CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance gamma-cyhalothrin[1]

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ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State the United Kingdom, for the pesticide active substance gamma-cyhalothrin are reported. The context of the peer review was that required by Commission Regulation (EU) No 188/2011. The conclusions were reached on the basis of the evaluation of the representative uses of gamma-cyhalothrin as an insecticide on wheat and barley. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed. Critical areas of concern are identified as regards the long-term risk assessment for wild mammals and the risk assessment for aquatic organisms.

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KEY WORDS

gamma-cyhalothrin, peer review, risk assessment, pesticide, insecticide

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SUMMARY

Gamma-cyhalothrin is a new active substance for which in accordance with Article 6(2) of Council Directive 91/414/EEC the United Kingdom (hereinafter referred to as the 'RMS') received an application from Cheminova A/S for approval. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2004/686/EC.

The RMS provided its initial evaluation of the dossier on gamma-cyhalothrin in the Draft Assessment Report (DAR), which was received by the EFSA on 25 January 2008. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 additional information was requested from the applicant. The RMS's evaluation of the additional information was provided in the format of an updated DAR, which was received on 13 September 2012. The peer review was initiated on 3 October 2012 by dispatching the DAR for consultation of the Member States and the applicant Cheminova A/S.

Following consideration of the comments received on the DAR, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues and ecotoxicology, and EFSA should adopt a conclusion on whether gamma-cyhalothrin can be expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC, in accordance with Article 8 of Commission Regulation (EU) No 188/2011.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of gamma-cyhalothrin as an insecticide on wheat and barley, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

In the section identity, physical-chemical properties and analytical methods data gaps were identified regarding monitoring methods in the environmental matrices as well as in body fluids and tissues.

In the mammalian toxicology section, data gaps were identified for toxicological information to assess the toxicity profile of the plant metabolites CPCA, PBA and PBA(OH) and to clarify whether the sperm effects that were reported in published literature in mice treated with low doses of lambda-cyhalothrin in a formulation have an impact on the outcome of the risk assessment.

The consumer risk assessment is considered provisional owing to the fact that the residue definition for risk assessment in plant and livestock matrices could not be finalised due to insufficient toxicological data for metabolite CPCA.

The available information on the fate and behaviour in the environment was considered sufficient to complete the necessary environmental exposure assessments at the EU level for the representative uses assessed.

A low acute and long-term risk to birds was concluded. A low acute risk to wild mammals was concluded, however, a high long-term risk to wild mammals was indicated in the available assessment. A data gap was also identified to address the potential for biomagnification in aquatic and terrestrial food chains. A high risk to aquatic organisms was indicated using surface water exposure estimates calculated assuming the maximum permissible level of risk mitigation according to the FOCUS Landscape and Risk Mitigation guidance (FOCUS, 2007). A low risk to honey bees, soil-dwelling organisms, non-target terrestrial plants and sewage treatment organisms was concluded. A low risk to non-target arthropods was also indicated but this is pending on a data gap to confirm the relevance of the exposure in the available higher tier data to the representative uses.

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BACKGROUND

In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009[3], Council Directive 91/414/EEC[4] continues to apply with respect to the procedure and conditions for approval for active substances for which a decision recognising in principle the completeness of the dossier was adopted in accordance with Article 6(3) of that Directive before 14 June 2011.

Commission Regulation (EU) No 188/2011[5] (hereinafter referred to as 'the Regulation') lays down the detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market on 26 July 1993. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant for comments on the initial evaluation in the Draft Assessment Report (DAR) provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

In accordance with Article 8 of the Regulation, EFSA is required to adopt a conclusion on whether the active substance is expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC within 4 months from the end of the period provided for the submission of written comments, subject to an extension of 2 months where an expert consultation is necessary, and a further extension of up to 8 months where additional information is required to be submitted by the applicant(s) in accordance with Article 8(3).

In accordance with Article 6(2) of Council Directive 91/414/EEC the United Kingdom (hereinafter referred to as the 'RMS') received an application from Cheminova A/S for approval of the active substance gamma-cyhalothrin. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2004/686/EC[6].

The RMS provided its initial evaluation of the dossier on gamma-cyhalothrin in the DAR, which was received by the EFSA on 25 January 2008 (The United Kingdom, 2008). In accordance with the procedure laid down in Article 11(6) of Commission Regulation (EU) No 188/2011, additional information was requested from the applicant. The RMS's evaluation of the additional information was provided in the format of an updated DAR, which was received on 13 September 2012 (The United Kingdom, 2012). The peer review was initiated on 3 October 2012 by dispatching the updated DAR to the Member States and the applicant Cheminova A/S for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 8(3) of the Regulation were considered in a telephone conference between the EFSA, the RMS, and the European Commission on 4 February 2013. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32, as last amended.

[5] Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ L 53, 26.2.2011, p. 51-55.

[6] Commission Decision 2004/686/EC of 29 September 2004 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of proquinazid, IKI-220 (flonicamid) and gamma-cyhalothrin in Annex I to Council Directive 91/414/EEC. OJ L 313, 12.10.2004, p. 21-22.

concluded that additional information should be requested from applicant and that the EFSA should organise an expert consultation in the areas of mammalian toxicology, residues and ecotoxicology.

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

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

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

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

- the comments received on the updated DAR,
- the Reporting Table (4 February 2013),
- the Evaluation Table (31 January 2014),
- the reports of the scientific consultation with Member State experts (where relevant),
- the comments received on the assessment of the additional information (where relevant),
- the comments received on the draft EFSA conclusion.

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

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

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Gamma-cyhalothrin is the ISO common name for (*S*)-α-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate or (*S*)-α-cyano-3-phenoxybenzyl (1*R*)-*cis*-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropane-carboxylate (IUPAC).

The representative formulated product for the evaluation was 'Corello' (GF-317)', a capsule suspension (CS) formulation containing 60 g/L gamma-cyhalothrin (5.92 % w/w).

The representative uses evaluated comprise of applications by foliar spraying to control a range of insects on winter and spring wheat and barley. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

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

It should be noted that gamma-cyhalothrin is one of the isomers forming the substances which have their own ISO common name lambda-cyhalothrin and cyhalothrin. (The chemical names and structures are given in Appendix B)

The minimum purity of gamma-cyhalothrin technical material is 980 g/kg. No FAO specification exists.

The proposed specification for the technical material is based on industrial scale production. 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 gamma-cyhalothrin or the representative formulation. The main data regarding the identity of gamma-cyhalothrin and its physical and chemical properties are given in Appendix A.

Adequate analytical methods using chiral chromatography are available for the determination of gamma-cyhalothrin in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material. It should be noted that the CIPAC method for lambda-cyhalothrin (463/CS/M/) is also applicable to gamma-cyhalothrin CS formulations, however this method does not distinguish between gamma-cyhalothrin and its enantiomer.

The proposed residue definition for monitoring in food of plant and animal origin is gamma-cyhalothrin and its enantiomer (any ratio of constituent isomers in lambda-cyhalothrin). The compounds of the residue definition of gamma-cyhalothrin in food and feed of plant origin can be monitored by the multi-residue method DFG S19 (GC-ECD and GC-MS or GC-MS/MS) with a LOQ of 0.01 mg/kg in each commodity group. The multi-residue method DFG S19 (LC-MS/MS) is also appropriate for monitoring the compounds of the residue definition in food and feed of animal origin with a LOQ of 0.01 mg/kg in muscle, liver, kidney, fat, milk and eggs.

The residue definition proposed for environmental matrices is gamma-cyhalothrin. The methods proposed for monitoring are not capable of distinguishing between residues of gamma-cyhalothrin and lambda-cyhalothrin, as a consequence a data gap has been identified for methods capable of determining the residues according to the residue definition. It should be noted however, that monitoring of the constituent isomers of lambda-cyhalothrin in soil (as sum of isomers) is possible using a modified version of DFG S19 (GC-ECD and GC-MS) with a LOQ of 0.05 mg/kg, and in drinking water and surface water by an LC-MS/MS method with a LOQ of 0.0003 µg/L. Residues of

the constituent isomers of lambda-cyhalothrin (as sum of isomers) in the air can be monitored by GC-MS with a LOQ of 0.15 µg/m^3. The residue definition for monitoring in body fluids and tissues was set as gamma-cyhalothrin, as a consequence a data gap has been identified for an enforcement method capable of determining selectively gamma-cyhalothrin. It should be noted that a GC-MS method with a LOQ of 0.025 µg/mL exists to determine the sum of the constituent isomers of lambda-cyhalothrin in whole blood and urine.

2. Mammalian toxicity

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

Gamma-cyhalothrin was discussed together with lambda-cyhalothrin at the Pesticides Peer Review Experts' Meeting 108 in November 2013; as the gamma-cyhalothrin assessment is linked to the assessment of lambda-cyhalothrin, the meeting report on lambda-cyhalothrin is also relevant for gamma-cyhalothrin.

The batches used in the toxicological studies support the proposed technical specification. No relevant impurity has been identified.

Gamma-cyhalothrin is the biologically most active isomer of cyhalothrin (consisting of four isomers) and lambda-cyhalothrin (consisting of two isomers), and was also considered as the toxicologically active component of cyhalothrins isomers. A small number of toxicity studies were submitted on gamma-cyhalothrin and a bridging case has been presented taking into account studies performed with cyhalothrin and lambda-cyhalothrin to support the full toxicological evaluation of gamma-cyhalothrin.

Toxicokinetics and metabolism of gamma-cyhalothrin are considered unlikely to be different from cyhalothrin and lambda-cyhalothrin, for which these data were comparable to each other. Cyhalothrins are incompletely absorbed after oral administration; variable results were obtained pending on the study conditions (radiolabel, vehicle and dose used), therefore oral absorption was considered to be approximately 25 % in rat based on urine excretion, and 50 % in dogs when comparing plasma kinetics upon oral and intravenous administrations. Cyhalothrins are rapidly and extensively distributed, metabolised and excreted, although some accumulation was observed in fat.

Gamma-cyhalothrin is acutely toxic after ingestion, highly toxic after inhalation and it is of moderate toxicity upon contact with the skin, showing an overall higher acute toxicity than cyhalothrin or lambda-cyhalothrin. High toxicity was also noted after ocular instillation of gamma-cyhalothrin precluding a proper assessment of the eye irritation properties of the substance, which is a mild skin irritant but a strong skin sensitiser according to a maximisation test of Magnusson and Kligman[7].

Clinical signs of neurotoxicity characteristics of poisoning by type II pyrethroids (such as salivation, incoordination, postural abnormalities, hyperexcitability, tremors) are the critical findings observed upon short-term administration of gamma-cyhalothrin, which were observed at lower dose levels than in case of cyhalothrin and lambda-cyhalothrin. Dogs appear to be more sensitive to cyhalothrin administration and the relevant short-term NOAEL of 0.5 mg/kg bw per day was observed in the 1-year study in dogs conducted with lambda-cyhalothrin. Long-term studies were solely conducted on cyhalothrin and presented similar NOAELs of 1.7 and 1.8 mg/kg bw per day in rats and mice, respectively. No genotoxic or carcinogenic potential was observed, and cyhalothrins did not cause reproductive or developmental effects in rats and rabbits. However, as sperm effects are reported in the published literature in mice treated with low doses of lambda-cyhalothrin in a formulation, a data

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

gap was identified during the experts' meeting to clarify whether this potential concern affects the outcome of the risk assessment. The lowest relevant NOAEL was seen in the multigeneration study in rats showing an offspring NOAEL of 0.5 mg cyhalothrin/kg bw per day, based on decrease in body weight gain.

Regarding metabolites that were found in plant residues, **CPCA**, **PBA** and **PBA(OH)**, insufficient toxicological information has been provided to conclude on their toxicity profile and a data gap was identified. One further metabolite, identified in plants as **epimer** of gamma-cyhalothrin, was found to be less acutely toxic than gamma-cyhalothrin; regarding repeated dose toxicity, the epimer was tested in the cyhalothrin studies in the same proportion as gamma-cyhalothrin. Therefore, theoretically, as a worst case, the reference values of gamma-cyhalothrin could apply to this metabolite. It is however noted that, considering the critical effects of cyhalothrin (clinical signs seen also in acute toxicity) and decreased body weight gain, it is reasonable to expect that the metabolite is of lower toxicity than gamma-cyhalothrin also upon repeated dose exposure.

The acceptable daily intake (**ADI**) of gamma-cyhalothrin is 0.0012 mg/kg bw per day, based on the NOAEL of 0.5 mg cyhalothrin/kg bw per day from the multigeneration study in rat, applying an uncertainty factor (UF) of 400, i.e. a standard UF of 100 and an additional factor of four to convert from cyhalothrin to gamma-cyhalothrin. The acceptable operator exposure level (**AOEL**) is 0.0003 mg/kg bw per day, based on the same NOAEL of 0.5 mg cyhalothrin/kg bw per day, 400 UF applied, and correcting for the limited oral absorption by 25 %. The acute reference dose (**ARfD**) is 0.0025 mg/kg bw, based on the NOAEL of 0.5 mg lambda-cyhalothrin/kg bw per day from the 1-year study in dogs, applying an UF of 200, a standard UF of 100 and an additional factor of two to convert from lambda- to gamma-cyhalothrin.

Dermal absorption for the representative formulation is 2 % for the concentrate, 12 % for a low spray dilution of 0.13 g/L, and 32 % for a high spray dilution of 0.0074 g/L. It is however noted that for the latter spray dilution (0.0074 g/L), 24 % dermal absorption would be applicable if risk managers consider that the EFSA guidance document on dermal absorption (EFSA PPR Panel, 2012) should not be applied.

Personal protective equipment (PPE), such as gloves during mixing and loading operations, and gloves, coveralls and sturdy footwear during applications according to the German model is required to ensure that the estimated **operator exposure** is below the AOEL. **Worker** undertaking crop inspection exposure is estimated to exceed the AOEL even when the use of PPE (gloves) is considered (representing 163 % of the AOEL – or 122 % of the AOEL if considering 24 % dermal absorption for the in-use spray dilution). Using a re-entry exclusion interval of 9 days, worker systemic exposure is calculated to represent 132 % of the AOEL (99 % using 24 % dermal absorption), while an exclusion period of 21 days is required to ensure that worker exposure does not exceed the AOEL, representing 100 % of the AOEL. **Bystander exposure** is estimated to represent up to 5.7 % of the AOEL according to the scenarios currently considered at the EU level. It is noted that according to current UK standards (under recommendations of the Bystander Risk Assessment Working Group (BRAWG)), a further bystander exposure scenario representing a bystander re-entering treated areas (30 min. duration) during the exclusion period is calculated to be 305 – 407 % for an unprotected bystander, and 109 – 145 % for a bystander wearing one layer of clothing (varying percentage pending on the dermal absorption used for the spray dilution, 24 or 32 % respectively); the parameters used in these scenarios are however still under discussion at European level and no final conclusion can be drawn at this stage.

3. Residues

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

The metabolism in primary crops was investigated with gamma-cyhalothrin in cereals (wheat) and fruit (grapes), and with the racemate lambda-cyhalothrin in pulses and oilseeds (soya and cotton) and in cereals (wheat). Both active substances were radio labelled in the cyclopropyl ring and in the phenoxyphenyl ring. Based on the metabolism data for gamma-cyhalothrin and lambda-cyhalothrin, similar pathways were concluded for both compounds, with the parent compound being by far the major residue, and CPCA (cyclopropyl label specific) as well as PBA plus its hydroxy-derivative PBA(OH) (phenoxyphenyl label specific) being identified as the pertinent metabolites for both active substances in the crops investigated. The conversion of gamma-cyhalothrin to the epimer was determined in cereals and was found to be not significant (max. 4 %).

Metabolism data with gamma-cyhalothrin in rotational crops are not available, but reference was made to a study conducted with cyclopropyl- and phenoxyphenyl- labelled lambda-cyhalothrin in rotational wheat, lettuce and carrots. It is assumed that no significant difference in the nature of residues (disregarding the enantiomer-specific aspect) is expected in the metabolic pathway between the active substances both in soil and plants, therefore bridging of the data is considered acceptable. The TRR was significantly higher in rotational crops in the cyclopropyl-labelled study, indicating preferential uptake of metabolites containing the cyclopropyl moiety, of them CPCA invariably being the major residue in rotational carrots (52 % TRR), lettuce (61 % TRR) and wheat straw (34 % TRR). The parent was either not detected or present in a negligible proportion (< 1 % TRR). In both primary and rotational crop studies, CPCA was a predominant metabolite in grapes (13 % TRR), pulses and oilseed leaves (24 – 27 % TRR) and in the edible parts of the rotational crops (34 to 61 % TRR). No toxicological information has been available for CPCA. Pending on the outcome of the requested information on the toxicological properties of CPCA (see section 2), it was suggested to include CPCA in the residue definition for risk assessment. Therefore, the peer review defined the residue in plants for the risk assessment of gamma-cyhalothrin provisionally as gamma-cyhalothrin and CPCA. Currently it is not known, if both compounds have to be considered separately or as their sum in the consumer risk assessment.

For the PBA / PBA (OH) metabolites, which are common metabolites to many of the pyrethroids in general, the Pesticides Peer Review Experts' Meeting on mammalian toxicology concluded that the toxicological properties were not sufficiently addressed. It is noted that PBA is subject to ongoing European and worldwide research activities concerning its occurrence in humans and potential health effects. Pending on the toxicological profile of the aforementioned metabolites, it needs to be considered if a similar risk assessment approach as for the triazole derivative metabolites (TDMs) will have to be chosen in future.

The analytical methods proposed for monitoring are only able to analyse the enantiomeric pair 1*R*, *cis*, *Z-S*' and 1*S*, *cis*, *Z-R*' (*alias* lambda-cyhalothrin), and therefore may not be capable of distinguishing between gamma-cyhalothrin (1*R*, cis, *Z-S*' enantiomer alone) and lambda-cyhalothrin. Hence, the peer review suggested to define the residue for monitoring in plants as sum of gamma-cyhalothrin and its enantiomer (equivalent to any ratio of constituent enantiomers of lambda-cyhalothrin), considering that lambda-cyhalothrin is commonly defined as a 1:1 ratio of constituent enantiomers, however this enantiomer ratio is unlikely to be found in the residues upon application of gamma-cyhalothrin.

It is further acknowledged, that there are differences in the toxicological reference values proposed for lambda-cyhalothrin and gamma-cyhalothrin, and therefore, from the risk assessors point of view it would be desirable if an analytical distinction could be made, however this seems currently not possible on a routine basis. It is noted that, according to the applicant, a normal phase HPLC-UV (225 nm) method, using a chiral D-P column, is available and could be validated if the residue definition for monitoring should be set as gamma-cyhalothrin.

A sufficient number of acceptable residue trials with gamma-cyhalothrin conducted in wheat and barley in Northern Europe are available and permit the proposal of an MRL for wheat and barley.

As for the representative uses, data on the nature and level of residues upon industrial and household processing were not submitted in cereal products, and were not triggered due to the low residues in cereal grains. Satisfactory residue storage stability data are available.

Dietary intakes of gamma-cyhalothrin were significant for ruminants due to the residues found in cereal straw. Metabolism data with gamma-cyhalothrin in livestock are not available; however, metabolism in goat and poultry was studied using lambda-cyhalothrin. The parent is the major compound in all tissues, except in liver and kidney, where, depending on the labelling, metabolites CPCA or PBA are the predominant compounds of the total residues.

In addition, livestock feeding studies are available for lambda-cyhalothrin in cows and, for both lambda-cyhalothrin and gamma-cyhalothrin, in poultry. In poultry feeding studies, residues of lambda-cyhalothrin were higher (up to 2-fold) than those found for gamma-cyhalothrin at the same dose level, suggesting that the enantiomer 1*R*, *cis*, *Z-S*' (gamma-cyhalothrin) may be metabolised more rapidly than the enantiomer 1*S*, *cis*, *Z-R*', also present in lambda-cyhalothrin.

The residue definition for risk assessment in all livestock matrices was set as gamma-cyhalothrin and provisionally CPCA and, for monitoring, it is suggested to define the residue as the sum of gamma-cyhalothrin and its enantiomer (any ratio of constituent enantiomers of lambda-cyhalothrin).

Overall, the use of lambda-cyhalothrin livestock metabolism and feeding data to support gamma-cyhalothrin is considered to be acceptable. The lambda-cyhalothrin data can be considered to be worse case in terms of proposing MRLs in products of animal origin. However, as for the risk assessment of gamma-cyhalothirn, the residues of CPCA might be underestimated in the studies with lambda-cyhalothrin as gamma-cyhalothrin may be metabolised more rapidly to CPCA (see above).

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMo). In the chronic dietary risk assessment the TMDI for gamma-cyhalothrin was calculated as 31 % (NL child) of the ADI of 0.0012 mg/kg bw per day, and in the acute dietary risk assessment the intake of gamma-cyhalothrin was at a maximum 50 % of the ARfD of 0.0025 mg/kg bw for milk and milk products (UK infant). No assessment can currently be conducted for CPCA due to the pending toxicological property assessment for this compound and therefore the consumer risk assessment presented above is considered provisional.

4. Environmental fate and behaviour

In soil laboratory incubations under aerobic conditions in the dark, gamma-cyhalothrin exhibited moderate persistence, forming the major (> 10 % applied radioactivity (AR)) metabolite 3-(4-OHPh) (max. 12.2 % AR). Metabolite PBA (max. 8.2 % AR in the dark control of the soil photolysis study), which exhibited very low to low persistence, was present at levels that trigger a groundwater exposure assessment. Another degradation product, DMCPA, was also detected in the new guideline soil photolysis study (The United Kingdom, 2014) at max. 14.2 % AR in the dark control samples and therefore required further assessment. Metabolite DMCPA exhibited low persistence in soil. Mineralisation of the phenoxy ring ^{14}C radiolabel to carbon dioxide accounted for 24 - 40 % AR whilst that of the cyclopropyl ring ^{14}C radiolabel was greater, accounting for 53 % AR both after 90 - 95 days. The formation of unextractable residues for these radiolabels accounted for 19 - 49 % AR after 90 - 95 days. Chiral chromatography identified that, in the soils investigated under dark laboratory conditions, isomerisation of gamma-cyhalothrin to other cyhalothrin isomers was limited (< 5 – 9 % at 62 - 95 days). In anaerobic soil incubations, where either cyclopropane or phenoxy labelled gamma-cyhalothrin was dosed, no mineralisation occurred and extracted radioactivity was minimal at 3 - 3.5 % AR at 120 days. A laboratory soil photolysis study indicated that, while photodegradation may contribute to the dissipation of gamma-cyhalothrin from soil, it is not a significant route of degradation. No significant isomerisation of gamma-cyhalothrin at the α-cyano carbon (from *S* to *R*) occurred in either light exposed or dark control samples. Gamma-cyhalothrin can be considered immobile in soil; metabolite 3-(4-OHPh) exhibits medium to low mobility in soil (based on

estimations with HPLC and QSAR methods), and metabolites PBA and DMCPA exhibit very high to high mobility. The adsorption of gamma-cyhalothrin and its soil metabolites was not pH dependent.

