CONCLUSION ON PESTICIDE PEER REVIEW

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

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SUMMARY

Fenpyrazamine is a new active substance for which in accordance with Article 6(2) of Council Directive 91/414/EEC[3] Austria received an application from Sumitomo Chemical Agro Europe S.A.S for inclusion in Annex I to Directive 91/414/EEC. Complying with Article 6 of Directive 91/414/EEC, the completeness of the dossier was evaluated and confirmed by Commission Decision of 10 March 2010 (2010/150/EU)[4].

Following the agreement between the European Commission and the European Food Safety Authority (EFSA) for the EFSA to organise a peer review of those new active substances for which the decision on the completeness of the dossier had been published after June 2002, the designated rapporteur Member State Austria (RMS) provided its initial evaluation of the dossier on fenpyrazamine in the Draft Assessment Report (DAR), which was received by the EFSA on 17 January 2011.

The peer review was initiated on 28 January 2011 by dispatching the DAR for consultation of the Member States and the applicant Sumitomo Chemical Agro Europe S.A.S. Following consideration of the comments received on the DAR, it was concluded that EFSA should conduct a focused peer review in the areas of mammalian toxicology and ecotoxicology and deliver its conclusions on fenpyrazamine.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of fenpyrazamine as a fungicide in glasshouses on tomato, aubergine, pepper, and cucurbits with edible peel, and field use on grapes as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

In the area of identity, physical/chemical/technical properties and methods of analysis one data gap was identified for a shelf-life study.

No data gaps or areas of concern were identified regarding mammalian toxicology.

No data gaps were identified in the residues section. Based on the plant metabolism studies conducted on three different plant groups, residues in plants were defined as fenpyrazamine for monitoring and as sum of fenpyrazamine and S-2188-DC expressed as fenpyrazamine for risk assessment. MRLs and

[1] On request from the European Commission, Question No EFSA-Q-2011-00391, issued on 6 December 2011.

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

[4] OJ No L 61, 11.3.2010, p. 35

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conversion factors were proposed for all representative uses. No chronic or acute risks were identified for consumers, the highest IEDI being only 3% of the ADI and the highest IESTI 38% of the ARfD.

The fate and behaviour in the environment of fenpyrazamine was investigated with a complete battery of studies. Exposure assessments for soil, suface water and groundwater were presented following the FOCUS scheme. No data gaps or areas of concern were identified with respect to fate and behaviour in the environment.

The risk to non-target species was assessed as low.

KEY WORDS

Fenpyrazamine, peer review, risk assessment, pesticide, fungicide

TABLE OF CONTENTS

BACKGROUND

In accordance with Article 6(2) of Council Directive 91/414/EEC[5] Austria received an application from Sumitomo Chemical Agro Europe S.A.S for inclusion of the active substance fenpyrazamine in Annex I to Directive 91/414/EEC. Complying with Article 6 of Directive 91/414/EEC, the completeness of the dossier was evaluated and confirmed by Commission Decision of 10 March 2010 (2010/150/EU)[6].

Following the agreement between the European Commission and the EFSA for the EFSA to organise a peer review of those new active substances for which the completeness of the dossier had been officially confirmed after June 2002, the RMS Austria provided its initial evaluation of the dossier on fenpyrazamine in the DAR, which was received by the EFSA on 17 January 2011 (Austria, 2011a).

The peer review was initiated on 28 January 2011 by dispatching the DAR to Member States and the applicant Sumitomo Chemical Agro Europe S.A.S for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The comments were evaluated by the RMS in column 3 of the Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

The scope of the peer review and the necessity for additional information, to be submitted by the applicant in accordance with Article 8(3) of Commission Regulation (EC) No 188/2011[7], was considered in a telephone conference between the EFSA, the RMS, and the European Commission on 10 May 2011. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was concluded that the EFSA should organise a consultation with Member State experts in the areas of mammalian toxicology and ecotoxicology, and that further information should be requested from the applicant in the areas of physical-chemical properties and environmental fate and behaviour.

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

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

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in November 2011.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a fungicide in glasshouses on tomato, aubergine, pepper, and cucurbits with edible peel, and field use on grapes, as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the

[5] OJ No L 230, 19.8.1991, p. 1. Directive as last amended by L 20, 22.1.2005, p.19 and by L309, 24.11.2009, p.1
[6] OJ No L 61, 11.3.2010, p. 35
[7] OJ No L 53, 26.2.2011, p. 51

conclusion. The Peer Review Report (EFSA, 2011) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (10 May 2011),
- the Evaluation Table (2 December 2011),
- the report of the scientific consultation with Member State experts (where relevant),
- the comments received on the assessment of the additional information (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of November 2011 containing all individually submitted addenda (Austria, 2011b)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Fenpyrazamine is the ISO common name for S-allyl 5-amino-2,3-dihydro-2-isopropyl-3-oxo-4-(*o*-tolyl)pyrazole-1-carbothioate (IUPAC).

The representative formulated product for the evaluation was 'S-2188 50 WG' a water dispersible granule (WG) containing 500 g/kg fenpyrazamine.

The representative uses evaluated comprise foliar spraying against *Botrytis* in glasshouses on tomato, aubergine, pepper and cucurbits with edible peel, and field use on grapes. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000), and SANCO/825/00 rev. 7 (European Commission, 2004a).

The minimum purity of the active substance as manufactured is 94 % w/w (based on pilot plant production). There are no relevant impurities and no FAO specification.

The main data regarding the identity of fenpyrazamine and its physical and chemical properties are given in Appendix A.

There is one data gap identified for a formulation shelf-life study.

The method of analysis for products of plant origin is by LC-MS/MS (DFG S 19). A method of analysis for products of animal origin is not required as no MRLs are proposed. Soil, water and air are analysed by LC-MS/MS. A method of analysis for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000 – rev. 10-final (European Commission, 2003), SANCO/222/2000 rev. 7 (European Commission, 2004b), SANCO/10597/2003 – rev. 8.1, May 2009 (European Commission, 2009).

Fenpyrazamine was discussed at the Pesticide Peer Review 88 Experts' Meeting on mammalian toxicology. The technical specification is supported by the batches used in the toxicological studies and the impurities are not considered to be toxicologically relevant.

Absorption and excretion of fenpyrazamine was extensive. Oral absorption was estimated at higher than 80%. There was no evidence for accumulation. The main metabolic pathway identified was elimination of the allylsufanylcarbonyl group followed by hydroxylation and dealkylation and further conjugation with sulfate and glucoronide.

Low acute toxicity is observed when fenpyrazamine is administered by the oral, dermal and inhalation routes. No skin or eye irritation was observed and there was no potential for skin sensitisation.

In short-term oral studies with rats, mice and dogs, the critical effects were observed in the liver (increased weight, hepatocelluar hypertrophy; rats, mice and dogs) and in the thyroid (follicular cell

hypertrophy; rats). The mouse and dog were the most sensitive species. The relevant short-term oral NOAEL is 28 mg/kg bw/d (90-d mouse study) and 25 mg/kg bw/d (90-d and 1-y dog study).

The weight of evidence suggests that fenpyrazamine is unlikely to be genotoxic.

In long-term studies with rats and mice, the critical effects were observed in the liver (hepatocelular hypertrophy and increased liver weight; mice and male rats) and haematology (shortened prothrombin time, decreased MCH and MCV; female rats). The relevant long-term NOAELs are 12.7 mg/kg bw/d for the rat and 176 mg/kg bw/d for the mouse. Liver (carcinoma) and thyroid (follicular carcinoma) tumours were observed in the long-term study in male rats at 107 mg/kg bw/d. Based on the mechanistic studies the RMS concluded that the mode of action (MOA) for liver and thyroid tumours would be comparable to the MOA of phenobarbital. On this basis the tumours were not considered relevant to humans and no proposal for classification and labelling was made. During the commenting phase it was questioned whether it was sufficiently demonstrated that the MOA is comparable to the phenobarbital MOA and whether this MOA is relevant to humans (especially for liver tumours). No further discussion regarding their relevance and proposed classification and labelling took place during the peer-review process. For risk assessment purposes a clear NOAEL of 51.9 mg/kg bw/d has been identified for these tumours.

In the muligeneration toxicity study in rats decreased number of implantations was considered to be the effect of systemic effects in maternal animals (increased liver and thyroid weight, hepatocellular and thyroid cell hypertrophy). No adverse effects were observed in the fertility parameters. Reduced body weight was observed in the offspring. The agreed parental is 20.3 mg/kg bw/d, the offspring NOAEL is 28.5 mg/kg bw/d and the reproductive NOAEL is 73.7 mg/kg bw/d. In the developmental toxicity studies, there was no evidence of teratogenicity, and the relevant maternal NOAELs are 30 mg/kg bw/d for the rat and rabbit. The developmental NOAELs are 30 and 125 mg/kg bw/d, respectively for the rabbit and the rat.

No potential for neurotoxicity was observed in the neurotoxicity studies.

The data available indicated that the metabolite **S-2188-OH** is probably of comparable toxicity as the precursor **S-2188-DC** and parent compound fenpyrazamine. Regarding the **allyl mercaptan** metabolite, it was agreed that its toxicological profile is covered by the parent. Thus, the reference values for fenpyrazamine are also applicable to these metabolites if needed.

The acceptable daily intake (**ADI**) is 0.13 mg/kg bw/d, based on the NOAEL of 12.7 mg/kg bw/d (2-y rat study) and applying a safety factor of 100. The margin of safety with regard to tumours (liver and thyroid) is 823. The acceptable operator exposure level (**AOEL**) is 0.2 mg/kg bw/d, based on the parental NOAEL of 20.3 mg/kg bw/d (multigeneration study) and applying a safety factor of 100. No correction for oral absorption is needed to derive the AOEL. The acute reference dose (**ARfD**) is 0.3 mg/kg bw based on the maternal and developmental NOAEL of 30 mg/kg bw/d (rabbit developmental study), and applying a safety factor of 100. The relevant dermal absorption values for 'S-2188-50 WG' are 0.1% for the concentrate and 0.8% for the dilution.

Considering the representative use of 'S-2188-50 WG' in vineyards and glasshouses (tomato, aubergine, pepper and cucurbits) the estimated operator exposure is below the AOEL even without the use of personal protective equipment (PPE). Worker, bystander and resident exposure are below the AOEL.

