Conclusion regarding the peer review of the pesticide risk assessment of the active substance

fluazinam.

Finalised: 26 March 2008

SUMMARY

Fluazinam is one of the 79 substances of the third stage Part A of the review programme covered by Commission Regulation (EC) No 1490/2002[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU-Commission a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the EU-Commission.

Austria being the designated rapporteur Member State submitted the DAR on fluazinam in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 3 January 2006. The peer review was initiated on 23 June 2006 by dispatching the DAR for consultation of the Member States and the sole applicant ISK Biosciences Europe. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed on during a written procedure in May 2007. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in July and October 2007.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States February-March 2008 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as fungicide as proposed by the notifier which comprises foliar spraying to potatoes against late blight and tuber blight (*Phytophtora infestans*). Full details of the GAP can be found in the attached end points.

The representative formulated product for the evaluation was “Fluazinam 500SC”, a suspension concentrate (SC) containing 500 g/L fluazinam.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible. Adequate methods are available to monitor all compounds given in the respective

[1] OJ No L 224, 21.08.2002, p. 25, as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19)

residue definitions for monitoring for food/feed of plant origin, for environmental matrices and for body fluids and tissues.

Concerning the mammalian toxicology, the toxicokinetic studies have shown that oral absorption of fluazinam was 35% of the administered dose. In the acute studies, fluazinam was harmful by inhalation (Xn, R20), severely irritating to the eyes (Xi, R41) and skin sensitizer (R43).
The liver was the target organ in repeat dose studies with rats, mice and dogs. Some haematological changes were also observed in dogs, and the increased vacuolation of white matter in brain and spinal cord observed at high doses was demonstrated to be directly related to one impurity. Therefore it was agreed that the level of this impurity in the technical specification should not exceed the amount present in the toxicological batches, i.e. 0.2%. Based on the effects observed in the skin in the repeat dose study by dermal administration, the classification Xi, R38 Irritating to the skin was proposed for fluazinam. In the genotoxicity studies, no mutagenic potential was observed *in vitro* or *in vivo*. There was no carcinogenic potential in long term studies. In the reproduction studies, the fertility parameters and the offspring were not affected, but the indications of teratogenicity in the rat studies led to the proposal of classification Reprotox. Cat. 3, R63 Possible risk of harm to the unborn child. No adverse effect on the nervous system was observed in specific neurotoxicity studies with rats.
The relative toxicity of the plant metabolite trifuoro-acetic acid (TFAA) in comparison with fluazinam could not be established based on the available data.
The acceptable daily intake (ADI) is 0.01 mg/kg bw/day, the acute reference dose (ARfD) 0.07 mg/kg bw and the acceptable operator exposure level (AOEL) 0.004 mg/kg bw/day, all derived with the use of a safety factor 100. The dermal absorption values were 1.5% for the concentrate and 7% for the dilution. The operator exposure estimate is below the AOEL according to the German model when personal protective equipment is used, and the worker exposure estimates (during crop inspection or harvesting) are below the AOEL with the use of personal protective equipment.

Based on appropriate metabolism studies, the metabolism of fluazinam in potatoes is clearly elucidated. Parent compound, AMPA-FLUAZINAM and AMGT are present at harvest in potato tubers at low but comparable amounts and are included in the residue definition for risk assessment. A further degradation product was identified as TFAA. This metabolite is present at very low levels in potato tubers but also in rotational crops. As information on its toxicological properties is lacking, the proposed residue definition is provisional.
For enforcement, the residue definition can be restricted to parent compound. Supervised residue trials show that the MRL for potatoes can be set at the LOQ (limit of quantification level).
Livestock exposure to fluazinam residues is very low and the setting of a residue definition and MRLs in animal products is not necessary.
Under restriction of the information to be provided on the toxicological relevance of TFAA and if appropriate on the actual consumer exposure to this metabolite, no dietary risk is expected resulting from the representative use of fluazinam in potatoes.
It must be noted that the issue related to TFAA is a generic issue and potentially concerns a range of active substances containing a trifluoromethyl moiety.

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Under dark aerobic conditions at 20 ºC, fluazinam is medium to high persistent in soil. Substitution of phenyl ring chlorine by hydroxyl in fluazinam yields the major soil metabolite HYPA that was shown to be moderate to high persistent under these conditions. Other minor metabolites identified resulted from the reduction of the phenyl nitro groups to form the corresponding anilines. In the experiment performed in the most recent study (1soil) up to 14 minor metabolites were found and none of them individually exceeded 4.7 % AR. Metabolites resulting from the cleavage of the bridging amino group have not been identified in any of the available studies. After 90 d non extractable residues reached levels of 16.7 – 50.5 % AR and mineralization was almost negligible.

Fluazinam was low to moderate persistent under dark anaerobic conditions due to the relatively rapid reduction of the nitro groups to form the MAPA, AMPA-FLUAZINAM and DAPA metabolites. Higher amounts of non extractable residues were formed under these conditions.

Photolysis was shown to contribute to the degradation of fluazinam in soil. HYPA and AMPA-FLUAZINAM are found as minor photolysis metabolites.

There are field dissipation studies available in UK (two sites), Germany (four sites) and USA (four sites). USA field trials were considered not relevant for EU conditions and were not used in the risk assessment. The potential effect of photolysis on the degradation of fluazinam in these field trials was discussed in the experts' meeting. The meeting agreed that the kinetic parameters derived from the field trials were not appropriate for use in environmental modelling and that new FOCUS PEC_{SW} and FOCUS PEC_{GW} will need to be calculated on basis of laboratory data. Furthermore, since the studies were performed on bare soil they were not considered representative of the uses proposed. Therefore new PEC soil calculation using the longest laboratory half life and application every two years for potato was regarded as necessary by the meeting. After the experts meeting, new PEC soil have been presented by the rapporteur Member State in an updated addendum to B.8 following the parameters agreed by the meeting.

According batch soil adsorption / desorption studies available fluazinam may be considered slight to low mobile and HYPA low to medium mobile.

Fluazinam may be considered stable at pH 4 and it is rapidly hydrolysed at pH 7 and pH 9. The major hydrolysis metabolite at pH 7 and 9 was CAPA that is stable to hydrolysis under normal environmental conditions.

Aqueous photolysis may contribute to the environmental dissipation of fluazinam. Fluazinam is not readily biodegradable according the available study.

In water sediment systems fluazinam partitioned with the sediment and was converted to a number of metabolites through substitution of chlorine atom and reduction of nitro groups. Among these metabolites only AMPA-FLUAZINAM reached levels above 10 % in the sediment phase. Non extractable residues amounted up to 55 % AR after 100 d and mineralization was practically negligible. There are no indications that the amino bridge between the two rings is broken during the degradation. Dissipation rate of metabolite AMPA-FLUAZINAM was calculated with data of one of the systems. The rapporteur Member State provided in an addendum the whole system kinetic parameters for HYPA based on a multicompartmental fitting of the data of both systems. The

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rapporteur Member State identified shortcomings in the water/sediment study that do not invalidate it in its integrity but need to be considered when using the results for risk assessment.
PEC_{SW} for fluazinam and for the major sediment metabolite AMPA-FLUAZINAM were presented in the DAR for the representative use in potatoes. The input parameters used in the applicant's calculation for fluazinam were not agreed by the meeting. After the meeting, the rapporteur Member State presented new FOCUS PEC_{SW} and PEC_{SED} for Fluazinam and HYPA using the input parameters agreed by the meeting of experts in the updated addendum to B.8.
Potential ground water contamination by fluazinam and the major soil metabolite HYPA for the representative use in potatoes may be considered negligible with the available modelling.
Fluazinam may be relatively persistent in air but a high degree of uncertainty is associated to the estimation of its atmospheric half life. However, it is not volatile enough to perform an experimental measurement of its atmospheric photochemical stability.

The risk assessment followed the Guidance Document on Risk Assessment for Birds and Mammals (SANCO/4145/2000). It is not considered necessary to calculate the risk to herbivorous birds and mammals in potatoes as potato leaves are considered unpalatable. Therefore the risk to herbivorous birds and mammals is considered to be low. Based on the first tier risk assessment the risk to insectivorous birds and mammals can be regarded as low for the representative use of fluazinam evaluated. As the Log Pow of fluazinam exceeds 3, the risk to birds and mammals from secondary poisoning was assessed. The risk to fish-eating birds and mammals can be considered as low. Also the risk to earthworm eating birds can be considered as low, whereas as further refinement is still required to identify low risk for earthworm eating mammals. No risk is expected for birds or mammals from the ingestion of contaminated drinking water.
Fish was the most sensitive aquatic organisms on an acute and chronic time scale in the standard dataset. All scenarios were acceptable at FOCUSsw step 4, including a buffer zone of 10 m. The risk to aquatic invertebrates and algae is considered low at FOCUS Step 3 and Step 2 respectively. The risk to HYPA and G-504 is inconclusive due to lack of toxicity data. The risk to sediment dwelling organisms is concluded to be low, but risk assessment based on sediment concentrations is missing.
The risk for bees and NTA is considered low from the representative use of fluazinam. As for the earthworms the acute risk assessment indicated indicating a low acute risk to earthworms. Whereas the reproductive study on earthworms did not meet the Annex VI trigger, a field study with earthworms addressed the long term risk to earthworms. Given the $DT_{90field}$ in soil for fluazinam and the observed effects on earthworms and *A. rhopalosiphi*, a study on the effects on collembolan was submitted. The toxicity to collembolan triggered a litterbag study. At litterbag study was submitted bud not accepted as the exposure was to low. A data gap was identified for a new litterbag study, in which the new PECplateau is covered. In this study the presence of and effects on macro organisms should be checked.
The risk to soil non-target micro-organisms and non-target plants is considerer to be low for both fluazinam and HYPA.

Key words: Fluazinam, peer review, risk assessment, pesticide, fungicide

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BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000, as amended by Commission Regulation (EC) No 1095/2007 regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Fluazinam is one of the 79 substances of the third stage, part A, covered by the Regulation (EC) No 1490/2002 designating Austria as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Austria submitted the report of its initial evaluation of the dossier on fluazinam, hereafter referred to as the draft assessment report, received by EFSA on 3 January 2006. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 11(2) of the Regulation (EC) No 1490/2002 the revised version of the draft assessment report was distributed for consultation on 23 June 2006 to the Member States and the main applicant ISK Biosciences Europe as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives from Member States identified and agreed during a written procedure in May 2007 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in experts' meetings in July and October 2007. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in February-March 2008 leading to the conclusions as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR).

In accordance with Article 11(4) of the Regulation (EC) No 1490/2002, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as

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finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received;
- the resulting reporting table (rev. 1.1 of 18 June 2007)

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation;
- the evaluation table (rev. 2-1 of 4 March 2008).

Given the importance of the draft assessment report including its addendum (compiled version of February 2008 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Fluazinam is the ISO common name for 3-chloro-*N*-(3-chloro-5-trifluoromethyl-2-pyridyl)-*α,α,α*-trifluoro-2,6-dinitro-*p*-toluidine (IUPAC)

Fluazinam belongs to the class of pyridine fungicides. Fluazinam is a fungicide with protective action with activity against fungi from the class of *Oomycetes*. It uncouples mitochondrial oxidative phosphorylation, inhibiting spore germination, hyphal penetration, growth and sporulation. Fluazinam is used to control grey mould and downy mildew on vines; apple scab; southern blight and white mould on peanuts and late blight and tuber blight on potatoes.

The representative formulated product for the evaluation was "Fluazinam 500SC", a suspension concentrate (SC) containing 500 g/L fluazinam, registered under different trade names in Europe.

The representative uses evaluated comprise foliar spraying against *Phytophtora infestans* (late blight and tuber blight) in potatoes before the disease attack, up to growth stage of BBCH 95-97, in all EU countries, up to a maximum 10 applications at a maximum individual application rate per spray of 200 g a.s./ha, with an interval of 7 to 10 days between applications.

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SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of fluazinam is 960 g/kg. No FAO specifications exist.

The rapporteur Member State assessed the technical materials originating from three alternative manufacturing locations according to guidance document SANCO/10597/2003 –rev. 7 and considered them to be equivalent.

The experts of the PRAPeR 31 meeting identified a data gap for justification or data to support the proposed level for one impurity, and also justification for the presence of some impurities in the technical specification or a revised specification. It should be noted that the meeting indicated that a revised specification without these impurities would be acceptable. The rapporteur Member State and the PRAPeR 29 meeting identified impurity 5[2] as relevant in the technical active substance and proposed a limit of 0.2% in the technical specification.

However, since clarification is required with respect to certain impurities concerning the proposed maximum levels in the technical material, the specification for the technical material as a whole should be regarded as provisional for the moment.

Beside the specification 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 fluazinam or the respective formulation.

However, the following data gaps were identified by the experts of PRAPeR 31 meeting:

- to address pH dependence of log P_{ow}
- the content of the relevant impurity and the pourability before and after storage must be determined in the 2 years shelf life study

The main data regarding the identity of fluazinam and its physical and chemical properties are given in appendix 1.

Adequate analytical methods (HPLC-UV) are available for the determination of fluazinam in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material. An analytical method for the determination of the relevant impurity in the formulation is also available.

Sufficient test methods and data relating to physical, chemical and technical properties and analytical methods are available to ensure that quality control measurements of the plant protection product are possible.

Adequate methods are available to monitor fluazinam residues in food/feed of plant origin and environmental matrices, however an ILV for LC-MS/MS plant method is required.

Several methods are available to monitor residues of fluazinam in plant matrices with a LOQ 0.01 mg/kg for each matrix.

[2] Impurity 5: 5-chloro-*N*-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-4,6-dinitro-*o*-toluidine

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The German modular multi-method DFG S19 was considered by the experts of PRAPeR 31 meeting not suitable as an enforcement method for the determination of residues of fluazinam in matrices of plant origin (potatoes, grapes and wine) based on additional data from a German ring test.
Adequate methods are available to determine residues of fluazinam in soil with a LOQ of 0.01 mg/kg, in water (drinking water, groundwater, surface water) with a LOQ of 0.1 µg/L and in air with a LOQ of 1 µg/m³.
HPLC-MS/MS methods are available to monitor residues of fluazinam in food of animal origin (milk, eggs, meat, liver, fat and bovine blood) with a LOQ of 0.01 mg/kg.

Since fluazinam is not classified as toxic, the available analytical methods for the determination of fluazinam residues in body fluids and tissues are considered additional information.

2. Mammalian toxicology

Fluazinam was discussed by the experts in mammalian toxicology in July 2007 (PRAPeR 29, Round 6). As the actual levels of some impurities in the toxicological batches and their toxicological relevance were unknown, the experts agreed that the batches could not be concluded as being representative of the technical specification (see also 2.8).
EFSA notes: the notifier provided the rapporteur Member State with a statement on the levels of impurities in the technical specification and in the toxicological batches (evaluated in the addendum rev.3 to Volume 3 of December 2007, but not peer-reviewed).

2.1. Absorption, Distribution, Excretion and Metabolism (Toxicokinetics)

The extent of oral absorption was discussed in the expert meeting. Two additional biliary excretion studies presented in the addendum (June 2007) showed a higher oral absorption of 48%, but the experts agreed that the worst case value should be kept, i.e. 35% of oral absorption from the initial studies.
The highest concentrations at 24 h were detected in fat, liver and kidneys, with a low potential for bioaccumulation. The excretion occurred via faeces (>88 %), and also via urine (2 – 4 %). The metabolic pathway of fluazinam in rats involves reduction of one or both nitro groups (to form AMPA-FLUAZINAM[3] or DAPA[4]) without metabolic cleavage of the two rings, and conjugations.

2.2. Acute toxicity

Fluazinam was of low acute oral and dermal toxicity in rats (oral LD_{50} values ≥ 4100 mg/kg bw, dermal LD_{50} >2000 mg/kg bw). For the toxicity by inhalation, the experts agreed that the new study provided in the addendum (June 2007) was more reliable, giving a LC_{50} >1.1 mg/L. This was not the

[3] AMPA-FLUAZINAM: 2-(6-amino-3-chloro-α,α,α-trifluoro-2-nitro-*p*-toluidino)-3-chloro-5-(trifluoromethyl)pyridine
[4] DAPA: 3-chloro-2-(2,6-diamino-3-chloro- *α,α,α*-trifluoromethyl-*p*-toluidino)-3-chloro-5-(trifluoromethyl)pyridine

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highest dose technically achievable and a range-finding study showed a high mortality at 4 mg/L. According to this, the proposed classification was **Xn, R20 Harmful by inhalation**.

Fluazinam was mildly irritating to the skin and severely irritating to the eyes, and caused skin sensitisation in two tests (Maximisation test and Buehler-Test). The resulting proposal for classification is **Xi, R41 Severely irritating to the eyes** and **Xi, R43 May cause sensitisation by skin contact**.

2.3. SHORT TERM TOXICITY

Repeated oral administration of fluazinam was performed in rats, mice and dogs. The liver was the target organ in most of the studies with increased weights and periacinar hypertrophy.

In studies with rodents, the agreed NOAELs were 5.21 mg/kg bw/day in the 4-week rat study, 4.1 mg/kg bw/day in the 13-week rat study, and 7.9 mg/kg bw/day in the 4-week mouse studies. Increased vacuolation of white matter in brain and spinal cord was observed at high dose in mice (607 mg/kg bw/day) but this effect was concluded to be due to an impurity (see 2.8).

In the 4-week and 13-week dog studies, the NOAELs for liver effects were 5 and 10 mg/kg bw/day. A dystrophy of the pigment epithelium of the tapetal fundus in the retina was observed in the majority of the animals including controls, with evidence of reversibility in a supplementary 11-week oral study (200 mg/kg bw/day) with a recovery period of 5 weeks. In the 52-week dog study, no eye pigmentation and no lesion of the retina were observed up to 50 mg/kg bw/day. The agreed NOAEL was 1 mg/kg bw/day, based on haematological changes, increased liver weight, liquefied contents of the gastro-intestinal tract, and mucosal lymphoid hyperplasia of the stomach. The two last findings were assumed to be due to irritative properties of fluazinam. Vacuolation of white matter in brain and spinal cord was also observed at the high dose but attributed to the presence of one impurity (see 2.8).

Dermal administration to rats for 3 weeks revealed changes in clinical chemistry parameters (increased AST) and histological changes in the skin (acanthosis, dermatitis) at the low dose. Based on these dermal effects, the experts agreed to propose classification with **Xi, R38 Irritating to skin**.

2.4. GENOTOXICITY

Mutagenicity assays performed *in vitro* included gene mutation tests in bacteria (*S. typhimurium* and *E.coli*) and in mammalian cells (mouse lymphoma), a chromosomal aberration test in mammalian cells (Chinese hamster lung fibroblasts) and a DNA repair test in bacteria (*Bacillus subtilis*). All the results were negative, showing that fluazinam has no genotoxic potential *in vitro*.

In the *in vivo* micronucleus test, no induction of micronuclei could be observed, therefore no evidence of genotoxic potential *in vivo* has been shown.

2.5. LONG TERM TOXICITY

In the two chronic/carcinogenicity studies with rats, the main changes were observed in the liver, pancreas, lung, lymph nodes and testes. No increased incidence of tumours was shown. The resulting overall NOAEL is 1.9 mg/kg bw/day.

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In the two long term studies with mice, the NOAEL for general toxicity is 1.12 mg/kg bw/day based on effects in the liver. An increased incidence of liver cell tumours (adenomas and carcinomas) was observed in males at 107 mg/kg bw/day and above, and was within the historical control range in the highest dose group. In addition, vacuolation of the white matter in the brain and cervical spinal cord was observed in both sexes at dose levels of 107 mg/kg bw/day and above (but attributed to the presence of one impurity, see 2.8).

