CONCLUSION ON PESTICIDE PEER REVIEW

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

Issued on 30 September 2008

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[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU-Commission a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within six months a conclusion on the risk assessment to the EU-Commission.

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 01 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 as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as insecticide as proposed by the notifier, 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, aphids. Full details of the GAP can be found in the attached end points.

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

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

Since clarification is required with respect to the proposed maximum levels of certain impurities in the technical material, the specification as a whole should currently be regarded as provisional.
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 origin, soil and water, however data gaps were identified for residue methods in food/feed of animal origin air and body fluids and tissues.

As for mammalian toxicity, bifenthrin is "Toxic if swallowed" (R 25), it is toxic by inhalation (R 23 "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 studz with an SF 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 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 metabolism studies on apples, cotton seed and corn plants bifenthrin was found to be the predominant residue. No significant cis- trans-isomerisation and translocation of residues through the plant were observed. Only for wheat/triticale and rye grown in Northern Europe sufficient residue trials have been submitted. Additional residue trial data are required to cover the notified use on n cereals in Northern and Southern Europe. On the basis of the available trials in cereals MRLs were only provisionally proposed. The representative uses in pome fruit and grapes are currently not supported by residue trials carried out according to the notified cGAP.
For the use on cereals no processing studies are required. The requirement of such studies for the uses on pome fruit and grapes has to be evaluated once sufficient data on residue trails are available.

Metabolism studies on rotational crops show that no significant residues are expected in parts of rotational crops intended for human consumption after application of bifenthrin on cereals according to the notified GAP.
Metabolism studies on lactating goats and laying hens show that metabolism, mainly by oxidation, cleavage of the ester binding and conjugation, is more extensive in some of the compartments. The experts meeting decided to include metabolites in the provisional residue definition for risk assessment for liver and kidney and eggs respectively. On the basis of provisional dietary burden calculations for intake of cereal and straw only, significant up-take of residues is only expected for cattle.
Taking into account the intake of cereals and of animal products only, consumer exposure is expected to be below the toxicological reference values. However, this risk assessment is only indicative and pending additional data for diverse areas of the residue section.

In soil under aerobic conditions bifenthrin exhibits moderate to high persistence forming the major soil metabolite TFP acid[2] (accounting for up to 11.6% of applied radioactivity (AR)) which exhibits moderate persistence and the minor non transient metabolite 4'-OH bifenthrin[3] (accounting for up to 8.3% AR) which exhibits low 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 is a data gap identified to confirm this and a data gap is identified for soil mobility data on TFP acid. There was no indication that adsorption of either bifenthrin or 4'-OH bifenthrin was pH dependent. TFP acid might be expected to exhibit 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 mitigation being applied at step 4 for the applied for intended uses on cereals. For the metabolite 4'-OH bifenthrin , appropriate FOCUS step 2 sediment calculations were carried out. These values are the basis for the risk assessment discussed in this conclusion. A data gap was identified for PEC in surface water for the major soil metabolite TFP acid that may runoff or drain to surface water. There is also a data gap identified for a further runoff mitigation assessment with respect to bifenthrin in the FOCUS runoff scenarios.

[2]TFP acid: (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylic acid
[3]4'-OH bifenthrin: (4'-hydroxy-2-methylbiphenyl-3-yl)methyl (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate

The potential for groundwater exposure from the applied for intended uses on cereals by bifenthrin 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 all 9 FOCUS groundwater scenarios. However for the metabolite TFP acid, data gaps are identified for the information required to further assess groundwater exposure potential. Contamination of groundwater above the 0.1 µg/L limit by TFP acid might be expected in at least some, if not all FOCUS groundwater scenarios if all the necessary data to complete exposure simulations were available. Thus it is expected that a non relevance assessment will be necessary for TFP acid. Such an assessment that could be considered by the peer review is not available. Satisfactory environmental exposure assessments are not available for the applied for intended uses on grapes and pome fruit.

A low risk was indicated in the first-tier risks assessment for birds and mammals for all the evaluated uses except for the long-term risk to insectivorous birds and for the acute risk to mammals in orchards. A potential high long-term risk from the exposure of bifenthrin to mammals was identified for all the intended uses. A data gap was identified for the applicant to refine the long-term risk for mammals for all the intended uses. A new data gap was identified after the PRAPeR meeting by EFSA, for the applicant to refine the long-term risk to insectivorous birds and the acute risk to mammals in orchards. The risk of bifenthrin to earthworm-eating birds was considered to be low in cereals. A potential risk was identified for earthworm-eating mammals in cereals and a refinement of the risk was required. The risk assessment for fish eating birds and mammals should be re-estimated when the revised BCF would become available. The risk to fish-eating birds and mammals was however considered to be low.

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 non-spray buffer zone) were below the Annex VI trigger values. Two higher tier studies were available to refine the assessment for invertebrates. From the mesocosm study a NOAEC of 0.015 µg a.s./L was derived. It was proposed to apply an assessment factor of 3 to this value to 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 NOAEC from the mesocosm and initial FOCUS PEC_{sw} Step 4 with 20 m no-spray buffer zones in cereals. No safe use was identified for fish when applying the maximum 25m no spray-buffer zone. Due to the $logP_{ow}$ of 7.3 for bifenthrin the potential to bioconcentrate was considered to be high. The experts agreed that the potential for bifenthrin to accumulate in aquatic organisms needs to be further addressed. Two data gaps were identified during the experts meeting, The first one was for the submission of a refined risk assessment for fish and the second for the submission of the ecotoxicological studies with the TFP acid since there is the potential for exposure to this metabolite in water bodies associated with treated crops.

The experts concluded that a high risk was identified for bifenthrin to bees for all the evaluated uses. Risk mitigation measures were identified as being necessary. It could be concluded from the available

information that there is a high risk to non-target arthropods (NTA) for in-field and off-filed areas within the treated area from the use in cereals. Risk mitigation measures are required to refine the risk to NTA in the off-field areas. A non-spray buffer zone of 5 m was identified as being necessary for cereals. A data gap was identified for the applicant to refine the risk to non-target arthropods. The acute risk assessment of bifenthrin and TFP acid to earthworms was assessed as low in cereals. However, the long-term risk to earthworms in cereals from exposure to both these compounds was considered to be potential high, and needed to be further addressed. A litterbag study (Walker H. 2005) was included in the dossier and this study did not show any effects of bifenthrin to the litter bag decomposition. Member State experts at the PRAPeR 52 meeting agreed that for pyrethroid compounds, the litter bag study does not cover the potential for there being a risk for soil macro-organisms. A data gap was identified to the applicant to address the risk to non-target soil macro-organisms. The risk to non-target plants needs to be addressed. The risk to micro-organisms and biological methods of sewage treatment was assessed as low for all the applied for representative uses evaluated.

Key words bifenthrin, peer review, risk assessment, pesticide, insecticide

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BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. 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, hereafter referred to as the draft assessment report, received by EFSA on 15 December 2005. Following an administrative evaluation, the draft assessment report 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 main applicant FMC Chemicals, as identified by the rapporteur Member State.

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

Taking into account the requested information received from the notifier, a scientific discussion took place in experts' meetings in 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 as laid down in this report.

In accordance with Article 11c(1) of the amended Regulation (EC) No 1490/2002, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received
- the resulting reporting table (rev. 1-0 of 7 December 2007)
- the consultation report

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

- the reports of the scientific expert consultation
- the evaluation table (rev. 2-1, 29 September 2008)

Given the importance of the draft assessment report including its addendum (compiled version of September 2008 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

By the time of the presentation of this conclusion to the EU-Commission, the rapporteur Member State has made available amended parts of the draft assessment report (Vol 2, Vol 3 B7) which take into account mostly editorial changes. Since these revised documents still contain confidential information, the documents cannot be made publicly available. However, the information given can be found in the original draft assessment report together with the peer review report, both of which are publicly available.

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 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 comprise foliar spraying to control sucking and biting insects, mites, aphids in cereals, grape and pome fruit, in all EU countries, at maximum two applications, at

maximum application rate per treatment of 10 g a.s./ha (cereals), 30 g a.s./ha (grape) and 50 g a.s./ha (pome fruit) respectively, with interval between applications of 2 weeks.
It should be noted however, that the uses on grape and pome fruit are no longer supported by the notifier for annex I inclusion.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of bifenthrin is 930 g/kg. There is no FAO specification available.

Information was requested concerning the ratio of the diastereoisomers (*Z*)-(1*R*)-*cis*-acid and (*Z*)-(1*S*)-*cis*-acid, which form the active substance. The notifier's statement, that the mixture of (*Z*)-(1*R*)-*cis*-acid and (*Z*)-(1*S*)-*cis*-acid is a racemate, was presented in a corrigendum to Volume 4 of the DAR. The RMS clarified that the dossier does not contain any information on enantiomeric composition with respect to the *cis* configuration at the cyclopropane moiety of the starting material.

Three manufacturing sources were presented in the DAR, however with five batch data originated only from one source. The five batch data from all manufacturing plants were evaluated by the RMS in an addendum, however in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, the new studies could not be considered in the peer review. The specification for the reference source was only partially accepted by the PRAPeR 51 meeting of experts. The meeting requested justification for the inclusion of the impurities which were not quantified but specified, or their removal from the specification. As a consequence the assessment of the equivalence of the technical materials was not possible. New data gaps were identified for a revised technical specification for the reference source and for five batch data for the new additional source.
Additionally the following data gaps were identified:
-information on the starting materials for the production of the technical material for the two additional manufacturing sources.
-validation data concerning linearity of method APG 492 for the determination of pure active substance and impurities in the active substance as manufactured
Since clarification is required with respect to the proposed maximum levels of certain impurities in the technical material, the specification as a whole should currently (September 2008) be regarded as provisional.

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, the following data gaps were identified:

- determination of the boiling point
- a 2 years shelf life study for the NPE-free formulation
- an aqueous quantum yield study (see also point 4.2.1)

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

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 methods are available to monitor bifenthrin residues in food/feed of plant origin, soil and water, however data gaps were identified for residue methods in food/feed of animal origin, in air and body fluids and tissues.
Residues of bifenthrin in food of plant origin can be monitored by GC-ECD and GC-MS with LOQ of 0.01 mg/kg (cereals). Uses on grape and pome fruit are no longer supported by the notifier for annex I inclusion, however additional validation data would be required for the method for high water content matrices. The applicability of the multi-residue method DFG S19 was evaluated in an addendum to vol. 3, however could not be taken into account in the peer-review, in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007.
There are no methods available to monitor bifenthrin residues in food/feed of animal origin, except the GC-ECD method to monitor residues of bifenthrin in eggs with LOQ of 0.01 mg/kg. It should be noted that methods have been submitted and evaluated in addenda by the RMS, however could not be taken into account in the peer-review, in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007.
Residues of bifenthrin in soil and sediment can be monitored by GC-ECD and GC-MS with LOQ of 0.005 mg/kg.
Bifenthrin residues in surface water can be determined by GC-MS with LOQ of 1 ng/l.

Acceptable methods are required to monitor bifenthrin residues in air and in body fluids and tissues.
The primary method for blood evaluated by the RMS in an addendum could not be considered in the peer review in view of the restrictions concerning the acceptance of new (i.e. newly submitted)

studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007.

2. Mammalian toxicology

Bifenthrin was discussed in a meeting of experts in July 2008 (PRAPeR 54 subgroup 1).

The 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 impurities structure were present in parent bifentrhrin, and similar to another impurity which was covered in the toxicological batches.
The meeting concluded that the batches tested in mammalian toxicity package were representative of the declared technical specification.

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 did not show any potential for accumulation.
Bifenthrin is extensively metabolised, mainly via hydrolysis, oxidation and conjugation.

2.2. Acute toxicity

Bifenthrin is classified as “Toxic if swallowed” with the risk phrase R 25 (oral LD50 in rats 54.5 mg/kg bw); it is toxic to rat by inhalation (LC50 1.01 mg/L, risk phrase R 23 “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.

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 repeat 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 overall body of 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 meeting. The tumours occurring in mice exposed to bifenthrin were multi-site (urinary bladder, lung, liver, leukaemia) and therefore without robust mechanistic data the carcinogenic potential of bifenthrin could not be excluded.

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) 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 notifier, 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 the tumours do not impact on the risk assessment.

2.6. REPRODUCTIVE TOXICITY

In a two generation study in the rat, there was no effect on reproductive performance at up to and including the highest dose level. The relevant maternal NOAEL is 60 ppm (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).

The developmental neurotoxicity potential of bifenthrin was considered during the 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 b.w./day. When tested in 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 is available on the metabolites.

During the meeting, the experts of the meeting on residues (running in parallel) sent a question about relevance of BP-acid[4] (proposed for residue definition for animal products) and OH-methyl bifenthrin[5] (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 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 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 bifenthrin's are applicable, as specific toxicological information on the metabolites is missing.

The relevance of isomers of TFP acid[6] in groundwater (expected to exceed 0.1 µg/L in some FOCUS scenarios) needs to be considered following the guidance document on the assessment of the relevance of metabolites in groundwater (Sanco/221/2000-rev.10). EFSA note: this consideration will require more extensive experimental evidence, should the proposed classification of the parent (R23, R25 and R40 Carc. Cat 3) be confirmed in the context of the European Chemicals Agency (EChA) programme for classification and labelling under Directive 67/548. As a consequence of Commission Regulation (EC) No. 1095/2007, no assessment was available that could be considered by the peer review.

2.9. MEDICAL DATA

Health surveillance programmes conducted in the main applicant's company did not show any unexplained or significant changes from the baseline or values falling outside the reference ranges for

[4] BP-acid: 2-methyl-3-phenylbenzoic acid
[5] OH-methyl bifenthrin: (2-methylbiphenyl-3-yl)methyl (1*RS*,3*RS*)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2-hydroxymethyl-2-methylcyclopropanecarboxylate (unknown stereochemistry).
[6] TFP acid: (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylic acid

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 meeting of experts.

ADI
The meeting agreed the ADI should be 0.015 mg/kg bw/day based on the 1-yr dog with an SF 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 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).

2.11. DERMAL ABSORPTION

An *in vivo* study in rat showed that amount of bifenthrin eliminated in the urine and faeces was less than 1% of the dose applied, even after 24 hours exposure. The amount absorbed (including the amount in the skin) was 55.14% at 10 hours and 69.1% at 24 hours.
A second *in vivo* study in rats dermally dosed with an aqueous emulsion gave a better representation of the dermal absorption of bifenthrin. At 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 meeting agreed to use the proposed dermal absorption is 17.83% (rounded to 18%) for the concentrate and dilution.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative formulation of Bifenthrin is Talstar 8SC to be applied on cereals, grapes and pomefruits at application rates of 0.008-0.050 kg a.s/ha.

During the meeting of experts the RMS was asked to recalculate operator, worker and bystander exposure considering the new AOEL. Results are summarized below. The RMS provided refined calculations only for the use on cereals.

Operator

The following parameters were used:
Crop: cereal
Dose: 10g a.s./ha (or 0.125 l/ha)
Application type: tractor mounted/trailed boom sprayer hydraulic nozzles
Container size: 1 litre (default value)
Dermal penetration: 18 %
The exposure takes into account the last agreed AOEL: 0.0075 mg/kg bw/d
Both models UK POEM and BBA are used (UK-POEM: 50ha, 6h; BBA: 20 ha, 6 h)

Model	**Application method (crop)**	**Systemic exposure (mg/kg bw/day)**		**% of systemic AOEL**	
		No PPE	**PPE**	**No PPE**	**PPE**
UK POEM	Field crop spraying	0.0251	0.0022	336	29*
German	Field crop spraying	0.0023	-	31	-

* Gloves during mixing/loading and application

The operator exposure assessment showed levels below the AOEL even without the use of PPE (German model).

