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CONCLUSION ON PESTICIDE PEER REVIEW

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

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ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State Sweden, for the pesticide active substance lambda-cyhalothrin are reported. The context of the peer review was that required by Commission Regulation (EU) No 1141/2010 as amended by Commission Implementing Regulation (EU) No 380/2013. The conclusions were reached on the basis of the evaluation of the representative uses of lambda-cyhalothrin as an insecticide on wheat, tomatoes, plums, potatoes and peaches. 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. A high risk to aquatic organisms has been identified.

KEY WORDS

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

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[1] On request from the European Commission, Question No EFSA-Q-2013-00660, approved on 23 April 2014.
[2] Correspondence: pesticides.peerreview@efsa.europa.eu
[3] Clarification is provided regarding the determination of potential endocrine disrupting properties in accordance with the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No. 1107/2009. The original Conclusion is available on request, as is a version showing all the changes that were made.

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SUMMARY

Commission Regulation (EU) No 1141/2010, as amended by Commission Implementing Regulation (EU) No 380/2013, (hereinafter referred to as ’the Regulation’) lays down the procedure for the renewal of the approval of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishes the list of those substances. Lambda-cyhalothrin is one of the active substances listed in the Regulation.

The RMS provided its initial evaluation of the dossier on lambda-cyhalothrin in the Renewal Assessment Report (RAR), which was received by the EFSA on 28 February 2013. The peer review was initiated on 15 March 2013 by dispatching the RAR for consultation of the Member States and the applicants Task Force Lambda and Syngenta Task Force.

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

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of lambda-cyhalothrin as an insecticide on wheat, tomato, plum, potato and peach, as proposed by the applicants. Full details of the representative uses can be found in Appendix A to this report.

Data gaps were identified in the section identity, physical and chemical properties and analytical methods.

In the mammalian toxicology section, data gaps were identified for toxicological information to assess the toxicity profile of the plant metabolites V (PBA) and XXIII (PBA(OH)) and to address the relevance of several impurities (that are not part of the isomers present in cyhalothrin) in the technical specification. The interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. However data gaps were identified to clarify whether the sperm effects reported in published literature in mice treated with low doses of lambda-cyhalothrin in a formulation have an impact on the outcome of the risk assessment, and to investigate further the endocrine activity of lambda-cyhalothrin (issue not finalised). The estimated worker and bystander exposures exceed the AOEL for some of the representative uses. In addition, the compliance of the batches used in the key toxicological studies to the proposed technical specification has not been fully demonstrated.

The consumer risk assessment could not be finalised as the proposed residue definition for risk assessment remains provisional for processed commodities and considering also the uncertainties related to the identified data gaps.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level for the representative uses, with the notable exception that information is missing regarding the potential conversion/preferential degradation of isomers of lambda-cyhalothrin in the aquatic compartment. This leads to additional uncertainty in the available risk assessments than would be the case if lambda-cyhalothrin were not made up of isomers. A second notable exception is that satisfactory surface water exposure assessments to address the aquatic risk assessment for lambda-cyhalothrin are not available for the representative uses assessed on spring wheat, tomato and plum (‘Karate 10CS’ and ‘Kaiso sorbie 5% EG’), and peach (‘Lambda-Cyhalothrin 100 CS’). Finally, a data gap was identified for satisfactory information to address the levels of metabolites formed from the phenoxy-^{14}C labelled lambda-cyhalothrin when applied at doses

below the water solubility in the aquatic environment, therefore the complete route of degradation of lambda-cyhalothrin in the aquatic compartment could not be finalised.

In the section on ecotoxicology a critical area of concern was indicated as a high risk to aquatic organisms was identified for all representative uses. A low risk to birds was concluded, however, a high risk to mammals was identified for all the representative uses with the exception of the use on tomatoes in glasshouses. The assessment of the potential for biomagnification in aquatic and terrestrial food chains could not be finalised with the available information. A high risk to honey bees was identified for the representative uses on peach and plum orchards whereas a low risk was indicated for all other uses. A high risk to non-target arthropods was concluded for all representative uses with the exception of the use on tomatoes in glasshouses. A low risk was concluded for earthworms, soil macro- and microorganisms, non-target terrestrial plants and sewage treatment organisms.

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BACKGROUND

Commission Regulation (EU) No 1141/2010[4] (hereinafter referred to as 'the Regulation'), as amended by Commission Implementing Regulation (EU) No 380/2013[5] lays down the detailed rules for the procedure of the renewal of the approval of a second group of active substances. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicants for comments on the initial evaluation in the Renewal Assessment Report (RAR) provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

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

In accordance with Article 4 of the Regulation Sweden (hereinafter referred to as the 'RMS') received an application from the applicants Task Force Lambda and Syngenta Task Force for the renewal of approval of the active substance lambda-cyhalothrin. Complying with Article 11 of the Regulation, the RMS checked the completeness of the dossier and informed the applicants, the Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on lambda-cyhalothrin in the RAR (Sweden, 2013), which was received by the EFSA on 28 February 2013. The peer review was initiated on 15 March 2013 by dispatching the RAR to Member States and the applicants Task Force Lambda and Syngenta Task Force for consultation and comments. In addition, the EFSA conducted a public consultation on the RAR. 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 applicants were invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicants' 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 applicants in accordance with Article 16(3) of the Regulation were considered in a telephone conference between the EFSA, the RMS, and the European Commission on 5 July 2013. On the basis of the comments received, the applicants' response to the comments and the RMS's evaluation thereof it was concluded that additional information should be requested from the applicants and that the EFSA should organise an expert consultation in the areas of mammalian toxicology, environmental fate and behaviour and ecotoxicology. According to Article 16(2) of the Regulation the European Commission decided to consult the EFSA. The mandate was received on 12 July 2013.

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

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

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

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

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

- the comments received on the RAR,
- the Reporting Table (8 July 2013),
- the Evaluation Table (22 April 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 RAR including its final addendum (compiled version of February 2014 containing the clean revisions of the RAR and the individually submitted addenda (Sweden, 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

Lambda-cyhalothrin is the ISO common name for the reaction product comprising equal quantities of (*R*)-α-cyano-3-phenoxybenzyl (1*S*,3*S*)-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate
or of
(*R*)-α-cyano-3-phenoxybenzyl (1*S*)-*cis*-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3-phenoxybenzyl (1*R*)-*cis*-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate (IUPAC).

The representative formulated products for the evaluation were 'Karate 10CS (A12690B)', a capsule suspension (CS) containing 100 g/L lambda-cyhalothrin (9.43 % w/w) and 'Kaiso sorbie 5% EG (CA2352)', an emulsifiable granule (EG) containing 50 g/kg lambda-cyhalothrin for the Syngenta Task Force (STF), while 'Lambda-Cyhalothrin 100 CS (HAG 400 01 I)', a capsule suspension (CS) containing 100 g/L lambda-cyhalothrin (9.87 % w/w) and 'Lambda 50 EC (LC50-2)', an emulsifiable concentrate (EC) containing 50 g/L lambda-cyhalothrin for the Task Force Lambda (TFL).

The representative uses evaluated comprise applications by foliar spraying to control a range of insects on wheat, potato, plum, peach and outdoor and indoor applications on tomato. Full details of the GAPs can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

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

It should be noted that the isomers forming lambda-cyhalothrin are two of the four isomers forming the substance with ISO common name cyhalothrin. One of the isomers forming lambda-cyhalothrin is forming the substance with ISO common name gamma-cyhalothrin (the chemical names and structures are given in Appendix B).

The minimum purity of lambda-cyhalothrin technical material is 900 g/kg, which meets the requirements of the FAO specification 463/TC (January 2013) of minimum 810 g/kg.

It should be mentioned that the minimum purity for the first inclusion was 810 g/kg, which is equal to what is given in the available FAO specification for lambda-cyhalothrin, however the specification for the first approval, containing significantly higher levels of impurities, was not covered by the profile of the toxicological batches used at that time (see section 2)

The proposed revised reference specification is based on batch data from industrial scale production from Syngenta Limited sources.

All other sources relevant for the renewal of lambda-cyhalothrin have been assessed for equivalence against the new reference specification and have in principle been deemed as equivalent. A formal data gap for procedural reasons was identified for a revised specification for the minimum active ingredient content according to the proposal in the RAR for Syngenta. Data gaps were identified for revised specification removing the non-relevant impurities below 1 g/kg for Nufarm and for SAPEC AGRO S.A.

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 lambda-cyhalothrin or the representative formulations. Data gaps were however identified for a shelf-life study of

'Lambda 50 EC' formulation, surface tension of the neat formulation and data on emulsifiabilty for 'Lambda 50 EC', and data on suspensibility and pourability for 'Lambda-Cyhalothrin 100 CS'. The main data regarding the identity of lambda-cyhalothrin and its physical and chemical properties are given in Appendix A.

Adequate analytical methods using GC-FID or HPLC-UV are available for the determination of lambda-cyhalothrin in the technical materials and in the representative formulations as well as for the determination of the respective impurities in the technical materials. It should be noted that CIPAC methods for lambda-cyhalothrin are also available (463/EC/M/, 463/WP/M/, 463/CS/M/).

The proposed residue definition for monitoring in food of plant and animal origin is lambda-cyhalothrin. Lambda-cyhalothrin can be monitored in food and feed of plant origin by the QuEChERS multi-residue method (GC-MS) with a LOQ of 0.01 mg/kg in each commodity group, and also with the multi-residue method using LC-MS/MS with a LOQ of 0.01 mg/kg in wheat grain, apple, avocado and lemon.

The multi-residue method DFG S19 (GC-MS) is appropriate for monitoring lambda-cyhalothrin in food and feed of animal origin with a LOQ of 0.01 mg/kg in muscle, liver, kidney, fat, milk and eggs. A multi-residue method using LC-MS/MS also exists for monitoring lambda-cyhalothrin in cow milk, eggs, meat and liver with a LOQ of 0.01 mg/kg in each matrix. It should be noted however that a data gap was identified for additional validation data concerning the analysis of fat (relevant for TFL).

Monitoring of lambda-cyhalothrin in soil (as sum of cyhalothrin isomers) is possible by the multi-residue method using GC-MS with a LOQ of 0.01 mg/kg, or by the multi-residue method using LC-MS/MS with a LOQ of 0.05 mg/kg.

Lambda-cyhalothrin (as sum of cyhalothrin isomers) in ground water and surface water can be monitored by the multi-residue method (GC-MS) with a LOQ of 0.002 µg/L or by the multi-residue method using LC-MS/MS with a LOQ of 0.1 µg/L, however a data gap was identified to validate the methods for surface water to the appropriate LOQ.

Residues of lambda-cyhalothrin in the air can be monitored by GC-MS with a LOQ of 0.075 $\mu g/m^3$.

Lambda-cyhalothrin residues in body fluids and tissues can be monitored with the multi-residue method DFG S19 (GC-MS) with a LOQ of 0.01 mg/kg (swine blood, bovine meat, liver, kidney and fat) and also with LC-MS/MS with a LOQ of 0.05 mg/L in blood serum and urine.

2. Mammalian toxicity

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

Lambda-cyhalothrin was discussed at the Pesticides Peer Review Experts' Meeting 108 in November 2013.

The compliance of the batches used in the key toxicological studies to the proposed technical specification has not been fully demonstrated, as it appears that some impurities have not been tested or have not been tested at an appropriate level. The relevance of several impurities (that are not part of the isomers present in cyhalothrin) has not been addressed and a data gap has been identified. It is noted that the original specification for the first approval was not covered by the profile of the toxicological batches at that time.

Lambda-cyhalothrin consists of two out of the four isomers of cyhalothrin and the dossier included studies performed with lambda-cyhalothrin and cyhalothrin. Bridging from cyhalothrin to lambda-cyhalothrin is accepted as both substances exhibited similar toxicological effects, however, as lambda-cyhalothrin appears to be more toxic, it was assumed that all toxicity expressed as cyhalothrin would derive from the lambda-cyhalothrin isomers.

Toxicokinetics and metabolism of lambda-cyhalothrin and cyhalothrin did not present significant differences. Cyhalothrins (cyhalothrin and lambda-cyhalothrin) are rapidly but incompletely absorbed after oral administration; variable results were obtained pending on the study conditions (radiolabel, vehicle and dose used), therefore oral absorption was considered to be approximately 25 % in rat based on urine excretion, and 50 % in dogs when comparing plasma kinetics upon oral and intravenous administrations. Cyhalothrins are rapidly and extensively distributed, metabolised and excreted, although some accumulation was observed in fat.

Lambda-cyhalothrin is acutely toxic after ingestion, highly toxic after inhalation and it is of moderate toxicity upon contact with the skin, showing an overall higher acute toxicity than cyhalothrin. In an acute oral toxicity study in mice, the substance is even highly toxic after ingestion. No skin irritation and slight eye irritation were observed but the substance was regarded as a skin sensitiser based on studies performed with cyhalothrin and gamma-cyhalothrin (which consists of one isomer of lambda-cyhalothrin) as no conclusion could be reached on the basis of the submitted skin sensitisation studies performed with lambda-cyhalothrin.

Clinical signs of neurotoxicity characteristics of poisoning by type II pyrethroids (such as salivation, incoordination, postural abnormalities, hyperexcitability, tremors) are the critical findings observed upon short-term administration of lambda-cyhalothrin. Dogs appear to be more sensitive to cyhalothrin administration and the relevant short-term NOAEL of 0.5 mg/kg bw per day was observed in the 1-year dog study conducted with lambda-cyhalothrin. Long-term studies were solely conducted on cyhalothrin and presented similar NOAELs of 1.7 and 1.8 mg/kg bw per day in rats and mice, respectively. No genotoxic or carcinogenic potential was observed, and cyhalothrins did not cause reproductive or developmental effects in rats or rabbits. However, as sperm effects are reported in the published literature in mice treated with low doses of lambda-cyhalothrin (tested in a formulation), a data gap was identified to clarify whether this potential concern may affect the outcome of the risk assessment. The lowest relevant NOAEL was seen in the multigeneration study in rats showing an offspring NOAEL of 0.5 mg cyhalothrin/kg bw per day, based on decrease in body weight gain. Increased breathing rate was the critical effect observed in an acute neurotoxicity study, for which the NOAEL was 2.5 mg/kg bw; brain morphological changes were the critical effects observed in a developmental neurotoxicity study for which the NOAEL was 4.9 mg/kg bw per day.

Lambda-cyhalothrin is not classified or proposed to be classified as carcinogenic category 2 or toxic for reproduction category 2, in accordance with the provisions of Regulation (EC) No 1272/2008, and therefore the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. With regard to the assessment for a potential endocrine mode of action, some *in vitro* studies from the open literature describe interactions of lambda-cyhalothrin with receptors of the endocrine and immune systems. Considering the sperm effects in mice (see above) and the brain morphological changes in the developmental neurotoxicity study, the available data are not sufficient to clarify the potential endocrine activity. In particular, some of the validated tests indicated in the OECD Conceptual Framework (OECD, 2012a), and analysed in the EFSA Scientific Opinion on the hazard assessment of endocrine disruptors (EFSA, 2013) are not available. Level 2 tests include the oestrogen receptor (ER) and the androgen receptor (AR) binding assays, the ER transactivation assay (OECD, 2012b), the steroidogenesis assay (OECD, 2011) and the aromatase assay. Level 2 also includes a test for ER agonists and antagonists (OECD, 2012c) and assays for thyroid hormone-mediated modalities (although not yet validated). Furthermore, the level 3 *in vivo* screening assays include two validated tests, one sensitive to oestrogen agonists/antagonists (uterotrophic assay in rodents, OECD, 2007) and one sensitive to androgen agonists/antagonists (Hershberger assay in rodents, OECD, 2009). Therefore a data gap has been identified for the level 2 and/or 3 OECD tests. The potential for endocrine disrupting effects could not be finalised as an endocrine-mediated mode of action could not be ruled out regarding the brain morphological changes observed in the developmental neurotoxicity study (and possible sperm effects, which have to be clarified in the first place) (issue not finalised).

Toxicological studies were provided on some metabolites of lambda-cyhalothrin (metabolite **Ia, II**, **III, V (PBA), VI** and **XIII)**. Regarding metabolites **V (PBA)** and **XXIII (PBA(OH))**, a data gap was identified for toxicological information allowing to assess the human exposure to these compounds (see also section 3). With regard to the metabolite **R157836** (enantiomeric pair *cis* A), it was concluded that it is not of higher toxicity than the parent and the reference values of the parent, lambda-cyhalothrin are applicable. As concerns the metabolites **IV** and **gamma-lactone**, no toxicological data have been provided. It is noted that the toxicological properties of the metabolites Ia, IV and gamma-lactone may need to be further addressed pending on the outcome of further data requested in section 3.

The acceptable daily intake (**ADI**) of lambda-cyhalothrin is 0.0025 mg/kg bw per day, based on the NOAEL of 0.5 mg cyhalothrin/kg bw per day from the multigeneration study in rat, applying an uncertainty factor (UF) of 200, i.e. a standard UF of 100 and an additional factor of two to convert from cyhalothrin to lambda-cyhalothrin. The acceptable operator exposure level (**AOEL**) is 0.00063 mg/kg bw per day, based on the same NOAEL of 0.5 mg cyhalothrin/kg bw per day, 200 UF applied, and correcting for the limited oral absorption by 25 %. The acute reference dose (**ARfD**) is 0.005 mg/kg bw, based on the NOAEL of 0.5 mg lambda-cyhalothrin/kg bw per day from the 1-year study in dogs, applying the standard UF of 100.

With regard to the dermal absorption, the default value of 100 % was considered too conservative by the experts and it was agreed to use a higher default value of 25 % of the applied dose for the concentrated and diluted formulations.

For the **operators**, personal protective equipment (PPE) has to be worn during mixing and loading (gloves, and also broad brimmed headwear for the hand-held application in orchards), and during application (gloves, hood and visor/broad brimmed headwear, coverall and sturdy footwear) to ensure that the exposure does not exceed the AOEL for all proposed scenarios.

The estimated exposure of protected **workers** harvesting tomatoes or orchard fruits, as well as the exposure of unprotected workers performing crop inspections of potatoes treated with 20 g lambda-cyhalothrin/ha exceeds the AOEL. The exposure of unprotected workers performing crop inspections in cereals and potatoes treated with 7.5 g lambda-cyhalothrin/ha is estimated to be below the AOEL.

Bystander exposure was estimated not to exceed the AOEL for applications in cereals, potatoes and tomatoes outdoor, while for indoor treated tomatoes bystander exposure is not considered relevant. Bystander exposure to orchard treatments was estimated not to exceed the AOEL only under certain conditions, i.e. if bystanders remain at a minimum distance of 10 m from the spray application of maximum 10 g/ha, or if treatments are made on late fruit crops with 22.5 g/ha and bystanders remain at a minimum distance of 10 m from the spray application. Bystanders standing at 3 m or 10 m from the orchard spraying (25 g lambda-cyhalothrin/ha or early fruit crop treatments of 22.5 g/ha) are exposed to levels of lambda-cyhalothrin exceeding the AOEL. The exposure estimates for residents did not exceed the AOEL for any of the representative uses, considering that residents remain at a minimum distance of 10 m from the spray application (estimates to take into account lower distance are not available).

3. Residues

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

The metabolism of lambda-cyhalothrin in primary crops was investigated in fruits (tomato), cereals (wheat) and in pulses/oilseeds (soya bean and cotton leaves). Metabolism studies conducted with the racemate cyhalothrin were also submitted in fruits (apple) and leafy crops (cabbage). Lambda-cyhalothrin was radiolabelled either in the cyclopropyl ring, phenoxyphenyl ring or benzyl ring. Cyhalothrin was radiolabelled in the cyclopropyl ring only. Based on the metabolism data for lambda-cyhalothrin and cyhalothrin, the bridging between these data is considered as acceptable since the metabolic pathway was demonstrated to be similar, with the parent compound being the predominant compound of the total residues in all the crops under investigation (37 - 95 % TRR). Besides, the metabolite **Ia** resulting from the cleavage of the parent compound and containing the cyclopropyl moiety was identified as a significant metabolite in soya bean and cotton leaves only (17 - 25 % TRR). Although no metabolites' identification was attempted in the pulses/oilseeds seeds, EFSA is of the opinion that the metabolism of lambda-cyhalothrin was sufficiently and confidently investigated in fruit crops, leafy crops and cereals.

From residue trials conducted on wheat, tomatoes and plums, a slight isomeric conversion from lambda-cyhalothrin (enantiomer pair *cis* B) to the enantiomeric pair *cis* A (metabolite R157836) was observed (<10 % TRR). Nevertheless, the impact of the change in the ratio of the isomers on the toxicological burden the consumer is exposed to is of low concern, since it is assumed that the metabolite R157836 is not of higher toxicity than lambda-cyhalothrin. Chiral analysis of the enantiomers of lambda-cyhalothrin were also conducted on kale, lettuce and apple residue samples showing that the initial 1:1 enantiomeric ratio was maintained in each crop at harvest, indicating no preferential degradation/conversion between the 2 enantiomers of lambda-cyhalothrin. Significant conversion of lambda-cyhalothrin versus the other cyhalothrin isomers was also observed, but in cotton leaves only.

Confined rotational crop studies were conducted with cyclopropyl- and phenoxyphenyl-labelled lambda-cyhalothrin in wheat, lettuce and carrots after a bare soil treatment at a dose rate of 0.47 kg a.s./ha (9 N rate). The total radioactive residues were significantly higher in rotational crops conducted with the cyclopropyl labelling, indicating a preferential uptake of metabolites containing the cyclopropyl moiety, thereof metabolite **Ia** being the major compound of the total residues in carrot root (52 % TRR), lettuce (61 % TRR) and wheat straw (34 % TRR). The parent compound was either not detected or present at a negligible proportion (<1 % TRR) in wheat straw only. No metabolites' identification was conducted in wheat grain. Rotational crop field trials were conducted on radish/turnip, lettuce/spinach, barley/wheat, alfalfa and mustard leaves following harvest of a treated primary crop (cotton) at a total dose rate of 0.5 kg a.s./ha (1.2 N rate considering the PEC soil for lambda-cyhalothrin) and resulted in residues of lambda-cyhalothrin and metabolite **Ia** below the LOQ in the edible parts at 30 and 60 day plant-back intervals.

The residue definition for monitoring and risk assessment is proposed as lambda-cyhalothrin and can be extended to all categories of crops. A complete residue data set was submitted for plums, tomatoes and spring/winter wheat (STF GAP) to derive MRLs on these crops. A data gap was identified for 3 a complete residue data set on peach (Southern Europe GAP) and for sufficient GAP-compliant residue trials on potatoes covering respectively Northern and Southern Europe to demonstrate the expected no-residue situation. Furthermore, since the STF and TFL GAPs on wheat are different, a complete residue data set covering respectively the Northern and Southern TFL GAPs is also required. It is highlighted that the acceptability of some of the residue trials on plums is pending on the submission of the validation data for the analytical method (RAM 81). Furthermore, reliable storage stability studies on lambda-cyhalothrin should be submitted in order to demonstrate that degradation of residues during the storage of samples is not expected. The acceptability of the residue data sets for all the crops will need to be reconsidered accordingly.

Lambda-cyhalothrin remained stable under hydrolytic conditions representative of pasteurisation and baking, brewing and boiling (82 - 91 % TRR), whilst a significant degradation occurred at sterilisation by hydrolytic cleavage of the parent molecule into metabolites **Ia** (cyclopropyl label specific) (59 % TRR), **IV** (phenyl label specific) (63 % TRR) and **gamma-lactone** (15 % TRR). Since there is insufficient information available on the toxicological properties of these metabolites (see section 2), their possible inclusion in the residue definition for risk assessment for processed commodities has to be considered. Meanwhile, acceptable processing studies on tomatoes demonstrated that residues of compounds **Ia**, **IV** and **gamma-lactone** in sterilised canned tomatoes were below the LOQ (<0.01 mg/kg), whilst no processing residue trials addressing the magnitude of these metabolites in fruit (plum, peach) processed products that may undergo heating by processing were available. A data gap was identified to provide such processing trials. If it turns out that these metabolites are quantified in the processed fruit commodities, the toxicological properties of these metabolites may need to be addressed and the residue definition for risk assessment in processed commodities revisited appropriately.

The livestock dietary intake of lambda-cyhalothrin exceeded the trigger value (0.1 mg/kg DM) for ruminants only, with wheat straw being the major contributor. This calculation should be reconsidered based on the additional residue trials requested on potatoes and wheat. Metabolism studies on ruminants and poultry were submitted. At the calculated dietary burden, no significant residues (>0.01 mg/kg) were expected in any matrix, except in fat (0.012 ppm). Lambda-cyhalothrin was the predominant compound in all tissues, except in liver and kidney, where the metabolites resulting from the cleavage of the active substance containing either the cyclopropyl moiety (metabolites **Ia and XI)** or the phenoxybenzyl moiety **(**metabolites **V (PBA)**, **XXIII (PBA(OH))** and **XIII)** were recovered predominantly. A change in the ratio of enantiomers within the *cis B* pair of diastereoisomers (lambda-cyhalothrin) was observed in milk, muscle and fat. This preferential isomeric conversion is assumed to have a negligible impact on the overall consumer risk assessment in view of the low contribution of the animal matrices to the dietary burden.

Livestock feeding studies were submitted in cows and also in poultry, although not triggered. At the calculated dietary burden, the magnitude of the residues of lambda-cyhalothrin and its metabolites **Ia**, **XI**, **V (PBA)** and **XXIII (PBA(OH))** (free and conjugated) was below the LOQ of the method (0.01 mg/kg) in all matrices, except in fat where residues of lambda-cyhalothrin were quantified. Although the magnitude of metabolite **XIII** was not determined in the feeding study, based on the metabolism study and considering the representative uses, it is assumed that this metabolite will not be detected at a quantifiable level in kidney (>LOQ). Nevertheless, EFSA highlights that considering the European authorised uses with feed items, an increase of the dietary burden is expected, and in that specific case the magnitude of the compounds **Ia**, **XI**, **V (PBA)**, **XIII** and **XXIII (PBA(OH))** should be reconsidered and their toxicological properties may need to be addressed. Since the submitted residue storage stability data did not cover the storage period of the residue samples from the ruminant feeding study regarding lambda-cyhalothrin and metabolite **XI**, a data gap was identified to provide new storage stability data for these compounds in all matrices.

The residue definition for monitoring and risk assessment in livestock matrices is set as lambda-cyhalothrin.

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

The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMo). No chronic or acute intake concerns were identified; TMDI: 10.8 % of ADI (WHO cluster diet B) and IESTI: 46.5 % of ARfD for tomatoes, BE child. The consumer risk assessment presented hereabove has to be regarded as provisional since the proposed residue definition for risk assessment remains provisional for processed commodities and considering the uncertainties due to the identified data gaps.

4. Environmental fate and behaviour

Lambda-cyhalothrin was discussed at the Pesticides Peer Review Experts' Teleconference 97 (TC 97) in November 2013.

Cyhalothrin is manufactured as enantiomer pairs *cis* A and *cis* B. Lambda-cyhalothrin is the optimised product containing largely pair *cis* B, which in turn is a racemic mixture of two enantiomers: 1R,*cis*,Z-S'and 1S,*cis*,Z-R'. For the evaluation of the environmental fate and behaviour for the potential renewal of the approval of lambda-cyhalothrin in the framework of Commission Regulation (EU) No 1141/2010, it was only relied on data on lambda-cyhalothrin.

The regulatory dossier provides information on the behaviour of each individual lambda-cyhalothrin enantiomer in the soil compartment. Separation and quantification of the diastereoisomers (by TLC and normal phase HPLC) and the enantiomers (by chiral phase HPLC) was performed at two sampling points in some of the soils investigated to address the soil metabolism of lambda-cyhalothrin. The results give a clear indication for a conversion of the B- to the A-diastereoisomer in neutral and alkaline soils, but no conclusion can be drawn about a change of the diasteroisomer ratio over time. The enantiomer ratio of the racemate lambda-cyhalothrin was observed to shift during degradation in soil under aerobic and anaerobic conditions towards a lower fraction of the 1R,*cis*Z-S' enantiomer (also known as gamma-cyhalothrin), forming part of the *cis* B diastereoisomer pair. The shift was attributed to preferential degradation of the 1R,*cis*Z-S' enantiomer in soil, which is the most toxic enantiomer of lambda-cyhalothrin. Therefore, the peer review concluded that the available soil exposure assessment is conservative, even if the data do not allow a quantification of the impact of the selective degradation of the enantiomers. However, it is not known if any of the enantiomers and/or diastereoisomers of lambda-cyhalothrin were degraded more quickly than the other in the aquatic compartment, of if any conversion of the enantiomers occurred in the natural surface waters. Consequently, a data gap was identified for this issue. Metabolites Ia and XV also have chiral centres, but the chromatography utilised in the pertinent studies in the environmental fate section did not resolve the isomers. References made to these metabolites in sections 4, 6 and Appendix A therefore relate to the sum of the isomers that may constitute the metabolite of unknown enantiomer / diastereoisomer ratio. It is considered, however, that the margin of safety in the available risk assessments for these metabolites is large enough so that the uncertainty on the relative toxicity and contributions to the total residue levels of the isomers does not change the final conclusion on the risk assessments.

In soil laboratory incubations under aerobic conditions in the dark, lambda-cyhalothrin exhibited moderate to high persistence, forming the major (> 10 % applied radioactivity (AR)) metabolite **Ia** (max. 22.9 % AR) and metabolite **XV** (max. 12.1 % AR). Both metabolites exhibited low to moderate persistence in soil. Metabolite **V (PBA)**, which exhibited moderate to medium persistence, was present at levels that trigger a groundwater exposure assessment. Mineralisation of the cyclopropyl and phenoxy ring ^{14}C radiolabels to carbon dioxide accounted for 12 - 46 % AR after 120 days. The formation of unextractable residues (not extracted by acetonitrile and acetonitrile:water) for these radiolabels accounted for 12 - 44 % AR after 120 days. In anaerobic soil incubations lambda-cyhalothrin exhibited medium to high persistence. Metabolite V (PBA) was identified in these anaerobic incubations at a maximum level of 31.4 % AR. As anaerobic conditions in soil can not be completely excluded for the representative uses on winter cereals in Northern Europe, metabolite V (PBA) was further considered in the environmental exposure assessment under these specific conditions. A laboratory soil photolysis study was considered to indicate that photodegradation at the soil surface does not represent a significant process contributing to transformation. Lambda-cyhalothrin and metabolite XV can be considered immobile in soil. Metabolite Ia exhibited very high to high soil mobility, with stronger adsorption under acidic conditions. Metabolite V (PBA) was estimated[7] to exhibit medium mobility in soil. Dissipation rates of lambda-cyhalothrin were determined in field studies submitted for the first approval of lambda-cyhalothrin. Results were

[7] Estimated by the quantitative structure activity relationship (QSAR) calculation software EPI Suite v. 4.10 and EPI Web v.4.0.

available from four German soils and six US soils. The results from the US studies were considered by the peer review as indicative only since no pedological and climatic comparison to European conditions was made.

Phototransformation of lambda-cyhalothrin was investigated under irradiation in a pH 5 buffer solution (direct photolysis) and in natural water (indirect photolysis). Compound V (PBA) was identified as a major metabolite, reaching 10.4 % AR within 2 days and a maximum of 28.5 % AR after 15 days. In laboratory incubations in dark aerobic natural sediment water systems, dissipation of lambda-cyhalothrin from the water phase primarily through partitioning to sediment was relatively rapid. Maximum amounts of lambda-cyhalothrin in sediment reached 70.2 % AR at day 1. The major metabolite formed in the water/sediment systems was metabolite Ia (maximum formation 29.4 % AR in water, 10.6 % AR in sediment at 30 days). Metabolite XV was found at max. 10.5 % AR in the whole system (max. 9.6 % AR in the sediment at day 14). The route of degradation was determined with ^{14}C-cyclopropyl label at two different test concentrations (3 and 30 µg/L), while ^{14}C-phenoxy label was only used at test concentration 30 µg/L, greatly exceeding the water solubility of lambda-cyhalothrin of 5 µg/L. Following the Pesticides Peer Review Experts' Teleconference 97, a data gap was identified for the applicant to address the level of metabolites formed from the phenoxy-^{14}C labelled lambda-cyhalothrin, when applied at doses below the water solubility in the aquatic environment. The fraction of unextractable residues increased slowly over the duration of the study in the organic rich system (Old Basing, sandy loam, 7.5 % o.c. (organic carbon) in sediment), whereas in the sand system (Virginia Water, 0.5 % o.c. sediment) the unextractable residues peaked after 30 days and then declined. By the study end, 15 – 31 % and 42 – 48 % AR had been mineralized in the Old Basing and the Virginia Water water/sediment systems, respectively. The analytical method employed did not allow investigation of possible isomerisation. Nor was the ratio of enantiomers investigated. Therefore, a data gap was identified to address this issue.

After the Pesticides Peer Review Experts' TC 97 revised surface water and sediment exposure assessments (Predicted environmental concentrations (PEC) calculations) were submitted by the RMS for lambda-cyhalothrin and metabolites Ia, V (PBA) and XV, using the FOCUS (FOCUS, 2001) step 1 and step 2 approach. FOCUS step 3 calculations were also available for metabolite XV. Re-calculations at steps 3 and 4[8] to reflect the final agreed endpoints are not available for some of the representative uses applied for, such as peaches, spring wheat (for products 'Karate 10 CS' and 'Kaiso sorbie 5% EG' only), the high dose in tomato (1-2 x 25 g a.s./ha) or the high dose in plums (25 g a.s./ha). The step 4 calculations valid for the representative uses on winter wheat, spring wheat (products 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC' only), seed potatoes and potatoes appropriately followed the FOCUS (FOCUS, 2007) guidance, with 95 % drift reducing nozzles, and combined no-spray buffer zones with vegetative buffer strips of up to 20 m (reducing solute flux and volume in run-off by 90 % and these values for erosion and sediment mass by 90 %) being implemented for the run-off scenarios. The SWAN tool (version 1.1.4) was appropriately used to implement these mitigation measures in the simulations. For the indoor treatment of tomatoes (2 x 25 g/ha, 12 day interval, 25 % interception), the PEC calculations were appropriately carried out by the RMS using the FOCUS (2001) step 1 and step 2 approach (version 2.1) of the steps 1-2 in FOCUS calculator), which was then modified by post processing of the spray drift input results (option no run-off or drainage was selected) to obtain a 0.1 % emission of lambda-cyhalothrin from greenhouses being re-deposited on adjacent surface water bodies. This approach has been accepted by Member State experts as an assumption that can be used in EU level surface water exposure assessments for greenhouse uses and is referred to in FOCUS (2008) guidance as being appropriate, except when applications are made with ultra low volume application techniques, when 0.2 % emission is prescribed.

The necessary groundwater exposure assessments for lambda-cyhalothrin and metabolites Ia, V (PBA) and XV were carried out using FOCUS (FOCUS, 2000) scenarios and the models PELMO 4.4.3, PELMO 5.5.3, PEARL 4.4.4 and MACRO 4.4.2. The potential for groundwater exposure from the

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

representative uses by lambda-cyhalothrin and these three metabolites above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios. The presented groundwater exposure assessment for metabolites Ia and XV did not consider the potential conversion/preferential degradation of isomers of these metabolites in the environmental compartments. However, based on the available PECgw results (≤ 0.003 µg/L for metabolite V (PBA) and 0.071 µg/L for metabolite Ia), the degradation kinetics in soil and the fact that a worst case K_{Foc} value was used in the simulations for metabolite Ia, it is unlikely that this deficiency would have an impact on the final assessment of these metabolites.

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 107 (November 2013).

The compliance of the batches used in the ecotoxicological studies to the proposed technical specification has not been fully demonstrated.

On the basis of the available data and first-tier risk assessments a low acute and long-term risk to **birds** from dietary exposure was concluded for all representative uses.

A low acute risk to **wild mammals** from dietary routes of exposure was also concluded for the representative uses on wheat and potatoes using first-tier risk assessment assumptions, while a high acute risk was indicated for the representative uses in field tomatoes, plum orchards and peach orchards. A refined assessment was available which was sufficient to demonstrate a low acute risk in peach and plum orchards. No suitable refinements were available for the representative use in field tomatoes and therefore a high risk was concluded and a data gap was identified.

The first-tier long-term risk assessment, from dietary exposure, indicated a high risk to wild mammals for all representative field uses. Refined risk assessments were available only for small herbivorous mammals, but they were not sufficient to demonstrate a low risk (e.g. for the representative uses in plum and peach orchards) or the argumentation was not considered to be robust (e.g. to demonstrate that field voles (*Microtus agrestis*) will not utilise tomato and potato fields across the EU). No refined risk assessments were provided to address the risk to large herbivorous, small insectivorous and small omnivorous mammals. Furthermore, no refined risk assessment was available to address the long-term risk to mammals for the use on wheat. Overall, a high long-term risk to wild mammals was concluded for the representative field uses. A data gap was therefore identified for further information to address the long-term risk to mammals, from dietary routes of exposure, for all representative field uses.

A low acute and long-term risk to birds and mammals from dietary routes of exposure was concluded for the representative uses in glasshouses. A low risk to birds and mammals from the consumption of contaminated water was concluded for all representative uses. A low long-term risk to earthworm-eating birds was indicated for all representative field uses. However, a high long-term risk to earthworm-eating mammals was indicated, therefore a data gap was concluded for further information to address the long-term risk to earthworm-eating mammals for all representative field uses. A low long-term risk to fish-eating birds and mammals was concluded for all representative uses with the exception of the use on peach and plum orchards (Southern Europe), where no risk assessment was available. A data gap was therefore concluded for a risk assessment to address the long-term risk to fish-eating birds and fish-eating mammals for the representative uses on peach and plum orchards in Southern Europe.

An assessment of the potential for biomagnification in terrestrial vertebrates was available. However, the depuration values used in the available modelling were not considered appropriate and consequently the assessment for the potential for biomagnification remains open. No assessment was available to address the potential for biomagnification in aquatic food chains. A data gap is identified for further information to address the potential for biomagnification in terrestrial and aquatic food chains.

During the peer review it was highlighted that an avian short-term dietary study with the mallard duck was available in some Member States but was not included in the applicants' dossier. Although a short-term dietary study is not used for risk assessments performed in accordance with the EFSA guidance document (EFSA, 2009), the experts at the Pesticides Peer Review Experts' Meeting 107 (November 2013) considered that this study should be made available given that the dietary LC_{50} value was less than the value for the bobwhite quail which was included in the dossier. Therefore, a formal data gap was identified for the short-term avian dietary study with the mallard duck (Roberts et al, 1985).

The available **aquatic toxicity data** and risk assessments were discussed at the Pesticides Peer Review Experts Meeting 107. The experts agreed that, on the basis of the available data for multiple species, a refined acute toxicity endpoint for fish could be used for risk assessment in accordance with the recommendations of the EFSA (2006). Further data were also available which allowed for a refined Regulatory Acceptable Concentration (RAC) value to be derived, which was used in the (acute and chronic) risk assessment for aquatic invertebrates. The RAC value was based on a mesocosm study performed with a capsule suspension formulation (CS), in addition to a number of studies from the literature. The experts at the meeting considered that CS formulations may potentially lead to a reduction in exposure to the active substance, as the active substance may be degraded prior to the breakdown of the capsule. Consequently, the experts at the meeting agreed that the refined RAC value was only appropriate for the representative CS formulations. Furthermore, due to the exposure profile within the mesocosm study, the experts agreed that the RAC value only covers scenarios where exposure is from spray-drift only.

A low risk to **algae** was indicated for all representative uses with the exception of the uses on peach and plum orchards in Southern Europe, where a high risk was indicated using the available FOCUS step 2 PEC values.

For the representative uses in glasshouse tomatoes (Northern and Southern Europe), a high acute and chronic risk to fish and aquatic invertebrates was concluded. A low risk to algae and sediment dwelling organisms was indicated with the available assessment.

For the representative uses on peaches and plums (Southern Europe), a high risk to fish (acute and chronic), aquatic invertebrates (acute and chronic) and sediment-dwelling organisms was indicated using FOCUS step 2 PEC values and the tier-1 toxicity data. No further refinements were available for the representative uses on peaches and plums (Southern Europe).

For the representative uses on spring and winter wheat (Northern and Southern Europe), field tomatoes (Northern and Southern Europe), plums (Northern Europe, late applications), seed potatoes and potatoes, a high risk to fish (acute and chronic), aquatic invertebrates (acute and chronic) and sediment-dwelling organisms was indicated in all relevant FOCUS step 3 scenarios.

Further refinements were performed using FOCUS step 4 PEC values (assuming 95 % drift reduction and 90 % run-off reduction), and using the refined effect assessments described above. These refinements were only available for the representative uses on winter and spring wheat (Northern and Southern Europe, for the representative uses covered by 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'), potatoes (Northern and Southern Europe) and seed potatoes. No further refinements were performed for the representative uses on plums (Northern Europe, late applications), field tomatoes (Northern and Southern Europe) and winter and spring wheat (Northern and Southern Europe, for the representative uses covered by 'Kaiso Sorbie 5% EG' and 'Karatae 10 CS'). Regarding the acute risk assessment for **fish**, a high risk was indicated, using the available FOCUS step 4 exposure estimates, in 5/9 FOCUS scenarios for the use on winter wheat (Northern and Southern Europe), in 2/5 FOCUS scenarios for the use on spring wheat (Northern and Southern Europe), in 6/6 scenarios for seed potatoes in Southern Europe, in 6/6 scenarios for potatoes in Southern Europe and in 2/6 scenarios for seed potatoes (Northern Europe, 4 applications). The acute risk to fish was assessed as low for all relevant FOCUS scenarios, at FOCUS step 4, for the use on potatoes in Northern Europe. Regarding the chronic risk assessment for fish, a low risk was indicated for all relevant FOCUS scenarios at FOCUS step 4 for the uses on winter and spring wheat (Northern and Southern Europe), seed potatoes and potatoes in Northern Europe, however, a high chronic risk to fish was indicated for 6/6 FOCUS scenarios for the representative uses on seed potatoes and potatoes in Southern Europe.

Where appropriate (i.e. for the CS formulations and where the exposure was demonstrated to be from spray-drift only), the refined RAC value for **aquatic invertebrates** (acute and chronic) were used together with the available FOCUS step 4 PEC values. On the basis of this assessment, a high risk was indicated for all relevant FOCUS scenarios for the uses on spring and winter wheat (Northern and Southern Europe), seed potatoes and potatoes (Northern and Southern Europe). A low risk to **sediment-dwelling organisms** was indicated for the uses on winter and spring wheat (Northern and Southern Europe) and potatoes (Northern and Southern Europe).

On the basis of the available data and risk assessments a low risk to aquatic organisms from the pertinent metabolites Ia, XV and V was concluded for all representative uses. A data gap was concluded for identification of potential degradation products formed from the phenoxy-^{14}C labelled lambda-cyhalothrin when applied at doses below the water solubility in the aquatic environment (see section 4). Therefore, should any additional pertinent metabolites be identified then further risk assessments may be required.

Overall, a high risk was identified for **aquatic organisms** from exposure to lambda-cyhalothrin for all the representative uses. It should be further noted that a data gap was identified for information about conversion/preferential degradation of isomers of lambda-cyhalothrin in the aquatic compartment (see section 4). Consequently, there is additional uncertainty as to whether the exposure and risk assessment is worst case. Several data gaps were identified for further risk assessments (see section 7).

For **honey bees**, oral and contact hazard quotients (HQ_{oral} and $HQ_{contact}$) were calculated using the available toxicity data with the active substance and three of the four representative formulations (‘Lambda-Cyhalothrin 100 CS’, ‘Karate 10CS’ and ‘Lambda 50 EC’). The calculated $HQ_{contact}$ values indicated a high risk from the active substance for all representative field uses, whilst the HQ_{oral} values for the active substance were all less than the trigger value indicating a low risk. The available toxicity data indicated that the active substance, when formulated in two of the representative formulations (‘Karate 10CS’ and ‘Lambda 50 EC’), was orally more toxic than the technical. The HQ_{oral} values based on toxicity data for these formulations indicated a high risk. The $HQ_{contact}$ values based on toxicity data for ‘Karate 10CS’ and ‘Lambda 50 EC’ indicated a high risk for all representative field uses, whereas the $HQ_{contact}$ values for ‘Lambda-Cyhalothrin 100 CS’ indicated a low contact risk for all representative field uses with the exception of the use on peaches.

