CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance beta-cypermethrin[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 beta-cypermethrin 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 beta-cypermethrin as an insecticide on oilseed rape, wheat and maize. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified as regards the risk to aquatic organisms, bees and non-target arthropods.

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KEY WORDS

Beta-cypermethrin, peer review, risk assessment, pesticide, insecticide

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SUMMARY

Beta-cypermethrin 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 Cerexagri S.A.S. (subsidiary of United Phosphorus Ltd.) 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 2011/266/EU.

The RMS provided its initial evaluation of the dossier on beta-cypermethrin in the Draft Assessment Report (DAR), which was received by the EFSA on 5 April 2013. The peer review was initiated on 18 April 2013 by dispatching the DAR for consultation of the Member States and the applicant Cerexagri S.A.S.

Following consideration of the comments received on the DAR, it was concluded that additional information should be requested from the applicant and EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour and ecotoxicology, and EFSA should adopt a conclusion on whether beta-cypermethrin 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 beta-cypermethrin as an insecticide in oilseed rape, wheat and maize, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

Data gaps were identified for the section physical and chemical properties and analytical methods.

In the mammalian toxicology section, two data gaps were identified: the first one for medical data, and the second one for information/data to address the toxicological profile of the metabolite PBA.

Based on the available information a residue definition was proposed for the cereal group only. Provisionally, the same residue definition was proposed for products of animal origin, pending on the submission of additional information on the fate of the cyclopropyl moiety of beta-cypermethrin and on the toxicity of the metabolite PBA. In addition, data gaps were identified to submit a metabolism study on pulses/oilseeds and residue trials on oilseed rape and maize silage. Based on the available data, no chronic or acute concerns were identified for the consumers. The consumer risk assessment should be considered provisional pending on the submission of the requested data.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level for the representative uses assessed, with the exception of a satisfactory characterisation of the route of degradation of beta-cypermethrin in soil under illuminated conditions. Therefore the residue definitions set for soil, groundwater and surface water are uncertain (might not be complete). Another data gap was identified to address the impact of the enantiomeric composition of beta-cypermethrin and its metabolite cyperamide in the environment (aquatic compartment only). For the representative uses, the potential for groundwater exposure above the parametric drinking water limit of 0.1 µg/L was assessed as low for beta-cypermethrin and its metabolites PBA, CPA and cyperamide.

Several data gaps were identified in the ecotoxicology section, i.e. to further address the risk to aquatic organisms, bees, non-target arthropods and soil organisms. A critical area of concern was identified for aquatic organisms, bees and non-target arthropods.

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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 Cerexagri S.A.S. (subsidiary of United Phosphorus Ltd.) for approval of the active substance beta-cypermethrin. 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 2011/266/EU[6].

The RMS provided its initial evaluation of the dossier on beta-cypermethrin in the DAR (The United Kingdom, 2013), which was received by the EFSA on 5 April 2013. The peer review was initiated on 18 April 2013 by dispatching the DAR to Member States and the applicant Cerexagri S.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 1 August 2013. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was concluded that additional information should be requested from the applicant and that the EFSA should organise an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour and ecotoxicology.

[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 2011/266/EU of 2 May 2011 recognising in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of beta-cypermethrin, eugenol, geraniol and thymol in Annex I to Council Directive 91/414/EEC. OJ L 114, 4.5.2011, p. 3-4.

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 April 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 oilseed rape, wheat and maize, as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2014) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (2 August 2013),
- the Evaluation Table (12 May 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 final addendum (compiled version of February 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

Beta-cypermethrin is the ISO common name for the reaction mixture comprising the enantiomeric pair (*R*)-α-cyano-3-phenoxybenzyl (1*S*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate in ratio approximately 2:3 with the enantiomeric pair (*R*)-α-cyano-3-phenoxybenzyl (1*S*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3-phenoxybenzyl (1*R*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
or
reaction mixture comprising the enantiomeric pair (*R*)-α-cyano-3-phenoxybenzyl (1*S*)-*cis*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3-phenoxybenzyl (1*R*)-*cis*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate in ratio approximately 2:3 with the enantiomeric pair (*R*)-α-cyano-3-phenoxybenzyl (1*S*)-*trans*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3-phenoxybenzyl (1*R*)-*trans*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (IUPAC).

The representative formulated product for the evaluation was 'ATOIAB03 100 g/L beta-cypermethrin EC', an emulsifiable concentrate (EC) formulation containing 100 g/L beta-cypermethrin (10.1 % w/w).

The representative uses evaluated comprise applications by foliar spraying to control a range of insects in oilseed rape, wheat and maize. Full details of the GAPs can be found in the list of endpoints 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 the unresolved isomeric mixture of this substance has the ISO common name cypermethrin. It should be also mentioned that beta-cypermethrin is a mixture of the substances with ISO common names of alpha-cypermethrin and theta-cypermethrin. The (*S*)-α-cyano isomers of beta-cypermethrin are also part of the substance with the ISO common name of zeta-cypermethrin. (The chemical names and structures are given in Appendix B).

The minimum purity of beta-cypermethrin technical material is 960 g/kg. The specified limits for alpha-cypermethrin (Cis-2) are 360 - 430 g/kg and for theta-cypermethrin (Trans-2) 550 - 630 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 beta-cypermethrin or the representative formulation. Data gaps were identified for additional information about the packaging used in the shelf-life study and information on the emulsifiability of the formulation using CIPAC water A. The main data regarding the identity of beta-cypermethrin and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of beta-cypermethrin in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material.

The proposed residue definition for monitoring in food of plant and animal origin is "*beta-cypermethrin, sum of constituent isomers of beta-cypermethrin, expressed as beta-cypermethrin*". The

components of the residue definition of beta-cypermethrin in food and feed of plant origin can be monitored by GC-ECD with a LOQ of 0.01 mg/kg for high water, dry, acidic and high fat crop groups. The multi-residue methods DFG S19 and QuEChERS are applicable for the determination of cypermethrin (all isomers) residues. Data gaps were however identified for additional confirmatory data for the residue methods for plants or new confirmatory methods, and for information on the extraction efficiency of the analytical methods used for the determination of the residues of the active substance in plants according to the guidance document SANCO/825/00 rev. 8.1 (European Commission, 2010).

GC-ECD methods exist for monitoring the components 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, however data gaps were identified for additional confirmatory data for the residue methods for animal matrices or new confirmatory methods. A data gap was also identified for information to address the extraction efficiency of the residue method for milk and fat.

The residue definition proposed for environmental matrices is beta-cypermethrin, expressed as the sum of all cypermethrin isomers. Monitoring of beta-cypermethrin in soil is possible by GC-MS with a LOQ of 0.02 mg/kg. Residues of beta-cypermethrin (as sum of isomers) in drinking water can be monitored by GC-MS with a LOQ of 0.1 µg/L, and in surface water by GC-HRMS with a LOQ of 0.001 µg/L. A data gap was however identified for validation data for an additional fragment ion according to the guidance document SANCO/825/00 rev. 8.1 (European Commission, 2010) for the residue methods for soil and water.

A validated method of analysis for air at the relevant LOQ of 0.24 µg/m^3 was identified as a data gap (see section 2, AOEL of 0.0008 mg/kg bw per day) as the LOQ of the existing method was 4.5 µg/m^3.

Beta-cypermethrin residues can be determined in body fluids and tissues by GC-ECD with a LOQ of 0.005 mg/L for urine and 0.005 mg/kg for blood. A data gap was identified for a confirmatory method for the residue method for body fluids and tissues.

2. Mammalian toxicity

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

Beta-cypermethrin was discussed at the Pesticides Peer Review Experts' Meeting 108 on mammalian toxicology (November 2013).

The impurities present in the technical material are not considered toxicologically relevant. The batches tested in the toxicological studies can be considered as representative of the technical specification, except for the one used for the long-term rat study. On the basis of the available data, the relative toxicity of the single isomers could not be concluded but the bridging of data between cypermethrin and beta-cypermethrin was considered as appropriate for toxicokinetics, mouse carcinogenicity, rabbit developmental toxicity and medical data.

The toxicokinetic endpoints for beta-cypermethrin are bridged from studies performed with cypermethrin, and are supported by studies performed with zeta-cypermethrin and alpha-cypermethrin. With an oral absorption value of 50 %, beta-cypermethrin is expected to be widely distributed in the body, mainly in well perfused or lipophilic organs, with no bioaccumulation after repeated administration.

Beta-cypermethrin is of high acute oral toxicity, of moderate toxicity by the inhalation route and of low dermal toxicity. It is slightly irritating to the eye and produces irreversible colouration of the eye. It is not a skin irritant or a skin sensitiser.

Clinical signs of neurotoxicity characteristics of poisoning by type II pyrethroids (such as salivation, incoordination, postural abnormalities, hyperexcitability, tremors) are observed upon short-term oral administration of beta-cypermethrin. In short-term studies, the dog has been shown to be the most sensitive species, the relevant NOAEL being 0.3 mg/kg bw per day based on reduced body weight gain in the 1-year study. In the genotoxicity and carcinogenicity studies, beta-cypermethrin showed no indications of mutagenic, clastogenic or tumorigenic effects. In the 2-year rat study, the NOAEL was 12.3 mg/kg bw per day on the basis of clinical signs of neurotoxicity, decreased body weight and liver findings. The results of a long-term mouse study with cypermethrin were bridged for beta-cypermethrin, confirming that the mouse is not the most sensitive species with a NOAEL of 67 mg/kg bw per day and no evidence of treatment-related tumours.

In the multigeneration rat study, the parental NOAEL was 12 mg/kg bw per day based on clinical findings (neurotoxicity). No adverse effects on the reproductive parameters or on the offspring were observed, with a NOAEL of 30 mg/kg bw per day. In the rat developmental toxicity study, the maternal NOAEL was 30 mg/kg bw per day on the basis of clinical signs and reduced body weight, and no adverse effects were observed in foetuses up to 300 mg/kg bw per day. For the rabbit developmental toxicity, it was agreed to combine the range-finding study with beta-cypermethrin and the full study with cypermethrin, leading to a maternal and developmental NOAEL of 120 mg/kg bw per day (highest dose tested with cypermethrin).

As regards neurotoxicity, no NOAEL could be identified in two acute neurotoxicity studies in rats, demonstrating a LOAEL of 20 mg/kg bw on the basis of altered motor activity in males. The results of a rat developmental neurotoxicity study with beta-cypermethrin were discussed by the experts. The agreed maternal NOAEL is 3 mg/kg bw per day based on an increased incidence of clinical signs and decreased body weight gain. For the pups of the phase I (lactational exposure), the NOAEL is 12 mg/kg bw per day based on increased motor activity. For the pups of the phase II (exposed by gavage), the LOAEL is 0.5 mg/kg bw per day on the basis of clinical signs, decreased body weight, clonic convulsions, altered grooming and death. The majority of the experts agreed that the findings after gavage of pups were relevant for human risk assessment. It is noted that the toxicity of the other cypermethrins might need further evaluation on the basis of these new data of developmental neurotoxicity with beta-cypermethrin.

No toxicity studies with metabolites of beta-cypermethrin were available. In relation to the metabolite PBA, common to pyrethroid active substances and to which human exposure has been demonstrated, a data gap was identified for toxicological information and/or data (see also section 3).

As no information was provided for medical data, a data gap was identified.

The acceptable daily intake (**ADI**) and the acute reference dose (**ARfD**) for beta-cypermethrin are 0.0016 mg/kg bw (per day), based on the developmental neurotoxicity study and applying an uncertainty factor (UF) of 300 to cover the use of a LOAEL and the uncertainties regarding the relevance of the effects observed in pups after gavage for the human risk assessment. On the same basis, the acceptable operator exposure level (**AOEL**) is 0.0008 mg/kg bw per day, applying additionally a correction for an oral absorption value of 50 %. The agreed dermal absorption values are 7 % for the concentrate and 5 % for the dilution.

The operator exposure estimates performed with the German model indicate a level of exposure below the AOEL with the use of appropriate personal protective equipment (PPE) during mixing and loading (gloves), and during application (coverall and gloves). The exposure estimates for workers re-entering oilseed rape and wheat crops for inspection without PPE are below the AOEL. For the use on maize, the exposure estimates for workers handling treated crops is below the AOEL only when protective gloves are worn. The exposure of bystanders is predicted to be below the AOEL.

3. Residues

The conclusion 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 recommendations on livestock burden calculations stated in JMPR reports (JMPR, 2004 and 2007).

Beta-cypermethrin was discussed at the Pesticides Peer Review Experts' Meeting 112 on residues (February 2014).

The metabolism in plant was investigated in cereals (barley), using ^{14}C-beta-cypermethrin either labelled on the cyclopropyl or benzylphenyl moiety and experimental designs representative of the supported uses, with a total of 2 applications at 20 and 26 g a.s./ha. Beta-cypermethrin was by far the major component of the radioactive residues, accounting for *ca.* 80 % TRR in all plant samples collected 11 and 21 days after the last application. Additional metabolites resulting from the hydrolysis of the active substance at the ester bond were also identified, but representing less than 5 % TRR. Scientific publication on the metabolism of cypermethrin in cabbage confirmed the metabolism observed for beta-cypermethrin in cereals. Additional information was provided on the metabolism of the metabolite PBA in plants. The isomeric composition of the residues, investigated in some studies, suggest a preferential isomeric conversion from the *cis*- to the *trans*-isomers.

Based on these data, the residue definition for monitoring and risk assessment, limited to cereals, was initially proposed in the DAR as "*cypermethrin, including other mixtures of constituent isomers (sum of isomers)"*, in order to cover all existing mixtures of cypermethrin isomers. This proposal was discussed in the Pesticides Peer Review Experts' Meeting 112 in the light of the new toxicological reference values agreed for beta-cypermethrin during the Pesticides Peer Review Experts' Meeting 108 on mammalian toxicology. Considering that the ADI and ARfD values for beta-cypermethrin are significantly lower than those proposed for the other cypermethrin mixtures, the residue definition for monitoring and risk assessment was concluded as "*beta-cypermethrin, sum of constituent isomers of beta-cypermethrin, expressed as beta-cypermethrin"*. Moreover, the experts in the meeting concluded on the need to reconsider the toxicity of the other cypermethrins in the light of the new toxicological studies in rats (pups) conducted with beta-cypermethrin. The toxicity ratios within the different cypermethrin mixtures were calculated to be up to 125. Such ratios are not consistent with the fact that the constituent isomers of beta-cypermethrin represent at least 44 % of the constituent isomers of the other cypermethrin mixtures.

The vast majority of the submitted residue trials were not conducted in compliance with the representative GAPs, as they were performed with an exaggerated number of treatments or using overdosed application rates or significantly shorter intervals between applications. These trials were however concluded to be appropriate to derive a MRL of 0.02* mg/kg for wheat and maize, as residues in grains were all below the LOQ under such exaggerated conditions. In contrast, no MRL was proposed for rape seed as this crop group is not covered by the plant metabolism studies and since trials conducted according to the representative use were not provided. Data gaps were therefore identified on these points in addition to a clarification of the intended GAPs on oilseed rape. Data on residues in maize at silage growth stage are also requested. The residue trial data are supported by the storage stability studies where beta-cypermethrin residues were shown to be stable at least 2 years in high starch-, high oil- and high water-content matrices, when stored frozen at -18°C. Processing studies were not submitted and are not required for wheat and maize as residues in grains were all below the LOQ. Submission of processing studies on rape seed might be necessary, if significant residues are observed in the requested trials.

Animal intakes were calculated to be 0.27 and 0.65 mg/kg DM for dairy and beef cattle, respectively, and therefore an animal metabolism study was submitted. However, the estimated intakes were concluded to underestimate the actual intakes, as information on residues in maize silage was not

* MRL is proposed at the level of LOQ.

available. The metabolism was investigated in lactating cow using ^{14}C-beta-cypermethrin labelled on the benzylphenyl moiety only, at dose rates of 1 and 10 mg/kg in diet over seven and five days. Beta-cypermethrin was detected as the major component in fat and milk (*ca.* 80 % TRR), while almost not present in liver and kidney, where the residues were mainly composed of the metabolite PBA and its glutamic acid conjugate, accounting together up to 50 % TRR in liver and 69 % TRR in kidney. Following discussions in the Pesticides Peer Review Experts' Meeting 112, a similar residue definition as for cereals was agreed for products of animal origin. However, information on the metabolism in animals using ^{14}C labelling on the cyclopropyl moiety is requested. In addition, since a significant increase of the animal burden is anticipated considering the possible residue levels in maize silage, metabolite PBA is expected to be present at significant levels in liver and kidney, and therefore the toxicological profile of this metabolite should be addressed. Considering that the PBA metabolite and its derivatives are common metabolites to most of the pyrethroid compounds, a common assessment approach as for the triazole derivative metabolites (TDM) should be considered. Based on a cow feeding study conducted at dose rates of 1.5, 4.5 and 15 mg/kg in feed over 36 consecutive days, MRLs were proposed for ruminant products only. However, the residue definition and MRL proposals for products of animal origin should be considered provisional, pending on the submission of the requested information.

No chronic or acute concerns were identified for the consumers. Using the EFSA PRIMo model and considering the MRL proposals for wheat, maize grains and for ruminant products, the highest TMDI was calculated to be 29 % of the ADI (FR toddler) and the highest IESTI is 78 % of the ARfD (milk, UK infant). This consumer risk assessment should be considered provisional, pending on the submission of the additional information requested on oilseed rape, maize silage and the metabolite PBA.

4. Environmental fate and behaviour

Beta-cypermethrin was discussed at the Pesticides Peer Review Experts' Meeting 110 on fate and behaviour (January 2014).

Beta-cypermethrin consists of 4 (2 *cis*-isomers and 2 *trans*-isomers) of the 8 stereo-isomers that comprise cypermethrin. The environmental data package indicated that the *cis* and *trans*-isomers may degrade at different rates under some circumstances. Nevertheless, the exposure assessment presented in the fate and behaviour section considered both isomers as the active substance. The sum of both isomers was used as data input for calculation of the degradation rates, and all PEC (Predicted Environmental Concentration) values were calculated based on total beta-cypermethrin present in each environmental compartment. The enantiomers of beta-cypermethrin and its metabolites CPA and cyperamide, however, have not been separately analysed in any of the studies performed to investigate the fate and behaviour of beta-cypermethrin in the environment. No information on the levels of "S" and "R" isomers is available. Therefore, for those processes in which microbial metabolisation is involved, some degree of enantioselective transformation cannot be excluded. This is also the situation for metabolites that contain chiral carbon atoms. Nevertheless, it is considered that the margin of safety in the available risk assessments for metabolite CPA and metabolite cyperamide (soil compartment only) are large enough so that the uncertainty on the relative toxicity and contributions to the total residue levels of the isomers of these metabolites do not change the conclusion of low risk. However, a data gap was identified to address the impact of the enantiomeric composition of beta-cypermethrin and its metabolite cyperamide in the environment (aquatic compartment only).

The route and rate of degradation of beta-cypermethrin was investigated in four aerobic soils using ^{14}C-benzyl and ^{14}C-cyclopropyl labelled beta-cypermethrin at 50 % Maximum Water Holding Capacity (MWHC) and 20°C. Beta-cypermethrin degraded in aerobic soil via the formation of the two major metabolites, **PBA** (max. 17.1 % AR (Applied Radioactivity)) and **CPA** (max. 27.1 % AR), bound residues (max. 34.0 % AR) and $^{14}CO_2$ (max. 45.1 % AR). A kinetic analysis of beta-cypermethrin concluded that either DFOP or FOMC kinetics resulted in acceptable fits to derive endpoints for triggers and PEC soil calculations, and indicated that beta-cypermethrin exhibited

medium to high persistence in soil. Metabolite PBA exhibited low persistence in soil and metabolite CPA exhibited low to moderate persistence in soil. The stereoisomeric test substance ^{14}C-beta-cypermethrin consisted of approximately 40 % *cis*-isomers and 60 % *trans*-isomers. Over the study period the *trans* isomers degraded more rapidly than the *cis* isomers so that by the end of the study the ratio of *cis:trans* isomers reached approximately 1:1. As the *1R cis aS* isomer is the most active isomer, during the peer review it was considered whether the fate and behaviour endpoints calculated for the mixture of the *cis* and the *trans* isomers were appropriate to perform a conservative environmental exposure assessment. Overall, the experts concluded that the available exposure assessments for groundwater and surface water can be relied upon. In order to sustain this conclusion, a new kinetic fitting of the soil degradation data for each of the *cis* / *trans* isomers of the active substance separately was provided by the RMS (refer to Addendum to the DAR, January 2014 in United Kingdom, 2014). The fitting of the individual diastereoisomers broadly supports the conclusion that the different rates of degradation in soil of the diastereoisomers of beta-cypermethrin have been accounted for in the exposure assessment in general. The only exception is the soil exposure assessment, where the fast phase was included in the PEC soil calculations, and therefore a margin of lack of effect on the calculated exposure (by a factor of up to 4 including enantiomers and diasteroisomers) needs to be accounted for in the risk characterisation (see section 5). Alternatively, Member States may wish to re-consider PECsoil calculations based on the soil degradation rates estimated for the *1R cis aS* isomer in order to ensure a conservative risk assessment for soil organisms. The photodegradation of ^{14}C-phenyl-labelled beta-cypermethrin was investigated on the soil surface of a silt loam soil under artificial sunlight. In another study, the metabolite **cyperamide** was the most significant metabolite in the irradiated samples of the ^{14}C-cyano-labelled cypermethrin, reaching a peak of 32.6 % AR at 7 d. Therefore, cyperamide was triggered for inclusion in the exposure assessment. The experts agreed that, based on the information available, there was uncertainty regarding the possibility of formation of photolytic transformation products following cleavage of the ester link with respect to the cyclopropyl ring portion of the molecule. Therefore a data gap was identified on this issue. Beta-cypermethrin can be considered immobile in soil; metabolite PBA exhibited high soil mobility and metabolite CPA exhibited very high soil mobility. There was no evidence of a correlation of adsorption with pH for either beta-cypermethrin or metabolites PBA and CPA.

