EFSA Journal 2011;9(5):2096

CONCLUSION ON PESTICIDE PEER REVIEW

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

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SUMMARY

Fluquinconazole is one of the 79 substances of the third stage part A of the review programme covered by Commission Regulation (EC) No 1490/2002[3], as amended by Commission Regulation (EC) No 1095/2007[4]. In accordance with the Regulation, at the request of the Commission of the European Communities (hereafter referred to as 'the Commission'), the EFSA organised a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by Ireland, being the designated rapporteur Member State (RMS). The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of fluquinconazole in Annex I to Council Directive 91/414/EEC.

Following the Commission Decision of 5 December 2008 (2008/934/EC)[5] concerning the non-inclusion of fluquinconazole in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant BASF Aktiengesellschaft made a resubmission application for the inclusion of fluquinconazole in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008[6]. The resubmission dossier included further data in response to the issues identified in the DAR and during the PRAPeR expert meetings.

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, Ireland being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 13 April 2010.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 26 April 2010. The EFSA collated and forwarded all comments received to the Commission on 9 June 2010.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission requested the EFSA to conduct a focused peer review in the areas of fate and behaviour and ecotoxicology and deliver its conclusions on fluquinconazole.

[1] On request from the European Commission, Question No EFSA-Q-2010-01020, issued on 25 February 2011.
[2] Correspondence: pesticides.peerreview@efsa.europa.eu
[3] OJ L224, 21.08.2002, p.25
[4] OJ L 246, 21.9.2007, p. 19
[5] OJ L 333, 11.12.2008, p. 11
[6] OJ L 15, 18.01.2008, p.5

Suggested citation: European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance fluquinconazole. EFSA Journal 2011;9(5):2096. [112 pp.] doi:10.2903/j.efsa.2011.2096. Available online: www.efsa.europa.eu/efsajournal.htm

The conclusions laid down in this report were reached on the basis of the evaluation of the representative use of fluquinconazole as a fungicide on wheat, as proposed by the applicant. Full details of the representative use can be found in Appendix A to this report.

A data gap was identified in the section analytical methods.

A conclusion on whether the batches used in the key toxicological studies cover the technical specification cannot be drawn from the available information, leading to a critical area of concern and a data gap. Further data gaps were identified on the relevance of the impurities present in the technical specification and for toxicological information on the triazole derivative plant metabolites (1,2,4-triazole, triazolyl alanine and triazolyl acetic acid).

The consumer exposure assessment was not finalised. Data gaps are identified in the residue section to provide fluquinconazole supervised residue trials on wheat for southern Europe to complete the residue database and to address the contribution of the potential residues of metabolite dione in rotational crops and also the contribution of the Triazole Derivate Metabolites (TDMs) present in primary crops, processed products, rotational crops and ruminant matrices to the overall consumer exposure.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level for the representative use assessed. The potential for groundwater contamination above the parametric drinking water limit of 0.1µg/L from this use was assessed as low for fluquinconazole and its breakdown product 1,2,4-triazole. For the relevant breakdown product dione, contamination of groundwater might be expected in vulnerable situations as represented by the Hamburg, Kremsmünster, Okehampton and Piacenza FOCUS scenarios (FOCUS annual average recharge concentrations leaving the top 1m soil layer were estimated to be 0.283 to 0.615µg/L). Concentrations of this breakdown product were < 0.1µg/L at the remaining 5 FOCUS groundwater scenarios. Fluquinconazole that enters the atmosphere by the formation of aerosols at the time of spraying may be subject to long range atmospheric transport to remote areas, as it has an atmospheric half-life estimated at longer than 2 days.

The acute risk to insectivorous mammals (i.e. wood mouse) needs to be further addressed. A high long-term risk to insectivorous and herbivorous birds and mammals was indicated for the representative use, therefore a data gap and a critical area of concern was identified. A low risk to aquatic organisms was assessed. The potential for endocrine disruptive effects on fish were considered calculating the TER based on the ELS endpoint with an assessment factor of 50. However, a data gap was identified to submit the finalised FFLC study. The risk was considered low for bees, non-target arthropods, earthworms, soil-macro and micro-organisms, non-target plants and methods for sewage treatment plants.

KEY WORDS

Fluquinconazole, peer review, risk assessment, pesticide, fungicide

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BACKGROUND

Legislative framework

Commission Regulation (EC) No 1490/2002[7], as amended by Commission Regulation (EC) No 1095/2007[8] lays down the detailed rules for the implementation of the third stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC. This regulates for the European Food Safety Authority (EFSA) the procedure for organising, upon request of the Commission of the European Communities (hereafter referred to as 'the Commission'), a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the designated rapporteur Member State.

Commission Regulation (EC) No 33/2008[9] lays down the detailed rules for the application of Council Directive 91/414/EEC for a regular and accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC but which were not included in Annex I. This regulates for the EFSA the procedure for organising the consultation of Member States and the applicant for comments on the Additional Report provided by the designated RMS, and upon request of the Commission the organisation of a peer review and/or delivery of its conclusions on the active substance.

Peer review conducted in accordance with Commission Regulation (EC) No 1490/2002

Fluquinconazole is one of the 79 substances of the third stage part A of the review programme covered by Commission Regulation (EC) No 1490/2002, as amended by Commission Regulation (EC) No 1095/2007. In accordance with the Regulation, at the request of the Commission, the EFSA organised a peer review of the DAR (Ireland, 2005) provided by the designated rapporteur Member State, Ireland, which was received by the EFSA on 15 April 2005.

The peer review was initiated on 22 December 2005 by dispatching the DAR to Member States and the applicant BASF Aktiengesellschaft for consultation and comments. 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 Reporting Table containing the RMS' evaluation of the comments in column 3 was further considered by the EFSA, resulting in a conclusion in column 4.

All points that were identified as unresolved at the end of the comment evaluation phase, and which required further consideration in the peer review process, were compiled by the EFSA in the format of an Evaluation Table. The issues identified in the Evaluation Table, as well as further information made available by the applicant upon request, were evaluated in a series of scientific meetings with Member State experts in September 2006 and May 2007. The outcome of the expert discussions was reported in the final column of the Evaluation Table.

The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of fluquinconazole in Annex I to Council Directive 91/414/EEC.

Peer review conducted in accordance with Commission Regulation (EC) No 33/2008

Following the Commission Decision of 5 December 2008 (2008/934/EC)[10] concerning the non-inclusion of fluquinconazole in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant BASF Aktiengesellschaft made a resubmission application for the inclusion of fluquinconazole in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008.

[7] OJ L224, 21.08.2002, p.25
[8] OJ L246, 21.9.2007, p.19
[9] OJ L 15, 18.01.2008, p.5
[10] OJ L 333, 11.12.2008, p. 11

The resubmission dossier included further data in response to the issues identified in the DAR and during the PRAPeR expert meetings.

In accordance with Article 18, Ireland being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report (Ireland, 2010) was received by the EFSA on 13 April 2010.

In accordance with Article 19, the EFSA distributed the Additional Report and the DAR to Member States and the applicant for comments on 26 April 2010. The EFSA collated and forwarded all comments received to the Commission on 9 June 2010. At the same time, the collated comments were forwarded to the RMS for compilation 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.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 23 July 2010 the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on fluquinconazole within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were required to be submitted by the applicant in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicant in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the Commission on 12 July 2010, the applicant was also invited to give its view on the need for additional information. On the basis of the comments received, the applicant's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that the EFSA should organise a consultation with Member State experts in the areas of fate and behaviour and ecotoxicology and that further information should be requested from the applicant in all areas.

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 consultation with Member State experts, 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 discussions where these 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 2011.

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 wheat 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, 2011) comprises the following documents:

- the comments received on the DAR and the Additional Report,

- the Reporting Table (revision 1-1, 17 October 2006) and Reporting Table (revision 1-1, 5 July 2010)
- the Evaluation Table (5 September 2007) and Evaluation Table (23 February 2011)
- the report(s) of the scientific consultation with Member State experts (where relevant).

Given the importance of the DAR and the Additional Report including its addendum (Ireland, 2011; compiled version of January 2011 containing all individually submitted addenda) and the peer review report (EFSA, 2011), both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Fluquinconazole is the ISO common name for 3-(2,4-dichlorophenyl)-6-fluoro-2-(1*H*-1,2,4-triazol-1-yl)quinazolin-4(3*H*)-one (IUPAC).

The representative formulated product for the evaluation was 'Flamenco Plus', a suspo-emulsion (SE) containing 54 g/l fluquinconazole and 174 g/l prochloraz, registered under different trade names in Europe.

The representative use evaluated comprises spraying on wheat against various fungal diseases. 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: Guidance for generating and reporting methods of analysis (European Commission, 2000) and guidance document on residue analytical methods (European Commission, 2004b)

The minimum purity of fluquinconazole technical material is 955 g/kg. No FAO specification is 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 fluquinconazole or the representative formulation. The main data regarding the identity of fluquinconazole and its physical and chemical properties are given in appendix A.

Adequate analytical methods are available for the determination of fluquinconazole and the impurities in the technical material and for the determination of the active substance in the representative formulation. Fluquinconazole residues in food of plant and animal origin can be monitored by multi-residue methods using GC-MS or HPLC-MS/MS or by single methods using GC-ECD. Adequate analytical methods are available for monitoring the residues of fluquinconazole in the environmental compartments. A data gap was identified for the determination of fluquinconazole residues in body fluids and tissues for formal reasons as the validation for the DFG S19 method for the determination of fluquinconazole in blood could not be considered in the peer review.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: Guidance Document on the relevance of the metabolites (European Commission 2003), Guidance Document on dermal absorption (European Commission, 2004a), Guidance Document on the equivalence of technical material (European Commission, 2009)

Fluquinconazole was discussed at the PRAPeR 04 Experts Meeting on mammalian toxicology in September 2006. A conclusion on whether the batches used in the key toxicological studies cover the current proposed technical specification cannot be drawn from the available information, leading to a critical area of concern and a data gap. The relevance of the impurities - except one that is not relevant - has not been addressed and a data gap was identified.

Fluquinconazole is acutely toxic by inhalation and if swallowed. It is harmful in contact with skin. Skin or eye irritation and skin sensitisation were not observed. Upon short-term exposure, reduced body weight was a critical effect observed in dogs; the liver is the target organ in the three species tested (rat, mouse and dog) additionally, the kidneys were affected in rats. The relevant short-term NOAEL is 0.2 mg/kg bw/day derived from the 1-year and 90-day dog studies. No genotoxic potential was observed either *in vitro* or *in vivo*. Long-term administration of fluquinconazole resulted in the same target organs affecting rats and mice; liver tumours were observed in both species and on this basis, classification as a carcinogen category 3, R40 “Limited evidence of a carcinogenic effect” is proposed. The thyroid was also affected in rats, leading to the formation of thyroid tumours in both sexes, these tumours are considered rat specific due to the mechanism of action and not relevant to humans. The relevant long-term toxicity and carcinogenicity NOAEL is 0.44 mg/kg bw/day derived from the 2-year rat study. No effect on the reproduction was observed up to the highest dose tested of 6.8 mg/kg bw/day showing parental and offspring toxicity; young rats were more sensitive to fluquinconazole toxicity than the adults and the offspring NOAEL is 0.3 mg/kg bw/day based on clinical signs and reduced pup viability observed at higher dose levels. Developmental toxicity as increased post-implantation loss in rats and increased variant sternebrae in rabbits was associated with maternal toxicity; a NOAEL of 2 mg/kg bw/day for both maternal and developmental toxicity is found in both species. No neurotoxic potential is attributed to the active substance.

Toxicological studies were presented on a minor rat metabolite, dione, showing that the metabolite is less acutely toxic than the parent compound, the short-term (28-day) toxicity was also lower than fluquinconazole. No genotoxic potential is attributed to the dione metabolite either *in vitro* or *in vivo*. The reference values of the parent are applicable to this metabolite. Based on the peer review proposal to classify the parent as a carcinogen, the metabolite should be considered relevant according to the guidance document on the assessment of the relevance of metabolites in groundwater (European Commission, 2003), this classification proposal is however not reflected in the Annex VI of Regulation (EC) No 1272/2008 (decision published in 2001 - 28th ATP[11]).

No toxicological information was presented in the dossier on the triazole derivative plant metabolites (1,2,4-triazole, triazolyl alanine and triazolyl acetic acid) and a data gap is identified.

The acceptable daily intake (ADI) of fluquinconazole is set at 0.002 mg/kg bw/day, based on the overall NOAEL from the 1-year and 90-day dog studies and applying a safety factor of 100; the acceptable operator exposure level (AOEL) is 0.001 mg/kg bw/day, based on the same NOAEL from the dog studies, 100 safety factor and 60 % correction for limited oral absorption (in rats). The acute reference dose (ARfD) is 0.02 mg/kg bw based on both developmental toxicity studies in rat and rabbit.

The estimated operator exposure level is below the AOEL when the use of personal protective equipment (PPE) is considered, such as gloves during mixing and loading; and gloves, protective garment and sturdy footwear during application according to the German model. Bystander exposure is estimated to remain below the AOEL. Although EFSA considers that the worker esposure risk assessment estimates present some drawbacks, and that the resulting values should be somewhat higher, the outcome remains unchanged, i.e., estimated worker exposure is be below the AOEL when PPE is worn.

3. Residues

The conclusion in the residue section 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, 2007). The metabolism of fluquinconazole has been investigated in apples and grapevines (fruit crops), in carrots (root and tuber vegetables) and in spring wheat (cereals) using foliar spray application of fluquinconazole with only the dichlorophenyl-U-[^{14}C] labelling form (apples, grapevines, carrots) and with both the dichlorophenyl-U-[^{14}C] and the triazolyl-U-[^{14}C] labellings on spring wheat (2.5 N rate). No metabolite was investigated in apple since only 8 % of the applied radioactivity was recovered in the fruit. In grapevines, fluquinconazole was detected as the major compound of the total residues, accounting at harvest for up to 90.5 % TRR with the metabolite dione (AEC 596912) (3.5 % TRR)

[11] 28th ATP: OJ L225, 21.8.2001, p.1, Commission Directive 2001/59/EC of 6 August 2001 adapting to technical progress for the 28th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provision relating to the classification, packaging and labelling of dangerous substances.

resulting from the cleavage of the triazole quinazoline linkage. In spring wheat, fluquinconazole remained the predominant compound in grain and straw (up to 95 % TRR) while the metabolite dione was recovered at a level <1 % TRR in straw and was not detected in grain. For the triazolyl labelled moiety, the residues in grain were mainly constituted of the triazole derivate metabolite (triazolyl alanine - 30 % TRR), whilst up to 66 % TRR were not characterised further. The metabolic profile of fluquinconazole in rotational crops sown 32 days after soil treatment at a rate of 250 g a.s./ha was shown to be consistent with that observed in the primary crops. Fluquinconazole and the TDMs (Triazolyl alanine and Triazolyl acetic acid) constituted the relevant indicators of the total residues in the edible parts of the rotated crops. The metabolite dione was not detected in wheat grain and was recovered at a very low level in the other extracts (0.003 to 0.035 mg/kg in wheat forage, hay and straw). At a 120 day-plant back interval, the metabolic pattern of fluquinconazole in the rotated crops was similar but indicated that at the 1 N rate, the level of the metabolite dione was expected to be >0.01 mg/kg in radish roots and lettuce and > 0.05 mg/kg in wheat straw while it was detected at a trace level in wheat grain (*circa* 0.001 mg/kg). Based on these studies, the residue definition for monitoring was limited to the parent fluquinconazole, only. For risk assessment, considering the significant presence of TDMs in wheat grain and rotational crops and their toxicological pertinence, two separate residue definitions were proposed: 1) Parent fluquinconazole and 2) TDMs. This second residue definition has to be regarded as provisional pending finalisation of a global and harmonised approach for all the active substances of the triazole chemical group. In the future, if additional uses are supported, triazole-labelled studies on fruit crops and root and tuber vegetables should be required in order to extend the residue definition for risk assessment to all categories of crops.

A sufficient number of residue trials supported the use in northern Europe only while a data gap was identified to complete the fluquinconazole residue data package on wheat covering southern Europe. In addition, further residue trials to determine the residue levels of TDMs in wheat grain and straw are required to comply with the proposed residue definition for risk assessment. The storage stability studies demonstrated that fluquinconazole residues were stable in wheat grain and straw for 31 and 12 months, respectively and therefore covered the storage time period of the samples of the valid residue trials.

Rotational crops field trials were conducted on winter barley, cabbage, beans and potatoes with a plant back interval after treated wheat harvesting of 1 month for barley and cabbage and 8 months for beans and potatoes. The residues of fluquinconazole were found to be below the LOQ (<0.05 mg/kg) in cabbage (heads), beans (immature pods, haulms, mature beans without pods), potatoes (immature and mature tubers, foliage) and barley (grain) and below the LOQ of 0.1 mg/kg in barley (ears, stalks, straw). In view of the metabolic pattern of fluquinconazole observed in rotated crops and the higher residue level of the metabolite dione recovered at the 120 day-plant back interval, a data gap has been identified to provide additional field trials to determine the magnitude of the residues of fluquinconazole, the metabolite dione and the TDMs in representative rotated crops at the plant back interval of 120 days. These rotational crops field trials should be carried out at a dose rate of application representative of the soil plateau concentration reached for fluquinconazole and the metabolite dione, respectively. Pending the outcome of the requested rotational field trials, the residue definition for risk assessment set as fluquinconazole for plant commodities would have to be revisited.

Fluquinconazole was shown to be stable under pasteurisation while at baking/brewing and boiling, degradation of the parent compound occurred with the formation of the metabolites dione (7% of AR) and 1,2,4-triazole (9% of AR). Hydrolysis studies simulating sterilisation were not considered as required for the representative use. Information on the magnitude of the residues of fluquinconazole in processed wheat matrices was not triggered since the residues in wheat grains were below 0.05 mg/kg. The residue level of TDMs in processed products may need to be addressed pending the outcome of the requested residue trials on TDMs in wheat grain.

The livestock dietary intake triggered the investigation of the nature of the residues of fluquinconazole in ruminant matrices. The parent compound constituted the predominant compound of the total residues in milk and in all tissues (21 to 99 % TRR). At 1 N rate, the metabolite dione occurred mainly in muscle (21 % TRR-0.004 mg/kg), liver (13.6 % TRR-0.05 mg/kg), kidney (18 % TRR-0.011 mg/kg), edible offals (4.3 % TRR-0.0028 mg/kg) and fat (<1% TRR-0.0033 mg/kg) while it was detected in milk but not quantified. The residue definition for monitoring was defined as fluquinconazole only while for risk assessment, it is proposed to include both fluquinconazole and the metabolite dione in the residue definition as it was considered as toxic as the parent compound as far as the long-term exposure is concerned (refer to section 2). Conversion factors for monitoring to risk assessment were derived from the metabolism data for muscle (2), liver (3), kidney (4), fat (1), milk (1) and edible offals (1). Based on a feeding study, MRLs were proposed for milk, ruminants tissues and offals. Storage stability data showed that fluquinconazole residues were stable in milk and edible offals for up to 20 months, in liver for 6 months and in fat for 13 months. No information was provided concerning the likely formation or the intake of TDMs and their possible transfer to ruminant products, although these metabolites were shown to represent the major part of the residues in cereal grains and in rotational crops. A data gap was therefore identified to request a ruminant metabolism study labelled on the triazole ring of the parent molecule in order to propose a residue definition for risk assessment on TDMs in animal products. Pending on the outcome of the ruminant metabolism study, a feeding study addressing respectively the nature and the magnitude of TDM potentially present in milk and ruminant tissues may be required. A metabolism study on poultry was submitted although the intake was not triggered. Therefore no residue definition and no MRLs are proposed for poultry products.

No chronic and acute intake concern was identified using the EFSA PRIMo model (TMDI: 66.1 % of the ADI and IESTI: 18.6 % of the ARfD). A refinement of the chronic intake calculation using the STMR values for wheat grain and ruminant matrices established an IEDI of 21.4 % of the ADI. However, these estimations have to be considered as provisional as the contribution of the TDMs in primary crops, processed products, rotational crops and in ruminant matrices to the overall consumer exposure was not taken into account. It is also noted that the metabolite dione may leach to ground water at significant levels (refer to section 4). The 0.1µg/L trigger was exceeded in 4 of the pertinent FOCUS winter cereals scenarios with a maximum concentration of 0.615 µg/L being estimated for the FOCUS Piacenza winter cereals scenario. Therefore, an additional exposure of the consumers can be expected when ground water is used as drinking water though this route of exposure is not considered as significant (<5% ADI and ARfD, respectively).

4. Environmental fate and behaviour

In soil laboratory incubations under aerobic conditions in the dark, fluquinconazole exhibited high to very high persistence, forming the major (>10% applied radioactivity (AR)) breakdown products dione (max. 29 % AR) and 1,2,4-triazole (max. 19 % AR), which exhibited high to very high and low to moderate persistence, respectively. The available data indicate that breakdown of fluquinconazole in soil to these two compounds is primarily an abiotic process. Mineralisation of the dichlorophenyl ring radiolabel to carbon dioxide accounted for 0.1 – 0.8 % AR after 93 days increasing to a maximum of 2.9% AR after 365 days. These values for the triazolyl ring radiolabel were 0.4-2.1 % AR increasing to a maximum of 10.4 % AR. The formation of unextractable residues (not extracted by Soxhlet acetonitrile, followed by Soxhlet acetonitrile:water, both radiolabels had similar values after 93 days) accounted for 2.4 – 15.5 % AR. In anaerobic soil incubations the same pattern of breakdown was observed though, the levels of the two breakdown products formed were higher than under aerobic conditions. Fluquinconazole and dione exhibited low mobility in soil. 1,2,4-triazole exhibited high to very high soil mobility. There were no indications that the adsorption of these three compounds was pH dependent. In satisfactory field dissipation studies carried out at 15 sites in England, France (mid and south) and Germany (in all trials spray applications were to the soil surface on bare soil plots in late spring) fluquinconazole exhibited high to very high persistence. Sample analyses were carried out for the parent fluquinconazole and dione, though the patterns of dione detections did not enable DT values to be estimated for dione. Field DT_{50} for fluquinconazole were normalised to the FOCUS reference temperature of 20ºC following FOCUS (2006) guidance (time step normalisation approach) using an Arrhenius activation energy of 92.4 kJ mol^{-1} (measured value at pH 7 in aqueous solution)[12] (see Appendix A).

In sterile aqueous hydrolysis studies at pH 7 and 25ºC the half life of fluquinconazole was estimated to be 21.9 days. It's hydrolysis Arrhenius activation energy calculated to be 92.4 kJ mol^{-1} at pH 7. Under more alkaline conditions (pH 9) fluquinconazole was more labile. Under acidic conditions (pH 5) it was more stable (Arrhenius activation energy calculated to be 167 kJ mol^{-1}). The hydrolytic breakdown products dione and 1,2,4-triazole were demonstrated to be essentially stable to further hydrolytic breakdown at environmentally relevant pH and temperatures. Aqueous photolyic investigations indicated that light did not enhance the breakdown of fluquinconazole but that light energy can enhance the breakdown of dione in aqueous solution.