Worker

The dermal exposure during re-entry activities was estimated by the following formula:
D = DFR x TF x W x dose x DA x 0.001/60

where DFR = dislodgeable Foliar Residues per 1 kg a.s./ha (number application x 2)
TF = Transfer factor (2500 cm²/person/h)
W = work rate (1 hour – to assess treatment effectiveness)
Dose = 0.01 kg a.s./ha
DA = dermal absorption 18 %
Body weight = 60 kg/person

D = 1 x 2 x 2500 x 1 x 0.01 x 0.001 x 0.18/60 = 0.00015 mg a.s./kg b.w./day.

This figure represents 2 % of the AOEL (0.0075 mg /kg b.w./day).

Bystander.

Total systemic exposure of bystanders was estimated to be 0.30 % of the proposed systemic AOEL (according to Lloyd and Bell, 1983).

3. Residues

The active substance bifenthrin was discussed at the PRAPeR 55 expert meeting for residues in July 2008.

It is noted that bifenthrin is a mixture of two optical isomers (*Z*)-(1*R*)-*cis*-acid and (*Z*)-(1*S*)-*cis*-acid (enantiomers). It should also be noted that the methods of analysis used in all the residue studies were not stereoselective. Thus the regulatory dossier provides no information on the behaviour of each individual bifenthrin enantiomer in plants and livestock or the enantiomers of 4'-OH bifenthrin in livestock. Therefore all residues reported in this conclusion are for the sum of the two enantiomers. It is not known if either isomer is degraded more quickly than the other in the matrices studied.

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

The metabolism of bifenthrin was investigated in apples, cotton seed and corn plants.

After three applications of phenyl ^{14}C-labelled bifenthrin at a rate corresponding to 480 g a.s./ha each (9.6N compared to critical annual application rate) or one application of cylclopropyl ^{14}C-labelled bifenthrin at a rate corresponding to 240 g a.s./ha (4.8N) on apples TRR decreased to approximately 0.60 mg/kg within 21 days after the (last) application. Residues were found mostly in the peel and were almost completely extractable. Bifenthin was the only radioactive compound identified and accounted for the majority of the radioactivity. In samples of leaves of treated apple trees bifenthrin accounted for the majority of the radioactive residues. Small amounts of BP acid[7] were found in the study with phenyl ^{14}C label.

After application of phenyl or cyclopropyl ^{14}C-labelled bifenthrin on leaves of cotton plants or soil, the majority of the radioactivity remained at the site of application with only small amounts being transferred to untreated plant parts. Bifenthrin was the main radioactive compound in leave samples. Additionally, small amounts of BP acid, BP alcohol[8], TFP[9] acid, 4'-OH bifenthrin[10] (only after soil treatment) and unidentified metabolites were found.

[7] BP acid: 2-methyl-3-phenylbenzoic acid
[8] BP alcohol: 2-methyl-3-phenylbenzyl alcohol
[9] TFP acid: (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylic acid
[10] 4'-OH bifenthrin: (4'-hydroxy-2-methylbiphenyl-3-yl)methyl (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate

Metabolism of phenyl and cyclopropyl ^{14}C-labelled bifenthrin on maize was studied after foliar application on young maize at a total rate of 0.53 kg/ha and after post emergence soil treatment at a rate of 2.3 kg/ha. TRR in treated leaves decreased from approximately 30 mg/kg to approximately 20 mg/kg within 30 days after the treatment. Bifenthrin accounted for the majority of TRR. The main metabolite was 4'-OH bifenthrin besides small amounts of BP acid, BP alcohol, BP aldehyde[11], TFP acid and unidentified compounds. For silage, leaves, stalks and husks after soil treatment and for grain after foliar or leave applications the radioactivity found was not significantly different from controls.

Overall, in all three crops unchanged bifenthrin is the predominant residue. Two metabolic pathways have been identified:

- hydroxylation of the terminal phenyl ring leading to 4'-OH bifenthrin;
- cleavage of the compound leading to TFP acid and BP alcohol, the later being progressively oxidised to BP aldehyde and BP acid. These metabolites are further conjugated 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 studies.

The proposed residue definition for monitoring and risk assessment is constituent isomers of bifenthrin.

The notifier has submitted residue trials on pome fruit, grapes and cereal carried out in Northern and Southern Europe to support the notified uses. Some of the studies have been only submitted in April 2007. In view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulations (EC) No 1490/2002 and 1095/2007, the new studies could not be considered in the peer review. In the reporting table rev.1-2 (18.04.2008) the RMS was asked to provide in an addendum to the DAR summary tables of supervised residue trials with all parameters needed for a clear understanding for consideration in the meeting of experts. The RMS was asked to note that new residue trials cannot be considered. The RMS provided Revision 2 to the DAR Volume 3 B7 (June 2008) to address this open point. The experts meeting relied on the revision when discussing the completeness of the data basis of residue trials with regard to the notified uses. However, when preparing the draft conclusion EFSA detected that the tables in revision 2 included several new studies. Therefore, the conclusions of the meeting concerning cereals had to be revised. The newly submitted residue trials were identified by EFSA in consultation with the RMS.

The meeting noted that 8 residue trials for wheat and triticale support the notified GAP for Northern Europe and 2 trials on wheat support the notified GAP for Southern Europe. As no residues in grain above the LOQ were detected in these trials they were regarded as sufficient to propose an MRL at

[11] BP aldehyde: 2-methyl-3-phenylbenzyl aldehyde

LOQ. EFSA notes that both trials on wheat grown in Southern Europe were only submitted in April 2007. Consequently, no trials eligible for evaluation support the notified use in wheat in Southern Europe. Therefore, only a provisional MRL for wheat and triticale can be proposed based on the trials carried out in Northern Europe only. EFSA states that extrapolation to rye is possible. A data gap was identified by EFSA after the meeting of experts. Sufficient residue trial data according to the critical GAP for wheat grown in Southern Europe are required.

The experts meeting noted that 9 trials on barley and 2 in oats grown in Northern Europe, but only 2 trials on barley grown in Southern support the GAPs for these crops. The experts identified a data gap for a sufficient number of trials for barley grown in Southern Europe. A provisional MRL was proposed on the basis of the results of barley and oats grown in Northern Europe. EFSA notes that both residue trials on barley for Southern Europe and three of the trials on barley in Northern Europe were only submitted in April 2007 and that only 6 trials on barley and 2 trials on oats are eligible for evaluation. EFSA notes that the provisional MRLs for barley and oats therefore are only supported by 6 trials on barley and 2 trials on oats respectively carried out in Northern Europe. It is noted that according to draft guidance document SANCO 7525/VI/-rev.8, extrapolation is possible only from trials on barley to oats when the active substance is used up to or close to harvest (last application after the consumable part of the crop has started to form). Further trials on barley grown in Northern and Southern Europe are required to confirm this MRL and to provide a sufficient data basis for a robust risk assessment. Therefore, in addition to the data gap identified by the experts meeting concerning residue trials for barley grown in Southern Europe, EFSA after the experts meeting identified a data gap concerning the submission of two further trials for barley grown in Northern Europe.

The experts meeting concluded that many of the residue trials on pome fruit and grapes were not carried out according to the notified cGAP especially concerning the number of applications. Sufficient residue trials in accordance with the notified cGAPs for Northern and Southern Europe on pome fruit and grapes respectively are required. EFSA notes that some of the residue trials included in revision 2 to the DAR Volume 3 B7 (June 2008) were only submitted in April 2007 and therefore not eligible for evaluation in the pee review.

Studies on storage stability show that bifenthrin is stable 49 months in apples, maize silage and maize stover, 34 months in maize grain, 24 months in cottonseed, 6 months in potato tuber and processed parts and 15 months in dry peas.

The effect of processing on the nature of residues was investigated in buffer solution under test conditions simulating pasteurisation and baking. Bifenthrin was shown to hydrolyse during processing to a significant extent (less than 50 % of the initial amount was recovered unchanged). However the study did not use radiolabelled bifenthrin and the degradation products were not identified.

One study on the effect of processing on the residue levels is available for apple juice production and two studies for processing of grapes.

The studies on the effect of processing on the nature and on the level of residues respectively were reported in the DAR, but the completeness and validity of the data basis were not evaluated in the DAR and were also not discussed by the experts.

The experts meeting concluded that no studies on the effect of processing on the nature and level of residues are required for cereals for the application of bifenthrin due to the low residue concentrations and low intake of residues. However, they noted that valid studies on the effect of processing on the nature of residues and additional studies on the effect of processing on the level of residues will probably be required for apples and grapes. The requirement of further studies has to be decided when the requested residue trials for apples and grapes have been submitted and evaluated.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

Confined rotational crop studies are available. Phenyl or cyclopropyl ^{14}C-labelled bifenthrin was applied to soil at 560 g a.s./ha (28N of the critical annual rate for wheat). Lettuce, sugar beets and wheat were planted after 30, 60 and 120 days of ageing, wheat also after 7 and 12 months. Translocation of radioactive residues was low (TRR were below 0.05 mg/kg in consumable parts of the crops, but up to 0.37 mg/kg in wheat straw). The metabolite pattern was determined in wheat straw and found to be similar to the pattern observed in primary crops. After application of bifenthrin on cereals according to the notified cGAP, no residues above 0.01 mg/kg are expected in parts of rotational crops intended for human consumption.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

The metabolism of bifenthrin has been studied in ruminants and poultry. After dosing lactating goats with phenyl or cyclopropyl ^{14}C-labelled bifenthrin at 2.3 mg/kg b.w. for 7 days TRR excreted in faeces and urine accounted for 95% of the radioactivity recovered. The radioactive residues in milk reached a plateau after 4 days at an average of approximately 0.9 mg/kg (max. 1.5 mg/kg). In tissues, highest concentrations of TRR were found in liver (max. 3.9 mg/kg) and in fat (max. 2.8 mg/kg). Whereas bifenthrin was the main radioactive compound identified in milk, muscle and fat, metabolism was more extensive in kidney and liver where bifenthrin only accounted for max. 22% and 44% of TRR respectively. The main metabolites observed were BP acid (max. 35%) and OH-methyl bifenthrin[12] (max. 3.9%).

For laying hens dosed with phenyl or cyclopropyl ^{14}C-labelled bifenthrin the majority of the radioactivity was found in excreta. The radioactive residues in egg yolk reached a plateau after 7/8 days at approximately 3 mg/kg with lower levels of radioactivity in egg white (0.02-0.04 mg/kg). In tissues, highest TRR were found in liver and fat (approximately 2 mg/kg). The main radioactive

[12] OH-methyl bifenthrin: (2-methylbiphenyl-3-yl)methyl (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2-(hydroxymethyl)-2-methylcyclopropanecarboxylate (unknown stereochemistry).

compound found in fat and muscle was bifenthrin (max. 53% and 44% respectively). OH-methyl bifenthrin and its fatty acid conjugates (together max. 26% and 13%) were the next significant metabolites. In egg yolk similar amounts of bifenthrin (max. 44%) and of OH-methyl bifenthrin and its fatty acid conjugates (max. 40%) were found. In liver the significant metabolites were OH-methyl bifenthrin and its fatty acid conjugates (together max. 47%) and TFP acid (25%).

Three main routes of metabolism were observed in livestock: oxidation of one of the methyl groups of the cyclopropane ring, oxidation of the biphenyl group and cleavage of the ester binding to form TPF-acid and BP-alcohol. Some metabolites result from a combination of these mechanisms. Furthermore, conjugation of metabolites to lipid substances was observed.

In revision 2 to the DAR Volume 3 B7 (June 2008) the notifier noted that in the livestock metabolism studies the extractable residues in liver and kidney consist of approximately 50% bifenthrin and 50% BP acid and the extractable residues in egg yolk consist of approximately 50% bifenthrin and 50% hydroxymethyl bifenthrin and its fatty acid conjugates. It was suggested to take these metabolites into account for the risk assessment.

This suggestion was discussed by the experts meeting. The PRAPeR meeting 54 on toxicology concluded that for residues of BP acid and for hydroxyl-methyl bifenthrin and its fatty acid conjugates the reference values of bifenthrin could be applied. On this basis and on the basis of the results of the livestock metabolism study, the experts proposed the following provisional residue definitions for animal products: for monitoring: constituent isomers of bifenthrin; for risk assessment: for liver and kidney: sum of constituent isomers of bifenthrin and BP acid expressed as bifenthrin (conversion factor of 2 for monitoring to risk assessment); for eggs: sum of constituent isomers of bifenthrin and hydroxyl-methyl bifenthrin and its fatty acid conjugates, expressed as bifenthrin (conversion factor of 2 for monitoring to risk assessment); for all other animal products: constituent isomers of bifenthrin. The residue definitions and conversion factors are pending the availability of storage stability data to confirm the levels of metabolites. It is noted that a storage stability study has already been submitted in April 2007. However, in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulations (EC) No 1490/2002 and 1095/2007, the new study could not be considered in the peer review.

EFSA notes that the results of the animal transfer studies which also covered the analysis of metabolites (see below) were not taken into account by the experts meeting for deriving conversion factors. Residue levels were below LOQ in the feeding studies of chicken for all samples and analytes. Therefore, the study cannot be used to calculate conversion factors. Whereas, residue levels were above LOQ in some samples analysed in the studies on dairy cows, the presentation of the results of the study in the DAR does not allow deciding if they are suitable to calculate conversion factors. EFSA notes, that for the risk assessment for intake of cereals treated with bifenthrin the application of the proposed conversion factors does not have a relevant impact (see section 3.3).

However, the estimation should be re-addressed for further uses for which intake of higher residue levels of bifenthrin is expected taking into account the animal transfer studies. Therefore, EFSA after the experts meeting identified the need for revision of the residue definition for risk assessment for animal products and the calculation of the conversion factors for the use on pome fruit.

Calculations of the dietary burden for livestock included in the DAR are based on the results of newly submitted data. A calculation carried out by EFSA for intake of cereal grain and straw on the basis of the highest residues found in the originally submitted studies shows the following results: 0.07 mg/kg diet (DM)/day for dairy cattle, 0.15 mg/kg diet (DM)/day for beef cattle, 0.02 mg/kg diet (DM)/day for chicken and 0.02 mg/kg diet (DM)/day for pigs. EFSA states that these calculations have to be regarded as provisional and have to be up-dated when sufficient data for all notified representative uses on cereals and apples are available. It is noted that the data used in this calculation are different from the data used in Revision 2 to the DAR Volume 3 B7 (June 2008) which are included in studies not eligible for evaluation. However, the deviation from the results of the calculation in Revision 2 does not change the conclusions concerning MRL proposals for animal products.

Animal transfer studies were carried out on dairy cattle dosed at 5, 15 and 50 mg/kg feed for 28 days. In the lowest dose group (83 and 33 times the provisionally estimated intake for diary cattle and beef cattle respectively) bifenthrin residues were <0.1 mg/kg in muscle and liver samples, max. 0.1 mg/kg in kidney samples and max. 1.82 mg/kg (mean: 0.85 mg/kg) in fat. For this dose level milk reached a plateau after 5 days at 0.08 mg/kg (max. 0.16 mg/kg). In further studies levels of BP alcohol, BP acid and 4'-hydroxy bifenthrin in animal tissues were investigated. For the lowest dose group only low levels of BP Alcohol were found in peritoneal fat. In the highest dose group BP-alcohol was found in all fat samples and in some of the muscle samples. Low quantifiable levels of BP-alcohol and BP-acid were found in some of the liver and kidney samples.

EFSA notes that dose rates in the animal transfer studies on cattle were considerably higher than the estimated dietary burden for intake of cereals grain and straw. They show bioaccumulation and linear relationship between residue intake through feed and of residue levels in tissues is not given. EFSA notes that for the proposal of reliable MRLs feeding studies representative for the expected intake for livestock should ideally be available. It is noted that the dietary burden calculations are not finalised and higher intake of bifenthrin residues is expected when also the intake of apple pomace is taken into account. The acceptability of the feeding studies should be re-evaluated upon receipt of all outstanding relevant data.