The route and rate of benzyl-labelled ^{14}C-beta-cypermethrin, and cyclopropyl-labelled ^{14}C-beta-cypermethrin was investigated in two water/sediment systems. Beta-cypermethrin rapidly partitioned from the water to the sediment phase (max 50.7 % AR after 0.25 d). The stereoisomeric test substance ^{14}C-beta-cypermethrin consisted of approximately 40 % *cis*-isomers and 60 % *trans*-isomers. The *trans*-isomers degraded in the whole system more quickly than the *cis*-isomers and at the end of the study there was a greater proportion of *cis*-isomers in the whole system than *trans*-isomers. Two major metabolites of ^{14}C-beta-cypermethrin were formed: PBA and CPA. Metabolite PBA peaked at levels up to 38.5 % AR and up to 13.9 % AR in the water phase and in the sediment, respectively. The metabolite CPA was formed at maximum amounts of 53.4 % AR in the water phase and 22.4 % AR in the sediment. A kinetic analysis of the whole system data indicated that beta-cypermethrin is low persistent in the aquatic compartment. The necessary surface water and sediment exposure assessments (PECsw and PECsed) were appropriately carried out using the agreed FOCUS (FOCUS, 2001) scenarios approach for beta-cypermethrin and its soil and water/sediment metabolites PBA, CPA and cyperamide at steps 1-4 (steps 1-2 only for metabolites)[7]. The step 4 calculations appropriately followed the FOCUS (FOCUS, 2007) guidance with mitigation measures, such as no-spray buffer zones up to 20 m. Although the available aquatic exposure assessment is based on degradation rates of beta-cypermethrin calculated for the mixture of the *cis* and *trans* isomers, the fact that spray drift exposure is the dominant route driving the peak concentrations provides appropriate values for short-term aquatic risk assessments.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2009) scenarios and the models PEARL v 3.3.3 and PELMO v 3.3.2 for the active substance

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

beta-cypermethrin and the metabolites PBA, CPA and cyperamide. In the absence of studies on the rate of degradation and adsorption of the metabolite cyperamide, an estimation of the K_{doc} input value was performed based on the parent K_{oc} (130031 ml/g), applying appropriate correction factors as used by KOCWIN programme forming part of the EPI Suite software (v. 4.1). A default 1/n value was used together with a conservative DT_{50} value and a formation fraction of 10 000 and 0.9, respectively. The potential for groundwater exposure from the representative uses by beta-cypermethrin and its 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 the pertinent 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).

Some aspects of the assessment were discussed at the Pesticides Peer Review Experts' Meeting 111 on ecotoxicology (February 2014).

The different degradation of the *cis/trans* isomers (i.e. the fact that the *trans* isomers degraded more rapidly than the *cis* isomers and the *1R cis aS* is the most active) was considered for the risk assessment for non-target species. It was concluded that it is not a critical issue when the degradation rate of the active substance is not taken into account for the exposure assessment. For bees and non-target arthropods it was concluded that the issue could be further considered by addressing the data gaps identified (see section 7). For soil organisms, where soil PECplateau was used, it was agreed to update the risk assessment to take into account the margin of lack of effect of a factor of 4, as indicated in the fate and behaviour section (see also paragraph below on earthworms).

On the basis of the available data and first-tier risk assessments a low acute and long-term risk to **birds** and **wild mammals** from dietary exposure was concluded for all representative uses. A low risk to birds and mammals was concluded also from the consumption of contaminated water and from secondary poisoning for all representative uses.

Data were available on **aquatic organisms** for the active substance and the formulated product; acute tests on fish were also available for two metabolites PBA and CPA. The most sensitive organisms, both on acute and long-term scale, were the aquatic invertebrates. The risk assessment was indicated as low for **algae** and for the metabolites at FOCUS step 1 for all representative uses. No data were available for the metabolite cyperamide, therefore a data gap has been identified. Risk assessments at FOCUS steps 3 and 4 were provided for fish, aquatic invertebrates and sediment-dwelling organisms. The TERs calculated with FOCUS step 3 PECsw and using standard toxicity endpoints indicated a high risk to all aquatic organisms for all scenarios. At FOCUS step 4, the acute risk to **fish** was indicated as low for all scenarios for the representative use on oilseed rape, provided that mitigation measures, such as no-spray buffer zones up to 20 m are applied. However, the acute risk to fish was indicated as high for 8/9 scenarios for the representative use in maize and for 7/9 scenarios for the representative use in wheat. It is highlighted that the above acute risk assessments were also based on a surrogate toxicity endpoint from a modified toxicity study on rainbow trout, which was discussed and agreed at the Pesticides Peer Review Experts' Meeting 111. The chronic risk to fish is indicated as low for all representative uses for all scenarios. The risk to aquatic **invertebrates** was indicated as high for the FOCUS step 4 scenarios for all representative uses, even with mitigation measures (i.e. no-spray buffer zone of 20 m). The two mecocosm studies available on aquatic invertebrates were considered not appropriate to determine an endpoint. In the absence of a clear reliable endpoint from the higher tier studies, the standard toxicity endpoints were used for the risk assessment for aquatic invertebrates. The risk for **sediment-dwelling organisms** was indicated as low for the representative use in oilseed rape, but it was indicated as high for the other representative uses (i.e. maize and wheat),

with one exception, i.e. the situations covered by the scenarios D5 for the use in maize. Overall, a high risk was identified for aquatic organisms for all representative uses. Several data gaps were identified for further risk assessments (see section 7) and a critical area of concern was indicated.

For **honey bees**, contact and oral hazard quotients (HQ_o and HQ_c) were calculated on the basis of acute oral and contact toxicity data with the formulated product. The HQ values indicated a high risk for all representative uses. Three honey bee semi-field studies and one valid field study were available with two types of formulations (WG and EC). Two of three tunnel tests were performed on *Phacelia* at application rates of 10 g a.s./ha and 35.1 g a.s./ha. Mortality and behavioural effects were observed in the study at 10 g a.s./ha; the short duration of the study could not allow a proper assessment of the brood development. Except for the reduced foraging in the first two days, no adverse effects were observed in the study at 35.1 g a.s./ha. The remaining tunnel test was performed on wheat at 20 g a.s./ha and showed mortality and abnormal behavioural effects as well as adverse brood developmental effects. The field study was performed on *Phacelia* at an application rate of 10 g a.s./ha, therefore it was considered useful only for the representative use on oilseed rape. This study could demonstrate that the evening applications could mitigate the risk, but abnormal behavioural effects and mortality higher than the control were observed. Overall, a high risk could not be excluded and data gaps were identified to further address the risk for bees for the representative uses evaluated, including the effectiveness of mitigation measures.

For **non-target arthropods,** 100 % mortality occurred in the laboratory studies with the standard species (i.e. *Aphidius rhopalosiphi* and *Typhlodromus pyri*). An extended laboratory test on *A. rhopalosiphi* showed high mortality and reproduction effects. The available semi-field and field tests on several additional species did not demonstrate a potential for recovery and recolonisation. Overall, an in-field and off-field high risk to non-target arthropods could not be excluded. Therefore a data gap was identified to further address the risk.

The acute risk to **earthworms** from beta-cypermethrin was indicated as low for all representative uses. For the chronic risk, the toxicity endpoint for the active substance was corrected by a factor of 4 to account for the uncertainty concerning the amounts of the 4 isomers in the accumulated PEC and their potential for different toxicity. With this approach, a high risk was identified for the representative uses in maize and wheat (the risk was indicated as low for the use on oilseed rape). A field study performed on grassland was available showing no differences on abundance and biodiversity between the treated plot at 35 g a.s./ha and the control. However, the levels of the exposure in this study may have been underestimated due to crop interception by the representative crops lower than in case of grassland; thus this study cannot be used for the risk assessment of the representative uses. It is concluded that the risk to earthworms should be further addressed for the representative uses on maize and wheat (data gap). A litter bag study was available. There is a general consensus to consider this test useful to address the organic matter breakdown, but it cannot be considered appropriate to address the effects on the overall community structure for non-target soil organisms. This was already acknowledged and discussed during the peer review of other active substances. A data gap was therefore identified to further address the risk to other **soil non-target macroorganisms** for all representative uses. The risk to earthworms from the metabolites PBA, CPA and cyperamide was assessed as low.

It is noted that a data gap was concluded for the fate and behaviour of the cyclopropyl ring moiety of beta-cypermethrin in soil under illuminated conditions (see section 4). Therefore, should any additional pertinent metabolites be identified then further risk assessments for soil and aquatic organisms may be required.

The risk to soil microorganisms, terrestrial non-target plants and biological methods for sewage treatment plants was considered as low.

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

6.1. Soil[(a)]

Compound (name and/or code)	Persistence	Ecotoxicology
beta-cypermethrin (sum of isomers)	medium to high persistence biphasic kinetics: laboratory DT_{50} 15.2 - 43.4 days, DT_{90} 257-734 days (20°C, 50% MWHC soil moisture)	Data gap for chronic risk to earthworms and for soil macroorganisms.
PBA	low persistence Single first-order (SFO) DT_{50} 1.86 – 9.85 days (20°C, 50% MWHC soil moisture)	Low risk
CPA	low to moderate persistence Single first-order (SFO) DT_{50} 2.56 – 23.0 days (20°C, 50% MWHC soil moisture)	Low risk
cyperamide (soil photolysis)	no data available (worst case DT_{50} of 1000 days used for modelling)	Low risk

(a): Provisional as a data gap was identified for a satisfactory characterisation of the route of degradation of beta-cypermethrin in soil under illuminated conditions.

6.2. Ground water[(a)]

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
beta-cypermethrin (sum of isomers)	immobile K_{Foc} 41167-249607 mL/g	No	Yes	Yes	High risk for aquatic organisms in surface water
PBA	high mobility K_{Foc} 58.8-90.1 mL/g	No	No data	No data available	Low risk for aquatic organisms in surface water
CPA	very high mobility K_{Foc} 11.0-13.4 mL/g	No	No data	No data available	Low risk for aquatic organisms in surface water
cyperamide (soil photolysis)	immobile K_{doc} = 27058 mL/g (KOCWIN programme of EPI Suite software estimation)	No	No data	No data available	Data gap for aquatic organisms in surface water

(a): Provisional as a data gap was identified for a satisfactory characterisation of the route of degradation of beta-cypermethrin in soil under illuminated conditions.

6.3. Surface water and sediment[(a)]

Compound (name and/or code)	Ecotoxicology
beta-cypermethrin (sum of isomers)	High risk for aquatic organisms
PBA	Low risk
CPA	Low risk
cyperamide (soil photolysis)	Data gap

(a): Provisional as a data gap was identified for a satisfactory characterisation of the route of degradation of beta-cypermethrin in soil under illuminated conditions.

6.4. Air

Compound (name and/or code)	Toxicology
beta-cypermethrin (sum of isomers)	LC_{50} 1.06 mg/L; H332 Harmful if inhaled, H335 May cause respiratory irritation

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

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

- Additional information about the packaging used in the shelf-life study (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Information on the emulsifiability of the formulation using CIPAC water A (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Additional confirmatory data for the residue methods for plants or new confirmatory methods (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Information on the extraction efficiency of the analytical methods used for the determination of the residues of the active substance in plants according to the guidance document SANCO/825/00 rev. 8.1 (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Additional confirmatory data for the residue methods for animal matrices or new confirmatory methods (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Information to address the extraction efficiency of the residue method for milk and fat (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Validation data for an additional fragment ion according to the guidance document SANCO/825/00 rev. 8.1 for the residue methods for soil and water (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Validated method of analysis for air at the relevant LOQ of 0.24 $\mu g/m^3$ (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Confirmatory residue method of analysis for body fluids and tissues (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Medical data for beta-cypermethrin are required, taking into account the possible bridging of data with cypermethrin (relevant for all representative uses; submission date proposed by the applicant: unknown; see section 2).
- Data/information to address the toxicological profile of metabolite PBA, major metabolite identified in liver and kidney of livestock and common to pyrethroid active substances (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see sections 2 and 3).
- A metabolism study covering the pulses/oilseed group is required to cover the use of beta-cypermethrin on oilseed rape (relevant for the representative use on oilseed rape; submission date proposed by the applicant: unknown; see section 3).

- Clarification of the representative GAPs on oilseed rape and residue trials conducted in compliance with the supported GAPs are required. If significant residues are observed in the requested trials, processing studies on rape seed might be required (relevant for the representative use on oilseed rape; submission date proposed by the applicant: unknown; see Evaluation Table data requirement 3.4 and section 3).

- Residue trials on maize conducted according to the representative GAPs and providing information on the residue levels in whole plant at silage growth stage (relevant for the representative use on maize; submission date proposed by the applicant: unknown; see section 3).

- Data on the metabolism in livestock animals using ^{14}C-labelling on the cyclopropyl moiety of beta-cypermethrin (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 3).

- Satisfactory information to address the impact of the enantiomeric composition of beta-cypermethrin and its metabolite cyperamide in the environment (aquatic compartment only) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4).

- Satisfactory information to address the route of degradation and formation of potential transformation product(s) from the cyclopropyl ring moiety of beta-cypermethrin was not available for soil under illuminated conditions. Should any additional pertinent metabolites be identified, then the risk to soil and aquatic organisms should be addressed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see sections 4 and 5).

- The risk to aquatic organisms from the metabolite cyperamide needs to be addressed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).

- The acute risk to fish needs to be further addressed (relevant for the representative uses in maize and wheat; submission date proposed by the applicant: unknown; see section 5).

- The risk to aquatic invertebrates, including those feeding in sediment, needs to be further addressed (relevant for all representative uses; submission date proposed by the applicant: unknown; see section 5).

- The risk to sediment-dwelling organisms needs to be further addressed (relevant for the representative uses in maize (with the exception of the situations covered by the scenarios D5) and wheat; submission date proposed by the applicant: unknown; see section 5).

- The risk to bees needs to be further addressed, including the effectiveness of mitigation measures. The different degradation of the isomers should also be taken into account (relevant for all representative uses; submission date proposed by the applicant: unknown; see section 5).

- The risk to non-target arthropods needs to be further addressed. The different degradation of the isomers should also be taken into account (relevant for all representative uses; submission date proposed by the applicant: unknown; see section 5).

- The chronic risk to earthworms needs to be further addressed (relevant for the representative uses in maize and wheat; submission date proposed by the applicant: unknown; see section 5).

- The risk to soil macroorganisms needs to be further addressed (relevant for all representative uses; 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) during mixing and loading (gloves) as well as during application (coverall and gloves) have to be considered to ensure that the operator exposure estimates do not exceed the AOEL in all proposed scenarios (see section 2).

- Workers have to wear protective gloves when handling the treated maize crops in order to have an exposure estimate below the AOEL (see section 2).

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 fate and behaviour of the cyclopropyl ring moiety of beta-cypermethrin in soil under illuminated conditions has not been addressed. Consequently, the environmental risk assessment (for soil and aquatic organisms) and groundwater exposure assessment for any transformation products that might be formed from this portion of the molecule could not be finalised.

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.

2. High risk to aquatic organisms (the risk assessment was driven by the aquatic invertebrates).

3. High risk to bees and non-target arthropods.

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		Oilseed rape	Wheat	Maize
Operator risk	Risk identified			
	Assessment not finalised			
Worker risk	Risk identified			
	Assessment not finalised			
Bystander risk	Risk identified			
	Assessment not finalised			
Consumer risk	Risk identified			
	Assessment not finalised			
Risk to wild non target terrestrial vertebrates	Risk identified			
	Assessment not finalised			
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	X[3]	X[3]	X[3]
	Assessment not finalised	X[1]	X[1]	X[1]
Risk to aquatic organisms	Risk identified	X[2]	X[2]	X[2]
	Assessment not finalised	X[1]	X[1]	X[1]
Groundwater exposure active substance	Legal parametric value breached			
	Assessment not finalised			
Groundwater exposure metabolites	Legal parametric value breached			
	Parametric value of 10µg/L[(a)] breached			
	Assessment not finalised	X[1]	X[1]	X[1]
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): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

REFERENCES

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

EFSA (European Food Safety Authority), 2007. Opinion on a request from EFSA related to the default Q_{10} value used to describe the temperature effect on transformation rates of pesticides in soil. The EFSA Journal 2007, 622, 1-32, doi:10.2903/j.efsa.2008.622

EFSA (European Food Safety Authority), 2009. Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA. EFSA Journal 2009;7(12):1438, 358 pp. doi:10.2903/j.efsa.2009.1438

EFSA (European Food Safety Authority), 2014. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance beta-cypermethrin. Available online: www.efsa.europa.eu

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2012. Guidance on Dermal Absorption. EFSA Journal 2012;10(4):2665, 30 pp. doi:10.2903/j.efsa.2012.2665

European Commission, 1999. Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, 1607/VI/97 rev.2, 10 June 1999

European Commission, 2000. Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. SANCO/3030/99 rev.4, 11 July 2000

European Commission, 2002a. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev.2 final, 17 October 2002

European Commission, 2002b. Guidance Document on Aquatic Ecotoxicology Under Council Directive 91/414/EEC. SANCO/3268/2001 rev 4 (final), 17 October 2002

European Commission, 2003. Guidance Document on Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC. SANCO/221/2000-rev. 10 - final, 25 February 2003

European Commission, 2010. Guidance document on residue analytical methods. SANCO/825/00 rev. 8.1, 16 November 2010

European Commission, 2012. Guidance Document on the Assessment of the Equivalence of Technical Materials of Substances Regulated under Council Directive 91/414/EEC. SANCO/10597/2003 – rev. 10.1, 13 July 2012

FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2001. FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp., as updated by the Generic Guidance for FOCUS surface water scenarios, version 1.1 dated March 2012

FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2007. Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.

FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2009. Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. Report of the FOCUS Workgroup, EC Document Reference SANCO/13144/2010-version.1. 604

pp, as outlined in Generic Guidance for Tier 1 FOCUS groundwater Assessment, version 2.0 dated January 2011

JMPR (Joint Meeting on Pesticide Residues), 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Rome, Italy, 20–29 September 2004, Report 2004, 383 pp.

JMPR (Joint Meeting on Pesticide Residues), 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Geneva, Switzerland, 18–27 September 2007, Report 2007, 164 pp.

SETAC (Society of Environmental Toxicology and Chemistry), 2001. Guidance Document on Regulatory Testing and Risk Assessment procedures for Plant Protection Products with Non-Target Arthropods. ESCORT 2

The United Kingdom, 2013. Draft Assessment Report (DAR) on the active substance beta-cypermethrin prepared by the rapporteur Member State the United Kingdom in the framework of Commission Regulation (EU) No 188/2011, March 2013.

The United Kingdom, 2014. Final Addendum to Draft Assessment Report on beta-cypermethrin, compiled by EFSA, February 2014. Available online: www.efsa.europa.eu

APPENDICES

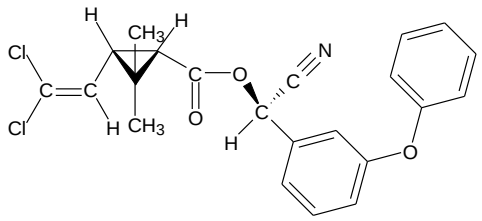
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

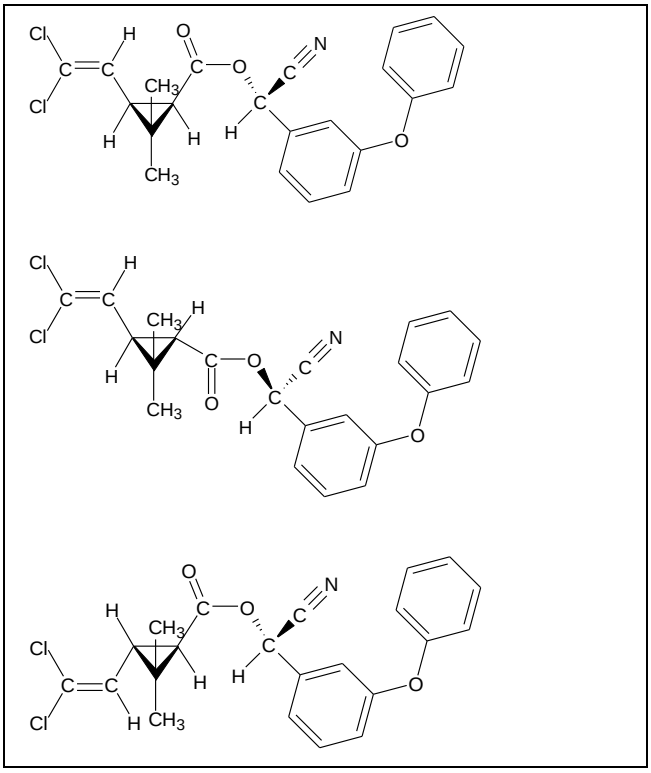
Identity, Physical and Chemical Properties, Details of Uses, Further Information

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

Rapporteur Member State	UK
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	A reaction mixture comprising two enantiomeric pairs in ratio ca. 2:3 of (*R*)-α-cyano-3-phenoxybenzyl (1*S*)-*cis*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate **and** (*S*)-α-cyano-3-phenoxybenzyl (1*R*)-*cis*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate **with** (*R*)-α-cyano-3-phenoxybenzyl (1*S*)-*trans*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate **and** (*S*)-α-cyano-3-phenoxybenzyl (1*R*)-*trans*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
Chemical name (CA) ‡	cyano (3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl) -2,2-dimethylcycpropanecarboxylate
CIPAC No ‡	632
CAS No ‡	65731-84-2
EC No (EINECS or ELINCS) ‡	265-898-0
FAO Specification (including year of publication) ‡	None.
Minimum purity of the active substance as manufactured ‡	960 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None.
Molecular formula ‡	$C_{22}H_{19}Cl_2NO_3$
Molar mass ‡	416.3 g/mol
Structural formula ‡	



Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	63-67 °C (98.7%)
Boiling point (state purity) ‡	Decomposition occurred ≥ 256°C (98.7%)
Temperature of decomposition (state purity)	≥ 256°C (98.7%)
Appearance (state purity) ‡	White powder (98.7%)
Vapour pressure (state temperature, state purity) ‡	2 x 10^{-5} Pa at 25°C (98.7%)
Henry's law constant ‡	9.1 x 10^{-8} Pa m^3 mol^{-1} (98.7%)
Solubility in water (state temperature, state purity and pH) ‡	< 0.9 mg/L at 20°C (pH 5) (98.7%) < 0.9 mg/L at 20°C (pH 7) (98.7%) < 0.9 mg/L at 20°C (pH 9) (98.7%)
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20-25°C (98.7%): heptane: 14 g/L methanol: 45 g/L toluene: > 1000 g/L dichloromethane: > 1000 g/L acetone: > 1000 g/L ethyl acetate: > 1000 g/L chloroform: > 1000 g/L 1,4-dioxan: > 1000 g/L "aromatic solvent" : > 1000 g/L octanol: 26 g/L mineral paraffinic oil: 6 g/L methyl esters C_8-C_{10}: 332 g/L methyl esters C_{11}-C_{20}: 143 g/L
Surface tension ‡ (state concentration and temperature, state purity)	Not required due to low solubility in water (< 1 mg/L)
Partition co-efficient ‡ (state temperature, pH and purity)	log $P_{O/W}$ = 5.8 at 20°C (effect of pH not studied as compound unlikely to dissociate) (98.7%)
Dissociation constant (state purity) ‡	Not determined due to low solubility in water however it is also not expected from its structure that beta-cypermethrin will dissociate.
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Solutions prepared in methanol as water solubility is low: λ_{max} (nm) ε ($mol^{-1}cm^{-1}$) acidic 204 44881 277 714 neutral 203 61241 basic 208 39764 310 2756 (98.7%)
Flammability ‡ (state purity)	Not highly flammable (98.7%) Not auto-flammable (98.7%)
Explosive properties ‡ (state purity)	Beta-cypermethrin does not demonstrate explosive properties (98.7%)
Oxidising properties ‡ (state purity)	Not oxidising.

