CONCLUSION ON PESTICIDE PEER REVIEW

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

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ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State Germany, for the pesticide active substance fluopyram are reported. The context of the peer review was that required by Commission Regulation (EU) No 188/2011. The conclusions were reached on the basis of the evaluation of the representative uses of fluopyram as a fungicide on table and vine grapes and greenhouse and field tomatoes and strawberries. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed and concerns were identified.

KEY WORDS

Fluopyram, peer review, risk assessment, pesticide, fungicide

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SUMMARY

Fluopyram is a new active substance for which in accordance with Article 6 (2) of Council Directive 91/414/EEC[3] Germany received an application from Bayer CropScience for inclusion in Annex I to Directive 91/414/EEC. Complying with Article 6 of Directive 91/414/EEC, the completeness of the dossier was evaluated and confirmed by Commission Decision 2009/464/EC of 15 June 2009[4].

The RMS provided its initial evaluation of the dossier on fluopyram in the Draft Assessment Report (DAR), which was received by the EFSA on 30 August 2011. The peer review was initiated on 12 September 2011 by dispatching the DAR for consultation of the Member States and the applicant Bayer CropScience.

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

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of fluopyram as a fungicide on table and vine grapes and greenhouse and field tomatoes and strawberries as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

No data gaps were identified for the sections identity, physical and chemical properties and analytical methods.

No data gaps or areas of concern were identified in the mammalian toxicology section.

The available data in the residues section were sufficient to proposed residue definitions for plant and animal commodities and to derive MRLs. No acute or chronic risks for the consumers were identified.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level for the representative uses assessed. For these representative uses, the potential for groundwater exposure above the parametric drinking water limit of 0.1µg/L was assessed as low for fluopyram and its minor but non transient soil transformation product fluopyram 7-hydroxy.

A high long-term risk to birds was identified for the representative field uses. A hight long-term risk to mammals was identified for the representative use on grapes. A high risk to acquatic organisms was identified for the representative filed use. Data gaps were identified in the ecotoxicological section: 1) to further address the long-term risk for insectivorous birds and for herbivorous mammals: 2) to further consider the potential effects on the endocrine system of birds and fish; 3) to provide an aquatic risk assessment based on FOCUS step 4 calculations.

[3] OJ No L 230, 19.8.1991, p. 1. Directive as last amended by L 20, 22.1.2005, p.19 and by L309, 24.11.2009, p.1

[4] Commission Decision 2009/464/EC of 15 June 2009 recognising in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of fluopyram in Annex I to Council Directive 91/414/EEC, OJ No L 151 16.6.2009, p. 37 - 38

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BACKGROUND

In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009,[5] Council Directive 91/414/EEC[6] continues to apply with respect to the procedure and conditions for approval for active substances for which a decision recognising in principle the completeness of the dossier was adopted in accordance with Article 6(3) of that Directive before 14 June 2011.

Commission Regulation (EU) No 188/2011[7] (hereinafter referred to as 'the Regulation') lays down the detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market on 26 July 1993. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant for comments on the initial evaluation in the Draft Assessment Report (DAR) provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

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

In accordance with Article 6(2) of Council Directive 91/414/EEC Germany (hereinafter referred to as the 'RMS') received an application from Bayer CropScience for approval of the active substance fluopyram. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision Commission Decision 2009/464/EC of 15 June 2009[8].

The RMS provided its initial evaluation of the dossier on fluopyram in the DAR, which was received by the EFSA on 30 August 2011 (Germany, 2011). The peer review was initiated on 12 September 2011 by dispatching the DAR to Member States and the applicant Bayer CropScience for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 8(3) of the Regulation were considered in a telephone conference between the EFSA, the RMS, and the European Commission on 23 January 2012. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was concluded that additional information should be requested from applicant and the EFSA should organise an expert consultation in the areas of e.g. mammalian toxicology, residues fate and behaviour and ecotoxicology.

[5] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ No L 309, 24.11.2009, p. 1-50.
[6] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32, as last amended.
[7] Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51-55.
[8] Commission Decision 2009/464/EC of 15 June 2009 recognising in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of fluopyram in Annex I to Council Directive 91/414/EEC, OJ No L 151 16.6.2009, p. 37 - 38

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

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

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in November/December 2012.

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 table and vine grapes and greenhouse and field tomatoes and strawberries, 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, 2012) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (23 January 2012),
- the Evaluation Table (11 Dedcember 2012)
- the reports of the scientific consultation with Member State experts (where relevant),
- the comments received on the assessment of the additional information (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of November 2012 containing all individually submitted addenda (Germany, 2012)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Fluopyram is the ISO common name for *N*-{2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]ethyl-α,α,α-trifluoro-*o*-toluamine (IUPAC).

The representative formulated product for the evaluation was 'Fluopyram SC 500', a suspension concentrate (SC), containing 500 g/l fluopyram.

The representative uses evaluated comprise foliar spray applications, as a fungicide, for the control of a variety of fungal diseases on table and vine grapes and greenhouse and field tomatoes and strawberries. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

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

The minimum purity of the active substance is 960 g/kg. No FAO specification exists.

The technical specification is based on pilot plant production. The specification might have to be reconsidered when the data of the large scale production are available. The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of fluopyram or the representative formulation. It should be noted however that the formulation should not be stored at temperatures higher than 40 °C. The main data regarding the identity of fluopyram and its physical and chemical properties are given in Appendix A.

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

Appropriate GC-MS analytical methods are available for the post-registration monitoring of fluopyram in food and feed of plant origin, with LOQs of 0.01 mg/kg in wheat grain, orange, oilseed rape, lettuce and peas seed. The residue definition for monitoring in food and feed of animal origin was set as sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram. Residues of fluopyram and fluopyram-benzamide, in animal matrices can be determined by LC-MS/MS with LOQs of 0.01 mg/kg for each compound. Adequate LC-MS/MS methods are available for the monitoring of fluopyram in soil, in water and in the air with LOQs of 0.001 mg/kg, 0.05 µg/l and 4 µg/m^3, respectively. A method for residues in body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

2. Mammalian toxicity

The following guidance document was followed in the production of this conclusion: European Commission, 2004b. Guidance Document on Dermal Absorption. SANCO/222/2000 rev. 7, 19 March 2004.

Fluopyram was discussed during the Pesticides Peer Review Meeting 92 held in Parma in July 2012.

Fluopyram is rapidly and extensively absorbed after oral administration (93% in 48 hours). After absorption it is widely distributed and extensively metabolised, and almost completely excreted after 168 hours. Fluopyram is not acutely toxic via oral, dermal and inhalation routes; it is not a skin or eye irritant, nor a skin sensitiser. The relevant oral No Observed Adverse Effect Levels (NOAELs) in subchronic studies are 12.5 mg/kg bw per day in the rat, 5.4 mg/kg bw per day in the mouse and 13.2

mg/kg bw per day in the dog, mainly based on liver effects (all species) and haematological effects (dog and rat). Fluopyram did not show genotoxic potential. After chronic repeated exposure, the relevant NOAEL is 1.2 mg/kg bw per day in the rat (2-year study) and 4.2 mg/kg bw per day in the mouse (18-month study), based on decreased bodyweight, and liver, thyroid and kidney effects; in addition rats showed adverse eye effects. Further to this, liver cell adenoma and carcinoma were recorded in female rats at 89 mg/kg bw per day (therefore the R40 - Limited evidence of a carcinogenic effect Carc. Cat. 3 - was proposed[9]; a non-genotoxic threshold mechanism was proposed based on mechanistic data). Fluopyram did not cause effects on fertility, with the relevant maternal and offspring NOAEL of 14.5 mg/kg bw per day, and the reproductive NOAEL of 83 mg/kg bw per day. Fluopyram was not teratogenic and signs of fetotoxicity were confined to the high dose level with clear maternal toxicity in both rats and rabbits (relevant maternal NOAEL 30 mg/kg bw per day in the rat and 25 mg/kg bw per day in the rabbit; developmental NOAEL 150 mg/kg bw per day and 25 mg/kg bw per day in the rat and rabbit, respectively). Fluopyram did not show any specific potential for neurotoxicity (NOAEL 50 mg/kg bw per day in females). The agreed Acceptable Daily Intake (ADI) is 0.012 mg/kg bw per day based on the NOAEL of the 2-year study applying an Uncertainty Factor (UF) of 100. The Acute Reference Dose (ARfD) is 0.5 mg/kg bw based on the acute neurotoxicity NOAEL with an UF of 100. The AOEL was set of 0.05 mg/kg bw per day based on the NOAEL of the 90-day study in mouse (UF of 100). The operator (no Personal Protective Equipment – PPE – worn), worker and bystander exposure assessment was below the AOEL.

3. Residues

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

Metabolism in plants was investigated in three plant groups, using ^{14}C-fluopyram either labelled on the phenyl or the pyridyl moiety and using experimental designs representative of the supported uses. In addition, the metabolism was studied in pepper grown indoors on artificial substrate, the active substance being applied by drip irrigation.

After foliar applications, fluopyram constitutes the major component of the radioactive residues, accounting for more than 85% TRR in grape, potato leaves and bean leaves, collected 4 to 51 days after the last application. Fluopyram was however observed in lower proportions in potato tubers and bean seeds, representing 5% to 21% TRR. In these matrices the residues were mostly composed of the metabolites resulting from the cleavage of the parent molecule; fluopyram-benzamide (M25), fluopyram-PAA (M40) and fluopyram-PCA (M43). A similar metabolic profile was observed in pepper following drip irrigation with fluopyram, fluopyram-PCA and fluopyram-PAA-glycosides accounting for 16% to 44% TRR in fruits. The metabolic pathway in the rotational crop studies was shown to be similar. Parent fluopyram was detected as the major component of the residues (20% to 94% TRR in all plant parts analysed) irrespective of the plant back intervals, besides the metabolites M25, M33, M43 and M45 resulting from the cleavage of the active substance and detected in significant levels in cereal grains. However, it must be noted that the hydroxylated metabolites and their conjugates occurred in much higher proportions in rotational crops than in primary crops, especially in the Swiss chard samples where fluopyram-7-OH (M08) was detected up to 39% TRR (0.08 mg/kg). Globally, the metabolism of fluopyram can be regarded as similar in all plant groups and consists as a first step, of the hydroxylation of the parent compound to the metabolites fluopyram-7-OH (M08) and fluopyram-8-OH (M18), which undergo further hexose conjugations. Cleavage of the hydroxylated metabolites and subsequent oxidation give two distinct groups of metabolites; those containing the trifluoromethyl-phenyl moiety [fluopyram-benzamide (M25), fluopyram-benzoic acid (M33)] and those containing the pyridyl moiety [fluopyram-PAA (M40), fluopyram-PCA (M43)].

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

As fluopyram was identified as the major component of the residues in the vast majority of the samples analysed in the primary and rotational crops, the residue definition for monitoring was limited to the parent fluopyram. For risk assessment, considering that fluopyram-benzamide (M25) was observed in significant proportions and levels in the bean metabolism study, the residue definition was proposed as "sum of fluopyram, fluopyram-benzamide expressed as fluopyram".

A sufficient number of trials was submitted to propose MRLs for grape, tomato and strawberry. As samples were analysed for fluopyram and its metabolites M25, M40 and M43, a conversion factor for risk assessment of 1.1 was proposed for the fruiting crop groups. Fluopyram is a highly persistent compound (DT_{50} >300 days) and the need to set MRLs in rotational crops was discussed in the Pesticides Peer Review teleconference TC 68. A default MRLs of 0.1 mg/kg was proposed for root/tuber and leafy crops and of 0.01 mg/kg for cereals and oilseed and per annual crops, grown in rotation with crops treated with fluopyram. These proposals were derived from the rotational field studies conducted at the exaggerated dose rate of 500 g a.s./ha, since this dose level was considered to be more representative of the predicted concentration plateau reached in soil after 10 years of consecutive uses (0.08 mg/kg soil, 20 cm depth). Fluopyram and fluopyram-benzamide were stable under standard hydrolysis conditions simulating pasteurisation, boiling/baking and sterilisation. Processing studies on grape, tomato and strawberry were provided and processing factors were calculated for several processed fractions.

The residue definition for products of animal origin was also discussed during the Pesticides Peer Review teleconference TC 68, although no intakes are expected by livestock when considering the representatives uses on grape, tomato and strawberry. In contrast to plants, fluopyram was extensively metabolised in animals. Fluopyram was almost not detected in poultry and goat matrices where the vast majority of the radioactive residues were identified as fluopyram-benzamide (M25) that accounted for 49% to 99% TRR in fat and muscle. The residue definition for monitoring was therefore proposed as the sum of "fluopyram, fluopyram-benzamide, expressed as fluopyram". For risk assessment, considering that the metabolites fluopyram-E/Z-olefine (M02, M03) were observed in significant proportions and levels in poultry and ruminant fat (22% to 28% TRR), the residue definition was proposed as “sum fluopyram, fluopyram benzamide (M25), fluopyram-E/Z-olefine (M02, M03) expressed as fluopyram”. Conversion factors of 1.1 (milk, liver, kidney) and 1.5 (fat) were derived from the feeding studies conducted on cow and poultry where samples were analysed according to the residue definition for risk assessment. Based on the representative uses, the setting of MRLs for animal products is not required.

No chronic or acute risks were identified for the consumers. Using the EFSA PRIMo model, the STMRs calculated on the sum fluopyram and fluopyram-benzamide and the default MRLs proposed for rotational crops, the highest IEDI is 20% of the ADI (WHO, diet Cluster B). The highest acute intake was calculated to be 13% of the ARfD for table grape (DE, Child).

4. Environmental fate and behaviour

Fluopyram was discussed during the Pesticides Peer Review Meeting 93 held in Parma in July 2012.