Honey bee semi-field (tunnel study) and field studies were available with two of the four representative formulations (‘Karate 10CS’ (or similar formulation) and ‘Lambda-Cyhalothrin 100 CS’) on flowering *Phacelia tanacetifolia* or oilseed rape. Adult honey bee mortality was observed in the tunnel study performed with ‘Lambda-Cyhalothrin 100 CS’ but the magnitude and the duration of this effect was considered not relevant. The study included detailed bee brood assessments and no clear adverse effect was observed. Some effects on mortality were also observed in the field studies performed with the representative formulation ‘Karate 10CS’ (and similar formulation). On the basis of these studies, overall, a low risk to honey bees was concluded for the representative uses in spring and winter cereals (Northern and Southern Europe), potatoes and seed potatoes (Northern and Southern Europe) and field tomatoes (Northern and Southern Europe).

It should be noted that, due to the variation in toxicity observed in the available acute studies, the experts at the Pesticides Peer Review Experts' Meeting 107 did not consider appropriate to read-across the available higher tier data between the different formulations. Therefore, whilst a low risk to bees was concluded for the representative field uses of lambda-cyhalothrin, further consideration of the risk posed by the plant protection products is required. In addition, it was not considered appropriate to extrapolate the studies performed on flowering *Phacelia tanacetifolia* and oilseed rape to crops other than field crops. Consequently, the available studies were not considered suitable to address the risk to honey bees for the representative use on peach and plum orchards and a data gap was identified to further address the risk.

A low risk to honey bees was concluded for the representative uses in glasshouse tomatoes. No assessment of the risk to pollinators which may be used in glasshouses was available.

The first-tier risk assessment for **non-target arthropods** indicated a high risk both in-field and off-field for all representative field uses. Numerous non-target arthropod field studies were made available, however only three studies were considered to be valid and relevant in relation to the representative uses of lambda-cyhalothrin. These studies, performed with 'Karate 10CS' in cereal fields in Denmark, Germany and Italy, were discussed at the Pesticides Peer Review Experts' Meeting 107. For the studies performed in Denmark and Germany the experts agreed that recovery of in-field populations of non-target arthropods had not been demonstrated within 1 year after application. As a result, a high risk to non-target arthropods was concluded for the representative use on spring and winter sown cereals in Northern Europe and a data gap was identified for further refinements.

The experts considered that the available field study performed in Italy did indicate the potential for recovery of in-field populations of non-target arthropods within 1 year. The experts highlighted some uncertainty with this conclusion given the variability in abundance within the controls for a number of species. However, overall, it was agreed that a low risk to in-field populations of non-target arthropods could be concluded for the representative uses on spring sown cereals in Southern Europe.

No further risk assessment was available to address the risk to in-field populations of non-target arthropods for the representative uses on field tomatoes, plums, peaches and potatoes in Northern and Southern Europe, therefore a data gap was identified. The risk to off-field non-target arthropods was discussed at the Pesticides Peer Review Experts' Meeting 107. The experts raised a concern regarding the proposed risk mitigation measures, which were considered to be unrealistic (e.g. in-field no-spray buffer zones of 50 m). Consequently, the experts considered that further information should be required to demonstrate a low risk to off-field populations of non-target arthropods. Therefore, a data gap was identified for all representative field uses. A low risk to non-target arthropods was concluded for the representative use on tomatoes in glasshouses.

A low risk to **earthworms, soil macroorganisms** and **soil microorganisms** from lambda-cyhalothrin and the pertinent soil metabolites Ia, V and XV was concluded for all representative uses. A low risk to **non-target terrestrial plants** and **sewage treatment organisms** was also concluded.

As discussed in section 2 some indications of interactions of lambda-cyhalothrin with receptors of the endocrine and immune systems were observed in *in vitro* studies in mammals from the open literature (see section 2). However, the available information was considered insufficient to clarify the potential endocrine activity in mammals. As a consequence, a data gap was identified for the level 2 and/or 3 OECD tests (see section 2). The outcome of these studies should be considered in relation to the ecotoxicological assessment. A number of non-target organism studies, which are included in level 4 and 5 of the OECD Conceptual Framework (OECD, 2012a) (e.g. fish full-life-cycle study), were available. However, these studies alone are not sufficient to investigate all the relevant mechanisms and they may not be sufficient to detect all adverse effects which could be caused by an endocrine mechanism. Overall, insufficient information was available to perform an assessment of whether lambda-cyhalothrin has **endocrine disrupting properties** that may cause adverse effects on non-target organisms (issue not finalised).

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

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
lambda-cyhalothrin	moderate to high persistence laboratory single first order or biphasic soil DT_{50} 19.7-163 days (DT_{90} 82-2330 days, 20°C and pF2)	Low risk to soil-dwelling organisms.
metabolite Ia	low to moderate persistence laboratory single first order or biphasic soil DT_{50} 2.4-19.1 days (DT_{90} 10.2-63.9 days, 20°C and pF2)	Low risk to soil-dwelling organisms.
metabolite XV	low to moderate persistence laboratory single first order or biphasic soil DT_{50} 2.9-24.2 days (DT_{90} 25.2-80.3 days, 20°C and pF2)	Low risk to soil-dwelling organisms.
metabolite V (PBA) (anaerobic conditions)	moderate to medium persistence laboratory SFO soil DT_{50} 13.9-61.9 days (20°C and pF2)	Low risk to soil-dwelling organisms.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
lambda-cyhalothrin	Immobile $K_{Foc} \geq 38000$ mL/g	No	Yes	Yes	A high risk to aquatic organisms was indicated in the surface water risk assessment.
metabolite Ia	Very high to high mobility K_{Foc} 13-93 mL/g pH dependent (lower mobility as pH decreases).	No	No data	Rat oral LD_{50} > 4990 mg/kg bw Rat dermal LD_{50} > 2000 mg/kg bw Unlikely to be genotoxic	A low risk to aquatic organisms was indicated in the surface water risk assessment.
metabolite XV	Immobile $K_{Foc} \geq 60000$ mL/g	No	No data	No data, data not required	A low risk to aquatic organisms was indicated in the surface water risk assessment.
metabolite V (PBA) (anaerobic conditions)	Medium mobility $K_{doc} = 217.8$ mL/g (estimated with EPI Suite v. 4.10 and EPI Web v.4.0)	No	No data	Rat oral LD_{50} = 3000 mg/kg bw No further data necessary as groundwater metabolite	A low risk to aquatic organisms was indicated in the surface water risk assessment.

6.3. Surface water and sediment[(a)]

Compound (name and/or code)	Ecotoxicology
lambda-cyhalothrin	A high risk to aquatic organisms was indicated for all representative uses.
metabolite Ia	A low risk to aquatic organisms was indicated.
metabolite XV	A low risk to aquatic organisms was indicated.
metabolite V (PBA) (aqueous photolysis)	A low risk to aquatic organisms was indicated.

(a): Provisional residue definition as a data gap has been identified for a complete route of degradation of lambda-cyhalothrin in the aquatic compartment.

6.4. Air

Compound (name and/or code)	Toxicology
lambda-cyhalothrin	Rat LC_{50} inhalation 0.066 mg/L air/4 h (nose-only): very toxic by inhalation

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

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

- Revised specification for the minimum active ingredient content according to the proposal in the RAR (relevant for Syngenta; submission date proposed by the applicant: already submitted to the RMS, see section 1).

- Revised specification removing the non-relevant impurities below 1 g/kg (relevant for Nufarm; submission date proposed by the applicant: unknown; see section 1).

- Revised specification removing the non-relevant impurities below 1 g/kg (relevant for SAPEC AGRO S.A.; submission date proposed by the applicant: unknown; see section 1).

- Shelf-life study of ‘Lambda 50 EC’ formulation (relevant for the uses of ‘Lambda 50 EC’ in the representative GAP; submission date proposed by the applicant: 2014, see section 1 and Evaluation Table data requirement 1.3).

- Surface tension of the neat formulation and data on emulsifiability for ‘Lambda 50 EC’ (relevant for the uses of ‘Lambda 50 EC’ in the representative GAP; submission date proposed by the applicant: unknown, see section 1).

- Data on suspensibility and pourability for ‘Lambda-Cyhalothrin 100 CS’ (relevant for the uses of ‘Lambda-Cyhalothrin 100 CS’ in the representative GAP; submission date proposed by the applicant: unknown, see section 1).

- Additional validation data of the LC-MS/MS method concerning the analysis of fat (relevant for TFL; submission date proposed by the applicant: unknown, see section 1).

- Enforcement residue method for surface water capable of determining the residues according to the residue definition in the environmental matrices (relevant for STF/TFL; submission date proposed by the applicant: unknown, see section 1).

- Toxicological information allowing to assess the relevance of several impurities (that are not isomers of cyhalothrin) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2).

- Clarification whether the sperm effects that were reported in published literature in mice treated with low doses of lambda-cyhalothrin tested in a formulation have an impact on the outcome of the risk assessment (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2).

- Considering the sperm effects in mice (see previous data gap) and the brain morphological changes in the developmental neurotoxicity study, further tests according to the OECD Conceptual Framework (level 2 and/or 3) are needed to screen the potential endocrine activity of lambda-cyhalothrin (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see sections 2 and 5).

- Toxicological information on metabolites V (PBA) and XXIII (PBA(OH)) as these are common metabolites of pyrethroid active substances to which human exposure has been demonstrated (submission date proposed by the applicant: unknown; see sections 2 and 3).

- A complete residue data set on peach (Southern Europe) (relevant for TFL; submission date proposed by the applicant: unknown; see section 3).
- Sufficient GAP-compliant residue trials on potatoes covering respectively Northern and Southern Europe (relevant for TFL; submission date proposed by the applicant: unknown; see section 3).
- A complete residue dataset on spring/winter wheat covering respectively Northern and Southern Europe (relevant for TFL; submission date proposed by the applicant: unknown; see section 3).
- Validation data package of the analytical method (RAM 81) used to determine the residues of lambda-cyhalothrin in plums (relevant for STF; submission date proposed by the applicant: unknown; see section 3).
- Storage stability data on lambda-cyhalothrin residues in plants (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 3).
- Processing residue trials addressing the magnitude of compounds Ia, IV and gamma-lactone in fruit (plum, peach) processed products that may undergo heating by processing (relevant for TFL/STF; submission date proposed by the applicant: unknown; see section 3).
- Residue storage stability data on lambda-cyhalothrin and compound XI in ruminants matrices (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 3).
- Information about conversion/preferential degradation of isomers of lambda-cyhalothrin in the aquatic compartment was not available (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see sections 4 and 5).
- Satisfactory information to address the levels of metabolites formed from the phenoxy-^{14}C labelled lambda-cyhalothrin when applied at doses below the water solubility in the aquatic environment. Should any additional pertinent metabolites be identified then the risk to aquatic organisms should be addressed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see sections 4 and 5).
- Further information is required to address the acute risk to mammals from dietary routes of exposure (relevant for the representative use uses on field tomatoes; submission date proposed by the applicant: unknown; see section 5).
- Further information is required to address the long-term risk to mammals from dietary routes of exposure and from secondary poisoning to earthworm-eating mammals (relevant for all representative field uses; submission date proposed by the applicant: unknown; see sections 5).
- A risk assessment to address the long-term risk to fish-eating birds and mammals (relevant for the representative use on peach and plum orchards in Southern Europe; submission date proposed by the applicant: unknown; see sections 5).
- Further information is required to address the potential for biomagnification in terrestrial and aquatic food chains (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see sections 5).
- The short-term avian dietary study with the mallard duck (Roberts et al, 1985) should be made available (formal data gap arisen at the Pesticides Peer Review Experts' Meeting 107 (November 2013); submission date proposed by the applicant: unknown; see sections 5).

- Further information is required to address the acute risk to fish in situations represented by: D1, D2, D3, D5 and D6 (5/9) FOCUS scenarios for the use on winter wheat (Northern and Southern Europe); D1 and D3 (2/5) FOCUS scenarios for the use on spring wheat (Northern and Southern Europe); R1 and R3 (2/6) FOCUS scenarios for the use on seed potatoes in Northern Europe; all relevant FOCUS scenarios for the uses on potatoes (Southern Europe), seed potatoes (Southern Europe), field tomatoes (Northern and Southern Europe, plums (Northern and Southern Europe), peaches and glasshouse tomatoes (Northern and Southern Europe) (submission date proposed by the applicant: unknown; see sections 4 and 5).

- Further information is required to address the chronic risk to fish in all relevant FOCUS scenarios (relevant for the representative uses on seed potatoes and potatoes in Southern Europe; field tomatoes (Northern and Southern Europe); plums (Northern and Southern Europe); peaches, glasshouse tomatoes (Northern and Southern Europe); submission date proposed by the applicant: unknown; see sections 4 and 5).

- Further information is required to address the risk to aquatic invertebrates (acute and chronic) (relevant for all representative uses; submission date proposed by the applicant: unknown; see sections 4 and 5).

- Further information is required to address the risk to sediment-dwelling organisms (relevant for representative uses on plums (Northern and Southern Europe), field tomatoes (Northern and Southern Europe) and peaches; submission date proposed by the applicant: unknown; see sections 4 and 5).

- Further information is required to address the risk to algae (relevant for the representative use on peach and plum orchards in Southern Europe; submission date proposed by the applicant: unknown; see sections 4 and 5).

- Further information is required to address the risk to honey bees (relevant for the representative uses on peach and plum orchards; submission date proposed by the applicant: unknown; see sections 5).

- Further information is required to address the risk to in-field populations of non-target arthropods (relevant for all representative field uses with the exception of spring sown wheat in Southern Europe; submission date proposed by the applicant: unknown; see sections 5).

- Further information is required to address the risk to off-field populations of non-target arthropods (relevant for all representative field uses; submission date proposed by the applicant: unknown; see sections 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 broad brimmed headwear for hand-held application in orchards), and during application (gloves, hood and visor/broad brimmed headwear, coverall and sturdy footwear) have to be considered to ensure that operator exposure does not exceed the AOEL for all proposed scenarios (see section 2).

- Bystander exposure to orchard treatments was estimated not to exceed the AOEL only if certain parameters are considered, i.e., bystanders remaining at least at 10 m distance from a maximum spray application of 10 g/ha, or if treatments are made on late fruit crops treated with 22.5 g/ha with bystanders remaining at least at 10 m distance from a maximum spray application (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 in accordance with Article 29(6) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council and as set out in Commission Regulation (EU) No 546/2011,[9] and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as an issue that could not be finalised where the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

1. Lambda-cyhalothrin is not classified or proposed to be classified as carcinogenic category 2 or toxic for reproduction category 2, in accordance with the provisions of Regulation (EC) No 1272/2008, and therefore the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. However, an endocrine-mediated mode of action could not be ruled out regarding the brain morphological changes observed in the developmental neurotoxicity study (and possible sperm effects, which have to be clarified in the first place) and the potential for endocrine disrupting effects could not be finalised (see Sections 2 and 5).

2. The consumer risk assessment could not be finalised as the proposed residue definition for risk assessment remains provisional for processed commodities and considering the uncertainties due to the identified data gaps.

3. A complete route of degradation of lambda-cyhalothrin in the aquatic compartment could not be finalised as satisfactory information to address the levels of metabolites formed from the phenoxy-^{14}C labelled lambda-cyhalothrin when applied at doses below the water solubility is not available. Consequently, the risk to aquatic organisms from any additional pertinent metabolites could not be finalised.

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

9.2. Critical areas of concern

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

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

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

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

5. It could not be fully demonstrated that the batches used in the toxicological and ecotoxicological studies are compliant to the proposed technical specification, as it appears that some impurities have not been tested (or not at an appropriate level) in the toxicological studies.

6. A high acute and chronic risk to aquatic organisms was indicated for all representative uses, even when, where available, the risk assessment was performed using exposure estimates which assumed the maximum permissible risk mitigation according to the FOCUS Landscape and Mitigation Guidance Document (FOCUS, 2007).

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.)

In addition to the issues indicated, all columns are grey as it could not be fully demonstrated that the technical material specification proposed was comparable to the material used in the (eco)toxicological testing and the testing that was used to derive the toxicological reference values.

Representative use		**Winter wheat 7.5 g a.s./ha** **N/SEU**	**Spring wheat 7.5 g a.s./ha** **N/SEU**	**Potato 7.5 g a.s./ha** **NEU**	**Seed Potato 7.5 g a.s./ha** **NEU**	**Seed Potato 20 g a.s./ha** **SEU**	**Potato 20 g a.s./ha** **SEU**	**Tomato outdoor 12.5 g a.s./ha** **NEU**	**Tomato outdoor 25 g a.s./ha** **SEU**	**Tomato indoor 25 g a.s./ha** **N/SEU**	**Plum orchard 10 g a.s./ha** **NEU**	**Plum orchard 25 g a.s./ha** **SEU**	**Peach orchard 22.5 g a.s./ha** **SEU**
Operator risk	Risk identified												
	Assessment not finalised												
Worker risk	Risk identified					X	X	X	X	X	X	X	X
	Assessment not finalised												
Bystander risk	Risk identified											X	X[*]
	Assessment not finalised												
Consumer risk	Risk identified												
	Assessment not finalised	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]
Risk to wild non target terrestrial vertebrates	Risk identified	X	X	X	X	X	X	X	X		X	X	X
	Assessment not finalised	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]

[*] Only for early application

Representative use		Winter wheat 7.5 g a.s./ha N/SEU	Spring wheat 7.5 g a.s./ha N/SEU	Potato 7.5 g a.s./ha NEU	Seed Potato 7.5 g a.s./ha NEU	Seed Potato 20 g a.s./ha SEU	Potato 20 g a.s./ha SEU	Tomato outdoor 12.5 g a.s./ha NEU	Tomato outdoor 25 g a.s./ha SEU	Tomato indoor 25 g a.s./ha N/SEU	Plum orchard 10 g a.s./ha NEU	Plum orchard 25 g a.s./ha SEU	Peach orchard 22.5 g a.s./ha SEU
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	X	X	X	X	X	X	X	X		X	X	X
	Assessment not finalised												
Risk to aquatic organisms	Risk identified	X[6]	X[6]	X[6]	X[6]	X[6]	X[6]	X[6]	X[6]	X[6]	X[6]	X[6]	X[6]
	Assessment not finalised	X[3,4]	X[3,4]	X[3,4]	X[3,4]	X[3,4]	X[3,4]	X[3,4]	X[3,4]	X[3,4]	X[3,4]	X[3,4]	X[3,4]
Groundwater exposure active substance	Legal parametric value breached												
	Assessment not finalised												
Groundwater exposure metabolites	Legal parametric value breached[(a)]												
	Parametric value of 10µg/L[(b)] breached												
	Assessment not finalised												
Comments/Remarks													

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

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

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

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APPENDICES

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

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

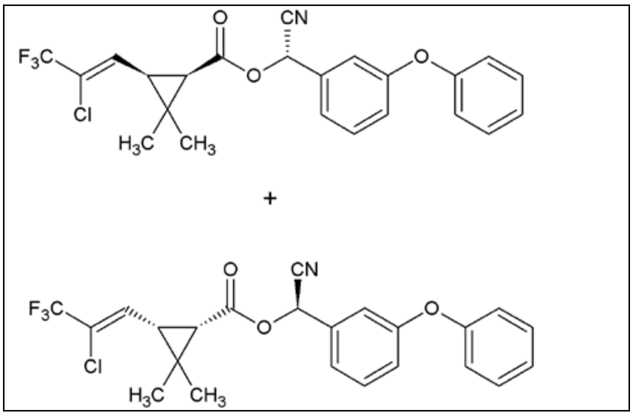
Active substance (ISO Common Name) ‡	lambda-cyhalothrin
Function (e.g. fungicide)	insecticide

Rapporteur Member State	Sweden
Co-Rapporteur Member Sate	Spain

Identity

Chemical name (IUPAC) ‡	A 1:1 mixture of: (*R*)-α-cyano-3-phenoxybenzyl (1*S*,3*S*)-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate or of (*R*)-α-cyano-3-phenoxybenzyl (1*S*)-*cis*-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3-phenoxybenzyl (1*R*)-*cis*-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate
Chemical name (CA) ‡	(*R*)-cyano(3-phenoxyphenyl)methyl (1*S*,3*S*)-*rel*-3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate
CIPAC No ‡	463
CAS No ‡	91465-08-6
EC No (EINECS or ELINCS) ‡	415-130-7
FAO Specification (including year of publication) ‡	FAO/WHO Specification 463/TC (2013): Min. purity: 810 g/kg The maximum acidity shall be 0.5 g/kg, calculated as H_2SO_4
Minimum purity of the active substance as manufactured ‡	900 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Open
Molecular formula ‡	$C_{23}H_{19}ClF_3NO_3$
Molecular mass ‡	449.9 g/mol

Structural formula ‡



Physical and chemical properties

Melting point (state purity) ‡	49.2°C (99.0 % w/w)
Boiling point (state purity) ‡	No boiling point before decomposition (99.0 % w/w)
Temperature of decomposition	Approximately 275°C at atmospheric pressure (99.0 % w/w)
Appearance (state purity) ‡	Purified grade : white solid with no characteristic odour (99.0 % w/w) Technical grade : light beige solidified melt (94.0 % w/w) ; white solid (98.8 % w/w) ; no characteristic odour (96.5 % w/w)
Vapour pressure (state temperature, state purity) ‡	2 x 10^{-7} Pa at 20°C (extrapolated from data generated in the temperature range 60-80°C; 99.0 % w/w purity)
Henry's law constant ‡	0.02 Pa·m^3/mol at 20°C (calculated using the vapour pressure and water solubility at pH 6.5)
Solubility in water (state temperature, state purity and pH) ‡	Parent At 20°C (99.0%w/w) 4 µg/Lat pH 5.0 (buffered water) 5 µg/L at pH 6.5 (purified water) 4 µg/L at pH 9.2 (buffered water) Metabolites IA (99.7 % w/w): 56.0 mg/L at 20°C in non-buffered purified water (pH 4.5-4.6) V (PBA) (100 % w/w):): 26.0 mg/L at 20°C in non-buffered purified water (pH 4.2-4.3) XV (95.2 % w/w): 0.15 mg/L at 20°C non-buffered purified water (pH 5.0)
Solubility in organic solvents ‡ (state temperature, state purity)	>250 g/L in methanol, acetone, ethyl acetate, 1,2-dichloroethane and p-xylene at 25°C, 67-80 g/L in n-heptane at 20°C (97.2%w/w) >500g/L in acetone, dichloromethane, ethyl acetate, hexane, methanol and toluene at 25°C, 210 g/L in n-octanol at 25°C (94.0 % w/w)
Surface tension ‡ (state concentration and temperature, state purity)	Not applicable as the solubility in water is < 1 mg/L
Partition co-efficient ‡ (state temperature, pH and purity)	5.5 at 20°C (neutral pH; 97.2 % w/w); no pH effect anticipated
Dissociation constant (state purity) ‡	No dissociation within environmentally relevant pH range
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	At neutral pH (methanol; 99.0 % w/w): 254 nm (min.), ε 1090 M^{-1}·cm^{-1}, 277 nm (max): ε 2070 M^{-1}·cm^{-1}
Flammability ‡ (state purity)	Not highly flammable (94.0 % w/w) Auto-ignition temperature: 390°C ± 5 °C (94.0 % w/w), 380°C (97.4 % w/w) Flash-point: 225 ± 8°C (94.0 % w/w), 230°C (97.4 % w/w)
Explosive properties ‡ (state purity)	Not explosive (94.0 % w/w)
Oxidising properties ‡ (state purity)	Not oxidizing in molten form at 90°C (94.0 % w/w)

Summary of representative uses evaluated (lambda-cyhalothrin)

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (day) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	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		
Spring Wheat	EU-N	Karate 10CS Kaiso sorbie	F	Cereal aphids (Sitobio, Rhopalosiphon padi, Metapolophium etc) Aphids as virus vectors Psammotettix alienus (Wheat dwarf virus vector), Zabrus, Oulemma, Delia sp., Gall midges (Sitodiplosis and Contarina sp.) and thrips.	CS EG	100 g/L 50 g/kg	foliar spray	BBCH 10-85	2	18	1.25-3,75	200-600	7.5		The last application should be made no later than at growth stage BBCH 83-85 STF
Winter Wheat	EU-N	Karate 10CS Kaiso sorbie	F		CS EG	100 g/L 50 g/kg	foliar spray	BBCH 10-85	2	18	1.25-3,75	200-600	7.5		

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (day) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	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		
Spring Wheat	EU-S	Karate 10CS Kaiso sorbie	F	Cereal aphids (Sitobio, Rhopalosiphon padi, Metapolophium etc) Aphids as virus vectors Psammotettix alienus (Wheat dwarf virus vector), Zabrus, Oulemma, Delia sp., Gall midges (Sitodiplosis and Contarina sp.) and thrips.	CS EG	100 g/L 50 g/kg	foliar spray	BBCH 10-85	2	18	0.75-1.07	700-1000	7.5		The last application should be made no later than at growth stage BBCH 83-85 STF
Winter Wheat	EU-S	Karate 10CS Kaiso sorbie	F		CS EG	100 g/L 50 g/kg	foliar spray	BBCH 10-85	2	18	0.75-1.07	700-1000	7.5		
Winter Wheat	EU-N	Lambda-Cyhalothrin 100 CS Lambda 50 EC	F	Aphids (Virus vectors)	CS EC	100 g/L 50 g/L	Tractor mounted sprayer, broadcast, ground directed spray	BBCH 10 to 29 (≈ Oct./EU-N)	1-2	14	1.875-3.75	200-400	7.5		RMS comment: Note that winter wheat may be treated both in Oct and Jun. TFL

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (day) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	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		
Winter Wheat	EU-N	Lambda-Cyhalothrin 100 CS Lambda 50 EC	F	Aphids	CS EC	100 g/L 50 g/L	Tractor mounted sprayer, broadcast, ground directed spray	BBCH 30 to 79 (≈ Jun./EU-N)	1-2	14	0.75-1.07	200-400	7.5	30	RMS comment: Note that winter wheat may be treated both in Oct and Jun. TFL
Spring Wheat	EU-N	Lambda-Cyhalothrin 100 CS Lambda 50 EC	F	Aphids	CS EC	100 g/L 50 g/L	Tractor mounted sprayer, broadcast, ground directed spray	BBCH 30 to 79 (≈ Jun./EU-N)	1-2	14	0.75-1.07	200-400	7.5	30	TFL
Winter Wheat	EU-S	Lambda-Cyhalothrin 100 CS Lambda 50 EC	F	Aphids (Virus vectors)	CS EC	100 g/L 50 g/L	Tractor mounted sprayer, broadcast, ground directed spray	BBCH 10 to 29 (Nov./EU-S)	1-2	14	0.75-1.07	200-400	7.5		RMS comment: Note that winter wheat may be treated both in Nov and May. TFL

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (day) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	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		
Winter Wheat	EU-S	Lambda-Cyhalothrin 100 CS Lambda 50 EC	F	Aphids	CS EC	100 g/L 50 g/L	Tractor mounted sprayer, broadcast, ground directed spray	BBCH 30 to 79 (May/EU-S)	1-2	14	0.75-1.07	200-400	7.5	30	RMS comment: Note that winter wheat may be treated both in Nov and May. TFL
Spring Wheat	EU-S	Lambda-Cyhalothrin 100 CS Lambda 50 EC	F	Aphids	CS EC	100 g/L 50 g/L	Tractor mounted sprayer, broadcast, ground directed spray	BBCH 30 to 79 (May/EU-S)	1-2	14	0.75-1.07	200-400	7.5	30	TFL
Tomato	EU-N	Karate 10CS Kaiso sorbie	F	Aphids for open field tomato use Whitefly (Trialeurodes and bemisia). Heliothis armigera and virescens	CS EG	100 g/L 50 g/kg	foliar spray	BBCH 10-89	2	12	1.25-15.625	80-1000	12.5	3	STF
Tomato	EU-S	Karate 10CS Kaiso sorbie	F		CS EG	100 g/L 50 g/kg	foliar spray	BBCH 10-89	2	12	2.5-31.25	80-1000	25	3	STF
Tomato	EU-N/S	Karate 10CS Kaiso sorbie	G		CS EG	100 g/L 50 g/kg	foliar spray	BBCH 10-89	2	12	1.25-12.5	200-2000	25	3	STF

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (day) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	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		
Plum	EU-N	Karate 10CS Kaiso sorbie	F	Cydia funebrana Aphids	CS EG	100 g/L 50 g/kg	foliar spray	BBCH 10-85(1)	2	10-14	0.66-1	1000-1500	10	7	STF
Plum	EU-S	Karate 10CS Kaiso sorbie	F		CS EG	100 g/L 50 g/kg	foliar spray	BBCH 10-85(1)	2	10-14	1.66-2.5	1000-1500	25	7	STF
Seed Potato	EU-N	Lambda-Cyhalothrin 100 CS Lambda 50 EC	F	Aphids (Virus vectors)	CS EC	100 g/L 50 g/L	Tractor mounted sprayer, broadcast, ground directed spray	BBCH 15-39 (≈ Apr.)	2	7	1.25-1.875	400-600	7.5		RMS comment: Note that Seed Potato may be treated both in Apr and Jun-Sep. Refers to potatoes that are to be used as seed potatoes inthe next year. TFL

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (day) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	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		
Seed Potato	EU-N	Lambda-Cyhalothrin 100 CS Lambda 50 EC	F	Aphids, Colorado potato beetles	CS EC	100 g/L 50 g/L	Tractor mounted sprayer, broadcast, ground directed spray	BBCH 40 to 85 (Jun. - Sep.)	2	7	1.25-1.875	400-600	7.5	3	RMS comment: Note that Seed Potato may be treated both in Apr and Jun-Sep. Refers to potatoes that are to be used as seed potatoes inthe next year. TFL
Potato	EU-N	Lambda-Cyhalothrin 100 CS Lambda 50 EC	F	Aphids, Colorado potato beetles	CS EC	100 g/L 50 g/L	Tractor mounted sprayer, broadcast, ground directed spray	BBCH 40-85 (Jun. - Sep.)	2	7	1.25-1.875	400-600	7.5	3	RMS comment: Refers to potatoesharvested forconsumption. TFL

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (day) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	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		
Seed Potato	EU-S	Lambda-Cyhalothrin 100 CS Lambda 50 EC	F	Aphids (virus vectors)	CS EC	100 g/L 50 g/L	Tractor mounted sprayer, broadcast, ground directed spray	BBCH 15-39 (Mar.)	1		2-5	400-1000	20		RMS comment: Note that Seed Potato may be treated both in Mar and May-Sep (min. 8(-10) days interval between applications). Refers to potatoes that are to be used as seed potatoes inthe next year. TFL

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (day) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	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		
Seed potato	EU-S	Lambda-Cyhalothrin 100 CS Lambda 50 EC	F	Aphids, Colorado potato beetles	CS EC	100 g/L 50 g/L	Tractor mounted sprayer, broadcast, ground directed spray	BBCH 40-85 (May - Sep.)	1		2-5	400-1000	20	3	RMS comment: Note that Seed Potato may be treated both in Mar and May-Sep. (min. 8(-10) days interval between applications). Refers to potatoes that are to be used as seed potatoes in the next year. TFL
Potato	EU-S	Lambda-Cyhalothrin 100 CS Lambda 50 EC	F	Aphids, Colorado potato beetles	CS EC	100 g/L 50 g/L	Tractor mounted sprayer, broadcast, ground directed spray	BBCH 40-85 (May – Sep).	2	8	2-5	400-1000	20	3	RMS comment: Refers to potatoes harvested for consumption. TFL

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (day) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	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		
Peach	EU-S	Lambda-Cyhalothrin 100 CS	F	Thrips	CS	100 g/L	foliar application	BBCH 53-69 (≈ Mar. – Apr.) BBCH 81-87 (≈ June.-Oct.)	1-2	30	2.25-3.75	600-1000	22.5	7	TFL

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*eg.* fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) eg. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) eg. wettable powder (WP), watersoluble granule (WG)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, eg. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, eg. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

(1) During the written procedure the RMS indicated that the GAP for plums should be BBCH 10-79. EFSA proposes to leave unchanged the reported NEU and SEU GAPs on plums with regard to the BBCH GS (10-85). Indeed, at the proposed earlier BBCH 10-79, the PHI value of 7 days may become unappropriate.

Methods of Analysis

Analytical methods for the active substance

Technical as (analytical technique)	GC-FID or HPLC-UV
Impurities in technical as (analytical technique)	Information considered confidential and are thus presented in the Annex C for the respective participating companies
Plant protection product (analytical technique)	GC-FID or HPLC-UV

Analytical methods for residues

Residue definitions for monitoring purposes

Food of plant origin	lambda-cyhalothrin
Food of animal origin	lambda-cyhalothrin
Soil	lambda-cyhalothrin (as the sum of cyhalothrin isomers)
Water surface	lambda-cyhalothrin (as the sum of cyhalothrin isomers)
Water drinking/ground	lambda-cyhalothrin (as the sum of cyhalothrin isomers)
Air	lambda-cyhalothrin
Body fluids and tissues	lambda-cyhalothrin

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	STF Multi-residue method QuEChERS GC-MS (LOQ = 0.01 mg/kg) Lambda-cyhalothrin (parent) in wheat grain, lettuce, oilseed rape and whole orange. or TFL Multi-residue method LC-MS/MS (LOQ = 0.01 mg/kg) Lambda-cyhalothrin (parent) in wheat grain, apple, avocado and lemon.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	STF Multi-residue method DFG-S19 GC-MS (LOQ = 0.01 mg/kg) Lambda-cyhalothrin (parent) in hen eggs, whole milk, bovine meat, liver, kidney and fat or TFL Multi-residue method LC-MS/MS (LOQ = 0.01 mg/kg) Lambda-cyhalothrin (parent) in cow milk, hen eggs, meat (beef) and pig liver. Data gap for additional validation data concerning the analysis of fat.
Soil (analytical technique and LOQ)	STF Multi-residue method GC-MS (LOQ = 0.01 mg/kg) Lambda-cyhalothrin (parent). or TFL Multi-residue method LC-MS/MS (LOQ = 0.05 mg/kg) Lambda-cyhalothrin (parent).
Water (analytical technique and LOQ)	<u>Drinking water:</u> STF Multi-residue method

	GC-MS LOQ = 0.002 µg/L Lambda-cyhalothrin + diastereomer A (cyhalothrin) in ground and drinking water. or TFL Multi-residue method LC-MS/MS LOQ = 0.1 µg/L Lambda-cyhalothrin + diastereomer A (cyhalothrin) in tap and ground water. <u>Surface water:</u> Data gap (the above mentioned methods validated also for surface water do not comply with the required LOQ).
Air (analytical technique and LOQ)	STF Multi-residue method GC-MS (LOQ = 0.075 µg/m$^{3)}$ Lambda-cyhalothrin (parent).
Body fluids and tissues (analytical technique and LOQ)	STF Multi-residue method DFG-S19 GC-MS (LOQ = 0.01 mg/kg) Lambda-cyhalothrin (parent) in bovine meat, liver, kidney and fat and swine blood. or TFL Multi-residue method LC-MS/MS (LOQ = 0.05 mg/L) Lambda-cyhalothrin (parent) in human urine and animal blood serum.

Classification and labelling with regard to physical and chemical data

Classification according to Council Directive 67/548/EEC / Regulation (EC) No 1272/2008:	None
RMS proposal:	None

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 absorption, variable results obtained pending on study conditions (radiolabel, dose, etc.): In man: 50-64 % (based on urine excretion of the metabolite (TFMCA (metabolite XI). In rat: 25 % (based on excretion in urine). In dog: 50 % (based on comparison of plasma kinetics between oral and intravenous route).
Distribution ‡	Rapidly and extensively distributed, with highest levels in fat.
Potential for accumulation ‡	Accumulation in fat: half-life: 23-30.5 days for the decline in adipose tissue.
Rate and extent of excretion ‡	Rapid excretion in urine and faeces; 90 % within 48 hours.
Metabolism in animals ‡	Extensively metabolised, mainly by cleavage of ester bond and further transformation to conjugated metabolites
Toxicologically relevant compounds ‡ (animals and plants)	Lambda-cyhalothrin
Toxicologically relevant compounds ‡ (environment)	Lambda-cyhalothrin

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	56 mg/kg bw (rat) 19.9 mg/kg bw (mouse)	T; R25 (rat) /T+; R28 (mouse) H300 (mouse)/H301 (rat)
Rat LD_{50} dermal ‡	632 mg/kg bw	Xn; R21 H311
Rat LC_{50} inhalation ‡	0.066 mg/L air (4 hours exposure, nose-only)	T+; R26 H330
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Slight irritant	
Skin sensitisation ‡	Skin sensitiser based on read across from gamma-cyhalothrin (present in lambda-cyhalothrin) and cyhalothrin (containing lambda-cyhalothrin) studies	Xi; R43 H317

Short-term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Rat: CNS (clinical signs of neurotoxicity via dermal and inhalation), liver toxicity, reduced bw gain Dog: CNS (clinical signs of neurotoxicity)	
Relevant oral NOAEL ‡	1-year, dog: 0.5 mg/kg bw per day 90-day, rat: 2.6 mg/kg bw per day	R48/22 H373
Relevant dermal NOAEL ‡	21-day, rat: 10 mg/kg bw per day	R48/21 H373
Relevant inhalation NOAEL ‡	21-day, rat: 0.3 µg/L air (corresponding to an inhaled dose of 0.08 mg/kg bw per day)	

Genotoxicity ‡ (Annex IIA, point 5.4)

	Unlikely to be genotoxic	

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

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

Reproductive toxicity (Annex IIA, point 5.6)
Reproduction toxicity

Reproduction target / critical effect ‡	Multigeneration rat [cyhalothrin] Parental toxicity: Reduced bw gain Offspring toxicity: Reduced survival after birth at parental toxic doses and reduced bw gain Reproductive toxicity: no adverse effect Data required on effects of lambda-cyhalothrin on sperm parameters in mice	
Relevant parental NOAEL ‡	1.5 mg/kg bw per day [cyhalothrin]	
Relevant reproductive NOAEL ‡	5.2 mg/kg bw per day [cyhalothrin]	
Relevant offspring NOAEL ‡	0.5 mg/kg bw per day [cyhalothrin]	

Developmental toxicity

Developmental target / critical effect ‡	[cyhalothrin] Rat and rabbit: Maternal toxicity: Clinical signs (neurotoxicity), reduced bw gain Developmental toxicity: No effects	
Relevant maternal NOAEL ‡	Rat and rabbit: 10 mg/kg bw per day [cyhalothrin]	
Relevant developmental NOAEL ‡	Rat : 15 mg/kg bw per day –the highest dose tested [cyhalothrin] Rabbit : 30 mg/kg bw per day – the highest dose tested [cyhalothrin]	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	rat: NOAEL: 2.5 mg/kg bw based on increased breathing rate noted at ≥10 mg/kg bw and clinical signs of neurotoxicity noted at 35 mg/kg bw	
Repeated neurotoxicity ‡	Subchronic neurotoxicity: No study considered necessary NOAEL in the dog: 0.5 mg/kg bw per day based on neurotoxicity noted at 3.5 mg/kg bw per day (1-year, dog) Developmental neurotoxicity, rat [lambda-cyhalothrin] : Maternal NOAEL: 4.9 mg/kg bw per day based on reduced bw gain noted at 11.4 mg/kg bw per day Developmental NOAEL: 4.9 mg/kg bw per day based on reduced pup survival and reduced bw Developmental neurotoxicity NOAEL: 4.9 mg/kg bw per day based on brain morphological findings at 11.4 mg/kg bw per day.	
Delayed neurotoxicity ‡	No data – not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Endocrinology: There are some *in vitro* studies from the open literature describing interaction of lambda-cyhalothrin with receptors of the endocrine system: - Lambda-cyhalothrin was reported to exhibit estrogen activity in the E-Screen assay utilizing a human breast carcinoma cell line (MCF-7). - Lambda-cyhalothrin was reported to have a weak antiandrogen activity in the yeast (anti) androgen screen assay. - Lambda-cyhalothrin was reported acting as a mild antagonist on the thyroid-beta receptor in a transactivation assay. Data gap: further tests according to the OECD Conceptual Framework (level 2 and/or 3) are needed to screen the potential endocrine activity of lambda-cyhalothrin. Immunotoxicity: There are some *in vitro* studies from the open literature describing that lambda-cyhalothrin may affect the immune system: - In two *in vitro* tests from the open literature, cytotoxicity of lambda-cyhalothrin on the macrophage cell line RAW 264.7 was noted. However, in the available standard toxicity studies on cyhalothrin and lambda-cyhalothrin, there was no indication of immunotoxicity.
Studies performed on metabolites or impurities ‡	**Metabolite 1a** : Rat oral LD_{50} > 4990 mg/kg bw Rat dermal LD_{50} > 2000 mg/kg bw Non irritant to eyes and skin, non sensitiser at 10% dose level Negative in 2 Ames tests and in mammalian cell gene mutation assay *in vitro* Clastogenic *in vitro* in human lymphocytes chromosome aberration test Negative *in vivo* mouse micronucleus test **Metabolite II** Rat oral LD_{50} (females) > 2000 mg/kg bw Negative in Ames test, mammalian cell gene mutation and chromosome aberration assays *in vitro* **Metabolite III** Rat oral LD_{50} (females) 300-2000 mg/kg bw Negative in Ames test, mammalian cell gene mutation and chromosome aberration assays *in vitro* **Metabolite V (PBA)** Rat oral LD_{50} = 3000 mg/kg bw **Metabolite VI** Rat oral LD_{50} 300-2000 mg/kg bw Negative in Ames test, mammalian cell gene mutation and chromosome aberration assays *in vitro*

	Metabolite XIII Rat oral LD_{50} (females) > 2000 mg/kg bw Negative in Ames test, mammalian cell gene mutation and chromosome aberration assays *in vitro.* **Metabolite V (PBA) and XXIII (PBA(OH)):** A data gap was identified for the assessment of toxicological information allowing to assess human exposure to these metabolites. With regard to the metabolite **R157836** (enantiomeric pair A), the reference values of lambda-cyhalothrin are applicable.

Medical data ‡ (Annex IIA, point 5.9)

	Cases of subjective facial sensation (also known as 'SFS' or paraesthesia) have occurred at all stages of lambda-cyhalothrin handling, from small-scale laboratory work to commercial synthesis and formulation operations. SFS is a collection of skin-associated symptoms, including itching, tingling, burning, cold or numbness due to skin contact with lambda-cyhalothrin. The face is most commonly affected. These symptoms can cause discomfort and may in some individuals last for up to 34 hours after exposure. Recovery is apparently complete and there is no evidence of lasting damage. 6 microgram a.s. applied to a cm^2 of facial skin can cause SFS. A query of the Syngenta internal database for lambda-cyhalothrin produced a total of 807 reports of adverse health effects since 1983. 160 cases are associated with the synthesis of the active ingredient and 647 the subsequent production of formulated products. 771 are recorded as SFS incidents, the remaining 36 as adverse reactions other than SFS (skin- and eye irritation, cough, runny nose, wheezy chest). Cases of intoxications (mostly occupational) have been reported. These were associated with SFS, mild skin/eye irritation or nausea. Cases of suicide attempts were described as severe or greater. Ingestions of 10 ml (1 case), 100 ml (2 cases) and 1 litre (1 case) of a typical lambda-cyhalothrin formulation (5EC) all showed complete recovery whilst one case of an 82 yr lady who ingested 90 mg Karate® 5EC subsequently died. There is no specific antidote for pyrethroids. Any treatment can only be symptomatic.

