CONCLUSION ON PESTICIDE PEER REVIEW

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

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ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State the United Kingdom, for the pesticide active substance pyriofenone are reported. The context of the peer review was that required by Commission Regulation (EU) No 188/2011. The conclusions were reached on the basis of the evaluation of the representative uses of pyriofenone as a fungicide on cereals and grapes. 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.

KEY WORDS

pyriofenone, peer review, risk assessment, pesticide, fungicide

[1] On request from the European Commission, Question No EFSA-Q-2012-00426, approved on 14 March 2013.

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Suggested citation: European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance pyriofenone. EFSA Journal 2013;11(4):3147. [84 pp.] doi:10.2903/j.efsa.2013.3147. Available online: www.efsa.europa.eu/efsajournal

SUMMARY

Pyriofenone is a new active substance for which in accordance with Article 6(2) of Council Directive 91/414/EEC the United Kingdom (hereinafter referred to as the 'RMS') received an application from ISK BioSciences Europe N.V. for approval. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2010/785/EU of 17 December 2010.

The RMS provided its initial evaluation of the dossier on pyriofenone in the Draft Assessment Report (DAR), which was received by the EFSA on 30 January 2012. The peer review was initiated on 20 February 2012 by dispatching the DAR for consultation of the Member States and the applicant ISK BioSciences Europe N.V.

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

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of pyriofenone as a fungicide against powdery mildew on cereals, and against mildew on grapes, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

A data gap was identified in the section identity.

A data gap was identified in the mammalian toxicology section to address the relevance of the individual impurities in comparison with the toxicological profile of pyriofenone.

Based on the available studies, the plant residue definition for monitoring and risk assessment was proposed as pyriofenone for cereals and the fruit crop group. A data gap was identified to submit additional residue trials on barley in southern Europe. No risk was identified for the consumers.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level for the representative uses assessed. For these representative uses, the potential for groundwater exposure above the parametric drinking water limit of 0.1 µg/L was assessed as low for pyriofenone and its anaerobic metabolites 3HDPM and 2MDPM.

In the ecotoxicology section, a data gap was identified to further consider the risk of bound residues in sediment to sediment-dwelling organisms.

TABLE OF CONTENTS

BACKGROUND

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

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

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

In accordance with Article 6(2) of Council Directive 91/414/EEC the United Kingdom (hereinafter referred to as the 'RMS') received an application from ISK BioSciences Europe N.V. for approval of the active substance pyriofenone. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2010/785/EU of 17 December 2010.[6]

The RMS provided its initial evaluation of the dossier on pyriofenone in the DAR, which was received by the EFSA on 30 January 2012 (United Kingdom, 2012). The peer review was initiated on 20 February 2012 by dispatching the DAR to Member States and the applicant ISK BioSciences Europe N.V. for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 8(3) of the Regulation were considered in a telephone conference between the EFSA, the RMS, and the European Commission on 30 May 2012. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was concluded that additional information should be requested from the applicant and the EFSA should organise an expert consultation in the areas of mammalian toxicology and ecotoxicology.

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ No L 309, 24.11.2009, p. 1-50.
[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32, as last amended.
[5] Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51-55.
[6] Commission Decision 2010/785/EU of 17 December 2010 recognising in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of pyriofenone in Annex I to Council Directive 91/414/EEC . OJ No L 335, 18.12.2010, p. 64-65.

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

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

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in February – March 2013.

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 a fungicide on cereals and grapes, as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2013) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (30 May 2012),
- the Evaluation Table (11 March 2013),
- the reports of the scientific consultation with Member State experts (where relevant),
- the comments received on the assessment of the additional information (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of January 2013 containing all individually submitted addenda (United Kingdom, 2013)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Pyriofenone is the ISO common name for (5-chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-*o*-tolyl)methanone (IUPAC).

The representative formulated products for the evaluation were 'IKF-309 180SC', a suspension concentrate (SC), containing 180 g/l pyriofenone and 'IKF-309 300SC', a suspension concentrate (SC), containing 300 g/l pyriofenone.

The representative uses evaluated comprise foliar spray applications, as a fungicide, for the control of powdery mildew on cereals (wheat, rye, barley, spelt, oats, triticale) and for controlling mildew on grapes. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

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

The minimum purity of the active substance is 965 g/kg. No FAO specification exists.

The technical specification is based on a pilot plant production. A data gap was identified for further information/data to confirm the identity of two impurities to fully support the provisional specification. Further consideration of the impurity profile and technical specification may be necessary when batch data for commercial-scale production are available. 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 pyriofenone or the representative formulations. The main data regarding the identity of pyriofenone and its physical and chemical properties are given in Appendix A.

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

Appropriate HPLC-MS/MS analytical methods are available for the post-registration monitoring of pyriofenone in food and feed of plant origin, with LOQs of 0.01 mg/kg in wheat grain, wheat straw, grape, cabbage head and oilseed rape seeds. Monitoring method in food and feed of animal origin is not required as no residue definition was set. Adequate HPLC-MS/MS methods are available for the monitoring of pyriofenone in soil, in water and in air with LOQs of 0.001 mg/kg, 0.05 µg/l and 18 µg/m^3, respectively. A method for residues in body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

2. Mammalian toxicity

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

Pyriofenone was discussed at the Pesticides Peer Review Meeting 98 in November 2012.

The batches used in the toxicological studies support the technical specification as presented for the pilot scale production. A data gap was identified to address the relevance of the individual impurities in comparison with the toxicological profile of the active substance (except for one impurity that has been tested independently).

Low acute toxicity has been observed when pyriofenone was administered by the oral, dermal and inhalation routes. No skin or eye irritation was observed and no potential for skin sensitisation was reported in a Local Lymph Node Assay (LLNA).

The main target organ of pyriofenone in rats, mice and dogs upon short-term and long-term exposure were the liver, with increased liver weight, increased enzyme activity and hepatocellular hypertrophy, kidneys and blood including prolongation of clotting time. The relevant short-term NOAEL was 15 mg/kg bw per day from the combined 90-day and 1-year studies in dogs, that is supported by the 90-day rat study (NOAEL 17.9 mg/kg bw per day) and the relevant long-term NOAEL was 7.25 mg/kg bw per day from the 2-year study in rats. Increased combined incidences of hepatocellular adenomas and carcinomas were observed in male rats accompanied by reduced survival suggesting that classification as a category 2 carcinogen, H351 'suspected of causing cancer' may be required[7]. Hepatic enzyme induction and cell proliferation studies conducted on rats and mice were considered insufficient to demonstrate conclusively a phenobarbital-like mode of action regarding the appearance of liver tumours. However, the final decision on classification should be taken under Regulation (EC) No 1272/2008[8]. No genotoxic potential is attributed to pyriofenone.

No adverse effects were observed on fertility and reproduction in rats or on the foetal development in rats and rabbits; no potential for neurotoxicity was observed in acute and short-term neurotoxicity studies in rats.

Acute toxicity by the oral route in female rats and *in vitro* bacterial mutagenicity tests were performed on the metabolite 4HDPM and one impurity; both compounds presented an oral LD_{50} > 2000 mg/kg bw in females and did not present mutagenic potential. 4HDPM was found in rat metabolism studies and therefore the reference values of the parent are applicable to the metabolite.

The acceptable daily intake (ADI) of pyriofenone is 0.07 mg/kg bw per day, based on the NOAEL of 7.25 mg/kg bw per day from the rat, 2-year study, applying the standard uncertainty factor (UF) of 100. The acceptable operator exposure level (AOEL) is 0.15 mg/kg bw per day, based on the NOAEL of 15 mg/kg bw per day from the combined 90-day and 1-year dog studies, supported by the 90-day rat study with a NOAEL of 17.9 mg/kg bw per day; 100 UF applied, no correction being required regarding oral absorption. No acute reference dose (ARfD) is allocated as it was considered not necessary.

The estimated operator and worker exposure levels are below the AOEL when no personal protective equipment (PPE) is considered. Estimated bystander exposure was below the AOEL.

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

The metabolism in plants was investigated using ^{14}C-pyriofenone labelled either on the phenyl or pyridyl ring. Studies were conducted on the fruiting crop group (grape, tomato) and on cereals (wheat), with a total of 2 or 3 foliar applications at *ca.* 100 g a.s./ha. The parent pyriofenone was the major component of radioactive residues, representing more than 50% TRR in all plant samples collected 7 to 40 days after the last application, except in wheat grains where it accounted for only 13 to 29% TRR (*ca.* 0.01 mg/kg). The rest of the radioactive residues was composed of a vast number of

[7] 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.

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

individual fractions, including several hydroxy metabolites related to pyriofenone, each observed at low level and proportion (mostly <2% TRR). The metabolism was seen to be similar in all plants investigated and proceeds first by demethylation at the positions 3 or/and 4 of the phenyl moiety to give the hydroxy metabolites 3HDPM, 4HDPM and 2MDPM, followed by further glucose conjugations. Additional demethylation of the 3HDPM metabolite at the carbon 2 gives the 4MDPM metabolite. A similar metabolic pathway was observed in the confined rotational crop study where the radioactive residues were shown to be constituted mainly of the parent and of the 4HDPM glucose and malonylglucose conjugates. As the parent pyriofenone was shown to be the major component of the radioactive residues in both primary and rotational crops, the proposed residue definition for monitoring and risk assessment was limited to pyriofenone for cereals and for fruiting crops.

MRLs proposals were derived for grapes and cereals from the available residue trials. Additional trials were however requested on barley to complete the data set in southern EU. These residue data are supported by storage stability studies showing pyriofenone residues to be stable for at least one year in grape, cereal grains and straw, when stored frozen at -20°C. Pyriofenone was stable under standard hydrolysis conditions and processing factors were proposed for raisin, grape juice and wine.

A goat metabolism study was provided where animals were dosed over 5 consecutive days with ^{14}C-pyriofenone at ca. 0.3 mg/kg bw per day, corresponding approximately to a 17N and 50N dose rate for dairy and beef cattle respectively. Pyriofenone was intensively excreted and less than 1.5% of the administered radioactivity was recovered in goat matrices. As the TRRs in muscle, fat and milk were less than 0.005 mg/kg, the characterisation of the residues was only investigated in kidney and liver where the total residues were up to 0.05 and 0.16 mg/kg respectively. Most of the radioactivity was characterised as fractions L12, L13/K13 or L14/K14 accounting individually for 8% to 60% TRR (0.01 to 0.04 mg eq./kg) and identified following various enzymatic or acid/basic hydrolysis, as mixtures of glucuronide conjugates of 2MDPM and 3- and/or 4HDPM. Having regard to the representative uses, the setting of a residue definition and MRLs for ruminant products are not required. However, based on the available data, EFSA proposes to define the residues for ruminant products as pyriofenone for monitoring and the sum of pyriofenone and 2MDPM (free and conjugated) for risk assessment. These residue definitions should be regarded as provisional, pending the recalculation of the animal dietary burden, in view of potential further uses.

No chronic risk was identified for consumers. Using the EFSA PRIMo model and the MRL values proposed for grape and cereals, the highest TMDI was calculated to be 1% of the ADI (FR, all population). No acute risk assessment was performed as it was concluded that the setting of an ARfD was not necessary for pyriofenone.

4. Environmental fate and behaviour

In soil laboratory incubations under aerobic conditions in the dark, pyriofenone exhibited medium to high persistence, no major metabolites were formed. Mineralisation of the phenyl and pyridyl ring ^{14}C radiolabels to carbon dioxide accounted for 26.5 % and 15.2 % after 364 days, respectively. The formation of unextracted residues (not extracted by acetonitrile/water 4:1 v/v, followed by acetonitrile/water 1:1 v/v, followed by Soxhlet reflux treatments) for these radiolabels accounted for 30.2 % (phenyl ring) and 33.3 % (pyridyl ring) after 364 days. In anaerobic soil incubations pyriofenone exhibited low persistence, two metabolites were formed above 10 % AR, 2MDPM (22.5 % at day 15) and 3HDPM (32.0 % at day 3). The kinetic analysis of the anaerobic laboratory degradation results concluded that no acceptable fits could be derived and no valid DT_{50} values or formation fractions could be calculated for the metabolites 2MDPM and 3HDPM. Pyriofenone exhibited low to slight mobility in soil. Mobility studies according to the OECD Guideline for the Testing of Chemicals No. 106 was conducted for the metabolites 3HDPM and 2MDPM. Due to low recovery, reliable Freundlich adsorption coefficients and K_{Foc} values could not be determined using the batch equilibrium method for either 3HDPM or 2MDPM. For the metabolite 3HDPM the overall recovery was considered adequate in the preliminary experiment and an acceptable Kd was determined. For both metabolites, mobility studies were available following the OECD Guideline for the Testing of Chemicals No. 121 (HPLC screening method). According to the opinion

SCP/KOC/002-final (European Commission, 2002d), HPLC methods are not appropriate to estimate Koc-values if no Koc values for a range of structurally related test substances are available. This is not the case for these two metabolites and therefore following this pertinent guidance, the studies performed with the HPLC method and the endpoints derived from them, should not be relied on in regulatory exposure assessments. In satisfactory field dissipation studies carried out in Italy, UK, Germany and France (1 in each country, spray application made in May or June to bare soil) pyriofenone exhibited moderate to medium persistence. Sample analyses were only carried out for the parent pyriofenone. The DT_{50} values from the field trials were normalised to FOCUS reference conditions following FOCUS (2006) kinetic guidance[9] and subsequently used in FOCUS groundwater and surface water simulations.

In laboratory incubations in dark aerobic natural sediment water systems, pyriofenone exhibited low to moderate persistence, forming no metabolites above 10 %. The unextractable sediment fraction (not extracted by two times ambient temperature (sonicating), followed by acetonitrile, followed by 1 acid and 2 base ambient temperature extractions, followed by soxhlet reflux) was the major sink for both the phenyl and pyridyl ^{14}C radiolabel in the Calwich Abbey Lake water/sediment system, accounting for 83.9 % AR (phenyl ^{14}C radiolabel) and 84.4 % AR (pyridyl ^{14}C radiolabel) at the study end (100 days). Mineralisation of these radiolabels accounted for only 1.4 % AR (phenyl ^{14}C radiolabel) and 0.4 % AR (pyridyl ^{14}C radiolabel) at the end of the study. The results from the Swiss Lake water/sediment system where the sediment consisted of a high proportion of sand (98 %) did not show as clear results as the Calwich Abbey Lake water/sediment system. The Swiss Lake water/sediment system accounted for 40.6 % AR (phenyl ^{14}C radiolabel) and 56.7 % AR (pyridyl ^{14}C radiolabel) at the study end (100 days). Mineralisation of these radiolabels accounted for 16.8 % AR (phenyl ^{14}C radiolabel) and 1.6 % AR (pyridyl ^{14}C radiolabel) at the end of the study. The rate of decline of pyriofenone in a laboratory aqueous sterile natural water photolysis experiment indicated slow transformation with no metabolites being formed at levels triggering further assessment.