3. Residues

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

Metabolism in plants was investigated using ^{14}C-fenpyrazamine labelled either on the phenyl ring or the pyrazolyl moiety. Studies were conducted on grape (fruiting crop), lettuce (leafy crop) and oilseed rape (pulses/oilseed crop) with a total of 2 or 3 foliar applications and experimental designs representative of the supported uses. The metabolism was seen to be comparable in all plant groups. The parent fenpyrazamine was by far the major component of radioactive residues, accounting for 50% to 94% of the TRRs in all plant samples collected 14 to 45 days after the last application, except in oilseed rape seeds where it represented only *ca.* 20% TRR (0.005 to 0.007 mg/kg). In addition to the parent, only two further compounds were identified in plants; the metabolite S-2188-DC detected up to 11% TRR in lettuce and the metabolite S-2188-OH, detected in lower proportions, below 5% TRR. Globally, the metabolism of fenpyrazamine in plants was seen to be limited and to proceed by the cleavage of the carbamate bound on the pyrazolyl moiety to give the metabolite S-2188-DC which, by hydroxylation, forms the metabolite S-2188-OH. A similar degradation pathway was observed in rotational crops where residues were mostly composed of the parent fenpyrazamine and of its metabolites S-2188-OH and S-2188(OH)$_2$, the latter not being observed in primary crops and formed from the metabolite S-2188-OH by loss of the amine group. Metabolite S-2188-DC detected in primary crops was however not detected in rotational crops, except in wheat forage (1% TRR).

As the parent was shown to be the major component of the residues, the definition for monitoring was limited to fenpyrazamine. For risk assessment, considering that S-2188-DC was present at up to 11% TRR in lettuce (1.2 mg/kg, 1.4N study) and detected in significant amounts in the supervised residue trials conducted on grape (up to 0.39 mg/kg), the definition was proposed as "*sum of fenpyrazamine and S-2188-DC, expressed as fenpyrazamine*".

A sufficient number of supervised residue trials were provided to propose MRLs on wine grape, table grape, tomato, pepper and cucurbits with edible peel. All samples were analysed for fenpyrazamine and its metabolite S-2188-DC, and conversion factors for risk assessment were calculated for all representative crops. In addition, samples were also analysed for metabolite S-2188-OH in most of the residue trials. This metabolite was generally not detected, except in some situations but at levels close to the LOQ (<0.01 mg/kg). Cold rotational crop studies confirmed that residues of fenpyrazamine and S-2188-OH are not expected to be present in following crops. The residue data are supported by storage stability studies showing fenpyrazamine and S-2188-DC residues to be stable up to one year in grapes, oilseed rape seeds, lettuce and cereal grains, when stored frozen at -18°C.

Fenpyrazamine was shown to be stable under standard hydrolysis conditions simulating pasteurisation and baking/brewing/boiling, but a slight degradation to the metabolite S-2188-DC was observed under sterilisation (*ca.* 10% of the applied radioactivity). The degradation to the metabolite S-2188-DC under high temperatures was confirmed in the processing studies conducted on grapes. S-2188-DC was the major component of the residues in red wine resulting from heated must (70°C, 15 min), whereas fenpyrazamine remained the main component of the residues in white wine produced without any heating step. Based on these studies, processing factors and conversion factors were proposed for raisins, juice and wines.

Goat and poultry metabolism studies were provided, although the crops supported in the framework of this evaluation are not fed to animals. Studies were performed at a dose rate of 10 mg/kg in diet with ^{14}C-fenpyrazamine labelled on the pyrazolyl moiety only, as no cleavage of the bridge between the phenyl- and pyrazolyl- rings occur in the rat metabolism. Fenpyrazamine was intensively excreted. Only 0.2% and 0.8% of the administered radioactivity was recovered in poultry and goat matrices respectively (including eggs and milk). Contrary to plants, the metabolism in animals was more extensive and more complex, with numerous metabolites or fractions characterised, all accounting for very low levels, mostly below 0.03 mg/kg. Fenpyrazamine was only observed in significant proportions in fat and in the goat liver, but was almost not detected in all other goat and poultry matrices. In goat matrices, the radioactive residues were mainly composed of the two metabolites S-2188-DC and S-2188-CH_2OH-DC (free and conjugated), whereas in poultry matrices S-2188-DC was only detected in significant proportions in the egg white (25% TRR), the major component of the residues in egg yolk, muscle and liver being the metabolite MPPZ (16% to 34% TRR, but

chromatographic peaks not resolved). Considering that both fenpyrazamine and S-2188-DC represent 10% to 40% of the TRR in all animal matrices (except poultry muscle and liver, less than 5% TRR), the residue definition for monitoring in animal matrices was proposed as sum of fenpyrazamine and S-2188-DC expressed as fenpyrazamine. For risk assessment, EFSA proposes to provisionally include in the residue definition the metabolites S-2188-CH_2OH-DC and MPPZ as they were observed in similar or higher levels than the parent and S-2188-DC in some matrices (muscle, liver, kidney). This proposal should be reconsidered once uses are defined on feed crops and having regard to residue intakes by animals.

No chronic or acute risks were identified for consumers. Using the EFSA PRIMo model, the HR and STMR values derived from the supervised residue trials according to the residue definition for risk assessment, and the processing factor for wine, the highest IEDI is only 3% of the ADI (WHO cluster diet B) and the highest IESTI 38% of the ARfD (table grape, DE child).

4. Environmental fate and behaviour

The route and rate of degradation of fenpyrazamine (^{14}C-radiolabelled) in soil was investigated in four soils under laboratory conditions. Fenpyrazamine exhibits a moderate persistence in soil by transformation to a number of minor metabolites, CO_2 and unextracted residues. In some of the soils fenpyrazamine degradation showed biphasic behaviour. At the end of the experiments (120 d), mineralization reached 5.2 – 8.5 % AR ($^{14}CO_2$) and unextracted residues were increasing up to 38. 9 – 69.9 % AR. Degradation of fenpyrazamine was not investigated under anaerobic conditions. Anaerobic conditions are not expected to occur over prolonged periods of time for the representative uses, and therefore the data are not essential to finalize the EU risk assessment. However, further information may be needed in case other uses are considered for approval. Fenpyrazamine was shown to be stable to photolysis in soil under laboratory conditions.

The fate and behaviour of fenpyrazamine in soil was also investigated in a field dissipation / degradation study in four sites (UK, Germany, Italy and France (S)). Decline in these soils was normalized in order to derive half-lives to be used in environmental modelling. Since a biphasic decline was observed in the normalized data, slow phase DT_{50} or DT_{90}/3.32 was used to derive pseudo first order DT_{50}.

PECs of fenpyrazamine in soil were calculated by the RMS on basis of the worst case best fit (DFOP) kinetics of the non-normalized field studies. Multiple applications and application in consecutive seasons were simulated to obtain time dependent and TWA concentrations. Plateau was reached after two (grape) or three years (tomato).

Batch adsorption/desorption studies were performed with fenpyrazamine in five soils. According to these experiments it may be expected that fenpyrazamine will exhibit high to low mobility in soil.

Fenpyrazamine may be considered stable to hydrolysis at pH 4 and pH 7 at 20 °C. At the same temperature, fenpyrazamine hydrolyzed at pH 9 with an estimated half-life of 24 d. Main hydrolysis metabolites were S-2188-DC and S-2188-OH. Aqueous photolysis of fenpyrazamine was investigated in laboratory conditions under simulated sunlight for one day equivalent to 30 UK midsummer days. Fenpyrazamine is rapidly photolysed in water (DT_{50} = 1.7 d) yielding major metabolites S-2188-DC (max 63.8 % AR after 7 d, DT_{50} = 12.5 d) and MCNI (max 17.7 % AR after 30 d, end of study. Besides these two metabolites, a high number of minor metabolites were produced. A ready biodegradability study is available. Fenpyrazamine is considered not to be readily biodegradable.

Degradation/dissipation of fenpyrazamine in the aquatic environment was investigated in two water sediment systems. Fenpyrazamine partially partitions to the sediment and degrades to a number of metabolites of which only two exceeded the 10 % AR in the water phase (**S-2188-DC** and **S-2188-OH**). In line with the effect observed in the hydrolysis study, degradation was faster in the system with more alkaline pH ($DT_{50\ whole\ system\ (pH\ 8.6)}$ = 19; $DT_{50\ whole\ system\ (pH\ 6.4)}$ = 66.2). However, other relevant

parameters such as microbial biomass differ largely between the two systems, and with the data available it is not possible to determine the actual contribution of pH to the rate of degradation of fenpyrazamine in biologically active aquatic systems. Depending on the system investigated, mineralization reached 3.1 to 8.5 % AR and non-extractable residues in the sediment between 17.2 - 47.4 % AR after 100 d. $PEC_{SW/sed}$ were calculated for fenpyrazamine and metabolites S-2188-DC, S-2188-OH and MCNI with FOCUS SW scheme up to Step 2. For glasshouse use on tomato the PEC_{SW} was estimated using an estimated loss of 0.1 % to surface water.

Potential groundwater contamination was addressed by the calculation of the 20 years 80th percentile concentration at 1 m depth with FOCUS GW models (PELMO and PEARL) using normalized field half-lives as input parameters. For the representative use on tomato in glasshouses, the outdoor use was simulated as a worst case surrogate. The limit of 0.1 µg/L was not exceeded by any of the uses (grapes and tomato) or scenarios simulated.

5. Ecotoxicology

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

The acute and short-term risk to insectivorous birds was assessed as low for the representative use in grapevine at the first tier level, while the long-term TER was slightly below the Annex VI trigger. However, the next refinement, based on the PT value of 0.79 and the NOEC of 82.9 mg a.s./kg bw/day, both agreed by experts during the Pesticides Peer Review Experts' Teleconference TC57, indicated a low risk. It was pointed out that the PT value was derived from a study in orchards in the UK. However, as this PT value is sufficiently conservative (95th percentile), and was previously peer reviewed for other active substances, the extrapolation to insectivorous birds in grapevine was considered acceptable. The acute and long-term risk to small herbivorous mammals was assessed as low at the first tier level. Due to the log P_{ow} >3, the risk assessment from secondary poisoning to earthworm- and fish-eating birds and mammals was carried out, and the resulting TERs were above the Annex VI trigger, indicating a low risk. The risk from consumption of contaminated water was indicated as low. No exposure for birds and mammals is expected following the representative glasshouse uses.

Toxicity studies were provided with fenpyrazamine, the formulated product 'S-2188 50 WG' and the metabolites S-2188-DC, S-2188-OH, and MCNI. On the basis of the available acute toxicity data with the active substance, fenpyrazamine is toxic to aquatic organisms. The lowest endpoint for the active substance was observed in the chronic study on *Chironomus riparius* (NOEC = 0.32 mg a.s./L), while the most sensitive species, based on a study performed with the formulation, was *Pseudokirchneriella subcapitata* (E_bC_{50} = 0.28 mg a.s./L). The risk assessment with FOCUS step 1 indicated a high risk for aquatic organisms for the use on grapevine for the active substance and the formulation, but a low risk for the metabolites. The risk was indicated as low by the next assessment with FOCUS step 2. Although the TERs were not calculated for the representative glasshouse uses, the risk assessment was considered to be covered by the field use.

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

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

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
fenpyrazamine	moderate (DT_{50} = 23.6 – 39 d)	The risk was assessed as low for soil-dwelling organisms

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
fenpyrazamine	high to low (K_{Foc} = 112 – 731 mL/g)	No	Yes	Yes	Toxic to aquatic organisms. The most sensitive species, based on a study performed with the formulation, was *Pseudokirchneriella subcapitata* (E_bC_{50} = 0.28 mg a.s./L, regulatory endpoint applying a safety factor of 10 is 0.028 mg a.s./L). The risk was assessed as low.