In soil laboratory incubations under aerobic conditions in the dark, fluopyram exhibited high to very high persistence, forming the minor (<10% applied radioactivity (AR)) metabolite M08 7-hydroxy (which remained at a maximum of *ca.* 4% AR from 62 days to the end of an incubation (121 days)), which exhibited low to moderate persistence. Mineralisation of the phenyl and pyridyl ring ^{14}C radiolabels to carbon dioxide accounted for *ca.* 4 - 24 % AR after 120-133 days. The formation of unextractable residues (not extracted by aqueous calcium chloride followed by acetonitrile / water including microwave extraction) for these radiolabels accounted for *ca.* 6 – 15 % AR after 120-133 days. In anaerobic soil incubations fluopyram was essentially stable. Fluopyram exhibited medium mobility in soil. M08 7-hydroxy exhibited high soil mobility. It was concluded that the adsorption of fluopyram and M08 7-hydroxy was not pH dependent. In satisfactory field dissipation studies carried out in Germany, the UK, Sweden, Northern France, Spain and Italy (1 in each country, spray

application made in June or July to the bare soil surface on plots where grass subsequently emerged) fluopyram exhibited high to very high persistence. Sample analyses were only carried out for the parent fluopyram. Three US field trial sites (in Washington, New York and North Dakota, from the 5 available) were also selected as being sufficiently representative for Europe to be normalised to FOCUS reference conditions following FOCUS (2006) kinetics guidance[10]. The normalised DT_{50} from these 3 US trials were added to the dataset of European field trials (following their normalisation) before being subsequently used in FOCUS groundwater and surface water simulations.

In laboratory incubations in dark aerobic natural sediment water systems, fluopyram slowly partitioned from water to sediment where it exhibited very high persistence. The unextractable sediment fraction (not extracted by acetonitrile / water including heated accelerated solvent extraction) was a minor sink for the phenyl and pyridyl ^{14}C radiolabel, accounting for *ca.* 3 – 8 % AR at study end (120 days). Mineralisation of these radiolabels accounted for only <0.4 – 1.8 % AR at the end of the study. The rate of decline of fluopyram in a laboratory aqueous natural water photolysis experiment indicated slow transformation with no metabolites being formed at levels triggering further assessment. Surface water and sediment exposure assessments (Predicted environmental concentrations (PEC) calculations) were carried out for fluopyram, using the FOCUS (FOCUS, 2001) step 1, 2 and 3 approaches[11].

For the representative greenhouse use, the necessary surface water and sediment exposure assessments (PEC) have been completed using the FOCUS (2001) step 1 and step 2 approach (version 2.1 of the steps 1-2 in FOCUS calculator), which was then modified by post processing the spray drift input results (option no runoff or drainage was selected) to obtain a 0.2 % emission of fluopyram from greenhouses being re-deposited on adjacent surface water bodies. This approach has been accepted by Member State experts as an assumption that can be used in EU level surface water exposure assessments for greenhouse uses and is referred to in FOCUS (2008) guidance as being appropriate for ultra low volume application but also covers the lower emission (0.1%) that this guidance indicates may be applied in the context of high volume spraying.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2009) scenarios and the model PELMO 4.4.3[12] for the active substance fluopyram and the metabolite M08 7-hydroxy. The input parameters for fluopyram used in the modelling, were the median normalised (to FOCUS reference temperature and soil moisture content) field DT_{50} from the available European trial sites and 3 US trial sites and arithmetic mean standard batch adsorption values. For M08 7-hydroxy, a geomean Laboratory DT_{50} and arithmetic mean kinetic formation fraction and standard batch adsorption values were used. The potential for groundwater exposure from the representative uses by fluopyram and M08 7-hydroxy above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios.

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

The experts at the Pesticides Peer Review 93 meeting discussed the available fluopyram aged sorption experiments. They concluded that the experiments had been appropriately conducted. However they had serious reservations, regarding the way the endpoints that the leaching models need when aged sorption is implemented in simulations, had been derived from the experiments. They also concluded that the parameterisation approach of the leaching simulations that incorporated aged sorption had not been appropriate. In particular, as aged sorption and degradation rate observed in an experiment are strongly correlated, they felt it was not defensible to combine aged sorption endpoints from a laboratory experiment, with field degradation rate experiment DT values, where a completely different

[10] Normalisation utilised a Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7
[11] Simulations utilised a Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7
[12] Simulations utilised a Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7

soil was present. Consequently the simulations provided using aged adsorption, are considered unreliable, and have not been included in Appendix A.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a, 2002b, 2002c), SETAC (2001), and EFSA (2009).

The acute and short-term first tier risk assessment for **birds** (insectivorous and herbivorous) was indicated as low for all the field representative uses, while a high long-term risk cannot be excluded. A first tier long-term risk assessment according to the new EFSA guidance document on birds and mammals (EFSA, 2009) was performed, including all the generic focal species relevant for the representative uses. The high long-term risk to insectivorous birds was confirmed. In addition, a high risk was indicated for small omnivorous birds for the representative field use in strawberry and for frugivorous birds for all the field representative uses. It was agreed that further quantitative assessment was not needed for small omnivorous birds because the first tier TER was 4.8. A risk assessment refinement for frugivorous and insectivorous birds was provided and discussed during the Pesticides Peer Review Meeting 94 in July 20012. As part of the refinement, a long-term endpoint of 7.2 mg a.s. /kg bw per day, based on the body weight reduction in surviving 14-day offspring, was proposed. However, at this endpoint, a statistically significant reduction on 14 day offspring body weight was still observed. The experts at the Pesticides Peer Review meeting 94 agreed that this effect (~8%) may not be biologically relevant. However, this was considered a source of uncertainty in the risk characterisation. Therefore, there was a general consensus to retain the endpoint of 4.5 mg a.s. /kg bw per day as more appropriate for risk assessment. The refined risk assessment for frugivorous birds considered measured residue data on tomatoes, strawberries and grapes. On the basis of these data, a low risk was concluded. The refined risk assessment for insectivorous birds included ecological data, i.e. focal species (yellow wagtail, *Motacilla flava,* for tomatoes and strawberries, black redstart, *Phoenicurus ochruros*, for vines) and PT values. The ecological relevance of the focal species along with their representativeness for the representative field uses in both northern and southern European Member States was questioned by the experts. Although it was acknowledged that it is difficult to select species which are ecologically relevant for all Member States, the available data were considered not sufficient to support the focal species selection. To cover the uncertainties regarding the choice of these focal species, the experts proposed to use the 90th percentile PT values, instead of the mean values. The 90th percentile values, would cover also other uncertainties associated with these parameters, such as extrapolation and representativeness for situation other than those of the field study. No data were available to refine the PD values. New TER values were provided in the Addendum 4 dated 30th August 2012 which were calculated based on agreed refinement options and taking into account the new EFSA guidance document on birds and mammals (EFSA, 2009). A high long-term risk to insectivorous birds was indicated for all the representative field uses.

The first tier acute risk to **mammals** (medium and small herbivorous) was indicated as low for all the field representative uses. The long-term risk was also indicated as low for the uses on tomatoes, strawberries, while a TER below the trigger was calculated for small herbivorous mammals in grapes. A refined risk assessment was proposed based on residue decline in short-grass *i.e.* DT_{50} of 4.9 days. The appropriateness of the proposed residue decline data was questioned by the experts, being based on 2 studies performed in USA and not under European conditions (different climatic conditions may have an impact on the results). Further data on leafy crops were provided in the Addendum 4 of August 2012 (Germany, 2012) to further support the DT_{50} of 4.9 days. A geometric mean DT_{50} of 3.05 days was derived from all these residues trials in different leafy crops. This value was considered robust to support the DT_{50} of 4.9 days in short grass. As requested during the peer review, the moving time-window approach was used to calculate the highest combination of $MAF_m \times TWA$. A value of 0.61 was proposed in the Addendum 2 of June 2012 (Germany, 2012), however, the calculations were not included. The refined TER of 4.4 still indicated a high risk. Overall, EFSA considered it necessary to set a data gap for further information to address the long-term risk to small herbivorous mammal for the field use in grape.

Since the Log P_{ow} was higher than 3 (3.3), the risk from secondary poisoning for earthworm- and fish-eating birds and mammals was assessed. A high first tier risk was identified for earthworm eating birds for the field uses in strawberries and grapes. However, a refined risk assessment, based on an experimental BCF value for earthworm, indicated a low risk for all representative uses.

The risk from consumption of contaminated water was assessed as low.

Several studies on fish, aquatic invertebrates, sediment-dwelling organisms, algae and higher tier plants were available. The lowest reliable endpoint driving the acute risk assessment to aquatic organisms was observed in a study with *Americamysis bahia*, while the lowest chronic endpoint was from a study on *Pimephales promelas*. A risk assessment based on FOCUS step 2 PECsw indicated a high acute and chronic risk to fish and a high acute risk to aquatic invertebrates for all the field representative uses. The TERs calculated with FOCUS step 3 PECsw still indicated an high risk for aquatic invertebrates in 3 scenarios out of 4 for the uses in tomatoes and strawberries and 1 scenario out of 5 for the use in grapes (data gap was identified for FOCUS step 4 calculations).

Potential endocrine disruptor effects in birds and fish were discussed at the Pesticides Peer Review Meeting 94. It was noted that endocrine disruption effects could not be excluded with the available data. Therefore a data gap was identified to further address this issue for birds and fish. No direct endocrine disrupting effects were evident in mammals. It was agreed that indirect effects observed on the endocrine system were not of concern for wild mammals because they occurred at higher doses that the endpoint used for risk assessment.

The risk was assessed as low for bees, non-target arthropods, earthworms, soil macro- and microorganisms, terrestrial non-target plants and biological methods for sewage treatment plants for all the representative uses. In addition the risk was considered low for birds and mammals and aquatic organisms for the greenhouse uses in tomatoes and strawberries.

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
Fluopyram	High to very high persistence. Single first-order DT_{50lab} 162-464 days (20ºC and 55% MWHC) DT_{50lab} = 746 days (single first order) and 654 days (biphasic kinetics) (25 ºC and 75% of 1/3 bar, DT90 2360-2950 days) EU field trials DT_{50} 145-347 days (biphasic kinetics DT_{90} 512->1370 days) and 147 days (single first order)	Low risk identified for soil living organisms

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
Fluopyram	Medium mobility (K_{Foc} = 233-400 mL/g)	No	Yes	Yes	Yes
M08 7-hydroxy	High mobility (K_{foc} = 85-149)	No	No data available, assessment not triggered.		No data available, assessment not triggered.

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Fluopyram	High risk indicated for aquatic invertebrates with FOCUS step 3. Data gap for FOCUS step 4 calculations

6.4. Air

Compound (name and/or code)	Toxicology
Fluopyram	Not acutely toxic via inhalation

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

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

- A high risk to aquatic organisms is identified for the representative field uses. Consideration of exposure mitigation measures for the pertinent routes of entry to surface water bodies, such as FOCUS step 4 calculations following FOCUS landscape and mitigation guidance, that respect the ceiling on mitigation routes indicated in this guidance was not available (relevant for the representative uses evaluated on vines in geoclimatic situations represented by the D6 scenarios and for the field uses in tomatoes and strawberries in geoclimatic situations represented by the R3, R4 and D6 scenarios); submission date proposed by the applicant: unknown; see section 5)

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

- The long-term risk to herbivorous mammals needs to be further addressed (relevant for representative use on grape; submission date proposed by the applicant: unknown; see section 5)

- The potential effects on the endocrine system of birds and fish should be further addressed. (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5)

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

- The formulation should not be stored at temperature > 40°C.

9. Concerns

9.1. Issues that could not be finalised

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

1. The assessment of the potential endocrine disruptor effects in birds and fish could not be finalised.

9.2. Critical areas of concern

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

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

- None

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

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

Representative use		**Grape vines** (table grapes)	**Grape vines** (wine grapes)	**Strawberries** (field)	**Tomatoes** (field)	**Strawberries** (greenhouse)	**Tomatoes** (greenhouse)
Operator risk	Risk identified						
	Assessment not finalised						
Worker risk	Risk identified						
	Assessment not finalised						
Bystander risk	Risk identified						
	Assessment not finalised						
Consumer risk	Risk identified						
	Assessment not finalised						
Risk to wild non target terrestrial vertebrates	Risk identified	X	X	X	X		
	Assessment not finalised					X[1]	X[1]
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified						
	Assessment not finalised						
Risk to aquatic organisms	Risk identified	1/5 FOCUS scenarios	1/5 FOCUS scenarios	3/4 FOCUS scenarios	3/4 FOCUS scenarios		
	Assessment not finalised						
Groundwater exposure active substance	Legal parametric value breached						
	Assessment not finalised						
Groundwater exposure metabolites	Legal parametric value breached						
	Parametric value of 10µg/L[(a)] breached						
	Assessment not finalised						
Comments/Remarks							

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

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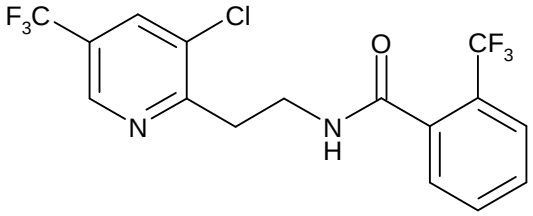
APPENDICES

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

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

Active substance (ISO Common Name) ‡	fluopyram
Function (*e.g.* fungicide)	fungicide
Rapporteur Member State	Federal Republic of Germany
Co-rapporteur Member State	none

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	*N*-{2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]ethyl}-α,α,α-trifluoro-*o*-toluamide
Chemical name (CA) ‡	*N*-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide
CIPAC No ‡	807
CAS No ‡	658066-35-4
EC No (EINECS or ELINCS) ‡	none
FAO Specification (including year of publication) ‡	none
Minimum purity of the active substance as manufactured ‡	960 g/kg (pilot plant)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	none
Molecular formula ‡	$C_{16}H_{11}ClF_6N_2O$
Molecular mass ‡	396.72
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	117.5 °C (99.8%)
Boiling point (state purity) ‡	318 – 321°C (correlated range) under decomposition (99.8%)
Temperature of decomposition (state purity)	300 – 395 °C (99.8)
Appearance (state purity) ‡	White odourless powder (99.8% and 97.5%)
Vapour pressure (state temperature, state purity) ‡	1.2 x 10^{-6} Pa at 20 °C (99.8%)
Henry's law constant ‡	2.98 x 10^{-5} Pa m^3 mol^{-1}
Solubility in water (state temperature, state purity and pH) ‡	16 mg/L at 20 °C (pH 7, no pH dependency) (99.8%)
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20 °C in g/L (99.8%): acetone >250 dichlormethane >250 dimethyl sulfoxide >250 ethyl acetate >250 heptane 0.66 methanol >250 toluene 62.2
Surface tension ‡ (state concentration and temperature, state purity)	59.4 mN/m at 20°C (90 % saturated solution) (97.5%)
Partition co-efficient ‡ (state temperature, pH and purity)	log $P_{O/W}$ = 3.3 at 20 °C (99.4%)
Dissociation constant (state purity) ‡	No pK_a value could be detected in the range of 2 < pK_a < 12. (screening method)
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	acetonitrile solution: λ_{max} (nm); ε (L.mol^{-1}.cm^{-1}) 216 14877 270 4332 ε at 290 nm below 10 L.mol^{-1}.cm^{-1}
Flammability ‡ (state purity)	Not highly flammable No self-ignition up to 400 °C
Explosive properties ‡ (state purity)	No oxidising properties
Oxidising properties ‡ (state purity)	No explosive properties