2.6. REPRODUCTIVE TOXICITY

In a rat two-generation study, the parental NOAEL was 1.5 mg/kg bw/day based on periacinar hepatocytic fatty changes in males. The reproductive NOAEL was 7.26 mg/kg bw/day based on a decreased number of implantation sites and mean litter size in the second generation. The same value was agreed for the offspring NOAEL, i.e. 7.26 mg/kg bw/day, based on a decreased pup weight during lactation.

In the two rabbit teratology studies, similar maternal NOAELs were obtained from both studies and the experts agreed for the value of 4 mg/kg bw/day (from the second study). For the foetal development, the NOAEL was 1 mg/kg bw/day in the first study (LOAEL 3 mg/kg bw/day) based on delayed ossification, and 7 mg/kg bw/day in the second study (LOAEL 12 mg/kg bw/day) based on litter losses, skeletal abnormalities and placental abnormalities.

One rat teratology study was presented in the DAR, and an additional study was provided in the addendum (June 2007). The agreed maternal NOAEL was 10 mg/kg bw/day based on a decreased body weight gain in both studies. Even though there was no indication of teratogenicity in the second study but reduced ossification, the incidence of cleft palates in three litters in the first study at the highest dose level (250 mg/kg bw/day) were considered as significant and lead to the proposed classification **Xn, Toxic to reproduction category 3, R63 Possible risk of harm to the unborn child**. The agreed developmental NOAEL was also 10 mg/kg bw/day based on incomplete ossification at the mid dose level.

2.7. NEUROTOXICITY

In both acute and subchronic (13-week) neurotoxicity studies with rats, no neurotoxic effect was observed up to the highest dose tested (2000 mg/kg bw in acute, 69 mg/kg bw/day in subchronic administration). The NOAEL for systemic toxicity was 50 mg/kg bw in the acute study, and 21 mg/kg bw/day in the subchronic study.

2.8. FURTHER STUDIES

Metabolites:

The metabolites HYPA (**G-450**[5]**)** and MAPA (**G-525**[6]**)** were detected in liver, kidney, muscle, fat and eggs of laying hens but not in rat metabolism. HYPA was slightly more acutely toxic than fluazinam

[5] HYPA: 5-(3-chloro-5-trifluoromethyl-2-pyridylamino)- α,α,α- trifluoro-4,6-dinitro-*o*-cresol

[6] MAPA: 2-chloro-6-(3-chloro-5-trifluoromethyl-2-pyridylamino)-α,α,α--trifluoro-5-nitro-*m*-toluidine

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after oral administration (mouse LD_{50} 331 mg/kg bw) whereas MAPA showed only low acute oral toxicity (mouse LD_{50} > 5000 mg/kg bw).
In a first test *in vitro*, HYPA was mutagenic towards *S. typhimurium* TA98 without metabolic activation. In a second Ames test, HYPA showed no evidence of mutagenic activity, either in the presence or absence of metabolic activation. *In vivo* tests showed that HYPA does not induce micronuclei in the bone marrow cells of male and female mice.
In a bacterial reverse mutation test, MAPA did not show mutagenic activity at any dose level.

The metabolite **TFAA**[7] is found in primary and rotational crops but not in the rat metabolism. It has been classified by ECB in 1979 (2nd ATP) as Xn; R20 – C; R35 for the toxicological hazards. However, recent literature indicates a potentially higher acute oral toxicity than fluazinam, and possible teratogenic effects. The same metabolite has been discussed by the Scientific Committee for Plants for the new active substance flurtamone (included in Annex I). They concluded that the available toxicological information was still insufficient. Additional information was provided and evaluated by the Standing Committee on the Food Chain and Animal Health (4th July 2003), where one MS considered that the relevance of this metabolite needs to be addressed further when granting authorisations at MS level. In the case of fluazinam, the experts agreed to set a data gap for the applicant to address the toxicological properties of the plant metabolite TFAA, also in comparison with the toxicity of fluazinam.
EFSA notes: the notifier submitted to the rapporteur Member State in November 2007 a toxicological comparison between fluazinam and TFAA (evaluated by the rapporteur Member State in the addendum rev.3 to Volume 3 of December 2007, but not peer-reviewed), and in January 2008 a developmental toxicity study with TFAA (not peer-reviewed).

Impurities:
Based on the available information (some acute toxicity and mutagenicity tests, limited information about the levels in the toxicological batches), the toxicological relevance of some impurities could not be concluded. More specifically, the toxicological effects of the **impurity-5**[8] were discussed by the experts. The single oral administration to male mice at 5 mg/kg bw caused clinical signs, decreased body weights, and the animals were killed 24h after dosing. Necropsy findings included increased brain weights, oedema of the brain and vacuolation of white matter in the brain. In a comparative neurotoxicity study with mice, rats and dogs, decreased spontaneous motor activity was observed in mice and rats, but no gross lesions were present in mice or dogs. In mice and rats, the vacuolation of white matter in the brain was minimal and diffuse, whereas it was only trace and focal in dogs.
The experts agreed that the impurity-5 was of toxicological relevance, demonstrated to be responsible for the vacuolation of the white matter in rats, mice and dogs, with a lowest effect level of 0.1 mg/kg bw/day seen in the 52-week study in dogs. With the available information on toxicological batches (addendum to Vol.4, June 2007), the experts concluded that it had been tested up to 0.2%, which was considered the acceptable limit for the technical specification.

[7] TFAA: trifluoroacetic acid
[8] Impurity-5: 5-chloro-*N*-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-4,6-dinitro-*o*-toluidine

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2.9. MEDICAL DATA

In manufacturing plant personnel and farmers, cases of allergic contact dermatitis were reported. Symptoms typically develop over a few hours to several days following exposure. Affected individuals make a full recovery within a short period of time. A case of occupational asthma has been reported in a worker of a fungicide formulation plant exposed to powdered fluazinam. Exposure conditions were very extreme: exhaust ventilation was shut off and no indication of personal respiratory equipment is mentioned in the report. It is noted that in the currently notified fluazinam TGAI manufacturing sites, the production line is completely sealed during synthesis of the product.

2.10. ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) AND ACUTE REFERENCE DOSE (ARFD)

ADI

The agreed **ADI was 0.01 mg/kg bw/day** based on the 2-year mouse study, supported by the 52-week dog study and applying a safety factor of 100.

ARfD

For the setting of the acute reference dose, the experts considered the available developmental studies in rats and rabbits. They agreed that the effects in the second rabbit study were more critical, leading to an **ARfD of 0.07 mg/kg bw** with the use of a safety factor of 100.

EFSA notes: This provides a margin of safety of 3571 with regard to the dose level where teratogenic effects were observed (250 mg/kg bw/day), and 714 with regard to the no observed effect level for teratogenic effects leading to the proposal for classification (50 mg/kg bw/day).

AOEL

The experts agreed to use the NOAEL of the 52-week dog study (1 mg/kg bw/day), supported by the rabbit developmental study. With the agreed correction for oral absorption (35%) and the use of a safety factor of 100, the resulting **AOEL was 0.004 mg/kg bw/day** (rounded value).

2.11. DERMAL ABSORPTION

Based on *in vivo* and *in vivo* dermal absorption studies with the SC formulation concentrate containing 500 g fluazinam/L (equivalent to the representative formulation "Fluazinam 500 SC"), the agreed values were 1.5% for the concentrate and 7% for the dilution.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative formulation "Fluazinam 500 SC" is a suspension concentrate containing 500 g/L (38.8 %) fluazinam for use on potatoes.

Operator

The application rate is 0.2 kg a.s./ha in 200 – 500 L water/ha using tractor mounted sprayers.

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The operator exposure estimates were calculated using both the German model[9] and the UK-POEM model[10] (see table below).

Estimated exposure presented as % of AOEL (0.004 mg/kg bw/day), according to calculations with the German and UK POEM model. The default for body weight of operator is 70 kg in the German model and 60 kg in the UK-POEM model.

Use	Model	Without PPE	With PPE
Potatoes	German BBA	258	13**
	UK POEM	1362	219*

*PPE (personal protective equipment): gloves during mixing/loading (M/L) and application (A)

**PPE: gloves during M/L/A; standard protective garment, sturdy footwear, hood and visor during A

The results according to the POEM model exceed the AOEL even if personal protective equipment is used (gloves). The exposure estimates with the German model exceed the AOEL only if no protective equipment is used. If the operator wears gloves, standard protective garment, hood and visor, boots, the estimated exposure will be 13 % of AOEL.

Worker

The experts agreed that immediately after treatment, only crop inspection activities are realistic for approximately 2 hours whereas harvesting should be considered 7 days after application. Therefore the estimated exposure during inspection activities is 925% of the AOEL without PPE and 50% of the AOEL with the use of PPE (clothes and gloves). During harvesting, the estimated exposure is 450% of the AOEL without PPE and 25% of the AOEL with the use of PPE (clothes and gloves).

It was highlighted that during harvesting, a limited contact was expected with foliage on which the dislodgeable residues were measured, whereas no quantification of the residues on the surface of the potatoes was available. Therefore the calculated exposure involving the use of PPE to be below the AOEL might be a bit overestimated.

Bystander

Short exposure duration of bystanders outside the treatment areas is estimated to be 5.4 % of the AOEL of 0.004 mg/kg bw/day (Lloyd and Bell, 1983).

3. Residues

Fluazinam was discussed by the experts in residues in July 2007 (PRAPeR 30, Round 6).

[9] German model: Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products; Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirschaft, Berlin-Dahlem, no. 277

[10] UK model: Scientific Subcommittee on Pesticides and British Agrochemicals Joint Medical Panel., Estimation of Exposure and Absorption of Pesticides by Spray Operators [UK MAFF] 1986 and the Predictive Operator Exposure Model [POEM], UK MAFF 1992

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3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

The metabolism of fluazinam has been investigated in potatoes, peanuts, grapes and apples. The compound was labelled either in the nitrophenyl or the pyridyl ring. In potatoes the study reflected the representative use supported for this crop. No major difference in fluazinam metabolism was observed amongst the investigated 3 crop groups.

First steps of the metabolic pathway of fluazinam in plants involve reduction of one or both nitro groups to form AMPA-FLUAZINAM or DAPA, loss of the phenyl ring chlorine by glutathione conjugation to form AMGT[11] and substitution of one nitro group by a hydroxyle group. Further metabolism proceeds through cleavage of the compound, followed by opening and fragmentation of the resulting pyridyl and nitrophenyl moieties. TFAA was identified as a result of this fragmentation process, present together with other ultimate unidentified degradation products entering the carbon pool of the plant.

The metabolic pattern in the edible part of the investigated commodities varies widely. Parent compound was found to be by far the major constituent of the residue in raw fruits after foliar application even for PHIs up to 71 days. It was also identified in potato tubers at low amounts together with similar amounts of structurally related compounds (AMPA-FLUAZINAM, AMGT), while in nutmeat only TFAA derivatives were present. The metabolism study in grapes investigated the transfer of residues to wine. The parent compound was not found and AMGT appeared to be a major metabolite, although present in low amounts. Processing of apples to juice leads to similar findings.

Based on the metabolic pattern in potato tubers the residue definition for monitoring is proposed to consist in fluazinam only as the parent compound can be considered as an appropriate marker compound. This definition is restricted to potatoes. For other commodities, the expert meeting concluded that further discussion were needed, considering inter alia the appropriate intended uses, and the changes occurring in the residue pattern during processing.

The residue definition for risk assessment should in addition include structurally related compounds, when they may contribute in a significant way to the toxicological burden. This is the case of AMPA-FLUAZINAM and AMGT as they are present in potatoes tubers at levels comparable to the parent compound. No toxicological data allow considering them clearly less toxic than the parent compound, but considering the rat metabolism their intrinsic toxicity is covered by the toxicological studies with the parent compound. No other plant metabolite, structurally related to the parent compound, appeared at levels similar to that of the parent compound in any of the submitted metabolism studies. Therefore, the residue definition for risk assessment, including the parent compound, AMPA-FLUAZINAM and AMGT, can be considered as valid for all plant commodities. For potatoes, a conversion factor of 3 was agreed based on the metabolism data only, considering that the overall low consumer exposure allows some uncertainty in setting this conversion factor.

[11] AMGT: 3-[[4-amino-3-[[3-chloro-5-(trifluoromethyl)-2-pyridyl]amino]- *α*,*α*,*α*-trifluoro-6-nitro-*o*-tolyl]thio]-2-(β-D-glucopyranosyloxy)propionic acid

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A concern exists related to TFAA. The hazardous nature of this metabolite could not be fully evaluated during the peer-review (refer to point 2.8). Depending on the outcome of the required information in order to identify and characterize the eventual toxicological properties of TFAA, a specific risk assessment related to this metabolite may be needed. It must however be pointed out that this metabolite is not specific of fluazinam and can be produced through metabolic or degradation processes from a wide range of pesticides containing a C-CF_3 moiety.

Therefore the currently proposed residue definition for risk assessment may need to be later reconsidered for inclusion of TFAA, either in addition to the parent compound, AMPA-FLUAZINAM and AMGT, or as a specific entity to be considered separately.

A sufficient number of supervised residue trials were conducted in Northern and Southern Europe in potatoes. Only fluazinam residues were analysed and were consistently below the Limit Of Quantification (0.01 mg/kg) of the analysis method in tubers. These studies can be considered as reliable based on storage stability studies in deep-freeze conditions showing that fluazinam residues are stable in plant commodities homogenates including potatoes for at least 12 months.

Given the low residue level in raw potatoes, studies investigating the effect of processing on the nature and levels of residues are not necessary.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

Fluazinam or fluazinam related compounds based on the two-ring structure are not found in rotational crops. Residues in rotational crops are fragments from either the phenyl or the pyridine ring after cleavage and extensive metabolic degradation of the parent molecule. In confined studies TFAA was present in amounts exceeding 0.05 mg/kg in mature lettuce, carrots roots and barley grains, after application of the total annual rate of fluazinam on bare soil. ^{14}C was also found to have been reincorporated into natural plant products such as starch.

No field crop rotation study has been submitted.

The residue definitions for monitoring and risk assessment proposed for primary crops are also applicable to rotational crops. The concern related to TFAA is similarly applicable to rotational crops.

Based on the available information no particular restriction related to rotational crops is needed.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

Due to the very low level of residues expected in potatoes, livestock exposure is well below 0.1 mg/kg diet. Although not required in these conditions metabolism studies in lactating goats and laying hens were provided.

In both animals the active compound is extensively degraded. Only in hens tissues and eggs minor amounts of fluazinam were found.

Major residual compounds in goat tissues were the reduction products AMPA-FLUAZINAM and DAPA. Beside sulfamate conjugates of these compounds, no other metabolite was identified.

In laying hens AMPA-FLUAZINAM is a major metabolite in all tissues. DAPA, MAPA, HYPA as well as cysteine conjugates of dechlorinated fluazinam and AMPA-FLUAZINAM were also present.

Metabolism in livestock and rats may be considered as similar. No accumulation of the active substance and its metabolites is expected in animal commodities.

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Considering the very low exposure of livestock to fluazinam residues resulting from the representative use in potatoes, no residue definition for food of animal origin is proposed and feeding studies are not necessary.

The expert meeting discussed of a possible residue definition for animal products in the hypothesis of further uses of fluazinam leading to a significant livestock exposure. This discussion was however not conclusive given no indication was available on the residue pattern livestock would be exposed to.

3.3. CONSUMER RISK ASSESSMENT

Under restriction of the information to be provided on the toxicological relevance of TFAA, and on the actual consumer exposure to this metabolite, no risk for the consumer resulting from the use of fluazinam according to the representative uses in potatoes is expected.

Chronic exposure

The rapporteur Member State conducted chronic dietary exposure assessment according to the Theoretical Maximum Daily Intake (TMDI) calculation model of WHO using the WHO typical European diet for adult consumers and the German national diet for 4 to 6 years of age girl.

Residues in potatoes were considered to be at the level of LOQ proposed as MRL (0.01 mg/kg). No contribution to consumer intake from animal commodities was considered. Based on these assumptions, the calculated TMDIs did not exceed 0.5 % of the ADI in both examined population of consumers.

Acute exposure

The acute exposure to residues of fluazinam in potatoes has been assessed by the rapporteur Member State according to the WHO model for conducting National Estimates of Short Term Intakes (NESTI) calculations. Large portion consumption data for UK adult population were used. Children exposure is not relevant for the effect the ARfD is based on. Calculations were carried out considering residues of fluazinam in potatoes being at the level of LOQ proposed as MRL level (0.01 mg/kg) and a unit to unit variability factor of 7. Under these conditions the adult consumer exposure was about 1 % of the ARfD.

It is noted that the acute and chronic intake calculations mentioned here above did not included the conversion factor of 3 related to the residue definition for risk assessment as mentioned under point 3.1. Nevertheless this does not alter the derived general outcome.

3.4. PROPOSED MRLS

In accordance with the results of supervised residue trials the MRL is proposed to be set at 0.01* mg/kg (LOQ) in potatoes.

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4. Environmental fate and behaviour

Fluazinam was discussed in the meeting of experts on fate and behaviour in the environment PRAPeR 27 on the basis of the DAR and the addendum to Vol 3 rev. 1 (June 2007).

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

The route of degradation of fluazinam under aerobic conditions at 20 ºC in soil was investigated in two studies with three soils (pH 6.4 - 7.1, OM 1.7 – 4.4 %, clay 7 – 22 %) and fluazinam ^{14}C labelled either at the pyridil or the phenyl ring. The active substance was applied at rates equivalent to 0.74, 1 or 5 kg / ha (application rate for the representative use 10 x 200 g / ha). Substitution of phenyl ring chlorine by hydroxyl yields the major soil metabolite **HYPA** (max 13.9 % after 40 d).[4] Other minor metabolites identified resulted from the reduction of the phenyl nitro groups to form the corresponding anilines. In the first study (Bharti, H. and Bewick, D.W. (1985)), considerable amount of the residue remained un-identified due to the fact that in the analytical method employed (TLC) this residue was not eluted and remained in the origin (up to 16 % AR after 361 d in the phenyl labelled experiment, as amended in addendum to B.8). Therefore, this study may not be considered to adequately address the route of degradation of Fluazinam. In the experiment performed in the most recent study (1soil) up to 14 minor metabolites were found and none of them individually exceeded 4.7 % AR. No further identification of these minor metabolites was attempted. Metabolites resulting form the cleavage of the bridging amino group have not been identified in any of the available studies. After 90 d non extractable residues reached levels of 16.7 – 50.5 % AR and mineralization was almost negligible (radioactivity trapped in the ethanolamine trap = 0.9 – 2.2 % AR after 90 d, attributed to CO_2).

In one of the studies degradation under anaerobic conditions at 20 ºC was investigated in one soil (pH 6.9, OM 4.4 %, clay 22 %) at rates equivalent to 1 and 2 Kg a.s. / ha. Anaerobic conditions were established from the beginning of the experiment and after 30 d of aerobic incubation. Under these conditions, the major metabolites found were **MAPA**[5] (max. 9 – 31.2 % AR) and **DAPA**[3] (max. 12.0 % AR after 90 d) which are formed by reduction of the NO_2 groups of the phenyl ring. Higher amounts of non extractable residues were formed under anaerobic conditions (max 60.6 % AR after 180 d, end of the study). Non extractable residue of one sample (phenyl labelled, 180 DAT, 60.6 % AR) of the anaerobic experiment (flooded after 30 d of aerobic conditions) was investigated by extraction with sodium pyrophosphate, considered able to extract organic matter under mild conditions. Most of the radioactivity extracted in this way (33.2 % AR) remained in the water phase (29.2 % AR) when partitioned with organic solvents. No further characterization was performed.