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
fenpyrazamine (water and sediment)	Toxic to aquatic organisms. The most sensitive species, based on a study performed with the formulation, was *Pseudokirchneriella subcapitata* (E_bC_{50} = 0.28 mg a.s./L, regulatory endpoint applying a safety factor of 10 is 0.028 mg a.s./L). The risk was assessed as low.
S-2188-DC (water and sediment)	The risk was assessed as low.
S-2188-OH (water)	The risk was assessed as low.
MCNI (water)	The risk was assessed as low.

6.4. Air

Compound (name and/or code)	Toxicology
fenpyrazamine	Low toxicity to rats, LC_{50}> 4.84 mg/L (maximum attainable concentration), 4 hours, nose only

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

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

- Storage stability shelf-life study (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).

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

None.

9. Concerns

9.1. Issues that could not be finalised

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

None.

9.2. Critical areas of concern

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

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

None.

9.3. Overview of the concerns for each representative use considered

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

Representative use		**Grapes** (1 x 600 g a.s./ha)	**Tomato / aubergine** (3 x 600 g a.s./ha)	**Pepper** (3 x 600 g a.s./ha)	**Cucurbits with edible peel** (3 x 600 g a.s. /ha)
Operator risk	Risk identified				
	Assessment not finalised				
Worker risk	Risk identified				
	Assessment not finalised				
Bystander risk	Risk identified				
	Assessment not finalised				
Consumer risk	Risk identified				
	Assessment not finalised				
Risk to wild non target terrestrial vertebrates	Risk identified				
	Assessment not finalised				
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified				
	Assessment not finalised				
Risk to aquatic organisms	Risk identified				
	Assessment not finalised				
Groundwater exposure active substance	Legal parametric value breached				
	Assessment not finalised				
Groundwater exposure metabolites	Legal parametric value breached				
	Parametric value of 10µg/L[(a)] breached				
	Assessment not finalised				
Comments/Remarks					

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

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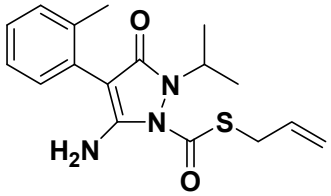
APPENDICES

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

Active substance (ISO Common Name) ‡	Fenpyrazamine
Function (*e.g.* fungicide)	Fungicide
Rapporteur Member State	Austria
Co-rapporteur Member State	---

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	*S*-allyl 5-amino-2-isopropyl-4-(2-methylphenyl)-3-oxo-2,3-dihydropyrazole-1-carbothioate or *S*-allyl 5-amino-2,3-dihydro-2-isopropyl-3-oxo-4-(o-tolyl)pyrazole-1-carbothioate
Chemical name (CA) ‡	5-amino-2,3-dihydro-2-(1-methylethyl)-4-(2-methylphenyl)-3-oxo-1*H*-pyrazole-1-carbothioic-acid *S*-2-propen-1-yl ester or *S*-2-propen-1-yl 5-amino-2,3-dihydro-2-(1-methylethyl)-4-(2-methylphenyl)-3-oxo-1*H*-pyrazole-1-carbothioate
CIPAC No ‡	832
CAS No ‡	473798-59-3
EC No (EINECS or ELINCS) ‡	Not allocated
FAO Specification (including year of publication) ‡	No FAO specification is available at the time of evaluation
Minimum purity of the active substance as manufactured ‡	94.0 % w/w (based on a pilot plant production)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	No relevant impurities
Molecular formula ‡	$C_{17}H_{21}N_3O_2S$
Molecular mass ‡	331.43 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	116.4 °C (389.6 K) 99.3% w/w
Boiling point (state purity) ‡	239.8 °C (513.0 K) 99.3% w/w at a nominal pressure of 745 mm/Hg
Temperature of decomposition (state purity)	No decomposition was observed
Appearance (state purity) ‡	PGAI 99.3% w/w White (Munsell: N9.5/90%) at 21.7 °C Solid at 25 °C
	TGAI 94.7% w/w Very pale yellow (Munsell: 10Y 9/2) at 20.7 °C Solid at 25 °C
Vapour pressure (state temperature, state purity) ‡	$<10^{-5}$ Pa at 25 °C 99.3% w/w 2.89×10^{-8} Pa at 25 °C (calculated by MPBPWin)
Henry's law constant ‡	1.62×10^{-4} Pa.m^3/mole at 20 °C parameters for calculation: vapour pressure: 10^{-5} Pa water solubility: 20.4 mg/L at 20 °C
Solubility in water (state temperature, state purity and pH) ‡	99.3% w/w Water solubility at neutral pH at 20 °C: 20.4 mg/L
	The effect of pH on water solubility was not determined as Fenpyrazamine does not dissociate under acidic or basic conditions
Solubility in organic solvents ‡ (state temperature, state purity)	99.3% w/w n-hexane: 902 mg/L n-octanol: 84403 mg/L (99174 mg/kg) toluene: 112978 mg/L (126297 mg/kg) acetone: > 250 g/L (> 250 g/kg) methanol: > 250 g/L (> 250 g/kg) dichloromethane: > 250 g/L (>250 g/kg) ethyl acetate: > 250 g/L (> 250 g/kg) 94.7% w/w n-hexane: 811 mg/L n-octanol: 99223 mg/L (105230 mg/kg) toluene: 129308 mg/L (132262 mg/kg) acetone: > 250 g/L (> 250 g/kg) methanol: > 250 g/L (> 250 g/kg) dichloromethane: > 250 g/L (>250 g/kg) ethyl acetate: > 250 g/L (> 250 g/kg)
Surface tension ‡ (state concentration and temperature, state purity)	94.7% w/w 66.9 mN/m at a concentration of 90% of the saturation solubility and 20 ºC
Partition co-efficient ‡ (state temperature, pH and purity)	99.3% w/w n-octanol/water partition coefficient: 3307.32 log Pow = 3.52 at 25 ± 1 ºC and pH: 7.2

	The effect of pH on partition coefficient was not determined as Fenpyrazamine does not dissociate under acidic or basic conditions.
Dissociation constant (state purity) ‡	99.3% w/w No dissociation activity was observed in the approximate pH range 1 – 13
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	99.3% w/w

Solution	λ_{max} (nm)	ε [L x · cm^{-1} x mol^{-1}]
Acidic pH 1.4-1.5	243	16600
	274	13800
Unadjusted pH 7.8-8.1	243	16700
	274	13900
Basic pH 12.7	N/A	N/A

Flammability ‡ (state purity)	94.7% w/w Not flammable and not auto-flammable
Explosive properties ‡ (state purity)	Not explosive statement
Oxidising properties ‡ (state purity)	Not oxidising statement

Summary of representative uses evaluated (*fenpyrazamine*)*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment						PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number (k)		interval between applications (min)	g as/hL		water L/ha		g as/ha		
									min	max		min	max	min	max	min	max	
grapevine	N	S-2188 50 WG**	F	*Botrytis*	WG	500	Foliar application	BBCH 87	1	1	n.a.	60	600	100	1000	600	600	14	
	S	S-2188 50 WG**	F	*Botrytis*	WG	500	Foliar application	BBCH 87	1	1	n.a.	40	600	100	1000	400	600	14/7*	
Tomato, aubergine	N & S	S-2188 50 WG**	G	*Botrytis*	WG	500	Foliar application	BBCH 87	2	3	10-14	27	120	500	1500	400	600	3	
Pepper	N & S	S-2188 50 WG**	G	*Botrytis*	WG	500	Foliar application	BBCH 87	2	3	10-14	27	120	500	1500	400	600	3	
Cucurbits with edible peel	N & S	S-2188 50 WG**	G	*Botrytis*	WG	500	Foliar application	BBCH 87	2	3	10-14	27	120	500	1500	400	600	3	

* 14 days in wine grapes, 7 days in table grapes

** Specification No. 12 (for details please refer to Volume 4)

Remarks:

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

Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.2)

Technical as (analytical technique)	HPLC-UV
Impurities in technical as (analytical technique)	HPLC-UV, GC-FID, Karl Fischer titration
Plant protection product (analytical technique)	HPLC-UV

Analytical methods for residues (Annex IIA, point 4.3)

Residue definitions for monitoring purposes

Food of plant origin		Fenpyrazamine
Food of animal origin		Sum fenpyrazamine and S-2188-DC expressed as fenpyrazamine
Soil		Fenpyrazamine
Water	surface	Fenpyrazamine
	drinking/ground	Fenpyrazamine
Air		Fenpyrazamine

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	LC-MS/MS (DFG S 19) LOQ: 0.01 mg/kg grapes, oilseed rape, carrot, green pepper, cereals, tomato
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required as no MRLs are proposed
Soil (analytical technique and LOQ)	LC-MS/MS LOQ: 0.01 mg/kg
Water (analytical technique and LOQ)	LC-MS/MS LOQ: 0.1 µg/l (drinking water), 1 µg/l (surface water)
Air (analytical technique and LOQ)	LC-MS/MS LOQ: 0.2 µg/m³
Body fluids and tissues (analytical technique and LOQ)	Not required as the active substance is not classified as toxic or very toxic.

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 9)

	Peer review proposal
Active substance	No classification required (Directive 67/548/EEC and Regulation 1272/2008/EEC)

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Extensive (> 80%), almost totally metabolised after administration of single oral low and high dose
Distribution ‡	Evenly distributed, highest amount in liver and kidney
Potential for accumulation ‡	No potential for accumulation
Rate and extent of excretion ‡	> 80% via urine in males and females
Metabolism in animals ‡	Extensively metabolized; main metabolites in urine and feces: S-2188-DC, MPPZ , MPPZ sulphate, S-2188-CH_2OH-DC
Toxicologically relevant compounds ‡ (animals and plants)	Fenpyrazamine
Toxicologically relevant compounds ‡ (environment)	Fenpyrazamine

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 2000 mg/kg bw	
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 4.84 mg/L (maximum attainable concentration), 4 hours, nose only	
Skin irritation ‡	Not irritating	
Eye irritation ‡	Not irritating	
Skin sensitisation ‡	Not sensitising (M&K)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Liver (increased organ weight, hepatocellular hypertrophy) (rat, dog and mouse) and thyroid (follicular cell hypertrophy) (rat)	
Relevant oral NOAEL ‡	90 days rat: 64 mg/kg bw/d 90 days and 1 year dog: 25 mg/kg bw/d 90 days mouse: 28 mg/kg bw/d	
Relevant dermal NOAEL ‡	28 days rat: 300 mg/kg bw/d	
Relevant inhalation NOAEL ‡	No data - not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