Summary of representative uses evaluated (*Fluopyram*)*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	Growth stage & season (j)	number min/max (k)	Interval between applications (min)	g as/hL min-max (l)	Water L/ha min-max	g as/ha min-max (l)		
Grape (Table)	EU	Fluopyram SC 500	F	*Botrytis*	SC	500 g/L	spraying	BBCH 61-89	2	12	15.625 – 250	100-1600	250	3	
Grape (Wine)	EU	Fluopyram SC 500	F	*Botrytis*	SC	500 g/L	spraying	BBCH 61-87	2	12	15.625 – 250	100-1600	250	21	
Strawberries	EU	Fluopyram SC 500	F G	*Botrytis*	SC	500 g/L	spraying	BBCH 61-89	2	7	16.66 – 83.33	300-1500	250	1	
Tomato	EU-S	Fluopyram SC 500	F G	*Botrytis*	SC	500 g/L	spraying	BBCH 55-89	2	7	16.66 – 83.33	500-1500	250	3	

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

Methods of Analysis

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

Technical as (analytical technique)	HPLC-UV
Impurities in technical as (analytical technique)	HPLC-UV; ion chromatography
Plant protection product (analytical technique)	GC-FID

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		fluopyram
Food of animal origin		sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram
Soil		fluopyram
Water	surface	fluopyram
	drinking/ground	fluopyram
Air		fluopyram

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	GC-MS 0.01 mg/kg (wheat grain, orange, oilseed rape, lettuce, peas seed) confirmation by three ions, ILV included, DFG S19 (EN 12393) method
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	LC-MS/MS 0.02 mg/kg (milk, egg, meat, fat, liver, kidney) confirmation by second MS/MS transition, ILV included
Soil (analytical technique and LOQ)	LC-MS/MS 0.001 mg/kg confirmation by second MS/MS transition
Water (analytical technique and LOQ)	LC-MS/MS 0.05 µg/L (drinking water, surface water) confirmation by second MS/MS transition
Air (analytical technique and LOQ)	LC-MS/MS 4 µg/m³ (ambient air, warm humid air) confirmation by second MS/MS transition
Body fluids and tissues (analytical technique and LOQ)	not required, not classified as T / T+

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

	RMS/peer review proposal
Active substance	

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Rapid, more than 93 % within 48 h, based on urinary (7.3 %) and biliary (78.5 %) excretion and amount in carcass (7.6 %) experiment with [phenyl-UL-^{14}C]-labelled compound and even higher with [pyridyl-2,6-^{14}C]-labelled compound; remarkable enterohepatic circulation was obseved in the non-cannulation trials
Distribution ‡	Wide, highest residues in liver, kidneys, and to a lesser extent, in erythrocytes, adrenals, thyroid and ovaries after 168 h accounting for 2-6 % of the administered dose in total; plasma C_{max}: ~1.5-2.2 µg/g (T_{max}: 11-15 h post application), AUC: 107-148 µg/g x h; mean residence time 52-84 h
Potential for accumulation ‡	Low evidence for accumulation (log $P_{O/W}$ = 3.3 and 6 % res. after 168 h, but results of repeated dose study do not show accumulation)
Rate and extent of excretion ‡	Nearly complete within 168 h (urine: 35-45 % / 45-60 % (m/f); faeces: 47-64 % / 39-53 % with most part excreted within 72 h
Metabolism in animals ‡	Extensively metabolised (hydroxylation, oxidation and molecular cleavage yielding the benzamide followed by conjugation with glutathione, glucuronic acid or sulphate); large number of metabolites that may be allocated to different groups and occur mostly in low amounts only, most abundant metabolites: fluopyram benzamide, fluopyram pyridyl acetic acid, 7-OH-phenol fluopyram, 7- or 8-OH fluopyram and fluopyram ethyl diol glucuronide accounting each for 6-28 % of the administered dose
Toxicologically relevant compounds ‡ (animals and plants)	Fluopyram and metabolites
Toxicologically relevant compounds ‡ (environment)	--

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 2000 mg/kg bw	
Rat LD50 dermal ‡	> 2000 mg/kg bw	
Rat LC50 inhalation ‡	> 5.11 mg/L air (4-h exposure, nose only)	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non-irritant	
Skin sensitisation ‡	Non-sensitiser (LLNA)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Rat: liver (organ wt ↑, clinical chemistry changes including blood coagulation parameters, histopathology findings); thyroid (organ wt ↑, histopathology findings, alterations in hormone levels); kidney (organ wt ↑, histopathology findings, accumulation of α_2-globulin in proximal tubules); blood (few changes in RBC parameters); bw ↓ Mouse: liver (organ wt ↑, clinical chemistry changes, histopathology findings); at higher doses: mortality, clinical signs and bw ↓ Dog: blood (RBC), liver (organ wt ↑, clinical chemistry changes, histopathology findings); bw (gain) and food consumption ↓ with few other findings (disturbance of estrous cycle and atrophic thymus) considered secondary to bw effects	
Relevant oral NOAEL ‡	90-d, rat: 12.5 mg/kg bw per day (200 ppm) 90-d, dog, LOAEL: 28.5 mg/kg bw per day (800 ppm) 1-yr, dog: 13.2 mg/kg bw per day (400 ppm) 90-d, mouse: 5.4 mg/kg bw per day (30 ppm)	
Relevant dermal NOAEL ‡	28-d (5 d/wk), rat: local effects: > 1000 mg/kg bw per day systemic effects: 300 mg/kg bw per day	
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 ‡	Bw ↓; liver & thyroid (organ wt ↑, clinical chemistry changes, histopathology findings) and kidney (degenerative histopathological findings) Additionally in rats: mortality in males (avoiding administration of higher doses); eye (retinal atrophy, lens degeneration, corneal opacity and oedema)	
Relevant NOAEL ‡	2-yr, rat: 1.2 mg/kg bw per day (30 ppm) 18-mo, mouse: 4.2 mg/kg bw per day (30 ppm)	
Carcinogenicity ‡	Liver cell adenoma and carcinoma in female rats at highest dose of 89 mg/kg bw per day (1500 ppm), no evidence in males up to highest dose of 375 ppm Follicular cell adenoma in thyroid of male mice at highest dose of 105 mg/kg bw per day (750 ppm)	R 40

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Adult: bw (gain) ↓, changes in haematological and clinical chemistry parameters, liver & kidney (histological findings) Reproduction and fertility: no evidence for impairment of fertility and reproduction Offspring: bw (gain) ↓, marginal developmental delay, spleen and thymus wt ↓	
Relevant parental NOAEL ‡	14.5 mg/kg bw per day (220 ppm)	
Relevant reproductive NOAEL ‡	83 mg/kg bw per day (1200 ppm)	
Relevant offspring NOAEL ‡	14.5 mg/kg bw per day (220 ppm)	

Developmental toxicity

Developmental target / critical effect ‡	Maternal: Rat: bw gain and food consumption ↓, liver (enlarged, hepatocelluar hypertrophy) Rabbit: bw gain and food consumption ↓ Developmental: Rat: foetal wt ↓, few skeletal and visceral (thymus, ureter) variations ↑ Rabbit: foetal wt ↓, incidence of small foetuses ↑	
Relevant maternal NOAEL ‡	Rat: 30 mg/kg bw per day Rabbit: 25 mg/kg bw per day	
Relevant developmental NOAEL ‡	Rat: 150 mg/kg bw per day Rabbit: 25 mg/kg bw per day	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	Rat: motor and locomotor activity ↓; urine stain and lower body temperature at higher doses, no microscopic lesions in nervous system up to 2000 mg/kg bw NOAEL: 125/50 mg/kg bw (m/f)	
Repeated neurotoxicity ‡	90-d, rat: no evidence for neurotoxicity at dose levels causing already systemic effects on bw, clinical chemistry parameter and organ weights NOAEL (neurotox): 164 mg/kg bw per day (2500 ppm) NOAEL (systemic): 33.2 mg/kg bw per day (500 ppm)	
Delayed neurotoxicity ‡	No data – not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Studies on liver enzyme induction and thyroid hormone levels suggest a non-genotoxic threshold mechanism for carcinogenicity.

Studies performed on metabolites or impurities ‡	AE C657188 (Fluopyram-pyridyl carboxylic acid, plant metabolite, also common to the a.s. fluopicolide): Rat LD50 oral: >2000 mg/kg bw (mortality at 4000 mg/kg bw in a preliminary trial); No genotoxic potential *in vitro*; 28-d, rat: no evidence of toxicity up to the highest dose level of 1574 mg/kg bw per day (20000 ppm) AE 1344122 (Fluopyram methyl sulfoxide, plant metabolite, also common to the a.i. fluopicolide): Rat LD50 oral: >2000 mg/kg bw; No genotoxic potential *in vitro*; 28-d, rat: minor clinical signs, bw effects, clinical chemistry and histological findings at 20000 ppm, NOAEL 152 mg/kg bw per day (2000 ppm)

Medical data ‡ (Annex IIA, point 5.9)

Limited, new compound. No adverse effects reported in people so far who had been in contact with that a.s. during development and manufacturing

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.012 mg/kg bw per day	2-yr, rat	100
AOEL ‡	0.05 mg/kg bw per day	90-d, mouse	100
ARfD ‡	0.5 mg/kg bw	Acute neurotoxicity, rat	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (e.g. name 50 % EC)	Fluopyram SC 500: 0.2 % for the concentrate (applied dose appr. 5 mg/cm^2) and 2 % for the dilution (applied dose appr. 0.005 mg/cm^2) based on rat *in vivo* and comparative *in vitro* rat and human skin

Exposure scenarios (Annex IIIA, point 7.2)

Operator	The estimated exposure to Fluopyram SC 500 according to the German Model is below the systemic AOEL (≤ 14.5 % of the systemic AOEL for fluopyram for high crop and field crop applications without PPE). The estimated exposure to Fluopyram SC 500 according to the UK POEM is below the systemic AOEL (≤ 88.8 % of the systemic AOEL for fluopyram for high crop and field crop applications with PPE). The estimated exposure to Fluopyram SC 500 according to the German Model and an exposure study is below the systemic AOEL (≤ 17.9 % of the systemic AOEL for

	fluopyram for greenhouse applications without PPE).
Workers	The estimated exposure to Fluopyram SC 500 is below the systemic AOEL (≤ 15.4 % of the AOEL for fluopyram without PPE).
Bystanders	The estimated exposure to Fluopyram SC 500 is below the systemic AOEL for fluopyram (≤ 0.24 % of the AOEL for bystanders and ≤ 0.12 % of the AOEL for residents).

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

	RMS/peer review proposal
Substance classified (name)	Directive 67/548/EEC: substance not listed up to and including 30th ATP Regusaltion (EC) 1272/2008: not listed up to and includingATP 3 Xn - Harmful R40 - Limited evidence of a carcinogenic effect (Carc. Cat. 3)

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

Plant groups covered	- Foliar applications: Fruits: (Grape) Root and tubers: (Potato) Pulses/oilseeds: (Bean) - Drip irrigation: Fruits: (Pepper)
Rotational crops	Spring wheat, Swiss chard, turnips
Metabolism in rotational crops similar to metabolism in primary crops?	Yes. Fluopyram and the metabolites resulting from the cleavage of the parent (fluopyram-benzamide (M25) and fluopyram-PCA (M43)) major components of the residues in rotational crops. 7-hydroxy metabolites observed in higher proportions than in primary crops.
Processed commodities	Standard hydrolysis studies simulating pasteurisation, boiling/baking and sterilisation conducted with fluopyram and metabolites M08, M25, M40 and M43.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes. Fluopyram, M08, M25 and M43 stable under standard conditions. In contrast, M40 almost totally degraded to M46 under all representative conditions, but no concern since M40 not present in significant levels in raw agricultural commodities.
Plant residue definition for monitoring	Fluopyram (Harmonised EU/US EPA/CAN PMRA proposal)
Plant residue definition for risk assessment	Sum fluopyram, fluopyram-benzamide (M25), expressed as fluopyram
Conversion factor (monitoring to risk assessment)	Fruit crops: 1.1

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

Animals covered	Ruminants, poultry, fish
Time needed to reach a plateau in milk and eggs	Approx. 8 days (milk) and 21 days (eggs)
Animal residue definition for monitoring	Sum fluopyram, fluopyram-benzamide (M25), expressed as fluopyram
Animal residue definition for risk assessment	Sum fluopyram, fluopyram-benzamide (M25), fluopyram-E/Z-olefine (M02/M03), expressed as fluopyram
Conversion factor (monitoring to risk assessment)	1.5 Fat: 1.1 Milk, liver, kidney: 1 Muscle:
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No

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

	Residues in rotational crops cannot be excluded. (Default MRL proposals have been made for root/tuber crops, leafy crops, cereals, oilseeds and perennial crops grown in rotation to primary crops treated with fluopyram)

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

Fluopyram, M25, M40 and M43: Stable at least 2 years in water-, starch-, protein- and oil- containing matrices and at least 6 months in acidic matrices, when stored at or below -18°C **M08 and M45:** Stable at least 2 years in water and starch containing matrices when stored at or below -18°C

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

	Ruminant:	**Poultry:**	**Pig:**
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	none	none	None
Potential for accumulation (yes/no):	no	no	no
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	no	no	no
	Feeding studies: Beef: 14.4 mg/kg DM Poultry: 0.49 mg/kg DM Residue levels in matrices : Mean (max) mg/kg (Sum fluopyram + M25, expressed as fluopyram)		
Muscle	0.30 (0.45)	0.05 (0.05)	-
Liver	1.92 (2.25)	0.17 (0.17)	-
Kidney	0.29 (0.39)	-	-
Fat	0.22 (0.37)	0.05 (0.05)	-
Milk	0.26 (0.39)		
Eggs		0.09 (0.10)	

Note: based on the representative uses, MRLs were not proposed for products of animal origin, as grapes, strawberries and tomatoes are not fed to animals.