Summary of representative uses evaluated (*Beta-cypermethrin*)

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	g a.s./hL min- max	water L/ha min max	g a.s./ha min- max		
Oilseed rape	Northern and Southern Europe	'ATOIAB03 100g/L beta-cypermethrin EC'	F	Insects	EC	100 g/L	Spraying	Autumn: BBCH 10-18 (Cotyledons - 8 leaves unfolded) Spring: BBCH 30-69 (From stem elongation to end of flowering)	Autumn: 1 Spring: 1	100 d	Autumn: 2 – 6.7 Spring: 2 – 6.7	150 - 500	Autumn: 10 Spring: 10	28	Months of application: August to November March to May Max. 20 g a.s./ha per season
Wheat	Northern and Southern Europe	'ATOIAB03 100g/L beta-cypermethrin EC'	F	Insects	EC	100 g/L	Spraying	Autumn: BBCH 11-23 (1 leaf to tillering) Spring: BBCH 41-75 (From booting to milky grain)	Autumn: 1 Spring: 1	100 d	Autumn: 3 – 10 Spring: 4 –13.3	150 - 500	Autumn: 15 Spring: 20	21	Months of application: September to November May to July Max. 35 g a.s./ha per season

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	g a.s./hL min- max	water L/ha min max	g a.s./ha min- max		
Maize	Northern Europe	'ATOIAB03 100g/L beta-cypermethrin EC'	F	Insects	EC	100 g/L	Spraying	BBCH 12-14 (2-4 leaf stage) or BBCH 18-53 (to tassel emergence)	1	n.a.	1.5 – 3.75 or 7 – 23.3	400 – 1000 or 150 - 500	15 or 35	75	Months of application: May or June to July Max. 35 g a.s./ha per season
Maize	Southern Europe	'ATOIAB03 100g/L beta-cypermethrin EC'	F	Insects	EC	100 g/L	Spraying	BBCH 12-19 (2-10 leaf stage) or BBCH 51-75 (tassel emergence to milky grain)	1	n.a.	1.5 – 3.75 or 7 – 23.3	400 – 1000 or 150 - 500	15 or 35	30	Months of application: May or June to July Max. 35 g a.s./ha per season

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised 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 plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Methods of Analysis

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

Technical as (analytical technique)	HPLC-UV detection at 278 nm or 234nm
Impurities in technical as (analytical technique)	HPLC-UV
Plant protection product (analytical technique)	HPLC-UV, detection at 278 nm

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	beta-cypermethrin, sum of constituent isomers of beta-cypermethrin, expressed as beta-cypermethrin. [Limited to cereals only]
Food of animal origin	beta-cypermethrin, sum of constituent isomers of beta-cypermethrin, expressed as beta-cypermethrin. [For ruminants only]
Soil	Beta-cypermethrin (sum of cypermethrin isomers)
Water surface	Beta-cypermethrin (sum of cypermethrin isomers)
drinking/ground	Beta-cypermethrin (sum of cypermethrin isomers)
Air	Beta-cypermethrin (sum of cypermethrin isomers)
Body fluids and tissues	Beta-cypermethrin (sum of beta-cypermethrin isomers)

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Beta-cypermethrin: GC-ECD (0.01 mg/kg for high water, dry, acidic and high fat crop groups). DFG S19 and QuEChERS applicable for cypermethrin (all isomers) Data gap: additional confirmatory data, extraction efficiency.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Beta-cypermethrin: GC-ECD (0.01 mg/kg) for muscle, fat, liver, kidney, milk, eggs. Applicability to cypermethrin (all isomers) demonstrated. Data gap: additional confirmatory data, extraction efficiency of the residue method for milk and fat.
Soil (analytical technique and LOQ)	Beta-cypermethrin: GC-MS (0.02 mg/kg) Data gap: validation data for an additional fragment ion.
Water (analytical technique and LOQ)	Beta-cypermethrin: GC-MS (0.1 µg/L) for drinking and ground water. GC-HRMS (0.001 µg/L) for surface water. Data gap: validation data for an additional fragment ion.

Air (analytical technique and LOQ)	Beta-cypermethrin: HPLC-UV (4.5 µg/m^3) Data gap for a validated method of analysis for air at the relevant LOQ of 0.24 µg/m^3.
Body fluids and tissues (analytical technique and LOQ)	Beta-cypermethrin: GC-ECD (0.005 mg/L for urine, 0.005 mg/kg for blood) Data gap: confirmatory method.

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

	RMS/peer review proposal
Active substance	-

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Relatively rapid; Tmax 3-4 hours; Oral absorption 50 % based on urinary excretion (within 24h) and tissue concentrations.
Distribution ‡	Widely distributed, mainly in well perfused (liver, kidney, heart) or lipophilic (ovaries, fat, skin) organs.
Potential for accumulation ‡	No bioaccumulation after repeated administration.
Rate and extent of excretion ‡	75 % excreted in 24 hours, in urine and faeces
Metabolism in animals ‡	Hydrolysis of ester bond to give cyclopropane carboxylic acid and phenoxybenzyl moieties; subsequent oxidation and or conjugation.
Toxicologically relevant compounds ‡ (animals and plants)	Beta-cypermethrin
Toxicologically relevant compounds ‡ (environment)	Beta-cypermethrin

° data bridged from cypermethrin

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	93 mg/kg bw	T; R25 H301
Rabbit LD_{50} dermal ‡	>5000 mg/kg bw	
Rat LC_{50} inhalation ‡	1.06 mg/L	Xn ;R20, R37* H332; H335*
Skin irritation ‡	Not irritating	
Eye irritation ‡	Persistent discolouration	Xi; R41 H318
Skin sensitisation ‡	Not sensitising	

*consistent with other cypermethrins

Short-term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Rat: clinical signs of neurotoxicity, decreased body weight and serum glucose Mouse: clinical signs of neurotoxicity, decreased body weight, clinical chemistry Dog: consistent body weight gain reduction	
Relevant oral NOAEL ‡	Rat (90-day): <10 mg/kg bw per day Mouse (28-day): 63.3 mg/kg bw per day Dog (1-year): 0.3 mg/kg bw per day	
Relevant dermal NOAEL ‡	No data submitted	
Relevant inhalation NOAEL ‡	No data submitted	

Genotoxicity ‡ (Annex IIA, point 5.4)

In vitro studies	Ames test negative; chromosome aberration test and forward mutation assay in mammalian cells negative	
In vivo studies	Mouse micronucleus test negative	
Potential for genotoxicity	Beta-cypermethrin is unlikely to be genotoxic.	

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

Target/critical effect ‡	Rat : clinical signs of neurotoxicity, decreased body weight and liver histopathology Mouse* : decreased body weight, neutrophil and platelet counts	
Relevant NOAEL ‡	Rat (2-year): 12.3 mg/kg bw per day Mouse (101 weeks)* : 67 mg/kg bw per day	
Carcinogenicity ‡	Rat: no evidence of a carcinogenic potential Mouse*: no evidence of a carcinogenic potential	

* Cypermethrin data

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental toxicity: clinical signs (neurotoxicity) Offspring toxicity: no adverse effect Reproductive toxicity: no adverse effect	
Relevant parental NOAEL ‡	12 mg/kg bw per day	
Relevant reproductive NOAEL ‡	30 mg/kg bw per day	
Relevant offspring NOAEL ‡	30 mg/kg bw per day	

Developmental toxicity

Developmental target / critical effect ‡	Maternal toxicity: clinical signs and reduced body weight (rat) Developmental toxicity: no adverse effect (rat and rabbit)	
Relevant maternal NOAEL ‡	Rat: 30 mg/kg bw per day Rabbit*: 120 mg/kg bw per day	
Relevant developmental NOAEL ‡	Rat : 300 mg/kg bw per day Rabbit* : 120 mg/kg bw per day	

* Cypermethrin data

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	LOAEL 20 mg/kg bw based on altered motor activity in males.	
Repeated neurotoxicity ‡	No data available, not required.	

Developmental neurotoxicity ‡	Maternal NOAEL: 3 mg/kg bw per day, based on clinical signs and decreased body weight gain Pup NOAEL (phase I, lactational exposure): 12 mg/kg bw per day based on increased motor activity. Pup LOAEL (phase II, direct dosing of suckling pups; days 10-16 post-partum): 0.5 mg/kg bw per day, based on clinical signs, decreased body weight, clonic convulsions, altered grooming and death.	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	None
Studies performed on metabolites or impurities ‡	None

Medical data ‡ (Annex IIA, point 5.9)

Data gap for recent medical data

Summary (Annex IIA, point 5.10)	Value (mg/kg bw (per day))	Study	Uncertainty factor
ADI ‡	0.0016	Developmental neurotoxicity; phase II pups	300*
AOEL ‡	0.0008	Developmental neurotoxicity; phase II pups	600*°
ARfD ‡	0.0016	Developmental neurotoxicity; phase II pups	300*

* additional UF of 3 for the use of a LOAEL
° additional correction for an oral absorption value of 50 %

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (‘Beta-cypermethrin 10 EC’)	7% for concentrate; 5% for dilution (1+500).

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Use in maize crops (reflecting the highest application rate) Exposure estimates with the German model (% of AOEL): - without use of PPE (personal protective equipment): 340 % - with use of gloves during mixing and loading, coverall and gloves during application: 13 % Exposure estimates with the UK POEM (% of AOEL):

	- without use of PPE: 3664 % - with use of gloves during mixing and loading or when handling contaminated surfaces: 448 %
Workers	Exposure estimates with EUROPOEM for the crop inspection in oilseed rape and wheat: 48 to 94 % of the AOEL without use of PPE. Exposure estimates with EUROPOEM for the crop inspection and hand harvesting in maize are respectively 153 % and 306 % of the AOEL without use of PPE 43 % and 86 % of the AOEL with use of gloves
Bystanders	The levels of systemic exposure for bystanders are predicted to be 75 % of the AOEL for vapour exposure, 5 % of the AOEL for spray drift and 2 % of the AOEL for children's exposure to drift fallout.

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

Substance classified	Beta-cypermethrin
Harmonised classification:	Currently not listed in Annex VI of Regulation (EC) No 1272/2008[8] (as amended).
RMS/peer review proposal[9]:	Considering the criteria of Directive 67/548/EEC[10] (as amended): R25 – Toxic if swallowed R20 – Harmful by inhalation R37 – Irritating to the respiratory system R41 – Risk of serious damage to eyes Considering the criteria of Regulation (EC) No 1272/2008 (as amended): H301 – Toxic if swallowed (Cat 3) H332 – Harmful if inhaled (Cat 4) H335 – May cause respiratory irritation H318 – Causes serious eye damage (Cat 1)

[8] 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.

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

[10] 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	Cereals (barley) [study on beta-cypermethrin] [Foliar treatment]
Rotational crops	Leafy vegetable (lettuce), root vegetable (carrot) and cereal (barley)
Metabolism in rotational crops similar to metabolism in primary crops?	Confined rotational crop study on leafy crop (lettuce), root crop (carrot) and cereal (barley) with plant back intervals of 29 and 61 days
Processed commodities	Not applicable (processing studies are not required)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable (processing studies are not required)
Plant residue definition for monitoring	beta-cypermethrin, sum of constituent isomers of beta-cypermethrin, expressed as beta-cypermethrin [Limited to cereals only]
Plant residue definition for risk assessment	beta-cypermethrin, sum of constituent isomers of beta-cypermethrin, expressed as beta-cypermethrin [Limited to cereals only]
Conversion factor (monitoring to risk assessment)	Not applicable (identical residue definitions are proposed for monitoring and risk assessment)

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

Animals covered	Lactating cow
Time needed to reach a plateau concentration in milk and eggs	Milk: *ca*. 5 days Eggs: Not submitted/not required (Metabolism study in poultry is not necessary since estimated intakes related to the representative uses are below the trigger value of 0.1 mg/kg DM)
Animal residue definition for monitoring	beta-cypermethrin, sum of constituent isomers of beta-cypermethrin, expressed as beta-cypermethrin **Provisional,** pending information on the toxicity of metabolite PBA and the fate of the cyclopropyl moiety.
Animal residue definition for risk assessment	beta-cypermethrin, sum of constituent isomers of beta-cypermethrin, expressed as beta-cypermethrin **Provisional,** pending information on the toxicity of metabolite PBA and the fate of the cyclopropyl moiety.
Conversion factor (monitoring to risk assessment)	Not applicable (identical residue definitions are proposed for monitoring and risk assessment)
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Yes (log P_{ow}: 5.8) Highest tissue residues measured in fat (lactating cow)

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

Low TRR were observed in rotational crops at 29 and 61 day PBI [study at 1N maximum total dose for wheat and maize GAP; 1.8N maximum total dose for oilseed rape GAP]. The highest TRR observed was 0.02 mg/kg in straw and chaff. The residues found were characterised as far as was possible, and no components were present at significant levels. Due to the expectation of low soil residues, it was concluded that it was not necessary to extend the study to 365 days.

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

When stored at -18° C, residues of beta-cypermethrin are stable for at least 24 months in: - high water content matrices (cereal plant, cabbage) - high starch content matrices (barley grain) - high oil content matrices (oilseed) Stability of residues confirmed for at least 12 months high water- (grape, tomato, beet tops), high starch- (potato, beet roots) content matrices.

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

	Ruminant:	**Poultry:**	**Pig:**
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes(1) Dairy: 0.27 Beef: 0.65 mg/kg DM	No	No
Potential for accumulation (yes/no):	Yes (in fat only)	n/a	n/a
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Yes (in fat only)	n/a	n/a
	A feeding study was performed in lactating dairy cows that were orally dosed with beta-cypermethrin at concentrations of 0 (control), 1.5 (2.3N), 4.5 (6.9N) and 15 (23.1N) mg/kg in feed. The relevant feeding rate is 1.5 mg/kg (2.3N) Residue levels in matrices: Mean (max) mg/kg		
Muscle	<0.01 (<0.01)	n/a	n/a
Liver	<0.01 (<0.01)	n/a	n/a
Kidney	<0.01 (<0.01)	n/a	n/a
Fat	0.022 (0.044)	n/a	n/a
Milk	≤0.002 (≤0.002)		
Eggs		n/a	

(1): Animal burden calculations and N rates provisional, to be reconsidered when data on residues in maize at silage growth stage available

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

Crop	Northern/ Southern Region, field or glasshouse	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to representative use	HR (c)	STMR (b)
Rape seed	NEU & SEU (field)	Trials according to cGAP not available				
Wheat grain	NEU (field)	7x <0.02	The available trials are not compliant with the cGAP as conducted with 3 applications and shorter interval between applications. , but they are considered appropriate to propose an MRL, as all values <LOQ.	0.02*	<0.02	<0.02
	SEU (field)	3x <0.01, 5x <0.02				
Wheat straw	NEU (field)	0.197; 0.314; 0.533; 0.570; 0.656; 0.823; 1.098	HR and STMR derived from the merged datasets[(d)]	n/a	1.098	0.613
	SEU (field)	0.218; 0.470; 0.687; 0.762; 0.854				
Maize grain	NEU (field)	2x <0.01; 6x <0.02	The available trials are not compliant with the cGAP as conducted with 2 or 3 applications (instead of 1), but they are considered appropriate to propose an MRL, as all values in grain <LOQ. Additional data in maize plant at silage growth stage are requested.	0.02*	<0.02	<0.02
	SEU (field)	2x <0.01; 6x <0.02				

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 2x 0.1, 2x 0.15, 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue
(d) The available (combined) residue trial endpoints for wheat straw (STMR: 0.613 mg/kg; HR: 1.098 mg/kg) **do not** reflect the supported GAP (i.e. exaggerated/overdosed trials) and are taken as a **worst-case** residue situation for the purposes of the estimated animal dietary burden calculation presented in Section B.7.16.1, Table 7.16.1-1 of the DAR (The United Kingdom, 2013).
* The MRL is proposed at the LOQ.

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

ADI	0.0016 mg/kg bw per day
TMDI (% ADI) according to EFSA PRIMo model	Highest TMDI: 29 % ADI (FR, toddler)
TMDI (% ADI) according to national (UK) diets	-
IEDI (EFSA PRIMo model) (% ADI)	-
NEDI (UK model) (% ADI)	-
Factors included in IEDI and NEDI	
ARfD	0.0016 mg/kg bw
IESTI (EFSA PRIMo model) (% ARfD)	78% ARfD (UK Infants – milk)
NESTI (UK model) (% ARfD)	78% of the ARfD (UK Infants – milk)
Factors included in IESTI and NESTI	

†: Beta-cypermethrin residues found in fat tissues during the lactating cow feeding study [at a comparable dose rate of 1.5 mg/kg (2.3N) in feed]

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Not applicable (as quantifiable residues of beta-cypermethrin are not expected in the treated edible crops there is no need to investigate the effects of industrial and/or household processing.)				

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

Wheat grain:	0.02* mg/kg
Maize grain:	0.02* mg/kg
Products of animal origin (ruminants): Fat: Milk: Muscle: Kidney: Liver:	 0.05 mg/kg 0.01* mg/kg 0.01* mg/kg 0.01* mg/kg 0.01* mg/kg **N.B.** The proposed MRLs for ruminant products are considered as provisional.

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

Environmental fate and behaviour

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

Mineralization after 100 days ‡	40.8 % after 120 d, [^{14}C-benzyl]-label (n= 4) 45.1 % after 120 d, [^{14}C- cyclopropyl]-label (n= 4)
Non-extractable residues after 100 days ‡	34.0 % after 120 d, [^{14}C-benzyl]-label (n= 4) 31.5 % after 79 d, [^{14}C-cyclopropyl]-label (n= 4)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	PBA (3-phenoxybenzoic acid) – 17.1 % at 7 d (n= 4) CPA (cyclopropanecarboxylic acid) – 27.1 % at 15 d (20°C), 27.5 % at 79 d (10°C) (n= 4) [^{14}C-benzyl]-label & [^{14}C-cyclopropyl]-label

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

Anaerobic degradation ‡ Mineralization after 100 days	5.7 % after 120 d, [^{14}C-benzyl]-label (n= 1) 1.8 % after 120 d, [^{14}C-cyclopropyl]-label (n= 1)
Non-extractable residues after 100 days	7.1 % after 120 d, [^{14}C-benzyl]-label (n= 1) 5.8 % after 120 d, [^{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 – 60.8 % at 90 d [^{14}C-benzyl]-label (n= 1) CPA – 61.8 % at 90 d, [^{14}C-cyclopropyl]-label (n= 1)
Soil photolysis ‡ Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	PBA – 15.4 % at 13 d (n= 1) [^{14}C- phenyl] label. PBA – 11.7 % at 7 d (n= 3). Cyperamide – 32.6 % at 7 d [^{14}C- cyclopropyl], [^{14}C-cyano] & [^{14}C- benzyl] labels.

