4'-hydroxy-2-methyl-3-biphenylyl)methyl (1*RS*,3*RS*)-3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate	
BP-alcohol	(2-methyl-3-biphenylyl)methanol 2-methyl-3-phenylbenzyl alcohol	
BP-aldehyde	2-methyl-3-biphenylcarbaldehyde 2-methyl-3-phenylbenzyl aldehyde	
BP-acid	2-methyl-3-biphenylcarboxylic acid 2-methyl-3-phenylbenzoic acid	
OH-methyl bifenthrin **Hydroxyl-methyl bifenthrin**	(2-methyl-3-biphenylyl)methyl (1*RS*,3*RS*)-3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2-(hydroxymethyl)-2-methylcyclopropanecarboxylate (unknown stereochemistry)	

* 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
AOAC	Association of Official Analytical Chemists
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BAF	biomagnification factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstract 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
DFOP	double first order in parallel kinetics
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_{50}	effective concentration
EC	European Commission
ECHA	European Chemical 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)
ETE	estimated theoretical exposure
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor

FAO	Food and Agriculture Organisation of the United Nations
FC	field capacity
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FOMC	first-order multi-compartment
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-MSD	gas chromatography with mass selective detector
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GPC	gel permeation chromatography
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
$HC_5^{0.05}$	hazard concentration (lower limit)
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high performance liquid chromatography – mass spectrometry
HPLC-UV	high performance liquid chromatography with ultra violet detector
HQ	hazard quotient
HS	hockey stick kinetics
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
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
MHC	moisture holding capacity
mL	millilitre
mm	millimetre
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
NOEAEC	no observed ecological adverse effect concentration
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NPE	nonylphenol ethoxylate
OC	organic carbon content
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
PNEC	predicted no effect concentration
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
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
TK	technical concentrate
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
WHO	World Health Organisation
wk	week
yr	year