In laboratory incubations in dark aerobic natural sediment water systems (pH of water 8.1 and sediment 7.6-8), fluquinconazole exhibited moderate persistence, forming the major breakdown products dione (max. 22-24 % AR in water and 44-47 %AR in sediment) and 1,2,4-triazole (max. 29-32 % AR in water and 26-37% AR in sediment). The unextractable sediment fraction (not extracted by Soxhlet acetonitrile, followed by Soxhlet acetonitrile:water) was a sink for the ^{14}C radiolabels, accounting for 5-8 % AR for the dichlorophenyl ring and 17-25 % AR for the triazolyl ring at study end (100 days). Mineralisation of these radiolabels accounted for only 0.4 – 0.7 % AR (dichlorophenyl ring) and 1.6-2.8% AR (triazolyl ring) at 100 days.

The necessary surface water and sediment exposure assessments (Predicted environmental concentrations (PEC) estimates) were completed for the breakdown products dione and 1,2,4-triazole, using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 1.1 of the Steps 1-2 in FOCUS calculator). For the active substance fluquinconazole, appropriate step 3 calculations (FOCUS, 2001) and for the FOCUS scenario D2 step 4 calculations were available[13]. The step 4 calculations for D2, fixed the crop interception factor to 50% for the first application and 70% for the second which represents the growth stages specified for the representative use (BBCH 25-59)[14].

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[15] for the active substance fluquinconazole and the breakdown products dione and 1,2,4-triazole. The potential for groundwater exposure from the representative uses by fluquinconazole and 1,2,4-triazole above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios. For the relevant [16] breakdown product dione, contamination of groundwater might be expected in vulnerable situations as represented by the Hamburg, Kremsmünster Okehampton and Piacenza FOCUS scenarios (FOCUS annual average recharge concentrations leaving the top 1m soil layer were estimated to be up to 0.347, 0.283, 0.507 and 0.615µg/L respectively). Concentrations of this breakdown product were < 0.1µg/L at the remaining 5 FOCUS groundwater scenarios.

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[12] As agreed in PRAPeR 22 (May 2007) and confirmed as appropriate in PRAPeR 84 (November 2010).

[13] For fluquinconazole simulations utilised the agreed (PRAPeR 22 and PRAPeR 84) Arrhenius activation energy of 92.4kJ mol^{-1} (pH 7 aqueous hydrolysis measured value) and Walker equation coefficient of 0 that assumes that soil moisture was always sufficient for the assumed primarily abiotic hydrolytic breakdown to occur under all soil moisture conditions. The soil depth dependent degradation factors were set to 1 for all soil layers as is appropriate when biotic degradation is expected to be limited.

[14] For the appropriate application window simulated (8 April-29 May resulting in applications on the 7 and 29 May), the Step 3 calculations use crop interception of only 15-45%.

[15] For fluquinconazole simulations utilised the agreed (PRAPeR 22 and PRAPeR 84) Arrhenius activation energy of 92.4kJ mol^{-1} and Walker equation coefficient of 0. The soil depth dependent degradation factors were set to 1 for all soil layers as is appropriate when biotic degradation is expected to be limited. For dione and 1,2,4-triazole the EFSA (2007) Arrhenius activation energy of 65.4kJ mol^{-1} and Walker equation coefficient of 0.7 were utilised. The standard soil depth dependent degradation factors as defined by FOCUS (2000) were utilised for these breakdown products. This is appropriate as the breakdown products are expected to be degraded by primarily microbially mediated processes. These simulations complied with EFSA (2004).

[16] Following European Commission (2003) guidance (see sections 2 and 6).

Fluquinconazole is not expected (based on measurements) to volatilise to any significant extent from plant surfaces and soil. However as it is applied as a spray it may enter the atmosphere forming aerosols at the time of spraying. Fluquinconazole that reaches the atmosphere would be expected to be subject to long range atmospheric transport as it has an atmospheric half life estimated (via quantitative structure activity relationship calculations for photochemical oxidative reaction with hydroxyl radicals) at longer than 2 days (4.7 days). This is identified as a critical area of concern.
The PEC in soil, surface water, sediment, and groundwater covering the representative uses assessed can be found in Appendix A of this conclusion.

5. Ecotoxicology

The risk assessment was based on the the guidance document on Terrestrial Ecotoxicology (European Commission, 2002a), the guidance document on Aquatic Ecotoxicology (European Commission, 2002b), the guidance document on the Risk Assessment for Birds and Mammals (European Commission, 2002c), the guidance document on Regulatory Testing and Risk Assessment Procedures (SETAC, 2001), and the guidance document on the Risk Assessment for Birds and Mammals (EFSA, 2009)A low acute and short-term risk was assessed for insectivorous and large herbivorous birds, while a high long-term risk was identified using standard the first tier assessment. The risk assessment at the next tier was based on the focal species Skylark (*Alauda arvensis*). To refine the PD and the PT values two datasets were taken into account: one based on literature data (named “UK scenario”) and the second based on a field study conducted in Austria (named “Austria scenario”). For each dataset two dietary regimes were identified for skylark to cover the representative uses. Indeed, skylark is predominantly herbivorous in spring (i.e at the time of the early use) and predominantly insectivorous in summer (i.e. at the time of the late use). Member States experts expressed concerns at the PRAPeR 85 meeting over the PD values used in the “UK scenario” because these values were quantified by the applicant based on graphical observations. The experts concluded that such values could be used in the risk assessment only if they represent a worst-case. For the PT values the experts agreed to use the median 90th percentile (i.e. PT=0.92 for the “UK scenario” and PT=0.941 for the “Austria scenario”). Besides the ecological data, mean measured foliar residues and residue decline in cereal plants and refined RUD values were introduced in the TER calculations. Nevertheless, the long-term risk was still indicated as high and a data gap was set for further refinement of the long-term risk assessment for insectivorous and herbivorous birds for the representative use. A critical area of concern was therefore identified.

A low acute risk was assessed for insectivorous mammals, while a high long-term risk was identified with the first tier assessment. A high acute and long-term risk was indicated for herbivorous mammals. To refine both the acute and the long-term risk assessment two focal species were considered: wood mouse (*Apodemus silvaticus*) and common hare (*Lepus europeus*), along with other options for refinement (i.e. measured foliar residues and residue decline in cereal plants and refined RUD values). The acute risk was assessed as low for common hare based on initial measured foliar residue. It is noted that PD values were included in the refined acute risk assessment provided for wood mouse. However, PD values cannot be used for acute risk refinement because omnivorous species may obtain its daily feed demand from one type of food. In addition, the experts expressed concerns over the PT and the PD values related to these species because several uncertainties were identified in the studies from which they where generated. Therefore, it was agreed to use the default PT value of 1 for both species. The PD value should be expressed in terms of dry weight for both species, and in the PD value for hare, the weeds obtained within the crop should be included, to result in PD adding up to 1. Overall, a data gap was identified to further address the acute risk for wood mouse and the long-term risk for insectivorous mammals (i.e. wood mouse) and herbivorous mammals (i.e common hare). A critical area of concern was therefore identified.

Since logPow=3.24, the risk assessment for secondary poisoning has been conducted. A low risk was identified for earthworm-eating birds based on max PECs plateau =0.1288 mg/kg, while the TER for earthworm-eating mammals was below the Annex VI trigger indicating the need of further refinement of the risk assessment (data gap). A low risk was identified for fish-eating birds and mammals based on the max 21d-twa PECsw at FOCUS step2 (=6.678 µg a.s./L).

A low risk is expected from consumption of contaminated water considering the puddle scenario.

Fluquinconazole is very toxic to aquatic organisms on the basis of available data. The lowest endpoint was observed in a study with the active substance on algae (*Selenastrum capricornutum*, E_bC_{50}= 0.014 mg a.s/L). Acute studies with formulated product and the metabolites dione (AE C596912) and 1,2,4-triazole on fish, aquatic invertebrates and algae were available. The formulation and the metabolite dione were more toxic than the active substance for fish and aquatic invertebrates and slightly less toxic for algae. The metabolite 1,2,4-triazole was less toxic than the parent.

A high risk was indicated for algae at FOCUS step2 based on the toxicity endpoint of fluquinconazole and for fish based on the acute toxicity endpoint of the formulated product. The TER calculations for fish at FOCUS step 3 indicated a low risk in all scenarios, while the TERs for algae were below the annex VI trigger only in the scenario D2 (ditch and stream). A subsequent risk assessment, based on an appropriate refinement of some exposure model input parameterisation (relating to crop interception, i.e. a FOCUS step4 simulation, though no mitigation measures were introduced), indicated a low risk. A risk assessment was conducted for the metabolites 1,2,4-triazole and dione at FOCUS step 1 and step2, respectively: all the TERs were above the Annex VI trigger, indicating a low risk for aquatic organisms regarding these metabolites.

Fluquinconazole may be a potential endocrine disruptor for fish. A full fish life cycle (FFLC) study was not available in the dossier. However, it was pointed out during the peer review, that assessment factor of 50 could cover the variation between the ELS and the FFLC study for ergosterol synthesis inhibitor fungicides. If an assessment factor of 50 is applied to the early life stage (ELS) endpoint, the TERs with PECsw at FOCUS step 3 are above this assessment factor, indicating that the potential endocrine disruptor effects could be considered covered by the ELS. A FFLC study was finalised after the resubmission dossier. This could not be taken in consideration during the peer review but it will be useful to further address this issue. Therefore a data gap is identified.

A high risk was indicated for bees based on the lowest endpoint observed in a study with the formulated product. However, this study was considered unreliable because food avoidance at high test concentrations was observed and the observed mortality was related to starvation of bees. The risk was assessed as low on the basis of another available study in which no food avoidance occurred.

A high in-field risk was identified for the two standard species (*Typhlodromus pyri* and *Aphidius rhopalosiphi*) indicating the need to further address the potential for recovery of the treated area. Extended laboratory studies were available with the two standard species and additional species (i.e. *Coccinella septempunctata* and *Chrysoperla carnea* and *Poecilus cupreus*). According to SETAC (2001), no effects >50% were observed at an exposure equivalent to the application rate of 4.6 L/ha, except for *T. pyri* (LR50 was determined as 1.3 L/ha). However, mortality and reproduction effects observed in an aged residue study on *T. pyri* were <50%. Therefore, the potential for the in-field recovery could be considered addressed.

A low acute risk was identified for earthworms. However, high long-term risk was identified for earthworms at the first tier of assessment. The risk was subsequently addressed by a field study, where long-term effects on earthworm abundance, biomass or reproduction were not observed at 900 g.as./ha. The acute and chronic risk to earthworms and collembola was assessed as low for the metabolites dione and 1,2,4-triazole, respectively.

A low risk was assessed for other soil-macro-organisms, soil-micro-organisms, other non-target 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
fluquinconazole	high to very high persistence single first order DT_{50} 186-441 days (20°C, 40% MWHC soil moisture) Field studies: both single first order and biphasic DT_{50} 17.5-777 days (DT_{90} 462–40402 days)	The risk for soil organisms was assessed as low.
dione	high to very high persistence single first order DT_{50} 231-567 days (20°C, pF2 or 40% MWHC soil moisture)	The risk for soil organisms was assessed as low.
1,2,4-triazole	low to moderate persistence single first order DT_{50} 6.3-12.3 days (20°C, 40% MWHC soil moisture)	The risk for soil organisms was assessed as low.

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

fluquinconazole	low mobility K_{Foc} 750-1153 mL/g	No	Yes	Yes	Yes. Fluquinconazole is very toxic to aquatic organisms. The lowest endpoint was observed in a study with the active substance on algae (*Selenastrum capricornutum*, E_bC_{50}= 0.014 mg a.s/L, regulatory endpoint including an assessment factor of 10 0.0014 mg a.s/L). The risk to aquatic organisms in surface water was assessed as low.

dione	low mobility K_{Foc} 567-999 mL/g	Yes at 4 (Hamburg, Okehampton, Kremsmünster & Piacenza) out of 9 scenarios, where the concentration range was 0.283-0.615 µg/L	No data, data would have been required if it had not been concluded that dione was toxicologically relevant in the context of groundwater relevance assessment guidance.	Yes, based on the peer review proposal of classification of the parent as Carc. Cat. 3, R40. Classification proposal by the peer review of the parent compound fluquinconazole as Carc. Cat. 3, R40, not reflected in Regulation (EC) No 1272/2008 Annex VI – decision published in 2001 (28th ATP[17]). Rat LD_{50} oral > 5000 mg/kg bw; Rat LD_{50} dermal > 5000 mg/kg bw; Non-irritant (skin and eyes), non-sensitiser; NOAEL = 124 mg/kg bw/day (28-day oral, rat); No genotoxic potential *in vitro/in vivo*.	Yes. The risk to aquatic organisms in surface water was assessed as low.

[17] 28th ATP: OJ L225, 21.8.2001, p.1, Commission Directive 2001/59/EC of 6 August 2001 adapting to technical progress for the 28th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provision relating to the classification, packaging and labelling of dangerous substances.

1,2,4-triazole	high to very high mobility K_{Foc} 43-120 mL/g	No	No data, assessment not triggered.	Yes, classified as Repr. Cat. 3; R63 according to Regulation (EC) No 1272/2008 Annex VI (24th ATP[18]).	Yes. The risk to aquatic organisms in surface water was assessed as low.

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
fluquinconazole	Fluquinconazole is very toxic to aquatic organisms. The lowest endpoint was observed in a study with the active substance on algae (*Selenastrum capricornutum*, E_bC_{50}= 0.014 mg a.s/L, regulatory endpoint including an assessment factor of 10 0.0014 mg a.s/L). The risk to aquatic organisms was assessed as low.
dione	The risk to aquatic organisms was assessed as low.
1,2,4-triazole	The risk to aquatic organisms was assessed as low.

6.4. Air

Compound (name and/or code)	Toxicology
fluquinconazole	Rat LC_{50} inhalation 0.514 mg/L air/4h, classified as T, R23 “toxic by inhalation”
1,2,4-triazole	No data (not classified regarding inhalation in Regulation (EC) No 1272/2008 Annex VI)

[18] 24th ATP: OJ L305, 16.11.1998, p.1-181, Commission Directive 98/73/EC of 18 September 1998 adapting to technical progress for the 24th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provision relating to the classification, packaging and labelling of dangerous substances

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

- Analytical method for the determination of fluquinconazole residues in body fluids and tissues (relevant for all representative uses; submission date proposed by the applicant: data already submitted, however could not be considered in the peer review due to the restrictions of Commission Regulation (EC) No. 33/2008, see section 1).

- The applicant has to address whether the batches used in the key toxicological studies, namely batches CR 19387/01/2/3 cover the technical specification (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2).

- The toxicological relevance of impurities – except one that is not relevant - has to be addressed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2).

- Toxicological information on the triazole derivative plant metabolites (1,2,4-triazole, triazolyl alanine and triazolyl acetic acid) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2 and 3).

- A complete fluquinconazole residue trials data package on wheat covering southern Europe is required (relevant for the representative use on wheat; submission date proposed by the applicant: unknown, see section 3).

- Additional residue trials to determine the residue levels of TDMs in wheat grain and straw are required to comply with the proposed residue definition for risk assessment in plants (relevant for the representative use on wheat; submission date proposed by the applicant: unknown, see section 3).

- Data to address the magnitude of TDMs in processed products unless residue trials data on TDMs in wheat grain indicate that these studies are not triggered (relevant for the representative use on wheat; submission date proposed by the applicant: unknown, see section 3).

- Rotational crop field trials to determine the magnitude of the residues of fluquinconazole, the metabolite dione and the TDMs in representative rotated crops at 120 day plant back intervals (relevant for the representative use on wheat; submission date proposed by the applicant: unknown, see section 3).

- A ruminant metabolism study labelled in the triazolyl ring of the parent fluquinconazole is required in order to propose a residue definition for risk assessment on TDMs in animal products (relevant for the representative use on wheat; submission date proposed by the applicant: unknown, see section 3).

- An overall consumer risk assessment considering the contribution of the TDMs in primary crops, processed products, rotational crops and products of animal origin (relevant for the representative use on wheat; submission date proposed by the applicant: unknown, see section 3).

- The acute risk to wood mouse needs to be further addressed (relevant for all representative uses evaluated submission date proposed by the applicant: unknown; see section 5)

- The long-term risk to insectivorous and herbivorous birds and mammals needs to be further addressed (relevant for all representative uses evaluated submission date proposed by the applicant: unknown; see section 5)

- The risk for earthworm-eating mammals needs to be further addressed (relevant for all representative uses evaluated submission date proposed by the applicant: unknown; see section 5)

- A Full Fish Life Cycle (FFLC) study should be provided to further address the potential for endocrine disruptor effects on fish (relevant for all representative uses evaluated submission date proposed by the applicant: study finalised after the Additional Report resubmission; see section 5).

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- Estimated operator exposure is below the AOEL when PPE (gloves during mixing and loading; gloves, protective garment and sturdy footwear) are worn according to the German model (see section 2).

- Estimated worker exposure is below the AOEL when PPE is worn (see section 2).

ISSUES THAT COULD NOT BE FINALISED

- The consumer dietary intake risk assessment could not be finalised due to the outstanding data on the toxicity and the contribution of the residues of the Triazole Derivative Metabolites (TDMs) present in primary crops, in processed products, in rotational crops and in products of animal origin and also the contribution of the potential residues of metabolite dione in rotational crops to the overall consumer exposure.

- The risk assessment for earthworm-eating mammals could not be finalised. The TER based on the first tier assessment was slight below the Annex VI trigger and a data gap was set for further risk refinement.

- The acute risk to wood mouse could not be finalised.

CRITICAL AREAS OF CONCERN

- No conclusion could be reached whether the batches used in the key toxicological studies are representative of the technical specification.

- Fluquinconazole that enters the atmosphere by the formation of aerosols at the time of spraying may be subject to long range atmospheric transport to areas remote from its use. (The available information indicates that it will have an atmospheric half-life of greater than 2 days).

- A high long-term risk to insectivorous and herbivorous birds and mammals was identified for the representative use. A high acute risk to wood mouse could not be excluded.

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[19] For further guidance documents see http://ec.europa.eu/food/plant/protection/resources/publications_en.htm#council (EC) or http://www.oecd.org/document/59/0,3343,en_2649_34383_1916347_1_1_1_1,00.html (OECD)

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APPENDICES

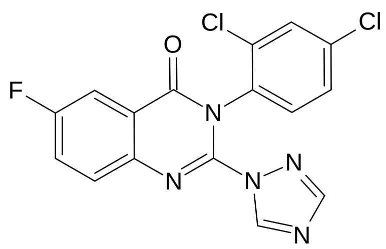
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE

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

Active substance (ISO Common Name) ‡	Fluquinconazole
Function (*e.g.* fungicide)	Fungicide

Rapporteur Member State	Ireland
Co-rapporteur Member State	None

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	3-(2,4-dichlorophenyl)-6-fluoro-2-(1*H*-1,2,4-triazol-1-yl)quinazolin-4(3*H*)-one
Chemical name (CA) ‡	3-(2,4-dichlorophenyl)-6-fluoro-2-(1*H*-1,2,4-triazol-1-yl)-4(3*H*)-quinazolinone
CIPAC No ‡	474
CAS No ‡	136426-54-5
EC No (EINECS or ELINCS) ‡	411-960-9
FAO Specification (including year of publication) ‡	None
Minimum purity of the active substance as manufactured ‡	955 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Open
Molecular formula ‡	$C_{16}H_8Cl_2FN_5O$
Molecular mass ‡	376.2 g/mol
Structural formula ‡	

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

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	190.8°C (onset) – 193.5°C (peak) (99.6 %)
Boiling point (state purity) ‡	Fluquinconazole does not show a boiling point. (99.6 %)
Temperature of decomposition (state purity)	320°C (onset) (99.6 %)
Appearance (state purity) ‡	Pure material: white crystalline solid at 22°C (99.7 %)
	Technical material: white crystalline solid at 22°C (purity not specified)
Vapour pressure (state temperature, state purity) ‡	6.4×10^{-9} Pa (20°C, 99.3 %)
Henry's law constant ‡	2.09×10^{-6} Pa m^3 mol^{-1} at 20°C.
Solubility in water (state temperature, state purity and pH) ‡	0.90 g/L at *ca.* 20°C (pH 3.8) (99.3 %) 1.15 g/L at *ca.* 20°C (pH 6.6) (99.3 %) 1.21 g/L at *ca.* 20°C (pH 10.7) (99.3 %)
	No significant pH dependence was found.
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20°C in g/L (99.3 %) acetone: 38-50 dichloromethane: 120-150 dimethylsulphoxide: 50-200 ethyl acetate: 30-38 ethanol: 3.48 hexane: 0.114 methanol: 4.41 propan-2-ol: 1.32 toluene: 14.01 *p*-xylene: 9.88
Surface tension ‡ (state concentration and temperature, state purity)	70.91 mN/m at 20°C (90 % saturated solution) (96.8 %)
Partition co-efficient ‡ (state temperature, pH and purity)	log $P_{O/W}$ = 3.24 at 20 °C (pH 5.58) (99.3 %)
	Effect of pH was not investigated since there is no dissociation in water in the environmentally relevant pH range.
Dissociation constant (state purity) ‡	pKa_1 = 0.9 ± 0.1 pKa_2 = -4.4 ± 0.2 (Note that purity was not given as the dissociation constants were estimated using modelling software)

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Neutral (methanol) solution: λ_{max} (nm); ε ($L.mol^{-1}.cm^{-1}$) 307 4928 (99.4 %) Acidic (methanol/HCL (90/10, v/v)) solution: λ_{max} (nm); ε ($L.mol^{-1}.cm^{-1}$) 307 4894 (99.4 %) Basic (methanol/NaOH (90/10, v/v)) solution: λ_{max} (nm); ε ($L.mol^{-1}.cm^{-1}$) 321 3876 307 2818 (99.4 %)
Flammability ‡ (state purity)	Not flammable (97.8%) The test substance could not be ignited (it melted) therefore the main test was unnecessary.
Explosive properties ‡ (state purity)	Not explosive (97.8 %) The heat of decomposition (416 J/g) was below 500 J/g therefore a main test for explosive properties is not required.
Oxidising properties ‡ (state purity)	Not oxidising (99.9%).

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland	Revised September 2010	Fluquinconazole

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

Summary of representative uses evaluated (Fluquinconazole)*.

Crop and/or situation (a)	Member State or Country	Product name	F, G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s (i)	Method kind (f-h)	Growth stage & season (j)	Number Min-max (k)	Interval between applications (min)	Kg a.s./hL Min-max	Water L/ha Min-max	Kg a.s./ha Min-max		
Wheat	Europe North & South	FLAMENCO Plus BAS 616 01F	F	Erysiphe graminis Septoria tritici Septoria nodorum Puccinia striformis Puccinia recondite Fusarium spp	SE	54 g/L* + 174 g/L**	Spraying	Beg. Of infection (25) up to 59	2	21 days	0.031-0.083* 0.100-0.267**	150-400	0.125* 0.400**	35-60	2.3 L per treatment harvest time depending on climatic conditions [1], [2], [3]

*Fluquinconazole

**Prochloraz

[1] No conclusion could be reached whether the batches used in the key toxicological studies are representative of the technical specification.

[2] The consumer dietary intake risk assessment could not be finalised due to the outstanding data on the contribution of the potential residues of the metabolite dione in rotational crops and also the contribution of the Triazole Derivative Metabolite (TDMs) present in primary crops, in processed products, in rotational crops and in products of animal origin to the overall consumer exposure.