In laboratory incubations in dark aerobic natural sediment water systems, dissipation of gamma-cyhalothrin from the water phase primarily through partitioning to sediment was relatively rapid. Maximum amounts of gamma-cyhalothrin in sediment reached 69 – 77 % AR at 15 days. Chiral HPLC analysis of the sediment extracts showed that gamma-cyhalothrin undergoes extensive isomeric conversion in the Italian system (higher pH), but the extent of formation of the other isomer(s) produced in the experiment was not quantitatively measured. However, taking into consideration that the kinetic data were reported as degradation of gamma-cyhalothrin, which is considered the most biologically active isomer (see section 2), it can be concluded that the degradation rates obtained utilising gamma-cyhalothrin can be considered to produce the most conservative values with regard to risk assessment. The major metabolites formed in the water/sediment systems were PBA (maximum formation 26.5 % AR in water, 18.9 % AR in sediment at 33 days) and DMCPA (maximum formation 64.9 % AR in water, 18.4 % AR in sediment at 58 days). At the study end (100 days) mineralisation to CO_2 was fairly extensive, accounting for 32 – 37 % AR, with the exception of the cyclopropane radiolabel in the low organic carbon system where CO_2 only accounted for 2.1 % AR. The first-order DT_{50} (non-linear regression) for the photochemical degradation of gamma-cyhalothrin to non-cyhalothrin breakdown products was 6.9 test system days at 20ºC, equivalent to 10.6 days of summer sunlight at a latitude of 40 °N. There was no degradation in the dark control samples under the test conditions. The necessary surface water and sediment exposure assessments (Predicted environmental concentrations (PEC) calculations) were carried out for gamma-cyhalothrin and metabolites PBA, DMCPA and 3-(4-OHPh), using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 2.1 of the steps 1-2 in FOCUS calculator). For the active substance gamma-cyhalothrin, appropriate step 3 (FOCUS, 2001) and step 4 calculations were available[8] using the longest degradation half-life values as input. The step 4 exposure assessment was performed with either the introduction of a 40 m buffer zone or assuming 95 % reduction in spray drift by using low drift nozzles (The United Kingdom, 2014). However, it should be noted that a buffer zone of 40 m will result in a spray drift reduction exceeding the maximum value of 95 % recommended by the FOCUS Landscape and Mitigation Guidance (FOCUS, 2007), and therefore this extent of spray drift mitigation can not be accepted.

The necessary groundwater exposure assessments were carried out using FOCUS (FOCUS, 2000) scenarios and the models PEARL v. 4.4.4 and PELMO v. 3.3.2 (gamma-cyhalothrin only) for the active substance gamma-cyhalothrin and metabolites PBA, DMCPA and 3-(4-OHPh). The potential for groundwater exposure from the representative uses by gamma-cyhalothrin and these three metabolites 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.

The PEC in soil, surface water, sediment and groundwater covering the representative uses assessed can be found in Appendix A of this conclusion.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a and 2002b), SETAC (2001) and EFSA (2009). The ecotoxicological risk assessment for gamma-cyhalothrin was discussed at the Pesticides Peer Review Experts' Meeting 107 (November 2013).

On the basis of the available data and risk assessments a low acute and long-term dietary risk to **birds** from the representative uses of gamma-cyhalothrin was concluded. A low acute risk to wild **mammals** was also concluded, however, a high long-term risk was indicated on the basis of the available first-tier risk assessment. No refined risk assessment was available and therefore a data gap was identified for further information to address the long-term risk to wild mammals from dietary routes of exposure.

[8] Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA PPR Panel, 2007) and Walker equation coefficient of 0.7.

As the log P_{ow} of gamma-cyhalothrin is greater than three, risk assessments were available to address the risk to earthworm-eating and fish-eating birds and mammals following bioaccumulation; a low risk was indicated. A low risk to birds and mammals from the consumption of contaminated water was also concluded. An assessment of the potential for biomagnification in terrestrial vertebrates was available and the RMS concluded a low risk of gamma-cyhalothrin biomagnifying in terrestrial food chains. However, the parameters used in the assessment were not agreed by EFSA (i.e. the half-life for elimination) and therefore the assessment could not be finalised. Furthermore, no assessment was available to address the potential for biomagnification in aquatic food chains. Consequently, a data gap was identified to address the potential for biomagnification in terrestrial and aquatic food chains.

Acute and chronic aquatic toxicity data were available and used to assess the risk to **aquatic organisms**. A low risk to algae was indicated. A high acute risk to fish was indicated using FOCUS step 2 surface water exposure estimates. Additional data using the formulated product and modified exposure (i.e. performed in the presence of sediment) were available and were discussed at the expert meeting. The experts agreed that the endpoint from the modified toxicity study performed with the formulated product could be used to refine the acute risk assessment for fish, but only when the exposure profile indicates exposure from spray-drift only. Where the exposure is predicted to be over a longer time period or for multiple exposure peaks (e.g. from run-off) then the refined endpoint was not considered to be suitable. In these cases, the lowest acute fish toxicity endpoint, together with the standard assessment factor of 100, should be used for risk assessment (i.e. tier-1 regulatory acceptable concentration (RAC)). Further risk assessments (FOCUS step 3 and 4) using the refined endpoint and accounting for the maximum exposure peak were available. However, detailed consideration of the exposure profiles and whether subsequent exposure peaks would exceed the tier-1 RAC value were not available. Therefore a data gap was identified for further consideration of the acute risk assessment for fish.

Data demonstrating the chronic toxicity of gamma-cyhalothrin to *Pimephales promelas* were available. However, it was noted that the studies were not performed with the fish species which was found to be the most sensitive in the acute toxicity studies (*Lepomis macrochirus*). This issue was discussed at the Pesticides Peer Review Experts' Meeting 107 and the experts agreed that additional chronic toxicity data for *Lepomis macrochirus* were not required; however, it should be acknowledged that there is some uncertainty with the available chronic risk assessment for fish. Using FOCUS step 3 exposure estimates and a toxicity endpoint from the available fish full life cycle study, a high chronic risk to fish was indicated. However, when risk mitigation measures, such as no-spray buffer zones or low drift nozzles, were taken into account, a low chronic risk to fish was indicated.

A high acute risk to **aquatic invertebrates** was indicated using the available FOCUS step 2 exposure estimates. The available chronic aquatic invertebrate toxicity study was discussed at the experts' meeting and the experts agreed that the endpoint was not sufficiently reliable for risk assessment. Therefore, no lower tier risk assessments were available to assess the chronic risk to aquatic invertebrates. Several higher tier studies and literature papers were available and were used to derive a refined RAC value for aquatic invertebrates (i.e. a concentration at which a low acute and chronic risk to aquatic invertebrates is expected). The available information was discussed at the Pesticides Peer Review Experts' Meeting 107. On the basis of the available data, the experts agreed on a refined RAC value of 0.3 ng a.s./L, which was considered to be relevant only when the exposure profile indicates exposure from spray-drift only. Where the exposure is predicted to be over a longer time period or for multiple exposure peaks (e.g. from run-off exposure) then the refined endpoint was not considered to be suitable. Using the refined RAC value, a high risk to aquatic invertebrates was indicated in all FOCUS surface water exposure scenarios even when the maximum level of risk mitigation according to the FOCUS Landscape and Risk Mitigation guidance (FOCUS, 2007) was taken into account (5/5 scenarios for the representative use on spring cereals and 9/9 scenarios for the representative use on winter cereals). Consequently, a high acute and chronic risk to aquatic invertebrates was concluded and a data gap was identified for further information to address the acute and chronic risk to aquatic invertebrates. It was indicated that the primary route of exposure was via spray drift in the majority of the FOCUS surface water exposure scenarios. The exception to this was the R4 scenario, where run-

off was indicated as the primary source of exposure after risk mitigation for spray-drift. As discussed above, the refined RAC value is not considered suitable where run-off is the primary route of exposure. Additionally, even when the primary route of exposure is via spray-drift, it is still necessary to ensure that subsequent exposure peaks (long-term or multiple exposures) do not exceed the first-tier RAC values. A further data gap was therefore concluded for detailed consideration of the FOCUS exposure profiles and the suitability of the use of the refined RAC value for the risk assessment for aquatic invertebrates. As discussed above, the endpoint from the available chronic aquatic invertebrate toxicity study was not considered to be sufficiently reliable for risk assessment, therefore, where the refined RAC value of 0.3 ng/L is not considered appropriate on the basis of the exposure profile, a new chronic aquatic toxicity study is required. Consequently, a further data gap was identified for a chronic toxicity study with aquatic invertebrates in situations where the available refined RAC value is not considered appropriate.

A low chronic risk to **sediment-dwelling organisms** was indicated for all relevant FOCUS scenarios for the representative use in spring sown cereals. A low chronic risk to sediment-dwelling organisms was also indicated for 8/9 FOCUS scenarios for the representative use in winter cereals, however, a high risk was indicated in the R3 scenario. No refined risk assessment was available and consequently a data gap was concluded for further consideration of the chronic risk to sediment-dwelling organisms in situations which are represented by the R3 FOCUS scenario (relevant only for the representative use in winter cereals).

A low risk to aquatic organisms from the pertinent surface water metabolites DMCPA, PBA and 3-(4-OHPh) was concluded.

Acute oral and contact toxicity data for **honey bees** were available and were used for risk assessment. The first-tier risk assessment for honey bees indicated a low acute oral risk, however a high acute contact risk was identified. Several higher tier field studies were available and discussed at the Pesticides Peer Review Experts' Meeting 107. Two field studies, performed on flowering oilseed rape and *Phacelia tanacetifolia,* were considered to be useful for the risk assessment for the representative uses on cereals. Some uncertainties with the studies were noted, but overall the experts considered that the studies indicated only a low and transient effect on honey bees. Therefore, on the basis of the available information, a low risk to honey bees from the representative uses in winter and spring cereals was concluded.

Toxicity data with the standard tier-1 species of **non-target arthropods** were available and used for risk assessment. A high in-field and off-field risk to non-target arthropods was indicated in the first-tier risk assessment. A higher tier field study, performed in Southern England on cereals in spring, was available. Low abundance of the most sensitive species, in both the control and treatment plots, created uncertainty with the interpretation of the potential for recovery. However, under the conditions of the study, it was considered that the potential for recovery was demonstrated, indicating a low risk to non-target arthropods. However, no consideration of the relevance of the field study to other application regimes or locations in Northern EU is available (i.e. to cover the representative uses). Therefore, a data gap is concluded for further consideration of the relevance of the available field study to the representative uses of gamma-cyhalothrin.

A low risk to **earthworms** from gamma-cyhalothrin and the relevant soil metabolite 3-(4-OHPh) was concluded. Metabolite DMCPA was also identified as a relevant soil metabolite requiring consideration in the ecotoxicology assessment (see section 4). No data or risk assessments were available to address the risk to earthworms from DMCPA. However, given the high margin of safety obtained for the acute earthworm risk assessment for the parent substance (i.e. TER values greater than a factor of 10 above the trigger value), a low acute risk to earthworms from the metabolite DMCPA was concluded. DMCPA is of low persistence in soil and therefore a chronic risk assessment was not necessary.

A low risk to **soil micro-organisms**, **non-target terrestrial plants** and **sewage treatment organisms** was also concluded.

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

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
gamma-cyhalothrin	Moderate persistence Single first order DT_{50} 16.6-33.8 days (20°C, pF2 soil moisture)	Low risk to soil-dwelling organisms.
3-(4-OHPh)	Very low persistence Single first-order DT_{50} 0.012-0.024 days (20°C, pF2 soil moisture)	Low risk to soil-dwelling organisms.
DMCPA[(a)]	Low persistence Single first-order DT_{50} 1.63-5.06 days (20°C, pF2 soil moisture)	Low risk to soil-dwelling organisms.

(a): Major (> 10% AR) metabolite identified in the dark control samples of the soil (75% of field moisture capacity at 1/3 bar) photolysis study.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
gamma-cyhalothrin	Immobile K_{doc} 30941-94425 mL/g	No	Yes	Yes	High risk to aquatic organisms indicated in the surface water assessment.
3-(4-OHPh)	Medium to low mobility K_{doc} 324-548 mL/g (HPLC and QSAR methods)	No	No data	Negative Ames test	Low risk to aquatic organisms was indicated in the surface water assessment.
PBA	Very high to high mobility K_{Foc} 47-71 mL/g	No	No data	No data available	Low risk to aquatic organisms was indicated in the surface water assessment.
DMCPA	Very high to high mobility K_{doc} 27-120 mL/g	No	No data	Negative Ames test Rat, oral LD_{50} > 2000 mg/kg bw	Low risk to aquatic organisms was indicated in the surface water assessment.

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
gamma-cyhalothrin	High acute and chronic risk to aquatic invertebrates with maximum permissible risk mitigation in all relevant $FOCUS_{sw}$ scenarios. High acute risk to fish was also indicated at FOCUS step 2.
3-(4-OHPh)	Low risk to aquatic organisms
PBA	Low risk to aquatic organisms
DMCPA	Low risk to aquatic organisms

6.4. Air

Compound (name and/or code)	**Toxicology**
gamma-cyhalothrin	Rat LC_{50} inhalation 0.0282-0.0402 mg/L air/4 h (nose-only): very toxic by inhalation

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

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- Enforcement residue method for monitoring of gamma-cyhalothrin in body fluids and tissues (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown, see section 1).
- Enforcement residue methods capable of determining the residues according to the residue definition in the environmental matrices (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown, see section 1).
- Clarification whether the sperm effects that were reported in published literature in mice treated with low doses of lambda-cyhalothrin in a formulation have an impact on the outcome of the risk assessment (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2).
- Toxicological information to assess the toxicity profile of the plant metabolites CPCA, PBA and PBA(OH) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2).
- Further information to address the long-term risk to wild mammals from dietary routes of exposure (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).
- Information to address the potential for biomagnification in terrestrial and aquatic food chains (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).
- Further consideration of the acute risk assessment for fish (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).
- Further information to address the acute and chronic risk to aquatic invertebrates. In addition, detailed consideration of the FOCUS exposure profiles and the suitability of the available refined risk assessment for aquatic invertebrates should be provided. A chronic toxicity study with aquatic invertebrates is required in situations where the available refined RAC value is not considered appropriate (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).
- Further information to address the chronic risk to sediment-dwelling organisms in situations which are represented by the R3 FOCUS scenario (relevant only for the representative use in winter cereals; submission date proposed by the applicant: unknown; see section 5).
- Further consideration of the relevance of the available non-target arthropod field study to the representative uses of gamma-cyhalothrin (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).

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

- Personal protective equipment (PPE), such as gloves during mixing and loading operations, and gloves, coveralls and sturdy footwear during applications according to the German model are required to ensure that the estimated operator exposure is below the AOEL (see section 2).

- PPE, such as gloves and an exclusion re-entry interval of 21 days are required to ensure that the estimated worker exposure does not exceed the AOEL (representing 100 % of the AOEL). Considering a dermal absorption value of 24 % (disregarding the recent EFSA guidance document on dermal absorption, EFSA PPR Panel, 2012), PPE (gloves) and an exclusion re-entry interval of 9 days are required to obtain a level of exposure corresponding to 99 % of the AOEL.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

1. The consumer risk assessment is considered provisional owing to the fact that the residue definition for risk assessment in plant and livestock matrices could not be finalised due to insufficient toxicological data for metabolite CPCA.

2. The assessment of the potential for biomagnification in terrestrial and aquatic food chains could not be finalised with the available information.

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

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

3. A high long-term risk to wild mammals was indicated.

4. A high acute and chronic risk to aquatic invertebrates was indicated using a higher tier effects endpoint together with surface water exposure estimates calculated assuming the maximum permissible level of risk mitigation according to the FOCUS Landscape and Risk Mitigation guidance (FOCUS, 2007). A high acute risk to fish was also indicated in the available assessment.

9.3. Overview of the concerns identified for each representative use considered

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

Representative use		Winter wheat	Winter barley	Spring wheat	Spring barley
Operator risk	Risk identified				
	Assessment not finalised				
Worker risk	Risk identified				
	Assessment not finalised				
Bystander risk	Risk identified				
	Assessment not finalised				
Consumer risk	Risk identified				
	Assessment not finalised	X[1]	X[1]	X[1]	X[1]
Risk to wild non target terrestrial vertebrates	Risk identified	X[3]	X[3]	X[3]	X[3]
	Assessment not finalised	X[2]	X[2]	X[2]	X[2]
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified				
	Assessment not finalised				
Risk to aquatic organisms	Risk identified	9/9 $FOCUS_{sw}$ scenarios[4]	9/9 $FOCUS_{sw}$ scenarios[4]	5/5 $FOCUS_{sw}$ scenarios[4]	5/5 $FOCUS_{sw}$ scenarios[4]
	Assessment not finalised	X[2]	X[2]	X[2]	X[2]
Groundwater exposure active substance	Legal parametric value breached				
	Assessment not finalised				
Groundwater exposure metabolites	Legal parametric value breached[(a)]				
	Parametric value of 10µg/L[(b)] breached				
	Assessment not finalised				
Comments/Remarks					

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

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

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

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APPENDICES

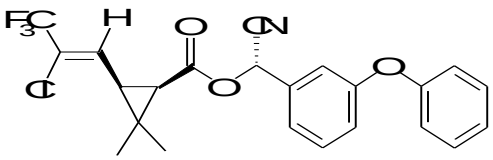
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

Active substance (ISO Common Name) ‡	Gamma-cyhalothrin
Function (*e.g.* fungicide)	Insecticide

Rapporteur Member State	UK
Co-rapporteur Member State	None

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	(*S*)-α-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate or (*S*)-α-cyano-3-phenoxybenzyl (1*R*)-*cis*-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate
Chemical name (CA) ‡	(*S*)-cyano(3-phenoxyphenyl)methyl (1*R*,3*R*)-3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate
CIPAC No ‡	768
CAS No ‡	76703-62-3
EEC No (EINECS or ELINCS) ‡	Not allocated
FAO Specification (including year of publication)‡	Not available
Minimum purity of the active substance as manufactured ‡	980 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured	None
Molecular formula ‡	$C_{23}H_{19}ClF_3NO_3$
Molar mass ‡	449.85 g/mol
Structural formula ‡	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	55.6 °C (100 %)
Boiling point (state purity) ‡	Substance decomposes before boiling
Temperature of decomposition (state purity)	245 °C
Appearance (state purity) ‡	Off white fluffy solid (100 %, technical)
Vapour pressure (state temperature, sate purity) ‡	3.45 x 10^{-7} Pa at 20 °C (100 %)
Henry's law constant ‡	0.0221 Pa m^3 mol^{-1}
Solubility in water (state temperature, state purity and pH) ‡	2.1 ± 0.6 µg/l at 20°C (100 %): (effect of pH not required as the active substance does not dissociate)
Solubility in organic solvents ‡ (state temperature, state purity)	At 19°C (100 %): heptane 30.7 g/l *p*-xylene > 500 g/kg 1,2-dichloroethane > 500 g/kg methanol 138 g/l 1-octanol 36.6 g/l acetone > 500 g/kg ethyl acetate > 500 g/kg
Surface tension ‡ (state concentration and temperature, state purity)	Not tested as water solubility of the solid substance is less than 1 mg/l
Partition co-efficient ‡ (state temperature, pH and purity)	log Pow = 4.96 at 19°C (100 %) (effect of pH not required as the active substance does not dissociate)
Dissociation constant (state purity) ‡	Not required as gamma-cyhalothrin does not contain any ionisable protons.
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Solution in methanol (100 %) λ_{max} (nm); ε ($L.mol^{-1}.cm^{-1}$) pH 7.92 204 45700 pH 0.83 204 45600 pH 12.77 219 29600
Flammability ‡ (state purity)	Not flammable (100 %) Auto ignition temperature: 398°C
Explosive properties ‡ (state purity)	Not explosive (100 %)
Oxidising properties ‡ (state purity)	Not oxidising (100 %)

Summary of representative uses evaluated (Gamma-cyhalothrin)

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 (day) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i) g/l	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min) days	kg a.s./hL min max	water L/ha min max	kg a.s./ha min max		
Winter and Spring Wheat	Northern EU	'Corello' GF-317	F	a range of insects	CS	60	Foliar	BBCH 12 - 77	3	10	From 0.001125 to 0.00225	200 - 400	0.0045 x 3	28	Max total of 0.0135 kg a.s./ha in 3 applications in 1 season
Winter and Spring Barley	Northern EU	'Corello' GF-317	F	a range of insects	CS	60	Foliar	BBCH 12 - 75	3	10	From 0.001125 to 0.00225	200 - 400	0.0045 x 3	28	Max total of 0.0135 kg a.s./ha in 3 applications in 1 season

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Techn. Monograph no 2, 6th Edition. Rev May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Methods of Analysis

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

Technical a.s. (principle of method)	Gamma-cyhalothrin: GC-FID with internal standard. Enantiomer: HPLC-DAD
Impurities in technical a.s. (principle of method)	Impurities are determined using external standard gas chromatography, normal phase liquid chromatography and titration methods.
Plant protection product (principle of method)	Gamma-cyhalothrin: HPLC-UV Enantiomer: HPLC-UV CIPAC method 463/CS/M/ demonstrated to be applicable

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	Gamma-cyhalothrin and its enantiomer (alias: any ratio of constituent isomers of lambda-cyhalothrin)
Food of animal origin	Gamma-cyhalothrin and its enantiomer (alias: any ratio of constituent isomers of lambda-cyhalothrin)
Soil	Gamma-cyhalothrin
Water surface	Gamma-cyhalothrin
drinking/ground	Gamma-cyhalothrin
Air	Gamma-cyhalothrin
Body fluids and tissues	Gamma-cyhalothrin

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	DFG S19 (GC-ECD and GC-MS or GC-MS/MS) Commodity — LOQ Cereal grain — 0.01 mg/kg Grapes — 0.01 mg/kg Oranges — 0.01 mg/kg Oilseed — 0.01 mg/kg Note: No ILV linearity data for confirmatory technique for grapes and oilseeds. No ILV data for high water crops were provided.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	DFG S19 (LC-MS/MS; validated for 2 ion transitions): Commodity — LOQ Muscle — 0.01 mg/kg Liver — 0.01 mg/kg Kidney — 0.01 mg/kg Fat — 0.01 mg/kg Milk — 0.01 mg/kg Eggs — 0.01 mg/kg

Soil (analytical technique and LOQ)	DFG S19 (GC-ECD and GC-MS) LOQ = 0.05 mg/kg. The method is not capable of distinguishing between residues of gamma-cyhalothrin and lambda-cyhalothrin. Data gap.
Water (analytical technique and LOQ)	LC-MS/MS (validated for 2 ion transitions) LOQ = 0.0003 µg/L The method is not capable of distinguishing between residues of gamma-cyhalothrin and lambda-cyhalothrin. Data gap.
Air (analytical technique and LOQ)	GC-MS LOQ = 0.15 µg/m^3 The method is not capable of distinguishing between residues of gamma-cyhalothrin and lambda-cyhalothrin. Data gap.
Body fluids and tissues (analytical technique and LOQ)	GC-MS (validated for 3 ions) LOQ = 0.025 µg/mL in whole blood and urine The method is not capable of distinguishing between residues of gamma-cyhalothrin and lambda-cyhalothrin. Data gap.