Although no significant intake of bifenthrin residues is expected for chicken for uses on cereals animal transfer studies have been provided by the notifier. Laying hens were dosed bifenthrin at 0.0025, 0.025 (3 times the provisionally estimated intake for chicken) and 0.25 mg/kg DM/day mg/kg

feed for 28 days. All samples were analysed for bifenthrin, some additionally for BP alcohol, TFP acid or hydroxyl methyl bifenthrin. Residues were found to be below LOQ in all samples analysed.

The experts meeting concluded that storage stability data for bifenthrin and its metabolites in animal products are needed to prove the validity of the feeding studies. Respective studies have been submitted in April 2007. In view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulations (EC) No 1490/2002 and 1095/2007, the new studies could not be considered in the peer review. Therefore a data gap concerning a valid storage stability study was formulated.

3.3. CONSUMER RISK ASSESSMENT

In addendum 1 to Volume 3 B7 (August 2008) the RMS provided an acute and chronic risk assessment for the consumer on basis of the reference values for bifenthrin concluded by the PRAPeR 54 meeting, provisionally proposed MRLs and conversion factors with the EFSA PRAPeR model.
The chronic risk assessment showed the highest residue intake for the French model for toddlers (TMDI = 2.9 % ADI). The TMDI for WHO Cluster diet B and D respectively was 0.8% ADI.
According to the assessment provided by the RMS the acute exposure is not expected to exceed the ARfD. The calculation indicates that the NESTIs are maximal 4% of the ARfD (for intake of milk and milk products by UK infant).

A calculation for the chronic risk assessment for the intake on the basis of provisionally proposed MRLs (see section 3.4) and the provisionally proposed conversion factors (see section 3.2) with the EFSA PRAPeR model was carried out by EFSA. It showed that the Dutch model for children (TMDI = 2.8% ADI) is the most critical models for the chronic intake. The TMDI for the WHO Cluster diet B was 1.3% ADI. It is noted that the application of conversion factors does not significantly change the result of the initial calculation.
The acute exposure is not expected to exceed the ARfD. NESTIs for consumer/intake combinations calculated on the basis of the suggested MRLs are maximal 4% of the ARfD (for intake of milk/milk products by children). When applying the proposed conversion factors for liver and kidney, NESTIs are max. 2.7% of the ARD (for intake of bovine liver by children).

EFSA notes that the risk assessment was not peer-reviewed. It is only indicative and in terms of the notified representative uses it underestimates the possible risk as it is based only on the intake of wheat and rye and food of animal origin. For the notified uses on grapes and apples not enough data were available to carry out the risk assessment. The final assessment is pending the submission of additional data and the re-evaluation for all intended uses.

In addition, EFSA notes that the applicant should address the risk assessment with regard to the enantiomers of bifenthrin and its metabolites as the nature of the final residue with regard to isomers was not studied.

3.4. PROPOSED MRLS

Based on the results of residue trials on wheat and triticale respectively carried out in Northern Europe EFSA provisionally suggests MRLs of 0.01* mg/kg for wheat, triticale and rye. Based on the results of residue trials on barley and oats respectively carried out in Northern Europe EFSA provisionally suggests MRLs of 0.05 mg /kg for barley and oats.
The proposals are pending the submission of the requested data on residue trials.
The submitted data are not sufficient to propose MRLs for grapes and pome fruit.

On the basis of the results of the feeding studies on dairy cows and the calculations of the dietary burden the RMS proposed the following MRLs in Revision 2 to the DAR Volume 3 B7 (June 2008): 0.1 mg/kg for ruminant fat, 0.05* mg/kg for ruminant meat, 0.05* mg/kg for ruminant kidney and liver, 0.01* mg/kg for ruminant milk and 0.05* for ruminant milk fat. The proposals are provisional pending the submission of further data (for further details on data gaps see section 3.1 and 3.2).

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 all the fate and behaviour studies were not stereoselective. Therefore the regulatory dossier provides no information on the behaviour of each individual bifenthrin enantiomer or the enantiomers of the metabolites TFP acid and 4'-OH bifenthrin in the environment. Therefore all residues reported as bifenthrin or these two metabolites in this conclusion are for the sum of the 2 enantiomers. It is not known if either isomer of these three compounds is degraded more quickly than the other in the environmental matrices studied. Originally the applicant applied for intended uses on cereals, grapes and pome fruit, but during the peer review chose to only support uses on cereal crops. The environmental exposure assessment has not been finalised for the uses on grapes and pome fruit. Therefore; for the uses in grapes and pome fruit data gaps for the predicted environmental concentrations to be calculated for the different environmental compartments, have been identified in this conclusion.

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 radiolabel (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[13], 4'-OH bifenthrin[14], BP-acid[15] and BP-alcohol[16] 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 on a further 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 these 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 (see appendix 1 for the values at 120 days).

In radiolabelled field soil residue samples taken in a rotational crop study (seasonally open greenhouse, semi field experiment in North America, Singer 1991) 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 cop study (Bixler, 1986).

Reliable data on anaerobic degradation in soil were not available. A data gap was therefore identified for a laboratory anaerobic soil degradation study that is necessary to complete an exposure

[13]TFP acid: (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylic acid
[14]4'-OH bifenthrin: (4'-hydroxy-2-methylbiphenyl-3-yl)methyl (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate
[15] BP acid: 2-methyl-3-phenylbenzoic acid
[16] BP alcohol: 2-methyl-3-phenylbenzyl alcohol

assessment in territories where anaerobic conditions cannot be excluded (see DAR for the reasoning of the RMS that was agreed by the peer review). In a laboratory soil photolysis study, no novel photodegradation products were identified. These 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 an additional 2 soils at 22°C and 40% maximum water holing capacity (MWHC). DT_{50} were: 67-203 days (single first order non linear regression). After normalisation to FOCUS reference conditions[17] (20°C and -10kPa soil moisture content) this range of single first order DT_{50} is 53-192 days). (see pages 23-29 including Table 8.2.20 of the document the RMS named corrigendum 2 to Vol. 3 B.8 of the DAR dated June 2008) for the kinetic assessments and normalisation. The resulting FOCUS reference condition geomean DT_{50} is 106.4 days, median DT_{50} 115.2 days.

The major (> 10 %AR) degradation product, TFP acid and non transient metabolite occurring at >5%AR 4'-OH bifenthrin have been investigated in laboratory rate of degradation studies (Roohi and Lowden, 2007 and Oddy and Mackenzie,2007) where these metabolites were applied as test substance that the RMS evaluated on pages 33-38 and 30-33 of the document the RMS named corrigendum 2 to Vol. 3 B.8 of the DAR dated June 2008. However when following European Commission regulations (EC) 1490/2002 and 1095/2007 it was not possible to consider the results from these studies in the peer review or consequently this conclusion. However the kinetic assessments for these metabolites from a laboratory study where bifenthrin was dosed as test substance as reported on pages 38-41 of the document the RMS named corrigendum 2 to Vol. 3 B.8 of the DAR dated June 2008 were agreed as acceptable by the member state experts (contrary to the view of the applicant with respect to TFP acid). Consequently a TFP acid single first order DT_{50} of 16.1 days (25°C, 63% of 1/3 bar (pF2.5) MHC), associated kinetic formation fraction 0.05 (17.3 days normalised to FOCUS reference conditions, 20°C and -10kPa) and 4'-OH bifenthrin single first order DT_{50} of 9.1 days (25°C, 63% of 1/3 bar (pF2.5) MHC), associated kinetic formation fraction 0.43 (9.8 days normalised to 20°C and -10kPa) are the only peer reviewed values available. As a consequence of Commission regulations (EC) 1490/2002 and 1095/2007, data gaps have to be maintained for information on the rate of degradation of TFP acid and 4'-OH bifenthrin in at least 2 further soils, though data are available and the RMS has evaluated these data and these data have the potential to address these data gaps.

[17] Using section 2.4.2 of the generic guidance for FOCUS groundwater scenarios, version 1.1 dated April 2002, assuming a Q10 of 2.2 and Walker equation coefficient 0.7.

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 on page 74 of the document the RMS named corrigendum 2 to Vol. 3 B.8 of the DAR dated June 2008 were the appropriate values from these trials. However they considered that as the experiments of Singer 1991 were semi field experiments that these 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 spread of data were too great (as concluded by the RMS, see pages 57-60 of the document the RMS named corrigendum 2 to Vol. 3 B.8 of the DAR dated June 2008). Therefore the range of a more reliable field dissipation study single first order DT_{50} for bifenthrin is 56 to 254 days (4 trial sites). In a further 3 experiments (2 additional trial sites, 1 experiment was from a site where the other experiment gave an SFO fit) double first order in parallel (DFOP) DT_{50} were 13 to 37 days, (associated DT_{90} 221 to 461 days). At a further site a first order multi compartment model (FOMC) DT_{50} was 43.5 days[18], (associated DT_{90} calculated (extrapolated) as 85955 days, though the later sampled time points were not well described by the curve). After a time step normalisation to reference soil temperature and soil moisture conditions, following the recommendations described in Chapter 9 of FOCUS kinetics guidance[19] (see pages 67 to 74 of the document the RMS named corrigendum 2 to Vol. 3 B.8 of the DAR dated June 2008) single first order DT_{50} for bifenthrin are 46 to 117 days (5 trial sites, shorter value of the 2 available for the Champaign loam excluded). At the remaining 2 trial sites the DFOP DT_{50} were 9.7 and 13.9 days (DT90 125 and 496 days respectively). Note the slower of the two phase DFOP DT_{50} of 57.8 and 266.6 days were used for calculating the FOCUS geomean. Consequently a FOCUS reference condition geometric mean single first order DT_{50} appropriate for use in FOCUS modelling of 84.6 days is calculated.

The longest available reliable field dissipation bifenthrin not normalised single first order soil DT_{50} of 254 days was agreed by the experts from the member states for use in PEC soil calculations (noting that calculations need to include the potential for accumulation). As a more conservative value of 274 days had been used in the calculations available (that included accumulation), consequently experts agreed that new calculations were not required. The resulting conservative PEC for the applied for intended use on cereals only can be found in appendix 1 and the document the RMS

[18] α=0.2132 ß=1.7508

[19]) "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration" Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp, the normalisation was done assuming a Q10 of 2.2 and Walker equation coefficient of 0.7.

named corrigendum 2 to Vol. 3 B.8 of the DAR dated June 2008 (that considered 25% crop interception and a 20cm soil mixing depth to calculate the 'valley' plateau, (0.0034 mg/kg) then added the final seasons two applications to 5cm, so the PEC would not cover minimum tillage practices for cereals, maximum accumulation concentration 0.0231 mg/kg). For TFP acid it was agreed as appropriate to multiply the maximum accumulated PEC soil for bifenthrin by the maximum observed molar formation (11.6%) and the ratio of the relative molecular (weights 242.5/422.9).

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_{doc} 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 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 argued 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 (see page 108 of the document the RMS named corrigendum 2 to Vol. 3 B.8 of the DAR dated June 2008). The member state experts agreed that for the relatively low application rates being requested as the applied for intended uses and the low persistence indicated for this metabolite (single first order DT_{50} 9.8 days, but a value is only available from a single soil) exceptionally they were content to consider groundwater modelling using the adsorption value of 130526mL/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.

It can be noted that the results from some new experimental work are available (Mills and Mackenzie, 2007) evaluated by the RMS on pages 78-80 of the document the RMS named corrigendum 2 to Vol. 3 B.8 of the DAR dated June 2008) that it was not possible to consider in the peer review or this conclusion as a consequence of European Commission regulations (EC) 1490/2002 and 1095/2007. However it can also be noted that these experimental data are unlikely to satisfy the data gap agreed by the member state experts: 'Soil adsorption measurements following the SCP opinion SCP/KOC/002-Final (adopted on 18 July 2002) in at least 3 different soils, as the guideline followed in the available experiments used a method that this SCP opinion 'did not recommend'.

Information on the soil adsorption of TFP acid is triggered but was not available. The applicant made the case that adsorption might be expected to be similar to the structurally related compound DCVA[20] which is a metabolite of cypermethrin. As adsorption data for DCVA were not in the applicants dossier, making reference to this is precluded by European Commission regulation (EC) 1095/2007, which prevents the use of new or additional studies (including data published in the open literature or another dossier, unless they are potentially adverse) in the peer review. As TFP acid is a carboxylic acid the member state experts expectation was that this metabolite will have low adsorption which is pH dependant and adsorption will decrease as pH increases. As a worst case, in the absence of data, an adsorption value of 0mL/g might be used in leaching assessments. The member state experts confirmed that a data gap for experimental data was appropriate to have reliable information for any future assessments that might be required.

Again it can be noted that the results from some new experimental work are available (Mills and Mackenzie, 2007) evaluated by the RMS on pages 78-80 of the document the RMS named corrigendum 2 to Vol. 3 B.8 of the DAR dated June 2008) that it was not possible to consider in the peer review or this conclusion as a consequence of European Commission regulations (EC) 1490/2002 and 1095/2007. However it can also be noted that these experimental data are unlikely to satisfy the data gap agreed by the member state experts: 'Soil adsorption measurements following the SCP opinion SCP/KOC/002-Final (adopted on 18 July 2002) in at least 3 different soils' for the same reasons noted above for 4'-OH bifenthrin.

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. Measurement of the UV visible absorption spectrum of aqueous solutions of bifenthrin indicated that direct aqueous photolysis of bifenthrin would be expected as there was significant absorption over the relevant wavelengths for sunlight of 290 to *ca.* 300nm and a satisfactory sterile aqueous photolysis study was not available. The member state experts agreed that due to strong adsorption, rapid partitioning of bifenthrin to sediment would be expected, so a sterile aqueous photolysis study was not necessary to complete the aquatic risk assessment. However the experts agreed that a data gap for a study to establish a valid quantum yield was appropriate, as this value has utility in assessment of fate and behaviour in the atmosphere. A ready biodegradability test (OECD 301B) 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

[20] DCVA: (1*R*,3*RS*)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylic acid

sediment system) and 93 days (0.7%oc sediment system)(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 identified 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 7-12 % AR and 3-27 %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.

FOCUS surface water modelling was evaluated up to step 4 for bifenthrin (See pages 120-124 for steps 1-3 and pages 124-128 step 4 of the document the RMS named corrigendum 2 to Vol. 3 B.8 of the DAR dated June 2008 for full details of the simulations agreed as the most appropriate available by the meeting of experts). The peer review agreed the output of these simulations with the exception of the step 4 runoff scenarios where it was unclear if the runoff mitigation used (80% for the water load and 95% for sediment load) might exceed the maximum runoff mitigation (overall 90% load) that is noted as being appropriate for EU level assessment in the FOCUS landscape and mitigation guidance[21]. The member state experts proposed a data gap for the applicant to address this (i.e. provide new step 4 calculations for the runoff scenarios or demonstrate that the overall mitigation of runoff inputs resulting from the currently available calculations was < 90%). Therefore the step 4 bifenthrin PEC that are agreed endpoints and included in appendix 1 just represent spray drift mitigation resulting from no spray buffer zones up to 25m. (Only values for drainage scenarios are presented). It should also be noted that the upper limit of spray drift mitigation noted as being appropriate for EU level assessment in the FOCUS landscape and mitigation guidance (95%) is respected by this 25m no spray buffer zone but mitigation provided by a 30m no spray buffer would be too great. A data gap is identified for PEC in surface water for the major soil metabolite TFP acid. Agreed FOCUS step 2 PEC sediment values for 4'-OH bifenthrin that can be a major metabolite in sediment are available. Whilst step 3 PEC sediment for 4'-OH bifenthrin are presented on pages 124-128 of the document the RMS named corrigendum 2 to Vol. 3 B.8 of the DAR dated June 2008, these are not agreed endpoints as the values presented are from simulations when only a single application was assumed and for PEC in sediment for a substance with such a high K_{oc} that may persist in sediment, the use from 2 applications should have been simulated for use in risk assessment.

[21] FOCUS (2007). "Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations". Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.