[3] the long-term risk to birds and mammals was assessed as high. A data gap was set and a critical area of concern was identified. The risk for fish-eating mammals was not finalised.

* 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	(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

Rapporteur Member State	**Month and year**	**Active Substance (Name)**
Ireland	Revised September 2010	Fluquinconazole

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

(h)	Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (CO-RMS – Poland)	Revised September 2010	Fluquinconazole

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

Technical as (analytical technique)	HPLC-UV
Impurities in technical as (analytical technique)	The following methods were used for analysis of the various impurities: 1. HPLC-UV 2. GC-FID. Confirmation was done using GC-MS. 3. Karl-Fisher titration (water content).
Plant protection product (analytical technique)	The analysis was carried out by reversed phase liquid chromatography at 40°C with UV detection at 240nm.

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Fluquinconazole
Food of animal origin		Fluquinconazole (ruminants only)
Soil		Fluquinconazole
Water	surface	Fluquinconazole
	drinking/ground	Fluquinconazole
Air		Fluquinconazole

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (CO-RMS – Poland)	Revised September 2010	Fluquinconazole

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	1. Two multi-residue methods are available: DFG S19 (GPC with GC-MS). LOQ = 0.05 mg/kg (for grain and apples) QuEChERS (LC-MS/MS) LOQ = 0.01 mg/kg 2. Cereals (grain and straw) were analysed using GC-ECD LOQ = 0.15 mg/kg for both grain and straw 3. GC-ECD (apples, grapes and wine) LOQ = 0.05 mg/kg (apples and grapes) LOQ = 0.01 mg/l (wine) 4. GC-ECD (sugar beet roots and tops) LOQ = 0.05 mg/kg 5. HPLC-MS/MS LOQ = 0.01 mg/kg (wheat, oilseed rape, grape and orange)

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (CO-RMS – Poland)	Revised September 2010	Fluquinconazole

Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Multi method DFG S19 GC-ECD LOQ = 0.02 mg/kg (Milk, bovine meat, bovine fat and whole chicken eggs) 1. The multi-residue method DFG S19 is the recommended method for the determination of fluquinconazole in food of animal origin. GC-MS served as a confirmatory method of analysis utilising the most intense fragmentation ion at 340 m/z for quantitation, supporting confirmatory ions were found at 342 and 313 m/z. The method was independently validated. LOQ = 0.02 mg/kg 2. GC-ECD (animal tissues -subcutaneous and peritoneal fat, muscle, heart, liver and kidney and milk. LOQ = 0.05 mg/kg 3. DFG S19 GC-MS (milk and cream) For milk, quantification was by 340 m/z fragment ion with fragment ions 342 m/z and 313 m/z used for confirmation. For cream, quantification was by 340 m/z fragment ion with fragment ions 342 m/z and 298 m/z used for confirmation. GC-MS/MS (confirmatory method). For milk, the parent ion was 340 m/z; 298 m/z daughter ion for quantitation and the daughter ion 313 m/z for confirmation. For cream, the parent ion was 340 m/z; 298 m/z daughter ion for quantitation and the daughter ion 313 m/z for confirmation LOQ = 0.01 mg/kg (milk) LOQ = 0.04 mg/kg (cream)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (CO-RMS – Poland)	Revised September 2010	Fluquinconazole

Soil (analytical technique and LOQ)	GC-ECD LOQ = 0.05 mg/kg (fluquinconazole) LOQ = 0.05 mg/kg (dione metabolite) 1. Acetonitrile was used to soxhlet extract soil. Water was used to dilute the soil extract followed by partitioning into 1:1 hexane:diethyl ether. The cleaned up extract was then analysed by GC-ECD. A SPE cartridge was used for samples that required further clean up prior to GC determination. LOQ = 0.05 mg/kg (fluquinconazole) and 0.05 mg/kg (dione metabolite). 2. GC-MS was used to analyse for fluquinconazole and the dione metabolite (confirmatory method). Detection of fluquinconazole was based on the observation of 4 confirmatory ions: m/z 340 (target ion), 342, 313 and 298 (qualifier ions).
Water (analytical technique and LOQ)	GC-MS LOQ = 0.05 µg/L (Drinking water) GC-MS LOQ = 1 µg/L (Surface water) LC-MS/MS LOQ = 0.03 µg/L (Surface and groundwater)
Air (analytical technique and LOQ)	1. GC-ECD LOQ = 1.5 µg/m^3 (air) 2. GC-MS (confirmatory method). The monitoring ions were 342, 340, 313 and 298 m/z. Further confirmatory method: GC-MS LOQ = 0.14 µg/m^3
Body fluids and tissues (analytical technique and LOQ)	Open: GC-MS LOQ = 50 ng/ml (For fluquinconazole in whole blood. Linearity data remains outstanding.) DFG S19 (LC-MS/MS) LOQ = 0.01 mg/l [Note that this method could not be taken into account in the peer review due to the restrictions of Commission Regulation (EC) 33/2008.]

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

	RMS/peer review proposal
Active substance	No classification required.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland	Dec 2010	Fluquinconazole

Mammalian toxicology

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Rapidly adsorbed, 57- 68 % based on urine and biliary excretion, cage wash and carcass residues 48 h after administration.
Distribution ‡	Widely distributed, highest residues in the sex glands (preputial/clitoris), fatty tissues, liver and blood.
Potential for accumulation ‡	Indication of bioaccumulation upon repeated administration (blood and fat).
Rate and extent of excretion ‡	Slowly excreted ($T_{½}$ 65 h), > 90% after 7 days; Major route is faecal excretion (~ 80 % after 168 h) for males and females, with renal (5 – 9 % after 168 h) and biliary (9 – 21 % after 48 h) comprising lesser routes (dichlorophenyl radiolabelled fluquinconazole). Higher renal excretion was observed when fluquinconazole was radiolabelled on the triazole group.
Metabolism in animals ‡	Majority of adsorbed dose is metabolised to 1,2,4 triazole and the dione plus polar conjugates (up to 10 minor metabolites). In faeces, main radioactivity represented unchanged fluquinconazole and up to 14 minor metabolites.
Toxicologically relevant compounds ‡ (animals and plants)	fluquinconazole
Toxicologically relevant compounds ‡ (environment)	fluquinconazole

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	112 mg/kg bw (rat) 180 mg/kg bw (mouse)	**T, R25**
Rat LD_{50} dermal ‡	2679 mg/kg bw in males 625 mg/kg bw in females	**Xn, R21**
Rat LC_{50} inhalation ‡	0.514 mg/L air/4h (head only)	**T, R23**
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non-irritant	
Skin sensitisation ‡	Non-sensitiser (M&K)	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland	Dec 2010	Fluquinconazole

Mammalian toxicology

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Dog: Reduced body weight gain, increased liver weight and clinical parameters. Rat: Clinical signs, liver (increased liver weight, increased incidence and severity of centrilobular hypertrophy, and biochemical changes) and kidney (weight and microscopic changes). Mouse: Liver: increased liver weight, ALT and increased incidence of centrilobular hypertrophy.	
Relevant oral NOAEL ‡	1-year & 90-day, dog: 0.2mg/kg bw/d 90-day, rat: 1.01 mg/kg bw/d 90-day, mouse: 3.1 mg/kg bw/d	
Relevant dermal NOAEL ‡	28-day, rat: 8 mg/kg bw/d based on increased absolute and relative liver weight and increased incidence and severity of centrilobular hypertrophy.	
Relevant inhalation NOAEL ‡	No data - not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

	No genotoxic potential	

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

Target/critical effect ‡	Liver: (↑ liver to body weight ratio; centrilobular hepatocyte hypertrophy; enzyme induction; tumours rat and mouse). Kidney: ↑ kidney to body weight ratio in rats both sexes and ↑ chronic progressive nephropathy in female rats. Thyroid: Increased glandular activity and tumours in rats both sexes (however not relevant to humans).	
Relevant NOAEL ‡	0.44 mg/kg bw/d (2-year rat) 1.05 mg/kg bw/d (18-month mice)	
Carcinogenicity ‡	Liver tumours in female rats and mice, both sexes; thyroid tumours in rats, both sexes (not relevant to humans). NOAEL for carcinogenicity: 0.44 mg/kg bw/d (2-year rat)	**Xn, Carc. Cat.3 R40**

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Mammalian toxicology

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental: clinical signs, reduced body weight gain, increased kidney and liver weights, histopathological changes. Reproductive: None. Offspring: Clinical signs and decreased pup viability in F1b and F2 litters.	
Relevant parental NOAEL ‡	0.7 mg/kg bw/d	
Relevant reproductive NOAEL ‡	6.8 mg/kg bw/d	
Relevant offspring NOAEL ‡	0.3 mg/kg bw/d	

Developmental toxicity

Developmental target / critical effect ‡	Rat: Maternal : Clinical signs, ↓ body wt gain Developmental : ↑ Post-implantation loss, skeletal variations Rabbit: Maternal : mortality, abortions, clinical signs, body weight loss. Developmental : ↑ variant sternbrae	
Relevant maternal NOAEL ‡	Rat and rabbit: 2.0 mg/kg bw/d	
Relevant developmental NOAEL ‡	Rat and rabbit: 2.0 mg/kg bw/d	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data-not required.	
Repeated neurotoxicity ‡	No data-not required	
Delayed neurotoxicity ‡	No data-not required	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Mammalian toxicology

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	1) Liver enzyme induction after 14 days dosing with 200 ppm in CD-1 mice: Increased liver weight; microsomal content, CYP 450 and cytochrome b5 activities 2) Liver enzyme induction after 4 days dosing with 10 mg/kg bw/day in male SD rats: Increased liver weight; microsomal content, CYP 450 and CYP 1A and 2B activities Not a direct acting thyroid blocker, indirect mechanism shown in perchlorate discharge test. Fluquinconazole induces the activity of the UDPGT liver enzyme after 8 days, with increased levels of TSH and decreased levels of T4, not fully reversible at the end of the recovery period.
Studies performed on metabolites or impurities ‡ **dione metabolite (SN 596912):**	
Rat LD_{50} oral	> 5000 mg/kg bw
Rat LD_{50} dermal	> 5000 mg/kg bw
Skin irritation	Non-irritant
Eye irritation	Non-irritant
Skin sensitisation	Non-sensitiser (Buehler test, 3 applications)
28-day oral, female rats	NOAEL = 124 mg/kg bw/day based on a transient (20 days) reduction in activity and muscle tone at 1290 mg/kg bw/day.
Ames test, *in vitro* clastogenicity in human lymphocytes, mouse lymphoma *in vitro* gene mutation, *in vivo* mouse micronucleus test	No genotoxic potential

Medical data ‡ (Annex IIA, point 5.9)

	No adverse effects reported during routine medical surveillance of manufacturing plants; no clinical cases or poisoning incidents reported from possible exposure to fluquinconazole.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Mammalian toxicology

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	**0.002** mg/kg bw/day	Dog, 1-year & 90-day	100
AOEL ‡	0.001 mg/kg bw/day	Dog, 1-year & 90-day	Overall 167* 100 +60 %
ARfD ‡	0.02 mg/kg bw/day	Rat & rabbit developmental studies	100

* Correction for low oral absorption (60 %).

Dermal absorption ‡ (Annex IIIA, point 7.3)

Flamenco Plus 5 % SE	Concentrate: 1 % Spray dilutions:4 % Rat *in vivo* and flux comparative *in vitro* (human/rat skin)

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Tractor mounted equipment (application rate 0.140 kg fluquinconazole/ha - 2.6 l product/ha[20])	
	UK POEM model:	% of AOEL
	Without PPE	2433 %
	With PPE (gloves during M/L)	2257 %
	With PPE (gloves during M/L & applic.)	425 %
	German BBA model:	% of AOEL
	Without PPE	891 %
	With PPE (gloves during M/L)	692 %
	With PPE (gloves during M/L & applic.)	566 %
	With PPE (gloves during M/L; gloves, protective garment & sturdy footwear during application)	63 %
Workers	8% with PPE[21]	
Bystanders	13 % of AOEL	

[20] This dose was part of the initial dossier on fluquinconazole, but is no longer supported by the applicant. Nevertheless it represents a worst case in relation to the current representative application rate of 0.125 kg fluquinconazole/ha.

[21] EFSA found some drawbacks in the parameters used when estimating worker exposure and considers that the resulting values should be somewhat higher than the ones presented. Nevertheless the outcome is unchanged: estimated worker exposure is below the AOEL when PPE is used.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland	Dec 2010	Fluquinconazole

Mammalian toxicology

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

	Peer review proposal
Fluquinconazole	T, R23/25 “Toxic by inhalation and if swallowed” Xn, R21 “Harmful in contact with skin” Xn, Carc. Cat.3 R40 “Limited evidence of a carcinogenic effect”
	Regulation (EC) No 1272/2008 Annex VI
Fluquinconazole	T “Toxic” T, R23/25 “Toxic by inhalation and if swallowed” T, R48/25 “Toxic: danger of serious damage to health by prolonged exposure if swallowed” Xn; R21 “Harmful in contact with skin” Xi; R38 “Irritating to skin”

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland	September 2010 EFSA January 2011	Fluquinconazole

Residues

Plant groups covered	-Apples and grapevines (fruit crops), carrots (root and tuber vegetables) – Foliar spray (dichlorophenyl-U-[^{14}C]) -Spring wheat (cereals) - Foliar spray (dichlorophenyl-U-[^{14}C] and triazolyl-U-[^{14}C])
Rotational crops	**Initial DAR (February 2005):** A confined rotational crop metabolism study conducted with fluquinconazole labelled on the dichlorophenyl and triazolyl rings on leafy crops (lettuce), root and tuber vegetables (radish), and on cereals (spring wheat) sown at a plant back interval of 120 days after soil treatment at a dose of *circa* 750 g a.s./ha (3N) was provided **Addendum to the DAR (April 2010):** A confined rotational crop metabolism study conducted with fluquinconazole labelled on the dichlorophenyl and triazolyl rings on leafy crops (lettuce), root and tuber vegetables (radish), and on cereals (spring wheat) sown at a plant back interval of 32 days after soil treatment at a dose of 250 g a.s./ha (1N) was provided. Fluquinconazole is high to very high persistent (DT_{50}: 186-441 days). Metabolite dione is high to very high persistent (DT_{50}: 231-567 days).
Metabolism in rotational crops similar to metabolism in primary crops?	Yes. The metabolic profile of fluquinconazole in rotational crops sown 32 days after soil treatment at a rate of 250 g a.s./ha showed that fluquinconazole and the TDMs (Triazolyl alanine and Triazolyl acetic acid) constituted the relevant indicators of the total residues in the edible parts of the rotated crops. The metabolite dione was not detected in wheat grain and was recovered at a very low level in the other extracts (0.003 to 0.035 mg/kg in wheat forage, hay and straw) whilst at a 120 day-plant back interval, the metabolic pattern of fluquinconazole in the rotated crops was similar but indicated that at the 1 N rate, the level of the metabolite dione was expected to be >0.01 mg/kg in radish roots and lettuce and > 0.05 mg/kg in wheat straw while it was detected at a trace level in wheat grain (*circa* 0.001 mg/kg).

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland	September 2010 EFSA January 2011	Fluquinconazole

Residues

Processed commodities	**Hydrolysis study from the original DAR (February 2005):** Study conducted with fluquinconazole labelled on the dichlorophenyl ring only. Heating at 90°C, for 20 min. at pH 4 to simulate the pasteurisation process. Heating at 100°C, for 60 min at pH 5 to simulate the baking, brewing and boiling process. Results indicated that fluquinconazole was stable when subjected to the conditions of the hydrolysis experiment and was recovered at a level of 97 % of AR (pasteurisation) and 87 % of AR (baking, brewing and boiling). **Hydrolysis study submitted in the addendum to the initial DAR (April 2010):** Study conducted with fluquinconazole labelled on the dichlorophenyl and triazolyl rings under hydrolytic conditions representative of: -Pasteurisation (pH 4, 90°C, 20min) – no degradation of fluquinconazole. -Baking, brewing & boiling (pH 5, 100°C, 60 min) - hydrolysis of the parent compound into the metabolite dione (AEC 596912) (7% of AR) and 1,2,4-triazole (9% of AR). -Sterilisation: not relevant for the representative use.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	The residue definitions for monitoring and risk assessment derived for primary crops are also valid for the processed wheat commodities. -Processing studies to address the magnitude of the residues of fluquinconazole in processed wheat matrices are not triggered. -The magnitude of TDMs in processed products may need to be addressed pending the outcome of the residue trials on TDMs in wheat grain.
Plant residue definition for monitoring	Fluquinconazole
Plant residue definition for risk assessment	1) Parent fluquinconazole – Provisional, pending the outcome of the requested rotational field trials regarding the residue level of the metabolite dione. 2) TDM – Provisional, pending finalisation of a global and harmonised approach for all the active substances of the triazole chemical group regarding the assessment of consumer exposure to TDMs - Restricted to cereals (foliar application), only.
Conversion factor (monitoring to risk assessment)	To be determined following the outcome of TDM review.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland	September 2010 EFSA January 2011	Fluquinconazole

Residues

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

Animals covered	Lactating cows Metabolism study not triggered for poultry.
Time needed to reach a plateau concentration in milk and eggs	Fluquinconazole: A plateau was reached in milk after 4 days of dosing. Open for the TDMs in milk.
Animal residue definition for monitoring	Fluquinconazole (ruminants only)
Animal residue definition for risk assessment	-Fluquinconazole and metabolite dione expressed as fluquinconazole (ruminants only) -Open for the TDM – pending the submission of a new metabolism study adressing the fate of TDMs in ruminants matrices.
Conversion factor (monitoring to risk assessment)	Fluquinconazole: Fat, milk, edible offals: 1, Muscle: 2, Liver: 3, Kidney: 4. To be determined following the outcome of TDM review.
Metabolism in rat and ruminant similar (yes/no)	Open; pending the additional data requested on TDM in ruminant matrices.
Fat soluble residue: (yes/no)	-Fluquinconazole: Yes. log $P_{O/W}$ = 3.24 at 20°C Open for TDMs.

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

	Rotational crops field trials were conducted on winter barley, cabbage, beans and potatoes with a plant back interval after treated wheat harvesting of 1 month for barley and cabbage and 8 months for beans and potatoes. The residues of fluquinconazole were found to be below the LOQ (<0.05 mg/kg) in cabbage (heads), beans (immature pods, haulms, mature beans without pods), potatoes (immature and mature tubers, foliage) and barley (grain) and below the LOQ of 0.1 mg/kg in barley (ears, stalks, straw). A data gap has been identified to provide additional cold field trials to determine the magnitude of the residues of fluquinconazole, (AEC 596912) metabolite dione and the TDMs in representative rotated crops at the 120 day-plant back interval.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland	September 2010 EFSA January 2011	Fluquinconazole

Residues

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

	Under frozen storage conditions, fluquinconazole is: -stable in cereal grain for up to 31 months. -stable in wheat straw for up to 12 months. -stable in cabbage for up to 20 months. -stable in cattle milk and edible offals for up to 20 months. -stable in cattle liver up to 6 months. -stable in cattle fat for 13 months. The storage time period of the samples from the wheat residue trials and from the ruminant feeding study is covered. Open for TDMs.

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland	September 2010 EFSA January 2011	Fluquinconazole

Residues

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 -Dairy cattle: 0.6837 mg/kg diet DM -Beef cattle: 1.6895 mg/kg DM	No 0.0163 mg/kg diet DM	No 0.019 mg/kg diet DM
Potential for accumulation (yes/no):	Yes	N/A	N/A
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Yes	N/A	N/A
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices: Mean (max) mg/kg		
Overdosing factor	**2 N**		
Muscle	0.04 mg/kg(1)	N/A	-
Liver	0.23 mg/kg(1)	N/A	-
Kidney	0.17 mg/kg(1)	N/A	-
Fat	1.4 mg/kg(1)	N/A	-
Overdosing factor	**1 N**	-	-
Milk	0.031 mg/kg(2)		
Eggs		N/A	

N/A: Not applicable.
(1): Actual highest residue value from the 3 replicates for each matrix recovered in the feeding study at the dose of 60 mg/animal/day.
(2):Mean residue value over the dosing period of 29 days at 20 mg/animal/day.

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 Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Wheat grain	North of EU	5 x <0.01, 5 x <0.02, 0.02 mg/kg	Residue trials to determine the residue levels of TDMs in wheat grain are required.	0.05 mg/kg	0.02 mg/kg	0.02 mg/kg
Wheat grain	South of EU	0.02, 0.04 A complete fluquinconazole residue trials database is required.		-	-	-
Wheat straw	North of EU	0.11, 0.7, 0.71, 0.72, 0.77, 0.81, 0.85, 1.2, 1.7, 2.1, 2.9 mg/kg	Residue trials to determine the residue levels of TDMs in wheat straw are required.	N/A	2.9 mg/kg	0.81 mg/kg
Wheat straw	South of EU	0.92, 2.4 A complete fluquinconazole residue trials database is required.		N/A	-	-

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

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Ireland	Revised September 2010 EFSA January 2011	Fluquinconazole

Residues

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)[7]

ADI	0.002 mg/kg bw/day
TMDI (% ADI) according to EFSA PRIMo Model rev.2A[(1)]	**A) Residue definition for risk assessment in plant matrices: fluquinconazole-provisional.** **B) Residue definition for risk assessment in ruminant matrices : Fluquinconazole + metabolite dione expressed as fluquinconazole equiv..** 66.1 % of ADI (NL child)[(1)] The calculation was performed using the following values: -MRL proposals for wheat grain and ruminants matrices. -Conversion factors for monitoring to risk assessment for ruminants matrices. **C) TDMs-provisional:** Risk assessment not finalised pending the outcome of the TDM review.
<u>IEDI (% ADI) according to EFSA PRIMo Model rev.2A[(1)]</u>	21.4 % of ADI (NL child)[(1)] (STMR values for wheat grain derived from residue trials and STMR values for milk and ruminants tissues derived from the available feeding study considering also the conversion factors for monitoring to risk assessment).
ARfD	0.02 mg/kg bw
<u>IESTI (% ARfD) according to EFSA PRIMo Model rev.2A[(1)]</u>	**A) Residue definition for risk assessment in plant matrices: fluquinconazole-provisional.** **B) Residue definition for risk assessment in ruminant matrices : Fluquinconazole + metabolite dione expressed as fluquinconazole equiv..** 18.6 % of ARfD (Milk and milk products) [(1)] The calculation was performed using the following values: -Highest residue values for wheat grain and ruminants tissues, mean residue value for milk. -Conversion factors for monitoring to risk assessment for ruminants matrices. **C) TDMs-provisional:** Risk assessment not finalised pending the outcome of the TDM review.

[(1)]: The consumer chronic and acute risk assessment is provisional considering only the consumers'exposure to residues of fluquinconazole recovered in wheat grain and ruminants'matrices. This assessment has to be regarded as provisional as the contribution of the potential residues of the metabolite dione in rotational crops and the TDMs in primary crops, in processed products, in rotational crops and in ruminants'matrices to the overall consumer exposure has to be addressed.