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

	RMS/peer review proposal
Active substance	None

Impact on Human and Animal Health

Endpoints are for studies with gamma-cyhalothrin unless stated otherwise.

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

Rate and extent of absorption ‡	[Lambda-cyhalothrin] Relatively rapid absorption, variable results obtained pending on study conditions (radiolabel, vehicle, dose, etc.): in man 50 – 64 % oral absorption based on the excretion of a metabolite DMCPA (TFMCA) in urine; in dog: 50 % absorption based on plasma kinetics comparison between oral and intravenous routes; in rat 25 % based on urine excretion.
Distribution ‡	[Lambda-cyhalothrin and cyhalothrin] Rapidly and extensively distributed, with highest levels in fat.
Potential for accumulation‡	[Lambda-cyhalothrin and cyhalothrin] Accumulation in fat: half-life of 23 - 30.5 days for the decline of residues in adipose tissue.
Rate and extent of excretion ‡	[Lambda-cyhalothrin] Rapid excretion in urine and faeces; 90 % within 48 hours.
Metabolism in animals ‡	[Lambda-cyhalothrin and cyhalothrin] Extensive metabolism via ester cleavage and conjugation.
Toxicologically relevant compounds ‡ (animals and plants)	Gamma-cyhalothrin
Toxicologically relevant compounds ‡ (environment)	Gamma-cyhalothrin

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	55 mg/kg bw	H301
Rat LD_{50} dermal ‡	1643 mg/kg bw	H312
Rat LC_{50} inhalation ‡	0.0282 - 0.0402 mg/L air/4 h (nose only aerosol exposure)	H330
Skin irritation ‡	Mild irritant	-
Eye irritation ‡	Irritant, severe systemic toxicity upon ocular administration precludes full *in vivo* eye irritation testing	Open
Skin sensitisation ‡	Strong sensitiser (M&K)	H317

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Clinical signs (neurological effects) in rat and dog, liver toxicity and decreased body weight gain (rat)	
Relevant oral NOAEL ‡	90-day, rat: 2.6 mg/kg bw per day [gamma-	H372

	cyhalothrin] 1-year, dog: 0.5 mg/kg bw per day [lambda-cyhalothrin]	
Relevant dermal NOAEL ‡	No data – not required	
Relevant inhalation NOAEL ‡	No data – not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

Unlikely to be genotoxic	

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

Target/critical effect ‡	[cyhalothrin] Rat: Reduced bw gain, increased liver weight and clinical chemistry changes Mouse: CNS (clinical signs of neurotoxicity), reduced bw gain	
Relevant NOAEL ‡	1.7 mg/kg bw per day (2-year rat)[cyhalothrin] 1.8 mg/kg bw per day (2-year mouse) [cyhalothrin]	
Carcinogenicity ‡	[cyhalothrin] No evidence of a carcinogenic potential	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	[cyhalothrin] Parental and offspring toxicity: reduced body weight gain Reproductive toxicity: no specific effect Data required on effects of gamma-cyhalothrin on sperm parameters	
Relevant parental NOAEL ‡	1.5 mg/kg bw per day [cyhalothrin]	
Relevant reproductive NOAEL ‡	5.2 mg/kg bw per day [cyhalothrin]	
Relevant offspring NOAEL ‡	0.5 mg/kg bw day [cyhalothrin]	

Developmental toxicity

Developmental target / critical effect ‡	Rat [gamma-cyhalothrin]: Maternal toxicity: reduced bw gain Developmental toxicity: no effects Rabbit [cyhalothrin]: Maternal toxicity: Clinical signs, reduced bw gain	

	Developmental toxicity: no effects	
Relevant maternal NOAEL ‡	Rat: 0.5 mg/kg bw per day [gamma-cyhalothrin] Rabbit: 10 mg/kg bw per day [cyhalothrin]	
Relevant developmental NOAEL ‡	Rat: 2 mg/kg bw per day [gamma-cyhalothrin] Rabbit: 30 mg/kg bw per day [cyhalothrin]	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	[lambda-cyhalothrin] NOAEL 2.5 mg/kg bw based on increased breathing rate noted at ≥10 mg/kg bw and clinical signs of neurotoxicity noted at 35 mg/kg bw	
Repeated neurotoxicity ‡	No data – not required as neurotoxicity end-points have been evaluated in other studies with cyhalothrins	
Delayed neurotoxicity ‡	No data – not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data
Studies performed on metabolites or impurities ‡	Toxicological data on metabolites: Inactive isomer of lambda-cyhalothrin: Low acute oral toxicity, rat LD_{50} > 2000 mg/kg bw. 3-(4-OHPh): Negative in a bacterial reverse mutation assay DMCPA: Low acute oral toxicity, rat LD_{50} > 2000 mg/kg bw. Negative in a bacterial reverse mutation assay CPCA: Data required to assess the toxicity of the metabolite relevant to consumer exposure. PBA(OH): Negative in a bacterial reverse mutation assay Data required to assess the toxicity of the metabolite relevant to consumer exposure. PBA: Data required to assess the toxicity of the metabolite relevant to consumer exposure. Epimer: Negative in a bacterial reverse mutation assay Moderate acute oral toxicity, rat LD_{50} > 300 mg/kg bw

Medical data ‡ (Annex IIA, point 5.9)

Reports of paraesthesia and respiratory irritation in field workers; incidents involving cough, vomiting, facial paraesthesia and sensitivity were reported in manufacturing plant personnel.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.0012 mg/kg bw per day	multigeneration study in rat [cyhalothrin]	400[(1)]
AOEL ‡	0.0003 mg/kg bw per day	multigeneration study in rat [cyhalothrin]	Overall 1600 (400[(1)] + 25%[(2)])
ARfD ‡	0.0025 mg/kg bw	1-year dog study [lambda-cyhalothrin]	200[(3)]

[(1)] additional UF of 4 to convert from cyhalothrin to gamma-cyhalothrin
[(2)] correction for low oral absorption (25 %).
[(3)] additional UF of 2 to convert from lambda- to gamma-cyhalothrin

Dermal absorption (Annex IIIA, point 7.3) ‡

'Corello' (GF-317) 60 g/L gamma-cyhalothrin CS formulation	Concentrate: 2 % Low spray dilution (0.13 g a.s./L): 12 % based on rat *in vivo* and comparative *in vitro* (human/rat skin) High spray dilution (0.0074 g a.s./L): 32 %[(4)] based on *in vitro* data through human skin

[(4)] It is noted that for the high spray dilution (0.0074 g a.s./L), 24% dermal absorption would be applicable if risk managers consider that the EFSA guidance document on dermal absorption (EFSA PPR Panel, 2012) should not be applied.

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Estimated exposure using tractor mounted equipment (application rate: 0.125 g gamma-cyhalothrin/ha)
	German model — % of AOEL
	No PPE: 301 %
	PPE (gloves during M/L) 281 %
	PPE (gloves during M/L, gloves + coverall + sturdy footwear during application): 21 %
	UK-POEM model
	No PPE: 1936 %
	PPE (gloves during M/L): 1683 %
	PPE (gloves during M/L and application): 279 %

Workers		% of AOEL
	No PPE:	582 %
	PPE (gloves):	163 %[(5)]
	PPE (gloves) & re-entry interval of 9 days	132 %[(6)]
	PPE (gloves) & re-entry interval of 21 days	100 %
Bystanders		% of AOEL
	- Exposure to spray drift field crop sprayers study:	4.8 %
	- Exposure to vapour post application (adults & children):	< 1 %
	- Exposure to spray drift fallout children's exposure model:	5.7 %

(5) 122 % of the AOEL if considering 24 % dermal absorption for the in-use spray dilution.

(6) It is noted that, if risk managers consider that 24 % dermal absorption should be considered (see note 4 under dermal absorption), this scenario would result in worker exposure reflecting 99 % of the AOEL.

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

Substance	Gamma-cyhalothrin
Harmonised classification	Currently not listed in Annex VI of Regulation (EC) No 1272/2008[9] (as amended)
RMS/peer review proposal[10]	Considering the criteria of Directive 67/548/EEC (as amended)[11] T+ 'VERY TOXIC' (R26) 'Very toxic by inhalation' (R25) 'Toxic if swallowed' (R21) 'Harmful in contact with skin' (R43) 'May cause sensitisation by skin contact' (R48/22) 'Harmful: danger of serious damage to health by prolonged exposure if swallowed' Considering the criteria of Regulation (EC) 1272/2008 (as amended): 'DANGER' Acute tox 3 H301 'Toxic if swallowed' Acute tox 4 H312 'Harmful in contact with skin' Acute tox 1 H330 'Fatal if inhaled' Skin sens 1 H317 'May cause an allergic skin reaction' STOT-RE 1 H372 'Causes damage to nervous system through prolonged or repeated exposure'

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

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

[11] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. OJ 196, 16.8.1967, p. 1–98.

Residues

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

Plant groups covered	Wheat and grape (gamma-cyhalothrin) wheat, cotton and soybean (lambda-cyhalothrin)
Rotational crops	Study with lambda-cyhalothrin No further data required
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Data not required for the representative uses.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	n/a
Plant residue definition for monitoring	Gamma-cyhalothrin and its enantiomer (alias: any ratio of constituent isomers of lambda-cyhalothrin)
Plant residue definition for risk assessment	Gamma-cyhalothrin and CPCA (provisional) The inclusion of the metabolite CPCA and whether it should be considered separately or together with the parent in the risk assessment is provisional pending on the outcome of the requested information on its toxicological properties.
Conversion factor (monitoring to risk assessment)	None

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

Animals covered	Studies with lambda-cyhalothrin (goat, hen)
Animal residue definition for monitoring	Gamma-cyhalothrin and its enantiomer (alias: any ratio of constituent isomers of lambda-cyhalothrin)
Animal residue definition for risk assessment	Gamma-cyhalothrin and CPCA (provisional) The inclusion of the metabolite CPCA and whether it should be considered separately or together with the parent in the risk assessment is provisional pending on the outcome of the requested information on its toxicological properties.
Conversion factor (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	Yes (based on lambda-cyhalothrin studies)
Fat soluble residue: (yes/no)	Yes

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

	Based on data generated with lambda-cyhalothrin, it is unlikely that there would be significant residues of gamma-cyhalothrin in rotational or succeeding crops. The most abundant residue in rotational wheat, lettuce and carrots was CPCA. However, using the application rate proposed for the representative use, residues of CPCA >0.01 mg/kg are not expected.

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

Only moderate degradation of gamma-cyhalothrin occurs in broccoli, tomato, cotton seed, wheat grain, field peas, grape wine and corn oil when stored at -20 °C for a period of up to 385 days.

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 0.133 mg/kg DM (dairy) 0.314 mg/kg DM (Beef)	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 (1.0 mg/kg bw/day i.e. 10N) Residue levels* in matrices : Mean (max) mg/kg		
Muscle	< 0.01 mg/kg	-	-
Liver	Max 0.03 mg/kg	-	-
Kidney	Max 0.02 mg/kg	-	-
Fat	Max 0.5 mg/kg	-	-
Milk	Max 0.03 mg/kg		
Eggs		-	

(*) Based on ruminant study conducted with lambda-cyhalothrin.

Note: Although not triggered by the representative uses, feeding studies were submitted in poultry with gamma-cyhalothrin and lambda-cyhalothrin, and were comparatively assessed in the peer review in order to conclude whether bridging of livestock data between gamma-cyhalothrin and lambda-cyhalothrin is possible.

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)	HR
Winter/Spring wheat grain	Northern region	Monitoring: Gamma-cyhalothrin: 15x <0.01 Risk assessment (provisional): Gamma-cyhalothrin: 15x <0.01 CPCA (estimated)*: 15x <0.01	9 trials on winter wheat, 6 trials on spring wheat – all acceptable	0.01	GCH: <0.01 CPCA: <0.01	GCH: <0.01 CPCA: <0.01
Winter/Spring wheat straw	Northern region	Monitoring: Gamma-cyhalothrin: 0.08, 0.11, 0.12, 0.13, 2x 0.15, 0.16, 0.19, 0.20, 2x 0.22, 0.25, 0.31, 0.33, 0.51 Risk assessment (provisional): Gamma-cyhalothrin: 0.08, 0.11, 0.12, 0.13, 2x 0.15, 0.16, 0.19, 0.20, 2x 0.22, 0.25, 0.31, 0.33, 0.51 CPCA (estimated)*: 0.011, 0.015, 0.017, 0.018, 2x 0.021, 0.022, 0.026, 0.028, 2x0.031, 0.035, 0.043, 0.046, 0.071		n/a	GCH: 0.19 CPCA: 0.03	GCH: 0.51 CPCA: 0.07
Winter/Spring barley grain	Northern region	Monitoring: Gamma-cyhalothrin: 1x < 0.01, 6x 0.01, 4x 0.02, 1x 0.03 Risk assessment (provisional): Gamma-cyhalothrin: 1x < 0.01, 6x 0.01, 4x 0.02, 1x 0.03 CPCA (estimated)*: <0.001, 6x 0.0007, 4x 0.0013, 0.002	7 trials on winter barley, 5 trials on spring barley– all acceptable	0.05	GCH: 0.01 CPCA: <0.01	GCH: 0.03 CPCA: <0.01
Winter/Spring barley straw	Northern region	Monitoring: Gamma-cyhalothrin: 0.09, 0.11, 0.16, 0.18, 2 x 0.20, 2x 0.26, 0.27, 2x 0.31, 0.49 Risk assessment (provisional): Gamma-cyhalothrin: 0.09, 0.11, 0.16, 0.18, 2x 0.20, 2x 0.26, 0.27, 2x 0.31, 0.49 CPCA (estimated)*: 0.013, 0.015, 0.022, 0.025, 2x 0.028, 2x 0.036, 0.038, 2x 0.043, 0.068		n/a	GCH: 0.23 CPCA: 0.03	GCH: 0.49 CPCA: 0.07

(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 critical GAP
*CPCA residue levels estimated on the basis of available metabolism data – see section B.7 of Addendum 2 to the DAR (The United Kingdom, 2014).

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

ADI	0.0012 mg/kg bw/day
TMDI (% ADI) according to WHO European diet	13 % (WHO cluster diet B)
TMDI (% ADI) according to national (to be specified) diets	31 % (NL child) 23 % (FR infant) 17 % (ES child) 16 % (DE child)
IEDI (WHO European Diet) (% ADI)	n/a
NEDI (specify diet) (% ADI)	0.00105 mg/kg bw/day (87 %), Infant total NEDI, UK model
Factors included in IEDI and NEDI	n/a
ARfD	0.0025 mg/kg bw
IESTI (% ARfD)	50 % (milk and milk products)
NESTI (% ARfD) according to national (to be specified) large portion consumption data	0.00124 mg/kg bw/day (50 %), UK Infant consuming milk
Factors included in IESTI and NESTI	n/a

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

Residue levels in the raw agricultural commodity were all significantly below 0.1 mg/kg. The highest residues were < 0.01 mg/kg for wheat grain and 0.03 mg/kg for barley grain. Therefore processing studies are not required.

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

Wheat	0.01 mg/kg
Barley	0.05 mg/kg
Meat, fat & preparations of meat	0.1 mg/kg

Note: ***Existing MRLs for lambda-cyhalothrin***

Wheat	*0.02 mg/kg*
Barley	*0.05 mg/kg*
Meat, fat & preparations of meat	*0.02 mg/kg*

Fate and Behaviour in the Environment

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

Mineralisation after 100 days	24 - 40 % after 90 - 95d, [^{14}C-phenoxy]-label (n= 3) 53.3 % after 90d, [^{14}C-cyclopropyl]-label (n= 1)
Non-extractable residues after 100 days	31 - 49 % after 90 - 95d [^{14}C-phenoxy]-label (n= 3) 19.4 % after 90d [^{14}C-cyclopropyl]-label (n= 1)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	3-(4-OHPh)– 7.2 - 12.2 % peak at 17d (n= 2) Phenoxy label PBA 5.7 % - 7.7 % at 3d and 7d (phenoxy-14C-cyhalothrin) (refer also to soil photolysis) DMCPA (refer to soil photolysis)

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

Anaerobic degradation

Non-extractable residues after 100 days	3.5 % after 120d, [^{14}C-phenoxy]-label (n= 1) 3.0 % after 120d, [^{14}C-cyclopropyl]-label (n= 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	PBA 8.4 % 17 DAT 3-(4-OHPh) 12.2 % 17 DAT

Soil photolysis

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	DMCPA 14.2 % 16 d (dark control) PBA 8.2 % AR peak at 16d (dark control)

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

Parent	Aerobic conditions							
Soil texture / moiety	Soil pH	O.C. (%)	Soil moisture content	Temp. (^{o}C)	DT_{50} (days)	χ^2	DT_{50} at 20°C - 10kPa (days)	Method of Calculation
Clay loam / gamma-cyhalothrin	5.8	1.0	40 % MHC (27.4 %)	20	33.0	3.3	32.5	SFO K_p:0.0210
Silt loam/ gamma-cyhalothrin	5.8	1.2	75 % 1/3 bar field capacity (18.6 %)	25	27.3	9.1	33.8	SFO K_p:0.0254
Sandy loam/ gamma-cyhalothrin	6.3	0.57	85 % 1/3 bar field capacity (6.2 %)	25	23.2	6.0	16.6	SFO K_p:0.0298
18 Acres I sandy loam / cyhalothrin*	6.8	2.7	40 % MWHC (29.2 %)	20	28.2	5.7	28.2	SFO K_p:0.0246
Geometric mean							26.8	

3-(4-OHPh)	Aerobic conditions							
Soil type / moiety	OC (%)	pH	t. °C / % MWHC	DT_{50}/DT_{90} (d)	Formation fraction	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Loamy Sand / 3-4-hydroxyphenoxy) benzaldehyde	1.93	5.5	20 / 50%	0.021 / 0.069	-	0.021	-	SFO X^2 13.7
Sandy loam / 3-4-hydroxyphenoxy) benzaldehyde	0.99	6.7	20 / 50%	0.024/ 0.079	-	0.024	-	SFO X^2 12.8
Clay / 3-4-hydroxyphenoxy) benzaldehyde	1.66	7.1	20 / 50%	0.022/ 0.072	-	0.012	-	SFO X^2 7.2
Silt Loam *	1.17	5.8	25/ 85% 1/3 bar	10*	-	12.4*	-	*

*Conservative overestimate (from Cook, 2001) used for PECgw calculations data are summarised in Addendum 1 (The United Kingdom, 2014).

PBA	Aerobic conditions							
Soil type / moiety	OC (%)	pH	t. °C / % MWHC	DT_{50}/DT_{90} (d)	Formation fraction	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Loamy sand / PBA	2.1	5.5	20 / 50%	0.38 / 1.3	-	0.38	-	SFO X^2 4.7
Sandy loam / PBA	1	6.6	20 / 50%	0.8 / 2.8	-	0.79	-	SFO X^2 3.9
Clay / PBA	0.7	7.2	20 / 50%	2.1 / 7	-	1.13	-	SFO X^2 1.8
Geometric mean						0.7		

DMCPA	Aerobic conditions							
Soil type / moiety	OC (%)	pH	t. °C / % MWHC	DT_{50}/DT_{90} (d)	Formation fraction	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Loamy sand / DMCPA	1.8	5.5	20 / 50%	1.63 / 5.41	-	1.63	-	SFO X^2 4.0
Sandy loam / DMCPA	0.9	6.8	20 / 50%	5.52 / 18.3	-	5.06	-	SFO X^2 5.8
Loam / DMCPA	2.3	7.2	20 / 50%	2.62 / 8.70	-	2.23	-	SFO X^2 2.2
Geometric mean						2.6		

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent							
Soil Type	OC %	Soil pH	Kd (ml/g)	Kf	Koc (ml/g)	Kfoc	1/n
Silt loam (Arkansas, US)	1.18	5.8	743 908	-	62982 76921	-	-
Sandy loam (Madera, US)	0.57	6.3	241 237	-	42317 41548	-	-
Loamy sand (Cuckney, UK)	1.97	7.3	735 610	-	37325 30941	-	-
Sandy loam (Crimplesham, UK)	0.81	6.7	765 737	-	94425 90959	-	-
Arithmetic mean					59677		
pH dependence, Yes or No					No		

3-(4-OHPh)							
Soil Type	OC %	Soil pH	Kd (ml/g)	Kf	Koc (ml/g)	Kfoc	1/n
HPLC (LaMar & Quistad 2010)	-	-	-	-	324	-	-
HPLC (Ponte 2013)	-	-	-	-	490	-	-
QSAR	-	-	-	-	548	-	-

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

Column leaching	No data submitted, none required
Aged residues leaching	No data submitted, none required
Lysimeter/ field leaching studies	No data submitted, none required

PBA							
Soil Type	OC %	Soil pH	K (ml/g)	Kf	Koc (ml/g)	Kfoc	1/n
Speyer 2.2 (Loamy sand)	2.1	5.5	1.22	-		58	0.914
Speter 2.3 (Sandy Loam)	1.0	6.6	0.691	-		71	0.864
Speyer 6S (Clay)	1.7	7.2	0.793	-		47	0.865
Arithmetic mean						59	0.88
pH dependence, Yes or No			No				

DMCPA							
Soil Type	OC %	Soil pH	K (ml/g)	Kf	Koc (ml/g)	Kfoc	1/n
Speyer 2.2 (Loamy sand)	1.8	5.5	2.13	-	120	-	-
Speter 2.3 (Sandy Loam)	0.9	6.8	0.25	-	27	-	-
Speyer 2.4 (Loam)	2.3	7.2	0.88	-	39	-	-
Arithmetic mean					62		-
pH dependence, Yes or No			No				

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 33.8 days (20°C) Kinetics: SFO Lab: representative worst case from lab studies.
Application data	Spring and winter cereals Depth of soil layer: (5 cm). 25 % plant interception Application rates: (g a.s./ha) Winter and spring cereals: 3 x 4.5 at 10 d intervals.

$PEC_{(s)}$ (mg/kg)	Multiple application Actual	Multiple application Time weighted average
Initial	0.0112	-
24h	0.0109	0.0110
2d	0.0107	0.0109
4d	0.0103	0.0107
7d	0.0097	0.0104
21d	0.0072	0.0091
28d	0.0063	0.0085
50d	0.0040	0.0070
100d	0.0014	0.0047

Accumulation:	As the DT_{90} value of gamma-cyhalothrin is < 1 year accumulation calculations are not a requirement.
Metabolite: 3-(4-OHPh)	Based on a peak formation of compound 3-(4-OHPh) of 12.2 % AR and a molecular weight of 214 (molecular weight of parent gamma-cyhalothrin = 449.9) a simple conversion factor of 0.058 can be used to derive metabolite PECsoil from parent. On this basis initial PECsoil values of 0.00065 mg/kg for cereal uses would be derived for compound 3-(4-OHPh).
Metabolite: DMCPA	Based on a peak formation of compound DMCPA of 14.2 % AR and a molecular weight of 242.6 (molecular weight of parent gamma-cyhalothrin = 449.9) a simple conversion factor of 0.054 can be used to derive metabolite PECsoil from parent. On this basis initial PECsoil values of 0.00060 mg/kg for cereal uses would be derived for compound DMCPA.