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

The conclusions of the peer review were that with the available database of studies (less than minimum annex II data requirements, for TFP acid and 4'-OH bifenthrin), the following chemical substance input parameters at FOCUS reference conditions would be the most appropriate to be used in FOCUS groundwater scenario modelling in the absence of additional data (pertinent data gaps are already outlined in sections 4.1.2 and 4.1.3). Bifenthrin single first order normalised field DT_{50} of 85 days, K_{foc} 236610 mL/g, 1/n=1.0; 4'-OH bifenthrin single first order laboratory DT_{50} 9.8 days, kinetic formation fraction of 4'-OH bifenthrin from bifenthrin 1.0, K_{foc} 130526 mL/g, 1/n=1.0; TFP acid single first order laboratory DT_{50} 17.3 days, kinetic formation fraction of TFP acid from bifenthrin 1.0, K_{foc} 0 mL/g, 1/n=1.0.

The applied for representative uses of applications to spring and winter planted cereals only were simulated using FOCUS PELMO 3.3.2 and PEARL 3.3.3 using substance input parameters for bifenthrin and 4'-OH bifenthrin that were close enough to those indicated above such that the difference would not be expected to effect the modelling output results. These results were that bifenthrin and 4'-OH bifenthrin were calculated to be present in leachate leaving the top 1m soil layer at 80th percentile annual average concentrations of <0.001µg/L at all 9 FOCUS groundwater scenarios. (See pages 107-110 of the document the RMS named corrigendum 2 to Vol. 3 B.8 of the DAR dated June 2008 for full details of the simulations). It was therefore concluded that the potential for contamination of groundwater above the 0.1µg/L parametric drinking water limit by parent bifenthrin and 4'-OH bifenthrin from the applied for representative uses in cereals only, is low over a broad range of vulnerable groundwater situations across Europe.

For the metabolite TFP acid, data gaps are identified for appropriate input parameters (geomean single first order soil DT_{50} from at least 2 further soils (an RMS evaluated but not peer reviewed study is available, so results for 4 soils are probably available), arithmetic mean kinetic formation fraction from parent bifenthrin, reliable K_{foc} from at least 3 different soils which should include an alkaline pH, as pH dependence is expected the use of a mean value is probably not appropriate) to be used in FOCUS scenario groundwater modelling using both PEARL and either PELMO or PRZM where the bifenthrin input parameters should be a single first order soil DT_{50} of 85 days (derived from field values normalised to FOCUS reference conditions) and K_{foc} 236610 mL/g, 1/n=1.0. Note that some simulations are available (See pages 109-110 of the document the RMS named corrigendum 2 to Vol. 3 B.8 of the DAR dated June 2008 for further details) that use some too favourable input parameters: bifenthrin DT_{50} too long (96 days used, peer reviewed value 85 days), TFP acid DT_{50} that is too short on the basis of the single agreed peer reviewed value (11 days used, peer reviewed agreed single value 17.3 days) and K_{foc} that might be too high (0.21 mL/g, 1/n 1 used, no peer reviewed value available). These simulations indicate that at 3 out of 6 FOCUS spring cereal scenarios and 3

out of 9 FOCUS winter cereal scenarios, TFP acid is calculated to be present in leachate leaving the top 1m soil layer at 80th percentile annual average concentrations above 0.1µg/L. Therefore the assessment of the potential for groundwater exposure by TFP acid must remain open whilst the identified data gaps are not filled. It cannot be completely excluded that if all the necessary data were available and appropriate simulations were carried out, that no scenarios would be shown to have 80th percentile annual average concentrations below 0.1µg/L. However under acid soil conditions it might well be that 0.1µg/L might not be breached in some climates. It is expected that non relevance assessments will be necessary for TFP acid. However these could not have been considered by the peer review due to the provisions of Commission Regulation (EC) No. 1095/2007.

4.3. FATE AND BEHAVIOUR IN AIR

The vapour pressure of bifenthrin ($1.78x10^{-5}$ Pa at 20°C) means that bifenthrin would be classified under the national scheme of The Netherlands as very slightly volatile, indicating 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 $1.5x10^{6}$ 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 of experts for ecotoxicology on 1st July 2008 on basis of the draft assessment report and the Addendum 2 Vol 3 (B.9).
The representative evaluated uses of bifenthrin *TALSTAR 8SC* were the use as insecticide with 1-2 applications in cereals (max 0.010 kg a.s./ha), in grapes (max 0.030 kg a.s./ha) and pome fruit (max 0.050 kg a.s./ha) with a 2 weeks interval between applications. The applicant informed the RMS and EFSA that they would provide no further or updated assessment to support the grape and orchard intended uses.

The risk assessment was conducted according to the following guidance documents: SANCO/4145/2000 (birds and mammals), SANCO/3268/2001 (aquatic environment), SANCO/10329/2002 (terrestrial environment), ESCORT 2 (non-target arthropods).

'In view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, the

new (i.e. newly submitted) studies provided after the DAR was first provided by the RMS to EFSA could not be considered in the peer review.'

The section on fate and behaviour in the environment concluded that "the environmental exposure assessment has not been finalised for the uses on grapes and pome fruit. Therefore; for the uses in grapes and pome fruit data gaps for the predicted environmental concentrations to be calculated for the different environmental compartments, have been identified in this conclusion".
As a consequence the risk assessment for secondary poisoning to birds and mammals, soil and aquatic organisms for the uses in grapes and pome fruit are outstanding. Pertinent data gaps are therefore identified.

5.1. RISK TO TERRESTRIAL VERTEBRATES

The acute and dietary LD_{50}/NOED for birds were 1800 mg a.s./kg bw /day and 104.5 mg a.s./kg bw /day. The long-term reproductive endpoint NOEC was 6.63 mg a.s./kg bw/d. The assessment of short-term risk the calculations was 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.
First tier risk assessment for birds resulted in TER values above the Annex VI triggers values for cereals. EFSA has some concerns about the RUD values used in the first tier risk assessment for grapes and orchards presented in the DAR. Therefore, the first tier risk assessment for birds for grapes and orchards were re-estimated by EFSA. This re-estimation resulted in TER values above the Annex VI trigger values for grapes and for orchards, except for the long-term TER for insectivorous birds in orchard.
In conclusion, the acute, short-term and long-term risk to birds was considered to be low for all the evaluated uses. However, a potential high long-term risk was identified for the insectivorous birds in orchards.
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 TER value above the Annex VI trigger value suggesting that the acute risk to mammals was low for cereals. First tier risk assessment for grapes and orchards were re-estimated by EFSA while drafting the conclusion and resulted in an acute TER value above the Annex VI trigger value for the use in grapes. However, the acute TER value for herbivorous mammals was below the Annex VI trigger value in the use in orchards. Indicating that the acute risk of bifenthrin to mammals was low for grapes but not for orchards.
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 TER_{lt} values of 93.4 and 3.9 for insectivorous and herbivorous mammals, respectively, for cereals. First tier risk assessment for grapes and orchards were re-estimated by EFSA and resulted in long-term TER values below the Annex VI trigger value for grapes and orchards for herbivorous mammals.

In conclusion in the first tier risk assessment, a potential high long-term risk of bifenthrin to mammals was identified for all the intended uses. Therefore a refinement of the long term risk to mammals is required for all the evaluated uses.

Bifenthrin has a log P_{ow} of 7.3, therefore the risk from secondary poisoning should be considered. In cereals the risk assessment for earthworm-eating birds resulted in TER value above the Annex VI trigger, whereas the TER value for earthworm-eating mammals breached the trigger. This suggests that the risk of bifenthrin to earthworm-eating birds was considered to be low in cereals; however, a potential high risk was identified for earthworm-eating mammals in cereals and a refinement of the risk is required.

The member state experts agreed that the potential for bifenthrin to accumulate in aquatic organisms needs to be further addressed. A new data gap was identified during the meeting, for the applicant to submit further information to address the risk of bioaccumulation in lines with the aquatic guidance document. Therefore, the risk for fish eating birds and mammals should be re-estimated once an appropriate BCF value can be identified. However, a risk assessment was provided based on the range of BCF values available (1,330-30,000). TERs in the range of 8,823 to 265,200 for fish-eating birds and mammals indicated a low risk. The margin of safety suggested that revision of the BCF would not change the conclusion for fish-eating birds and mammals.

The risk to birds and mammals from intake of contaminated drinking water from surface water or puddles was considered to be low for cereals. The risk through drinking water for the use in grapes and orchards was not addressed in the DAR. The TER values were estimated by EFSA based on 10 g birds and mammals. TERs values for birds and mammals were 222 and 9 for the use in grapes, and TER values were 667 and 27 for the use in orchards. The TERs were above the Annex VI trigger value, except the TER for mammals in the grapes scenario. The risk to birds and mammals from uptake of drinking water from leaf axils were considered to be low for grapes and orchard, except for mammals that intake contaminated water in the grapes scenario. Therefore, further refinement was necessary to address the risk to mammals from drinking contaminated puddle water in grapes.

In conclusion, the acute, short-term and long-term risk to birds was low for all the evaluated uses; however, a potential high long-term risk was identified for insectivorous birds in orchards. A data gap was identified for the refinement of the long-term risk to insectivorous birds in orchards. The acute risk of bifenthrin to mammals was low for cereals and for grapes but not for orchards. A potential high long-term risk of bifenthrin to herbivorous mammals was identified for all the intended uses. A data gap was identified after the PRAPeR meeting by EFSA, for the applicant to refine the acute risk of bifenthrin to mammals in orchards and a data gap to provide a refinement for the long-term risk for

mammals for all the intended uses. The risk from the use of bifenthrin to earthworm-eating birds was considered low for cereals. A potential high risk was identified for earthworm eating mammals in cereals and a refinement of the risk assessment was required. The risk assessment for fish eating birds and mammals should be re-estimated when the revised BCF would become available. The risk to fish-eating birds and mammals was however considered to be low.

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. EC_{50} values for fish and Daphnids were 0.10 and 0.11 µg a.s./L, respectively. With regards 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 and aquatic invertebrates. However, a low risk was identified for alga at FOCUS Step1. The TER calculations for fish and aquatic invertebrates based on PEC_{sw} step 3 did not meet the Annex VI criteria. The TER estimation based on the FOCUS PECsw step 4 (20-25 m no-spray buffer zone) were below the Annex VI trigger value of 100 and 10 for fish and aquatic invertebrates.

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; 6-8 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 NOAEC 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 NOAEC suggested by RMS, a review by Blake (2007) was provided by the applicant. Blake's review proposed an NOEAEC of 0.037 µg a.s./L, based on arguments that direct effects on zooplankton was recovered within 42 days. 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. A HC_5 value derived from a single-species toxicity data for arthropods was 0.017 µg/L, supported the NOEAEC derived from the mesocosm study. RMS in addendum 2 (June 2008) clarified their selection of a NOEAEC of NOAEC = 0.015 µg a.s /L in the DAR . 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 required 84 days after the treatment to recover. The time to recovery 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 in to account indirect effects and could not be directly compared to a NOAEC from the mesocosm study. For these reasons the RMS still considered that that the use the NOAEC =

0.015 µg a.s./L, (as proposed in the DAR), was the most appropriate regulatory endpoint for this mesocosm study. The member state experts at the PRAPeR meeting discussed the endpoint. It was unclear to the member state experts if the HC_5 of 0.017 µg/L presented in the review by Blake (2007) was the minimum or the mean value. In case it was a $HC_5^{0.05}$ value, member states considered it to be a protective endpoint for the class 2 effects from the mesocosm. The meeting considered that further details were 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. In conclusion it was agreed with available information that the NOEAEC of = 0.015 µg a.s./L should be used with an assessment factor of 3, as proposed by RMS.

It was agreed to apply an assessment factor of 3 to this value to 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 NOAEC from the mesocosm and initial FOCUS PEC_{sw} Step 4 with 20 m non-spray buffer zones in cereals.

The risk to sediment dwelling organisms was addressed by means of a chronic study with *Chironomus riparius*. 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.

Due to the $logP_{ow}$ of 7.3 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 partioning to sediment decreased the bioavalability 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. 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 from 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 needs to be further addressed. Hence, the experts agreed that the potential for bifenthrin to accumulate in aquatic organisms needs 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 RMS (Gries and Schanne (2006)) 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 cannot be considered by the peer review or this conclusion.

The experts agreed to propose a new data gap to the applicant should address the uncertainty related to the BCF estimation in order to derive a valid BCF.
A new data gap was identified during the PRAPeR 52 meeting, applicant to submit a further address the risk of bioaccumulation in line with the aquatic guidance document.
In conclusion three data gaps were identified during the meeting of experts, first one for the submission of a refined risk assessment for fish / aquatic vertebrates (testing of further fish species may well be necessary) and the second for the submission of the ecotoxicological studies with the TFP acid, since aquatic organisms were expected to be exposed to this metabolite (see section 4.2.1). The potential for bifenthrin to bioaccumulate in aquatic organisms needs to be further addressed.

5.3. RISK TO BEES

Bifenthrin was highly toxic to bees. LD_{50} from oral and contact tests with TALSTAR 8SC were 0.01 and 0.0016 µg a.s./bee, respectively. Hazard quotients were calculated to be in the range of 2000 to 10000 for oral exposure and 12500 to 62500 for contact exposure for the different uses. 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". None of the higher tier tests were conducted in vineyards or orchards and wheat was the only cereal in which impacts on bees were tested. The tests were run in attractive crops like alfalfa or *Phacelia tanecetifolia*. Six studies were conducted at dose rates of 30 g a.s./ha or higher and four studies with a dose rate of 50 g a.s./ha or higher. None of these studies included more than one application. 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 52 meeting concluded that a high risk could not be excluded for bifenthrin to bees for the evaluated use in cereals and the risk to bees should be managed by using appropriate mitigation measures. (SPe safety phrase to avoid the application during the bee flight).

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 with *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}s 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. In-field HQ values for *A. rhopalosiphi* were in the range of 2.08 to 10.4 for the different uses and from 150 to 752 for *T. pyri*.

Off-field HQ values for the more sensitive *T. pyri* were 0.43 at 5m from the field in cereals, 1.47 at 15 m in vine and 1.20 at 40 m in orchards.

The LR_{50} derived for *C. septempunctata* was even lower than the one for *T. pyri* (0.03 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} = 0.03 g a.s./ha as the endpoint for the *C. septempunctata* .

Two aged residue studies with *A. rhopalosiphi* and *C. septempunctata* demonstrated several 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 fields studies with low application rate 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, vine and orchards. Risk mitigation measures are required to refine the risk to NTA in the off-field areas. A non-spray buffer zone of 5 m, was required for cereals. Hazard quotients for use in vine or orchards were provided in the DAR.

A data gap was identified for the applicant to refine the in-field risk to non-target arthropods.

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 to 2.13 mg TALSTAR 8SC/kg soil, equivalent to 0.168 mg a.s./kg soil. TER values were calculated using the soil maximum PEC (accumulated value calculated at 23.1µg /kg soil) and were found to be well above the Annex VI trigger for acute effects indicating a low acute risk of bifenthrin to earthworms. The TER values for chronic effects were 3.64 for the use in cereals. Thus the long-term risk to earthworms in cereals was considered to be high and needs to be further addressed, e.g. by a field study. 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 PECsoil values was above the Annex VI trigger values. The experts in the meeting agreed that a chronic risk assessment was not necessary for the metabolite, due to the low persistence of the metabolite. EFSA considered after the meeting that this needs changing as there will be long term exposure even though the soil half life is short as the degradation rate of the precursor parent bifenthrin is very slow. So the reasoning is not scientifically correct and the data gap for the applicant to address the chronic risk to earthworms for this metabolite was identified.

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

A litterbag study (Walker H. 2005) 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 was presented by the RMS in Addendum 2, that was considered by the meeting of experts. This study shows no effects of bifenthrin on the litter decomposition. However the experts at the PRAPeR 52 meeting agreed that the litter bag study did not cover the risk for the macro organisms in the case of pyrethroid compounds.