	Not genotoxic *in vitro* and *in vivo*	

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

Target/critical effect ‡	Rat: Shortened prothrombin time, decreased MCH and MCV (females) Hepatocellular hypertrophy, increased liver weight, increased GGT (males) Mouse: Increased liver weight, hepatocellular hypertrophy (females and males)	
Relevant NOAEL ‡	Rat: 15.6 mg/kg bw/d (females); 12.7 mg/kg bw/d (males) Mouse: 283 mg/kg bw/d (females); 176 mg/kg bw/d (males)	
Carcinogenicity ‡	Hepatocarcinoma and thyroid follicular carcinoma at 107 mg/kg bw/d in males.	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental effects: increased liver weight, hepatocellular hypertrophy (males); increased thyroid weight and thyroid cell hypertrophy (females) Developmental effects: reduced pup weight Reproductive effects: number of implantations	
Relevant parental NOAEL ‡	20.3 mg/kg bw/day (400 ppm)	
Relevant reproductive NOAEL ‡	73.7 mg/kg bw/day (1000 ppm)	
Relevant offspring NOAEL ‡	28.5 mg/kg bw/day (400 ppm)	

Developmental toxicity

Developmental target / critical effect ‡	Rat: Maternal effects: reduced body weight gain Developmental effects: reduced body	

	weight, increased placental weight, visceral and skeletal variations and delayed ossification at maternally toxic dose Rabbit Maternal effects: reduced food consumption, reduced body weight, abortions/premature deliveries Developmental effects: abortions/premature deliveries No teratogenic potential	
Relevant maternal NOAEL ‡	Rat: 30 mg/kg bw/day Rabbit: 30 mg/kg bw/day	
Relevant developmental NOAEL ‡	Rat: 125 mg/kg bw/day Rabbit: 30 mg/kg bw/day	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	Acute rat, NOAEL: 80 mg/kg bw Effects: reduced total distance time (males) and reduced total number of rearings (males and females)	
Repeated neurotoxicity ‡	90 days rat, NOAEL: 87.6 mg/kg bw/d Effects: reduced body weight and body weight gain	
Delayed neurotoxicity ‡	No data – not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	One *in vitro* and one *in vivo* mechanistic study showing activation of hepatic enzymes (CYP2B) with consequent perturbation of pituitary-thyroid axis and formation of liver and thyroid tumours in male rats.
Studies performed on metabolites or impurities ‡	S-2188-DC (major metabolite in rat): Acute oral rat, LD_{50} > 500 mg/kg bw Negative reverse mutation test in bacterial systems

Medical data ‡ (Annex IIA, point 5.9)

Limited information – new substance

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.13 mg/kg bw/d	2 years rat	100
AOEL ‡	0.2 mg/kg bw/d	Two generation study rat (supported by 90 days and 1 year dog, 90 days mouse, 1 generation reproduction study rat)	100
ARfD ‡	0.3mg/kg bw	Developmental study rabbit	100

Dermal absorption ‡ (Annex IIIA, point 7.6)

Formulation (S-2188 50 WG)	0.1% for concentrate 0.8% spray dilution based on *in vivo* rat study and on *in vitro* study

Exposure scenarios (Annex IIIA, point 7.3 – 7.6)

Operator	POEM model Grapes, tractor mounted, air-assisted sprayer : without PPE: 67% of AOEL with PPE[8]: 52% of AOEL Glasshouse (tomato, aubergine, pepper, cucurbits with edible peel), hand-held sprayer (low-level target): without PPE: 10% of AOEL with PPE: 5% of AOEL BBA model Grapes, tractor mounted, air-assisted sprayer: without PPE: 4% of AOEL with PPE[9]: 1.5% of AOEL Glasshouse (tomato, aubergine, pepper, cucurbits with edible peel), hand-held sprayer (high-level target): without PPE: 3% of AOEL with PPE: 2.5% of AOEL Dutch model

[8] PPE in POEM model : gloves during mixing/loading and application.
[9] PPE in BBA model : gloves during mixing/loading and application, sturdy footwear during application.

	Glasshouse (tomato, aubergine, pepper, cucurbits with edible peel), hand-held sprayer: without PPE: 11% of AOEL with PPE[10]: 1.1% of AOEL EUROPOEM Glasshouse (tomato, aubergines, pepper, cucurbits with edible peel), lance: without PPE: 4% of AOEL with PPE[11]: 1% of AOEL
Workers	Grapevines (one application): 9.6% of AOEL for the unprotected worker 0.5% of AOEL for the protected worker[12] (Krebs et al). Glasshouse (worst case 3 applications): 28.8% of AOEL for the unprotected worker 1.45% of AOEL for the protected worker (Krebs et al).
Bystanders	Grapevines Adults: 0.15% of AOEL (Martin et al., 2008) Children: 0.13% of AOEL (Martin et al., 2008) Adults: 1.58% of AOEL (Lloyd and Bell, 1983 – 1987) Glasshouse Bystander exposure is not expected.
Residents	Grapevines Adults: 0.15% of AOEL (Martin et al., 2008) Children: 0.44% of AOEL (Martin et al., 2008) Glasshouse Resident exposure is not expected.

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 9)

Substance classified (Fenpyrazamine)	No classification and labelling proposed by the RMS

[10] PPE in Dutch model : gloves and coverall
[11] PPE in EUROPOEM : gloves and coverall
[12] Protective clothing and gloves.

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

Plant groups covered	Fruit crops: Grapevine Leafy crops: Lettuce Pulses/oilseeds: Oilseed rape
Rotational crops	Confined studies on cereals (wheat), leafy crops (lettuce) and root crops (carrots) and field studies on carrot, lettuce, tomato and barley.
Metabolism in rotational crops similar to metabolism in primary crops?	In addition to fenpyrazamine and S-2188-OH detected in primary crops, metabolite S-2188-$(OH)_2$ was found in rotational crops (up to *ca.* 10% TRR)
Processed commodities	Fenpyrazamine stable under conditions representing pasteurisation and baking/brewing /boiling but degraded to S-2188-DC (8.6%) under sterilisation. No other hydrolysis products were formed.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes, fenpyrazamine and S-2188-DC major components in processed commodities.
Plant residue definition for monitoring	Fenpyrazamine
Plant residue definition for risk assessment	Sum fenpyrazamine and S-2188-DC, expressed as fenpyrazamine
Conversion factor (monitoring to risk assessment)	Table grape: 1.2 Wine grape: (see processing studies) Sweet pepper: 1.1 tomato and aubergine: 1.0 cucurbits edible peel: 1.1

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	Egg yolk: day 6, Egg white: day 2, Milk: day 3
Animal residue definition for monitoring	Sum fenpyrazamine and S-2188-DC, expressed as fenpyrazamine
Animal residue definition for risk assessment	Sum of fenpyrazamine, S-2188-DC, S-2188-CH_2OH-DC and MPPZ (provisional)
Conversion factor (monitoring to risk assessment)	Not evaluated
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No (even if log P_{ow} >3 for parent) when considering metabolism study data as residue levels in fat not significantly different from levels in other matrices. To be confirmed when feeding studies are required.

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

No residues expected in rotational crops, since field studies at GAP have shown residues of both fenpyrazamine and S-2188-OH to be <LOQ (0.01 mg/kg) in the succeeding crops (carrot, lettuce, tomato and barley).

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

- Fenpyrazamine and S-2188-DC residues stable up to 12 months in grapes, oilseed rape (seeds), lettuce and cereal grains when stored at -18°C or below. - Metabolite S-2188-OH is stable up to 12 months in grape, oilseeds and cereal grains and 6 months in lettuce when stored at -18 °C. These stability studies cover commodities with high water, high oil and high starch content.

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

	Ruminant:	**Poultry:**	**Pig:**
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	No	No	No
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No	No	No
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	Not required	Not required	Not required
Liver	Not required	Not required	Not required
Kidney	Not required	Not required	Not required
Fat	Not required	Not required	Not required
Milk	Not required		
Eggs		Not required	

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

Crop	Northern/ Southern Region, field or glasshouse	Trials results relevant to the representative uses **(fenpyrazamine)** (a)	Recommendation/comments	**MRL** estimated from trials according to the representative use	**HR**	**STMR**
Wine grape (PHI 14 days)	N-EU	0.18, 2x 0.23, 0.29, 0.49, 0.52, 0.54, 0.74	Northern and southern datasets similar (U-test, 5%). MRL derived from the merged values: R_{max}: 1.46 R_{ber}: 1.53	2	1.20	0.41
	S-EU	0.06, 0.08, 0.13, 0.15, 0.37, 0.62, 1.00, 1.20				
Table grape (PHI 7 days)	S-EU	0.06, 0.14, 0.15, 0.22, 0.37, 1.00, 2x 1.20	R_{max}: 2.14 R_{ber}: 2.30	2	1.20	0.30
Cherry tomato	Glasshouse	2x 0.28, 0.46, 0.65, 0.67, 1.40, 1.50, 1.65	Extrapolation to aubergines R_{max}: 2.66 R_{ber}: 2.95	3	1.65	0.66
Sweet Pepper	Glasshouse	0.47, 0.48, 0.58, 0.63, 0.69, 0.94, 1.00, 1.10	R_{max}: 1.52 R_{ber}: 1.97	2	1.10	0.66
Cucumber	Glasshouse	0.08, 0.10, 2x 0.11, 0.13, 0.14, 0.15, 0.26,	Extrapolation to cucurbits with edible peel R_{max}: 0.31 R_{ber}: 0.30	0.3	0.26	0.12

Summary of residues data (Fenpyrazamine +S-2188-DC) according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern/ Southern Region, field or glasshouse	Trials results relevant to the representative uses **(Fenpyrazamine + S-2188-DC)** (a)	Recommendation/comments	**HR**	**STMR**
Wine grape (PHI 14 days)	N-EU	0.22, 0.26, 0.29, 0.33, 0.60, 0.63, 0.69, 0.85	STMR and HR derived from the merged values (N+S-EU) since datasets similar (U-test, 5%)	1.59	0.39
	S-EU	0.07, 0.09, 2x 0.16, 0.44, 0.91, 1.11, 1.59			
Table grape (PHI 7 days)	S-EU	0.07, 0.16, 0.17, 0.28, 0.44, 1.11, 1.59, 1.76	None	1.76	0.36
Cherry tomato	Glasshouse	0.29, 0.37, 0.47, 0.71, 0.70, 1.43, 1.53, 1.68	Extrapolation to protected aubergines	1.68	0.70
Sweet Pepper	Glasshouse	0.55, 0.59, 0.71, 0.75, 0.895, 1.00, 1.03, 1.24	None	1.24	0.820
Cucumber	Glasshouse	0.09, 2x 0.12, 0.14, 0.15, 0.16, 0.23, 0.33	Extrapolation to protected cucurbits with edible peel	0.33	0.15