Summary (Annex IIA, point 5.10)	Value	Study	Uncertainty factor
ADI ‡	0.0025 mg/kg bw per day	multigeneration, rat [cyhalothrin]	200[(1)]
AOEL ‡	0.00063 mg/kg bw per day	multigeneration, rat [cyhalothrin]	200[(1)] + 25%[(2)]
ARfD ‡	0.005 mg/kg bw	1-year, dog	100

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

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulations (Kaiso Sorbie, EG, 5%; Lambda 50 EC, 5%; Lambda-Cyhalothrin 100 CS, 10%; Karate 10CS, 10%)	25% concentrate and dilution, default value

Exposure scenarios (Annex IIIA, point 7.2)

Operator	• Cereals, tractor application (application rate: 7.5 g a.i./ha) German model — % of AOEL No PPE — 347-378% PPE (gloves during M/L, & (gloves), coverall and sturdy footwear during application) — 15-47% UK POEM model — % of AOEL No PPE — 1698-4343% PPE ((RPE), gloves during M/L & applic) — 182-331% • Tomato, outdoor, tractor application (application rate: 25 g a.s./ha): German model — % of AOEL No PPE — 1155-1260% PPE (gloves during M/L, & gloves, coverall and sturdy footwear during application) — 49-57% UK POEM model — % of AOEL No PPE — 13484-15251% PPE ((RPE), gloves during M/L & applic) — 1436-1713% • Tomato, outdoor, hand-held (application rate: 25 g a.s./ha): German model — % of AOEL No PPE — 888-3498% PPE (gloves during M/L & gloves, hood and visor/broad brimmed headwear & coverall and sturdy footwear during application) — 72-74% UK POEM model — % of AOEL No PPE — 8996-22093% PPE ((RPE), gloves during M/L & application, coverall and sturdy footwear) — 1412-1688%

	• Tomato, indoor application, hand-held: Dutch model % of AOEL No PPE 2891% PPE (gloves & coverall and RPE) 289% IVA model (75% percentile) % of AOEL No PPE 5133% PPE (protective clothing, gloves) 114-144% IVA model (geometric mean) % of AOEL No PPE 1870% PPE (protective clothing, gloves) 44% • Orchards, tractor application (application rate: 25g a.s./ha): German model % of AOEL No PPE 1542-1584% PPE (gloves during M/L & gloves, hood and visor, coverall and sturdy footwear during applic) 73-76% UK POEM model % of AOEL No PPE 5331% PPE ((RPE), gloves during M/L & application) 1445-1594% • Orchards, hand-held (application rate: 22.5 g a.s./ha): German model % of AOEL No PPE 3148% PPE (broad brimmed headwear, gloves during M/L, gloves, coverall and sturdy footwear during appl) 92% • Potato, tractor application (20 g a.s./ha): German model % of AOEL No PPE 1008% PPE (gloves during M/L & gloves, coverall and sturdy footwear during application) 40% UK POEM model % of AOEL No PPE 2705% PPE (gloves during M/L & application) 354%
Workers	Cereals (crop inspection, 2 applications): % of AOEL No PPE 36-90% Tomato, harvesting (25 g a.s./ha, 2 applications) No PPE 1984% PPE (gloves, long sleeved shirt, long trousers) 413% Tomato, harvesting (12.5 g a.s./ha, 2 applications) No PPE 992% PPE (gloves, long sleeved shirt, long trousers) 206% Orchards (25 g a.s./ha, 2 applications) No PPE 3571% PPE (gloves, long sleeved shirt, long trousers) 1786% Orchards (10 g a.s./ha, 2 applications) No PPE 1429%

	PPE (gloves, long sleeved shirt, long trousers) 714% Potato (20 g a.s./ha, 2 applications) No PPE 238% Potato (7.5 g a.s./ha, 2 applications) No PPE 90%
Bystanders and residents	• Cereals, tractor application (7.5 g a.s./ha) Bystander at 10m from spraying: % of AOEL Adults 1.5% Children 1.3% Residential exposure to drift deposits at 10m from spraying: Adults 0.2% Children 0.3% • Orchards (25 g a.s./ha) Bystander at 3m from spraying: % of AOEL Adults 483% Children 377% Bystander at 10m from spraying: Adults 196% Children 153% Residential exposure to drift deposits at 10m from spraying: Adults 20-23% Children 38-43% • Orchards – early fruit crops (22.5 g a.s./ha) Bystander at 3m from spraying % of AOEL Adults 435% Children 340% Bystander at 10m from spraying Adults 176% Children 138% Residential exposure to drift deposits at 10m from spraying: Adults 24% Children 43% • Orchards – late fruit crops (22.5 g a.s./ha) Bystander at 10m from spraying % of AOEL Adults 54% Children 42% • Orchards (10 g a.s./ha) Bystander at 3m from spraying % of AOEL Adults 193% Children 151% Bystander at 10m from spraying Adults 78% Children 61%

	• Potato (20 g a.s./ha) Bystander at 10m from spraying — % of AOEL Adults 4.1% Children 3.6% Residential exposure to drift deposits at 10m from spraying: Adults 0.5% Children 0.9% • Tomato (outdoors) (25 g a.s./ha) Bystander at 10m from spraying: — % of AOEL Adults 26% Children 28% Residential exposure to drift deposits at 10m from spraying (from high crops spaying as worst case): Adults 20-23% Children 38-43% • Tomato indoor application Bystander exposure not relevant

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

Substance	Lambda-cyhalothrin
Harmonised classification	Current classification according to Regulation (EC) No 1272/2008 (CLP Regulation): GHS06 DANGER Acute Tox. 3, H301 ("Toxic if swallowed") Acute Tox. 4, H312 ("Harmful in contact with skin") Acute Tox. 2, H330 ("Fatal if inhaled") Current classification according to Council Directive 67/548/EEC (DSD classification): **T+** VERY TOXIC Xn; R21 "Harmful in contact with skin" T; R25 "Toxic if swallowed" T+; R26 "Very toxic by inhalation"
RMS/peer review proposal[11]	Considering the criteria of Regulation (EC) 1272/2008[12] (as amended): GHS06 DANGER Acute Tox. 2, H300 "Fatal if swallowed" Acute Tox. 3, H311 "Toxic in contact with skin" Skin sens 1, H317 "May cause an allergic skin reaction"

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

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

	Acute Tox. 2, H330 “Fatal if inhaled” STOT RE. 2, H373 “May cause damage to organ through prolonged or repeated exposure” Considering the criteria of Directive 67/548/EEC[13] (as amended): T+ VERY TOXIC Xn; R21 “Harmful in contact with skin” T+; R26 “Very toxic by inhalation” T+; R28 “Very Toxic if swallowed” Xi; R43 “May cause sensitisation by skin contact” Xn; R48/21/22 “Harmful: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed”

[13] 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

Plant groups covered	-Lambda-cyhalothrin metabolism fully addressed in fruits (tomato, apple), leafy crops (cabbage) and cereals (wheat) -Metabolism data on pulses and oilseeds (cotton, soya beans) (Indicative information on leaves only).
Rotational crops	Carrots, lettuce, wheat
Metabolism in rotational crops similar to metabolism in primary crops?	No : -Lambda-cyhalothrin detected at a trace level in wheat straw only (<1 % TRR) -Compound Ia: 52 % TRR (carrot root), 61 % TRR (lettuce), 34 % TRR (wheat straw).
Processed commodities	Plums, tomato, beans with pods, cotton, soya bean, sorghum, wheat, corn
Residue pattern in processed commodities similar to residue pattern in raw commodities?	-Yes for pasteurisation and baking, brewing and boiling -Sterilisation: Extensive degradation of lambda-cyhalothrin into metabolites Ia, IV, gamma-lactone (R947650)
Plant residue definition for monitoring	Lambda-cyhalothrin
Plant residue definition for risk assessment	Lambda-cyhalothrin. Provisional residue definition for processed commodities including lambda-cyhalothrin only.
Conversion factor (monitoring to risk assessment)	Not applicable

Metabolism in livestock

Animals covered	Goat, poultry
Time needed to reach a plateau concentration in milk and eggs	Milk: 4 days Eggs: 7-9 days
Animal residue definition for monitoring	Lambda-cyhalothrin
Animal residue definition for risk assessment	Lambda-cyhalothrin
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	yes

Residues in succeeding crops

	Rotational crop field trials on root and tuber crops (radish/turnip), leafy crops (lettuce/spinach),cereals (barley/wheat), alfalfa and mustard leaves following harvest of a treated primary crop (cotton) at a total dose rate of 0.5 kg a.s./ha (1.2 N rate considering the calculated PEC soil for lambda-cyhalothrin). Residues of lambda-cyhalothrin and metabolite Ia below the LOQ (<0.01 mg/kg) in all crops at 30 and 60 days plant-back intervals.

Stability of residues

	-High water content commodities: 26 months (provisional). -Dry commodities: 26 months (provisional). -High oil content commodities: 26 months (provisional). - muscle, liver, fat, egg: 3 months

	- milk: 4 months -Compounds Ia, V, XXIII: 36-43 months in milk, eggs, muscle, kidney, liver, fat.

Residues from livestock feeding studies

	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 Beef cattle: 0.237 mg/kg DM (0.01 mg/kg bw per d) -Dairy cattle: 0.110 mg/kg DM (0.004 mg/kg bw per d)	No	No
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Yes	No	No studies Not required
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Lowest feeding level: -Ruminants: (1 mg/kg DM) (0.036 mg/kg bw per d) -Poultry: (1 mg/kg DM) (0.06 mg/kg bw per d) Residue levels of lambda-cyhalothrin in matrices at the lowest feeding level: (max) mg/kg		
Muscle	<0.01 mg/kg	<0.002	Not relevant
Liver	0.03 mg/kg	<0.005	Not relevant
Kidney	0.02 mg/kg	Not relevant	Not relevant
Fat	0.50 mg/kg	0.028	Not relevant
Milk	0.03 mg/kg		
Eggs		<0.005	

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs

Crop	Nouthern Southern Region, field or glasshouse	Trials results relevant to the representative uses (mg/kg) (a)	Recommendation/comments	MRL estimated from trials according to representative use	HR (c)	STMR (b)
Peaches (TFL)	SEU (major crop) field	No trial compliant with GAP.	8 residue trials are required.	-	-	-
Plums (STF)	NEU (major crop)/ SEU (minor crop) field	NEU -Fruit with stone: No valid residue trials. -Fruit without stone: 4x<0.01; <0.01(1); 0.01(1); 0.01; 2x0.02(1) SEU -Fruit with stone: No valid residue trials. -Fruit without stone: 5x<0.01; 0.01; 3x0.02		0.04 (provisional) (2)	0.02 (provisional) (2)	0.01 (provisional) 2)
Seed potatoes (TFL)	NEU field	No trials at GAP (see potatoes below)	GAP covered by the requested residue trials on potatoes.	-	-	-
Potatoes (TFL)	NEU (major crop) field	<0.01	Sufficient trials are required to demonstrate the expected no-residue situation	0.01* (provisional) (2)	<0.01 (provisional) (2)	<0.01 (provisional) (2)
Seed potatoes (TFL)	SEU field	No trials at GAP	GAP covered by the requested residue trials on potatoes.	-	-	-
Potatoes (TFL)	SEU (major crop) field	No trials at GAP	Sufficient trials are required to demonstrate the expected no-residue situation	-	-	-
Tomatoes (STF)	NEU/SEU (major crop)	NEU (field) 8x<0.01 SEU (field)	GAP-compliant residue trials	0.05 (provisional) (2)	0.04 (provisional) (2)	0.02 (provisional) (2)

Crop	**Nouthern Southern Region, field or glasshouse**	**Trials results relevant to the representative uses (mg/kg) (a)**	**Recommendation/comments**	**MRL estimated from trials according to representative use**	**HR (c)**	**STMR (b)**
	field and glasshouse	5x<0.01, 0.01, 2x0.02 EU (glasshouse) 4x<0.01, 2x0.01, 4x0.02, 2x0.03, 0.04				
Winter wheat grain (STF)	NEU/SEU (major crop) field	NEU 12x<0.01 SEU 8x<0.01	GAP-compliant residue trials	0.01* (provisional) (2)	<0.01 (provisional) (2)	<0.01 (provisional) (2)
Winter wheat straw (STF)	NEU/SEU field	NEU 0.05, 0.08, 0.13, 0.15, 2x0.23, 0.24, 2x0.27, 0.29, 0.33, 0.34 SEU 0.10, 2x0.16, 0.20, 0.27, 0.28, 0.34, 0.35	GAP-compliant residue trials	-	0.35 (provisional) (2)	0.24 (provisional)(2)
Winter wheat grain (TFL)	NEU/SEU (major crop) field	No trials compliant with GAP	A complete residue data set is required.	No proposal	-	-
Winter wheat straw (TFL)	NEU/SEU field	No trials compliant with GAP	A complete residue data set is required.	No proposal	-	-

(1): The acceptability of the reported residue trials on plums is pending on the outcome of the requested validation data on method RAM 81 in accordance with the current pre-registration guidelines.
(2): Provisional MRLs because of the requested residues storage stability data.
(a) Numbers of trials in which particular residue levels were reported e.g. 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue i.e. the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

Consumer risk assessment – Not finalised considering the identified data gaps (see section 3)

ADI	0.0025 mg/kg bw per d
TMDI (% ADI) – EFSA PRIMo-Revision 2	10.8 % ADI (WHO Cluster diet B)
Factors included in TMDI	MRL
ARfD	0.005 mg/kg bw
IESTI (% ARfD) – EFSA PRIMo-Revision 2	46.5 % ARfD (tomatoes) 30.8 % ARfD (potatoes) 24.8 % ARfD (Milk and milk products) 13.2 % ARfD (Plums)
Factors included in IESTI	HR

Processing factors

Crop/process/processed product	Number of studies	Processing factors		Amount transferred (%) (optional)
		Transfer factor	Yield factor	
Lambda-cyhalothrin				
Beans with pods/Canned beans (separated beans)	4 (0.91, 0.67, 0.73, 1.43)	0.82		
Beans with pods/Canned beans (whole can)	4 (0.43, 0.29, 0.36, 0.71)	0.40		
Beans with pods/Cooked beans	4 (0.96, 0.76, 0.64, 1.22)	0.86		
Beans with pods/Washed beans	6 (1.09, 1.13, 0.92, 0.71, 0.91, 1.33)	1.01		
Cotton seed/Crude oil	1	0.20		
Cotton seed/Hulls	1	0.10		
Cotton seed/Meal	1	<0.10		
Cotton seed/Refined oil	1	0.01		
Plums/Dried plums	1	3.0		
Plums/Washed fruit	1	1.0		
Plums/Jam	1	1.0		
Plums/Juice	1	0.5		
Sorghum/Flour	1	1.00		
Sorghum/Starch	1	<0.17		
Tomato/Canned fruit	4 (<0.11, <0.10, <0.10, <0.10)	<0.10		
Tomato/Juice	5 (0.06, <0.08, <0.13, <0.13, <0.13)	<0.13		
Tomato/Ketchup	1	0.22		
Tomato/Paste	5 (0.23, 0.11, <0.07, <0.09, 0.31)	<0.11		
Tomato/Puree	5 (0.08, <0.11, <0.07, <0.09, 0.25)	<0.09		
Tomato/Sun dried tomato	4 (5.00, 3.33, 5.14, 7.50)	5.07		
Tomato/Washed fruit	8 (1.08, 0.89, 1.00, 0.86, 1.88, 0.90, 0.86, 0.71)	0.90		
Wheat grain/Bran	1	4.00		
Wheat grain/Low grade flour	1	0.50		
Wheat grain/Patent flour	1	0.50		
Wheat grain/Shorts and germ	1	1.50		

Crop/process/processed product	Number of studies	Processing factors		Amount transferred (%) (optional)
		Transfer factor	Yield factor	
Soya bean/Meal	1	<1		
Soya bean/Crude oil	1	<1		
Soya bean/Refined oil	1	<1		
Corn/Meal	1	<1		
Corn/Flour	1	<1		
Corn/Crude oil	1	<1		
Corn/Refined oil	1	<1		

Proposed MRLs

Peaches	-
Plums	0.04 (provisional)
Potatoes	0.01* (provisional)
Tomatoes	0.05(provisional)
Wheat	0.01* (provisional)
Muscle(ruminants, poultry)	0.01*(provisional)
Liver (ruminants, poultry)	0.01*(provisional)
Kidney (ruminants)	0.01*(provisional)
Fat (ruminants)	0.2 (provisional)
Poultry fat	0.01*(provisional)
Milk	0.01*(provisional)
Birds' eggs	0.01*(provisional)

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

Environmental fate and behavior

Route of degradation (aerobic) in soil

Mineralization after 100 days ‡	36 % (92 d); 15-46 % (120 d) (^{14}C-cyclopropyl label, n=5) 12-30% (120 d) (^{14}C-phenoxy label, n=7)
Non-extractable residues after 100 days ‡	17 % (92 d); 13-29 % (120 d) (^{14}C-cyclopropyl label) 12-44 % (120 d) (^{14}C-phenoxy label)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Ia – max 22.9% (90 d) V (PBA) – max 5.8 and 6.2% after 14 and 28 days in one soil XV – max 12.1% (63 d)

Route of degradation in soil – Supplemental studies

Anaerobic degradation ‡ Mineralization after 100 days	max 7.6-11.4 % (29-60 d) (^{14}C-cyclopropyl label) max 16% (7 d)/8.4% (86 d) (^{14}C-phenoxy label)
Non-extractable residues after 100 days	7-13 % (90 d) (^{14}C-cyclopropyl label) 12-25 % (90 d) (^{14}C-phenoxy label)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Ia – max 35.9 % (90 d anaerobic phase) V (PBA) – max 31.4 % (90 d anaerobic phase)
Soil photolysis ‡ Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	None

Rate of degradation in soil

Laboratory studies ‡

lambda-cyhalothrin	Aerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St (χ^2)	Method of calculation
18 Acres sandy clay loam	5.5	20 ± 2°C / pF2	19.7 / 2330		2.1	FOMC
			17.5 / 323	141.5	2.7	DFOP k_2
Nebraska loam	7.0[a]	20 ± 2°C / pF2	36.9 / 123		12.6	SFO
			19.8/ 158	60.3	2.8	DFOP k_2
Marsillargues silty clay	7.3	20 ± 2°C / pF2	24.8 / 82		11.8	SFO
			16.2 / 141.7	42.7	5.5	FOMC
Speyer 5M sandy loam[#]	7.2	20.1 ± 0.1°C / pF2	49.4 / 164	49.4	12.1	SFO
			27.5 / 274.7	115.5	5.7	DFOP k_2
Am Fischteich silt Loam	5.6	20.1 ± 0.1°C / pF2	108 / 359	108	13.5	SFO
			59.8 / not calc	673	2.5	DFOP k_2
Speyer 2.2 loamy sand	5.5	20.1 ± 0.1°C / pF2	163 / 541		5.8	SFO
			303 / 934000		2.9	FOMC
				1000		default*
Geometric mean DT_{50}				**174.6**		

[a] pH in water; for the other soils; in $CaCl_2$

[#]from the combined datasets for cyclopropyl- and phenoxy-labelled lambda provided in Adam 2012c ([Cyclopropyl-1-14C]Lambda-Cyhalothrin – Route and Rate of Degradation in One Soil, Innovative Environmental Services (IES) Ltd, Witterswil, Switzerland, IES No. : 20110032) and Adam 2012d [Phenoxy-U-14C]Lambda-Cyhalothrin – Route and Rate of Degradation in Four Soils, Innovative Environmental Services (IES) Ltd, Witterswil, Switzerland, IES No. : 20110031).

*the pattern of degradation is clearly bi-phasic but since it was not possible to obtain a reliable DT50 from the second phase of the bi-phasic kinetics, a worst case value of 1000 days was proposed at the Pesticide Peer Review Teleconference 97.

Estimated DT_{50} at 10°C using Q_{10} = 2.58 and geometric mean DT_{50} at reference conditions:	450.5 days

Metabolite Ia	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	f.f.[a]	DT_{50} / DT_{90} (d) 20°C pF2/10kPa	St (χ^2)	Method of calculation
18 Acres sandy clay loam	5.4	20 ±2°C / pF2	3.1 / 10.2	-	3.1 / 10.2	11.8	SFO
			2.4 / 13.4	-		9.1	FOMC
Gartenacker loam	7.1	20 ±2°C / pF2	4.0 / 13.4	-	4.0 / 13.4	12.4	SFO
Marsillargues silty clay	7.6	20 ±2°C / pF2	15.8 / 52.5	-	15.8 / 52.5	6.8	SFO
Speyer 5M sandy loam	7.2	20 ±2°C / pF2	19.1 / 63.6	-	19.1 / 63.6	24.1	SFO
Speyer 2.2 loamy sand	5.5	20 ±2°C / pF2	8.0 / 26.5	-	8.0 / 26.5	17.8	SFO
Am Fischteich silt Loam	5.6	20 ±2°C / pF2	5.4 / 63.9	-		6.1	FOMC
					19.3 / 63.9		FOMC DT_{90}/3.3.2
Geometric mean DT_{50}					**8.9**		

[a] Formation fraction not available; metabolite applied as test substance

Metabolite V (PBA)	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	f.f.	DT_{50} / DT_{90} (d) 20°C pF2/10kPa	St (χ^2)	Method of calculation
Speyer 5M sandy loam	7.2	20.1 ± 0.1°C/ pF2	13.9 / 46.3	0.243	13.9 / 46.3	13.6	SFO[a]
Speyer 2.2 loamy sand	5.5	20.1 ± 0.1°C/ pF2	61.9 / 206	0.256	61.9 / 206	19.9	SFO[a]
Am Fischteich silt Loam	5.6	20.1 ± 0.1°C/ pF2	60.0 / 199	0.106	60.0 / 199	17.4	SFO[a]
Arithmetic mean				**0.202**			
Geometric mean DT_{50}					**37.2**		

[a] SFO for metabolite, FOMC for parent

Metabolite XV	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	f.f.	DT_{50} / DT_{90} (d) 20°C pF2/10kPa	St (χ^2)	Method of calculation
18 Acres sandy clay loam	5.5	20 ±2°C / pF2	24.1 / 80.1	0.158	24.1 / 80.1	10.9	SFO[c]
Nebraska loam	7.0[a]	20 ±2°C / pF2	14.7 / 49.0	0.182	14.7 / 49.0	21.8	SFO[d]
Marsillargues silty clay	7.3	20 ±2°C / pF2	24.2 / 80.3	0.121	24.2 / 80.3	33.7	SFO[d]
East Anglia loamy sand	7.6[b]	20 ±2°C / pF2	2.9 / 48.6	-[e]		6.3	FOMC
					14.6 / 48.6		FOMC DT_{90}/3.32
Frensham sandy loam	6.6[b]	20 ±2°C / pF2	7.6 / 25.2	-[e]	7.6 / 25.2	13.1	SFO
Hyde Farm sandy clay loam	6.9[b]	20 ±2°C / pF2	5.4 / 31.7	-[e]		4.3	FOMC
					9.6 /31.7		FOMC DT_{90}/3.32
Arithmetic mean				**0.154**			
Geometric mean DT_{50}					**14.5**		

[a] pH in water, otherwise in $CaCl_2$
[b] Method for pH determination not stated
[c] SFO for metabolite, FOMC for parent
[d] SFO for metabolite, DFOP for parent
[e] Formation fraction not available; metabolite applied as test substance

Field studies

lambda-cyhalothrin in formulated product							
Soil type (indicate if bare or cropped soil was used)	Location (country or USA state)	pH	Depth (cm)	DT_{50} / DT_{90} (d) (actual)	St (χ^2)	DT_{50} (d) (norm., SFO)	Method of calculation (actual $DT_{50/90}$)
Varendorf sandy loam	Germany	5.7	30 cm (d 0:10 cm)	10.1 / 33.6	17.1	NA [a]	SFO
Mechtersheim silty clay loam	Germany	7.5	30 cm (d 0: 10 cm)	21.8 / 72.6	12.2	NA [a]	SFO
Wang-Inzkofen silt loam	Germany	7.2	30 cm (d 0:10 cm)	28.0 / 93.0	15.7	NA [a]	SFO
Gachenbach-Etzlberg sandy loam	Germany	7.0	30 cm (d 0:10 cm)	47.5 / 158	11.7	NA [a]	SFO

[a] not required since data were not used as model input for PEC_{gw} and PEC_{SW} calculations.

pH dependence ‡ (yes / no) (if yes type of dependence)	no
Soil accumulation and plateau concentration ‡	not required

Laboratory studies ‡

lambda-cyhalothrin	Anaerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} / DT_{90} (d) 20°C pF2/10kPa	St (χ^2)	Method of calculation
Speyer 5M sandy loam	7.3	20.8 ± 0.25 / n.a.	134 / 445	n.a.	3.5-3.8	SFO
18 Acres sandy clay loam	5.9	20 ± 2°C / n.a.	99 / 330	n.a.	6.0	SFO

n.a. Not applicable for anaerobic phase

Soil adsorption/desorption ‡

lambda-cyhalothrin							
Soil type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
18 Acres	2.7	6.3	1892	**70100**	1290	47800	0.97
Frensham	1.2	6.2	1245	103800	464	**38000**	0.85
Vicksburg	0.7	6.0	3180	430000	1470	199000	0.89
Goldsboro	1.6	6.6	2115	132200	5350	345000	1.20
Hyde Farm	1.1	6.5	3810	346000	1780	162000	0.89
East Anglia	1.0	8.0	1970	200000	2080	210000	1.01
Wisborough	2.0	6.0	5880	298000	5440	276000	0.99
ERTC	0.3	6.8	2100	724000	1960	676000	0.99
NRTC	2.1	6.2	4490	209000	2360	110000	0.91
Virginia waters	2.6	6.6	6890	270000	1500	59000	0.80
”Mesocosm”	2.5	7.9	7610	305000	33000	1325000	1.21
Millstream	1.0	8.3	3470	352000	5560	562000	0.96
Iron Hatch	0.5	8.3	2400	518000	2520	548000	1.01
Old Basing	4.4	7.8	4870	110000	1660	**38000**	0.85
pH dependence (yes/no)			No				

note: “worst-case” values for exposure assessment for water indicated in bold

Metabolite Ia							
Soil type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
18 Acres sandy clay loam	3.2	5.4	2.97	91.9	3.01	93	1.01
Gartenacker loam	2.5	7.1	0.345	13.8	0.314	13	0.95
Marsillargues loam	0.58	7.6	0.094	16.2	0.079	14	0.89
Speyer 5 M sandy loam	1.0	7.3	0.35	34	0.188	18	0.52
Am Fischteich silt loam	1.7	6.4	0.39	23	0.351	21	0.97
Speyer 2.2 loamy sand	1.3	5.4	1.22	92	1.06	79	0.95
Arithmetic mean				**45.2**		**40**	**0.88**
pH dependence (yes/no)			Yes; stronger adsorption under acidic conditions; suggested input for modelling: worst-case K_{Foc} 13 mL/g together with 1/n 0.95.				

Metabolite XV							
Soil type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Hyde Farm sandy clay loam	1.9	6.9	1400	71000	1200	**60000**	0.98
East Anglia loamy sand	1.3	7.6	1200	58000	1600	78000	1.05
Kenny Hill sandy loam	3.0	8.5	1300	69000	1900	110000	1.08
Champaign silty clay	2.0	5.1	1800	62000	2000	67000	1.01
Frensham sandy loam	1.5	6.6	1400	92000	1100	75000	0.97
18 Acres sandy loam	1.8	7.4	800	61000	900	68000	1.02
pH dependence (yes/no)			No				

note: “worst-case” values for exposure assessment for water indicated in bold

Metabolite V (PBA)		
	K_{oc} (mL/g)	1/n
Estimated Koc in EPI Suite v.4.10	217.8	1.0 (default)

Mobility in soil

Column leaching ‡	Column leaching study with 3 soils (71-89% sand) in duplicate; 200 mm water applied over 48 hours; <0.65 µg/l in all but one replicate soil column, in which 0.86 µg/l was found in leachate. The conservative nature of the test conditions considered to support the low potential for leaching of lambda-cyhalothrin.
Aged residues leaching ‡	not available; not required
Lysimeter/field leaching studies ‡	not available; not required

PEC (soil)

lambda-cyhalothrin in 'Karate 10 CS' and 'Kaiso sorbie 5% EG' Method of calculation	DT_{50} (d): 174.6 d (to address uncertainty over rate of degradation under field conditions in S EU) Kinetics: SFO Field or Lab: Geomean lab data
Application data	Crop: Plums (covers the other representative uses of Karate 10 CS and Kaiso sorbie 5% EG) Depth of soil: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 50 Number of applications: 2 Interval (d): 10 Application rate(s): 25 g a.s./ha
	Crop: Wheat Depth of soil: 5 cm (20 cm for background concentration) Soil bulk density: 1.5 g/cm^3 % plant interception: 25 Number of applications: 2 Interval (d): 18 Application rate(s): 7.5 g a.s./ha

$PEC_{(s)}$ (µg/kg dry wt) lambda-cyhalothrin in Karate 10 CS Crop: Plums	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-		32.7	
Long term 21d	-	-	-	31.4
Plateau concentration	43.1 with a corresponding 21-d TWA 41.4			

$PEC_{(s)}$ (µg/kg dry wt) lambda-cyhalothrin in Karate 10 CS Crop: Wheat	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-		14.5	
Long term 21d	-	-	-	13.9
Plateau concentration	15.7 with a corresponding 21-d TWA 15.0			

Metabolite Ia following use of 'Karate 10 CS' and 'Kaiso sorbie 5% EG' Method of calculation	Molecular weight relative to the parent: 0.539 DT_{50} (d): 19.1 Kinetics: SFO Field or Lab: lab
Application data	Calculated from max plateau PECs for parent using max observation in soil 22.9 % Crop: Plums (covers the other representative uses of 'Karate 10 CS' and 'Kaiso sorbie 5% EG') Depth of soil: 5 cm

PEC$_{(s)}$ (µg/kg dry wt) Metabolite Ia	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-		5.3	
Plateau concentration	Not required			

Metabolite XV following use of 'Karate 10 CS' and 'Kaiso sorbie 5% EG'	Molecular weight relative to the parent: 1.036 DT_{50} (d): 24.2 Kinetics: SFO Field or Lab: lab
Method of calculation Application data	Calculated from max plateau PECs for parent using max observation in soil 12.1 % Crop: Plums (covers the other representative uses of Karate 10 CS and Kaiso sorbie 5% EG) Depth of soil: 5 cm

PEC$_{(s)}$ (µg/kg dry wt) Metabolit XV	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-		5.4	
Long term 21d	-	-	-	4.1
Plateau concentration	Not required			

Metabolite V (PBA) following use of 'Karate 10 CS' and 'Kaiso sorbie 5% EG' in winter wheat assuming anaerobic conditions	Molecular weight relative to the parent: 0.476 DT_{50} (d) parent: 134 d (worst-case anaerobic) DT_{50} (d) metabolite: not used Kinetics: SFO Field or Lab: lab
Method of calculation Application data	Calculated from max PECs for parent using max observation in soil 31.4 % Crop: Winter wheat (assuming anaerobic conditions may prevail for autumn use) Depth of soil: 5 cm

PEC$_{(s)}$ (µg/kg dry wt) Metabolit V	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-		2.1	
Plateau concentration	Not required			

PEC (soil)

lambda-cyhalothrin in 'Lambda-Cyhalothrin 100CS' and 'Lambda 50EC' Method of calculation	DT_{50} (d): 174.6 d (to address uncertainty over rate of degradation under field conditions in S EU) Kinetics: SFO Field or Lab: Geomean lab data
Application data	Crop: Seed potatoes (covers the other representative uses of 'Lambda-Cyhalothrin 100CS' and 'Lambda 50EC') Depth of soil: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 50

	Number of applications: 2 (once at BBCH 15-39, and once at BBCH 40-85) Interval (d): 8 Application rate(s): 20 g a.s./ha

$PEC_{(s)}$ (µg/kg dry wt) lambda-cyhalothrin in Karate 10 CS	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-		26.2	
Long term 21d	-	-	-	25.1
Plateau concentration	27.1 with a corresponding 21-d TWA 26.0			

Metabolite Ia following use of 'Lambda-Cyhalothrin 100CS' and 'Lambda 50EC' Method of calculation	Molecular weight relative to the parent: 0.539 DT_{50} (d): 19.1 Kinetics: SFO Field or Lab: lab
Application data	Calculated from max PECs for parent using max observation in soil 22.9 % Crop: Seed potatoes (covers the other representative uses of 'Lambda-Cyhalothrin 100CS' and 'Lambda 50EC') Depth of soil: 5 cm

$PEC_{(s)}$ (µg/kg dry wt) Metabolit Ia	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-		3.3	
Plateau concentration	Not required			

Metabolite XV following use of 'Lambda-Cyhalothrin 100CS' and 'Lambda 50EC' Method of calculation	Molecular weight relative to the parent: 1.036 DT_{50} (d): 24.2 Kinetics: SFO Field or Lab: lab
Application data	Calculated from max PECs for parent using max observation in soil 12.1 % Crop: Seed potatoes (covers the other representative uses of 'Lambda-Cyhalothrin 100CS' and 'Lambda 50EC') Depth of soil: 5 cm

$PEC_{(s)}$ (µg/kg dry wt) Metabolit XV	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-		3.4	
Long term 21d	-	-	-	2.6
Plateau concentration	Not required			

Metabolite V (PBA) following use of 'Lambda-Cyhalothrin 100CS' and 'Lambda 50EC' in winter wheat assuming anaerobic conditions Method of calculation	Molecular weight relative to the parent: 0.476 DT_{50} (d) parent: not used DT_{50} (d) metabolite: 1000 d Kinetics: SFO Field or Lab: default value

Application data	Calculated from max PECs for parent using theoretical max formation 100% Crop: Winter wheat (assuming anaerobic conditions may prevail for autumn use) Depth of soil: 5 cm

$PEC_{(s)}$ (µg/kg dry wt) Metabolit V	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-		7.0	
Plateau concentration	Not required			

Route and rate of degradation in water

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 4 (50°C): stable
	pH 7 (20°C): DT_{50} 167 d (SFO)
	pH 7 (25°C): DT_{50} 87.4 d (SFO)
	pH 9 (20°C): DT_{50} 17.8 d (SFO)
	pH 9 (25°C): DT_{50} 1.3 d (SFO)
Photolytic degradation of active substance and metabolites above 10 % ‡	Direct photolysis: DT_{50} (actual): -- DT_{50} (re-calculated to summer Sunlight 30-50ºN): 8.5 days (SFO) Metabolites: met. V (max 10.5%, 9 d) Indirect photolysis: DT_{50} (actual): -- DT_{50} (re-calculated to summer Sunlight 30-50ºN): 11.4 days (SFO) Metabolites: met. V (max 10.4%, 2 d; 28.5%, 15 d)
Quantum yield of direct phototransformation in water at Σ > 290 nm	not submitted; not required
Readily biodegradable ‡ (yes/no)	not submitted; not required

Degradation in water/sediment*

lambda-cyhalothrin	Distribution: mainly to sediment Max in water: 71.5% (Old Basing) - 49.3% (Virginia water) (both on day 0) Max in sediment: 70.2% (day 1) (Old Basing) – 60.9% (day 4) (Virginia water)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole system	St. (χ^2)	DT_{50}-DT_{90} water [a]	St. (χ^2)	DT_{50}-DT_{90} sed	St. (χ^2)	Method of calc.
Old Basing sandy loam 7.5 % OC	7.2-7.8	7.8	20 ± 2°C	21.0 / 69.8	7.8	0.19 / 3.3	9.7	-	-	whole system:SFO water:FOMC
Virginia water sand 0.5 % OC	6.8-7.2	7.1	20 ± 2°C	10.9 / 36.1	8.6	0.28 / 5.0	8.6	-	-	whole system:SFO water:FOMC
Geometric mean DT_{50}:				**15.1**						

[a] DT_{50}/DT_{90} in water represents dissipation – separate $DegT_{50}$/$DegT_{90}$ not obtained for water and sediment, respectively.

*Results from a study with ^{14}C-cyclopropyl label lambda-cyhalothrin. A data gap has been identified for satisfactory information to address the levels of metabolites formed from the phenoxy-^{14}C labelled lambda-cyhalothrin when applied at doses below the water solubility in the aquatic environment.

Metabolite Ia	Max formation in whole system: 22.0 % (day 30 in Old Basing); 29.4 % (day 30 in Virginia water) Distribution: Max in water: 11.4 % (day 30 in Old Baisng); 29.4 % (day 30 in Virginia water) Max in sediment: 10.6 % (day30 in Old Basing); 5.3 % (day 58 in Virginia water)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole system	St. (χ^2)	DT_{50}-DT_{90} water	St. (χ^2)	DT_{50}-DT_{90} sed	St. (χ^2)	Metod of calc.
Old Basing sandy loam 7.5 % OC	7.2-7.8	7.8	20 ± 2°C	10.9 / 36.3	16.3	-	-	-	-	SFO-SFO
Virginia water sand 0.5 % OC	6.8-7.2	7.1	20 ± 2°C	5.4 / 17.9	15.4	-	-	-	-	SFO-SFO
Geometric mean DT_{50}:				**7.7**						

Metabolite XV	Max formation in whole system: <10 % (Old Basing); 10.5 % (day 14 in Virginia water) Distribution: Max in water:1.3 % (day 4 in Virginia water) Max in sediment: 9.6 % (day 14 in Virginia water)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole system	St. (χ^2)	DT_{50}-DT_{90} water	St. (χ^2)	DT_{50}-DT_{90} sed	St. (χ^2)	Metod of calc.
Old Basing sandy loam 7.5 % OC	7.2-7.8	7.8	20 ± 2°C	6.6 / 21.8	24.6	-	-	-	-	SFO-SFO
Virginia water sand 0.5 % OC	6.8-7.2	7.1	20 ± 2°C	5.1 / 17.0	13.6	-	-	-	-	SFO-SFO
Geometric mean DT_{50}:				**5.8**						

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization X% after n days (end of study) [a]	Non-extractable residues in sed. Max x% after n days [a]	Non-extractable residues in sed. % at end of study [a]
Old Basing sandy loam 7.5 % OC	7.2-7.8	7.8	15.2-31.0 % (98 d)	24.4-37.6 % (98 d)	24.4-37.6 % (98 d)
Virginia water sand 0.5 % OC	6.8-7.2	7.1	42.3-48.8 % (98 d)	27.8 % (58 d) – 33.2 % (d 30)	17.4-21.8 % (98 d)

[a] Results given as range to reflect that results were obtained from two positions of labelling (cyclopropyl and phenoxy).

PEC (surface water) and PEC (sediment)

lambda-cyhalothrin in 'Karate 10 CS' and 'Kaiso sorbie 5% EG'. Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 2.1 Molecular weight (g/mol): 449.9 Water solubility (mg/L): 0.005 Koc: 38000 DT_{50} soil (d): 174.6 DT_{50} water/sediment system (d): 15.1 DT_{50} water (d): 15.1 DT_{50} sediment (d): 15.1
Parameters used in FOCUSsw step 3 and 4	Version control no.'s of FOCUS software: PRZM 1.1.1, MACRO 4.4.2, TOXSWA 3.3.1, SWAN 3.0.0 Vapour pressure: 0

	Koc/Kom (mL/g): 38000 / 22000 1/n: 1 DT_{50} soil (d):175 DT_{50} water (d): 1000 DT_{50} sediment (d): 15.1
Application rate	Crop: winter wheat Crop interception: minimal crop cover (25%) Number of applications: 1, 2 Interval (d): 18 Application rate(s): 7.5 g a.s./ha Application window: Step 1&2: Oct-Feb (N-EU, S-EU) Step 3&4: day of emergence and 49 days onwards (in runs for metabolite XV 40-66 days onwards) Step 4 calculations covered by FOCUS Step 4 simulations provided for 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'
	Crop: spring wheat Crop interception: minimal crop cover (25%) Number of applications: 1, 2 Interval (d): 18 Application rate(s): 7.5 g a.s./ha Application window: Step 1&2: Mar-May (N-EU, S-EU) Step 3 (applies only to metabolite XV): day of emergence and 53-61 days onwards
	Crop: tomato Crop interception: minimal crop cover (25%) Number of applications: 1, 2 Interval (d): 12 Application rate(s): 12.5 (N-EU) and 25 (S-EU) g a.s./ha; at Step 3& 4 for the parent only 12.5 g a.s./ha modelled Application window: Step 1&2: Mar-May (N-EU, S-EU); no run-off/drainage for glasshouse use Step 3: day of emergence and 43 days onwards (in runs for metabolite XV 46 days onwards) Step 4 no valid calculations available
	Crop: plums (early, late) Crop interception: early: no intercept; late: full canopy Number of applications: 1, 2 Interval (d): 10 Application rate(s): 10 (N-EU) and 25 (S-EU) g as/ha at Step 3& 4 for the parent only late applications of 10 g a.s./ha modelled Application window: Step 1&2: Mar-May (early); Jun-Sep (late) Step 3: day of emergence and 41 onwards (in runs for metabolite XV 46 days (early) / 40 days (late onwards) Step 4 mitigation: no valid calculations available

FOCUS STEP 1 [a] lambda-cyhalothrin in 'Karate 10 CS' and 'Kaiso sorbie 5% EG'	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
		Actual	TWA 21-day	Actual	TWA 21-day
Winter cereals	0 h	0.23	0.067	36.8	
Spring cereals	0 h	0.23	0.067	36.8	
Tomatoes N-EU	0 h	0.39	0.11	61.3	
Tomatoes S-EU	0 h	0.78	0.22	123	

Tomatoes indoor	0 h	0.033	0.009	5.11	
Plums early N-EU	0 h	2.08	0.152	49.0	
Plums early S-EU	0 h	5.19	0.381	123	
Plums late N-EU	0 h	1.18	0.120	49.0	
Plums late S-EU	0 h	2.94	0.301	123	

[a] Data provided by RMS after expert consultation TC 97

FOCUS STEP 2 [a, b] lambda-cyhalothrin in 'Karate 10 CS' and 'Kaiso sorbie 5% EG'	Day after overall maximum	PECsw (µg/L) [a]		PECsed (µg/kg) [a]	
		Actual	TWA 21-day	Actual	TWA 21 -day
Winter cereals N-EU	0 h	0.069	0.024	13.6	
Winter cereals S-EU	0 h	0.069	0.020	11.0	
Spring cereals N-EU	0 h	0.069	0.012	5.77	
Spring Cereals S-EU	0 h	0.069	0.020	11.0	
Tomatoes N-EU	0 h	0.115	0.020	9.80	
Tomatoes S-EU	0 h	0.230	0.068	37.3	
Tomatoes Glasshouse	0 h	0.008	0.0006	0.083	
Plum early appl N-EU	0 h	0.973	0.072	17.8	
Plum early appl S-EU	0 h	2.43	0.216	6.81	
Plums late appl N-EU	0 h	0.524	0.033	68.2	
Plums late appl S-EU	0 h	1.31	0.085	20.6	

[a] Data provided by RMS after expert consultation TC 97
[b] Data presented represent max result either from one or two applications.