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

Laboratory studies ‡

Parent – modelling endpoints	Aerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} (d)*	DT_{50} (d) 20°C pF2/10kPa*	Chi square error (%)	Method of calculation
Loamy sand	5.4	20 °C / 50 %	14.2 (fast phase) 177 (slow phase)	14.2 (fast phase) 177 (slow phase)	0.4-2.8	DFOP ^{14}C-(b) k1 = 0.0581 k2 = 0.0052 g = 0.416 ^{14}C-(c) k1 = 0.0408 k2 = 0.00295 g = 0.536

Sandy loam	6.4	20 °C / 50 %	10.8 (fast phase) 164 (slow phase)	9.99 (fast phase) 152 (slow phase)	2.7-2.9	DFOP ^{14}C-(b) k1 = 0.0756 k2 = 0.0058 g = 0.462 ^{14}C-(c) k1 = 0.0546 k2 = 0.0031 g = 0.586
Clay	7.2	20 °C / 50 %	7.7 (fast phase) 110 (slow phase)	4.32 (fast phase) 61.7 (slow phase)	1.4-2.3	DFOP ^{14}C-(b) k1 = 0.09366 k2 = 0.0065 g = 0.567 ^{14}C-(c) k1 = 0.0865 k2 = 0.0061 g = 0.501
Silt Loam	6.6	20 °C / 50 %	9.5 (fast phase) 176 (slow phase)	8.22 (fast phase) 152 (slow phase)	2.4-3.5	DFOP ^{14}C-(b) k1 = 0.0745 k2 = 0.0044 g = 0.7110 ^{14}C-(c) k1 = 0.0708 k2 = 0.0035 g = 0.739
Geometric mean			10.3 (fast) 154 (slow)	8.42 (fast phase) 126 (slow phase)		

*geomean of label positions
^{14}C-(c) = [^{14}C-cyclopropyl] beta-cypermethrin
^{14}C-(b) = ^{14}C-benzyl] beta-cypermethrin

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

Parent – trigger endpoints	Aerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	Chi square error (%)	Method of calculation
Loamy sand	5.4	20 °C / 50 %	43.4/734	-	0.4-2.5	FOMC ^{14}C-(b) alpha = 0.5669 beta = 18.165 DFOP ^{14}C-(c) k1 = 0.0408 k2 = 0.00295 g = 0.536
Sandy loam	6.4	20 °C / 50 %	29.6/632	-	2.8-2.9	FOMC ^{14}C-(b) alpha = 0.5269 beta = 11.183 DFOP ^{14}C-(c) k1 = 0.0756 k2 = 0.0058 g = 0.462
Clay	7.2	20 °C / 50 %	20.2/330	-	1.4-2.7	FOMC ^{14}C-(b) alpha = 0.5740 beta = 7.6050 DFOP ^{14}C-(c) ^{14}C-(c) k1 = 0.0865 k2 = 0.0061 g = 0.501
Silt Loam	6.6	20 °C / 50 %	15.2/257	-	2.4-3.5	DFOP ^{14}C-(b) k1 = 0.0745 k2 = 0.0044 g = 0.7110 ^{14}C-(c) k1 = 0.0708 k2 = 0.0035 g = 0.739
Geometric mean			25.1/445			

- = not required

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)							
Laboratory studies ‡							
Parent – Cis isomers	Aerobic conditions						
Isomer	Soil type	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	Chi square error (%)	Method of calculation
Cis	Loamy sand	5.4	20 °C / 50 %	78.8/262	-	3.4	SFO
	Sandy loam	6.4	20 °C / 50 %	65.4/217	-	5.1	SFO
	Clay	7.2	20 °C / 50 %	56.3/187	-	5.1	SFO
	Silt Loam	6.6	20 °C / 50 %	103/391	-	4.7	DFOP K1 = .00483 K2 = 0.0356 g = 0.334
Geometric mean				73.9/254			

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)							
Laboratory studies ‡							
Parent – Trans isomers	Aerobic conditions						
Isomer	Soil type	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	Chi square error (%)	Method of calculation
Trans	Loamy sand	5.4	20 °C / 50 %	29.7/400	-	3.4	DFOP K1 = 0.0037 K2 = 0.0556 g = 0.438
	Sandy loam	6.4	20 °C / 50 %	19.4/337	-	5.1	DFOP K1 = 0.0040 K2 = 0.0752 g = 0.385
	Clay	7.2	20 °C / 50 %	12.2/262	-	5.1	DFOP K1 = 0.0041 K2 = 0.0942 g = 0.290
	Silt Loam	6.6	20 °C / 50 %	9.6/263	-	4.7	DFOP K1 = .00483 K2 = 0.0356 g = 0.334
Geometric mean				16.1/310			

Metabolite PBA – modelling endpoints	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	Chi square error (%)	Method of calculation
Loamy sand	5.4	20 °C / 50 %	1.82/6.05		1.82	19.6	SFO
Sandy loam	6.4	20 °C / 50 %	5.98/19.9		5.53	7.1	SFO
Clay	7.2	20 °C / 50 %	8.50/28.2		4.77	7.1	SFO peak down
Silt Loam	6.6	20 °C / 50 %	9.85/32.7		8.48	23.8	SFO peak down
Geometric mean			5.49/18.3	*	4.49		

* = a value of 1 was used in the groundwater modelling

Metabolite CPA – modelling endpoints	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	Chi square error (%)	Method of calculation
Loamy sand	5.4	20 °C / 50 %	2.56/8.50		2.56	14.2	SFO
Sandy loam	6.4	20 °C / 50 %	13.4/44.6		12.4	7.0	SFO
Clay	7.2	20 °C / 50 %	23.0/76.3		12.9	24.7	SFO peak down
Silt Loam	6.6	20 °C / 50 %	14.3/47.6		12.3	7.5	SFO peak down
Geometric mean			10.3/34.3	*	8.42		

* = a value of 1 was used in the groundwater modelling

Metabolite PBA – trigger endpoints	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	Chi square error (%)	Method of calculation
Loamy sand	5.4	20 °C / 50 %	1.86/6.17			15.9	SFO
Sandy loam	6.4	20 °C / 50 %	6.77/22.5			6.77	SFO
Clay	7.2	20 °C / 50 %	8.5/28.2			7.1	SFO (peak down)
Silt Loam	6.6	20 °C / 50 %	9.85/32.7			23.8	SFO (peak down)
Geometric mean			5.70/18.9				

Metabolite CPA – trigger endpoints	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	Chi square error (%)	Method of calculation
Loamy sand	5.4	20 °C / 50 %	2.56/8.50			14.2	SFO
Sandy loam	6.4	20 °C / 50 %	13.4/44.6			7.0	SFO
Clay	7.2	20 °C / 50 %	23.0/76.3			24.7	SFO (peak down)
Silt Loam	6.6	20 °C / 50 %	14.3/47.6			7.5	SFO (peak down)
Geometric mean			10.3/34.3				

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	No field studies carried out. Calculated plateau concentration of 0.0108 mg/kg reached after 5 years application of 2 x 10 g a.s/ha per annum (crop interception 40% and 80% -90 day interval).

Laboratory studies ‡

Parent	Anaerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	Chi square	Method of calculation
Silt loam [^{14}C-benzyl]	6.44	20 °C / flooded	24.0/1016	-	11.7	FOMC alpha = 0.460 beta = 6.821
Silt loam [^{14}C-cyclopropane]	6.44	20 °C / flooded	23.3/191	-	7.3	DFOP k1 = 0.22287 k2 = 0.00957 g = 0.377
Geometric mean			23.6/441			

Laboratory studies ‡

Parent						
Soil type	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	Chi square	Method of calculation
Sandy loam [^{14}C-benzyl]	6.4	10 °C	73.8/1209	n.a.	2.4	FOMC
Sandy loam [^{14}C-cyclopropane]	6.4	10 °C	73.6/1107	n.a.	2.8	FOMC

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
LUFA 2.2 loamy sand	2.16	5.4	-	-	889	41167	0.946
LUFA 2.3 sandy loam	0.98	6.4	-	-	1622	165556	1.016
LUFA 6S clay	1.75	7.2	-	-	1116	63795	0.985
Fraunhofer 02-A silt loam	1.30	6.6	-	-	3245	249607	1.072
Arithmetic mean/median					1718/ 1369	130031/ 114676	1.005/ 1.001
pH dependence, Yes or No			No				

Metabolite PBA							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
LUFA 2.3 sandy loam	0.98	6.4	-	-	0.88	90.1	0.84
LUFA 6S clay	1.75	7.2	-	-	1.06	60.5	0.88
Fraunhofer 02-A silt loam	1.30	6.6	-	-	0.76	58.8	0.88
Arithmetic mean					0.9	69.8	0.87
pH dependence (yes or no)			No				

Metabolite CPA							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
LUFA 2.3 sandy loam	0.98	6.4	-	-	0.123	12.6	0.71
LUFA 6S clay	1.75	7.2	-	-	0.193	11.0	0.63
Fraunhofer 02-A silt loam	1.30	6.6	-	-	0.174	13.4	0.76
Arithmetic mean					0.16	12.4	0.7
pH dependence (yes or no)			No				

Metabolite cyperamide
Estimated K_{doc} = 27058 mL/g In the absence of studies on adsorption of the metabolite cyperamide, an estimation of the Koc input value was performed based on the parent Koc (130031 ml/g) applying appropriate correction factors as used by KOCWIN programme forming part of the EPI Suite software (v. 4.1).

Parent	
Method of calculation	DT_{50} (d): 17 days (fast phase) 235 days (slow phase) Kinetics: DFOP k1 = 0.0408 k2 = 0.00295 g = 0.536 Lab: worst case from lab studies.
Application data	Crop: Oilseed Rape Depth of soil layer: 5 cm. Soil bulk density: 1.5 g/cm^3 % plant interception: 40 % and 80 % Number of applications: 2 Interval (d): 90 days Application rate(s): 2 x 10 g a.s./ha

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-		0.0080	
Short term 24h	-		0.0078	0.0079
2d		-	0.0076	0.0078
4d			0.0073	0.0076
Long term 7d			0.0069	0.0074
28d			0.0048	0.0061
50d	-	-	0.0038	0.0053
100d			0.0028	0.0042
Plateau concentration	0.0108 mg/kg after yr 5			

Metabolite PBA	
Method of calculation	Molecular weight relative to the parent: 0.515 DT_{50} (d): 9.85 days Kinetics: SFO Field or Lab: representative worst case from lab studies.
Application data	Application rate assumed: 3.42 g a.s./ha (assumed PBA is formed at a maximum of 17.1 % of the applied dose)

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.001		-	
Short term 24h	0.001	0.001	-	-
2d	0.001	0.001	-	-

4d	0.001	0.001	-	-
Long term 7d	0.001	0.001	-	-
28d	0.000	0.001	-	-
50d	0.000	0.000	-	-
100d	0.000	0.000	-	-
Plateau concentration	0.0011 mg/kg after yr 5			

Metabolite CPA Method of calculation	Molecular weight relative to the parent: 0.502 DT_{50} (d): 23.0 days Kinetics: SFO Field or Lab: representative worst case from lab studies.			
Application data	Application rate assumed: 5.5 g a.s./ha (assumed CPA is formed at a maximum of 27.5 % of the applied dose)			
$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.001		-	
Short term 24h	0.001	0.001	-	-
2d	0.001	0.001	-	-
4d	0.001	0.001	-	-
Long term 7d	0.001	0.001	-	-
28d	0.001	0.001	-	-
50d	0.000	0.001	-	-
100d	0.000	0.000	-	-
Plateau concentration	0.0014 mg/kg after yr 5			

Metabolite cyperamide Method of calculation	Molecular weight relative to the parent: 1.043 DT_{50} (d): not calculated Kinetics: not calculated Field or Lab: representative worst case from lab studies.			
Application data	Application rate assumed: 6.52 g a.s./ha (assumed cyperamide is formed at a maximum of 32.6 % of the applied dose)			
$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.004		-	
Short term 24h	-	-	-	-
2d	-	-	-	-
4d	-	-	-	-
Long term 7d	-	-	-	-
28d	-	-	-	-
50d	-	-	-	-
100d	-	-	-	-
Plateau concentration	0.0049 mg/kg after yr 5			

Parent	
Application data	Crop: Maize Depth of soil layer: 5 cm. Soil bulk density: 1.5 g/cm^3 % plant interception: 25 % Number of applications: 1 Application rate(s): 1 x 35 g a.s./ha

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.0350		-	
Short term	24h	0.0342	0.0346	-	-
	2d	0.0334	0.0342	-	-
	4d	0.0320	0.0355	-	-
Long term	7d	0.0300	0.0324	-	-
	28d	0.0209	0.0268	-	-
	50d	0.0165	0.0231	-	-
	100d	0.0124	0.0186	-	-
Plateau concentration		0.0434 mg/kg after yr 5			

Metabolite PBA	
Method of calculation	Molecular weight relative to the parent: 0.515 DT$_{50}$ (d): 9.85 days Kinetics: SFO Field or Lab: representative worst case from lab studies.
Application data	Application rate assumed: 5.985 g a.s./ha (assumed PBA is formed at a maximum of 17.1 % of the applied dose)

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.003		-	
Short term	24h	0.003	0.003	-	-
	2d	0.003	0.003	-	-
	4d	0.002	0.003	-	-
Long term	7d	0.002	0.002	-	-
	28d	0.000	0.001	-	-
	50d	0.000	0.001	-	-
	100d	0.000	0.000	-	-
Plateau concentration		0.0037 mg/kg after yr 5			

Metabolite CPA	
Method of calculation	Molecular weight relative to the parent: 0.502 DT$_{50}$ (d): 23.0 days Kinetics: SFO Field or Lab: representative worst case from lab studies.
Application data	Application rate assumed: 9.625 g a.s./ha (assumed CPA is formed at a maximum of 27.5 % of the applied dose)

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.005		-	
Short term	24h	0.005	0.005	-	-
	2d	0.005	0.005	-	-
	4d	0.004	0.005	-	-

Long term	7d	0.004	0.004	-	-
	28d	0.002	0.003	-	-
	50d	0.001	0.002	-	-
	100d	0.000	0.002	-	-
Plateau concentration		0.0062 mg/kg after yr 5			

Metabolite cyperamide Method of calculation	Molecular weight relative to the parent: 1.043 DT_{50} (d): not calculated Kinetics: not calculated Field or Lab: representative worst case from lab studies.
Application data	Application rate assumed: 11.41 g a.s./ha (assumed cyperamide is formed at a maximum of 32.6 % of the applied dose)

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.012		-	
Short term	24h	-	-	-	-
	2d	-	-	-	-
	4d	-	-	-	-
Long term	7d	-	-	-	-
	28d	-	-	-	-
	50d	-	-	-	-
	100d	-	-	-	-
Plateau concentration		0.0148 mg/kg after yr 5			

Parent Application data	Crop: winter wheat Depth of soil layer: 5 cm. Soil bulk density: 1.5 g/cm^3 % plant interception: 25 % and 90 % 25 % (1st application) 90 % (2nd application) Number of applications: 2 Interval (d): 90 days Application rate(s): 15 g a.s./ha and 20 g a.s./ha

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		-		0.0150	
Short term	24h	-	-	0.0147	0.0148
	2d	-	-	0.0143	0.0147
	4d	-	-	0.0137	0.0143
Long term	7d	-	-	0.0129	0.0139
	28d	-	-	0.0090	0.0115
	50d	-	-	0.0071	0.0099
	100d	-	-	0.0053	0.0080
Plateau concentration		0.0194 mg/kg after yr 5			

Metabolite PBA				
Method of calculation	Molecular weight relative to the parent: 0.515 DT_{50} (d): 9.85 days Kinetics: SFO Field or Lab: representative worst case from lab studies.			
Application data	Application rate assumed: 5.985 g a.s./ha (assumed PBA is formed at a maximum of 17.1 % of the applied dose)			
$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.002		-	
Short term 24h	0.001	0.001	-	-
2d	0.001	0.001	-	-
4d	0.001	0.001	-	-
Long term 7d	0.001	0.001	-	-
28d	0.000	0.001	-	-
50d	0.000	0.000	-	-
100d	0.000	0.000	-	-
Plateau concentration	0.0027 mg/kg after yr 5			

Metabolite CPA				
Method of calculation	Molecular weight relative to the parent: 0.502 DT_{50} (d): 23.0 days Kinetics: SFO Field or Lab: representative worst case from lab studies.			
Application data	Application rate assumed: 9.625 g a.s./ha (assumed CPA is formed at a maximum of 27.5 % of the applied dose)			
$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.001		-	
Short term 24h	0.001	0.001	-	-
2d	0.001	0.001	-	-
4d	0.001	0.001	-	-
Long term 7d	0.001	0.001	-	-
28d	0.000	0.001	-	-
50d	0.000	0.001	-	-
100d	0.000	0.000	-	-
Plateau concentration	0.0056 mg/kg after yr 5			

Metabolite cyperamide				
Method of calculation	Molecular weight relative to the parent: 1.043 DT_{50} (d): not calculated Kinetics: not calculated Field or Lab: representative worst case from lab studies.			
Application data	Application rate assumed: 11.41 g a.s./ha (assumed cyperamide is formed at a maximum of 32.6 % of the applied dose)			
$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.006		-	
Short term24h	-	-	-	-
2d	-	-	-	-

4d	-	-	-	-
Long term7d	-	-	-	-
28d	-	-	-	-
50d	-	-	-	-
100d	-	-	-	-
Plateau concentration	0.0075 mg/kg after yr 5			

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 3: cis-/trans-cypermethrin, 1302/ 923 days at pH 3 at 25 °C
	pH 7: cis-/trans-cypermethrin, 221/136 days at 25 °C
	pH 11: cis and trans < 1 d at 25 °C
	cyperamide, CPA and M2 (3-phenoxybenzaldehyde). Amounts reached not given in the study.
Photolytic degradation of active substance and metabolites above 10 % ‡	Natural light, 50°N; DT_{50} 2.49 days 3-phenoxybenzaldehyde (M2) – 10.9 % AR 3-phenoxybenzoic acid (M3/ PBA) – 22.2 % AR phenol (M4) – 13.0 % AR
Quantum yield of direct phototransformation in water at Σ > 290 nm	0.235 molecules degraded $photon^{-1}$
Readily biodegradable ‡ (yes/no)	No data submitted, substance considered not ready biodegradable.

Degradation in water / sediment

Parent – modelling endpoints		Distribution (Max. sed 50.7 % after 0.25 d)							
Water / sediment system	pH water phase	pH sed	t. °C	Label position	DT_{50} whole sys.	Chi-square error (%)	DT_{50} water	DT_{50} sed	Method of calculation
River	8.4	6.11	20	^{14}C-(benzyl)	31.3	9.9	n/c	n/c	FOMC/ 3.322
				^{14}C-(cyclopropyl)	16.7	10.2	n/c	n/c	FOMC/ 3.322
Pond	8.0	6.76	20	^{14}C-(benzyl)	22.4	7.1	n/c	n/c	Slow phase DFOP
				^{14}C-(cyclopropyl)	20.9	4.3	n/c	n/c	Slow phase DFOP
Geometric mean					22.2				

n/c = not calculated

Parent – persistence endpoints		Distribution (Max. sed 50.7 % after 0.25 d)							
Water / sediment system	pH water phase	pH sed	t. °C	Label position	DT_{50} /DT_{90} whole sys.	Chi-square error (%)	DT_{50} /DT_{90} water	DT_{50} /DT_{90} sed	Method of calculation
River	8.4	6.11	20	^{14}C-(benzyl)	1.90/104	9.9	n/c	n/c	FOMC
				^{14}C-(cyclopropyl)	1.46/55.4	10.2	n/c	n/c	FOMC
Pond	8.0	6.76	20	^{14}C-(benzyl)	4.9/53.2	7.1	n/c	n/c	DFOP

				^{14}C-(cyclopropyl)	1.8/46.8	4.3	n/c	n/c	DFOP
Geometric mean					2.22/ 61.5				

n/c = not calculated

PBA – persistence and modelling endpoints	Distribution - max in water 38.5% after 2 d. Max. sed 13.9 % after 29 d							
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	Chi-square error (%)	DT_{50}-DT_{90} water	DT_{50}-DT_{90} sed	Method of calculation
River	8.4	6.11	20	38.9	13	n/c	n/c	SFO
Pond	8.0	6.76	20	6.35	27.9	n/c	n/c	SFO
Geometric mean				15.7		n/c	n/c	

n/c = not calculated

CPA - persistence and modelling endpoints	Distribution - max in water 53.4% after 29 d. Max. sed 22.4 % after 62 d)							
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	Chi-square error (%)	DT_{50}-DT_{90} water	DT_{50}-DT_{90} sed	Method of calculation
River	8.4	6.11	20	43.6	22.0	n/c	n/c	SFO
Pond	8.0	6.76	20	59.2	9.4	n/c	n/c	SFO
Geometric mean				50.8		n/c	n/c	

n/c = not calculated

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. Max x % after n d	Non-extractable residues in sed. Max x % after n d (end of the study)
River	8.4	6.11	35.4 % after 100 d	41.2 % after 83 d	37.7 % after 100 d
Pond	8.0	6.76	61.4% after 100 d	40.4% after 62 d	28.1% after 100 d

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: STEPS 1-2 version 1.1. Molecular weight (g/mol): 416.3 Water solubility (mg/L): 0.00121 K_{OC} (L/kg): 130031 DT_{50} soil (d): 126 days (Lab –slow phase DFOP). DT_{50} water/sediment system (d): 22.2 (representative worst case from sediment water studies) DT_{50} water (d): 22.2 (whole system used) DT_{50} sediment (d): 1000 (default) Crop interception (%): 'minimal crop cover'.
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: SWASH 3.1 Vapour pressure: 0.0 Koc/Kom: 130031/75424 1/n: 0.99
Application rate	Crop: Winter Oilseed Rape Crop interception: Calculated by model Number of applications: 2 Interval (d): 90 Application rate(s): 10 g a.s./ha Application window: 1 October to 30 April
Application rate	Crop: Maize Crop interception: Calculated by model Number of applications: 1 Interval (d): n/a Application rate(s): 35 g a.s./ha Application window: 1 June to 1 July
Application rate	Crop: Winter Wheat Crop interception: Calculated by model Number of applications: 2 Interval (d): 90 days Application rate(s): 1 x 15 g a.s./ha + 1 x 20 g a.s./ha Application window: 1 Oct to 30 Apr

Crop	Step	Region	Compartment	Max PEC Beta-cypermethrin
Winter Oilseed Rape	Step 1	N EU	Water [µg/L]	0.11
			Sediment [µg /kg]	24.86
		S EU	Water [µg/L]	0.11
			Sediment [µg /kg]	24.86
	Step 2	N EU	Water [µg/L]	0.09
			Sediment [µg /kg]	12.87
		S EU	Water [µg/L]	0.09
			Sediment [µg /kg]	10.53
Maize	Step 1	N EU	Water [µg/L]	0.39
			Sediment [µg /kg]	87.0
		S EU	Water [µg/L]	0.39
			Sediment [µg /kg]	87.0
	Step 2	N EU	Water [µg/L]	0.32
			Sediment [mg/kg]	34.25
		S EU	Water [µg/L]	0.32
			Sediment [mg/kg]	27.87
Winter Wheat	Step 1	N EU	Water [µg/L]	0.39
			Sediment [mg/kg]	87.0
		S EU	Water [µg/L]	0.39
			Sediment [mg/kg]	87.0

	Step 2	N EU	Water [µg/L]	0.32
			Sediment [mg/kg]	34.25
		S EU	Water [µg/L]	0.32
			Sediment [mg/kg]	27.87