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

Hydrolytic degradation of the active substance and metabolites > 10%.	pH 5: 1155 d at 25 °C(1st order, linear regression r^2=0.027) pH 7: 136 d at 25°C (1st order, linear regression r^2=0.52) pH 9: 0.5-1.1 d at 25°C (1st order, non-linear and linear regression r^2=0.992-0.77) Natural water (pH 8.5): 27 d at 25°C (1st order, linear regression r^2=0.47) Italian natural water (pH 8.2): 2.1 d at 25°C (1st order, non-linear regression) At pH 9: PBA at 45.6 to 57 % at 32 or 30 d PBAld at 56 to 73.8 % at 4 d Unknown 1 at 35 % at 30 d Unknown 2 at 24.5 % at 1 d DMCPA at 99 % at 32 d
Photolytic degradation of active substance and metabolites above 10%	DT_{50} : 6.9 test system days (equivalent to 10.6 d of summer sunlight at 40°N) Artificial sunlight (xenon), pH 5 PBA at 42 % at 15 d DMCPA at 45 % at 21 d Unknown (mw = 240) at 22.9 % at 15 d Unknown (mw = 274) at 15.5 % at 21 d
Quantum yield of direct phototransformation in water at Σ> 290 nm	3.2×10^{-5}
Readily biodegradable (yes/no)	Not readily biodegradable, candidate for R53.

Degradation in water / sediment

Parent	Distribution: Max. in sed. 69 - 77 % after 15 d									
Water / sediment system	pH w	pH sed	t. °C	DT_{50}-DT_{90} whole	χ^2 (%)	DT_{50}-DT_{90} water	χ^2 (%)	DT_{50}-DT_{90} sed	χ^2 (%)	Method of calculation
Haut Languedoc, France / sand	5.9	6.1	20	46.3 – 154	7.3	8.8-29.1	17.9	74.4 – 14.3	7.3	SFO (All)
Altogarda, Italy / sandy loam	8.2	7.9	20	22.7 – 75.3	11.3	4.0-13.3	2.4	14.3 – 47.4	1.8	SFO (All)
Metabolite PBA	Distribution: Max in water 26.5 % after 33 d. Max. in sed. 18.9 % after 33 d									
Metabolite DMCPA	Distribution: Max in water 64.9 % after 58 d. Max. in sed. 18.4 % after 58 d									

Mineralization and non extractable residues

Water / sediment system	pH w	pH sed	Mineralization	Non-extractable residues in sed.
Haut Languedoc, France / sand	5.9	6.1	32.2 % at end of study (100 d) (phenoxy radiolabel) 2.1 % at end of study (100 d) (cyclopropane radiolabel)	28.6 % at end of study (100d) (phenoxy radiolabel) 9.0 % at end of study (100 d) (cyclopropane radiolabel)
Altogarda, Italy / sandy loam	8.2	7.9	37.1 % at 58d (phenoxy radiolabel) 37.1 % at end of study (100 d) (cyclopropane radiolabel)	34.0 % at 58 d (phenoxy radiolabel) 33.4 % at end of study (100 d) (cyclopropane radiolabel)

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: Version 2.1 (2001) Molecular weight 449.9 g/mol: Water solubility 0.0021 mg/L: K_{OC}/K_{OM}: 59677mL/g DT_{50} soil : 26.8 days (geometric mean) DT_{50} water/sediment system : 46.4 days DT_{50} water (d): 46.4 days DT_{50} sediment (d): 1000 days Crop: Cereals (Winter and Spring)
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software (version numbers are for the model): SWASH 3.1; MACRO 4.4.2; PRZM 3.1.1; TOXSWA 2.6. Vapour pressure: 1.03 x $^{10-7}$ at 20ºC Koc: 59677 mL/g 1/n: 0.9 DT_{50} soil 26.8 days DT_{50} water 46.4 days DT_{50} sediment 1000 days Q_{10}: 2.58
Application rate	Crop: Cereals (winter and spring) Number of applications: 3. Interval: 10 days Application rate: 1 x 4.5 g a.s./ha (single) Spring, 3 x 4.5 g a.s./ha (multiple) Winter, 3 x 4.5 g a.s./ha (multiple) Application window:

Scenario	Winter cereals (autumn application)	Winter cereals (spring application)	Spring cereals
	1st application		
D1	23-Oct (296)	07-Mar (066)	17-Jun (168)
D2	28-Nov (332)	12-Mar (071)	-
D3	10-Dec (344)	29-Feb (01 Mar) (060)	20-Apr (110)
D4	26-Oct (299)	01-Mar (060)	30-May (150)
D5	27-Nov (331)	07-Mar (066)	08-Apr (098)
D6	30-Dec (364)	05-Mar (064)	-

R1	27-Nov (331)	17-Mar (076)	-
R2	-	-	-
R3	15-Dec (349)	01-Mar (060)	-
R4	10-Dec (344)	05-Mar (64)	29-Mar (088)

PBA Parameters used in FOCUSsw step 1 and 2	Molecular weight: 214.2 g/mol Water solubility 16.9 mg/L Soil or water metabolite: occurs in soil and water/sediment systems Koc: 59 mL/g (geomean) DT_{50} Soil 0.7 days DT_{50} water/sediment system: 1000 days (default) Crop: Cereals (winter and spring) Maximum occurrence observed Soil: 8.4 % AR Water/sediment system: 45.5 % AR
DMCPA Parameters used in FOCUSsw step 1 and 2	Molecular weight: 242.6 g/mol Water solubility: 33.4 mg/L Soil or water metabolite: occurs in soil and sediment/water systems Koc: 62 mL/g (geomean) DT_{50} soil 2.6 days DT_{50} water/sediment system: 1000 days (default) Crop interception Crop: Cereals (winter and spring) Maximum occurrence observed Soil: 14.2 % AR Water/sediment system: 83.3 % AR
3-(4-OHPh) Parameters used in FOCUSsw step 1 and 2	Molecular weight: 214.2 g/mol Water solubility: 219.2 mg/L Soil or water metabolite: occurs in soil systems Koc: 324 (worst case) DT_{50} soil 12.7 days (worst case overestimate) DT_{50} water/sediment system: 1000 days (default) Crop: Cereals (winter and spring) Maximum occurrence observed Soil: 12.2 % AR Water/sediment system: 0.0 % AR (default 0.001 % used)

Calculated concentration of **gamma-cyhalothrin** in the water body according to FOCUS Step 1 (v2.1). All crops, all applications (modelled as 1 x 4.5 g a.s./ha), Northern Europe and Southern Europe.
Max PECsw 0.06
Max PECsed 11.25

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.0600	-	11.1104	-
1	0.0188	0.0394	11.2476	11.1790
2	0.0186	0.0291	11.0808	11.1715
4	0.0180	0.0237	10.7547	11.0442
7	0.0172	0.0211	10.2833	10.8184
14	0.0155	0.0187	9.2623	10.2912
21	0.0140	0.0174	8.3427	9.7923
28	0.0126	0.0164	7.5144	9.3245
42	0.0102	0.0147	6.0963	8.4766
50	0.0091	0.0139	5.4096	8.0397
100	0.0043	0.0101	2.5632	5.9253

Calculated concentration of **gamma-cyhalothrin** in the water body according to FOCUS Step 2 (v2.1). All crops, all applications (modelled as 1 x 4.5 g a.s./ha), Northern Europe.
Max PECsw 0.04
Max PECsed 1.80

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.0414	-	1.8048	-
1	0.0139	0.0277	1.8033	1.8040
2	0.0050	0.0186	1.8017	1.8033
4	0.0037	0.0109	1.7986	1.8017
7	0.0030	0.0076	1.7939	1.7994
14	0.0030	0.0053	1.7830	1.7939
21	0.0029	0.0045	1.7722	1.7885
28	0.0029	0.0041	1.7615	1.7831
42	0.0029	0.0037	1.7402	1.7723
50	0.0029	0.0036	1.7281	1.7662
100	0.0027	0.0032	1.6547	1.7287

Calculated concentration of **gamma-cyhalothrin** in the water body according to FOCUS Step 2 (v2.1). All crops, late applications (modelled as 1 x 4.5 g a.s./ha), Southern Europe.
Max PECsw 0.04
Max PECsed 3.31

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.0414	---	3.3066	---
1	0.0139	0.0277	3.3037	3.3051
2	0.005	0.0186	3.3008	3.3037
4	0.0062	0.0112	3.2951	3.3008
7	0.0055	0.0088	3.2865	3.2965
14	0.0054	0.0071	3.2666	3.2865
21	0.0054	0.0065	3.2468	3.2766
28	0.0054	0.0063	3.2271	3.2667
42	0.0053	0.0059	3.1881	3.247
50	0.0053	0.0058	3.166	3.2358
100	0.005	0.0055	3.0314	3.167

Calculated concentration of **gamma-cyhalothrin** in the water body according to FOCUS Step 1 (v2.1). All crops, early applications (modelled as 3 x 4.5 g a.s./ha), Northern Europe.
Max PECsw 0.18
Max PECsed 33.7

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.1800		33.3311	
1	0.0565	0.1183	33.7429	33.5370
2	0.0557	0.0872	33.2425	33.5145
4	0.0541	0.0710	32.2640	33.1327
7	0.0517	0.0633	30.8500	32.4551
14	0.0466	0.0562	27.7870	30.8735
21	0.0419	0.0522	25.0281	29.3768
28	0.0378	0.0491	22.5431	27.9736
42	0.0306	0.0441	18.2888	25.4297
50	0.0272	0.0417	16.2287	24.1191
100	0.0129	0.0304	7.6895	17.7758

Calculated concentration of **gamma-cyhalothrin** in the water body according to FOCUS Step 2 (v2.1). All crops, early applications (modelled as 3 x 4.5 g a.s./ha), Northern Europe.
Max PECsw 0.03
Max PECsed 4.22

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.0314	---	4.2172	---
1	0.0113	0.0214	4.2135	4.2154
2	0.0048	0.0147	4.2099	4.2135
4	0.0079	0.0096	4.2026	4.2099
7	0.007	0.0085	4.1916	4.2044
14	0.0069	0.0077	4.1662	4.1917
21	0.0069	0.0075	4.141	4.179
28	0.0068	0.0073	4.1159	4.1663
42	0.0067	0.0071	4.0661	4.1412
50	0.0067	0.0071	4.0379	4.1269
100	0.0064	0.0068	3.8663	4.0392

Calculated concentration of **gamma-cyhalothrin** in the water body according to FOCUS Step 2 (v2.1). All crops, late applications (modelled as 3 x 4.5 g a.s./ha), Northern Europe.
Max PECsw 0.031
Max PECsed 9.55

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.0314	---	9.5522	---
1	0.0113	0.0214	9.5519	9.552
2	0.0048	0.0147	9.5436	9.5499
4	0.0169	0.0107	9.527	9.5426
7	0.0158	0.013	9.5022	9.5306
14	0.0157	0.0143	9.4446	9.502
21	0.0156	0.0148	9.3873	9.4733
28	0.0155	0.0149	9.3304	9.4447
42	0.0153	0.0151	9.2176	9.3878
50	0.0152	0.0151	9.1538	9.3554
100	0.0145	0.015	8.7647	9.1566

Calculated concentration of **gamma-cyhalothrin** in the water body according to FOCUS Step 2 (v2.1). All crops, late applications (modelled as 3 x 4.5 g a.s./ha), Southern Europe.
Max PECsw 0.031
Max PECsed 7.77

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.0314	---	7.7736	---
1	0.0113	0.0214	7.7669	7.7703
2	0.0048	0.0147	7.7601	7.7669
4	0.0139	0.0103	7.7467	7.7601
7	0.0128	0.0115	7.7265	7.75
14	0.0127	0.0121	7.6797	7.7266
21	0.0127	0.0123	7.6331	7.7032
28	0.0126	0.0124	7.5868	7.6799
42	0.0124	0.0124	7.4951	7.6335
50	0.0123	0.0124	7.4432	7.6072
100	0.0118	0.0123	7.1268	7.4455

Calculated concentration of **PBA** in the water body according to FOCUS Step 1 (v2.1). All crops, all applications (modelled as 1 x 4.5 g a.s./ha), Northern Europe and Southern Europe.
Max PECsw 0.065
Max PECsed 0.038

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.0646		0.0328	
1	0.0639	0.0642	0.0377	0.0353
2	0.0638	0.064	0.0377	0.0365
4	0.0637	0.0639	0.0376	0.0371
7	0.0636	0.0638	0.0375	0.0373
14	0.0633	0.0636	0.0374	0.0374
21	0.063	0.0635	0.0372	0.0373
28	0.0627	0.0633	0.037	0.0373
42	0.0621	0.063	0.0366	0.0371
50	0.0617	0.0628	0.0364	0.037
100	0.0596	0.0618	0.0352	0.0364

Calculated concentration of **PBA** in the water body according to FOCUS Step 2 (v2.1). All crops, all applications (modelled as 1 x 4.5 g a.s./ha), Northern Europe.
Max PECsw 0.009
Max PECsed 0.005

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.009	---	0.005	---
1	0.0085	0.0087	0.005	0.005
2	0.0085	0.0086	0.005	0.005
4	0.0087	0.0086	0.005	0.005
7	0.0084	0.0085	0.005	0.005
14	0.0084	0.0085	0.0049	0.005
21	0.0083	0.0084	0.0049	0.0049
28	0.0083	0.0084	0.0049	0.0049
42	0.0082	0.0084	0.0048	0.0049
50	0.0082	0.0083	0.0048	0.0049
100	0.0079	0.0082	0.0046	0.0048

Calculated concentration of **PBA** in the water body according to FOCUS Step 2 (v2.1). All crops, late applications (modelled as 1 x 4.5 g a.s./ha), Southern Europe.
Max PECsw 0.009
Max PECsed 0.005

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.009	---	0.0051	---
1	0.0085	0.0087	0.0051	0.0051
2	0.0085	0.0086	0.0051	0.0051
4	0.0088	0.0086	0.0051	0.0051
7	0.0086	0.0086	0.005	0.0051
14	0.0085	0.0086	0.005	0.005
21	0.0085	0.0086	0.005	0.005
28	0.0085	0.0085	0.005	0.005
42	0.0084	0.0085	0.0049	0.005
50	0.0083	0.0085	0.0049	0.005
100	0.0081	0.0083	0.0047	0.0049

Calculated concentration of **PBA** in the water body according to FOCUS Step 1 (v2.1). All crops, all applications (modelled as 3 x 4.5 g a.s./ha), Northern Europe and Southern Europe.
Max PECsw 0.194
Max PECsed 0.112

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.1937		0.0984	
1	0.1916	0.1927	0.1131	0.1058
2	0.1915	0.1921	0.113	0.1094
4	0.1912	0.1918	0.1128	0.1112
7	0.1908	0.1915	0.1126	0.1118
14	0.1899	0.1909	0.1121	0.1121
21	0.189	0.1904	0.1115	0.112
28	0.1881	0.19	0.111	0.1118
42	0.1863	0.189	0.1099	0.1113
50	0.1852	0.1885	0.1093	0.1111
100	0.1789	0.1853	0.1056	0.1092

Calculated concentration of **PBA** in the water body according to FOCUS Step 2 (v2.1). All crops, early applications (modelled as 3 x 4.5 g a.s./ha), Northern Europe.
Max PECsw 0.019
Max PECsed 0.011

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.0189	---	0.0108	---
1	0.0186	0.0188	0.0108	0.0108
2	0.0186	0.0187	0.0108	0.0108
4	0.0187	0.0187	0.0107	0.0108
7	0.0182	0.0185	0.0107	0.0107
14	0.0181	0.0184	0.0107	0.0107
21	0.0181	0.0183	0.0106	0.0107
28	0.018	0.0182	0.0106	0.0107
42	0.0178	0.0181	0.0105	0.0106
50	0.0177	0.018	0.0104	0.0106
100	0.0171	0.0177	0.0101	0.0104

Calculated concentration of **PBA** in the water body according to FOCUS Step 2 (v2.1). All crops, late applications (modelled as 3 x 4.5 g a.s./ha), Northern Europe.
Max PECsw 0.019
Max PECsed 0.011

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.019	---	0.0109	---
1	0.0185	0.0187	0.0109	0.0109
2	0.0185	0.0186	0.0109	0.0109
4	0.0185	0.0185	0.0109	0.0109
7	0.0184	0.0185	0.0109	0.0109
14	0.0183	0.0184	0.0108	0.0109
21	0.0182	0.0184	0.0108	0.0108
28	0.0182	0.0183	0.0107	0.0108
42	0.018	0.0183	0.0106	0.0108
50	0.0179	0.0182	0.0105	0.0107
100	0.0173	0.0179	0.0102	0.0105

Calculated concentration of **PBA** in the water body according to FOCUS Step 2 (v2.1). All crops, late applications (modelled as 3 x 4.5 g a.s./ha), Southern Europe.
Max PECsw 0.019
Max PECsed 0.011

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.0189	---	0.0109	---
1	0.0186	0.0188	0.0109	0.0109
2	0.0186	0.0187	0.0109	0.0109
4	0.0189	0.0187	0.0108	0.0109
7	0.0184	0.0186	0.0108	0.0108
14	0.0183	0.0185	0.0108	0.0108
21	0.0182	0.0184	0.0107	0.0108
28	0.0181	0.0183	0.0107	0.0108
42	0.018	0.0182	0.0106	0.0107
50	0.0179	0.0182	0.0105	0.0107
100	0.0172	0.0179	0.0101	0.0105

Calculated concentration of **DMCPA** in the water body according to FOCUS Step 1 (v2.1). All crops, all applications (modelled as 1 x 4.5 g a.s./ha), Northern Europe and Southern Europe.
Max PECsw 0.125
Max PECsed 0.076

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.1247		0.0658	
1	0.1232	0.1239	0.0764	0.0711
2	0.1231	0.1235	0.0763	0.0737
4	0.1229	0.1233	0.0762	0.075
7	0.1227	0.1231	0.076	0.0755
14	0.1221	0.1227	0.0757	0.0757
21	0.1215	0.1224	0.0753	0.0756
28	0.1209	0.1221	0.075	0.0755
42	0.1197	0.1215	0.0742	0.0752
50	0.1191	0.1212	0.0738	0.075
100	0.115	0.1191	0.0713	0.0738

Calculated concentration of **DMCPA** in the water body according to FOCUS Step 2 (v2.1). All crops, all applications (modelled as 1 x 4.5 g a.s./ha), Northern Europe.
Max PECsw 0.023
Max PECsed 0.014

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.023	---	0.014	---
1	0.0226	0.0228	0.014	0.014
2	0.0226	0.0227	0.014	0.014
4	0.0225	0.0226	0.014	0.014
7	0.0225	0.0226	0.0139	0.014
14	0.0224	0.0225	0.0139	0.0139
21	0.0223	0.0224	0.0138	0.0139
28	0.0222	0.0224	0.0137	0.0139
42	0.022	0.0223	0.0136	0.0138
50	0.0218	0.0222	0.0135	0.0138
100	0.0211	0.0218	0.0131	0.0135

Calculated concentration of **DMCPA** in the water body according to FOCUS Step 2 (v2.1). All crops, late applications (modelled as 1 x 4.5 g a.s./ha), Southern Europe.
Max PECsw 0.029
Max PECsed 0.017

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.0285	---	0.0174	---
1	0.0281	0.0283	0.0174	0.0174
2	0.028	0.0282	0.0174	0.0174
4	0.028	0.0281	0.0173	0.0174
7	0.0279	0.028	0.0173	0.0174
14	0.0278	0.028	0.0172	0.0173
21	0.0277	0.0279	0.0171	0.0173
28	0.0275	0.0278	0.0171	0.0172
42	0.0273	0.0277	0.0169	0.0171
50	0.0271	0.0276	0.0168	0.0171
100	0.0262	0.0271	0.0162	0.0168

Calculated concentration of **DMCPA** in the water body according to FOCUS Step 1 (v2.1). All crops, all applications (modelled as 3 x 4.5 g a.s./ha), Northern Europe.
Max PECsw 0.374
Max PECsed 0.229

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.374		0.1973	
1	0.3695	0.3718	0.2291	0.2132
2	0.3693	0.3706	0.2289	0.2211
4	0.3687	0.3698	0.2286	0.2249
7	0.368	0.3692	0.2281	0.2264
14	0.3662	0.3681	0.227	0.227
21	0.3644	0.3672	0.2259	0.2268
28	0.3627	0.3663	0.2249	0.2265
42	0.3592	0.3645	0.2227	0.2256
50	0.3572	0.3635	0.2214	0.225
100	0.345	0.3573	0.2139	0.2213

Calculated concentration of **DMCPA** in the water body according to FOCUS Step 2 (v2.1). All crops, early applications (modelled as 3 x 4.5 g a.s./ha), Northern Europe.
Max PECsw 0.0443
Max PECsed 0.027

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.0443	---	0.0268	---
1	0.0433	0.0438	0.0268	0.0268
2	0.0432	0.0435	0.0268	0.0268
4	0.0432	0.0434	0.0268	0.0268
7	0.0431	0.0433	0.0267	0.0268
14	0.0429	0.0431	0.0266	0.0267
21	0.0427	0.043	0.0264	0.0266
28	0.0425	0.0429	0.0263	0.0266
42	0.0421	0.0427	0.0261	0.0264
50	0.0418	0.0426	0.0259	0.0264
100	0.0404	0.0418	0.025	0.0259

Calculated concentration of **DMCPA** in the water body according to FOCUS Step 2 (v2.1). All crops, late applications (modelled as 3 x 4.5 g a.s./ha), Northern Europe.
Max PECsw 0.053
Max PECsed 0.032

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.0531	---	0.0323	---
1	0.0521	0.0526	0.0323	0.0323
2	0.0521	0.0523	0.0323	0.0323
4	0.052	0.0522	0.0322	0.0323
7	0.0519	0.0521	0.0321	0.0322
14	0.0516	0.0519	0.032	0.0321
21	0.0514	0.0518	0.0318	0.0321
28	0.0511	0.0517	0.0317	0.032
42	0.0506	0.0514	0.0314	0.0318
50	0.0504	0.0513	0.0312	0.0317
100	0.0486	0.0504	0.0301	0.0312

Calculated concentration of **DMCPA** in the water body according to FOCUS Step 2 (v2.1). All crops, late applications (modelled as 3 x 4.5 g a.s./ha), Southern Europe.
Max PECsw 0.050
Max PECsed 0.031