Photolysis of fluazinam in soil was investigated in one study with fluazinam ^{14}C labelled either at the pyridil or the phenyl ring. The test system was exposed to simulated sunlight with a 12 h light / 12 h dark cycles for 30 d at 25 ºC and a light intensity comparable to Southern European conditions. Photolysis was shown to contribute to the degradation of fluazinam in soil. HYPA and AMPA-FLUAZINAM are found as minor metabolites. However, in the original DAR it was reported that up to 23.6 % AR extracted was not identified and characterized. Applicant provided a position paper

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based on the detailed examination of the chromatographic data in this study that was summarized and assessed by the rapporteur Member State in the addendum to B.8. According this additional information none of the individual regions pertaining to the non-identified extractable radioactivity represented more than 4.6 % AR. The meeting of the experts agreed that no further information was therefore necessary.

4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

Rate of degradation of fluazinam in soil under aerobic conditions at 20 ºC was investigated in the same studies presented to establish the route of degradation. Degradation in an additional soil was investigated in a separated study with non radiolabelled material. According these studies fluazinam is medium to high persistent in soil (DT_{50} = 17.1 – 226 d).

The degradation of the major aerobic metabolite HYPA under aerobic conditions at 20 ºC in soil was investigated in one study with three soils (pH 5.2 – 6.2, OC 0.9 – 2.3 %, clay 2.8 – 32.2 %. 30 – 61 % MWHC). This metabolite was shown to be moderate to high persistent under these conditions (DT_{50} = 54 – 148 d) (typing errors in the original DAR were amended in addendum to B.8).

In the dossier presented to EFSA, a study investigating the degradation of HYPA under aerobic conditions at 20 ºC in one soil (pH 7.4, OM 5.6 %, clay 37 %) was found.[12] This study was missed in the dossier presented to the rapporteur Member State and therefore it was not assessed in the original DAR. The study was subsequently required and presented to the rapporteur Member State who summarized and assessed it in the addendum to B.8. The study was found acceptable by the rapporteur Member State. In this study HYPA was very high persistent (DT_{50} = 396 d) in soil. The rapporteur Member State assessment was agreed by the meeting of experts.

Fluazinam was low to moderate persistent (DT_{50} = 3.9 – 26 d) under anaerobic conditions due to the relatively rapid reduction of the nitro groups to form the MAPA, AMPA-FLUAZINAM and DAPA metabolites.

According to the available photolysis study, photolysis may contribute moderately to the environmental dissipation of fluazinam in soil.

There are field dissipation studies available in UK (two sites), Germany (four sites) and USA (four sites). USA field trials were considered not relevant for EU conditions and were not used in the risk assessment. Two trials were performed on bare and cropped soil but data only allowed calculating reliable half lives for the bare soil experiments. Therefore, the potential contribution of photolysis to the degradation of fluazinam under field conditions was not evaluated. In these trials fluazinam is low to moderate persistent (DT_{50} = 8.3 – 40.8 d). The potential effect of photolysis on the degradation of fluazinam in these field trials was discussed in the experts' meeting on basis of the applicant's position paper summarized and assessed by the rapporteur Member State in the DAR. The meeting agreed that the kinetic parameters derived from the field trials were not appropriate for use in environmental modelling and that new FOCUS PEC_{SW} and FOCUS PEC_{GW} will need to be calculated on basis of laboratory data. Also since the studies were performed on bare soil they were not

[12] Johnson, R.I. 2000. R270682: Laboratory Degradation Study in One Soil Type. GLP: Yes.

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considered representative of the uses proposed. Therefore new PEC soil calculation using the longest laboratory half life and application every two years for potato was regarded as necessary by the meeting. After the experts meeting, new PEC soil have been presented by the rapporteur Member State in an updated addendum to B.8 following the parameters agreed by the meeting. The calculated maximum peak of 0.8 mg/kg is reached after 5 years. Since input parameters were peer reviewed the new values may also be considered peer reviewed. The expert meeting provided also some advice on how the field studies could be used for a refined PEC.[13]

PEC soil of HYPA were calculated in the addendum based on worst case laboratory half life (DT_{50} = 396 d) and maximum amount observed in laboratory studies (13.9 %). Maximum peak PEC soil (0.37 mg /kg) is reached after three years.

4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

Batch soil adsorption / desorption studies were performed with fluazinam in four soils (pH 6.0 – 7.7; OC 0.48 - 2.55 %; clay 7.2 – 38.0 %) and major soil metabolite HYPA in six soils (pH 4.7 – 8.1; OC 0.50 – 3.1; clay 6 – 28 %). According this studies fluazinam may be considered to be slight to low mobile (K_{fOC} = 1705 – 2316 mL/g) and HYPA low to medium mobile (K_{foc} = 450 - 1700 mL/g).

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

The hydrolysis of fluazinam (14C-labelled at the phenyl ring) was investigated in sterile aqueous buffer solutions at pH 4, 7 and 9. The experiments were run at 50 ºC (pH 4) or 25 ºC (pH 7 and 9). Fluazinam may be considered stable at pH 4 and it is rapidly hydrolysed at pH 7 (DT_{50} = 2.7 – 4.5 d) and pH 9 (DT_{50} = 3.5 – 3.9 d). The major hydrolysis metabolite at pH 7 and 9 was CAPA[14]. This metabolite is only further hydrolysed at 50 ºC and therefore may be considered stable under normal environmental conditions.

Photolysis of fluazinam (14C-labelled at the phenyl ring and pyridine ring) was investigated in water (pH 5) at 25 ºC. Test samples were exposed to simulated sun light (filtered xenon lamp simulating summer sun at 43 ºN) for 30 d (12 h light / dark cycles). Under these conditions photolytic degradation was rapid ($DT_{50\ irradiated}$ = 2.5 d / $DT_{50\ dark}$ = stable). A number of metabolites were formed of which only G-504[15] was formed at levels above the 10 % AR (17 % AR). Minor metabolites identified were AMPA-FLUAZINAM (max. 4.1 % AR after 10 d) and HYPA (max. amount not reported). Aqueous photolysis may contribute to the environmental dissipation of fluazinam.

Fluazinam is not readily biodegradable according the available study.

Fate and behaviour of fluazinam in aquatic environment under dark aerobic conditions at 20 ºC was investigated in one study with two systems (pH_{water} = 5.6 – 6.9; pH_{sed} = 5.8 – 6.6, OC 3.3 – 4.3 %). Fluazinam partitioned with the sediment and was converted to a number of metabolites through

[13] Report of PRAPeR EXPERT MEETING 27 (10 – 13 July 2007). Fluazinam.
[14] CAPA: 5-chloro-6-(3-chloro-2,6-dinitro-4-trifluoromethylanilino) nicotinic acid
[15] G-504: 4,9-dichloro-6-nitro-8-(trifluoromethyl)-pyrido-[1,2-*a*]benzimidazole-2-carboxylic acid

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substitution of chlorine atom and reduction of nitro groups ($DT_{50\ water}$ = 2.4 – 3.0; $DT_{50\ whole\ system}$ = 3.1 – 5.7 d). Among these metabolites only **AMPA-FLUAZINAM**[2] reached levels above 10 % in the sediment phase. Non extractable residues amounted up to 55 % AR after 100 d and mineralization was practically negligible (CO_2 = 2.0 – 2.2 after 100 d). There are no indications that the amino bridge between the two rings is brokendown during the degradation. Dissipation rate of metabolite AMPA-FLUAZINAM was calculated with data of one of the systems ($DT_{50\ sed}$ = 33.9 d). The rapporteur Member State provided in an addendum the whole system kinetic parameters for HYPA based on a multicompartmental fitting of the data of both systems (HYPA: $DT_{50\ whole\ system}$ = 27.9 – 51.0 d; ff = 0.06 – 0.08). The rapporteur Member State identified shortcomings in the study that do not invalidate it in its integrity but need to be considered when using the results for risk assessment. In particular the rapporteur Member State highlighted the similarity of the sediments in the two systems tested (with rather high carbon content) that may prevent the generalization of the kinetic results.

$PEC_{SW\ /\ SED}$ for fluazinam and for the major sediment metabolite AMPA-FLUAZINAM were presented in the DAR for the representative use in potatoes. The input parameters used in the applicant's calculation for fluazinam were not agreed by the meeting. In particular, the proposed canopy dislodgeable residues half life of 3.7 d obtained from a single trial site was not agreed to be representative for a EU assessment and the default FOCUS of 10 d should be used instead. Also the degradation half lives in soil, surface water and sediment and the assumed effect of vegetative strips on run off mitigation[16] used for FOCUS Step 4 calculations were not agreed by the meeting and new calculations were deemed necessary. Based on the results of the water / sediment study EFSA and the rapporteur Member State agreed after the meeting of experts that AMPA-FLUAZINAM should be considered a major sediment metabolite but not a major surface water metabolite.

PEC_{SW} for the soil metabolite HYPA were presented by the rapporteur Member State in an addendum to the DAR and discussed in the experts meeting. However, new calculations were required since new information on the degradation of HYPA in soil became available. New input parameters were agreed by the meeting.

After the meeting, the rapporteur Member State presented new FOCUS PEC_{SW} and PEC_{SED} for Fluazinam and HYPA using the input parameters agreed by the meeting of experts in the updated addendum to B.8. For fluazinam calculations were performed up to FOCUS Step 4 considering spray drift mitigation by buffer zones of 5 and 10 m. Multiple and single application were simulated. FOCUS Step 3 and Step 4 with 5 m buffer zone show higher PEC_{SW} / PEC_{SED} when a single application is assumed (due to short half life of fluazinam). When 10 m buffer zone is assumed the results are some times higher with 8 applications.

For HYPA new PEC_{SW} / PEC_{SED} have been provided by the rapporteur Member State in the updated addendum up to FOCUS Step 3. In this case, multiple applications (6 – 8) give the highest PEC values. The meeting of experts noted that, due to the fact that the SWASH shell only allows up to a

[16] Opinion of the PPR Panel on the final report of the FOCUS Landscape and Mitigation Factors (EFSA Journal (2006) 437, 1-30.

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maximum of 8 applications, the actual representative use (up to 10 applications) is not covered by this risk assessment with respect to metabolite HYPA.

4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

Potential ground water contamination by fluazinam and the major soil metabolite HYPA has been addressed by the rapporteur Member State in the updated addendum by FOCUS PEARL and PELMO models for the representative use in potatoes using the input parameters agreed by the meeting of experts. The predicted 80th percentile leachate concentration at 1 m depth is < 0.001 μg / L for both compounds in all the relevant scenarios.

4.3. FATE AND BEHAVIOUR IN AIR

Fluazinam may be relatively persistent in air. The rapporteur Member State calculation estimated a half life due to photochemical degradation of 163 d in air. However, half life may be shorter depending on the rate of reaction of the amino bridge. Therefore, the rapporteur Member State considered that half life in air is > 2 d. The meeting of experts discussed the uncertainty associated to the atmospheric photochemical half life. It was noted that no compound in the Atkinson's data base could be adequately compared to fluazinam. A data gap for experimental measurements was identified. According the physicochemical parameters this substance is expected to have a medium to high potential for volatilization. Due to the uncertainty in the atmospheric half life long range transport cannot be completely excluded. After the meeting of experts the notifier provided a statement from Dr. Atkinson indicating that fluazinam is not volatile enough to perform an experimental measurement of the atmospheric photochemical half life. The rapporteur Member State included the assessment of this statement in the final updated addendum. The rapporteur Member State and EFSA agreed to consider this data requirement as fulfilled.

5. Ecotoxicology

Fluazinam was discussed by the experts on ecotoxicology in July 2007 (PRAPeR 28, Round 6).

5.1. RISK TO TERRESTRIAL VERTEBRATES

The representative use for fluazinam is in potatoes. The standard scenarios in the Guidance Document on Risk Assessment for Birds and Mammals (SANCO/4145/2000) for a leafy crop are a medium herbivorous and insectivorous bird and a medium herbivorous mammal. It is not considered necessary to calculate the risk to herbivorous birds and mammals in potatoes as potato leaves are considered unpalatable. Therefore the risk to herbivorous birds and mammals is considered to be low. Nevertheless TER-values for herbivorous birds and mammals were calculated in the DAR. Only the long term TER values for herbivorous mammals is below the Annex VI trigger value but as stated above this scenario is not considered relevant due to the unpalatability of the potato leaves.

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Based on the first tier risk assessment the risk to insectivorous birds can be regarded as low for the representative use of fluazinam evaluated. Because potato foliage is considered to be not a preferred feed source for mammals, the risk to insectivorous mammals feeding on large insects on the ground was additionally assessed. The resulting TER-values are above the Annex VI trigger value indicating a low risk to insectivorous mammals from the representative use of fluazinam evaluated.

As the Log Pow of fluazinam exceeds 3, the risk to birds and mammals from secondary poisoning was assessed. The risk to fish-eating birds and mammals can be considered as low. Also the risk to earthworm eating birds can be considered as low but a further refinement of the risk to earthworm-eating mammals is considered necessary. The notifier provided a refinement of the risk to earthworm-eating mammals whereby PT and PD values were estimated more adequately for the hedgehog as focal species. The rapporteur Member State accepted the hedgehog as an adequate species for risk refinement in potato crops, as shrews were assumed not to find sufficient plant cover in potatoes. The rapporteur Member State calculated a TER of 29 based on the same data and more conservative assumptions in addendum 1 (June, 2007). The refined risk assessment was rejected in the expert meeting (PRAPeR 28). The meeting questioned the hedgehog as focal species, use of PT of 0.5 and the origin of a FIR/bw of 0.16. Use of the hedgehog for refinement would require more supportive information. A data gap was identified to refine the risk assessment for earthworm eating mammals using wood mouse (*Apodemus sylvaticus*) as focal species, as this species had been used as focal species in refined risk assessment for other substances. Notifier did submit a refined risk assessment with wood mouse, which was assessed by the rapporteur Member State in Addendum rev. 2, July 2007. The risk assessment include residue uptake from earthworms and insect larvae and refinement of PD and PT. However, this risk assessment has not been peer reviewed and therefore, the data gap for addressing the risk to earthworm eating mammals is maintained. A possible refinement would be to obtain real residue data for earthworms so that the intake values may be refined.

The risk to birds and mammals from ingestion of contaminated drinking water was assessed according to SANCO/4145/2000. The acute and short term risk from this exposure route to birds can be considered as low as well as the acute risk to mammals. A long term risk was considered necessary due to the potential long exposure time following (up to) 10 applications in leafy crop. Notifier submitted a risk assessment which is included in addendum 1 (June, 2007). The expert meeting agreed to the conclusion that the risk was low.

5.2. RISK TO AQUATIC ORGANISMS

Fish was the most sensitive aquatic organisms on an acute and chronic time scale in the standard dataset.

All acute TER values for fish are above 10 for all FOCUS Step 3 scenarios. The lowering of the Annex VI trigger value from 100 to 10 was considered appropriate since 5 fish species were tested and the data confirmed a narrow range of sensitivities. Hence the acute risk to aquatic organisms is considered to be low. However, it was recommended in the review process to use the opinion of the

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PPR Panel[17] on reducing uncertainty factor. A new risk assessment applying the second lowest toxicity value (0.055 mg a.s./L for *L. macrochirus*) was presented in addendum 1 (June 2007), and agreed at the expert meeting (PRAPeR 28). The risk to all scenarios was low at FOCUSsw step 4 with a buffer zone of 5 m. The risk assessment was subsequently updated following new PECsw calculations after the fate expert meeting (PRAPe 27). The Annex VI trigger was not meet in two out of the eight scenarios at FOCUSsw step 3. The to scenarios failing to meet the Annex VI trigger was D4 stream and R1 stream. All scenarios meet the Annex VI trigger at FOCUSsw step 4, including a non-spray buffer zone of 10 m.

The chronic TER-values for fish for 6 out of 8 FOCUS Step 4 scenarios, including a 5 m bufferzone, do not meet the trigger of 10. Therefore 2 further refinement options are proposed.
The first option makes use of 1-day TWA FOCUS Step 4 PEC values (again including a 5 m bufferzone). The use of 1-day TWA PEC values is considered appropriate as the chronic endpoint for fish comes from a flow-through fish full life cycle study with 278 days continuous exposure. Based on these PEC values the chronic risk to aquatic organisms can be considered as low if risk mitigation measures, such as a 5 m bufferzone, are taken into account.
The second option makes use of a comparison of the exposure regime in the fish full life cycle study with the FOCUS scenarios according to the PPR Panel opinion on dimoxystrobin[18]. This latter approach was discussed and accepted in the expert meeting (PRAPeR 28). The measured concentration at the NOEC divided by 10 (Ecotoxicological Trigger Concentration - ETC) was compared to the exposure profile from the worst case FOCUS scenario (R3 stream single and multiple application). A conservative risk assessment was subsequently updated following new PECsw calculations after the fate expert meeting (addendum rev 2., July 2007), without considering the proposed refinement option At FOCUSsw step 3 the trigger was not meet in any of the 8 scenarios. The risk is considered low for all scenarios at FOCUSsw step 4, including a buffer zone of 10 m.

Additional laboratory acute tests with aquatic invertebrates were submitted after the original DAR was compiled and were evaluated by the rapporteur Member State in the Addendum of June 2007. The most sensitive endpoints were obtained from the copepod species *Acanthocyclops venustus* (96-h EC10 = 0.2 µg a.s./L; 96-h EC_{50} = 4.6 µg a.s./L), which is by a factor of 25 more sensitive than the *Daphnia magna* endpoint submitted in the original dossier. However, it was concluded that valid and reliable endpoints for a further risk assessment are not available and the results of the study are not relevant for the risk assessment. The risk assessment based on aquatic invertebrates is adequately addressed with the conventional risk assessment. This decision was agreed at PRAPeR 28.

[17] Opinion of the PPR Panel on a request from EFSA related to the assessment of the acute and chronic risk to aquatic organisms with regard to the possibility of lowering the uncertainty factor if additional species were tested. (Question N° EFSA-Q-2005-042). Adopted on 14 december 2005.
[18] Opinion of the PPR Panel on a request from EFSA related to the evaluation of dimoxystrobin (The EFSA Journal (2005), 178 1-45).

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In the DAR the risk to sediment dwellers was considered to be low at FOCUSsw step 4 applying a non-spray buffer zone of 5 m, based on PEC and NOEC in the water phase. Following new PECsw calculations after the fate expert meeting (addendum rev. 2 of July 2007) the same conclusion was reached with a non-spay buffer zone of 10 m, again based on water concentrations. However, the risk to sediment dwellers still needs to be assessed on the basis of sediment concentrations, as the worst case scenarios differs for the water phase and the sediment phase depending on number of applications, fate properties and size of non-spray buffer zones (see section 4.2.1).