Surface water and sediment exposure assessments (Predicted environmental concentrations (PEC) calculations) were carried out for pyriofenone, using the FOCUS (FOCUS, 2001) step 1, 2 and 3 approaches[10]. For the anaerobic metabolites formed above 10 % (3HDPM and 2MDPM) surface water and sediment exposure assessments (PEC calculations) were carried out, using the FOCUS (FOCUS, 2001) step 1 and 2 approaches. Anaerobic conditions were not considered to commonly occur in vine growing areas. An exposure assessment was therefore only carried out on the cereal representative uses for the anaerobic metabolites. For both metabolites a DT_{50} of 100 days was used in the simulations. This DT_{50} value was not calculated directly from the data but simply selected and shown to be conservative when the metabolites' degradation was fitted with this value and compared to measured concentrations. A formation fraction of 1 was assumed for both metabolites. Adsorption values derived from the HPLC screening method were used in the surface water simulations for the anaerobic metabolites. Regarding the metabolite 3HDPM, an acceptable K_{doc}-value of 506 mL/g was calculated from the preliminary experiment (OECD 106). The preliminary experiment investigated only a single concentration and therefore a 1/n of 1[11] would need to be used in surface water simulations at step 3 and above combined with the K_{doc}-value of 506 mL/g. The K_{doc}-value (506 mL/g) derived from the preliminary test was higher than the K_{doc}-value (384.6 mL/g) derived from the HPLC screening method. The K_{doc}-value derived from the HPLC method was therefore considered to be a worst case value. For metabolite 2MDPM no valid results from mobility studies were available. The available surface water simulations were performed with K_{doc}-value derived from the HPLC screening method. For the two anaerobic metabolites (3HDPM and 2MDPM) the available surface water simulations were considered to be indicative and the input parameters were regarded as sufficient (including the use of the adsorption values derived from HPLC method) for the step 1 and 2 calculations needed to complete the EU-level assessment for the representative uses. The motivation

[9] Normalisation utilised a Q10 of 2.58 (following EFSA PPR, 2007) and Walker equation coefficient of 0.7
[10] Simulations utilised a Q10 of 2.58 (following EFSA PPR, 2007) and Walker equation coefficient of 0.7
[11] FOCUS, 2001, updated by Generic Guidance for Tier 1 FOCUS Ground Water Assessments, Version: 2.1, Date: December 2012, 7.4.8 Exponent of the Freundlich isotherm.

for this is that the metabolites are only relevant under anaerobic conditions and that in the ecotoxicology section the risk to all aquatic organisms was assessed as low. When national authorisation is requested, consideration should be given by individual Member States regarding the importance of anaerobic degradation for the specific use (crop, application timing and area of use). A better adsorption estimate for 2MDPM might be required, when margins of safety on the risk assessment are eroded for the uses being assessed. The data necessary would be soil adsorption estimates following the principles in OECD guideline 106 and also following the advice for labile test substances in the opinion SCP/KOC/002-final (European Commission, 2002d) for 2MDPM.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2000) scenarios and the models PEARL 3.3.3 and PELMO 3.3.2[12] for the active substance pyriofenone and the anaerobic soil metabolites 3HDPM and 2MDPM. Anaerobic conditions were not considered to commonly occur in vine growing areas. An exposure assessment was therefore only carried out on the cereal representative uses for the anaerobic metabolites. For the anaerobic metabolite 3HDPM, a DT_{50} of 20 days and a formation fraction from the parent of 0.8 were used in the simulations. For the anaerobic metabolite 2MDPM, a DT_{50} of 18 days and a formation fraction of 1 from 3HDPM were used in the simulations. These DT_{50} values and formation fractions were not calculated directly from the data but simply selected and shown to be conservative when the metabolites' degradation was fitted with this value and compared to measured concentrations. K_{doc}-values derived from the HPLC screening method were used in the groundwater simulations for the anaerobic metabolites. Regarding the use of these HPLC screening method adsorption estimates, the same considerations already described above regarding the surface water exposure assessment are relevant. The potential for groundwater exposure from the representative uses by pyriofenone in aerobic soils and the metabolites 3HDPM and 2MDPM in anaerobic soils, above the parametric drinking water limit of 0.1 µg/L, was concluded to be low in geo-climatic situations that are represented by all 9 FOCUS groundwater scenarios. For the two anaerobic metabolites (3HDPM and 2MDPM) the available groundwater simulations were considered to be indicative and the input parameters (including the use of the adsorption values derived from HPLC method) were regarded as sufficient to complete the EU-level assessment for the representative uses. The motivation for this is that the metabolites are only relevant under anaerobic conditions and all the simulated concentrations in groundwater were $\leq$ 0.001 µg/L in all 9 FOCUS groundwater scenarios. When national authorisation is requested, consideration should be given by individual Member States regarding the importance of anaerobic degradation for the specific use (crop, application timing and area of use). A better adsorption estimate for 2MDPM might be required, should margins of safety on the groundwater exposure assessment compared to the parametric regulatory limit be eroded, for the uses being assessed. The data necessary would be soil adsorption estimates following the principles in OECD guideline 106 and also following the advice for labile test substances in the opinion SCP/KOC/002-final (European Commission, 2002d) for 2MDPM.

The valid 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 is based on the following documents: European Commission (2002a, 2002b, 2002c), SETAC (2001).

Pyriofenone was discussed at the Pesticides Peer Review Meeting 99 in November 2012.

The risk for birds and mammals, including the risk from secondary poisoning (i.e. for earthworm- and fish-eating birds and mammals), was assessed as low.

[12] Simulations complied with EFSA (EFSA PPR, 2004) and correctly utilised the agreed Q10 of 2.58 (following EFSA PPR, 2007) and Walker equation coefficient of 0.7

Toxicity studies with the active substance and the formulations were available for fish, aquatic invertebrates, sediment-dwelling organisms and algae. Also studies with the metabolites 3HDPM and 2MDPM were available but considered not valid (except a study with 2MDPM on algae) because they failed to meet several validity criteria. The risk to all aquatic organisms was assessed as low for the active substance with PECsw at FOCUS step 3. The risk characterisation for the metabolites was carried out by assuming they are 10 times more toxic than the parent compound combined with FOCUS step 2 exposure estimates. It was noted that there were a number of unidentified metabolites in sediment which sum up to more than 10 % AR. To cover the risk to sediment organisms considering the formation dynamics of the sediment metabolites (both unidentified and identified), the experts at the Pesticides Peer Review Meeting 99 agreed to calculate the TER for these metabolites, by taking into account the FOCUS step 2 PECsw for the parent. Overall, a low risk to aquatic organisms was assessed for all of the metabolites. A concern was raised during the written procedure regarding the bound residues in sediment (*i.e*. the potential accumulation of bound residues in sediment or their potential bioavailability) and that they might theoretically pose a risk to sediment-dwelling organisms. No information was available to address this concern so it could not be excluded that the exposure to bound residues will be lower than the PECsw used to perform the above mentioned risk assessment for sediment-dwellers from exposure to unidentified extractable metabolites. Therefore, EFSA identified a data gap to further consider the risk of bound residues in sediment to sediment-dwelling organisms.

The risk was assessed as low for honeybees, non-target arthropods, earthworms, soil macro- and microorganisms, non-target terrestrial plants and biological methods for sewage treatment plants.

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
Pyriofenone	Medium to high persistence. Single first-order DT_{50lab} 54.9-201 days (20°C and pF2 soil moisture) Biphasic kinetic $DT_{50field}$ 88-209 days (normalised DT_{90}/3.322)	The risk was assessed as low for soil-living organisms
3HDPM[a]	No data available.	The risk was assessed as low for soil-living organisms
2MDPM[a]	No data available.	The risk was assessed as low for soil-living organisms

(a): Relevant only for cereal use (anaerobic metabolites).

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
Pyriofenone	Low to slight mobility. (K_{Foc} = 705-2720 mL/g)	No	yes	Yes	Low risk for aquatic organisms living in surface water

3HDPM[a]	Low mobility. (K_{doc} = 506 mL/g)	No	-	Yes, based on the toxicological properties of the parent, suggesting that it would require classification as Carc. Cat. 2, H351[13]	Low risk for aquatic organisms living in surface water
2MDPM[a]	No data available.	No	-	Yes, based on the toxicological properties of the parent, suggesting that it would require classification as Carc. Cat. 2, H351	Low risk for aquatic organisms living in surface water

(a): Relevant only for cereal use (anaerobic metabolites).

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
Pyriofenone	Low risk for aquatic organisms living in surface water
3HDPM[a]	Low risk for aquatic organisms living in surface water
2MDPM[a]	Low risk for aquatic organisms living in surface water

(a): Relevant only for cereal use (anaerobic metabolites).

6.4. Air

Compound (name and/or code)	**Toxicology**

[13] 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 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, p. 1-1355.

Pyriofenone	Rat LC_{50} inhalation > 5.18 mg/L air per 4h (nose-only), no classification required

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

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

- Further information/data to confirm the identity of two impurities to fully support the provisional specification (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- The relevance of the impurities present in the technical specification needs to be addressed, except for the one impurity for which an acute oral study and an Ames test were provided (relevant for the representative uses evaluated; submission date proposed by the applicant: unknown; see section 2).
- Additional supervised residue trials on barley to complete the data set in southern EU (relevant for use in barley; submission date proposed by the applicant: unknown; see section 3).
- To further consider the risk of bound residues in sediment to sediment-dwelling organisms (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).

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

- None

9. Concerns

9.1. Issues that could not be finalised

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

- None

9.2. Critical areas of concern

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

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

- None

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

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

Representative uses		**All representative uses**
Operator risk	Risk identified	
	Assessment not finalised	
Worker risk	Risk identified	
	Assessment not finalised	
Bystander risk	Risk identified	
	Assessment not finalised	
Consumer risk	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial vertebrates	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	
Groundwater exposure active substance	Legal parametric value breached	
	Assessment not finalised	
Groundwater exposure metabolites	Legal parametric value breached	
	Parametric value of 10µg/L[(a)] breached	
	Assessment not finalised	
Comments/Remarks		

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2. Where there is no superscript number see sections 2 to 6 for further information.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

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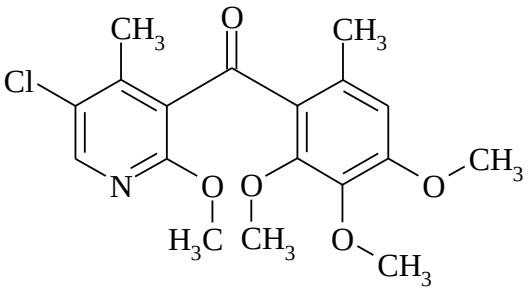
APPENDICES

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) ‡	Pyriofenone
Function (*e.g.* fungicide)	Fungicide
Rapporteur Member State	UK
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	(5-chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-*o*-tolyl)methanone
Chemical name (CA) ‡	(5-chloro-2-methoxy-4-methyl-3-pyridinyl) (2,3,4-trimethoxy-6-methylphenyl)methanone
CIPAC No ‡	827
CAS No ‡	688046-61-9
EC No (EINECS or ELINCS) ‡	Not allocated
FAO Specification (including year of publication) ‡	Not allocated
Minimum purity of the active substance as manufactured ‡	965g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Open
Molecular formula ‡	$C_{18}H_{20}NO_5Cl$
Molecular mass ‡	365.8 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	93 -95 °C (99.19%)

Boiling point (state purity) ‡	Not determinable
Temperature of decomposition (state purity)	Decomposes >100°C (99.19%)
Appearance (state purity) ‡	White crystalline powder (99.19%) White powder (97.88%)
Vapour pressure (state temperature, state purity) ‡	1.9 x 10^{-6} Pa at 25°C (99.19%)
Henry's law constant ‡	1.9 x 10^{-4} $Pa.m^3mol^{-1}$
Solubility in water (state temperature, state purity and pH) ‡	1.56 mg/L at 20°C (99.19%, pH 6.6)
Solubility in organic solvents ‡ (state temperature, state purity)	Solubilities at 20 °C (97.88%):

Solvent	Solubility (g/L)
heptane	9.2
xylene	>250
1,2-dichloroethane	>250
acetone	>250
methanol	23.6
octanol	17.8
ethyl acetate	>250

Surface tension ‡ (state concentration and temperature, state purity)	72.0 mN/m at 20°C. (90 % saturated solution) (99.19%)
Partition co-efficient ‡ (state temperature, pH and purity)	log $P_{O/W}$ = 3.2 at 20 °C (pH 7.2 – 7.5) (99.19%)
Dissociation constant (state purity) ‡	pKa : Not reported. No ionisable proton is expected, but there is some evidence that pyridinyl N is weakly basic (Molecular Orbital calculations and soil sorption behaviour).
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Solution: purified water (neutral pH) λ_{max} 298 (nm); ε 495 ($L.mol^{-1}.cm^{-1}$)
Flammability ‡ (state purity)	Not highly flammable (97.88%)
Explosive properties ‡ (state purity)	Not explosive (97.88%)
Oxidising properties ‡ (state purity)	Not oxidising (97.88%)

Summary of representative uses evaluated (pyriofenone)*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/max (k)	interval between applications (min)	g as/hL min-max (l)	Water L/ha min-max	kg as/ha min-max (l)		
Wheat, rye (TRZAW TRZAS SECCW SECCS)	Northern and Southern Europe	IKF-309 180SC	F	Powdery mildew (*Blumeria graminis)*	SC	180 g/l	Tractor mounted/ trailed boom sprayer fitted with hydraulic nozzles	BBCH 49/50 or 65 spring-summer (at last application)	max 2	According to BBCH	45	200 - 300	0.090	BBCH 65	
Barley, Spelt, Oats, Triticale (HORVW HORVS TRZSP AVESS TTLSO TTLSS TTLWI)	Northern and Southern Europe	IKF-309 180SC	F	Powdery mildew (*Blumeria graminis)*	SC	180 g/l	Tractor mounted/ trailed boom sprayer fitted with hydraulic nozzles	BBCH 49/50 spring-summer (at last application)	max 2	According to BBCH	18 - 45	200 - 300	0.090	BBCH 49/50	
Grapes VITVI	Northern and Southern Europe	IKF-309 300SC	F	Mildew (*Erysiphe necator)*	SC	300 g/l	Tractor mounted/ trailed vineyard air blast sprayer	BBCH 85 summer (at last application)	max 3	14 days	9 - 13	700 - 1000	0.090	28	

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s). (a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure) (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I) (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989 (f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).** (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application (k) Indicate the minimum and maximum number of application possible under practical conditions of use (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha (m) PHI - minimum pre-harvest interval

Methods of Analysis

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

Technical as (analytical technique)	HPLC-UV (DAD); quantification at 220nm
Impurities in technical as (analytical technique)	See confidential Volume 4 of the DAR, p.17
Plant protection product (analytical technique)	HPLC-UV (DAD); quantification at 235nm

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Pyriofenone
Food of animal origin		Not required, considering the representative uses
Soil		Pyriofenone
Water	surface	Pyriofenone
	drinking/ground	Pyriofenone
Air		Pyriofenone

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Pyriofenone residues in plant and plant products (wheat grain, wheat straw, grape, and cabbage head) were extracted with acidified acetonitrile; residues in oilseed rape (seed) were extracted with acetone. The resulting extracts were cleaned up using SPE and analysed by LC-MS/MS, monitoring for the precursor ion m/z 366 and the product ion m/z 184 (and 209 for confirmation). Wheat and grape were validated on a HPLC-MS/MS system using a C8 column; cabbage and oilseed rape on a UPLC-MS/MS system using a C18 column. Limit of determination for all commodities was 0.01 mg/kg. Acceptable validation and ILV data were submitted.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	No method was submitted or required as positive residues of pyriofenone are unlikely to occur in animal products, based on animal metabolism studies and the residue levels in crops.
Soil (analytical technique and LOQ)	Pyriofenone residues in soil were determined by extraction with acidified acetonitrile and the resulting extracts cleaned up using SPE and analysed by HPLC-MS/MS monitoring for the precursor ion m/z 366 and the product ion m/z 184 [and 209 for confirmation], using a Intersil ODS-3 column. Limit of determination was 0.001 mg/kg. Acceptable validation data were submitted.

Water (analytical technique and LOQ)	Pyriofenone residues in water were determined by adding acetonitrile to the samples and analysing the resulting solution by HPLC-MS/MS monitoring for the precursor ion m/z 366 and the product ion m/z 184 [and 209 for confirmation], using a C8 column. The limit of determination was 0.05 µg/l. Acceptable validation data were submitted.
Air (analytical technique and LOQ)	Pyriofenone residues in air were determined by drawing air through a Tenax adsorption tube and extracting the tube with acetonitrile. The resulting extracts were analysed by HPLC-MS/MS monitoring for the precursor ion m/z 366 and the product ion m/z 184 [and 209 for confirmation], using a C8 column Limit of determination was 18 µg/m^3. Acceptable validation data were submitted.
Body fluids and tissues (analytical technique and LOQ)	In support of therapeutic and diagnostic regimes, no methods of analysis were submitted or required as pyriofenone is not classified as toxic.