A data gap was identified to the applicant to address the risk to non-target soil macro-organisms. It might be possible to use the available data on NTA to support the risk assessment for these organisms.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The formulation TALSTAR 8SC 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 2.9 times above the plateau concentration in orchards 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 peer review or this conclusion as a consequence of European Commission regulations (EC) 1490/2002 and 1095/2007 as this is a new (i.e. newly submitted) study. Consequently a data gap was identified for the submission of a risk assessment to non-target plants.

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 from the proposed uses. The risk to biological methods of sewage treatments plants is considered to be low.

6. Residue definitions

Soil

Definitions for risk assessment: constituent isomers of bifenthrin and isomers of TFP acid[22]

Definitions for monitoring: at least constituent isomers of bifenthrin but a data gap need to be filled before this can be finalised.

[22]TFP acid: (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylic acid

Water

Ground water

Definitions for exposure assessment: constituent isomers of bifenthrin, isomers of TFP acid and isomers of 4'-OH bifenthrin[23]

Definitions for monitoring: at least constituent isomers of bifenthrin but data gaps need to be filled before this can be finalised.

Surface water

Definitions for risk assessment: water: constituent isomers of bifenthrin and isomers of TFP acid

Sediment: constituent isomers of bifenthrin and isomers 4'-OH bifenthrin

Definitions for monitoring: at least constituent isomers of bifenthrin but data gaps need to be filled before this can be finalised.

Air

Definitions for risk assessment: constituent isomers of bifenthrin

Definitions for monitoring: constituent isomers of bifenthrin

Food of plant origin

Definitions for risk assessment: constituent isomers of bifenthrin

Definitions for monitoring: constituent isomers of bifenthrin

Food of animal origin

Definitions for risk assessment: **provisional:** for liver and kidney: sum of constituent isomers bifenthrin and BP-acid[24] expressed as bifenthrin (conversion factor of 2 for monitoring to risk assessment); for eggs: sum of constituent isomers bifenthrin and OH-methyl bifenthrin[25] and its fatty acid conjugates, expressed as bifenthrin (conversion factor of 2 for monitoring to risk assessment); for all other animal products: constituent isomers bifenthrin

Definitions for monitoring: **provisional:** constituent isomers of bifenthrin

[23] 4'-OH bifenthrin: (4'-hydroxy-2-methylbiphenyl-3-yl)methyl (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate

[24] BP-acid: 2-methyl-3-phenylbenzoic acid

[25] OH-methyl bifenthrin: (2-methylbiphenyl-3-yl)methyl (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2-(hydroxymethyl)-2-methylcyclopropanecarboxylate (unknown stereochemistry).

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

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Bifenthrin isomers	Moderate to high persistence Single first order DT_{50} 53-192 days (20°C, -10kPa soil moisture) Single first order DT_{50} 56-254 days (field studies) DFOP DT_{50} 13-37 days (DT90 221-461 days, field studies)	The LC_{50corr} > 8 mg a.s./kg soil. The risk of bifenthrin was identified as low. A potential high long-term risk was identified for earthworms.
Isomers of TFP acid	Moderate persistence Single first order DT_{50} 17.3 days (20°C, -10kPa soil moisture)	Data gap

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
Bifenthrin isomers	immobile K_{foc} 130526-301611	No	Yes	Yes	Yes

Compound (name and/or code)	**Mobility in soil**	**> 0.1 µg / L 1m depth for the representative uses** **(at least one FOCUS scenario or relevant lysimeter)**	**Pesticidal activity**	**Toxicological relevance**	**Ecotoxicological activity**
	mL/g				
Isomers of TFP acid	Data gap	Data gap, but expected to be > 0.1µg/L in some, if not all FOCUS scenarios.	Data gap	Data gap. More extensive experimental evidence will be required, should the proposed classification of the parent (R23, R25 and R40 Carc. Cat 3) be confirmed in the context of the European Chemicals Agency (EChA) programme for classification and labelling under Directive 67/548.	Data gap
isomers of 4'-OH bifenthrin	Data gap but expected immobile	No	No data available assessment not triggered	No data available assessment not triggered	Assessed as low

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Bifenthrin isomers	A potential high risk was identified for all the aquatic organisms.
Isomers of TFP acid (water only)	Data gap
isomers of 4'-OH bifenthrin (sediment only)	A low risk was identified for aquatic organism.

Air

Compound (name and/or code)	Toxicology
Bifenthrin isomers	Harmful by inhalation (R23 proposed, based on LC50 1.01 mg/L)

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

- A revised specification for the technical material for the reference source (relevant for all representative uses evaluated, data gap identified by PRAPeR 51 meeting (June 2008), date of submission unknown; refer to chapter 1)
- Five batch data for the new additional source (relevant for all representative uses evaluated, data gap identified by PRAPeR 51 meeting (June 2008), data already submitted and evaluated in an addendum, not peer-reviewed; in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, refer to chapter 1)
- Information on the enantiomeric composition with respect to the *cis* configuration at the cyclopropane moiety of the starting material (relevant for all representative uses evaluated, data gap identified by EFSA after the expert meetings(September 2008), date of submission unknown; refer to chapter 1).
- Information on the starting materials for the production of the technical material for the two additional manufacturing sources (relevant for all representative uses evaluated, data gap identified by PRAPeR 51 meeting (June 2008), date of submission unknown; refer to chapter 1).
- Validation data concerning linearity of method APG 492 for the determination of pure active substance and impurities in the active substance as manufactured (relevant for all representative uses evaluated, data gap identified by PRAPeR 51 meeting (June 2008), date of submission unknown; refer to chapter 1)
- Determination of the boiling point (relevant for all representative uses evaluated, data gap identified by RMS confirmed by PRAPeR 51 meeting (June 2008), date of submission unknown; refer to chapter 1)
- A 2 years shelf life study for the NPE-free formulation (relevant for all representative uses evaluated, data gap identified by RMS confirmed by PRAPeR 51 meeting (June 2008), date of submission unknown; refer to chapter 1)
- A sterile aqueous quantum yield photolysis study with bifenthrin as test substance (relevant for all representative uses evaluated, data gap identified by PRAPeR 52 meeting (June 2008), date of submission unknown; refer to chapter 1 and 4.2.1)
- Methods for the determination of bifenthrin residues in food/feed of animal origin, except eggs (relevant for all representative uses evaluated, data gap identified by PRAPeR 51 meeting (June 2008), data already submitted, evaluated in an addendum, not peer-reviewed in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007; refer to chapter 1)

- Method for the determination of bifenthrin residues in air (relevant for all representative uses evaluated, data gap identified by PRAPeR 51 meeting (June 2008), date of submission unknown; refer to chapter 1)
- Primary and confirmatory method for the determination of bifenthrin residues in body fluids and tissues (relevant for all representative uses evaluated, data gap identified by RMS, confirmed by PRAPeR 51 meeting (June 2008), date of submission unknown, however some data were already submitted and evaluated in an addendum, not peer-reviewed in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007; refer to chapter 1)
- Operator, worker and bystander risk assessment for uses on grapes and pomefruits (relevant for uses on grapes and pomefruits, data gap identified at PRAPeR meeting 49, date of submission unknown; refer to chapter 2.12)

- Sufficient number of pome fruit residue trials in accordance with the GAP for Northern and Southern Europe products (relevant for representative uses on pome fruit; identified by PRAPeR 55 meeting and EFSA after the meeting respectively; study reports containing some additional trials have been submitted in April 2007; however they could not be considered by the peer review as a consequence of Commission Regulations (EC) No 1490/2002 and 1095/2007; sub mission date proposed by the notifier for further requested trials: unknown; refer to point 3.1.1).
- Sufficient number of grape residue trials in accordance with the GAP for Northern and Southern Europe products (relevant for representative uses on grapes; identified by PRAPeR 55 meeting, submission date proposed by the notifier: unknown; refer to point 3.1.1).
- Sufficient number of residue trials for barley in accordance with the GAP for Northern and Southern Europe products (relevant for representative uses on cereals (barley and oats); identified by PRAPeR 55 meeting and EFSA after the meeting respectively; study reports containing some additional trials have been submitted in April 2007; however they could not be considered by the peer review as a consequence of Commission Regulations (EC) No 1490/2002 and 1095/2007; sub mission date proposed by the notifier for further requested trials: unknown; refer to point 3.1.1).
- Sufficient number of residue trials for wheat/triticale in accordance with the GAP for Southern Europe products (relevant for representative uses on cereals; identified by EFSA, study reports containing 2 trials have been submitted in April 2007, however they could not be considered by the peer review as a consequence of Commission Regulations (EC) No 1490/2002 and 1095/2007; refer to point 3.1.1).
- Storage stability data for bifenthrin and its metabolites in animal products (relevant for representative uses on cereals and pome fruit); study reports have been submitted in April 2007,

however they could not be considered by the peer review as a consequence of Commission Regulations (EC) No 1490/2002 and 1095/2007; refer to point 3.2).

- Impact of possibly different metabolism of enantiomers on the consumer risk assessment of bifenthrin needs to be addressed (relevant for all applied for intended uses; identified by EFSA after the experts meeting, submission date proposed by the notifier: unknown; refer to point 3.3).
- A groundwater relevance assessment for isomers of TFP acid, according to the Guidance Document on the assessment of relevance of metabolites in groundwater Sanco/221/2000-rev.10 (relevant for at least the representative uses evaluated on cereals; submission date proposed by the notifier: unknown; refer to points 2.8 and 4.2.2)
- An anaerobic soil degradation study dosed with bifenthrin (relevant for the representative uses evaluated on cereals and pome fruit in territories where anaerobic soil conditions cannot be excluded; submission date proposed by the notifier: unknown; refer to point 4.1.1)
- Aerobic rate of degradation studies in at least a further 2 different soils for the soil metabolites TFP acid and 4'-OH bifenthrin (relevant for all representative uses evaluated; two study reports are available and have been evaluated by the RMS, however these could not be considered by the peer review as a consequence of Regulations (EC) No 1490/2002 amended by Regulation (EC) No 1095/2007; refer to point 4.1.2)
- Soil adsorption measurements following recommendations contained in SCP opinion SCP/KOC/002-Final (adopted on 18 July 2002) in at least three different soils covering a range of pH including alkaline soils for the soil metabolites TFP acid and 4'-OH bifenthrin (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; refer to point 4.1.3)
- Groundwater and surface water (including sediment) exposure estimates (Predicted environmental concentrations (PEC)) are required for TFP acid using the results of the data gaps identified for soil adsorption and soil degradation rate estimates for this metabolite, using FOCUS scenarios and tools. For groundwater the PEARL model and PELMO or PRZM model should be used for simulations (relevant for the representative uses evaluated on cereals; submission date proposed by the notifier: unknown; refer to points 4.2.1 and 4.2.2)
- Demonstration required that the overall runoff mitigation achieved by the bifenthrin step 4 runoff scenario FOCUS surface water calculations (as reported on pages 124 to 128 of the document the RMS names corrigendum 2 to volume 3 B.8 of the DAR) are not greater than 90%. If the overall mitigation is greater than 90%, new FOCUS step 4 calculations in line with FOCUS guidance (2007) are required (relevant for the representative uses evaluated on cereals; submission date proposed by the notifier: unknown; refer to point 4.2.1)
- PEC in soil (including accumulation from use in successive years), surface water, sediment and groundwater and consequent soil dwelling organism and aquatic risk assessments (relevant for the uses in grapes and pome fruit; the applicant has indicated that they are no longer supporting the assessment of use in these crops at the EU level; refer to points 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 toxicity and/or on the degradation of the 2 isomers in the environment is needed. (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; refer to sections 4 and 5).
- The long-term risk to insectivorous birds from bifenthrin needs to be addressed by a refined assessment (relevant for use in orchards; the applicant has indicated that they are no longer supporting the assessment of use in these crops at the EU level; data gap identified in the DAR ; refer to point 5.1)
- The acute risk of bifenthrin to mammals needs to be addressed by a refined assessment. (relevant for orchards; the applicant has indicated that they are no longer supporting the assessment of use in these crops at the EU level, data gap was identified after the peer review process by EFSA; refer to point 5.1)
- A refinement of the risk characterisation is required for the earthworm-eating mammals in the cereals scenario. (relevant for cereals; submission date proposed by the notifier: Unknown; data gap was identified by in the Addendum 2; refer to point 5.1)
- The risk for fish eating birds and mammals should be re-estimated once the BCF value will be available.(relevant for all representative uses evaluated; submission date proposed by the notifier: Unknown; data gap identified in the PRAPeR 53; refer to point 5.1)
- Further refinement is necessary to address the risk to mammals from drinking contaminated puddle water in grapes (relevant for grapes; the applicant has indicated that they are no longer supporting the assessment of use in this crop at the EU level; data gap was identified after peer review by EFAS; refer to point 5.1)
- The long-term risk for mammals needs to be refined (relevant for all evaluated uses; submission date proposed by the notifier: Unknown; data gap was identified in the DAR by RMS; refer to point 5.1)
- The uncertainty related to the BCF estimation from fish studies in order to derive a valid BCF needs to be addressed. (relevant for all representative uses evaluated; submission date proposed by the notifier: Unknown, note a new fish bio-accumulation study is available and has been evaluated by the RMS, however this could not be considered by the peer review as a consequence of Regulations (EC) No 1490/2002 amended by Regulation (EC) No 1095/2007. This data gap relates to a consideration of the uncertainty indicated by all the available studies; data gap was identified during the PRAPeR 53 meeting; refer to point 5.2)
- The risk of bioaccumulation needs to be addressed further in the aquatic risk assessment in line with the aquatic guidance document (relevant for all representative uses evaluated; submission date proposed by the notifier: Unknown; data gap was identified during the PRAPeR 53 meeting; refer to point 5.2)

- It was identified that a refined risk assessment to fish is necessary (relevant for cereals; submission date proposed by the notifier: Unknown; data gap identified in the DAR by the RMS; refer to point 5.2)
- Studies investigating the potential effects of TFP acid to aquatic organisms are required (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; data gap was identified in the Addendum 2 by the RMS; refer to point 5.2)
- A refined risk characterisation to non-target arthropods is outstanding to identify safe uses (relevant for all representative uses evaluated; submission date proposed by the notifier: Unknown; data gap was identified in the Addendum by the RMS: refer to point 5.4)
- A refinement of the long-term risk of bifenthrin and TFP acid to earthworms (relevant for all representative uses evaluated; submission date proposed by the notifier: Unknown; data gap was identified in the Addendum by the RMS refer to point 5.5)
- The risk to non-target soil macro-organisms needs to be addressed. The applicant may wish to take into account the available data on non target arthropods should they address this in the future. (relevant for all representative uses evaluated; submission date proposed by the notifier: Unknown; data gap was identified in the PRAPeR 53 expert meeting : refer to point 5.5)
- A risk assessment to non-target plants. (relevant for all evaluated uses; a study report is available and has been evaluated by the RMS, however this could not be considered by the peer review as a consequence of Regulations (EC) No 1490/2002 amended by Regulation (EC) No 1095/2007; data gap was identified in the PRAPeR 53 expert meeting refer to point 5.8)

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, mites, aphids in cereals, grape and pome fruit, in all EU countries, at maximum two applications, at maximum application rate per treatment of 10 g a.s./ha (cereals), 30 g a.s./ha (grape) and 50 g a.s./ha (pome fruit) respectively, with interval between applications of 2 weeks. It should be noted however, that the uses on grape and pome fruit are no longer supported by the notifier for annex I inclusion.

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

Since clarification is required with respect to the proposed maximum levels of certain impurities in the technical material, the specification as a whole should currently be regarded as provisional.

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 is possible.
Adequate methods are available to monitor bifenthrin residues in food/feed of plant origin, soil and water, however data gaps were identified for residue methods in food/feed of animal origin air and body fluids and tissues.