Winter oilseed rape

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D2	Ditch	0	0.06		0.39	
		24	0.03	0.03	0.34	0.39
		2d	0.02	0.03	0.32	0.38
		4d	0.02	0.02	0.31	0.38
		7d	0.01	0.02	0.28	0.38
		14d	0.00	0.01	0.24	0.35
		21d	0.00	0.01	0.23	0.33
		28d	0.00	0.01	0.21	0.31
		42d	0.00	0.00	0.18	0.28
D2	Stream	0	0.05		0.33	
		24	0.02	0.03	0.26	0.33
		2d	0.02	0.02	0.24	0.33
		4d	0.01	0.02	0.21	0.33
		7d	0.00	0.02	0.18	0.32
		14d	0.00	0.01	0.14	0.28
		21d	0.00	0.01	0.12	0.24
		28d	0.00	0.00	0.11	0.22
		42d	0.00	0.00	0.09	0.18
D3	Ditch	0 h	0.06		0.25	
		24 h	0.02	0.03	0.24	0.25
		2 d	0.01	0.02	0.21	0.24
		4 d	0.01	0.01	0.18	0.23
		7 d	0.00	0.01	0.15	0.21
		14 d	0.00	0.01	0.11	0.17
		21 d	0.00	0.00	0.09	0.15
		28 d	0.00	0.00	0.08	0.13
		42 d	0.00	0.00	0.06	0.11
D4	pond	0 h	0.002		0.05	
		24 h	0.001	0.002	0.05	0.05
		2 d	0.001	0.001	0.05	0.05
		4 d	0.001	0.001	0.05	0.05
		7 d	0.001	0.001	0.05	0.05
		14 d	0.001	0.001	0.05	0.05
		21 d	0.001	0.001	0.05	0.05
		28 d	0.000	0.001	0.05	0.05
		42 d	0.000	0.001	0.05	0.05
D4	stream	0 h	0.05		0.13	
		24 h	0.001	0.01	0.06	0.10
		2 d	0.00	0.01	0.04	0.08
		4 d	0.00	0.00	0.03	0.06
		7 d	0.00	0.00	0.02	0.04
		14 d	0.00	0.00	0.02	0.03
		21 d	0.00	0.00	0.01	0.03
		28 d	0.00	0.00	0.01	0.02
		42 d	0.00	0.00	0.01	0.02

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D5	pond	0 h	0.002		0.049	
		24 h	0.001	0.002	0.049	0.049
		2 d	0.001	0.002	0.049	0.049
		4 d	0.001	0.001	0.049	0.049
		7 d	0.001	0.001	0.049	0.049
		14 d	0.001	0.001	0.049	0.049
		21 d	0.001	0.001	0.048	0.049
		28 d	0.001	0.001	0.048	0.049
		42 d	0.000	0.000	-	0.049
D5	stream	0 h	0.053		0.15	
		24 h	0.003	0.02	0.09	0.13
		2 d	0.001	0.01	0.06	0.10
		4 d	0.000	0.00	0.04	0.08
		7 d	0.000	0.00	0.03	0.06
		14 d	0.000	0.00	0.02	0.05
		21 d	0.000	0.00	0.02	0.04
		28 d	0.000	0.00	0.02	0.03
		42 d	0.000	0.00	0.01	0.03
R1	pond	0 h	0.002		0.07	
		24 h	0.001	0.001	0.071	0.071
		2 d	0.001	0.001	0.071	0.071
		4 d	0.001	0.001	0.071	0.071
		7 d	0.001	0.001	0.071	0.071
		14 d	0.001	0.001	0.070	0.071
		21 d	0.001	0.001	0.070	0.071
		28 d	0.000	0.001	0.069	0.071
		42 d	0.001	0.001	0.067	0.070
R1	stream	0 h	0.037		0.59	
		24 h	0.000	0.005	0.58	0.58
		2 d	0.000	0.002	0.58	0.58
		4 d	0.000	0.001	0.58	0.58
		7 d	0.000	0.001	0.58	0.58
		14 d	0.000	0.001	0.57	0.58
		21 d	0.000	0.000	0.57	0.58
		28 d	0.000	0.000	0.57	0.57
		42 d	0.000	0.000	0.58	0.57
R3	stream	0 h	0.053		3.61	
		24 h	0.001	0.013	3.60	3.61
		2 d	0.000	0.007	3.60	3.60
		4 d	0.000	0.004	3.59	3.60
		7 d	0.000	0.002	3.60	3.60
		14 d	0.000	0.001	3.57	3.59
		21 d	0.000	0.001	3.55	3.58
		28 d	0.000	0.001	3.60	3.56
		42 d	0.000	0.000	-	3.40

- = Time of Maximum PEC too close to the end of the simulation to calculate a PEC.

Maize

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3	Ditch	0	0.17		0.60	
		24	0.04	0.08	0.51	0.58
		2d	0.02	0.05	0.42	0.54
		4d	0.00	0.03	0.32	0.47
		7d	0.00	0.02	0.25	0.40
		14d	0.00	0.01	0.18	0.30
		21d	0.00	0.01	0.14	0.26
		28d	0.00	0.01	0.13	0.23
		42d	0.00	0.00	0.10	0.19
D4	Pond	0	0.007		0.10	
		24	0.005	0.005	0.10	0.10
		2d	0.004	0.005	0.10	0.10
		4d	0.004	0.004	0.10	0.10
		7d	0.003	0.004	0.10	0.10
		14d	0.002	0.003	0.10	0.10
		21d	0.002	0.003	0.09	0.10
		28d	0.001	0.003	0.09	0.10
		42d	0.001	0.002	0.09	0.10
D4	Stream	0 h	0.14		0.22	
		24 h	0.00	0.01	0.06	0.12
		2 d	0.00	0.01	0.05	0.09
		4 d	0.00	0.00	0.03	0.06
		7 d	0.00	0.00	0.02	0.05
		14 d	0.00	0.00	0.02	0.03
		21 d	0.00	0.00	0.01	0.03
		28 d	0.00	0.00	0.01	0.02
		42 d	0.00	0.00	0.01	0.02
D5	Pond	0 h	0.007		0.10	
		24 h	0.005	0.005	0.10	0.10
		2 d	0.004	0.005	0.10	0.10
		4 d	0.004	0.004	0.10	0.10
		7 d	0.003	0.004	0.10	0.10
		14 d	0.002	0.003	0.09	0.10
		21 d	0.002	0.003	0.09	0.10
		28 d	0.001	0.003	0.09	0.10
		42 d	0.001	0.002	0.09	0.09
D5	Stream	0 h	0.15		0.20	
		24 h	0.00	0.01	0.06	0.10
		2 d	0.00	0.01	0.04	0.08
		4 d	0.00	0.00	0.03	0.06
		7 d	0.00	0.00	0.02	0.04
		14 d	0.00	0.00	0.02	0.03
		21 d	0.00	0.00	0.01	0.02
		28 d	0.00	0.00	0.01	0.02
		42 d	0.00	0.00	0.01	0.02
D6	Ditch	0 h	0.16		0.47	
		24 h	0.01	0.06	0.30	0.41
		2 d	0.00	0.03	0.22	0.35
		4 d	0.00	0.02	0.17	0.27
		7 d	0.00	0.01	0.13	0.22

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		14 d	0.00	0.01	0.09	0.16
		21 d	0.00	0.00	0.08	0.14
		28 d	0.00	0.00	0.07	0.12
		42 d	0.00	0.00	0.06	0.10
R1	Pond	0 h	0.007		0.58	
		24 h	0.005	0.005	0.58	0.58
		2 d	0.004	0.005	0.58	0.58
		4 d	0.004	0.004	0.58	0.58
		7 d	0.003	0.004	0.58	0.58
		14 d	0.002	0.003	0.58	0.58
		21 d	0.002	0.003	0.58	0.58
		28 d	0.002	0.003	0.57	0.58
		42 d	0.002	0.002	-	0.58
R1	Stream	0 h	0.12		13.0	
		24 h	0.00	0.02	13.0	13.0
		2 d	0.00	0.01	13.0	13.0
		4 d	0.00	0.01	13.0	13.0
		7 d	0.00	0.00	12.9	13.0
		14 d	0.00	0.00	12.9	13.0
		21 d	0.00	0.00	12.8	12.9
		28 d	0.00	0.00	12.8	12.9
		42 d	0.00	0.00	-	12.8
R2	Stream	0 h	0.15		29.0	
		24 h	0.00	0.02	29.0	29.0
		2 d	0.00	0.01	29.0	29.0
		4 d	0.00	0.00	28.9	29.0
		7 d	0.00	0.00	28.9	29.0
		14 d	0.00	0.00	28.8	28.9
		21 d	0.00	0.00	28.6	28.9
		28 d	0.00	0.00	28.5	28.8
		42 d	0.00	0.00	28.3	28.7
R3	Stream	0 h	0.16		7.06	
		24 h	0.01	0.05	7.05	7.06
		2 d	0.00	0.03	7.05	7.06
		4 d	0.00	0.01	7.04	7.05
		7 d	0.00	0.01	7.03	7.04
		14 d	0.00	0.00	7.01	7.03
		21 d	0.00	0.00	6.99	7.02
		28 d	0.00	0.00	6.97	7.01
		42 d	0.00	0.00	6.93	6.99
R4	Stream	0 h	0.12		12.7	
		24 h	0.00	0.02	12.7	12.7
		2 d	0.00	0.01	12.7	12.7
		4 d	0.00	0.01	12.7	12.7
		7 d	0.00	0.00	12.7	12.7
		14 d	0.00	0.00	12.6	12.7
		21 d	0.00	0.00	12.6	12.7
		28 d	0.00	0.00	12.5	12.6
		42 d	0.00	0.00	12.4	12.6

- = Time of Maximum PEC too close to the end of the simulation to calculate a PEC.

Winter wheat

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D1	Ditch	0	0.11		0.72	
		24	0.05	0.06	0.71	0.72
		2d	0.03	0.05	0.69	0.72
		4d	0.02	0.04	0.63	0.71
		7d	0.01	0.03	0.56	0.68
		14d	0.00	0.01	0.47	0.61
		21d	0.00	0.01	0.42	0.56
		28d	0.00	0.01	0.40	0.53
		42d	0.00	0.01	0.37	0.51
D1	Stream	0	0.09		0.30	
		24	0.00	0.01	0.24	0.29
		2d	0.00	0.00	0.19	0.26
		4d	0.00	0.00	0.14	0.22
		7d	0.00	0.00	0.11	0.19
		14d	0.00	0.00	0.08	0.14
		21d	0.00	0.00	0.07	0.12
		28d	0.00	0.00	0.06	0.10
		42d	0.00	0.00	0.05	0.09
D2	Ditch	0 h	0.12		0.73	
		24 h	0.05	0.06	0.66	0.73
		2 d	0.04	0.05	0.62	0.72
		4 d	0.03	0.04	0.58	0.72
		7 d	0.02	0.03	0.52	0.71
		14 d	0.00	0.02	0.44	0.67
		21 d	0.00	0.02	0.42	0.61
		28 d	0.00	0.01	0.37	0.57
		42 d	0.00	0.01	0.33	0.51
D2	stream	0 h	0.096		0.50	
		24 h	0.00	0.01	0.40	0.50
		2 d	0.00	0.01	0.38	0.49
		4 d	0.00	0.00	0.32	0.49
		7 d	0.00	0.00	0.29	0.48
		14 d	0.00	0.00	0.22	0.42
		21 d	0.00	0.00	0.20	0.37
		28 d	0.00	0.00	0.17	0.34
		42 d	0.00	0.00	0.14	0.28
D3	ditch	0 h	0.11		0.40	
		24 h	0.03	0.05	0.33	0.39
		2 d	0.01	0.04	0.28	0.36
		4 d	0.00	0.02	0.22	0.31
		7 d	0.00	0.01	0.18	0.27
		14 d	0.00	0.01	0.14	0.21
		21 d	0.00	0.00	0.12	0.19
		28 d	0.00	0.00	0.11	0.17
		42 d	0.00	0.00	0.10	0.15
D4	pond	0 h	0.004		0.09	
		24 h	0.003	0.003	0.09	0.09
		2 d	0.003	0.003	0.09	0.09
		4 d	0.002	0.003	0.09	0.09
		7 d	0.002	0.002	0.09	0.09

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		14 d	0.001	0.002	0.09	0.09
		21 d	0.001	0.002	0.09	0.09
		28 d	0.001	0.002	0.09	0.09
		42 d	0.001	0.001	0.08	0.09
D4	stream	0 h	0.084		0.20	
		24 h	0.00	0.003	0.09	0.15
		2 d	0.00	0.002	0.07	0.11
		4 d	0.00	0.001	0.05	0.09
		7 d	0.00	0.000	0.04	0.07
		14 d	0.00	0.000	0.03	0.05
		21 d	0.00	0.000	0.02	0.04
		28 d	0.00	0.000	0.02	0.03
		42 d	0.00	0.000	0.01	0.03
D5	pond	0 h	0.004		0.09	
		24 h	0.003	0.003	0.09	0.09
		2 d	0.003	0.003	0.09	0.09
		4 d	0.002	0.003	0.09	0.09
		7 d	0.002	0.002	0.09	0.09
		14 d	0.001	0.002	0.09	0.09
		21 d	0.001	0.002	0.08	0.09
		28 d	0.001	0.002	0.08	0.09
		42 d	0.001	0.001	-	0.09
D5	stream	0 h	0.09		0.23	
		24 h	0.00	0.004	0.13	0.19
		2 d	0.00	0.002	0.09	0.15
		4 d	0.00	0.001	0.07	0.12
		7 d	0.00	0.001	0.05	0.09
		14 d	0.00	0.000	0.04	0.07
		21 d	0.00	0.000	0.03	0.06
		28 d	0.00	0.000	0.03	0.05
		42 d	0.00	0.000	0.02	0.04
D6	ditch	0 h	0.112		0.52	
		24 h	0.004	0.03	0.52	0.52
		2 d	0.001	0.02	0.52	0.52
		4 d	0.000	0.01	0.51	0.52
		7 d	0.000	0.01	0.49	0.52
		14 d	0.000	0.00	0.45	0.51
		21 d	0.000	0.00	0.42	0.49
		28 d	0.000	0.00	0.37	0.48
		42 d	0.000	0.00	0.29	0.44
R1	pond	0 h	0.004		0.13	
		24 h	0.003	0.004	0.13	0.13
		2 d	0.003	0.003	0.13	0.13
		4 d	0.002	0.003	0.13	0.13
		7 d	0.002	0.003	0.13	0.13
		14 d	0.002	0.002	0.13	0.13
		21 d	0.001	0.002	0.13	0.13
		28 d	0.001	0.002	0.13	0.13
		42 d	0.001	0.002	0.12	0.13
R1	Stream	0 h	0.075		1.17	
		24 h	0.00	0.011	1.16	1.16
		2 d	0.00	0.006	1.16	1.16

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		4 d	0.00	0.003	1.15	1.16
		7 d	0.00	0.002	1.15	1.15
		14 d	0.00	0.001	1.14	1.15
		21 d	0.00	0.001	1.14	1.15
		28 d	0.00	0.001	1.13	1.14
		42 d	0.00	0.000	-	1.13
R3	Stream	0 h	0.11		11.8	
		24 h	0.005	0.034	11.8	11.8
		2 d	0.001	0.018	11.7	11.8
		4 d	0.000	0.010	11.7	11.7
		7 d	0.000	0.006	11.7	11.7
		14 d	0.000	0.003	11.6	11.7
		21 d	0.000	0.002	11.6	11.7
		28 d	0.000	0.002	-	11.6
		42 d	0.000	0.001	-	11.3
R4	Stream	0 h	0.074		11.9	
		24 h	0.00	0.011	11.9	11.9
		2 d	0.00	0.005	11.9	11.9
		4 d	0.00	0.003	11.9	11.9
		7 d	0.00	0.002	11.9	11.9
		14 d	0.00	0.001	11.8	11.9
		21 d	0.00	0.001	11.7	11.8
		28 d	0.00	0.001	11.7	11.8
		42 d	0.00	0.001	11.6	11.8

- = Time of Maximum PEC too close to the end of the simulation to calculate a PEC.

FOCUS STEP 4 PECsw for beta-cypermethrin from a single application of 1 x 10 g a.s./ha to oilseed rape

Crop	Scenario	Peak PECsw (µg/L)		
		5m	10m	20m
Oilseed rape	D2 ditch	0.016	0.008	0.004
	D2 stream	0.019	0.010	0.005
	D3 ditch	0.015	0.008	0.004
	D4 pond	0.002	0.001	0.001
	D4 stream	0.018	0.010	0.005
	D5 pond	0.002	0.001	0.001
	D5 stream	0.019	0.010	0.005
	R1 pond	0.002	0.001	0.001
	R1 stream	0.014	0.007	0.004
	R3 stream	0.019	0.010	0.005

FOCUS STEP 4 PECsw for beta-cypermethrin from a single application of 1 x 35 g a.s./ha to maize

Crop	Scenario	Peak PECsw (µg/L)		
		5m	10m	20m
Maize	D3 ditch	0.054	0.029	0.015
	D4 pond	0.006	0.004	0.003
	D4 stream	0.060	0.032	0.016
	D5 pond	0.006	0.004	0.003
	D5 stream	0.064	0.034	0.002
	D6 Ditch	0.054	0.028	0.015
	R1 pond	0.006	0.004	0.003
	R1 stream	0.048	0.026	0.013
	R2 stream	0.065	0.034	0.018
	R3 stream	0.068	0.036	0.019
	R4 stream	0.048	0.026	0.013

FOCUS STEP 4 PECsw for beta-cypermethrin from a single application of 1 x 20 g a.s./ha to winter cereals

Crop	Scenario	Peak PECsw (µg/L)		
		5m	10m	20m
Winter cereals	D1 ditch	0.031	0.016	0.009
	D1 stream	0.033	0.018	0.009
	D2 ditch	0.031	0.016	0.009
	D2 stream	0.035	0.018	0.010
	D3 ditch	0.031	0.016	0.009
	D4 pond	0.003	0.002	0.002
	D4 stream	0.031	0.016	0.009
	D5 pond	0.003	0.002	0.002
	D5 stream	0.034	0.018	0.009
	D6 ditch	0.030	0.016	0.008
	R1 pond	0.004	0.003	0.002
	R1 stream	0.027	0.014	0.008
	R3 stream	0.039	0.021	0.011
	R4 Stream	0.027	0.014	0.008

PBA Parameters used in FOCUSsw step 1 and 2	Molecular weight: 214.2 Water solubility (mg/L): 1000 Soil and water metabolite: Koc/Kom (L/kg): 69.8/40.5 DT_{50} soil (d): 4.49 days (Lab. In accordance with FOCUS, SFO) DT_{50} water/sediment system (d): 15.7 DT_{50} water (d): 15.7 DT_{50} sediment (d): 1000 Crop interception (%): 'minimal crop cover' Maximum occurrence observed (% molar basis with respect to the parent) Soil: 17.1 % Water/sediment: 41.2 %
CPA	Molecular weight: 209.1 Water solubility (mg/L): 1000 Soil and water metabolite: Koc/Kom (L/kg): 12.4/7.19 DT_{50} soil (d): 8.42 days (Lab. In accordance with FOCUS, SFO) DT_{50} water/sediment system (d): 50.8 DT_{50} water (d): 50.8 DT_{50} sediment (d): 1000 Crop interception (%): 'minimal crop cover' Maximum occurrence observed (% molar basis with respect to the parent) Soil: 27.5% Water/sediment: 73.6%
Cyperamide	Molecular weight: 434.3 Water solubility (mg/L): 1000 Soil metabolite: Koc/Kom (L/kg): 27058/15695 DT_{50} soil (d): 10000 d (conservative default) DT_{50} water/sediment system (d): 10,000 DT_{50} water (d): 10,000 DT_{50} sediment (d): 10,000 Crop interception (%): 'minimal crop cover' Maximum occurrence observed (% molar basis with respect to the parent) Soil: 32.6 % Water/sediment: 7.8 % (In the 'river' water-sediment system 'unidentified metabolite 1' was found to be a number of compounds not exceeding 7.8 %. It was therefore conservatively assumed that cyperamide was formed at a maximum 7.8 % in water-sediment systems).
Application rate	Crop: Winter Oilseed Rape Number of applications: 2 Interval (d): 90 Application rate(s): 10 g a.s./ha Depth of water body: 30 cm Application window: Oct-Feb
	Crop: Maize Number of applications: 1 Interval (d): n/a Application rate(s): 35 g a.s./ha Depth of water body: 30 cm Application window: June-Sept

	Crop: Winter cereals Number of applications: 2 Interval (d): 90 Application rate(s): 1 x 15 g a.s./ha + 1 x 20 g a.s./ha. Depth of water body: 30 cm Application window: Oct-Feb
Main routes of entry	Spray drift

Crop	Step	Region	Compartment	Max PEC PBA	Max PEC CPA	Max PEC cyperamide
Winter Oilseed Rape	Step 1	N EU	Water [µg/L]	0.29	0.97	0.08
			Sediment [µg /kg]	0.19	0.11	16.55
		S EU	Water [µg/L]	0.29	0.97	0.08
			Sediment [µg /kg]	0.19	0.11	16.55
	Step 2	N EU	Water [µg/L]	0.06	0.13	0.02
			Sediment [µg /kg]	0.04	0.02	5.04
		S EU	Water [µg/L]	0.05	0.11	0.02
			Sediment [µg /kg]	0.03	0.01	4.05
Maize	Step 1	N EU	Water [µg/L]	1.01	1.7	0.13
			Sediment [µg /kg]	0.66	0.20	28.96
		S EU	Water [µg/L]	1.01	1.7	0.13
			Sediment [µg /kg]	0.66	0.20	28.96
	Step 2	N EU	Water [µg/L]	0.24	0.54	0.04
			Sediment [mg/kg]	0.17	0.07	11.05
		S EU	Water [µg/L]	0.21	0.45	0.03
			Sediment [mg/kg]	0.14	0.06	8.87
Winter Wheat	Step 1	N EU	Water [µg/L]	1.01	1.7	0.13
			Sediment [mg/kg]	0.66	0.20	28.96
		S EU	Water [µg/L]	1.01	1.7	0.13
			Sediment [mg/kg]	0.66	0.20	28.96
	Step 2	N EU	Water [µg/L]	0.24	0.54	0.03
			Sediment [mg/kg]	0.17	0.07	4.53
		S EU	Water [µg/L]	0.21	0.45	0.03
			Sediment [mg/kg]	0.14	0.06	6.70

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS models PEARL and PELMO, with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: PEARL (v 3.3.3) PELMO (v .3.3.2) Scenarios: Châteaudun, Hamburg, Jokionen, Kremsmunster, Okehampton, Piacenza, Porto, Sevilla, Thiva. Crop: Maize, Winter Oilseed Rape, Winter cereals <u>Parent</u> Geometric mean parent DT_{50lab} 8.42 d (fast phase) and 126 d (slow phase) normalisation to pF2, 20 °C). K_{FOC}: parent, arithmetic mean, 130031 ml/g, $^1/_n$= 0.99. <u>Metabolites:</u> **PBA** geomean DT_{50}lab, 4.49 d, normalisation to pF2, 20°C). $K_F$oc: PBA, arithmetic mean, 69.8 ml/g, $^1/_n$= 0.87 Formation fraction = 1 **CPA** geomean DT_{50}lab, 8.42 d, normalisation to pF2, 20°C). $K_F$oc: CPA, arithmetic mean, 12.4 ml/g, $^1/_n$= 0.70 Formation fraction = 1 **Cyperamide** geomean DT_{50}lab, 10 000 d). $K_F$oc: Cyperamide, 27058 ml/g, $^1/_n$= 0.9* Formation fraction = 1 *When only QSAR estimate of adsorption is available, the consensus of Member State fate experts is that an assumption of a 1/n of 1 is appropriate. However, in this particular case, for the representative uses assessed, it is unlikely that this inconsistency will have an impact on the results of the groundwater exposure assessment for metabolite cyperamide.
Application rate	Application rate and number of applications: 2 x 10 g a.s./ha (Winter oilseed rape) 1 x 35 g a.s./ha (Maize) 1 x 15 g a.s./ha + 1 x 20 g a.s./ha (winter cereals) Time of application (month or season): Autumn and Spring (Winter oilseed rape) Late Spring or Summer (Maize) Autumn and Spring (Winter Cereals)

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

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			PBA	CPA	Cyperamide
PEARL /Oilseed Rape	Châteaudun	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001
PELMO/Oilseed Rape	Châteaudun	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			PBA	CPA	Cyperamide
PEARL /Maize	Châteaudun	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001
PELMO/ Maize	Châteaudun	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			PBA	CPA	Cyperamide
PEARL /Winter Cereals	Châteaudun	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001

PELMO/Winter Cereals	Châteaudun	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001

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

Direct photolysis in air ‡	Not studied - no data requested.
Quantum yield of direct phototransformation	Not calculated.
Photochemical oxidative degradation in air ‡	DT_{50} of 0.499 days derived by the Atkinson model (version 1.88). OH (12 h) concentration assumed = 1.5 x 10^6/cm^3
Volatilisation ‡	from plant surfaces: not studied
	from soil surfaces: not studied
Metabolites	Not available

Method of calculation	Expert judgement, based on vapour pressure and dimensionless Henry's Law Constant.