Rapporteur Member State	**Month and year**	**Active Substance (Name)**
Ireland	Revised September 2010 EFSA January 2011	Fluquinconazole

Residues

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)[(1)]

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Wheat grain/Whole meal	3	0.25; 0.65; 0.20	-	-
Wheat grain/Bran	3	1.0; 0.65; 0.40	-	-
Wheat grain/Bread, whole meal	2	0.40; 0.20	-	-
Wheat grain/Flour	1	0.20	-	-
Wheat grain/Meal, type 550	2	0.85; 0.25	-	-
Wheat grain/semolina	1	0.20	-	-

[(1)]: If it is triggered by the outcome of the residue trials on TDMs in wheat grain, the magnitude of TDM residues in processed wheat grain has to be addressed.

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

Wheat grain	0.05 mg/kg (northern Europe)
Milk	0.03 mg/kg
Ruminant liver	0.2 mg/kg
Ruminant kidney	0.1 mg/kg
Ruminant meat	0.05 mg/kg
Ruminant fat	1 mg/kg
Ruminant edible offals	0.2 mg/kg

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

List of end points

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

Mineralization after 100 days ‡	*0.1 - 2.9* % after 119 - 365 d, [^{14}C]-Fluquinconazole, dichlorophenyl-label (n= 3 soils at 20^{0}C); *0.3 – 10.4* % after 119 - 365 d, [^{14}C]-Fluquinconazole, triazolyl-label (n= 3 soils at 20^{0}C); Sterile conditions: < *0.1* % after 119 d, [^{14}C]-Fluquinconazole, dichlorophenyl-label (n= 3 soils at 20^{0}C);
Non-extractable residues after 100 days ‡	*4.1-24.5 %* after 93 - 365d, [^{14}C]-Fluquinconazole, dichlorophenyl-label (n= 3 soils at 20^{0}C); *7.0-32.9 %* after 119 - 365 d, [^{14}C]-Fluquinconazole, triazolyl-label (n= 3 soils at 20^{0}C); Sterile conditions: *22.0* % after 231 d, [^{14}C]-Fluquinconazole, dichlorophenyl-label (n= 1 soil at 20^{0}C);
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Dione - *7.5-28.7* % after 119-365 d, [^{14}C]-Fluquinconazole, dichlorophenyl-label (n= 3 soils at 20^{0}C) 1,2,4-Triazole – *9.0 – 18.9* % after 119 – 182 d, [^{14}C]-Fluquinconazole, triazolyl-label (n= 3 soils at 20^{0}C);

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

Anaerobic degradation ‡

Mineralization after 100 days	n= 2 soils (30-32 days conditioning under aerobic conditions followed by 367-438 days anaerobic incubation *0.1* % after 399 - 468 d, [^{14}C]-Fluquinconazole, dichlorophenyl-label (n= 2 soils at 20^{0}C); *0.6* % after 122-468 d, [^{14}C]-Fluquinconazole, triazolyl-label (n= 2 soils at 20^{0}C);
Non-extractable residues after 100 days	*10.9 -15.0* % after 399 - 468 d, [^{14}C]-Fluquinconazole, dichlorophenyl-label (n= 2 soils at 20^{0}C); *17.1-19.7* % after 339-468 d, [^{14}C]-

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	Fluquinconazole, triazolyl-label (n= 2 soils at 20^0C);
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Dione – *53.0-73.8* % after 339-468 d, [^{14}C]-Fluquinconazole, dichlorophenyl-label (n= 2 soils at 20^0C) 1,2,4-Triazole – *45.2 – 68.1* % after 220 – 468 d, [^{14}C]-Fluquinconazole, triazolyl-label (n= 2 soils at 20^0C);
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Mineralisation: *0.9* % after 29.7 d (irradiated samples), not detected after 29.7 d (non-irradiated samples), [^{14}C]-Fluquinconazole, dichlorophenyl-label (n= 1 soil at 24^0C); NER: *9.2* % after 3.7 d (irradiated samples), *11.9* % after 10.7 d (non-irradiated samples), [^{14}C]-Fluquinconazole, dichlorophenyl-label (n= 1 soil at 24^0C); Metabolites: Dione – *7.5* % after 24.7 d (irradiated samples), not detected after 29.7 d (non-irradiated samples), [^{14}C]-Fluquinconazole, dichlorophenyl-label (n= 1 soil at 24^0C);

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

Laboratory studies ‡

Parent	Aerobic conditions

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Soil type	OC [%]	pH	t. °C / soil moisture content [%]	DT_{50} / DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam	1.4	7.0	20 °C / 24.5 %	186 / 620	n.a	n.a	SFO; linear regression
Silty clay loam	3.4	5.8	20 °C / 32.4 %	415 / 1383	n.a	0.985	SFO; linear regression
Loamy sand	2.3	6.5	20 °C / n.a	441 / 1466	n.a	0.99	SFO; linear regression

Dione	Aerobic conditions							
Soil type	OC [%]	pH	t. °C / soil moisture content [%]	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa *	χ^2	Method of calculation
Silty clay loam	3.4	5.8	20 °C / 32.4 %	567/----	0.905	542	n.a.	SFO
Sandy loam	2.4	7.0	20 °C / 18.1 %	512/----	n.a	483	n.a.	SFO
Loamy sand	0.58	6.3	20 °C / 17.2 %	294/----	n.a	268	5.5	SFO
Sandy loam	2.4	7.1	20 °C / 9.4 %	231/----	n.a.	224	4.9	SFO
Loamy sand	1.78	5.8	20 °C / 16.5 %	338/----	n.a.	314	5.8	SFO
Geometric mean			----	----	----	346	-----	
Comments			All the DT_{50} values reported in this table are the result of the kinetic fitting for the modelling purposes (using SFO kinetic model).					

*normalised using a Walker equation coefficient of 0.7.

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1,2,4-triazole	Aerobic conditions							
Soil type (USDA)		pH ($CaCl_2$)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa *	St. (r^2)	Method of calculation
Sandy loam		6.4	20°C / 40 % MWHC	6.32 / 21.0		5.0	0.75	SFO
Loamy sand		5.8	20°C / 40 % MWHC	9.91 / 33.0		9.9	0.81	SFO
Silt loam		6.7	20°C / 40 % MWHC	12.27 / 40.8		8.2	0.95	SFO
Geometric mean						7.4		

*normalised using a Walker equation coefficient of 0.7.

Field studies ‡

1) Best-fit results:

Fluquinconazole	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	OC [%]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	χ^2	DT_{50} (d) Norm.	Method of calculation
Sandy silt loam; soil dissipation, bare soil	Bernassay; France	2.60	6.8	0-30	532.1	1771.3	27.0	Not calcul.	SFO
Sandy silt loam; soil dissipation, bare soil	Cerelles; France	1.7	6.5	0-30	261.4	868.5	19.4	Not calcul.	SFO
Sandy loam; soil dissipation; bare soil	Ondes; France	n.a	n.a	n.a.	355.3	1151.3	21.4	Not calcul.	SFO
Silty loam; soil dissipation; bare soil	Elsenfeld-Rück; Germany	2.1	7.0-7.1	0-10 (+10-20 for some samp.)	132.5	40402.9	7.7	Not calcul.	FOMC
Sandy loam; soil dissipation study; bare soil	Schwichteler; Germany	2.1-6.3	5.3-6.3	0-10 (+10-20 for some samp.)	644.5	2093.3	9.6	Not calcul.	SFO

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Loam; soil dissipation study; bare soil	Meissner Vockerode; Germany	2.1-2.6	5.4-6.0	0-10 (+10-20 for some samp.)	777.4	2587.2	12.6	Not calcul.	SFO
Sandy loam; soil dissipation study; bare soil	Niederkirchen; Germany	1.5	7.3	0-10 (+10-20 for some samp.)	26.5	1205.0	6.9	Not calcul.	DFOP
Silty loam; soil dissipation study; bare soil	Goch Nierswalde; Germany	3.5-3.9	5.5-5.9	0-10 (+10-20 for some samp.)	703.7	2325.8	17.1	Not calcul.	SFO
Sand; soil dissipation study; bare soil	Celle; Kleinhellen; Germany	3.6-4.0	5.2-5.9	0-10 (+10-20 for some samp.)	576.4	1918.8	16.0	Not calcul.	SFO
Sandy loam; soil accumulation study – year 1; bare soil	La Mole; France	2.7	6.1	0-10 (+10-20 for some samp.)	147.5	490.0	21.7	Not calcul.	SFO
Sandy loam; soil accumulation study – year 2; bare soil	La Mole; France	2.7	6.1	0-10 (+10-20 for some samp.)	17.5	462.3	20.0	Not calcul.	FOMC
Sandy loam; soil accumulation study – year 3; bare soil	La Mole; France	2.7	6.1	0-10 (+10-20 for some samp.)	269.7	896.0	15.5	Not calcul.	SFO
Loam; soil accumulation study – year 1; bare soil	Maillane; France	1.9-3.9	7.9-8.2	0-30	142.8	474.5	14.3	Not calcul.	SFO
Loam; soil accumulation study – year 2; bare soil	Maillane; France	1.9-3.9	7.9-8.2	0-30	78.8	9585.0	8.4	Not calcul.	FOMC
Loam; soil accumulation study – year 3; bare soil	Maillane; France	1.9-3.9	7.9-8.2	0-30	72.1	3989.7	7.3	Not calcul.	FOMC
Silty clay loam;	Tours; France	1.9	8.4	0-30	227.5	755.7	29.6	Not	SFO

Fate and Behaviour in the Environment

soil accumulation study – year 1; bare soil								calcul.	
Silty clay loam; soil accumulation study – year 2; bare soil	Tours; France	1.9	8.4	0-30	449.3	1535.1	11.9	Not calcul.	SFO
Silty clay loam; soil accumulation study – year 3; bare soil	Tours; France	1.9	8.4	0-3-	358.2	1211.9	13.1	Not calcul.	SFO
Loam; soil accumulation study – year 1; bare soil	Devon; UK	4.9-10.5	5.0-5.3	0-10 (+10-20 for some samp.)	261.9	869.9	20.7	Not calcul.	SFO
Loam; soil accumulation study – year 2; bare soil	Devon; UK	4.9-10.5	5.0-5.3	0-10 (+10-20 for some samp.)	353.2	1151.3	9.4	Not calcul.	SFO
Loam; soil accumulation study – year 3; bare soil	Devon; UK	4.9-10.5	5.0-5.3	0-10 (+10-20 for some samp.)	342.3	1151.3	7.9	Not calcul.	SFO
Loam; soil accumulation study – year 1; bare soil	Kent; UK	2.0	8.3	0-10 (+10-20 for some samp.)	52.1	23150.4	9.6	Not calcul.	FOMC
Loam; soil accumulation study – year 2; bare soil	Kent; UK	2.0	8.3	0-10 (+10-20 for some samp.)	148.6	1607.7	9.9	Not calcul.	DFOP
Loamy sand; soil accumulation study – year 1; bare soil	Pershore; UK	1.7	7.5	0-10 (+10-20 for some samp.)	532.5	1771.3	14.9	Not calcul.	SFO
Loamy sand; soil accumulation study – year 2; bare soil	Pershore; UK	1.7	7.5	0-10 (+10-20 for some samp.)	332.4	1096.5	7.5	Not calcul.	SFO
Loamy sand; soil accumulation	Pershore; UK	1.7	7.5	0-10 (+10-20	494.6	1644.7	15.7	Not calcul.	SFO

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study – year 3; bare soil				for some samp.)					
Geometric mean/median					n.a.	n.a.	n.a	n.a	n.a

2) Normalised SFO results

*normalisation used Arrhenius activation energy 92.4kJmol-1 (Q10=3.84) and a Walker equation coefficient of 0.0.

Fluquinconazole	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	OC [%]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	χ^2	DT_{50} (d) Norm.*	Method of calculation
Sandy silt loam; soil dissipation; bare soil	Benassay (France)	2.6	6.8	0-30	226.5	752.3	25.89	226.5	SFO
Sandy silt loam; soil dissipation, bare soil	Cerelles; France	1.7	6.5	0-30	134.4	446.5	17.53	134.4	SFO
Sandy loam; soil dissipation; bare soil	Ondes; France	n.a	n.a	n.a.	225.5	749.2	20.19	225.5	SFO
Silty loam; soil dissipation; bare soil	Elsenfeld-Rück; Germany;	2.1	7.0-7.1	0-10 (+10-20 for some samp.)	101.0	335.5	7.70	101.0	SFO
Sandy loam; soil dissipation study; bare soil	Schwichteler; Germany	2.1-6.3	5.3-6.3	0-10 (+10-20 for some samp.)	265.3	881.3	7.42	265.3	SFO
Loam; soil dissipation study; bare soil	Meissner Vockerode; Germany	2.1-2.6	5.4-6.0	0-10 (+10-20 for some samp.)	343.8	1151.3	12.41	343.8	SFO
Sandy loam; soil	Niederkirchen;	1.5	7.3	0-10	99.1	329.3	17.45	99.1	SFO

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dissipation study; bare soil	Germany			(+10-20 for some samp.)					
Silty loam; soil dissipation study; bare soil	Goch Nierswalde; Germany	3.5-3.9	5.5-5.9	0-10 (+10-20 for some samp.)	261.9	869.9	16.59	261.9	SFO
Sand; soil dissipation study; bare soil	Celle; Kleinhellen; Germany	3.6-4.0	5.2-5.9	0-10 (+10-20 for some samp.)	213.3	708.4	14.80	213.3	SFO
Sandy loam; soil accumulation study – year 1; bare soil	La Mole; France	2.7	6.1	0-10 (+10-20 for some samp.)	149.2	495.7	20.45	149.2	SFO
Sandy loam; soil accumulation study – year 2; bare soil	La Mole; France	2.7	6.1	0-10 (+10-20 for some samp.)	63.7	211.5	24.76	63.7	SFO
Sandy loam; soil accumulation study – year 3; bare soil	La Mole; France	2.7	6.1	0-10 (+10-20 for some samp.)	95.9	318.6	15.38	95.9	SFO
Loam; soil accumulation study – year 1; bare soil	Maillane; France	1.9-3.9	7.9-8.2	0-30	114.6	380.8	14.61	114.6	SFO
Loam; soil accumulation study – year 2;	Maillane; France	1.9-3.9	7.9-8.2	0-30	163.7	543.7	10.09	163.7	SFO

bare soil									
Loam; soil accumulation study – year 3; bare soil	Maillane; France	1.9-3.9	7.9-8.2	0-30	127.2	422.5	6.87	127.2	SFO
Silty clay loam; soil accumulation study – year 1; bare soil	Tours; France	1.9	8.4	0-30	133.3	442.7	30.31	133.3	SFO
Silty clay loam; soil accumulation study – year 2; bare soil	Tours; France	1.9	8.4	0-30	219.4	728.8	10.44	219.4	SFO
Silty clay loam; soil accumulation study – year 3; bare soil	Tours; France	1.9	8.4	0-3-	210.2	698.4	13.96	210.2	SFO
Loam; soil accumulation study – year 1; bare soil	Devon; UK	4.9-10.5	5.0-5.3	0-10 (+10-20 for some samp.)	93.1	309.4	20.42	93.1	SFO
Loam; soil accumulation study – year 2; bare soil	Devon; UK	4.9-10.5	5.0-5.3	0-10 (+10-20 for some samp.)	161.5	536.5	10.76	161.5	SFO
Loam; soil accumulation study – year 3; bare soil	Devon; UK	4.9-10.5	5.0-5.3	0-10 (+10-20 for some samp.)	119.0	395.3	7.86	119.0	SFO
Loam; soil accumulation study – year 1; bare soil	Kent; UK	2.0	8.3	0-10 (+10-20 for some samp.)	84.6	280.9	18.83	84.6	SFO

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Loam; soil accumulation study – year 2; bare soil	Kent; UK	2.0	8.3	0-10 (+10-20 for some samp.)	96.5	320.6	13.56	96.5	SFO
Loamy sand; soil accumulation study – year 1; bare soil	Pershore; UK	1.7	7.5	0-10 (+10-20 for some samp.)	188.3	625.7	13.86	188.3	SFO
Loamy sand; soil accumulation study – year 2; bare soil	Pershore; UK	1.7	7.5	0-10 (+10-20 for some samp.)	113.1	375.7	9.36	113.1	SFO
Loamy sand; soil accumulation study – year 3; bare soil	Pershore; UK	1.7	7.5	0-10 (+10-20 for some samp.)	161.1	535.7	13.58	161.1	SFO
Geometric mean/ ***median***					161.9/ ***150.9***	538.1 **501.2**	------	161.9/ ***150.9***	-----
Comments:					For field trials with more than one year data, the geometric mean of individual years was calculated first, prior to calculating the overall geometric mean or median. The "actual" and the "normalised" DT_{50} values are the same because of the normalisation procedure applied by the Notifier – it was a timestep normalisation of the sampling times, which were subsequently used, together with the corresponding measured residue concentrations, as input parameters, in the kinetic fitting.				

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pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	Results from residue studies (n=43 plots) Fluquinconazole: maximum mean concentration in soil of 0.78 mg/kg reached after initial application in field studies; range of mean concentrations in soil of <0.05 – 0.78 mg/kg over a 3-year period in field studies. Metabolites: Results from residue studies (n=39 plots), Dione: maximum mean concentration in soil of 0.21 mg/kg reached after 2 years 6 months in field studies; range of mean concentrations in soil of <0.02 – 0.21 mg/kg over a 3-year period in field studies

Laboratory studies ‡

Fluquinconazole (parent)	Anaerobic conditions						
Soil type	OC [%]	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Loamy sand	1.6	7.0	20^0C/-----	170/---- 156/----	-----	0.97 0.95	SFO linear regression SFO multi-compartment model
Silty loam	3.8	5.8	20^0C/-----	268/---- 236/----	-----	0.75 0.84	SFO linear regression SFO multi-compartment model
Geometric mean/median			-----	-----	-----	-----	-----
Dione (metabolite)	Anaerobic conditions						
Not determined							
1,2,4-Triazole (metabolite)	Anaerobic conditions						
Not determined							

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Fluquinconazole (parent)	Soil photolysis						
Soil type	OC [%]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam	1.8	7.1	24^0C/ light intensity corresponding to the natural sunlight at the lattitudes 40-50N/ 12-hours long day	92.4/307.0 (irradiated sample) 256.7/852.8 (dark control) 144.4/479.7 (net photolysis)	----- ---- -----	0.92 0.98 -----	SFO
Geometric mean/median			-----	-----	-----	-----	-----
Dione (metabolite)	Soil photolysis						
Not determined							
1,2,4-Triazole (metabolite)	Soil photolysis						
Not determined							

Soil DT_{50} values recommended for modelling calculations

Type of calculations	Substance	DT_{50} [days]	Remarks
PEC_{SOIL}	Fluquinconazole	777.4	Value recommended for calculation of 1-year PEC_{SOIL} – worst case unnormalised field SFO DT_{50} value (best fit), obtained in Meissner Vockerode trial.
		α = 0.286 β = 12.8839	The kinetic parameters obtained for FOMC fit in Elsenfeld-Rück field trial – recommended to be used for the calculation of the accumulation potential.
	Dione	669	The SFO value obtained from the slow phase DFOP fit for Lufa 2.2 soil (the longest laboratory value obtained this way).
	1,2,4-Triazole	12.27	The longest SFO value obtained in the

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			laboratory studies; EFSA agreed endpoint.
PEC_{GW}	Fluquinconazole	150.9	The median of the normalised SFO kinetic endpoints from the field studies.
	Dione	346	The geomean normalised SFO DT_{50} value obtained for the extended data base on the soil degradation kinetics of the Dione in the laboratory.
	1,2,4-Triazole	7.4	The geomean normalised SFO DT_{50}; EFSA agreed endpoint.
PEC_{SW}	Fluquinconazole	150.9	The median of the normalised SFO kinetic endpoints from the field studies.
	Dione	346	The geomean normalised SFO DT_{50} value obtained for the extended data base on the soil degradation kinetics of the Dione in the laboratory.
	1,2,4-Triazole	7.4	The geomean normalised SFO DT_{50}; EFSA agreed endpoint.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Fluquinconazole (parent)							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam	1.6	7.5	16.2	----	11.8	793	0.916
Silt loam	3.3	7.2	25.0	----	16.1	1153	0.891
Sandy loam	1.4	5.9	36.5	----	25.9	785	0.921
Sand	0.7	5.8	7.5	----	5.3	750	0.836
Arithmetic mean					14.8	870	0.891
pH dependence, Yes or No			No				

Dione (metabolite)							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay loam	2.8	7.6	----	----	15.9	567	0.932
Clay loam	2.0	6.9	----	----	20.0	999	0.951
Sandy loam	1.0	4.2	----	----	8.5	850	0.964
Sandy loam	2.0	7.4	----	----	14.3	715	0.908
Arithmetic mean					14.7	783.0	0.939

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

pH dependence (yes or no)	No

Metabolite 1,2-4 triazole ‡							
Soil Type(USDA)	OC %	Soil pH ($CaCl_2$)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Silty clay	0.70	8.8			0.833	120	0.897
Clay loam	1.74	6.9			0.748	43	0.827
Sand	0.12	4.8			0.234	202	0.885[1]
Silty clay loam	0.70	7.0			0.722	104	0.922
Sandy loam	0.81	6.9			0.720	89	1.016
Arithmetic mean (of 4 values excluding the very low OC sand that was considered not representative of agricultural soils)					0.756	89	0.9155
pH dependence (yes or no)	No						

Agreed End-point for calculating FOCUS modelling arithmetic mean Kfoc of 89 mL/g, 1/n 0.92 excluding results of the sand soil.