The rapporteur Member State requests studies with soil metabolite HYPA due to possible exposure via drainage and run-off. A risk assessment for HYPA was provided in addendum 1 (June 2007) and it was accepted in the expert meeting. With a similar toxicity of the metabolite as the parent, TER values were above the triggers at FOCUS step 3 calculations. Notifier did submit preliminary studies with fish and daphnia where HYPA appears to be less toxic than the parent substance. New FOCUS PECsw data was submitted for HYPA after the fate expert meting (PRAPeR 28). Still assuming similar toxicity as the parent, the new TER values did not meet the Annex VI trigger in 3 of the 9 scenarios. However, there are still concerns, that the new PECsw data for HYPA is not the worst case (see fate section 4.2.1). Hence, it is not possible to draw a conclusion on the risk of HYPA to aquatic organisms. MS will have to undertake a risk assessment including new PEC calculations and finalised toxicity data with fish and daphnia.

The metabolite G-504[14] occurs in the photolysis study at a max of 17% after 10 days. A data gap was identified during the expert meeting for ecotoxicity data for G-504 for all groups of aquatic organisms.

Fluazinam partitions in concentrations above 10% into the sediment. A chronic study on *Chironomus riparius* was submitted. The risk to sediment dwelling organisms can be considered as low if risk mitigation measures such as a 5 m buffer zone are taken into account. Also the metabolite AMPA-FLUAZINAM partitions into the sediment. However, the risk to sediment dwelling organisms is concluded to be low from AMPA-FLUAZINAM.

No studies with higher aquatic plants, such as *Lemna gibba*, are considered necessary as fluazinam is not an herbicide.

As the LogPow of fluazinam exceeds 3, the BCF in fish was determined. The resulting BCF of 1090 exceeds the Annex VI trigger value of 100 for not readily biodegradable products. Less than 95% depuration was observed after 14 days. To address this, a fish full life cycle study is available. Based on this study the chronic risk to fish can be considered as low (see above). Furthermore the risk to fish-eating birds and mammals is considered to be low. Therefore, in conclusion, the risk for bioaccumulation is considered to be low. Fluazinam was extensively metabolised in fish organisms to AMPA-FLUAZINAM, without any evidence of accumulation. Thus, the risk of AMPA-

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FLUAZINAM to bioconcentrate in fish and to bio-accumulate in aquatic systems is expected to be low.

Log Pow values were requested during the review and provided in addendum 1 (June 2007).
Log Pow values of 3.99 and 2.55 was calculated with US EPA EPISUITE and KOWWIN for AMPA-FLUAZINAM and HYPA respectively. The validity of these logPow values was questioned. The phys-chem expert meeting (PRAPeR 31) recommended that logPow should be derived experimentally for HYPA, to provide a more reliable basis for assessing if further risk assessment is triggered.

5.3. RISK TO BEES

An acute contact and oral toxicity study with fluazinam is available. Also the lead formulation Fluazinam 500 SC was tested. During the contact phase of the study with the formulation, the product was sprayed on the bees in such a way that the bees were wetted completely and evenly. The spray concentration was 0.2% which corresponds to an application rate of 400 g a.s./ha. No significant mortality was observed at this dose which exceeds a single application rate of the representative use.
To calculate the HQ values a multiple application factor (MAF) was taken into account[19]. The factor taken is the standard MAF for 8 applications for leaf dwelling arthropods. It is not considered necessary to take a MAF for 10 applications into account as the trigger value for bees was validated without the use of a MAF. The resulting HQ values do not breach the Annex VI trigger value indicating a low risk to bees for the representative use of fluazinam in potatoes.

5.4. RISK TO OTHER ARTHROPOD SPECIES

A standard laboratory study on *Aphidius rhopalosiphi* is available. The tested dose rate was too low to proof that the in-field HQ value is below 2. The off-field HQ is far below 2.

Further to this study extended laboratory studies with the following species are available: *A. rhopalosiphi, Typhlodromus pyri, Chrysoperla carnea, Pterostichus melanarius* and lycosid spiders. Effects were below 50% for all species at dose rates which reflect the representative use except for mortality with *A. rhopalosiphi*. In the extended laboratory study with *A. rhopalosiphi*, the wasps were exposed to either the upper side of a treated potato leave or the underside. 3% was mortality was observed for wasps exposed to the underside and 78.1 % mortality was observed for wasps exposed to the upper side which gives a mean mortality of 40.6%. It is considered acceptable by the rapporteur Member State to take the mean value into account as aphids are primarily found on the underside of potato leaves and it is argued that for typical arthropods the mean mortality rate between under- and upper-side of the leaves would be the significant one. The risk to non-target arthropods is considered low with no need for risk mitigation.

[19] It should be noted that it is standard practice to calculate the hazard quotient (HQ) for bees based on a single application. There is no requirement to adjust for multiple applications by use of a multiple application factor (MAF) and this would be out of line with other evaluations.

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5.5. RISK TO EARTHWORMS

A study on the acute effects of fluazinam and the lead formulation Fluazinam 500SC on earthworms is available. The endpoints were corrected for the organic content in the test soil as the LogPow of fluazinam exceeds 2. The resulting TER values are above the Annex VI trigger value indicating a low acute risk to earthworms from the representative use of fluazinam evaluated.

A study on the effects of fluazinam on reproduction was submitted as 10 applications are foreseen for the representative use evaluated. Effects on reproduction were observed at the lowest concentration tested of 0.35 mg a.s./kg soil. Also this endpoint needs to be corrected for the organic content in the test soil. The resulting TER value is far below the Annex VI trigger value and a higher tier risk assessment is considered necessary. Therefore a field study was made available. In this field study fluazinam was applied 10 times at a rate of 200 g a.s./ha with an interval of 7 days. At none of the sampling times significant effects on population and total biomass were observed. Based on this study, the long term risk to earthworms from fluazinam can be regarded as addressed for the representative use evaluated. Further details on the field study were presented in addendum 1 (June 2007). The conclusion of the study was agreed in the expert meeting (PRAPeR 28), if the exposure in the study would cover the estimated plateau concentration in soil. This was the case, as the estimated plateau concentration in soil (0.8 mg as/kg) is similar to the concentration in soil after multiple applications during in a single season (0.78 mg as/kg).

An acute toxicity study with the soil metabolite HYPA is available. The resulting TER-value respects the Annex VI trigger value indicating a low acute risk to earthworms from this metabolite. The long term risk to earthworms from this metabolite is considered to be covered by the available field study (see above).

5.6. RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

Given the $DT_{90field}$ in soil for fluazinam and the observed effects on earthworms and *A. rhopalosiphi*, a study on the effects on collembolan was submitted. Effects on mortality were observed at the lowest concentration tested of 1.57 mg a.s./kg soil. This endpoint needs to be corrected for the high organic content of the test soil as the LogPow exceeds 2. The resulting TER value, which is less than 1.45, triggers a litterbag study. A summary of the litterbag study was included in addendum 1 (June 2007). The expert meeting (did not accept the study, as the exposure concentration in the study did not cover the expected plateau soil concentration. A data gap was identified for a higher tier study (e.g. a new litterbag study), in which the new PECplateau is covered. In a new study the presence of and effects on macro organisms should be considered.

Also the effects of the soil metabolite HYPA were tested on *Folsomia candida*. The resulting TER-value respects the trigger value of 5 indicating a low risk to other soil non-target macro-organisms from the soil metabolite HYPA for the representative use evaluated.

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5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The effects of the lead formulation Fluazinam 500 SC were tested on soil microbial respiration and nitrogen transformation. Effects were less than 25 % at day 28 at 2.27 mg a.s./kg d.w. soil. This tested concentration exceeds the predicted environmental concentration in soil of 0.8 mg a.s./kg soil and therefore the risk to soil non-target micro-organisms from fluazinam is considered to be low for the representative use evaluated.

Also the effects of the soil metabolite HYPA were tested on soil microbial respiration and nitrogen transformation. Effects were less than 25 % at day 28 at 0.38 mg a.s./kg d.w. soil. This tested concentration exceeds the predicted environmental concentration in soil of 0.37 mg a.s./kg soil and therefore the risk to soil non-target micro-organisms from HYPA is considered to be low.

5.8. RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

Fluazinam is a fungicide so there is no requirement for non-target plant data. However, available data has been evaluated. Studies on the influence of fluazinam on seedling emergence, seed germination and plant vigour of 6 dicotyledon species and 4 monocotyledon species are available. The maximum effects observed was a 28% reduction on fresh weight for cucumber at 1.5 kg a.s./ha from the vegetative vigour study. Therefore it can be concluded that effects were far below 50% at the maximum single application rate of 200 g a.s./ha.

Also a growth test with the soil metabolite HYPA is available. The EC_{50} for the three species tested is above the highest concentration tested of 100 mg/kg soil.

Based on these studies, the risk to non-target plants from the representative use of fluazinam is considered to be low.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

The respiration rate EC_{50} for fluazinam equals 118 mg a.s./L. The EC_{50} for *Pseudomonas putida* exceeds 1.53 mg a.s./L. Based on this study the risk to biological methods of sewage treatment is considered to be low for the representative use of fluazinam evaluated.

6. Residue definitions

Soil

Definitions for risk assessment: fluazinam, HYPA[20], MAPA[21] (anaerobic conditions only) and DAPA[22] (anaerobic conditions only).

Definitions for monitoring: fluazinam

[20] HYPA: 5-(3-chloro-5-trifluoromethyl-2-pyridylamino)- α,α,α- trifluoro-4,6-dinitro-*o*-cresol

[21] MAPA: 2-chloro-6-(3-chloro-5-trifluoromethyl-2-pyridylamino)-α,α,α--trifluoro-5-nitro-*m*-toluidine

[22] DAPA: 3-chloro-2-(2,6-diamino-3-chloro- α,α,α-trifluoromethyl-*p*-toluidino)-3-chloro-5-(trifluoromethyl)pyridine

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Water

Ground water

Definitions for exposure assessment: fluazinam, HYPA, MAPA (anaerobic conditions only) and DAPA (anaerobic conditions only).

Definitions for monitoring: fluazinam

Surface water

Definitions for risk assessment: fluazinam, G-504[23] and HYPA.

Definitions for monitoring: fluazinam, HYPA and G-504 (HYPA and G-504 pending ecotoxicological assessment).

Air

Definitions for risk assessment: fluazinam

Definitions for monitoring: fluazinam

Food of plant origin

Definitions for risk assessment: Sum of fluazinam, AMPA-FLUAZINAM [24] and AMGT[25], expressed as fluazinam (provisional)

Definitions for monitoring: fluazinam

Food of animal origin

Definitions for risk assessment: Not required as animal exposure is extremely low.

Definitions for monitoring: Not required as animal exposure is extremely low.

[23] G-504: 4,9-dichloro-6-nitro-8-(trifluoromethyl)-pyrido-[1,2-*a*]benzimidazole-2-carboxylic acid

[24] AMPA-FLUAZINAM: 2-(6-amino-3-chloro-α,α,α-trifluoro-2-nitro-*p*-toluidino)-3-chloro-5-(trifluoromethyl)pyridine.

[25] AMGT: 3-[[4-amino-3-[[3-chloro-5-(trifluoromethyl)-2-pyridyl]amino]- *α*,*α*,*α*-trifluoro-6-nitro-*o*-tolyl]thio]-2-(β-D-glucopyranosyloxy)propionic acid.

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Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

Soil

Compound (name and/or code)	**Persistence**	**Ecotoxicology**
Fluazinam	Medium to high persistent in soil (DT50 = 17.1 – 226 d)	The acute risk to earthworms is considered low and the long-term risk is addressed in a field study. Non conclusion on safe use for other soil non-target macro-organisms is reached. A data gap is identified for a new higher tier study with focus on macro organisms. The risk is considered to be low for other soil non-target micro-organisms, to non-target plants and STP.
HYPA	Moderate to very high persistent (DT50 = 54 – 148 d)	The acute risk to earthworms is low. The risk to other soil non-target macro-organisms and micro-organisms is considered to be low, as is the risk to non-target plants.
MAPA (anaerobic conditions only)	Anaerobic conditions considered not relevant of the EU representative use	Anaerobic conditions considered not relevant of the EU representative use
DAPA (anaerobic conditions only)	Anaerobic conditions considered not relevant of the EU representative use	Anaerobic conditions considered not relevant of the EU representative use

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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 relevance**
HYPA	Low to medium mobile (K_{foc} = 450 – 1700 mL/g)	FOCUS (PEARL and PELMO); No	No assessment required. No data available.	No assessment required. Acute and genotox data available.	No assessment required. No data available.
MAPA (anaerobic conditions only)*	No data available	Not calculated.	No data available	No assessment required. Acute and genotox data available.	No assessment required. No data available.
DAPA (anaerobic conditions only)*	No data available	Not calculated	No data available	No assessment required. No data available	No assessment required. No data available.

* Anaerobic conditions considered not relevant of the EU representative use

Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
Fluazinam (surface water and sediment)	Very toxic to aquatic organisms, the risk assessment indicated a high risk to aquatic organisms. Further risk assessment is required. Low risk to sediment dwelling organisms if a no-spray buffer zone is taken in to account. The risk for bioaccumulation is considered to be low.
HYPA	Toxicity data not validated, no aquatic risk assessment available A reliable logPow is required to assess the potential for bioaccumulation.
G-504	Data gap for aquatic toxicity data, no aquatic risk assessment available

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Air

Compound (name and/or code)	**Toxicology**
Fluazinam	Harmful by inhalation (1.1 mg/L<LC_{50}< 4 mg/L)

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

- Justification or data to support the proposed level for one impurity and also justification for the presence of some impurities in the technical specification (relevant for all representative uses evaluated; identified by PRAPeR 31 expert meeting; submission date: quality control data submitted in November 2007, presented in an addendum to vol.4, not peer- reviewed; refer to chapter 1).
- After the experts' meeting a data gap to address pH dependence of log P_{ow} and the content of the relevant impurity and the pourability before and after storage must be determined in the 2 years shelf life study (relevant for all representative uses evaluated; identified by the RMS in vol. 1 level 4; submission date proposed by the notifier: unknown; refer to chapter 1)
- An ILV for the LC-MS/MS method for plant matrices is required (relevant for all representative uses evaluated; identified by PRAPeR 31 expert meeting; submission date proposed by the notifier: unknown; refer to chapter 1).
- Assessment of the representativeness of the toxicological batches (with regard to the levels of impurities and their toxicological relevance) in comparison with the technical specification (relevant for all representative uses evaluated; assessment by the RMS of an additional position paper provided in the addendum rev.3 to Volume 3 of December 2007, but not peer-reviewed; refer to point 2.8).
- Assessment of the toxicological properties of the plant metabolite TFAA in comparison with the parent compound fluazinam (relevant for all representative uses evaluated; position paper provided to the RMS in November 2007 but not peer-reviewed, new developmental toxicity study with TFAA submitted to the RMS on the 8th January 2008 but not peer-reviewed; refer to point 2.8).
- Information allowing the assessment of the risk for the consumer resulting from the intake of TFAA if as outcome of the required toxicological information it is concluded that this metabolite is to be considered as a relevant hazard for consumer safety and toxicological reference values are fixed (relevant for the representative use in potatoes; no submission date proposed by the notifier; refer to point 3.1.1).
- A refined risk assessment to earthworm eating mammals is required (relevant for all uses; no submission date proposed; refer to point 5.1).
- Risk assessment based on both PEC_{SW} and PEC_{SED} for fluazinam calculated according FOCUS SW scheme up to Step 4 considering only spray drift mitigation by buffer zones was confirmed by the fate expert's meeting (PRAPeR 27) (relevant for the representative use evaluated; no submission date proposed; EU risk assessment has been completed on basis of the calculations provided by the RMS; refer to point 5.2).
- Final aquatic toxicity studies with the soil metabolite HYPA for fish and daphnia are required (relevant for all uses; no submission date proposed; refer to point 5.2).
- A refined aquatic risk assessment for HYPA is required including revised PECsw concentration (relevant for all uses; no submission date proposed; refer to point 5.2).

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- A data gap was identified at the expert meeting for toxicity data for G-504 for all groups of aquatic organisms (relevant for all uses; no submission date proposed; refer to point 5.2).
- A data gap for a study on logPow for HYPA was identified at the experts' meeting on physical-chemical properties to decide if further risk assessment is triggered for the metabolites (relevant for all uses; s no submission date proposed; refer to point 5.2).
- A data gap for a new higher tier study, in which the new PECsoil plateau is covered and the presence of and effects on macro organisms are monitored (relevant for all uses; no submission date proposed; refer to point 5.6).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as proposed by the applicant which comprise foliar spraying against *Phytophtora infestans* (late blight and tuber blight) in potatoes before the disease attack, up to growth stage of BBCH 95-97, in all EU countries, up to a maximum 10 applications at a maximum individual application rate per spray of 200 g a.s./ha, with an interval of 7 to 10 days between applications.

The representative formulated product for the evaluation was "Fluazinam 500SC", a suspension concentrate (SC) containing 500 g/l fluazinam, registered under different trade names in Europe.

Adequate analytical methods are available to monitor fluazinam residues in food/feed of plant origin and environmental matrices and also in body fluids and tissues.
Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection products are possible.

Concerning the mammalian toxicology, the toxicokinetic studies have shown that oral absorption of fluazinam was 35% of the administered dose. In the acute studies, fluazinam was harmful by inhalation (**Xn, R20**), severely irritating to the eyes (**Xi, R41**) and skin sensitizer (**R43**).
The liver was the target organ in repeat dose studies with rats, mice and dogs. Some haematological changes were also observed in dogs, and the increased vacuolation of white matter in brain and spinal cord observed at high doses was demonstrated to be directly related to one impurity. Based on the effects observed in the skin in the repeat dose study by dermal administration, the classification **Xi, R38** (Irritating to the skin) was proposed. In the genotoxicity studies, no mutagenic potential was observed in vitro or in vivo. There was no carcinogenic potential in long term studies. In the reproduction studies, the fertility parameters and the offspring were not affected, but the indications of teratogenicity in the rat studies led to the proposal of classification **Reprotox. Cat. 3, R63** (Possible risk of harm to the unborn child). No adverse effect on the nervous system was observed in specific neurotoxicity studies with rats.

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The relative toxicity of the plant metabolite trifuoro-acetic acid (TFAA) in comparison with fluazinam could not be established based on the available data. The impurity 5 has been demonstrated to be responsible of the vacuolation of the white matter in rats, mice and dogs and the acceptable maximum level in the technical specification was agreed to be 0.2%. Neither the toxicological relevance of several impurities nor the representativeness of the toxicological batches with regard to the technical specification could be concluded.

The acceptable daily intake (**ADI**) is 0.01 mg/kg bw/day, the acute reference dose (**ARfD**) 0.07 mg/kg bw and the acceptable operator exposure level (**AOEL**) 0.004 mg/kg bw/day, all derived with the use of a safety factor 100. The dermal absorption values were 1.5% for the concentrate and 7% for the dilution. The operator exposure estimate is below the AOEL according to the German model when personal protective equipment is used, and the worker exposure estimates (during crop inspection or harvesting) are below the AOEL with the use of personal protective equipment.

Based on appropriate metabolism studies, the metabolism of fluazinam in potatoes is clearly elucidated. Parent compound, AMPA-FLUAZINAM and AMGT are present at harvest in potato tubers at low but comparable amounts and are included in the residue definition for risk assessment. A further degradation product was identified as TFAA. This metabolite is present at very low levels in potato tubers but also in rotational crops. As information on its toxicological properties is lacking, the proposed residue definition is provisional.

For enforcement, the residue definition can be restricted to parent compound. Supervised residue trials show that the MRL for potatoes can be set at the LOQ (limit of quantification level).

Livestock exposure to fluazinam residues is very low and the setting of a residue definition and MRLs in animal products is not necessary.