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

	RMS proposal
Active substance	No classification required

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Rapidly absorbed (> 80%) and extensively metabolised at low dose levels
Distribution ‡	Widespread with the highest levels in liver, kidney, whole blood and abdominal fat
Potential for accumulation ‡	Some evidence of accumulation mainly in RBC following repeat dosing but inconclusive
Rate and extent of excretion ‡	Rapid excretion
Metabolism in animals ‡	Demethylation of the methoxy groups at the 3- and/or 4- positions on the benzene ring followed by glucuronide conjugation
Toxicologically relevant compounds ‡ (animals and plants)	Pyriofenone
Toxicologically relevant compounds ‡ (environment)	Pyriofenone

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 2000 mg/kg bw	
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 5.18 mg/L air per 4-hour (nose-only)	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Slight irritant	
Skin sensitisation ‡	Negative in a mouse LLNA	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Rat: increased liver weight and reduced ALT activity in males; prolonged APTT and reduced bilirubin in females Mouse: increased liver weight Dog: increased alkaline phosphatase activity, reduced APTT and increased liver and kidney weight	
Relevant oral NOAEL ‡	90-day, rat: 17.9 mg/kg bw per day 90-day, mouse: 61 mg/kg bw per day 90-day, dog: 15 mg/kg bw per day 1-year, dog: 13.7 mg/kg bw per day	
Relevant dermal NOAEL ‡	28-day, rat: 300 mg/kg bw per day, based on prolonged APTT (also seen in oral studies)	

Relevant inhalation NOAEL ‡	No data-not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

	Based on the negative results from a mouse micronucleus study and rat UDS assay, it is concluded that pyriofenone did not exhibit any genotoxic or clastogenetic potential *in vivo*	

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

Target/critical effect ‡	Rat: significant changes in the prothrombin time, increased incidence/severity of chronic nephropathy Male mice: liver toxicity at all dose levels tested (liver masses, hepatocellular hypertrophy of unknown aetiology and hepatocyte necrosis) and cortical mineralisation in kidneys Female mice: granular kidney and chronic progressive nephropathy	
Relevant NOAEL ‡	7.25 mg/kg bw per day; 2-year rat Male mice: LOAEL 77.6 mg/kg bw per day, Female mice: 167 mg/kg bw per day; 18-month mouse	
Carcinogenicity ‡	Rat: increased combined incidence of hepatocellular adenoma and carcinoma in males at 197 mg/kg bw per day (associated with reduced male survival) NOAEL for carcinogenity: 36.4 mg/kg bw per day No treatment-related carcinogenic effect observed in mice	Cat 2 (CLP)

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental: haematological changes, gross findings (dark coloured livers and distension of the large intestine), and increased organ weights and histopathological findings in the liver, kidneys and thyroid Reproduction: no specific effects on fertility Offspring: reduced pup weights and reduced spleen weights	

Relevant parental NOAEL ‡	64.1 mg/kg bw per day	
Relevant reproductive NOAEL ‡	334 mg/kg bw per day	
Relevant offspring NOAEL ‡	64.1 mg/kg bw per day	

Developmental toxicity

Developmental target / critical effect ‡	Rat: Maternal: increased organ weights (liver & caecum). Developmental: increased incidence of skeletal variations) Rabbit: Maternal: abortions and reduced food consumption. Developmental: decrease in thymic remnants in foetuses.	
Relevant maternal NOAEL ‡	Rat: 30 mg/kg bw per day Rabbit: 100 mg/kg bw per day	
Relevant developmental NOAEL ‡	Rat: 30 mg/kg bw per day Rabbit: 100 mg/kg bw per day	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	Rat: no neurological effects up to 2000 mg/kg bw (highest dose tested) General toxicity: NOAEL of 500 mg/kg bw per day (based on palpebral closure, body tone and piloerection at 2000 mg/kg bw per day).	
Repeated neurotoxicity ‡	90-day rat: no neurological effects up to 927 and 1147 in males and females, respectively (highest dose levels tested) General toxicity: NOAEL of 62 mg/kg bw per day (based on reduced body weight in males at 310 mg/kg bw per day	
Delayed neurotoxicity ‡	No data-not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Mechanistic studies were performed in rats and mice on hepatic enzyme induction and cell proliferation. These studies are considered to be insufficient to demonstrate that pyriofenone induces liver tumours in rats by a phenobarbitone-like mechanism.
Studies performed on metabolites or impurities ‡	**Metabolite 4HDPM**: Rat LD_{50} oral > 2000 mg/kg bw Negative Ames test

Medical data ‡ (Annex IIA, point 5.9)

No evidence of adverse effects in manufacturing plant personnel.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.07 mg/kg bw per day	rat, 2-year study	100
AOEL ‡	0.15 mg/kg bw per day	dog, 90-day & 1-year studies; supported by 90-day rat study	100
ARfD ‡	Not required	-	-

Dermal absorption ‡ (Annex IIIA, point 7.3)

IKF-309 180SC (180 g/L SC)	Concentrate: 0.3% Spray dilutions:12% Based on *in vitro* data for human skin
IKF-309 300SC (300 g/L SC)	Concentrate: 0.2% Spray dilutions: 6% Based on *in vitro* data for human skin

Exposure scenarios (Annex IIIA, point 7.2)

Operator	IKF-309 180SC. The following levels of exposure are predicted for operators without PPE. Application rate: 90 g pyriofenone/ha (cereals)		
	Application method	Model	% of AOEL

	Field crop sprayer	German Model	4%
		UK POEM	26%
	IKF-309 300SC. The following levels of exposure are predicted for operators without PPE. Application rate: 90 g pyriofenone/ha (grapes)		
	Application method	Model	% of AOEL
	Broadcast air-assisted sprayer	German Model	5%
		UK POEM	11%
	Knapsack sprayer	German Model	3%
		UK POEM	18%
Workers	IKF-309 180SC. Estimates using the EUROPOEM worker re-entry model predict a level of systemic exposure equivalent to 7% of the AOEL for an unprotected worker inspecting a treated cereal crop.		
	IKF-309 300SC. Estimates using the EUROPOEM worker re-entry model predict a level of systemic exposure equivalent to 19% of the AOEL for an unprotected worker harvesting treated grapes.		
Bystanders	IKF-309 180SC. The following levels of exposure are predicted for unprotected bystanders.		
	Model/data	% of AOEL	
	Surrogate vapour exposure calculations (Siebers *et al*)	0.4%	
	Measurements of simulated bystander exposure to spray drift (Lloyd *et al* 1983)	0.09%	
	Children's exposure to drift fallout (US EPA)	0.07%	
	IKF-309 300SC. The following levels of exposure are predicted for unprotected bystanders.		
	Model/data	% of AOEL	
	Surrogate vapour exposure calculations (Californian EPA)	6%	
	Measurements of simulated bystander exposure to spray drift (Lloyd *et al* 1987)	0.3%	
	Children's exposure to drift fallout (US EPA)	0.4%	

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

	RMS/peer review proposal[14]
Pyriofenone	Directive 67/548/EEC Limited evidence of a carcinogenic effect (Carc Cat 3, R40) Regulation (EC 1272/2008) Suspected of causing cancer (Cat 2, H351)
	Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation): Currently not available

[14]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 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.

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

Plant groups covered	Cereals (wheat) Fruit crops: (grape and tomato) Foliar applications
Rotational crops	Cereals (wheat), leafy crop (lettuce) and root/tuber crop (carrot). Re-plant intervals of 31, 122, and 364 days.
Metabolism in rotational crops similar to metabolism in primary crops?	Yes. A general decrease in pyriofenone and metabolite levels was noted.
Processed commodities	Pyriofenone stable under standard hydrolysis conditions simulating pasteurisation, baking/boiling and sterilisation
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes. No significant new metabolites arise from processing (grapes).
Plant residue definition for monitoring	Pyriofenone
Plant residue definition for risk assessment	Pyriofenone
Conversion factor (monitoring to risk assessment)	None

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

Animals covered	Lactating ruminant (goat)
Time needed to reach a plateau concentration in milk and eggs	3 days (goat milk). Eggs not studied and not required.
Animal residue definition for monitoring	Not required, considering the representative uses (Provisionally, EFSA proposal: pyriofenone for ruminant products).
Animal residue definition for risk assessment	Not required, considering the representative uses (Provisionally, EFSA proposal: "sum of pyriofenone and 2MDPM (free and conjugated)" for ruminant products).
Conversion factor (monitoring to risk assessment)	Not required
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No. <0.01% TRR for 10 mg/day dose

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

Confined rotational crop study performed with a single application on bare soil at 284 g a.s./ha (1.6N cereal GAP), equivalent to 2.4 times the plateau concentration in soil reached after 5 years of consecutive applications.

- Cereal (wheat) grain:
  <0.01mg/kg (TRR) all re-plant intervals.
- Leafy crops (lettuce):
  <0.01mg/kg (TRR) 31 and 122 day re-plant intervals (365 days not studied).
- Root crops (carrot):
  upto 0.029 mg/kg pyriofenone for early harvest root (122 day re-plant interval).

No field trials submitted.

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

Stable in wheat grain, wheat straw and grape for at least 12 months at approximately -20°C.

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

	Ruminant	**Poultry**	**Pig:**
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	**Yes** 0.4 mg/kg (dry matter)	**No** 0.008 mg/kg (dry matter)	**No** 0.009 mg/kg (dry matter)
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues	No	Not studied	Not studied
	Feeding studies were not required. Based on dietary intakes and goat metabolism data, residues in products of animal origin are not expected to be >0.01 mg/kg.		
Muscle	n/a	n/a	n/a
Liver	n/a	n/a	n/a
Kidney	n/a	n/a	n/a
Fat	n/a	n/a	n/a
Milk	n/a		
Eggs		n/a	

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

Crop	Northern or Southern Region field or glasshouse	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to representative use	HR (c)	STMR (b)
Wheat	Northern	Grain: 11x <0.01 Straw: <0.01, 0.02, 0.04, 0.05, 2x 0.07, 0.08, 0.12, 0.29, 0.33, 0.66	Additional trials not requested in SEU (wheat major crop) as all values are below the LOQ (<0.01 mg/kg)	**0.01**	0.01 0.66	0.01 0.07
	Southern	Grain: 4x <0.01 Straw: 0.04, 0.08, 0.10, 0.15			0.01 0.15	0.01 0.09
Barley	Northern	Grain: 8x <0.01, 2x 0.01, 0.02 Straw: 0.01, 2x 0.02, 2x 0.05. 0.07, 2x 0.12, 0.18, 0.25, 0.48	Provisional MRL derived from the merged data sets: R_{ber}: 0.02; R_{max}: 0.02	**0.03** (provisional)	0.02 0.48	0.01 0.07
	Southern	Grain: 2x <0.01, 0.01, 0.02 Straw: 0.08, 0.09, 0.18, 0.32	As barley is a major crop in SEU, additional trials are requested		0.02 0.32	0.01 0.14
Grape	Northern	2x 0.05, 0.06, 0.07, 0.08, 2x 0.10, 0.14	NEU and SEU data sets similar (U-test, 5%). MRL derived from the merged data sets: R_{ber}: 0.20 R_{max}: 0.16 STMR: 0.08 HR: 0.14	**0.2**	0.14	0.08
	Southern	0.02, 2x 0.03, 0.04, 0.06, 0.08, 0.10, 2x 0.11			0.11	0.06

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 2x 0.1, 2x 0.15, 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

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

ADI	0.07 mg/kg bw per day
TMDI (% ADI) according to EFSA PRIMo model	Highest TMDI: 1% (FR, all population)
TMDI (% ADI) according UK model v1.1	Highest TMDI: 3% (Adults & Vegetarians) No processing factors used.
IEDI (% ADI) according to EFSA PRIMo model	Highest EIDI: 0.5% (FR, all population)
NEDI (% ADI) according UK model v1.1	Highest EIDI: <1% (Adults & Vegetarians in UK)
Factors included in IEDI and NEDI	STMR for grapes (0.08 mg/kg) and for cereals (0.01 mg/kg). No processing factors used.
ARfD	ARfD not required.
IESTI (% ARfD)	-
NESTI (% ARfD) according to national	-
Factors included in IESTI and NESTI	-

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

Crop/processed product	Number of studies	Processing factors		Amount transferred (%)
		Transfer factor (individual values)	Yield factor	
Grape/Young wine (Red and white wine processing)	**4**[a]	**0.09** (0.04; 0.08; 0.10; 0.11)		
Grape/Aged wine (Red and white wine processing)	**4**[a]	**0.09** (0.04; 0.08; 0.10; 0.15)		
Grape/Juice (filtered/pasteurised) (white & red grapes)	**4**[a]	**0.08** (0.04; 0.07; 0.08; 0.10)		
Grape/Raisin (white and red grape)	6[b]	**2.9** (range: 1.5 to 5.0)		

[a]: Additional studies with residue levels in RAC close to the LOQ not taken into account.
[b]: 6 studies (1N and 3N dose rates in 2 studies leading to a total of 8 individual values)

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

Wheat grain (extrapolated to rye and triticale)	0.01* mg/kg
Barley grain (extrapolated to oats)	0.03 mg/kg (provisional)
Grapes	0.2 mg/kg

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

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

Mineralization after 100 days ‡	26.5 % after 364 d, [^{14}C-(phenyl)]-label (n = 1) 15.2 % after 364d, [^{14}C-(pyridyl)]-label (n = 1) Sterile conditions: 1 % after 30 d [^{14}C-(phenyl)]-label (n = 1) <0.1% after 30 d [^{14}C-(pyridyl)]-label (n = 1)
Non-extractable residues after 100 days ‡	30.2 % after 364 d, [^{14}C-(phenyl)]-label (n= 1) 33.3 % after 364 d, [^{14}C-(pyridyl)]-label (n= 1) Sterile conditions: 1.4 % after 30 d [^{14}C-(phenyl)]-label (n = 1) 1.3% after 30 d [^{14}C-(pyridyl)]-label (n = 1)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	No metabolites requiring further consideration

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

Anaerobic degradation ‡	
Mineralization after 100 days	0.2% after 60 d, [^{14}C-(phenyl)]-label (n= 1) Not detected after 120 d, [^{14}C-(pyridyl)]-label (n= 1) Sterile conditions: Not tested
Non-extractable residues after 100 days	88.1 % after 120 d, [^{14}C-(phenyl)]-label (n= 1) 91%% after 120 d, [^{14}C-(pyridyl)]-label (n= 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	2MDPM = 22.5 % at 15 d [^{14}C-(pyridyl)]-label (n= 1) 3HDPM = 32.0 % at 3 d [^{14}C-(pyridyl)]-label (n= 1)
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No metabolites were formed in significant quantities and none require consideration for a risk assessment.

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

Parent	Aerobic conditions						
Soil type	X[15]	pH $CaCl_2$	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (Chi-square)	Method of calculation
Sandy loam (Calke)		5.4	20 °C / pF2	201/667	201	4.0	SFO#
				186/830	186	2.1	DFOP#
Sandy loam (Bromsgrove)		4.4	20 °C / pF2	92.1/306	92.1	2.4	SFO
Clay loam (Evesham 3)		7.0	20 °C / pF2	67.7/225	67.7	3.7	SFO
Clay loam – 20°C (Elmton)		7.2	20 °C / pF2	54.9/182	54.9	0.9	SFO
Clay loam – 10°C (Elmton)		7.2	10 °C / pF2	149/494	57.7	2.6	SFO
Geometric mean (SFO fits only)				91.1/302*	91.1*		

= The SFO fit was accepted to derive endpoints for modelling and the DFOP fit was accepted to derive endpoints for triggers.

* = The geometric mean is of the SFO values only, it does not include the DFOP value for triggers. Soils incubated at 10°C were not included in the geometric mean calculation.

Field studies ‡

Parent	Aerobic conditions									
Soil type (United Kingdom).	Location (country or USA state).	X[1]	pH ($CaCl_2$)	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (Chi^2)	DT_{50} (d) Norm.	Method of calculation	Pseudo DT50 (d) for modelling (normalised DT90/3.322)

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

Clay loam (bare soil)	Italy		7.39	30	32.8	1983	15.2	93	SFO (normalised) FOMC (unnormalised)	93
Clay loam (bare soil)	UK		6.57	30	21.6	509	26.9	14.9	FOMC	88
Silt clay loam (bare soil)	Germany		7.39	30	11.2	413	15.4	10.4	FOMC	109
Clay loam (bare soil)	France		6.76	30	10.5	2415	27.5	21	FOMC	209
Geometric mean/median					17.0/ 16.4	1002/ 1246		23.5/ 18.0		116.9
Met 1	Aerobic conditions									
Soil type	Location		pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (r2)	DT_{50} (d) Norm.	Method of calculation	
Sandy loam										
Silty clay loam										
Geometric mean/median										

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	Plateau concentration of 0.134 mg/kg reached after 5 years application of 3 x 90 g/ha per annum (vines). 60% interception at each application was assumed. Plateau concentration of 0.070 mg/kg reached after 5 years application of 2 x 90 g/ha per annum (cereals). A conservative 50% interception was assumed for each application.

Laboratory studies ‡

Parent	Anaerobic conditions – total soil and water system							
Soil type	X[16]	pH $CaCl_2$	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa		St. (Chi-square)	Method of calculation
Sandy loam ^{14}C-(phenyl)- and ^{14}C-(pyridyl)-IKF-309		5.3	20 °C / flooded soil	1.60/5.31	1.60		19.2	SFO
Geometric mean				1.60/5.31	1.60			
3HDPM	Anaerobic conditions – total soil and water system							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	Chi-square	Method of calculation
2MDPM	Anaerobic conditions – total soil and water system							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	Chi-square	Method of calculation

* = Not calculated. In the groundwater modelling a conservative formation fraction from parent to 3HDPM of 0.8, and from 3HDPM to 2MDPM of 1, was used.