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

Crop	Northern or Southern Region, field or glasshouse	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to representative use	HR (HR_M) (c)	STMR ($STMR_M$) (b)
Table grape	S-EU	Fluopyram (n=10): 0.30, 0.34, 0.36, 0.55, 0.58, 0.60, 0.63, 0.66, 0.96, 1.0 Fluopyram + benzamide (n=10): 0.31, 0.35, 0.37, 0.58, 0.60, 0.61, 0.64, 0.68, 0.97, 1.0	S-EU and N-EU datasets not significantly different (U-test, 5%). MRL derived from the merged data: R_{ber}: 1.36, R_{max}: 1.14 Additional residue data available for North American trials also supporting a harmonised MRL of 1.5 mg/kg.	1.5	1.0 (1.0)	0.59 (0.58)
	N-EU	Fluopyram (n=7): 0.48, 0.51, 0.57, 0.58, 0.63, 0.70, 1.0 Fluopyram + benzamide (n=7): 0.49, 0.52, 0.58, 0.60, 0.64, 0.71, 1.0				
Wine grape	S-EU	Fluopyram (n=10): 0.13, 0.22, 0.26, 0.28, 0.34, 0.35, 0.41, 0.44, 0.61, 0.63 Fluopyram + benzamide (n=10): 0.15, 0.23, 0.28, 0.29, 2x 0.36, 0.43, 0.45, 0.62, 0.65	S-EU and N-EU datasets not significantly different (U-test, 5%). MRL derived from the merged data: R_{ber}: 1.17 R_{max}: 0.81 Reduced data set for NE (n=7) considered acceptable for MRL setting.	1	0.68 (0.65)	0.43 (0.41)
	N-EU	Fluopyram (n=7): 0.29, 0.36, 0.44, 0.46, 0.56, 0.63, 0.65 Fluopyram + benzamide (n=7): 0.31, 0.37, 0.46, 0.49, 0.59, 0.64, 0.68				
Strawberry	Greenhouse	Fluopyram (n=8): 0.12, 0.18, 0.20, 0.25, 0.28, 0.33, 0.71, 0.79 Fluopyram + benzamide (n=8): 0.13, 0.19, 0.20, 0.26, 0.29, 0.34, 0.72, 0.80	MRL derived from indoor residue trials: R_{ber}: 1.23 R_{max}: 1.16	1.5	0.80 (0.79)	0.28 (0.27)
	S-EU	Fluopyram (n=9): 0.12, 0.19, 0.25, 2x 0.27, 0.31, 0.33, 0.34, 0.52 Fluopyram + benzamide (n=9): 0.13, 0.20, 0.26, 2x 0.28, 0.32, 0.34, 0.35, 0.54				

Crop	Northern or Southern Region, field or glasshouse	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to representative use	HR (HR_M) (c)	STMR ($STMR_M$) (b)
	N-EU	Fluopyram (n=9): 0.15, 2x 0.17, 0.19, 0.24, 0.35, 0.36, 0.43, 0.69 Fluopyram + benzamide (n=9): 0.16, 2x 0.18, 0.20, 0.25, 0.36, 0.37, 0.44, 0.70				
Tomato	GH	Fluopyram (n=12): 0.13, 3x 0.15, 0.16, 2x 0.19, 0.24, 0.28, 0.36, 0.44, 0.62 Fluopyram + benzamide (n=12): 0.14, 3x 0.16, 0.17, 2x 0.20, 0.25, 0.29, 0.37, 0.45, 0.63	Application in indoor trials exceed the cGAP rate by +20%. This is considered acceptable (justification in Vol. 3, B.7.6). MRL derived from indoor data R_{ber}: 0.68 R_{max}: 0.66	0.7	0.63 (0.62)	0.20 (0.19)
	S-EU	Fluopyram (n=10): 0.03, 0.09, 0.13, 0.16, 0.19, 2x 0.22, 2x 0.24, 0.30 Fluopyram + benzamide (n=10): 0.04, 0.10, 0.14, 0.17, 0.20, 2x 0.23, 2x 0.25, 0.31				

(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: STMR: median residue according to definition for risk assessment; $STMR_M$: median residue according to definition for monitoring
(c) HR: Highest residue according to residue definition for risk assessment; HR_M: Highest residue according to residue definition for monitoring.

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

ADI	0.012 g/kg bw per day
TMDI (% ADI) according to WHO European diet	Not calculated.
TMDI (% ADI) according to national (to be specified) diets	Not calculated.
IEDI (% ADI) according to EFSA PRIMo model	20% (WHO, Cluster B)
NEDI (specify diet) (% ADI)	-
Factors included in IEDI and NEDI	None.
ARfD	0.5 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo model	Highest IESTI: 13% ARfD (Table grape, DE Child)
NESTI (% ARfD) according to national (to be specified) large portion consumption data	-
Factors included in IESTI and NESTI	Processing factor for wine (PF 0.15)

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

Crop/processed product	Number of studies	Processing factors		Amount transferred (%)
		Transfer factor	Yield factor	
Grape/Berry, washed	5	0.62		
Grape/Pomace (wet)	4	3.4		
Grape/Pomace (dried)	4	6.6		
Grape/Red wine (must heated)	4	0.15		
Grape/Juice	5	0.54		
Grape/Jelly	1	0.14		
Grape/Raisin	5	2.9		
Strawberry/Washed	5	0.81		
Strawberry/Washed/Cooked	1	0.73		
Strawberry/Preserve	4	0.32		
Strawberry/Jam	4	0.61		
Tomato/Fruit washed	5	0.67		
Tomato/Fruit, peeled	4	0.10		
Tomato/Juice (pasteurized)	5	0.42		
Tomato/Tomato Preserve/canned	5	0.21		
Tomato/Tomato puree (pasteurized)	5	0.73		
Tomato/Tomato paste	1	0.46		
Tomato/Cooked tomato	1	0.22		
Tomato/Dried tomato	1	4.4		

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

Table grapes	1.5 mg/kg
Wine grapes	1 mg/kg
Strawberries	1.5 mg/kg
Tomatoes	0.7 mg/kg
Rotational crop default MRLs	
RC root/tuber, leafy crops	0.1 mg/kg
RC cereals, oilseeds, perennial crops	0.01* mg/kg
RC fruiting crops	no proposal, no data available

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

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

Mineralisation after 100 days ‡	4.7-24% after 120 to 133 days [14C- pyridyl-2,6]-label (n=6) 4.1-16.2 % after 120-133 days [14C- phenyl-UL]-label (n = 6)
Non-extractable residues after 100 days ‡	6.2-15.1% after 120 to 133 days [^{14}C- pyridyl-2,6]-label (n = 6) 7-13.8 % after 120-133 days [^{14}C- phenyl-UL]-label (n = 6)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	M08 7-hydroxy max. 4.2 % at 62 d (n = 4) [^{14}C- pyridyl-2,6] & [^{14}C- phenyl-UL] labels

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

Anaerobic degradation ‡

Mineralisation after 100 days	<1.1 /0.8 % after 92 days, [^{14}C- phenyl- /pyridyl]-label (n = 1) Sterile conditions: *x* % after *x* d (n = *x*)
Non-extractable residues after 100 days	4.7-4.8% after 92 days [^{14}C- phenyl- /pyridyl]-label (n = 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	no metabolites

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Stable to photolysis

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

Laboratory studies

Parent	Aerobic conditions						
Soil type	X[13]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	Chi² (%)	Method of calculation
[pyridyl-2,6-^{14}C]AE C656948							
Hoefchen a. Hohenseh, silt loam		6.7	20°C/ 55% MWHC	210/ 697	160	0.64	SFO
Laacherhof AXXa, sandy loam		6.2	20°C/ 55% MWHC	464/ >1000	391	1	SFO
Laacherhof Wurmwiese, sandy loam		5.2	20°C/ 55% MWHC	250/ 829	211	0.74	SFO
Dollendorf, clay loam		7.3	20°C/ 55% MWHC	162/ 538	117	1.6	SFO
Porterville,, US, sandy loam		7.9	25°C / 75% of 1/3 bar	561/ >1000	596 [b]	3.4	SFO
Springfield, US, silty clay loam		6.5	25°C / 75% of 1/3 bar	583/ >1000 (slow DT_{50} 765, k1=0.112 k2=0.000907 g= 0.152)	717 [b] (941) [b]	2.9	DFOP (slow DT_{50} DFOP)
Geometric mean/median					309/ 301[a]		
[phenyl-UL-^{14}C]AE C656948							
Hoefchen a. Hohenseh, silt loam		6.7	20°C/ 55% MWHC	221/735	168	1.1	SFO
Laacherhof AXXa, sandy loam		6.2	20°C/ 55% MWHC	231/761	195	1.3	SFO
Laacherhof Wurmwiese, sandy loam		5.2	20°C/ 55% MWHC	339/>1000	285	1.8	SFO
Laacherhof AIIIa , loam		7.3	20°C/ 55% MWHC	165/549	119	0.73	SFO
Porterville,, US, sandy loam		7.9	25°C / 75% of 1/3 bar	746/>1000	795 [b]	2.4	SFO
Springfield, US, silty clay loam		6.5	25°C / 75% of 1/3 bar	654/>1000 (slow DT_{50} 990, k1=0.0924, k2=7e-4 g=0.2098)	805 [b] (1219) [b]	2.9	DFOP (slow DT_{50} DFOP)
Geometric mean/median					320 / 240[a]		

[a] for DFOP kinetic the slow DT_{50} is used
[b] for t-normalisation Q10 = 2.58 is used

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

Met 1 M08 7-hydroxy	Aerobic conditions							
Soil type	X[1]	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	Chi² (%)	Method of calculation
Höfchen, silt loam, phenyl-labelled,		6.6	20°C/ 55%	13.2 /43.7	0.6327	10.0	9.3	SFO
Höfchen, silt loam, pyridyl- labelled		6.7	20°C/ 55%	5.9 /19.5	0.9406	4.5	9.7	SFO
Geo.mean				13.2	0.7867	6.7		SFO
Laacher Hof AXXa, sandy loam phenyl-labelled		6.6	20°C/ 55%	17.3/57.6	0.6727	14.6	6.3	SFO
Laacher Hof AXXa, sandy loam pyridyl-labelled		6.2	20°C/ 55%	10.8/35.9	1	9.1	15.7	SFO
Geo.mean				13.7	0.8364	11.5		
Laacher Hof Wurmwiese, loam, phenyl-labelled		5.5	20°C/ 55%	14.1/46.8	1	10.8	7.1	SFO
Laacher Hof Wurmwiese, sandy loam, pyridyl-labelled		5.2	20°C/ 55%	8.5/28.2	1	5.9	27.7	SFO
Geo.mean				10.9	1	7.96		
Laacherhof AIIIa, clay loam, phenyl-labelled			20°C/ 55%	17.7/ 58.7	0.5459	13.5	9.0	SFO
Dollendorf II, clay loam (Laacherhof AIIIa) pyridyl-labelled		7.3	20°C/ 55%	5.8/19.3	1	4.2	24.5	SFO
Geometric mean/median						8.1/8.0		
Arithmetic mean					0.8338			

Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	Chi^2 (%)	DT_{50} (d) Norm. (SFO)	Chi^2 (%) (norm., SFO)	Method of calculation
European field studies									
Silt loam (bare soil)	Burscheid, Germany, R 2005 0326/1	6.9	0-20	145	1080	7.3	92.8	6.8	DFOP
Sandy loam (bare soil)	Little Shelford, UK, R 2005 0328/8	8.1	0-20	164	1370	6.9	123.1	12.2	DFOP
Loam (bare soil)	Staffanstorp, Sweden, R 2005 0329/6	8.1	0-20	179	> 1000	5.9	100.0	12.3	DFOP
Silt loam (bare soil)	Vatteville, France, R 2005 0331/8	7.3	0-20	347[a]	> 1000	10.1	124.4	9.9	DFOP
Loam (bare soil)	Vilobi d'Onyar, Spain, R 2005 0332/6	6.7	0-20	147	487	22.0	87.4	19.0	SFO
Silt loam (bare soil)	Albaro, Italy, R 2005 0333/4	8.2	0-20	21.2	512	7.0	115.5[b]	6.0	DFOP
Geometric mean/median (European field studies)							106.2/ 107.8		
US field studies									
Loamy sand (bare ground)	New York, USA	6.2	0-30	539	3340	10	228.4	13.5	SFO
Loam (bare ground)	North Dakota, USA	7.0	0-30	83	19300	3.7	744.0 [b]	7.1	DFOP
Sandy loam (bare ground)	Washington, USA	8.1	0-30	163	1690	3.6	257.5 [b]	3.0	DFOP
Geometric mean/median (US field studies)							352.4/ 257.5		
Geometric mean/median (European and US studies)							158.4/ **123.1**[c]		

[a] results in a worst case PECsoil

[b] rate k and DT_{50} represent the second slow phase of a DFOP fit, which is appropriate for modelling purpose according FOCUS kinetics

[c] Concluded to use the median DT_{50} of the 9 European and US field trials for PECsw, PECsed and PECgw calculations due to the increased number of DT_{50} values available (according to FOCUS, 2011).