Under restriction of the information to be provided on the toxicological relevance of TFAA and if appropriate on the actual consumer exposure to this metabolite, no dietary risk is expected resulting from the representative use of fluazinam in potatoes.

It must be noted that the issue related to TFAA is a generic issue and potentially concerns a range of active substances containing a trifluoromethyl moiety.

Under dark aerobic conditions at 20 ºC, fluazinam is medium to high persistent in soil (DT_{50} = 17.1 – 226 d). Substitution of phenyl ring chlorine by hydroxyl in fluazinam yields the major soil metabolite HYPA (max 13.9 % after 40 d). HYPA was shown to be moderate to high persistent under these conditions (DT_{50} = 54 – 396 d).Other minor metabolites identified resulted from the reduction of the phenyl nitro groups to form the corresponding anilines. Metabolites resulting from the cleavage of the bridging amino group have not been identified in any of the available studies. After 90 d non extractable residues reached levels of 16.7 – 50.5 % AR and mineralization was almost negligible (radioactivity trapped in the ethanolamine trap = 0.9 – 2.2 % AR after 90 d, attributed to CO_2).

Fluazinam was low to moderate persistent (DT_{50} = 3.9 – 26 d) under dark anaerobic conditions due to the relatively rapid reduction of the nitro groups to form the MAPA (max. 9 – 31.2 % AR), AMPA-FLUAZINAM and DAPA (max. 12.0 % AR after 90 d) metabolites. Higher amounts of non

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extractable residues were formed under these conditions (max 60.6 % AR after 180 d, end of the study).

Photolysis was shown to contribute to the degradation of fluazinam in soil. HYPA and AMPA-FLUAZINAM are found as minor photolysis metabolites.

There are field dissipation studies available in UK (two sites), Germany (four sites) and USA (four sites). USA field trials were considered not relevant for EU conditions and were not used in the risk assessment. The potential effect of photolysis on the degradation of fluazinam in these field trials was discussed in the experts' meeting on basis of the applicant's position paper summarized and assessed by the rapporteur Member State in the DAR. The meeting agreed that the kinetic parameters derived from the field trials were not appropriate for use in environmental modelling and that new FOCUS PEC_{SW} and FOCUS PEC_{GW} will need to be calculated on basis of laboratory data. Also since the studies were performed on bare soil they were not considered representative of the uses proposed. Therefore new PEC soil calculation using the longest laboratory half life and application every two years for potato was regarded as necessary by the meeting. After the experts' meeting, new PEC soil have been presented by the rapporteur Member State in an updated addendum to B.8 following the parameters agreed by the meeting. Since input parameters were peer reviewed the new values may also be considered peer reviewed.

According batch soil adsorption / desorption studies available fluazinam may be considered slight to low mobile (K_{foc} = 1705 – 2316 mL/g) and HYPA low to medium mobile (K_{foc} = 450 - 1700 mL/g).

Fluazinam may be considered stable at pH 4 and it is rapidly hydrolysed at pH 7 (DT_{50} = 2.7 – 4.5 d) and pH 9 (DT_{50} = 3.5 – 3.9 d). The major hydrolysis metabolite at pH 7 and 9 was CAPA. This metabolite is stable to hydrolysis under normal environmental conditions.

Aqueous photolysis may contribute to the environmental dissipation of fluazinam. A number of metabolites were formed of which only G-504 was formed at levels above the 10 % AR (17 % AR). Minor metabolites identified were AMPA-FLUAZINAM (max. 4.1 % AR after 10 d) and HYPA (max. amount not reported).

Fluazinam is not readily biodegradable according the available study.

In water sediment systems fluazinam partitioned with the sediment and was converted to a number of metabolites through substitution of chlorine atom and reduction of nitro groups ($DT_{50\ water}$ = 2.4 – 3.0; $DT_{50\ whole\ system}$ = 3.1 – 5.7 d). Among these metabolites only AMPA-FLUAZINAM reached levels above 10 % in the sediment phase. Non extractable residues amounted up to 55 % AR after 100 d and mineralization was practically negligible (CO_2 = 2.0 – 2.2 after 100 d). There are no indications that the amino bridge between the two rings is broken during the degradation. Dissipation rate of metabolite AMPA-FLUAZINAM was calculated with data of one of the systems ($DT_{50\ sed}$ = 33.9 d). The rapporteur Member State provided in an addendum the whole system kinetic parameters for HYPA based on a multicompartmental fitting of the data of both systems (HYPA: $DT_{50\ whole\ system}$ = 27.9 – 51.0 d; ff = 0.06 – 0.08). The rapporteur Member State identified shortcomings in the study that do not invalidate it in its integrity but need to be considered when using the results for risk assessment.

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PEC_{SW} for fluazinam and for the major sediment metabolite AMPA-FLUAZINAM were presented in the DAR for the representative use in potatoes. The input parameters used in the applicant's calculation for fluazinam were not agreed by the meeting.

After the meeting, the rapporteur Member State presented new FOCUS PEC_{SW} and PEC_{SED} for Fluazinam and HYPA using the input parameters agreed by the meeting of experts in the updated addendum to B.8.

Potential ground water contamination by fluazinam and the major soil metabolite HYPA for the representative use in potatoes may be considered negligible with the available modelling.

Fluazinam may be relatively persistent in air but a high degree of uncertainty is associated to the estimation of its atmospheric half life. However, it is not volatile enough to perform an experimental measurement of its atmospheric photochemical stability.

The risk assessment followed the Guidance Document on Risk Assessment for Birds and Mammals (SANCO/4145/2000). It is not considered necessary to calculate the risk to herbivorous birds and mammals in potatoes as potato leaves are considered unpalatable. Therefore the risk to herbivorous birds and mammals is considered to be low. Based on the first tier risk assessment the risk to insectivorous birds and mammals can be regarded as low for the representative use of fluazinam evaluated. As the Log Pow of fluazinam exceeds 3, the risk to birds and mammals from secondary poisoning was assessed. The risk to fish-eating birds and mammals can be considered as low. Also the risk to earthworm eating birds can be considered as low, whereas as further refinement is still required to identify low risk for earthworm eating mammals. No risk is expected for birds or mammals from the ingestion of contaminated drinking water.

Fish was the most sensitive aquatic organisms on an acute and chronic time scale in the standard dataset. All scenarios were acceptable at FOCUSsw step 4, including a buffer zone of 10 m. The risk to aquatic invertebrates and algae is considered low at FOCUS Step 3 and Step 2 respectively. The risk to HYPA and G-504 is inconclusive due to lack of toxicity data. The risk to sediment dwelling organisms is concluded to be low, but risk assessment based on sediment concentrations is missing.

The risk for bees and NTA are considered low from the representative use of fluazinam. As for the earthworms the acute risk assessment indicated indicating a low acute risk to earthworms. Whereas the reproductive study on earthworms did not meet the Annex VI trigger, and a field study with earthworms addressed the long term risk to earthworms. Given the $DT_{90field}$ in soil for fluazinam and the observed effects on earthworms and *A. rhopalosiphi*, a study on the effects on collembolan was submitted. The toxicity to collembolan triggered a litterbag study. At litterbag study was submitted bud not accepted as the exposure was to low. . A data gap was identified for a new litterbag study, in which the new PECplateau is covered. In this study the presence of and effects on macro organisms should be checked.

The risk to soil non-target micro-organisms and non-target plants is considerer to be low for both fluazinam and HYPA.

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

- Use of personal protective equipment is necessary to have operator and worker exposure estimates below the AOEL (refer to point 2.12).

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- Based on the reviewed aquatic data a no-spray buffer zone 10 m is required to demonstrate TER values above the Annex VI trigger in all scenarios. However, further risk mitigation may be required to address the risk to sediment dwellers based on assessment of sediment concentrations. Furthermore, additional information is available which indicates that a copepoda species is more sensitive than Daphnia, but the reliability of this data is not peer reviewed. In case of Annex I inclusion, further assessment may be considered at MS level.
- Aquatic risk assessment for the metabolite HYPA only covers up to a maximum of eight applications (8 x 200g a.s. /ha) when representative use proposed considers a maximum of 10 applications possible (10 x 200 g a.s. / ha).

Critical areas of concern

- A final consumer risk assessment covering TFAA is at this stage not possible to conduct due to lacking data on its toxicological properties and its practical occurrence in primary and rotational crops.
- The final conclusion for the metabolite HYPA is missing in the aquatic risk assessment, as HYPA PECsw calculation and toxic effect data were not finalised during the peer review process.
- No final conclusion can be drawn for the risk to earthworm eating mammals in the mammals risk assessment.
- No final conclusion can be drawn for the risk to macro-soil organisms in the terrestrial risk assessment.
- It is not possible to conclude on the risk of metabolite G-504 to aquatic organisms.

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APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

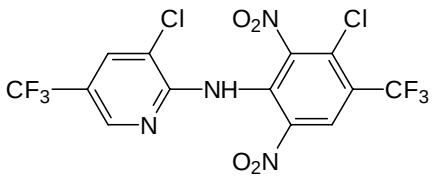
(Abbreviations used in this list are explained in appendix 2)

Appendix 1.1 Identity, Physical and Chemical Properties, Details of Uses, Further Information

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

Rapporteur Member State	Austria
Co-rapporteur Member State	not relevant

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	3-chloro-N-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α- trifluoro-2, 6-dinitro-p-toluidine
Chemical name (CA) ‡	3-chloro-N-[3-chloro-2, 6-dinitro-4-trifluoromethyl) phenyl]-5-(trifluoromethyl)-2-pyridinamine
CIPAC No ‡	521
CAS No ‡	79622-59-6
EC No (EINECS or ELINCS) ‡	not available
FAO Specification (including year of publication) ‡	no FAO specification is available at the time of evaluation
Minimum purity of the active substance as manufactured ‡	960 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	5-chloro-*N*-(3-chloro-5-trifluoromethyl-2-pyridyl)-*α,α,α*-trifluoro-4,6-dinitro-*o*-toluidine Max. content: 2.0 g/kg
Molecular formula ‡	$C_{13}H_4Cl_2F_6N_4O_4$
Molecular mass ‡	465.1 g/mol
Structural formula ‡	

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	117 °C		(99.8% w/w)
Boiling point (state purity) ‡	not applicable		
Temperature of decomposition (state purity)	test substance not stable >150 °C		(99.8% w/w)
Appearance (state purity) ‡	PGAI: yellow, crystalline solid odorless		(100% w/w) at 20 – 22 °C
	TGAI: yellow, solid weak aromatic hydrocarbon-like		(97.7% w/w) at 23 – 24 °C
Vapour pressure (state temperature, state purity) ‡	$(7.5 \pm 0.8) \times 10^{-3}$ Pa	at 20 °C	(99.8% w/w)
Henry's law constant ‡	25.9 $Pa.m^3.mol^{-1}$	at 20 °C	
Solubility in water (state temperature, state purity and pH) ‡	at 20 ± 1 °C 1.06×10^{-4} g/L in buffered solution (at pH 5) 1.35×10^{-4} g/L in buffered solution (at pH 7) 2.72×10^{-3} g/L in buffered solution (at pH 9)		(99.8% w/w)
Solubility in organic solvents ‡ (state temperature, state purity)	at 25 °C	[g/L]	(96.8% w/w)
	acetone	853	
	dichloromethane	675	
	ethyl acetate	722	
	ethyl ether	231	
	hexane	8	
	methanol	192	
	octanol	41	
	toluene	451	
Surface tension ‡ (state concentration and temperature, state purity)	66.3 mN/m at 20 °C (90% saturated solution) [additional information – water solubility < 1mg/L]		(95.5% w/w)
Partition co-efficient ‡ (state temperature, pH and purity)	$\log P_{O/W}$ = 4.03 at 25 °C pH: 5.5 – 7.0		(96.8% w/w)
	data on pH dependency still open		
Dissociation constant (state purity) ‡	pK_A = 7.34 (20 ± 1 °C)		(99.9% w/w)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	concentration: 4.66 x 10^{-5} mol/L		(99.8% w/w)
	solvent	$\lambda_{max\ [nm]}$	ε_{max} [L·mol^{-1}·cm^{-1}]
	MeOH/HCl 90/10 (0.1 N) v/v	238	21900
	MeOH	238 325	21200 5150
	MeOH/NaOH 90/10 (0.1 N) v/v	260 341 479	18100 20100 3710
	ε above 290 nm in neutral and alkaline solution > 10		
Flammability ‡ (state purity)	Not highly flammable		(96.7% w/w)
Explosive properties ‡ (state purity)	No explosive properties		(97.8% w/w)
Oxidising properties ‡ (state purity)	No oxidising properties		(97.3% w/w)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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Summary of representative uses evaluated (*Fluazinam*)

Crop and/ or situation	Member State or Country	Product Name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)	Remarks:
(a)			(b)	I	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 (l) min – max	water L/ha min – max	g as/ha (l) min – max	(m)	
Potatoes	Europe	Fluazinam 500SC	F	*Phytophtora infestans* (late blight and tuber blight)	SC	500 g/L	Field boom sprayer with hydraulic boom and nozzles	first application when warning systems forecast indicates significant disease attack last treatment BBCH 95-97	10	7 to 10 day intervals depending on the disease pressure	40 – 100	200 – 500	max. 200	7	

(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)	(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). **Certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(b)	Outdoor or field use (F), greenhouse application (G) or indoor application (I)	(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
I	*e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds	(k)	Indicate the minimum and maximum number of application possible under practical conditions of use
(d)	*e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(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
(e)	GCPF Codes – GIFAP Technical Monograph No 2, 1989	(m)	PHI – minimum pre-harvest interval
(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		

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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Appendix 1.2 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
Plant protection product (analytical technique)	HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Fluazinam
Food of animal origin		Up to now no residue definition is proposed.
Soil		Fluazinam
Water	surface	Fluazinam
	drinking/ground	Fluazinam
Air		Fluazinam

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	<u>Fluazinam:</u> LC-MS/MS enforcement method LOQ = 0.01 mg/kg) fluazinam (potato, grape, wine) An ILV is required
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	No residue definition is proposed up to now therefore no analytical method is required.
Soil (analytical technique and LOQ)	<u>Fluazinam:</u> LC-MS/MS LOQ = 0.01 mg/kg <u>HYPA:</u> HPLC-UV LOQ = 0.01 mg/kg [additional information; metabolite HYPA is not included in the current residue definition] HPLC-UV and LC-MS/MS LOQ = 0.01 mg/kg
Water (analytical technique and LOQ)	<u>Drinking water (Fluazinam):</u> LC-MS/MS LOQ = 0.1 µg/L <u>Surface water (Fluazinam):</u> LC-MS/MS LOQ = 0.1 µg/L

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Air (analytical technique and LOQ)	Fluazinam: HPLC-UV and LC-MS/MS LOQ = 1.0 µg/m^3
Body fluids and tissues (analytical technique and LOQ)	Fluazinam is no longer classified as toxic. Thus the analytical methods in tissues and body fluids are regarded as additional information Body fluids (Fluazinam): LC-MS/MS LOQ = 0.01 mg/L Tissues (Fluazinam): LC-MS/MS LOQ = 0.01 mg/kg

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

	RMS/EPCO proposal	ECB decision
Active substance or variant	RMS: none	

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Appendix 1.3 Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)	
Rate and extent of absorption:	Rapid but limited; 35 % absorbed based on excretion rates in bile and urine
Distribution:	Liver, fat and kidneys
Potential for accumulation:	No evidence for accumulation
Rate and extent of excretion:	Rapid, mainly via feces (> 84 % within 24h), also via urine (2 – 4 %)
Metabolism in animals	Almost completely metabolized by hydroxylation, followed by conjugation
Toxicologically relevant compounds (animals and plants)	Parent compound Metabolite TFAA (trifluoroacetic acid)
Toxicologically relevant compounds (environment)	Parent compound Impurity 5 (5-chloro-*N*-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-4,6-dinitro-o-toluidine)

Acute toxicity (Annex IIA, point 5.2)	
Rat LD_{50} oral	$\geq$ 4100 mg/kg bw
Rat LD_{50} dermal	> 2000 mg/kg bw
Rat LC_{50} inhalation	> 1.1 mg/l air /4h (nose only, dust aerosol) **Xn, R 20**
Skin irritation	mildly irritating (no class. required)
Eye irritation	severely irritating **Xi, R 41**
Skin sensitisation	Sensitising (M & K, Buehler) **Xi, R 43**

Short term toxicity (Annex IIA, point 5.3)	
Target / critical effect	reduced body weight gain, histopathological changes in the liver (rat, mouse and dog), histopathological changes in the stomach (dog)
Relevant oral NOAEL	1 mg/kg bw/d (52-week dog) 4.1 mg/kg bw/d (13-week rat)
Relevant dermal NOAEL	LOAEL 10 mg/kg bw/d (21-day rat) **Xi, R 38** dermal effects (acanthosis, dermatitis) at all doses
Relevant inhalation NOAEL	No data – not required

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Genotoxicity (Annex IIA, point 5.4)	
	No genotoxic potential

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)	
Target/critical effect	Liver (weight ↑; histopathological changes)
Relevant NOAEL	1.12 mg/kg bw/d (104-week mouse) 1.9 mg/kg bw/d (104-week rat)
Carcinogenicity	No carcinogenic potential

Reproductive toxicity (Annex IIA, point 5.6)	
Reproduction target / critical effect	Parental: body weight (gain) ↓; liver effects Reproduction: gestation length ↑; implantation sites and litter sizes ↓ Offspring: body weight (gain) ↓ during lactation
Relevant parental NOAEL	1.5 mg/kg bw/d (rat, 2-generation)
Relevant reproductive NOAEL	7.26 mg/kg bw/d (rat, 2-generation)
Relevant offspring NOAEL	7.26 mg/kg bw/d (rat, 2-generation)
Developmental target / critical effect	Maternal: liver (rat and rabbit), lung (rabbit) Foetal: postimplantation loss↑ (rat and rabbit), ossification incomplete (rat and rabbit), fetal and placental weight ↓ (rat), significant abnormalities at maternal toxic doses (cleft palate in rats, placental and skeletal abnormalities in rabbits) **Xn, R 63**
Relevant maternal NOAEL	Rat: 10 mg/kg bw/d Rabbit: 4 mg/kg bw/d
Relevant developmental NOAEL	Rat: 10 mg/kg bw/d Rabbit: 1 mg/kg bw/d (1st study); 7 mg/kg bw/d (2nd study[26])

Neurotoxicity (Annex IIA, point 5.7)	
Acute neurotoxicity target / critical effect	No neurotoxic effect
Relevant NOAEL	50 mg/kg bw (based on decreased locomotor activity)
Repeated neurotoxicity target / critical effect (13 weeks rat)	No neurotoxic effect
Relevant NOAEL	21 mg/kg bw/d (based on decreased body weight gain)

[26] This study (Tesh, 1988) was considered more appropriate by the experts for the setting of the ARfD.

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Other toxicological studies (Annex IIA, point 5.8)	
Metabolites	G-450, HYPA: LD_{50} oral mouse 331 mg/kg bw 1. Ames-test: slight reverse mutagenicity against S. typhimurium TA98 without S-9 mix. 2. Ames-test: negative Micronucleus test: negative G-525, MAPA: LD_{50} oral mouse > 5000 mg/kg bw, Ames-test: negative TFAA: data required
Impurities	Impurity-5: neurotoxic effect with a non-linear dose-response for the production of white matter vacuolation in the brain in rats, mice and dogs with a threshold, below which no white matter vacuolation occurs, at approximately 0.1 mg/kg bw/d of Impurity-5.