= In the surface water modelling conservative soil DT50 values of 100 days were used for both metabolites and in the groundwater modelling soil DT50 values of 20 days (3HDPM) and 18 days (2MDPM) were used. Those formation fractions and DT50 values were not calculated directly from the data but simply selected through a manual iterative procedure and shown to be conservative when the metabolite degradation was fitted with these values and compared to measured concentrations.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH $CaCl_2$	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam	0.7	4.6	-	-	12.9	1840	0.98
Sandy loam	3.5	5.4	-	-	33.3	951	0.86
Sandy clay loam	4.3	7.0	-	-	30.3	705	0.88
Clay loam	1.6	7.3	-	-	19.4	1210	0.91
Loamy sand	0.5	4.3	-	-	13.6	2720	0.91
Arithmetic mean/median					21.9/ 19.4	1485/ 1210	0.91/ 0.91
pH dependence, Yes or No			Yes				

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

Metabolite 1 ‡ 3HDPM							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
7	4.2	7	21.3	506			1[#]
Arithmetic mean/median						-	
pH dependence (yes or no)			-				

Metabolite 2 ‡ 2MDPM							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Arithmetic mean/median						-	
pH dependence (yes or no)			-				

The preliminary experiment investigated only a single concentration and therefore a 1/n of 1 would need to be used in surface water and groundwater simulations combined with the Koc-value of 506 mL/g.

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

Column leaching ‡	Not carried out
Aged residues leaching ‡	Not carried out
Lysimeter/ field leaching studies ‡	Not carried out
Parent Method of calculation	DT_{50} (d): 201 days Kinetics: SFO Representative worst case from lab and field studies.
Application data	Crop: Cereals Depth of soil layer: 5 cm. Soil bulk density: 1.5 g/cm^3 % plant interception: 1st application = 50% 2nd application = 90% Number of applications: 2 Interval (d): 14 days Application rate(s): 90 g as/ha A tillage depth of 5.0 cm was considered for calculating the background concentration. ESCAPE, program version 1.0 (Estimation of soil Concentrations After Pesticide application) was used for the calculations.

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.0694	
Short term	24h			0.0691	0.0693
	2d			0.0689	0.0691
	4d			0.0684	0.0689
Long term	7d			0.0677	0.0685
	14d			0.0661	0.0677
	21d			0.0645	0.0669
	28d			0.0630	0.0661
	42d			0.0600	0.0647
	50d			0.0584	0.0638
	100d			0.0491	0.0598

Accumulation PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.0969	
Short term	24h			0.0966	0.0968
	2d			0.0964	0.0966
	4d			0.0959	0.0964
Long term	7d			0.0952	0.0961
	14d			0.0936	0.0952
	21d			0.0920	0.0944
	28d			0.0905	0.0937
	42d			0.0875	0.0922
	50d			0.0859	0.0913
	100d			0.0767	0.0873

Application data

Crop: Vines
Depth of soil layer: 5 cm.
Soil bulk density: 1.5 g/cm^3
% plant interception:
1st application = 60%
2nd application = 60%
3rd application = 60%
Number of applications: 3
Interval (d): 14 days
Application rate(s): 90 g a.s/ha
A tillage depth of 5.0 cm was considered for calculating the background concentration
ESCAPE, program version 1.0 (Estimation of soil Concentrations After Pesticide application) was used for the calculations.

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.1375	
Short term	24h			0.1370	0.1372
	2d			0.1365	0.1370
	4d			0.1356	0.1365
Long term	7d			0.1342	0.1358
	14d			0.1310	0.1342
	21d			0.1279	0.1326
	28d			0.1248	0.1310
	42d			0.1189	0.1280
	50d			0.1157	0.1263
	100d			0.0974	0.1164

Accumulation PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.1920	
Short term	24h			0.1915	0.1918
	2d			0.1911	0.1915
	4d			0.1901	0.1911
Long term	7d			0.1887	0.1904
	14d			0.1855	0.1887
	21d			0.1824	0.1871
	28d			0.1794	0.1856
	42d			0.1735	0.1825
	50d			0.1702	0.1808
	100d			0.1519	0.1710

Metabolite I – 3HDPM Method of calculation	Molecular mass: 351.79 g/mol Molecular weight relative to the parent: 0.96 DT_{50} (d): 100 days (the DT50 value was not calculated directly from the data but simply selected and shown to be conservative when the metabolite degradation was fitted using that value and compared to measured concentrations). Kinetics: SFO Field or Lab: Conservative value selected to address uncertainty in kinetic fitting of laboratory data.
Application data	Application rate assumed: 2 x 90 g a.s/ha % plant interception: 1st application = 50% 2nd application = 90% 3HDPM is formed at a maximum of 32 % of the applied dose. A tillage depth of 5.0 cm was considered for calculating the background concentration ESCAPE, program version 1.0 (Estimation of soil

	Concentrations After Pesticide application) was used for the calculations. The metabolites are calculated as sequence, pyriofenone → 3HDPM → 2MDPM.

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			0.0055	
Short term 24h			0.0055	0.0055
2d			0.0055	0.0055
4d			0.0055	0.0055
Long term 7d			0.0055	0.0055
14d			0.0055	0.0055
21d			0.0055	0.0055
28d			0.0055	0.0055
42d			0.0054	0.0055
50d			0.0054	0.0055
100d			0.0051	0.0055

Accumulation PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			0.0099	
Short term 24h			0.0099	0.0099
2d			0.0099	0.0099
4d			0.0099	0.0099
Long term 7d			0.0099	0.0099
14d			0.0099	0.0099
21d			0.0099	0.0099
28d			0.0099	0.0099
42d			0.0098	0.0099
50d			0.0098	0.0099
100d			0.0094	0.0099

Metabolite II – 2MDPM Method of calculation	Molecular mass: 337.76 g/mol Molecular weight relative to the parent: 0.92 DT_{50} (d): 100 days (the DT_{50} value was not calculated directly from the data but simply selected and shown to be conservative when the metabolite degradation was fitted using that value and compared to measured concentrations). Kinetics: SFO Field or Lab: Conservative value selected to address uncertainty in kinetic fitting of laboratory data.
Application data	Application rate assumed: 2 x 90 g a.s/ha % plant interception: 1st application = 50% 2nd application = 90% 2MDPM is formed at a maximum of 22.5 % of the applied dose) A tillage depth of 5.0 cm was considered for

	calculating the background concentration ESCAPE, program version 1.0 (Estimation of soil Concentrations After Pesticide application) was used for the calculations. The metabolites are calculated as sequence, pyriofenone → 3HDPM → 2MDPM.

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.0010	
Short term	24h			0.0010	0.0010
	2d			0.0010	0.0010
	4d			0.0010	0.0010
Long term	7d			0.0010	0.0010
	14d			0.0010	0.0010
	21d			0.0010	0.0010
	28d			0.0010	0.0010
	42d			0.0010	0.0010
	50d			0.0010	0.0010
	100d			0.0009	0.0010

Accumulation PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.0020	
Short term	24h			0.0020	0.0020
	2d			0.0020	0.0020
	4d			0.0020	0.0020
Long term	7d			0.0020	0.0020
	14d			0.0020	0.0020
	21d			0.0020	0.0020
	28d			0.0020	0.0020
	42d			0.0020	0.0020
	50d			0.0020	0.0020
	100d			0.0019	0.0020

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 4: No degradation at 50 °C
	pH 7: No degradation at 50 °C
	pH 9: No degradation at 50 °C
Photolytic degradation of active substance and metabolites above 10 % ‡	DT_{50} : 261 hours in purified water Natural light, 40°N; DT_{50} 33 days No metabolites occurred above 10% AR
Quantum yield of direct phototransformation in water at Σ > 290 nm	6.38 $\times 10^{-5}$ molecules degraded per photon.
Readily biodegradable ‡ (yes/no)	No.

Degradation in water / sediment

Parent	Distribution (Max. sed 55.8 % after 2 d)								
Water / sediment system	Label	pH water phase	pH sed	t. °C	DT_{50}/DT_{90} whole sys.	St. (Chi^2)	DT_{50}-DT_{90} water	DT_{50}- DT_{90} sed	Method of calculation
Calwich Abbey	^{14}C-(phenyl)-	8.26	7.2	20°C	5.5/18.4	11.6	Not calculated	Not calculated	SFO
Calwich Abbey	^{14}C-(pyridyl)-	8.26	7.2	20°C	4.5/15.0	12.7	Not calculated	Not calculated	SFO
Swiss Lake	^{14}C-(phenyl)-	5.80	4.9	20°C	13.8/46.0	13.8	Not calculated	Not calculated	SFO
Swiss Lake	^{14}C-(pyridyl)-	5.80	4.9	20°C	14.5/48.3	8.6	Not calculated	Not calculated	SFO
Geometric mean[#]					8.4/28.0				

[#] = Geometric mean of label positions from each system taken first before calculating overall geometric mean.

Mineralization and non extractable residues						
Water / sediment system	Radio label position	pH water phase	pH sed	Mineralization x % after n d.	Non-extractable residues in sed. Max x % after n d	Non-extractable residues in sed. Max x % after n d (end of the study)
Calwich Abbey	^{14}C-(phenyl)-	8.26	7.7	1.4% after 100 days (end of study)	83.9% after 100 days	83.9% at end of study
Calwich Abbey	^{14}C-(pyridyl)	8.26	7.7	0.4% after 100 days (end of study)	84.4% after 100 days	84.4% at end of study
Swiss Lake	^{14}C-(phenyl)	5.80	6.0	16.8% after 100 days (end of study)	45.2% after 60 days	40.6% at end of study
Swiss Lake	^{14}C-(pyridyl)	5.80	6.0	1.6% after 100 days (end of study)	56.7% after 100 days	56.7% at end of study

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

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 1.1 Molecular weight (g/mol): 365.8 Water solubility (mg/L): 1.56 K_{OM}/ K_{OC} (L/kg): 408.9/705 DT_{50} soil (d): 117 days (geomean field value. In accordance with FOCUS, SFO + pseudo SFO) DT_{50} water/sediment system (d): 8.4 (geometric mean from sediment water studies) DT_{50} water (d): 1000 (default) DT_{50} sediment (d): 8.4 (whole system) Crop interception (%): 50 (cereals) 50 (vines, early) 70 (vines, late) Application timing: March-May (Cereals) June to September (Cereals) March-May (Early applications, Vines) June-Sept (Late applications, Vines) October-Feb (Late applications, Vines)
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: 1.1 Vapour pressure: 1.90 x 10^{-6} Kom/Koc: 408.9/705 1/n: 0.88
Application rate	Crop: spring and winter cereals Crop interception: Calculated by model Number of applications: 2 Interval (d): 14 Application rate(s): 90 g as/ha Application window: Scenario specific depending on harvest date.
Application rate	Crop: vines Crop interception: Calculated by model Number of applications: 3 Interval (d): 14 Application rate(s): 90 g as/ha Application window: 1 April – 29 May (early applications) Between 86 days prior to harvest and 28 days prior to harvest (late applications)

Spring and Winter Cereals

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	32.6		218.0	
	24 h	29.3	30.9	206.3	212.2
	2 d	27.0	29.5	190.0	205.1
	4 d	22.9	27.2	161.1	190.1
	7 d	17.8	24.2	125.8	169.8
	14 d	10.0	18.9	70.6	132.7
	21 d	5.62	15.1	39.6	106.3

	28 d	3.15	12.4	22.2	87.3
	42 d	0.99	8.89	7.00	62.6

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	3.58		23.4	
	24 h	3.45	3.52	22.4	22.9
	2 d	3.32	3.45	21.5	22.4
	4 d	3.06	3.32	19.9	21.6
	7 d	2.72	3.13	17.7	20.4
	14 d	2.06	2.76	13.4	17.9
	21 d	1.57	2.44	10.2	15.8
	28 d	1.19	2.17	7.71	14.1
	42 d	0.68	1.75	4.44	11.4
Southern EU	0 h	6.48		43.8	
	24 h	6.35	6.41	41.2	42.5
	2 d	6.10	6.32	39.6	41.5
	4 d	5.64	6.09	36.6	39.8
	7 d	5.01	5.76	32.5	37.5
	14 d	3.80	5.07	24.7	33.0
	21 d	2.88	4.48	18.7	29.2
	28 d	2.18	3.99	14.2	26.0
	42 d	1.26	3.22	8.16	21.0

FOCUS STEP 3 PECsw and PECsed for IKF-309 from 1 application of 90 g a.s/ha to Spring Cereals

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D1	Ditch	0	1.33		6.22	
		24	1.31	1.32	6.21	6.22
		2d	1.30	1.31	6.21	6.22
		4d	1.30	1.30	6.20	6.21
		7d	1.27	1.30	6.16	6.21
		14d	1.19	1.28	6.06	6.19
		21d	1.14	1.28	5.98	6.17
		28d	1.15	1.26	5.89	6.15
		42d	1.03	1.23	5.66	6.10
D1	Stream	0 h	0.84		3.86	
		24 h	0.71	0.82	3.86	3.86
		2 d	0.37	0.82	3.86	3.86
		4 d	0.01	0.81	3.85	3.86
		7 d	0.78	0.81	3.83	3.86
		14 d	0.73	0.80	3.76	3.85
		21 d	0.80	0.80	3.72	3.83
		28 d	0.79	0.78	3.68	3.82
		42 d	0.75	0.77	3.53	3.79
D3	ditch	0 h	0.57		0.36	
		24 h	0.37	0.48	0.32	0.36
		2 d	0.11	0.35	0.26	0.34
		4 d	0.01	0.20	0.17	0.30

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		7 d	0.00	0.11	0.11	0.24
		14 d	0.00	0.06	0.05	0.17
		21 d	0.00	0.04	0.03	0.13
		28 d	0.00	0.03	0.02	0.10
		42 d	0.00	0.02	0.01	0.07
D4	pond	0 h	0.18		0.92	
		24 h	0.18	0.18	0.92	0.92
		2 d	0.18	0.18	0.92	0.92
		4 d	0.17	0.18	0.92	0.92
		7 d	0.17	0.18	0.92	0.92
		14 d	0.16	0.17	0.90	0.92
		21 d	0.15	0.17	0.88	0.92
		28 d	0.16	0.17	0.86	0.91
		42 d	0.14	0.16	0.81	0.90
D4	stream	0 h	0.49		0.47	
		24 h	0.00	0.25	0.47	0.47
		2 d	0.00	0.22	0.46	0.47
		4 d	0.00	0.20	0.46	0.46
		7 d	0.00	0.17	0.45	0.46
		14 d	0.00	0.12	0.38	0.45
		21 d	0.00	0.12	0.31	0.43
		28 d	0.00	0.11	0.31	0.41
		42 d	0.00	0.08	0.33	0.39
D5	pond	0 h	0.08		0.36	
		24 h	0.08	0.08	0.36	0.36
		2 d	0.08	0.08	0.36	0.36
		4 d	0.08	0.08	0.36	0.36
		7 d	0.07	0.08	0.35	0.36
		14 d	0.07	0.08	0.35	0.35
		21 d	0.06	0.07	0.34	0.35
		28 d	0.06	0.07	0.32	0.35
		42 d	0.06	0.07	0.29	0.34
D5	stream	0 h	0.49		0.17	
		24 h	0.00	0.10	0.16	0.17
		2 d	0.00	0.09	0.16	0.16
		4 d	0.00	0.06	0.15	0.16
		7 d	0.00	0.06	0.16	0.16
		14 d	0.00	0.04	0.14	0.16
		21 d	0.00	0.04	0.14	0.15
		28 d	0.00	0.03	0.13	0.15
		42 d	0.00	0.02	0.09	0.14
R4	stream	0 h	1.45		1.29	
		24 h	0.00	0.79	1.03	1.21
		2 d	0.00	0.73	0.85	1.11
		4 d	0.00	0.37	0.65	0.99
		7 d	0.00	0.31	0.48	0.85
		14 d	0.00	0.22	0.23	0.74
		21 d	0.00	0.15	0.12	0.61
		28 d	0.00	0.11	0.07	0.51

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		42 d	0.00	0.08	0.02	0.37

FOCUS STEP 3 PECsw and PECsed for IKF-309 from 2 applications of 90 g a.s/ha to Spring Cereals