As for mammalian toxicity, bifenthrin is "Toxic if swallowed" (R 25), it is toxic by inhalation (R 23 "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-yr dog with an SF 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 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 metabolism studies on apples, cotton seed and corn plants bifenthrin was found to be the predominant residue. No significant cis- trans-isomerisation and translocation of residues through the plant were observed. Only for wheat/triticale and rye grown in Northern Europe sufficient residue trials have been submitted. Additional residue trial data are required for barley and oats in Northern Europe and all cereal crops grown in Southern Europe. On the basis of the available trials in cereals MRLs were only provisionally proposed. The representative uses in pome fruit and grapes are currently not supported by residue trials carried out according to the notified cGAP.
For the use on cereals no processing studies are required. The requirement of such studies for the uses on pome fruit and grapes has to be evaluated once sufficient data on residue trails are available. Metabolism studies on rotational crops show that no significant residues are expected in parts of rotational crops intended for human consumption after application of bifenthrin on cereals according to the notified GAP.

Metabolism studies on lactating goats and laying hens show that metabolism, mainly by oxidation, cleavage of the ester binding and conjugation, is more extensive in some of the compartments. The experts meeting decided to include metabolites in the provisional residue definition for risk assessment for liver and kidney and eggs respectively. On the basis of provisional dietary burden calculations for intake of cereal and straw only, significant up-take of residues is only expected for cattle.
Taking into account the intake of cereals and of animal products only, consumer exposure is expected to be below the toxicological reference values. However, this risk assessment is only indicative and pending additional data for diverse areas of the residue section.

The peer reviewed information available on the fate and behaviour in the environment is sufficient to carry out an appropriate environmental exposure assessment at the EU level with the notable exceptions that the groundwater and surface water exposure assessments for the major soil metabolite TFP acid cannot be finalised (satisfactory information on soil adsorption is missing and sufficient peer reviewed soil persistence information is not available). Also further information is required to refine via mitigation measures the surface water exposure from bifenthrin in run off situations. Satisfactory environmental exposure assessments are not available for the applied for intended uses on grapes and pome fruit. The available soil exposure assessment does not cover minimal tillage production systems for cereals. For the applied for intended uses on cereals, the potential for groundwater exposure by bifenthrin and its soil metabolite 4'-OH bifenthrin above the parametric drinking water limit of 0.1 µg/L, is low. Using the available information, it is likely that in at least some vulnerable groundwater situations the metabolite TFP acid will have the potential to be present in groundwater above 0.1µg/L. A groundwater non relevance assessment for TFP acid that could be considered by the peer review is not available.

The long-term risk to insectivorous birds and the acute risk to mammals in orchards need further refinement. A potential high long-term risk of bifenthrin to mammals was identified for all the intended uses and needs further refinement. A potential risk was identified for earthworm-eating mammals in cereals and also needs further refinement. The risk assessment for fish eating birds and mammals should be re-estimated when the revised BCF would become available. The risk to fish-eating birds and mammals was however considered to be low.
From the mesocosm study a NOAEC of 0.015 µg a.s./L was derived. It was proposed to apply a safety factor of 3 to this value to 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 NOAEC from the mesocosm and initial FOCUS PEC_{sw} Step 4 with 20 m non-spray buffer zones in cereals. No safe use was identified for fish / aquatic vertebrates when the largest appropriate (95% spray drift reduction) no spray buffer zone of 25m was considered. The risk to aquatic vertebrates therefore needs further refinement through additional effects data.

The experts agreed that the potential for bifenthrin to accumulate in aquatic organisms needs to be addressed further. A data gap was identified for the submission of aquatic ecotoxicity studies with the metabolite TFP acid.

A high risk was identified for bifenthrin to bees for all the evaluated uses so it is necessary to manage the risk to bees by using appropriate mitigation measures. There is a high risk to non-target arthropods (NTA) for in-field and off-field areas from the use in cereals. Risk mitigation measures are required to refine the risk to NTA in the off-field areas. A non-spray buffer zone of 5 m was identified as necessary for cereals. A data gap was identified to the applicant to refine the risk to NTA. The long-term risk to earthworms in cereals was considered to be potential high, and needs to be further addressed for both bifenthrin and TFP acid.

A litterbag study showed no effects of bifenthrin to the litter bag decomposition. Member States at the PRAPeR 52 meeting agreed that the litter bag study did not cover the risk for the macro organisms in the case of pyrethroid compounds. A data gap was identified to the applicant to address the risk to non-target soil macro-organisms. The risk to non-target plants should be addressed.

The risk to micro-organisms and biological methods of sewage treatment was assessed as low for all representative uses.

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, 2 of the 8 experiments available have half lives longer than 6 months (in 4 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 DT50) can be greater than 6 months.

Bioaccumulation potential:
Evidence that the bio-concentration factor or bio-accumulation factor in aquatic species is greater than 5000
Relevant studies are available on 3 different fish species. Bio-concentration 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).* Note that a data gap is identified in relation to further information being required in relation to finalising a conclusion on the BCF.

Monitoring data in biota indicating a bio-accumulation 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 or
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 1.5×10^6 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" (R 25), it is toxic by inhalation (R 23 "toxic by inhalation" proposed) and is a skin sensitiser (R43 "May cause skin sensitisation by skin contact" proposed). The main effect observed for repeated exposures is tremor and/or neurotoxic effects.

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

- Non-spray buffer zones of 20 m are required to protect the aquatic invertebrates for the use in cereals (refer to point 5.2).
- The experts at the PRAPeR 52 meeting concluded that a high risk was identified for bifenthrin to bees for all the evaluated uses and to manage the risk to bees by using appropriate mitigation measures. (SPe safety phrase to avoid the application during the bee flight).
- Non-spray buffer zone of 5 m is required to protect the non target arthropods in the off- field treated areas for the use in cereals (refer to point 5.4).

Critical areas of concern

- Risk assessment for the consumer cannot be finalised due to data gaps identified in different areas of the residue section.
- The groundwater exposure assessment for the major soil metabolite TFP acid is not finalised. If all the necessary data were available and appropriate simulations were carried out, at least some, if not all FOCUS groundwater scenarios would indicate concentrations above the parametric drinking water limit of 0.1µg/L. A groundwater relevance assessment for TFP acid that could be considered by the peer review is not available.
- Long-term risk to mammals needs further refinement for all the evaluated uses.
- The risk to earthworm-eating mammals in cereals should be refined.
- For the use in cereals the maximum drift mitigation (95%) agreed in EU guidance that is provided by a no spray zone of 25 m is insufficient to demonstrate there will not be an impact on aquatic vertebrates using the available ecotoxicology data.
- The assessment of the bioconcentration factor to use in the environmental risk characterisation is not finalised.
- The in-field risk to non-target arthropods should be refined.
- The chronic risk of bifenthrin and its metabolite TFP acid to earthworms should be further addressed.
- The risk to non-target soil macro-organisms needs to be refined.
- The risk of bifenthrin to non-target plants needs to be addressed.

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

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

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	

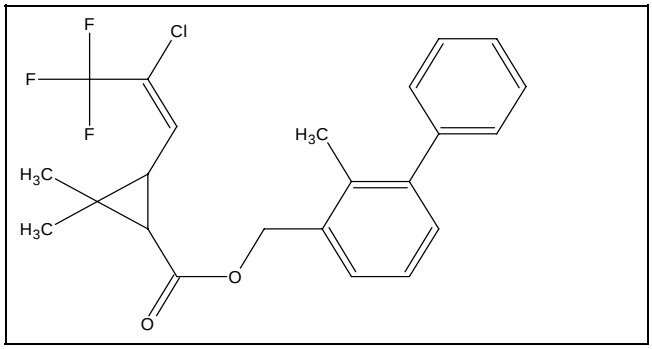
Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	2-methylbiphenyl-3-ylmethyl (1*RS*)-*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-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2,-dimethyl-cyclopropanecarboxylate
CIPAC No ‡	415
CAS No ‡	82657-04-3
EC No (EINECS or ELINCS) ‡	NA
FAO Specification (including year of publication) ‡	None
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	none
Molecular formula ‡	$C_{23}H_{22}ClF_3O_2$
Molecular mass ‡	422.88 g/mol

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

Appendix 1 – list of endpoints

Structural formula ‡



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

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Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	68.9-70.2 °C (98.8 %)
Boiling point (state purity) ‡	Study required
Temperature of decomposition (state purity)	Study required
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 n-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 $P_{O/W}$ = 7.3 at 20°C (pH 5)
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%)

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

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Oxidising properties ‡ (state purity)	No oxidizing properties (94.93%)

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

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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		
Cereals	EU N & S	TALSTAR 8SC	F	Sucking and biting insects Virus vectors (aphids)	SC	80 g/L	Spraying	Acc. to official warnings	1-2	2 weeks	0.002 - 0.0066	150-400	0.008-0.010	28/35 d	[1] [2] [3]
Grape	EU N & S	TALSTAR 8SC	F	Sucking and biting insects Mite Virus vectors (aphids)	SC	80 g/l	Spraying	Acc. to official warnings	1-2	2 weeks	0.002 - 0.015	200 - 1000	0.020-0.030	7 d 21 d	South table north and south wine [1] [2] [3] [4]

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

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Pome fruit	EU N & S	TALSTAR 8SC	F	Sucking and biting insects Mite	SC	80 g/l	Spraying	Acc. to official warnings	1-2	2 weeks	0.002 - 0.005	1000	0.020-0.050	14 d	[1] [2] [3] [4]

* For uses where the column "Remarks" is marked in grey further consideration is necessary.
Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

[1] The environmental risk assessment is not finalised
[2] The groundwater assessment for the metabolite TFP acid is not finalised
[3] Risk assessment not finalised in the residue section
[4] The operator, worker and bystander risk assessment is not finalised

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

Appendix 1 – list of endpoints

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		constituent isomers of bifenthrin
Food of animal origin		constituent isomers of bifenthrin (provisional)
Soil		constituent isomers of bifenthrin (provisional)
Water	surface	constituent isomers of bifenthrin (provisional)
	drinking/ground	constituent isomers of bifenthrin (provisional)
Air		Bifenthrin

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 cereals ILV: cereals
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	*Bifenthrin* GC-ECD LOQ: 0.01 mg/kg for egg Data required for other matrices
Soil (analytical technique and LOQ)	*Bifenthrin* GC-ECD and GC-MSD LOQ: 0.005 mg/kg for soil and sediment
Water (analytical technique and LOQ)	*Bifenthrin* GC-MS (3 ions) LOQ = 1 ng/L for surface water
Air (analytical technique and LOQ)	*Bifenthrin* Fully validated method required

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

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Body fluids and tissues (analytical technique and LOQ)	Data gap

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

	RMS/peer review proposal
Active substance	none

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

Appendix 1 – list of endpoints

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 rate in 4-6 hours
Distribution ‡	Fate and skin mainly (3% of the dose remains in tissues)
Potential for accumulation ‡	No, T ½ = 51 days (fat), 50 days (skin), 19 days (liver), 28 days (kidney), 40 days (ovaries and sciatic nerve)
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
Toxicologically relevant compounds ‡ (animals and plants)	No main metabolites, all less than 10%
Toxicologically relevant compounds ‡ (environment)	

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)	

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

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	NOAEL: 1.50 mg/kg/day (1 year dog)	
Relevant dermal NOAEL ‡	NOAEL: 50 mg/kg/day (rat)	
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-y 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 b.w./day; females: 37 mg/kg b.w./day	
Carcinogenicity ‡	Bladder tumors in male mice (statistically significant at 92 mg/kg b.w./day)	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 b.w./day	
Relevant reproductive NOAEL ‡	5 mg/kg b.w./day	
Relevant offspring NOAEL ‡	5 mg/kg b.w./day	

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	

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

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Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	NOAEL: 35 mg/kg	
Repeated neurotoxicity ‡	NOAEL: (2.9 mg/kg/day males; 3.7 mg/kg/day females)	
Delayed neurotoxicity ‡	LD_{50} 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)

Mechanism studies ‡	-
Studies performed on metabolites or impurities ‡	For studies on 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 Eye irritation/pain and/or redness 4 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

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

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

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (e.g. name 50 % EC)	Talstar 8 SC In vivo, rat: 18 %, concentrated and diluted

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Cereals: UK POEM: - without PPE 336% of AOEL - with PPE: 29% AOEL BBA: 31 % of AOEL (without PPE)
Workers	Cereals: 1.11 % of AOEL
Bystanders	Cereals: 0. 30 % of AOEL

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

	RMS/peer review proposal
Substance classified (bifenthrin)	Carc cat3, R40, T, R23, R25, R43

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

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

Plant groups covered	Cereals (maize),oilseed (cotton) and fruit (apple)
Rotational crops	Lettuce, sugar beet, wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	No valid studies available. (a)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	No valid studies available. (a)
Plant residue definition for monitoring	Constituent isomers of bifenthrin
Plant residue definition for risk assessment	Constituent isomers of bifenthrin
Conversion factor (monitoring to risk assessment)	None

(a) Not required for notified use on cereals due to low residue concentrations. Requirement for use on pome fruit and grapes to be decided when residue trials are available.

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

Animals covered	Goat and hen
Time needed to reach a plateau concentration in milk and eggs	5 days in milk, 7/8 days in egg yolk
Animal residue definition for monitoring	**Provisional:** constituent isomers of bifenthrin
Animal residue definition for risk assessment	**Provisional:** for liver and kidney: sum of constituent isomers of bifenthrin and BP acid expressed as bifenthrin (a) for eggs: sum of constituent isomers of bifenthrin and hydroxyl-methyl bifenthrin and its fatty acid conjugates, expressed as bifenthrin (a) for other animal products: constituent isomers of bifenthrin (a)
Conversion factor (monitoring to risk assessment)	2 for eggs, liver and kidney (a)
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Yes

(a) EFSA notes that the residue definition and conversion factors should be revised for further uses for which intake of higher residue levels of bifenthrin is expected taking into account the animal transfer studies

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

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

After application of bifenthrin on cereals according to the notified cGAP, no residues above 0.01 mg/kg are expected in parts of rotational crops intended for human consumption.

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

Bifenthrin stable under frozen conditions (-18°C): at least 49 months in apples, maize silage and maize stover, at least 34 months in maize grain at least 24 months in cottonseed, at least 6 months in potato tuber and processed parts at least 15 months in dry peas (a)

(a) A data gap for storage stability data for bifenthrin and its metabolites in animal products has been formulated. A respective study has been submitted in April 2007. However, in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulations (EC) No 1490/2002 and 1095/2007, the new study could not be considered in the peer review.

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: (a)	no	no
Potential for accumulation (yes/no):	yes		
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	yes		
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	< 0.1 mg/kg (b)	not relevant	not relevant
Liver	< 0.1 mg/kg (b)	not relevant	not relevant
Kidney	≤ 0.1 mg/kg (b)	not relevant	not relevant
Fat	0.85 mg/kg (1.82 mg/kg)	not relevant	not relevant

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

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	(b)		
Milk	0.08 mg/kg (0.16 mg/kg) (b)		
Eggs		not relevant	

(a) Provisional calculation for intake of wheat/triticale grain and straw only
Dairy cattle: 0.07 mg/kg DM/day
Beef cattle: 0.15 mg/kg DM/day

(b) Feeding group: 5 mg/kg/day, EFSA notes that for the proposal of MRLs feeding studies representative for the dietary burden calculations for the notified representative ideally should be available. (For further details refer to the conclusion on peer review, section 3.2).

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

Appendix 1 – list of endpoints

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

Established by EFSA after the experts meeting and sent to RMS and MSs for comments during written procedure. (For details see conclusion on peer review, section 3.1.1.)