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

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

ADI	0.13 mg/kg bw/day	
TMDI (% ADI) according Primo, rev.2	Highest TMDI: 13 % ADI (WHO cluster diet B)	
IEDI (% ADI) according to Primo, rev.2 (FR infant)	Highest IEDI: 3% ADI (WHO Cluster diet B)	
IEDI (WHO European Diet) (% ADI)	Not relevant	
NEDI (specify diet) (% ADI)	Not relevant	
Factors included in TMDI, IEDI and NEDI	TMDI: MRLs and conversion factors IEDI: STMR (fenpyrazamine + S-2188-DC) and PF (1.38) and yield factor (0.7) for wine grapes	
ARfD	0.3 mg/kg bw	
IESTI (% ARfD) According to Primo, rev.2	38 % ARfD	Table grape
	33 % ARfD	Tomato
	26 % ARfD	Pepper
	14 % ARfD	Aubergine (egg plant)
	6 % ARfD	Cucumber
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not relevant, as the EFSA Primo, rev.2 model was used.	
Factors included in IESTI and NESTI	IESTI: HR (fenpyrazamine + S-2188-DC) and PF (1.38) and yield factor (0.7) for wine grapes	

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

Crop/ process/ processed product	Number of studies	Factors **Median** (individual values)		Amount Transferred (%)
		Processing factor (PF)	Conversion Factor (CF)	
Grape → white wine	3	**0.78** (0.60, 0.78, 1.38)	**1.3** (1.2, 1.3, 1.4)	--
Grape → red wine **(heated must)**	3	0.28 (0.19, 0.28, 0.48)	3.4 (1.9, 3.4, 3.9)	--
Grape → red wine (must not heated)	0	Processing including heating of the must does not represent a worst case in order to derive a PF for red wine, since fenpyrazamine is degraded to S-2188-DC under such conditions. Therefore, the highest PF derived for white wine (**1.38) is taken as a default PF for red wine** (as the vast majority of the red wines are produced without heating of the must), with a conversion factor of 1.3.		
Grape → Juice (pasteurised)	3	**0.13** (0.06, 0.09, 0.16, 0.31)	**1.6** (1.4, 1.5, 1.7, 2.4)	--
Grape → raisins	3	**1.67** (1.62, 1.67, 2.8)	**1.1** (1.0, 1.1, 1.1)	--

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

Wine grape (N-EU, S-EU)	2
Table grape (S-EU)	2
Tomato	3
Aubergine (egg plant)	3 (extrapolation from tomato)
Sweet pepper	2
Cucurbits with edible peel	0.3

Route of degradation (aerobic) in soil (Annex IIA, point 7.1)

Mineralization after 100 days ‡	6.2-8.5 % after 120 d, [pyrazolyl-^{14}C]-label (n[13]= 4) 5.2 % after 120 d, [phenyl-^{14}C]-label (n= 1)
Non-extractable residues after 100 days ‡	38.9-69.9 % after 120 d, [pyrazolyl-^{14}C]-label (n= 4) 64.0 % after 120 d, [phenyl-^{14}C]-label (n= 1)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	No metabolite above 5 % of AR.

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.2 and 7.1.3)

Anaerobic degradation ‡

Mineralization after 100 days	Not performed.
Non-extractable residues after 100 days	Not performed.
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not performed.

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Fenpyrazamine stable to soil photolysis. No metabolite formed.

[13] n corresponds to the number of soils.

Rate of degradation in soil (Annex IIA, point 7.2 and 7.3, Annex IIIA, point 9.1 and 9.2)

Laboratory studies ‡

Fenpyrazamine		Aerobic conditions								
Soil type	OC %	pH (H_2O)	t. °C / Soil moisture g $100g^{-1}$	DT_{50} /DT_{90} (d)	k_1 value	k_2 value	g value	DT_{50} (d) 20°C pF2/10 kPa	χ^2 (%)	Method of calculation
Sandy loam	2.9	7.5	20 °C / 29.4	36.6* / 121.6*,[d]	-	-	-	29.9*	7.3[b] / 5.7[c]	SFO
Sandy loam	1.7	5.2	20 °C / 15.1	39.0 / 1846.8[d]	0.0477	0.0008	0.58	750.6[a,d]	3.0	DFOP
Loam	4.2	7.9	20 °C / 34.6	23.6 / 78.3	-	-	-	21.3	8.1	SFO
Silt loam	3.7	6.9	20 °C / 36.2	28.7 / 515.5[d]	0.0723	0.0030	0.53	206.0[a,d]	2.7	DFOP
Geometric mean								**99.6**		

* Geometric mean from [pyrazolyl-^{14}C] and [phenyl-^{14}C] labels

[a] DFOP kinetics – slow k rate proposed by RMS, normalised values

[b] [Phenyl-^{14}C] label

[c] [Pyrazolyl-^{14}C] label

[d] Values extrapolated past the incubation time

Field studies ‡

Fenpyrazamine			Aerobic conditions										
Soil type (indicate if bare or cropped soil was used)	Location (country or USA state)	OC %	pH (H_2O)	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	k_1 value	k_2 value	g value	Pseudo-DT_{50} (d) Norm.[a]	Pseudo-DT_{50} (d) not Norm[e]	χ^2 (%)[b]	Method of calculation[b]
Sand	UK[c]	2.7	7.4	0 - 30	4.1[d]	133.9[d]	0.2864[d]	0.0079[d]	0.7132[d]	20.2	88.1	11.4	FOMC
Loamy sand	Germany	4.9	5.7	0 - 30	3.2[d]	98.4[d]	0.3273[d]	0.0092[d]	0.7525[d]	7.7	75.3	10.0	FOMC
Clay	Italy	1.2	8.5	0 - 30	0.4[d]	86.6[d]	4.2146[d]	0.0163[d]	0.5896[d]	39.8	42.5	8.1	DFOP
Clay	France	1.0	8.4	0 - 30	4.6[d]	60.3[d]	4.154	0.028	0.429	28.5	24.0	10.0	DFO

	(sout h)						6[d]	9[d]	1[d]				P
Geometric mean										**20.5**			

[a] Values normalised using time-step normalisation on a daily basis. Pseudo-SFO calculated by dividing DT_{90} with 3.32 for FOMC kinetics, and ln (2) / slow rate k for DFOP kinetics.

[b] refers to the method of calculation of the normalised values

[c] Residue at 29 DAT omitted from kinetic evaluation

[d] DFOP kinetic on non-normalised data

[e] Non-normalised pseudo-SFO DT_{50} values calculated by dividing DT_{90} with 3.32 for FOMC kinetics, and ln (2) / slow rate k for DFOP kinetics. These values are

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	Not studied - no data requested
Laboratory studies ‡	Not performed.

Soil adsorption (Annex IIA, point 7.4.1 and 7.4.2)

Fenpyrazamine ‡							
Soil Type	OC %	Soil pH (H_2O)	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Clay loam	4.8	8.0	-	-	9.36	195	0.880
Silt loam	2.8	7.0	-	-	7.87	292	0.906
Loam	3.8	6.0	-	-	4.27	112	0.932
Loamy sand	0.8	5.1	-	-	5.85	731	0.953
Sandy loam	3.2	5.9	-	-	6.99	218	0.886
Arithmetic mean					**6.87**	**310**	**0.911**
pH dependence, Yes or No			No				

Soil desorption (Annex IIA, point 7.4.1 and 7.4.2)

Fenpyrazamine ‡							
Soil Type	OC %	Soil pH (H_2O)	K_d (mL/g)	K_{oc} (mL/g)	$K_{f\text{-}des}$ (mL/g)	$K_{foc\text{-}des}$ (mL/g)	1/n
Clay loam	4.8	8.0	-	-	10.82	225	0.859
Silt loam	2.8	7.0	-	-	9.11	338	0.892
Loam	3.8	6.0	-	-	5.07	133	0.929
Loamy sand	0.8	5.1	-	-	7.63	954	0.951
Sandy loam	3.2	5.9	-	-	8.62	269	0.895
Arithmetic mean					**8.25**	**384**	**0.905**
pH dependence, Yes or No			No				

Mobility in soil (Annex IIA, point 7.4, Annex IIIA, point 9.3)

Column leaching ‡	Not studied – no data requested
	Not studied – no data requested
Aged residues leaching ‡	Not studied – no data requested
	Not studied – no data requested
Lysimeter/ field leaching studies ‡	Not studied – no data requested

PEC (soil) (Annex IIIA, point 9.4)

Fenpyrazamine Method of calculation	Non-normalised values from field study (site UK): k_1: 0.2864, k_2: 0.0079, g: 0.7132 Kinetics: DFOP Field or Lab: representative worst case from field studies.
Application data	Crop: Grapevine (single application) Depth of soil layer: 5 cm. Soil bulk density: 1.5 g cm^{-3} % plant interception: 85 Number of applications: 1 Interval (d): - Application rate(s): 600 g as/ha Crop: Tomatoes (glasshouse use, outdoor PEC_s calculated, multiple application) Depth of soil layer: 5 cm. Soil bulk density: 1.5 g cm^{-3} % plant interception: 80 Number of applications: 3 Interval (d): 10 Application rate(s): 600 g as/ha

	Grapevine			
$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.120		nc	
Short term 24h	0.098	0.109	nc	nc
2d	0.082	0.099	nc	nc

	4d	0.061	0.085	nc	nc
Long term	7d	0.044	0.071	nc	nc
	28d	0.028	0.042	nc	nc
	50d	0.023	0.035	nc	nc
	100d	0.016	0.027	nc	nc

Plateau concentration	0.001 mg/kg after 2 yr

PEC$_{(s)}$ (mg/kg)		**Tomatoes**			
		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		nc		0.249	
Short term	24h	nc	nc	0.217	0.232
	2d	nc	nc	0.194	0.219
	4d	nc	nc	0.162	0.198
Long term	7d	nc	nc	0.137	0.176
	28d	nc	nc	0.102	0.136
	50d	nc	nc	0.086	0.121
	100d	nc	nc	0.058	0.101

Plateau concentration	0.002 mg/kg after 3 yr

Route and rate of degradation in water (Annex IIA, point 7.5 - 7.8)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	Fenpyrazamine [pyrazolyl-^{14}C] and [phenyl-^{14}C]: pH 4: stable at 50 °C, estimated as stable at 20 °C No metabolite
	Fenpyrazamine [pyrazolyl-^{14}C] and [phenyl-^{14}C]: pH 7: 32.6 d at 50 °C (1st order, r^2=1), estimated as stable at 20 °C Metabolites: S-2188-DC: 54.2 %AR (50 d) S-2188-OH: 8.7 %AR (50 d)
	Fenpyrazamine [pyrazolyl-^{14}C] and [phenyl-^{14}C]: pH 9: 11 d at 25 °C (1st order, r^2=1), estimated 24 d at 20 °C Metabolites: S-2188-DC: 54.2 %AR (17 d)

Photolytic degradation of active substance and metabolites above 10 % ‡	Fenpyrazamine [pyrazolyl-^{14}C] and [phenyl-^{14}C]: DT_{50} : 1.7 d Natural light, 54°N; DT_{50} 1.7 days Metabolites: S-2188-DC: 63.8 %AR (7 d) Estimated DT_{50} at 54°N 12.5 days MCNI: 17.7 %AR (30 d) No degradation observed
Quantum yield of direct phototransformation in water at Σ > 290 nm	0.021 mol · Einstein $^{-1}$
Readily biodegradable ‡ (yes/no)	No