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D1	Ditch	0	1.33		6.22	
		24	1.31	1.32	6.22	6.22
		2d	1.30	1.31	6.21	6.22
		4d	1.30	1.30	6.20	6.22
		7d	1.27	1.30	6.17	6.21
		14d	1.19	1.28	6.06	6.19
		21d	1.14	1.28	5.98	6.17
		28d	1.15	1.26	5.89	6.15
		42d	1.03	1.23	5.66	6.11
D1	Stream	0 h	0.84		3.86	
		24 h	0.71	0.82	3.86	3.86
		2 d	0.37	0.82	3.86	3.86
		4 d	0.01	0.81	3.85	3.86
		7 d	0.78	0.81	3.83	3.86
		14 d	0.73	0.80	3.76	3.85
		21 d	0.80	0.80	3.72	3.83
		28 d	0.79	0.78	3.68	3.82
		42 d	0.75	0.77	3.53	3.79
D3	ditch	0 h	0.50		0.35	
		24 h	0.32	0.42	0.31	0.35
		2 d	0.10	0.31	0.26	0.33
		4 d	0.01	0.17	0.18	0.29
		7 d	0.00	0.10	0.12	0.24
		14 d	0.00	0.05	0.06	0.17
		21 d	0.00	0.06	0.03	0.16
		28 d	0.00	0.04	0.02	0.14
		42 d	0.00	0.03	0.01	0.11
D4	pond	0 h	0.18		0.93	
		24 h	0.18	0.18	0.93	0.93
		2 d	0.18	0.18	0.93	0.93
		4 d	0.18	0.18	0.92	0.93
		7 d	0.17	0.18	0.92	0.93
		14 d	0.16	0.18	0.91	0.92
		21 d	0.15	0.17	0.89	0.92
		28 d	0.16	0.17	0.86	0.92
		42 d	0.14	0.16	0.81	0.91
D4	stream	0 h	0.42		0.47	
		24 h	0.00	0.25	0.47	0.47
		2 d	0.00	0.22	0.46	0.47
		4 d	0.00	0.20	0.46	0.46
		7 d	0.00	0.17	0.45	0.46
		14 d	0.00	0.12	0.38	0.45
		21 d	0.00	0.12	0.31	0.43

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		28 d	0.00	0.11	0.31	0.41
		42 d	0.00	0.08	0.33	0.39
D5	pond	0 h	0.08		0.36	
		24 h	0.08	0.08	0.36	0.36
		2 d	0.08	0.08	0.36	0.36
		4 d	0.08	0.08	0.36	0.36
		7 d	0.07	0.08	0.35	0.36
		14 d	0.07	0.08	0.35	0.35
		21 d	0.06	0.07	0.34	0.35
		28 d	0.06	0.07	0.32	0.35
		42 d	0.06	0.07	0.33	0.34
D5	stream	0 h	0.43		0.17	
		24 h	0.00	0.10	0.16	0.17
		2 d	0.00	0.09	0.16	0.16
		4 d	0.00	0.06	0.15	0.16
		7 d	0.00	0.06	0.16	0.16
		14 d	0.00	0.04	0.14	0.16
		21 d	0.00	0.04	0.14	0.15
		28 d	0.00	0.03	0.13	0.15
		42 d	0.00	0.03	0.09	0.14
R4	stream	0 h	1.45		1.29	
		24 h	0.00	0.79	1.03	1.21
		2 d	0.00	0.73	0.85	1.11
		4 d	0.00	0.37	0.65	0.99
		7 d	0.00	0.31	0.48	0.85
		14 d	0.00	0.22	0.23	0.74
		21 d	0.00	0.15	0.12	0.61
		28 d	0.00	0.11	0.07	0.51
		42 d	0.00	0.08	0.02	0.37

FOCUS STEP 3 PECsw and PECsed for IKF-309 from 1 application of 90 g a.s/ha to Winter Cereals

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D1	Ditch	0	1.17		4.52	
		24	1.10	1.13	4.52	4.52
		2d	1.05	1.10	4.52	4.52
		4d	0.97	1.06	4.50	4.52
		7d	0.87	1.00	4.47	4.51
		14d	0.69	0.98	4.28	4.50
		21d	0.54	0.96	3.77	4.47
		28d	0.40	0.95	3.68	4.46
		42d	0.22	0.92	3.92	4.44
D1	Stream	0 h	0.65		2.86	
		24 h	0.63	0.64	2.85	2.85
		2 d	0.63	0.63	2.85	2.85
		4 d	0.63	0.63	2.85	2.85
		7 d	0.61	0.63	2.84	2.85
		14 d	0.57	0.61	2.84	2.85

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		21 d	0.55	0.60	2.83	2.85
		28 d	0.57	0.59	2.81	2.84
		42 d	0.50	0.58	2.64	2.83
D2	ditch	0 h	1.48		3.48	
		24 h	0.70	1.01	3.44	3.47
		2 d	0.62	0.97	3.39	3.46
		4 d	0.69	0.92	3.28	3.45
		7 d	0.90	0.87	3.16	3.41
		14 d	0.56	0.78	2.75	3.34
		21 d	1.11	0.73	2.33	3.24
		28 d	1.15	0.70	2.78	3.18
		42 d	0.48	0.65	3.05	3.13
D2	stream	0 h	0.92		2.12	
		24 h	0.41	0.59	2.10	2.11
		2 d	0.38	0.53	2.06	2.10
		4 d	0.40	0.51	2.01	2.09
		7 d	0.57	0.47	1.94	2.07
		14 d	0.35	0.44	1.70	2.03
		21 d	0.71	0.42	1.48	1.98
		28 d	0.71	0.41	1.65	1.94
		42 d	0.30	0.39	1.28	1.91
D3	ditch	0 h	0.57		0.33	
		24 h	0.32	0.46	0.28	0.32
		2 d	0.07	0.32	0.23	0.31
		4 d	0.01	0.17	0.15	0.26
		7 d	0.00	0.10	0.10	0.21
		14 d	0.00	0.05	0.05	0.15
		21 d	0.00	0.03	0.03	0.11
		28 d	0.00	0.03	0.02	0.09
		42 d	0.00	0.02	0.01	0.06
D4	pond	0 h	0.15		0.80	
		24 h	0.15	0.15	0.79	0.80
		2 d	0.15	0.15	0.79	0.80
		4 d	0.15	0.15	0.79	0.79
		7 d	0.15	0.15	0.79	0.79
		14 d	0.14	0.15	0.78	0.79
		21 d	0.13	0.15	0.76	0.79
		28 d	0.14	0.14	0.74	0.79
		42 d	0.13	0.14	0.70	0.78
D4	stream	0 h	0.49		0.44	
		24 h	0.00	0.20	0.44	0.44
		2 d	0.00	0.18	0.44	0.44
		4 d	0.00	0.16	0.42	0.44
		7 d	0.00	0.13	0.39	0.44
		14 d	0.00	0.11	0.33	0.43
		21 d	0.00	0.11	0.29	0.41
		28 d	0.00	0.10	0.34	0.39
		42 d	0.00	0.08	0.28	0.37
D5	pond	0 h	0.08		0.33	

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		24 h	0.08	0.08	0.33	0.33
		2 d	0.08	0.08	0.33	0.33
		4 d	0.07	0.08	0.33	0.33
		7 d	0.07	0.08	0.33	0.33
		14 d	0.07	0.07	0.32	0.33
		21 d	0.06	0.07	0.32	0.33
		28 d	0.06	0.07	0.30	0.33
		42 d	0.05	0.07	0.28	0.32
D5	stream	0 h	0.50		0.16	
		24 h	0.00	0.09	0.16	0.16
		2 d	0.00	0.08	0.15	0.16
		4 d	0.00	0.06	0.15	0.15
		7 d	0.00	0.06	0.15	0.15
		14 d	0.00	0.04	0.13	0.15
		21 d	0.00	0.04	0.13	0.14
		28 d	0.00	0.03	0.12	0.14
		42 d	0.00	0.03	0.08	0.13
D6	ditch	0 h	0.58		0.86	
		24 h	0.53	0.55	0.85	0.86
		2 d	0.49	0.53	0.81	0.86
		4 d	0.42	0.49	0.69	0.85
		7 d	0.26	0.43	0.51	0.81
		14 d	0.04	0.28	0.24	0.68
		21 d	0.01	0.19	0.12	0.55
		28 d	0.00	0.14	0.06	0.45
		42 d	0.00	0.10	0.01	0.32
R1	pond	0 h	0.15		0.47	
		24 h	0.14	0.14	0.47	0.47
		2 d	0.14	0.14	0.46	0.47
		4 d	0.14	0.14	0.45	0.47
		7 d	0.13	0.14	0.43	0.47
		14 d	0.12	0.13	0.40	0.46
		21 d	0.10	0.12	0.37	0.45
		28 d	0.10	0.12	0.34	0.43
		42 d	0.09	0.12	0.29	0.42
R1	stream	0 h	1.15		0.80	
		24 h	0.00	0.61	0.68	0.76
		2 d	0.00	0.31	0.59	0.71
		4 d	0.00	0.15	0.54	0.63
		7 d	0.00	0.14	0.39	0.59
		14 d	0.03	0.11	0.23	0.56
		21 d	0.00	0.08	0.15	0.51
		28 d	0.00	0.07	0.20	0.44
		42 d	0.00	0.05	0.06	0.37
R3	stream	0 h	1.21		1.28	
		24 h	0.24	1.03	1.10	1.23
		2 d	0.01	0.55	0.95	1.15
		4 d	0.00	0.28	0.78	1.02
		7 d	0.00	0.16	0.63	0.89

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		14 d	0.00	0.09	0.41	0.71
		21 d	0.00	0.06	0.26	0.59
		28 d	0.00	0.07	0.38	0.54
		42 d	0.00	0.06	0.20	0.47
R4	stream	0 h	1.97		2.20	
		24 h	1.51	1.45	1.77	2.07
		2 d	0.46	1.39	1.46	1.92
		4 d	0.00	0.72	1.12	1.68
		7 d	0.90	0.59	1.22	1.53
		14 d	0.00	0.37	0.60	1.27
		21 d	0.00	0.25	0.31	1.05
		28 d	0.00	0.19	0.16	0.87
		42 d	0.00	0.12	0.05	0.63

FOCUS STEP 3 PECsw and PECsed for IKF-309 from 2 applications of 90 g a.s/ha to Winter Cereals

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D1	Ditch	0	1.10		4.52	
		24	1.03	1.06	4.52	4.52
		2d	0.99	1.04	4.52	4.52
		4d	0.91	1.01	4.50	4.52
		7d	0.82	1.00	4.47	4.51
		14d	0.65	0.98	4.28	4.50
		21d	0.50	0.96	3.77	4.47
		28d	0.38	0.95	3.68	4.46
		42d	0.56	0.92	3.78	4.45
D1	Stream	0 h	0.65		2.86	
		24 h	0.63	0.64	2.85	2.85
		2 d	0.63	0.63	2.85	2.85
		4 d	0.63	0.63	2.85	2.85
		7 d	0.61	0.63	2.84	2.85
		14 d	0.57	0.61	2.84	2.85
		21 d	0.55	0.60	2.83	2.85
		28 d	0.57	0.59	2.81	2.84
		42 d	0.50	0.58	2.64	2.83
D2	ditch	0 h	1.48		3.48	
		24 h	0.70	1.01	3.44	3.47
		2 d	0.62	0.91	3.39	3.46
		4 d	0.69	0.87	3.28	3.45
		7 d	0.90	0.82	3.16	3.41
		14 d	0.56	0.74	2.75	3.34
		21 d	1.11	0.73	3.11	3.24
		28 d	1.15	0.72	3.12	3.18
		42 d	0.48	0.65	3.07	3.13
D2	stream	0 h	0.92		2.24	
		24 h	0.41	0.65	2.12	2.21
		2 d	0.38	0.64	2.02	2.19
		4 d	0.40	0.61	1.94	2.17

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		7 d	0.57	0.59	1.87	2.13
		14 d	0.35	0.48	1.58	2.04
		21 d	0.71	0.42	1.31	1.98
		28 d	0.71	0.41	1.06	1.97
		42 d	0.30	0.39	0.69	1.96
D3	ditch	0 h	0.50		0.33	
		24 h	0.28	0.40	0.29	0.32
		2 d	0.06	0.28	0.23	0.31
		4 d	0.01	0.15	0.16	0.27
		7 d	0.00	0.09	0.11	0.22
		14 d	0.00	0.04	0.06	0.16
		21 d	0.00	0.06	0.03	0.15
		28 d	0.00	0.04	0.02	0.14
		42 d	0.00	0.03	0.01	0.11
D4	pond	0 h	0.15		0.80	
		24 h	0.15	0.15	0.80	0.80
		2 d	0.15	0.15	0.80	0.80
		4 d	0.15	0.15	0.80	0.80
		7 d	0.15	0.15	0.79	0.80
		14 d	0.14	0.15	0.78	0.80
		21 d	0.13	0.15	0.77	0.80
		28 d	0.14	0.14	0.75	0.79
		42 d	0.13	0.14	0.70	0.78
D4	stream	0 h	0.43		0.44	
		24 h	0.00	0.20	0.44	0.44
		2 d	0.00	0.18	0.44	0.44
		4 d	0.00	0.16	0.42	0.44
		7 d	0.00	0.13	0.39	0.44
		14 d	0.00	0.11	0.33	0.43
		21 d	0.00	0.11	0.29	0.41
		28 d	0.00	0.10	0.34	0.39
		42 d	0.00	0.08	0.28	0.37
D5	pond	0 h	0.08		0.33	
		24 h	0.08	0.08	0.33	0.33
		2 d	0.08	0.08	0.33	0.33
		4 d	0.07	0.08	0.33	0.33
		7 d	0.07	0.08	0.33	0.33
		14 d	0.07	0.07	0.32	0.33
		21 d	0.06	0.07	0.32	0.33
		28 d	0.06	0.07	0.30	0.33
		42 d	0.05	0.07	0.31	0.32
D5	stream	0 h	0.44		0.16	
		24 h	0.00	0.09	0.16	0.16
		2 d	0.00	0.08	0.15	0.16
		4 d	0.00	0.06	0.15	0.15
		7 d	0.00	0.06	0.15	0.15
		14 d	0.00	0.04	0.13	0.15
		21 d	0.00	0.04	0.13	0.14
		28 d	0.00	0.03	0.12	0.14

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		42 d	0.00	0.03	0.08	0.13
D6	ditch	0 h	0.54		1.00	
		24 h	0.49	0.51	0.99	1.00
		2 d	0.45	0.49	0.96	1.00
		4 d	0.39	0.45	0.83	0.99
		7 d	0.23	0.39	0.62	0.95
		14 d	0.04	0.25	0.30	0.81
		21 d	0.01	0.28	0.15	0.74
		28 d	0.00	0.24	0.08	0.70
		42 d	0.00	0.16	0.02	0.55
R1	pond	0 h	0.15		0.49	
		24 h	0.15	0.15	0.49	0.49
		2 d	0.15	0.15	0.48	0.49
		4 d	0.14	0.15	0.47	0.49
		7 d	0.13	0.14	0.45	0.49
		14 d	0.12	0.14	0.42	0.48
		21 d	0.11	0.13	0.38	0.47
		28 d	0.10	0.12	0.35	0.45
		42 d	0.09	0.12	0.30	0.44
R1	stream	0 h	1.15		0.80	
		24 h	0.00	0.61	0.68	0.76
		2 d	0.00	0.31	0.59	0.71
		4 d	0.00	0.15	0.54	0.63
		7 d	0.00	0.14	0.39	0.59
		14 d	0.03	0.11	0.23	0.56
		21 d	0.00	0.08	0.15	0.51
		28 d	0.00	0.07	0.20	0.44
		42 d	0.00	0.05	0.06	0.37
R3	stream	0 h	1.21		1.28	
		24 h	0.24	1.03	1.10	1.24
		2 d	0.01	0.55	0.95	1.15
		4 d	0.00	0.28	0.78	1.02
		7 d	0.00	0.16	0.63	0.90
		14 d	0.00	0.09	0.41	0.72
		21 d	0.00	0.06	0.27	0.59
		28 d	0.00	0.07	0.38	0.55
		42 d	0.00	0.06	0.20	0.47
R4	stream	0 h	1.97		2.20	
		24 h	1.51	1.48	1.77	2.08
		2 d	0.46	1.39	1.46	1.92
		4 d	0.00	0.72	1.12	1.68
		7 d	0.90	0.58	1.22	1.53
		14 d	0.00	0.37	0.60	1.27
		21 d	0.00	0.25	0.31	1.05
		28 d	0.00	0.19	0.17	0.87
		42 d	0.00	0.13	0.05	0.63

Vines - Early applications

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	48.8	-	327	-
	24 h	43.9	46.4	309	318
	2 d	40.4	44.2	285	308
	4 d	34.3	40.7	241	285
	7 d	26.7	36.3	189	255
	14 d	15.0	28.3	106	199
	21 d	8.42	22.7	59.4	159
	28 d	4.73	18.6	33.3	131
	42 d	1.49	13.3	10.5	93.8

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	5.07	---	33.3	---
	24 h	4.90	4.99	31.8	32.5
	2 d	4.71	4.89	30.6	31.9
	4 d	4.35	4.71	28.3	30.6
	7 d	3.86	4.45	25.1	28.9
	14 d	2.93	3.91	19.0	25.4
	21 d	2.22	3.46	14.4	22.5
	28 d	1.69	3.08	11.0	20.0
	42 d	0.97	2.49	6.30	16.2
Southern EU	0 h	9.25	---	62.7	---
	24 h	9.07	9.16	59.0	60.8
	2 d	8.72	9.03	56.7	59.3
	4 d	8.06	8.71	52.4	56.9
	7 d	7.16	8.24	46.5	53.7
	14 d	5.43	7.25	35.3	47.2
	21 d	4.12	6.41	26.8	41.7
	28 d	3.12	5.71	20.3	37.1
	42 d	1.80	4.61	11.7	30.0

FOCUS STEP 3 maximum PECsw and PECsed for IKF-309 from 1 application of 90 g a.s/ha to Vines ('early applications').