FOCUS STEP 3 lambda-cyhalothrin in 'Karate 10 CS' and 'Kaiso sorbie 5% EG'[a] Crop: Winter cereals	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day
ONE APPLICATION						
D1	ditch	0 h	0.0467	0.015	0.229	
D1	stream	0 h	0.0409		0.0998	
D2	ditch	0 h	0.0467		0.195	
D2	stream	0 h	0.0402		0.0706	
D3	ditch	0 h	0.0459		0.0942	
D4	pond	0 h	0.00159		0.0155	
D4	stream	0 h	0.0399		0.0618	
D5	pond	0 h	0.00159		0.0165	
D5	stream	0 h	0.0431		0.0738	
D6	ditch	0 h	0.0465		0.181	
R1	pond	0 h	0.00162		0.027	
R1	stream	0 h	0.0304		0.163	
R3	stream	0 h	0.0426		0.442	0.356
R4	stream	0 h	0.0305		0.398	
TWO APPLICATIONS						
D1	ditch	0 h	0.0488	0.0187	0.378	
D1	stream	0 h	0.0354		0.0984	
D2	ditch	0 h	0.0408		0.170	
D2	stream	0 h	0.0347		0.061	
D3	ditch	0 h	0.0402		0.0948	
D4	pond	0 h	0.00182		0.0257	
D4	stream	0 h	0.0345		0.056	
D5	pond	0 h	0.00192		0.027	
D5	stream	0 h	0.0373		0.0689	
D6	ditch	0 h	0.0406		0.158	
R1	pond	0 h	0.00264		0.0503	

R1	stream	0 h	0.0263		0.321	
R3	stream	0 h	0.0369		0.888	
R4	stream	0 h	0.0264		0.863	0.735

[a] Data provided for product 'Karate 10CS'

FOCUS STEP 3 lambda-cyhalothrin in 'Karate 10 CS' and 'Kaiso sorbie 5% EG'[a] Crop: Tomatoes	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day
ONE APPLICATION						
D6	ditch	0 h	0.0769	0.00375	0.185	
R2	stream	0 h	0.0672		2.53	2.22
R3	stream	0 h	0.0715		1.17	
R4	stream	0 h	0.0508		1.42	
TWO APPLICATIONS						
D6	ditch	0 h	0.0672	0.00428	0.162	
R2	stream	0 h	0.0581		4.87	4.27
R3	stream	0 h	0.0621		2.24	
R4	stream	0 h	0.0439		2.94	

[a] Data provided for product 'Karate 10CS'

FOCUS STEP 3 lambda-cyhalothrin in 'Karate 10 CS' and 'Kaiso sorbie 5% EG'[a] Crop: Plums late	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day
ONE APPLICATION						
D3	ditch	0 h	0.357	0.0271	0.985	0.452
D4	pond	0 h	0.016		0.155	
D4	stream	0 h	0.358		0.536	
D5	pond	0 h	0.016		0.138	
D5	stream	0 h	0.387		0.660	
R1	pond	0 h	0.016		0.147	
R1	stream	0 h	0.274		0.392	
R2	stream	0 h	0.367		0.359	
R3	stream	0 h	0.386		0.652	
R4	stream	0 h	0.274		0.390	
TWO APPLICATIONS						
D3	ditch	0 h	0.285	0.0456	1.07	
D4	pond	0 h	0.0187		0.263	
D4	stream	0 h	0.286		0.429	
D5	pond	0 h	0.0211		0.227	
D5	stream	0 h	0.310		0.589	
R1	pond	0 h	0.0197		0.246	
R1	stream	0 h	0.220		0.333	
R2	stream	0 h	0.294		0.456	
R3	stream	0 h	0.309		0.938	0.699
R4	stream	0 h	0.219		0.331	

[a] Data provided for product 'Karate 10CS'

lambda-cyhalothrin in 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'. Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 2.1 Molecular weight (g/mol): 449.9 Water solubility (mg/L): 0.005 Koc (mL/g): 38000 DT_{50} soil (d): 174.6 DT_{50} water/sediment system (d): 15.1

	DT_{50} water (d): 15.1 DT_{50} sediment (d): 15.1
Parameters used in FOCUSsw step 3 and 4	Version control no.'s of FOCUS software: SWASH 1.1 including FOCUS-PRZM 1.1.1, FOCUS-MACRO 4.4.2, FOCUS-TOXSWA 2.2.1; SWAN 1.1.4 Vapour pressure: 2×10^{-7} Koc/Kom (mL/g): 38000 / 22000 1/n: 1 DT_{50} soil (d): 70.9 DT_{50} water/sediment system (d): 15.1 DT_{50} water (d): 1000 DT_{50} sediment (d): 15.1
Application rate	Crop: winter wheat BBCH 10-29 Crop interception: minimal crop cover (25%) Number of applications: 1, 2 Interval (d): 14 Application rate(s): 7.5 g a.s./ha Application window: Step 1&2: Oct-Feb (N-EU, S-EU), Step 3&4: 1 day after emergence and 44 days onwards Step 4 mitigation: 95% nozzle reduction, 20 m vegetated run-off buffer (90% reduction)
	Crop: winter wheat BBCH 30-79 Crop interception: average crop cover (50%) Number of applications: 1, 2 Interval (d): 14 Application rate(s): 7.5 g a.s./ha Application window: Step 1&2: Mar-May (N-EU, S-EU) Step 3&4: 112 days before harvest and 44 days onwards Step 4 mitigation: 95% nozzle reduction, 20 m vegetated run-off buffer (90% reduction)
	Crop: spring wheat BBCH 30-79 Crop interception: minimal crop cover (25%) Number of applications: 1, 2 Interval (d): 14 Application rate(s): 7.5 g a.s./ha Application window: Step 1&2: Jun-Sep (N-EU), Mar-May (S-EU) Step 3&4: 112 days before harvest and 44 days onwards Step 4 mitigation: 95% nozzle reduction, 20 m vegetated run-off buffer (90% reduction)
	Crop: potato/seed potato BBCH 15-39, 40-85 Crop interception: full crop cover (70%) Number of applications: 1, 2 Interval (d): 7 (N-EU), 8 (S-EU), Application rate(s): 7.5 (N-EU) and 20 g a.s./ha (S-EU) Application window: Step 1&2: Jun-Sep (N-EU, S-EU) Step 3&4: 30 days after emergence and 37 days onwards Step 4 mitigation: 95% nozzle reduction, 20 m vegetated run-off buffer (90% reduction)
	Crop: potato/seed potato, BBCH 15-39, 40-85 Crop interception: minimum crop cover (15%) Number of applications: 1, 4 (N-EU), 1, 2 (S-EU) Interval (d): 7 (N-EU), 8 (S-EU) Application rate(s): 7.5 (N-EU) and 20 g a.s./ha (S-EU)

	Application window: Step 1&2: Mar-May (N-EU, S-EU) Step 3&4: 3 days after emergence and 30/37 days onwards Step 4 mitigation: 95% nozzle reduction, 20 m vegetated run-off buffer (90% reduction)
	Crop: peach (late) (only Lambda-cyhalothrin 100 CS) Crop interception: full canopy (70%) Number of applications: 1, 2 Interval (d): 30 Application rate(s): 22.5 g as/ha Application window: Step 1&2: Mar-May (late; S-EU) Step 3&4: not run at Step 3 and 4

FOCUS STEP 1 [a] lambda-cyhalothrin in 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
		Actual	TWA 21-day	Actual	TWA 21-day
Winter & spring cereals N/S EU	0 h	0.23	0.067	36.8	
Potatoes N EU	0 h	0.23	0.067	36.8	
Potatoes S EU	0 h	0.63	0.18	98.1	
Seed potatoe N EU	0 h	0.47	0.13	73.5	
Seed potato S EU	0 h	0.63	0.18	98.1	
Peach, late application S EU	0 h	2.65	0.27	110.3	

[a] Data provided by RMS after expert consultation TC 97

FOCUS STEP 2 [a, b] lambda-cyhalothrin in 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'	Day after overall maximum	PECsw (µg/L) [a]		PECsed (µg/kg) [a]	
		Actual	TWA 21-day	Actual	TWA 21 -day
Winter cereals (fall appl.) N EU	0 h	0.069	0.024	13.8	
Winter cereals (fall appl.) S EU	0 h	0.069	0.020	11.1	
Winter cereals (spring appl.) N EU	0 h	0.069	0.020	11.1	
Winter cereals (spring appl.) S EU	0 h	0.069	0.020	11.1	
Spring cereals N EU	0 h	0.069	0.020	11.1	
Spring cereals S EU	0 h	0.069	0.020	11.1	
Potatoes (Jun-Sep) N EU	0 h	0.069	0.020	11.1	
Potatoes (Jun-Sep) S EU	0 h	0.18	0.024	10.2	
Seed potatos (Mar-May) N EU	0 h	0.069	0.022	12.5	
Seed potatos (Mar-May) S EU	0 h	0.18	0.061	34.0	
Peach, late applications S EU	0 h	1.2	0.079	19.1	

[a] Data provided by RMS after expert consultation TC 97
[b] Data presented represent max result either from one or two applications.

FOCUS STEP 3 lambda-cyhalothrin in 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC' Crop: Winter wheat, BBCH 10-29	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day
ONE APPLICATION						
D1	ditch	0 h	0.0467	0.0149	0.228	
D1	stream	0 h	0.0409		0.0998	
D2	ditch	0 h	0.0467		0.195	
D2	stream	0 h	0.0402		0.0705	
D3	ditch	0 h	0.0459		0.0942	
D4	pond	0 h	0.00159		0.0154	

D4	stream	0 h	0.0399		0.0618	
D5	pond	0 h	0.00159		0.0164	
D5	stream	0 h	0.0431		0.0737	
D6	ditch	0 h	0.0465		0.181	
R1	pond	0 h	0.00162		0.0265	
R1	stream	0 h	0.0304		0.156	
R3	stream	0 h	0.0421		3.290	
R4	stream	0 h	0.0301		0.309	
TWO APPLICATIONS						
D1	ditch	0 h	0.0487	0.0186	0.375	
D1	stream	0 h	0.0354		0.0984	
D2	ditch	0 h	0.0408		0.170	
D2	stream	0 h	0.0347		0.0609	
D3	ditch	0 h	0.0402		0.0948	
D4	pond	0 h	0.00182		0.0256	
D4	stream	0 h	0.0345		0.0560	
D5	pond	0 h	0.00192		0.0269	
D5	stream	0 h	0.0373		0.0689	
D6	ditch	0 h	0.0406		0.158	
R1	pond	0 h	0.00217		0.0496	
R1	stream	0 h	0.0263		0.314	
R3	stream	0 h	0.0371		3.596	
R4	stream	0 h	0.0261		0.693	

FOCUS STEP 3 lambda-cyhalothrin in 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC' Crop: Winter wheat, BBCH 30-79	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day
ONE APPLICATION						
D1	ditch	0 h	0.0467	0.0147	0.222	
D1	stream	0 h	0.0409		0.0997	
D2	ditch	0 h	0.0468		0.212	
D2	stream	0 h	0.0416		0.188	
D3	ditch	0 h	0.0462		0.111	
D4	pond	0 h	0.00159		0.0141	
D4	stream	0 h	0.0393		0.0500	
D5	pond	0 h	0.00159		0.0156	
D5	stream	0 h	0.0372		0.0216	
D6	ditch	0 h	0.0464		0.143	
R1	pond	0 h	0.00161		0.0243	
R1	stream	0 h	0.0304		0.359	
R3	stream	0 h	0.0427		0.421	
R4	stream	0 h	0.0305		1.077	
TWO APPLICATIONS						
D1	ditch	0 h	0.0454	0.0158	0.3150	
D1	stream	0 h	0.0353		0.0923	
D2	ditch	0 h	0.0415		0.2370	
D2	stream	0 h	0.0360		0.1630	
D3	ditch	0 h	0.0405		0.1170	
D4	pond	0 h	0.0020		0.0223	
D4	stream	0 h	0.0345		0.0546	
D5	pond	0 h	0.0020		0.0241	
D5	stream	0 h	0.0350		0.0324	
D6	ditch	0 h	0.0408		0.187	
R1	pond	0 h	0.0020		0.0427	

R1	stream	0 h	0.0263		0.741	
R3	stream	0 h	0.0372		0.867	
R4	stream	0 h	0.0264		2.019	

FOCUS STEP 3 lambda-cyhalothrin in 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC' Crop: Spring wheat, BBCH 30-79	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day
ONE APPLICATION						
D1	ditch	0 h	0.0464	0.00432	0.137	
D1	stream	0 h	0.0365		0.0257	
D3	ditch	0 h	0.0462		0.108	
D4	pond	0 h	0.00159		0.0140	
D4	stream	0 h	0.0382		0.0380	
D5	pond	0 h	0.00159		0.0152	
D5	stream	0 h	0.0388		0.0263	
R4	stream	0 h	0.0305		1.292	
TWO APPLICATIONS						
D1	ditch	0 h	0.0412	0.0128	0.204	
D1	stream	0 h	0.0353		0.0864	
D3	ditch	0 h	0.0404		0.112	
D4	pond	0 h	0.00192		0.0221	
D4	stream	0 h	0.034		0.0446	
D5	pond	0 h	0.00182		0.0220	
D5	stream	0 h	0.0348		0.0307	
R4	stream	0 h	0.0264		2.589	

FOCUS STEP 3 lambda-cyhalothrin in 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC' Crop: (Seed) potato, 1-2 x 20 g/ha	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day
ONE APPLICATION (BBCH 15-39)						
D3	ditch	0 h	0.1020	0.00478	0.2380	
D4	pond	0 h	0.0041		0.0348	
D4	stream	0 h	0.0808		0.0503	
D6, 1st	ditch	0 h	0.1000		0.1490	
D6, 2nd	ditch	0 h	0.0998		0.1420	
R1	pond	0 h	0.0042		0.182	
R1	stream	0 h	0.0693		2.051	
R2	stream	0 h	0.0933		5.350	
R3	stream	0 h	0.0995		2.123	
ONE APPLICATION (BBCH 40-85)						
D3	ditch	0 h	0.102		0.237	
D4	pond	0 h	0.00411		0.0366	
D4	stream	0 h	0.0807		0.0501	
D6, 1st	ditch	0 h	0.102		0.241	
D6, 2nd	ditch	0 h	0.102	0.00742	0.268	
R1	pond	0 h	0.00687		0.251	
R1	stream	0 h	0.0707		3.501	
R2	stream	0 h	0.0948		6.647	
R3	stream	0 h	0.0997		3.002	
TWO APPLICATIONS (BBCH 15-39, and 40-85)						

D3	ditch	0 h	0.0883		0.209	
D4	pond	0 h	0.00426		0.046	
D4	stream	0 h	0.0695		0.0433	
D6, 1st	ditch	0 h	0.0883		0.211	
D6, 2nd	ditch	0 h	0.0882		0.203	
R1	pond	0 h	0.0106	0.00858	0.399	
R1	stream	0 h	0.0608		4.777	
R2	stream	0 h	0.0803		11.400	
R3	stream	0 h	0.0858		5.026	
TWO APPLICATIONS (BBCH 40-85)						
D3	ditch	0 h	0.0887		0.26	
D4	pond	0 h	0.00507		0.0591	
D4	stream	0 h	0.0758		0.0746	
D6, 1st	ditch	0 h	0.0887		0.249	
D6, 2nd	ditch	0 h	0.0908	0.0178	0.393	
R1	pond	0 h	0.0138		0.518	
R1	stream	0 h	0.0609		7.470	
R2	stream	0 h	0.0816		13.899	
R3	stream	0 h	0.0858		6.149	

FOCUS STEP 3 lambda-cyhalothrin in 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC' Crop: (Seed) potato, 1, 2, 4 x 7.5 g/ha	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day
ONE APPLICATION (BBCH 15-39)						
D3	ditch	0 h	0.0382	0.00179	0.0891	
D4	pond	0 h	0.00154		0.013	
D4	stream	0 h	0.0303		0.0189	
D6, 1st	ditch	0 h	0.0375		0.0557	
D6, 2nd	ditch	0 h	0.0374		0.0532	
R1	pond	0 h	0.00193		0.0698	
R1	stream	0 h	0.026		0.794	
R2	stream	0 h	0.035		2.007	
R3	stream	0 h	0.0373		0.796	
ONE APPLICATION (BBCH 40-85)						
D3	ditch	0 h	0.0382		0.089	
D4	pond	0 h	0.00154		0.0137	
D4	stream	0 h	0.0303		0.0188	
D6, 1st	ditch	0 h	0.0382		0.0904	
D6, 2nd	ditch	0 h	0.0382	0.00278	0.1	
R1	pond	0 h	0.00258		0.0941	
R1	stream	0 h	0.0265		1.313	
R2	stream	0 h	0.0355		2.492	
R3	stream	0 h	0.0374		1.126	
TWO APPLICATIONS (BBCH 15-39)						
D3	ditch	0 h	0.0332		0.0953	
D4	pond	0 h	0.00175		0.0199	
D4	stream	0 h	0.0261		0.0162	
D6, 1st	ditch	0 h	0.0326		0.0537	
D6, 2nd	ditch	0 h	0.0326		0.0515	
R1	pond	0 h	0.00185	0.00312	0.144	
R1	stream	0 h	0.0228		1.724	
R2	stream	0 h	0.0301		4.253	
R3	stream	0 h	0.0323		1.650	
TWO APPLICATIONS (BBCH 40-85)						

D3	ditch	0 h	0.0333		0.0975	
D4	pond	0 h	0.0019		0.0222	
D4	stream	0 h	0.0284		0.028	
D6, 1st	ditch	0 h	0.0332		0.0934	
D6, 2nd	ditch	0 h	0.034	0.00667	0.147	
R1	pond	0 h	0.00516		0.194	
R1	stream	0 h	0.0228		2.792	
R2	stream	0 h	0.0306		5.211	
R3	stream	0 h	0.0322		2.277	
FOUR APPLICATIONS (BBCH 15-39, and 40-85)						
D3	ditch	0 h	0.0257		0.0739	
D4	pond	0 h	0.00244		0.0305	
D4	stream	0 h	0.0212		0.0156	
D6, 1st	ditch	0 h	0.0257		0.0712	
D6, 2nd	ditch	0 h	0.0257		0.0677	
R1	pond	0 h	0.0027	0.00651	0.315	
R1	stream	0 h	0.0178		3.987	
R2	stream	0 h	0.0238		8.842	
R3	stream	0 h	0.0252		3.748	

FOCUS STEP 4 lambda-cyhalothrin in ‘Lambda-Cyhalothrin 100 CS’ and ‘Lambda 50 EC’ Crop: Winter wheat, BBCH 10-29	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day
ONE APPLICATION						
D1	ditch	0 h	0.00226	0.000722	0.0111	
D1	stream	0 h	0.0019		0.00465	
D2	ditch	0 h	0.00226		0.00942	
D2	stream	0 h	0.00187		0.00329	
D3	ditch	0 h	0.00222		0.00456	
D4	pond	0 h	0.000097		0.000936	
D4	stream	0 h	0.00186		0.00288	
D5	pond	0 h	0.000097		0.000999	
D5	stream	0 h	0.00201		0.00344	
D6	ditch	0 h	0.00225		0.00876	
R1	pond	0 h	0.0001		0.0221	
R1	stream	0 h	0.00142		0.159	
R3	stream	0 h	0.00197		0.329	
R4	stream	0 h	0.0014		0.0323	
TWO APPLICATIONS						
D1	ditch	0 h	0.00231	0.000884	0.0178	
D1	stream	0 h	0.00191		0.00530	
D2	ditch	0 h	0.00194		0.00813	
D2	stream	0 h	0.00187		0.00330	
D3	ditch	0 h	0.00191		0.00450	
D4	pond	0 h	0.000135		0.00190	
D4	stream	0 h	0.00186		0.00302	
D5	pond	0 h	0.000143		0.00200	
D5	stream	0 h	0.00201		0.00371	
D6	ditch	0 h	0.00193		0.00751	
R1	pond	0 h	0.000201		0.0449	
R1	stream	0 h	0.00142		0.0321	
R3	stream	0 h	0.00201		0.360	
R4	stream	0 h	0.00141		0.0701	

FOCUS STEP 4 lambda-cyhalothrin in 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC' Crop: Winter wheat, BBCH 30-79	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day
ONE APPLICATION						
D1	ditch	0 h	0.00226	0.000713	0.0107	
D1	stream	0 h	0.0019		0.00465	
D2	ditch	0 h	0.00227		0.0103	
D2	stream	0 h	0.00194		0.00879	
D3	ditch	0 h	0.00224		0.00538	
D4	pond	0 h	0.000097		0.000857	
D4	stream	0 h	0.00183		0.00233	
D5	pond	0 h	0.000097		0.000954	
D5	stream	0 h	0.00173		0.00101	
D6	ditch	0 h	0.00225		0.00694	
R1	pond	0 h	0.000099		0.00208	
R1	stream	0 h	0.00142		0.0362	
R3	stream	0 h	0.00199		0.0422	
R4	stream	0 h	0.00142		0.108	
TWO APPLICATIONS						
D1	ditch	0 h	0.00216	0.000751	0.0149	
D1	stream	0 h	0.00191		0.00498	
D2	ditch	0 h	0.00197		0.0113	
D2	stream	0 h	0.00194		0.00879	
D3	ditch	0 h	0.00192		0.00555	
D4	pond	0 h	0.000146		0.00166	
D4	stream	0 h	0.00186		0.00294	
D5	pond	0 h	0.000148		0.00180	
D5	stream	0 h	0.00189		0.00175	
D6	ditch	0 h	0.00194		0.00888	
R1	pond	0 h	0.000157		0.0433	
R1	stream	0 h	0.00142		0.0747	
R3	stream	0 h	0.002		0.0870	
R4	stream	0 h	0.00146		0.203	

FOCUS STEP 4 lambda-cyhalothrin in 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC' Crop: Spring wheat, BBCH 30-79	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day
ONE APPLICATION						
D1	ditch	0 h	0.00225	0.000209	0.00665	
D1	stream	0 h	0.0017		0.00120	
D3	ditch	0 h	0.00223		0.00522	
D4	pond	0 h	0.000097		0.000852	
D4	stream	0 h	0.00178		0.00177	
D5	pond	0 h	0.000097		0.000930	
D5	stream	0 h	0.00181		0.00123	
R4	stream	0 h	0.00142		0.130	
TWO APPLICATIONS						
D1	ditch	0 h	0.00196	0.000608	0.00969	
D1	stream	0 h	0.0019		0.00466	

D3	ditch	0 h	0.00192		0.00530	
D4	pond	0 h	0.000143		0.00164	
D4	stream	0 h	0.00183		0.00240	
D5	pond	0 h	0.000135		0.00164	
D5	stream	0 h	0.00188		0.00165	
R4	stream	0 h	0.00152		0.260	

FOCUS STEP 4 lambda-cyhalothrin in 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC' Crop: (Seed) potato, 1-2 x 20 g/ha	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day
ONE APPLICATION (BBCH 15-39)						
D3	ditch	0 h	0.00511		0.0119	
D4	pond	0 h	0.000194		0.00164	
D4	stream	0 h	0.00407		0.00253	
D6, 1st	ditch	0 h	0.00502		0.00747	
D6, 2nd	ditch	0 h	0.00501		0.00712	
R1	pond	0 h	0.000532	0.000428	0.0187	
R1	stream	0 h	0.00349		0.206	
R2	stream	0 h	0.0047		0.536	
R3	stream	0 h	0.00501		0.213	
ONE APPLICATION (BBCH 40-85)						
D3	ditch	0 h	0.00511		0.0119	
D4	pond	0 h	0.000194		0.00173	
D4	stream	0 h	0.00406		0.00252	
D6, 1st	ditch	0 h	0.00511		0.0121	
D6, 2nd	ditch	0 h	0.00512	0.000372	0.0134	
R1	pond	0 h	0.000726		0.0268	
R1	stream	0 h	0.00356		0.352	
R2	stream	0 h	0.00477		0.665	
R3	stream	0 h	0.00502		0.301	
TWO APPLICATIONS (BBCH 15-39, and 40-85)						
D3	ditch	0 h	0.00447		0.0106	
D4	pond	0 h	0.000246		0.00265	
D4	stream	0 h	0.00352		0.00220	
D6, 1st	ditch	0 h	0.00447		0.0107	
D6, 2nd	ditch	0 h	0.00447		0.0103	
R1	pond	0 h	0.00112	0.0009	0.0409	
R1	stream	0 h	0.00424		0.480	
R2	stream	0 h	0.00407		1.141	
R3	stream	0 h	0.00436		0.510	
TWO APPLICATIONS (BBCH 40-85)						
D3	ditch	0 h	0.00449		0.0132	
D4	pond	0 h	0.000292		0.00341	
D4	stream	0 h	0.00385		0.00378	
D6, 1st	ditch	0 h	0.00449		0.0126	
D6, 2nd	ditch	0 h	0.00459	0.000900	0.0199	
R1	pond	0 h	0.00146		0.532	
R1	stream	0 h	0.00355		0.750	
R2	stream	0 h	0.00414		1.391	
R3	stream	0 h	0.00435		0.617	

FOCUS STEP 4 lambda-cyhalothrin in 'Lambda-Cyhalothrin	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day

100 CS' and 'Lambda 50 EC' Crop: (Seed) potato, 1, 2, 4 x 7.5 g/ha						
ONE APPLICATION (BBCH 15-39)						
D3	ditch	0 h	0.00192		0.00448	
D4	pond	0 h	0.000097		0.00082	
D4	stream	0 h	0.00163		0.00101	
D6, 1st	ditch	0 h	0.00188		0.0028	
D6, 2nd	ditch	0 h	0.00188		0.00267	
R1	pond	0 h	0.000203	0.000163	0.0717	
R1	stream	0 h	0.0014		0.0798	
R2	stream	0 h	0.00188		0.201	
R3	stream	0 h	0.002		0.0800	
ONE APPLICATION (BBCH 40-85)						
D3	ditch	0 h	0.00192		0.00447	
D4	pond	0 h	0.000097		0.000862	
D4	stream	0 h	0.00163		0.00101	
D6, 1st	ditch	0 h	0.00192		0.00454	
D6, 2nd	ditch	0 h	0.00192	0.00014	0.00504	
R1	pond	0 h	0.000272		0.0968	
R1	stream	0 h	0.00143		0.132	
R2	stream	0 h	0.00191		0.249	
R3	stream	0 h	0.00201		0.113	
TWO APPLICATIONS (BBCH 15-39)						
D3	ditch	0 h	0.0016		0.00459	
D4	pond	0 h	0.000134		0.000153	
D4	stream	0 h	0.00136		0.000844	
D6, 1st	ditch	0 h	0.00157		0.00259	
D6, 2nd	ditch	0 h	0.00157		0.0148	
R1	pond	0 h	0.000406	0.000327	0.0848	
R1	stream	0 h	0.00154		0.173	
R2	stream	0 h	0.00157		0.426	
R3	stream	0 h	0.00169		0.166	
TWO APPLICATIONS (BBCH 40-85)						
D3	ditch	0 h	0.0016		0.0047	
D4	pond	0 h	0.000146		0.0017	
D4	stream	0 h	0.00148		0.00146	
D6, 1st	ditch	0 h	0.0016		0.0045	
D6, 2nd	ditch	0 h	0.00164	0.000322	0.00711	
R1	pond	0 h	0.000547		0.199	
R1	stream	0 h	0.00133		0.280	
R2	stream	0 h	0.00159		0.522	
R3	stream	0 h	0.00167		0.231	
FOUR APPLICATIONS (BBCH 15-39, and 40-85)						
D3	ditch	0 h	0.00128		0.00368	
D4	pond	0 h	0.000232		0.0029	
D4	stream	0 h	0.00113		0.00113	
D6, 1st	ditch	0 h	0.00128		0.00355	
D6, 2nd	ditch	0 h	0.00128		0.00337	
R1	pond	0 h	0.000848	0.000683	0.0323	
R1	stream	0 h	0.00285		0.401	
R2	stream	0 h	0.00127		0.885	
R3	stream	0 h	0.00225		0.376	

Metabolite Ia following use of 'Karate 10 CS' and 'Kaiso sorbie 5% EG' Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 2.1 Molecular weight (g/mol): 242.5 Water solubility (mg/L): 56.0 Koc (mL/g): 13 DT_{50} soil (d): 8.9 DT_{50} water/sediment system (d): 7.7 DT_{50} water (d): 7.7 DT_{50} sediment (d): 7.7 Maximum occurrence observed (% molar basis with respect to the parent) soil: 22.9 Water/Sediment: 29.4
Parameters used in FOCUSsw step 3 and 4	Not performed
Application rate	See parent

FOCUS STEP 1 [a] Metabolite Ia following use of 'Karate 10 CS' and 'Kaiso sorbie 5% EG'	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
		Actual	TWA 21-day	Actual	TWA 21-day
Winter cereals	0 h	0.629	0.282	0.079	
Spring cereals	0 h	0.629	0.283	0.079	
Tomatoes N-EU	0 h	1.05	0.47	0.13	
Tomatoes S-EU	0 h	2.10	0.942	0.263	
Tomatoes indoor	0 h	0.087	0.039	0.011	
Plums early N-EU	0 h	1.16	0.499	0.105	
Plums early S-EU	0 h	2.80	1.25	0.263	
Plums late N-EU	0 h	0.977	0.438	0.105	
Plums late S-EU	0 h	2.44	1.09	0.263	

[a] Data provided by RMS after expert consultation TC 97

FOCUS STEP 2 [a, b] Metabolite Ia following use of 'Karate 10 CS' and 'Kaiso sorbie 5% EG'	Day after overall maximum	PECsw (µg/L) [a]		PECsed (µg/kg) [a]	
		Actual	TWA 21-day	Actual	TWA 21 -day
Winter cereals N-EU	0 h	0.112	0.050	0.014	
Winter cereals S-EU	0 h	0.091	0.041	0.012	
Spring cereals N-EU	0 h	0.050	0.022	0.006	
Spring Cereals S-EU	0 h	0.091	0.041	0.012	
Tomatoes N-EU	0 h	0.092	0.041	0.011	
Tomatoes S-EU	0 h	0.339	0.152	0.043	
Tomatoes Glasshouse	0 h	0.002	0.0008	0.0001	
Plum early appl N-EU	0 h	0.216	0.097	0.026	
Plum early appl S-EU	0 h	0.761	0.341	0.090	
Plums late appl N-EU	0 h	0.090	0.051	0.010	
Plums late appl S-EU	0 h	0.253	0.113	0.030	

[a] Data provided by RMS after expert consultation TC 97
[b] Data presented represent max result either from one or two applications.

Metabolite Ia following use of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC' Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 2.1 Molecular weight (g/mol): 242.5 Water solubility (mg/L): 56.0 Koc (mL/g): 13.0 DT_{50} soil (d): 8.9 DT_{50} water/sediment system (d): 7.7

	DT_{50} water (d): 7.7 DT_{50} sediment (d): 7.7 Maximum occurrence observed (% molar basis with respect to the parent) soil: 22.9 Water/Sediment: 29.4
Parameters used in FOCUSsw step 3 and 4	Not performed
Application rate	See parent

FOCUS STEP 1 [a] Metabolite Ia following use of 'Lambda-Cyhalothrin 100CS' and 'Lambda 50EC'	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
		Actual	TWA 21-day	Actual	TWA 21-day
Winter & Spring cereals N/S EU	0 h	0.63	0.28	0.079	
Potatoes N-EU	0 h	0.63	0.28	0.079	
Potatoes S-EU	0 h	1.7	0.75	0.21	
Seed potatoes N-EU	0 h	0.63	0.28	0.079	
Seed potatoes S-EU	0 h	1.7	0.75	0.21	
Peach late	0 h	1.1	0.49	0.11	

[a] Data provided by RMS after expert consultation TC 97

FOCUS STEP 2 [a, b] Metabolite Ia following use of 'Lambda-cyhalothrin 100CS' and 'Lambda 50EC'	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
		Actual	TWA 21-day	Actual	TWA 21 -day
Winter cereals (fall appl.) N EU	0 h	0.12	0.054	0.015	
Winter cereals (fall appl.) S EU	0 h	0.098	0.044	0.012	
Winter cereals (spring appl.) N EU	0 h	0.038	0.017	0.0046	
Winter cereals (spring appl.) S EU	0 h	0.068	0.030	0.0085	
Spring cereals N EU	0 h	0.053	0.024	0.0065	
Spring cereals S EU	0 h	0.098	0.044	0.012	
Potatoes (Jun-Sep) N EU	0 h	0.031	0.014	0.0037	
Potatoes (Jun-Sep) S EU	0 h	0.11	0.049	0.013	
Seed potatos (Mar-May) N EU	0 h	0.070	0.031	0.0086	
Seed potatos (Mar-May) S EU	0 h	0.034	0.15	0.042	
Peach, late applications S EU	0 h	0.21	0.094	0.025	

[a] Data provided by RMS after expert consultation TC 97
[b] Data presented represent max result either from one or two applications.

Metabolite V (PBA) following use of in 'Karate 10 CS' and 'Kaiso sorbie 5% EG' Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 214.2 Water solubility (mg/L): 0.005 Koc (mL/g): 159 DT_{50} soil (d): 37.2 DT_{50} water/sediment system (d): 1000 DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Maximum occurrence observed (% molar basis with respect to the parent) Soil: 31.4 (max observed in anaerobic soil, day 90) Water/Sediment: 28.5 (max observed in photolysis study in natural water, day 15)
Application rate	As for parent except that minimum crop cover (25% interception) was assumed instead for zero interception for the early applications to plums. No data were presented for application to tomato in glasshouse.

FOCUS STEP 1 [a] Metabolite V (PBA)	Day after overall	PECsw (µg/L)		PECsed (µg/kg)	
		Actual	TWA 21-day	Actual	TWA 21-day

following use of ‘Karate 10 CS’ and ‘Kaiso sorbie 5% EG’	maximum				
Winter cereals	0 h	0.64		1.00	
Spring cereals	0 h	0.64		1.00	
Tomatoes N-EU	0 h	1.06		1.67	
Tomatoes S-EU	0 h	2.12		3.35	
Plums early N-EU	0 h	1.09		1.65	
Plums early S-EU	0 h	2.72		4.13	
Plums late N-EU	0 h	0.96		1.49	
Plums late S-EU	0 h	2.41		3.73	

[a] Simulation of two applications always produced higher PECsw and PECsed than single applications; only the results from multiple applications are shown in the table.

FOCUS STEP 2 [a] Metabolite V (PBA) following use of ‘Karate 10 CS’ and ‘Kaiso sorbie 5% EG’	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
		Actual	TWA 21-day	Actual	TWA 21 -day
Winter cereals N-EU	0 h	0.20		0.31	
Winter cereals S-EU	0 h	0.16		0.26	
Spring cereals N-EU	0 h	0.09		0.14	
Spring Cereals S-EU	0 h	0.16		0.26	
Tomatoes N-EU	0 h	0.15		0.24	
Tomatoes S-EU	0 h	0.56		0.89	
Plum early appl N-EU	0 h	0.31		0.48	
Plum early appl S-EU	0 h	1.06		1.64	
Plums late appl N-EU	0 h	0.14		0.21	
Plums late appl S-EU	0 h	0.40		0.61	

[a] Simulation of two applications always produced higher PECsw and PECsed than single applications; only the results from multiple applications are shown in the table.

Metabolite V (PBA) following use of in ‘Lambda-Cyhalothrin 100CS’ and ‘Lambda 50EC’ Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 214.2 Water solubility (mg/L): 26 Koc (mL/g): 221 DT_{50} soil (d): 37.2 DT_{50} water/sediment system (d): 1000 DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Maximum occurrence observed (% molar basis with respect to the parent) Soil: 6.2 (max observed in aerobic soil, day 28) Water/Sediment: 28.5 (max observed in water/sed study was close to 10%; max 10.5% in study on direct photolysis day 9; max 28.5% in photolysis study in natural water, day 15, however after 48 h in this study level was 10.4%)
Application rate	Step 1: As for parent Step 2: As for parent, though no data available for use in cereals

FOCUS STEP 1 [a] (PBA) following use of ‘Lambda-Cyhalothrin 100CS’ and ‘Lambda 50EC’	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
		Actual	TWA 21-day	Actual	TWA 21-day
Winter & Spring cereals N/S EU	0 h	0.12		0.26	
Potatoes N-EU	0 h	0.12		0.26	

Potatoes S-EU	0 h	0.32		0.70	
Seed potatoes N-EU	0 h	0.24		0.53	
Seed potatoes S-EU	0 h	0.32		0.70	
Peach	0 h	2.51		0.41	

[a] Simulation of two applications always produced higher PECsw and PECsed than single applications; only the results from multiple applications are shown in the table.

FOCUS STEP 2 [a] Metabolite V (PBA) following use of 'Lambda-Cyhalothrin 100CS' and 'Lambda 50EC'	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
		Actual	TWA 21-day	Actual	TWA 21 -day
Winter cereals (fall appl.) N EU	0 h	-		-	
Winter cereals (fall appl.) S EU	0 h	-		-	
Winter cereals (spring appl.) N EU	0 h	-		-	
Winter cereals (spring appl.) S EU	0 h	-		-	
Spring cereals N EU	0 h	-		-	
Spring cereals S EU	0 h	-		-	
Potatoes (Mar-May) N EU	0 h	0.01		0.02	
Potatoes (Jun-Sep) S EU	0 h	0.04		0.08	
Seed potatos (Mar-May) N EU	0 h	0.04		0.08	
Seed potatos (Mar-May) S EU	0 h	0.10		0.22	
Peach (Mar-May) S EU	0 h	0.82		0.14	

[a] Simulation of two applications always produced higher PECsw and PECsed than single applications; only the results from multiple applications are shown in the table.

Metabolite XV following use of in 'Karate 10 CS' and 'Kaiso sorbie 5% EG' Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 2.1 Molecular weight (g/mol): 465.9 Water solubility (mg/L): 0.005 Koc (mL/g): 60000 DT_{50} soil (d): 14.5 DT_{50} water/sediment system (d): 5.8 DT_{50} water (d): 5.8 DT_{50} sediment (d): 5.8 Maximum occurrence observed (% molar basis with respect to the parent) Soil: 12.1 Water/Sediment: 10.5
Parameters used in FOCUSsw step 3 and 4	Version control no.'s of FOCUS software: SWASH 1.1 including FOCUS-PRZM 1.1.1, FOCUS-MACRO 4.4.2, FOCUS-TOXSWA 3.3.1 Koc (mL/g): 60000 1/n: 1 DT_{50} soil (d): 14.5 DT_{50} water (d): 1000 DT_{50} sediment (d): 5.8
Application rate	See parent, though single applications not considered at Step 3 for metabolite XV.

FOCUS STEP 1 [a] Metabolite XV following use of 'Karate 10 CS' and 'Kaiso sorbie 5% EG'	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
		Actual	TWA 21-day	Actual	TWA 21-day
Winter cereals	0 h	0.0114	0.0016	2.33	
Spring cereals	0 h	0.0114	0.0016	2.32	
Tomatoes N-EU	0 h	0.038	0.005	7.73	
Tomatoes S-EU	0 h	0.076	0.011	15.5	
Tomatoes indoor	0 h	0.003	0.0005	0.645	

Plums early N-EU	0 h	0.222	0.010	6.88	
Plums early S-EU	0 h	0.555	0.024	17.2	
Plums late N-EU	0 h	0.124	0.007	6.19	
Plums late S-EU	0 h	0.111	0.006	1.58	

[a] Most data provided by RMS after expert consultation TC 97

FOCUS STEP 2 [a, b] Metabolite XV following use of 'Karate 10 CS' and 'Kaiso sorbie 5% EG'	Day after overall maximum	PECsw (µg/L) [a]		PECsed (µg/kg) [a]	
		Actual	TWA 21-day	Actual	TWA 21 -day
Winter cereals N-EU	0 h	0.008	0.001	1.06	
Winter cereals S-EU	0 h	0.0075	0.0008	0.852	
Spring cereals N-EU	0 h	0.0075	0.0006	0.443	
Spring Cereals S-EU	0 h	0.0075	0.0008	0.852	
Tomatoes N-EU	0 h	0.013	0.001	0.811	
Tomatoes S-EU	0 h	0.025	0.003	3.12	
Tomatoes Glasshouse	0 h	0.0009	0.0001	0.0060	
Plum early appl N-EU	0 h	0.106	0.005	1.373	
Plum early appl S-EU	0 h	0.265	0.014	5.503	
Plums late appl N-EU	0 h	0.057	0.004	0.507	
Plums late appl S-EU	0 h	0.143	0.007	1.58	

[a] Most data provided by RMS after expert consultation TC 97
[b] Data presented represent max result either from one or two applications.