Degradation in water / sediment

Fenpyrazamine	Distribution (Max. sed 31.1 % after 14 d, mean of both labels)									
Water / sediment system	pH water phase	pH sed (H_2O)	t. °C	DT_{50}/DT_{90} whole sys.	St. (r^2)[a]	DT_{50}-DT_{90} water[b]	St. (r^2)[a]	DT_{50}-DT_{90} sed[b]	St. (r^2)	Method of calculation
Silty clay loam or Clay loam	8.6	7.5	20	19.0 / 63.2	0.99	nc	nc	nc	nc	SFO
Sand	6.4	6.1	20	66.2 / 220.1	0.90	nc	nc	nc	nc	SFO
Geometric mean				**35.5 / 118**		**nc**		**nc**		**-**

[a] arithmetic mean between [pyrazolyl-^{14}C] and [phenyl-^{14}C] labels

[b] dissipation value

S-2188-DC	Distribution (max in water 11.1 % after 7 d., max. sed 8.3 % after 14 d, mean of both labels)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
Silty clay loam or Clay loam	8.6	7.5	20	nc	-	nc	-	nc	-	-
Sand	6.4	6.1	20	nc	-	nc	-	nc	-	-
Geometric mean/median				**nc**		**nc**		**nc**		**-**

S-2188-OH	Distribution (max in water 10.8 after 30 d., max. sed 4 % after 100 d, mean of both labels)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
Silty clay loam or Clay loam	8.6	7.5	20	nc	-	nc	-	nc	-	-

Sand	6.4	6.1	20	nc	-	nc	-	nc	-	-
Geometric mean/median				**nc**		**nc**		**nc**		**-**

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization % after 100 d. (end of the study).	Non-extractable residues in sed. Max in % after n d	Non-extractable residues in sed. Max in % after 100 d (end of the study)
Silty clay loam or Clay loam	8.6	7.5	[Pyrazolyl-^{14}C]: 8.5 [Phenyl-^{14}C]: 5.5	[Pyr-^{14}C]: 47.0 (100) [Ph-^{14}C]: 47.4 (100)	[Pyrazolyl-^{14}C]: 47.0 [Phenyl-^{14}C]: 47.4
Sand	6.4	6.1	[Pyrazolyl-^{14}C]: 3.3 [Phenyl-^{14}C]: 3.1	[Pyr-^{14}C]: 19.5 (100) [Ph-^{14}C]: 17.2 (100)	[Pyrazolyl-^{14}C]: 19.5 [Phenyl-^{14}C]: 17.2

PEC surface water and PEC sediment (Annex IIIA, point 9.7 and 9.8)

Fenpyrazamine	Version control no. of FOCUS calculator: v. 1.1
Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 331.43 Water solubility (mg/L): 20.4 K_{FOC} (L/kg): 310 DT_{50} soil (d): 20.5 days (Geomean pseudo-DT_{50}, field, time-step normalisation, Q_{10} of 2.58) DT_{50} water/sediment system (d): 35.5 (representative worst case from sediment water studies) DT_{50} water (d): 35.5 DT_{50} sediment (d): 1000 Crop interception (%): 85 Plant uptake: 0
Parameters used in FOCUSsw step 3 (if performed)	Not performed.
Application rate	Crop: Vines, late applns. Crop interception: full canopy (70 %) Number of applications: 1 Interval (d): - Application rate(s): 600 g as/ha Application window: June - September

FOCUS STEP 1 Vines, late applns.	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	157.6		438.7	
	24 h	149.9	153.7	464.7	451.7
	2 d	147.0	151.1	455.8	456.0
	4 d	141.4	147.6	438.3	451.5
	7 d	133.3	143.2	413.4	440.4
	14 d	116.3	133.9	360.6	413.4
	21 d	101.5	125.5	314.5	387.9
	28 d	88.5	117.8	274.3	364.4
	42 d	67.3	104.4	208.7	323.0
	50 d	57.6	97.7	178.5	302.2
	100 d	21.7	67.2	67.3	208.1

FOCUS STEP 2 Vines, late applns.	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	22.9		67.5	
	24 h	21.4	22.1	66.6	67.1
	2 d	21.1	21.7	65.7	66.6
	4 d	20.5	21.2	63.9	65.7
	7 d	19.7	20.7	61.2	64.3
	14 d	17.8	19.7	55.5	61.3
	21 d	16.2	18.8	50.4	58.5
	28 d	14.7	18.0	45.7	55.9
	42 d	12.1	16.4	37.5	51.1
	50 d	10.8	15.6	33.6	48.6
	100 d	5.4	11.7	16.7	36.4

Application rate	Crop: Glasshouse Loss to surface water: 0.1 % of application rate into a 30 cm deep waterbody as performed in The Netherlands Number of applications: 3 Interval (d): none (worst case assumption) Application rate(s): 600 g as/ha Application window: not applicable

PEC_{SW}	0.60 µg L^{-1}
PEC_{SED}	Not calculated.

S-2188-DC	Molecular weight: 231.29
Parameters used in FOCUSsw step 1 and 2	Water solubility (mg/L): 1 (*unknown, default*) Soil or water metabolite: water metabolite K_{oc} (L/kg): 10 (*unknown, default*) DT_{50} soil (d): 1000 (*unknown, worst-case*) DT_{50} water/sediment system (d): 1000 (*unknown, worst-case*) DT_{50} water (d): 1000 (*unknown, worst-case*) DT_{50} sediment (d): 1000 (*unknown, worst-case*) Crop interception (%): 85 Maximum occurrence observed (%) Total water-sediment: 20.5 Water: 64 (photolysis study) Sediment: 8.3
Parameters used in FOCUSsw step 3 (if performed)	Not performed.
Application rate	Crop: Vines, late applns. Crop interception: full canopy (70 %) Number of applications: 1 Interval (d): - Application rate(s): 600 g as/ha Application window: June - September
Main routes of entry	Water-sediment, photolysis

FOCUS STEP 1 Vines, late applns.	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	7.2		0.0	
	24 h	7.1	7.1	0.7	0.4
	2 d	7.1	7.1	0.7	0.5
	4 d	7.1	7.1	0.7	0.6
	7 d	7.0	7.1	0.7	0.7
	14 d	7.0	7.0	0.7	0.7
	21 d	7.0	7.0	0.7	0.7
	28 d	6.9	7.0	0.7	0.7
	42 d	6.9	7.0	0.7	0.7
	50 d	6.8	7.0	0.7	0.7
	100 d	6.6	6.8	0.7	0.7

FOCUS STEP 2 Vines, late applns.	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	7.2		0.7	
	24 h	7.1	7.1	0.7	0.7
	2 d	7.1	7.1	0.7	0.7
	4 d	7.1	7.1	0.7	0.7
	7 d	7.0	7.1	0.7	0.7
	14 d	7.0	7.1	0.7	0.7
	21 d	7.0	7.0	0.7	0.7
	28 d	6.9	7.0	0.7	0.7
	42 d	6.9	7.0	0.7	0.7
	50 d	6.8	7.0	0.7	0.7
	100 d	6.6	6.8	0.7	0.7

Application rate	Crop: Glasshouse Loss to surface water: 0.1 % of application rate into a 30 cm deep waterbody as performed in The Netherlands, based on the relative molecular weight to the parent and the maximum appearance in water. Number of applications: 3 Interval (d): none (worst case assumption) Application rate(s): 600 g as/ha

	Application window: not applicable

PEC_{SW}	0.27 µg L^{-1}
PEC_{SED}	Not calculated.

S-2188-OH	Molecular weight: 247.29
Parameters used in FOCUSsw step 1 and 2	Water solubility (mg/L): 1 (*unknown, default*) Soil or water metabolite: water metabolite K_{oc} (L/kg): 10 (*unknown, default*) DT_{50} soil (d): 1000 (*unknown, worst-case*) DT_{50} water/sediment system (d): 1000 (*unknown, worst-case*) DT_{50} water (d): 1000 (*unknown, worst-case*) DT_{50} sediment (d): 1000 (*unknown, worst-case*) Crop interception (%): 85 Maximum occurrence observed (%) Total water-sediment: 15.9 Water: 12.5 Sediment: 4.4
Parameters used in FOCUSsw step 3 (if performed)	Not performed.
Application rate	Crop: Vines, late applns. Crop interception: full canopy (70 %) Number of applications: 1 Interval (d): - Application rate(s): 600 g as/ha Application window: June - September
Main routes of entry	Water-sediment

FOCUS STEP 1 Vines, late applns.	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	1.9		0.0	
	24 h	1.9	1.9	0.2	0.1
	2 d	1.9	1.9	0.2	0.1
	4 d	1.9	1.9	0.2	0.2
	7 d	1.9	1.9	0.2	0.2
	14 d	1.9	1.9	0.2	0.2
	21 d	1.9	1.9	0.2	0.2
	28 d	1.9	1.9	0.2	0.2
	42 d	1.8	1.9	0.2	0.2
	50 d	1.8	1.9	0.2	0.2
	100 d	1.8	1.8	0.2	0.2

FOCUS STEP 2 Vines, late applns.	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	1.9		0.2	
	24 h	1.9	1.9	0.2	0.2
	2 d	1.9	1.9	0.2	0.2
	4 d	1.9	1.9	0.2	0.2
	7 d	1.9	1.9	0.2	0.2
	14 d	1.9	1.9	0.2	0.2
	21 d	1.9	1.9	0.2	0.2
	28 d	1.9	1.9	0.2	0.2
	42 d	1.8	1.9	0.2	0.2
	50 d	1.8	1.9	0.2	0.2
	100 d	1.8	1.8	0.2	0.2

Application rate	Crop: Glasshouse Loss to surface water: 0.1 % of application rate into a 30 cm deep waterbody as performed in The Netherlands, based on the relative molecular weight to the parent and the maximum appearance in water Number of applications: 3 Interval (d): none (worst case assumption) Application rate(s): 600 g as/ha

	Application window: not applicable

PEC_{SW}	0.07 µg L^{-1}
PEC_{SED}	Not calculated.