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6	Ditch	0	0.51	-	0.41	-
		24	0.38	0.45	0.39	0.41
		2d	0.21	0.37	0.35	0.40
		4d	0.08	0.25	0.29	0.38
		7d	0.03	0.16	0.22	0.34
		14d	0.01	0.09	0.12	0.27
		21d	0.00	0.06	0.07	0.22
		28d	0.00	0.06	0.04	0.19
		42d	0.00	0.05	0.01	0.19

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R1	pond	0 h	0.03		0.10	
		24 h	0.03	0.03	0.10	0.10
		2 d	0.03	0.03	0.10	0.10
		4 d	0.03	0.03	0.10	0.10
		7 d	0.03	0.03	0.09	0.10
		14 d	0.02	0.03	0.08	0.10
		21 d	0.02	0.02	0.08	0.09
		28 d	0.02	0.02	0.07	0.09
		42 d	0.01	0.02	0.05	0.09
R1	stream	0 h	0.95		0.43	
		24 h	0.00	0.61	0.31	0.39
		2 d	0.00	0.31	0.24	0.34
		4 d	0.00	0.15	0.17	0.28
		7 d	0.00	0.09	0.11	0.23
		14 d	0.00	0.07	0.06	0.18
		21 d	0.00	0.05	0.03	0.16
		28 d	0.00	0.04	0.02	0.14
		42 d	0.00	0.04	0.02	0.14
R2	stream	0 h	0.59		0.68	
		24 h	0.36	0.58	0.54	0.63
		2 d	0.00	0.31	0.46	0.58
		4 d	0.00	0.16	0.35	0.50
		7 d	0.00	0.09	0.27	0.43
		14 d	0.00	0.05	0.16	0.32
		21 d	0.00	0.03	0.10	0.26
		28 d	0.00	0.02	0.06	0.21
		42 d	0.00	0.02	0.02	0.16
R3	stream	0 h	0.76		0.48	
		24 h	0.00	0.68	0.37	0.45
		2 d	0.08	0.36	0.38	0.40
		4 d	0.00	0.22	0.26	0.34
		7 d	0.00	0.13	0.18	0.28
		14 d	0.00	0.06	0.10	0.20
		21 d	0.00	0.05	0.06	0.16
		28 d	0.04	0.04	0.11	0.13
		42 d	0.00	0.02	0.03	0.10
R4	stream	0 h	1.48		1.28	
		24 h	1.37	1.33	0.94	1.18
		2 d	0.00	1.13	0.74	1.07
		4 d	0.00	0.57	0.52	0.89
		7 d	0.00	0.33	0.36	0.73
		14 d	0.00	0.17	0.19	0.52
		21 d	0.00	0.11	0.10	0.40
		28 d	0.00	0.09	0.05	0.32
		42 d	0.00	0.06	0.02	0.23

FOCUS STEP 3 maximum PECsw and PECsed for IKF-309 from 3 applications of 90 g a.s/ha to Vines ('early applications').

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6	Ditch	0	0.50		0.89	
		24	0.46	0.48	0.88	0.89
		2d	0.42	0.46	0.84	0.89
		4d	0.36	0.43	0.74	0.87
		7d	0.21	0.37	0.56	0.84
		14d	0.04	0.23	0.27	0.71
		21d	0.01	0.27	0.13	0.72
		28d	0.00	0.23	0.06	0.67
		42d	0.00	0.18	0.01	0.53
R1	pond	0 h	0.04		0.15	
		24 h	0.04	0.04	0.15	0.15
		2 d	0.04	0.04	0.15	0.15
		4 d	0.03	0.04	0.14	0.15
		7 d	0.03	0.04	0.14	0.15
		14 d	0.03	0.03	0.13	0.14
		21 d	0.03	0.03	0.14	0.14
		28 d	0.03	0.03	0.14	0.14
		42 d	0.03	0.03	0.11	0.14
R1	stream	0 h	0.95		0.43	
		24 h	0.00	0.61	0.31	0.39
		2 d	0.00	0.31	0.24	0.34
		4 d	0.00	0.15	0.17	0.28
		7 d	0.00	0.09	0.11	0.23
		14 d	0.00	0.07	0.06	0.18
		21 d	0.00	0.05	0.03	0.16
		28 d	0.00	0.04	0.02	0.14
		42 d	0.00	0.04	0.02	0.14
R2	stream	0 h	0.59		0.68	
		24 h	0.36	0.58	0.54	0.63
		2 d	0.00	0.31	0.46	0.58
		4 d	0.00	0.16	0.35	0.50
		7 d	0.00	0.09	0.27	0.43
		14 d	0.00	0.05	0.16	0.32
		21 d	0.00	0.03	0.10	0.26
		28 d	0.00	0.02	0.06	0.21
		42 d	0.00	0.02	0.02	0.16
R3	stream	0 h	0.76		0.48	
		24 h	0.00	0.68	0.37	0.45
		2 d	0.08	0.36	0.38	0.41
		4 d	0.00	0.22	0.26	0.38
		7 d	0.00	0.13	0.18	0.31
		14 d	0.00	0.06	0.10	0.23
		21 d	0.00	0.05	0.06	0.18
		28 d	0.04	0.04	0.11	0.15
		42 d	0.00	0.02	0.03	0.12
R4	stream	0 h	1.48		1.29	
		24 h	1.37	1.33	0.95	1.18
		2 d	0.00	1.13	0.74	1.07
		4 d	0.00	0.57	0.52	0.90

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		7 d	0.00	0.33	0.37	0.74
		14 d	0.00	0.17	0.20	0.53
		21 d	0.00	0.11	0.10	0.41
		28 d	0.00	0.09	0.05	0.33
		42 d	0.00	0.06	0.02	0.23

Vines - Late applications

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	53.6		327	
	24 h	46.2	49.9	325	326
	2 d	42.5	47.1	300	319
	4 d	36.0	43.1	254	298
	7 d	28.1	38.3	198	267
	14 d	15.8	29.8	111	209
	21 d	8.86	23.9	62.5	167
	28 d	4.97	19.6	35.1	137
	42 d	1.57	14.1	11.0	98.5

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	8.69		54.5	
	24 h	8.22	8.45	53.4	54.0
	2 d	7.90	8.26	51.3	53.2
	4 d	7.30	7.93	47.4	51.3
	7 d	6.48	7.48	42.1	48.5
	14 d	4.92	6.57	32.0	42.6
	21 d	3.73	5.81	24.2	37.7
	28 d	2.83	5.18	18.4	33.6
	42 d	1.63	4.17	10.6	27.1
Southern EU	0 h	7.43		45.7	
	24 h	6.97	7.20	45.3	45.5
	2 d	6.70	7.02	43.5	44.9
	4 d	6.19	6.73	40.2	43.4
	7 d	5.50	6.35	35.7	41.0
	14 d	4.17	5.57	27.1	36.1
	21 d	3.16	4.93	20.5	32.0
	28 d	2.40	4.39	15.6	28.5
	42 d	1.38	3.54	8.96	23.0

FOCUS STEP 3 maximum PECsw and PECsed for IKF-309 from 1 application of 90 g a.s/ha to Vines (late applications).

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6	Ditch	0	1.54		2.11	
		24	1.41	1.47	1.08	2.11
		2d	1.33	1.42	1.99	2.10
		4d	1.15	1.33	1.72	2.06
		7d	0.69	1.16	1.30	1.97
		14d	0.11	0.74	0.64	1.66
		21d	0.02	0.51	0.38	1.36
		28d	0.01	0.39	0.25	1.12
		42d	0.00	0.26	0.12	0.83
R1	pond	0 h	0.06		0.17	
		24 h	0.05	0.05	0.17	0.17
		2 d	0.05	0.05	0.17	0.17
		4 d	0.05	0.05	0.17	0.17
		7 d	0.05	0.05	0.17	0.17
		14 d	0.04	0.05	0.17	0.17
		21 d	0.04	0.05	0.17	0.17
		28 d	0.04	0.04	0.17	0.17
		42 d	0.03	0.04	0.16	0.17
R1	stream	0 h	1.13		0.17	
		24 h	0.00	0.24	0.12	0.15
		2 d	0.00	0.12	0.10	0.13
		4 d	0.00	0.06	0.06	0.11
		7 d	0.00	0.04	0.04	0.08
		14 d	0.00	0.02	0.02	0.06
		21 d	0.00	0.01	0.02	0.04
		28 d	0.00	0.01	0.01	0.04
		42 d	0.00	0.01	0.01	0.03
R2	stream	0 h	1.52		0.24	
		24 h	0.00	0.20	0.20	0.23
		2 d	0.00	0.10	0.17	0.21
		4 d	0.00	0.06	0.13	0.18
		7 d	0.00	0.04	0.09	0.15
		14 d	0.00	0.02	0.06	0.11
		21 d	0.00	0.02	0.09	0.10
		28 d	0.00	0.02	0.15	0.09
		42 d	0.00	0.01	0.06	0.10
R3	stream	0 h	1.60		1.11	
		24 h	0.01	0.82	0.89	1.08
		2 d	0.00	0.76	0.74	1.04
		4 d	0.00	0.51	0.56	0.93
		7 d	0.00	0.29	0.42	0.79
		14 d	0.00	0.15	0.25	0.59
		21 d	0.00	0.13	0.17	0.47
		28 d	0.00	0.10	0.13	0.40
		42 d	0.00	0.08	0.08	0.31
R4	stream	0 h	1.94		1.14	

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		24 h	0.01	1.75	0.79	1.03
		2 d	0.00	0.90	0.58	0.90
		4 d	0.00	0.45	0.37	0.72
		7 d	0.00	0.26	0.22	0.55
		14 d	0.00	0.15	0.09	0.36
		21 d	0.00	0.10	0.04	0.26
		28 d	0.00	0.07	0.02	0.22
		42 d	0.69	0.06	0.74	0.16

FOCUS STEP 3 maximum PECsw and PECsed for IKF-309 from 3 applications of 90 g a.s/ha to Vines ('late applications').

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6	Ditch	0	1.41		2.42	
		24	1.28	1.34	2.38	2.41
		2d	1.19	1.29	2.29	2.40
		4d	1.02	1.20	2.01	2.37
		7d	0.61	1.04	1.54	2.28
		14d	0.10	0.66	0.77	1.95
		21d	0.02	0.78	0.45	1.90
		28d	0.01	0.66	0.30	1.80
		42d	0.00	0.64	0.14	1.62
R1	pond	0 h	0.11		0.38	
		24 h	0.11	0.11	0.38	0.38
		2 d	0.11	0.11	0.38	0.38
		4 d	0.10	0.11	0.38	0.38
		7 d	0.10	0.10	0.37	0.38
		14 d	0.09	0.10	0.36	0.37
		21 d	0.08	0.09	0.35	0.37
		28 d	0.07	0.09	0.35	0.37
		42 d	0.06	0.08	0.34	0.36
R1	stream	0 h	0.97		0.17	
		24 h	0.00	0.21	0.13	0.15
		2 d	0.00	0.10	0.10	0.14
		4 d	0.00	0.05	0.07	0.11
		7 d	0.00	0.03	0.05	0.09
		14 d	0.00	0.02	0.03	0.06
		21 d	0.00	0.02	0.02	0.07
		28 d	0.00	0.02	0.01	0.06
		42 d	0.00	0.02	0.01	0.06
R2	stream	0 h	1.29		0.24	
		24 h	0.00	0.20	0.20	0.23
		2 d	0.00	0.10	0.17	0.21
		4 d	0.00	0.06	0.13	0.18
		7 d	0.00	0.04	0.09	0.15
		14 d	0.00	0.02	0.06	0.11
		21 d	0.00	0.02	0.09	0.10
		28 d	0.00	0.02	0.15	0.09

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		42 d	0.00	0.01	0.06	0.10
R3	stream	0 h	1.36		1.11	
		24 h	0.01	0.82	0.89	1.08
		2 d	0.00	0.76	0.74	1.04
		4 d	0.00	0.51	0.56	0.92
		7 d	0.00	0.29	0.42	0.79
		14 d	0.00	0.15	0.25	0.59
		21 d	0.00	0.13	0.17	0.47
		28 d	0.00	0.10	0.13	0.39
		42 d	0.00	0.08	0.08	0.30
R4	stream	0 h	1.94		1.14	
		24 h	0.01	1.75	0.79	1.03
		2 d	0.00	0.90	0.58	0.90
		4 d	0.00	0.45	0.37	0.72
		7 d	0.00	0.26	0.22	0.55
		14 d	0.00	0.14	0.09	0.36
		21 d	0.00	0.10	0.04	0.26
		28 d	0.00	0.08	0.02	0.22
		42 d	0.69	0.06	0.74	0.16

PECsw values calculated for the formulations using the SWASH spray drift calculator for use in the aquatic risk assessment with the formulated products

	Water body	Maximum initial PECsw (µg/L)
Cereals[#] (1 x 0.5 litres product /ha)	Pond	0.12
	Stream[+]	2.60
	Ditch	3.50
Vines, early* (1 x 0.3 litres product /ha)	Pond	0.06
	Stream[+]	1.53
	Ditch	1.86
Vines, late* (1 x 0.3 litres product/ha)	Pond	0.20
	Stream[+]	4.64
	Ditch	5.59

= IKF-309 180 SC
* = IKF-309 300 SC
[+] = For the stream scenarios 20% of the upstream catchment is assumed to be treated which normally contributes drift inputs via the stream water flowing into the waterbody. However, it was considered by the RMS that the formulation would not stay intact in the upstream water and would not therefore contribute to the formulation PEC in the waterbody.