Medical data (Annex IIA, point 5.9)	
	Studies on worker exposure indicate allergic contact dermatitis and occupational asthma (Draper et al, 2003)

Summary (Annex IIA, point 5.10)	**Value**	**Study**	**Safety factor**
ADI	0.01 mg/kg bw/d	2-yr mouse, supported by 1-yr dog	100
AOEL	0.004 mg/kg bw/d	1-yr dog, supported by rabbit developmental	100 (35%*)
ArfD (acute reference dose)	0.07 mg/kg bw/d	rabbit, developmental	100

*Correction for oral absorption

Dermal absorption (Annex IIIA, point 7.3)	
Representative product: Fluazinam 500 SC	Concentrate: 1.5% Spray dilutions: 7% Rat *in vivo* and comparative *in vitro* (human/rat skin)

Acceptable exposure scenarios (including method of calculation)	
Operator	Tractor field application: BBA model: 258 % of AOEL without PPE 13 % of AOEL with PPE POEM model: 1362 % of AOEL without PPE 219 % of AOEL with PPE

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Workers	For crop inspection activities (2 hours) 925% of AOEL without PPE 50 % of AOEL, with PPE For harvesting activities (7 d after application) 450% of AOEL without PPE 25% of AOEL, with PPE
Bystanders	According to Lloyd and Bell (1983) : 5.4% of AOEL

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

Active substance	Xn, R 20; Xi; R 38 – 41 – 43; Reprotox. Cat.3, R 63
Preparation	Xn, R 63; Xi; R43

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Appendix 1.4 Residues

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

Plant groups covered	Root vegetables (potatoes) pulses/oilseeds (peanuts) fruits (grapes, apples)
Rotational crops	Lettuce, carrots, barley
Metabolism in rotational crops similar to metabolism in primary crops	To a large extent comparable; two exceptions: - TFAA occurred in significant amounts in all rotational crops; in primary crops (potatoes, peanut foliage and apples) it was observed in trace amounts only. - Parent fluazinam was not detected in any extract from any rotational crop sample.
Processed commodities	No processing studies required.
Residue pattern in processed commodities similar to residue pattern in raw commodities	No processing studies required.
Plant residue definition for monitoring	Fluazinam (restricted to potatoes)
Plant residue definition for risk assessment	Sum of Fluazinam, AMPA-FLUAZINAM and AMGT, expressed as Fluazinam (provisional, as no risk assessment related to TFAA can be conducted as this stage)
Conversion factor (monitoring to risk assessment)	3 (for potatoes only).

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

Animals covered	Lactating goat Laying hen
Time needed to reach a plateau concentration in milk and eggs	Milk: plateau level reached during the run of the study (4 days). Eggs: plateau level not reached during the run of the study (4 days).
Animal residue definition for monitoring	Not required.
Animal residue definition for risk assessment	Not required.
Conversion factor (monitoring to risk assessment)	Not required.
Metabolism in rat and ruminant similar (yes/no)	Yes.
Fat soluble residue: (yes/no)	Yes (log $P_{O/W}$ = 4.03 at 25 °C), but no accumulation of active substance or metabolites in animal tissues, milk and eggs was observed.

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

Total radioactive residues declined with the last planting interval; fluazinam was not accumulated by plants after uptake from soil. Parent fluazinam was not detected in any extract from any crop sample. Related residues still retaining the basic fluazinam structural two ring moiety remained below any relevant level in edible parts of the crops. The main part of the radioactivity recovered was found to be TFAA (trifluoro-acetic acid) at a significant level up to 0.27 mg/kg. Fluazinam was not translocated into deeper soil layers but it could be observed that fluazinam or related residues were persistent in the upper soil layer.

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

Potato tubers: 26 months

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	no	no	Not required.
Potential for accumulation (yes/no):	no	no	Not required.
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues	no	no	Not required.
	Feeding studies: not required. Residue levels in matrices : Mean (max) mg/kg		
Muscle Liver Kidney Fat Milk Eggs	Not relevant.		

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Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the intended use	HR I	STMR (b)
Potatoes (tubers)	Northern Region	PHI = 7 days: 13 x <0.01	Within the 13 residue trials 8 decline/degradation studies resulted in residues <0.01 mg/kg at PHI = 0.	0.01 *	<0.01	<0.01
Potatoes (tubers)	Southern Region	PHI = 14 – 15 days: 3 x <0.01	Only three trials have been performed in the Southern Region including 6 applications at the critical rate + 25% (250 g/ha). Although the PHI was not at the GAP, the lack of residues even at 0 day PHI intervals observed in the residue decline studies described above as well as the results of the plant metabolism study in potatoes demonstrate that no residues of fluazinam above the LOQ of 0.01 mg/kg in potatoes are expected.	0.01 *	<0.01	<0.01

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

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

ADI	0.01 mg/kg bw/d		
TMDI (% ADI)	TMDI (European diet; adult of 60 kg): 0.4 % of ADI		
TMDI (% ADI) according to national (to be specified) diets	TMDI (German diet; girl of 13.5 kg body weight): 0.5 % of ADI.		
IEDI (European Diet) (% ADI)	Not relevant.		
NEDI (specify diet) (% ADI)	Not relevant.		
Factors included in IEDI and NEDI	Not relevant.		
ARfD	0.07 mg/kg bw/d		
IESTI (%ARfD)	Only UK diet used for acute exposure assessment		
NESTI (%ARfD) according to national (to be specified) large portion consumption data	potatoes (UK diet)	adult aged 16 – 64 years, vegetarian and elderly-residential: 0.3 %	infant 0.5 - 1 years: 2.2% (not relevant)
Factors included in I(N)ESTI	Variability factor 7		

*) The consumer risk assessment has to be regarded as provisional, as no risk assessment related to TFAA can be conducted as this stage).

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

Crop/process/processed crop	Number of studies	Transfer factor
Not necessary.	---	---

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

Potatoes	0.01* mg fluazinam/kg

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Appendix 1.5 Fate and Behaviour in the Environment

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

Mineralization after 100 days	1.2-2.2 % after 90 d, [^{14}C-phenyl]-label (n = 2) 0.4-1.2 % after 90 d, [^{14}C-pyridyl]-label (n = 2) 2.7 % after 120 d, mixture of the two label positions (n=1) Sterile conditions: <0.1 % after 30 d (n = 1, only phenyl label measured)
Non-extractable residues after 100 days	16.7-37.1 % after 90 d, [^{14}C-phenyl]-label (n = 2) 15.8-35.5 % after 90 d, [^{14}C-pyridyl]-label (n = 2) 46.6 % after 120 d, mixture of the two label pos. (n = 1) Sterile conditions: 6.2 % after 30 d (n= 1, only phenyl label measured)
Metabolites requiring further consideration – name and/or code, % of applied (range and maximum)	HYPA [^{14}C-phenyl]-label: 8.2 % (day 14) and 5.9 % (day 7) [^{14}C-pyridyl]-label: 9.3 % (day 180) and 5.6 % (day 14) Mixture of the two label positions: 13.9 % (day 48) Sterile conditions: <0.5 % after 30 d

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

Anaerobic degradation

Mineralization after 100 days	0.8 % after 90 d, [^{14}C-phenyl]-label 0.2 % after 90 d, [^{14}C-pyridyl]-label
Non-extractable residues after 100 days	46.9 % after 90 d, [^{14}C-phenyl]-label 41.6 % after 90 d, [^{14}C-pyridyl]-label
Metabolites that may require further consideration for risk assessment – name and/or code, % of applied (range and maximum)	MAPA [^{14}C-phenyl]-label: 31.2 % (day 14) [^{14}C-pyridyl]-label: 27.4 % (day 14) DAPA [^{14}C-phenyl]-label: 12.0 % (day 90) [^{14}C-pyridyl]-label: 11.6 % (day 90)

Soil photolysis

Metabolites that may require further consideration for risk assessment – name and/or code, % of applied (range and maximum)	[^{14}C-phenyl]-label and [^{14}C-pyridyl]-label: Photolysis significantly increases degradation of fluazinam on soil. Conversion to bound residues even more extensive under light conditions. HYPA as a product of soil metabolism, whereas AMPA slightly higher under light: up to 5 % AR (light) versus <1 % AR (dark) Non-identified radioactivity:

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Phenyl-label: 10.6 – 1.8 % AR (multiple minor peaks with each individual peak <4.3 % AR) Pyridyl-label: 4.9 – 14.6 % AR (multiple minor peaks with each individual peak <4.3 % AR)

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

Laboratory studies (Labelling at phenyl- or pyridyl-ring of fluazinam possible)

Fluazinam	Aerobic conditions						
Soil type	Applic. Rate	pH	T °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam	1 kg/ha	6.9	20 °C / 40 %	Phenyl: 96 / 320 Pyridyl: 63 /210	n.c.	0.91 0.81	SFO
Sandy loam	5 kg/ha	6.9	20 °C / 40 %	Phenyl: 174 /578 Pyridyl: 171 /568	n.c.	0.62 0.56	SFO
Geometric mean DT_{50}:				116 *****days			
Loamy sand	1 kg/ha	6.4	20 °C/ 40 %	Phenyl: 263 / 873 Pyridyl: 189 / 628 Geomean DT_{50}: 226*****	n.c.	0.89 0.95	SFO
Sandy loam	0.74 kg/ha	7.1	20 °C/ 40 %	Mixture: 17***** / n.c.	n.c.	0.99	SFO
Sandy soil	0.56 kg/ha	5.4	20 °C/ 40 %	Unlabelled: 62***** / n.c.	n.c.	0.96	SFO
Sandy loam	1 kg/ha	6.9	10 °C/ 40 %	Phenyl: 212 Pyridyl: 139	-	-	Arrhenius equ. Q_{10}: 2.2
Geometric mean DT_{50} of 20 °C samples (both labels) calculated from *****values: 72.5 days							
HYPA	Aerobic conditions						
Soil type	Applic. Rate	pH	T °C / % MWHC	DT_{50}/DT_{90} (d)	Label position	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Sand	0.16 mg/kg	5.2	20 °C / 40 %	148 / 490	Unlabelled	148*****	0.99	SFO
Loamy sand	0.16 mg/kg	5.6	20 °C / 40 %	74 / 245	Unlabelled	74*****	0.96	SFO
Clay loam	0.16 mg/kg	6.2	20 °C / 40 %	54 / 179	Unlabelled	49.3*****	0.96	SFO
Clay loam	3.5 mg/kg	7.4	20 °C / WHC pF 2.3	396***** / 1317	Unlabelled	not calculated	0.45 (X^2 = 2.7)	SFO
Sandy loam	Study with parent	7.1	20 °C/ 40 %	105*****	-	not calculated	0.99	SFO
Geometric mean DT_{50} (*…values included in the calculation): 117.6 days								

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Field studies

Fluazinam (formulated)	Aerobic conditions							
Soil type (inidicate if bare or cropped soil was used).	Location	Application kg ai/ha	pH	Depth (cm)	DT_{50} / DT_{50} NORM 20 °C (d)	DT_{90} (d) *	St. (r^2) DT_{50} / DT_{90}*	Method of calculation DT_{50}
Clay loam (bare soil)	UK	10 x 0.3	6.6	10	35 / 24	193 *	0.88 / 0.89*	SFO / 20 °C norm.
Sandy clay loam (bare)	UK	10 x 0.3	7.5	10	41 / 26	254 *	0.82 / 0.71*	SFO / 20 °C norm.
Loamy sand (bare)	Germany	1 x 1.35	6.1	10	28 / 21	161 *	0.97 / 0.97*	SFO / 20 °C norm.
Sandy loam (bare)	Germany	1 x 1.35	6.1	10	8.3 / 8.4	67 *	0.98 / 0.97*	SFO / 20 °C norm.
Clay (bare soil)	Germany	1 x 1.35	5.3	10	13.4 /13.5	144 *	0.97 / 0.94*	SFO / 20 °C norm.
Clay loam (bare soil)	Germany	1 x 1.35	6.8	10	16 / 13.6	127 *	0.98 / 0.90*	SFO / 20 °C norm.
Geometric mean: DT_{50}: 20.4 and DT_{50} normalised to 20 °C: 16.4								
HYPA	Aerobic conditions							
Soil type	Location	Depth (cm)	pH	Maximum concentration detected				
Clay loam (bare soil)	UK	10	6.6	0.09 mg/kg (dw)				
Sandy clay loam (bare)	UK	10	7.5	0.09 mg/kg (dw)				
Loamy sand (bare)	Germany	10	6.1	<0.01 mg/kg (dw)				
Sandy loam (bare)	Germany	10	6.1	0.01 mg/kg (dw)				
Clay (bare soil)	Germany	10	5.3	<0.01 mg/kg (dw)				
Clay loam (bare soil)	Germany	10	6.8	0.02 mg/kg (dw)				

* DT_{90}: Timme and Frehse best fit

pH dependence (yes / no) (if yes type of dependence)	no
Soil accumulation and plateau concentration	Fluazinam: No accumulation expected HYPA: Calculated environmental plateau concentration after 3 years: 0.37 mg/kg

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Soil adsorption/desorption (Annex IIA, point 7.1.2)

Fluazinam							
Soil Type	OC %	Soil pH	Kd	Koc	Kf	Kfoc (mL/g)	1/n
Sand	0.48	6.0	126	26 250	11.12	2 316	0.6204
Loamy sand	2.55	6.0	261	10 245	43.48	1 705	0.6813
Silt loam	1.42	7.7	227	15 986	27.19	1 915	0.6504
Clay loam	2.0	7.1	264	13 237	37.88	1 894	0.6492
Arithmetic mean:					26.6	1 958	0.65
pH dependence:			no				

HYPA							
Soil Type	OC %	Soil pH	Kd	Koc	Kf	Kfoc (mL/g)	1/n
Sandy loam	3.1	7.7	20	640	14	450*	Not stated
Sandy loam	1.9	8.1	18	950	13	700*	0.84
Loamy sand	1.8	7.9	12	640	8.1	450*	Not stated
Coarse sand	0.5	5.7	6.6	1 400	4.3	920*	Not stated
Silty clay loam	1.5	5.0	35	2 400	19	1 300	0.75
Sandy loam	1.6	4.7	51	3 200	26	1 700	Not stated
Arithmetic mean:					12	920 630* (excluding acidic soils) - used for modelling	
pH dependence:			in acidic soils higher Kfoc were observed				

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

Column leaching	Fluazinam formulated (SC): soils: sand, loamy sand, sandy loam Application rate: 750 g ai/ha Elution (mm): 200 mm Time period (d): 2 d
	Leachate: residues of fluazinam in the leachates below the LOD (i.e. <2 µg/L)
Aged residues leaching	Not submitted, not required
Lysimeter/ field leaching studies	Not submitted, not required

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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PEC (soil) (Annex IIIA, point 9.1.3)

Fluazinam Method of calculation	DT_{50} (d): 226 days (Worst case from lab studies) Kinetics: 1st order
Application data	Crop: potatoes Depth of soil layer: 20 cm, and 5 cm in the last year 50 % and 80 % plant interception (68 % on average) Application rates: 200 g as/ha every two years Number of applications: 10 Interval (d): 7

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial (after the last application)	0.133		0.78	
Plateau max. concentration	0.8 mg/kg after 5 y (including 68 % interception on average)			

HYPA Method of calculation	Molecular weight relative to the parent: 0.960 DT_{50} (d): 396 (Worst case from laboratory studies, no moisture correction) Kinetics: SFO
Application data	Application rate assumed: 10 x 200 g as/ha; 7 d interval; (assumed HYPA is formed at a maximum of 13.9 % of the applied dose)

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial (after last application)	0.018		0.175	
Plateau max. concentration	0.37 mg/kg after 3 yr (including 50 % interception)			

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

Hydrolytic degradation of the active substance and metabolites > 10%.	pH 4: stable (50 °C)
	Fluazinam: DT_{50} pH 7: (25 °C) 1st order: Phenyl-label: 4.5 d r^2=0.970 Pyridyl-label: 2.7 d r^2=0.996 CAPA: Phenyl-label: 92.3 % AR (day 29 = study termination) Pyridyl-label: 95.1 % AR (day 29 = study termination)
	Fluazinam: DT_{50} pH 9: (25 °C) 1st order: Phenyl-label: 3.5 d r^2=0.997 Pyridyl-label: 3.9 d r^2=0.998 CAPA: Phenyl-label: 94.0 % AR (day 29 = study termination) Pyridyl-label: 102.6 % AR (day 29 = study termination)
Photolytic degradation of active substance and metabolites above 10%	Fluazinam: DT_{50}: (25 °C) Light: 2.5 d for both label positions (linear regression, r^2=0.977-0.994) Dark: no significant degradation G-504: Phenyl-label: 17.1 % AR (day 10) Pyridyl-label: 14.0 % AR (day 7) Light intensitiy at wavelenghts >290 nm: Between 10^{-5} and 10^{-4} W/cm^2/nm. Comparable to natural sunlight 42° 43´ N
Quantum yield of direct phototransformation in water at Σ > 290 nm	1.7 x 10^{-5} mol · Einstein $^{-1}$
Readily biodegradable (yes/no)	Not ready biodegradable

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Degradation in water / sediment

Parent	Phenyl: Max. in water 73.7 % after 0 hours ("Virginia") and 72.5 % after 0 hours ("Emperor") Pyridyl: Max. in water 65.3 % after 6 hours ("Virginia") and 63.5 % after 6 hours ("Emperor") Phenyl: Max. in sediment 34.7 % after 48 hrs ("Virginia") and 33.8 % after 24 hrs ("Emperor") Pyridyl: Max. in sediment 17.0 % after 0 hrs ("Virginia") and 31.5 % after 48 hrs ("Emperor")										
Water / sediment system	pH water	pH sed	% C_{org}	T °C	DT_{50} / DT_{90} whole sys. (days)	r^2	DT_{50} / DT_{90} water (days)	r^2	DT_{50} / DT_{90} sediment (days)	r^2	Method of calculation
"Virginia Water"	6.9	6.6	3.3	20	Mean both labels: 2.9 / 32 ***** RMS: Phenyl: 3.3 / 10.9 Pyridyl: 2.9 / 9.7	0.68 0.99 0.98	RMS: Phenyl: 1.93 / 6.41 Pyridyl: 2.85 / 9.47	0.97 0.99	Mean both labels: DT_{50} 3.0 RMS: Phenyl: 2.42 / 8.03 Pyridyl: 3.35 / 11.1	0.91 0.97 0.94	Single 1st order kinetics
"Emperor Lake"	5.6	5.8	4.3	20	Mean both labels: 3.2 / 35.4 ***** RMS: Phenyl: 5.2 / 17.4 Pyridyl: 6.2 / 20.6	0.96 0.97 0.98	RMS Phenyl: 1.84 / 6.12 Pyridyl: 4.25 / 14.1	0.94 0.98	Mean both labels: DT_{50} 12.1 RMS: Phenyl: 6.41 / 21.3 Pyridyl: 9.5 / 31.5	0.73 0.76 0.77	Single 1st order kinetics
Arithmetic mean:					3.1 / 33.7 ***** RMS: Phenyl: 4.3 / 14.2 Pyridyl: 4.6 / 15.2		RMS: Phenyl: 1.9 / 6.3 Pyridyl: 3.5 / 11.8		RMS: Phenyl: 4.4 / 14.7 Pyridyl: 6.4 / 21.3		
***** Timme/Frehse (square root 1st order)!											