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.0502	---	0.0305	---
1	0.0492	0.0497	0.0305	0.0305
2	0.0491	0.0494	0.0304	0.0305
4	0.0491	0.0492	0.0304	0.0304
7	0.049	0.0491	0.0303	0.0304
14	0.0487	0.049	0.0302	0.0303
21	0.0485	0.0489	0.03	0.0303
28	0.0482	0.0487	0.0299	0.0302
42	0.0478	0.0485	0.0296	0.03
50	0.0475	0.0484	0.0294	0.03
100	0.0459	0.0475	0.0284	0.0294

Calculated concentration of **3-(4-OHPh)** in the water body according to FOCUS Step 1 (v2.1). All crops, all applications (modelled as 1 x 4.5 g a.s./ha), Northern Europe and Southern Europe.
Max PECsw 0.049
Max PECsed 0.287

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.0488		0.2874	
1	0.0488	0.0488	0.2872	0.2873
2	0.0487	0.0488	0.287	0.2872
4	0.0487	0.0487	0.2866	0.287
7	0.0486	0.0487	0.2861	0.2867
14	0.0483	0.0486	0.2847	0.2861
21	0.0481	0.0484	0.2833	0.2854
28	0.0479	0.0483	0.2819	0.2847
42	0.0474	0.0481	0.2792	0.2833
50	0.0471	0.048	0.2777	0.2825
100	0.0455	0.0471	0.2682	0.2777

Calculated concentration of **3-(4-OHPh)** in the water body according to FOCUS Step 2 (v2.1) All crops, all applications (modelled as 1 x 4.5 g a.s./ha) Northern Europe.
Max PECsw <0.001
Max PECsed <0.001

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	<0.001	---	<0.001	---
1	<0.001	<0.001	<0.001	<0.001
2	<0.001	<0.001	<0.001	<0.001
4	<0.001	<0.001	<0.001	<0.001
7	<0.001	<0.001	<0.001	<0.001
14	<0.001	<0.001	<0.001	<0.001
21	<0.001	<0.001	<0.001	<0.001
28	<0.001	<0.001	<0.001	<0.001
42	<0.001	<0.001	<0.001	<0.001
50	<0.001	<0.001	<0.001	<0.001
100	<0.001	<0.001	<0.001	<0.001

Calculated concentration of **3-(4-OHPh)** in the water body according to FOCUS Step 2 (v2.1). All crops, late applications (modelled as 1 x 4.5 g a.s./ha), Southern Europe.
Max PECsw 0.001
Max PECsed 0.001

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	<0.001	---	<0.001	---
1	<0.001	<0.001	<0.001	<0.001
2	<0.001	<0.001	<0.001	<0.001
4	<0.001	<0.001	<0.001	<0.001
7	<0.001	<0.001	<0.001	<0.001
14	<0.001	<0.001	<0.001	<0.001
21	<0.001	<0.001	<0.001	<0.001
28	<0.001	<0.001	<0.001	<0.001
42	<0.001	<0.001	<0.001	<0.001
50	<0.001	<0.001	<0.001	<0.001
100	<0.001	<0.001	<0.001	<0.001

Calculated concentration of **3-(4-OHPh)** in the water body according to FOCUS Step 1 (v2.1). All crops, all applications (modelled as 3 x 4.5 g a.s./ha), Northern Europe.
Max PECsw 0.146
Max PECsed 0.862

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	0.1464		0.8623	
1	0.1463	0.1464	0.8617	0.862
2	0.1462	0.1463	0.8611	0.8617
4	0.146	0.1462	0.8599	0.8611
7	0.1457	0.1461	0.8582	0.8602
14	0.145	0.1457	0.854	0.8582
21	0.1443	0.1453	0.8499	0.8561
28	0.1436	0.145	0.8458	0.854
42	0.1422	0.1443	0.8376	0.8499
50	0.1414	0.1439	0.833	0.8476
100	0.1366	0.1414	0.8046	0.8331

Calculated concentration of **3-(4-OHPh)** in the water body according to FOCUS Step 2 (v2.1). All crops, early applications (modelled as 3 x 4.5 g a.s./ha), Northern Europe.
Max PECsw <0.001
Max PECsed <0.001

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	<0.001	---	<0.001	---
1	<0.001	<0.001	<0.001	<0.001
2	<0.001	<0.001	<0.001	<0.001
4	<0.001	<0.001	<0.001	<0.001
7	<0.001	<0.001	<0.001	<0.001
14	<0.001	<0.001	<0.001	<0.001
21	<0.001	<0.001	<0.001	<0.001
28	<0.001	<0.001	<0.001	<0.001
42	<0.001	<0.001	<0.001	<0.001
50	<0.001	<0.001	<0.001	<0.001
100	<0.001	<0.001	<0.001	<0.001

Calculated concentration of **3-(4-OHPh)** in the water body according to FOCUS Step 2 (v2.1). All crops, late applications (modelled as 3 x 4.5 g a.s./ha). Northern Europe.
Max PECsw <0.001
Max PECsed <0.001

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	<0.001	---	<0.001	---
1	<0.001	<0.001	<0.001	<0.001
2	<0.001	<0.001	<0.001	<0.001
4	<0.001	<0.001	<0.001	<0.001
7	<0.001	<0.001	<0.001	<0.001
14	<0.001	<0.001	<0.001	<0.001
21	<0.001	<0.001	<0.001	<0.001
28	<0.001	<0.001	<0.001	<0.001
42	<0.001	<0.001	<0.001	<0.001
50	<0.001	<0.001	<0.001	<0.001
100	<0.001	<0.001	<0.001	<0.001

Calculated concentration of **3-(4-OHPh)** in the water body according to FOCUS Step 2 (v2.1). All crops, late applications (modelled as 3 x 4.5 g a.s./ha). Southern Europe.
Max PECsw <0.001
Max PECsed <0.001

Days after PEC_{max}	PEC_{sw} (µg/L)		PEC_{sed} (µg/kg)	
	PEC_{act}	PEC_{twa}	PEC_{act}	PEC_{twa}
0	<0.001	---	<0.001	---
1	<0.001	<0.001	<0.001	<0.001
2	<0.001	<0.001	<0.001	<0.001
4	<0.001	<0.001	<0.001	<0.001
7	<0.001	<0.001	<0.001	<0.001
14	<0.001	<0.001	<0.001	<0.001
21	<0.001	<0.001	<0.001	<0.001
28	<0.001	<0.001	<0.001	<0.001
42	<0.001	<0.001	<0.001	<0.001
50	<0.001	<0.001	<0.001	<0.001
100	<0.001	<0.001	<0.001	<0.001

Summary of global maximum Step 3 and 4 PECsw and PECsed values following single and multiple applications of gamma-cyhalothrin to winter and spring cereals (max PEC value **in bold**).

Crop	**Global Max. PECsw, µg/l (Step 3)**	**Global Max. PECsed, µg/kg dw (Step 3)**	**Global Max. PECsw, µg/l (Step 4, 20m buffer)**	**Global Max. PECsed, µg/kg dw (Step 4, 20 m buffer)**	**Global Max. PECsw, µg/l (Step 4, 5m buffer; 75% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 5m buffer; 75 % nozzle reduction)**	**Global Max. PECsw, µg/l (Step 4, 10 m buffer; 50% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 10 m buffer; 50% nozzle reduction)**	**Global Max. PECsw, µg/l (Step 4, 95% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 95% nozzle reduction)**
Spring cereals (multiple applications)	0.0221 (D1, ditch)	0.387 (D1, ditch)	0.00166 (D1, ditch)	0.274 (R4, stream)	0.00139 (D1, stream)	0.274 (R4, stream)	0.00139 (D1, stream)	0.274 (R4, stream)	0.000988 (D1, ditch)	0.274 (R4, stream)
Spring cereals (single applications)	**0.0254** (D1, ditch,)	0.181 (D1, ditch)	0.00223 (D1, stream)	0.0760 (R4, stream)	0.00195 (D1, stream)	0.0760 (R4, stream)	0.00195 (D1, stream)	0.0760 (R4, stream)	0.00112 (D1, ditch)	0.0759 (R4, stream)
Winter cereals (multiple autumn applications)	0.0209 (D1, ditch)	**1.866** (R3, stream)	0.00149 (R3, stream)	**1.832** (R3, stream)	0.00149 (R3, stream)	**1.832** (R3, stream)	0.00149 (R3, stream)	**1.832** (R3, stream)	0.00105 (R4, stream)	**1.832** (R3, stream)
Winter cereals (multiple spring applications	0.0187 (D6, ditch,)	0.191 (R4, stream)	0.00147 (D2, ditch)	0.189 (R4, stream)	0.00146 (R3, stream)	0.189 (R4, stream)	0.00146 (R3, stream)	0.189 (R4, stream)	0.000868 (R3, stream)	0.189 (R4, stream)
Winter cereals (single autumn applications)	**0.0254** (D1, ditch)	0.183 (D1, ditch)	**0.00236** (D5, stream)	0.104 (R4, stream)	**0.00206** (D5, stream)	0.104 (R4, stream)	**0.00206** (D5, stream)	0.104 (R4, stream)	**0.00117 (D5, stream)**	0.104 (R4, stream)
Winter cereals (single spring applications)	**0.0254** (D2, ditch)	0.168 (D2, ditch)	0.00233 (R3, stream)	0.0669 (R4, stream)	0.00204 (R3, stream)	0.0669 (R4, stream)	0.00204 (R3, stream)	0.0669 (R4, stream)	0.00116 (R3, stream)	0.0669 (R4, stream)

Step 3 and 4 PECsw and PECsed values following **multiple** applications of gamma-cyhalothrin on **spring** cereals (maximum value in bold)

Scenario	Water body	Step 3		Step 4							
		Global Max. PECsw, µg/l (default buffer, m)	Global Max. PECsed, µg/kg dw (default buffer, m)	**Global Max. PECsw, µg/l (Step 4, 20m buffer)**	**Global Max. PECsed, µg/kg dw (Step 4, 20 m buffer)**	**Global Max. PECsw, µg/l (Step 4, 5m buffer; 75% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 5m buffer; 75% nozzle reduction)**	**Global Max. PECsw, µg/l (Step 4, 10 m buffer; 50% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 10 m buffer; 50% nozzle reduction)**	**Global Max. PECsw, µg/l (Step 4, 95% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 95% nozzle reduction)**
D1	Ditch	**0.0221** (1m)	**0.387** (1m)	**0.00166**	0.0310	0.00132	0.0249	0.00132	0.0249	**0.000988**	0.0187
D1	Stream	0.0161 (1.5m)	0.104 (1.5m)	0.00139	0.00983	**0.00139**	0.00983	**0.00139**	0.000676	0.000828	0.00597
D3	Ditch	0.0184 (1m)	0.128 (1m)	0.00141	0.0108	0.00112	0.00869	0.00112	0.00869	0.000839	0.00657
D4	Pond	0.000852 (3.5m)	0.0324 (3.5m)	0.000362	0.0142	0.000117	0.00478	0.000239	0.00949	<0.000001	<0.000001
D4	Stream	0.0157 (1.5m)	0.0544 (1.5m)	0.00135	0.00513	0.00135	0.00513	0.00135	0.00513	0.000806	0.00311
D5	Pond	0.000865 (3.5m)	0.0339 (3.5m)	0.000367	0.0148	0.000119	0.00500	0.000242	0.00993	<0.000001	<0.000001
D5	Stream	0.0158 (1.5m)	0.0248 (1.5m)	0.00137	0.00228	0.00137	0.00228	0.00137	0.00228	0.000812	0.00137
R4	Stream	0.0120 (1.5m)	0.276 (1.5m)	0.00104	**0.274**	0.00104	**0.274**	0.00104	**0.274**	0.000621	**0.274**

Step 3 and 4 PECsw and PECsed values following **single** applications of gamma-cyhalothrin on **spring** cereals (maximum value in bold)

Scenario	Water body	Step 3		Step 4							
		Global Max. PECsw, µg/l (default buffer, m)	Global Max. PECsed, µg/kg dw (default buffer, m)	**Global Max. PECsw, µg/l (Step 4, 20m buffer)**	**Global Max. PECsed, µg/kg dw (Step 4, 20 m buffer)**	**Global Max. PECsw, µg/l (Step 4, 5m buffer; 75% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 5m buffer; 75% nozzle reduction)**	**Global Max. PECsw, µg/l (Step 4, 10 m buffer; 50% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 10 m buffer; 50% nozzle reduction)**	**Global Max. PECsw, µg/l (Step 4, 95% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 95% nozzle reduction)**
D1	Ditch	**0.0254** (1m)	**0.181** (1m)	0.00170	0.0127	0.00170	0.0127	0.00170	0.0127	**0.00112**	0.00850
D1	Stream	0.0222 (1.5m)	0.0961 (1.5m)	**0.00223**	0.0104	**0.00195**	0.00915	**0.00195**	0.00915	0.00110	0.00529
D3	Ditch	0.0251 (1m)	0.103 (1m)	0.00168	0.00755	0.00168	0.00755	0.00168	0.00755	0.00111	0.00507
D4	Pond	0.000827 (3.5m)	0.0160 (3.5m)	0.000331	0.00655	0.000163	0.00330	0.000247	0.00493	<0.000001	<0.000001
D4	Stream	0.0208 (1.5m)	0.0362 (1.5m)	0.00209	0.00382	0.00182	0.00335	0.00182	0.00335	0.00103	0.00192
D5	Pond	0.000827 (3.5m)	0.0165 (3.5m)	0.000331	0.00675	0.000163	0.00340	0.000247	0.00507	<0.000001	<0.000001
D5	Stream	0.0196 (1.5m)	0.0140 (1.5m)	0.00197	0.00143	0.00172	0.00125	0.00172	0.00125	0.000975	0.000713
R4	Stream	0.0165 (1.5m)	0.0771 (1.5m)	0.00166	**0.0760**	0.00145	**0.0760**	0.00145	**0.0760**	0.000822	**0.0759**

Step 3 and 4 PECsw and PECsed values following **multiple** applications of gamma-cyhalothrin on **winter** cereals (autumn application) (maximum value in bold)

Scenario	Water body	Step 3		Step 4							
		Global Max. PECsw, µg/l (default buffer, m)	Global Max. PECsed, µg/kg dw (default buffer, m)	**Global Max. PECsw, µg/l (Step 4, 20m buffer)**	**Global Max. PECsed, µg/kg dw (Step 4, 20 m buffer)**	**Global Max. PECsw, µg/l (Step 4, 5m buffer; 75% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 5m buffer; 75% nozzle reduction)**	**Global Max. PECsw, µg/l (Step 4, 10 m buffer; 50% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 10 m buffer; 50% nozzle reduction)**	**Global Max. PECsw, µg/l (Step 4, 95% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 95% nozzle reduction)**
D1	Ditch	**0.0209** (1m)	0.260 (1m)	**0.00158**	0.0209	0.00126	0.0167	0.00126	0.0167	0.000941	0.0125
D1	Stream	0.0161 (1.5m)	0.0919 (1.5m)	0.00139	0.00868	0.00139	0.00868	0.00139	0.00868	0.000828	0.00526
D2	Ditch	0.0185 (1m)	0.145 (1m)	0.00141	0.0121	0.00112	0.00972	0.00112	0.00972	0.000840	0.00733
D2	Stream	0.0142 (1.5m)	0.0160 (1.5m)	0.00122	0.00143	0.00122	0.00143	0.00122	0.00143	0.000729	0.000860
D3	Ditch	0.0182 (1m)	0.100 (1m)	0.00139	0.00848	0.00111	0.00682	0.00111	0.00682	0.000829	0.00515
D4	Pond	0.000918 (3.5m)	0.0335 (3.5m)	0.000389	0.0147	0.000126	0.00495	0.000256	0.00982	<0.000001	<0.000001
D4	Stream	0.0157 (1.5m)	0.0586 (1.5m)	0.00135	0.00554	0.00135	0.00554	0.00135	0.00554	0.000806	0.00336
D5	Pond	0.000825 (3.5m)	0.0346 (3.5m)	0.000350	0.0151	0.000113	0.00510	0.000231	0.0101	<0.000001	<0.000001
D5	Stream	0.0169 (1.5m)	0.0629 (1.5m)	0.00146	0.00593	0.00146	0.00593	0.00146	0.00593	0.000870	0.00360
D6	Ditch	0.0180 (1m)	0.0668 (1m)	0.00138	0.00562	0.00110	0.00452	0.00110	0.00452	0.000819	0.00341
R1	Pond	0.000954 (3.5m)	0.0441 (3.5m)	0.000431	0.0256	0.000169	0.0162	0.000299	0.0209	0.000058	0.0114
R1	Stream	0.0119 (1.5m)	0.247 (1.5m)	0.00103	0.245	0.00103	0.245	0.00103	0.245	0.000656	0.245
R3	Stream	0.0168 (1.5m)	**1.866** (1.5m)	0.00149	**1.832**	**0.00149**	**1.832**	**0.00149**	**1.832**	0.000905	**1.832**
R4	Stream	0.0119 (1.5m)	0.295 (1.5m)	0.00105	0.293	0.00105	0.293	0.00105	0.293	**0.00105**	0.293

Step 3 and 4 PECsw and PECsed values following **multiple** applications of gamma-cyhalothrin on **winter** cereals (spring application) (maximum value in bold)

Scenario	Water body	Step 3		Step 4							
		Global Max. PECsw, µg/l (default buffer, m)	Global Max. PECsed, µg/kg dw (default buffer, m)	**Global Max. PECsw, µg/l (Step 4, 20m buffer)**	**Global Max. PECsed, µg/kg dw (Step 4, 20 m buffer)**	**Global Max. PECsw, µg/l (Step 4, 5m buffer; 75% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 5m buffer; 75% nozzle reduction)**	**Global Max. PECsw, µg/l (Step 4, 10 m buffer; 50% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 10 m buffer; 50% nozzle reduction)**	**Global Max. PECsw, µg/l (Step 4, 95% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 95% nozzle reduction)**
D1	Ditch	0.0186 (1m)	0.167 (1m)	0.00142	0.0136	0.00133	0.0109	0.00113	0.0109	0.000845	0.00823
D1	Stream	0.0155 (1.5m)	0.0420 (1.5m)	0.00134	0.00393	0.00134	0.00393	0.00134	0.00393	0.000799	0.00238
D2	Ditch	0.0192 (1m)	0.210 (1m)	**0.00147**	0.0174	0.00117	0.0140	0.00117	0.0140	0.000875	0.0105
D2	Stream	0.0161 (1.5m)	0.107 (1.5m)	0.00139	0.00976	0.00139	0.00976	0.00139	0.00976	0.000828	0.00588
D3	Ditch	0.0183 (1m)	0.112 (1m)	0.00140	0.00939	0.00111	0.00755	0.00111	0.00755	0.000832	0.00570
D4	Pond	0.000808 (3.5m)	0.0348 (3.5m)	0.000343	0.0152	0.000111	0.00512	0.000226	0.0102	<0.000001	<0.000001
D4	Stream	0.0147 (1.5m)	0.0214 (1.5m)	0.00127	0.00195	0.00127	0.00195	0.00127	0.00195	0.000756	0.00117
D5	Pond	0.000872 (3.5m)	0.0344 (3.5m)	0.000370	0.0150	0.000120	0.00507	0.000244	0.0101	<0.000001	<0.000001
D5	Stream	0.0159 (1.5m)	0.0258 (1.5m)	0.00137	0.00236	0.00137	0.00236	0.00137	0.00236	0.000817	0.00142
D6	Ditch	**0.0187** (1m)	0.188 (1m)	0.00143	0.0156	0.00114	0.0126	0.00114	0.0126	0.000851	0.00947
R1	Pond	0.000822 (3.5m)	0.0383 (3.5m)	0.000349	0.0198	0.000114	0.0109	0.000231	0.0151	0.000012	0.00681
R1	Stream	0.0119 (1.5m)	0.177 (1.5m)	0.00103	0.174	0.00103	0.174	0.00103	0.174	0.000613	0.174
R3	Stream	0.0169 (1.5m)	0.0970 (1.5m)	0.00146	0.0828	**0.00146**	0.0828	**0.00146**	0.0828	**0.000868**	0.0823
R4	Stream	0.0119 (1.5m)	0.191 (1.5m)	0.00103	**0.189**	0.00103	**0.189**	0.00103	**0.189**	0.000611	**0.189**

Step 3 and 4 PECsw and PECsed values following **single** applications of gamma-cyhalothrin on **winter** cereals (**autumn** application timing) (maximum value in bold)

Scenario	Water body	Step 3		Step 4							
		Global Max. PECsw, µg/l (default buffer, m)	Global Max. PECsed, µg/kg dw (default buffer, m)	**Global Max. PECsw, µg/l (Step 4, 20m buffer)**	**Global Max. PECsed, µg/kg dw (Step 4, 20 m buffer)**	**Global Max. PECsw, µg/l (Step 4, 5m buffer; 75% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 5m buffer; 75% nozzle reduction)**	**Global Max. PECsw, µg/l (Step 4, 10 m buffer; 50% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 10 m buffer; 50% nozzle reduction)**	**Global Max. PECsw, µg/l (Step 4, 95% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 95% nozzle reduction)**
D1	Ditch	**0.0254** (1m)	**0.183** (1m)	0.00170	0.0129	0.00170	0.0129	0.00170	0.0129	0.00112	0.00859
D1	Stream	0.0222 (1.5m)	0.0962 (1.5m)	0.00223	0.0104	0.00195	0.00916	0.00195	0.00916	0.00110	0.00529
D2	Ditch	0.0252 (1m)	0.120 (1m)	0.00168	0.00870	0.00168	0.00870	0.00168	0.00870	0.00112	0.00583
D2	Stream	0.0197 (1.5m)	0.0220 (1.5m)	0.00197	0.00230	0.00172	0.00201	0.00172	0.00201	0.000976	0.00115
D3	Ditch	0.0250 (1m)	0.0932 (1m)	0.00167	0.00684	0.00167	0.00684	0.00167	0.00684	0.00111	0.00460
D4	Pond	0.000828 (3.5m)	0.0171 (3.5m)	0.000331	0.00702	0.000163	0.00353	0.000247	0.00528	<0.000001	<0.000001
D4	Stream	0.0217 (1.5m)	0.0631 (1.5m)	0.00218	0.00686	0.00190	0.00602	0.00190	0.00602	0.00108	0.00347
D5	Pond	0.000828 (3.5m)	0.0173 (3.5m)	0.000331	0.00708	0.000163	0.00357	0.000247	0.00533	<0.000001	<0.000001
D5	Stream	0.0234 (1.5m)	0.0744 (1.5m)	**0.00236**	0.00809	**0.00206**	0.00710	**0.00206**	0.00710	**0.00117**	0.00410
D6	Ditch	0.0247 (1m)	0.0686 (1m)	0.00165	0.00502	0.00165	0.00502	0.00165	0.00502	0.00109	0.00337
R1	Pond	0.000827 (3.5m)	0.0205 (3.5m)	0.000331	0.0112	0.000163	0.00805	0.00027	0.00961	0.000027	0.00491
R1	Stream	0.0164 (1.5m)	0.109 (1.5m)	0.00165	**0.107**	0.00144	**0.107**	0.00144	**0.107**	0.000816	**0.107**
R3	Stream	0.0232 (1.5m)	0.0625 (1.5m)	0.00233	0.0436	0.00203	0.0436	0.00203	0.0436	0.00115	0.0435
R4	Stream	0.0163 (1.5m)	0.106 (1.5m)	0.00164	0.104	0.00143	0.104	0.00143	0.104	0.000810	0.104