3HDPM Parameters used in FOCUSsw step 1 and 2	Molecular weight: 351.79 Water solubility (mg/L): 7.49 Soil or water metabolite: Water (8.4% AR) and soil (32% AR) metabolite. Koc/Kom (L/kg): 384.6/223.1 DT_{50} soil (d): 100 (this DT_{50} value was not calculated directly from the data but simply selected and shown to be conservative when the metabolite degradation was fitted with this values and compared to measured concentrations). DT_{50} water/sediment system (d): 1000 DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Crop interception (%): 50% Maximum occurrence observed (% molar basis with respect to the parent) Water: 3.1% Sediment: 5.3%
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	-
Main routes of entry	-

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	12.34		46.94	
	24h	12.29	12.31	47.25	47.10
	2d	12.28	12.30	47.22	47.17
	4d	12.26	12.28	47.15	47.17
	7d	12.23	12.27	47.05	47.14
	14d	12.18	12.24	46.83	47.04
	21d	12.12	12.21	46.60	46.93
	28d	12.06	12.18	46.37	46.82
	42d	11.94	12.12	45.93	46.60

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	1.22		4.65	
	24 h	1.21	1.21	4.65	4.65
	2 d	1.21	1.21	4.64	4.65
	4 d	1.21	1.21	4.64	4.64
	7 d	1.20	1.21	4.63	4.64
	14 d	1.20	1.20	4.61	4.63
	21 d	1.20	1.20	4.58	4.62
	28 d	1.20	1.20	4.56	4.60
	42 d	1.20	1.20	4.52	4.58
Southern EU	0 h	2.35	---	9.00	---
	24 h	2.34	2.35	9.00	9.00
	2 d	2.34	2.34	8.99	9.00
	4 d	2.34	2.34	8.98	8.99
	7 d	2.33	2.34	8.96	8.98

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	14 d	2.32	2.33	8.91	8.96
	21 d	2.31	2.33	8.87	8.94
	28 d	2.30	2.32	8.83	8.91
	42 d	2.27	2.31	8.74	8.87

2MDPM Parameters used in FOCUSsw step 1 and 2	Molecular weight: 337.76 Water solubility (mg/L): 16.6 Soil or water metabolite: Water (8.5% AR) and soil (22.5% AR) metabolite Koc/Kom (L/kg): 111.4/64.6 DT_{50} soil (d): 100 (this DT_{50} value was not calculated directly from the data but simply selected and shown to be conservative when the metabolite degradation was fitted with this value and compared to measured concentrations). DT_{50} water/sediment system (d): 1000 DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Crop interception (%): 50% Maximum occurrence observed (% molar basis with respect to the parent) Water: 4.0% Sediment: 6.3%
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	-
Main routes of entry	-

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	10.98		12.09	
	24h	10.96	10.97	12.21	12.15
	2d	10.95	10.96	12.20	12.18
	4d	10.94	10.95	12.18	12.18
	7d	10.91	10.94	12.16	12.18
	14d	10.86	10.91	12.10	12.15
	21d	10.81	10.89	12.04	12.12
	28d	10.76	10.86	11.98	12.10
	42d	10.65	10.81	11.87	12.04

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	1.11		1.23	
	24 h	1.11	1.11	1.23	1.23
	2 d	1.10	1.10	1.22	1.23
	4 d	1.10	1.10	1.21	1.23
	7 d	1.10	1.10	1.21	1.23
	14 d	1.10	1.10	1.21	1.23

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	21 d	1.09	1.10	1.21	1.22
	28 d	1.08	1.10	1.21	1.22
	42 d	1.07	1.09	1.20	1.21
Southern EU	0 h	2.12	---	2.35	---
	24 h	2.11	2.11	2.35	2.35
	2 d	2.11	2.11	2.35	2.35
	4 d	2.11	2.11	2.35	2.35
	7 d	2.10	2.11	2.34	2.35
	14 d	2.09	2.10	2.33	2.34
	21 d	2.08	2.10	2.32	2.34
	28 d	2.07	2.09	2.31	2.33
	42 d	2.05	2.08	2.28	2.32

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS models PEARL and PELMO, with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: PEARL (v 3.3.3) PELMO (v .3.3.2) Scenarios (list of names): Châteaudun, Hamburg, Jokionen, Kremsmunster, Okehampton, Piacenza, Porto, Sevilla, Thiva. Crop: Cereals (Spring and Winter), Vines (early and late applications) <u>Parent</u> Geometric mean parent DT_{50}; Aerobic soil: 117 d (field, normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58). Anaerobic soil: 1.5 days (lab, pF2 and 20°C) K_{OC}: parent, lowest value, 705 ml/g, $^1/_n$= 0.88. <u>Metabolites</u>: 3HDPM DT_{50} lab, 20 days. pF2, 20 °C). K_{OC}: 3HDPM, 384.6 ml/g, $^1/_n$= 0.9. Formation fraction from parent = 0.8 2MDPM DT_{50} lab, 18 days. pF2, 20 °C). K_{OC}: 2MDPM, 111.4 ml/g, $^1/_n$= 0.9. Formation fraction from 3HDPM = 1 Those formation fractions and DT50 values were not calculated directly from the data but simply selected through a manual iterative procedure and shown to be conservative when the metabolite degradation was fitted with these values and compared to measured concentrations.
Application rate	Application rate: 90 g a.s/ha. No. of applications: 2 (cereals), 3 (vines) Time of application (month or season): <u>Aerobic</u> Cereals: 74 and 60 days prior to harvest. Vines: 1, 15 and 29 April (early season) 56,42,and 28 days prior to harvest (late season) <u>Anaerobic</u> Cereals: 1 and 15 October

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

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			1	2	3
PEARL and PELMO /Winter and Spring Cereals. Aerobic soil	Châteaudun	<0.001			
	Hamburg	<0.001			
	Jokionen	<0.001			
	Kremsmunster	<0.001			
	Okehampton	<0.001			
	Piacenza	<0.001			
	Porto	<0.001			
	Sevilla	<0.001			
	Thiva	<0.001			

	Scenario	Parent (µg/L)		Metabolite (µg/L)		
		Early applications	Late applications	1	2	3
PEARL /Vines/ Aerobic soil	Châteaudun	<0.001	<0.001			
	Hamburg	<0.001	<0.001			
	Kremsmunster	<0.001	<0.001			
	Piacenza	0.002	0.003			
	Porto	<0.001	<0.001			
	Sevilla	<0.001	<0.001			
	Thiva	<0.001	<0.001			

	Scenario	Parent (µg/L)		Metabolite (µg/L)		
		Early applications	Late applications	1	2	3
PELMO /Vines/ Aerobic soil	Châteaudun	<0.001	<0.001			
	Hamburg	<0.001	<0.001			
	Kremsmunster	<0.001	<0.001			
	Piacenza	<0.001	<0.001			
	Porto	<0.001	<0.001			
	Sevilla	<0.001	<0.001			
	Thiva	<0.001	<0.001			

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			3HDPM	2MDPM	
PEARL /Winter Cereals. Anaerobic soil	Châteaudun	<0.001	<0.001	<0.001	
	Hamburg	<0.001	<0.001	<0.001	
	Jokionen	<0.001	<0.001	<0.001	
	Kremsmunster	<0.001	<0.001	<0.001	
	Okehampton	<0.001	<0.001	<0.001	
	Piacenza	<0.001	<0.001	0.001	
	Porto	<0.001	<0.001	<0.001	
	Sevilla	<0.001	<0.001	<0.001	
	Thiva	<0.001	<0.001	<0.001	

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			3HDPM	2MDPM	
PELMO /Winter Cereals.	Châteaudun	<0.001	<0.001	<0.001	
	Hamburg	<0.001	<0.001	<0.001	
	Jokionen	<0.001	<0.001	<0.001	

	Kremsmunster	<0.001	<0.001	<0.001	
	Okehampton	<0.001	<0.001	<0.001	
	Piacenza	<0.001	<0.001	0.001	
	Porto	<0.001	<0.001	<0.001	
	Sevilla	<0.001	<0.001	<0.001	
	Thiva	<0.001	<0.001	<0.001	

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			3HDPM	2MDPM	
PEARL /Spring Cereals. Anaerobic soil	Châteaudun	<0.001	<0.001	<0.001	
	Hamburg	<0.001	<0.001	<0.001	
	Kremsmunster	<0.001	<0.001	<0.001	
	Piacenza	<0.001	<0.001	<0.001	
	Porto	<0.001	<0.001	<0.001	
	Sevilla	<0.001	<0.001	<0.001	
	Thiva	<0.001	<0.001	<0.001	

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			3HDPM	2MDPM	
PELMO /Spring Cereals. Anaerobic soil	Châteaudun	<0.001	<0.001	<0.001	
	Hamburg	<0.001	<0.001	<0.001	
	Kremsmunster	<0.001	<0.001	<0.001	
	Piacenza	<0.001	<0.001	<0.001	
	Porto	<0.001	<0.001	<0.001	
	Sevilla	<0.001	<0.001	<0.001	
	Thiva	<0.001	<0.001	<0.001	

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

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	-
Photochemical oxidative degradation in air ‡	DT_{50} of 0.630 hours derived by the Atmospheric Oxidation Programme (v 1.92). OH (12 h) concentration assumed = 1.5E6 OH/cm^3
Volatilisation ‡	No data submitted
	No data submitted
Metabolites	None.

PEC (air)

Method of calculation	Expert judgement, based on vapour pressure, and DT_{50} in air.

$PEC_{(a)}$

Maximum concentration	negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: IKF-309, 3HDPM and 2MDPM Surface Water: IKF-309, 3HDPM and 2MDPM Sediment: IKF-309, 3HDPM and 2MDPM

Ground water: IKF-309, 3HDPM and 2MDPM Air: IKF-309

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

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

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

Not required.

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

Species	Test substance	Time scale	End point (mg/kg bw per day)	End point (mg/kg feed)
Birds ‡				
Collinus virginianus	Pyriofenone	Acute	**> 2000**	-
Anas platyrhynchos	Pyriofenone	Acute	Study not suitable	-
Collinus virginianus	Pyriofenone	Short-term	**> 980**	> 5000
Anas platyrhynchos	Pyriofenone	Short-term	> 1290	> 5000
Collinus virginianus	Pyriofenone	Long-term reproductive	**94**	1000
Anas platyrhynchos	Pyriofenone	Long-term reproductive	119	1000
Mammals ‡				
Rat	Pyriofenone	Acute	**> 2000**	-
Rat	IKF-309 180SC	Acute	**> 2000**	-
Rat	IKF-309 300SC	Acute	**> 2000**	-
Rat	Pyriofenone	Long-term	**64.1**	1000

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

Cereals early and late (0.09 kg a.s./ha)

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Large herbivorous bird	Acute	6.75	> 296	10
Insectivorous bird	Acute	4.87	> 411	10
Large herbivorous bird	Short-term	4.21	> 233	10
Insectivorous bird	Short-term	2.71	> 361	10
Large herbivorous bird	Long-term	2.23	42	5
Insectivorous bird	Long-term	2.71	35	5
Earthworm-eating birds	Long-term	Daily Dose (mg/kg bw per day): 0.084628	1111	5
Fish-eating birds	Long-term	Daily Dose (mg/kg bw per day): 0.1505	624	5
Tier 1 (Mammals)				
Small herbivorous mammal	Acute	21.32	> 93.8	10
Insectivorous mammal	Acute	0.79	> 2520	10
Small herbivorous mammal	Long-term	7.05	9.1	5
Insectivorous mammal	Long-term	0.29	221.67	5

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Earthworm-eating mammals	Long-term	Daily Dose (mg/kg bw per day): 0.107709	595	5
Fish-eating mammals		Daily Dose (mg/kg bw per day): 0.1348	476	5

Grapes early and late (0.09 kg a.s./ha)

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Insectivorous bird	Acute	4.87	> 411	10
Insectivorous bird	Short-term	2.71	> 361	10
Insectivorous bird	Long-term	2.71	35	5
Earthworm-eating birds	Long-term	Daily Dose (mg/kg bw per day): 0.152331	617	5
Fish-eating birds	Long-term	Daily Dose (mg/kg bw per day): 0.2154	364	5
Tier 1 (Mammals)				
Small herbivorous mammal	Acute	13.83	> 145	10
Small herbivorous mammal	Long-term	4.57	14.0	5
Earthworm-eating mammals	Long-term	Daily Dose (mg/kg bw per day): 0.193876	331	5
Fish-eating mammals		Daily Dose (mg/kg bw per day): 0.0932	688	5

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg a.s./l)
Fish ‡				

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg a.s./l)
Oncorhynchus mykiss	Pyriofenone	Acute (semi-static)	LC_{50}	> 1.44 [mm]
Cyprinus carpio	Pyriofenone	Acute (semi-static)	LC_{50}	**> 1.41** [mm]
Oncorhynchus mykiss	'IKF-309 180SC'	Acute (semi-static)	LC_{50}	21.5 [mm] **128.7** mg formulation/l
Oncorhynchus mykiss	'IKF-309 300SC'	Acute (semi-static)	LC_{50}	13.7 [mm] **51.1** mg formulation/l
Pimephales promelas	Pyriofenone	Chronic (semi-static)	NOEC	**1.27** [mm]
Oncorhynchus mykiss	3HDPM	Acute (static)	EC_{50}	Study not suitable for risk assessment
Aquatic invertebrates ‡				
Daphnia magna	Pyriofenone	Acute (semi-static)	EC_{50}	**> 1.55** [mm]
Daphnia magna	Pyriofenone	Chronic (static)	NOEC	**0.0899** [mm]
Daphnia magna	'IKF-309 180SC'	Acute (semi-static)	EC_{50}	28.6 [mm] **171.3** mg formulation/l
Daphnia magna	'IKF-309 300SC'	Acute (semi-static)	EC_{50}	31.4 [mm] **117** mg formulation/l
Daphnia magna	3HDPM	Acute (static)	EC_{50}	Study not suitable for risk assessment
Daphnia magna	2MDPM	Acute (static)	EC_{50}	Study not suitable for risk assessment
Sediment-dwelling organisms ‡				
Chironomus riparius	Pyriofenone	28 d (static)	NOEC (emergence)	**1.6** [nom]
Algae ‡				
Pseudokirchneriella subcapitata	Pyriofenone	72 h (static)	Biomass E_bC_{50} Growth E_rC_{50} Yield E_yC_{50}	0.676 [mm] 1.77 **0.422**
Pseudokirchneriella subcapitata	'IKF-309 180SC'	72 h (static)	Biomass E_bC_{50} Growth E_rC_{50} Yield E_yC_{50}	0.241 [mm] 1.44 mg formulation/l 1.16 6.95 mg formulation/l 0.220 **1.32** mg formulation/l
Pseudokirchneriella subcapitata	'IKF-309 300SC'	72 h (static)	Biomass E_bC_{50} Growth E_rC_{50} Yield E_yC_{50}	0.575 [nom] 2.15 mg formulation/l 2.78 10.37 mg formulation/l 0.516 **1.93** mg formulation/l
Pseudokirchneriella subcapitata	3HDPM	72 h (static)	EC_{50} NOEC	Study not suitable for risk assessment

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg a.s./l)
Pseudokirchneriella subcapitata	2MDPM	72 h (static)	EC_{50} NOEC	Study not suitable for risk assessment
Pseudokirchneriella subcapitata	3HDPM	72 h (static)	EC_{50} NOEC	Study not suitable for risk assessment
Pseudokirchneriella subcapitata	2MDPM	72 h (static)	EC_{50} NOEC [1]	> **0.418** [mm] 0.418

[mm] Concentrations are stated as mean measured concentrations
[nom] Concentrations are stated as nominal concentrations
Figures in **bold** are worst case and will be used in the risk assessment
[1] This study only used one concentration and therefore the usual endpoints could not be calculated, however at this concentration there were no effects on growth rate, biomass or yield.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)
FOCUS Step1

Cereals early and late (0.09 kg a.s./ha)

Test substance	Organism	Toxicity (µg a.s./l)	Time scale	PEC_i (µg a.s./l)	TER	Annex VI Trigger
Active substance						
Pyriofenone	Fish	> 1410	Acute	32.58	> **43.28**	100
Pyriofenone	Fish	1270	Chronic	32.58	38.98	10
Pyriofenone	Aquatic invertebrates	> 1550	Acute	32.58	> **47.58**	100
Pyriofenone	Aquatic invertebrates	89.9	Chronic	32.58	**2.76**	10
Pyriofenone	Algae	422	Chronic	32.58	12.95	10
Pyriofenone	Sediment-dwelling organisms [1]	1600	Chronic	32.58	49.11	10
Metabolites						
3HDPM	Fish	> 141 [2]	Acute	12.34	> **11.43**	100
3HDPM	Aquatic invertebrates	> 155 [2]	Acute	12.34	> **12.56**	100
3HDPM	Algae	42.2 [2]	Chronic	12.34	**3.42**	10
2MDPM	Fish	> 141 [2]	Acute	10.98	> **12.84**	100
2MDPM	Aquatic invertebrates	> 155 [2]	Acute	10.98	> **14.12**	100
2MDPM	Algae	> 418	Chronic	10.98	> 38.07	10
Unidentified metabolites	Sediment-dwelling organisms [1]	160[2]	Chronic	32.58	**4.91**	10

[1] Since the toxicity test for the active substance was a spiked water test the PEC_{sw} is used for the risk assessment
[2] Since the metabolite studies were not suitable for use the toxicity value is taken as 10 times that of pyriofenone
Figures in **bold** indicate those scenarios that fail at Step 1 so will be carried through to further Steps