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

Column leaching ‡	Elution volume (mm): *200* mm Time period (d): *2* d (48 hours)
	Leachate: <0.11 – 0.16 % total residues/radioactivity in leachate No sectioning of the soil column took place, hence % radioactivity in the column segments at varying depths not reported. No characterisation of leachate sample
Aged residues leaching ‡	Aged for (d): 100 d Time period (d): 27 d Elution volume (mm): 570 mm

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

	Analysis of soil residues post ageing (soil residues pre-leaching): Fluquinconazole: - 73.6 - 87.6%AR after 102 - 108 d, [^{14}C]-Fluquinconazole, dichlorophenyl-label (n= 3 soils) - 74.0 – 85.8% AR after 102 – 108 d, [^{14}C]-Fluquinconazole, triazolyl-label (n= 3 soils); Dione: 6.4 – 10.5%AR after 102 - 108 d, [^{14}C]-Fluquinconazole, dichlorophenyl-label (n= 3 soils); 1,2,4-Triazole: 3.9 – 9.5% AR after 102 – 108 d, [^{14}C]-Fluquinconazole, triazolyl-label (n= 3 soils);
	Leachate: - 0.1 – 0.7 % total residues/radioactivity in leachate – [^{14}C]-Fluquinconazole, dichlorophenyl-label (n= 3 soils); composition of leachate – no data available; - 1.3 – 8.9% total residues/radioactivity in leachate – [^{14}C]-Fluquinconazole, triazolyl-label (n= 3 soils); composition of leachate – no data available; Distribution in the soil profile: - [^{14}C]-Fluquinconazole, dichlorophenyl-label (n= 3 soils): 40.3 – 70.6% retained on the surface of treated soil; 27.4 – 51.1% within the top 5 cm; 0.2 – 6.6% retained in 5-10 cm segment; 0.1 – 0.3% retained in 10-15 cm segment; 0.1% retained in 15-20 cm segment; <0.1 – 0.2% retained in 20-25 cm segment; <0.1 – 0.3% retained in 25-30 cm segment; most of the recovered radioactivity is parent compound; - ^{14}C]-Fluquinconazole, triazolyl-label (n= 3 soils): 38.1 – 74.4% retained on the surface of treated soil; 10.1 – 42.3% within the top 5 cm; 0.8 – 4.5% retained in 5-10 cm segment; 0.6 – 0.9% retained in 10-15 cm segment; 0.2 – 0.7% retained in 15-20 cm segment; 0.1 – 0.6% retained in 20-25 cm segment; 0.1 – 0.7% retained in 25-30 cm segment; ; most of the recovered radioactivity is parent compound;

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

Lysimeter/ field leaching studies ‡	Location: Cottenham UK; Icklingham UK Study type: lysimeter Soil properties: Cottenham: texture – sandy loam, pH = 5.0 – 6.5, OM= 2.4 - <0.2%, Iclingham: texture - sand, pH = 5.8 – 7.0, OM= 2.3 – 0.3%, Dates of application : first application: 10/May/1990, next in 3-week intervals Crop : no crop, application to bare soil: Number of applications: 1-2 years, 5 applications per year Duration: 1 or 2 years. Application rate: 112.5 g/ha/year Average annual rainfall (mm): 811 mm Average annual leachate volume (mm): 291.9 mm for all lysimeters tested over 2 years, 57.6 mm for all lysimeters tested over 1 year % radioactivity in leachate (maximum/year): 0.54%AR (year 2) Peak concentration: 1.20 µg a.s eq/l (combined residues after 84 days from lysimeter 35, Fluquinconazole was not detected in leachate, triazole was detected at 0.05 µg a.s eq/l from lysimeter 37 24/12/91, triazolyl acetic acid was detected at 0.1 µg a.s eq/l from lysimeter 35 20/09/90.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

PEC (soil) (Annex IIIA, point 9.1.3)

Fluquinconazole – parent compound Method of calculation	For 1-year PEC_{SOIL} calculations DT_{50} (d): 777.4 days Kinetics: SFO Field or Lab: representative worst case from field studies. For the accumulation potential: DT_{50} (d) – not used; Other kinetic parameters: α = 0.286 β = 12.8839 Kinetics: FOMC Field or Lab: representative worst case from field studies (based on DT_{90} value).; Calculations performed using "Escape ver. 1.0" modelling tool Calculation mode: residues from different applications treated separately over one year (for the calculation of the accumulation potential only).
Application data	Crop: cereals, spring and winter Depth of soil layer: 5 cm for 1-year PEC_{SOIL} calculations and the accum. PEC_{SOIL} after reaching max., 20 cm for background concentration in calculation of the accumulation potential. Soil bulk density: 1.5 g/cm^3 % plant interception: -single application – 50% - multiple application: 50% for first application, 70% for second application Number of applications: 1-2 Interval (d):21 days (multiple application) Application rate(s): Single application: 125 g a.s./ha; Multiple application: 125 g a.s./ha/treatment

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.0833		0.1318	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

Short term 24h	0.0833	0.0833	0.1317	0.1317
2d	0.0832	0.0833	0.1316	0.1317
4d	0.0830	0.0832	0.1313	0.1316
Long term 7d	0.0828	0.0831	0.1310	0.1314
28d	0.0813	0.0823	0.1285	0.1302
50d	0.0797	0.0815	0.1260	0.1289
100d	0.0762	0.0797	0.1205	0.1261

Plateau concentration	Single application / year: Final background conc: 0.0128 mg/kg after 10 years; max accum. PEC_S = 0.0961 mg/kg Multiple application: Final background conc: 0.0156 mg/kg after 12 years; max accum. PEC_S = 0.1288 mg/kg

Dione (metabolite) Method of calculation	Molecular weight relative to the parent: 325.1/378.2 (note: the correct MW factor is 325.1/376.2) DT_{50} (d): 669 days Kinetics: SFO – from the slowest phase of DFOP Field or Lab: representative worst case from laboratory studies (loamy sand soil, pH 5.8). Calculations performed using "Escape ver. 1.0" modelling tool Calculation mode: residues from different applications treated separately over one year (for the calculation of the accumulation potential only).
Application data	Application rate assumed: Single application: 125 g as/ha; multiple application: 2 x 125 g as/ha; Assumed formation fraction: 0.905

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.0221		0.0353	
Short term 24h	0.0221	0.0221	0.0353	0.0353
2d	0.0221	0.0221	0.0353	0.0353

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

4d	0.0221	0.0221	0.0353	0.0353
Long term 7d	0.0221	0.0221	0.0353	0.0353
28d	0.0221	0.0221	0.0353	0.0353
50d	0.0221	0.0221	0.0353	0.0353
100d	0.0220	0.0221	0.0352	0.0353

Plateau concentration	Calculations were performed assuming FOMC model for the parent compound – fluquinconazole. Single application / year: Final background conc: 0.0370 mg/kg after 12 years; max accum. PEC_S = 0.0677 mg/kg Multiple application: Final background conc: 0.0591 mg/kg after 12 years; max accum. PEC_S = 0.1082 mg/kg

1,2,4-Triazole (metabolite) Method of calculation	Molecular weight relative to the parent: 69.1/378.2 (note: the correct MW factor is 69.1/376.2) DT_{50} (d): 12.27 days Kinetics: SFO Field or Lab: representative worst case from laboratory studies. Calculations performed using "Escape ver. 1.0" modelling tool Calculation mode: residues from different applications treated separately over one year (for the calculation of the accumulation potential only).
Application data	Application rate assumed: Single application: 125 g as/ha; multiple application: 2 x 125 g as/ha; Assumed formation fraction: 0.905

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.0002		0.0003	
Short term 24h	0.0002	0.0002	0.0003	0.0003

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

2d	0.0002	0.0002	0.0003	0.0003
4d	0.0002	0.0002	0.0003	0.0003
Long term 7d	0.0002	0.0002	0.0003	0.0003
28d	0.0002	0.0002	0.0003	0.0003
50d	0.0002	0.0002	0.0003	0.0003
100d	0.0002	0.0002	0.0003	0.0003

Plateau concentration	Calculations were performed assuming FOMC model for the parent compound – fluquinconazole. <u>Single application/year</u>: Final background conc: 0.0003 mg/kg after 10 years; max accum. PEC_S = 0.0021 mg/kg <u>Multiple application:</u> Final background conc: 0.0004 mg/kg after 10 years; max accum. PEC_S = 0.0029 mg/kg

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	<u>pH 4:</u> Fluquinconazole: at T = 25^{0}C DT_{50} = 194 days (dichlorophenyl label, 1st order, r^2=0.981); <u>pH 5:</u> Fluquinconazole: at T = 25^{0}C DT_{50} = 2024 days (dichlorophenyl label, 1st order, r^2=0.514); Metabolites: Dione at pH 4, T = 25^{0}C: 10.2%AR (day 30); DT_{50} at 50^{0}C: stable; Triazole: at pH 5, T = 25^{0}C stable
	pH 7: Fluquinconazole: at T = 25°C DT_{50} = 21.9 days (dichlorophenyl label, 1st order, r^2=0.998); Dione: 59.0 %AR (day 30); DT_{50}: at 50^{0}C: stable; Triazole: 94.3%AR at 35^{0}C (day 30); DT_{50}: at 25^{0}C, stable;

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Fate and Behaviour in the Environment

	pH 9: 25°C, DT_{50} = 0.354 days (dichlorophenyl label, 1st order, r^2=0.999) and DT_{50} = 0.346 days (triazolyl label, 1st order, r^2=0.999); Dione: at T = 25^0C max. 67.7 %AR after ~ 1 day; DT_{50}: at T = 50^0C DT_{50} = 8.4 days (1st order, r^2 = 0.9898), at T = 25^0C DT_{50} = 193 days (1st order, r^2 = 0.9855); Triazole: at T = 25^0C max. 86.6%AR after ~1 day; DT_{50}: at 25^0C, stable; SN61638: at T = 35^0C max. 25.7 %AR after ~1 day, at T = 25^0C max. 23.5 after ~1day

Photolytic degradation of active substance and metabolites above 10 % ‡	**Fluquinconazole**: Xenon arc lamp, pH = 4, T = 25^0C – photolytically stable;
	Dione: Xenon arc lamp, T = 25^0C :
	pH = 4 – DT_{50} = 2.32 h,
	pH = 9 – DT_{50} = 1.37 h,
	Quantum yield:
	Φ = 2.90 E-3 – 3.63 E-3
	Estimated DT_{50} at 40°N:
	pH = 4 DT_{50} = 2.56 days (Spring), 2.28 days (Summer), 3.75 days (autumn);
	pH = 9 DT_{50} = 1.87 days (Spring), 1.69 days (Summer), 2.68 days (autumn);
	Estimated DT_{50} at 50°N:
	pH = 4 DT_{50} = 3.15 days (Spring), 2.67 days (Summer), 3.97 days (autumn);
	pH = 9 DT_{50} = 2.25 days (Spring), 1.92 days (Summer), 3.97 days (autumn);
	
	Triazole: for λ . 290 nm ε < 10 $L*mol^{-1}*cm^{-1}$ – the compouund is not expected to absorb light in environmentally relevant part of UV-Vis spectrum, therefore it is not expected to undergo photolytic degradation in water under environmental conditions

Quantum yield of direct phototransformation in water at Σ > 290 nm	Dione: Φ = 2.90 E-3 – 3.63 E-3 [$mol*Einstein^{-1}$]

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

Readily biodegradable (yes/no) ‡	**Fluquinconazole**: max. 3.0% mineralised after 28 days – not readily biodegradable. **Dione:** in closed bottle test oxygen consumption was equivalent to 26% ThOD – not readily biodegradable. **Triazole:** biodegradability not tested – assumed not readily biodegradable

Degradation in water / sediment

Fluquinconazole (parent)	Distribution: water: max 70.9% AR (dichlorophenyl label) – 82.4% AR (triazolyl label) on day 0.25; sediment: max. 51.5 %AR (dichlorophenyl label) on day 0 – 46.3 % AR (triazolyl label) on day 1									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys. (d)	min χ^2 err.	DT_{50}-DT_{90} water (d)	St. (r^2)	DT_{50}-DT_{90} sed (d)	St. (r^2)	Method of calculation
Mill Stream Pond (MSP)	8.1	7.6	20	36.76/ 121.82	19.45	2.6/----	0.98	140.3/----	0.98	Whole system: SFO; Water and sediment compartments: 1st order multicompartment
Iron Hatch Stream (IHS)	8.1	8.0	20	11.99/ 39.83	12.76	4.3/----	0.98	61.7/----	0.94	Whole system: SFO; Water and sediment compartments: 1st order multicompartment

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Fate and Behaviour in the Environment

Geometric mean		DT_{50} = 21 days (geomean)/ DT_{90} not calculated		----		----		

Dione (metabolite)	Distribution: water: max 21.8 – 23.9 %AR on day 14; sediment: max. 47.0 %AR (IHS system) at day 100; whole system: 61.2% AR (IHS system) on day 100									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys. (d)	St. (r^2)	DT_{50}-DT_{90} water (d)	r^2	DT_{50}-DT_{90} sed (d)	St. (r^2)	Method of calculation
Mill Stream Pond (MSP)	8.1	7.6	20	Not determined	---	73.1	0.92	Not determined	---	1st order multicom-partment
Iron Hatch Stream (IHS)	8.1	8.0	20	Not determined	---	89.3	0.98	Not determined	---	1st order multicom-partment

1,2,4-Triazole (metabolite)	Distribution: water: max 28.8 – 31.6%AR after 14 – 63 days; sediment: max. 37.4 %AR (IHS system) on day 63; whole system: 69.0% AR (IHS system) on day 63									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Mill Stream Pond (MSP)	8.1	7.6	20	Not determined	---	41.9	0.87	Not determined	---	1st order multicom-partment
Iron Hatch Stream (IHS)	8.1	8.0	20	Not determined	---	100.0	0.96	Not determined	---	1st order multicom-partment

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

Mineralisation and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralisation	Non-extractable residues in sediment - Max	Non-extractable residues in sediment at the end of the study
Mill Stream Pond (MSP)	8.1	7.6	0.7 – 2.8% after 100 days (end of the study)	5.1 – 25.1% AR (on day 100)	5.1 – 25.1% AR (on day 100)
Iron Hatch Stream (ISP)	8.1	8.0	0.4 – 1.6% after 100 days (end of the study)	7.7 – 17.2% AR (on day 100)	7.7 – 17.2% AR (on day 100)

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

Fluquinconazole Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: ver. 1.1 Molecular weight (g/mol): 378.2 (note: the correct MW is 376.2) Water solubility (mg/L): 1.1 K_{OC} (L/kg): 870 DT_{50} soil (d): 150.9 days (median from normalised field results, SFO kinetics) DT_{50} water/sediment system (d): 1000 days (FOCUS default value) DT_{50} water (d): 21days (geomean of two whole system values) DT_{50} sediment (d): 1000 days Crop interception (%): 50% for both single and multiple applications
Parameters used in FOCUSsw step 3 (if performed)	Version control no.’s of FOCUS software: SWASH ver. 2.1 Vapour pressure: 6.4 E-9 [Pa] (20^0C) Koc: 870 [L/g] 1/n: 0.891 Activation energy (TOXSWA): 92.4 kJ/mol; Exponent (Macro) [1/K]: 0.1340 Q_{10} factor (PRZM) 3.84 Walker equation coefficient 0.0 (MACRO and PRZM).
Application rate	Crop: spring (SC) and winter cereals (WC)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Fate and Behaviour in the Environment

	Crop interception: at Steps 1&2 50% for both single and multiple applications, at Step 3 calculated by the model (depending on the application dates) Number of applications: 1 (single application) or 2 (multiple applications Interval (d): 21 days (for multiple applications) Application rate(s): 125 g as/ha for single application, 2 x 125 g as/ha for multiple application Application window: at Steps 1&2 – March-May for both spring and winter cereals; At Step 3 the following application windows were assumed: a) single application: <u>Spring cereals:</u> D1 – 25/05 – 15/07 D3 – 21/04 – 11/06 D4 – 16/05 – 06/07 D5 – 05/04 – 26/05 R4 – 05/04 – 26/05 <u>Winter cereals:</u> D1 – 11/05 – 01/07 D2 – 08/04 – 29/05 D3 – 07/04 – 28/05 D4 – 02/05 – 22/06 D5 – 22/03 – 12/05 D6 – 17/03 – 07/05 R1 – 08/04 – 29/05 R3 – 17/03 – 07/05 R4 – 22/03 – 12/05 b) multiple applications: <u>Spring cereals:</u> D1 – 25/05 – 15/07 D3 – 21/04 – 11/06 D4 – 16/05 – 06/07 D5 – 05/04 – 26/05 R4 – 05/04 – 26/05 <u>Winter cereals:</u>

List of end points

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Fate and Behaviour in the Environment

	D1 – 11/05 – 01/07 D2 – 08/04 – 29/05 D3 – 07/04 – 28/05 D4 – 02/05 – 22/06 D5 – 22/03 – 12/05 D6 – 17/03 – 07/05 R1 – 08/04 – 29/05 R3 – 17/03 – 07/05 R4 – 22/03 – 12/05

1) **Results for the single application at 125 g a. s./ha**

The results of the STEP-1 calculations of PEC_{SW} and PEC_{SED} (WC = SC).

Time [days]	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA
0	20.440	----	167.824	----
1	19.179	19.809	166.855	167.340
2	18.556	19.338	161.438	165.736
4	17.371	18.647	151.125	160.980
7	15.733	17.743	136.877	153.653
14	12.487	15.896	108.639	137.934
21	9.911	14.314	86.227	124.290
28	7.867	12.948	68.439	112.465
42	4.956	10.732	43.114	93.245
50	3.806	9.711	33.103	84.388
100	0.731	5.787	6.356	50.299

The results of the STEP-2 calculations of PEC_{SW} and PEC_{SED} (WC = SC).

Time [days]	North Europe				South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	2.484	----	20.745	----	4.378	----	37.211	----
1	2.309	2.396	20.426	20.585	4.141	4.259	36.637	36.924
2	2.273	2.344	20.111	20.427	4.077	4.184	36.073	36.640
4	2.204	2.291	19.496	20.115	3.953	4.100	34.970	36.079
7	2.103	2.232	18.609	19.658	3.773	3.998	33.379	35.261
14	1.887	2.113	16.693	18.646	3.384	3.786	29.942	33.445
21	1.693	2.004	14.974	17.703	3.036	3.593	26.859	31.755

28	1.518	1.904	13.432	16.825	2.723	3.414	24.093	30.179
42	1.222	1.724	10.808	15.241	2.191	3.093	19.387	27.338
50	1.079	1.632	9.546	14.429	1.935	2.927	17.123	25.881
100	0.497	1.919	4.393	10.534	0.891	2.137	7.879	18.895

The results of the STEP-3 calculations of PEC_{SW} and PEC_{SED} in WC.

Time [days]	FOCUS Scenario							
	D1 Ditch				D1 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	1.163	----	7.862	----	0.710	----	4.171	----
1	1.078	1.117	n. c.[1)]	7.861	0.228	0.549	n. c.[1)]	4.165
2	1.018	1.081	n. c.[1)]	7.860	0.0205	0.375	n. c.[1)]	4.164
4	0.934	1.027	n. c.[1)]	7.858	7.22 E-3	0.372	n. c.[1)]	4.164
7	0.846	0.967	n. c.[1)]	7.851	4.36 E-3	0.370	n. c.[1)]	4.161
14	0.691	0.866	n. c.[1)]	7.812	2.48 E-3	0.359	n. c.[1)]	4.129
21	0.557	0.786	n. c.[1)]	7.781	1.80 E-3	0.353	n. c.[1)]	4.102
28	0.444	0.714	n. c.[1)]	7.754	1.43 E-3	0.349	n. c.[1)]	4.077
42	0.288	0.610	n. c.[1)]	7.685	1.01 E-3	0.347	n. c.[1)]	4.006
50	0.224	0.575	n. c.[1)]	7.640	8.59 E-4	0.342	n. c.[1)]	3.963
100	0.0642	0.528	n. c.[1)]	7.425	4.32 E-4	0.307	n. c.[1)]	3.818
Time [days]	FOCUS Scenario							
	D2 Ditch				D2 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	1.248	----	9.235	----	0.903	----	5.382	----
1	0.500	1.077	9.226	9.232	0.835	0.866	5.363	5.379
2	0.683	1.044	9.183	9.225	0.788	0.838	5.357	5.375
4	0.580	0.993	9.147	9.200	0.727	0.796	5.329	5.365
7	0.462	0.945	9.051	9.165	0.710	0.751	5.284	5.348
14	0.351	0.772	8.887	9.095	0.255	0.534	5.197	5.309
21	0.313	0.648	8.750	9.026	0.198	0.427	5.115	5.274
28	n. c.[1)]	0.582	n. c.[1)]	8.960	0.188	0.389	n. c.[1)]	5.236
42	n. c.[1)]	0.570	n. c.[1)]	8.834	0.148	0.358	n. c.[1)]	5.155
50	n. c.[1)]	0.549	n. c.[1)]	8.770	0.126	0.345	n. c.[1)]	5.114
100	n. c.[1)]	0.480	n. c.[1)]	8.499	0.0509	0.286	n. c.[1)]	4.937
Time [days]	FOCUS Scenario							
	D3 Ditch				D4 Pond			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.790	----	0.418	----	0.0807	----	0.779	----
1	0.325	0.593	0.363	0.409	0.0806	0.0807	0.779	0.779
2	0.0367	0.369	0.303	0.387	0.0801	0.0807	0.779	0.779
4	4.34 E-3	0.190	0.230	0.341	0.0790	0.0805	0.779	0.779
7	1.67 E-3	0.110	0.178	0.289	0.0769	0.0801	0.778	0.779

14	4.94 E-4	0.0554	0.128	0.223	0.0716	0.0790	0.776	0.779
21	2.58 E-4	0.0371	0.106	0.189	0.0671	0.0775	0.774	0.778
28	1.74 E-4	0.0278	0.0928	0.167	0.0729	0.0756	0.770	0.778
42	9.8 E-5	0.0186	0.0765	0.140	0.0671	0.0740	n. c.[1)]	0.777
50	8.5 E-5	0.0156	0.0704	0.129	0.0622	0.0733	n. c.[1)]	0.776
100	3.5 E-5	7.85 E-3	0.0503	0.0942	0.0406	0.0647	n. c.[1)]	0.750

1) n. c. = not calculated – simulated period was too short for calculation of PEC at the given time point.

The results of the STEP-3 calculations of PEC_{SW} and PEC_{SED} in WC - continued.

Time [days]	FOCUS Scenario							
	D4 Stream				D5 Pond			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.674	----	0.334	----	0.0651	----	0.607	----
1	4.22 E-4	0.127	0.334	0.334	0.0647	0.0650	0.607	0.607
2	3.20 E-4	0.108	0.332	0.334	0.0639	0.0649	0.607	0.607
4	2.07 E-4	0.0935	0.328	0.333	0.0620	0.0644	0.607	0.607
7	1.15 E-4	0.0717	0.320	0.332	0.0592	0.0634	0.607	0.607
14	4.2 E-5	0.0608	0.295	0.327	0.0539	0.0608	n. c.[1)]	0.607
21	1.8 E-5	0.0603	0.271	0.319	0.0493	0.0584	n. c.[1)]	0.607
28	1.3 E-5	0.0542	0.250	0.311	0.0453	0.0561	n. c.[1)]	0.605
42	8 E-6	0.0416	0.222	0.307	0.0395	0.0519	n. c.[1)]	0.600
50	7 E-6	0.0400	0.211	0.308	0.0370	0.0499	n. c.[1)]	0.595
100	3 E-6	0.0249	n. c.[1)]	0.277	n. c.[1)]	0.0398	n. c.[1)]	0.493
Time [days]	FOCUS Scenario							
	D5 Stream				D6 Ditch			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.640	----	0.188	----	0.797	----	1.315	----
1	2.90 E-3	0.0718	0.184	0.187	0.704	0.746	1.302	1.314
2	2.76 E-3	0.0634	0.179	0.187	0.634	0.709	1.270	1.310
4	2.39 E-3	0.0489	0.169	0.184	0.519	0.647	1.178	1.296
7	2.07 E-3	0.0413	0.157	0.179	0.292	0.543	1.036	1.260
14	1.41 E-3	0.0306	0.140	0.167	0.0597	0.344	0.807	1.150
21	1.06 E-3	0.0236	0.129	0.159	0.0200	0.241	0.678	1.045
28	6.56 E-4	0.0209	0.120	0.151	9.83 E-3	0.184	0.596	0.959
42	5.4 E-5	0.0173	0.134	0.142	4.36 E-3	0.125	0.495	0.833
50	2.2 E-5	0.0156	0.140	0.140	3.17 E-3	0.106	0.455	0.781
100	1.0 E-5	0.0103	n. c.[1)]	0.125	8.70 E-4	0.0559	0.319	0.587
Time [days]	FOCUS Scenario							
	R1 Pond				R1 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.0383	----	0.270	----	0.521	----	0.297	----
1	0.0372	0.0378	0.270	0.270	1.40 E-4	0.135	0.274	0.289

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

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2	0.0361	0.0373	0.270	0.270	9.6 E-5	0.0675	0.257	0.280
4	0.0341	0.0362	0.269	0.270	5.0 E-5	0.0339	0.253	0.266
7	0.0313	0.0348	0.267	0.270	2.1 E-5	0.0325	0.226	0.255
14	0.0260	0.0318	0.263	0.269	3.7 E-5	0.0247	0.197	0.235
21	0.0218	0.0301	0.255	0.268	5.2 E-5	0.0198	0.182	0.224
28	0.0301	0.0297	0.250	0.266	0.0145	0.0159	0.232	0.226
42	0.0198	0.0289	0.237	0.261	1.03 E-04	0.0130	0.197	0.221
50	0.0164	0.0281	0.227	0.259	4.3 E-5	0.0115	0.204	0.219
100	8.69 E-3	0.0230	0.236	0.244	7.4 E-5	7.88 E-3	0.195	0.204

1) n. c. = not calculated – simulated period was too short for calculation of PEC at the given time point.