Step 3 and 4 PECsw and PECsed values following **single** applications of gamma-cyhalothrin on **winter** cereals (**spring** application timing) (maximum value in bold)

Scenario	Water body	Step 3		Step 4							
		Global Max. PECsw, µg/l (default buffer, m)	Global Max. PECsed, µg/kg dw (default buffer, m)	**Global Max. PECsw, µg/l (Step 4, 20m buffer)**	**Global Max. PECsed, µg/kg dw (Step 4, 20 m buffer)**	**Global Max. PECsw, µg/l (Step 4, 5m buffer; 75% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 5m buffer; 75% nozzle reduction)**	**Global Max. PECsw, µg/l (Step 4, 10 m buffer; 50% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 10 m buffer; 50% nozzle reduction)**	**Global Max. PECsw, µg/l (Step 4, 95% nozzle reduction)**	**Global Max. PECsed, µg/kg dw (Step 4, 95% nozzle reduction)**
D1	Ditch	0.0250 (1m)	0.0928 (1m)	0.00167	0.00681	0.00167	0.00681	0.00167	0.00681	0.00111	0.00458
D1	Stream	0.0169 (1.5m)	0.00999 (1.5m)	0.00170	0.00102	0.00149	0.000892	0.00149	0.000892	0.000842	0.000507
D2	Ditch	**0.0254** (1m)	**0.168** (1m)	0.00170	0.0119	0.00170	0.0119	0.00170	0.0119	0.00112	0.00793
D2	Stream	0.0223 (1.5m)	0.147 (1.5m)	0.00224	0.0156	0.00196	0.0136	0.00196	0.0136	0.00111	0.00782
D3	Ditch	0.0251 (1m)	0.0954 (1m)	0.00167	0.00699	0.00167	0.00699	0.00167	0.00699	0.00111	0.00470
D4	Pond	0.000827 (3.5m)	0.0169 (3.5m)	0.000331	0.00693	0.000163	0.00349	0.000247	0.00521	<0.000001	<0.000001
D4	Stream	0.0204 (1.5m)	0.0293 (1.5m)	0.00205	0.00311	0.00179	0.00273	0.00179	0.00273	0.00101	0.00156
D5	Pond	0.000827 (3.5m)	0.0166 (3.5m)	0.000331	0.00678	0.000163	0.00341	0.000247	0.00510	<0.000001	<0.000001
D5	Stream	0.0197 (1.5m)	0.0143 (1.5m)	0.00198	0.00146	0.00173	0.00127	0.00173	0.00127	0.000978	0.000724
D6	Ditch	0.0251 (1m)	0.106 (1m)	0.00168	0.00770	0.00168	0.00770	0.00168	0.00770	0.00111	0.00517
R1	Pond	0.000827 (3.5m)	0.0177 (3.5m)	0.000331	0.00841	0.000163	0.00522	0.000247	0.00682	0.000004	0.00245
R1	Stream	0.0165 (1.5m)	0.0644 (1.5m)	0.00166	0.0630	0.00145	0.0630	0.00145	0.0630	0.000821	0.0629
R3	Stream	0.0232 (1.5m)	0.0650 (1.5m)	**0.00233**	0.0336	**0.00204**	0.0336	**0.00204**	0.0336	**0.00116**	0.0334
R4	Stream	0.0165 (1.5m)	0.0678 (1.5m)	0.00165	**0.0669**	0.00144	**0.0669**	0.00144	**0.0669**	0.000818	**0.0669**

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

FOCUS modelling studies using FOCUS PEARL 4.4.4 and FOCUS-PELMO 3.3.2 (parent compound only)	Scenarios :Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva (where applicable)
Inputs and results presented for winter and cereal GAP (3 x 4.5 g a.s./ha, 10 day interval	Crop: Winter and spring cereals Q_{10}: 2.58 **Gamma-cyhalothrin** Normalised geometric mean DT_{50lab} 26.8 days. K_{doc}: 59677 mL/g, $^1/_n$ = 0.9* **3-(4-OHPh)** Molecular weight: soil DT_{50}12.4 d (conservative overestimate from the silt loam in Cook, 2001) Formation fraction: 1.0 K_{doc}: 324 mL/g, $^1/_n$ = 0.9* plant uptake = 0 **PBA** Molecular weight: 214.2 Normalised geometric mean DT_{50lab} 0.7 days. Formation fraction: 1.0 K_{Foc}: 59 mL/g, $^1/_n$ = 0.88 plant uptake = 0 **DMCPA** Molecular weight: 242.6 Normalised geometric mean DT_{50lab} 2.6 days. Formation fraction: 1.0 K_{doc}: 62 mL/g, $^1/_n$ = 1 plant uptake = 0 * a 1/n = 1.0 should be used as worst case when only Kd estimated (no impact on the results is expected in this case)
Application rate	Winter and spring cereals Application rate: 4.5 g a.s./ha. No. of applications: 3, 10 day interval 25 % crop interception Spring cereals:1st March (first application) Winter cereal (autumn application): 1st September (first application)
Gamma-cyhalothrin PEC_{gw}	For all requested crops at every FOCUS standard scenario defined as growing that crop 80th percentile

annual average concentrations of gamma-cyhalothrin a in leachate (recharge) at the 1 m evaluation depth were <0.001µg/L.

Maximum 80th percentile annual average 3-(4-OHPh) concentration (µg/L) at 1m after application to cereals using PELMO (v.5.5.3.)

Scenario	Winter cereals (Autumn application)	Winter cereals (Spring application)	Spring Cereals
Châteaudun	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	<0.001
Jokioinen	<0.001	<0.001	<0.001
Kremsmünster	<0.001	<0.001	<0.001
Okehampton	<0.001	<0.001	<0.001
Piacenza	<0.001	<0.001	-
Porto	<0.001	<0.001	<0.001
Sevilla	<0.001	<0.001	-
Thiva	<0.001	<0.001	-

Maximum 80th percentile annual average PBA concentration (µg/L) at 1m after application to cereals using PELMO (v.5.5.3.)

Scenario	Winter cereals (Autumn application)	Winter cereals (Spring application)	Spring Cereals
Châteaudun	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	<0.001
Jokioinen	<0.001	<0.001	<0.001
Kremsmünster	<0.001	<0.001	<0.001
Okehampton	<0.001	<0.001	<0.001
Piacenza	<0.001	<0.001	-
Porto	<0.001	<0.001	<0.001
Sevilla	<0.001	<0.001	-
Thiva	<0.001	<0.001	-

PEC_{gw} (µg/L) at 1 m depth for DMCPA after application of 3 × 4.5 g a.s./ha to winter and spring cereals at BBCH 12 – 77 calculated using PEARL (v.4.4.4)

Scenario	Winter Cereals (Autumn application)	Winter Cereals (Spring application)	Spring Cereals
Châteaudun	< 0.001	< 0.001	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001
Piacenza	< 0.001	< 0.001	-
Porto	< 0.001	< 0.001	< 0.001
Sevilla	< 0.001	< 0.001	-
Thiva	< 0.001	< 0.001	-

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

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	3.2×10^{-5}
Photochemical oxidative degradation in air ‡	DT_{50} of 4.08 hours derived by the Atkinson model (AOPWIN version 1.90). OH (12 h) concentration assumed = 1.5×10^{6} molecules per cm^3
Volatilisation ‡	from plant surfaces (BBA guideline): 0 % after 24 h
	from soil surfaces (BBA guideline): 8.2 % after 24 h
Metabolites	None

PEC (air)

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

$PEC_{(a)}$

Maximum concentration	Assumed to be negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which a groundwater exposure assessment is triggered.	Soil: gamma-cyhalothrin, 3-(4-OHPh), DMCPA Surface water: gamma-cyhalothrin, 3-(4-OHPh), DMCPA, PBA Sediment: gamma-cyhalothrin, 3-(4-OHPh), DMCPA, PBA Ground water: gamma-cyhalothrin, 3-(4-OHPh), DMCPA, PBA Air: gamma-cyhalothrin

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

Soil (indicate location and type of study)	No data available
Surface water (indicate location and type of study) Ground water (indicate location and type of study)	Cyhalothrin was monitored in surface water in France only (364 samples from 71 sites). Lambda-cyhalothrin was somewhat more frequently monitored, i.e. in surface water and groundwater in France, Greece and Norway, and in drinking water in Greece. In total, 839 samples were analysed from 394 sites in the period 1995-1999 (305 groundwater samples from 180 sites, 429 surface water samples from 201 sites and 105 drinking water samples from 13 sites). Neither cyhalothrin nor lambda-cyhalothrin were detected in any of the samples. Where details were available, the limits of detection were in the range 0.05-

	0.005 µg L^{-1}. Nevertheless, a multi-residue analysis was used in Greece with <10% recovery of lambda-cyhalothrin on extraction. It was therefore concluded that the concentrations could at best be considered to be below 0.1 µg L^{-1}, despite the low limit of detection given. In the French collation of data, the detection limits were not specified, but the statistical analyses presented in the report gave average, mean and 90 percentile concentrations as well below 0.1 µg L^{-1}.
Air (indicate location and type of study)	No data available

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

Candidate for R53

Effects on Non-target Species

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

Species	Test substance	Time scale	End point (mg/kg bw per/day)	End point (mg/kg feed)
Birds				
Bobwhite quail (*Colinus virginianus*)	Technical gamma-cyhalothrin	Acute	LD_{50} >2000	-
Bobwhite quail (*Colinus virginianus*)	Formulation GF-317 (60 g a.s./L)	Acute	LD_{50} >5000 (equivalent to >300 mg a.s./kg bw)	-
Mallard duck (*Anas platyrhynchos*)	Technical gamma-cyhalothrin	Short-term	LD_{50} >429	LC_{50} >4430
Bobwhite quail (*Colinus virginianus*)	Technical gamma-cyhalothrin	Short-term	LD_{50} 224.6	LC_{50} 2644
Mallard duck (*Anas platyrhynchos*)	Technical lambda-cyhalothrin	Long-term	NOEC 1.35 mg gamma-cyhalothrin/kg bw per day[1]	30 mg lambda-cyhalothrin/kg diet
Mammals				
Rat	Technical gamma-cyhalothrin	Acute	LD_{50} >50 (males) LD_{50} >55 (females)	-
Rat	Formulation GF-317 (60 g a.s./L)	Acute	LD_{50} 3257 - 4444 (equivalent to 195.4 - 266.6 mg a.s./kg bw)	-
Rat	cyhalothrin	Long-term (multi-generation study)	0.125 mg gamma-cyhalothrin/kg bw per day)[2]	NOAEL 30 ppm cyhalothrin
Additional higher tier studies				
None submitted.				

[1] Please note this endpoint is from a study conducted with lambda-cyhalothrin. The endpoint in mg/kg diet has been converted in to a daily dose and then converted (i.e. divided by 2) so that it is in mg of gamma-cyhalothrin.

[2] Please note this endpoint is from a study conducted with cyhalothrin. The endpoint in mg/kg diet has been converted in to a daily dose and then converted (i.e. divided by 4) so that it is in mg of gamma-cyhalothrin.

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

Winter and spring wheat and barley, 3 x 4.5 g a.s./ha, 10 day interval, BBCH 12-75/77

Category (*e.g.* insectivorous bird)	Time-scale	DDD (mg a.s./kg bw per day)	TER	Annex VI Trigger
Screening step (Birds)				
Small omnivorous bird	Acute	1.072	>280	10
Small omnivorous bird	Long-term/ reproduction	0.28	**4.8**	5
Tier I (Birds)				
BBCH 10-29 Large herbivorous bird "goose"	Long-term/ reproduction	0.0695	19.4	5
BBCH 10-29 Small omnivorous bird "lark"		0.0468	28.9	5
BBCH 30-39 Small omnivorous bird "lark"		0.0232	58.23	5
BBCH 41-70 Small omnivorous bird "lark"		0.0142	95.3	5
BBCH 71-89 Small omnivorous bird "lark"		0.0142	95.3	5
BBCH 71-89 Small insectivorous bird "passerine"		0.0962	14.0	5
Bioaccumulation				
Earthworm-eating bird[1]	Long-term/ reproduction	0.0105	129	5
Fish-eating bird[1,2]	Long-term/ reproduction	0.0031	436	5
Higher Tier refinement (birds): None				
Consumption of contaminated water:				
Puddle scenario relevant to cereals. Application rate to acute toxicity endpoint ratio = 0.015 Application rate to reproductive endpoint ratio = 3.33 Ratios <3000 (trigger for sorptive substances), therefore no further consideration required.				
Biomagnification assessment				
Data gap				

[1] Secondary poisoning dietary risk (log Pow a.s. >3 (EFSA (2009) GD);

[2] Assessment based on BCF value from lambda-cyhalothrin RAR and a 21-day time weighted average from the worst case FOCUS Step 3 scenario, i.e. D1 ditch, multiple applications in autumn to winter wheat.

TERs in **bold** are less than the trigger value

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

Winter and spring wheat and barley, 3 x 4.5 g a.s./ha, 10 day interval, BBCH 12-75/77

Category (*e.g.* insectivorous bird)	Time-scale	DDD (mg a.s./Kg bw/day)	TER	Annex VI Trigger
Screening step (Mammals)				
Small herbivorous mammal	Acute	0.799	>62.6	10
Small herbivorous mammal	Long-term/ reproduction	0.21	0.60	5
Tier I (Mammals)				
BBCH 10-19[1] Large herbivorous mammal "lagomorph"	Long-term/ reproduction	0.0957	**1.31**	5
BBCH 10-19[1] Small omnivorous mammal "mouse"	Long-term/ reproduction	0.0335	**3.73**	5
BBCH 10-19[1] Small insectivorous mammal "shrew"	Long-term/ reproduction	0.0180	6.94	5
BBCH 20-29 Small insectivorous mammal "shrew"	Long-term/ reproduction	0.0082	15.24	5
BBCH 20-29 Small omnivorous mammal "mouse"	Long-term/ reproduction	0.0335	**3.73**	5
BBCH 30-39 Small insectivorous mammal "shrew"	Long-term/ reproduction	0.0082	15.24	5
BBCH 30-39 Small omnivorous mammal "mouse"	Long-term/ reproduction	0.0167	7.49	5
BBCH ≥40 Small insectivorous mammal "shrew"	Long-term/ reproduction	0.0082	15.24	5
BBCH ≥40 Small herbivorous mammal "vole"	Long-term/ reproduction	0.0932	**1.34**	5
BBCH ≥40 Small omnivorous mammal "mouse"	Long-term/ reproduction	0.0099	12.63	5
Bioaccumulation				
Earthworm-eating mammal[2]	Long-term/ reproduction	0.0128	9.77	5
Fish-eating mammal[2,3]	Long-term/ reproduction	0.0028	45.2	5
Higher Tier refinement (mammals): None submitted, data gap				
Consumption of contaminated water:				
Puddle scenario relevant to mammals. Application rate to acute toxicity endpoint ratio = 0.09 Application rate to reproductive endpoint ration = 18 Ratios <3000 (trigger for sorptive substances), therefore no further consideration required.				

[1] Includes 'early shoots' scenario;
[2] Secondary poisoning dietary risk (log P_{ow} a.s. >3 (EFSA (2009) GD))
[3] Assessment based on BCF value from lambda-cyhalothrin RAR and a 21-day time weighted average from the worst case FOCUS Step 3 scenario, i.e. D1 ditch, multiple applications in autumn to winter wheat.
TERs in **bold** are less than the assessment factor

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

Group	Test substance	Time-scale	Endpoint	Toxicity (µg a.s./L)
Laboratory tests				
Fish				
L. macrochirus	Gamma-cyhalothrin	Acute 96h, flow-through	Mortality LC_{50}	0.0354 (mm)
L. macrochirus	Gamma-cyhalothrin	Acute 96h, flow-through	Mortality LC_{50}	0.0631 (mm)
L. macrochirus	'Gamma-cyhalothrin 60 g/L CS'	96 hr semi-static	Mortality LC_{50}	1.80 (mm)
L. macrochirus	'Gamma-cyhalothrin 60 g/L CS'	96 hr static with sediment	Mortality LC_{50}	12 (mm)
O. mykiss	Gamma-cyhalothrin	Acute 96h, flow-through	Mortality LC_{50}	0.0721 (mm)
O. mykiss	Gamma-cyhalothrin	Acute 96h, flow-through	Mortality LC_{50}	0.170 (mm)
O. mykiss	GF-317	Acute 96h, flow-through	Mortality LC_{50}	1.32 (mm)
P. reticulate	Gamma-cyhalothrin	Acute 96h, flow-through	Mortality LC_{50}	0.170 (mm)
B. rerio	Gamma-cyhalothrin	Acute 96h, flow-through	Mortality LC_{50}	0.270 (mm)
P. promelas	Gamma-cyhalothrin	Acute 96h, flow-through	Mortality LC_{50}	0.340 (mm)
Leuciscus idus	'Gamma-cyhalothrin 60 g/L CS'	96 hr semi-static	Mortality LC_{50}	1.20 (mm)
Leuciscus idus	'Gamma-cyhalothrin 60 g/L CS'	96 hr static with sediment	Mortality LC_{50}	2.2 (mm)
P. promelas	Gamma-cyhalothrin	Chronic 35-day ELS	NOEC	0.0379 (mm)
P. promelas	lambda-cyhalothrin	Full fish life cycle study	NOEC	0.031 (lambda cyhalothrin) 0.0155 (gamma-cyhalothrin)
Aquatic invertebrates				
D. magna	Gamma-cyhalothrin	Acute 48h, static	Mortality EC_{50}	0.045 (mm)
D. magna	Gamma-cyhalothrin	Acute 48h, static	Mortality EC_{50}	0.0994 (mm)
D. magna	GF-317	Acute 48h, static	Mortality EC_{50}	0.54 (mm)
Gammarus pseudolimnaeus	Gamma-cyhalothrin	Acute 48h, static	Mortality EC_{50}	0.00305 (mm)
Gammarus pseudolimnaeus (neonates)	Gamma-cyhalothrin	Acute 96h, static	Mortality EC_{50}	0.000446 (mm)
Gammarus pseudolimnaeus	GF-317	Acute 96h, static	Mortality EC_{50}	0.0167 (mm)
D. magna	Gamma-cyhalothrin	Chronic 21d, static	NOEC	Data gap[2]

Group	Test substance	Time-scale	Endpoint	Toxicity (µg a.s./L)
Algae				
P. subcapitata	Gamma-cyhalothrin	Growth 72h, static	E_bC_{50}	2850 (mm)
P. subcapitata	GF-317	Growth 72h, static	E_bC_{50}	11900 (mm)
Sediment dwellers				
C. riparius (water phase)[1]	Gamma-cyhalothrin	Chronic 28d, static	NOEC	0.0469 (mm)
C. riparius (sediment phase)[1]	Gamma-cyhalothrin	Chronic 28d, static	NOEC	12.6 µg a.s./kg sediment (nom)

mm= mean measured concentration; nom = nominal concentration

[1] It should be noted that the larvae were fed throughout the study, and as the Log K_{ow} is close to 5, the above endpoints may underestimate the toxicity (see OECD test guideline 219 for further details).

[2] Data gap for new chronic aquatic invertebrate study in situations where the refined RAC value is not considered appropriate.

Group	Test substance	Time-scale	Endpoint	Toxicity (µg a.s./L)
Metabolites				
Fish				
L. macrochirus	DMCPA	Acute 96h, static	Mortality, LC_{50}	>14000 (mm)[1]
Oncorhynchus mykiss	DMCPA	Acute 96h, semi-static	Mortality, LC_{50}	>15800 (mm)[1]
L. macrochirus	PBA	Acute 96h, semi-static	Mortality, LC_{50}	36300 (nom)[1]
Oncorhynchus mykiss	PBA	Acute 96h, static	Mortality, LC_{50}	13300 (nom)[1]
Oncorhynchus mykiss	PBA	Acute 96h, static	Mortality, LC_{50}	17700 (mm)
Aquatic invertebrates				
D. magna	DMCPA	Acute 48h, static	Mortality, EC_{50}	85300 (mm)
D. pulex	DMCPA	Acute 48h, static	Mortality, EC_{50}	105000 (nom)[1]
D. magna	PBA	Acute 96h, static	Mortality, LC_{50}	85000 (mm)[1]
D. magna	PBA	Acute 96h, static	Mortality, LC_{50}	42300 (mm)
D. magna	3-(4-OHPh)	Acute 48-hr Semi-static	Mortality, EC_{50}	11910(mm)
Algae				
Pseudokirchneriella subcapitata	PBA	Growth 72-hr static	E_rC_{50} E_yC_{50}	37900 (mm) 8590 (mm)

mm= mean measured concentration; nom = nominal concentration

[1] Data evaluated as part of the lambda-cyhalothrin review, RMS Sweden

Higher tier data/use of multiple species data
Acute toxicity to fish: On the basis of the available data (performed with the formulated product and modified toxicity studies performed in the presence of sediment), in situations where exposure is from spray-drift only, the RAC value is 22 ng a.s./L (i.e. 2.2 µg a.s./L/100 = 0.022 µg a.s./L). For longer term exposure or for multiple exposure peaks (e.g. from run-off exposure) the RAC is 0.354 ng a.s./L (i.e. 0.0354 µg a.s./L/100 = 0.000354 µg a.s./L).
A microcosm study was submitted which assessed the effects of gamma-cyhalothrin on aquatic invertebrates

present in a mesocosm. Gamma-cyhalothrin, as GF-317, was applied three times at weekly intervals. The NOEC for the most sensitive taxa, *Chaoborus* sp. and *Caenis* sp. was at, or close to, 5 ng a.s./L with reductions in abundance at 5 ng a.s./L only detected on a single sampling date (lasting less than 2 – 3 weeks). **At 5 ng a.s./L the** transient population effects for these two taxa had no detectable impact on the invertebrate community and the $NOEC_{community}$ in this study was 5 ng a.s./L
On the basis of the available microcosm study taken together with a number of literature papers the experts at the Pesticides Peer Review Meeting (107, November 2013) agreed a RAC value of 0.3 ng a.s./L for situations where there are only single exposure peaks (from each application) i.e. in situations where the exposure is from spray drift only.