FOCUS STEP 3 Metabolite XV in 'Karate 10 CS' and 'Kaiso sorbie 5% EG' Crop: Winter cereals	Water body	Day after overall maximum	PECsw (µg/L) [a]		PECsed (µg/kg) [b]	
			Actual	TWA	Actual	TWA
D1	ditch	0 h	< 0.001		0.038	
D1	stream	0 h	< 0.001		0.010	
D2	ditch	0 h	< 0.001		0.017	
D2	stream	0 h	< 0.001		0.006	
D3	ditch	0 h	< 0.001		0.009	
D4	pond	0 h	< 0.001		0.003	
D4	stream	0 h	< 0.001		0.006	
D5	pond	0 h	< 0.001		0.003	
D5	stream	0 h	< 0.001		0.007	
D6	ditch	0 h	< 0.001		0.016	
R1	pond	0 h	< 0.001		0.004	
R1	stream	0 h	< 0.001		0.030	
R3	stream	0 h	< 0.001		0.055	
		21 d	-		-	0.0773
R4	stream	0 h	< 0.001		0.049	

[a] Data provided for product 'Karate 10CS'
[b] Data provided by RMS

FOCUS STEP 3 Metabolite XV in 'Karate 10 CS' and 'Kaiso sorbie 5% EG' Crop: Spring cereals	Water body	Day after overall maximum	PECsw (µg/L) [a]		PECsed (µg/kg) [b]	
			Actual	TWA	Actual	TWA
D1	ditch	0 h	< 0.001		0.020	

D1	stream	0 h	< 0.001		0.009	
D3	ditch	0 h	< 0.001		0.011	
D4	pond	0 h	< 0.001		0.002	
D4	stream	0 h	< 0.001		0.004	
D5	pond	0 h	< 0.001		0.002	
D5	stream	0 h	< 0.001		0.003	
R4	stream	0 h	< 0.001		0.103	
		21 d	-		-	0.1712

[a] Data provided for product 'Karate 10CS'
[b] Data provided by RMS

FOCUS STEP 3 Metabolite XV in 'Karate 10 CS' and 'Kaiso sorbie 5% EG' Crop: Tomatoes (12.5 g/ha)	Water body	Day after overall maximum	PECsw (µg/L) [a]		PECsed (µg/kg) [b]	
			Actual	TWA	Actual	TWA
D6	ditch	0 h	< 0.001		0.016	
R2	stream	0 h	< 0.001		0.219	
		21 d	-		-	0.3748
R3	stream	0 h	< 0.001		0.079	
R4	stream	0 h	< 0.001		0.159	

[a] Data provided for product 'Karate 10CS'
[b] Data provided by RMS

FOCUS STEP 3 Metabolite XV in 'Karate 10 CS' and 'Kaiso sorbie 5% EG' Crop: Tomatoes (25 g/ha)	Water body	Day after overall maximum	PECsw (µg/L) [a]		PECsed (µg/kg) [b]	
			Actual	TWA	Actual	TWA
D6	ditch	0 h	< 0.001		0.032	
R2	stream	0 h	< 0.001		0.471	
		21 d	-		-	0.7826
R3	stream	0 h	< 0.001		0.168	
R4	stream	0 h	< 0.001		0.336	

[a] Data provided for product 'Karate 10CS'
[b] Data provided by RMS

FOCUS STEP 3 Metabolite XV in 'Karate 10 CS' and 'Kaiso sorbie 5% EG' Crop: Plums early (10 g/ha)	Water body	Day after overall maximum	PECsw (µg/L) [a]		PECsed (µg/kg) [b]	
			Actual	TWA	Actual	TWA
D3	ditch	0 h	< 0.001		0.187	
		21 d	-		-	0.2733
D4	pond	0 h	< 0.001		0.064	
D4	stream	0 h	< 0.001		0.067	
D5	pond	0 h	< 0.001		0.073	
D5	stream	0 h	< 0.001		0.048	
R1	pond	0 h	< 0.001		0.071	
R1	stream	0 h	< 0.001		0.066	

R2	stream	0 h	< 0.001		0.063	
R3	stream	0 h	< 0.001		0.131	
R4	stream	0 h	< 0.001		0.079	

[a] Data provided for product 'Karate 10CS'
[b] Data provided by RMS

FOCUS STEP 3 Metabolite XV in 'Karate 10 CS' and 'Kaiso sorbie 5% EG' Crop: Plums late (10 g/ha)	Water body	Day after overall maximum	PECsw (µg/L) [a]		PECsed (µg/kg) [b]	
			Actual	TWA	Actual	TWA
D3	ditch	0 h	< 0.001		0.106	
		21 d	-		-	0.1672
D4	pond	0 h	< 0.001		0.025	
D4	stream	0 h	< 0.001		0.045	
D5	pond	0 h	< 0.001		0.023	
D5	stream	0 h	< 0.001		0.059	
R1	pond	0 h	< 0.001		0.024	
R1	stream	0 h	< 0.001		0.034	
R2	stream	0 h	< 0.001		0.037	
R3	stream	0 h	< 0.001		0.067	
R4	stream	0 h	< 0.001		0.038	

[a] Data provided for product 'Karate 10CS'
[b] Data provided by RMS

FOCUS STEP 3 Metabolite XV in 'Karate 10 CS' and 'Kaiso sorbie 5% EG' Crop: Plums early (25 g/ha)	Water body	Day after overall maximum	PECsw (µg/L) [a]		PECsed (µg/kg) [b]	
			Actual	TWA	Actual	TWA
D3	ditch	0 h	< 0.001		0.468	
		21 d	-		-	0.6837
D4	pond	0 h	< 0.001		0.161	
D4	stream	0 h	< 0.001		0.168	
D5	pond	0 h	< 0.001		0.184	
D5	stream	0 h	< 0.001		0.120	
R1	pond	0 h	< 0.001		0.178	
R1	stream	0 h	< 0.001		0.166	
R2	stream	0 h	< 0.001		0.160	
R3	stream	0 h	< 0.001		0.328	
R4	stream	0 h	< 0.001		0.202	

[a] Data provided for product 'Karate 10CS'
[b] Data provided by RMS

FOCUS STEP 3 Metabolite XV in 'Karate 10 CS' and 'Kaiso sorbie 5% EG' Crop: Plums late (25 g/ha)	Water body	Day after overall maximum	PECsw (µg/L) [a]		PECsed (µg/kg) [b]	
			Actual	TWA	Actual	TWA
D3	ditch	0 h	< 0.001		0.265	
		21 d	-		-	0.4178
D4	pond	0 h	< 0.001		0.062	

D4	stream	0 h	< 0.001		0.113	
D5	pond	0 h	< 0.001		0.056	
D5	stream	0 h	< 0.001		0.147	
R1	pond	0 h	< 0.001		0.061	
R1	stream	0 h	< 0.001		0.087	
R2	stream	0 h	< 0.001		0.093	
R3	stream	0 h	< 0.001		0.169	
R4	stream	0 h	< 0.001		0.095	

[a] Data provided for product 'Karate 10CS'
[b] Data provided by RMS

Metabolite XV following use of 'Lambda-Cyhalothrin 100CS' and 'Lambda 50EC' Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 2.1 Molecular weight (g/mol): 465.9 Water solubility (mg/L): 0.15 Koc (mL/g): 60000 DT_{50} soil (d): 14.5 DT_{50} water/sediment system (d): 5.8 DT_{50} water (d): 5.8 DT_{50} sediment (d): 5.8 Maximum occurrence observed (% molar basis with respect to the parent) Soil: 12.1 Water/Sediment: 10.5
Parameters used in FOCUSsw step 3 and 4	Version control no.'s of FOCUS software: SWASH 3.1.2, FOCUS-TOXSWA 3.3.1 Koc (mL/g): 60000 1/n: 1 DT_{50} soil (d): 14.5 DT_{50} water (d): 1000 DT_{50} sediment (d): 5.8
Application rate	See parent

FOCUS STEP 1 Metabolite XV following use of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'	Day after overall maximum	PECsw (µg/L) [a]		PECsed (µg/kg) [a]	
		Actual	TWA	Actual	TWA
Winter & spring cereals	0 h	0.02		4.64	
	21 d	-	0.00	-	1.74
Potatoes N-EU	0 h	0.02		4.64	
	21 d	-	0.00	-	1.74
Potatoes S-EU	0 h	0.06		12.38	
	21 d	-	0.01	-	4.63
Seed potatoes N-EU	0 h	0.05		9.28	
	21 d	-	0.01	-	3.47
Seed potatoes S-EU	0 h	0.06		12.38	
	21 d	-	0.01	-	4.63
Peach late	0 h	0.14		7.02	
	21 d	-	0.01	-	2.87

[a] Data provided by RMS

FOCUS STEP 2 Metabolite XV following use of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'	Day after overall maximum	PECsw (µg/L) [a, b]		PECsed (µg/kg) [a, b]	
		Actual	TWA	Actual	TWA
winter cereals – fall appl N- EU	0 h	0.007 (0.008)		1.122 (0.753)	
	21 d	-	0.001 (0.001)	-	0.412 (0.276)
winter cereals – fall appl S-EU	0 h	0.007 (0.008)		0.905 (0.609)	
	21 d	-	0.001 (0.001)	-	0.332 (0.223)
winter cereals – spring appl N-EU	0 h	0.007 (0.008)		0.325 (0.226)	
	21 d	-	0.001 (0.001)	-	0.119 (0.083)
winter cereals – spring appl S-EU	0 h	0.007 (0.008)		0.615 (0.417)	
	21 d	-	0.001 (0.001)	-	0.226 (0.153)
Spring cereals N-EU	0 h	0.007 (0.008)		0.470 (0.321)	
	21 d	-	0.001 (0.001)	-	0.173 (0.118)
Spring cereals S-EU	0 h	0.007 (0.008)		0.905 (0.609)	
	21 d	-	0.001 (0.001)	-	0.332 (0.223)
Potatoes N-EU (Jun-Sep)	0 h	0.007 (0.008)		0.240 (0.149)	
	21 d	-	0.001 (0.000)	-	0.088 (0.055)
Potatoes S-EU (Jun-Sep)	0 h	0.018 (0.020)		0.885 (0.550)	
	21 d	-	0.001 (0.001)	-	0.325 (0.202)
Seed potatoes N-EU (Mar-May)	0 h	0.005 (0.008)		0.884 (0.360)	
	21 d	-	0.001 (0.001)	-	0.324 (0.132)
Seed potatoes SEU (Mar-May)	0 h	0.018 (0.020)		3.034 (1.828)	
	21 d	-	0.003 (0.002)	-	1.113 (0.671)
Peach S-EU	0 h	0.099 (0.128)		1.313 (1.268)	
	21 d	-	0.005 (0.007)	-	0.484 (0.469)

[a] Data provided by RMS
[b] Results given in parentheses: PEC after single application

FOCUS STEP 3 metabolite XV use of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC' Crop: Winter wheat, BBCH 10-29	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day
ONE APPLICATION						
D1	ditch	0 h	0.000000		0.000000	
D1	stream	0 h	0.000000		0.000000	
D2	ditch	0 h	0.000000		0.000001	
D2	stream	0 h	0.000000		0.000000	
D3	ditch	0 h	0.000000		0.000000	
D4	pond	0 h	0.000000		0.000000	
D4	stream	0 h	0.000000		0.000001	
D5	pond	0 h	0.000000		0.000000	
D5	stream	0 h	0.000000		0.000000	
D6	ditch	0 h	0.000000		0.000001	
R1	pond	0 h	0.000003		0.000056	

R1	stream	0 h	0.000028		0.000735	
R3	stream	0 h	0.000021		0.00724	
R4	stream	0 h	0.000039		0.00358	
TWO APPLICATIONS						
D1	ditch	0 h	0.000000		0.000000	
D1	stream	0 h	0.000000		0.000000	
D2	ditch	0 h	0.000000		0.000001	
D2	stream	0 h	0.000000		0.000001	
D3	ditch	0 h	0.000000		0.000000	
D4	pond	0 h	0.000000		0.000001	
D4	stream	0 h	0.000001		0.000003	
D5	pond	0 h	0.000000		0.000000	
D5	stream	0 h	0.000000		0.000000	
D6	ditch	0 h	0.000001		0.000001	
R1	pond	0 h	0.000007		0.000108	
R1	stream	0 h	0.000055		0.001370	
R3	stream	0 h	0.000044		0.011100	
R4	stream	0 h	0.000078		0.00779	

FOCUS STEP 3 metabolite XV use of ‘Lambda-Cyhalothrin 100 CS’ and ‘Lambda 50 EC’ Crop: Winter wheat, BBCH 30-79	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day
ONE APPLICATION						
D1	ditch	0 h	0.000000		0.000000	
D1	stream	0 h	0.000000		0.000000	
D2	ditch	0 h	0.000000		0.000001	
D2	stream	0 h	0.000000		0.000000	
D3	ditch	0 h	0.000000		0.000000	
D4	pond	0 h	0.000000		0.000000	
D4	stream	0 h	0.000000		0.000001	
D5	pond	0 h	0.000000		0.000000	
D5	stream	0 h	0.000000		0.000000	
D6	ditch	0 h	0.000000		0.000000	
R1	pond	0 h	0.000004		0.000175	
R1	stream	0 h	0.000028		0.00449	
R3	stream	0 h	0.000021		0.00525	
R4	stream	0 h	0.000032		0.0148	
TWO APPLICATIONS						
D1	ditch	0 h	0.000000		0.000000	
D1	stream	0 h	0.000000		0.000000	
D2	ditch	0 h	0.000000		0.000001	
D2	stream	0 h	0.000000		0.000000	
D3	ditch	0 h	0.000000		0.000000	
D4	pond	0 h	0.000000		0.000001	
D4	stream	0 h	0.000000		0.000000	
D5	pond	0 h	0.000000		0.000001	
D5	stream	0 h	0.000000		0.000000	
D6	ditch	0 h	0.000000		0.000000	
R1	pond	0 h	0.000008		0.000360	
R1	stream	0 h	0.000056		0.009270	
R3	stream	0 h	0.000041		0.010800	
R4	stream	0 h	0.000065		0.027700	

FOCUS STEP 3 metabolite XV use of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC' Crop: Spring wheat, BBCH 30-79	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day
ONE APPLICATION						
D1	ditch	0 h	0.000000		0.000000	
D1	stream	0 h	0.000000		0.000000	
D3	ditch	0 h	0.000000		0.000000	
D4	pond	0 h	0.000000		0.000001	
D4	stream	0 h	0.000000		0.000001	
D5	pond	0 h	0.000000		0.000000	
D5	stream	0 h	0.000000		0.000000	
R4	stream	0 h	0.000033		0.0149	
TWO APPLICATIONS						
D1	ditch	0 h	0.000000		0.000000	
D1	stream	0 h	0.000000		0.000000	
D3	ditch	0 h	0.000000		0.000000	
D4	pond	0 h	0.000000		0.000001	
D4	stream	0 h	0.000001		0.000003	
D5	pond	0 h	0.000000		0.000000	
D5	stream	0 h	0.000000		0.000000	
R4	stream	0 h	0.000067		0.0299	

FOCUS STEP 3 metabolite XV use of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC' Crop: (Seed) potato, 1-2 x 20 g/ha	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day
ONE APPLICATION (BBCH 15-39)						
D3	ditch	0 h	0.000000		0.000000	
D4	pond	0 h	0.000000		0.000004	
D4	stream	0 h	0.000002		0.000009	
D6, 1st	ditch	0 h	0.000003		0.000005	
D6, 2nd	ditch	0 h	0.000003		0.000006	
R1	pond	0 h	0.000034		0.001240	
R1	stream	0 h	0.000120		0.020900	
R2	stream	0 h	0.000026		0.062100	
R3	stream	0 h	0.000087		0.027400	
ONE APPLICATION (BBCH 40-85)						
D3	ditch	0 h	0.000000		0.000000	
D4	pond	0 h	0.000000		0.000002	
D4	stream	0 h	0.000001		0.000003	
D6, 1st	ditch	0 h	0.000001		0.000003	
D6, 2nd	ditch	0 h	0.000001		0.000003	
R1	pond	0 h	0.000051		0.00188	
R1	stream	0 h	0.000104		0.0413	
R2	stream	0 h	0.000027		0.0758	
R3	stream	0 h	0.000088		0.0358	
TWO APPLICATIONS (BBCH 15-39, and 40-85)						
D3	ditch	0 h	0.000000		0.000000	
D4	pond	0 h	0.000001		0.000007	
D4	stream	0 h	0.000003		0.000015	
D6, 1st	ditch	0 h	0.000004		0.000009	

D6, 2nd	ditch	0 h	0.000005		0.000010	
R1	pond	0 h	0.000072		0.002700	
R1	stream	0 h	0.000248		0.047400	
R2	stream	0 h	0.000053		0.132000	
R3	stream	0 h	0.000171		0.065200	
TWO APPLICATIONS (BBCH 40-85)						
D3	ditch	0 h	0.000000		0.000000	
D4	pond	0 h	0.000000		0.000003	
D4	stream	0 h	0.000001		0.000006	
D6, 1st	ditch	0 h	0.000003		0.000006	
D6, 2nd	ditch	0 h	0.000003		0.000006	
R1	pond	0 h	0.000102		0.003890	
R1	stream	0 h	0.000207		0.086700	
R2	stream	0 h	0.000054		0.158000	
R3	stream	0 h	0.000177		0.078700	

FOCUS STEP 3 metabolite XV use of ‘Lambda-Cyhalothrin 100 CS’ and ‘Lambda 50 EC’ Crop: (Seed) potato, 1, 2, 4 x 7.5 g/ha	Water body	Day after overall maximum	PECsw (µg/L)		PECsed (µg/kg)	
			Actual	TWA 21-day	Actual	TWA 21-day
ONE APPLICATION (BBCH 15-39)						
D3	ditch	0 h	0.000000		0.000000	
D4	pond	0 h	0.000000		0.000002	
D4	stream	0 h	0.000001		0.000003	
D6, 1st	ditch	0 h	0.000001		0.000002	
D6, 2nd	ditch	0 h	0.000001		0.000002	
R1	pond	0 h	0.000013		0.00477	
R1	stream	0 h	0.000046		0.00812	
R2	stream	0 h	0.00001		0.0233	
R3	stream	0 h	0.000032		0.0103	
ONE APPLICATION (BBCH 40-85)						
D3	ditch	0 h	0.000000		0.000000	
D4	pond	0 h	0.000000		0.000001	
D4	stream	0 h	0.000000		0.000001	
D6, 1st	ditch	0 h	0.000001		0.000001	
D6, 2nd	ditch	0 h	0.000001		0.000001	
R1	pond	0 h	0.000019		0.000705	
R1	stream	0 h	0.000039		0.0155	
R2	stream	0 h	0.00001		0.0284	
R3	stream	0 h	0.000033		0.0144	
TWO APPLICATIONS (BBCH 15-39)						
D3	ditch	0 h	0.000000		0.000000	
D4	pond	0 h	0.000000		0.000003	
D4	stream	0 h	0.000001		0.000007	
D6, 1st	ditch	0 h	0.000002		0.000004	
D6, 2nd	ditch	0 h	0.000002		0.000004	
R1	pond	0 h	0.000026		0.000978	
R1	stream	0 h	0.000090		0.017100	
R2	stream	0 h	0.000020		0.049200	
R3	stream	0 h	0.000065		0.021300	
TWO APPLICATIONS (BBCH 40-85)						
D3	ditch	0 h	0.000000		0.000000	
D4	pond	0 h	0.000000		0.000001	
D4	stream	0 h	0.000001		0.000001	
D6, 1st	ditch	0 h	0.000001		0.000001	

D6, 2nd	ditch	0 h	0.000001		0.000001	
R1	pond	0 h	0.000038		0.000072	
R1	stream	0 h	0.000077		0.00155	
R2	stream	0 h	0.00002		0.0284	
R3	stream	0 h	0.000066		0.0145	
FOUR APPLICATIONS (BBCH 15-39, and 40-85)						
D3	ditch	0 h	0.000000		0.000000	
D4	pond	0 h	0.000000		0.000006	
D4	stream	0 h	0.000002		0.000012	
D6, 1st	ditch	0 h	0.000003		0.000007	
D6, 2nd	ditch	0 h	0.000004		0.000008	
R1	pond	0 h	0.000053		0.002070	
R1	stream	0 h	0.000180		0.036900	
R2	stream	0 h	0.000039		0.102000	
R3	stream	0 h	0.000128		0.048200	

PEC (groundwater)

lambda-cyhalothrin, metabolite Ia, metabolite V (PBA) and **metabolite XV** in 'Karate 10 CS' and 'Kaiso sorbie 5% EG' Parameters used in FOCUSgw	Models used: FOCUS-PELMO 5.5.3 and FOCUS-PEARL 4.4.4 Scenarios: Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva <u>Lambda-cyhalothrin:</u> Koc/Kom (mL/g): 38000 / 22040 1/n: 1 DT_{50} soil (d): 175 <u>Metabolite Ia:</u> Koc/Kom (mL/g): 13.0 / 7.54 1/n: 0.95 DT_{50} soil (d): 8.9 Formation fraction: 0.65 from parent; 1.0 from XV <u>Metabolite V (PBA):</u> Koc/Kom (mL/g): 159 / 92.2* 1/n: 0.965 DT_{50} soil (d): 37.2 Formation fraction: 0.20 *derived from the deltamethrin monograph. These adsorption properties should not be considered valid as they were not submitted for the purpose of renewal of the approval of lambda-cyhalothrin. However, the adsorption coefficient is slightly more conservative than the value estimated with the QSAR method (=217.8 mL/g) and therefore the GW modelling can be considered acceptable. <u>Metabolite XV:</u> Koc/Kom (mL/g): 60000 / 34800 1/n: 1 DT_{50} soil (d): 14.5 Formation fraction: 0.15
Application rate	Crop: Winter Cereals Application rate: 7.5 g a.s. / ha No. of applications: 2 Time of application: 1, 7 days after emergence Crop interception: 25%

	Crop: Spring Cereals Application rate: 7.5 g a.s. / ha No. of applications: 2 Time of application: 1, 7 days after emergence Crop interception: 25%
	Crop: Tomato (fruiting vegetables) Application rate: 25 g a.s. / ha No. of applications: 2 Time of application: 1, 14 days after emergence Crop interception: 50%
	Crop: Plum (pome/stone fruit) Application rate: 25 g a.s. / ha No. of applications: 2 Time of application: 2, 14 days pre-harvest Crop interception: 80%

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

Lambda-cyhalothrin, metabolite XV, metabolite V (PBA) – products 'Karate 10 CS' and 'Kaiso sorbie 5% EG'[a]					
Model: FOCUS-PELMO 5.5.3 and FOCUS-PEARL 4.4.4					
Scenario	**winter wheat 2 x 7.5 g/ha**	**spring wheat 2 x 7.5 g/ha**	**tomatoes 2 x 25 g/ha**	**plums 2 x 25 g/ha, early**	**plums 2 x 25 g/ha, late**
Chateaudun	lambda-cyhalothrin and metabolite XV: all PECgw < 0.001 µg/l for all uses in all scenarios in both FOCUS models metabolite V (PBA) : all PECgw at or below 0.001 µg/l – except for one value at 0.002 µg/l for plums 2 x 25 g/ha, early application (FOCUS-PEARL Hamburg)				
Hamburg					
Jokioinen					
Kremsmünster					
Okehampton					
Piacenza					
Porto					
Sevilla					
Thiva					

(a) Data provided for product 'Karate 10 CS

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

Metabolite Ia – products 'Karate 10 CS' and 'Kaiso sorbie 5% EG'[a]					
Model: FOCUS-PELMO 5.5.3					
Scenario	**winter wheat 2 x 7.5 g/ha**	**spring wheat 2 x 7.5 g/ha**	**tomatoes 2 x 25 g/ha**	**plums 2 x 25 g/ha, early**	**plums 2 x 25 g/ha, late**
Chateaudun	0.002	0.001	0.006	0.007	0.005
Hamburg	0.022	0.022	-	0.043	0.024
Jokioinen	0.024	0.023	-	0.047	0.026
Kremsmünster	0.007	0.007	-	0.018	0.009
Okehampton	0.019	0.018	-	0.035	0.024
Piacenza	0.013	-	0.025	0.020	0.012
Porto	0.018	0.018	0.039	0.021	0.020
Sevilla	0.003	-	0.008	0.006	0.006
Thiva	0.003	-	0.005	0.004	0.004

(a) Data provided for product 'Karate 10 CS'

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

Metabolite Ia – products 'Karate 10 CS' and 'Kaiso sorbie 5% EG'[a]					
Model: FOCUS-PEARL 4.4.4					
Scenario	**winter wheat 2 x 7.5 g/ha**	**spring wheat 2 x 7.5 g/ha**	**tomatoes 2 x 25 g/ha**	**plums 2 x 25 g/ha, early**	**plums 2 x 25 g/ha, late**
Chateaudun	0.001	0.001	0.007	0.008	0.005
Hamburg	0.020	0.022	-	0.051	0.028
Jokioinen	0.016	0.016	-	0.044	0.023
Kremsmünster	0.006	0.006	-	0.014	0.007
Okehampton	0.014	0.014	-	0.024	0.016

Piacenza	0.006	-	0.018	0.013	0.007
Porto	0.009	0.012	0.022	0.013	0.010
Sevilla	<0.001	-	0.006	0.004	0.003
Thiva	0.002	-	0.003	0.004	0.003

(a) Data provided for product ‘Karate 10 CS’

lambda-cyhalothrin, metabolite Ia, metabolite V (PBA) and **metabolite XV** in ‘Lambda-Cyhalothrin 100 CS’ and ‘Lambda 50 EC’ Parameters used in FOCUSgw	Models used: FOCUS-PELMO 4.4.3 Scenarios: Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva Models used: FOCUS-MACRO 4.4.2 Scenarios: Châteaudun <u>Lambda-cyhalothrin:</u> Koc (mL/g): 38000 1/n: 1 DT_{50} soil (d): 174.6 <u>Metabolite Ia:</u> Koc (mL/g): 13 1/n: 0.95 DT_{50} soil (d): 8.9 Formation fraction (PELMO / MACRO): 1 / 0.539 <u>Metabolite V (PBA):</u> Koc (mL/g): 221* 1/n: 1 DT_{50} soil (d): 37.2 Formation fraction (PELMO / MACRO): 0.20 / 0.095 *estimated in OECD Toolbox ver. 3.1. It is unlikely that the use of the different endpoints from the agreed value of 217.8 mL/g has an impact on the final results of the GW exposure assessment for metabolite V. Therefore, the peer review considered the FOCUS GW modelling for metabolite V (PBA) as valid. <u>Metabolite XV:</u> Koc (mL/g): 60000 1/n: 1 DT_{50} soil (d): 14.5 Formation fraction (PELMO / MACRO): 0.15 / 0.16
Application rate	Crop: Winter cereals Application rate: 7.5 g a.s. / ha No. of applications: 4 Time of application: PELMO: 16, 30, 44, 58 days after emergence MACRO: 0, 14, 28, 42 days after emergence Crop interception: 25 %
	Crop: Potato Application rate: 20 g a.s. / ha No. of applications: 2 Time of application: PELMO: 10, 17 days after emergence MACRO: 0, 7 days after emergence Crop interception: 15 %
	Crop: Potato Application rate: 7.5 g a.s. / ha

	No. of applications: 4 Time of application: PELMO: 10, 17, 24, 31 days after emergence MACRO: 0, 7, 14, 21 days after emergence Crop interception: 15 %
	Crop: Peach (pome/stone fruit) (‘Lambda-Cyhalothrin 100 CS’) Application rate: 22.5 g a.s. / ha No. of applications: 2 Time of application: PELMO: 0, 31 days after emergence MACRO: 0, 30 days after emergence Crop interception: 50% **Results:** FOCUS GW modelling based on the endpoints revised at the expert consultation (TC 97) is not available for the representative use on peach. However, comparing the above results for wheat and potato with previous modelling results (using non-agreed endpoints) the peer review concluded it is unlikely that PECgw above the limit value 0.1 µg/l would be modelled for the use in peach using the agreed endpoints.

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

Lambda-cyhalothrin, metabolite XV, metabolite V (PBA) – products ‘Lambda-Cyhalothrin 100 CS’ and ‘Lambda 50 CS’			
Model: FOCUS-PELMO 4.4.3 and FOCUS-MACRO 4.4.2			
Scenario	**winter wheat 4 x 7.5 g/ha**	**potato 2 x 20 g/ha**	**potato 4 x 7.5 g/ha**
Chateaudun (PELMO)	lambda-cyhalothrin and metabolite XV: all PECgw < 0.001 µg/l for all uses in all scenarios in both FOCUS models metabolite V (PBA): all PECgw at or below 0.001 µg/l – except for 0.003 µg/l for potato (2 x 20 g/ha) in Okehampton and Porto, 0.002 µg/l for potato (2 x 20 g/ha) in Hamburg, Piacenza, and Chateaudun (MACRO), 0.002 µg/l for potato (4 x 7.5 g/ha) in Chateaudun (MACRO)		
Hamburg			
Jokioinen			
Kremsmünster			
Okehampton			
Piacenza			
Porto			
Sevilla			
Thiva			
Chateaudun (MACRO)			

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

Metabolite Ia – products ‘Lambda-Cyhalothrin 100 CS’ and ‘Lambda 50 CS’			
Model: FOCUS-PELMO 4.4.3 and FOCUS-MACRO 4.4.2			
Scenario	**winter wheat 4 x 7.5 g/ha**	**potato 2 x 20 g/ha**	**potato 4 x 7.5 g/ha**
Chateaudun (PELMO)	0.003	0.008	0.006
Hamburg	0.037	0.064	0.047
Jokioinen	0.040	0.071	0.052
Kremsmünster	0.012	0.023	0.017
Okehampton	0.035	0.055	0.040
Piacenza	0.020	0.033	0.025
Porto	0.035	0.051	0.038
Sevilla	0.004	0.009	0.006
Thiva	0.004	0.007	0.005
Chateaudun (MACRO)	0.015	0.025	0.019

PEC(gw) – from lysimeter/field leaching experiments

Not submitted; not required

Fate and behaviour in air

Direct photolysis in air ‡	not submitted; not required
Quantum yield of direct phototransformation	not submitted; not required
Photochemical oxidative degradation in air ‡	DT_{50} 12.2 hours (assuming global average OH-conc over 24 hours of 0.5 x 10^6 mol/cm^3)
Volatilisation ‡	from plant surfaces: < 12% loss over 24 hours
	from bare soil surfaces: < 10% loss over 24 hours
Metabolites	not investigated; not required

PEC (air)

Method of calculation	expected to be negligible

Residues requiring further assessment

Environmental occurring compounds requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which a groundwater exposure assessment was triggered	**Soil:** lambda-cyhalothrin, met. Ia and XV (also V (PBA) under anaerobic conditions) **Groundwater**: lambda-cyhalothrin, met Ia, V (PBA), and XV **Surface water** (provisional as a data gap has been identified for satisfactory information to address the levels of metabolites formed from the phenoxy-^{14}C labelled lambda-cyhalothrin when applied at doses below the water solubility in the aquatic environment): lambda-cyhalothrin, met Ia, XV, and V (PBA) **Sediment** (provisional as a data gap has been identified for satisfactory information to address the levels of metabolites formed from the phenoxy-^{14}C labelled lambda-cyhalothrin when applied at doses below the water solubility in the aquatic environment): lambda-cyhalothrin, met Ia and XV **Air**: lambda-cyhalothrin

Monitoring data

Soil	not submitted; not required
Groundwater	not submitted; not required
Surface water/sediment	not submitted; not required
Air	not submitted; not required

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

Not readily biodegradable

Ecotoxicology

Effects on terrestrial vertebrates

Species	Test substance	Time scale	End point (mg/kg bw per day)	End point (mg/kg bw/feed)
Birds ‡				
Anas platyrhynchos (Mallard duck)	lambda-cyhalothrin	Acute oral toxicity	3950	-
Colinus virginianus (Bobwhite quail)	lambda-cyhalothrin	Short-term dietary toxicity	>530	>5300
Anas platyrhynchos (Mallard duck)	lambda-cyhalothrin	Short-term dietary toxicity	n/c[1]	3948[1]
Anas platyrhynchos (Mallard duck)	lambda-cyhalothrin	Long-term dietary/ reproduction toxicity	3.3	30
Mammals ‡				
Rat	lambda-cyhalothrin	Acute oral toxicity	56[2]	-
Mouse	lambda-cyhalothrin	Acute oral toxicity	20[2]	-
	cyhalothrin	Multi-generation reproduction	0.5 mg cyhalothrin/kg bw per day (equivalent to 0.25 mg lambda cyhalothrin/kg bw per day)	-
Additional higher tier studies ‡				
No additional effect studies				

[1]Food avoidance observed in the short-term dietary study with the mallard duck. Consequently the daily dietary dose could not be calculated (n/c). The LC_{50} value is not considered accurate due to lack of dose response (due to food avoidance at the higher test concentrations). The study was not available in the dossier and therefore a data gap was identified.

[2]geomean 33.4 mg/kg bw is used for the risk assessment

Toxicity/exposure ratios for terrestrial vertebrates

Spring and winter cereals, application rate 2 x 0.0075 kg a.s./ha, 14 d interval . BBCH 10 - 85				
Indicator species/Category	**Time scale**	**DDD mg/kg bw per day**	**TER**	**Reg (EU) 546/2011 Trigger**
Screening step uptake via diet (Birds)				
Screening step	Acute	1.43	2762	10
Screening step	Reproduction	0.36	9.15	5
Tier 1– uptake via contaminated water (Birds)				
	Acute	-	Not required[1]	10
Tier 1 – secondary poisoning (Birds)				
Earthworm-eating bird	Reproduction	0.043[3]	77	5
Fish-eating bird	Reproduction	0.011[2]	305	5
Screening step and tier 1 – uptake via diet (Mammals)				
Screening step	Acute	1.07	31.3	10
Screening step	Reproduction	0.27	**0.9**	5
Small insectivorous mammal, BBCH 10-19	Reproduction	0.023	10.7	5
Small insectivorous mammal, BBCH ≥ 20	Reproduction	0.011	23.6	5
Small herbivorous mammal, BBCH ≥ 40	Reproduction	0.121	**2.1**	5

Spring and winter cereals, application rate 2 x 0.0075 kg a.s./ha, 14 d interval . BBCH 10 - 85				
Indicator species/Category	**Time scale**	**DDD mg/kg bw per day**	**TER**	**Reg (EU) 546/2011 Trigger**
Large herbivorous mammal, 'lagomorph' Early shoots	Reproduction	0.124	**2.0**	5
Small omnivorous mammal, BBCH 10-29	Reproduction	0.043	5.8	5
Small omnivorous mammal, BBCH 30-39	Reproduction	0.022	11.5	5
Small omnivorous mammal, BBCH ≥ 40	Reproduction	0.013	19.5	5
Tier 1– uptake via contaminated water (Mammals)				
	Acute	-	Not required[1]	10
Tier 1 – secondary poisoning (Mammals)				
Earthworm-eating mammal	Reproduction	0.0518[3]	**4.8**	5
Fish-eating mammal	Reproduction	0.0097[2]	26	5

[1] Not required on the basis of the screening step according to the EFSA Bird and Mammal Guidance Document (EFSA, 2009)
[2] Based on 21d TWA PECsw values, FOCUS Step 3
[3] Based on 21 day TWA PEC_{soil} =0.015 mg/kg dw in cereals
TER values presented in **bold** are less than the assessment factor

Field tomatoes, application rate 2 x 0.025 kg a.s./ha, 12 d interval BBCH 10 - 89				
Indicator species/Category	**Time scale**	**DDD mg/kg bw per day**	**TER**	**Reg (EU) 546/2011 Trigger**
Screening step and tier 1 – uptake via diet (Birds)				
Screening step	Acute	5.16	766	10
Screening step	Reproduction	1.20	**2.8**	5
Tier 1-Small insectivorous bird, BBCH ≥ 20	Reproduction	0.18	18	5
Tier 1-Small granivorous bird, BBCH ≥ 50	Reproduction	0.06	55	5
Tier 1-Small omnivorous bird, BBCH ≥ 50	Reproduction	0.06	55	5
Tier 1-Small insectivorous bird, BBCH 10 - 19	Reproduction	0.21	16	5
Tier 1-Small granivorous bird, BBCH 10 - 49	Reproduction	0.21	16	5
Tier 1-Small omnivorous bird, BBCH 10 - 49	Reproduction	0.20	17	5
Tier 1-Frugivorous bird "crow", BBCH 71-89	Reproduction	0.59	5.6	5
Tier 1-Frugivorous bird "starling" BBCH 71-89	Reproduction	0.38	8.6	5
Tier 1– uptake via contaminated water (Birds)				
	Acute	-	Not required[1]	10
Tier 1 – secondary poisoning (Birds)				
Earthworm-eating bird	Reproduction	0.117[2]	28	5
Fish-eating bird (note: 2x12.5 g/ha)[4]	Reproduction	0.0025[3]	1328	5

Field tomatoes, application rate 2 x 0.025 kg a.s./ha, 12 d interval BBCH 10 - 89				
Indicator species/Category	**Time scale**	**DDD mg/kg bw per day**	**TER**	**Reg (EU) 546/2011 Trigger**
Screening step and tier 1 – uptake via diet (Mammals)				
Screening step	Acute	4.43	756	10
Screening step	Reproduction	1.34	**0.18**	5
Small insectivorous mammal BBCH ≥ 20	Acute	0.18	190	10
Small herbivorous mammal BBCH ≥ 50	Acute	1.33	25	10
Small omnivorous mammal BBCH ≥ 50	Acute	0.17	19733.4	10
Small insectivorous mammal BBCH 10-19	Acute	0.25	134	10
Small herbivorous mammal BBCH 10-49	Acute	4.43	**7.6**	10
Small omnivorous mammal BBCH 10-49	Acute	0.56	60	10
Frugivorous mammal BBCH 71-89	Acute	1.47	23	10
Small insectivorous mammal BBCH ≥ 20	Reproduction	0.04	6.3	5
Small herbivorous mammal BBCH ≥ 50	Reproduction	0.40	**0.63**	5
Small omnivorous mammal BBCH ≥ 50	Reproduction	0.04	6.3	5
Small insectivorous mammal BBCH 10-19	Reproduction	0.08	**3.1**	5
Small herbivorous mammal BBCH 10-49	Reproduction	1.34	**0.19**	5
Small omnivorous mammal BBCH 10-49	Reproduction	0.14	**1.8**	5
Frugivorous mammal BBCH 71-89	Reproduction	0.47	**0.53**	5
Higher tier refinement – uptake via diet (Mammals)				
No acceptable refinement.				
Tier 1– uptake via drinking water (Mammals)				
	Acute	-	Not required[1]	10
Tier 1 – secondary poisoning (Mammals)				
Earthworm-eating mammal	Reproduction	0.143[2]	**1.7**	5
Fish-eating mammal (note 2x12.5 g/ha)[4]	Reproduction	0.0023[3]	113	5

[1] Not required on the basis of the screening step according to the EFSA Bird and Mammal Guidance Document (EFSA, 2009)
[2] Based on 21 day TWA PEC_{soil} values for 2 applications of 25 g a.s./ha in plums
[3] Based on 21d TWA PECsw values, FOCUS Step 3.
[4] Assessment performed for 2 applicatios of 12.5 g a.s./ha. Sufficient margin of safety obtained to indicate a low risk for 2 applications of 25 g a.s./ha
TER values presented in **bold** are less than the assessment factor

Peach and plum orchards, application rate 2 x 0.025 kg a.s./ha, 10 d interval				
Indicator species/Category	**Time scale**	**DDD mg/kg bw per day**	**TER**	**Reg (EU) 546/2011 Trigger**
Screening step and tier 1 – uptake via diet (Birds)				
Screening step	Acute	1.52	2599	10
Screening step	Reproduction	0.36	9.2	5
Tier 1– uptake via contaminated water (Birds)				
	Acute	-	Not required[1]	10
Tier 1 – secondary poisoning (Birds)				
Earthworm-eating bird	Reproduction	0.117[2]	28	5
Fish-eating bird	Reproduction		Data gap[4]	5
Screening step and tier 1 – uptake via diet (Mammals)				
Screening step	Acute	4.43	**7.56**	10
Screening step	Reproduction	1.44	**0.17**	5
Large herbivorous mammal, crop directed BBCH ≥ 40	Acute	0.34	98.5	10
Small herbivorous mammal, crop directed BBCH ≥ 40	Acute	1.33	25.2	10
Small omnivorous mammal crop directed BBCH ≥ 40	Acute	0.17	197	10
Large herbivorous mammal, crop directed BBCH 10- 19	Acute	0.91	36.8	10
Small herbivorous mammal, crop directed BBCH 10- 19	Acute	3.55	**9.44**	10
Small omnivorous mammal, crop directed BBCH 10- 19	Acute	0.45	74.4	10
Large herbivorous mammal, crop directed BBCH 20- 40	Acute	0.69	48.6	10
Small herbivorous mammal, crop directed BBCH 20- 40	Acute	2.66	12.6	10
Small omnivorous mammal, crop directed BBCH 20- 40	Acute	0.33	102	10
Frugivorous mammal, BBCH 71-79 currants	Acute	1.56	21.5	10
Large herbivorous mammal, crop directed BBCH ≥ 40	Reproduction	0.09	**2.8**	5
Small herbivorous mammal, crop directed BBCH ≥ 40	Reproduction	0.43	**0.58**	5
Small omnivorous mammal, crop directed BBCH ≥ 40	Reproduction	0.05	5.0	5
Large herbivorous mammal, crop directed BBCH 10- 19	Reproduction	0.23	**1.1**	5
Small herbivorous mammal, crop directed BBCH 10- 19	Reproduction	1.15	**0.22**	5
Small omnivorous mammal, crop directed BBCH 10- 19	Reproduction	0.12	**2.1**	5
Large herbivorous mammal, crop directed BBCH 20- 40	Reproduction	0.17	**1.5**	5
Small herbivorous mammal, crop directed BBCH 20- 40	Reproduction	0.86	**0.29**	5
Small omnivorous mammal, crop directed BBCH 20- 40	Reproduction	0.09	**2.8**	5
Frugivorous mammal, BBCH 71-79 currants	Reproduction	0.45	**0.56**	5

Peach and plum orchards, application rate 2 x 0.025 kg a.s./ha, 10 d interval				
Indicator species/Category	**Time scale**	**DDD mg/kg bw per day**	**TER**	**Reg (EU) 546/2011 Trigger**
Higher tier refinement – uptake via diet (Mammals)				
Small herbivorous mammal, BBCH <10-40[3]	Acute	2.21[3]	15	10
Small herbivorous mammal, BBCH <10-40[3]	Reproduction	0.72[3]	**0.3**	5
Tier 1 – uptake via contaminated water (Mammals)				
	Acute	-	Not required[1]	10
Tier 1 – secondary poisoning (Mammals)				
Earthworm-eating mammal	Reproduction	0.143[2]	**1.7**	5
Fish-eating mammal	Reproduction		Data gap[4]	5

[1] Not required on the basis of the screening step according to the EFSA Bird and Mammal Guidance Document (EFSA, 2009)
[2] Based on 21 day TWA PEC_{soil} values for 2 applications of 25 g a.s./ha in plums
[3] Refined using deposition values given in the FOCUS Groundwater Guidance Document (FOCUS, 2000).
[4] PECsw not available
TER values presented in **bold** are less than the assessment factor

Potato, application rate 2 x 0.020 kg a.s./ha, 8 d interval				
Indicator species/Category	**Time scale**	**DDD mg/kg bw per day**	**TER**	**Reg (EU) 546/2011 Trigger**
Screening step and tier 1 – uptake via diet (Birds)				
Screening step	Acute	4.45	888	10
Screening step	Reproduction	3.3	**3**	5
Small insectivorous bird, BBCH 10-19	Reproduction	0.19	17	5
Small omnivorous bird, BBCH 10-39	Reproduction	0.18	18	5
Small insectivorous bird, BBCH ≥20	Reproduction	0.16	20	5
Small omnivorous bird, BBCH ≥40	Reproduction	0.056	59	5
Tier 1– uptake via contaminated water (Birds)				
	Acute	-	Not required[1]	10
Tier 1 – secondary poisoning (Birds)				
Earthworm-eating bird	Reproduction	0.117[2]	28	5
Fish-eating bird	Reproduction	0.010	321	5
Screening step and tier 1 – uptake via diet (Mammals)				
Screening step	Acute	3.3	10.1	10
Screening step	Reproduction	0.82	**0.30**	5
Large herbivorous mammal, BBCH ≥40	Reproduction	0.073	**3.4**	5
Small herbivorous mammal, BBCH ≥40	Reproduction	0.368	**0.68**	5
Small omnivorous mammal, BBCH ≥40	Reproduction	0.039	6.4	5
Small insectivorous mammal, BBCH 10-19	Reproduction	0.071	**3.5**	5

Potato, application rate 2 x 0.020 kg a.s./ha, 8 d interval				
Indicator species/Category	**Time scale**	**DDD mg/kg bw per day**	**TER**	**Reg (EU) 546/2011 Trigger**
Small omnivorous mammal, BBCH 10-39	Reproduction	0.132	**1.9**	5
Large herbivorous mammal, BBCH 10-40	Reproduction	0.24	**1.03**	5
Small insectivorous mammal, BBCH ≥20	Reproduction	0.03	7.76	5
Higher tier refinement – uptake via diet (Mammals)				
No suitable refined risk assessment available.				
Tier 1– uptake via contaminated water (Mammals)				
	Acute	-	Not required[1]	10
Tier 1 – secondary poisoning (Mammals)				
Earthworm-eating mammal	Reproduction	0.143[2]	**1.7**	5
Fish-eating mammal	Reproduction	0.0092[a]	27	5

[1] Not required on the basis of the screening step according to the EFSA Bird and Mammal Guidance Document (EFSA, 2009)

a Based on 21d TWA PECsw values, FOCUS Step 3.