Kinetic parameter									
Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH	Depth (cm)	DT_{50} (d) actual	Kinetic parameter for DFOP			Chi^2 (%)	Method of calculation
					k1	k2	g		
Silt loam (bare soil)	Burscheid, Germany, R 2005 0326/1	6.9	0-20	145	0.0107	0.0015	0.49	7.3	DFOP
Sandy loam (bare soil)	Little Shelford, UK, R 2005 0328/8	8.1	0-20	164	0.035	0.0013	0.39	6.9	DFOP

Kinetic parameter									
Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH	Depth (cm)	DT_{50} (d) actual	Kinetic parameter for DFOP			Chi² (%)	Method of calculation
					k1	k2	g		
Loam (bare soil)	Staffanstorp, Sweden, R 2005 0329/6	8.1	0-20	179[a]	17.329	0.0018	0.3109	5.9	DFOP
Silt loam (bare soil)[b]	**Vatteville, France, R 2005 0331/8**	**7.3**	**0-20**	**347** [a]	**0.0341 DT50 = 20.33 d**	**0.0014 DT50 = 495.11 d**	**0.1804**	**10.1**	**DFOP**
				318	0.0406	0.0014	0.22	9.9	DFOP
Loam (bare soil)	Vilobi d'Onyar, Spain, R 2005 0332/6	6.7	0-20	147		-	-	22.0	SFO
Silt loam (bare soil)	Albaro, Italy, R 2005 0333/4	8.2	0-20	21	0.1199	0.0031	0.51	7.0	DFOP

[a] fitted by the notifier
[b]results in worst case PEC_{soil} values

Kinetic parameter									
Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH	Depth (cm)	DT_{50} (d) actual	Kinetic parameter for DFOP			Chi² (%)	Method of calculation
					k1	k2	g		
US field studies									
Sandy loam (bare ground)	Washington	8.1	0-30	163	0.0317	0.0010	0.411	3.6	DFOP
Loamy sand (bare ground)	New York	6.2	0-30	539	0.104	0.00058	0.319	10	DFOP
Loam (bare ground)	North Dakota	7.0	0-30	83	0.0377	8.13e-05	0.520	3.7	DFOP

pH dependence ‡ (yes / no) (if yes type of dependence)	no
Soil accumulation and plateau concentration ‡	Interim Results after 2 years application: (application rate 250 g a.i./ha once per year on grass): Plateau concentration in 0-10cm (sum of 0-50cm) layer: 228 (234) µg a.i./kg (German sandy loam) 237 (250) µg a.i./kg (France silt loam)

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	X[14]	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation

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

silt loam		6.4	20°C / 50% MWHC	> 1000			SFO

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH (water)	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Sandy loam	1.3	6.6			3.031	233.2	0.765
Silt loam	2.6	6.7			6.825	260.5	0.838
Loam	2.1	6.0			4.839	233.7	0.849
Loamy sand	1.1	5.6			2.941	267.3	0.846
Clay loam	1.1	7.0			4.396	399.7	0.837
Arithmetic mean/median					4.406	278.9	0.827
pH dependence, Yes or No			no				

M08 7-hydroxy ‡							
Soil Type	OC %	Soil pH (water)	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Loam	1.1	6.7			0.991	90.1	0.9241
Sandy loam	1.5	6.4			1.321	88.1	0.9391
Silt loam	1.6	7.0			2.390	149.4	0.9104
Sandy loam	1.6	5.3			1.362	85.1	0.9432
Arithmetic mean/median					1.516	103.2	0.9292
pH dependence (yes or no)			no				

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

Column leaching ‡	no study performed
Aged residues leaching ‡	no study performed
Lysimeter/ field leaching studies ‡	no study performed

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 1.DT_{50} = 20.327 days; 2.DT_{50} = 495.105 days; g = 0.1804 Kinetics: DFOP Field: representative worst case from EU-field studies.
Application data	Crop: tomatoes Depth of soil layer: 5 cm (PEC actual and twa) and 20 cm ($PEC_{background}$) Soil bulk density: 1.5 g/cm^3 % plant interception: 80 Number of applications: 2 Interval (d): 7 Application rate(s): 250 g as/ha
	Crop: vines Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 70 Number of applications: 2 Interval (d): 12 Application rate(s): 250 g as/ha
	Crop: strawberries Depth of soil layer: 5 cm (PEC actual and twa) and 20 cm ($PEC_{background}$) Soil bulk density: 1.5 g/cm^3 % plant interception: 60 Number of applications: 2 Interval (d): 7 Application rate(s): 250 g as/ha

Crop tomatoes

PEC($s_)$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			0.1302	
Short term			0.1294	0.1298
24 h				
2 d			0.1285	0.1294
4 d			0.1269	0.1285
Long term			0.1246	0.1273
7 d				
28 d			0.1128	0.1205
50 d			0.1053	0.1153
100 d			0.0953	0.1076

PEC(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Plateau concentration [a,c]	0.1707 mg/kg after 10 yr [b]			

[a] Plateau concentration (5 cm) = $PEC_{background}$ (20cm) + PEC_{soil} of 1st year (5 cm)
[b] according to the estimation 100% of the final plateau was reached after 10 years without crop rotation
[c] for the accumulated PEC, the ESCAPE option `separate consideration of residues from different applications´ is used

Crop vines

PEC(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			0.1954	
Short term			0.1941	0.1947
24 h				
2 d			0.1928	0.1941
4 d			0.1903	0.1928
Long term			0.1869	0.1910
7 d				
28 d			0.1693	0.1807
50 d			0.1580	0.1730
100 d			0.1429	0.1614
Plateau concentration [a,c]	0.4380 mg/kg after 10 yr [b]			

[a] Plateau concentration (5 cm) = $PEC_{background}$ (5 cm) + PEC_{soil} of 1st year (5cm)
[b] according to the estimation 100% of the final plateau was reached after 10 years without crop rotation
[c] for the accumulated PEC, the ESCAPE option `separate consideration of residues from different applications´ is used

Crop strawberry

PEC(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			0.2605	
Short term			0.2587	0.2596
24 h				
2 d			0.2571	0.2588
4 d			0.2538	0.2571
Long term			0.2492	0.2547
7 d				
28 d			0.2257	0.2410
50 d			0.2106	0.2307
100 d			0.1905	0.2152
Plateau concentration [a,c]	0.3414 mg/kg after 10 yr [b]			

[a] Plateau concentration (5 cm) = $PEC_{background}$ (20 cm) + PEC_{soil} of 1st year (5 cm)
[b] according to the estimation 100% of the final plateau was reached after 10 years without crop rotation
[c] for the accumulated PEC, the ESCAPE option `separate consideration of residues from different applications´ is used

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: stable at 50 °C
	pH 7: stable at 50 °C unident. metabolite: max.1.6 % AR
	pH 9: stable at 50 °C unident. metabolite: max.1.2 % AR
Photolytic degradation of active substance and metabolites above 10 % ‡	in aqueous buffer (pH7) at 25°C: [phenyl ^{14}C]-labelled: DT_{50}= 21 d [pyridyl ^{14}C]-labelled: DT_{50}= 25 d corresponding to DT_{50}= 57 d, resp. (Phoenix, USA) DT_{50}= 89 d, resp. (Athens, Greece) major transformation product : AE C656948 - lactam max. 13%
	in natural water from the river Rhine at 25°C : DT_{50}= 21 d corresponding to DT_{50}= 87 d, resp. (Phoenix, USA) DT_{50}= 135 d, resp. (Athens, Greece) No major transformation product, transformation product AE C656948 – lactam: max. 1.2%
Quantum yield of direct phototransformation in water at λ > 290 nm	not applicable
Readily biodegradable ‡ (yes/no)	No data submitted, substance considered not readily biodegradable.

Degradation in water / sediment

Parent	Distribution (max in water 26.3/ 25.5 % (phenyl/pyridyl ^{14}C]-labelled) after 120 d. Max in sediment 69.9/67.2 % (phenyl/pyridyl ^{14}C]-labelled) after 120 d)									
Water / sediment system	pH water phase	pH sed.	t. °C	DT_{50} - DT_{90} whole sys.	St. (r^2)	$DissT_{50}$ - $DissT_{90}$ water	St. (r^2)	DT_{50} - DT_{90} sed.	St. (r^2)	Method of calculation

Anglerweiher, Leverkusen, Germany	6.8	5.6	24	[phenyl ^{14}C]-labelled:						SFO (whole system); DFOP (water phase)
				1190 - 3960	0.8	25 - 284	2.1			
				[pyridyl ^{14}C]-labelled						
				1470 - 4900	1.3	26 - 293	1.8			
Lawrence, Jefferson County, Kansas, USA	7.3	5.3	n.m.[a]	[phenyl ^{14}C]-labelled:						SFO (whole system); DFOP (water phase)
				1000 - 3330	0.9	14- 215	1.5			
				[pyridyl ^{14}C]-labelled						
				648- 2150	1.7	17 - 221	4.8			
[a] not measured										
Geometric mean/median										

Calculated by PMRA

Mineralisation and non extractable residues					
Water / sediment system	pH water phase	pH sed.	Mineralisation x % after n d (end of the study)	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Anglerweiher, Leverkusen, Germany	6.8	5.6	< 0.4% (120 d)	2.9-3.7% (120 d)	2.9-3.7% (120 d)
Lawrence, Jefferson County, Kansas, USA	7.3	5.3	< 1.8% (90 d)	4.4-8.4% (120 d)	4.4-8.4% (120 d)

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

Parent	Version control no. of FOCUS calculator: Version 1.1
Parameters used in $FOCUS_{sw}$ step 1 and 2	Molecular weight (g/mol): 396.72 Water solubility (mg/L): 16 K_{OC}/K_{OM} (L/kg): 278.9/ 161.8 DT_{50} soil (d): 123.1 days (median, EU- and US-field data. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 1000 (default) DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Crop interception (%): 70
Parameters used in $FOCUS_{sw}$ step 3 (if performed)	Version control no.'s of FOCUS software: FOCUS_TOXSWA v2.2.1 Vapour pressure: $1.2 \cdot 10^{-6}$ Pa (20°C)

	K_{OC}/K_{OM}: 278.9 / 161.8 1/n: (Freundlich exponent general or for soil, susp. solids or sediment respectively) 0.8269
Application rate	Crop: tomatoes Crop interception: 70 Number of applications: 2 Interval (d): 7 Application rate(s): 250 g as/ha Application window: BBCH 55-89 (early application: 28 day after emergence, late application: 38 day before harvest)
	Crop: strawberries Crop interception: 70 Number of applications: 2 Interval (d): 7 Application rate(s): 250 g as/ha Application window: BBCH 61-89 (early application: 28 day after emergence, late application: 38 day before harvest)
	Crop: vines Crop interception: 70 Number of applications: 2 Interval (d): 12 Application rate(s): 250 g as/ha Application window: BBCH 61-89 (early application: 49 days after emergence, late application: 65 days before harvest)

Crop: field tomatoes and strawberries

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
PECmax		126.1		338.8	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
North- EU, Oct-Feb	0 h	20.7		56.9	
	24 h	20.4	20.6	56.9	56.9
	2 d	20.4	20.5	56.8	56.9
	4 d	20.4	20.4	56.8	56.8

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	7 d	20.3	20.4	56.6	56.8
	14 d	20.2	20.3	56.4	56.6
	21 d	20.1	20.3	56.1	56.5
	28 d	20.0	20.2	55.8	56.4
	42 d	19.7	20.1	55.3	56.1

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
South EU, Oct-Feb	0 h	17.2		47.2	
	24 h	16.9	17.1	47.1	47.2
	2 d	16.9	17.0	47.1	47.1
	4 d	16.9	16.9	47.0	47.1
	7 d	16.8	16.9	46.9	47.1
	14 d	16.8	16.9	46.7	46.9
	21 d	16.7	16.8	46.5	46.8
	28 d	16.6	16.8	46.3	46.7
	42 d	16.4	16.7	45.8	46.5

Parent Parameters used in $FOCUS_{sw}$ step 1 and 2	Version control no. of FOCUS calculator: Version 2.1 K_{OC} (L/kg): 278.9 DT_{50} soil (d): 123.1 days median, EU- and US-field data. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 1000 (default) option no runoff or drainage, spray drift input as prescribed but PEC factored (x0.2/2.8) to give 0.2% emission from a glasshouse reaching the FOCUS surface water body.
Application rate	Crop: tomatoes / strawberries (fruiting vegetables selected in FOCUS step 1-2 calculator) Number of applications: 2 Interval (d): 7 Application rate(s): 500 g as/ha (2x250 g as/ha representing maximum total annual dose)

Crop: glasshouse tomatoes and strawberries

FOCUS STEP 1 Scenario	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
	Actual	TWA	Actual	TWA
PECmax	0.33		0.49	

Tomatoes FOCUS step 3 - early application window

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6 Thiva	ditch	global max	4.697		4.289	
		24 h	2.318	3.602	4.216	4.278
		2 d	1.719	3.079	4.113	4.248
		4 d	1.151	2.376	3.885	4.168
		7 d	1.412	2.018	3.52	4.025
		14 d	0.275	1.424	2.922	3.769
		21 d	0.116	1.008	2.647	3.547
		28 d	0.0807	0.781	2.459	3.349
		42 d	0.0497	0.543	2.344	3.311
R2 Porto	stream	global max	2.854		3.215	
		24 h	0.117	0.117	2.589	2.948
		2 d	0.00502	0.00502	2.323	2.734
		4 d	0.00159	0.00159	2.076	2.553
		7 d	0.000743	0.000743	1.891	2.525
		14 d	0.000351	0.000351	1.661	2.427
		21 d	0.000238	0.000238	1.517	2.363
		28 d	0.000182	0.000182	1.41	2.314
		42 d	0.000124	0.000124	1.251	2.24
R3 Bologna	Stream	global max	7.51		5.239	
		24 h	1.203	5.937	4.457	5.051
		2 d	0.0389	3.138	3.992	4.736
		4 d	0.011	1.579	3.548	4.31
		7 d	0.808	1.496	3.197	3.938
		14 d	2.958	0.998	3.191	3.784
		21 d	0.00363	0.701	3.063	3.722
		28 d	0.00383	0.616	3.079	3.585
		42 d	0.174	0.451	2.46	3.352
R4 Roujan	Stream	global max	9.095		4.533	
		24 h	0.124	6.956	3.042	4.032
		2 d	0.0142	3.505	2.467	3.526
		4 d	0.0041	1.757	1.983	2.935
		7 d	0.00173	1.028	1.657	2.481
		14 d	0.00215	0.806	1.783	2.222
		21 d	0.00134	0.651	1.636	2.088
		28 d	0.000501	0.527	1.38	1.946

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		42 d	0.000232	0.356	1.135	1.716

Strawberries, FOCUS step 3 - early application window

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6 Thiva	ditch	global max	4.708		4.418	
		24 h	2.332	3.615	4.347	4.408
		2 d	1.734	3.093	4.245	4.378
		4 d	1.166	2.39	4.02	4.299
		7 d	1.424	2.031	3.658	4.158
		14 d	0.289	1.437	3.068	3.901
		21 d	0.13	1.022	2.797	3.682
		28 d	0.092	0.795	2.608	3.488
		42 d	0.0568	0.555	2.488	3.472
R2 Porto	stream	global max	1.215		3.542	
		24 h	0.000222	0.926	3.424	3.508
		2 d	0.00012	0.803	3.359	3.484
		4 d	0.00005	0.524	3.327	3.443
		7 d	0.000023	0.324	3.176	3.404
		14 d	0.000009	0.184	2.917	3.267
		21 d	0.000005	0.149	2.793	3.173
		28 d	0.000003	0.14	2.705	3.103
		42 d	0.000002	0.123	2.481	2.989
R3 Bologna	Stream	global max	7.51		5.239	
		24 h	1.203	5.937	4.457	5.051
		2 d	0.0389	3.138	3.992	4.736
		4 d	0.011	1.579	3.548	4.31
		7 d	0.808	1.496	3.197	3.938
		14 d	2.958	0.998	3.191	3.784
		21 d	0.00363	0.701	3.063	3.722
		28 d	0.00383	0.616	3.079	3.585
		42 d	0.174	0.451	2.46	3.352
R4 Roujan	Stream	global max	7.802		3.976	
		24 h	0.106	5.969	2.698	3.545
		2 d	0.0122	3.005	2.199	3.109