$PEC_{(a)}$ Maximum concentration	negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which a groundwater exposure assessment was triggered	**Soil** Provisionally* beta-cypermethrin (sum of isomers), PBA, CPA, cyperamide **Surface water** Provisionally* beta-cypermethrin (sum of isomers), PBA, CPA, cyperamide **Sediment** Provisionally* beta-cypermethrin (sum of isomers), PBA, CPA, cyperamide **Ground water** Provisionally* beta-cypermethrin (sum of isomers), PBA, CPA, cyperamide **Air** beta-cypermethrin (sum of isomers) * a data gap was identified for satisfactory information to address the route and potential transformation product(s) formation of the cyclopropyl ring moiety of beta-cypermethrin in soil under illuminated conditions.

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

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

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

Candidate for R53

Ectoxicology

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, *Collinus virginianus*	beta-cypermethrin	Acute‡	**>2000**	
Bobwhite quail, *Collinus virginianus*	beta-cypermethrin	Short-term	>1215	>5200
Mallard duck, (*Anas platyrhynchus*)	beta-cypermethrin	Short-term	>1151	>5200
Bobwhite quail, *Collinus virginianus*	beta-cypermethrin	Long-term‡	**13.1**	400
Mammals				
Rat female	Technical a.s. (97.8 %)	Acute‡	93	
Rat m / f	'Beta-cypermethrin 10EC'	Acute	734 / 652 Geomean = 692	
Dog	Beta-cypermethrin (97.6 %)	Long-term (1 year) ‡	0.3	
Rat & rabbit	Beta-cypermethrin (97.6 %)	Long-term (2 gen) ‡	30	
Additional higher tier studies				
None				

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

Maize at 35 g a.s./ha

Growth stage	Indicator or focal species	Time scale	DDD	TER	Annex VI Trigger
Screening Step (Birds)					
All	Omnivorous bird	Acute	5.558	>359.8	10
All	Omnivorous bird	Reproductive	1.202	10.90	5
Higher tier refinement (Birds)					
Not required					
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	4.774	19.6	10
All	Small herbivorous mammal	Reproductive	1.34	0.224	5
Tier 1 (Mammals)					
BBCH 10-19	Small insectivorous mammal "shrew"	Reproductive	0.07791	385.06	5
BBCH 10-29	Small herbivorous mammal "vole	Reproductive	1.341165	22.37	5
BBCH 10-29	Small omnivorous mammal "mouse"	Reproductive	0.14469	207.34	5
BBCH >20	Small insectivorous mammal "shrew"	Reproductive	0.035245	851.18	5
BBCH 30-39	Small herbivorous mammal "vole	Reproductive	0.669655	44.80	5
BBCH 30-39	Small omnivorous mammal "mouse"	Reproductive	0.072345	414.68	5
BBCH >40	Small herbivorous mammal "vole"	Reproductive	0.335755	89.35	5
BBCH >40	Small omnivorous mammal "mouse"	Reproductive	0.035245	851.18	5

Winter oilseed rape at 10 g a.s./ha

Growth stage	Indicator or focal species	Time scale	DDD	TER	Annex VI Trigger
Screening Step (Birds)					
See assessment for maize.					
Higher tier refinement (Birds)					
Not required					
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	2.368	39.5	10
All	Small herbivorous mammal	Reproductive	0.512	0.586	5
Tier 1 (Mammals)					
All season	Large herbivorous mammal "lagomorph"	Reproductive	0.07579	395.83	5
BBCH 10-19	Small insectivorous mammal "shrew"	Reproductive	0.02226	1347.71	5
BBCH 10-29	Small omnivorous mammal "mouse"	Reproductive	0.04134	725.69	5
BBCH >20	Small insectivorous mammal "shrew"	Reproductive	0.01007	2979.15	5
BBCH 30-39	Small omnivorous mammal "mouse"	Reproductive	0.01219	2461.03	5
BBCH >40	Small herbivorous mammal "vole"	Reproductive	0.09593	312.73	5
BBCH >40	Small omnivorous mammal "mouse"	Reproductive	0.01007	2979.15	5

Cereals at 15 or 20 g a.s./ha (BBCH <40 at 15 g a.s./ha and BBCH >40 at 20 g a.s./ha)

Growth stage	Indicator or focal species	Time scale	DDD	TER	Annex VI Trigger
Screening Step (Birds)					
See assessment for maize.					
Higher tier refinement (Birds)					
Not required					
Screening Step (Mammals)					
See assessment for oilseed rape					
Tier 1 (Mammals)					
BBCH 10-19	Small insectivorous mammal "shrew"	Reproductive	0.03339	898.47	5
Early (shoots)	Large herbivorous mammal "lagomorph"	Reproductive	0.177285	169.22	5
BBCH 10-29	Small omnivorous mammal "mouse"	Reproductive	0.06201	483.79	5
BBCH > 20	Small insectivorous mammal "shrew"	Reproductive	0.015105	1986.10	5
BBCH > 40	Small herbivorous mammal "vole"	Reproductive	0.23002	130.42	5
BBCH > 40	Small omnivorous mammal "mouse"	Reproductive	0.02438	1230.52	5

A low risk to birds and mammals was concluded also from the consumption of contaminated water and from secondary poisoning for all representative uses.

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (µg /L)
Laboratory tests ‡				
Fish				
Rainbow trout *(Oncorhynchus mykiss)*	a.s.	96 hr (flow-through)	Mortality, LC_{50} ‡	**0.39** [mm]
Rainbow trout *(Oncorhynchus mykiss)*	a.s.	96 hr (static + sediment)	Mortality, LC_{50}	5.5[stock sol] 2.24[im] 0.87[mm 2] 0.34[96hrm]
Bluegill sunfish *(Lepomis macrochirus)*	a.s.	96 hr (flow-through)	Mortality, LC_{50}	1.2 [mm]
Sheepshead minnow *(Cyprinodon variegates)*	a.s.	96 hr (flow-through)	Mortality, LC_{50}	2.4 [mm]
Fathead minnow *(Pimephales promelas)*	a.s.	34 d ELS (flow-through)	NOEC ‡	**0.37**[mm]
Rainbow trout *(Oncorhynchus mykiss)*	Preparation	96 hr (flow-through)	Mortality, LC_{50}	79 µg product/L [nom] 7.9 µg a.s./L
Rainbow trout *(Oncorhynchus mykiss)*	PBA	96 hr (semi static)	Mortality, LC_{50}	**>100000** [nom]
Rainbow trout *(Oncorhynchus mykiss)*	CPA	96 hr (static)	Mortality, LC_{50}	**>100000** [nom]
Aquatic invertebrates				
Daphnia magna	a.s.	48 h (static)	Mortality, EC_{50}	0.42 [mm]
Mysidopsis bahia	a.s.	96 hr (flow-through)	Mortality, LC_{50} ‡	**0.0059** [mm]
Mysidopsis bahia	a.s.	28 d (flow-through)	Reproduction, NOEC ‡	**0.0015** [mm]
Daphnia magna	Preparation	48 h (static)	Mortality, EC_{50}	3.9 µg product/L [im] 0.39 µg a.s./L
Sediment dwelling organisms				
Chironomus riparius	a.s.	28 d (static)	NOEC ‡	**0.06** [im]
Algae				
Pseudokirchneriella subcapitata	a.s.	72 h (static)	E_bC_{50} ‡ E_rC_{50} ‡	**>53** [im] >53 [im]
Pseudokirchneriella subcapitata	Preparation	72 h (static)	E_yC_{50} E_rC_{50}	8.4 µg product/L [nom] 0.84 µg a.s./L 19 µg product/L [nom] 1.9 µg a.s./L
Microcosm or mesocosm tests				
NOEC <0.055 µg a.s./L – effects were seen at all rates tested. NOEAEC = 0.13 µg a.s./L based on recovery within 8 weeks. The mesocosm contained zooplankton, but not many sensitive macro-invertebrates.				

[1] indicate whether based on nominal ([nom]) or mean measured concentrations ([mm]). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

[mm] = mean measured

[nom] = nominal

[stock sol] = mean measured stock solution

[im] = initial measured

[96hrm] = 96 hour measured

[2] The LC_{50} for rainbow trout of 0.87 µg a.s./L is a surrogate value as nominal values were used to calculate the LC_{50} instead of measured values.

Figures in **bold** are used in the risk assessment

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

FOCUS Step 1

Winter oilseed rape at 10 g a.s./ha

Test substance	Organism	Toxicity end point (µg/L)	Time scale	PEC_i (µg/L)	PEC_{twa}	TER	Annex VI Trigger
a.s.	Fish	0.39	Acute	0.11		**3.545**	100
a.s.	Fish	0.37	Chronic	0.11		**3.364**	10
a.s.	Aquatic invertebrates	0.0059	Acute	0.11		**0.054**	100
a.s.	Aquatic invertebrates	0.0015	Chronic	0.11		**0.014**	10
a.s.	Sediment-dwelling[1] organisms	0.06	Chronic	0.11		**0.545**	10
a.s.	Algae	53	Chronic	0.11		481.818	10
Metabolite PBA	Fish	>100000	Acute	1.01[2]		>99010	100
Metabolite CPA	Fish	>100000	Acute	1.7[2]		>58824	100

[1]Spiked water study, so PECsw used for the risk assessment
[2]For the metabolite PEC_i used is the highest from all the crops.
Figures in **bold** are below the trigger value

Maize at 35 g a.s./ha

Test substance	Organism	Toxicity end point (µg/L)	Time scale	PEC_i (µg/L)	PEC_{twa}	TER	Annex VI Trigger
a.s.	Fish	0.39	Acute	0.39		**1.000**	100
a.s.	Fish	0.37	Chronic	0.39		**0.949**	10
a.s.	Aquatic invertebrates	0.0059	Acute	0.39		**0.015**	100
a.s.	Aquatic invertebrates	0.0015	Chronic	0.39		**0.004**	10
a.s.	Sediment-dwelling[1] organisms	0.06	Chronic	0.39		**0.154**	10
a.s.	Algae	53	Chronic	0.39		135.897	10
Metabolite PBA	Fish	>100000	Acute	1.01[2]		>99010	100
Metabolite CPA	Fish	>100000	Acute	1.7[2]		>58824	100

[1]Spiked water study, so PECsw used for the risk assessment
[2]For the metabolite PEC_i used is the highest from all the crops.
Figures in **bold** are below the trigger value

Cereals at 20 g a.s./ha

Test substance	Organism	Toxicity end point (µg/L)	Time scale	PEC_i (µg/L)	PEC_{twa}	TER	Annex VI Trigger
a.s.	Fish	0.39	Acute	0.39		**1.000**	100
a.s.	Fish	0.37	Chronic	0.39		**0.949**	10
a.s.	Aquatic invertebrates	0.0059	Acute	0.39		**0.015**	100
a.s.	Aquatic invertebrates	0.0015	Chronic	0.39		**0.004**	10
a.s.	Sediment-dwelling[1] organisms	0.06	Chronic	0.39		**0.154**	10
a.s.	Algae	53	Chronic	0.39		135.897	10
Metabolite PBA	Fish	>100000	Acute	1.01[2]		>99010	100
Metabolite CPA	Fish	>100000	Acute	1.7[2]		>58824	100

[1]Spiked water study, so PECsw used for the risk assessment
[2]For the metabolite PEC_i used is the highest from all the crops.
Figures in **bold** are below the trigger value

FOCUS Step 2

Winter oilseed rape at 10 g a.s./ha

Test substance	N/S	Organism	Toxicity end point (µg/L)	Time scale	PECsw (µg/L)	TER	Annex VI Trigger
a.s.	N+S	Fish	0.39	Acute	0.09	**4.333**	100
a.s.	N+S	Fish	0.37	Chronic	0.09	**4.111**	10
a.s.	N+S	Aquatic invertebrates	0.0059	Acute	0.09	**0.066**	100
a.s.	N+S	Aquatic invertebrates	0.0015	Chronic	0.09	**0.017**	10
a.s.	N+S	Sediment-dwelling[1] organisms	0.06	Chronic	0.09	**0.667**	10

[1]Spiked water study, so PECsw used for the risk assessment
Figures in **bold** are below the trigger value

Maize at 35 g a.s./ha

Test substance	N/S	Organism	Toxicity end point (µg/L)	Time scale	PECsw (µg/L)	TER	Annex VI Trigger
a.s.	N+S	Fish	0.39	Acute	0.32	**1.219**	100
a.s.	N+S	Fish	0.37	Chronic	0.32	**1.156**	10
a.s.	N+S	Aquatic invertebrates	0.0059	Acute	0.32	**0.0018**	100
a.s.	N+S	Aquatic invertebrates	0.0015	Chronic	0.32	**0.005**	10
a.s.	N+S	Sediment-dwelling[1] organisms	0.06	Chronic	0.32	**0.188**	10

[1]Spiked water study, so PECsw used for the risk assessment
Figures in **bold** are below the trigger value

Cereals at 20 g a.s./ha

Test substance	N/S	Organism	Toxicity end point (µg/L)	Time scale	PECsw (µg/L)	TER	Annex VI Trigger
a.s.	N+S	Fish	0.39	Acute	0.32	**1.219**	100
a.s.	N+S	Fish	0.37	Chronic	0.32	**1.156**	10
a.s.	N+S	Aquatic invertebrates	0.0059	Acute	0.32	**0.018**	100
a.s.	N+S	Aquatic invertebrates	0.0015	Chronic	0.32	**0.005**	10
a.s.	N+S	Sediment-dwelling[1]	0.06	Chronic	0.32	**0.188**	10

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

[1]Spiked water study, so PECsw used for the risk assessment
Figures in **bold** are below the trigger value

Refined aquatic risk assessment using higher tier FOCUS modelling

FOCUS Step 3

Winter oilseed rape at 10 g a.s./ha

Test sub-stance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PECsw (µg/L)	TER	Annex VI trigger
a.s.	D2	Ditch	Fish	Acute	0.39	0.06	**6.5**	100
a.s.	D2	Stream	Fish	Acute	0.39	0.05	**7.8**	100
a.s.	D3	Ditch	Fish	Acute	0.39	0.06	**6.5**	100
a.s.	D4	Pond	Fish	Acute	0.39	0.002	195	100
a.s.	D4	Stream	Fish	Acute	0.39	0.05	**7.8**	100
a.s.	D5	Pond	Fish	Acute	0.39	0.002	195	100
a.s.	D5	Stream	Fish	Acute	0.39	0.053	**7.36**	100
a.s.	R1	Pond	Fish	Acute	0.39	0.002	195	100
a.s.	R1	Stream	Fish	Acute	0.39	0.037	**10.54**	100
a.s.	R3	Stream	Fish	Acute	0.39	0.053	**7.36**	100
a.s.	D2	Ditch	Fish	Chronic	0.37	0.06	**6.17**	10
a.s.	D2	Stream	Fish	Chronic	0.37	0.05	**7.40**	10
a.s.	D3	Ditch	Fish	Chronic	0.37	0.06	**6.17**	10
a.s.	D4	Pond	Fish	Chronic	0.37	0.002	185	10
a.s.	D4	Stream	Fish	Chronic	0.37	0.05	**7.40**	10
a.s.	D5	Pond	Fish	Chronic	0.37	0.002	185	10
a.s.	D5	Stream	Fish	Chronic	0.37	0.053	**6.98**	10
a.s.	R1	Pond	Fish	Chronic	0.37	0.002	185	10
a.s.	R1	Stream	Fish	Chronic	0.37	0.037	10.0	10
a.s.	R3	Stream	Fish	Chronic	0.37	0.053	**6.98**	10
a.s.	D2	Ditch	Aq inverts	Acute	0.0059	0.06	**0.098**	100
a.s.	D2	Stream	Aq inverts	Acute	0.0059	0.05	**0.118**	100
a.s.	D3	Ditch	Aq inverts	Acute	0.0059	0.06	**0.098**	100
a.s.	D4	Pond	Aq inverts	Acute	0.0059	0.002	**2.950**	100
a.s.	D4	Stream	Aq inverts	Acute	0.0059	0.05	**0.118**	100
a.s.	D5	Pond	Aq inverts	Acute	0.0059	0.002	**2.950**	100
a.s.	D5	Stream	Aq inverts	Acute	0.0059	0.053	**0.111**	100
a.s.	R1	Pond	Aq inverts	Acute	0.0059	0.002	**2.950**	100
a.s.	R1	Stream	Aq inverts	Acute	0.0059	0.037	**0.159**	100
a.s.	R3	Stream	Aq inverts	Acute	0.0059	0.053	**0.111**	100
a.s.	D2	Ditch	Aq inverts	Chronic	0.0015	0.06	**0.025**	10
a.s.	D2	Stream	Aq inverts	Chronic	0.0015	0.05	**0.030**	10
a.s.	D3	Ditch	Aq inverts	Chronic	0.0015	0.06	**0.025**	10
a.s.	D4	Pond	Aq inverts	Chronic	0.0015	0.002	**0.750**	10
a.s.	D4	Stream	Aq inverts	Chronic	0.0015	0.05	**0.030**	10
a.s.	D5	Pond	Aq inverts	Chronic	0.0015	0.002	**0.750**	10
a.s.	D5	Stream	Aq inverts	Chronic	0.0015	0.053	**0.028**	10
a.s.	R1	Pond	Aq inverts	Chronic	0.0015	0.002	**0.750**	10
a.s.	R1	Stream	Aq inverts	Chronic	0.0015	0.037	**0.041**	10
a.s.	R3	Stream	Aq inverts	Chronic	0.0015	0.053	**0.028**	10
a.s.	D2	Ditch	Sed inverts	Chronic	0.06	0.06	**1.000**	10
a.s.	D2	Stream	Sed inverts	Chronic	0.06	0.05	**1.200**	10
a.s.	D3	Ditch	Sed inverts	Chronic	0.06	0.06	**1.000**	10
a.s.	D4	Pond	Sed inverts	Chronic	0.06	0.002	30.0	10

Test sub-stance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PECsw (µg/L)	TER	Annex VI trigger
a.s.	D4	Stream	Sed inverts	Chronic	0.06	0.05	**1.200**	10
a.s.	D5	Pond	Sed inverts	Chronic	0.06	0.002	30.0	10
a.s.	D5	Stream	Sed inverts	Chronic	0.06	0.053	**1.132**	10
a.s.	R1	Pond	Sed inverts	Chronic	0.06	0.002	30.0	10
a.s.	R1	Stream	Sed inverts	Chronic	0.06	0.037	**1.622**	10
a.s.	R3	Stream	Sed inverts	Chronic	0.06	0.053	**1.132**	10