[2] Based on 21 day TWA PEC_{soil} values for 2 applications of 25 g a.s./ha in plums

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

Toxicity data for aquatic species (most sensitive species of each group)

Group/Species	Test substance	Time-scale	End point	Toxicity (µg a.s./L)
Laboratory tests ‡				
Fish				
Leuciscus idus	Lambda-cyhalothrin	96 h	EC_{50}	0.078 (mm)
Lepomis macrochirus	Lambda-cyhalothrin	96 h	LC_{50}	0.21 (mm)
Oncorrynchus mykiss	Lambda-cyhalothrin	96 h	LC_{50}	0.24 (mm)
Ictalurus punctatus	Lambda-cyhalothrin	96 h	LC_{50}	0.16 (mm)
Gasterosteus aculeatus	Lambda-cyhalothrin	96 h	LC_{50}	0.40 (mm)
Brachydanio rerio	Lambda-cyhalothrin	96 h	LC_{50}	0.64 (mm)
Pimephales promelas	Lambda-cyhalothrin	96 h	LC_{50}	0.70 (mm)
Oryzias latipes	Lambda-cyhalothrin	96 h	LC_{50}	1.4 (mm)
Poecilia reticulata	Lambda-cyhalothrin	96 h	LC_{50}	2.3 (mm)
Oncorrynchus mykiss	TFP acid (metabolite Ia)	96 h	LC_{50}	>10 800 (mm)
Lepomis macrochirus	TFP acid (metabolite Ia)	96 h	LC_{50}	>14 000 (mm)
Oncorrynchus mykiss	Cyhalothrin amide (metabolite II)	96 h	LC_{50}	18.7 (mm)
Pimephales promelas	3-phenoxy benzaldehyde (metabolite IV)	24 h	LC_{50}	60 (mm)
Oncorrynchus mykiss	3-phenoxy benzoic acid (metabolite V)	96 h	LC_{50}	13 300 (mm)
Lepomis macrochirus	3-phenoxy benzoic acid (metabolite V)	96 h	LC_{50}	36 300 (mm)
Oncorrynchus mykiss	Hydroxylated lambda-cyhalothrin (metabolite XV)	96 h	LC_{50}	0.84 (mm)
Cyprinus carpio	Karate 10 CS (100 g a.s./L)	96 h	LC_{50}	1.17 (mm)
Oncorrynchus mykiss	CA 2352 ('Kaiso sorbie 5% EG')	96 h	LC_{50}	0.395 (mm)
Cyprinus carpio	JF9509 (5% EC)	96 h	LC_{50}	0.5 (mm)
Oncorrynchus mykiss	Lambda-cyhalothrin 100 g/L CS formulation	96 h	LC_{50}	6.0 (mm)
Cyprinodon variegatus	Lambda-cyhalothrin	ELS 28 d	NOEC	0.25 (mm)
Pimephales promelas	Lambda cyhalothrin	FLC 300 d	NOEC	0.031 (mm)
Higher tier endpoint: Refined acute RAC = 2.1 ng/L (based on EFSA method 2[e] i.e. the ranking method where data for additional species are available).				
Aquatic invertebrates				
Daphnia magna	Lambda-cyhalothrin	48 h	EC_{50}	0.23 (mm)
Cyclops sp.	Lambda-cyhalothrin	48 h	EC_{50}	0.195[a] (mm)
Hyallella azteca	Lambda-cyhalothrin	48 h	EC_{50}	0.0018[a, d] (mm)
Chaoborus sp.	Lambda-cyhalothrin	48 h	EC_{50}	0.0022[a, d] (mm)

Group/Species	Test substance	Time-scale	End point	Toxicity (µg a.s./L)
Cloeon dipterum	Lambda-cyhalothrin	48 h	EC_{50}	0.0264[a] (mm)
Gammarus pulex	Lambda-cyhalothrin	48 h	EC_{50}	0.011[a] (mm)
Corixa sp.	Lambda-cyhalothrin	48 h	EC_{50}	0.026[a] (mm)
Hydracarina	Lambda-cyhalothrin	48 h	EC_{50}	0.041[a] (mm)
Ischnura elegans	Lambda-cyhalothrin	48 h	EC_{50}	0.102[a] (mm)
Ostracoda	Lambda-cyhalothrin	48 h	EC_{50}	2.04[a] (mm)
Daphnia pulex	TFP acid (metabolite Ia)	48 h	EC_{50}	105 000 (nom)
Daphnia magna	Lambda-cyhalothrin amide (metabolite II)	48 h	EC_{50}	>14.3 (mm)
Daphnia magna	3-phenoxy benzoic acid (metabolite V)	48 h	EC_{50}	85 000 (mm)
Daphnia magna	hydroxylated lambda-cyhalothrin (metabolite XV)	48 h	EC_{50}	0.16 (mm)
Daphnia magna	lambda-cyhalothrin 100 g/L CS formulation	48 h	EC_{50}	0.13 (mm)
Daphnia magna	lambda-cyhalothrin 100 g/L CS formulation	48 h	EC_{50}	2.36 (mm)
Daphnia magna	lambda-cyhalothrin 50 g/L EC formulation	48 h	EC_{50}	0.52 (mm)
Daphnia magna	lambda-cyhalothrin CA 2352 50 g/L EG formulation	48 h	EC_{50}	0.25 (mm)
Gammarus pulex	lambda-cyhalothrin CA 2352 50 g/L EG formulation	48 h	EC_{50}	0.0026 (mm)
Mysidopsis bahia	Lambda-cyhalothrin	28 d	NOEC	0.00022 (mm)
Daphnia magna	Lambda-cyhalothrin	21 d	NOEC	0.00198 (mm)
Higher tier endpoint: Refined acute RAC = 0.38 ng/L (based on EFSA method 1[e], i.e. the geometric mean of available acute data on aquatic invertebrates. Acute and chronic RAC = 0.3 ng/L. RAC was agreed on expert meeting and it is based on available laboratory data on lambda-cyhalothrin and gamma-cyhalothrin as well as field data on gamma-cyhalothrin. This RAC is only applicable for CS-formulations and when exposure to the aquatic environment is via spray drift only.				
Sediment dwelling organisms				
Chironomus riparius	Lambda-cyhalothrin	48 h	EC_{50}	1.5 (mm)
Chironomus riparius	Lambda-cyhalothrin	28 d	NOEC	0.13 (mm)[b]
Chironomus riparius	Lambda-cyhalothrin	28 d	NOEC	105 µg/kg sediment dw (mm)
Chironomus riparius	Lambda-cyhalothrin	28 d	NOEC	0.63 (mm) 2.35 µg/kg sediment dw (mm)[b]
Chironomus riparius	TFP acid (metabolite Ia)	28 d	NOEC	20 800 (mm)
Chironomus riparius	3-phenoxy Benzylalcohol (metabolite VI)	28 d	NOEC	11 000 (mm)

Group/Species	Test substance	Time-scale	End point	Toxicity (µg a.s./L)
Chironomus riparius	hydroxylated lambda-cyhalothrin (metabolite XV)	28 d	NOEC	580 µg/kg (mm)[b]
Algae				
Pseudokirchneriella subcapitata	Lambda-cyhalothrin	72 h	E_rC_{50} E_yC_{50}	5[c] 5[c]
Higher plant				
Not required in compliance with Reg (EU) 544/2011 article 8(2:8)				

[a] Endpoint based on geometric mean concentrations (80% of nominal concentrations). From Hamer *et al*. 1998.
[b] Food was added throughout the test possibly underestimating the exposure via contaminated food. This is not according to recommendations in the OECD 218/219.
[c] Endpoint set to water solubility for lambda-cyhalothrin.
[d] Endpoint below LOD for the analytical method used in the study (0.011 µg a.s./L). The endpoint should therefore only be considered as approximate.
[e] EFSA Journal doi:10.2903/j.efsa.2006.301

Toxicity/exposure ratios for the most sensitive aquatic organisms –

Maximum PECsw values (Focus step 1-3) and TER values for lambda-cyhalothrin – application of 'Karate 10 CS' and 'Kaiso sorbie 5% EG'									
Scenario		PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller acute	Sed- dweller prolonged
			L. idus	*P. promelas*	*H. azteca*	*M. bahia*	*P. subcapitata*	*C. riparius*	*C. riparius*
			LC_{50}	NOEC	LC_{50}	NOEC	EC_{50}	EC_{50}	NOEC
			0.078 µg/L	0.031 µg/L	0.0019 µg/L	0.00022 µg/L	5 µg/L	1.5 µg/L	0.13 µg/L
Spring wheat EU-N/S [2 x7.5 g as/ha] BBCH 10-85 Application interval 18 days									
FOCUS Step 1									
		0.23	**0.339**	**0.135**	**0.008**	**0.001**	21.7	**6.5**	**0.565**
FOCUS Step 2									
N EU		0.069[a]	**1.13**	**0.449**	**0.028**	**0.003**	-	**21.7**	**1.88**
S EU		0.069[a]	**1.13**	**0.449**	**0.028**	**0.003**	-	**21.7**	**1.88**
FOCUS Step 3									
		not available							
Winter wheat EU-N/S [2x7.5 g as/ha] BBCH 10-85 Application interval 18 days									
FOCUS Step 1									
		0.23	**0.339**	**0.135**	**0.008**	**0.001**	21.7	**6.52**	**0.565**
FOCUS Step 2									
N EU		0.069[a]	**1.13**	**0.449**	**0.028**	**0.003**	-	**21.7**	**1.88**
S EU		0.069[a]	**1.13**	**0.449**	**0.028**	**0.003**	-	**21.7**	**1.88**
FOCUS Step 3									
D1	Ditch	0.0488[b]	**160**	**0.64**	**0.04**	**0.005**	-	**30.7**	**2.66**
D1	Stream	0.0409	**1.91**	**0.758**	**0.046**	**0.005**	-	**36.7**	**3.18**
D2	Ditch	0.0467	**1.67**	**0.664**	**0.041**	**0.005**	-	**32.1**	**2.78**
D2	Stream	0.0402	**1.94**	**0.771**	**0.047**	**0.005**	-	**37.3**	**3.23**
D3	Ditch	0.0459	**1.70**	**0.675**	**0.041**	**0.005**	-	**32.7**	**2.83**
D4	Pond	0.00182[b]	**42.8**	17.1	**1.04**	**0.12**	-	824	71.4
D4	Stream	0.0399	**1.95**	**0.777**	**0.048**	**0.006**	-	**37.6**	**3.26**
D5	Pond	0.00159	**49.1**	**19.5**	**1.19**	**0.138**	-	943	81.8

Maximum PECsw values (Focus step 1-3) and TER values for lambda-cyhalothrin – application of 'Karate 10 CS' and 'Kaiso sorbie 5% EG'									
Scenario		PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller acute	Sed- dweller prolonged
			L. idus LC_{50} 0.078 µg/L	*P. promelas* NOEC 0.031 µg/L	*H. azteca* LC_{50} 0.0019 µg/L	*M. bahia* NOEC 0.00022 µg/L	*P. subcapitata* EC_{50} 5 µg/L	*C. riparius* EC_{50} 1.5 µg/L	*C. riparius* NOEC 0.13 µg/L
D5	Stream	0.0431	**1.81**	**0.719**	**0.044**	**0.005**	-	**34.8**	**3.02**
D6	Ditch	0.0465	**1.68**	**0.667**	**0.041**	**0.005**	-	**32.3**	**2.80**
R1	Pond	0.00264[b]	**29.6**	11.7	**0.72**	**0.08**	-	568	49.2
R1	Stream	0.0304	**2.57**	**1.02**	**0.063**	**0.007**	-	**49.3**	**4.28**
R3	Stream	0.0426	**1.83**	**0.728**	**0.045**	**0.005**	-	**35.2**	**3.05**
R4	Stream	0.0305	**2.56**	**1.02**	**0.062**	**0.007**	-	**49.2**	**4.26**
Field Tomato EU-N [2 x 12.5 g as/h]; BBCH 10-89 Application interval 12 days									
FOCUS Step 1		0.39	**0.200**	**0.079**	**0.005**	**0.001**	12.8	**3.85**	**0.333**
FOCUS Step 2 N EU		0.115[a]	**0.678**	**0.270**	**0.017**	**0.002**	43.5	**13.0**	**1.13**
FOCUS Step 3									
D6	Ditch	0.0769	**1.01**	**0.403**	**0.025**	**0.003**	65.0	**19.5**	**1.69**
R2	Stream	0.0672	**1.16**	**0.461**	**0.028**	**0.003**	74.4	**22.3**	**1.93**
R3	Stream	0.0715	**1.09**	**0.434**	**0.027**	**0.003**	69.9	**21.0**	**1.82**
R4	Stream	0.0508	**1.54**	**0.610**	**0.037**	**0.004**	98.4	**29.5**	**2.56**
Field Tomato EU-S [2x25 g as/h]; BBCH 10-89 Application interval 12 days									
FOCUS Step 1		0.78	**0.100**	**0.040**	**0.002**	**0.0003**	**6.41**	**1.92**	**0.167**
FOCUS Step 2 S EU		0.230[a]	**0.339**	**0.135**	**0.0083**	**0.0010**	22	**6.52**	**0.565**
FOCUS Step 3		Not available							
Tomato EU-N/S [2x25 g as/ha]; BBCH 10-89 Application interval 12 days. Indoor applications									
FOCUS Step 1		0.033	**2.36**	**0.939**	**0.058**	**0.0067**	152	**45.5**	**3.94**

Maximum PECsw values (Focus step 1-3) and TER values for lambda-cyhalothrin – application of 'Karate 10 CS' and 'Kaiso sorbie 5% EG'									
Scenario		PEC global max (μg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller acute	Sed- dweller prolonged
			L. idus LC$_{50}$ 0.078 μg/L	*P. promelas* NOEC 0.031 μg/L	*H. azteca* LC$_{50}$ 0.0019 μg/L	*M. bahia* NOEC 0.00022 μg/L	*P. subcapitata* EC$_{50}$ 5 μg/L	*C. riparius* EC$_{50}$ 1.5 μg/L	*C. riparius* NOEC 0.13 μg/L
FOCUS Step 2									
N/S EU		0.008	**9.75**	**3.88**	**0.24**	**0.03**	625	188	16.25
Plum EU-N [2 x 10 g as/ha]; BBCH <10-79 Application interval 10-14 days(min) early application									
FOCUS Step 1									
		2.08	**0.038**	**0.015**	**0.0009**	**0.0001**	**2.40**	**0.721**	**0.063**
FOCUS Step 2									
N EU		0.973[a]	**0.080**	**0.032**	**0.0020**	**0.0002**	**5.14**	**1.54**	**0.134**
FOCUS Step 3		Not available							
Plum EU-N [2 x 10 g as/ha ; BBCH <10-79 Application interval 10-14 days(min) late application									
FOCUS Step 1									
		1.18	**0.066**	**0.026**	**0.0016**	**0.0002**	**4.24**	**1.27**	**0.110**
FOCUS Step 2 late									
N EU		0.542[a]	**0.144**	**0.057**	**0.0035**	**0.0004**	**9.23**	**2.77**	**0.240**
FOCUS Step 3									
D3	Ditch	0.357	**0.218**	**0.087**	**0.005**	**0.0006**	14.0	**4.20**	**0.364**
D4	Pond	0.0187[b]	**4.17**	**1.66**	**0.10**	**0.012**	267	**80.2**	**6.95**
D4	Stream	0.358	**0.218**	**0.087**	**0.005**	**0.0006**	14.0	**4.19**	**0.363**
D5	Pond	0.0211[b]	**3.70**	**1.47**	**0.090**	**0.010**	237	**71.1**	**6.16**
D5	Stream	0.387	**0.202**	**0.080**	**0.005**	**0.0006**	12.9	**3.88**	**0.336**
R1	Pond	0.0197[b]	**3.96**	**1.57**	**0.096**	**0.011**	254	**76.1**	**6.60**
R1	Stream	0.274	**0.285**	**0.113**	**0.007**	**0.0008**	18.2	**5.47**	**0.474**
R2	Stream	0.367	**0.213**	**0.084**	**0.005**	**0.0006**	13.6	**4.09**	**0.354**
R3	Stream	0.386	**0.202**	**0.080**	**0.005**	**0.0006**	13.0	**3.89**	**0.337**
R4	Stream	0.274	**0.285**	**0.113**	**0.007**	**0.0008**	18.2	**5.47**	**0.474**

Maximum PECsw values (Focus step 1-3) and TER values for lambda-cyhalothrin – application of 'Karate 10 CS' and 'Kaiso sorbie 5% EG'								
Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller acute	Sed- dweller prolonged
		L. idus LC_{50} 0.078 µg/L	*P. promelas* NOEC 0.031 µg/L	*H. azteca* LC_{50} 0.0019 µg/L	*M. bahia* NOEC 0.00022 µg/L	*P. subcapitata* EC_{50} 5 µg/L	*C. riparius* EC_{50} 1.5 µg/L	*C. riparius* NOEC 0.13 µg/L
EU-S [2 x 25 g as/ha] ; BBCH <10-79 Application interval 10-14 days(min) early application								
FOCUS Step 1	5.19	**0.015**	**0.0060**	**0.0004**	**0.0000**	**0.963**	**0.289**	**0.025**
FOCUS Step 2 S EU	2.43[a]	**0.032**	**0.0128**	**0.0008**	**0.0001**	**2.06**	**0.617**	**0.053**
FOCUS Step 3	not available							
Plum EU-S [2 x 25 g as/ha] ; BBCH <10-79 Application interval 10-14 days(min) late application								
FOCUS Step 1	2.94	**0.027**	**0.011**	**0.001**	**0.000**	**1.70**	**0.510**	**0.044**
FOCUS Step 2 S EU	1.31[a]	**0.060**	**0.024**	**0.001**	**0.000**	**3.82**	**1.145**	**0.099**
FOCUS Step 3	not available							
Reg (EU) 546/2011 Trigger		100	10	100	10	10	100	10

[a] Maximum PEC_{sw} derived from single application
[b] PEC value for multiple applications

Maximum PECsw values, step 3, and TER values for lambda-cyhalothrin – using refined acute RAC for fish ‘Karate 10 CS’ and ‘Kaiso sorbie 5% EG’					
Scenario		**Single application**		**Multiple applications**	
		PEC global max (µg/L)	**TER Acute RAC 0.0021 µg/L**	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**
Winter wheat EU-N/S [2x7.5 g as/ha] BBCH 10-85 Application interval 18 days					
Step 3					
D1	Ditch	0.0467	**0.045**	0.0488	**0.043**
D1	Stream	0.0409	**0.051**	0.0354	**0.059**
D2	Ditch	0.0467	**0.045**	0.0408	**0.051**
D2	Stream	0.0402	**0.052**	0.0347	**0.061**
D3	Ditch	0.0459	**0.046**	0.0402	**0.052**
D4	Pond	0.00159	1.32	0.00182	1.15
D4	Stream	0.0399	**0.053**	0.0345	**0.061**
D5	Pond	0.00159	1.32	0.00192	1.09
D5	Stream	0.0431	**0.049**	0.0373	**0.056**
D6	Ditch	0.0465	**0.045**	0.0406	**0.052**
R1	Pond	0.00162	1.30	0.00264	**0.795**
R1	Stream	0.0304	**0.069**	0.0263	**0.080**
R3	Stream	0.0426	**0.049**	0.0369	**0.057**
R4	Stream	0.0305	**0.069**	0.0264	**0.080**
Field Tomato EU-N [2x12.5 g as/h]; BBCH 10-89 Application interval 12 days					
Step 3					
D6	Ditch	0.0769	**0.027**	0.0672	**0.031**
R2	Stream	0.0672	**0.031**	0.0581	**0.036**
R3	Stream	0.0715	**0.029**	0.0621	**0.034**
R4	Stream	0.0508	**0.041**	0.0439	**0.048**
Plum EU-N [2x10 g as/ha]; BBCH <10-79 Application interval 10-14 days(min) - Late					
Step 3					

Maximum PECsw values, step 3, and TER values for lambda-cyhalothrin – using refined acute RAC for fish 'Karate 10 CS' and 'Kaiso sorbie 5% EG'					
Scenario		**Single application**		**Multiple applications**	
		PEC global max (µg/L)	**TER Acute RAC 0.0021 µg/L**	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**
D3	Ditch	0.357	**0.006**	0.285	**0.007**
D4	Pond	0.016	**0.131**	0.0187	**0.112**
D4	Stream	0.358	**0.006**	0.286	**0.007**
D5	Pond	0.01	**0.131**	0.0211	**0.100**
D5	Stream	0.387	**0.005**	0.31	**0.007**
R1	Pond	0.016	**0.131**	0.0197	**0.107**
R1	Stream	0.274	**0.008**	0.22	**0.010**
R2	Stream	0.367	**0.006**	0.294	**0.007**
R3	Stream	0.386	**0.005**	0.309	**0.007**
R4	Stream	0.274	**0.008**	0.219	**0.010**
Trigger			**1**		**1**

Maximum PECsw values (FOCUS step 1-4) and TER values for lambda-cyhalothrin – application of ‘Lambda-Cyhalothrin 100 CS’ and ‘Lambda 50 EC’									
Scenario		PEC global max (µg/L)[b]	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller acute	Sed- dweller prolonged
			L. idus LC_{50} 0.078 µg/L	*P. promelas* NOEC 0.031 µg/L	*H. azteca* LC_{50} 0.0019 µg/L	*M. bahia* NOEC 0.00022 µg/L	*P. subcapitata* EC_{50} 5 µg/L	*C. riparius* EC_{50} 1.5 µg/L	*C. riparius* NOEC 0.13 µg/L
Winter wheat EU-N/S [2 x 7.5 g as/ha] BBCH 10-29 Application interval 14 days									
FOCUS Step 1									
		0.23	**0.339**	**0.135**	**0.008**	**0.001**	21.7	**6.52**	**0.565**
FOCUS Step 2									
N EU		0.069	**1.13**	**0.449**	**0.028**	**0.003**	-	**21.7**	**1.88**
S EU		0.069	**1.13**	**0.449**	**0.028**	**0.003**	-	**21.7**	**1.88**
FOCUS Step 3									
D1	ditch	0.0487	**1.60**	**0.637**	**0.039**	**0.005**	-	**30.8**	**2.67**
D1	stream	0.0409[b]	**1.90**	**0.758**	**0.046**	**0.005**	-	**36.7**	**3.18**
D2	ditch	0.0467[b]	**1.67**	**0.664**	**0.041**	**0.005**	-	**32.1**	**2.78**
D2	stream	0.0402[b]	**1.94**	**0.771**	**0.047**	**0.005**	-	**37.3**	**3.23**
D3	ditch	0.0459[b]	**1.69**	**0.675**	**0.041**	**0.005**	-	**32.7**	**2.83**
D4	pond	0.00182	**42.8**	17.0	**1.04**	**0.121**	-	824	71.4
D4	stream	0.0399[b]	**1.95**	**0.777**	**0.048**	**0.006**	-	**37.6**	**3.26**
D5	pond	0.00192	**40.6**	16.1	**0.990**	**0.115**	-	781	67.7
D5	stream	0.0431[b]	**1.81**	**0.719**	**0.044**	**0.005**	-	**34.8**	**3.02**
D6	ditch	0.0465[b]	**1.67**	**0.667**	**0.041**	**0.005**	-	**32.3**	**2.80**
R1	pond	0.00217	**35.9**	14.3	**0.876**	**0.101**	-	691	59.9
R1	stream	0.0304[b]	**2.56**	**1.02**	**0.063**	**0.007**	-	**49.3**	**4.28**
R3	stream	0.0421[b]	**1.85**	**0.736**	**0.045**	**0.005**	-	**35.6**	**3.09**
R4	stream	0.0301[b]	**2.59**	**1.03**	**0.063**	**0.007**	-	**49.8**	**4.32**
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips									
D1	ditch	0.00231	**33.7**	13.4	**0.823**	**0.095**	-	650	56.3
D1	stream	0.00191	**41.0**	16.3	**1.00**	**0.116**	-	789	68.4

Maximum PECsw values (FOCUS step 1-4) and TER values for lambda-cyhalothrin – application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'									
Scenario		PEC global max (µg/L)[b]	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller acute	Sed- dweller prolonged
			L. idus LC$_{50}$ 0.078 µg/L	*P. promelas* NOEC 0.031 µg/L	*H. azteca* LC$_{50}$ 0.0019 µg/L	*M. bahia* NOEC 0.00022 µg/L	*P. subcapitata* EC$_{50}$ 5 µg/L	*C. riparius* EC$_{50}$ 1.5 µg/L	*C. riparius* NOEC 0.13 µg/L
D2	ditch	0.00226[b]	**34.5**	13.7	**0.841**	**0.097**	-	664	57.5
D2	stream	0.00187[b]	**41.7**	16.6	**1.02**	**0.118**	-	802	69.5
D3	ditch	0.00222[b]	**35.1**	14.0	**0.856**	**0.099**	-	676	58.6
D4	pond	0.000135	577	230	14.1	**1.63**	-	11111	963
D4	stream	0.00186	**41.9**	16.7	**1.02**	**0.118**	-	806	69.9
D5	pond	0.000143	545	217	13.3	**1.54**	-	10490	909
D5	stream	0.00201	**38.8**	15.4	**0.945**	**0.109**	-	746	64.7
D6	ditch	0.00225[b]	**34.7**	13.8	**0.844**	**0.098**	-	667	57.8
R1	pond	0.000201	388	154	**9.45**	**1.09**	-	7463	647
R1	stream	0.00142[b]	**54.9**	21.8	**1.34**	**0.155**	-	1056	91.5
R3	stream	0.00201	**38.8**	15.4	**0.945**	**0.109**	-	746	64.7
R4	stream	0.00141	**55.3**	22.0	**1.35**	**0.156**	-	1064	92.2
Winter wheat EU-N/S [2 x 7.5 g as/ha] BBCH 30-79 Application interval 14 days									
FOCUS Step 1									
		0.23	**0.339**	**0.135**	**0.008**	**0.001**	21.7	**6.5**	**0.565**
FOCUS Step 2									
N EU		0.069	**1.13**	**0.449**	**0.028**	**0.003**	-	**21.7**	**1.88**
S EU		0.069	**1.13**	**0.449**	**0.028**	**0.003**	-	**21.7**	**1.88**
FOCUS Step 3									
D1	ditch	0.0467[b]	**1.67**	**0.664**	**0.041**	**0.005**	-	**32.1**	**2.78**
D1	stream	0.0409[b]	**1.91**	**0.758**	**0.046**	**0.005**	-	**36.7**	**3.18**
D2	ditch	0.0468[b]	**1.67**	**0.662**	**0.041**	**0.005**	-	**32.1**	**2.78**
D2	stream	0.0416[b]	**1.88**	**0.745**	**0.046**	**0.005**	-	**36.1**	**3.12**
D3	ditch	0.0462[b]	**1.69**	**0.671**	**0.041**	**0.005**	-	**32.5**	**2.81**
D4	pond	0.0020	**39.0**	**15.5**	**0.950**	**0.110**	-	750	65.0

Maximum PECsw values (FOCUS step 1-4) and TER values for lambda-cyhalothrin – application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'									
Scenario		PEC global max (µg/L)[b]	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller acute	Sed- dweller prolonged
			L. idus LC_{50} 0.078 µg/L	*P. promelas* NOEC 0.031 µg/L	*H. azteca* LC_{50} 0.0019 µg/L	*M. bahia* NOEC 0.00022 µg/L	*P. subcapitata* EC_{50} 5 µg/L	*C. riparius* EC_{50} 1.5 µg/L	*C. riparius* NOEC 0.13 µg/L
D4	stream	0.0393[b]	**1.99**	**0.789**	**0.048**	**0.006**	-	**38.2**	**3.31**
D5	pond	0.0020	**39.0**	**15.5**	**0.950**	**0.110**	-	750	65.0
D5	stream	0.0372[b]	**2.10**	**0.833**	**0.051**	**0.006**	-	**40.3**	**3.50**
D6	ditch	0.0464[b]	**1.68**	**0.668**	**0.041**	**0.005**	-	**32.3**	**2.80**
R1	pond	0.0020	**39.0**	**15.5**	**0.950**	**0.110**	-	750	65.0
R1	stream	0.0304[b]	**2.57**	**1.02**	**0.063**	**0.007**	-	**49.3**	**4.28**
R3	stream	0.0427[b]	**1.83**	**0.726**	**0.044**	**0.005**	-	**35.1**	**3.04**
R4	stream	0.0305[b]	**2.56**	**1.02**	**0.062**	**0.007**	-	**49.2**	**4.26**
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips									
D1	ditch	0.00226[b]	**34.5**	13.7	**0.841**	**0.097**	-	664	57.5
D1	stream	0.0019[b]	**41.1**	16.3	**1.00**	**0.116**	-	789	68.4
D2	ditch	0.00227[b]	**34.4**	13.7	**0.837**	**0.097**	-	661	57.3
D2	stream	0.00194[b]	**40.2**	16.0	**0.979**	**0.113**	-	773	67.0
D3	ditch	0.00224[b]	**34.8**	13.8	**0.848**	**0.098**	-	670	58.0
D4	pond	0.000146	**534**	212	**13.0**	**1.51**	-	10274	890
D4	stream	0.00186	**41.9**	16.7	**1.02**	**0.118**	-	806	69.9
D5	pond	0.000148	527	209	**12.8**	**1.49**	-	10135	878
D5	stream	0.00189	**41.3**	16.4	**1.01**	**0.116**	-	794	68.8
D6	ditch	0.00225[b]	**34.7**	13.8	**0.844**	**0.098**	-	667	57.8
R1	pond	0.000157	**497**	198	**12.1**	**1.40**	-	9554	828
R1	stream	0.00142[b]	**54.9**	21.8	**1.34**	**0.155**	-	1056	91.5
R3	stream	0.002	**39.0**	15.5	**0.950**	**0.110**	-	750	65.0
R4	stream	0.00146	**53.4**	21.2	**1.30**	**0.151**	-	1027	89.0
Spring wheat EU-N/S [2 x 7.5 g as/ha] BBCH 30-79 Application interval 14 days									
FOCUS Step 1									

Maximum PECsw values (FOCUS step 1-4) and TER values for lambda-cyhalothrin – application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'									
Scenario		PEC global max (µg/L)[b]	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller acute	Sed- dweller prolonged
			L. idus LC50 0.078 µg/L	*P. promelas* NOEC 0.031 µg/L	*H. azteca* LC50 0.0019 µg/L	*M. bahia* NOEC 0.00022 µg/L	*P. subcapitata* EC50 5 µg/L	*C. riparius* EC50 1.5 µg/L	*C. riparius* NOEC 0.13 µg/L
		0.23	**0.339**	**0.135**	**0.008**	**0.001**	21.739	**6.52**	**0.565**
FOCUS Step 2									
N EU		0.069	**1.13**	**0.449**	**0.028**	**0.003**	-	**21.7**	**1.88**
S EU		0.069	**1.13**	**0.449**	**0.028**	**0.003**	-	**21.7**	**1.88**
FOCUS Step 3									
D1	ditch	0.0464[b]	**1.68**	**0.668**	**0.0409**	**0.0047**	-	**32.3**	**2.80**
D1	stream	0.0365[b]	**2.14**	**0.849**	**0.0521**	**0.0060**	-	**41.1**	**3.56**
D3	ditch	0.0462[b]	**1.69**	**0.671**	**0.0411**	**0.0048**	-	**32.5**	**2.81**
D4	pond	0.00192	**40.6**	**16.1**	**0.9896**	**0.115**	-	781	67.7
D4	stream	0.0382[b]	**2.04**	**0.812**	**0.0497**	**0.0058**	-	**39.3**	**3.40**
D5	pond	0.00182	**42.9**	**17.0**	**1.04**	**0.121**	-	824	71.4
D5	stream	0.0388[b]	**2.01**	**0.799**	**0.0490**	**0.0057**	-	**38.7**	**3.35**
R4	stream	0.0305[b]	**2.56**	**1.02**	**0.0623**	**0.0072**	-	**49.2**	**4.26**
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips									
D1	ditch	0.00225[b]	**34.7**	13.8	**0.844**	**0.098**	-	667	57.8
D1	stream	0.0019	**41.1**	16.3	**1.00**	**0.116**	-	789	68.4
D3	ditch	0.00223[b]	**35.0**	13.9	**0.852**	**0.099**	-	673	58.3
D4	pond	0.000143	**545**	217	**13.3**	**1.54**	-	10490	909
D4	stream	0.00183	**42.6**	16.9	**1.04**	**0.120**	-	820	71.0
D5	pond	0.000135	**578**	230	**14.1**	**1.63**	-	11111	963
D5	stream	0.00188	**41.5**	16.5	**1.01**	**0.117**	-	798	69.1
R4	stream	0.00152	**51.3**	20.4	**1.25**	**0.145**	-	987	85.5
Seed potato EU-N [2 x 7.5 + 2 x 7.5 g as/ha] BBCH 15-39; BBCH 40 - 85; Application interval 7 days									
FOCUS Step 1									
		-	-	-	-	-	-	-	-

Maximum PECsw values (FOCUS step 1-4) and TER values for lambda-cyhalothrin – application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'									
Scenario		PEC global max (µg/L)[b]	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller acute	Sed- dweller prolonged
			L. idus LC$_{50}$ 0.078 µg/L	*P. promelas* NOEC 0.031 µg/L	*H. azteca* LC$_{50}$ 0.0019 µg/L	*M. bahia* NOEC 0.00022 µg/L	*P. subcapitata* EC$_{50}$ 5 µg/L	*C. riparius* EC$_{50}$ 1.5 µg/L	*C. riparius* NOEC 0.13 µg/L
FOCUS Step 2									
N EU		0.069	**1.13**	**0.449**	**0.028**	**0.003**	72.5	**21.7**	**1.88**
FOCUS Step 3									
D3	ditch	0.0382[b]	**2.04**	**0.812**	**0.050**	**0.006**	-	**39.3**	**3.40**
D4	pond	0.00244[c]	**31.97**	12.70	**0.78**	**0.09**	-	614	53.3
D4	stream	0.0303[b]	**2.57**	**1.02**	**0.063**	**0.007**	-	**49.5**	**4.29**
D6	ditch(1[st])	0.0375[b]	**2.08**	**0.827**	**0.051**	**0.006**	-	**40.0**	**3.47**
D6	ditch(2[nd])	0.0374[b]	**2.09**	**0.829**	**0.051**	**0.006**	-	**40.1**	**3.48**
R1	pond	0.0027[c]	**28.89**	11.48	**0.70**	**0.08**	-	556	48.15
R1	stream	0.026[b]	**3.00**	**1.19**	**0.073**	**0.008**	-	**57.7**	**5.00**
R2	stream	0.035[b]	**2.23**	**0.886**	**0.054**	**0.006**	-	**42.9**	**3.71**
R3	stream	0.0373[b]	**2.09**	**0.831**	**0.051**	**0.006**	-	**40.2**	**3.49**
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips									
D3	ditch	0.00192[b]	**40.6**	16.1	**0.990**	**0.115**	-	781	67.7
D4	pond	0.000232[c]	336	134	**8.19**	**0.95**	-	6466	560
D4	stream	0.00163[b]	**47.9**	19.0	**1.17**	**0.135**	-	920	79.8
D6	ditch(1[st])	0.00192	**40.6**	16.2	**0.99**	**0.11**	-	781	67.7
D6	ditch(2[nd])	0.00192	**40.6**	16.2	**0.99**	**0.11**	-	781	67.7
R1	pond	0.000848[c]	**92.0**	36.6	**2.24**	**0.26**	-	1769	153.3
R1	stream	0.00285[c]	**27.4**	10.9	**0.67**	**0.08**	1754	526	45.6
R2	stream	0.00191	**40.8**	16.2	**0.99**	**0.12**	2618	785	68.1
R3	stream	0.00225[c]	**34.7**	13.8	**0.84**	**0.10**	2222	667	57.8
Seed potato EU-S [20 g as/ha] BBCH 15-39									
FOCUS Step 1									
		-	-	-	-	-	-	-	-

Maximum PECsw values (FOCUS step 1-4) and TER values for lambda-cyhalothrin – application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'									
Scenario		PEC global max (µg/L)[b]	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller acute	Sed- dweller prolonged
			L. idus	*P. promelas*	*H. azteca*	*M. bahia*	*P. subcapitata*	*C. riparius*	*C. riparius*
			LC_{50}	NOEC	LC_{50}	NOEC	EC_{50}	EC_{50}	NOEC
			0.078 µg/L	0.031 µg/L	0.0019 µg/L	0.00022 µg/L	5 µg/L	1.5 µg/L	0.13 µg/L
FOCUS Step 2									
S EU		-	-	-	-	-	-	-	-
FOCUS Step 3									
D3	ditch	0.1020	**0.765**	**0.304**	**0.019**	**0.002**	49.0	**14.7**	**1.28**
D4	pond	0.0041	**19.0**	**7.56**	**0.463**	**0.054**	1220	366	31.7
D4	stream	0.0808	**0.965**	**0.384**	**0.024**	**0.003**	61.9	**18.6**	**1.61**
D6	ditch(1st)	0.1000	**0.780**	**0.310**	**0.019**	**0.002**	50.0	**15.0**	**1.30**
D6	ditch(2nd)	0.0998	**0.782**	**0.311**	**0.019**	**0.002**	50.1	**15.0**	**1.30**
R1	pond	0.0042	**18.6**	**7.38**	**0.452**	**0.052**	1190	357	31.0
R1	stream	0.0693	**1.13**	**0.447**	**0.027**	**0.003**	72.3	**21.6**	**1.88**
R2	stream	0.0933	**0.836**	**0.332**	**0.020**	**0.002**	53.6	**16.1**	**1.39**
R3	stream	0.0995	**0.784**	**0.312**	**0.019**	**0.002**	50.3	**15.1**	**1.31**
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips									
D3	ditch	0.00511	**15.3**	**6.07**	**0.372**	**0.043**	978	294	25.4
D4	pond	0.000194	402	160	**9.79**	**1.13**	25773	7732	670
D4	stream	0.00407	**19.2**	**7.62**	**0.467**	**0.054**	1229	369	31.9
D6	ditch(1st)	0.00502	**15.5**	**6.18**	**0.378**	**0.044**	996	299	25.9
D6	ditch(2nd)	0.00501	**15.6**	**6.19**	**0.379**	**0.044**	998	299	25.9
R1	pond	0.000532	**147**	58.3	**3.57**	**0.414**	9398	2820	244
R1	stream	0.00349	**22.4**	**8.88**	**0.544**	**0.063**	1433	430	37.2
R2	stream	0.0047	**16.6**	**6.60**	**0.404**	**0.047**	1064	319	27.7
R3	stream	0.00501	**15.6**	**6.19**	**0.379**	**0.044**	998	299	25.9
Seed potato EU-S [20 + 20 g as/ha] BBCH 15-39; BBCH 40-75. Single application BBCH 40-75									
FOCUS Step 1									
		0.63	**0.124**	**0.049**	**0.003**	**0.000**	7.937	**2.38**	**0.206**

Maximum PECsw values (FOCUS step 1-4) and TER values for lambda-cyhalothrin – application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'									
Scenario		PEC global max (µg/L)[b]	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller acute	Sed- dweller prolonged
			L. idus LC_{50} 0.078 µg/L	*P. promelas* NOEC 0.031 µg/L	*H. azteca* LC_{50} 0.0019 µg/L	*M. bahia* NOEC 0.00022 µg/L	*P. subcapitata* EC_{50} 5 µg/L	*C. riparius* EC_{50} 1.5 µg/L	*C. riparius* NOEC 0.13 µg/L
FOCUS Step 2									
S EU		0.18	**0.433**	**0.172**	**0.011**	**0.001**	27.778	**8.33**	**0.722**
FOCUS Step 3									
D3	ditch	0.102[b]	**0.765**	**0.304**	**0.019**	**0.002**	49.0	**14.7**	**1.28**
D4	pond	0.00507[c]	**15.38**	**6.11**	**0.37**	**0.04**	986	296	25.6
D4	stream	0.0807b	**0.967**	**0.384**	**0.024**	**0.003**	62.0	**18.6**	**1.61**
D6	ditch(1st)	0.102b	**0.765**	**0.304**	**0.019**	**0.002**	49.0	**14.7**	**1.28**
D6	ditch(2nd)	0.102b	**0.765**	**0.304**	**0.019**	**0.002**	49.0	**14.7**	**1.28**
R1	pond	0.0138[c]	**5.65**	**2.25**	**0.14**	**0.02**	362	109	**9.42**
R1	stream	0.0707b	**1.10**	**0.438**	**0.027**	**0.003**	70.7	**21.2**	**1.84**
R2	stream	0.0948b	**0.823**	**0.327**	**0.020**	**0.002**	52.7	**15.8**	**1.37**
R3	stream	0.0997b	**0.782**	**0.311**	**0.019**	**0.002**	50.2	**15.0**	**1.30**
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips									
D3	ditch	0.00511[b]	**15.3**	**6.07**	**0.372**	**0.043**	978	294	25.4
D4	pond	0.000292[c]	267	106	6.51	0.75	17123	5137	445
D4	stream	0.00407[b]	**19.2**	**7.64**	**0.468**	**0.054**	1232	369	32.0
D6	ditch(1st)	0.00511[b]	**15.3**	**6.07**	**0.372**	**0.043**	978	294	25.4
D6	ditch(2nd)	0.00512[b]	**15.2**	**6.06**	**0.371**	**0.043**	977	293	25.4
R1	pond	0.00146[c]	**53.4**	21.23	**1.30**	**0.15**	3425	1027	89
R1	stream	0.00424	**18.4**	**7.31**	**0.448**	**0.052**	1179	354	30.7
R2	stream	0.00477[b]	**16.4**	**6.50**	**0.398**	**0.046**	1048	314	27.3
R3	stream	0.00502[b]	**15.5**	**6.18**	**0.378**	**0.044**	996	299	25.9
Potato EU-N [2 x 7.5 g as/ha] BBCH 40-85 Application interval 7 days									
FOCUS Step 1									
		0.23	**0.339**	**0.135**	**0.008**	**0.001**	21.739	**6.52**	**0.565**

Maximum PECsw values (FOCUS step 1-4) and TER values for lambda-cyhalothrin – application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'									
Scenario		PEC global max (µg/L)[b]	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller acute	Sed- dweller prolonged
			L. idus LC_{50} 0.078 µg/L	*P. promelas* NOEC 0.031 µg/L	*H. azteca* LC_{50} 0.0019 µg/L	*M. bahia* NOEC 0.00022 µg/L	*P. subcapitata* EC_{50} 5 µg/L	*C. riparius* EC_{50} 1.5 µg/L	*C. riparius* NOEC 0.13 µg/L
FOCUS Step 2									
N EU		0.069	**1.13**	**0.449**	**0.028**	**0.003**	-	**21.7**	**1.88**
FOCUS Step 3									
D3	ditch	0.0382	**2.04**	**0.812**	**0.050**	**0.006**	-	**39.3**	**3.40**
D4	pond	0.0019	**41.1**	16.3	**1.00**	**0.116**	-	789	68.4
D4	stream	0.0303	**2.57**	**1.02**	**0.063**	**0.007**	-	**49.5**	**4.29**
D6	ditch(1st)	0.0382	**2.04**	**0.812**	**0.050**	**0.006**	-	**39.3**	**3.40**
D6	ditch(2nd)	0.0382	**2.04**	**0.812**	**0.050**	**0.006**	-	**39.3**	**3.40**
R1	pond	0.00516	**15.1**	**6.01**	**0.368**	**0.043**	-	291	25.2
R1	stream	0.0265	**2.94**	**1.17**	**0.072**	**0.008**	-	**56.6**	**4.91**
R2	stream	0.0355	**2.20**	**0.873**	**0.054**	**0.006**	-	**42.3**	**3.66**
R3	stream	0.0374	**2.09**	**0.829**	**0.051**	**0.006**	-	**40.1**	**3.48**
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips									
D3	ditch	0.00192	**40.6**	16.2	**0.990**	**0.115**	-	781	67.7
D4	pond	0.000146	**534**	212	**13.0**	**1.51**	-	10274	890
D4	stream	0.00163	**47.9**	19.0	**1.17**	**0.135**	-	920	79.8
D6	ditch(1st)	0.00192	**40.6**	16.1	**0.990**	**0.115**	-	781	67.7
D6	ditch(2nd)	0.00192	**40.6**	16.1	**0.990**	**0.115**	-	781	67.7
R1	pond	0.000547	143	56.7	**3.47**	**0.402**	-	2742	238
R1	stream	0.00154	**50.6**	20.1	**1.23**	**0.14**	-	974	84.4
R2	stream	0.00191	**40.8**	16.2	**0.995**	**0.115**	-	785	68.1
R3	stream	0.00201	**38.8**	15.4	**0.945**	**0.109**	-	746	64.7
Potato EU-S [2 x 20 g as/ha] BBCH 40-85 Application interval 8 days(min)									
FOCUS Step 1									
		0.63	**0.124**	**0.049**	**0.003**	**0.000**	7.937	**2.38**	**0.206**