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AMPA	Phenyl: Max. in water 2.5 % after 14 d ("Virginia") and 0.4 % after 14 d ("Emperor") Pyridyl: Max. in water 1.9 % after 7 d ("Virginia") and 0.9 % after 14 d ("Emperor") Phenyl: Max. in sediment 26.7 % after 14 d ("Virginia") and 18.9 % after 7 d ("Emperor") Pyridyl: Max. in sediment 20.2 % after 2 d ("Virginia") and 12.7 % after 14 d ("Emperor")										
Water / sediment system	pH water	pH sed	% C_{org}	T °C	DT_{50} / DT_{90} whole sys.	R^2	DT_{50} / DT_{90} water	r^2	DT_{50} / DT_{90} sed	r^2	Method of calculation
"Virginia Water"	6.9	6.6	3.3	20	not possible	-	<1.7 % AR	-	not possible	-	-
"Emperor Lake"	5.6	5.8	4.3	20	Mean both labels: DT_{50}: 32 Simple linear exponential decay	0.95	<0.6 % AR	-	Phenyl: 24.0 / 79.8 Pyridyl: 43.7 / 145	0.95 0.91	Single 1st order kinetics
Arithmetic mean:					-		-		33.9 / 113		
Mineralization and non extractable residues											
Water / sediment system	pH water	pH sed	% C_{org}	Mineralisation after 100 d (end of the study)	Non-extractable residues in sediment : Max. % after n days		Non-extractable residues in sediment: % after 100 d (end of the study)				
"Virginia Water"	6.9	6.6	3.3	Phenyl: 2 % Pyridyl: 2 %	Phenyl: 59.2 (day 100) Pyridyl: 51.0 (day 100)		Phenyl: 59.2 Pyridyl: 51.0				
"Emperor Lake"	5.6	5.8	4.3	Phenyl: 3.0 % Pyridyl: 1.4 %	Phenyl: 57.8 (day 61) Pyridyl: 52.8 (day 61)		Phenyl: 57.9 Pyridyl: 50.6				

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

Parent	Molecular weight (g/mol): 465.1
Parameters used in FOCUSsw Step 1 and 2	Water solubility (mg/L): 0.135 DT_{50} soil (d): 72.5 (overall geomean lab) DT_{50} whole system (d): 4.45 Crop interception: 50 % average
Parameters used in FOCUSsw Step 3	Vapour pressure : 7.5 x 10^{-3} Pa Kfoc (L/kg) : 1 958 1/n : 0.65 DT_{50} on crop (d): 10 DT_{50} water (d): 1000 DT_{50} sediment (d): 4.45
$FOCUS_{SW}$ Step 4	5 m and 10 m buffer zone : Reduction of drift : FOCUS drift calculator Reduction of runoff: none Reduction of drainage: none
Application rate	Crop: potatoes Number of applications:

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	max. number of applications possible in SWASH: 8, D6 and R2: 6 applications Interval (d): 7 Application rate(s): 200 g as/ha Depth of water body: 30 cm (FOCUS Step 1 + 2) Application window: FOCUS Step 1 + 2: June – September FOCUS Step 3: D3, D4: 14/6 – 1/9 D6: 3/5 – 7/7 and 23/8 – 5/10 R1: 8/6 – 25/8 R2: 5/4 – 23/6 R3: 23/5 – 10/8
Main routes of entry	Spray drift (FOCUS Step 1-3)

Fluazinam Maximum PEC_{SW} and PEC_{SED}

Region	Step 1		Step 2 *	
	PEC_{SW} (µg/L)	**PEC_{SED} (µg/kg dw)**	**PEC_{SW} (µg/L)**	**PEC_{SED} (µg/kg dw)**
Northern Europe	203	3620	14.0	269
Southern Europe			20.7	400

* PEC values for multiple applications; PEC values at Step 2 for single applications are lower.

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Fluazinam PEC_{SW} **Step 3 – single application**

Scenario	Water body	Appl. rate (g ai/ha)	PEC_{SW} (µg/L)				PEC_{SED} (µg/kg dw)			
			Max	1 d TWA	2 d TWA	28 d TWA	Max	1 d TWA	2 d TWA	28 d TWA
D3	Ditch	1 x 200	**1.030**	0.350	0.180	0.013	0.253	0.248	0.237	0.077
D4	Pond*	1 x 200	0.041	0.031	0.024	0.002	0.037	0.037	0.037	0.015
	Stream	1 x 200	0.854	0.052	0.026	0.002	0.038	0.036	0.035	0.011
D6	Ditch 1st	1 x 200	1.014	0.209	0.105	0.007	0.151	0.146	0.137	0.039
	Ditch 2nd *	1 x 200	1.016	0.181	0.091	0.006	0.128	0.120	0.109	0.022
R1	Pond	1 x 200	0.040	0.030	0.023	0.003	0.042	0.042	0.041	0.023
	Stream	1 x 200	0.714	0.129	0.065	0.007	0.538	0.515	0.490	0.243
R2	Stream	1 x 200	0.945	0.078	0.039	0.003	0.519	0.495	0.471	0.172
R3	Stream	1 x 200	1.009	0.238	0.119	0.009	0.171	0.164	0.155	0.065

* For the TOXWA run only, 1/n value of fluazinam set to 0.70 (see 'note')

Fluazinam PEC_{SW} and PEC_{SED} **Step 3 – multiple application**

Scenario	Water body	Appl. rate (g ai/ha)	PEC_{SW} (µg/L)				PEC_{SED} (µg/kg dw)			
			Max	1 d TWA	2 d TWA	28 d TWA	Max	1 d TWA	2 d TWA	28 d TWA
D3	Ditch	8 x 200	0.562	0.199	0.105	0.030	0.209	0.205	0.197	0.141
D4	Pond	8 x 200	0.022	0.017	0.014	0.004	0.045	0.045	0.045	0.030
	Stream	8 x 200	0.487	0.049	0.024	0.004	0.054	0.053	0.050	0.025
D6	Ditch 1st *	6 x 200	**0.611**	0.202	0.103	0.021	0.191	0.187	0.177	0.096
	Ditch 2nd	6 x 200	0.607	0.211	0.117	0.027	0.217	0.213	0.205	0.109
R1	Pond	8 x 200	0.046	0.041	0.037	0.009	0.150	0.150	0.150	0.115
	Stream	8 x 200	0.512	0.186	0.112	0.028	2.573	2.460	0.341	1.245
R2	Stream	6 x 200	0.561	0.080	0.042	0.010	2.422	2.310	2.197	0.800
R3	Stream	8 x 200	0.550	0.130	0.065	0.026	0.327	0.314	0.297	0.192

* For the TOXWA run only, 1/n value of fluazinam set to 0.70 (see 'note')

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Fluazinam PEC_{SW} and PEC_{SED} **Step 4 – 5 m buffer (single application)**

Scenario	Water body	Appl. rate (g ai/ha)	PEC_{SW} (µg/L)				PEC_{SED} (µg/kg dw)			
			Max	1 d TWA	2 d TWA	28 d TWA	Max	1 d TWA	2 d TWA	28 d TWA
D3	Ditch	1 x 200	0.336	0.115	0.059	0.004	0.083	0.081	0.078	0.025
D4	Pond*	1 x 200	0.037	0.028	0.022	0.002	0.033	0.033	0.033	0.014
	Stream	1 x 200	0.356	0.022	0.011	0.001	0.016	0.015	0.014	0.005
D6	Ditch 1st	1 x 200	0.331	0.068	0.034	0.002	0.050	0.048	0.045	0.013
	Ditch 2nd *	1 x 200	0.331	0.059	0.030	0.002	0.042	0.039	0.036	0.007
R1	Pond	1 x 200	0.036	0.027	0.021	0.003	0.040	0.039	0.038	0.021
	Stream	1 x 200	0.298	0.054	0.027	0.004	0.515	0.493	0.469	0.236
R2	Stream	1 x 200	0.394	0.032	0.016	0.002	0.519	0.495	0.471	0.172
R3	Stream	1 x 200	**0.421**	0.100	0.050	0.004	0.075	0.072	0.067	0.039

* For the TOXWA run only, 1/n value of fluazinam set to 0.70 (see 'note')

Fluazinam PEC_{SW} and PEC_{SED} **Step 4 – 5 m buffer (multiple application)**

Scenario	Water body	Appl. rate (g ai/ha)	PEC_{SW} (µg/L)				PEC_{SED} (µg/kg dw)			
			Max	1 d TWA	2 d TWA	28 d TWA	Max	1 d TWA	2 d TWA	28 d TWA
D3	Ditch	8 x 200	0.182	0.065	0.034	0.010	0.068	0.067	0.065	0.046
D4	Pond	8 x 200	0.020	0.016	0.013	0.004	0.042	0.041	0.041	0.028
	Stream	8 x 200	0.202	0.020	0.010	0.002	0.023	0.022	0.021	0.011
D6	Ditch 1st *	6 x 200	0.197	0.064	0.033	0.007	0.061	0.060	0.057	0.031
	Ditch 2nd	6 x 200	0.195	0.072	0.038	0.009	0.070	0.069	0.067	0.035
R1	Pond	8 x 200	0.046	0.041	0.037	0.009	0.150	0.150	0.150	0.115
	Stream	8 x 200	**0.284**	0.186	0.112	0.023	2.561	2.449	2.330	1.226
R2	Stream	6 x 200	0.232	0.080	0.042	0.007	2.401	2.290	2.178	0.794
R3	Stream	8 x 200	0.228	0.098	0.050	0.018	0.296	0.285	0.269	0.155

* For the TOXWA run only, 1/n value of fluazinam set to 0.70 (see 'note')

Fluazinam PEC_{SW} and PEC_{SED} **Step 4 – 10 m buffer (single application)**

Scenario	Water body	Appl. rate (g ai/ha)	PEC_{SW} (µg/L)				PEC_{SED} (µg/kg dw)			
			Max	1 d TWA	2 d TWA	28 d TWA	Max	1 d TWA	2 d TWA	28 d TWA
D3	Ditch	1 x 200	0.175	0.060	0.031	0.002	0.043	0.042	0.041	0.013
D4	Pond*	1 x 200	0.026	0.020	0.016	0.002	0.024	0.024	0.024	0.010
	Stream	1 x 200	0.190	0.012	0.006	0.000	0.008	0.008	0.008	0.003
D6	Ditch 1st	1 x 200	0.172	0.036	0.018	0.001	0.026	0.025	0.023	0.007
	Ditch 2nd *	1 x 200	0.175	0.031	0.016	0.001	0.022	0.021	0.019	0.004
R1	Pond	1 x 200	0.025	0.019	0.015	0.002	0.034	0.033	0.033	0.017
	Stream	1 x 200	0.159	0.035	0.018	0.004	0.507	0.486	0.462	0.234
R2	Stream	1 x 200	0.210	0.017	0.009	0.001	0.519	0.495	0.471	0.172
R3	Stream	1 x 200	**0.224**	0.053	0.027	0.003	0.074	0.070	0.066	0.035

* For the TOXWA run only, 1/n value of fluazinam set to 0.70 (see 'note')

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Fluazinam PEC_{SW} and PEC_{SED} **Step 4 – 10 m buffer (multiple application)**

Scenario	Water body	Appl. rate (g ai/ha)	PEC_{SW} (µg/L)				PEC_{SED} (µg/kg dw)			
			Max	1 d TWA	2 d TWA	28 d TWA	Max	1 d TWA	2 d TWA	28 d TWA
D3	Ditch	8 x 200	0.095	0.034	0.018	0.005	0.036	0.035	0.034	0.024
D4	Pond	8 x 200	0.014	0.011	0.009	0.004	0.030	0.030	0.029	0.020
	Stream	8 x 200	0.106	0.011	0.005	0.001	0.012	0.011	0.011	0.006
D6	Ditch 1st *	6 x 200	0.103	0.034	0.017	0.004	0.032	0.031	0.030	0.016
	Ditch 2nd	6 x 200	0.101	0.037	0.020	0.005	0.037	0.036	0.035	0.018
R1	Pond	8 x 200	0.046	0.041	0.037	0.008	0.150	0.150	0.150	0.115
	Stream	8 x 200	**0.253**	0.186	0.112	0.022	2.557	2.445	2.326	1.220
R2	Stream	6 x 200	0.120	0.080	0.042	0.005	2.394	2.283	2.172	0.791
R3	Stream	8 x 200	0.140	0.098	0.050	0.016	0.285	0.275	0.260	0.143

* For the TOXWA run only, 1/n value of fluazinam set to 0.70 (see 'note')

AMPA

Parameters used in FOCUSsw step 1 and 2

Molecular weight (g/mol): 435.1
Water solubility (mg/L): 0.14
Soil or water metabolite: water metabolite
Koc (L/kg): 920
DT_{50} soil (d): 95 (arithm. Mean of HYPA laboratory half-lives)
DT_{50} water (d): 32
DT_{50} sediment (d): 32
Maximum occurrence observed:
Soil: 2.2 % AR
Water/Sediment: 23.7 % AR

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	10.2		56.7	
	24h	7.82	9.03	72.0	64.3
	2d	7.66	8.39	70.4	67.8
	4d	7.33	7.94	67.4	68.3
	7d	6.87	7.58	63.2	67.0
	14d	5.90	6.98	54.3	62.8
	21d	5.07	6.48	46.7	58.7
	28d	4.36	6.03	40.1	54.8
	42d	3.22	5.28	29.6	48.1

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FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0h	1.11		8.92	
	24h	0.97	1.04	8.73	8.83
	2d	0.95	1.00	8.55	8.73
	4d	0.91	0.96	8.18	8.55
	7d	0.85	0.93	7.67	8.28
	14d	0.73	0.86	6.59	7.70
	21d	0.63	0.80	5.66	7.17
	28d	0.54	0.75	4.87	6.69
	42d	0.40	0.65	3.59	5.86
Southern EU	0h	1.35		11.1	
	24h	1.21	1.28	10.9	11.0
	2d	1.18	1.23	10.6	10.9
	4d	1.13	1.19	10.2	10.6
	7d	1.06	1.15	9.53	10.3
	14d	0.91	1.07	8.19	9.57
	21d	0.78	0.99	7.04	8.91
	28d	0.67	0.93	6.05	8.31
	42d	0.50	0.81	4.46	7.28

HYPA	
Parameters used in FOCUSsw step 1 and 2 (and step 3)	Molecular weight (g/mol): 446.7 Water solubility (mg/L): 10.45 Soil or water metabolite: water metabolite Kfoc (L/kg): 630 DT_{50} soil (d): 117.6 (geomean lab) DT_{50} whole system (d): 39.4 Maximum occurrence observed: Water/Sediment: 6.5 % AR
Parameters used in FOCUSsw step 3	1/n = 0.81 DT_{50} water (d): 1000 DT_{50} sediment (d): 39.4 Molar formation fraction in soil (% AR): 19.3

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HYPA maximum PEC_{SW} and PEC_{SED}

Region	Step 1		Step 2 *	
	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg dw)	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg dw)
Northern Europe	49.5	305	4.27	26.2
Southern Europe			6.25	38.7

* PEC values for multiple applications; PEC values at Step 2 for single applications are lower.

HYPA PEC_{SW} and PEC_{SED} **Step 3 – single application**

Scenario	Water body	Appl. rate (g ai/ha)	PEC_{SW} (µg/L)				PEC_{SED} (µg/kg dw)			
			Max	1 d TWA	2 d TWA	28 d TWA	Max	1 d TWA	2 d TWA	28 d TWA
D3	Ditch	1 x 200	0.066	0.049	0.030	0.002	0.040	0.040	0.038	0.019
D4	Pond	1 x 200	0.003	0.003	0.003	0.002	0.017	0.017	0.017	0.017
	Stream	1 x 200	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
D6	Ditch 1st	1 x 200	0.092	0.058	0.041	0.009	0.105	0.105	0.105	0.077
	Ditch 2nd	1 x 200	**0.147**	0.082	0.055	0.012	0.132	0.132	0.131	0.098
R1	Pond	1 x 200	0.011	0.011	0.011	0.009	0.132	0.132	0.132	0.132
	Stream	1 x 200	0.022	0.010	0.009	0.002	0.048	0.048	0.047	0.036
R2	Stream	1 x 200	0.012	0.011	0.006	0.002	0.216	0.214	0.212	0.190
R3	Stream	1 x 200	0.011	0.009	0.005	0.001	0.022	0.021	0.021	0.017

HYPA PEC_{SW} and **PEC_{SED} Step 3 – multiple application**

Scenario	Water body	Appl. rate (g ai/ha)	PEC_{SW} (µg/L)				PEC_{SED} (µg/kg dw)			
			Max	1 d TWA	2 d TWA	28 d TWA	Max	1 d TWA	2 d TWA	28 d TWA
D3	Ditch	8 x 200	0.036	0.031	0.023	0.007	0.070	0.070	0.069	0.056
D4	Pond	8 x 200	0.196	0.196	0.196	0.185	1.791	1.791	1.791	1.787
	Stream	8 x 200	0.437	0.334	0.287	0.112	0.735	0.734	0.733	0.660
D6	Ditch 1st	6 x 200	0.636	0.421	0.318	0.097	0.785	0.784	0.780	0.628
	Ditch 2nd	6 x 200	**0.889**	0.591	0.425	0.112	1.188	1.187	1.184	0.897
R1	Pond	8 x 200	0.059	0.058	0.058	0.049	0.588	0.588	0.588	0.586
	Stream	8 x 200	0.125	0.053	0.044	0.009	0.204	0.199	0.194	0.144
R2	Stream	6 x 200	0.071	0.064	0.037	0.009	0.776	0.768	0.759	0.672
R3	Stream	8 x 200	0.133	0.083	0.050	0.014	0.222	0.218	0.216	0.168

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Model(s) used: FOCUS PELMO 3.3.2 Scenarios (list of names): Châteaudun, Hamburg, Jokionen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva Crop: Potatoes FLUAZINAM DT_{50}: 72.5 days (geomean lab) Depth factor for degradation: FOCUS default K_{oc}: 1 985 (arithmetic mean n = 4) 1/n: 0.65 HYPA DT_{50}: 117.6 days (geomean lab) DT_{50}: 105 days (worst case laboratory value) * Depth factor for degradation: FOCUS default Kf_{OC} 630 (arith. Mean excluding two acidic soils with high Kf_{OC} values, n=4)* 1/n: 0.81
Application rate	Application rate: 200 g/ha. No. of applications: 10 Time of application: 4 weeks post emergence Plant uptake: 0 Interception: 50 % at each application

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

For fluazinam and metabolite HYPA: <0.001 µg/L in all of the scenarios

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 (aqueous solution)	$\Phi = 5.1 \times 10^{-5}$ (pH 5 buffer) $\Phi = 1.7 \times 10^{-5}$ (pH 6 distilled water) $\Phi = 2.1 \times 10^{-6}$ (pH 9 buffer) in molecules degraded per Einstein
Photochemical oxidative degradation in air	A DT_{50} of >2 days cannot be completely excluded (Atkinson method)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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Volatilisation	from plant surfaces: study not considered valid
	from soil surfaces: study not considered valid

PEC (air)

Method of calculation	According to the phys./chem. properties (vapour pressure: 7.5 ±8 x 10^{-3} Pa, water solubility: 0.135 mg/L, Henry´s law constant: 25.9 Pa x m^3/mol) fluazinam shows medium to high volatility. Fluazinam may be stable with regard to photochemical oxidative degradation in air. Calculation of a DT_{50} according to the method of Atkinson remains uncertain.