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

FOCUS Step 1

Spring and winter cereals 3 x 4.5 g gamma-cyhalothrin/ha

Test substance	Organism	Toxicity endpoint (µg/L)	Time scale	PEC (µg/L)[1]	TER	Annex VI Trigger
Gamma-cyhalothrin	Fish(*L. macrochirus*)	0.0354	Acute	0.18	**0.20**	100
	Fish (*P. promelas*)	0.0155	Chronic	0.18	**0.09**	10
	Aquatic invertebrate (*D. magna*)	0.045	Acute	0.18	**0.25**	100
	G. pseudolimnaeus	0.000446	Acute	0.18	**0.002**	100
	Sediment dwelling invertebrate (water phase) *C. riparius*	0.0469	Chronic	0.18	**0.26**	10
	Algae (*S. capricornutum*)	>2850	Growth	0.18	15833	10

[1]Global maximum predicted environment concentration in surface water
Values in **bold** breach the Annex VI trigger

Spring and winter cereals 3 x 4.5 g gamma-cyhalothrin/ha

Test substance	Organism	Toxicity endpoint (µg/kg)	Time scale	PEC (µg/kg)[1]	TER	Annex VI Trigger
Gamma-cyhalothrin	Sediment dwelling invertebrate (sediment phase) *C. riparius*	12.6	Chronic	33.7	**0.37**	10

[1] Global maximum predicted environment concentration in sediment
Values in **bold** breach the Annex VI trigger.

Metabolites

Spring and winter cereals 3 x 4.5 g gamma-cyhalothrin/ha

Test organism	Endpoint EC/LC_{50} µg/L	Step 1 (global max PEC)[1] µg/L	TER	Annex VI trigger
DMCPA				
Fish *L. macrochirus*	>14000	0.374	>37433	100
Aquatic invertebrates *D. magna*	85500	0.374	228610	100
PBA				
Fish *O. mykiss*	13300	0.1937	68663	100
Aquatic invertebrates	42300	0.1937	218379	100

D. magna				
Algae *P. subcapitata*	8590	0.1937	44347	10
3-(4-OHPh)				
Aquatic invertebrate *D. magna*	11910	0.1464	81352	100

[1]Global maximum predicted environment concentration surface water, FOCUS Step 1 (v2.1).

FOCUS Step 2

Spring and winter cereals 3 x 4.5 g gamma-cyhalothrin/ha in Northern and Southern Europe

Test substance	Organism	Toxicity endpoint (µg/L)	Time scale	PEC_i (µg/L)[1, 2]	TER	Annex VI Trigger
Gamma-cyhalothrin	Fish (*L. macrochirus*)	0.0354	Acute	0.0414	**0.86**	100
	Fish (*P. promelas*)	0.0155	Chronic	0.0414	**0.37**	10
	Aquatic invertebrate (*D. magna*)	0.045	Acute	0.0414	**1.09**	100
	G. pseudolimnaeus	0.000446	Acute	0.0414	**0.01**	100
	Sediment dwelling invertebrate (water spiked) *C. riparius*	0.0469	Chronic	0.0414	**1.13**	10

[1] Global maximum predicted environment concentration surface water.
[2] At Step 2 the maximum initial PEC_{sw} and PEC_{sed} values are the same for both northern and southern Europe
Values in **bold** are below the Annex VI trigger

FOCUS Step 2

Spring and winter cereals 3 x 4.5 g gamma-cyhalothrin/ha in Northern and Southern Europe

Test substance	Organism	Toxicity endpoint (µg/kg)	Time scale	PEC_i (µg/kg)[1, 2]	TER	Annex VI Trigger
Gamma-cyhalothrin	Sediment dwelling invertebrate (sediment spiked) *C. riparius*	12.6[2]	Chronic	4.2[2]	**2.9**	10

[1]Global maximum predicted environment concentration surface water.
[2] At Step 2 the maximum initial PEC_{sw} and PEC_{sed} values are the same for both northern and southern Europe.
Values in **bold** are below the Annex VI trigger

FOCUS Step 3 – fish (acute)

Spring and winter cereals 3 x 4.5 g gamma-cyhalothrin/ha (PEC values derived for a single application)

Test substance	Crop	Scenario	Test organism	Time scale	Toxicity endpoint (µg a.s./L)	Max PEC_{sw} (µg/L)	TER	Annex VI trigger
Gamma-cyhalothrin	Spring cereals	D1(ditch)	Fish (*L. idus*)	Acute	2.2[1]	0.0254	**86.61**	100
		D1(stream)				0.0222	**99.10**	
		D3(ditch)				0.0251	**87.65**	
		D4(pond)				0.000827[2]	2660.22	
		D4(stream)				0.0208	105.77	
		D5(pond)				0.000827[2]	2660.22	
		D5(stream)				0.0196	112.24	
		R4(stream)				0.0165	133.33	
	Winter cereals (autumn applns)	D1(ditch)	Fish (*L. idus*)	Acute	2.2[1]	0.0254	**86.61**	100
		D1(stream)				0.0222	**99.10**	
		D2(ditch)				0.0252	**87.30**	
		D2(stream)				0.0197	111.68	
		D3(ditch)				0.0250	88.00	
		D4(pond)				0.000828[2]	2657.00	
		D4(stream)				0.0217	101.38	
		D5(pond)				0.000828	2657.00	
		D5(stream)				0.0234	**94.02**	
		D6(ditch)				0.0247	**89.07**	
		R1(pond)				0.000827[2]	2660.22	
		R1(stream)				0.0164	134.15	
		R3(stream)				0.0232	**94.83**	
		R4(stream)				0.0163	134.97	
	Winter cereals (spring applns)	D1(ditch)	Fish (*L. idus*)	Acute	2.2[1]	0.0250	**88.00**	100
		D1(stream)				0.0169	130.18	
		D2(ditch)				0.0254	**86.61**	
		D2(stream)				0.0223	**98.65**	
		D3(ditch)				0.0251	**87.65**	
		D4(pond)				0.000827	2660.22	
		D4(stream)				0.0204	107.84	
		D5(pond)				0.00082[2]	2660.22	
		D5(stream)				0.0197	111.68	
		D6(ditch)				0.0251	**87.65**	
		R1(pond)				0.000827	2660.22	
		R1(stream)				0.0165	133.33	
		R3(stream)				0.0232	**94.83**	
		R4(stream)				0.0165	133.33	

[1] Endpoint derived from modified toxicity study performed with *Leuciscus idus* in the presence of sediment and conducted with the formulated product. Only relevant when exposure is from spray-drift **(data gap** identified for confirmation of which FOCUS exposure scenarios this refined toxicity value is suitable for)

[2] PEC values for multiple applications are marginally higher in the D4 (pond) and D5 (pond) for spring cereals, D4 (pond) and R1 (pond) for autumn applications to winter cereals and in D5 (pond) for spring applications to winter cereals). No TER value presented as the difference in PEC is inconsequential to the outcome of the assessment.

Values in **bold** are below the Annex VI trigger

FOCUS Step 3 – fish (chronic)

Spring and winter cereals 3 x 4.5 g gamma-cyhalothrin/ha (PEC values derived for a single application)

Test substance	Crop	Scenario	Test organism	Time scale	Toxicity endpoint (µg a.s./L)	Max PEC_{sw} (µg/L)	TER	Annex VI trigger
Gamma-cyhalothrin	Spring cereals	D1(ditch)	Fish (*Pimephales promelas*)	Chronic	0.0155	0.0254	**0.61**	10
		D1(stream)				0.0222	**0.70**	
		D3(ditch)				0.0251	**0.62**	
		D4(pond)				0.000827[1]	18.74	
		D4(stream)				0.0208	**0.75**	
		D5(pond)				0.000827[1]	18.74	
		D5(stream)				0.0196	**0.79**	
		R4(stream)				0.0165	**0.94**	
	Winter cereals (autumn applns)	D1(ditch)	Fish (*Pimephales promelas*)	Chronic	0.0155	0.0254	**0.61**	10
		D1(stream)				0.0222	**0.70**	
		D2(ditch)				0.0252	**0.62**	
		D2(stream)				0.0197	**0.79**	
		D3(ditch)				0.0250	**0.62**	
		D4(pond)				0.000828[1]	18.72	
		D4(stream)				0.0217	**0.71**	
		D5(pond)				0.000828[1]	18.72	
		D5(stream)				0.0234	**0.66**	
		D6(ditch)				0.0247	**0.63**	
		R1(pond)				0.000827	18.74	
		R1(stream)				0.0164	**0.95**	
		R3(stream)				0.0232	**0.67**	
		R4(stream)				0.0163	**0.95**	
	Winter cereals (spring applns)	D1(ditch)	Fish (*Pimephales promelas*)	Chronic	0.0155	0.0250	**0.62**	10
		D1(stream)				0.0169	**0.92**	
		D2(ditch)				0.0254	**0.61**	
		D2(stream)				0.0223	**0.70**	
		D3(ditch)				0.0251	**0.62**	
		D4(pond)				0.000827	18.74	
		D4(stream)				0.0204	**0.76**	
		D5(pond)				0.000827[1]	18.74	
		D5(stream)				0.0197	**0.79**	
		D6(ditch)				0.0251	**0.62**	
		R1(pond)				0.000827	18.74	
		R1(stream)				0.0165	**0.94**	
		R3(stream)				0.0232	**0.67**	
		R4(stream)				0.0165	**0.94**	

[1] PEC values for multiple applications are marginally higher in the D4 (pond) and D5 (pond) for spring cereals, D4 (pond) and R1 (pond) for autumn applications to winter cereals and in D5 (pond) for spring applications to winter cereals). No TER value presented as the difference in PEC is inconsequential to the outcome of the assessment.
Values in **bold** are below the Annex VI trigger.

FOCUS Step 3 – aquatic invertebrates (using RAC)

Spring and winter cereals 3 x 4.5 g gamma-cyhalothrin/ha (PEC values derived for a single application)
Assessment performed using RAC value of 0.000 3 µg a.s./L with a trigger value of 1

Test substance	Crop	Scenario	Test organism	Time scale	Toxicity endpoint (µg a.s./L)	Max PEC_{sw} (µg/L)	TER	Trigger value[1]
Gamma-cyhalothrin	Spring cereals	D1(ditch)	Aquatic invertebrates	RAC (acute and chronic)	0.0003	0.0254	**0.012**	1
		D1(stream)				0.0222	**0.014**	
		D3(ditch)				0.0251	**0.012**	
		D4(pond)				0.000827[2]	**0.363**	
		D4(stream)				0.0208	**0.014**	
		D5(pond)				0.000827[2]	**0.363**	
		D5(stream)				0.0196	**0.015**	
		R4(stream)				0.0165	**0.018**	
	Winter cereals (autumn applns)	D1(ditch)	Aquatic invertebrates	RAC (acute and chronic)	0.0003	0.0254	**0.012**	1
		D1(stream)				0.0222	**0.014**	
		D2(ditch)				0.0252	**0.012**	
		D2(stream)				0.0197	**0.015**	
		D3(ditch)				0.0250	**0.012**	
		D4(pond)				0.000828[2]	**0.362**	
		D4(stream)				0.0217	**0.014**	
		D5(pond)				0.000828	**0.362**	
		D5(stream)				0.0234	**0.013**	
		D6(ditch)				0.0247	**0.012**	
		R1(pond)				0.000827[2]	**0.363**	
		R1(stream)				0.0164	**0.018**	
		R3(stream)				0.0232	**0.013**	
		R4(stream)				0.0163	**0.018**	
	Winter cereals (spring applns)	D1(ditch)	Aquatic invertebrates	RAC (acute and chronic)	0.0003	0.0250	**0.012**	1
		D1(stream)				0.0169	**0.018**	
		D2(ditch)				0.0254	**0.012**	
		D2(stream)				0.0223	**0.013**	
		D3(ditch)				0.0251	**0.012**	
		D4(pond)				0.000827	**0.363**	
		D4(stream)				0.0204	**0.015**	
		D5(pond)				0.000827[2]	**0.363**	
		D5(stream)				0.0197	**0.015**	
		D6(ditch)				0.0251	**0.012**	
		R1(pond)				0.000827	**0.363**	
		R1(stream)				0.0165	**0.018**	
		R3(stream)				0.0232	**0.013**	
		R4(stream)				0.0165	**0.018**	

[1]As the assessment factor is incorporated in to the RAC value, the trigger value is 1.
[2] PEC values for multiple applications are marginally higher in the D4 (pond) and D5 (pond) for spring cereals, D4 (pond) and R1 (pond) for autumn applications to winter cereals and in D5 (pond) for spring applications to winter cereals). No TER value presented as the difference in PEC is inconsequential to the outcome of the assessment.
TERs in **bold** are less than the trigger value

FOCUS Step 3 – sediment dwelling organisms (chronic)

Spring and winter cereals 3 x 4.5 g gamma-cyhalothrin/ha (PEC values derived for a single application) (PEC values derived for a multiple applications)

Test substance	Crop	Scenario	Test organism	Time scale	Toxicity endpoint (µg a.s./kg)	Max PEC_{sed} (µg/kg)	TER	Annex VI trigger
Gamma-cyhalothrin	Spring cereals	D1(ditch)	Sediment dweller (*C. riparius*)	Chronic	12.6	0.387	33	10
		D1(stream)				0.104	121	
		D3(ditch)				0.128	98	
		D4(pond)				0.0324	389	
		D4(stream)				0.0544	232	
		D5(pond)				0.0339	372	
		D5(stream)				0.0248	508	
		R4(stream)				0.276	46	
	Winter cereals (autumn applns)	D1(ditch)	Sediment dweller (*C. riparius*)	Chronic	12.6	0.260	48	10
		D1(stream)				0.0919	137	
		D2(ditch)				0.145	87	
		D2(stream)				0.0160	788	
		D3(ditch)				0.100	126	
		D4(pond)				0.0335	376	
		D4(stream)				0.0586	215	
		D5(pond)				0.0346	364	
		D5(stream)				0.0629	200	
		D6(ditch)				0.0668	189	
		R1(pond)				0.0441	286	
		R1(stream)				0.247	51	
		R3(stream)				1.866	**7**	
		R4(stream)				0.295	43	
	Winter cereals (spring applns)	D1(ditch)	Sediment dweller (*C. riparius*)	Chronic	12.6	0.167	75	10
		D1(stream)				0.0420	300	
		D2(ditch)				0.210	60	
		D2(stream)				0.107	118	
		D3(ditch)				0.112	113	
		D4(pond)				0.0348	362	
		D4(stream)				0.0214	589	
		D5(pond)				0.0344	366	
		D5(stream)				0.0258	488	
		D6(ditch)				0.188	67	
		R1(pond)				0.0383	329	
		R1(stream)				0.177	71	
		R3(stream)				0.0970	130	
		R4(stream)				0.191	66	

Values in **bold** are below the Annex VI trigger

FOCUS Step 4 – Fish (acute)

Spring 3 x 4.5 g gamma-cyhalothrin/ha (PEC values derived for a single application)

Test substance	Crop	Scenario	Test organism	Time scale	Toxicity end point (µg a.s./L)[5]	Max PECsw				TER				Trigger
						20m[1]	5m (75%)[2]	10m (50%)[3]	95% redn[4]	20m	5m +75%	10m + 50%	95%	
Gamma-cyhalothrin	Spring cereals	D1 ditch	Fish	acute	2.2	0.00170	0.00170	0.00170	0.00112	1294	1294	1294	1964	100
		D1 stream			2.2	0.00223	0.00195	0.00195	0.00110	987	1128	1128	2000	100
		D3 ditch			2.2	0.00168	0.00168	0.00168	0.00111	1310	1310	1310	1982	100
		D4 pond			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		D4 stream			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		D5 pond			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		D5 stream			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		R4 stream			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100

[1] PEC based on 20 m buffer zone and no drift reduction nozzles
[2] PEC based on 5m buffer zone plus 75% drift reduction nozzles
[3] PEC based on 10m buffer zone plus 50% drift reduction nozzles
[4] PEC based on 95% drift reduction nozzles only
[5] Endpoint derived from modified toxicity study performed in the presence of sediment and conducted with the formulated product. Only relevant when exposure is from spray-drift **(data gap** identified for confirmation of which FOCUS exposure scenarios this refined toxicity value is suitable for)
n/r: not required

Winter cereals, autumn application, 3 x 4.5 g gamma-cyhalothrin/ha (PEC values derived for a single application)

Test substance	Crop	Scenario	Test organism	Time scale	Toxicity end point (µg a.s./L)[5]	Max PECsw				TER				Trigger
						20m[1]	5m (75%)[2]	10m (50%)[3]	95% redn[4]	20m	5m +75%	10m + 50%	95%	
Gamma-cyhalothrin	Winter cereals Autumn appln.	D1 ditch	Fish	acute	2.2	0.00170	0.00170	0.00170	0.00112	1294	1294	16471	1964	100
		D1 stream			2.2	0.00223	0.00195	0.00195	0.00110	987	1128	14359	2000	100
		D2 ditch			2.2	0.00168	0.00168	0.00168	0.00112	1310	1310	16667	1964	100
		D2 stream			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		D3 ditch			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		D4 pond			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		D4 stream			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		D5 pond			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		D5 stream			2.2	0.00236	0.00206	0.00206	0.00117	932	1068	13592	1880	100
		D6 ditch			2.2	0.00165	0.00165	0.00165	0.00109	1333	1333	16970	2018	100
		R1 pond			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		R1 stream			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		R3 stream			2.2	0.00233	0.00203	0.00203	0.00115	944	1084	13793	1913	100
		R4 stream			2.2	0.00164	0.00143	0.00143	0.000810	1341	1538	19580	2716	100

[1] PEC based on 20m buffer zone and no drift reduction nozzles
[2] PEC based on 5m buffer zone plus 75% drift reduction nozzles
[3] PEC based on 10m buffer zone plus 50% drift reduction nozzles
[4] PEC based on 95% drift reduction nozzles only
[5] Endpoint derived from modified toxicity study performed in the presence of sediment and conducted with the formulated product. Only relevant when exposure is from spray-drift **(data gap** identified for confirmation of which FOCUS exposure scenarios this refined toxicity value is suitable for)
n/r: not required

Winter cereals, spring application, 3 x 4.5 g gamma-cyhalothrin/ha (PEC values derived for a single application)

Test substance	Crop	Scenario	Test organism	Time scale	Toxicity end point (µg a.s./L)[5]	Max PECsw				TER				Trigger
						20m[1]	5m (75%)[2]	10m (50%)[3]	95% redn[4]	20m	5m +75%	10m + 50%	95%	
Gamma-cyhalothrin	Winter cereals Spring appln	D1 (ditch)	Fish	acute	2.2	0.00167	0.00167	0.00167	0.00111	1317	1317	16766	1982	100
		D1 (stream)			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		D2 (ditch)			2.2	0.00170	0.00170	0.00170	0.00112	1294	1294	16471	1964	100
		D2 (stream)			2.2	0.00224	0.00196	0.00196	0.00111	982	1122	14286	1982	100
		D3 (ditch)			2.2	0.00167	0.00167	0.00167	0.00111	1317	1317	16766	1982	100
		D4 (pond)			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		D4 (stream)			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		D5 (pond)			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		D5 (stream)			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		D6 (ditch)			2.2	0.00168	0.00168	0.00168	0.00111	1310	1310	16667	1982	100
		R1 (pond)			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		R1 (stream)			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100
		R3 (stream)			2.2	0.00233	0.00204	0.00204	0.00116	944	1078	13725	1897	100
		R4 (stream)			2.2	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	100

[1] PEC based on 20m buffer zone and no drift reduction nozzles
[2] PEC based on 5m buffer zone plus 75% drift reduction nozzles
[3] PEC based on 10m buffer zone plus 50% drift reduction nozzles
[4] PEC based on 95% drift reduction nozzles only
[5] Endpoint derived from modified toxicity study performed in the presence of sediment and conducted with the formulated product. Only relevant when exposure is from spray-drift **(data gap** identified for confirmation of which FOCUS exposure scenarios this refined toxicity value is suitable for)
n/r: not required

FOCUS Step 4 – Fish (chronic)

Spring cereals 3 x 4.5 g gamma-cyhalothrin/ha (PEC values derived for a single application)

Test substance	Crop	Scenario	Test organism	Time scale	Toxicity end point (µg a.s./L)	Max PECsw				TER				Trigger
						20m[1]	5m (75%)[2]	10m (50%)[3]	95% redn[4]	20m	5m +75 %	10m + 50%	95%	
Gamma-cyhalothrin	Spring cereals	D1 (ditch)	Fish	chronic	0.0155	0.0017	0.0017	0.0017	0.00112	**9.1**	**9.1**	**9.1**	13.8	10
		D1 (stream)			0.0155	0.00223	0.00195	0.00195	0.0011	**7.0**	**7.9**	**7.9**	14.1	10
		D3 (ditch)			0.0155	0.00168	0.00168	0.00168	0.00111	**9.2**	**9.2**	**9.2**	14.0	10
		D4 (pond)			0.0155	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	10
		D4 (stream)			0.0155	0.00209	0.00182	0.00182	0.00103	**7.4**	**8.5**	**8.5**	15.0	10
		D5 (pond)			0.0155	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	10
		D5 (stream)			0.0155	0.00197	0.00172	0.00172	0.000975	**7.9**	**9.0**	**9.0**	15.9	10
		R4 (stream)			0.0155	0.00166	0.00145	0.00145	0.000822	**9.3**	10.7	10.7	18.9	10

[1] PEC based on 20m buffer zone and no drift reduction nozzles;
[2] PEC based on 5m buffer zone plus 75% drift reduction nozzles;
[3] PEC based on 10m buffer zone plus 50% drift reduction nozzles;
[4] PEC based on 95% drift reduction nozzles only;
n/r: not required
TERs in **bold** are less than the trigger value

Winter cereals, autumn application, 3 x 4.5 g gamma-cyhalothrin/ha (PEC values derived for a single application)

Test substance	Crop	Scenario	Test organism	Time scale	Toxicity end point (µg a.s./L)	Max PECsw				TER				Trigger
						20m[1]	5m (75%)[2]	10m (50%)[3]	95% redn[4]	20m	5m +75 %	10m + 50%	95%	
Gamma-cyhalothrin	Winter cereals Autumn appln.	D1 (ditch)	Fish	chronic	0.0155	0.00170	0.00170	0.00170	0.00112	**9.1**	**9.1**	**9.1**	13.8	10
		D1 (stream)			0.0155	0.00223	0.00195	0.00195	0.00110	**7.0**	**7.9**	**7.9**	14.1	10
		D2 (ditch)			0.0155	0.00168	0.00168	0.00168	0.00112	**9.2**	**9.2**	**9.2**	13.8	10
		D2 (stream)			0.0155	0.00197	0.00172	0.00172	0.000976	**7.9**	**9.0**	**9.0**	15.9	10
		D3 (ditch)			0.0155	0.00167	0.00167	0.00167	0.00111	**9.3**	**9.3**	**9.3**	14.0	10
		D4 (pond)			0.0155	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	10
		D4 (stream)			0.0155	0.00218	0.00190	0.00190	0.00108	**7.1**	**8.2**	**8.2**	14.4	10
		D5 (pond)			0.0155	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	10
		D5 (stream)			0.0155	0.00236	0.00206	0.00206	0.00117	**6.6**	**7.5**	**7.5**	13.2	10
		D6 (ditch)			0.0155	0.00165	0.00165	0.00165	0.00109	**9.4**	**9.4**	**9.4**	14.2	10
		R1 (pond)			0.0155	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	10
		R1 (stream)			0.0155	0.00165	0.00144	0.00144	0.000816	**9.4**	10.8	10.8	19.0	10
		R3 (stream)			0.0155	0.00233	0.00203	0.00203	0.00115	**6.7**	**7.6**	**7.6**	13.5	10
		R4 (stream)			0.0155	0.00164	0.00143	0.00143	0.000810	**9.5**	10.8	10.8	19.1	10