MCNI	Molecular weight: 216.28
Parameters used in FOCUSsw step 1 and 2	Water solubility (mg/L): 1 (*unknown, default*) Soil or water metabolite: water metabolite K_{oc} (L/kg): 10 (*unknown, default*) DT_{50} soil (d): 1000 (*unknown, worst-case*) DT_{50} water/sediment system (d): 1000 (*unknown, worst-case*) DT_{50} water (d): 1000 (*unknown, worst-case*) DT_{50} sediment (d): 1000 (*unknown, worst-case*) Crop interception (%): 85 Maximum occurrence observed (%) Total water-sediment: - Water: 18 (photolysis study) Sediment: -
Parameters used in FOCUSsw step 3 (if performed)	Not performed.
Application rate	Crop: Vines, late applns. Crop interception: full canopy (70 %) Number of applications: 1 Interval (d): - Application rate(s): 600 g as/ha Application window: June - September
Main routes of entry	Photolysis

FOCUS STEP 1 Vines, late applns.	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	1.9		0.0	
	24 h	1.9	1.9	0.2	0.1
	2 d	1.9	1.9	0.2	0.1
	4 d	1.9	1.9	0.2	0.2
	7 d	1.9	1.9	0.2	0.2
	14 d	1.8	1.9	0.2	0.2
	21 d	1.8	1.8	0.2	0.2
	28 d	1.8	1.8	0.2	0.2
	42 d	1.8	1.8	0.2	0.2
	50 d	1.8	1.8	0.2	0.2
	100 d	1.7	1.8	0.2	0.2

FOCUS STEP 2 Vines, late applns.	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	1.9		0.2	
	24 h	1.9	1.9	0.2	0.2
	2 d	1.9	1.9	0.2	0.2
	4 d	1.9	1.9	0.2	0.2
	7 d	1.9	1.9	0.2	0.2
	14 d	1.8	1.9	0.2	0.2
	21 d	1.8	1.8	0.2	0.2
	28 d	1.8	1.8	0.2	0.2
	42 d	1.8	1.8	0.2	0.2
	50 d	1.8	1.8	0.2	0.2
	100 d	1.7	1.8	0.2	0.2

Application rate	Crop: Glasshouse Loss to surface water: 0.1 % of application rate into a 30 cm deep waterbody as performed in The Netherlands, based on the relative molecular weight of the parent and the maximum appearance in water Number of applications: 3 Interval (d): none (worst case assumption) Application rate(s): 600 g as/ha

	Application window: not applicable

PEC_{SW}	0.07 µg L^{-1}
PEC_{SED}	Not calculated

PEC (ground water) (Annex IIIA, point 9.6)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: PEARL 3.3.3, PELMO 3.3.2 Scenarios (list of names): Châteaudun, Hamburg, Kremsmünster, Piacenza, Porto, Sevilla, Thiva Crop: Vine, Tomatoes (glasshouse worst case) Geometric mean fenpyrazamine $DT_{50field}$ 20.5 d (time-step normalisation to pF2, 20 °C with Q_{10} of 2.58). $K_{f,OC}$: 310 L kg^{-1}, arithmetic mean, $^1/_n$= 0.911. Metabolites: none relevant for groundwater.
Application rate - Vines	Application rate: 600 g/ha. No. of applications: 1 Time of application (month or season): 1 September Crop interception (%): 85
Application rate - Tomatoes	Application rate: 600 g/ha. No. of applications: 3 Time of application (month or season): Relative application date for all relevant scenarios (4, 14 and 24 days prior to harvest, latest date) Crop interception (%): 80

PEC_{GW} - FOCUS modelling results (80th percentile annual average concentration at 1m)

PEARL 3.3.3 / **Vines**	Scenario	Fenpyrazamine (µg/L)
	Châteaudun	< 0.001
	Hamburg	< 0.001
	Kremsmünster	< 0.001
	Piacenza	< 0.001
	Porto	< 0.001
	Sevilla	< 0.001
	Thiva	< 0.001
PELMO 3.3.2 / **Vines**	Châteaudun	< 0.001
	Hamburg	< 0.001

	Kremsmünster	< 0.001
	Piacenza	< 0.001
	Porto	< 0.001
	Sevilla	< 0.001
	Thiva	< 0.001

PEARL 3.3.3 / **Tomatoes**	Scenario	Fenpyrazamine (µg/L)
	Châteaudun	< 0.001
	Piacenza	< 0.001
	Porto	< 0.001
	Sevilla	< 0.001
	Thiva	< 0.001
PELMO 3.3.2 / **Tomatoes**	Châteaudun	< 0.001
	Piacenza	< 0.001
	Porto	< 0.001
	Sevilla	< 0.001
	Thiva	< 0.001

Fate and behaviour in air (Annex IIA, point 7.10, Annex III, point 9.9)

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	Fenpyrazamine: Φ = 0.021
Photochemical oxidative degradation in air ‡	DT_{50} of 1.22 hours derived by the Atkinson model (version 1.9), OH (12 h) concentration assumed = 1.5 x 10^6 cm^{-3}
Volatilisation ‡	From plant surfaces: not studied
	From soil surfaces: not studied
Metabolites	None.

PEC (air)

Method of calculation	Not relevant, because of low vapour pressure.

$PEC_{(a)}$

Maximum concentration	Negligible.

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: Fenpyrazamine Surface Water: Fenpyrazamine, S-2188-DC, S-2188-OH, MCNI Sediment: Fenpyrazamine, S-2188-DC Ground water: Fenpyrazamine Air: Fenpyrazamine

Monitoring data, if available (Annex IIA, point 7.12)

Soil (indicate location and type of study)	No monitoring data, new active substance
Surface water (indicate location and type of study)	No monitoring data, new active substance
Ground water (indicate location and type of study)	No monitoring data, new active substance
Air (indicate location and type of study)	No monitoring data, new active substance

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data (Annex IIA, point 9)

Not readily biodegradable

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Bobwhite quail	a.s.	Acute	> 2000	/
Bobwhite quail	a.s.	Short-term	> 954	> 5000
Bobwhite quail	a.s.	Long-term	82.9	1000
Mammals ‡				
Rat	a.s.	Acute	> 2000	/
Rat	S-2188 50WG	Acute	> 2000	/
Rat	Metabolite S-2188 DC	Acute	> 500	/
Rat	a.s.	Long-term	28.5	400
Additional higher tier studies ‡				
Not required				

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

Grapevines, 1 x 0.6 kg a.s./ha

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Insectivorous bird	Acute	32	> 62	10
Insectivorous bird	Short-term	18	> 53	10
Insectivorous bird	Long-term	18	4.6	5
Earthworm-eating bird	Long-term	0.28 0.86*	299 96*	5
Fish-eating bird	Long-term	1.13	349 #	5
Bird drinking contaminated water	Acute	0.12	> 35145	10
Bird drinking contaminated water	Long-term	0.12	1457	5
Higher tier refinement (Birds)				
Insectivorous bird	Long-term	13.1	5.8	5
Tier 1 (Mammals)				
Small herbivorous mammal	Acute	71	> 113	10
Small herbivorous mammal	Acute product	71	> 56	10
Small herbivorous mammal	Long-term	5	5.7	5
Earthworm-eating mammal	Long-term	0.35 1.1*	81 26*	5

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Fish-eating mammal	Long-term	1.13	194#	5
Mammal drinking contaminated water	Acute	0.12	> 67361	10
Mammal drinking contaminated water	Long-term	0.12	960	5

* these figures are related to the glasshouse use (vegetables)
# based on FOCUS step 1 PECsw

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

Group	Test substance	Time scale (Test type)	Endpoint	Toxicity [1] [mg/L]
Laboratory tests ‡				
Fish				
Oncorhynchus mykiss	a.s.	96 h (flow-through)	Mortality, LC_{50}	5.2 mm
Oncorhynchus mykiss	a.s.	90 d (flow-through)	Mortality, NOEC	0.37 mm
Oncorhynchus mykiss	S-2188 50 WG	96 h (static)	Mortality, LC_{50}	18 form. 7.3 a.s. mm
Oncorhynchus mykiss	Metabolite S-2188-DC	96 h (static)	Mortality, LC_{50}	> 89 mm
Oncorhynchus mykiss	Metabolite S-2188-OH	96 h (static)	Mortality, LC_{50}	> 97 mm
Oncorhynchus mykiss	Metabolite MCNI	96 h (static)	Mortality, LC_{50}	> 52 mm
Aquatic invertebrate				
Daphnia magna	a.s.	48 h (static)	Immobility, EC_{50}	5.5 mm
Daphnia magna	a.s.	21 d (static)	Reproduction, NOEC	0.34 mm
Daphnia magna	S-2188 50 WG	48 h (static)	Immobility, EC_{50}	5.7 form. 2.6 a.s. mm
Daphnia magna	Metabolite S-2188-DC	21 d (static)	Immobility, EC_{50}	> 94 mm
Daphnia magna	Metabolite S-2188-OH	48 h (static)	Immobility, EC_{50}	> 98 mm
Daphnia magna	Metabolite MCNI	48 h (static)	Immobility, EC_{50}	> 50 mm
Sediment dwelling organisms				
Chironomus riparius	a.s.	28 d (static)	Emergence, NOEC	0.32 nom
Algae				
Pseudokirchneriella subcapitata	a.s.	72 h (static)	Biomass, E_bC_{50} Growth rate, E_rC_{50}	0.42 mm > 0.9 mm

Group	Test substance	Time scale (Test type)	Endpoint	Toxicity [1] [mg/L]
Pseudokirchneriella subcapitata	S-2188 50 WG	72 h (static)	Biomass, E_bC_{50} Growth rate, E_rC_{50}	0.62 form. 0.28 a.s. $_{mm}$ 1.5 form. 0.67 a.s. $_{mm}$
Pseudokirchneriella subcapitata	Metabolite S-2188-DC	72 h (static)	Biomass, E_bC_{50} Growth rate, E_rC_{50}	58 $_{mm}$ > 82 $_{mm}$
Pseudokirchneriella subcapitata	Metabolite S-2188-OH	72 h (static)	Biomass, E_bC_{50} Growth rate, E_rC_{50}	82 $_{mm}$ > 94 $_{mm}$
Pseudokirchneriella subcapitata	Metabolite MCNI	72 h (static)	Biomass, E_bC_{50} Growth rate, E_rC_{50}	25 $_{mm}$ > 45 $_{mm}$
Higher plant				
Not required				
Microcosm or mesocosm tests				
Not required				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether endpoints are presented as units of preparation or a.s.