PEC	
Maximum concentration	No harmonised method available to calculate PECair

Residues requiring further assessment	
Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) or other uses.	Soil: fluazinam, HYPA, MAPA (anaerobic conditions only) and DAPA (anaerobic conditions only) Surface Water: fluazinam, G-504, HYPA Sediment: fluazinam, AMPA, HYPA Ground water: fluazinam, HYPA, MAPA (anaerobic conditions only) and DAPA (anaerobic conditions only) Air: fluazinam

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

Soil (indicate location and type of study)	None available – not requested
Surface water (indicate location and type of study)	None available – not requested
Ground water (indicate location and type of study)	None available – not requested
Air (indicate location and type of study)	Data should be reported if available

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

R 53 Not readily biodegradable

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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Appendix 1.6 Effects on non target Species

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/d)	Endpoint (mg/kg feed)
Birds				
Colinus virginianus	a.s.	Acute	1782	-
Anas platyrhynchus	a.s.	Short-term	> 1230*	> 10600
Colinus virginianus	a.s.	Long-term	60.4	500
Mammals				
Rattus norvegicus, female	a.s.	Acute	4100	-
Rattus norvegicus	Fluazinam 500 SC	Acute	> 2000	-
Rattus norvegicus, male	a.s.	Long-term	5	100
Additional higher tier studies				
not relevant				

* Uncertain due to food avoidance. For the risk assessment there seem to be sufficient margin of safety.

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

potatoes 10 x 0.2 kg a.s./ha

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
medium herbivorous bird	Acute	26.5	67	10
	Short-term	15.7	> 78	10
	Long-term	8.4	7.2	5
insectivorous bird	Acute	10.8	165	10
	Short-term	6.0	> 205	10
	Long-term	6.0	10	5
earthworm-eating bird	Long-term	1.4	44	5
fish-eating bird	Long-term	9.2	6.5[1]	5
Tier 1 (Mammals)				
medium herbivorous mammal	Acute	16	421	10
	Long-term	3	1.6*	5
insectivorous mammal	Acute	2	2324	10

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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	Long-term	0.6	7.8	5
earthworm-eating mammal	Long-term	1.8	2.9[2]	5
fish-eating mammal	Long-term	0.14	35[3]	5

* as potato foliage is unpalatable to mammals, this scenario is considered not relevant
[1] based on FOCUS step 1 PEC
[2] refined with a weight-of-evidence approach (rapid metabolism and excretion, PT<1)
[3] based on FOCUS step 2 PEC

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[a)] (mg/L)
Laboratory tests				
Fish				
Lepomis macrochirus	fluazinam	96 hr (flow-through)	Mortality, LC50	0.055 (mm)
Pimephales promelas (Full life cycle study)	fluazinam	278 d (flow through)	F_0 reproduction and F_0 growth, NOEC	0.0029 (mm)
Oncorhynchus mykiss	Fluazinam 500SC	96 hr (flow-through)	Mortality, LC50	0.160 (mm) (0.0611 mg as/L)
Brachydanio rerio	AMPA	96 hr (static)	Mortality, LC50	> 0.089 (mm)
Aquatic invertebrate				
Daphnia magna	fluazinam	48 h (flow through)	Immobility, EC50	0.220 (mm)
Daphnia magna	fluazinam	21 d (static)	Growth, NOEC	0.0125 (nom)
Daphnia magna	Fluazinam 500SC	48 h (static)	Immobility, EC50	0.310 (nom) (0.119 mg as/L)
Daphnia magna	AMPA	48 h (static)	Immobility, EC50	> 0.260 (mm)
Sediment dwelling organisms				
Chironomus riparius [b]	fluazinam	28 d (static)	Emergence, NOEC	0.00625 (im)
Algae				
Pseudokirch subcap.	Fluazinam	96 h (static)	Biomass: E_bC50 Growth rate: E_rC50	0.16 (mm) > 0.22 (mm)
Pseudokirch subcap.	Fluazinam 500SC	72 h (static)	Biomass: E_bC50 Growth rate: E_rC50	1.4 (mm) (0.53 mg as/L) > 5.7 (mm) (> 2.2 mg as/L)

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[a)] (mg/L)
Scenedesmus subspicatus	AMPA	72 h (static)	Biomass: E_bC50 Growth rate: E_rC50	$\geq 0.240_{(mm)}$ $\geq 0.240_{(mm)}$
Microcosm or mesocosm tests				

[a] Concentration based on nominal ($_{nom}$), mean measured ($_{mm}$), initial measured ($_{im}$) concentrations.
[b] Water spiked test

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

FOCUS Step1

Potatoes (10 x 200 g a.s./ha, spring)

Test substance	Organism	Toxicity endpoint (mg a.s./L)	Time scale	PECmax (mg/L)	TER	Annex VI Trigger
fluazinam	Fish	0.055	Acute	0.203	0.3	100
fluazinam	Fish	0.0029	Chronic	0.203	0.014	10
fluazinam	Aquatic invertebrates	0.220	Acute	0.203	1.08	100
fluazinam	Aquatic invertebrates	0.0125	Chronic	0.203	0.062	10
fluazinam	Algae	0.160 > 0.220	Chronic	0.203	0.8 > 1.1	10
fluazinam	Sediment-dwelling organisms	0.00625	Chronic	0.203	0.031	10
Fluazinam 500 SC	Fish	0.0611	Acute	0.203	0.30	100
Fluazinam 500 SC	Aquatic invertebrates	0.119	Acute	0.203	0.59	100
Fluazinam 500 SC	Algae	0.53/> 2.2	Acute	0.203	2.6/11	10

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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FOCUS Step 2

Potatoes (10 x 200 g a.s./ha, spring), Southern Europe

Test substance	Organism	Toxicity endpoint (mg a.s./L)	Time scale	PECmax (mg/L)	TER	Annex VI Trigger
fluazinam	Fish	0.055	Acute	0.0207	2.7	100
fluazinam	Fish	0.0029	Chronic	0.0207	0.14	10
fluazinam	Aquatic invertebrates	0.220	Acute	0.0207	10.6	100
fluazinam	Aquatic invertebrates	0.0125	Chronic	0.0207	0.6	10
fluazinam	Algae	0.160 > 0.220	Chronic	0.0207	7.7/>10.6	10
fluazinam	Sediment-dwelling organisms	0.00625	Chronic	0.0207	0.3	10
Fluazinam 500 SC	Fish	0.0611	Acute	0.0207	3.0	100
Fluazinam 500 SC	Aquatic invertebrates	0.119	Acute	0.0207	5.7	100
Fluazinam 500 SC	Algae	0.53 > 2.2	Acute	0.0207	26/105	10

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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Refined aquatic risk assessment using higher tier FOCUS modelling.
FOCUS Step 3

Single application (1 x 200 g a.s./ha)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity endpoint(µg/L)	PEC (µg/L)	TER	Annex VI trigger
Fluazinam	D3	ditch	Fish	Acute	55	1.030	**53**	100
	D4	pond				0.041	1342	100
	D4	stream				0.854	**64**	100
	D6	ditch				1.016	**54**	100
	R1	pond				0.046*	1196	100
	R1	stream				0.714	**77**	100
	R2	stream				0.945	**58**	100
	R3	stream				1.009	**55**	100
Fluazinam	D3	ditch	Fish	chronic	2.9	1.030	**0.3**	10
	D4	pond				0.041	**7.1**	10
	D4	stream				0.854	**0.3**	10
	D6	ditch				1.016	**0.3**	10
	R1	pond				0.046*	**6.3**	10
	R1	stream				0.714	**0.4**	10
	R2	stream				0.945	**0.3**	10
	R3	stream				1.009	**0.3**	10
Fluazinam 500 SC	D3	ditch	Aquatic invertebrates	Acute	119	1.030	116	100
	D4	pond				0.041	2902	100
	D4	stream				0.854	139	100
	D6	ditch				1.016	117	100
	R1	pond				0.046*	2587	100
	R1	stream				0.714	167	100
	R2	stream				0.945	126	100
	R3	stream				1.009	118	100
Fluazinam	D3	ditch	Aquatic invertebrates	Chronic	12.5	1.030	12	10
	D4	pond				0.041	305	10
	D4	stream				0.854	15	10
	D6	ditch				1.016	12	10
	R1	pond				0.046*	272	10
	R1	stream				0.714	18	10
	R2	stream				0.945	13	10
	R3	stream				1.009	12	10

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity endpoint(µg/L)	PEC (µg/L)	TER	Annex VI trigger
Fluazinam	D3	ditch	Sediment dwelling organism	Chronic	6.25	1.030	**6.1**	10
	D4	pond				0.041	152	10
	D4	stream				0.854	**7.3**	10
	D6	ditch				1.016	**6.2**	10
	R1	pond				0.046*	136	10
	R1	stream				0.714	**8.8**	10
	R2	stream				0.945	**6.6**	10
	R3	stream				1.009	**6.2**	10

* worst case PECsw based on multiple application (8 x 200 g a.s./ha)

Refined aquatic risk assessment using higher tier FOCUS modelling.
FOCUS Step 4 (10 m bufferzone)

Single application (1 x 200 g a.s./ha)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity endpoint (µg/L)	PEC (µg/L)	TER	Annex VI trigger
Fluazinam	D3	ditch	Fish	acute	55	0.174	314	100
	D4	pond				0.026	2115	100
	D4	stream				0.190	290	100
	D6	ditch				0.175	314	100
	R1	pond				0.046*	1196	100
	R1	stream				0.253*	217	100
	R2	stream				0.210	262	100
	R3	stream				0.224	246	100
Fluazinam	D3	ditch	Fish	chronic	2.9	0.174	17	10
	D4	pond				0.026	112	10
	D4	stream				0.190	15	10
	D6	ditch				0.175	17	10
	R1	pond				0.046*	63	10
	R1	stream				0.253*	11	10
	R2	stream				0.210	14	10
	R3	stream				0.224	13	10
Fluazinam	D3	ditch	Sediment dwelling	Chronic	6.25	0.174	36	10
	D4	pond				0.026	240	10

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity endpoint (µg/L)	PEC (µg/L)	TER	Annex VI trigger
	D4	stream	organism			0.190	33	10
	D6	ditch				0.175	36	10
	R1	pond				0.046*	163	10
	R1	stream				0.253*	25	10
	R2	stream				0.210	30	10
	R3	stream				0.224	28	10

* worst case PECsw based on multiple application (8 x 200 g a.s./ha)

Bioconcentration				
	Active substance		AMPA	HYPA
LogPow	4.03		3.99	2.55
	phenyl label	phyridyl label		
Bioconcentration factor (BCFss)	1090*	960*	235**	-
Annex VI Trigger for the bioconcentration factor	100	100	100	100
Clearance time (days) (CT_{50})	6.0 ± 0.4	5.0 ± 0.3	-	-
Level of residues (%) in organisms after the 14 day depuration phase	22*	24*	-	-

* based on total ^{14}C residues
** determined by using the computer program BCFWIN (EPA 2004)

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

Test substance	Acute oral toxicity (LD50 µg/bee)	Acute contact toxicity (LD50 µg/bee)
a.s.	> 100	> 200
Fluazinam 500SC	> 101 µg a.s.	no effect after direct overspray at 0.2 % a.s.
Field or semi-field tests		
not required		

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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

potatoes 10 x 0.2 kg a.s./ha

Test substance	Route	Hazard quotient[1]	Annex VI Trigger
a.s.	contact	< 3.5	50
a.s.	oral	< 7	50

[1] exposure calculated as single rate x MAF

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} g/ha[1])
Typhlodromus pyri	no lab study		
Aphidius rhopalosiphi	Fluazinam 500 EC	Mortality	> 200 g a.s./ha

potatoes 10 x 0.2 kg a.s./ha (MAF 3.7)

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
Fluazinam 500 EC	*Aphidius rhopalosiphi*	> 200 g a.s.	< 3.7	< 0.06	2

[1] 1 m distance / 1.52 % drift rate

Further laboratory and extended laboratory studies

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1]	Endpoint	% adverse effect	Trigger
Aphidius rhopalosiphi	adult	Fluazinam 500 EC, potato leaves, 48 h	10 x 200 g a.s. (7-10 d)	mortality fecundity	3 / 78.1 / 40.6[a] -38 / -66 / -51	50 %
Typhlodromus pyri	proto-nymphs	Fluazinam 500 EC, potato leaves, 7 d	10 x 200 g a.s. (7-10 d)	mortality fecundity	- 5.5 / 6.1 / 0.3[a] 2.8 / -4.3 / -1[a]	50 %
Chrysoperla carnea	larvae - adult	Fluazinam 500 EC, potato leaves, 7 d	10 x 200 g a.s. (7-10 d)	mortality fecundity	18.8 / 11.8 / 15.2[a] 4.9 / -19 / -5.7[a]	50 %
Pterostichus melanarius	adults	Fluazinam 500 EC, overspray +soil appl., 6 d	200 g a.s.	mortality feeding act.	10 0	50 %
		Fluazinam 500 EC,soil appl.,6 d	2000 g a.s.	mortality feeding act.	0 0	50 %
lycosid spider	adults	Fluazinam 500 EC, overspray +soil appl., 6 d	200 g a.s.	mortality feeding act.	3.3 0	50 %

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Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1]	Endpoint	% adverse effect	Trigger
		Fluazinam 500 EC,soil appl.,6 d	2000 g a.s.	mortality feeding act.	0 0	50 %

[1] initial residues
[a] underside / upperside / both sides of leaves

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
Earthworms			
Eisenia fetida	Fluazinam	Acute 14 days	$LC50_{corr}$ > 500 mg/kg d.w.soil
Eisenia fetida	Fluazinam 500 SC	Acute 14 days	$LC50_{corr}$ > 341 mg a.s./kg d.w.soil
Eisenia andrei	Fluazinam 500 SC	Chronic 28 days	$NOEC_{corr}$ < 0.175 mg a.s./kg d.w.soil
Eisenia fetida	HYPA	Acute 14 days	$LC50_{corr}$ > 500 mg/kg d.w.soil
Collembola			
Folsomia candida	Fluazinam 500 SC	Chronic 28 days	$NOEC_{corr}$ < 0.785 mg a.s./kg d.w.soil
Folsomia candida	HYPA	Chronic 28 days	$NOEC_{corr}$: 3.04 mg/kg d.w.soil
Soil micro-organisms			
Nitrogen mineralisation	Fluazinam 500 SC	Chronic 28 days	1.19 % effect at day 28 at 2.27 mg a.s./kg d.w.soil
Nitrogen mineralisation	HYPA	Chronic 28 days	4.72 % effect at day 28 at 0.38 mg a.s./kg d.w.soil
Carbon mineralisation	Fluazinam 500 SC	Chronic 28 days	2.89 % effect at day 28 at 2.27mg a.s./kg d.w.soil
Carbon mineralisation	HYPA	Chronic 28 days	-5.67 % effect at day 28 at 0.38 mg a.s./kg d.w.soil
Field studies			
Lumbricus terrestis, Allobophora rosea, Stachellius mammalis	Fluazinam 500 SC	Chronic 12 month	no effects after application rate of 10 x 200 g a.s./ha (7 days interval) in grassland

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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Test organism	Test substance	Time scale	Endpoint
Soil micro- and macro organisms "litter bags"	Fluazinam 500 SC	Chronic 12 month	no effects after the application of 0.458 mg/kg plateau conc. and 100 g a.s./kg annual conc.

$EC50_{corr}$ or $NOEC_{corr}$: Corrected values (by a factor of 2) due a $LogP_{OW}$ of 4.02 for fluazinam and a $LogP_{OW}$ of 2.55 for HYPA

Toxicity/exposure ratios for soil organisms

Potatoes 10 x 200 g a.s./kg (7 days interval)

Test organism	Test substance	Time scale	initial PECs (mg/kg)	TER	TERcorr	Trigger
Eisenia fetida	Fluazinam	Acute	0.804	>1243	>622	10
Eisenia fetida	Fluazinam 500 SC	Acute	0.804	>848	>424	10
Eisenia andrei	Fluazinam 500 SC	Chronic	0.804	<0.44	<0.218	5
Eisenia fetida	HYPA	Acute	0.37	>2703	>1351	10
Collembola	Fluazinam 500 SC	Chronic	0.804	<1.95	<0.98	5
Collembola	HYPA	chronic	0.37	16	8	5

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

Preliminary screening data

10 species tested at 1.5 kg a.s./ha in screening seedling emergence and vegetative vigour tests: the only effect > 25 % was a 28 % reduction in biomass fresh weight in cucumber

Laboratory dose response tests

Most sensitive species	Test substance	ER50 (g/ha) vegetative vigour	ER50 (g/ha) emergence	Exposure (g/ha)	TER	Trigger
cucumber	fluazinam techn.	> 1500 g a.s.	> 1500 g a.s.	not relevant		

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

not required

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

Test type/organism	endpoint
Activated sludge	EC50: 118 mg a.s./L
Pseudomonas putida	EC50: > 1.53 mg a.s./L

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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Residues definition (consider all relevant metabolites requiring further assessment from the fate section)

Compartment	Ecotoxicologically relevant residue
soil	fluazinam
water	fluazinam, HYPA (preliminary)
sediment	fluazinam
groundwater	fluazinam

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

	RMS/EPCO proposal
Active substance	R 50/53
Preparation	R 50/53

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry

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LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year

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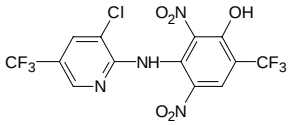
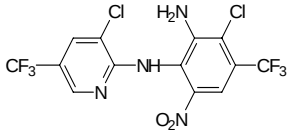
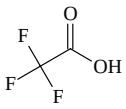
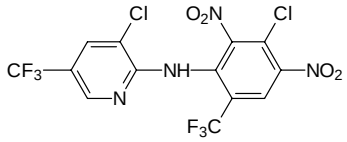
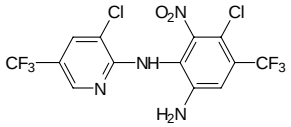
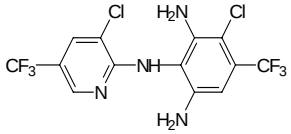
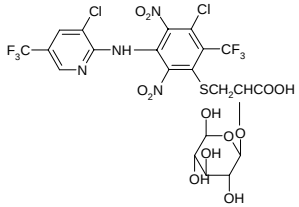
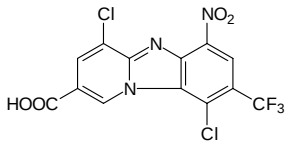
APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
HYPA	5-(3-chloro-5-trifluoromethyl-2-pyridylamino)- α,α,α- trifluoro-4,6-dinitro-o-cresol	
MAPA	2-chloro-6-(3-chloro-5-trifluoromethyl-2-pyridylamino)-α,α,α--trifluoro-5-nitro-m-toluidine	
TFAA	trifluoroacetic acid	
Impurity 5	5-chloro-N-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-4,6-dinitro-o-toluidine	
AMPA-FLUAZINAM	4-chloro-6-(3-chloro-5-trifluoromethyl-2-pyridylamino)-α,α,α-trifluoro-5-nitro-m-toluidine	
DAPA	4-chloro-2-(3-chloro-5-trifluoromethyl-2-pyridylamino)-5-trifluoromethyl-m-phenylenediamine	
AMGT	3-[[4-amino-3-[[3-chloro-5-(trifluoromethyl)-2-pyridyl]amino]- α,α,α-trifluoro-6-nitro-o-tolyl]thio]-2-(β-D-glucopyranosyloxy)propionic acid	
G-504	4,9-dichloro-6-nitro-8-(trifluoromethyl)-pyrido-[1,2-a]benzimidazole-2-carboxylic acid	

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