Maximum PECsw values (FOCUS step 1-4) and TER values for lambda-cyhalothrin – application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'									
Scenario		PEC global max (µg/L)[b]	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller acute	Sed- dweller prolonged
			L. idus LC$_{50}$ 0.078 µg/L	*P. promelas* NOEC 0.031 µg/L	*H. azteca* LC$_{50}$ 0.0019 µg/L	*M. bahia* NOEC 0.00022 µg/L	*P. subcapitata* EC$_{50}$ 5 µg/L	*C. riparius* EC$_{50}$ 1.5 µg/L	*C. riparius* NOEC 0.13 µg/L
FOCUS Step 2									
S EU		0.18	**0.433**	**0.172**	**0.011**	**0.001**	27.778	**8.33**	**0.722**
FOCUS Step 3									
D3	ditch	0.0887	**0.879**	**0.349**	**0.021**	**0.002**	-	**16.9**	**1.47**
D4	pond	0.00507	**15.4**	**6.11**	**0.375**	**0.043**	-	296	25.6
D4	stream	0.0758	**1.03**	**0.409**	**0.025**	**0.003**	-	**19.8**	**1.72**
D6	ditch(1st)	0.0887	**0.879**	**0.349**	**0.021**	**0.002**	-	**16.9**	**1.47**
D6	ditch(2nd)	0.0908	**0.859**	**0.341**	**0.021**	**0.002**	-	**16.5**	**1.43**
R1	pond	0.0138	**5.65**	**2.25**	**0.138**	**0.016**	-	109	**9.42**
R1	stream	0.0609	**1.28**	**0.509**	**0.031**	**0.004**	-	**24.6**	**2.14**
R2	stream	0.0816	**0.956**	**0.380**	**0.023**	**0.003**	-	**18.4**	**1.59**
R3	stream	0.0858	**0.909**	**0.361**	**0.022**	**0.003**	-	**17.5**	**1.53**
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips									
D3	ditch	0.00511	**15.3**	**6.1**	**0.37**	**0.04**	-	294	25.4
D4	pond	0.000292	267	106	**6.51**	**0.753**	-	5137	445
D4	stream	0.00407	**19.2**	**7.6**	**0.47**	**0.05**	-	369	31.9
D6	ditch(1st)	0.00511	**15.3**	**6.1**	**0.37**	**0.04**	-	294	25.4
D6	ditch(2nd)	0.00512	**15.2**	**6.1**	**0.37**	**0.04**	-	293	25.4
R1	pond	0.00146	**53.4**	21.2	**1.30**	**0.151**	-	1027	89.0
R1	stream	0.00424	**18.4**	**7.3**	**0.45**	**0.05**	-	354	30.7
R2	stream	0.00477	**16.4**	**6.5**	**0.40**	**0.05**	-	315	27.3
R3	stream	0.00502	**15.5**	**6.2**	**0.38**	**0.04**	-	299	25.9
Peach EU-S [2x22.5 g as/ha] BBCH 53-69; BBCH ≥81 Application interval 30 days(min)[a]									
FOCUS Step 1									
		2.65	**0.029**	**0.012**	**0.001**	**0.000**	**1.89**	**0.566**	**0.049**

Maximum PECsw values (FOCUS step 1-4) and TER values for lambda-cyhalothrin – application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'								
Scenario	PEC global max (µg/L)[b]	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller acute	Sed- dweller prolonged
		L. idus LC$_{50}$ 0.078 µg/L	*P. promelas* NOEC 0.031 µg/L	*H. azteca* LC$_{50}$ 0.0019 µg/L	*M. bahia* NOEC 0.00022 µg/L	*P. subcapitata* EC$_{50}$ 5 µg/L	*C. riparius* EC$_{50}$ 1.5 µg/L	*C. riparius* NOEC 0.13 µg/L
S EU	1.2	**0.065**	**0.026**	**0.002**	**0.000**	**4.17**	**1.250**	**0.108**
FOCUS Step 3 not available								
Reg (EU) 546/2011 Trigger		100	10	100	10	10	100	10

[a] Application to peach is applicable only for Lambda-Cyhalothrin 100 CS
[b] FOCUS step 3-4 PEC$_{SW}$ are based on multiple applications only
[c] PEC value for multiple applications (worst case)

Maximum PECsw values (FOCUS step 3-4) and TER values for lambda-cyhalothrin – using refined acute RAC for fish				
	Single application		**Multiple applications**	
Scenario	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**
Winter wheat EU-N/S [2x7.5 g as/ha] BBCH 10-29 Application interval 14 days				
Step 3				
D1 ditch	0.0467	**0.045**	0.0487	**0.043**
D1 stream	0.0409	**0.051**	0.0354	**0.059**
D2 ditch	0.0467	**0.045**	0.0408	**0.051**
D2 stream	0.0402	**0.052**	0.0347	**0.061**
D3 ditch	0.0459	**0.046**	0.0402	**0.052**
D4 pond	0.00159	1.32	0.00182	1.15
D4 stream	0.0399	**0.053**	0.0345	**0.061**
D5 pond	0.00159	1.32	0.00192	1.09
D5 stream	0.0431	**0.049**	0.0373	**0.056**
D6 ditch	0.0465	**0.045**	0.0406	**0.052**
R1 pond	0.00162	1.30	0.00217	**0.968**

Maximum PECsw values (FOCUS step 3-4) and TER values for lambda-cyhalothrin – using refined acute RAC for fish				
	Single application		**Multiple applications**	
Scenario	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**
R1 stream	0.0304	**0.069**	0.0263	**0.080**
R3 stream	0.0421	**0.050**	0.0371	**0.057**
R4 stream	0.0301	**0.070**	0.0261	**0.080**
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips				
D1 ditch	0.00226	**0.929**	0.00231	**0.909**
D1 stream	0.0019	1.11	0.00191	1.10
D2 ditch	0.00226	**0.929**	0.00194	1.08
D2 stream	0.00187	1.12	0.00187	1.12
D3 ditch	0.00222	**0.946**	0.00191	1.10
D4 pond	0.000097	21.6	0.000135	15.6
D4 stream	0.00186	1.13	0.00186	1.13
D5 pond	0.000097	21.6	0.000143	14.7
D5 stream	0.00201	1.04	0.00201	1.04
D6 ditch	0.00225	**0.933**	0.00193	1.09
R1 pond	0.0001	21	0.000201	10.4
R1 stream	0.00142	1.48	0.00142	1.48
R3 stream	0.00197	1.07	0.00201	1.04
R4 stream	0.0014	1.50	0.00141	1.49
Winter wheat EU-N/S [2x7.5 g as/ha] BBCH 30-79 Application interval 14 days				
Step 3				
D1 ditch	0.0467	**0.045**	0.0454	**0.046**
D1 stream	0.0409	**0.051**	0.0353	**0.059**
D2 ditch	0.0468	**0.045**	0.0415	**0.051**
D2 stream	0.0416	**0.050**	0.036	**0.058**
D3 ditch	0.0462	**0.045**	0.0405	**0.052**
D4 pond	0.00159	1.32	0.002	1.05
D4 stream	0.0393	**0.053**	0.0345	**0.061**

Maximum PECsw values (FOCUS step 3-4) and TER values for lambda-cyhalothrin – using refined acute RAC for fish				
	Single application		**Multiple applications**	
Scenario	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**
D5 pond	0.00159	1.32	0.002	1.05
D5 stream	0.0372	**0.056**	0.035	**0.060**
D6 ditch	0.0464	**0.045**	0.0408	**0.051**
R1 pond	0.00161	1.30	0.002	1.05
R1 stream	0.0304	**0.069**	0.0263	**0.080**
R3 stream	0.0427	**0.049**	0.0372	**0.056**
R4 stream	0.0305	**0.069**	0.0264	**0.080**
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips				
D1 ditch	0.00226	**0.929**	0.00216	**0.972**
D1 stream	0.0019	1.11	0.00191	1.10
D2 ditch	0.00227	**0.925**	0.00197	1.07
D2 stream	0.00194	1.08	0.00194	1.08
D3 ditch	0.00224	**0.938**	0.00192	1.09
D4 pond	0.000097	21.6	0.000146	14.4
D4 stream	0.00183	1.15	0.00186	1.13
D5 pond	0.000097	**21.6**	0.000148	14.2
D5 stream	0.00173	1.21	0.00189	1.11
D6 ditch	0.00225	**0.933**	0.00194	1.08
R1 pond	0.000099	21.2	0.000157	13.4
R1 stream	0.00142	1.48	0.00142	1.48
R3 stream	0.00199	1.06	0.002	1.05
R4 stream	0.00142	1.48	0.00146	1.44
Spring wheat EU-N/S [2x7.5 g as/ha] BBCH 30-79 Application interval 14 days				
Step 3				
D1 ditch	0.0464	**0.045**	0.0412	**0.051**
D1 stream	0.0365	**0.058**	0.0353	**0.059**
D3 ditch	0.0462	**0.045**	0.0404	**0.052**

Maximum PECsw values (FOCUS step 3-4) and TER values for lambda-cyhalothrin – using refined acute RAC for fish				
	Single application		Multiple applications	
Scenario	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**
D4 pond	0.00159	1.32	0.00192	1.09
D4 stream	0.0382	**0.055**	0.034	**0.062**
D5 pond	0.00159	1.32	0.00182	1.15
D5 stream	0.0388	**0.054**	0.0348	**0.060**
R4 stream	0.0305	**0.069**	0.0264	**0.080**
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips				
D1 ditch	0.00225	**0.933**	0.00196	1.07
D1 stream	0.0017	1.24	0.0019	1.11
D3 ditch	0.00223	**0.942**	0.00192	1.09
D4 pond	0.000097	21.6	0.000143	14.7
D4 stream	0.00178	1.18	0.00183	1.15
D5 pond	0.000097	21.6	0.000135	15.6
D5 stream	0.00181	1.16	0.00188	1.12
R4 stream	0.00142	1.48	0.00152	1.38
Seed potato EU-N [2x7.5 g as/ha] BBCH 15-39; Application interval 7 days				
Step 3				
D3 ditch	0.0382	**0.055**	0.0332	**0.063**
D4 pond	0.00154	1.36	0.00175	1.20
D4 stream	0.0303	**0.069**	0.0261	**0.080**
D6 ditch (1st)	0.0375	**0.056**	0.0326	**0.064**
D6 ditch (2nd)	0.0374	**0.056**	0.0326	**0.064**
R1 pond	0.00193	1.09	0.00185	1.14
R1 stream	0.026	**0.081**	0.0228	**0.092**
R2 stream	0.035	**0.060**	0.0301	**0.070**
R3 stream	0.0373	**0.056**	0.0323	**0.065**
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips				
D3 ditch	0.00192	1.09	0.0016	1.31

Maximum PECsw values (FOCUS step 3-4) and TER values for lambda-cyhalothrin – using refined acute RAC for fish				
	Single application		**Multiple applications**	
Scenario	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**
D4 pond	0.000097	21.6	0.000134	15.7
D4 stream	0.00163	1.29	0.00136	1.54
D6 ditch (1st)	0.00188	1.12	0.00157	1.34
D6 ditch (2nd)	0.00188	1.12	0.00157	1.34
R1 pond	0.000203	10.3	0.000406	5.17
R1 stream	0.0014	1.50	0.00154	1.36
R2 stream	0.00188	1.12	0.00157	1.34
R3 stream	0.002	1.05	0.00169	1.24
Seed potato EU-N [2x7.5 + 2x7.5 g as/ha] BBCH 15-39; BBCH 40-75 Application interval 7 days				
Step 3				
D3 ditch	-	-	0.0257	**0.082**
D4 pond	-	-	0.00244	**0.861**
D4 stream	-	-	0.0212	**0.099**
D6 ditch (1st)	-	-	0.0257	**0.082**
D6 ditch (2nd)	-	-	0.0257	**0.082**
R1 pond	-	-	0.0027	**0.778**
R1 stream	-	-	0.0178	**0.118**
R2 stream	-	-	0.0238	**0.088**
R3 stream	-	-	0.0252	**0.083**
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips				
D3 ditch	-	-	0.00128	1.64
D4 pond	-	-	0.000232	9.05
D4 stream	-	-	0.00113	1.86
D6 ditch (1st)	-	-	0.00128	1.64
D6 ditch (2nd)	-	-	0.00128	1.64
R1 pond	-	-	0.000848	2.48
R1 stream	-	-	0.00285	**0.737**

Maximum PECsw values (FOCUS step 3-4) and TER values for lambda-cyhalothrin – using refined acute RAC for fish				
	Single application		Multiple applications	
Scenario	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**
R2 stream	-	-	0.00127	1.65
R3 stream	-	-	0.00225	**0.933**
Seed potato EU-S [20 g as/ha] BBCH 15-39				
Step 3				
D3 ditch	0.102	**0.021**	-	-
D4 pond	0.0041	**0.512**	-	-
D4 stream	0.0808	**0.026**	-	-
D6 ditch (1st)	0.1	**0.021**	-	-
D6 ditch (2nd)	0.0998	**0.021**	-	-
R1 pond	0.0042	**0.500**	-	-
R1 stream	0.0693	**0.030**	-	-
R2 stream	0.0933	**0.023**	-	-
R3 stream	0.0995	**0.021**	-	-
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips				
D3 ditch	0.00511	**0.411**	-	-
D4 pond	0.000194	10.8	-	-
D4 stream	0.00407	**0.516**	-	-
D6 ditch (1st)	0.00502	**0.418**	-	-
D6 ditch (2nd)	0.00501	**0.419**	-	-
R1 pond	0.000532	3.95	-	-
R1 stream	0.00349	**0.602**	-	-
R2 stream	0.0047	**0.447**	-	-
R3 stream	0.00501	**0.419**	-	-
Seed potato EU-S [20 + 20 g as/ha] BBCH 15-39; BBCH 40-75. Single application BBCH 40-75.				
Step 3				
D3 ditch	0.102	**0.021**	0.0883	**0.024**
D4 pond	0.00411	**0.511**	0.00426	**0.493**

Maximum PECsw values (FOCUS step 3-4) and TER values for lambda-cyhalothrin – using refined acute RAC for fish				
	Single application		Multiple applications	
Scenario	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**
D4 stream	0.0807	**0.026**	0.0695	**0.030**
D6 ditch (1st)	0.102	**0.021**	0.0883	**0.024**
D6 ditch (2nd)	0.102	**0.021**	0.0882	**0.024**
R1 pond	0.00687	**0.306**	0.0106	**0.198**
R1 stream	0.0707	**0.030**	0.0608	**0.035**
R2 stream	0.0948	**0.022**	0.0803	**0.026**
R3 stream	0.0997	**0.021**	0.0858	**0.024**
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips				
D3 ditch	0.00511	**0.411**	0.00447	**0.470**
D4 pond	0.000194	10.8	0.000246	8.54
D4 stream	0.00406	**0.517**	0.00352	**0.597**
D6 ditch (1st)	0.00511	**0.411**	0.00447	**0.470**
D6 ditch (2nd)	0.00512	**0.410**	0.00447	**0.470**
R1 pond	0.000726	2.89	0.00112	1.88
R1 stream	0.00356	**0.590**	0.00424	**0.495**
R2 stream	0.00477	**0.440**	0.00407	**0.516**
R3 stream	0.00502	**0.418**	0.00436	**0.482**
Potato EU-N [2x7.5 g as/ha] BBCH 40-85 Application interval 7 days				
Step 3				
D3 ditch	0.0382	**0.055**	0.0333	**0.063**
D4 pond	0.00154	1.36	0.0019	1.11
D4 stream	0.0303	**0.069**	0.0284	**0.074**
D6 ditch (1st)	0.0382	**0.055**	0.0332	**0.063**
D6 ditch (2nd)	0.0382	**0.055**	0.034	**0.062**
R1 pond	0.00258	**0.814**	0.00516	**0.407**
R1 stream	0.0265	**0.079**	0.0228	**0.092**
R2 stream	0.0355	**0.059**	0.0306	**0.069**

Maximum PECsw values (FOCUS step 3-4) and TER values for lambda-cyhalothrin – using refined acute RAC for fish						
	Single application			**Multiple applications**		
Scenario	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**		**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**	
R3 stream	0.0374	**0.056**		0.0322	**0.065**	
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips						
D3 ditch	0.00192	1.09		0.0016	1.31	
D4 pond	0.000097	21.6		0.000146	14.4	
D4 stream	0.00163	1.29		0.00148	1.42	
D6 ditch (1st)	0.00192	1.09		0.0016	1.31	
D6 ditch (2nd)	0.00192	1.09		0.00164	1.28	
R1 pond	0.000272	7.72		0.000547	3.84	
R1 stream	0.00143	1.47		0.00133	1.58	
R2 stream	0.00191	1.10		0.00159	1.32	
R3 stream	0.00201	1.04		0.00167	1.26	
Potato EU-S [2x20 g as/ha] BBCH 40-85 Application interval 8 days(min)						
Step 3						
D3 ditch	0.102	**0.021**	-	0.0887	**0.024**	-
D4 pond	0.00411	**0.511**	-	0.00507	**0.414**	-
D4 stream	0.0807	**0.026**	-	0.0758	**0.028**	-
D6 ditch (1st)	0.102	**0.021**	-	0.0887	**0.024**	-
D6 ditch (2nd)	0.102	**0.021**	-	0.0908	**0.023**	-
R1 pond	0.00687	**0.306**	-	0.0138	**0.152**	-
R1 stream	0.0707	**0.030**	-	0.0609	**0.034**	-
R2 stream	0.0948	**0.022**	-	0.0816	**0.026**	-
R3 stream	0.0997	**0.021**	-	0.0858	**0.024**	-
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips						
D3 ditch	0.00511	**0.411**	-	0.00449	**0.468**	-
D4 pond	0.000194	10.83	-	0.000292	7.19	-
D4 stream	0.00406	**0.517**	-	0.00385	**0.545**	-
D6 ditch (1st)	0.00511	**0.411**	-	0.00449	**0.468**	-

Maximum PECsw values (FOCUS step 3-4) and TER values for lambda-cyhalothrin – using refined acute RAC for fish						
	Single application			**Multiple applications**		
Scenario	**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**		**PEC global max (µg/L)**	**TER Acute RAC 0.0021 µg/L**	
D6 ditch (2nd)	0.00512	**0.410**	-	0.00459	**0.458**	-
R1 pond	0.000726	2.893	-	0.00146	1.44	-
R1 stream	0.00356	**0.590**	-	0.00355	**0.592**	-
R2 stream	0.00477	**0.440**	-	0.00414	**0.507**	-
R3 stream	0.00502	**0.418**	-	0.00435	**0.483**	-
Trigger		1			**1**	

Maximum PECsw values and TER values for aquatic invertebartes (Focus step 4) and TER values for lambda-cyhalothrin– application of 'Lambda-Cyhalothrin 100 CS'			
Scenario		PEC global max (µg/L)	refined RAC (acute and chronic)
			0.0003 µg/L
Winter wheat EU-N/S [2x7.5 g as/ha] BBCH 10-29 Application interval 14 days			
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips			
D1	ditch	0.00231	**0.130**
D1	stream	0.0019	**0.158**
D2	ditch	0.00226	**0.133**
D2	stream	0.00187	**0.160**
D3	ditch	0.00222	**0.135**
D4	pond	0.000135	2.22
D4	stream	0.00186	**0.161**
D5	pond	0.000143	2.10
D5	stream	0.00201	**0.149**
D6	ditch	0.00225	**0.133**
R1	pond	0.000201	Refined RAC not relevant
R1	stream	0.00142	Refined RAC not relevant
R3	stream	0.00201	Refined RAC not relevant

Maximum PECsw values and TER values for aquatic invertebartes (Focus step 4) and TER values for lambda-cyhalothrin– application of ‘Lambda-Cyhalothrin 100 CS’			
Scenario		PEC global max (µg/L)	refined RAC (acute and chronic)
			0.0003 µg/L
R4	stream	0.00141	Refined RAC not relevant
Winter wheat EU-N/S [2x7.5 g as/ha] BBCH 30-79 Application interval 14 days			
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips			
D1	ditch	0.00226	**0.133**
D1	stream	0.0019	**0.158**
D2	ditch	0.00227	**0.132**
D2	stream	0.00194	**0.155**
D3	ditch	0.00224	**0.134**
D4	pond	0.000146	2.10
D4	stream	0.00186	**0.161**
D5	pond	0.000148	2.03
D5	stream	0.00189	**0.159**
D6	ditch	0.00225	**0.133**
R1	pond	0.000157	Refined RAC not relevant
R1	stream	0.00142	Refined RAC not relevant
R3	stream	0.002	Refined RAC not relevant
R4	stream	0.00146	Refined RAC not relevant
Spring wheat EU-N/S [2x7.5 g as/ha] BBCH 30-79 Application interval 14 days			
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips			
D1	ditch	0.00225	**0.133**
D1	stream	0.0019	**0.158**
D3	ditch	0.00223	**0.135**
D4	pond	0.000143	2.10
D4	stream	0.00183	**0.164**
D5	pond	0.000135	2.22
D5	stream	0.00188	**0.160**
R4	stream	0.00152	Refined RAC not relevant

Maximum PECsw values and TER values for aquatic invertebartes (Focus step 4) and TER values for lambda-cyhalothrin– application of 'Lambda-Cyhalothrin 100 CS'			
Scenario		PEC global max (µg/L)	refined RAC (acute and chronic)
			0.0003 µg/L
Seed potato EU-N [2x7.5 + 2x7.5 g as/ha] BBCH 15-39; BBCH 40-75 Application interval 7 days			
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips			
D3	ditch	0.00192	**0.156**
D4	pond	0.000232	1.29
D4	stream	0.00163	**0.184**
D6	ditch(1st)	0.00192	**0.16**
D6	ditch(2nd)	0.00192	**0.16**
R3	stream	0.00225	Refined RAC not relevant
Seed potato EU-S [20 g as/ha] BBCH 15-39			
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips			
D3	ditch	0.00511	**0.0587**
D4	pond	0.000194	1.55
D4	stream	0.00407	**0.0737**
D6	ditch(1st)	0.00502	**0.0599**
D6	ditch(2nd)	0.00501	**0.0599**
R1	pond	0.000532	Refined RAC not relevant
R1	stream	0.00349	Refined RAC not relevant
R2	stream	0.0047	Refined RAC not relevant
R3	stream	0.00501	Refined RAC not relevant
Seed potato EU-S [20 + 20 g as/ha] BBCH 15-39; BBCH 40-75. Single application BBCH 40-75			
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips			
D3	ditch	0.00511	**0.0587**
D4	pond	0.000292	1.03
D4	stream	0.00406	**0.0739**
D6	ditch(1st)	0.00511	**0.0587**
D6	ditch(2nd)	0.00512	**0.0586**

Maximum PECsw values and TER values for aquatic invertebartes (Focus step 4) and TER values for lambda-cyhalothrin– application of 'Lambda-Cyhalothrin 100 CS'			
Scenario		PEC global max (µg/L)	refined RAC (acute and chronic)
			0.0003 µg/L
R1	pond	0.00146	Refined RAC not relevant
R1	stream	0.00424	Refined RAC not relevant
R2	stream	0.00477	Refined RAC not relevant
R3	stream	0.00502	Refined RAC not relevant
Potato EU-N [2x7.5 g as/ha] BBCH 40-85 Application interval 7 days			
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips			
D3	ditch	0.00192	**0.156**
D4	pond	0.000146	2.055
D4	stream	0.00163	**0.184**
D6	ditch(1st)	0.00192	**0.156**
D6	ditch(2nd)	0.00192	**0.156**
R1	pond	0.000547	Refined RAC not relevant
R1	stream	0.00154	Refined RAC not relevant
R2	stream	0.00191	Refined RAC not relevant
R3	stream	0.00201	Refined RAC not relevant
Potato EU-S [2x20 g as/ha] BBCH 40-85 Application interval 8 days(min)			
Step 4 - 95% nozzle reduction + 90% run-off mitigation by vegetated buffer strips			
D3	ditch	0.00511	**0.0587**
D4	pond	0.000292	1.03
D4	stream	0.00406	**0.0739**
D6	ditch(1st)	0.00511	**0.0587**
D6	ditch(2nd)	0.00512	**0.0586**
R1	pond	0.00146	Refined RAC not relevant
R1	stream	0.00424	Refined RAC not relevant
R2	stream	0.00477	Refined RAC not relevant
R3	stream	0.00502	Refined RAC not relevant

Maximum PECsw values and TER values for aquatic invertebartes (Focus step 4) and TER values for lambda-cyhalothrin– application of 'Lambda-Cyhalothrin 100 CS'		
Scenario	PEC global max (µg/L)	refined RAC (acute and chronic)
		0.0003 µg/L
Peach EU-S [2x22.5 g as/ha] BBCH 53-69; BBCH ≥81 Application interval 30 days(min)a		
FOCUS Step 3-4 not available		

Maximum PECsw values (Focus step 1-2) and TER values for metabolite Ia– application of 'Karate 10 CS' and 'Kaiso sorbie 5% EG'							
Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller prolonged
		O. mykiss LC_{50} 10 800 µg/L	*N/A*	*D. magna* LC_{50} 105 000 µg/L	*N/A*	*N/A*	*C. riparius* NOEC 20 800 µg/L
Spring wheat EU-N/S [2 x7.5 g as/ha] BBCH 10-85 Application interval 18 days							
FOCUS Step 1							
	0.629	17 170	-	166 932	-	-	33 068
Winter wheat EU-N/S [2x7.5 g as/ha] BBCH 10-85 Application interval 18 days							
FOCUS Step 1							
	0.629	17 170	-	166 932	-	-	33 068
Field tomato EU-N [2x12.5 g as/h] and EU-S [2x25 g as/ha]; BBCH 10-89 Application interval 12 days							
FOCUS Step 1							
N EU	1.05	10 286	-	100 000	-	-	19 810
S EU	2.09	5 167	-	50 239	-	-	9 952
Tomato EU-N/S [2x25 g as/ha]; BBCH 10-89 Application interval 12 days. Indoor applications							
FOCUS Step 1							
	0.087	124 138	-	1 206 897	-	-	239 080
FOCUS Step 2							
N/S EU	0.0018	6 000 000	-	58 333 333	-	-	11 555 556
Plum EU-N [2x10 g as/ha] EU-S [2x25 g as/ha]; BBCH <10-79 Application interval 10-14 days(min)							
FOCUS Step 1 early							
N EU	1.16	9 310	-	90 517	-	-	17 931
S EU	2.78	3 885	-	37 770	-	-	7 482
FOCUS Step 1 late							
N EU	0.977	11 054	-	107 472	-	-	21 290
S EU	2.44	4 426	-	43 033	-	-	8 525

Maximum PECsw values (Focus step 1-2) and TER values for metabolite Ia– application of 'Karate 10 CS' and 'Kaiso sorbie 5% EG'							
Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller prolonged
		O. mykiss LC_{50} 10 800 µg/L	*N/A*	*D. magna* LC_{50} 105 000 µg/L	*N/A*	*N/A*	*C. riparius* NOEC 20 800 µg/L
Reg (EU) 546/2011 Trigger		100	10	100	10	10	10

Maximum PECsw values (Focus step 1-2) and TER values for metabolite Ia– application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'							
Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller prolonged
		O. mykiss LC_{50} 10800 µg/L	*N/A*	*D. magna* LC_{50} 105 000 µg/L	*N/A*	*N/A*	*C. riparius* NOEC 20 800 µg/L
Winter wheat EU-N/S [2x7.5 g as/ha] BBCH 10-29 Application interval 14 days							
FOCUS Step 1	0.63	17 143	-	166 667	-	-	33 016
Winter wheat EU-N/S [2x7.5 g as/ha] BBCH 30-79 Application interval 14 days							
FOCUS Step 1	0.63	17 143	-	166 667	-	-	33 016
Spring wheat EU-N/S [2x7.5 g as/ha] BBCH 30-79 Application interval 14 days							
FOCUS Step 1	0.63	17 143	-	166 667	-	-	33 016
Seed potato EU-N [2x7.5 + 2x7.5 g as/ha] BBCH ≤15; BBCH 40-75 Application interval 7 days							
FOCUS Step 1	0.63	17 143	-	166 667	-	-	33 016
Seed potato EU-S [20 + 20 g as/ha] BBCH ≥15; BBCH ≥40							

Maximum PECsw values (Focus step 1-2) and TER values for metabolite Ia– application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'							
Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller prolonged
		O. mykiss LC$_{50}$ 10800 µg/L	*N/A*	*D. magna* LC$_{50}$ 105 000 µg/L	*N/A*	*N/A*	*C. riparius* NOEC 20 800 µg/L
FOCUS Step 1	1.7	6 467	-	62 874	-	-	12 455
Potato EU-N [2x7.5 g as/ha] BBCH 40-75 Application interval 7 days							
FOCUS Step 1	0.63	17 143	-	166 667	-	-	33 016
Potato EU-S [2x20 g as/ha] BBCH ≥40 Application interval 8 days(min)							
FOCUS Step 1	1.7	6 353	-	61 765	-	-	12 235
Peach EU-S [2x22.5 g as/ha] BBCH 53-69; BBCH ≥81 Application interval 30 days(min)[a]							
FOCUS Step 1	1.1	9 818	-	95 455	-	-	18 909
Reg (EU) 546/2011 Trigger		100	10	100	10	10	10

[a] Application to peach is applicable only for Lambda-Cyhalothrin 100 CS

Maximum PECsw values (Focus step 1-2) and TER values for metabolite V– application of 'Karate 10 CS' and 'Kaiso sorbie 5 % EG'							
Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller prolonged
		O. mykiss LC$_{50}$ 13 300 µg/L	*N/A*	*D. magna* LC$_{50}$ 85 000 µg/L	*N/A*	*N/A*	*N/A*
Spring wheat EU-N/S [2 x7.5 g as/ha] BBCH 10-85 Application interval 18 days							
FOCUS Step 1	0.64	20 781	-	132 813	-	-	-

Maximum PECsw values (Focus step 1-2) and TER values for metabolite V– application of 'Karate 10 CS' and 'Kaiso sorbie 5 % EG'							
Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller prolonged
		O. mykiss LC$_{50}$ 13 300 µg/L	*N/A*	*D. magna* LC$_{50}$ 85 000 µg/L	*N/A*	*N/A*	*N/A*
Winter wheat EU-N/S [2x7.5 g as/ha] BBCH 10-85 Application interval 18 days							
FOCUS Step 1							
	0.64	20 781	-	132 813	-	-	-
Field Tomato EU-N [2x12.5 g as/h] and EU-S [2x25 g as/ha]; BBCH 10-89 Application interval 12 days							
FOCUS Step 1							
N EU	1.06	12 547	-	80 189	-	-	-
S EU	2.12	6 274	-	40 094	-	-	-
Tomato EU-N/S [2x25 g as/ha]; BBCH 10-89 Application interval 12 days. Indoor applications							
FOCUS Step 1							
	-	-	-	-	-	-	-
FOCUS Step 2							
N/S EU	-	-	-	-	-	-	-
Plum EU-N [2x10 g as/ha] EU-S [2x25 g as/ha]; BBCH <10-79 Application interval 10-14 days(min)							
FOCUS Step 1 early							
N EU	1.09	12 202	-	77 982	-	-	-
S EU	2.72	4 890	-	31 250	-	-	-
FOCUS Step 1 late							
N EU	0.96	13 854	-	88 542	-	-	-
S EU	2.41	5 519	-	35 270	-	-	-
Reg (EU) 546/2011 Trigger		100	10	100	10	10	10

Maximum PECsw values (Focus step 1-2) and TER values for metabolite V– application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'							
Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller prolonged
		O. mykiss LC_{50} 13 300 µg/L	*N/A*	*D. magna* LC_{50} 85 000 µg/L	*N/A*	*N/A*	*N/A*
Winter wheat EU-N/S [2x7.5 g as/ha] BBCH 10-29 Application interval 14 days							
FOCUS Step 1	0.12	110 833	-	708 333	-	-	-
Winter wheat EU-N/S [2x7.5 g as/ha] BBCH 30-79 Application interval 14 days							
FOCUS Step 1	0.12	110 883	-	708 333	-	-	-
Spring wheat EU-N/S [2x7.5 g as/ha] BBCH 30-79 Application interval 14 days							
FOCUS Step 1	0.12	110 883	-	708 333	-	-	-
Seed potato EU-N [2x7.5 + 2x7.5 g as/ha] BBCH ≤15; BBCH 40-75 Application interval 7 days							
FOCUS Step 1	0.24	55 417	-	354 167	-	-	-
Seed potato EU-S [20 + 20 g as/ha] BBCH ≥15; BBCH ≥40							
FOCUS Step 1	0.32	41 563	-	265 625	-	-	-
Potato EU-N [2x7.5 g as/ha] BBCH 40-75 Application interval 7 days							
FOCUS Step 1	0.12	110 833	-	708 333	-	-	-
Potato EU-S [2x20 g as/ha] BBCH ≥40 Application interval 8 days(min)							
FOCUS Step 1	0.32	41 563	-	265 625	-	-	-
Peach EU-S [2x22.5 g as/ha] BBCH 53-69; BBCH ≥81 Application interval 30 days(min)[a]							
FOCUS Step 1							

Maximum PECsw values (Focus step 1-2) and TER values for metabolite V– application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'							
Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller prolonged
		O. mykiss LC_{50} 13 300 µg/L	*N/A*	*D. magna* LC_{50} 85 000 µg/L	*N/A*	*N/A*	*N/A*
	2.51	5229	-	33865	-	-	-
Reg (EU) 546/2011 Trigger		100	10	100	10	10	10

[a] Application to peach is applicable only for Lambda-Cyhalothrin 100 CS

Maximum PECsw values (Focus step 1-3) and TER[a] values for metabolite XV– application of 'Karate 10 CS' and 'Kaiso sorbie 5 % EG'									
Scenario		PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller Acute	Sed- dweller prolonged[b]
			O. mykiss LC_{50} 0.84 µg/L	*N/A*	*D. magna* LC_{50} 0.16 µg/L	*N/A*	*N/A*	*N/A*	*C. riparius* NOEC 580 µg/kg
Spring wheat EU-N/S [2 x7.5 g as/ha] BBCH 10-85 Application interval 18 days									
FOCUS Step 1		-	-	-	-	-	-	-	-
FOCUS Step 2									
N EU		0.0075	112	-	**21.3**	-	-	-	1309
S EU		0.0075	112	-	**21.3**	-	-	-	681
FOCUS Step 3									
D1	Ditch	< 0.001	-	-	> 160	-	-	-	-
D1	Stream	< 0.001	-	-	> 160	-	-	-	-
D3	Ditch	< 0.001	-	-	> 160	-	-	-	-
D4	Pond	< 0.001	-	-	> 160	-	-	-	-
D4	Stream	< 0.001	-	-	> 160	-	-	-	-
D5	Pond	< 0.001	-	-	> 160	-	-	-	-
D5	Stream	< 0.001	-	-	> 160	-	-	-	-
R4	Stream	< 0.001	-	-	> 160	-	-	-	-

Maximum PECsw values (Focus step 1-3) and TER[a] values for metabolite XV– application of 'Karate 10 CS' and 'Kaiso sorbie 5 % EG'								
Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller Acute	Sed- dweller prolonged[b]
		O. mykiss LC$_{50}$ 0.84 µg/L	*N/A*	*D. magna* LC$_{50}$ 0.16 µg/L	*N/A*	*N/A*	*N/A*	*C. riparius* NOEC 580 µg/kg
Winter wheat EU-N/S [2x7.5 g as/ha] BBCH 10-85 Application interval 18 days								
FOCUS Step 1								
	-	-	-	-	-	-	-	-
FOCUS Step 2								
N EU	0.008	105	-	**20.0**	-	-	-	547
S EU	0.0075	112	-	**21.3**	-	-	-	681
FOCUS Step 3								
D1 Ditch	< 0.001	-	-	> 160	-	-	-	-
D1 Stream	< 0.001	-	-	> 160	-	-	-	-
D2 Ditch	< 0.001	-	-	> 160	-	-	-	-
D2 Stream	< 0.001	-	-	> 160	-	-	-	-
D3 Ditch	< 0.001	-	-	> 160	-	-	-	-
D4 Pond	< 0.001	-	-	> 160	-	-	-	-
D4 Stream	< 0.001	-	-	> 160	-	-	-	-
D5 Pond	< 0.001	-	-	> 160	-	-	-	-
D5 Stream	< 0.001	-	-	> 160	-	-	-	-
D6 Ditch	< 0.001	-	-	> 160	-	-	-	-
R1 Pond	< 0.001	-	-	> 160	-	-	-	-
R1 Stream	< 0.001	-	-	> 160	-	-	-	-
R3 Stream	< 0.001	-	-	> 160	-	-	-	-
R4 Stream	< 0.001	-	-	> 160	-	-	-	-
Tomato EU-N [2x12.5 g as/h] Tomato EU-S [2x25 g as/ha]; BBCH 10-89 Application interval 12 days								
FOCUS Step 1								
	-		-		-	-	-	-
FOCUS Step 2								

Maximum PECsw values (Focus step 1-3) and TER[a] values for metabolite XV– application of ‘Karate 10 CS’ and ‘Kaiso sorbie 5 % EG’									
Scenario		PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller Acute	Sed- dweller prolonged[b]
			O. mykiss LC_{50} 0.84 µg/L	*N/A*	*D. magna* LC_{50} 0.16 µg/L	*N/A*	*N/A*	*N/A*	*C. riparius* NOEC 580 µg/kg
N EU		0.013	**64.6**	**-**	**12.3**	**-**	-	-	715
S EU		0.025	**3.36**	**-**	**6.40**	**-**	-	-	186
FOCUS Step 3									
D6	Ditch	< 0.001	> 840	-	> 160	-	-	-	-
R2	Stream	< 0.001	> 840	-	> 160	-	-	-	-
R3	Stream	< 0.001	> 840	-	> 160	-	-	-	-
R4	Stream	< 0.001	> 840	-	> 160	-	-	-	-
Tomato EU-N/S [2x25 g as/ha]; BBCH 10-89 Application interval 12 days. Indoor applications[c]									
FOCUS Step 1									
		-	-	-	-	-	-	-	-
FOCUS Step 2									
N/S EU		0.0009	933	-	178	-	-	-	96667
Plum EU-N [2x10 g as/ha] EU-S [2x25 g as/ha] ; BBCH <10-79 Application interval 10-14 days(min) late application									
FOCUS Step 1									
		-	**-**	**-**	**-**	**-**	**-**	-	**-**
FOCUS Step 2									
N EU		0.057	**14.7**	**-**	**2.81**	**-**	**-**	-	1144
S EU		0.143	**5.87**	**-**	**1.12**	**-**	**-**	-	367
FOCUS Step 3									
D3	Ditch	< 0.001	> 840	-	> 160	-	-	-	**-**
D4	Pond	< 0.001	> 840	-	> 160	-	-	-	**-**
D4	Stream	< 0.001	> 840	-	> 160	-	-	-	**-**
D5	Pond	< 0.001	> 840	-	> 160	-	-	-	**-**
D5	Stream	< 0.001	> 840	-	> 160	-	-	-	**-**
R1	Pond	< 0.001	> 840	-	> 160	-	-	-	**-**

Scenario		PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller Acute	Sed- dweller prolonged[b]
Maximum PECsw values (Focus step 1-3) and TER[a] values for metabolite XV– application of 'Karate 10 CS' and 'Kaiso sorbie 5 % EG'									
			O. mykiss LC$_{50}$ 0.84 µg/L	*N/A*	*D. magna* LC$_{50}$ 0.16 µg/L	*N/A*	*N/A*	*N/A*	*C. riparius* NOEC 580 µg/kg
R1	Stream	< 0.001	> 840	-	> 160	-	-	-	-
R2	Stream	< 0.001	> 840	-	> 160	-	-	-	-
R3	Stream	< 0.001	> 840	-	> 160	-	-	-	-
R4	Stream	< 0.001	> 840	-	> 160	-	-	-	-
Plum EU-N [2x10 g as/ha] Plum EU-S [2x25 g as/ha] ; BBCH <10-79 Application interval 10-14 days(min) early application									
FOCUS Step 1									
		-	-	-	-	-	-	-	-
FOCUS Step 2									
N EU		0.106	**7.92**	-	**1.51**	-	-	-	422
S EU		0.265	**3.17**	-	**0.603**	-	-	-	105
FOCUS Step 3									
D3	Ditch	< 0.001	> 840	-	> 160	-	-	-	-
D4	Pond	< 0.001	> 840	-	> 160	-	-	-	-
D4	Stream	< 0.001	> 840	-	> 160	-	-	-	-
D5	Pond	< 0.001	> 840	-	> 160	-	-	-	-
D5	Stream	< 0.001	> 840	-	> 160	-	-	-	-
R1	Pond	< 0.001	> 840	-	> 160	-	-	-	-
R1	Stream	< 0.001	> 840	-	> 160	-	-	-	-
R2	Stream	< 0.001	> 840	-	> 160	-	-	-	-
R3	Stream	< 0.001	> 840	-	> 160	-	-	-	-
R4	Stream	< 0.001	> 840	-	> 160	-	-	-	-
Reg (EU) 546/2011 Trigger			100	10	100	10	10	100	10

[a] Values in bold fall below the Reg (EU) 546/2011 trigger value.
[b] TER values are calculated based on PEC$_{sed}$ step 1-3.