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

EU specific risk assessment

FOCUS Step 1

Grapevine, 1 x 0.6 kg a.s./ha, Northern and Southern Europe

Test substance	Organism	Toxicity endpoint [mg/L]	Time scale	PEC_i [mg/L]	TER	Annex VI Trigger [1]
a.s.	Fish	5.2	Acute	0.1576	**33.0**	100
a.s.	Fish	0.37	Chronic	0.1576	**2.35**	10
a.s.	Aquatic invertebrates	5.5	Acute	0.1576	**34.9**	100
a.s.	Aquatic invertebrates	0.34	Chronic	0.1576	**2.16**	10
a.s.	Algae	0.42	Chronic	0.1576	**2.66**	10
a.s.	Higher plants[2]		Chronic			10
a.s.	Sediment-dwelling organisms[3]	0.32	Chronic	0.1576 (PEC_{sw})	**2.03**	10
Metabolite S-2188-DC	Fish	> 89	Acute	0.00717	> 12413	100

Test substance	Organism	Toxicity endpoint [mg/L]	Time scale	PEC_i [mg/L]	TER	Annex VI Trigger [1]
Metabolite S-2188-DC	Aquatic invertebrates	> 94	Acute	0.00717	> 13110	100
Metabolite S-2188-DC	Algae	58	Chronic	0.00717	8089	10
Metabolite S-2188-OH	Fish	> 97	Acute	0.00192	> 50521	100
Metabolite S-2188-OH	Aquatic invertebrates	> 98	Acute	0.00192	> 51042	100
Metabolite S-2188-OH	Algae	82	Chronic	0.00192	42708	10
Metabolite MCNI	Fish	> 52	Acute	0.00189	> 27513	100
Metabolite MCNI	Aquatic invertebrates	> 50	Acute	0.00189	> 26455	100
Metabolite MCNI	Algae	25	Chronic	0.00189	13228	10
S-2188 50 WG	Fish	7.3 a.s.	Acute	0.1576	**46.3**	100
S-2188 50 WG	Aquatic invertebrates	2.6 a.s.	Acute	0.1576	**16.5**	100
S-2188 50 WG	Algae	0.28 a.s.	Chronic	0.1576	**1.78**	10

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

For the representative applications in glasshouses (tomato, aubergine, pepper and cucurbits, 2-3 x 0.6 kg a.s./ha, interval 10-14 d) PEC_{SW} values were calculated based on the Dutch-Model. PEC_{SW} values for the active substance fenpyrazamine and its relevant aquatic metabolites S-2188-DC, S-2188-OH and MCNI were determined to be 0.6, 0.27, 0.07 and 0.07 µg/L, respectively. Hence, the glasshouse risk assessment is covered by the field risk assessment for the representative use on grapevine.

FOCUS Step 2

Grapevine, 1 x 0.6 kg a.s./ha, Northern and Southern Europe

Test substance	N/S[1]	Organism	Toxicity endpoint [mg/L]	Time scale	$PEC_{act.}$ [mg/L]	TER	Annex VI Trigger
a.s.	S	Fish	5.2	Acute	0.0229	227	100
a.s.	S	Fish	0.37	Chronic	0.0229	16.2	10
a.s.	S	Aquatic invertebrates	5.5	Acute	0.0229	240	100

Test substance	N/S[1]	Organism	Toxicity endpoint [mg/L]	Time scale	$PEC_{act.}$ [mg/L]	TER	Annex VI Trigger
a.s.	S	Aquatic invertebrates	0.34	Chronic	0.0229	16.6	10
a.s.	S	Algae	0.42	Chronic	0.0229	18.3	10
a.s.		Higher plants		Chronic			10
a.s.	S	Sediment-dwelling organisms	0.32	Chronic	0.0229 (PEC_{sw})	14.85	10
S-2188 50 WG	S	Fish	7.3 a.s.	Acute	0.0229	319	100
S-2188 50 WG	S	Aquatic invertebrates	2.6 a.s.	Acute	0.0229	114	100
S-2188 50 WG	S	Algae	0.28 a.s.	Chronic	0.0229	12.2	10

[1] indicate whether Northern of Southern

Refined aquatic risk assessment using higher tier FOCUS modelling.

Not required

Bioconcentration				
	Fenpyrazamine	S-2188-DC	S-2188-OH	MCNI
log P_{OW}	3.52	0.23[2]	0.81[2]	2.65[2]
Bioconcentration factor (BCF)[1] ‡	8-9 (a.s.) * 283-289 (TRR)	-	-	-
Annex VI Trigger for the bioconcentration factor	100	-	-	-
Clearance time (days) (CT_{50})	< 1 d	-	-	-
(CT_{90})	-	-	-	-
Level of residues (%) in organisms after the 14 day depuration phase	1.5 %	-	-	-

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

Effects on honeybees (Annex IIA, point 8.7, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg a.s./bee)	Acute contact toxicity (LD_{50} µg a.s./bee)
a.s. ‡	> 100	/*
S-2188 50WG	60	> 100
Field or semi-field tests		

Test substance	Acute oral toxicity (LD_{50} µg a.s./bee)	Acute contact toxicity (LD_{50} µg a.s./bee)
not required		

* the acute contact trial was considered not valid due to high control mortality

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

EU specific risk assessment

Grapevine and vegetables (glasshouse), 1 x 0.6 kg a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	/	50
a.s.	oral	< 6	50
S-2188 50WG	Contact	< 6	50
S-2188 50WG	oral	10	50

Effects on other arthropod species (Annex IIA, point 8.8, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g a.s./ha)
Typhlodromus pyri ‡	S-2188 50WG	Mortality	> 1200
Aphidius rhopalosiphi ‡	S-2188 50WG	Mortality	> 1200

Grapevine, 1 x 0.6 kg a.s./ha

Test substance	Species	Effect (LR_{50} g a.s./ha)	HQ in-field	HQ off-field	Trigger
S-2188 50WG	*Typhlodromus pyri*	> 1200	< 0.5	< 0.01 / 0.04*	2
S-2188 50WG	*Aphidius rhopalosiphi*	> 1200	< 0.5	< 0.01 / 0.04*	2

* early / late application, drift at 1 m distance to crop

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
Not required						

Field or semi-field tests
Not required

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.9, 8.14 and 8.10. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point [1]
Earthworms			
Eisenia fetida	a.s.	Acute, 14 days	LC_{50} > 800 mg a.s./kg d.w. soil $LC_{50\ corr.}$ > 400 mg a.s./kg d.w. soil
Eisenia fetida	a.s.	Chronic, 56 days	NOEC = 9.6 mg a.s./kg d.w. soil $NOEC_{corr.}$ = 4.8 mg a.s./kg d.w. soil
Other soil macro-organisms			
Not required			
Soil micro-organisms			
Nitrogen mineralisation	a.s.	28 days	- 10% effect at day 28 at 0.8 mg a.s./kg d.w. soil (600 mg a.s/ha) - 12% effect at day 28 at 4.0 mg a.s./kg d.w. soil (3000 mg a.s./ha)
Carbon mineralisation	a.s.	28 days	+ 5% effect at day 28 at 0.8 mg a.s./kg d.w. soil (600 mg a.s/ha) + 5% effect at day 28 at 4.0 mg a.s./kg d.w. soil (3000 mg a.s./ha)
Field studies [2]			
Not required			

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

Toxicity/exposure ratios for soil organisms

EU specific risk assessment

Grapevine, 1 x 0.6 kg a.s./ha

Test organism	Test substance	Time scale	Soil PEC [2]	TER	Trigger
Earthworms					
Eisenia fetida	a.s.	Acute	0.12 mg/kg d.w. soil	> 3333	10
Eisenia fetida	a.s.	Chronic	0.12 mg/kg d.w. soil	40	5
Other soil macro-organisms					
not required					

[1] to be completed where first Tier triggers are breached
[2] indicate which PEC soil was used (e.g. plateau PEC)

Tomato, 3 x 0.6 kg a.s./ha, interval 10 – 14 days, indoor use

Test organism	Test substance	Time scale	Soil PEC [2]	TER	Trigger
Earthworms					
Eisenia fetida	a.s.	Acute	0.249 mg/kg d.w. soil	> 1606	10
Eisenia fetida	a.s.	Chronic	0.249 mg/kg d.w. soil	19.3	5

Test organism	Test substance	Time scale	Soil PEC [2]	TER	Trigger
Other soil macro-organisms					
not required					

[1] to be completed where first Tier triggers are breached
[2] indicate which PEC soil was used (e.g. plateau PEC)

Effects on non target plants (Annex IIA, point 8.12, Annex IIIA, point 10.8)

Preliminary screening data

Single species screening tests on rice, Japanese radish and kidney beans did not reveal adverse effects

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g a.s./ha) vegetative vigour	ER_{50} (g a.s./ha) emergence	Exposure[1] (g a.s./ha)	TER (early / late application)	Trigger
6 species	S-2188 50WG	> 600	> 600	16 / 48	> 37 / > 12	5

[1] drift rates at 3 m distance to field edge for early / late application (based on Ganzelmeier drift data)

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

Not required

Effects on biological methods for sewage treatment (Annex IIA 8.15)

Test type/organism	end point
Activated sludge	3 hour EC_{50} > 1000 mg a.s./L
Pseudomonas sp.	not required

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

Compartment	
soil	Fenpyrazamine
water	Fenpyrazamine, S-2188-DC, S-2188-OH, MCNI
sediment	Fenpyrazamine
groundwater	Fenpyrazamine

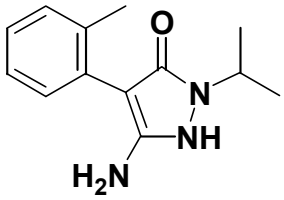
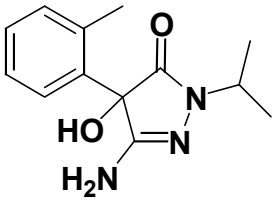
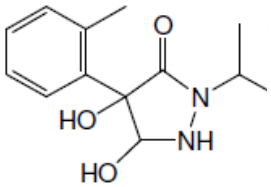
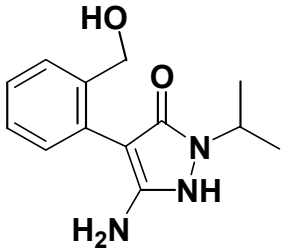
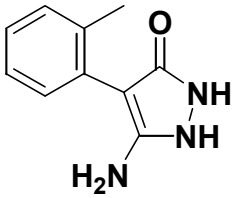
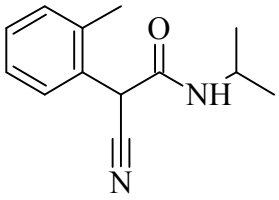
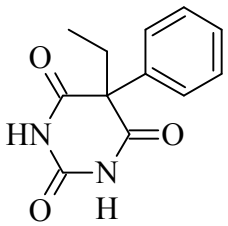
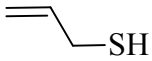
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 9 and Annex IIIA, point 11.3)

	peer review proposal
Active substance	N, R51/R53

peer review proposal

Preparation	N, R51/R53

APPENDIX B – USED COMPOUND CODES

Code/Trivial name	Chemical name	Structural formula
S-2188-DC	5-amino-1,2-dihydro-2-isopropyl-4-(o-tolyl)pyrazol-3-one	
S-2188-OH	5-amino-2,4-dihydro-4-hydroxy-2-isopropyl-4-(o-tolyl)pyrazol-3-one	
S-2188-$(OH)_2$	4,5-dihydroxy-4-(2-methylphenyl)-2-(propan-2-yl)pyrazolidin-3-one	
S-2188-CH_2OH-DC	5-amino-1,2-dihydro-4-(2-hydroxymethylphenyl)-2-isopropyl-pyrazol-3-one	
MPPZ	5-amino-1,2-dihydro-4-(o-tolyl) pyrazol-3-one	
MCNI	2-cyano-2-(2-methylphenyl)-N-(propan-2-yl)acetamide	
Phenobarbital	5-ethyl-5-phenylpyrimidine-2,4,6(1H,3H,5H)-trione	
Allyl mercaptan	prop-2-ene-1-thiol	

ABBREVIATIONS

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

g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram

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