Cereals early and late (0.09 kg a.s./ha), formulation data

Test substance	Organism	Toxicity end point (µg formulation/l)	Time scale	PEC_{sw} (µg/l)	TER	Annex VI Trigger
'IKF-309 180SC'	Fish	128700	Acute	3.50	36771	100
'IKF-309 180SC'	Aquatic invertebrates	171300	Acute	3.50	48943	100
'IKF-309 180SC'	Algae	1320	Chronic	3.50	377	10

Grapes early and late (0.09 kg a.s./ha)

Test substance	Organism	Toxicity (µg a.s./l)	Time scale	PEC_i (µg a.s./l)	TER	Annex VI Trigger
Pyriofenone	Fish	> 1410	Acute	53.62	**> 26.30**	100
Pyriofenone	Fish	1270	Chronic	53.62	23.69	10
Pyriofenone	Aquatic invertebrates	> 1550	Acute	53.62	**> 28.91**	100
Pyriofenone	Aquatic invertebrates	89.9	Chronic	53.62	**1.68**	10
Pyriofenone	Algae	422	Chronic	53.62	**7.87**	10
Pyriofenone	Sediment-dwelling organisms [1]	1600	Chronic	53.62	29.84	10
Unidentified metabolites	Sediment-dwelling organisms [1]	160	Chronic	53.62	**2.98**	10

[1] Since the toxicity test for the active substance was a spiked water test the PEC_{sw} is used for the risk assessment

Figures in **bold** indicate those scenarios that fail at Step 1 so will be carried through to further Steps

Grapes early and late (0.09 kg a.s./ha), formulation data

Test substance	Organism	Toxicity end point (µg formulation/l)	Time scale	PEC_{sw} (µg/l)	TER	Annex VI Trigger
'IKF-309 300SC'	Fish	51100	Acute	5.59	9141	100
'IKF-309 300SC'	Aquatic invertebrates	117000	Acute	5.59	20930	100
'IKF-309 300SC'	Algae	1930	Chronic	5.59	345	10

FOCUS Step 2

Cereals early and late (0.09 kg a.s./ha) worst case Southern Europe

Test substance	N/S	Organism	Toxicity (µg a.s./l)	Time scale	PEC_i (µg a.s./l)	TER	Annex VI Trigger
Active substance							
Pyriofenone	S	Fish	> 1410	Acute	6.48	> 217.59	100
Pyriofenone	S	Aquatic invertebrates	> 1550	Acute	6.48	> 239.20	100
Pyriofenone	S	Aquatic invertebrates	89.9	Chronic	6.48	13.87	10

Test substance	N/S	Organism	Toxicity (µg a.s./l)	Time scale	PEC_i (µg a.s./l)	TER	Annex VI Trigger
Metabolites							
3HDPM	S	Fish	> 141 [1]	Acute	2.35	> **60.00**	100
3HDPM	S	Aquatic invertebrates	> 155 [1]	Acute	2.35	> **65.96**	100
3HDPM	S	Algae	42.2 [1]	Chronic	2.35	17.96	10
2MDPM	S	Fish	> 141 [1]	Acute	2.12	> **66.51**	100
2MDPM	S	Aquatic invertebrates	> 155 [1]	Acute	2.12	> **73.11**	100
Unidentified metabolites	S	Sediment-dwelling organisms	160 [1]	Chronic	6.48	24.7	10

[1] Since the metabolite studies were not suitable for use the toxicity value is taken as 10 times that of pyriofenone

Grapes early and late (0.09 kg a.s./ha) worst case Southern Europe

Test substance	N/S	Organism	Toxicity (µg a.s./l)	Time scale	PEC_i (µg a.s./l)	TER	Annex VI Trigger
Active substance							
Pyriofenone	S	Fish	> 1410	Acute	9.25	> 152.43	100
Pyriofenone	S	Aquatic invertebrates	> 1550	Acute	9.25	> 167.57	100
Pyriofenone	S	Aquatic invertebrates	89.9	Chronic	9.25	**9.27**	10
Pyriofenone	S	Algae	422	Chronic	9.25	45.62	10
Unidentified metabolites	S	Sediment-dwelling organisms	160[1]	Chronic	9.25	17.3	10

[1] Since the metabolite studies were not suitable for use the toxicity value is taken as 10 times that of pyriofenone

Refined aquatic risk assessment for aquatic invertebrates using higher tier FOCUS modelling.

FOCUS Step 3

Cereals early and late (0.09 kg a.s./ha) worst case

Test substance	Scenario	Water body	Toxicity (µg a.s./l)	PEC_i (µg a.s./l)	TER	Annex VI Trigger
Pyriofenone	D1	ditch	89.9	1.33	67.59	10
Pyriofenone	D1	stream	89.9	0.84	107.02	10
Pyriofenone	D2	ditch	89.9	1.48	60.74	10
Pyriofenone	D2	stream	89.9	0.92	97.72	10
Pyriofenone	D3	ditch	89.9	0.57	157.72	10
Pyriofenone	D4	pond	89.9	0.18	499.44	10
Pyriofenone	D4	stream	89.9	0.49	183.47	10
Pyriofenone	D5	pond	89.9	0.08	1123.75	10

Pyriofenone	D5	stream	89.9	0.5	179.80	10
Pyriofenone	D6	ditch	89.9	0.58	155.00	10
Pyriofenone	R1	pond	89.9	0.15	599.33	10
Pyriofenone	R1	stream	89.9	1.15	78.17	10
Pyriofenone	R3	stream	89.9	1.21	74.30	10
Pyriofenone	R4	stream	89.9	1.97	45.63	10

Grapes early and late (0.09 kg a.s./ha) worst case Southern Europe

Test substance	Scenario	Number of applications	Toxicity (µg a.s./l)	PEC_i (µg a.s./l)	TER	Annex VI Trigger
Pyriofenone	D6	1	89.9	1.54	58.38	10
Pyriofenone	R1	1	89.9	0.055	1634.55	10
Pyriofenone	R1	1	89.9	1.13	79.56	10
Pyriofenone	R2	1	89.9	1.517	59.26	10
Pyriofenone	R3	1	89.9	1.60	56.19	10
Pyriofenone	R4	1	89.9	1.94	46.34	10
Pyriofenone	D6	3	89.9	1.41	63.76	10
Pyriofenone	R1	3	89.9	0.109	824.77	10
Pyriofenone	R1	3	89.9	0.965	93.16	10
Pyriofenone	R2	3	89.9	1.29	69.69	10
Pyriofenone	R3	3	89.9	1.36	66.10	10
Pyriofenone	R4	3	89.9	1.94	46.34	10

Refined aquatic risk assessment using formulation data.

Cereals early and late (0.09 kg a.s./ha) worst case Southern Europe using formulation data to refine the risk assessment for the metabolites

Test substance	N/S	Organism	Toxicity (µg a.s./l)	Time scale	PEC_i (µg a.s./l)	TER	Annex VI Trigger
Metabolites							
3HDPM	S	Fish	2150	Acute	2.35	915	100
3HDPM	S	Aquatic invertebrates	1370	Acute	2.35	583	100
2MDPM	S	Fish	2150	Acute	2.12	1014	100
2MDPM	S	Aquatic invertebrates	1370	Acute	2.12	646	100

[1] Since the metabolite studies were not suitable for use the toxicity value is taken as 10 times that of 'IKF-309 180SC'. This is used as a refinement step for the metabolites given the solubility concerns for pyriofenone.

Bioaccumulation

Endpoint		Pyriofenone	3HDPM	4HDPM
Log P_{ow}		3.2	-	-
Bioconcentration factor (BCF) [1] ‡		160	-	-
Annex VI Trigger for the bioconcentration factor		100	-	-
Clearance time (days)	(CT_{50})	-	-	-
	(CT_{90})	-	-	-
Average level and nature of residues (%) in organisms after the 6 day depuration phase [2]		0.0125 (0.9%)	< LOD [3]	< LOD [3]

[1] Only required if log $P_{O/W}$ > 3.
[2] High concentration test group
[3] LOD = 0.01 □g/g

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

Test substance	Acute oral toxicity (LD_{50} µg a.s./bee)	Acute contact toxicity (LD_{50} µg a.s./bee)
Pyriofenone ‡	> 100	> 100

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

Cereals (0.09 kg a.s./ha)

Test substance	Route	Application rate (g a.s./ha)	Hazard quotient	Annex VI Trigger
Pyriofenone	Contact	90	< 0.90	50
Pyriofenone	Oral	90	< 0.90	50

Grapes (0.09 kg a.s./ha)

Test substance	Route	Application rate (g a.s./ha)	Hazard quotient	Annex VI Trigger
Pyriofenone	Contact	90	< 0.90	50
Pyriofenone	Oral	90	< 0.90	50

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

Species	Test Substance	End point	Effect (LR_{50} g a.s./ha)
Typhlodromus pyri ‡	'IKF-309 180SC'	Mortality	> 1000
Aphidius rhopalosiphi ‡	'IKF-309 180SC'	Mortality	> 1035
Typhlodromus pyri ‡	'IKF-309 300SC'	Mortality	> 1000
Aphidius rhopalosiphi ‡	'IKF-309 300SC'	Mortality	> 1035

Cereals (0.09 kg a.s./ha)

Test substance	Species	Effect (LR_{50} g a.s./ha)	HQ in-field	HQ off-field [1]	Trigger
'IKF-309 180SC'	*Typhlodromus pyri*	> 1000	< 0.15	< 0.004	2
'IKF-309 180SC'	*Aphidius rhopalosiphi*	> 1035	< 0.15	< 0.004	2

[1] 1m drift rate used for cereals

Grapes (0.09 kg a.s./ha)

Test substance	Species	Effect (LR_{50} g a.s./ha)	HQ in-field	HQ off-field [1]	Trigger
'IKF-309 300SC'	*Typhlodromus pyri*	> 1000	< 0.21	< 0.014	2
'IKF-309 300SC'	*Aphidius rhopalosiphi*	> 1035	< 0.20	< 0.014	2

[1] 3m drift rate used for grapes

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

Test organism	Test substance	Time scale	End point
Earthworms			
Eisenia foetida	Pyriofenone ‡	Acute 14 days	LC_{50} > 1000 mg a.s./kg dw soil $LC_{50\ corr}$ >500 mg a.s./kg dw soil
Eisenia foetida	Pyriofenone ‡	Chronic 8 weeks	NOEC = 32.0 mg a.s./kg dw soil $NOEC_{corr}$ = 16.0 mg a.s./kg dw soil
Eisenia foetida	'IKF-309 180SC'	Acute 14 days	LC_{50} > 162 mg a.s./kg dw soil [1] $LC_{50\ corr}$ > 81 mg a.s./kg dw soil
Eisenia foetida	'IKF-309 300SC'	Acute 14 days	LC_{50} > 256 mg a.s./kg dw soil [1] $LC_{50\ corr}$ > 128 mg a.s./kg dw soil

[1] These end points have been corrected (LC_{50corr}) to calculate TERs below as the log Pow >2.0 and the peat content > 10 %.

Other soil macroorganisms			
Hypoaspis aculeifer	a.s. ‡	14 days	NOEC 1000 mg a.s./kg dw soil
Soil microorganisms			
Nitrogen mineralisation	Pyriofenone ‡	28 days	< 25 % effect at day 28 at 1.33 mg a.s./kg dw soil
Carbon mineralisation	Pyriofenone ‡	28 days	< 25 % effect at day 28 at 1.33 mg a.s./kg dw soil
Other Studies			
A litter bag study was submitted for the product 'IKF-309 300SC' and was considered acceptable for use. The percentage effect after 6 months compared to the control was 2.18 % and therefore demonstrated a low risk to soil non-target macroorganisms from the proposed use of pyriofenone on cereals and grapes.			

Toxicity/exposure ratios for soil organisms

Cereals (0.09 kg a.s./ha)

Test organism	Test substance	Time scale	Soil PEC [1]	TER	Trigger
Earthworms					
Eisenia foetida	pyriofenone	Acute	0.0969	>5160	10
Eisenia foetida	pyriofenone	Chronic	0.0969	165	5
Eisenia foetida	3HDPM[2]	Acute	0.0099	5050	10
Eisenia foetida	2MDPM[2]	Acute	0.0020	25000	10
Eisenia foetida	'IKF-309 180SC'	Acute	0.0969	>836	10
Other soil macro-organisms					
Hypoaspis aculeifer	pyriofenone ‡	14 day	0.0969	10320	5

[1] Plateau PECsoil mg/kg
[2] The toxicity value is taken as 10 times that of pyriofenone.

Grapes (0.09 kg a.s./ha)

Test organism	Test substance	Time scale	Soil PEC [1]	TER	Trigger
Earthworms					
Eisenia foetida	pyriofenone	Acute	0.1920	>2604	10
Eisenia foetida	pyriofenone	Chronic	0.1920	83	5
Eisenia foetida	'IKF-309 300SC'	Acute	0.1920	>422	10
Other soil macroorganisms					
Hypoaspis aculeifer	pyriofenone ‡	14 day	0.1920	5208	5

[1] Plateau PECsoil mg/kg

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

Endpoint	Test substance	Species	NOEC mg a.s./kg	PECsoil mg/kg	TER
Seedling emergence	'IKF-309 300SC'	All species	1000	0.1920	5208
Dry weight	'IKF-309 300SC'	Sugar beet	333.33	0.1920	1736
		Other species	1000	0.1920	5208
Height	'IKF-309 300SC'	Onion	250	0.1920	1302
		Sugar beet	12.35	0.1920	64
		Other species	1000	0.1920	5208

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

Test type/organism	End point
Activated sludge	EC_{50} > 1000 mg a.s./l

Ecotoxicologically relevant compounds

Compartment	Active substance / metabolite name
Soil	Pyriofenone, 3HDPM and 2MDPM [1]

Water	Pyriofenone, 3HDPM and 2MDPM [1]
Sediment	Pyriofenone only
Groundwater	Pyriofenone only

[1] Metabolites are relevant for cereal use only

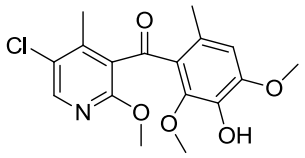
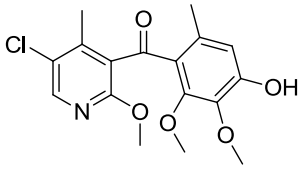
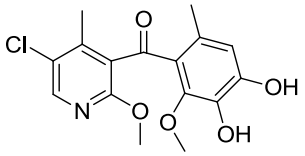
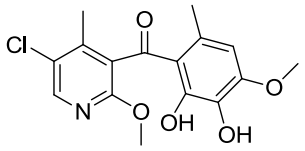
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)*

	RMS proposal
Pyriofenone	Directive 67/548/EEC R50 Very toxic to aquatic organisms R53 May cause long-term adverse effects in the aquatic environment Regulation (EC 1272/2008) H411 Toxic to aquatic life with long lasting effects

	RMS proposal
Preparations	Directive 67/548/EEC IKF-309 180SC: R51 Toxic to aquatic organisms R53 May cause long-term adverse effects in the aquatic environment IKF-309 300SC: R51 Toxic to aquatic organisms R53 May cause long-term adverse effects in the aquatic environment Regulation (EC 1272/2008) IKF-309 180SC: H411 Toxic to aquatic life with long lasting effects IKF-309 300SC: H412 Harmful to aquatic life with long lasting effects

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

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula
3HDPM	(5-chloro-2-methoxy-4-methyl-3-pyridinyl)(3-hydroxy-2,4-dimethoxy-6-methylphenyl)methanone	
4HDPM	(5-chloro-2-methoxy-4-methyl-3-pyridinyl)(4-hydroxy-2,3-dimethoxy-6-methylphenyl)methanone	
2MDPM	(5-chloro-2-methoxy-4-methyl-3-pyridinyl)(3,4-dihydroxy-2-methoxy-6-methylphenyl)methanone	
4MDPM	(5-chloro-2-methoxy-4-methyl-3-pyridinyl)(2,3-dihydroxy-4-methoxy-6-methylphenyl)methanone	

* 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
ALT	alanine aminotransferase (SGPT)
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
APTT	activated partial thromboplastin time
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
d	day
DAA	days after application
DAD	diode array detector
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FID	flame ionisation detector

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

mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen phosphorous detector
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RAC	raw agricultural commodity
RBC	red blood cells
REACH	Registration, Evaluation, Authorisation of CHemicals
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SPE	solid phase extraction
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value

TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UK POEM	United Kingdom Predictive Operator Exposure Model
UPLC-MS/MS	ultra performance liquid chromatography with tandem mass spectrometry
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WHO	World Health Organisation
wk	week
yr	year