The results of the STEP-3 calculations of PEC_{SW} and PEC_{SED} in WC - continued.

Time [days]	FOCUS Scenario							
	R3 Stream				R4 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.732	----	0.437	----	0.524	----	0.500	----
1	8.76 E-4	0.283	0.399	0.428	1.85 E-4	0.231	0.447	0.482
2	4.80 E-4	0.150	0.367	0.411	1.26 E-4	0.200	0.404	0.459
4	2.89 E-4	0.0757	0.329	0.383	6.4 E-5	0.104	0.353	0.424
7	1.31 E-4	0.0435	0.298	0.355	2.9 E-5	0.0824	0.412	0.421
14	4.1 E-5	0.0237	0.264	0.320	0.246	0.0565	0.317	0.391
21	2.2 E-5	0.0190	0.245	0.314	0.190	0.0413	0.281	0.361
28	6.16 E-4	0.0190	0.315	0.305	1.62 E-4	0.0323	0.259	0.339
42	9.4 E-5	0.0168	0.294	0.304	5.2 E-5	0.0215	0.230	0.308
50	7.99 E-4	0.0148	0.265	0.300	3.7 E-5	0.0181	0.218	0.295
100	4.9 E-5	9.19 E-3	0.210	0.266	1.3 E-5	9.06 E-3	0.228	0.245

1) n. c. = not calculated – simulated period was too short for calculation of PEC at the given time point.

The results of the STEP-3 calculations of PEC_{SW} and PEC_{SED} in SC.

Time [days]	FOCUS Scenario							
	D1 Ditch				D1 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	1.279	----	14.299	----	0.707	----	8.010	----
1	1.189	1.230	n. c.[1)]	14.293	0.226	0.679	n. c.[1)]	8.00
2	1.124	1.192	n. c.[1)]	14.290	0.0205	0.670	n. c.[1)]	7.996
4	1.032	1.133	n. c.[1)]	14.284	8.22 E-3	0.655	n. c.[1)]	7.990
7	0.931	1.067	n. c.[1)]	14.273	5.79 E-3	0.662	n. c.[1)]	7.980
14	0.752	1.033	n. c.[1)]	14.217	3.93 E-3	0.642	n. c.[1)]	7.932
21	0.574	1.016	n. c.[1)]	14.175	3.09 E-3	0.631	n. c.[1)]	7.894
28	0.443	1.002	n. c.[1)]	14.140	2.57 E-3	0.622	n. c.[1)]	7.860
42	0.277	0.992	n. c.[1)]	14.052	1.92 E-3	0.616	n. c.[1)]	7.772
50	0.221	0.984	n. c.[1)]	13.994	1.68 E-3	0.611	n. c.[1)]	7.712
100	0.479	0.911	n. c.[1)]	13.755	0.265	0.563	n. c.[1)]	7.515

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

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Time [days]	FOCUS Scenario							
	D3 Ditch				D4 Pond			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.791	----	0.429	----	0.114	----	1.066	----
1	0.346	0.601	0.374	0.420	0.114	0.114	1.066	1.066
2	0.0431	0.380	0.312	0.399	0.113	0.114	1.066	1.066
4	4.76 E-3	0.197	0.238	0.351	0.111	0.114	1.066	1.066
7	1.81 E-3	0.114	0.184	0.298	0.108	0.114	1.065	1.066
14	5.09 E-4	0.0574	0.133	0.230	0.101	0.112	1.062	1.066
21	2.59 E-4	0.0384	0.110	0.195	0.0938	0.110	1.058	1.066
28	1.68 E-4	0.0289	0.0956	0.172	0.0990	0.107	1.053	1.065
42	1.23 E-4	0.0193	0.0789	0.144	0.0922	0.103	n. c.[1)]	1.064
50	9.8 E-5	0.0162	0.0726	0.133	0.0856	0.102	n. c.[1)]	1.063
100	4.4 E-5	8.14 E-3	0.0518	0.0972	0.0558	0.0915	n. c.[1)]	1.032

1) n. c. = not calculated – simulated period was too short for calculation of PEC at the given time point.

The results of the STEP-3 calculations of PEC_{SW} and PEC_{SED} in SC - continued.

Time [days]	FOCUS Scenario							
	D4 Stream				D5 Pond			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.657	----	0.430	----	0.0682	----	0.657	----
1	1.19 E-3	0.185	0.429	0.429	0.0676	0.0681	0.657	0.657
2	1.12 E-3	0.160	0.426	0.429	0.0667	0.0679	0.657	0.657
4	9.90 E-4	0.143	0.421	0.428	0.0647	0.0674	0.657	0.657
7	7.92 E-4	0.118	0.411	0.426	0.0619	0.0663	0.657	0.657
14	4.45 E-4	0.0829	0.380	0.419	0.0564	0.0636	n. c.[1)]	0.657
21	2.40 E-4	0.0789	0.351	0.410	0.0516	0.0611	n. c.[1)]	0.656
28	1.16 E-4	0.0706	0.326	0.399	0.0474	0.0586	n. c.[1)]	0.655
42	1.4 E-5	0.0533	0.291	0.393	0.0426	0.0544	n. c.[1)]	0.648
50	1.1 E-5	0.0503	0.277	0.395	0.0402	0.0525	n. c.[1)]	0.642
100	7 E-6	0.0319	n. c.[1)]	0.362	n. c.[1)]	0.0433	n. c.[1)]	0.538
Time [days]	FOCUS Scenario							
	D5 Stream				R4 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.624	----	0.199	----	0.524	----	0.646	----
1	3.78 E-3	0.0757	0.196	0.199	1.85 E-4	0.311	0.572	0.622
2	3.54 E-3	0.0669	0.191	0.198	1.26 E-4	0.278	0.514	0.591
4	3.18 E-3	0.0489	0.180	0.196	6.4 E-5	0.144	0.445	0.543
7	2.67 E-03	0.0424	0.167	0.191	2.9 E-5	0.118	0.515	0.534
14	2.03 E-3	0.0311	0.151	0.178	0.358	0.0789	0.392	0.492
21	1.84 E-3	0.0256	0.139	0.169	0.244	0.0558	0.346	0.452
28	1.33 E-3	0.0228	0.130	0.162	2.10 E-4	0.0435	0.318	0.423
42	9.24 E-4	0.0189	0.153	0.153	6.7 E-	0.0290	0.281	0.383
50	4.58 E-4	0.0171	0.159	0.153	4.8 E-5	0.0244	0.265	0.366

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

100	1.2 E-5	0.0114	n. c.[1)]	0.140	1.6 E-5	0.0122	0.263	0.302

1) n. c. = not calculated – simulated period was too short for calculation of PEC at the given time point.

2) **Results for the double application at 2 x 125 g/ha**

The results of the STEP-1 calculations of PEC_{SW} and PEC_{SED} (WC = SC).

Time [days]	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA
0	40.879	----	335.648	----
1	39.617	40.248	344.670	340.159
2	39.590	39.926	344.431	342.355
4	39.535	39.744	343.954	343.273
7	39.453	39.637	343.239	343.412
14	39.262	39.497	341.578	342.910
21	39.072	39.387	339.925	342.190
28	38.883	39.285	338.279	341.418
42	38.507	39.088	335.012	339.826
50	38.294	38.978	333.160	338.908
100	36.990	38.308	321.811	333.180

The results of the STEP-2 calculations of PEC_{SW} and PEC_{SED} (WC = SC).

Time [days]	North Europe				South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	4.486	----	37.750	----	8.100	----	69.167	----
1	4.201	4.344	37.169	37.460	7.697	7.899	68.102	68.634
2	4.136	4.256	36.596	37.171	7.579	7.768	67.053	68.106
4	4.010	4.165	35.478	36.603	7.347	7.616	65.003	67.065
7	3.828	4.059	33.863	35.772	7.013	7.428	62.045	65.543
14	3.433	3.843	30.376	33.931	6.291	7.037	55.656	62.169
21	3.080	3.647	27.249	32.215	5.643	6.678	49.925	59.026
28	2.763	3.465	24.443	30.617	5.062	6.346	44.785	56.097
42	2.223	3.137	19.668	27.734	4.073	5.747	36.037	50.815
50	1.963	2.970	17.371	26.256	3.598	5.440	31.828	48.107
100	0.904	2.168	7.994	19.169	1.655	3.971	14.646	35.122

The results of the STEP-3 calculations of PEC_{SW} and PEC_{SED} in WC.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

Time [days]	FOCUS Scenario							
	D1 Ditch				D1 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	1.210	----	10.956	----	0.619	----	5.720	----
1	1.129	1.166	n. c.[1)]	10.954	0.201	0.534	n. c.[1)]	5.712
2	1.071	1.132	n. c.[1)]	10.954	0.0209	0.525	n. c.[1)]	5.711
4	0.987	1.079	n. c.[1)]	10.951	8.55 E-3	0.521	n. c.[1)]	5.710
7	0.894	1.018	n. c.[1)]	10.942	5.47 E-3	0.518	n. c.[1)]	5.706
14	0.729	0.913	n. c.[1)]	10.890	3.27 E-3	0.502	n. c.[1)]	5.663
21	0.588	0.828	n. c.[1)]	10.849	2.42 E-3	0.494	n. c.[1)]	5.626
28	0.470	0.786	n. c.[1)]	10.815	1.93 E-3	0.488	n. c.[1)]	5.592
42	0.769	0.781	n. c.[1)]	10.723	2.11 E-3	0.485	n. c.[1)]	5.495
50	0.593	0.770	n. c.[1)]	10.665	1.38 E-4	0.478	n. c.[1)]	5.436
100	0.129	0.701	n. c.[1)]	10.392	6.14 E-4	0.429	n. c.[1)]	5.244

Time [days]	FOCUS Scenario							
	D2 Ditch				D2 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	2.495	----	18.084	----	1.562	----	10.610	----
1	1.133	1.745	18.067	18.078	0.673	1.052	10.572	10.602
2	1.002	1.502	17.988	18.065	0.616	0.955	10.561	10.596
4	1.123	1.431	17.920	18.017	0.655	0.917	10.507	10.577
7	1.496	1.324	17.740	17.951	0.945	0.898	10.423	10.545
14	0.914	1.202	17.429	17.820	0.564	0.791	10.257	10.471
21	1.890	1.129	17.165	17.691	1.213	0.725	10.100	10.404
28	1.969	1.115	n. c.[1)]	17.566	1.220	0.693	n. c.[1)]	10.333
42	0.788	1.068	n. c.[1)]	17.336	0.479	0.685	n. c.[1)]	10.185
50	0.699	1.034	n. c.[1)]	17.220	0.425	0.655	n. c.[1)]	10.111
100	0.791	0.970	n. c.[1)]	16.754	0.453	0.606	n. c.[1)]	9.806

Time [days]	FOCUS Scenario							
	D3 Ditch				D4 Pond			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.692	----	0.483	----	0.173	----	1.564	----
1	0.350	0.541	0.434	0.475	0.172	0.173	1.564	1.564
2	0.0555	0.359	0.375	0.456	0.172	0.173	1.564	1.564
4	5.32 E-3	0.188	0.302	0.412	0.169	0.172	1.564	1.564
7	2.02 E-3	0.109	0.246	0.361	0.165	0.171	1.563	1.564
14	6.67 E-4	0.0550	0.191	0.293	0.154	0.169	1.559	1.564
21	4.06 E-4	0.0369	0.164	0.256	0.144	0.166	1.554	1.563
28	2.93 E-4	0.0277	0.147	0.231	0.155	0.162	n. c.[1)]	1.562
42	1.65 E-4	0.0346	0.125	0.200	0.142	0.159	n. c.[1)]	1.560
50	1.29 E-4	0.0291	0.116	0.193	0.132	0.157	n. c.[1)]	1.559
100	8.7 E-5	0.0147	0.0860	0.159	0.0862	0.138	n. c.[1)]	1.504

1) n. c. = not calculated – simulated period was too short for calculation of PEC at the given time point.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

The results of the STEP-3 calculations of PEC_{SW} and PEC_{SED} in WC - continued.

Time [days]	FOCUS Scenario							
	D4 Stream				D5 Pond			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.592	----	0.690	----	0.120	----	1.101	----
1	7.36 E-4	0.239	0.688	0.690	0.120	0.120	1.101	1.101
2	4.10 E-4	0.220	0.681	0.689	0.118	0.120	1.101	1.101
4	2.12 E-4	0.193	0.667	0.686	0.115	0.119	1.100	1.101
7	1.03 E-4	0.151	0.640	0.680	0.110	0.117	1.099	1.101
14	4.1 E-5	0.131	0.578	0.669	0.100	0.113	n. c.[1)]	1.100
21	2.6 E-5	0.130	0.561	0.651	0.0919	0.109	n. c.[1)]	1.099
28	1.9 E-5	0.118	0.670	0.632	0.0846	0.104	n. c.[1)]	1.097
42	1.3 E-5	0.0908	0.620	0.634	0.0741	0.0968	n. c.[1)]	1.087
50	1.1 E-5	0.0865	0.561	0.635	0.0693	0.0931	n. c.[1)]	1.079
100	6 E-6	0.0536	0.392	0.579	n. c.[1)]	0.0731	n. c.[1)]	0.893

Time [days]	FOCUS Scenario							
	D5 Stream				D6 Ditch			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.613	----	0.350	----	0.710	----	1.700	----
1	1.31 E-3	0.159	0.344	0.349	0.631	0.667	1.687	1.699
2	1.06 E-3	0.124	0.335	0.348	0.575	0.634	1.654	1.695
4	8.19 E-4	0.0898	0.317	0.344	0.470	0.579	1.557	1.681
7	4.40 E-4	0.0785	0.297	0.335	0.274	0.490	1.402	1.646
14	8.2 E-5	0.0578	0.267	0.315	0.0582	0.314	1.145	1.530
21	5.6 E-5	0.0476	0.246	0.300	0.0210	0.221	0.994	1.415
28	4.4 E-5	0.0421	0.228	0.287	0.0115	0.242	0.891	1.318
42	3.1.E-5	0.0346	0.256	0.269	5.26 E-3	0.215	0.757	1.172
50	2.7 E-5	0.0312	0.266	0.267	3.93 E-3	0.184	0.703	1.143
100	1.5 E-5	0.0202	n. c.[1)]	0.238	1.25 E-3	0.0948	0.505	0.942

Time [days]	FOCUS Scenario							
	R1 Pond				R1 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.0755	----	0.513	----	0.565	----	0.543	----
1	0.0734	0.0745	0.513	0.513	8.79 E-4	0.300	0.493	0.526
2	0.0712	0.0735	0.513	0.513	5.70 E-4	0.151	0.457	0.505
4	0.0672	0.0714	0.511	0.513	1.89 E-3	0.0775	0.450	0.473
7	0.0616	0.0685	0.508	0.513	6.04 E-4	0.0719	0.393	0.453
14	0.0511	0.0626	0.4999	0.511	0.0163	0.0541	0.338	0.412
21	0.0428	0.0584	0.486	0.508	1.35 E-4	0.0436	0.310	0.390
28	0.0609	0.0588	0.477	0.505	7.3 E-5	0.0351	0.395	0.393
42	0.0400	0.0567	0.451	0.497	1.06 E-04	0.0282	0.329	0.384

50	0.0331	0.0553	0.432	0.493	6.0 E-5	0.0251	0.344	0.377
100	0.0174	0.0428	0.449	0.465	2.6 E-5	0.0158	0.332	0.349

1) n. c. = not calculated – simulated period was too short for calculation of PEC at the given time point.

The results of the STEP-3 calculations of PEC_{SW} and PEC_{SED} in WC - continued.

Time [days]	FOCUS Scenario							
	R3 Stream				R4 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.638	----	0.515	----	0.711	----	0.940	----
1	3.34 E-3	0.283	0.462	0.499	1.25 E-3	0.520	0.813	0.900
2	1.52 E-3	0.150	0.422	0.477	8.02 E-4	0.477	0.716	0.850
4	7.97 E-4	0.131	0.373	0.455	0.538	0.247	0.604	0.771
7	4.07 E-4	0.0754	0.335	0.458	1.30 E-3	0.207	0.712	0.750
14	1.46 E-4	0.0464	0.292	0.436	5.50 E-4	0.135	0.520	0.683
21	0.400	0.0373	0.431	0.425	1.95 E-4	0.0916	0.451	0.621
28	5.53 E-4	0.0346	0.385	0.409	1.15 E-4	0.0712	0.409	0.575
42	3.43 E-4	0.0313	0.381	0.381	6.1 E-5	0.0475	0.356	0.512
50	1.67 E-4	0.0263	0.340	0.379	4.7 E-5	0.0399	0.334	0.486
100	8.0 E-5	0.0150	0.272	0.339	0.0990	0.0210	0.329	0.391

The results of the STEP-3 calculations of PEC_{SW} and PEC_{SED} in SC.

Time [days]	FOCUS Scenario							
	D1 Ditch				D1 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	1.345	----	17.458	----	0.843	----	9.643	----
1	1.298	1.321	n. c.[1)]	17.450	0.809	0.825	n. c.[1)]	9.632
2	1.278	1.304	n. c.[1)]	17.447	0.797	0.814	n. c.[1)]	9.627
4	1.309	1.297	n. c.[1)]	17.440	0.819	0.809	n. c.[1)]	9.620
7	1.261	1.292	n. c.[1)]	17.427	0.781	0.805	n. c.[1)]	9.607
14	1.193	1.257	n. c.[1)]	17.361	0.737	0.781	n. c.[1)]	9.549
21	1.167	1.236	n. c.[1)]	17.311	0.722	0.768	n. c.[1)]	9.502
28	1.237	1.218	n. c.[1)]	17.272	0.771	0.756	n. c.[1)]	9.462
42	1.102	1.206	n. c.[1)]	17.170	0.675	0.749	n. c.[1)]	9.356
50	1.047	1.196	n. c.[1)]	11.103	0.663	0.743	n. c.[1)]	9.285
100	0.688	1.108	n. c.[1)]	16.841	0.186	0.685	n. c.[1)]	9.053
Time [days]	FOCUS Scenario							
	D3 Ditch				D4 Pond			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.691	----	0.471	----	0.171	----	1.570	----

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

1	0.314	0.529	0.423	0.463	0.171	0.171	1.570	1.570
2	0.0431	0.338	0.366	0.444	0.170	0.171	1.569	1.570
4	4.65 E-3	0.176	0.295	0.401	0.167	0.171	1.569	1.570
7	1.93 E-3	0.102	0.242	0.351	0.163	0.170	1.568	1.569
14	7.40 E-4	0.0515	0.189	0.286	0.151	0.168	1.564	1.569
21	4.39 E-4	0.0345	0.162	0.251	0.141	0.165	1.557	1.569
28	3.02 E-4	0.0504	0.145	0.227	0.149	0.160	1.550	1.568
42	1.77 E-4	0.0340	0.123	0.206	0.138	0.155	n. c.[1)]	1.565
50	1.45 E-4	0.0287	0.115	0.199	0.128	0.154	n. c.[1)]	1.564
100	8.1 E-5	0.0144	0.0847	0.159	0.0837	0.137	n. c.[1)]	1.519

1) n. c. = not calculated – simulated period was too short for calculation of PEC at the given time point.

The results of the STEP-3 calculations of PEC_{SW} and PEC_{SED} in SC - continued.

Time [days]	FOCUS Scenario							
	D4 Stream				D5 Pond			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.591	----	0.638	----	0.0991	----	0.944	----
1	6.21 E-4	0.268	0.635	0.637	0.0984	0.0990	0.944	0.944
2	3.87 E-4	0.232	0.629	0.637	0.0972	0.0987	0.944	0.944
4	2.02 E-4	0.209	0.614	0.634	0.0943	0.0979	0.943	0.944
7	9.9 E-5	0.174	0.588	0.631	0.0903	0.0065	0.942	0.944
14	4.1 E-5	0.124	0.532	0.623	0.0823	0.0927	n. c.[1)]	0.943
21	2.7 E-5	0.118	0.515	0.606	0.0753	0.0890	n. c.[1)]	0.942
28	2.1 E-5	0.106	0.623	0.591	0.0693	0.0855	n. c.[1)]	0.940
42	1.5 E-5	0.0807	0.583	0.586	0.0624	0.0794	n. c.[1)]	0.930
50	1.3 E-5	0.0760	0.530	0.589	0.0589	0.0766	n. c.[1)]	0.922
100	3.51 E-3	0.0481	0.384	0.538	n. c.[1)]	0.0595	n. c.[1)]	0.774
Time [days]	FOCUS Scenario							
	D5 Stream				R4 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.599	----	0.286	----	0.453	----	0.645	----
1	1.87 E-3	0.109	0.282	0.286	8.23 E-4	0.312	0.571	0.621
2	1.82 E-3	0.0968	0.274	0.285	5.92 E-4	0.279	0.513	0.590
4	1.71 E-3	0.0710	0.259	0.281	3.51 E-4	0.145	0.443	0.552
7	1.49 E-03	0.0614	0.241	0.274	2.05 E-4	0.119	0.577	0.535
14	9.52 E-4	0.0452	0.218	0.257	1.01 E-4	0.0860	0.412	0.509
21	3.80 E-4	0.0373	0.201	0.244	6.7 E-5	0.0574	0.360	0.469
28	4.0 E-5	0.0332	0.187	0.234	5.0 E-5	0.0465	0.329	0.439
42	2.6 E-5	0.0274	0.221	0.221	3.3 E-5	0.0310	0.289	0.402
50	2.3 E-5	0.0247	0.230	0.221	2.7 E-5	0.0261	0.272	0.394
100	1.2 E-5	0.0163	n. c.[1)]	0.201	7.5 E-5	0.0131	0.465	0.373

1) n. c. = not calculated – simulated period was too short for calculation of PEC at the given time point.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

The results of the STEP-4 calculations of PEC_{SW} and PEC_{SED} double applications with crop interception manually edited to 50% for the first application and 70% for the second to ensure coherence with the application dates of 7 May and 29 May used in simulations for WC.