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/triticale	N	Grain: 8 x < 0.01 Straw: 0.07, 0.11, 0.13, 0.14, 0.18, 0.20, 2 x 0.24		grain 0.01	0.01 0.24	0.01 0.16
Wheat/triticale	S	none (d)	Residue trials required. (d)	open	open	open
Rye	N	none	Extrapolation from wheat/triticale possible	refer to wheat/ triticale (N)	refer to wheat/ triticale (N)	refer to wheat/ triticale (N)
Rye	S	none	Extrapolation from wheat possible, however wheat residue trials required in S-EU	open	open	open

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

Appendix 1 – list of endpoints

Barley	N	(d) Grain: 3 x <0.01, 0.012, 0.015, 0.023 Straw. 3 x 0.11, 2 x 0.20, 0.21	data set incomplete, 2 more residue trials required. (d)	grain 0.05[+]	0.023 [+] 0.21 [+]	0.01 [+] 0.16 [+]
Barley	S	none (d)	Residue trials required. (d)	open	open	open
Oats	N	Grain: 2 x <0.01 Straw: 0.06, 0.07	Further trials required, Extrapolation from barley possible, see above	refer to barley (N)	refer to barley (N)	refer to barley (N)
Oats	S	none	Extrapolation from barley possible, however barley residue trials required in S-EU.	open	open	open
Wine grapes Table grapes	N/S S	none	Residue trials required	open	open	open
Pome fruit	N/S	none	Residue trials required	open	open	open

(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
(d) Further residue trials have been submitted in April 2007. However, in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulations (EC) No 1490/2002 and 1095/2007, the new studies could not be considered in the peer review.

[+] preliminary results since data set incomplete
‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1 – list of endpoints

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

The assessment is only indicative and it is based only on the intake of cereals and food of animal origin. The final assessment is pending the submission of additional data and the re-evaluation for all intended uses.

Calculation provided by the RMS after the experts meeting. Sent to MSs for comments during written procedure.

ADI	0.015 mg bw/kg per day
TMDI (% ADI) according to WHO European diet	0.8% (WHO Cluster diet B and D) (a)
TMDI (% ADI) according to national (to be specified) diets	
IEDI (WHO European Diet) (% ADI)	
NEDI (specify diet) (% ADI)	
Factors included in IEDI and NEDI	
ARfD	0.03 mg/kg bw/day
IESTI (% ARfD)	
NESTI (% ARfD) according to national (to be specified) large portion consumption data	PRIMO : 4 % (for intake of milk and milk products by UK infant)
Factors included in IESTI and NESTI	conversion factor 2 for kidney, liver and eggs

(a) conversion factor 2 for kidney, liver and eggs

Calculation by EFSA. Sent to MSs for comments during written procedure.

ADI	0.015 mg bw/kg per day
TMDI (% ADI) according to WHO European diet	1.3% ADI (WHO European diet Cluster B) (a)
TMDI (% ADI) according to national (to be specified) diets	2.8% ADI (NL child)
IEDI (WHO European Diet) (% ADI)	
NEDI (specify diet) (% ADI)	
Factors included in IEDI and NEDI	
ARfD	0.03 mg/kg bw/day
IESTI (% ARfD)	4.1% (milk and milk products)
NESTI (% ARfD) according to national (to be specified) large portion consumption data	
Factors included in IESTI and NESTI	conversion factor 2 for kidney and liver

Appendix 1 – list of endpoints

(a) conversion factor 2 for kidney and liver

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			
Pome fruit	(a)			
Grapes	(a)			

(a) Requirement to be decided when residue trials are available and evaluated. Number of submitted processing studies not sufficient. Evaluation is only possible when valid studies on the effect of processing on the nature of residues is available.

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

Barley and oat grain	0.05 mg/kg (a)
Wheat, triticale and rye grain	0.01* mg/kg (a)
Wine grapes Table grapes	(b)
Pome fruit	(b)
Ruminant fat	0.1 mg/kg (c)
Ruminant meat	0.05* mg/kg (c)
Milk and whole cream cow's milk	0.01* mg/kg (c)
Milk fat	0.05* mg/kg (c)
Ruminant kidney and liver	0.05* mg/kg (c)

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

(a) Proposals are provisional pending the submission of requested data on residue trials. In addition to the data submitted in the original dossier further residue trials have been submitted in April 2007. However, in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulations (EC) No 1490/2002 and 1095/2007, the new studies could not be considered in the peer review.
(b) The submitted data are not sufficient to propose MRLs.
(c) EFSA notes that the proposed MRLs are provisional and derived only for the intake of cereals grain and straw. They are pending the submission and evaluation of diverse additional data. It is noted that some of the required studies have been submitted in April 2007. However, in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulations (EC) No 1490/2002 and 1095/2007, the new studies could not be considered in the peer review.

Appendix 1 – list of endpoints

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[26]= 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 : No reliable data. Data required.

Mineralization after 100 days	
Non-extractable residues after 100 days	
Metabolites that may require further	-

[26] n corresponds to the number of soils.

Appendix 1 – list of endpoints

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
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	X[27]	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	78.7 / 261.3	116.7	2.09	Non linear SFO
Silty clay loam		7.5	25 / 65% FC	111.7 / 371.2	113.8	7.88	Non linear SFO
Sandy loam		7.0	25 / 65% FC	99.6 / 330.9	92.6	10.52	Non linear SFO
Silt loam		7.1	25 / 65% FC	202.9 / 674.0	191.7	4.61	Non linear SFO
Loamy sand		6.0	22 / 40% MWHC	129.7 / 431.0	116.6	10.9	Non linear SFO
Sandy loam		6.2	22 / 40% MWHC	67.1 / 222.8	52.9	9.68	Non linear SFO
Geometric mean			-	-	106.4	-	Non linear SFO

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

Appendix 1 – list of endpoints

4'-OH bifenthrin	Aerobic conditions – calculated from parent. Data gap identified for values in additional soils.							
Soil type	X[1]	pH	t. °C / % FC	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%	9.1/30.3	0.43	9.8	9.1	Non linear SFO
Geometric mean			-					

TFP-acid	Aerobic conditions: – calculated from parent. Data gap identified for values in additional soils.							
Soil type	X[1]	pH	t. °C / % FC	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%	16.1/53.3	0.05	17.3	11.4	Non linear SFO
Geometric mean			-					

Field studies ‡ (actual values)

Bifenthrin	Aerobic conditions							
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	Method of calculation
Loamy sand (bare)	GA (USA)		4.5	30.5	16.4	437.2*	14.5	DFOP
Loam (bare)	IL (USA)		6.3	30.5	56.2	186.6	21.5	Non linear SFO
Silt loam (bare)	AR (USA)		6.4	30.5	94.6	314.2	18.3	Non linear SFO
Loam (bare)	IL (USA)		6.3	30.5	37.5	461.0*	19.1	DFOP
Silty clay loam (cropped)	CA (USA)		7.2	30.5	43.5	85955*	15.0	FOMC
Silt loam (cropped)	Netherlands		7.3	20	13.0	221.8	5.9	DFOP
Silt loam (cropped)	Netherlands		6.9	20	60.7	201.5	9.0	Non linear SFO
Silt loam (bare)	Germany		7.2	15	254.1	844.1*	21.6	Non linear SFO
Geometric mean					-	-	-	

Appendix 1 – list of endpoints

* Exceeds study duration

Field studies ‡ (normalised values)

Bifenthrin	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) 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
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	9.7	124.6	7.3	57.8*	DFOP
Silt loam (cropped)	Netherlands		6.9	20	45.6	151.6	10.0	45.6	Non linear SFO
Silt loam (bare)	Germany		7.2	15	116.7	387.6	20.8	116.7	Non linear SFO
Geometric mean					-	-	-	84.6	

* calculated as ln 2/k, k being the longest DFOP DT50

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	No accumulation study. For the applied for use on cereals a plateau concentration of 0.0034 mg/kg (mixing depth 20cm) is calculated (value before the final years 2 applications are added over 5cm depth)

Laboratory studies ‡

Parent	Anaerobic conditions: no reliable data available, data required

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Bifenthrin ‡

Appendix 1 – list of endpoints

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/median				236 610	-	-	-
pH dependence, Yes or No			No				

4'OH bifenthrin							
	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Estimated by QSAR (PCKOCWIN)				$5.23\ 10^6$			
Arithmetic mean/median							
pH dependence (yes or no)							

TFP acid : No data. Data gap identified.							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Arithmetic mean/median							
pH dependence (yes or no)							

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

Appendix 1 – list of endpoints

	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 studies, not required.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 276 days[28] Kinetics: non-linear SFO Field or Lab: worst case from field studies.
Application data	Crop: cereals Depth of soil layer: 5cm. For plateau concentration 20cm for accumulating years then 5cm for the 2 applications in the final year, (note this does not cover minimum tillage agricultural practice which is common for cereals) Soil bulk density: 1.5g/cm^3 % plant interception: 0 Number of applications: 2 Interval (d): 14 Application rate(s): 10 g as/ha

[28] The maximum field DT50 of 254 days should have been used for PECsoil calculation.

Appendix 1 – list of endpoints

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	-		19.7	
Short term	-	-		
24h			19.6	10.5
2d	-	-	19.6	11.0
4d	-	-	19.5	12.0
Long term 7d	-	-	19.3	13.0
28d	-	-	18.3	15.9
50d	-	-	17.3	16.6
100d	-	-	15.3	16.5
Plateau concentration	23.1 µg/kg (maximum including final years applications)			

4'-OH bifenthrin Method of calculation	Molecular weight relative to the parent: 438.9/422.9
Application data	Application rate: 10 g/ha Max formation fraction: 8.3 %
PECmax (t=0)	1.99 µg/kg

TFP-acid Method of calculation	Molecular weight relative to the parent: 242.5/422.9
Application data	Application rate: 10 g/ha Max formation fraction: 11.6%
PECmax (t=0)	1.54 µg/kg

Appendix 1 – list of endpoints

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 % ‡	No reliable data. Not required (due to the very high adsorption properties of bifenthrin the partitioning to sediment in natural water bodies would be rapid)
Quantum yield of direct phototransformation in water at ☒ > 290 nm	No data submitted, data gap identified.
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		-		-		

Appendix 1 – list of endpoints

4'-OH bifenthrin	Distribution (eg max in water 1.9-5.4% after 0 d. Max. sed 4.4-11.1 % after 99 d) DT50 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)

Parent 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): 1.4 10^{-5} K_{OC} (L/kg): 236610 DT_{50} soil (d): 87 days (Field SFO) DT_{50} water/sediment system (d): 158 DT_{50} water (d): 158 DT_{50} sediment (d): 1000 Crop interception (%): minimal crop canopy
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: 1.1 Vapour pressure: 2.4 10^{-5} Pa Koc: 236610 L/kg 1/n: 1 DT_{50} soil (d): 87 days (Field SFO) DT_{50} water (d): 158 DT_{50} sediment (d): 1000
FOCUS step 4	Version control no.'s of FOCUS software: 1.1

Appendix 1 – list of endpoints

	Vapour pressure: 2.4 10^{-5} Pa Koc: 236610 L/kg DT_{50} soil (d): 96.5 days (Field SFO) DT_{50} water (d): 161.1 DT_{50} sediment (d): 1000 1/n: 1 Vegetated filter strips of 20 m
Application rate	Crop: winter and spring cereals Crop interception: 25% Number of applications: 2 Interval (d): 14 Application rate(s): 10 g as/ha Application window: 14 days post emergence as the earliest date

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	0.2		51.01	

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		18.35	
Winter cereals, southern EU	0 h	0.08		14.92	
Spring cereals, northern EU	0 h	0.08		8.06	
Spring cereals, southern EU	0 h	0.08		14.92	

Appendix 1 – list of endpoints

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	0.4130	0.0534	0.6980
D1	Stream	0 h	0.0473	0.2220	0.0411	0.2440
D2	Ditch	0 h	0.0537	0.2740	0.0469	0.2670
D2	Stream	0 h	0.0419	0.0480	0.0363	0.0415
D3	Ditch	0 h	0.0533	0.2150	0.0467	0.2400
D4	Pond	0 h	0.0019	0.0384	0.0020	0.0605
D4	Stream	0 h	0.0463	0.1450	0.0400	0.1390
D5	Pond	0 h	0.0019	0.0392	0.0020	0.0630
D5	Stream	0 h	0.0499	0.1710	0.0432	0.1680
D6	Ditch	0 h	0.0525	0.1570	0.0459	0.1610
R1	Pond	0 h	0.0019	0.0500	0.0019	0.0884
R1	Stream	0 h	0.0352	0.3520	0.0304	0.7170
R3	Stream	0 h	0.0493	1.3190	0.0431	2.5700
R4	Stream	0 h	0.0349	1.4830	0.0302	3.0160

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	0.4190	0.0532	0.7290
D1	Stream	0 h	0.0473	0.2220	0.0410	0.2440
D3	Ditch	0 h	0.0535	0.2380	0.0469	0.2780
D4	Pond	0 h	0.0019	0.0378	0.0020	0.0618
D4	Stream	0 h	0.0443	0.0799	0.0394	0.1040
D5	Pond	0 h	0.0018	0.0382	0.0020	0.0627
D5	Stream	0 h	0.0419	0.0302	0.0397	0.0525
R4	Stream	0 h	0.0354	3.0210	0.0306	6.7300

Appendix 1 – list of endpoints

FOCUS Step 4 for winter cereals: 20m no-spray buffer [29]

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	0.0393
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
D4	Pond	0 h	0.0008	0.0115	0.0007	0.0181
D4	Stream	0 h	0.0046	0.0141	0.0038	0.0129
D5	Pond	0 h	0.0008	0.0115	0.0007	0.0175
D5	Stream	0 h	0.0049	0.0167	0.0041	0.0156
D6	Ditch	0 h	0.0038	0.0113	0.0033	0.0113

FOCUS Step 4 for spring cereals: 20m no-spray buffer[4]

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	0.0215	0.0036	0.0324
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

FOCUS Step 4: 25m no-spray buffer[4]

[29] There is a data gap for the applicant to demonstrate that the overall run off mitigation is < 90% (as the available simulations reduced the runoff water substance mass load by 80% and the sediment mass load by 95%) Hence, results for the run-off scenarios are not presented here.

Appendix 1 – list of endpoints

FOCUS STEP 4 Scenario Spring cereals	Water body	Day after overall maximum	25 m no-spray buffer Single application PECSW (µg/L) Actual
D1	Ditch	0 h	0.0034
D1	Stream	0 h	0.0039
D3	Ditch	0 h	0.0033
D4	Pond	0 h	0.0007
D4	Stream	0 h	0.0036
D5	Pond	0 h	0.0007
D5	Stream	0 h	0.0034

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): 9.8 days (Lab SFO from parent) DT_{50} water/sediment system (d): 1000 (default value) DT_{50} water (d): 1000 (default value) DT_{50} sediment (d): 1000 (default value) Crop interception (%): minimal crop canopy 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: - Step 1-2: March-May for spring cereals, October-February for winter cereals
Main routes of entry	Drift

Appendix 1 – list of endpoints

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	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		0.97	
Winter cereals, southern EU	0 h	0.01		0.80	
Spring cereals, northern EU	0 h	0.01		0.47	
Spring cereals, southern EU	0 h	0.01		0.56	

Metabolite TFP acid Parameters used in FOCUSsw step 1 and 2	PECsw for TFP acid were not validated. Data gap

Appendix 1 – list of endpoints

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: FOCUS PELMO 3.3.2 and FOCUS PEARL 3.3.3 Scenarios (list of names): all scenarios Crop: winter and spring cereals Geometric mean parent DT_{50lab} 96.5 d[30] K_{OC}: parent, arithmetic mean 236610, $^1/_n$= 1.
	Metabolite 4'OH bifenthrin DT_{50lab} 9.8 d (pF2, 20 °C with Q10 of 2.2). K_{OC} : 130526 (worst-case from the parent), $^1/_n$= 1 Formation fraction from the parent: 50%
	Metabolite TFP acid No reliable calculation. Data gap identified.
Application rate	Application rate: 10 g/ha. Crop interception: 25% No. of applications: 2 Time of application (month or season): 14 days after emergence

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

PECgw are less than 0.001 µg/l for bifenthrin and 4'OH bifenthrin for all scenarios and both winter and spring planted cereals.