Figures in **bold** are below the trigger value

Maize at 35 g a.s./ha

Test sub-stance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PECsw (µg/L)	TER	Annex VI trigger
a.s.	D3	Ditch	Fish	Acute	0.39	0.17	**2.29**	100
a.s.	D4	Pond	Fish	Acute	0.39	0.007	**55.71**	100
a.s.	D4	Stream	Fish	Acute	0.39	0.14	**2.79**	100
a.s.	D5	Pond	Fish	Acute	0.39	0.007	**55.71**	100
a.s.	D5	Stream	Fish	Acute	0.39	0.15	**2.6**	100
a.s.	D6	Ditch	Fish	Acute	0.39	0.16	**2.44**	100
a.s.	R1	Pond	Fish	Acute	0.39	0.007	**55.71**	100
a.s.	R1	Stream	Fish	Acute	0.39	0.12	**3.25**	100
a.s.	R2	Stream	Fish	Acute	0.39	0.15	**2.6**	100
a.s.	R3	Stream	Fish	Acute	0.39	0.16	**2.44**	100
a.s.	R4	Stream	Fish	Acute	0.39	0.12	**3.25**	100
a.s.	D3	Ditch	Fish	Chronic	0.37	0.17	**2.18**	10
a.s.	D4	Pond	Fish	Chronic	0.37	0.007	52.86	10
a.s.	D4	Stream	Fish	Chronic	0.37	0.14	**2.64**	10
a.s.	D5	Pond	Fish	Chronic	0.37	0.007	52.86	10
a.s.	D5	Stream	Fish	Chronic	0.37	0.15	**2.47**	10
a.s.	D6	Ditch	Fish	Chronic	0.37	0.16	**2.31**	10
a.s.	R1	Pond	Fish	Chronic	0.37	0.007	52.86	10
a.s.	R1	Stream	Fish	Chronic	0.37	0.12	**3.08**	10
a.s.	R2	Stream	Fish	Chronic	0.37	0.15	**2.47**	10
a.s.	R3	Stream	Fish	Chronic	0.37	0.16	**2.31**	10
a.s.	R4	Stream	Fish	Chronic	0.37	0.12	**3.08**	10
a.s.	D3	Ditch	Aq inverts	Acute	0.0059	0.17	**0.035**	100
a.s.	D4	Pond	Aq inverts	Acute	0.0059	0.007	**0.843**	100
a.s.	D4	Stream	Aq inverts	Acute	0.0059	0.14	**0.042**	100
a.s.	D5	Pond	Aq inverts	Acute	0.0059	0.007	**0.843**	100
a.s.	D5	Stream	Aq inverts	Acute	0.0059	0.15	**0.039**	100
a.s.	D6	Ditch	Aq inverts	Acute	0.0059	0.16	**0.037**	100
a.s.	R1	Pond	Aq inverts	Acute	0.0059	0.007	**0.843**	100
a.s.	R1	Stream	Aq inverts	Acute	0.0059	0.12	**0.049**	100
a.s.	R2	Stream	Aq inverts	Acute	0.0059	0.15	**0.039**	100
a.s.	R3	Stream	Aq inverts	Acute	0.0059	0.16	**0.037**	100
a.s.	R4	Stream	Aq inverts	Acute	0.0059	0.12	**0.049**	100
a.s.	D3	Ditch	Aq inverts	Chronic	0.0015	0.17	**0.009**	10
a.s.	D4	Pond	Aq inverts	Chronic	0.0015	0.007	**0.214**	10
a.s.	D4	Stream	Aq inverts	Chronic	0.0015	0.14	**0.011**	10
a.s.	D5	Pond	Aq inverts	Chronic	0.0015	0.007	**0.214**	10
a.s.	D5	Stream	Aq inverts	Chronic	0.0015	0.15	**0.010**	10
a.s.	D6	Ditch	Aq inverts	Chronic	0.0015	0.16	**0.009**	10
a.s.	R1	Pond	Aq inverts	Chronic	0.0015	0.007	**0.214**	10
a.s.	R1	Stream	Aq inverts	Chronic	0.0015	0.12	**0.013**	10
a.s.	R2	Stream	Aq inverts	Chronic	0.0015	0.15	**0.010**	10
a.s.	R3	Stream	Aq inverts	Chronic	0.0015	0.16	**0.009**	10

Test sub-stance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PECsw (µg/L)	TER	Annex VI trigger
a.s.	R4	Stream	Aq inverts	Chronic	0.0015	0.12	**0.013**	10
a.s.	D3	Ditch	Sed inverts	Chronic	0.06	0.17	**0.353**	10
a.s.	D4	Pond	Sed inverts	Chronic	0.06	0.007	**8.571**	10
a.s.	D4	Stream	Sed inverts	Chronic	0.06	0.14	**0.429**	10
a.s.	D5	Pond	Sed inverts	Chronic	0.06	0.007	**8.571**	10
a.s.	D5	Stream	Sed inverts	Chronic	0.06	0.15	**0.400**	10
a.s.	D6	Ditch	Sed inverts	Chronic	0.06	0.16	**0.375**	10
a.s.	R1	Pond	Sed inverts	Chronic	0.06	0.007	**8.571**	10
a.s.	R1	Stream	Sed inverts	Chronic	0.06	0.12	**0.500**	10
a.s.	R2	Stream	Sed inverts	Chronic	0.06	0.15	**0.400**	10
a.s.	R3	Stream	Sed inverts	Chronic	0.06	0.16	**0.375**	10
a.s.	R4	Stream	Sed inverts	Chronic	0.06	0.12	**0.500**	10

Figures in **bold** are below the trigger value

Cereals at 20 g a.s./ha

Test sub-stance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PECsw (µg/L)	TER	Annex VI trigger
a.s.	D1	Ditch	Fish	Acute	0.39	0.11	**3.55**	100
a.s.	D1	Stream	Fish	Acute	0.39	0.09	**4.33**	100
a.s.	D2	Ditch	Fish	Acute	0.39	0.12	**3.25**	100
a.s.	D2	Stream	Fish	Acute	0.39	0.096	**4.06**	100
a.s.	D3	Ditch	Fish	Acute	0.39	0.11	**3.55**	100
a.s.	D4	Pond	Fish	Acute	0.39	0.004	**97.50**	100
a.s.	D4	Stream	Fish	Acute	0.39	0.084	**4.64**	100
a.s.	D5	Pond	Fish	Acute	0.39	0.004	**97.50**	100
a.s.	D5	Stream	Fish	Acute	0.39	0.09	**4.33**	100
a.s.	D6	Ditch	Fish	Acute	0.39	0.112	**3.48**	100
a.s.	R1	Pond	Fish	Acute	0.39	0.004	**97.50**	100
a.s.	R1	Stream	Fish	Acute	0.39	0.075	**5.20**	100
a.s.	R3	Stream	Fish	Acute	0.39	0.11	**3.55**	100
a.s.	R4	Stream	Fish	Acute	0.39	0.074	**5.27**	100
a.s.	D1	Ditch	Fish	Chronic	0.37	0.11	**3.36**	10
a.s.	D1	Stream	Fish	Chronic	0.37	0.09	**4.11**	10
a.s.	D2	Ditch	Fish	Chronic	0.37	0.12	**3.08**	10
a.s.	D2	Stream	Fish	Chronic	0.37	0.096	**3.85**	10
a.s.	D3	Ditch	Fish	Chronic	0.37	0.11	**3.36**	10
a.s.	D4	Pond	Fish	Chronic	0.37	0.004	92.50	10
a.s.	D4	Stream	Fish	Chronic	0.37	0.084	**4.40**	10
a.s.	D5	Pond	Fish	Chronic	0.37	0.004	92.50	10
a.s.	D5	Stream	Fish	Chronic	0.37	0.09	**4.11**	10
a.s.	D6	Ditch	Fish	Chronic	0.37	0.112	**3.30**	10
a.s.	R1	Pond	Fish	Chronic	0.37	0.004	92.50	10
a.s.	R1	Stream	Fish	Chronic	0.37	0.075	**4.93**	10
a.s.	R3	Stream	Fish	Chronic	0.37	0.11	**3.36**	10
a.s.	R4	Stream	Fish	Chronic	0.37	0.074	**5.00**	10
a.s.	D1	Ditch	Aq inverts	Acute	0.0059	0.11	**0.054**	100
a.s.	D1	Stream	Aq inverts	Acute	0.0059	0.09	**0.066**	100
a.s.	D2	Ditch	Aq inverts	Acute	0.0059	0.12	**0.049**	100
a.s.	D2	Stream	Aq inverts	Acute	0.0059	0.096	**0.061**	100
a.s.	D3	Ditch	Aq inverts	Acute	0.0059	0.11	**0.054**	100
a.s.	D4	Pond	Aq inverts	Acute	0.0059	0.004	**1.475**	100
a.s.	D4	Stream	Aq inverts	Acute	0.0059	0.084	**0.070**	100
a.s.	D5	Pond	Aq inverts	Acute	0.0059	0.004	**1.475**	100
a.s.	D5	Stream	Aq inverts	Acute	0.0059	0.09	**0.066**	100

Test sub-stance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PECsw (µg/L)	TER	Annex VI trigger
a.s.	D6	Ditch	Aq inverts	Acute	0.0059	0.112	**0.053**	100
a.s.	R1	Pond	Aq inverts	Acute	0.0059	0.004	**1.475**	100
a.s.	R1	Stream	Aq inverts	Acute	0.0059	0.075	**0.079**	100
a.s.	R3	Stream	Aq inverts	Acute	0.0059	0.11	**0.054**	100
a.s.	R4	Stream	Aq inverts	Acute	0.0059	0.074	**0.080**	100
a.s.	D1	Ditch	Aq inverts	Chronic	0.0015	0.11	**0.014**	10
a.s.	D1	Stream	Aq inverts	Chronic	0.0015	0.09	**0.017**	10
a.s.	D2	Ditch	Aq inverts	Chronic	0.0015	0.12	**0.013**	10
a.s.	D2	Stream	Aq inverts	Chronic	0.0015	0.096	**0.016**	10
a.s.	D3	Ditch	Aq inverts	Chronic	0.0015	0.11	**0.014**	10
a.s.	D4	Pond	Aq inverts	Chronic	0.0015	0.004	**0.375**	10
a.s.	D4	Stream	Aq inverts	Chronic	0.0015	0.084	**0.018**	10
a.s.	D5	Pond	Aq inverts	Chronic	0.0015	0.004	**0.375**	10
a.s.	D5	Stream	Aq inverts	Chronic	0.0015	0.09	**0.017**	10
a.s.	D6	Ditch	Aq inverts	Chronic	0.0015	0.112	**0.013**	10
a.s.	R1	Pond	Aq inverts	Chronic	0.0015	0.004	**0.375**	10
a.s.	R1	Stream	Aq inverts	Chronic	0.0015	0.075	**0.020**	10
a.s.	R3	Stream	Aq inverts	Chronic	0.0015	0.11	**0.014**	10
a.s.	R4	Stream	Aq inverts	Chronic	0.0015	0.074	**0.020**	10
a.s.	D1	Ditch	Sed inverts	Chronic	0.06	0.11	**0.545**	10
a.s.	D1	Stream	Sed inverts	Chronic	0.06	0.09	**0.667**	10
a.s.	D2	Ditch	Sed inverts	Chronic	0.06	0.12	**0.500**	10
a.s.	D2	Stream	Sed inverts	Chronic	0.06	0.096	**0.625**	10
a.s.	D3	Ditch	Sed inverts	Chronic	0.06	0.11	**0.545**	10
a.s.	D4	Pond	Sed inverts	Chronic	0.06	0.004	15.0	10
a.s.	D4	Stream	Sed inverts	Chronic	0.06	0.084	**0.714**	10
a.s.	D5	Pond	Sed inverts	Chronic	0.06	0.004	15.0	10
a.s.	D5	Stream	Sed inverts	Chronic	0.06	0.09	**0.667**	10
a.s.	D6	Ditch	Sed inverts	Chronic	0.06	0.112	**0.536**	10
a.s.	R1	Pond	Sed inverts	Chronic	0.06	0.004	15.0	10
a.s.	R1	Stream	Sed inverts	Chronic	0.06	0.075	**0.800**	10
a.s.	R3	Stream	Sed inverts	Chronic	0.06	0.11	**0.545**	10
a.s.	R4	Stream	Sed inverts	Chronic	0.06	0.074	**0.811**	10

Figures in **bold** are below the trigger value

FOCUS Step 4

Winter oilseed rape at 10 g a.s./ha

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	Buffer zone distance	PECsw (µg/L)	TER	Annex VI trigger
D2	Ditch	Fish[1]	Acute	0.87	20m	0.004	217.5	100
D2	Stream	Fish[1]	Acute	0.87	20m	0.005	174.0	100
D3	Ditch	Fish[1]	Acute	0.87	20m	0.004	217.5	100
D4	Pond	Fish[1]	Acute	0.87	20m	0.001	870	100
D4	Stream	Fish[1]	Acute	0.87	20m	0.005	174.0	100
D5	Pond	Fish[1]	Acute	0.87	20m	0.001	870	100
D5	Stream	Fish[1]	Acute	0.87	20m	0.005	174.0	100
R1	Pond	Fish[1]	Acute	0.87	20m	0.001	870	100
R1	Stream	Fish[1]	Acute	0.87	20m	0.004	217.5	100
R3	Stream	Fish[1]	Acute	0.87	20m	0.005	174.0	100
D2	Ditch	Fish	Chronic	0.37	5m	0.016	23.13	10
D2	Stream	Fish	Chronic	0.37	5m	0.019	19.47	10
D3	Ditch	Fish	Chronic	0.37	5m	0.015	24.67	10
D4	Pond	Fish	Chronic	0.37	5m	0.002	185	10
D4	Stream	Fish	Chronic	0.37	5m	0.018	20.56	10
D5	Pond	Fish	Chronic	0.37	5m	0.002	185	10
D5	Stream	Fish	Chronic	0.37	5m	0.019	19.47	10
R1	Pond	Fish	Chronic	0.37	5m	0.002	185	10
R1	Stream	Fish	Chronic	0.37	5m	0.014	26.4	10
R3	Stream	Fish	Chronic	0.37	5m	0.019	19.47	10
D2	Ditch	Aq inverts	Acute	0.0059	20m	0.004	**1.475**	100
D2	Stream	Aq inverts	Acute	0.0059	20m	0.005	**1.180**	100
D3	Ditch	Aq inverts	Acute	0.0059	20m	0.004	**1.475**	100
D4	Pond	Aq inverts	Acute	0.0059	20m	0.001	**5.900**	100
D4	Stream	Aq inverts	Acute	0.0059	20m	0.005	**1.180**	100
D5	Pond	Aq inverts	Acute	0.0059	20m	0.001	**5.900**	100
D5	Stream	Aq inverts	Acute	0.0059	20m	0.005	**1.180**	100
R1	Pond	Aq inverts	Acute	0.0059	20m	0.001	**5.900**	100
R1	Stream	Aq inverts	Acute	0.0059	20m	0.004	**1.475**	100
R3	Stream	Aq inverts	Acute	0.0059	20m	0.005	**1.180**	100
D2	Ditch	Aq inverts	Chronic	0.0015	20m	0.004	**0.375**	10
D2	Stream	Aq inverts	Chronic	0.0015	20m	0.005	**0.300**	10
D3	Ditch	Aq inverts	Chronic	0.0015	20m	0.004	**0.375**	10
D4	Pond	Aq inverts	Chronic	0.0015	20m	0.001	**1.500**	10
D4	Stream	Aq inverts	Chronic	0.0015	20m	0.005	**0.300**	10
D5	Pond	Aq inverts	Chronic	0.0015	20m	0.001	**1.500**	10
D5	Stream	Aq inverts	Chronic	0.0015	20m	0.005	**0.300**	10
R1	Pond	Aq inverts	Chronic	0.0015	20m	0.001	**1.500**	10
R1	Stream	Aq inverts	Chronic	0.0015	20m	0.004	**0.375**	10
R3	Stream	Aq inverts	Chronic	0.0015	20m	0.005	**0.300**	10
D2	Ditch	Sed inverts	Chronic	0.06	20m	0.004	15.0	10
D2	Stream	Sed inverts	Chronic	0.06	20m	0.005	12.0	10
D3	Ditch	Sed inverts	Chronic	0.06	20m	0.004	15.0	10
D4	Pond	Sed inverts	Chronic	0.06	20m	0.001	60.0	10
D4	Stream	Sed inverts	Chronic	0.06	20m	0.005	12.0	10
D5	Pond	Sed inverts	Chronic	0.06	20m	0.001	60.0	10
D5	Stream	Sed inverts	Chronic	0.06	20m	0.005	12.0	10
R1	Pond	Sed inverts	Chronic	0.06	20m	0.001	60.0	10
R1	Stream	Sed inverts	Chronic	0.06	20m	0.004	15.0	10
R3	Stream	Sed inverts	Chronic	0.06	20m	0.005	12.0	10

[1] Refined fish toxicity endpoint (study with sediment)

Figures in **bold** are below the trigger value

Maize at 35 g a.s./ha

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	Buffer zone distance	PECsw (µg/L)	TER	Annex VI trigger
D3	Ditch	Fish[1]	Acute	0.87	20m	0.015	**58.00**	100
D4	Pond	Fish[1]	Acute	0.87	20m	0.003	290.00	100
D4	Stream	Fish[1]	Acute	0.87	20m	0.016	**54.38**	100
D5	Pond	Fish[1]	Acute	0.87	20m	0.003	290.00	100
D5	Stream	Fish[1]	Acute	0.87	20m	0.002	435.00	100
D6	Ditch	Fish[1]	Acute	0.87	20m	0.015	**58.00**	100
R1	Pond	Fish[1]	Acute	0.87	20m	0.003	290.00	100
R1	Stream	Fish[1]	Acute	0.87	20m	0.013	**66.92**	100
R2	Stream	Fish[1]	Acute	0.87	20m	0.018	**48.33**	100
R3	Stream	Fish[1]	Acute	0.87	20m	0.019	**45.79**	100
R4	Stream	Fish[1]	Acute	0.87	20m	0.013	**66.92**	100
D3	Ditch	Fish	Chronic	0.37	10m	0.029	12.76	10
D4	Pond	Fish	Chronic	0.37	10m	0.004	92.50	10
D4	Stream	Fish	Chronic	0.37	10m	0.032	11.56	10
D5	Pond	Fish	Chronic	0.37	10m	0.004	92.50	10
D5	Stream	Fish	Chronic	0.37	10m	0.034	10.88	10
D6	Ditch	Fish	Chronic	0.37	10m	0.028	13.21	10
R1	Pond	Fish	Chronic	0.37	10m	0.004	92.50	10
R1	Stream	Fish	Chronic	0.37	10m	0.026	14.23	10
R2	Stream	Fish	Chronic	0.37	10m	0.034	10.88	10
R3	Stream	Fish	Chronic	0.37	10m	0.036	10.28	10
R4	Stream	Fish	Chronic	0.37	10m	0.026	14.23	10
D3	Ditch	Aq inverts	Acute	0.0059	20m	0.015	**0.393**	100
D4	Pond	Aq inverts	Acute	0.0059	20m	0.003	**1.967**	100
D4	Stream	Aq inverts	Acute	0.0059	20m	0.016	**0.369**	100
D5	Pond	Aq inverts	Acute	0.0059	20m	0.003	**1.967**	100
D5	Stream	Aq inverts	Acute	0.0059	20m	0.002	**2.950**	100
D6	Ditch	Aq inverts	Acute	0.0059	20m	0.015	**0.393**	100
R1	Pond	Aq inverts	Acute	0.0059	20m	0.003	**1.967**	100
R1	Stream	Aq inverts	Acute	0.0059	20m	0.013	**0.454**	100
R2	Stream	Aq inverts	Acute	0.0059	20m	0.018	**0.328**	100
R3	Stream	Aq inverts	Acute	0.0059	20m	0.019	**0.311**	100
R4	Stream	Aq inverts	Acute	0.0059	20m	0.013	**0.454**	100
D3	Ditch	Aq inverts	Chronic	0.0015	20m	0.015	**0.100**	10
D4	Pond	Aq inverts	Chronic	0.0015	20m	0.003	**0.500**	10
D4	Stream	Aq inverts	Chronic	0.0015	20m	0.016	**0.094**	10
D5	Pond	Aq inverts	Chronic	0.0015	20m	0.003	**0.500**	10
D5	Stream	Aq inverts	Chronic	0.0015	20m	0.002	**0.750**	10
D6	Ditch	Aq inverts	Chronic	0.0015	20m	0.015	**0.100**	10
R1	Pond	Aq inverts	Chronic	0.0015	20m	0.003	**0.500**	10
R1	Stream	Aq inverts	Chronic	0.0015	20m	0.013	**0.115**	10
R2	Stream	Aq inverts	Chronic	0.0015	20m	0.018	**0.083**	10
R3	Stream	Aq inverts	Chronic	0.0015	20m	0.019	**0.079**	10
R4	Stream	Aq inverts	Chronic	0.0015	20m	0.013	**0.115**	10
D3	Ditch	Sed inverts	Chronic	0.06	20m	0.015	**4.0**	10
D4	Pond	Sed inverts	Chronic	0.06	20m	0.003	20.0	10
D4	Stream	Sed inverts	Chronic	0.06	20m	0.016	**3.750**	10
D5	Pond	Sed inverts	Chronic	0.06	20m	0.003	20.0	10
D5	Stream	Sed inverts	Chronic	0.06	20m	0.002	30.0	10
D6	Ditch	Sed inverts	Chronic	0.06	20m	0.015	**4.0**	10
R1	Pond	Sed inverts	Chronic	0.06	20m	0.003	20.0	10
R1	Stream	Sed inverts	Chronic	0.06	20m	0.013	**4.615**	10
R2	Stream	Sed inverts	Chronic	0.06	20m	0.018	**3.333**	10
R3	Stream	Sed inverts	Chronic	0.06	20m	0.019	**3.158**	10

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	Buffer zone distance	PECsw (µg/L)	TER	Annex VI trigger
R4	Stream	Sed inverts	Chronic	0.06	20m	0.013	**4.615**	10

[1] Refined fish toxicity endpoint (study with sediment)
Figures in **bold** are below the trigger value