Time [days]	FOCUS Scenario							
	D2 Ditch				D2 Stream			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	1.322	----	9.965	----	0.826	----	5.880	----

Dione (metabolite) Parameters used in FOCUSsw step 1 and 2	Molecular weight: 325.1 [g/mol] Water solubility (mg/L): 1.0 Soil or water metabolite: soil and water metabolite Koc (L/kg): 783 DT_{50} soil (d): 346 days (lab. SFO normalised, the geomean value obtained for the extended data base on the soil degradation kinetics of the Dione in the laboratory.) DT50 water/sediment system (d): 730 (representative worst case from sediment water studies) DT_{50} water (d): 29.30 DT_{50} sediment (d): 730 Crop interception (%): 50% for both single application and multiple applications Maximum occurrence observed in (%): Soil: 28.70 Water/sediment system: 61.20
Parameters used in FOCUSsw step 3 (if performed)	Not applicable – STEP 3 calculations not performed for this compound

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

Application rate	Crop: Spring (SC) and Winter Cereals (WC) Number of applications: 1 (single application) or 2 (multiple applications Interval (d): 21 days (for multiple applications) Application rate(s): 125 g as/ha for single application, 2 x 125 g as/ha for multiple application Application window: at Steps 1&2 – March-May for both spring and winter cereals;
Main routes of entry	As defined in FOCUS for Steps 1&2

1) **Results for the single application at 125 g a. s./ha**

The results of the STEP-1 calculations of PEC_{SW} and PEC_{SED} (WC = SC).

Time [days]	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA
0	5.644	----	39.388	----
1	5.326	5.485	41.700	40.544
2	5.321	5.404	41.660	41.112
4	5.311	5.360	41.581	41.366
7	5.295	5.335	41.463	41.433
14	5.260	5.307	41.188	41.379
21	5.225	5.285	40.915	41.270
28	5.191	5.266	40.644	41.147
42	5.122	5.230	40.107	40.890
50	5.084	5.209	39.804	40.740
100	4.848	5.087	37.958	39.807

The results of the STEP-2 calculations of PEC_{SW} and PEC_{SED} (WC = SC).

Time [days]	North Europe				South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.837	----	6.118	----	1.336	----	10.022	----
1	0.764	0.800	6.045	6.082	1.251	1.293	9.903	9.962
2	0.755	0.780	5.973	6.046	1.236	1.269	9.784	9.903
4	0.737	0.763	5.832	5.974	1.207	1.245	9.553	9.785
7	0.711	0.746	5.626	5.869	1.164	1.220	9.215	9.613

14	0.654	0.714	5.173	5.632	1.071	1.168	8.473	9.226
21	0.601	0.685	4.756	5.409	0.984	1.121	7.790	8.860
28	0.553	0.658	4.373	5.197	0.905	1.077	7.163	8.513
42	0.467	0.608	3.697	4.807	0.765	0.996	6.056	7.873
50	0.424	0.582	3.359	4.602	0.695	0.953	5.502	7.537
100	0.233	0.451	1.844	3.564	0.382	0.738	3.020	5.838

2) <u>Results for the multiple application at 2 x 125 g a. s./ha</u>

The results of the STEP-1 calculations of PEC_{SW} and PEC_{SED} (WC = SC).

Time [days]	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA
0	11.288	----	78.776	----
1	10.651	10.970	83.399	81.087
2	10.641	10.808	83.320	82.224
4	10.621	10.720	83.162	82,732
7	10.591	10.671	82.925	82.866
14	10.521	10.613	82.376	82.758
21	10.451	10.571	81.830	82.540
28	10.382	10.532	81.288	82.295
42	10.245	10.459	80.215	81.780
50	10.167	10.419	79.608	81.481
100	9.696	10.174	75.917	79.614

The results of the STEP-2 calculations of PEC_{SW} and PEC_{SED} (WC = SC).

Time [days]	North Europe				South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]		PEC_{SW} [µg/L]		PEC_{SED} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	1.497	----	11.054	----	2.474	----	18.701	----
1	1.380	1.438	10.923	10.988	2.335	2.405	18.478	18.589
2	1.364	1.405	10.792	10.923	2.307	2.363	18.258	18.479
4	1.331	1.376	10.537	10.794	2.252	2.321	17.825	18.260
7	1.284	1.347	10.164	10.603	2.173	2.274	17.195	17.937
14	1.181	1.289	9.346	10.176	1.998	2.179	15.810	17.215
21	1.086	1.237	8.593	9.772	1.837	2.092	14.537	16.532
28	0.998	1.188	7.901	9.390	1.689	2.009	13.366	15.885
42	0.844	1.099	6.680	8.684	1.428	1.858	11.300	14.691
50	0.767	1.052	6.068	8.314	1.297	1.778	10.266	14.065
100	0.421	0.814	3.331	6.439	0.712	1.377	5.636	14.893

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

1,2,4-Triazole (metabolite) Parameters used in FOCUSsw step 1 and 2	Molecular weight: 69.1 [g/mol] Water solubility (mg/L): 1000 Soil or water metabolite: soil and water metabolite Koc (L/kg): 89 DT_{50} soil (d): 7.4 days (lab. SFO normalised, the geomean value) DT_{50} water/sediment system (d): 730 (representative worst case from sediment water studies) DT_{50} water (d): 52.10 DT_{50} sediment (d): 730 Crop interception (%): 50% for both single application and multiple applications Maximum occurrence observed in (%): Soil: 18.90 Water/sediment system: 69.00
Parameters used in FOCUSsw step 3 (if performed)	Not applicable – STEP 3 calculations not performed for this compound
Application rate	Crop: Spring (SC) and Winter Cereals (WC) Number of applications: 1 (single application) or 2 (multiple applications Interval (d): 21 days (for multiple applications) Application rate(s): 125 g as/ha for single application, 2x125 g as/ha for multiple application Application window: at Steps 1&2 – March-May for both spring and winter cereals;
Main routes of entry	As defined in FOCUS for Steps 1&2

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

STEP 1 and STEP 2 PEC_{SW} and PEC_{SED} for 1,2,4-Triazole – single application at 125 g a.s./ha (WC = SC).

Time [days]	STEP 1				STEP 2							
					North Europe				South Europe			
	PEC_{sw} [µg/L]		PEC_{sed} [µg/kg dry sediment]		PEC_{sw} [µg/L]		PEC_{sed} [µg/kg dry sediment]		PEC_{sw} [µg/L]		PEC_{sed} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	1.431	----	1.145	----	0.216	----	0.188	----	0.305	----	0.267	----
1	1.414	1.423	1.259	1.202	0.209	0.213	0.186	0.187	0.296	0.300	0.264	0.265
2	1.413	1.418	1.258	1.230	0.206	0.210	0.184	0.186	0.293	0.297	0.261	0.264
4	1.410	1.415	1.255	1.243	0.202	0.207	0.179	0.184	0.286	0.293	0.254	0.261
7	1.406	1.412	1.252	1.248	0.194	0.203	0.173	0.181	0.276	0.288	0.245	0.256
14	1.397	1.407	1.243	1.248	0.179	0.195	0.159	0.173	0.253	0.276	0.226	0.246
21	1.388	1.402	1.235	1.245	0.164	0.187	0.146	0.166	0.233	0.265	0.208	0.236
28	1.379	1.397	1.227	1.241	0.151	0.180	0.135	0.160	0.214	0.255	0.191	0.227
42	1.360	1.388	1.211	1.239	0.128	0.166	0.114	0.148	0.181	0.236	0.161	0.210
50	1.350	1.383	1.202	1.229	0.116	0.159	0.103	0.142	0.165	0.226	0.147	0.201
100	1.288	1.351	1.146	1.202	0.064	0.123	0.057	0.110	0.090	0.175	0.081	0.156

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

STEP 1 and STEP 2 PEC_{SW} and PEC_{SED} for 1,2,4-Triazole – multiple application at 2 x 125 g a.s./ha (WC = SC).

Time [days]	STEP 1				STEP 2							
					North Europe				South Europe			
	PEC_{sw} [µg/L]		PEC_{sed} [µg/kg dry sediment]		PEC_{sw} [µg/L]		PEC_{sed} [µg/kg dry sediment]		PEC_{sw} [µg/L]		PEC_{sed} [µg/kg dry sediment]	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	2.862	-----	2.289	-----	0.297	-----	0.258	-----	0.395	-----	0.345	-----
1	2.829	2.846	2.518	2.404	0.287	0.292	0.255	0.257	0.383	0.389	0.341	0343
2	2.826	2.837	2.515	2.460	0.283	0.288	0.252	0.255	0.378	0.384	0.337	0341
4	2.821	2.830	2.511	2.486	0.276	0.284	0.246	0.252	0.369	0.379	0.327	0.337
7	2.813	2.824	2.503	2.495	0.267	0.279	0.237	0.248	0.356	0.372	0.317	0.331
14	2.794	2.814	2.487	2.495	0.245	0.267	0.218	0.238	0.327	0.357	0291	0.317
21	2.776	2.804	2.470	2.490	0.225	0.257	0.201	0.228	0.301	0.343	0.268	0.305
28	2.757	2.795	2.454	2.483	0.207	0.246	0.185	0.219	0.277	0.329	0.246	0.293
42	2.721	2.776	2.422	2.468	0.175	0.228	0.156	0.203	0.234	0.304	0.208	0.271

50	2.700	2.766	2.403	2.459	0.159	0.218	0.142	0.194	0.213	0.291	0.189	0.259
100	2575	2.701	2.292	2.403	0.087	0.169	0.078	0.150	0.117	0.226	0.104	0.201

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

The maximum PEC_{SW} and PEC_{SED} values obtained for fluquinconazole, dione and triazole at Steps 1 and 2 - single application at 125 g/ha.

Compound	Step 1		Step 2			
			North Europe		South Europe	
	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg dry sediment]	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg dry sediment]	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg dry sediment]
Fluquinconazole	20.440	167.824	2.484	20.745	4.378	37.211
Dione	5.644	41.700	0.837	6.118	1.336	10.022
Triazole	1.431	1.145	0.216	0.188	0.305	0.267

The maximum PEC_{SW} and PEC_{SED} values obtained for fluquinconazole, dione and triazole at Steps 1 and 2 – double application at 2 x 125 g/ha.

Compound	Step 1		Step 2			
			North Europe		South Europe	
	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg dry sediment]	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg dry sediment]	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg dry sediment]
Fluquinconazole	40.879	335.648	4.486	37.750	8.100	69.167
Dione	11.288	83.399	1.497	11.054	2.474	18.701
Triazole	2.862	2.289	0.297	0.258	0.395	0.345

The maximum PEC_{SW} and PEC_{SED} values obtained for fluquinconazole at Step 3.

I) Winter cereals						
FOCUS scenario	**Single application**			**Double application**		
	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg dry sediment]	Migration route	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg dry sediment]	Migration route
D1 ditch	1.163	7.862	Spray drift	1.210	10.956	Spray drift
D1 stream	0.710	4.171	Spray drift	0.619	5.720	Spray drift
D2 ditch	1.248	9.235	Drainage	2.495	18.084	Drainage
D2 stream	0.903	5.382	Spray drift	1.562	10.610	Drainage
D3 ditch	0.790	0.418	Spray drift	0.692	0.483	Spray drift
D4 pond	0.081	0.779	Drainage	0.173	1.564	Drainage
D4 stream	0.674	0.334	Spray drift	0.592	0.690	Spray drift
D5 pond	0.065	0.607	Drainage	0.120	1.101	Drainage
D5 stream	0.640	0.188	Spray drift	0.631	0.350	Spray drift
D6 ditch	0.797	1.315	Spray drift	0.710	1.700	Spray drift
R1 pond	0.038	0.270	Run-off	0.076	0.513	Run-off
R1 stream	0.521	0.297	Spray drift	0.565	0.543	Run-off
R3 stream	0.732	0.437	Spray drift	0.638	0.515	Spray drift
R4 stream	0.524	0.500	Spray drift	0.711	0.940	Run-off
II) Spring cereals						
FOCUS scenario	**Single application**			**Double application**		
	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg dry sediment]	Migration route	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg dry sediment]	Migration route
D1 ditch	1.279	14.299	Spray drift	1.345	17.458	Drainage
D1 stream	0.707	8.010	Spray drift	0.843	9.643	Drainage
D3 ditch	0.791	0.429	Spray drift	0.691	0.471	Spray drift
D4 pond	0.114	1.066	Drainage	0.171	1.570	Drainage
D4 stream	0.657	0.430	Spray drift	0.591	0.638	Spray drift

D5 pond	0.068	0.657	Drainage	0.099	0.944	Drainage
D5 stream	0.624	0.199	Spray drift	0.599	0.286	Spray drift
R4 stream	0.524	0.646	Spray drift	0.453	0.645	Spray drift

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, with appropriate FOCUSgw scenarios, according to FOCUS guidance.
	Model(s) used: FOCUS PEARL ver. 3.3.3, FOCUS PELMO ver. 3.3.2.
	Scenarios: Chateaudun, Hamburg, Jokioinen, Kremsmunster, Okehampton, Piacenza, Porto, Sevilla, Thiva for calculations with FOCUS PELMO and FOCUS PEARL,
	Crop: Winter Cereals, Spring Cereals,
	
	Substance-specific input parameters:
	Fluquinconazole (parent compound):
	M = 378.2 g/mol (note: the correct MW is 376.2)
	S_{H2O} = 1.1 mg/L (@ 20^0C);
	p = 0 Pa;
	DT_{50} = 150.9 days (median, field studies normalisation to 20^0C with Q_{10} = 3.84, Walker equation coefficient 0.0)
	K_{fOC} = 870 mL/g; K_{fOM} = 504.6 mL/g; 1/n = 0.891(all values arithmetic means).
	
	Dione (metabolite):
	M = 325.1 g/mol;
	S_{H2O} = 1.0 mg/L (@ 20^0C);
	p = ; 0 Pa;
	DT_{50} = 346 days (geomean, lab studies, normalisation to pF2, 20^0C with Q_{10} = 2.58, Walker equation coefficient 0.7)
	K_{fOC} = 783 mL/g; K_{fOM} = 454.2 mL/g; 1/n = 0.939 (all values arithmetic means).
	Transformation parent --> Dione *ff* = 0.905;
	
	1,2,4-Triazole (metabolite):
	M = 69.1 g/mol;

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

	S_{H2O} = 1000 mg/L (@ 20^0C); p = 0 Pa; DT_{50} = 7.4 days (geomean, lab studies, normalisation to pF2, 20^0C with Q_{10} = 2.58, Walker equation coefficient 0.7) K_{fOC} = 89 mL/g; K_{fOM} = 51.6 mL/g; 1/n = 0.92 (all values arithmetic means). Transformation parent --> 1,2,4-Triazole *ff* = 0.905;
Application rate	Application rate: 2 x 125 g as/ha – multiple applications; No. of applications: 2 – multiple applications; Interval between applications: 21 days (for multiple applications only); Crop interception: 50% (application 1) and 70% (application 2) for multiple applications; Time of application (month or season): **Multiple applications**: Spring cereals For scenarios: Chateaudun and Porto – 30/03 and 20/04; Hamburg, Kremsmunster and Okehampton – 21/04 and 12/05; Jokioinen – 07/06 and 28/06; Winter cereals: For scenarios: Chateaudun, Piacenza, Porto, Sevilla and Thiva – 17/03 and 07/04; Hamburg, Kremsmunster and Okehampton – 08/04 and 29/04; Jokioinen – 25/05 and 15/06;

PEC_{GW} values for spring cereals.

FOCUS Scenario	FOCUS PELMO ver. 3.3.2 80th percentile PEC_{GW} values [µg/L] for:			FOCUS PEARL ver. 3.3.3 80th percentile PEC_{GW} values [µg/L] for:		
	Fluquin-conazole	Dione	1,2,4-Triazole	Fluquin-conazole	Dione	1,2,4-Triazole
Châteaudun	<0.001	<0.001	<0.001	<0.001	0.021	<0.001
Hamburg	<0.001	0.023	<0.001	0.001	0.347	<0.001
Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Kremsmünster	<0.001	0.003	<0.001	<0.001	0.273	<0.001

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

Okehampton	<0.001	0.047	<0.001	0.001	0.445	<0.001
Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

PEC_{GW} values for winter cereals.

FOCUS Scenario	FOCUS PELMO ver. 3.3.2			FOCUS PEARL ver. 3.3.3		
	80th percentile PEC_{GW} values [µg/L] for:			80th percentile PEC_{GW} values [µg/L] for:		
	Fluquin-conazole	Dione	1,2,4-Triazole	Fluquin-conazole	Dione	1,2,4-Triazole
Châteaudun	<0.001	<0.001	<0.001	<0.001	0.035	<0.001
Hamburg	<0.001	0.086	<0.001	0.001	0.343	<0.001
Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Kremsmünster	<0.001	0.039	<0.001	<0.001	0.283	<0.001
Okehampton	<0.001	0.230	<0.001	0.002	0.507	<0.001
Piacenza	<0.001	0.349	<0.001	0.006	0.615	<0.001
Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Thiva	<0.001	<0.001	<0.001	<0.001	0.014	<0.001

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

Direct photolysis in air ‡	Not determined – no data request
Quantum yield of direct phototransformation	Not determined in air
Photochemical oxidative degradation in air ‡	**Fluquinconazole:** DT_{50} = 56.1 h (4.7 days) (Atkinson method; EU scenario (FOCUS Air), time frame: 12 hours, •OH concentration: 1.5 E6 [radicals/cm^3]); Metabolites: **Dione:** DT_{50} = 9.0 h (0.8 day) (Atkinson method; EU scenario (FOCUS Air), time frame: 12 hours, •OH concentration: 1.5 E6 [radicals/cm^3]); **1,2,4-Triazole:** DT_{50} = 107 days (Atkinson method; EU scenario (FOCUS Air), time frame: 12 hours, •OH concentration: 1.5 E6 [radicals/cm^3]) ;
Volatilisation ‡	from plant surfaces: Fluquinconazole was found to volatilise from plant surfaces (French beans) <1 % after 24 hours
	from soil surfaces: volatilisation loss of Fluquinconazole is estimated to be <0.00062% of the applied amount within 24 hours after treatment (Dow method) and was found to evaporate <1% in a volatilisation study conducted over 24 hour period.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

PEC (air)

Method of calculation	Expert judgement, based on vapour pressure, Henry's Law Constant, method of application, photochemical oxidative half-life in air and "Dow method" estimation of volatilisation loss from soil.

$PEC_{(a)}$

Maximum concentration	**Fluquinconazole:** negligible; **Triazole:** Not calculated owning to lack of data and suitable method.

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: Fluquinconazole, Dione, 1,2,4-Triazole; Surface Water: Fluquinconazole, Dione, 1,2,4-Triazole; Sediment: Fluquinconazole, Dione, 1,2,4-Triazole; Ground water: Fluquinconazole, Dione, 1,2,4-Triazole; Air: Fluquinconazole, 1,2,4-Triazole;

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

Soil (indicate location and type of study)	Relevant European data not available
Surface water (indicate location and type of study)	Relevant European data not available
Ground water (indicate location and type of study)	Relevant European data not available
Air (indicate location and type of study)	Relevant European data not available

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (Co RMS – Poland)	Revised April 2010; Revised and updated October 2010; revised and updated in December 2010 revised by EFSA in January 2011	Fluquinconazole

Fate and Behaviour in the Environment

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

Candidate for R53 – not readily biodegradable, very persistent in soil

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (CO-RMS - Poland	Revised April 2010 Revised by EFSA January 2011	Fluquinconazole

Ecotoxicology

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/day)	End point (mg/kg feed)
Birds ‡				
Bobwhite Quail & Mallard Duck	a.s.	Acute	LD_{50} > **2000**	
	Preparation	Acute	LD_{50} > **787**[1]	
Bobwhite Quail	a.s.	Short-term	DDD = 704	LC_{50} 4293
Mallard Duck	a.s.	Short	DDD >**210**	LC_{50} > 5200
	Preparation	Short	DDD >618 [2]	
Bobwhite Quail	a.s.	Long-term	DDD = **1.9**	NOEC = 28
Mammals ‡				
Rat	a.s.	Acute	LD_{50} = **112**	
Rat	Preparation	Acute	LD_{50} = 933	
Rat	a.s.	Long-term	NOAEL = **0.9**	
Additional higher tier studies ‡				

[1]Based on additive toxicity of fluquinconazole and prochloraz calculated according to FINNEY → 1/[estimated toxicity of Flamenco PLUS] = [Prop. Fluquinconazole]/[LD50fq] + [Prop. Prochloraz]/[LD50pz]. For acute toxicity → LD50fq = >2000 mg a.s./kg bw; LD50pz = 662 mg a.s./kg bw

[2]Based on additive toxicity of fluquinconazole and prochloraz calculated according to finney. For short-term toxicity → LC50fq = >210 mg a.s./kg bw/day; LC50pz = >1553 mg a.s./kg bw/day

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

Wheat 2 applications ×125 g a.s./ha

Indicator species/Category[2]	Time scale	ETE	TER	Annex VI Trigger[3]
Tier 1 – uptake via diet (Birds)				
Large herbivorous bird/early crop stage	Acute	9.61	208.2	10
insectivorous bird/early and late crop stage	Acute	6.76	296	10
Large herbivorous bird/early crop stage	Short-term	5.16	40.7	10
insectivorous bird/early and late crop stage	Short-term	3.77	56	10
Large herbivorous bird/early crop stage	Long-term	2.73	**0.7**	5

Rapporteur Member State	**Month and year**	**Active Substance (Name)**
Ireland (CO-RMS - Poland	Revised April 2010 Revised by EFSA January 2011	Fluquinconazole

Ecotoxicology

Indicator species/Category[2]	Time scale	ETE	TER	Annex VI Trigger[3]
insectivorous bird/early and late crop stage	Long-term	3.77	**0.5**	5
Higher tier refinement – uptake via diet (Birds)				
Skylark (*Alauda arvensis*)	Long-term	0.96[3] 0.91[4]	**1.98** **2.09**	5
Tier 1– uptake via consumption of contaminated water (Birds)				
Puddle scenario	Acute	0.0086	232592	10
Tier 1 – secondary poisoning (Birds)				
Earthworm-eating bird	Long-term	0.15[5]	12.3	5
Fish-eating bird	Long-term	0.12[6]	15.57	5
Tier 1– uptake via diet (Mammals)				
Small herbivorous mammals/early crop stage	Acute	29.71	**3.78**	10
insectivorous mammals//late crop stage	Acute	1.10	101.6	10
Small herbivorous mammals/early crop stage	Long-term	8.63	**0.1**	5
insectivorous mammals//late crop stage	Long-term	0.4	**2.25**	5
Higher tier refinement – uptake via diet (Mammals)				
Wood mouse	Acute		Data gap[7]	
Common hare	Acute	1.77[8]	63.28	10
Wood mouse	Long-term		Data gap[9]	5
Common hare	Long-term		Data gap[9]	
Tier 1– uptake via consumption of contaminated water (Mammals)				
Puddle scenario	Acute	0.0044	249644	10
Tier 1 – secondary poisoning (Mammals)				
Earthworm-eating mammals	Long-term	0.19[5]	**4.77**	5
Fish-eating mammals	Long-term	0.08[6]	12	5

[3] "UK scenario-early" (i.e. worst-case) based on: PD of 0.6 and measured foliar residue (leaves), PD of 0.35 and RUD of 25 (weed seeds), PD of 0.05 and RUD of 7.5(arthropods), PT of 0.92, refined ftwa of 0.268 (for leaves) and MAF factor of 1.026 and 1.23 for leaves and weed seeds, respectively. The PD values could be even worst.