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	No data. Data gap identified
Photochemical oxidative degradation in air ‡	DT50 = 8.7h derived by the Atkinson model, assuming a OH mean concentration of 1.5 10^6/cm^3

[30] The normalised geometric mean DT50 of 85 days (field value) should have been used.

Appendix 1 – list of endpoints

Volatilisation ‡	Vapor pressure : 2.4 10^{-5} Pa Henry's Law Constant: 7.74 10^{-5} Pa.m^3/mol Volatilisation from soil surfaces : max 1.97% AR (40°C, 75% MC, aor flow 16.7m/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	No data, not required

PEC$_{(a)}$

Maximum concentration	NA

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), TFP acid Surface Water: bifenthrin (constituent isomers), TFP acid Sediment: bifenthrin (constituent isomers), 4'OH bifenthrin Ground water: bifenthrin (constituent isomers), TFP acid, 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)	NA
Air (indicate location and type of study)	NA

Appendix 1 – list of endpoints

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

Candidate for R53

Appendix 1 – list of endpoints

In the original notification dossier, three representative uses were intended by FMC. According to the FMC letter of 2007/03/18, the GAP were revised and only the use on cereals is now sustained. Since the uses in grapes and pome fruit are not supported anymore, only data for the use on cereals were updated.

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	LD50 = 1800 #	
Mallard duck	a.s.	Acute	LD50 > 2150	
Bobwhite quail	a.s.	Short-term	LD50 = 569 per day	LC50 = 4450
Mallard duck	a.s.	Long-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	LD50 = 42.5 #	
rat	a.s.	Reproductive	NOAEL = 3 per day #	

: toxicity values used into 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

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Large herbivorous bird – 3000 g	Acute	0.75	2400	10
	Short-term	0.47	222	10
	Long-term	0.25	26.5	5
Insectivorous bird – 10 g	Acute	0.54	3330	10
	Short-term	0.30	348	10
	Long-term	0.30	22.1	5
Large herbivorous bird (puddle water)	Acute	1.15	1565	10
Insectivorous bird (puddle water)	Acute	3.6	500	10
Tier 1 (Mammals)				
Small herbivorous mammal – 25 g	Acute	2.37	17.9	10

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

Appendix 1 – list of endpoints

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
	Long-term	0.77	**3.9**	5
Insectivorous mammal – 10 g	Acute	0.09	482	10
	Long-term	0.03	93.4	5
Small herbivorous mammal (puddle water)	Acute	1.92	22.13	10
Insectivorous mammal (puddle water)	Acute	2.13	19.95	10

Risk from secondary poisoning

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Birds				
Earthworm-eating bird	Long-term	1.07	6.2	5
Fish-eating bird*	Long-term	0.000025 0.00011 0.00054	265200 60273 12278	5
Mammals				
Earthworm-eating mammal	Long-term	1.36	**2.3**	5
Fish-eating mammal*	Long-term	0.000016 0.00007 0.00034	187500 42857 8823	5

*. Three TERs are calculated based on BCF values of 1330, 6090 and 30000, respectively. A revised assessment should follow clarification on BCF values.

Orchards, 2 x 0.05 kg a.s./ha

Indicator species/Category	Time scale	ETE	TER*	Annex VI Trigger
Tier 1 (Birds)				
Insectivorous bird – 10 g	Acute	2.70	666	10
	Short-term	1.5	69.2	10
	Long-term	1.5	**4.39**	5
Insectivorous bird (puddle water)	Acute	2.7	667	10
Tier 1 (Mammals)				
Small herbivorous mammal – 25 g	Acute	7.1	**6**	10
	Long-term	2.37	**1.26**	5

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

Appendix 1 – list of endpoints

Indicator species/Category	Time scale	ETE	TER*	Annex VI Trigger
Small herbivorous mammal (puddle water)	Acute	1.5690	27	10

*TER values re-estimated by EFSA

Risk from secondary poisoning ***

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Birds				
Earthworm-eating bird	Long-term			5
Fish-eating bird**	Long-term			5
Earthworm-eating mammal	Long-term			5
Fish-eating mammal**	Long-term			5

**Pending on a clarification on BCF values
*****Pending of an available PECs and PECsw values in orchard.**

Vines, 2 x 0.03 kg a.s./ha

Indicator species/Category	Time scale	ETE	TER*	Annex VI Trigger
Tier 1 (Birds)				
Insectivorous bird – 10 g	Acute	1.622	1109	10
	Short-term	0.90	115.5	10
	Long-term	0.90	7.3	5
Insectivorous bird (puddle water)	Acute	8.1	222	10
Tier 1 (Mammals)				
Small herbivorous mammal – 25 g	Acute	4.25	10	10
	Long-term	1.423	**2.10**	5
Small herbivorous mammal (puddle water)	Acute	4.707	**9**	10

*TER values re-estimated by EFSA.

Risk from secondary poisoning ***

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

Appendix 1 – list of endpoints

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Birds				
Earthworm-eating bird	Long-term			5
Fish-eating bird**	Long-term			5
Mammals				
Earthworm-eating mammal	Long-term			5
Fish-eating mammal**	Long-term			5

**Pending on a clarification on BCF values
***Pending of an available PECs and PECsw values in vine .

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)	LC50	0.10 (nom)
L. macrochirus	a.s.	144 hr (flow-through)	LC50	0.30 (nom)
L. macrochirus	a.s.	96 hr (flow-through)	LC50	0.26 (mm)
S. gairdneri	a.s.	96 hr (flow-through)	LC50	0.10 (mm) #
P. pomelas	a.s.	96 hr (flow-through)	LC50	0.21 (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	TALSTAR 8SC	96 hr (semi-static)	LC50	30 µg a.s./L (nom) 380 µg product/L
O. mykiss	TALSTAR 10EC	192 hr (static with sediment)	LC50	5.49 µg a.s./L (nom) 54.9 µg product/L

*:this value comes from the full life cycle test on juvenile fish, McAllister, 1988, for juvenile fathead minnows.
#:toxicity values used in the TER calculations

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

Appendix 1 – list of endpoints

Aquatic invertebrate				
D. magna	a.s.	48 hr (flow-through, with laboratory soil)	EC50	<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)	EC50	<0.5 mg/kg (water and soil mixed) >0.5 mg/kg (unmixed) (nom)
D. magna	a.s.	48 hr (flow-through)	EC50	1.6 (nom)
D. magna	a.s.	48 hr (flow-through)	EC50	0.11 (mm) #
D. magna	a.s.	48 hr (static)	EC50	0.37 (mm)
C. dubia	a.s.	24 hr (static)	EC50	0.31 (mm)
T. platyurus	a.s.	24 hr (static)	EC50	5.7 (mm)
Hexagenia sp	a.s.	48 hr (static)	EC50	0.39 (mm)
Caddis fly	a.s.	48 hr (static)	EC50	0.12 (mm)
G. pulex	a.s.	48 hr (static)	EC50	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	TALSTAR 8SC	48 hr (static)	EC50	5.7 µg a.s./L (nom) 72 µg product/L

Sediment dwelling organisms				
C. riparius	a.s.	28 d	NOEC	0.32 (nom) #

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

Appendix 1 – list of endpoints

Algae				
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

[#] :toxicity values used in the TER calculations * :This NOEC does not cover effects on the embryonic stage.
** : Establish on effects on the survival only.

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 into 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)	PEC_{twa}	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
a.s.	Algae	> 100000	Chronic	0.2		> 500000	10

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

Appendix 1 – list of endpoints

Test substance	Organism	Toxicity end point (µg/L)	Time scale	PEC_i (µg/L)	PEC_{twa}	TER	Annex VI Trigger
a.s.	Sediment-dwelling[3] organisms	0.32	Chronic	0.2		**1.6**	10
TALSTAR 10EC	Fish	5.49 (nom)	Acute	0.2		**27.45**	100

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[6]	0.32	Chronic	0.08	**4**	10
TALSTAR 10EC	N and S	Fish	5.49 (nom)	Acute	0.08	**68.6**	100

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

cereals

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC (µg/L)	TER	Annex VI trigger
a.s.	D1	ditch	fish	Acute – 96h	0.10	0.0541	**1.85**	100
a.s.	D1	ditch	fish	Chronic – 30d	0.012	0.0541	**0.126**	10
a.s.	D1	ditch	All other organisms	4 m	0.015	0.0541	**0.28**	3

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

Appendix 1 – list of endpoints

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC (µg/L)	TER	Annex VI trigger
TALSTAR 10EC	D1	ditch	fish	Acute – 192 h	5.49	0.0541	101.5	100

FOCUS Step 4

Cereals with 25m no spray buffer zone

Scenario	Water body type	Test organism	Time scale	Toxicity end point	Buffer zone distance	PEC (µg/L)	TER	Annex VI trigger
D1	stream	fish	Acute – 96h	0.10	25 m	0.0036	**27.8**	100
D1	stream	fish	Chronic – 30d	0.012	25 m	0.0036	**3.3**	10
D1	stream	All other organisms	4 m	0.015	25 m	0.0036	4.16	3
D3	ditch	fish	Acute – 96h	0.10	25 m	0.0033	**30.3**	100
D3	ditch	fish	Chronic – 30d	0.012	25 m	0.0033	**3.6**	10
D3	ditch	All other organisms	4 m	0.015	25 m	0.0033	4.5	3

Bioconcentration	
	Active substance
$logP_{O/W}$	7.3
Bioconcentration factor (BCF) ‡	1030 - 30000
Annex VI Trigger for the bioconcentration factor	1000
Clearance time (days) (CT_{50})	6 - 42
Level and nature of residues (%) in organisms after the 14 day depuration phase	See studies

Other studies

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

Appendix 1 – list of endpoints

Group	Time scale	Stage	BCF	Clearance time
Fish (*L. Macrochirus*)	42 days	Adults	2140 (muscle)* 8720 (viscera)* 6090 (whole body)* 11750 (k1/k2)*	CT50 21-42 days
Fish (*C. carpio*)	70 days	Adults	1030-1330	CT50 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/bee or % effect)
a.s. ‡	0.1	100 % at 50 ppm*
TALSTAR 8SC	0.01 #	0.0016 #

* :values reported as indicative
# :toxicity values used into 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

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

Appendix 1 – list of endpoints

Test type	Parameter**	Measured as	Crop and dose (active substance)	Value (active substance)	Reference
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	LD50 48 h oral and contact Mortality in treated fields	*Phacelia tanecetifolia*, 50 g/ha	LD50 oral = 0.12 µg/bee LD50 oral multiple contacts = 0.00067 µg/bee LD50 topic = 0.044 µg/bee LD50 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	Schur, 2003

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

Appendix 1 – list of endpoints

Test type	Parameter**	Measured as	Crop and dose (active substance)	Value (active substance)	Reference
				Effects on brood development not 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	**12 500**	50
a.s.	oral	**2 000**	50

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

Appendix 1 – list of endpoints

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 %
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	LR50 = 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	LR50 = 0.113 g a.s./ha # NOED = 0.009 g a.s./ha (lethal effects)

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

Appendix 1 – list of endpoints

Species	Life stage	Test substance	Dose	Effect
Chrysoperla carnea	(larvae)	TALSTAR 8SC	Dose response test	LR50 = 5.132 g a.s./ha NOED = 2.279 g a.s./ha (lethal effects)
Coccinella septempunctata	(larvae)	TALSTAR 8SC	Dose response test	LR50 = 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 into 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
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.

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

Appendix 1 – list of endpoints

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	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 = 0.168 mg a.s./kg d.w.soil	NOEC = 0.084 mg a.s./kg d.w.soil [#]

[1] toxicity values are divided by 2 when log K_{ow} > 2.
[#] : values used into TER calculations.

Soil micro-organisms			
Nitrogen mineralisation	TALSTAR 8SC ‡		< 25 % effect up to 0.128 mg a.s./kg d.w.soil (2.9 times the field rate for orchards use)
Carbon mineralisation	TALSTAR 8SC ‡		< 25 % effect up to 0.128 mg a.s./kg d.w.soil (2.9 times the field rate for orchards use)

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	23.1	> 346	10
Eisenia fetida	TALSTAR 8SC	Acute	23.1	> 1688	10
Eisenia fetida	TALSTAR 8SC	Chronic	23.1	**3.64**	5

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

Data gap identified

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

Appendix 1 – list of endpoints

Most sensitive species	Test substance	ER_{50} (g/ha) Growth rate	ER_{50} (g/ha) emergence	Exposure[1] (g a.s./ha)	TER	Trigger
Data Gap						

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

Test type/organism	end point
Activated sludge	Bifenthrin : EC50 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, and a data gap needs to be filled before a decision can be made on TFP acid,
water	bifenthrin, and a data gap needs to be filled before a decision can be made on TFP acid
sediment	bifenthrin,
groundwater	bifenthrin, and a data gap needs to be filled before a decision can be made on TFP acid

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

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

Appendix 2 – abbreviations used in the list of endpoints

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

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

Appendix 2 – abbreviations used in the list of endpoints

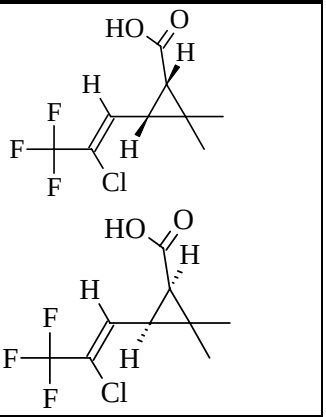
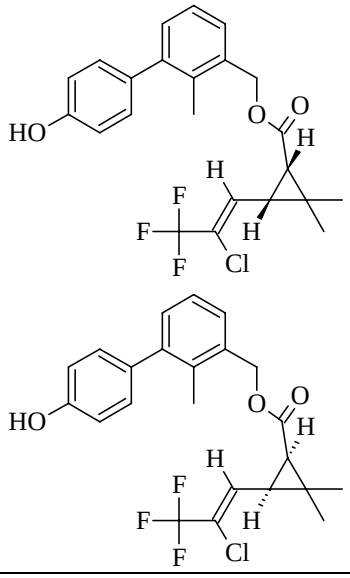
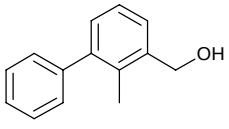
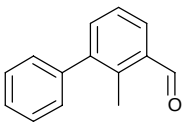
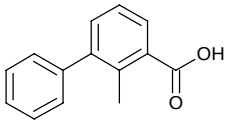
kg	kilogram
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
µg	microgram
mg	milligram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
pH	pH-value
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
STMR	supervised trials median residue
t	tonne (metric ton)

Appendix 2 – abbreviations used in the list of endpoints

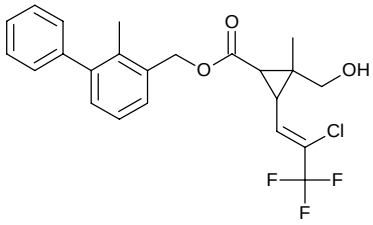
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year

Appendix 3 – Used compound code(s)

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
TFP acid	(1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylic acid	
4'-OH bifenthrin	(4'-hydroxy-2-methylbiphenyl-3-yl)methyl (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate	
BP-alcohol	2-methyl-3-phenylbenzyl alcohol (2-methylbiphenyl-3-yl)methanol	
BP-aldehyde	2-methyl-3-phenylbenzyl aldehyde 2-methylbiphenyl-3-carbaldehyde	
BP-acid	2-methyl-3-phenylbenzoic acid 2-methylbiphenyl-3-carboxylic acid	

Appendix 3 – Used compound code(s)

OH-methyl bifenthrin	(2-methylbiphenyl-3-yl)methyl (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2-(hydroxymethyl)-2-methylcyclopropanecarboxylate (unknown stereochemistry)	
DCVA Note this is not a metabolite of bifenthrin but of cypermethrin	(1*RS*,3*RS*)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylic acid