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		4 d	0.00355	1.506	1.778	2.6
		7 d	4.412	0.887	3.347	2.225
		14 d	0.00131	0.72	1.683	2.218
		21 d	0.000577	0.642	1.395	1.995
		28 d	0.000357	0.489	1.233	1.827
		42 d	0.000788	0.326	1.233	1.629

Tomatoes, strawberries, FOCUS step 3 - late application window

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6 Thiva	ditch	global max	6.21		5.854	
		1	3.042	4.727	5.764	5.84
		2	2.263	4.035	5.636	5.801
		4	1.523	3.117	5.356	5.701
		7	1.868	2.653	4.904	5.523
		14	0.401	1.886	4.172	5.194
		21	0.197	1.348	3.834	4.924
		28	0.142	1.056	3.593	4.687
		42	0.0878	0.742	3.424	4.705
R2 Porto	stream	global max	1.567		4.276	
		1	1.37	1.205	3.84	4.129
		2	1.202	1.048	3.61	4.082
		4	0.0031	0.683	3.495	4.033
		7	0.154	0.421	3.203	3.983
		14	0.000652	0.239	3.341	3.818
		21	0.677	0.193	3.554	3.721
		28	0.489	0.18	4.107	3.633
		42	0.000341	0.156	3.406	3.534
R3 Bologna	Stream	global max	6.525		5.064	
		1	0.866	5.013	4.94	4.939
		2	0.0334	2.631	4.407	4.889
		4	0.00978	1.528	3.845	4.642
		7	0.00447	0.877	3.456	4.283
		14	0.00778	0.818	3.128	3.864
		21	0.00515	0.707	2.797	3.713

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		28	0.00204	0.549	2.575	3.551
		42	0.00109	0.386	2.415	3.251
R4 Roujan	Stream	global max	9.095		4.533	
		1	0.124	6.956	3.042	4.032
		2	0.0142	3.505	2.467	3.526
		4	0.0041	1.757	1.983	2.935
		7	0.00173	1.028	1.657	2.481
		14	0.00215	0.806	1.783	2.222
		21	0.00134	0.651	1.636	2.088
		28	0.000501	0.527	1.38	1.946
		42	0.000232	0.356	1.135	1.716

Crop: vines

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
PECmax		134.9		338.8	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU, Oct-Feb	0 h	26.9		72.7	
	24 h	26.1	26.5	72.6	72.7
	2 d	26.0	26.3	72.6	72.6
	4 d	26.0	26.1	72.5	72.6
	7 d	26.0	26.1	72.3	72.5
	14 d	25.8	26.0	72.0	72.3
	21 d	25.7	25.9	71.6	72.2
	28 d	25.6	25.8	71.3	72.0
	42 d	25.3	25.7	70.6	71.6

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU, Oct-Feb	0 h	23.4		62.9	
	24 h	22.6	23.0	62.9	62.9

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	2 d	22.6	22.8	62.9	62.9
	4 d	22.5	22.7	62.8	62.9
	7 d	22.5	22.6	62.6	62.8
	14 d	22.4	22.5	62.3	62.6
	21 d	22.3	22.4	62.0	62.5
	28 d	22.2	22.4	61.7	62.3
	42 d	21.9	22.3	61.1	62.0

Vines, FOCUS step 3 - early application window

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6 Thiva	ditch	global max	5.693		8.759	
		24 h	5.062	5.348	8.693	8.753
		2 d	4.605	5.084	8.522	8.736
		4 d	3.772	4.639	7.998	8.671
		7 d	2.248	3.95	7.127	8.503
		14 d	0.418	3.479	5.687	7.905
		21 d	0.122	2.686	4.894	7.258
		28 d	0.0613	2.072	4.389	6.758
		42 d	0.029	1.404	3.743	6.021
R1 Weiherbach	pond	global max	0.403		1.905	
		24 h	0.394	0.398	1.905	1.905
		2 d	0.388	0.395	1.905	1.905
		4 d	0.377	0.388	1.905	1.905
		7 d	0.375	0.381	1.904	1.905
		14 d	0.348	0.372	1.901	1.905
		21 d	0.324	0.36	1.896	1.904
		28 d	0.304	0.348	1.888	1.904
		42 d	0.269	0.327	1.867	1.902
R1 Weiherbach	Stream	global max	2.766		1.263	
		24 h	0.00123	1.829	0.848	1.097
		2 d	0.000302	0.917	0.859	0.96
		4 d	0.000105	0.535	0.619	0.862

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		7 d	0.000042	0.306	0.499	0.738
		14 d	0.000689	0.23	0.588	0.717
		21 d	0.000994	0.179	0.471	0.655
		28 d	0.000149	0.134	0.413	0.602
		42 d	0.000099	0.0896	0.347	0.528
R2 Porto	Stream	global max	3.706		2.1	
		24 h	0.000582	2.64	2.1	1.883
		2 d	0.000277	1.421	2.1	1.693
		4 d	0.0001	0.712	2.1	1.461
		7 d	0.000041	0.461	2.1	1.275
		14 d	0.000591	0.231	2.1	1.067
		21 d	0.00366	0.173	2.1	0.958
		28 d	0.000352	0.13	2.1	0.885
		42 d	0.000116	0.0865	2.1	0.789
R3 Bologna	Stream	global max	3.911		1.908	
		24 h	0.0257	2.401	1.434	1.81
		2 d	0.00487	1.985	1.172	1.676
		4 d	0.00152	1.011	0.938	1.443
		7 d	0.000605	0.58	0.779	1.224
		14 d	0.000218	0.35	0.763	1.056
		21 d	0.000124	0.233	0.627	0.943
		28 d	0.00429	0.198	0.555	0.858
		42 d	0.000811	0.152	0.485	0.744
R4 Roujan	Stream	global max	4.015		2.655	
		24 h	1.801	4.001	1.868	2.398
		2 d	0.0117	2.236	1.511	2.125
		4 d	0.00292	1.121	1.212	1.784
		7 d	0.00112	0.641	1.016	1.514
		14 d	0.000404	0.363	0.815	1.22
		21 d	0.00023	0.242	0.714	1.071
		28 d	0.000156	0.182	0.648	0.975
		42 d	0.000093	0.121	0.562	0.852

Vines, FOCUS step 3 - late application

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6 Thiva	ditch	global max	5.689		8.615	
		24 h	5.058	5.344	8.549	8.609
		2 d	4.601	5.08	8.379	8.593
		4 d	3.768	4.635	7.86	8.527
		7 d	2.246	3.947	7.002	8.36
		14 d	0.415	3.475	5.596	7.77
		21 d	0.12	2.682	4.839	7.135
		28 d	0.06	2.068	4.363	6.818
		42 d	0.0283	1.401	3.762	6.815
R1 Weiherbach	pond	global max	0.235		1.208	
		24 h	0.23	0.232	1.208	1.208
		2 d	0.226	0.23	1.207	1.208
		4 d	0.22	0.227	1.207	1.208
		7 d	0.213	0.222	1.204	1.208
		14 d	0.199	0.214	1.199	1.207
		21 d	0.186	0.207	1.194	1.207
		28 d	0.175	0.2	1.181	1.206
		42 d	0.156	0.188	1.208	1.205
R1 Weiherbach	Stream	global max	2.775		0.457	
		24 h	0.00154	0.595	0.315	0.396
		2 d	0.0007	0.298	0.25	0.344
		4 d	0.00025	0.149	0.194	0.284
		7 d	0.000107	0.0853	0.16	0.238
		14 d	0.000041	0.0427	0.125	0.19
		21 d	0.000024	0.0568	0.108	0.165
		28 d	0.000013	0.0427	0.0976	0.151
		42 d	0.000008	0.0285	0.084	0.141
R2 Porto	Stream	global max	3.719		0.664	
		24 h	0.000715	0.906	0.477	0.593
		2 d	0.000349	0.457	0.395	0.53
		4 d	0.000135	0.229	0.322	0.452
		7 d	0.000061	0.131	0.276	0.39
		14 d	0.000024	0.0655	0.228	0.323
		21 d	0.000014	0.055	0.302	0.307
		28 d	0.000009	0.0507	0.386	0.293
		42 d	0.000005	0.0395	0.256	0.299

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R3 Bologna	Stream	global max	3.911		2.115	
		24 h	0.0261	2.431	1.942	2.054
		2 d	0.00519	1.854	1.625	2.006
		4 d	0.00176	1.086	1.347	1.864
		7 d	0.000799	0.622	1.159	1.651
		14 d	0.000678	0.342	0.955	1.376
		21 d	0.00455	0.299	0.848	1.226
		28 d	0.000732	0.224	0.777	1.127
		42 d	0.000241	0.209	0.685	0.999
R4 Roujan	Stream	global max	4.428		2.258	
		24 h	0.012	3.992	1.462	1.987
		2 d	0.0049	2.05	1.138	1.722
		4 d	0.00175	1.027	0.871	1.401
		7 d	0.00077	0.588	0.702	1.152
		14 d	0.000288	0.294	0.535	0.889
		21 d	0.00016	0.196	0.455	0.759
		28 d	0.000106	0.168	0.405	0.678
		42 d	0.408	0.126	0.825	0.584

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 model(s), with appropriate $FOCUS_{gw}$ scenarios, according to FOCUS guidance. Model(s) used: (with version control no.(s)) FOCUS PELMO 4.4.3 Scenarios (list of names): Châteaudun, Piacenza, Porto, Sevilla, Thiva , Hamburg, Jokioinen, Kremsmünster, Sevilla Crop: tomatoes, strawberries, vines Median parent $DT_{50field}$ 123.1 d (normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58). K_{OC}: parent, arithmetic mean or median 278.9, $^1/_n$ = 0.827. Metabolite: M08 7-hydroxy (minor metabolite) Formation fraction: 0.8338 Geometric mean metbolite DT_{50lab} 8.1 d (normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58). K_{OC}: metabolite, arithmetic mean or median 103.2, $^1/_n$ =

	0.9292.
Application rate	Crop: tomatoes Crop interception: 2 · 80% Application rate: 250 g/ha. No. of applications: 2 Interval (d): 7 Application window: BBCH 55-89 Time of application (month or season): Early application: 5 weeks after emergence Late application: 3 d before harvest
	Crop: strawberries Crop interception: 2 · 60% Application rate: 250 g/ha. No. of applications: 2 Interval (d): 7 Application window: BBCH 61-89 Time of application (month or season): Early application: 4 weeks after emergence Late application: 1 d before harvest
	Crop: vines Crop interception: early appl. 2 · 70%; late appl. 70 + 85% Application rate: 250 g/ha. No. of applications: 2 Interval (d): 12 Application window: BBCH 61 -89 Time of application (month or season): Early application: 7 weeks after emergence Late application: 3 d before harvest

PEC_{gw} - FOCUS PELMO 4.4.3 modelling results (80th percentile annual average concentration at 1 m depth)

tomatoes

Scenario	Early application		Late application	
	Parent (µg/L)	M08 7-hydroxy (µg/L)	Parent (µg/L)	M08 7-hydroxy (µg/L)
Chateaudun	<0.001	<0.001	<0.001	<0.001
Piacenza	0.003	0.003	0.005	0.005
Porto	0.001	0.001	0.001	0.002
Sevilla	<0.001	<0.001	<0.001	<0.001
Thiva	<0.001	<0.001	<0.001	<0.001

strawberries

Scenario	Early application		Late application	
	Parent (µg/L)	M08 7-hydroxy (µg/L)	Parent (µg/L)	M08 7-hydroxy (µg/L)
Hamburg	0.017	0.012	0.026	0.017
Kremsmünster	<0.001	<0.001	<0.001	<0.001
Jokioinen	0.007	0.006	0.010	0.007
Sevilla	<0.001	<0.001	<0.001	<0.001

vines

Scenario	Early application		Late application	
	Parent (µg/L)	M08 7-hydroxy (µg/L)	Parent (µg/L)	M08 7-hydroxy (µg/L)
Chateaudun	0.004	0.003	0.003	0.002
Hamburg	0.015	0.010	0.009	0.007
Kremsmunster	0.014	0.008	0.008	0.005
Piacenza	0.028	0.015	0.022	0.014
Porto	0.004	0.006	0.005	0.006
Sevilla	<0.001	<0.001	<0.001	<0.001
Thiva	<0.001	<0.001	<0.001	<0.001

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

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	not applicable
Photochemical oxidative degradation in air ‡	DT_{50} of 20.78 hours derived by the Atkinson model (version 1.91). OH (12 h) concentration assumed = $1.5 \cdot 10^6$
Volatilisation ‡	from plant surfaces (BBA guideline): no study performed
	from soil surfaces (BBA guideline): no study performed
Metabolites	None

PEC_{air}

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

$PEC_{(a)}$

Maximum concentration	No potential for long range transport

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.	Soil: fluopyram Surface Water: fluopyram Sediment: fluopyram Ground water: fluopyram, M08 7-hydroxy Air: fluopyram

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

Soil (indicate location and type of study)	No data available
Surface water (indicate location and type of study)	No data available
Ground water (indicate location and type of study)	No data available
Air (indicate location and type of study)	No data available

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

Species	Test substance	Time scale	Endpoint (mg/kg bw per dayay)	Endpoint (mg/kg feed)
Birds ‡				
Colinus virginianus	as	Acute	LD_{50} >2000	
	Preparation	Acute	No data	
Anas platyrhynchos	as	Short-term	>1643 nom	> 5000 nom
Colinus virginianus	as	Long-term	4.5 nom (NOAEL: 7.2 nom [1)])	50 nom (NOAEC: 80 nom [1)])
Mammals ‡				
rat	as	Acute	LD_{50} >2000	
rat	Preparation	Acute	LD_{50} >5000	
rat	as	Long-term	14.5 nom	220 nom
Additional higher tier studies ‡				
Not required				