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (CO-RMS - Poland	Revised April 2010 Revised by EFSA January 2011	Fluquinconazole

Ecotoxicology

[4] "AUSTRIA scenario-early" (i.e. worst-case) based on: PD of 0.02 and measured foliar residue (cereal shoots), PD of 0.09 and RUD of 40 (weed leaves) , PD of 0.14 (weed seeds) and RUD of 0.25, PD of 0.75 and RUD of 7.5(arthropods), PT of 0.941, refined ftwa of 0.268 (for leaves) and MAF factor of 1.026 and 1.23 for leaves and weed seeds, respectively.

[5] based on PEC soil plateau =0.1288.

[6] based on 21d- TWA PECsw FOCUS step2 = 6.678µg a.s./L

[7] PD values could not considered acceptable for the acute risk refinement.

[8] based on initial measured foliar residue.

[9] The long-term risk refinement provided was not accepted at the PRAPeR 85 due to the several uncertainties. However the TER were below the trigger.

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

Group	Test substance	Time-scale	Endpoint	Toxicity (mg a.s /L)
Laboratory tests				
Rainbow Trout (*Oncorhynchus mykiss*)	Fluquinconazole	Acute toxicity (96 h) – flow-through	LC_{50}	1.90
Mirror Carp (*Cyprinus carpio*)	Fluquinconazole	Acute toxicity (96 h) – flow-through	LC_{50}	1.895
Bluegill Sunfish (*Lepomis macrochirus*)	Fluquinconazole	Acute toxicity (96 h) – flow-through	LC_{50}	1.34
Rainbow Trout (*Oncorhynchus mykiss*)	Fluquinconazole	Chronic toxicity (21 d) – flow-through	NOEC	0.30
Fathead minnow (*Pimephales promelas*),	Fluquinconazole	Chronic toxicity (21 d) – flow-through	NOEC	0.17 (nominal) 0.154 (measured)
Water fleas *(Daphnia magna)*	Fluquinconazole	Acute toxicity (48 h) – static renewal	EC_{50}	>5.00
Water fleas *(Daphnia magna)*	Fluquinconazole	Chronic toxicity (21 d) – static renewal	NOEC	0.648
Selenastrum capricornutum	Fluquinconazole	Chronic toxicity (96 h) - static	E_bC_{50}	0.014
Lemna minor	Fluquinconazole	Chronic toxicity (14 d) - static	E_bC_{50}	1.4
Rainbow Trout (*Oncorhynchus mykiss*)	Flamenco Plus	Acute toxicity (96 h) – static renewal	LC_{50}	3.9 **0.76** mg a.s./L
Water fleas *(Daphnia magna)*	Flamenco Plus	Acute toxicity (48 h) – static	EC_{50}	7.3 1.42 mg a.s./L
Selenastrum capricornutum	Flamenco Plus	Chronic toxicity (72 h) – static	E_bC_{50}	2.1 0.41 mg a.s./L
Rainbow trout	AE C596912	Acute toxicity (96h) -	LC_{50}	>0.709

Rapporteur Member State	**Month and year**	**Active Substance (Name)**
Ireland (CO-RMS - Poland	Revised April 2010 Revised by EFSA January 2011	Fluquinconazole

Ecotoxicology

(*Oncorhynchus mykiss*)		static		
Water fleas *(Daphnia magna*)	AE C596912	Acute toxicity (48h) - static	EC_{50}	>0.56
Selenastrum capricornutum	AE C596912	Chronic toxicity (96 h) – static	E_bC_{50}	0.18
Rainbow trout (*Oncorhynchus mykiss*)	1,2,4-Triazole	Acute toxicity (96h) - static	LC_{50}	>100
Rainbow trout (*Oncorhynchus mykiss*)	1,2,4-Triazole	Chronic toxicity	NOEC	100
Water fleas *(Daphnia magna*)	1,2,4-Triazole	Acute toxicity (48h) - static	EC_{50}	>100
Selenastrum capricornutum	1,2,4-Triazole	Chronic toxicity (96 h) – static	E_bC_{50}	8.2
Rainbow trout (*Oncorhynchus mykiss*)	1,2,4-Triazole	28day – static renewal	NOEC	3.2
Microcosm or mesocosm tests				
Not triggered				

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (CO-RMS - Poland	Revised April 2010 Revised by EFSA January 2011	Fluquinconazole

Ecotoxicology

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

Maximum PEC_{sw} values and TER values for fluquinconazole – application to wheat at 125 g a.s./ha (2 applications)

Scenario	**PEC global max (µg L)**	**PEC twa, 28d (µg L)**	**fish acute**	**fish prolonged**	**Daphnia acute**	**Daphnia prolonged**	**Algae acute**	**Higher plant**	**Sed. dweller prolonged**	**Microcosm / Mesocosm**
			Lepomis macrochirus	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***S. subspicatus***	***Lemna* sp.**	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	ErC_{50}	NOEC	NOEC
			1340 µg/L	154 µg/L	>5000 µg/L	648 µg/L	14 µg/L	1400 µg/L	-	-
FOCUS Step 1	40.88		**32.78**	**3.77**	122.31	15.85	**0.34**	34.25		
FOCUS Step 2										
North Europe	4.49		298.71	34.33	-	-	**3.12**	-		
South Europe	8.10		165.43	19.01	-	-	**1.73**	-		
FOCUS Step 3*			-	-	-	-		-	-	-
D1 ditch	1.345		-	114.50	-	-	10.41	-	-	-
D1 stream	0.843		-	182.68	-	-	16.61	-	-	-
D2 ditch	2.495		-	61.72	-	-	**5.61**	-	-	-
D2 stream	1.562		-	98.59	-	-	**8.96**	-	-	-
D3 ditch	0.791		-	194.69	-	-	17.70	-	-	-
D4 pond	0.173		-	890.17	-	-	80.92	-	-	-
D4 stream	0.674		-	228.49	-	-	20.77	-	-	-
D5 pond	0.12		-	1283.33	-	-	116.67	-	-	-
D5 stream	0.64		-	240.63	-	-	21.88	-	-	-
D6 ditch	0.797		-	193.22	-	-	17.57	-	-	-
R1 pond	0.0755		-	2039.74	-	-	185.43	-	-	-

Rapporteur Member State	Month and year	Active Substance (Name)
Ireland (CO-RMS - Poland	Revised April 2010 Revised by EFSA January 2011	Fluquinconazole

Ecotoxicology

R1 stream	0.565	-	272.57	-	-	24.78	-	-	-
R3 stream	0.732	-	210.38	-	-	19.13	-	-	-
R4 stream	0.524	-	293.89	-	-	26.72	-	-	-
FOCUS Step 4**		-	-	-	-		-	-	-
D2 ditch	1.322	-	-	-	-	10.59	-	-	-
D2 stream	0.826	-	-	-	-	16.95	-	-	-
Annex VI Trigger**		100	10/50***	100	10	10	10	10	5

* Highest PECsw values
** Refinement of some exposure model input parameterisation (relating to crop interception)
*** Assessment factor to cover the variation between the ELS and the FFLC in order to address potential endocrine disruptor effects.

Maximum PEC_{sw} values and TER values for FLAMENCO PLUS – application to wheat at 125 g a.s./ha (2 applications)

Scenario	PEC global max (µg L)	PEC twa, 28d (µg L)	fish acute	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
			O. mykiss	***O. mykiss***	***Daphnia magna***	***Daphnia magna***	***S. subspicatus***	***Lemna* sp.**	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	ErC_{50}	NOEC	NOEC
			760 µg/L	-	1420 µg/L	-	410 µg/L	-	-	-
FOCUS Step 1	40.88		**18.59**	-	**34.74**	-	10.03	-		
FOCUS Step 2										
North Europe	4.49		**93.83**	-	175.31	-	-	-		
South Europe	8.10		169.42	-	316.54	-	-	-		

Rapporteur Member State	**Month and year**	**Active Substance (Name)**
Ireland (CO-RMS - Poland	Revised April 2010 Revised by EFSA January 2011	Fluquinconazole

Ecotoxicology

FOCUS Step 3*				-	-	-	-	-	-	-
D1 ditch	1.345		565.06	-	-	-	-	-	-	-
D1 stream	0.843		901.54	-	-	-	-	-	-	-
D2 ditch	2.495		304.61	-	-	-	-	-	-	-
D2 stream	1.562		486.56	-	-	-	-	-	-	-
D3 ditch	0.791		960.81	-	-	-	-	-	-	-
D4 pond	0.173		4393.06	-	-	-	-	-	-	-
D4 stream	0.674		1127.60	-	-	-	-	-	-	-
D5 pond	0.12		6333.33	-	-	-	-	-	-	-
D5 stream	0.64		1187.50	-	-	-	-	-	-	-
D6 ditch	0.797		953.58	-	-	-	-	-	-	-
R1 pond	0.0755		10066.23	-	-	-	-	-	-	-
R1 stream	0.565		1345.13	-	-	-	-	-	-	-
R3 stream	0.732		1038.25	-	-	-	-	-	-	-
Annex VI Trigger**			100	10	100	10	10	10	10	5

Maximum PECsw values and TER values for metabolite AE C596912

Scenario	**PEC global max (µg L)**	**PEC twa, 28d (µg L)**	**fish acute**	**fish prolonged**	**Daphnia acute**	**Daphnia prolonged**	**Algae acute**	**Higher plant**	**Sed. dweller prolonged**	**Microcosm / Mesocosm**
			O. mykiss	***O. mykiss***	***Daphnia magna***	***Daphnia magna***	***S. subspicatus***	***Lemna* sp.**	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	ErC_{50}	NOEC	NOEC
			>709 µg/L	-	>560 µg/L	-	180 µg/L	-	-	-

Rapporteur Member State	**Month and year**	**Active Substance (Name)**
Ireland (CO-RMS - Poland	Revised April 2010 Revised by EFSA January 2011	Fluquinconazole

Ecotoxicology

FOCUS Step 1	11.288		62.81	-	49.61		15.95			
FOCUS Step 2										
South Europe	2.474		286.58		226.35					
North Europe	1.497		473.61		374.08					
Annex VI Trigger**			100	10	100	10	10	10	10	5

Maximum PECsw values and TER values for metabolite 1,2,4-triazole

Scenario	**PEC global max (µg L)**	**PEC twa, 28d (µg L)**	**fish acute**	**fish prolonged**	**Daphnia acute**	**Daphnia prolonged**	**Algae acute**	**Higher plant**	**Sed. dweller prolonged**	**Microcosm / Mesocosm**
			O. mykiss	***O. mykiss***	***Daphnia magna***	***Daphnia magna***	***S. subspicatus***	***Lemna* sp.**	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	ErC_{50}	NOEC	NOEC
			>100000 µg/L	100000 µg/L	>100000 µg/L	-	8200 µg/L	-	-	-
FOCUS Step 1	2.86		34965.03	34965.03	34965.03	-	2867.13	-		
Annex VI Trigger**			100	10	100	10	10	10	10	5

Bioconcentration				
	Active substance	Metabolite 1	Metabolite 2	Metabolite 3
$\log P_{O/W}$	3.24			
Bioconcentration factor (BCF)[1] ‡	87			
Annex VI Trigger for the bioconcentration factor	100			
Clearance time (days) (CT_{50})	53% after 6 hours			
(CT_{90})	80% after 15 days			
Level and nature of residues (%) in organisms after the 14 day depuration phase	**15 days:** Whole fish → 80% Viscera → 87% Edible → 81% Carcass → 76%			

[1] only required if log $P_{O/W}$ >3.
* based on total ^{14}C or on specific compounds

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

Test substance	Acute oral toxicity (LD50 µg/bee)	Acute contact toxicity (LD50 µg/bee)
Fluquinconazole	>100	>100
Flamenco Plus (72h) (µg product/bee)	40*	313
Flamenco Plus (48h)) (µg product/bee)	168.2	>469.2
Field studies: Not triggered		

*high mortality due to starvation of bees because food avoidance occurred in the study.

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

wheat at 125 g a.s./ha (2 applications)

Test substance	Route	Hazard quotient	Annex VI Trigger
Fluquinconazole	Contact	< 1.3[1]	50
Fluquinconazole	oral	< 1.3[1]	50

Test substance	Route	Hazard quotient	Annex VI Trigger
Flamenco Plus	Contact	8.0[2] < 5.4[2]	50
Flamenco Plus	oral	**62.8**[2] 14.9[2]	50

[1] Based on the content of active substance within Flamenco Plus and the maximum application rate of 2.3 L/ha
[2] Based on the nominal density of Flamenco Plus of 1.092 g/ml and the maximum application rate of 2,3 l/ha.

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

Laboratory tests with standard sensitive species

Species	Test substance	Endpoint	Effect (LR50)
Typhlodromus pyri	Fluquinconazole	Mortality	<149.4 g a.s./ha
Aphidius rhopalosiphi	Fluquinconazole	Mortality	<149.4g a.s./ha
Typhlodromus pyri	FLAMENCO PLUS	Mortality	0.204L product/ha (47.2 g a.s./ha)
Aphidius rhopalosiphi	FLAMENCO PLUS	Mortality	0.166 L product/ha (38.4 g a.s./ha)

Crop and application rate

Test substance	Species	Effect (LR50)	HQ in-field	HQ off-field	Trigger
FLAMENCO PLUS	*Typhlodromus pyri*	0.204	**19.17**	0.46	2
FLAMENCO PLUS	*Aphidius rhopalosiphi*	0.166	**23.55**	0.56	2

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
Typhlodromus pyri	adults	FLAMENCO PLUS	Max 2.3 L/ha	Mortality Off spring production	28.4 **51**	50 %
Typhlodromus pyri	Protonymph	FLAMENCO PLUS	Control 0.23 0.575 1.15 2.3 4.6	Mortality	0.0 1.4 15.5 39.4 85.9 97.2 LR50 = 1.3 L product/ha	
Aphidius rhopalosiphi	adults	FLAMENCO PLUS	4.6 L/ha	mortality	0% LR50 >4.6 L product/ha	50 %

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
Coccinella sepempunctata	larvae	FLAMENCO PLUS	2.3 L/ha 4.6 L/ha	Mortality	40.5 97.6	
				egg production (eggs/female /day)	3.56 (control) 2.7 (2.3 L/ha)	
Coccinella sepempunctata	larvae	FLAMENCO PLUS	2.3 L/ha 4.6 L/ha	Mortality	8 -12	50 %
				egg production (eggs/female /day)	3.9 (control) 1.9 (2.3 L/ha) 3.1 (4.6 L/ha)	
Chrysoperla carnea	larvae	FLAMENCO PLUS	2.3 L/ha 4.6 L/ha	Mortality	-2.1 0%	50 %
				egg production (eggs/female /day)	14.8 18.6	
Poecilus cupreus	adults	FLAMENCO PLUS	4.6 L/ha	Mortality egg production (eggs/female /day)	0% 9.1	50 %

Field or semi-field tests
The extended laboratory study on the toxicity of residues aged under semi-field conditions was performed. In the study freshly dried residues (about 1 hour) of BAS 616 01 F, applied in semi-field conditions, had 20% effect on mortality and 12.1% effect on reproduction of *Typhlodromus pyri*. Observed effects are below the ESCORT 2 trigger value of 50% and it may be therefore concluded that BAS 616 01 F will not pose an high risk to *T. pyri* in-field population up to rate 4.6 L/ha.

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point
Earthworms			
Eisenia foetida	Fluquinconazole	Acute 14 days	LC_{50} >1000 mg a.s./kg d.w.soil LC_{50corr} >500 mg a.s./kg d.w.soil
Eisenia foetida	Fluquinconazole	Chronic 8 weeks	NOEC 0.5 mg a.s./kg d.w.soil (=150 g a.s/ha) $NOEC_{corr}$ 0.25 mg a.s./kg d.w.soil
Eisenia foetida	AE C596912	Acute	LC_{50} >1000 mg/kg d.w.soil
Eisenia foetida	AE C596912	Chronic 8 weeks	NOEC 10 mg a.s./kg d.w.soil
Eisenia foetida	1,2,4-Triazole	Acute	LC_{50} >1000 mg/kg d.w.soil
Eisenia foetida	1,2,4-Triazole	Acute	LC_{50} >1000 mg/kg d.w.soil
Eisenia foetida	1,2,4-Triazole	Chronic 8 weeks	NOEC 0.07081 mg a.s./kg d.w.soil
Eisenia foetida	FLEMENCO PLUS	Acute	LC_{50} 489 mg product/kg d.w.soil
Eisenia foetida	FLEMENCO PLUS	Chronic 8 weeks	NOEC 47 mg product/kg d.w.soil
Other soil macro-organisms			
Collembola			
Folsonia candida	1,2,4-Triazole	Chronic 28 days	NOEC 1.8 mg/kg d.w.soil
Soil micro-organisms			
Nitrogen mineralisation	Fluquinconazole		No effects up to 2.5 kg a.s./ha (3.33 mg a.s./kg d.w.soil)
	1,2,4-Triazole		No effects up to 7.5 kg a.s./ha (10 mg a.s./kg d.w.soil)
	1,2,4-Triazole		No effects upto 0.26 kg a.s./ha (0.353 mg a.s./kg d.w.soil)
	AE C596912		No effects up to 7.5 kg a.s./ha (10 mg a.s./kg d.w.soil)
	Fluquinconazole & Prochloraz SE (100+267 g/L)		No effects upto 22.44 mg product/kg soil 0.196 mg Fluquinconazole/kg soil 0.52 mg Prochloraz/kg soil
Carbon mineralisation	Fluquinconazole		No effects up to 2.5 kg a.s./ha (3.33 mg a.s./kg d.w.soil)
	1,2,4-Triazole		No effects up to 7.5 kg a.s./ha (10 mg a.s./kg d.w.soil)
	AE C596912		No effects up to 7.5 kg a.s./ha (10 mg a.s./kg d.w.soil)

Test organism	Test substance	Time scale	End point
	Fluquinconazole & Prochloraz SE (100+267 g/L)		No effects upto 22.44 mg product/kg soil 0.196 mg Fluquinconazole/kg soil 0.52 mg Prochloraz/kg soil
Field studies			
Field Study: ✓ The results of the field study indicate that fluquinconazole will have no significant effect on overall earthworm populations/communities when applied at a seasonal rate of 900 g a.s./ha (or equivalent long-term plateau concentration in soil) in crops where the soil has a mature grass cover. When considering applications to soil where crop/grass interception is lower than under these test conditions (e.g. cereals and seed treatments), the results indicate that fluquinconazole will have no significant effect on earthworm populations at exposure levels ≤ 0.26 mg/kg soil in the top 10 cm layer (this was the highest residue of fluquinconazole detected during the study). ✓ Soil litter degradation: No impact on soil litter degradation after application of 4.6 L/ha FLAMENCO PLUS			

Toxicity/exposure ratios for soil organisms

Crop and application rate

Test organism	Test substance	Time scale	Soil PEC plateau	TER	Trigger
Earthworms					
Eisenia foetida	Fluquinconazole	Acute	0.1288	3882	10
Eisenia foetida	Fluquinconazole	Chronic	0.1288	**1.9**	5
Eisenia foetida	AE C596912	Acute	0.0677	14771.0	10
Eisenia foetida	AE C596912	Chronic	0.0677	147.7	5
Eisenia foetida	1,2,4-Triazole	Acute	0.0029	344827.6	10
Eisenia foetida	1,2,4-Triazole	Chronic	0.0029	24.4	5
Eisenia foetida	FLEMENCO PLUS	Acute	0.5175	472.5	10
Eisenia foetida	FLEMENCO PLUS	Chronic	0.1925	45.4	5
Other soil macro-organisms					
Folsonia candida	1,2,4-Triazole	Chronic	0.0029	620	5

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

Preliminary screening data for fluquinconazole

Test organisms	**Testing endpoint**	**Test substance**	**Ecotoxicological endpoint**
7 monocots 5 dicots	Biological screening pre-emergence	Fluquinconazole Tech.	NOEC>1000 g a.s./ha
7 monocots	Biological	Fluquinconazole	20 % effect at 1000 g a.s./ha in 1

5 dicots	screening foliar applied	Tech.	monocot and 1 dicot

Preliminary screening data for FLAMENCO PLUS

Test organisms	**Testing endpoint**	**Test substance**	**Ecotoxicological endpoint**
11 monocots 17 dicots	Biological screening Tier 1 seedling-emergence	FLAMENCO PLUS	Max. 17 % effect in monocots and Max 29 % effect in dicots
11 monocots 17 dicots	Biological screening Tier 1 vegetative vigour	FLAMENCO PLUS	Max.15 % effect in monocots and Max 5 % effect in dicots

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

Test type/organism	end point
Activated sludge	EC50 (3h) >1000 mg/L

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

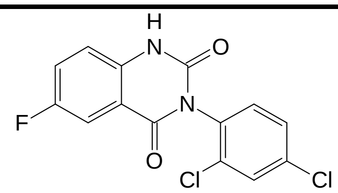
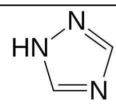
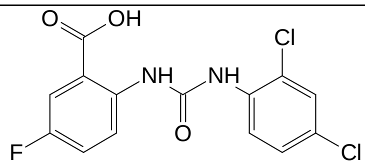
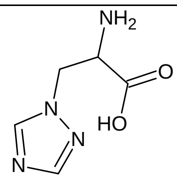
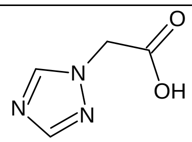
Compartment	
soil	Parent
water	Parent
sediment	Parent
groundwater	Parent

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

	RMS/peer review proposal
Active substance	Dangerous for the Environment N R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

	RMS/peer review proposal
Preparation	

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula**
dione AE C596912 FBC 96912 SN 596912 M615F001	3-(2,4-dichlorophenyl)-6-fluoro-2,4(1*H*,3*H*)-quinazolinedione	
1,2,4-triazole AE C500859	1*H*-1,2,4-triazole	
SN 616368	2-{[(2,4-dichlorophenyl)carbamoyl]amino}-5-fluorobenzoic acid	
triazolyl alanine	3-(1*H*-1,2,4-triazol-1-yl)-DL-alanine	
triazolyl acetic acid	1*H*-1,2,4-triazol-1-ylacetic acid	

*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
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
ATP	adaptation to technical progress
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstract Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
CYP 1A	Cytochrome P450, family 1, subfamily A
CYP 2B	Cytochrome P450, subfamily IIB
CYP 450	Cytochrome P450
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DFG	Deutshe Forschungsgemeinschaft method
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
EC	European Commission
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)

ELS	Early Life stage study on fish
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
F1b	filial generation first, second littering
F2	filial generation second
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FFLC	Full Fish Life Cycle study
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography – mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GPC	gel permeation chromatography
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 performance 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
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)

m	metre
M&K	Magnusson and Kligman maximisation test
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
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
QuEChERS	quick, easy, cheap, effective and safe method
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SE	Suspo-emulsion
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)

T4	thyroxine
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
UDPGT	uridine diphosphoglucuronyl transferase activity
UDS	unscheduled DNA synthesis
UK POEM	United Kingdom Predictive Operator Exposure Model
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year