Cereals at 20 g a.s./ha

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	Buffer zone distance	PECsw (µg/L)	TER	Annex VI trigger
D1	Ditch	Fish[1]	Acute	0.87	20m	0.009	**96.67**	100
D1	Stream	Fish[1]	Acute	0.87	20m	0.009	**96.67**	100
D2	Ditch	Fish[1]	Acute	0.87	20m	0.009	**96.67**	100
D2	Stream	Fish[1]	Acute	0.87	20m	0.01	**87.00**	100
D3	Ditch	Fish[1]	Acute	0.87	20m	0.009	**96.67**	100
D4	Pond	Fish[1]	Acute	0.87	20m	0.002	435.0	100
D4	Stream	Fish[1]	Acute	0.87	20m	0.009	**96.67**	100
D5	Pond	Fish[1]	Acute	0.87	20m	0.002	435.0	100
D5	Stream	Fish[1]	Acute	0.87	20m	0.009	**96.67**	100
D6	Ditch	Fish[1]	Acute	0.87	20m	0.008	108.75	100
R1	Pond	Fish[1]	Acute	0.87	20m	0.002	435.00	100
R1	Stream	Fish[1]	Acute	0.87	20m	0.008	108.75	100
R3	Stream	Fish[1]	Acute	0.87	20m	0.011	**79.09**	100
R4	Stream	Fish[1]	Acute	0.87	20m	0.008	108.75	100
D1	Ditch	Fish	Chronic	0.37	10m	0.016	23.13	10
D1	Stream	Fish	Chronic	0.37	10m	0.018	20.56	10
D2	Ditch	Fish	Chronic	0.37	10m	0.016	23.13	10
D2	Stream	Fish	Chronic	0.37	10m	0.018	20.56	10
D3	Ditch	Fish	Chronic	0.37	10m	0.016	23.13	10
D4	Pond	Fish	Chronic	0.37	10m	0.002	185.00	10
D4	Stream	Fish	Chronic	0.37	10m	0.016	23.13	10
D5	Pond	Fish	Chronic	0.37	10m	0.002	185.00	10
D5	Stream	Fish	Chronic	0.37	10m	0.018	20.56	10
D6	Ditch	Fish	Chronic	0.37	10m	0.016	23.13	10
R1	Pond	Fish	Chronic	0.37	10m	0.003	123.33	10
R1	Stream	Fish	Chronic	0.37	10m	0.014	26.43	10
R3	Stream	Fish	Chronic	0.37	10m	0.021	17.62	10
R4	Stream	Fish	Chronic	0.37	10m	0.008	26.43	10
D1	Ditch	Aq inverts	Acute	0.0059	20m	0.009	**0.656**	100
D1	Stream	Aq inverts	Acute	0.0059	20m	0.009	**0.656**	100
D2	Ditch	Aq inverts	Acute	0.0059	20m	0.009	**0.656**	100
D2	Stream	Aq inverts	Acute	0.0059	20m	0.01	**0.590**	100
D3	Ditch	Aq inverts	Acute	0.0059	20m	0.009	**0.656**	100
D4	Pond	Aq inverts	Acute	0.0059	20m	0.002	**2.950**	100
D4	Stream	Aq inverts	Acute	0.0059	20m	0.009	**0.656**	100
D5	Pond	Aq inverts	Acute	0.0059	20m	0.002	**2.950**	100
D5	Stream	Aq inverts	Acute	0.0059	20m	0.009	**0.656**	100
D6	Ditch	Aq inverts	Acute	0.0059	20m	0.008	**0.738**	100
R1	Pond	Aq inverts	Acute	0.0059	20m	0.002	**2.950**	100
R1	Stream	Aq inverts	Acute	0.0059	20m	0.008	**0.738**	100
R3	Stream	Aq inverts	Acute	0.0059	20m	0.011	**0.536**	100
R4	Stream	Aq inverts	Acute	0.0059	20m	0.008	**0.738**	100
D1	Ditch	Aq inverts	Chronic	0.0015	20m	0.009	**0.167**	10
D1	Stream	Aq inverts	Chronic	0.0015	20m	0.009	**0.167**	10
D2	Ditch	Aq inverts	Chronic	0.0015	20m	0.009	**0.167**	10
D2	Stream	Aq inverts	Chronic	0.0015	20m	0.01	**0.150**	10
D3	Ditch	Aq inverts	Chronic	0.0015	20m	0.009	**0.167**	10

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	Buffer zone distance	PECsw (µg/L)	TER	Annex VI trigger
D4	Pond	Aq inverts	Chronic	0.0015	20m	0.002	**0.750**	10
D4	Stream	Aq inverts	Chronic	0.0015	20m	0.009	**0.167**	10
D5	Pond	Aq inverts	Chronic	0.0015	20m	0.002	**0.750**	10
D5	Stream	Aq inverts	Chronic	0.0015	20m	0.009	**0.167**	10
D6	Ditch	Aq inverts	Chronic	0.0015	20m	0.008	**0.188**	10
R1	Pond	Aq inverts	Chronic	0.0015	20m	0.002	**0.750**	10
R1	Stream	Aq inverts	Chronic	0.0015	20m	0.008	**0.188**	10
R3	Stream	Aq inverts	Chronic	0.0015	20m	0.011	**0.136**	10
R4	Stream	Aq inverts	Chronic	0.0015	20m	0.008	**0.188**	10
D1	Ditch	Sed inverts	Chronic	0.06	20m	0.009	**6.667**	10
D1	Stream	Sed inverts	Chronic	0.06	20m	0.009	**6.667**	10
D2	Ditch	Sed inverts	Chronic	0.06	20m	0.009	**6.667**	10
D2	Stream	Sed inverts	Chronic	0.06	20m	0.01	**6.000**	10
D3	Ditch	Sed inverts	Chronic	0.06	20m	0.009	**6.667**	10
D4	Pond	Sed inverts	Chronic	0.06	20m	0.002	30.000	10
D4	Stream	Sed inverts	Chronic	0.06	20m	0.009	**6.667**	10
D5	Pond	Sed inverts	Chronic	0.06	20m	0.002	30.000	10
D5	Stream	Sed inverts	Chronic	0.06	20m	0.009	**6.667**	10
D6	Ditch	Sed inverts	Chronic	0.06	20m	0.008	**7.500**	10
R1	Pond	Sed inverts	Chronic	0.06	20m	0.002	30.000	10
R1	Stream	Sed inverts	Chronic	0.06	20m	0.008	**7.500**	10
R3	Stream	Sed inverts	Chronic	0.06	20m	0.011	**5.455**	10
R4	Stream	Sed inverts	Chronic	0.06	20m	0.008	**7.500**	10

[1] Refined fish toxicity endpoint (study with sediment)
Figures in **bold** are below the trigger value

Bioconcentration				
	Active substance	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$	5.8	-	-	-
Bioconcentration factor (BCF)[1] ‡	846[2]	-	-	-
Annex VI Trigger for the bioconcentration factor	100	-	-	-
Clearance time (days) (CT_{50})	2 days	-	-	-
(CT_{90})	8.6 days	-	-	
Level and nature of residues (%) in organisms after the 14 day depuration phase	8.2%	-	-	-

[1] only required if log P_{OW} >3.
[2] There is some uncertainty over the measurement of BCF as the measurements were based on radioactivity and did not distinguish between metabolites and active substance. Due to the high margin of safety currently in the risk assessment, it is not considered to be a concern for this substance.

Effects on honey bees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
Preparation ('ATOIAB03') ‡	0.50 (equivalent to 0.05 µg a.s./bee)	0.14 (equivalent to 0.014 µg a.s./bee)

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)

Field or semi-field tests

Field study

Crop	Application rate (g a.s./ha)	Effects observed
Phacelia	10	Application was made in the evening. Two formulations were used (EC and WG). Behaviour was abnormal at Northern Germany site (only on Day 1), but normal at Southern Germany site. Effects on mortality, foraging or brood development higher than the control were observed.

Tunnel tests

Crop	Application rate (g a.s./ha)	Effects observed
Phacelia	10	Application was made during or after foraging activity. Mortality for EC formulation remained high for the duration of the study, both from application during and after foraging activity. Mortality for WG formulation remained elevated for the 'after foraging' treatment. Increased flight activity was observed following treatment with beta-cypermethrin. Abnormal behaviours were noted on Day 1 following treatment with beta-cypermethrin. Effects on brood development were observed for both formulation types during short observation period (6 days)
Wheat	20	Application was made during or after foraging activity. Increased mortality for EC formulation, returning to control levels by Day 2 and to pre-treatment levels by Day 4. Increased mortality for WG formulation, which returned to control levels after one day when applied during bee flight, but remained elevated when applied after bee flight. Reduced flight activity, returning to control levels by Day 5 and to pre-treatment levels by Day 2, but time to recovery was longer than that in the control. Abnormal behaviours were observed on application day. Effects on brood development were observed for both formulations during short observation period (6 days).
Phacelia	35.1	Applications were made before bee flight activity in the morning. Reduced foraging, returning to control and pre-treatment levels by Day 2. No apparent effects of beta-cypermethrin on mortality, colony size, brood development or food storage in hives.

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

Test substance	Application rate (g a.s./ha)	Route	Hazard quotient	Annex VI Trigger
Preparation (‘ATOIAB03’)	10	Contact	**714**	50
		Oral	**200**	50
	15	Contact	**1071**	50
		Oral	**300**	50
	20	Contact	**1429**	50
		Oral	**400**	50
	35	Contact	**2500**	50
		Oral	**700**	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha[1])
Typhlodromus pyri ‡	‘Beta-cypermethrin 100 EC’	Mortality	100 % mortality at 12.5 g a.s./ha (lowest dose tested) **No LR_{50} can be calculated.**
Aphidius rhopalosiphi ‡	‘Beta-cypermethrin 100 EC’	Mortality	100 % mortality at 12.5 g a.s./ha (lowest dose tested) **No LR_{50} can be calculated.**

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
Aphidius rhopsalosiphi (parasitoid wasp)	adult	'Beta-cypermethrin 100 EC' Extended laboratory with application to maize plants	3.74, 94.5 and 135 g a.s./ha.	Mortality Reproduction	45 % at 3.74 g a.s./ha (fresh residues) 100 % at 94.5 g a.s./ha (fresh residues) and 82.5 % (42 day aged residue) 100% at 135 g a.s./ha (fresh and aged residue) 63.4% reduction in reproduction at 3.74 g a.s./ha (fresh residues) 47.6 % reduction in reproduction at 3.74 g a.s./ha (3 day aged residues)	50 %
Episyrphus balteatus (hoverfly)	larvae	'Beta-cypermethrin 100 EC' Application of test item to broad bean plants (kept outside)	3.74 g a.s./ha	Mortality Reproduction	25.39 % at 3.74 g a.s./ha. The hatching data were not suitable to make a reliable assessment of reproduction (hatching rate too low)	50 %
Chrysoperla carnea (green lacewing)	larvae	'Beta-cypermethrin 100 EC' Application of test item to broad bean plants (kept outside)	3.74 g a.s./ha	Mortality Reproduction	33.8 % at 3.74 g a.s./ha. No effect on reproduction at 3.74 g a.s./ha.	50 %

Field or semi-field tests

Test species	Test design	Effect
Arthropod fauna	Field study on winter wheat in the UK. Study initiated in winter and thus activity of arthropods limited at the start of study. Three applications were made: 15 g a.s./ha (T1: 4th December 1997), 20 g a.s./ha (T2: 25th May 1998) and 20 g a.s./ha (T3: 16th June 1998).	There were no significant effects in any of the treatments just before the 2nd application in the following May (T2), indicating recovery between T1 and T2. The numbers of spiders were reduced after both the T2 (May) and T3 (June) applications. The population of *Erigone* spp. had not started to recover before the T3 application and numbers remained significantly lower than the control until the end of the sampling period. The number of *Carabidae* was reduced after the T2 application, the number of *Staphylinidae* was reduced after the T2 application, the number of predatory empid flies was reduced after the T2 application and the number of parasitic wasps in the crop was reduced after both the T2 and T3 applications.
Arthropod fauna	Field study on maize in Southern Germany. Applications were made in June 2008. Single application of either drift rate (1 g a.s./ha) or field rate (35 g a.s./ha).	Significant effects occurred on a wide range of species in both the pitfall and suction samples. In most cases recovery occurred, but it often took over 300 days (web spiders, Collembola, Homoptera, Heteroptera, Juvenile *Oedothorax apicatus*, Juvenile *Phalangium opilio*, Other Erigoninae and *Brachinus* spp). A significant difference occurred between the control and field rate treatment at Day 379 in the pitfall data (*Brachinus* spp. and permutation tests). Effects on a range of taxa were also seen at the proposed drift rate. Recovery observed at proposed drift rate (1 g a.s./ha) within study period.

Effects on earthworms, other soil macroorganisms and soil microorganisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point[1]
Earthworms			
Eisenia foetida	a.s. ‡	Acute 14 days	LC_{50corr} >150 mg a.s./kg dw soil
Eisenia andrei	'Beta-cypermethrin 100 g/L EC' ‡	Chronic 56 days	$NOEC_{corr}$ (reproduction) = 0.243 mg a.s./kg dw soil
Field study	'Beta-cypermethrin 100 g/L EC'	12 months	No statistically significant effects following application of 35 g a.s./ha. **Note**: the levels of the exposure in this study may have been underestimated due to crop interception by the representative crops lower than in case of grassland.
Other soil macroorganisms			
Soil mite	a.s. ‡		No data were submitted.
Collembola			
	a.s. ‡		No data were submitted.
Soil microorganisms			
Nitrogen mineralisation	a.s. ‡	28 days	<25 % effect at 0.67 mg a.s./kg dw soil
	PBA ‡	28 days	<25 % effects at 0.12 mg metab/kg dw soil

Test organism	Test substance	Time scale	End point[1]
	CPA ‡	28 days	<25 % effects at 0.115 mg metabolite/kg dw soil
Carbon mineralisation	a.s. ‡	28 days	<25 % effect at 0.67 mg a.s./kg dw soil
	PBA ‡	28 days	<25 % effects at 0.12 mg metabolite/kg dw soil
	CPA ‡	28 days	<25 % effects at 0.115 mg metabolite/kg dw soil
Field studies[2]			
Litter bag: No significant effect relative to the control was observed on straw decomposition up to 6 months after litterbag burial in soil, treated with a plateau application of 16.28 g a.s./ha and an annual application rate of 35 g a.s./ha. (NOTE: The litter bag test addresses the organic matter breakdown, but it cannot be considered appropriate to address the effects on the overall community structure for non-target soil organisms. This was already acknowledged and discussed during the peer review of other active substances.)			

[1]: Corrected as log P_{ow} >2
[2] litter bag, field arthropod studies not included at point 8.3.2/10.5 above, and earthworm field studies

Toxicity/exposure ratios for soil organisms

Oilseed rape at 10 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
a.s.	Acute[3]	37.5	0.0108	3472	10
a.s.	Chronic[3]	0.06075	0.0108	5.63	5
PBA	Acute	30[1]	0.0011	13636	10
CPA	Acute	30[1]	0.0014	10714	10
Cyperamide	Acute	30[1]	0.0049	3061	10
Other soil macroorganisms					
No data were submitted					

[1]: No toxicity data available for metabolites, therefore 10x toxicity of a.s. was assumed in the first instance. No correction of endpoints has taken place for soil metabolites as log Pow values are <2.
[2] Maximum PEC soil was used
[3]: Toxicity of the active substance corrected by a factor of 2 to account for organic matter content and then by a further factor of 4 to account for uncertainty about the composition of isomers in the accumulated PEC.

Wheat at 20 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
a.s.	Acute[3]	37.5	0.0194	1933	10
a.s.	Chronic[3]	0.06075	0.0194	**3.13**	5
PBA	Acute	30[1]	0.0027	5556	10
CPA	Acute	30[1]	0.0056	2679	10
Cyperamide	Acute	30[1]	0.0075	2000	10
Other soil macroorganisms					
No data were submitted					

[1]: No toxicity data available for metabolites, therefore 10x toxicity of a.s. was assumed in the first instance. No correction of endpoints has taken place for soil metabolites as log Pow values are <2.
[2] Maximum PEC soil was used
[3]: Toxicity of the active substance corrected by a factor of 2 to account for organic matter content and then by a further factor of 4 to account for uncertainty about the composition of isomers in the accumulated PEC.

Maize at 35 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
a.s.	Acute[3]	37.5	0.0434	864	10
a.s.	Chronic[3]	0.06075	0.0434	**1.40**	5
PBA	Acute	30[1]	0.0037	4054	10
CPA	Acute	30[1]	0.0062	2419	10
Cyperamide	Acute	30[1]	0.0148	1014	10
Other soil macroorganisms					
No data were submitted					

[1]: No toxicity data available for metabolites, therefore 10x toxicity of a.s. was assumed in the first instance. No correction of endpoints has taken place for soil metabolites as log Pow values are <2.
[2] Maximum PEC soil was used
[3]: Toxicity of the active substance corrected by a factor of 2 to account for organic matter content and then by a further factor of 4 to account for uncertainty about the composition of isomers in the accumulated PEC.

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

Preliminary screening data

A non GLP study showed no effects on survival or growth or visual phytotoxic effects in any of the six tested species at 35 g a.s./ha. Therefore the EC_{50} is >35 g a.s./ha.

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

No data were submitted.

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

Test type/organism	End point
Activated sludge	EC_{50} >100 mg a.s./L

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

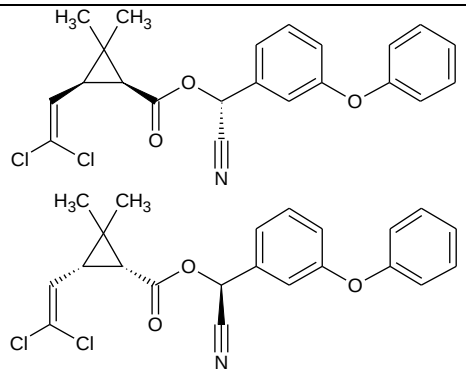
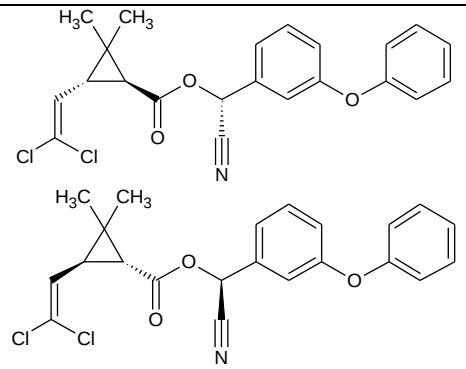
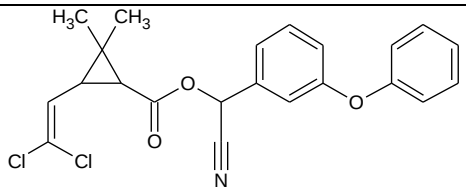
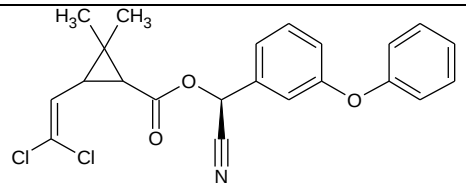
Compartment	
soil	Aerobic – PBA, CPA Anaerobic – PBA, CPA Photolysis – cyperamide
water	PBA CPA
sediment	PBA CPA
groundwater	PBA, CPA and cyperamide

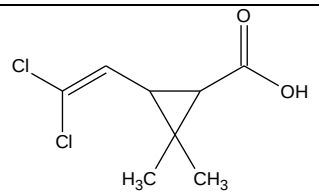
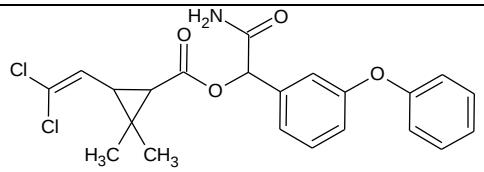
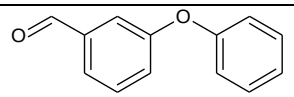
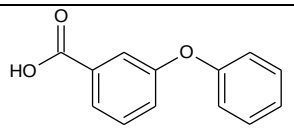
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal[11]
Active substance	Considering the criteria of Regulation (EC) No 1272/2008 (as amended): H400 MFactor 100 000 H410 MFactor 10 000

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

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name/SMILES notation**	Structural formula**
alpha-cypermethrin	(*R*)-α-cyano-3-phenoxybenzyl (1*S*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate 1:1 Cl/C(Cl)=C/[C@@H]3[C@H](C(=O)O[C@@H](C#N)c2cccc(Oc1ccccc1)c2)C3(C)C Cl/C(Cl)=C/[C@H]3[C@@H](C(=O)O[C@H](C#N)c2cccc(Oc1ccccc1)c2)C3(C)C	
theta-cypermethrin	(*R*)-α-cyano-3-phenoxybenzyl (1*S*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3-phenoxybenzyl (1*R*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate 1:1 Cl/C(Cl)=C/[C@H]3[C@H](C(=O)O[C@@H](C#N)c2cccc(Oc1ccccc1)c2)C3(C)C Cl/C(Cl)=C/[C@@H]3[C@@H](C(=O)O[C@H](C#N)c2cccc(Oc1ccccc1)c2)C3(C)C	
cypermethrin	(*RS*)-α-cyano-3-phenoxybenzyl (1*RS*,3*RS*;1*RS*,3*SR*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate Cl/C(Cl)=C/C3C(C(=O)OC(C#N)c2cccc(Oc1ccccc1)c2)C3(C)C	
zeta-cypermethrin	(*S*)-α-cyano-3-phenoxybenzyl (1*RS*,3*RS*;1*RS*,3*SR*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (*S*);(1*RS*,3*RS*) isomeric pair to the (*S*);(1*RS*,3*SR*) 45–55 to 55–45 Cl/C(Cl)=C/C3C(C(=O)O[C@H](C#N)c2cccc(Oc1ccccc1)c2)C3(C)C	

Code/Trivial name*	Chemical name/SMILES notation**	Structural formula**
CPA (unstated stereochemistry)	3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylic acid Cl\C(Cl)=C/C1C(C(=O)O)C1(C)C	
cyperamide (unstated stereochemistry)	2-amino-2-oxo-1-(3-phenoxyphenyl)ethyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate Cl/C(Cl)=C/C3C(C(=O)OC(c2cccc(Oc1ccccc1)c2)C(N)=O)C3(C)C	
M2 3-phenoxybenzaldehyde	3-phenoxybenzaldehyde O=Cc2cc(Oc1ccccc1)ccc2	
PBA	3-phenoxybenzoic acid O=C(O)c2cc(Oc1ccccc1)ccc2	

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

ABBREVIATIONS

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

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

mm	millimetre (also used for mean measured concentrations)
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
n.a.	not applicable
NEDI	national estimated daily intake
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEAEC	no observed ecological adverse effect concentration
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen phosphorous detector
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PBI	plant-back interval
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_{i}	predicted environmental concentration, initial value
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PRIMo	Pesticide Residue Intake Model
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
QuEChERS	quick, easy, cheap, effective and safe method
r^2	coefficient of determination
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
$t_{1/2}$	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 Organization
wk	week
yr	year