1) population-relevant endpoint used only for the refined risk assessment

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

Tomato (S-EU), 2 x 250 g a.s./ha, interval 7 d

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Medium herbivorous bird	Acute	23.1	> 86	10
Insectivorous bird	Acute	18.9	> 105.7	10
Medium herbivorous bird	Short-term	12.2	> 135	10
Insectivorous bird	Short-term	12.1	> 136	10
Medium herbivorous bird	Long-term	6.44	0.7	5
Insectivorous bird	Long-term	12.1	0.37	5
Higher tier refinement (Birds) a) Choice of focal species according to EFSA, 2009 b) Standard refinement of PD according to (EFSA, 2009) and second refinement according to agreed size distribution approach for invertebrate prey with 0.83 large and 0.17 small invertebrates leading to a RUD_{mix} of 9.2 based on standard RUD from SANCO/4145/2000 (0.83 x 5.1 + 0.17 x 29) c) Refinement of RUD for frugivorous birds based on measured residue data: RUD (tomato, S-EU) = 1.0 d) Refinement of PT for insectivorous birds based on radiotracking data: Yellow wagtail: PT (S-EU) = 0.93 e) MAF and twa according to EFSA Journal (2008) d) calculation presented based on the tier 1 endpoint and additionally on the higher tier endpoint				

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Small insectivorous bird (BBCH >20) - Yellow wagtail	Long-term	1.91	**2.4/3.8**	5
Small granivorous bird (BBCH >50) - Linnet	Long-term	0.72	10	5
Small omnivorous (BBCH >50) - Woodlark	Long-term	0.70	10.3	5
Frugivorous bird (BBCH 71-89) – Crow (worst case)	Long-term	0.12	60	5
Tier 1– uptake via drinking water – Puddles and surface water (birds) Covered by calculation for scenario for representative use in vine				
Tier 1 – secondary poisoning (birds)				
Earthworm-eating bird	Long-term	0.70	6.43	5
Fish-eating bird	Long-term	0.002	2895	5
Tier 1 (Mammals)				
Medium herbivorous mammals	Acute	8.53	> 234	10
Medium herbivorous mammals	Long-term	2.37	6.1	5
Higher tier refinement (Mammals) Not required				
Tier 1– uptake via drinking water – Puddles and surface water Covered by calculation for scenario for intended use in vine				
Tier 1 – secondary poisoning (mammals)				
Earthworm-eating mammal	Long-term	0.89	16.3	5
Fish-eating mammal	Long-term	0.002	9417	5

[1] in higher tier refinement provide brief details of any refinements used (e.g. residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

Strawberry (N- and S-EU), 2 x 250 g a.s./ha, interval 7 d

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Medium herbivorous bird	Acute	23.1	> 86	10
Insectivorous bird	Acute	18.9	> 105.7	10
Medium herbivorous bird	Short-term	12.2	> 135	10
Insectivorous bird	Short-term	12.1	> 136	10
Medium herbivorous bird	Long-term	6.44	0.7	5
Insectivorous bird	Long-term	12.1	0.37	5

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Higher tier refinement (Birds) a) Choice of focal species according to EFSA Journal (2008) 734: 1-181, Appendix A b) Standard refinement of PD according to EFSA Journal (2008) 734: 1-181, Appendix A c) Refinement of RUD for frugivorous birds based on measured residue data: RUD (strawberry, EU) = 1.3 d) Refinement of PT for insectivorous birds based on radiotracking data: Yellow wagtail: PT (N-EU) = 0.93 e) MAF and twa according to EFSA Journal (2008) d) calculation presented based on the tier 1 endpoint and additionally on the higher tier endpoint				
Small insectivorous bird (BBCH >20) - Yellow wagtail	Long-term	1.91	**2.4/3.8**	5
Small omnivorous (BBCH >40) - Woodlark	Long-term	0.93	7.7	5
Frugivorous bird (BBCH 61-89) - Starling	Long-term	0.28	26	5
Tier 1– uptake via drinking water – Puddles and surface water Covered by calculation for scenario for representative use in vine				
Tier 1/refined – secondary poisoning (birds)				
Earthworm-eating bird	Long-term	1.39/ 0.32	**3.24** /14.06	5
Fish-eating bird	Long-term	0.002	2895	5
Tier 1 (Mammals)				
Medium herbivorous mammals	Acute	8.53	> 234	10
Medium herbivorous mammals	Long-term	2.37	6.1	5
Higher tier refinement (Mammals) Not required				
Tier 1– uptake via drinking water – Puddles and surface water Covered by calculation for scenario for intended use in vine				
Tier 1 – secondary poisoning (mammals)				
Earthworm-eating mammal	Long-term	1.78	8.2	5
Fish-eating mammal	Long-term	0.002	9417	5

[1] in higher tier refinement provide brief details of any refinements used (e.g. residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

Vine (N- and S-EU), 2 x 250 g a.s./ha, interval 12 d

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Insectivorous bird	Acute	18.9	> 105.7	10
Insectivorous bird	Short-term	12.1	> 136	10
Insectivorous bird	Long-term	12.1	0.37	5

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Higher tier refinement (Birds) a) Choice of focal species according to EFSA Journal (2008) 734: 1-181, Appendix A b) Standard refinement of PD according to EFSA Journal (2008) 734: 1-181, Appendix A c) Refinement of RUD for frugivorous birds based on measured residue data: RUD (grape, EU) = 2.6 d) Refinement of PT for insectivorous birds based on radiotracking data: Black redstart: PT (S-EU): 0.75 e) MAF and twa according to EFSA Journal (2008) d) calculation presented based on the tier 1 endpoint and additionally on the higher tier endpoint				
Small insectivorous bird (BBCH >20) – Black redstart	Long-term	0.69 1.58	10.4 **2.9/4.6**	5
Small granivorous (BBCH >40) – Linnet	Long-term	0.72	10	5
Small omnivorous (BBCH >40) – Woodlark	Long-term	0.70	10.3	5
Frugivorous bird (ripening) – Song trush	Long-term	0.60	12	5
Tier 1– uptake via drinking water – Puddles (scenario for representative use in vine covers also intended uses in tomato and strawberry)				
10 g bird (insectivorous)	Acute	135	23.1	10
300 g bird (medium herbivorous)	Acute	44	70.9	10
Tier 1– uptake via drinking water – surface water (scenario for intended use in vine covers also intended uses in tomato and strawberry)				
10 g bird (insectivorous)	Acute	$7.29\ 10^{-3}$	427846	10
300 g bird (medium herbivorous)	Acute	$2.38\ 10^{-3}$	1310504	10
Tier 1/ refined – secondary poisoning (birds) Refinement based on bioaccumulation study in earthworm: BAF $(BCF)_{earthworm}$ = 0.85				
Earthworm-eating bird	Long-term	1.80 0.41	**2.5** 10.98	5
Fish-eating bird	Long-term	0.0057	1270	5
Tier 1 (Mammals)				
Small herbivorous mammal	Acute	20.7	> 96.5	10
Small herbivorous mammal	Long-term	6.72	**2.2**	5
Higher tier refinement (Mammals) a) Choice of focal species according to EFSA Journal (2008) 734: 1-181, Appendix A b) Standard refinement of PD according to EFSA Journal (2008) 734: 1-181, Appendix A c) Refinement of MAF and ftwa based on measured residue data for grass for small herbivorous mammal. The ftwa value has been recalculated using the moving time window approach. The resulting combined MAF x ftwa value for the refined risk assessment of the small herbivorous mammal in vine is 0.61				
Small herbivorous mammal, vole (BBCH >40) – Common vole	Long-term	3.31	4.4[4]	5

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Small omnivorous mammal, mouse (BBCH >40) – Wood mouse	Long-term	0.49	29.7	5
Tier 1– uptake via drinking water – Puddles (scenario for intended use in vine covers also intended uses in tomato and strawberry)				
25 g mammal	Acute	71.5	>28	10
3000 g mammal	Acute	44.5	>44.9	10
Tier 1– uptake via drinking water – surface water (scenario for intended use in vine covers also intended uses in tomato and strawberry)				
25 g mammal	Acute	$3.86\ 10^{-3}$	>518135	10
3000 g mammal	Acute	$2.4\ 10^{-3}$	>833333	10
Tier 1 – secondary poisoning (mammals)				
Earthworm-eating mammal	Long-Term	2.29	6.3	5
Fish-eating mammal	Long-Term	0.003	4150	5

[1] in higher tier refinement provide brief details of any refinements used (e.g. residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.
[4] The risk assessment still contains several conservative assumptions, therefore the risk is considered low

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

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
C. variegatus	as	96 hr (static)	Mortality, EC_{50}	>0.98 mm
P. promelas	as	33 d (flow-through)	Length and morphological / behavioral effects, NOEC	0.135 mm
O. mykiss	Preparation	96 hr (flow-through)	Mortality, LC_{50}	>120 nom (>49.8 as nom)
Aquatic invertebrate				
C. virginica	as	48 h (static)	Mortality, EC_{50}	>0.44 mm [2)]
A. bahia	as	48 h (static)	Mortality, EC_{50}	>0.6 nom >0.5 mm [2,3)]
D. magna	as	21 d (static)	Reproduction, NOEC	1.25 nom 1.22 mm
D. magna	Preparation	48 h (static)	Mortality, EC_{50}	>100 nom (>41.5 as nom)

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (mg/L)
Sediment-dwelling organisms				
C. riparius	as	28 d (static, spiked water)	Emergence, NOEC	1.39 nom
L. plumulosus	as	10 d (static, spiked sediment)	LC_{50}	>100 mg as/kg mm [4)]
Algae				
Skeletonema costatum	as	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>1.13 mm >1.13 mm
P. subcapitata	Preparation	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	10.2 ai nom 17.4 ai nom
	Fluopyram-lactam	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>9.4 nom >9.4 nom
Higher plant				
Lemna gibba	as	14 d (static)	Fronds, EC_{50}	2.32 nom
Lemna gibba	Preparation	14 d (static)	Fronds, EC_{50}	6.8 nom
Microcosm or mesocosm tests				
not required				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether endpoints are presented as units of preparation or as
[2] effect concentration above practical limit of water solubility under test conditions; species not considered as relevant endpoint since no sublethal or lethal effects occured at this concentration (NOEC)
[3] used as most sensitive endpoint in risk assessment, surrogate LC_{50} based on 10% mortality in treatment
[4] second 28d test with spiked sediment for *L. plumulosus* (supplemental) resulted in $NOEC_{growth}$ of 38 mg as/kg

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

FOCUS Step1

Not required as FOCUS step 2 and 3 are presented

FOCUS Step 2

Tomato (S-EU) and Strawberry (N- and S-EU), 2 x 250 g a.s./ha, interval 7 d
crop interception: full canopy, 70%, region and season: South Europe, Oct. - Feb., 4% runoff

Test substance	N/S[1]	Organism[2]	Toxicity endpoint (mg/L)	Time scale	PEC[3]	TER	Annex VI Trigger[4]
as	N	Fish	>0.98	Acute	0.0207	**47.3**	100
as	N	Fish	0.135	Chronic	0.0207	**6.52**	10
as	N	Aquatic invertebrates	>0.5	Acute	0.0207	**24.2**	100

Test substance	N/S[1]	Organism[2]	Toxicity endpoint (mg/L)	Time scale	PEC[3]	TER	Annex VI Trigger[4]
as	N	Aquatic invertebrates	1.25	Chronic	0.0207	60.39	10
as	N	Algae	>1.13	Chronic	0.0207	54.6	10
as	N	Higher plants[5]	2.32	Chronic	0.0207	112	10
as	N	Sediment-dwelling organisms[6]	1.39	Chronic	0.0207	67.2	10

[1] indicate whether Northern of Southern
[2] include critical groups which fail at Step 1.
[3] indicate whether maximum or twa values have been used.
[4] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
[5] only required for herbicides
[6] consider the need for PEC_{sw} and PEC_{sed} and indicate which has been used

Tomato (S-EU) and Strawberry (N- and S-EU), 2 x 250 g a.s./há single load 0.2% of annual application rate, relevant for glasshouse uses

Test substance	N/S[1]	Organism[2]	Toxicity endpoint (mg/L)	Time scale	PEC[3]	TER	Annex VI Trigger4
as	N&S	Aquatic invertebrates	>0.5	acute	0.00033	>1515	100
as	N&S	Fish	0.135	Chronic	0.00033	409	10

[1] indicate whether Northern of Southern
[2] include critical groups which fail at Step 1.
[3] indicate whether maximum or twa values have been used.

Vine (N- and S-EU), 2 x 250 g a.s./ha, interval 12 d
crop interception: full canopy, 70%, region and season: North Europe, Oct. - Feb., 5% runoff

Test substance	N/S[1]	Organism[2]	Toxicity endpoint (mg/L)	Time scale	PEC[3]	TER	Annex VI Trigger[4]
as	N	Fish	>0.98	Acute	0.0269	**36.4**	100
as	N	Fish	0.135	Chronic	0.0269	**5.02**	10
as	N	Aquatic invertebrates	>0.5	Acute	0.0269	**18.6**	100
as	N	Aquatic invertebrates	1.25	Chronic	0.0269	46.5	10
as	N	Algae	>1.13	Chronic	0.0269	42.0	10
as	N	Higher plants[5]	2.32	Chronic	0.0269	86.3	10
as	N	Sediment-dwelling organisms[6]	1.39	Chronic	0.0269	51.7	10

[1] indicate whether Northern of Southern
[2] include critical groups which fail at Step 1.
[3] indicate whether maximum or twa values have been used.