[1] PEC based on 20m buffer zone and no drift reduction nozzles;
[2] PEC based on 5m buffer zone plus 75% drift reduction nozzles;
[3] PEC based on 10m buffer zone plus 50% drift reduction nozzles;
[4] PEC based on 95% drift reduction nozzles only;
n/r: not required
TERs in **bold** are less than the trigger value

Winter cereals, spring application, 3 x 4.5 g gamma-cyhalothrin/ha (PEC values derived for a single application)

Test substance	Crop	Scenario	Test organism	Time scale	Toxicity end point (µg a.s./L)	Max PEC_{sw}				TER				Trigger
						20m[1]	5m (75%)[2]	10m (50%)[3]	95% redn[4]	20m	5m +75%	10m + 50%	95%	
Gamma-cyhalothrin	Winter cereals Spring appln	D1(ditch)	Fish	chronic	0.0155	0.00167	0.00167	0.00167	0.00111	**9.3**	**9.3**	**9.3**	14.0	10
		D1(stream)			0.0155	0.00170	0.00149	0.00149	0.000842	**9.1**	10.4	10.4	18.4	10
		D2(ditch)			0.0155	0.00170	0.00170	0.00170	0.00112	**9.1**	**9.1**	**9.1**	13.8	10
		D2(stream)			0.0155	0.00224	0.00196	0.00196	0.00111	**6.9**	**7.9**	**7.9**	14.0	10
		D3(ditch)			0.0155	0.00167	0.00167	0.00167	0.00111	**9.3**	**9.3**	**9.3**	14.0	10
		D4(pond)			0.0155	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	10
		D4(stream)			0.0155	0.00205	0.00179	0.00179	0.00101	**7.6**	**8.7**	**8.7**	15.3	10
		D5(pond)			0.0155	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	10
		D5(stream)			0.0155	0.00198	0.00173	0.00173	0.000978	**7.8**	**9.0**	**9.0**	15.8	10
		D6(ditch)			0.0155	0.00168	0.00168	0.00168	0.00111	**9.2**	**9.2**	**9.2**	14.0	10
		R1(pond)			0.0155	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	10
		R1(stream)			0.0155	0.00166	0.00145	0.00145	0.000821	**9.3**	10.7	10.7	18.9	10
		R3(stream)			0.0155	0.00233	0.00204	0.00204	0.00116	**6.7**	**7.6**	**7.6**	13.4	10
		R4(stream)			0.0155	0.00165	0.00144	0.00144	0.000818	**9.4**	10.8	10.8	18.9	10

[1] PEC based on 20m buffer zone and no drift reduction nozzles;
[2] PEC based on 5m buffer zone plus 75% drift reduction nozzles;
[3] PEC based on 10m buffer zone plus 50% drift reduction nozzles;
[4] PEC based on 95% drift reduction nozzles only;
n/r: not required
TERs in **bold** are less than the trigger value

FOCUS Step 4 – aquatic invertebrates

Spring and winter cereals 3 x 4.5 g gamma-cyhalothrin/ha

Scenario	Water body	Application	RAC value[3] µg a.s./L	FOCUS Step 3	FOCUS Step 4	
				PECsw µg/L	PECsw µg/L	Risk mitigation
D1	Ditch	Single	0.0003	0.0254	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0221	N/A[1]	
D1	Stream	Single	0.0003	0.0222	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0161	N/A[1]	
D3	Ditch	Single	0.0003	0.0251	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0184	N/A[1]	
D4	Pond	Single	0.0003	0.000827	0.000247	Sufficient mitigation is possible at FOCUS Step 4 (95 % spray drift reduction)
		Multi	0.0003	0.000852	0.000239	
D4	Stream	Single	0.0003	0.0208	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0157	N/A[1]	
D5	Pond	Single	0.0003	0.000827	0.000247	Sufficient mitigation is possible at FOCUS Step 4 (95 % spray drift reduction)
		Multi	0.0003	0.000865	0.000242	
D5	Stream	Single	0.0003	0.0196	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0158	N/A[1]	
R4	Stream	Single	0.0003	0.0165	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0120	N/A[1]	

[1] N/A: Not applicable. Where the FOCUS step 3 PEC values were >0.006 µg a.s./L, a low risk could not be achieved within the maximum risk mitigation according to the recommendations of FOCUS Landscape and Mitigation Factors in Aquatic Risk Assessment report (FOCUS, 2007)

[2] Not possible to mitigate within the maximum risk mitigation according to the recommendations of FOCUS Landscape and Mitigation Factors in Aquatic Risk Assessment report (FOCUS, 2007)

[3] RAC value based on available higher tier studies. Only relevant when exposure is from spray-drift **(data gap** identified for confirmation of which FOCUS exposure scenarios this refined toxicity value is suitable for).

Winter cereals, autumn application, 3 x 4.5 g gamma-cyhalothrin/ha

Scenario	Water body	Application	RAC value[3] µg a.s./L	FOCUS Step 3	FOCUS Step 4	
				PECsw µg/L	PECsw µg/L	Risk mitigation
D1	Ditch	Single	0.0003	0.0254	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0209	N/A[1]	
D1	Stream	Single	0.0003	0.0222	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0161	N/A[1]	
D2	Ditch	Single	0.0003	0.0252	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0185	N/A[1]	
D2	Stream	Single	0.0003	0.0197	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0142	N/A[1]	
D3	Ditch	Single	0.0003	0.0250	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0182	N/A[1]	
D4	Pond	Single	0.0003	0.000828	0.00247	Sufficient mitigation is possible at FOCUS Step 4 (within 95 % spray drift reduction)
		Multi	0.0003	0.000918	0.000256	
D4	Stream	Single	0.0003	0.0217	N/A	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0157	N/A	

Scenario	Water body	Application	RAC value[3] µg a.s./L	FOCUS Step 3	FOCUS Step 4	
				PECsw µg/L	PECsw µg/L	Risk mitigation
D5	Pond	Single	0.0003	0.000828	<0.000001	Sufficient mitigation is possible at FOCUS Step 4 (within 95 % spray drift reduction)
		Multi	0.0003	0.000825	<0.000001	
D5	Stream	Single	0.0003	0.0234	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0169	N/A[1]	
D6	Ditch	Single	0.0003	0.0247	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0180	N/A[1]	
R1	Pond	Single	0.0003	0.000827	0.000247	Sufficient mitigation is possible at FOCUS Step 4 (within 95 % spray drift reduction)
		Multi	0.0003	0.000954	0.000299	
R1	Stream	Single	0.0003	0.0164	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0119	N/A[1]	
R3	Stream	Single	0.0003	0.0232	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0168	N/A[1]	
R4	Stream	Single	0.0003	0.0163	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0119	N/A[1]	

[1] N/A: Not Applicable. Where the FOCUS step 3 PEC values were >0.006 µg a.s./L, a low risk could not be achieved within the maximum risk mitigation according to the recommendations of FOCUS Landscape and Mitigation Factors in Aquatic Risk Assessment report (FOCUS, 2007)

[2] Not possible to mitigate within the maximum risk mitigation according to the recommendations of FOCUS Landscape and Mitigation Factors in Aquatic Risk Assessment report (FOCUS, 2007)

[3] RAC value based on available higher tier studies. Only relevant when exposure is from spray-drift **(data gap** identified for confirmation of which FOCUS exposure scenarios this refined toxicity value is suitable for)

Winter cereals, spring application, 3 x 4.5 g gamma-cyhalothrin/ha

Scenario	Water body	Application	RAC value[3] µg a.s./L	FOCUS Step 3	FOCUS Step 4	
				PECsw µg/L	PECsw µg/L	Risk mitigation
D1	Ditch	Single	0.0003	0.0250	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0186	N/A[1]	
D1	Stream	Single	0.0003	0.0169	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0155	N/A[1]	
D2	Ditch	Single	0.0003	0.0254	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0192	N/A[1]	
D2	Stream	Single	0.0003	0.0223	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0161	N/A[1]	
D3	Ditch	Single	0.0003	0.0251	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0183	N/A[1]	
D4	Pond	Single	0.0003	0.000827	0.00247	Sufficient mitigation is possible at FOCUS Step 4 (within 95 % spray drift reduction)
		Multi	0.0003	0.000808	0.000226	
D4	Stream	Single	0.0003	0.0204	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0147	N/A[1]	
D5	Pond	Single	0.0003	0.000827	0.000247	Sufficient mitigation is possible at FOCUS Step 4 (within 95 % spray drift reduction)
		Multi	0.0003	0.000872	0.000244	
D5	Stream	Single	0.0003	0.0197	N/A[1]	Not possible to mitigate

Scenario	Water body	Application	RAC value[3] µg a.s./L	FOCUS Step 3	FOCUS Step 4	
				PECsw µg/L	PECsw µg/L	Risk mitigation
		Multi	0.0003	0.0159	N/A[1]	sufficiently[2]
D6	Ditch	Single	0.0003	0.0251	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0187	N/A[1]	
R1	Pond	Single	0.0003	0.000827	0.00247	Sufficient mitigation is possible at FOCUS Step 4 (within 95 % spray drift reduction)
		Multi	0.0003	0.000822	0.000231	
R1	Stream	Single	0.0003	0.0165	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0119	N/A[1]	
R3	Stream	Single	0.0003	0.0232	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0169	N/A[1]	
R4	Stream	Single	0.0003	0.0165	N/A[1]	Not possible to mitigate sufficiently[2]
		Multi	0.0003	0.0119	N/A[1]	

[1] N/A: Not Applicable. Where the FOCUS step 3 PEC values were >0.006 µg a.s./L, a low risk could not be achieved within the maximum risk mitigation according to the recommendations of FOCUS Landscape and Mitigation Factors in Aquatic Risk Assessment report (FOCUS, 2007)

[2] Not possible to mitigate within the maximum risk mitigation according to the recommendations of FOCUS Landscape and Mitigation Factors in Aquatic Risk Assessment report (FOCUS, 2007)

[3] RAC value based on available higher tier studies. Only relevant when exposure is from spray-drift **(data gap** identified for confirmation of which FOCUS exposure scenarios this refined toxicity value is suitable for)

Bioconcentration

Bioconcentration factor (BCF)	1660 - 2240 (study used lambda-cyhalothrin) 3635 from fish full life cycle study on lambda-cyhalothrin
Annex VI Trigger: for the bioconcentration factor	100 for compound not readily biodegradable
Clearance time (CT_{50}) (CT_{90})	9.1 days for whole fish from BCF study on lambda-cyhalothrin
Level of residues (%) in organisms after the 14 day depuration phase	79 %

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

Acute oral toxicity	Technical active substance: 4.2 µg a.s./bee GF-317: 1.259 µg a.s./bee
Acute contact toxicity	Technical active substance: 0.0050 µg a.s./bee GF-317: 0.03 µg a.s./bee

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

Application rate (kg a.s./ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
0.0045	All	Oral a.s.	1.071	50
0.0045	All	Contact a.s.	**900**	50
0.0045	All	Oral GF-317	3.57	50
0.0045	All	Contact GF-317	**150**	50

HQ values in **bold** are greater than the trigger value

Field or semi-field tests:
Aged foliar residue study: Study conducted according to US FIFRA 141-2 guideline. Bees were exposed to leaves sprayed at a rate of 17 g a.s./ha. Leaves were aged for 3, 6 or 24 hours prior to the exposure phase. There was 0 % mortality.

Cage test (EPPO 170 (1992)): 10 g a.s./ha applied to *Phacelia* early in the morning. Mortality levels not significantly different to control levels over 5 days.
Tunnel tests (EPPO 1/170 (3), 2001) and OECD 75 (2007)): *Phacelia*: 10 g a.s./ha applied. Increased mortality immediately after application, but returned to pre-treatment levels 2 DAT. Foraging activity statistically significantly different to control group up to 2 DAT. No effects on bee behaviour, colony strength or brood development. 27-day study (7-day exposure). *Brassica napus*: 4.8 g a.s./ha applied. Increased mortality immediately post-application but not statistically significantly different to control group. Mortality reached pre-treatment levels 1 DAT. <24 h effect on foraging (repellent effect). Not dose related. Lower activity at hive entrance immediately post-application on 0 DAT. No effects on bee behaviour, colony strength or brood development. 27-day study (7-day exposure). *Brassica napus*: 9.6 g a.s./ha applied. Increased mortality immediately post-application but not statistically significantly different to control group. Mortality reached pre-treatment levels 1 DAT. <24 h effect on foraging (repellent effect). Not dose related. No effects on bee behaviour, colony strength or brood development. 27-day study (7-day exposure).
Field studies (EPPO 1/170 (3), 2001) Field study on oilseed rape at BBCH75, treated once at 4.8 g a.s./ha. Field study on *Phacelia* treated once at BBCH65 at 4.8 g a.s./ha. These two studies indicate that exposure during foraging may result in a transient and relatively short-lived decrease in foraging which may result in an effect on colony weight but not strength.

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

Species	Stage	Test Substance	Endpoint	Hazard Quotient	Annex VI Trigger
Spring and winter cereals (3 applications at 4.5 g a.s./ha)					
A. rhopalosiphi	Adult	GF-317	LR_{50} = 0.23 g a.s./ha	HQ in-field: 45 HQ off-field: 0.9045	2 2
T. pyri	Protonymph	GF-317	LR_{50} = 0.0006 g a.s./ha	HQ in-field: 17250 HQ off-field: 347	2 2

Field or semi-field tests: Field test on cereals (in southern England) at 0.201 g a.s./ha and 10 g a.s./ha applied 3 times in May. At 0.201 g a.s./ha limited effects (14% of taxa affected) with recovery seen 4 weeks after final application with the exception of *Oedothoraz retsus* (males). The number of *Oedothoraz retsus* (males) was significantly different compared to the control 8 weeks after treatment (no further samples were taken in that year but the numbers were comparable to the control in the following spring). This may have been due to the low numbers observed in the control. Nevertheless, there is some uncertainty regarding the effects on this species. At 10 g a.s./ha 71 % of taxa affected. Majority had recovered 8 weeks after final application. Linyphiid spiders recovered within one year. A data gap is concluded for further consideration of the relevance of the available field study to the representative uses of gamma cyhalothrin.

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity	Gamma-cyhalothrin: LC_{50corr}: >650 mg a.s./kg soil GF-317: LC_{50corr}: >39 mg a.s./kg soil 3-(4-OHPh): LC_{50corr}: >500 mg/kg soil
Reproductive toxicity	GF-317: $NOEC_{corr}$: 0.25 mg a.s./kg soil

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Spring and winter cereals 3 x 4.5 g gamma-cyhalothrin/ha

Test organism	Test substance	Time scale	End point mg a.s./kg dw soil	PEC_{soil} mg a.s./kg dw soil	TER	Annex VI
Eisenia fetida	Gamma-cyhalothrin	Acute	>650	0.0112	>58036	10
Eisenia fetida	GF-317	Acute	>39	0.0112	>3482	10
Eisenia fetida	3-(4-OHPh)	Acute	>500	0.00065	>769231	10
Eisenia fetida	GF-317	Chronic	0.25	0.0112	22	5

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralisation	Effects of < 25 % at 75 g a.s./ha and 375 g a.s./ha Effects of < 25 % at 15 g a.s./ha, 150 g a.s./ha and 375 g a.s./ha (applied as GF-317)
Carbon mineralisation	Effects of < 25 % at 75 g a.s./ha and 375 g a.s./ha Effects of < 25 % at 15 g a.s./ha, 150 g a.s./ha and 375 g a.s./ha (applied as GF-317)

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

Data were submitted on the effects of gamma-cyhalothrin, formulated as GF-317, on a range of crop and weed plants. This study was conducted at rates equivalent to 0.6 to 9.6 g a.s./ha. No adverse effects were observed on the species of crop and weed plants tested.

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

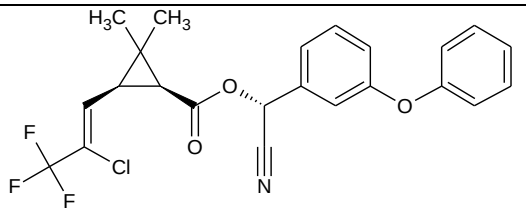
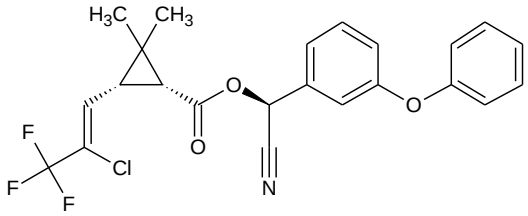
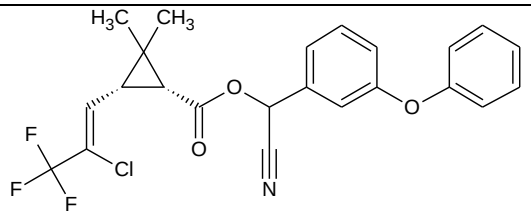
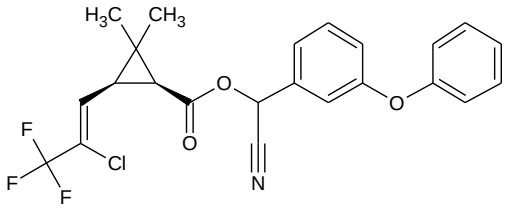
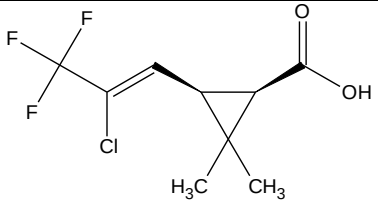
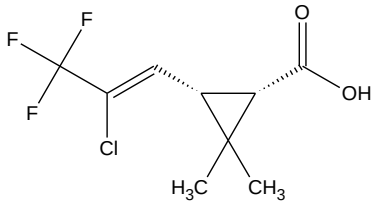
Test type/organism	end point
Activated sludge	3 hour EC_{50} >10 mg a.s./L

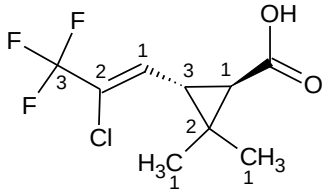
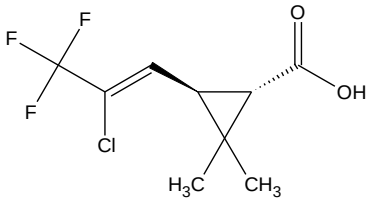
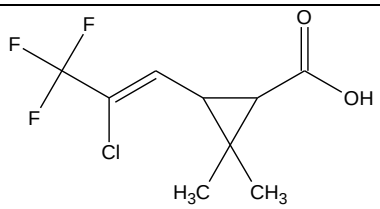
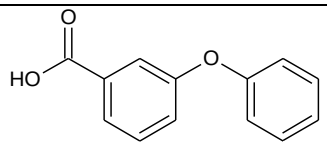
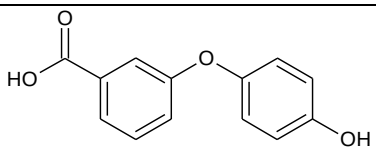
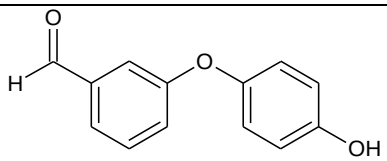
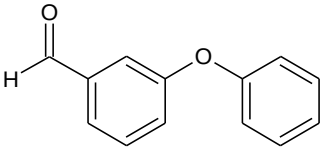
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)[12]

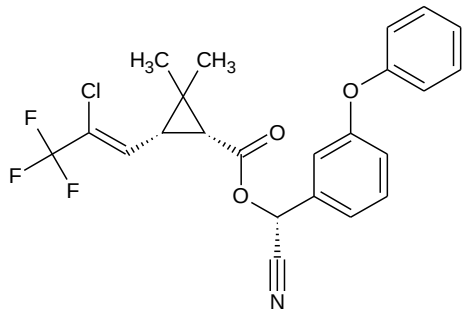
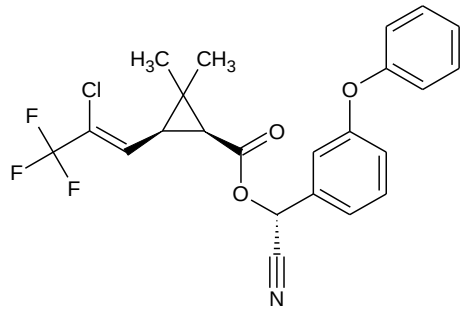
Active substance	N: Dangerous for the environment R50 – Very toxic to aquatic organisms R53 – May cause long-term adverse effects in the aquatic environment
	Acute category 1 Chronic category 1 M-factor: 1000000 (acute) and 10000 (chronic) Pictogram GHS09 Signal word Warning Hazard statements H401 Precautionary statements P273, P391, P501

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

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula**
lambda-cyhalothrin	(*R*)-α-cyano-3-phenoxybenzyl (1*S*,3*S*)-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate (*S*)-α-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate 1:1	 
cyhalothrin	(*RS*)-α-cyano-3-phenoxybenzyl (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate	 
DMCPA R119890 Compound Ia PP890 TFMCA	(1*RS*,3*RS*)-3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylic acid	 

Code/Trivial name*	Chemical name**	Structural formula**
R171403 Compound Ib	(1*RS*,3*SR*)-3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylic acid	 
CPCA Ia + Ib	3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylic acid	
PBA	3-phenoxybenzoic acid	
PBA(OH) 4-OH-3PBA	3-(4-hydroxyphenoxy)benzoic acid	
3-(4-OHPh)	3-(4-hydroxyphenoxy)benzaldehyde	
PBAld	3-phenoxybenzaldehyde	

Code/Trivial name*	Chemical name**	Structural formula**
epimer	(*R*)-cyano(3-phenoxyphenyl)methyl (1*R*,3*R*)-3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate	
inactive isomer of lambda-cyhalothrin	(*R*)-cyano(3-phenoxyphenyl)methyl (1*S*,3*S*)-3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate	

* The metabolite name in bold is the name used in the conclusion.

** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

ABBREVIATIONS

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

FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-DAD	high pressure liquid chromatography with diode array detector
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HPLC-UV	high pressure liquid chromatography with ultraviolet detector
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	inter laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
µg	microgram
mg	milligram
min	minute
M&K	Maximisation test of Magnusson & Kligman

mL	millilitre
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen phosphorous detector
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
POEM	Predictive Operator Exposure Model
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PRIMo	EFSA Pesticides Residues Intake Model
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RAC	regulatory acceptable concentration
REACH	Registration, Evaluation, Authorisation of CHemicals
RMS	rapporteur Member State
RPE	respiratory protective equipment
RUD	residue per unit dose
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
STOT-RE	specific target organ toxicity – repeated exposure
$t_{1/2}$	half-life (define method of estimation)
TDM	triazole derivative metabolites
TER	toxicity exposure ratio

TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year