Maximum PECsw values (Focus step 1-3) and TER values for metabolite XV– application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'								
Scenario		PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller prolonged[b]
			O. mykiss LC$_{50}$ 0.84 µg/L	*N/A*	*D. magna* LC$_{50}$ 0.16 µg/L	*N/A*	*N/A*	*C. riparius* NOEC 580 µg/kg
Winter wheat EU-N/S [2x7.5 g as/ha] BBCH 10-29 Application interval 14 days								
FOCUS Step 1								
		0.02	**42**	-	**8.0**	-	-	125
FOCUS Step 2								
N EU		0.008	105	-	**20.0**	-	-	-
S EU		0.008	105	-	**20.0**	-	-	-
FOCUS Step 3								
D1	ditch	<0.001	> 100	-	> 100	-	-	-
D1	stream	<0.001	> 100	-	> 100	-	-	-
D2	ditch	<0.001	> 100	-	> 100	-	-	-
D2	stream	<0.001	> 100	-	> 100	-	-	-
D3	ditch	<0.001	> 100	-	> 100	-	-	-
D4	pond	<0.001	> 100	-	> 100	-	-	-
D4	stream	<0.001	> 100	-	> 100	-	-	-
D5	pond	<0.001	> 100	-	> 100	-	-	-
D5	stream	<0.001	> 100	-	> 100	-	-	-
D6	ditch	<0.001	> 100	-	> 100	-	-	-
R1	pond	<0.001	> 100	-	> 100	-	-	-
R1	stream	<0.001	> 100	-	> 100	-	-	-
R3	stream	<0.001	> 100	-	> 100	-	-	-
R4	stream	<0.001	> 100	-	> 100	-	-	-
Winter wheat EU-N/S [2x7.5 g as/ha] BBCH 30-79 Application interval 14 days								
FOCUS Step 1								
		0.02	**42**	-	**8.0**	-	-	125

Maximum PECsw values (Focus step 1-3) and TER values for metabolite XV– application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'								
Scenario		PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller prolonged[b]
			O. mykiss LC_{50} 0.84 µg/L	*N/A*	*D. magna* LC_{50} 0.16 µg/L	*N/A*	*N/A*	*C. riparius* NOEC 580 µg/kg
FOCUS Step 2								
N EU		0.008	105	-	**20.0**	-	-	-
S EU		0.008	105	-	**20.0**	-	-	-
FOCUS Step 3								
D1	ditch	<0.001	> 100	-	> 100	-	-	-
D1	stream	<0.001	> 100	-	> 100	-	-	-
D2	ditch	<0.001	> 100	-	> 100	-	-	-
D2	stream	<0.001	> 100	-	> 100	-	-	-
D3	ditch	<0.001	> 100	-	> 100	-	-	-
D4	pond	<0.001	> 100	-	> 100	-	-	-
D4	stream	<0.001	> 100	-	> 100	-	-	-
D5	pond	<0.001	> 100	-	> 100	-	-	-
D5	stream	<0.001	> 100	-	> 100	-	-	-
D6	ditch	<0.001	> 100	-	> 100	-	-	-
R1	pond	<0.001	> 100	-	> 100	-	-	-
R1	stream	<0.001	> 100	-	> 100	-	-	-
R3	stream	<0.001	> 100	-	> 100	-	-	-
R4	stream	<0.001	> 100	-	> 100	-	-	-
Spring wheat EU-N/S [2x7.5 g as/ha] BBCH 30-79 Application interval 14 days								
FOCUS Step 1								
		0.02	**42**	-	**8.0**	-	-	125
FOCUS Step 2								
N EU		0.008	105	-	**20.0**	-	-	-
S EU		0.008	105	-	**20.0**	-	-	-
FOCUS Step 3								

Maximum PECsw values (Focus step 1-3) and TER values for metabolite XV– application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'								
Scenario		PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller prolonged[b]
			O. mykiss LC_{50} 0.84 µg/L	*N/A*	*D. magna* LC_{50} 0.16 µg/L	*N/A*	*N/A*	*C. riparius* NOEC 580 µg/kg
D1	ditch	<0.001	> 100	-	> 100	-	-	-
D1	stream	<0.001	> 100	-	> 100	-	-	-
D3	ditch	<0.001	> 100	-	> 100	-	-	-
D4	pond	<0.001	> 100	-	> 100	-	-	-
D4	stream	<0.001	> 100	-	> 100	-	-	-
D5	pond	<0.001	> 100	-	> 100	-	-	-
D5	stream	<0.001	> 100	-	> 100	-	-	-
R4	stream	<0.001	> 100	-	> 100	-	-	-
Seed potato EU-N [2x7.5 + 2x7.5 g as/ha] BBCH ≤15; BBCH 40-75 Application interval 7 days								
FOCUS Step 1								
		0.05	**17**	**-**	**3.2**	**-**	**-**	62.5
FOCUS Step 2								
N EU		0.008	105	-	**20.0**	-	-	-
FOCUS Step 3								
D3	ditch	<0.001	> 100	-	> 100	-	-	-
D4	pond	<0.001	> 100	-	> 100	-	-	-
D4	stream	<0.001	> 100	-	> 100	-	-	-
D6	ditch(1st)	<0.001	> 100	-	> 100	-	-	-
D6	ditch(2nd)	<0.001	> 100	-	> 100	-	-	-
R1	pond	<0.001	> 100	-	> 100	-	-	-
R1	stream	<0.001	> 100	-	> 100	-	-	-
R2	stream	<0.001	> 100	-	> 100	-	-	-
R3	stream	<0.001	> 100	-	> 100	-	-	-
Seed potato EU-S [20 g as/ha] BBCH ≥15								
FOCUS Step 1								

Maximum PECsw values (Focus step 1-3) and TER values for metabolite XV– application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'								
Scenario		PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller prolonged[b]
			O. mykiss LC_{50} 0.84 µg/L	*N/A*	*D. magna* LC_{50} 0.16 µg/L	*N/A*	*N/A*	*C. riparius* NOEC 580 µg/kg
		0.06	**14**	-	**2.7**	-	-	46.8
FOCUS Step 2								
S EU		0.0200	**42**	-	**8.0**	-	-	-
FOCUS Step 3								
D3	ditch	<0.001	> 100	-	> 100	-	-	-
D4	pond	<0.001	> 100	-	> 100	-	-	-
D4	stream	<0.001	> 100	-	> 100	-	-	-
D6	ditch(1st)	<0.001	> 100	-	> 100	-	-	-
D6	ditch(2nd)	<0.001	> 100	-	> 100	-	-	-
R1	pond	<0.001	> 100	-	> 100	-	-	-
R1	stream	<0.001	> 100	-	> 100	-	-	-
R2	stream	<0.001	> 100	-	> 100	-	-	-
R3	stream	<0.001	> 100	-	> 100	-	-	-
Seed potato EU-S [20 + 20 g as/ha] BBCH ≥15; BBCH ≥40								
FOCUS Step 1								
		0.06	**14**	-	**2.7**	-	-	46.8
FOCUS Step 2								
S EU		0.0200	**42**	-	**8.0**	-	-	
FOCUS Step 3								
D3	ditch	<0.001	> 100	-	> 100	-	-	-
D4	pond	<0.001	> 100	-	> 100	-	-	-
D4	stream	<0.001	> 100	-	> 100	-	-	-
D6	ditch(1st)	<0.001	> 100	-	> 100	-	-	-
D6	ditch(2nd)	<0.001	> 100	-	> 100	-	-	-
R1	pond	<0.001	> 100	-	> 100	-	-	-

Maximum PECsw values (Focus step 1-3) and TER values for metabolite XV– application of ‘Lambda-Cyhalothrin 100 CS’ and ‘Lambda 50 EC’								
Scenario		PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller prolonged[b]
			O. mykiss LC$_{50}$ 0.84 µg/L	*N/A*	*D. magna* LC$_{50}$ 0.16 µg/L	*N/A*	*N/A*	*C. riparius* NOEC 580 µg/kg
R1	stream	<0.001	> 100	-	> 100	-	-	-
R2	stream	<0.001	> 100	-	> 100	-	-	-
R3	stream	<0.001	> 100	-	> 100	-	-	-
Potato EU-N [2x7.5 g as/ha] BBCH 40-75 Application interval 7 days								
FOCUS Step 1								
		0.02	**42**	-	**8.0**	-	-	125
FOCUS Step 2								
N EU		0.0075	112	-	**21**	-	-	-
FOCUS Step 3								
D3	ditch	<0.001	> 100	-	> 100	-	-	-
D4	pond	<0.001	> 100	-	> 100	-	-	-
D4	stream	<0.001	> 100	-	> 100	-	-	-
D6	ditch(1st)	<0.001	> 100	-	> 100	-	-	-
D6	ditch(2nd)	<0.001	> 100	-	> 100	-	-	-
R1	pond	<0.001	> 100	-	> 100	-	-	-
R1	stream	<0.001	> 100	-	> 100	-	-	-
R2	stream	<0.001	> 100	-	> 100	-	-	-
R3	stream	<0.001	> 100	-	> 100	-	-	-
Potato EU-S [2x20 g as/ha] BBCH ≥40 Application interval 8 days(min)								
FOCUS Step 1								
		0.06	**14**	-	**2.7**	-	-	46.8
FOCUS Step 2								
S EU		0.018	**47**	-	**8.9**	-	-	-
FOCUS Step 3								
D3	ditch	<0.001	> 100	-	> 100	-	-	-

Maximum PECsw values (Focus step 1-3) and TER values for metabolite XV– application of 'Lambda-Cyhalothrin 100 CS' and 'Lambda 50 EC'								
Scenario		PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrate acute	Invertebrate prolonged	Algae	Sed- dweller prolonged[b]
			O. mykiss LC$_{50}$ 0.84 µg/L	*N/A*	*D. magna* LC$_{50}$ 0.16 µg/L	*N/A*	*N/A*	*C. riparius* NOEC 580 µg/kg
D4	pond	<0.001	> 100	-	> 100	-	-	-
D4	stream	<0.001	> 100	-	> 100	-	-	-
D6	ditch	<0.001	> 100	-	> 100	-	-	-
R1	pond	<0.001	> 100	-	> 100	-	-	-
R1	stream	<0.001	> 100	-	> 100	-	-	-
R2	stream	<0.001	> 100	-	> 100	-	-	-
R3	stream	<0.001	> 100	-	> 100	-	-	-
Peach EU-S [2x22.5 g as/ha] BBCH 53-69; BBCH ≥81 Application interval 30 days(min)								
FOCUS Step 1								
		0.14	**6.0**	**-**	**1.1**	**-**	**-**	82.6
FOCUS Step 2								
S EU		0.128	**6.6**	**-**	**1.3**	**-**	**-**	-
FOCUS Step 3								
D3	ditch	<0.001	> 100	-	> 100	-	-	-
D4	pond	<0.001	> 100	-	> 100	-	-	-
D4	stream	<0.001	> 100	-	> 100	-	-	-
D5	pond	<0.001	> 100	-	> 100	-	-	-
D5	stream	<0.001	> 100	-	> 100	-	-	-
R1	pond	<0.001	> 100	-	> 100	-	-	-
R1	stream	<0.001	> 100	-	> 100	-	-	-
R2	stream	<0.001	> 100	-	> 100	-	-	-
R3	stream	<0.001	> 100	-	> 100	-	-	-
R4	stream	<0.001	> 100	-	> 100	-	-	-
Reg (EU) 546/2011 Trigger			100	10	100	10	10	10

[a] Application to peach is applicable only for Lambda-Cyhalothrin 100 CS
[b] TER values for sediment dwelling invertebrates are based on PEC_{sed}. For further information. see Annex B.9 on the representative products.

Bioconcentration

	Active substance	Metabolite 1a
Log Po/w	5.5	
Bioconcentration factor (BCF) ‡	3635[a]	No data
Reg (EU) 546/2011 Trigger for BCF		
Clearance time (days) (CT_{50})		
Clearance time (days) (CT_{90})		
Level and nature of residues (%) in organisms after the 14 day depuration phase		

[a] based on total ^{14}C

Effects on honeybees

Test substance	Acute oral toxicity (LD_{50} µg a.s./bee)	Acute contact toxicity (LD_{50} µg a.s./bee)
Active substance ‡	0.91	0.038
Metabolite Ia	>165	>200
Karate 10CS (AI2690B)	0.17	0.055
Lambda 100CS (72 hour toxicity endpoints)	8.5	0.43
Lambda 50EC	0.118	0.112
Field or semi-field tests		

Test	**Test material**	**Dose range/evidence of exposure**	**Results**
Hecht-Rost 2012: Semi-field brood test (*Phacelia*) in Switzerland	'Lambda-Cyhalothrin 100 CS'	T1: 7.5 g as/ha T2: 15 g as/ha T3: 22.5 g as/ha 400L water/ha, single application. Two toxic references (Insegar 25 WG and Perfekthion). Statistical analysis performed. Foraging activity assessments performed. Tunnel study and no alternative foraging areas.	<u>T1: 7.5 g a.s./ha</u> Noticeable increase in mortality on the day of application. Increased mortality persisted or 6 days (ignoring 3 DAA). Comparable to control 7 DAA. Foraging activity was very slightly reduced compared to the control and the pre-application activity. No foraging activity 3 DAA for any treatment and control tunnel. Nervous bees and abnormal behaviour noted in the behaviour assessments. No differences between the treatment and the control were observed in the brood assessments. <u>T2: 15 g a.s./ha</u> Noticeable increase in mortality on the day of application. Increased mortality persisted or 2 days. Comparable to control 4 DAA onwards. Foraging activity was reduced compared to the control and pre-application activity (to a greater extent than for T1 and T3). No foraging activity 3 DAA for any treatment and control tunnel. Nervous bees and abnormal behaviour noted in the behaviour assessments. Brood termination rate increased for the duration of

Test	Test material	Dose range/evidence of exposure	Results
			the assessment. This is not consistent with T1 and T3. T3: 22.5 g a.s./ha Noticeable increase in mortality on the day of application. Increased mortality persisted for 6 days (ignoring 3 DAA). Comparable to control 7 DAA. Foraging activity was reduced compared to the control and pre-application activity (to a greater extent than for T1). No foraging activity 3 DAA for any treatment and control tunnel. Nervous bees and abnormal behaviour noted in the behaviour assessments. No differences between the treatment and the control were observed in the brood assessments (in fact lower brood termination rate compared to the control and T1).
Schur, 2000: Field study (flowering *Phacelia tanacetifolia*) in Germany	'Karate 10CS' (not identical to the representative formulation)	7.5 g a.s./ha, single application Pollen source identification; lower amounts of *phacelia* noted in treated than in control at 2 sites Field location was stated to be away from other flowering crops.	Increase in mortality immediately after application (0 DAA). In 1 replicate the increase in mortality was also apparent 1 DAA. Foraging numbers were considered reasonable prior to application. In all treatment replicates the foraging activity was decreased for 1 day. In one replicate lower numbers were observed on the treated plots for 2 days after application. Symptoms of intoxication were noted shortly after application (0 DAA).
Nengel 1998: Field study (flowering *Phacelia tanacetifolia*) in Germany	'Karate 10CS'	15 g a.s./ha, single application during bee flight. 2 trials. Pollen source identification. Field location was stated to be away from other flowering crops. The RMS noted heavy precipitation 5 DAA.	Increased mortality for 1 day after treatment in both trials. Signs of intoxication were also observed after application. Normal bee behaviour was reported for days 1 – 7 DAA. Foraging numbers were considered reasonable prior to application. Reduced flight intensity on 0 DAA in both treatments. A large proportion of the pollen was stated to have been *Phacelia*.
Nengel 1999b: Field study (flowering *Phacelia tanacetifolia*) in Germany	'Karate 10CS' (not identical to the representative formulation)	T1: 7.5 g a.s./ha T2: 15 g a.s./ha. single application during bee flight. Pollen source identification. Field location was	Increased mortality for 1-2 days in T1. Increased (higher level) was observed in T2 and persisted for 3 days. Signs of intoxication were also observed after application. Normal bee behaviour was reported for days 1 – 7 DAA. Foraging numbers were considered reasonable prior to application. Reduced flight intensity on 0 DAA in both treatments.

Test	Test material	Dose range/evidence of exposure	Results
		stated to be away from other flowering crops.	
Nengel 1999c: Field study (flowering *Phacelia tanacetifolia*) in Germany	Karate 10CS	T1: 7.5 g a.s./ha T2: 15 g a.s./ha. single application during bee flight. Pollen source identification	Increased mortality for 1 day in T1. Increased (higher level) was observed in T2 and persisted for 2 days. Signs of intoxication were also observed after application. Normal bee behaviour was reported for days 1 – 7 DAA. Foraging numbers were considered reasonable prior to application. Reduced flight intensity on 0 DAA in both treatments.

Hazard quotients for honey bees

lambda-cyhalothrin in'Karate 10CS'						
Crop	**Single application rate g a.s./ha**	**HQ oral lamba cyhalothrin**	**HQ contact lamba cyhalothrin**	**HQ oral Karate 10CS**	**HQ contact Karate 10CS**
Toxicity endpoint (µg a.s./bee)		0.91	0.038	0.17	0.55
Spring and winter wheat NEU and SEU	7.5	8.2	**197.4**	44.1	**136.4**
Tomato NEU	12.5	13.7	**328.9**	**73.5**	**227.3**
Tomato SEU	25	27.5	**657.9**	**147.1**	**454.5**
Tomato N/SEU Glasshouse	25	N/R	N/R	N/R	N/R
Plum NEU	10	11.0	**263.2**	**58.8**	**181.8**
Plum SEU	25	27.5	**657.9**	**147.1**	**454.5**
Trigger value		50			

N/R: Honey bee risk assessment not required for glasshouse use
HQ values in **bold** are greater than the trigger value of 50
SEU: Southern Europe
NEU: Northern Europe

lambda-cyhalothrin in'Kaiso sorbie 5% EG'					
Crop	**Single application rate g a.s./ha**	**HQ oral lamba cyhalothrin**	**HQ contact lamba cyhalothrin**	**HQ oral Kaiso Sorbie**	**HQ contact Kaiso Sorbie**
Toxicity endpoint (µg a.s./bee)		0.91	0.038	-	-
Spring and winter wheat NEU and SEU	7.5	8.2	**197.4**	-	-
Tomato NEU	12.5	13.7	**328.9**	-	-
Tomato SEU	25	27.5	**657.9**	-	-
Tomato N/SEU Glasshouse	25	N/R	N/R	N/R	N/R
Plum NEU	10	11.0	**263.2**	-	-
Plum SEU	25	27.5	**657.9**	-	-
Trigger value		50			

N/R: Honey bee risk assessment not required for glasshouse use
HQ values in **bold** are greater than the trigger value of 50

SEU: Southern Europe
NEU: Northern Europe

lambda-cyhalothrin in'Lambda-Cyhalothrin 100 CS'					
Crop	**Single application rate g a.s./ha**	**HQ oral lamba cyhalothrin**	**HQ contact lamba cyhalothrin**	**HQ oral Lambda-cyhalothrin 100 CS**	**HQ contact Lambda-cyhalothrin 100 CS**
Toxicity endpoint (µg a.s./bee)		0.91	0.038	8.5	0.43
Spring and winter wheat NEU and SEU	7.5	8.2	**197.4**	0.9	17.4
Seed potato NEU	7.5	8.2	**197.4**	0.9	17.4
Potato NEU	7.5	8.2	**197.4**	0.9	17.4
Seed potato SEU	20	22.0	**526.3**	2.4	46.5
Potato SEU	20	22.0	**526.3**	2.4	46.5
Peach SEU	22.5	24.7	**592.1**	2.6	**52.3**
Trigger value		50			

N/R: Honey bee risk assessment not required for glasshouse use
HQ values in **bold** are greater than the trigger value of 50
SEU: Southern Europe
NEU: Northern Europe

lambda-cyhalothrin in 'Lambda 50 EC'					
Crop	**Single application rate g a.s./ha**	**HQ oral lamba cyhalothrin**	**HQ contact lamba cyhalothrin**	**HQ oral Lambda 50 EC**	**HQ contact Lambda 50 EC**
Toxicity endpoint (µg a.s./bee)		0.91	0.038	0.118	0.112
Spring and winter wheat NEU and SEU	7.5	8.2	**197.4**	**63.6**	**67.0**
Seed potato NEU	7.5	8.2	**197.4**	**63.6**	**67.0**
Potato NEU	7.5	8.2	**197.4**	**63.6**	**67.0**
Seed potato SEU	20	22.0	**526.3**	**169.5**	**178.6**
Potato SEU	20	22.0	**526.3**	**169.5**	**178.6**
Trigger value		50			

N/R: Honey bee risk assessment not required for glasshouse use
HQ values in **bold** are greater than the trigger value of 50
SEU: Southern Europe
NEU: Northern Europe

Effects on other arthropod species
Laboratory tests with standard sensitive species

Species	Test substance	End point	Effect (LR_{50} g a.s./ha)
Typhlodromus pyri ‡	Lambda-cyhalothrin 50EC	mortality	0.0037
Aphidius rhopalosiphi ‡	Lambda-cyhalothrin 100 g/L CS (WF2639)	mortality	1.06
Aphidius rhopalosiphi ‡	Lambda-cyhalothrin 50 g/kg WG (YF8048A)	mortality	0.59

Test substance	**Species**	**Effect (LR_{50} g a.s./ha)**	**HQ in-field**	**HQ off-field (1 or 3 m distance)**	**Trigger**
Cereals, 2 x 7.5 g a.s./ha, 10 days interval, MAF = 1.7					

Test substance	Species	Effect (LR_{50} g a.s./ha)	HQ in-field	HQ off-field (1 or 3 m distance)	Trigger
Lambda-cyhalothrin	*Typhlodromus pyri*	0.0037	**3446**	**82**	2
Lambda-cyhalothrin	*Aphidius rhopalosiphi*	1.06	**12**	0.29	2
Tomato (<50 cm), field use in N-EU, 2 x 12.5 g a.s./ha, 12 days interval, MAF = 1.7					
Lambda-cyhalothrin	*Typhlodromus pyri*	0.0037	**5743**	**137**	2
Lambda-cyhalothrin	*Aphidius rhopalosiphi*	1.06	**20**	0.48	2
Tomato (<50 cm), field use in S-EU, 2 x 25 g as/ha, 12 days interval, MAF = 1.7					
Lambda-cyhalothrin	*Typhlodromus pyri*	0.0037	**11486**	**273**	2
Lambda-cyhalothrin	*Aphidius rhopalosiphi*	1.06	**40**	1.0	2
Plum orchards, N-EU, 2 x 10 g a.s./ha, 10 days interval, MAF = 1.7					
Lambda-cyhalothrin	*Typhlodromus pyri*	0.0037	**4595**	**1173**	2
Lambda-cyhalothrin	*Aphidius rhopalosiphi*	1.06	**16**	**4.1**	2
Plum orchards, S-EU, 2 x 25 g a.s./ha, 10 days interval, MAF = 1.7					
Lambda-cyhalothrin	*Typhlodromus pyri*	0.0037	**11486**	**2933**	2
Lambda-cyhalothrin	*Aphidius rhopalosiphi*	1.06	**40**	**10**	2
Peach orchards, S-EU, 2 x 22.5 g as/ha, 30 days interval					
Lambda-cyhalothrin	*Typhlodromus pyri*	0.0037	**6081**	**1776**	2
Lambda-cyhalothrin	*Aphidius rhopalosiphi*	1.06	**21**	**6.2**	2
Potato, N-EU, 2 x 7.5 g a.s./ha, 7 days interval, MAF = 1.7					
Lambda-cyhalothrin	*Typhlodromus pyri*	0.0037	**3446**	**82**	2
Lambda-cyhalothrin	*Aphidius rhopalosiphi*	1.06	**12**	0.29	2
Potato, S-EU, 1 x 20 g a.s /ha					
Lambda-cyhalothrin	*Typhlodromus pyri*	0.0037	**5405**	**150**	2
Lambda-cyhalothrin	*Aphidius rhopalosiphi*	1.06	**19**	0.52	2
Potato, S-EU, 20 x 2 g a.s./ha, 8 days interval, MAF = 1.7					
Lambda-cyhalothrin	Typhlodromus pyri	0.0037	**9189**	**219**	2
Lambda-cyhalothrin	*Aphidius rhopalosiphi*	1.06	**32**	0.76	2

Extended laboratory studies ‡

Species[d]	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	Fffect	Trigger value
Studies performed with fresh residues						
Typhlodromus pyri	protonymphs	Lambda-Cyhalothrin 50	Initial 0.0001 - 0.0081 g	Mortality fecundity	$LR_{50:}$ 0.0017 g a.s./ha	50%

Species[d]	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	Fffect	Trigger value
Studies performed with fresh residues						
		EC	a.s./ha		<50% effect on reproduction at 0.0009 g a.s./ha	
Aphidius rhopalospihi	adults	Karate 10 CS (A12690B) Leaf discs Fresh residues	Initial 0.05 to 0.5 g a.s./ha	Mortality fecundity	48h LR_{50} =0.35 g a.s./ha No sublethal effects at treatment rates of up to and including 0.5 g a.s./ha Karate 10 CS /ha .	50%
Typhlodromus pyri	protonymphs	Karate 10 CS (A12690B) Leaf discs Fresh residues	0.0006 – 0.023 g a.s./ha	Mortality fecundity	$LR_{50:}$ 0.0243 g a.s./ha <50% effect on reproduction at 0.009 g a.s./ha	50%
Orius insidiosus	3- to 4-day old nymphs	Karate 10 CS (A12690B) Leaf discs Fresh residues	Initial 0.004-0.1 g a.s./ha	Mortality fecundity	LR_{50} = 0.018 g a.s./ha <50% effect on reproduction at 0.020 g a.s./ha	50%
Chrysoperla carnea	2-3 days old larvae	'Karate 10 CS' (A12690B) Leaf discs Fresh residues	Initial 0.1-20 g a.s./ha	Mortality fecundity	LR_{50}= 4.3 g a.s./ha. The NOAEL on reproduction could be establish on the emergent Mortality fecundity adults at treatment rates of up to and including 2.0 g a.s./ha	50%
Aleochara bilineata	adult	'Karate 10 CS' (A12690B) Sandy soil Fresh residues	Initial 1.0 to 70 g a.s./ha	Mortality fecundity	LR_{50}= 5.5 g a.s./ha 60% reduction in reproduction at 7.5 g a.s./ha <50% effect on reproduction at 1 g a.s./ha	50%
Chrysoperla carnea	larvae	'Lambda-Cyhalothrin 100 CS' Leaf discs Fresh residues	0.0293 - 7.5 g a.s./ha	mortality	LR_{50} > 7.5 g a.s./ha ER_{50} reproduction >7.5 g a.s./ha	50%
Typhlodromus pyri	protonymphs	'Lambda-cyhalothrin 100 CS' Leaf discs Fresh residues	0.00148 – 0.12 g a.s./ha	Mortality fecundity	LR_{50} = 0.06 g a.s./ha <50% effect on reproduction at 0.00148 g a.s./ha	50%
Aphidius rhopalospihi	adult	Lambda-cyhalothrin (WG 50 g/kg) Leaf discs Fresh residues	0.62 – 7.5 g a.s./ha	Mortality fecundity	LR_{50} = 2.2 g a.s./ha ER_{50} reproduction = 1.3 g a.s./ha	50%

Species[d]	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	Fffect	Trigger value
Studies performed with fresh residues						
Typhlodromus pyri	protonymphs	Lambda-cyhalothrin (WG 50 g/kg) Leaf discs Fresh residues	0.26 – 10 g a.s./ha	Mortality	LR_{50} = 0.026 g a.s./ha	50%
Studies performed with aged						
Typhlodromus pyri	protonymphs	Lambda-cyhalothrin (WG 50 g/kg) 150 g/ha Aged apple leaves 27 days	7.5 g a.s./ha	Mortality fecundity	Mortality = 4.3%[c] Reduction in reproduction = 2.3 %	50%
Chrysoperla carnea	larvae	'Lambda-Cyhalothrin 100 CS' 7 day and 21 day aged residues dwarf bean leaves (*P. vulgare*) 7 and 21 Days	4.6 - 46 g a.s./ha	mortality Fecundity	**i) 7 day** Mortality > 80% for all treatments. Fecundity not assessed. **ii) 21 day** <10% effect on mortality for all treatments. <50% reudtcion in reproduction for all treatments.	50%
Aphidius rhopalospihi	adult	'Lambda-Cyhalothrin 100 CS' 7 day and 21 day aged residues days dwarf bean leaves (*P. vulgare*) and barley seedlings (*h.vulgare*)	4.6 - 46 g a.s./ha	mortality	**i) 7 day** Mortality > 89% for all treatments. Fecundity not assessed. **ii) 21 day** <10% effect on mortality for all treatments. <50% reudtcion in reproduction for all treatments.	50%

Field or semi-field tests on other arthropod species

Field or semi-field test
For the representative uses in cereals in northern Europe (Denmark), central Europe (Germany) and southern Europe (Italy), the effects on non-target arthropods of a multiple application regime of 3 x 10 g a.s./ha has been investigated in three studies. No acceptable field studies are available to assess the risk to NTA from the representative uses in tomatoes, potatoes and orchards (plums and peaches). Recovery was not demonstrated within 1 year in the available field data from Denmark and Germany for sensitive species such as Linyphid spiders. Hence, from the field data potential for recovery/re-colonisation is not demonstrated within 1 year after the first treatment for in-field habitats and within an ecologically relevant time for off-field habitats at the proposed use in cereal in central and northern EU. From the study in Italy, a potential recovery was indicated one year after the first treatment. There is no acceptable field data to cover the representative use in tomatoes, potatoes and orchards.

Effects on earthworms, other soil macroorganisms and soil microorganisms

Test organisms	Test substance	Time scale	End point[a]
Earthworms			
Eisenia fetida	lambda-cyhalothrin ‡	14 d	LC_{50Corr} >500 mg/kg
Eisenia fetida	lambda-cyhalothrin ‡	56 d	$NOEC_{Corr}$ 3.125 mg/kg
Eisenia fetida	TFP-acid (metabolite Ia)	56 d	NOEC 6.25 mg a.s./kg
Eisenia fetida	3-Phenoxybenzoic acid (metabolite V)	56 d	$NOEC_{Corr}$ 3.125 mg/kg
Eisenia fetida	hydroxylated lambda-cyhalothrin (metabolite XV)	14 d	LC_{50Corr} >500 mg/kg
Eisenia fetida	hydroxylated lambda-cyhalothrin (metabolite XV)	56 d	$NOEC_{Corr}$ 25 mg a.s./kg
Eisenia fetida	'Kaiso sorbie 5% EG'	14 d	$LC_{50\ Corr}$ >25 mg a.s./kg
Eisenia fetida	'Lambda-Cyhalothrin 100 CS'	14 d	$LC_{50\ Corr}$ >500 mg a.s./kg
Eisenia fetida	'Lambda 50EC'	56 d	$NOEC_{Corr}$ 0.39 mg a.s./kg
Other soil macroorganisms			
Folsomia candida	'Lambda-Cyhalothrin 100 CS'	28 d	$NOEC_{Corr}$ 2.73 mg a.s./kg
Hypoaspis aculeifer	'Lambda-Cyhalothrin 100 CS'	14 d	$NOEC_{Corr}$ 4.67 mg a.s./kg
Soil microorganisms			
n/a	hydroxylated lambda-cyhalothrin (metabolite XV)	28 d	0 % effect on nitrogen formation rate at day 0-28 at 0.025 mg/kg dw soil
n/a	Lambda-cyhalothrin 5% EC	28 d	≤ 21% effect on ammonium levels at day 0-28 at 1.67 mg formulation/kg. Effects of nitrogen formation rate not reported.
n/a	Lambda-cyhalothrin 10 % CS	28 d	0.3 % effect on nitrogen formation rate at day 0-28 at 0.52 mg formulation/kg d.w. soil (1.3 % at 0.10 mg formulation /kg dw soil)
Field studies			
Not required			

[a] Endpoint has been corrected with a factor of 2 due to log Pow >2.0 (e.g. LC_{50}corr)

Toxicity/exposure ratios for soil organisms

lambda-cyhalothrin in 'Karate 10 CS'2 x 25 g/ha to plums (covering applications to wheat and tomatoes)					
Test organism	**Test substance**	**Time scale**	**Soil PEC (mg/kg)[a]**	**TER**	**Reg (EU) 546/2011 Trigger**
Earthworms					
Eisenia fetida	lambda-cyhalothrin	Acute	0.0431	>11601	10
Eisenia fetida	lambda-	Chronic	0.0431	73	5

lambda-cyhalothrin in 'Karate 10 CS'2 x 25 g/ha to plums (covering applications to wheat and tomatoes)					
Test organism	**Test substance**	**Time scale**	**Soil PEC (mg/kg)[a]**	**TER**	**Reg (EU) 546/2011 Trigger**
	cyhalothrin				
Eisenia fetida	TFP-acid (metabolite Ia)	Chronic	0.0053	1179	5
Eisenia fetida	3-Phenoxy-benzoic acid (metabolite V)	Chronic	0.0021	1488	5
Eisenia fetida	hydroxylated lambda-cyhalothrin (metabolite XV)	Acute	0.0054	>92593	10
Eisenia fetida	hydroxylated lambda-cyhalothrin (metabolite XV)	Chronic	0.0054	9259	5
Other soil macroorganisms					
Folsomia candida	'Lambda-Cyhalothrin 100 CS'	Chronic	0.0431	63	5

[a] Initial PEC after 2 applications within one season.

lambda-cyhalothrin in 'Kaiso sorbie 5% EG'2 x 25 g/ha to plums (covering applications to wheat and tomatoes)					
Test organism	**Test substance**	**Time scale**	**Soil PEC (mg/kg)[a]**	**TER**	**Reg (EU) 546/2011 Trigger**
Earthworms					
Eisenia fetida	lambda-cyhalothrin	Acute	0.0431	>11601	10
Eisenia fetida	lambda-cyhalothrin	Chronic	0.0431	73	5
Eisenia fetida	TFP-acid (metabolite Ia)	Chronic	0.0053	1179	5
Eisenia fetida	3-Phenoxy-benzoic acid (metabolite V)	Chronic	0.0021	1488	5
Eisenia fetida	hydroxylated lambda-cyhalothrin (metabolite XV)	Acute	0.0054	>92593	10
Eisenia fetida	hydroxylated lambda-cyhalothrin (metabolite XV)	Chronic	0.0054	9259	5
Eisenia fetida	'Kaiso sorbie 5% EG'	Acute	0.0431	>580	10
Other soil macroorganisms					
Folsomia candida	'Lambda-cyhalothrin 100 CS'	Chronic	0.0431	63	5

[a] Initial PEC after 2 applications within one season.

lambda-cyhalothrin in 'Lambda-Cyhalothrin 100 CS'2 x 20 g/ha to potatoes (covering applications to wheat and peach)

Test organism	Test substance	Time scale	Soil PEC (mg/kg)[a]	TER	Reg (EU) 546/2011 Trigger
Earthworms					
Eisenia fetida	lambda-cyhalothrin	Acute	0.027	>18 518	10
Eisenia fetida	lambda-cyhalothrin	Chronic	0.027	116	5
Eisenia fetida	TFP-acid (metabolite Ia)	Chronic	0.0033	1 893	5
Eisenia fetida	3-Phenoxy-benzoic acid (metabolite V)	Chronic	0.0070	446	5
Eisenia fetida	hydroxylated lambda-cyhalothrin (metabolite XV)	Acute	0.003	>151 515	10
Eisenia fetida	hydroxylated lambda-cyhalothrin (metabolite XV)	Chronic	0.0034	7352	5
Eisenia fetida	Lambda-Cyhalothrin 100 CS	Acute	0.027	>18 518	10
Other soil macroorganisms					
Folsomia candida	'Lambda-Cyhalothrin 100 CS'	Chronic	0.027	101	5

[a] Initial PEC after 2 applications within one season.

lambda-cyhalothrin in 'Lambda 50 EC'2 x 20 g/ha to potatoes (covering applications to wheat)					
Test organism	**Test substance**	**Time scale**	**Soil PEC (mg/kg)[a]**	**TER**	**Reg (EU) 546/2011 Trigger**
Earthworms					
Eisenia fetida	lambda-cyhalothrin	Acute	0.027	>18 518	10
Eisenia fetida	lambda-cyhalothrin	Chronic	0.027	116	5
Eisenia fetida	TFP-acid (metabolite Ia)	Chronic	0.0033	1 893	5
Eisenia fetida	3-Phenoxy-benzoic acid (metabolite V)	Chronic	0.0070	446	5
Eisenia fetida	hydroxylated lambda-cyhalothrin (metabolite XV)	Acute	0.003	>151 515	10
Eisenia fetida	hydroxylated lambda-cyhalothrin (metabolite XV)	Chronic	0.0034	7352	5
Eisenia fetida	'Lambda 50 EC'	Chronic	0.027	18 518	5
Other soil macroorganisms					
Folsomia candida	'Lambda-Cyhalothrin 100 CS'	Chronic	0.027	101	5

[a] Initial PEC after two applications within one season.

Effects on non-target plants

Vegetation and vigour limit tests

No effects on the vegetative vigour on non-target plants were observed in the studies provided on the representative formulations.	
Formulation	NOEC (g a.s./ha)
'Kaiso sorbie 5% EG'	7.5
'Lambda-Cyhalothrin 100 CS'	30
'Lambda 50 EC'	30

Additional studies on non-target plants (e.g. semi-field or field studies)

Not required

Effects on biological methods for sewage treatment

Test type/organism	End point
Respiration activated sludge	NOEC 100 mg/L

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

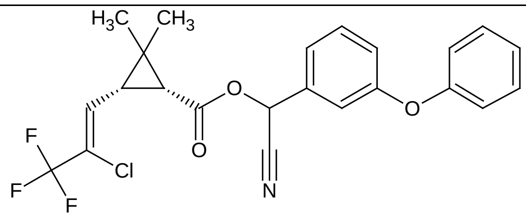
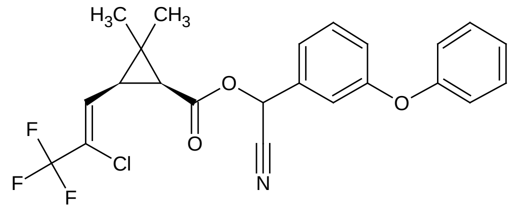
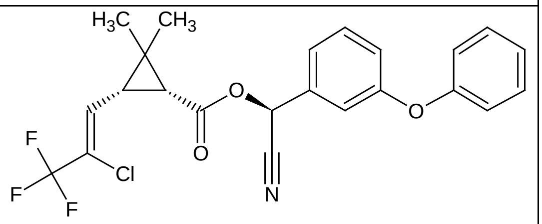
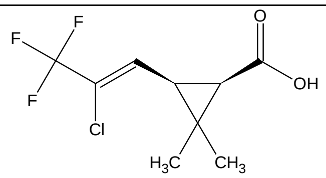
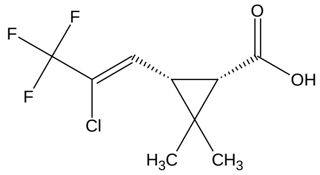
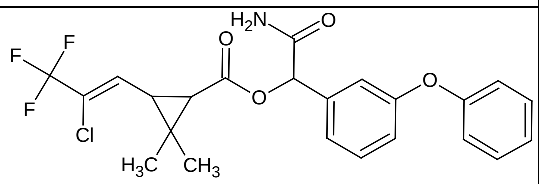
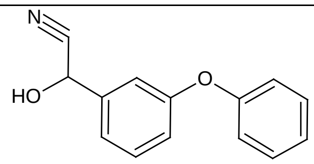
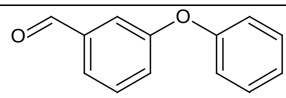
Compartment	
Soil	lambda-cyhalothrin
Groundwater	lambda-cyhalothrin
Surface water	lambda-cyhalothrin
Sediment	lambda-cyhalothrin

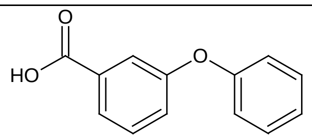
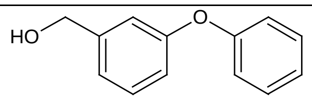
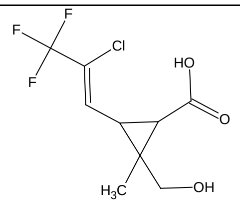
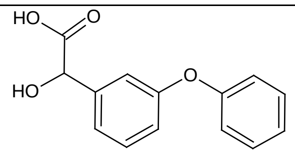
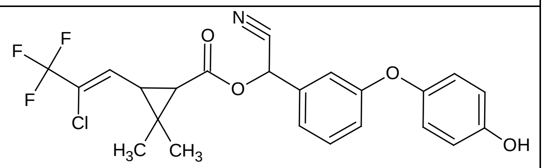
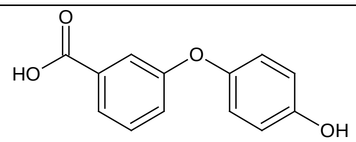
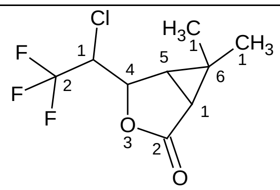
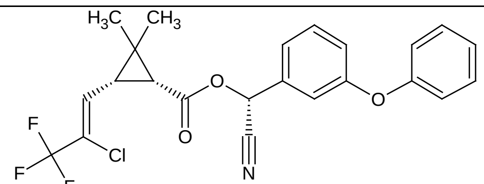
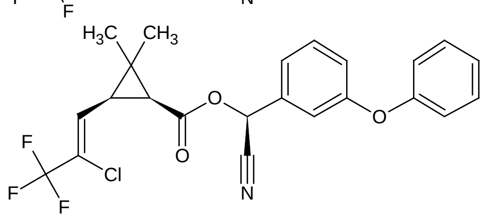
Classification and proposed labelling with regard to ecotoxicological data

Substance classified	Lambda-cyhalothrin
Classification according to Council Directive 67/548/EEC / Regulation (EC) No 1272/2008:	Dangerous Substance Directive 67/548/EEC N; R50/53 ("Very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment") Reg (EC) 1272/2008 Aquatic Acute 1 H400 Aquatic Chronic 1 H410 M-factor 10 000
Peer review proposal[14]	Dangerous Substance Directive 67/548/EEC N; R50/53 ("Very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment") Reg (EC) 1272/2008 Aquatic Acute 1 H400 Aquatic Chronic 1 H410 M-factor 100 000

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

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name/SMILES notation**	Structural formula**
cyhalothrin	(*RS*)-α-cyano-3-phenoxybenzyl (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate Cl\C(=C/[C@H]3[C@@H](C(=O)OC(C#N)c2cccc(Oc1ccccc1)c2)C3(C)C)C(F)(F)F Cl\C(=C/[C@@H]3[C@H](C(=O)OC(C#N)c2cccc(Oc1ccccc1)c2)C3(C)C)C(F)(F)F	 
gamma-cyhalothrin	(*S*)-α-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate Cl\C(=C/[C@H]3[C@@H](C(=O)O[C@H](C#N)c2cccc(Oc1ccccc1)c2)C3(C)C)C(F)(F)F	
Compound Ia	(1*RS*,3*RS*)-3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylic acid Cl\C(=C/[C@H]1[C@@H](C(=O)O)C1(C)C)C(F)(F)F Cl\C(=C/[C@@H]1[C@H](C(=O)O)C1(C)C)C(F)(F)F	 
II (unstated stereochemistry)	(1*RS*)-2-amino-2-oxo-1-(3-phenoxyphenyl)ethyl (1*RS*,3*RS*)-3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate Cl\C(=C/C3C(C(=O)OC(c2cccc(Oc1ccccc1)c2)C(N)=O)C3(C)C)C(F)(F)F	
III (unstated stereochemistry)	(2*RS*)-hydroxy(3-phenoxyphenyl)acetonitrile N#CC(O)c2cc(Oc1ccccc1)ccc2	
IV	3-phenoxybenzaldehyde O=Cc2cc(Oc1ccccc1)ccc2	

Code/Trivial name*	Chemical name/SMILES notation**	Structural formula**
V **(PBA)**	3-phenoxybenzoic acid O=C(O)c2cc(Oc1ccccc1)ccc2	
VI	(3-phenoxyphenyl)methanol OCc2cc(Oc1ccccc1)ccc2	
XI (unstated stereochemistry)	3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2-(hydroxymethyl)-2-methylcyclopropanecarboxylic acid Cl\C(=C/C1C(C(=O)O)C1(C)CO)C(F)(F)F	
XIII (unstated stereochemistry)	hydroxy(3-phenoxyphenyl)acetic acid O=C(O)C(O)c2cc(Oc1ccccc1)ccc2	
XV **(R211133)** (unstated stereochemistry)	(*RS*)-α-cyano-3-(4-hydroxyphenoxybenzyl (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate Cl\C(=C/C3C(C(=O)OC(C#N)c2cccc(Oc1ccc(O)cc1)c2)C3(C)C)C(F)(F)F	
XXIII **(PBA(OH))**	3-(4-hydroxyphenoxy)benzoic acid O=C(O)c2cc(Oc1ccc(O)cc1)ccc2	
gamma-lactone **(R947650)**	4-(1-chloro-2,2,2-trifluoroethyl)-6,6-dimethyl-3-oxa-bicyclo[3.1.0]hexan-2-one CC2(C)C1C(=O)OC(C(Cl)C(F)(F)F)C12	
metabolite R157836	(*R*)-α-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate Cl\C(=C/[C@H]3[C@@H](C(=O)O[C@@H](C#N)c2cccc(Oc1ccccc1)c2)C3(C)C)C(F)(F)F (*S*)-α-cyano-3-phenoxybenzyl (1*S*,3*S*)-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate Cl\C(=C/[C@@H]3[C@H](C(=O)O[C@H](C#N)c2cccc(Oc1ccccc1)c2)C3(C)C)C(F)(F)F	 

* 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
CLP	classification, labelling and packaging
cm	centimetre
CNS	central nervous system
CS	capsule suspension
d	day
DAA	days after application
DAT	days after treatment
DFG	Deutshe Forschungsgemeinschaft method
DM	dry matter
DSD	dangerous substances directive
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 (also used for Euroepan Commission)
EC_{50}	effective concentration
ECHA	European Chemicals Agency
EEC	European Economic Community
EG	emulsifiable granule
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER	oestrogen receptor
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union

EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FID	flame ionisation detector
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FOMC	first-order multi-compartment
g	gram
GAP	good agricultural practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
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-UV	high performance liquid chromatography with ultra violet detector
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
µg	microgram

mg	milligram
min	minute
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
NCI	negative chemical ionisation
NESTI	national estimated short-term intake
ng	nanogram
nm	nanometer
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen phosphorous detector
o.c.	organic carbon content
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
POEM	Predictive Operator Exposure Model
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
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
RAC	regulatory acceptable concentration
RAR	renewal assessment report
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
RMS	rapporteur Member State
RPE	respiratory protective equipment
RUD	residue per unit dose
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SMILES	Simplified molecular-input line-entry system

SSD	species sensitivity distribution
STF	Syngenta Task Force
STMR	supervised trials median residue
STOT-RE	specific target organ toxicity – repeated exposure
$t_{1/2}$	half-life (define method of estimation)
TDM	triazole derivative metabolites
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TFL	Task Force Lambda
TK	technical concentrate
TLC	thin layer chromatography
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
US	United States of America
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