[4] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
[5] only required for herbicides
[6] consider the need for PEC_{sw} and PEC_{sed} and indicate which has been used

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

Tomato (S-EU) and Strawberry (N- and S-EU), 2 x 250 g a.s./ha, interval 7 d

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity endpoint (µg/L)	Max. PEC[4] (µg/L)	TER	Annex VI trigger[5]
as	D6	ditch	Fish	Acute	>980	6.210	157.8	100
as	R2	stream	Fish	Acute	>980	2.854	343.4	100
as	R3	Stream	Fish	Acute	>980	7.510	130.5	100
as	R4	Stream	Fish	Acute	>980	9.095	107.8	100
as	D6	ditch	Fish	Chronic	135	6.210	21.7	10
as	R2	stream	Fish	Chronic	135	2.854	47.3	10
as	R3	Stream	Fish	Chronic	135	7.510	18.0	10
as	R4	Stream	Fish	Chronic	135	9.095	14.8	10
as	D6	ditch	Invertebrate	Acute	>500	6.210	**80.5**	100
as	R2	stream	Invertebrate	Acute	>500	2.854	175.2	100
as	R3	Stream	Invertebrate	Acute	>500	7.510	**66.6**	100
as	R4	Stream	Invertebrate	Acute	>500	9.095	**55.0**	100

[1] drainage (D1 - D6) and run-off (R1 - R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 2.
[4] indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used
[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

Vine (N- and S-EU), 2 x 250 g a.s./ha, interval 7 d

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity endpoint (µg/L)	Max. PEC[4] (µg/L)	TER	Annex VI trigger[5]
as	D6	ditch	Fish	Acute	>980	5.693	172.1	100
as	R1	Pond	Fish	Acute	>980	0.403	2432	100
as	R1	Stream	Fish	Acute	>980	2.775	353.2	100
as	R2	Stream	Fish	Acute	>980	3.719	263.5	100
as	R3	Stream	Fish	Acute	>980	3.911	250.6	100

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity endpoint (µg/L)	Max. PEC[4] (µg/L)	TER	Annex VI trigger[5]
as	R4	Stream	Fish	Acute	>980	4.428	221.3	100
as	D6	ditch	Fish	Chronic	135	5.693	23.7	10
as	R1	Pond	Fish	Chronic	135	0.403	335	10
as	R1	Stream	Fish	Chronic	135	2.775	48.7	10
as	R2	Stream	Fish	Chronic	135	3.719	36.3	10
as	R3	Stream	Fish	Chronic	135	3.911	34.5	10
as	R4	Stream	Fish	Chronic	135	4.428	30.5	10
as	D6	ditch	Invertebrate	Acute	>500	5.693	**87.8**	100
as	R1	Pond	Invertebrate	Acute	>500	0.403	1241	100
as	R1	Stream	Invertebrate	Acute	>500	2.775	180.2	100
as	R2	Stream	Invertebrate	Acute	>500	3.719	134.5	100
as	R3	Stream	Invertebrate	Acute	>500	3.911	127.9	100
as	R4	Stream	Invertebrate	Acute	>500	4.428	112.9	100

[1] drainage (D1 - D6) and run-off (R1 - R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 2.
[4] indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used
[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

FOCUS Step 4

Data gap for step 4 calculations and or higher tier effects data to refine the aquatic risk assessment
On the basis of a TER calculation with the LC_{50} surrogate values for *Americamysis bahia* in combination with the standard safety factor of 100 is conservative leaving the possibility for a refined evaluation (e.g. considering further reduction of the safety factor).

Bioconcentration

	Active substance	Metabolite3
log $P_{O/W}$	pH 7 3.3	--
Bioconcentration factor (BCF)[1] ‡	18 (whole fish, wet weight) 16 (whole fish, normalized to 6% lipid content)	
Annex VI Trigger for the bioconcentration factor	100	

Clearance time (days) (CT_{50})	3.4 days (at 6 µg as/L)/ 4.2 days (at 60 µg as/L) for whole fish	
(CT_{90})		
Level and nature of residues (%) in organisms after the 14 day depuration phase	Level at steady state: 0.581 mg/kg 14C (at 6 µg as/L) 4.75 mg/kg 14C (at 60 µg as/L) 75 % (nominal concentration of 6.0 µg/L) 80 % (nominal concentration of 60 µg/L) of the radioactivity was depurated from whole fish	

[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 (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
as ‡	> 102.3 µg/bee	> 100 µg/bee
Preparation[1] Fluopyram SC 500 (41.6 % Fluopyram)	> 214 µg product/bee	> 200 µg product/bee
Metabolite 1	–	–
Field or semi-field tests		
Not required.		

[1] for preparations indicate whether endpoint is expressed in units of as or preparation

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

Crop and application rate Grape/Strawberries/Tomato2 x 0.5 l Fluopyram 500 SC/ha, 2 x 250 g a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
as	Contact	< 2.5	50
as	oral	< 2.5	50
Preparation	Contact	< 3	50
Preparation	oral	< 2.9	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	Endpoint	Effect (LR_{50} mL/ha[1])

Species	Test Substance	Endpoint	Effect (LR_{50} mL/ha[1])
Typhlodromus pyri ‡	Fluopyram SC 500	Mortality	>2000
Aphidius rhopalosiphi ‡	Fluopyram SC 500	Mortality	>2000

[1] for preparations indicate whether endpoint is expressed in units of as or preparation

Tomato (S-EU) and Strawberry (N- and S-EU), 2 x 250 g a.s./ha, interval 7 d

Test substance	Species	Effect (LR_{50} mL/ha)	HQ in-field	HQ off-field[1]	Trigger
Fluopyram SC 500	*Typhlodromus pyri*	>2000	<0.43	<0.031	2
Fluopyram SC 500	*Aphidius rhopalosiphi*	>2000	<0.43	<0.031	2

[1] indicate distance assumed to calculate the drift rate

Vine (N- and S-EU), 2 x 250 g a.s./ha, interval 12 d

Test substance	Species	Effect (LR_{50} mL/ha)	HQ in-field	HQ off-field[1]	Trigger
Fluopyram SC 500	*Typhlodromus pyri*	>2000	<0.43	<0.010	2
Fluopyram SC 500	*Aphidius rhopalosiphi*	>2000	<0.43	<0.010	2

[1] indicate distance assumed to calculate the drift rate

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (mL/ha)[1],[2]	Endpoint	% effect[3]	Trigger value
Aleochara bilineata	adult	Fluopyram SC 500, soil, 69 d	2000	Reproduction	-9.6%	50 %

[1] indicate whether initial or aged residues
[2] for preparations indicate whether dose is expressed in units of as or preparation
[3] indicate if positive percentages relate to adverse effects or not

Field or semi-field tests
not required

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	Endpoint[1]
Earthworms			
Eisenia fetida	as ‡	Acute 14 days; 5% peat	LC_{50} >1000 mg as/kg d.w.soil

Test organism	Test substance	Time scale	Endpoint[1]
Eisenia fetida	Preparation	Acute 14 days; 5% peat	LC_{50} >1000 mg product/kg d.w.soil (LC_{50} >414 mg as/kg d.w.soil)
Eisenia fetida	Preparation	Chronic 8 weeks, 5% peat	NOEC = 5.62 L product/ha NOEC = 27.31 mg product/ kg d.w.soil (NOEC = 11.42 mg a.s./ kg d.w.soil)
Other soil macro-organisms			
Hypoaspis aculeifer	Preparation	chronic, 14 days, 5% peat	NOEC 1000 mg product/kg d.w.soil (NOEC 415 mg as/kg d.w.soil)
Collembola			
Folsomia candida	Preparation	chronic, 28 days, 5% peat	NOEC 250 mg product/kg d.w.soil (NOEC 103.8 mg as/kg d.w.soil)
Litter bag test			
Fluopyram SC 500	183 d duration, location Burscheid, Germany; 2 spray application with incorporation first one with 1535 g product/ha (=642 g a.s./ha) into the upper 10 cm soil layer to achieve plateau concentration of 428 µg a.s./kg TS; second spray application 13 days later with 717 g product/ha (= 300 g a.s./ha)		76 % degradation in control after 133 days (trigger is 60 %) wheat straw degradation in treated plots (rel. to control): after 30 days: 114.4 % (n.s.) after 92 days: 106.0 % (n.s.) after 173 days: 101.0 % (n.s.) NOEC ≥ 0,514 mg a.s./kg TS
Soil micro-organisms			
Nitrogen mineralisation	as ‡	28 d	< 25% effect at day 28 at 3.33 mg as/kg d.w.soil (2.5 kg as/ha)
	Fluopyram SC 500	28 d	< 25% effect at day 28 at 0.336 mg product/kg d.w.soil (5 L product/ha)
Carbon mineralisation	as ‡	28 d	< 25% effect at day 28 at 3.33 mg as/kg d.w.soil (2.5 kg as/ha)
	Fluopyram SC 500	28 d	< 25% effect at day 28 at 0.336 mg product/kg d.w.soil (5 L product/ha)
Field studies[2]			
not required			

[1] indicate where endpoint has been corrected due to log $P_{o/w}$ > 2.0 (e.g. LC_{50corr})
[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above and earthworm field studies

Toxicity/exposure ratios for soil organisms

Tomato (S-EU), 2 x 250 g a.s./ha, interval 7 d

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia foetida	as ‡	Acute	0.1707	>5858	10
Eisenia foetida	Preparation	Acute	0.1707	>2425	10
Eisenia foetida	Preparation	Chronic	0.1707	66.9	5
Other soil macro-organisms					
Hypoaspis aculeifer	Preparation	Chronic, 14 d	0.1707	2431	5
Folsomia candida	Preparation	Chronic, 28 d	0.1707	608	5

[1] to be completed where first Tier triggers are breached
[2] plateau PEC

Strawberry (N- and S-EU), 2 x 250 g a.s./ha, interval 7 d

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia foetida	as ‡	Acute	0.3414	>2929	10
Eisenia foetida	Preparation	Acute	0.3414	>1213	10
Eisenia foetida	Preparation	Chronic	0.3414	33.4	5
Other soil macro-organisms					
Hypoaspis aculeifer	Preparation	Chronic, 14 d	0.3414	1216	5
Folsomia candida	Preparation	Chronic, 28 d	0.3414	304	5

[1] to be completed where first Tier triggers are breached
[2] plateau PEC

Vine (N- and S-EU), 2 x 250 g a.s./ha, interval 12 d

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia foetida	as ‡	Acute	0.4380	>2283	10
Eisenia foetida	Preparation	Acute	0.4380	>945	10
Eisenia foetida	Preparation	Chronic	0.4380	26.1	5
Other soil macro-organisms					
Hypoaspis aculeifer	Preparation	Chronic, 14 d	0.4380	947	5
Folsomia candida	Preparation	Chronic, 28 d	0.4380	237	5

[1] to be completed where first Tier triggers are breached
[2] plateau PEC

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

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (mg as/ha)[2] vegetative vigour	ER_{50} (mg as/ha)[2] emergence	Exposure[1] (mg as/ha)[2]	TER	Trigger
Beta vulgaris	Fluopyram SC 500	>250		13.9 (2.77%) 40.1 (8.02%)	>18 >6.2	5
Fagopyrum esculentum	Fluopyram SC 500		>500	13.9 (2.77%) 40.1 (8.02%)	>36 >12.5	5

[1] based on Ganzelmeier drift data for field crops (tomato, strawberry) with 2.77% at 1m and for vine with 8.02% at 3 m distance

[2] dose is expressed in units of as

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

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

Test type/organism	endpoint
Activated sludge	>10000 mg a.s./L
Pseudomonas sp.	

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

Compartment	
soil	fluopyram
water	fluopyram
sediment	fluopyram
groundwater	fluopyram

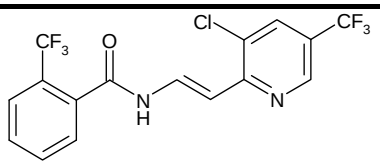
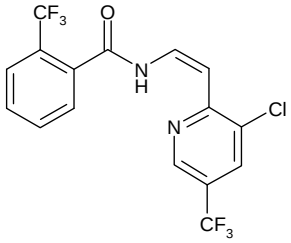
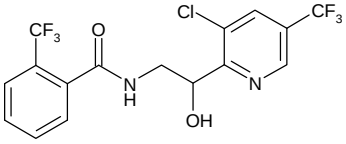
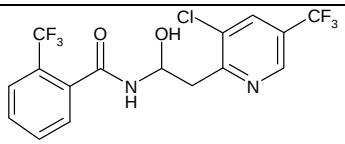
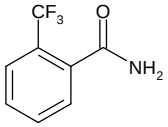
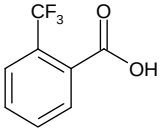
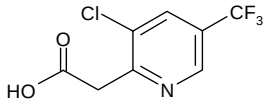
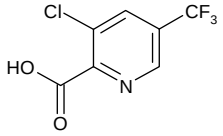
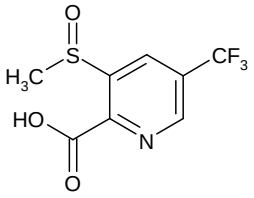
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

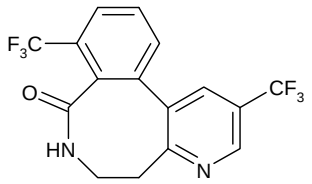
	RMS/peer review proposal
Active substance	R 51-53* (H411according CLP-VO 1272/2008) * based on NOEC = 0.135 mg a.s./L (*P. promelas*, 33 d, flow trhough)

RMS/peer review proposal

Preparation	R 51-53* (H411 according CLP-VO 1272/2008) * based on E_rC_{50} von 8,1 mg/L (*Lemna gibba*)

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula
Fluopyram-E-olefine (M02)	*N*-{(*E*)-2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]vinyl}-2-(trifluoromethyl)benzamide	
Fluopyram-Z-olefine (M03)	*N*-{(*Z*)-2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]vinyl}-2-(trifluoromethyl)benzamide	
Fluopyram-7-hydroxy (M08)	*N*-{2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]-2-hydroxyethyl}-2-(trifluoromethyl)benzamide	
Fluopyram-8-hydroxy (M18)	*N*-{2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]-1-hydroxyethyl}-2-(trifluoromethyl)benzamide	
Fluopyram-benzamide (M25)	2-(trifluoromethyl)benzamide	
Fluopyram-benzoic acid (M33)	2-(trifluoromethyl)benzoic acid	
Fluopyram-pyridyl-acetic acid Fluopyram-PAA (M40)	[3-chloro-5-(trifluoromethyl)pyridin-2-yl]acetic acid	
Fluopyram-pyridyl-carboxylic acid Fluopyram-PCA (M43) (AE C657188)	3-chloro-5-(trifluoromethyl)-2-pyridinecarboxylic acid	
fluopyram-methyl-sulfoxide (M45) (AE 1344122)	3-(methylsulfinyl)-5-(trifluoromethyl)-2-pyridinecarboxylic acid	

AE C656948–lactam (M47)	2,9-bis(trifluoromethyl)-6,7-dihydropyrido[2,3-*e*][2]benzazocin-8(5*H*)-one	

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

ABBREVIATIONS

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

GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
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
LLNA	local lymphe node assay
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration

NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen phosphorous detector
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RBC	Red blood cell
REACH	Registration, Evaluation, Authorisation of CHemicals
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertanty factor
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule

WHO	World Health Organisation
wk	week
yr	year