CONCLUSION ON PESTICIDE PEER REVIEW

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

Issued on 25 September 2008

SUMMARY

Penconazole is one of the 84 substances of the third stage Part B of the review programme covered by Commission Regulation (EC) No 1490/2002[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU-Commission a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within six months a conclusion on the risk assessment to the EU-Commission.

Germany being the designated rapporteur Member State submitted the DAR on penconazole in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 19 June 2007. Following a quality check on the DAR, the peer review was initiated on 1 October 2007 by dispatching the DAR for consultation of the Member States and the sole applicant Syngenta. Subsequently, the comments received on the DAR were examined and responded by the rapporteur Member State in the reporting table. This table was evaluated by EFSA to identify the remaining issues. The identified issues as well as further information made available by the applicant upon request were evaluated in a series of scientific meetings with Member State experts in May-June 2008.

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

This conclusion was reached on the basis of the evaluation of the representative uses as a fungicide on cucurbits and grapes. Full details of the GAP can be found in the attached list of endpoints.
The representative formulated product for the evaluation was "Topas 10 EC", an emulsifiable concentrate (EC).

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

Adequate methods are available to monitor all compounds given in the respective residue definition. Residues of penconazole in food of plant origin can be determined with a multi-method (The German S19 method has been validated). For the other matrices only single methods are available to determine residues of penconazole. A data gap was identified for a confirmatory method for surface water. It is noted that the residue definition for soil and water is provisional.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible. It is noted however, that further validation data are required for the impurity method and that there is no supported technical specification.

The toxicological studies on the metabolism of penconazole have shown an extensive oral absorption, a wide distribution in the body and an excretion mainly via urine. According to the results of acute oral toxicity testing, the agreed classification was **Xn, R22 Harmful if swallowed**. The main target organ in short term toxicity studies was the liver, and the dog was the most sensitive species. No genotoxic potential was observed during *in vitro* or *in vivo* tests, and no carcinogenicity was observed in rats or mice after long term exposure. In the reproductive toxicity studies, an increased incidence of dystocia was considered as an effect already observed with other triazoles, and to be forwarded to EChA for a decision upon classification (R62?- "Possible risk of impaired fertility"). Developmental effects were observed in the teratogenicity studies, and the classification **Reprotoxic Category 3 R63 Possible risk of harm to the unborn child** was proposed by the experts. Several plant metabolites were considered to be of the same or lower toxicity than penconazole. The Acceptable Daily Intake (ADI) and the Acceptable Operator Exposure Level (AOEL) were both 0.03 mg/kg bw/day based on the combined 90-day/1- year dog study. The Acute Reference Dose (ARfD) was 0.5 mg/kg bw based on early bodyweight changes in the rabbit developmental study. These reference values were all derived with the use of a safety factor of 100. The dermal absorption values were 5% for the dilution and 1% for the concentrate. The exposure estimates in different scenarios (field or greenhouse use) were all below the AOEL even without the use of personal protective equipment.

The metabolism of penconazole was tested in grapes, tomatoes and apples where triazole and phenyl labelled compound was applied. The meeting of experts considered that the grape data were not acceptable and they were not considered further. The apple and tomato data were acceptable and showed the same metabolic profile. The main metabolism route is oxidation at the 1, 2 and 3 positions on the alkyl chain. The triazole moiety metabolites are an issue for all the triazole fungicides and will be dealt with in a separate exercise. For completeness, a general data gap was identified for this issue which has been used in other triazole conclusions. No phenyl-ring-only metabolites were seen. The significant residues at harvest consisted of CGA 132465[2],

[2] CGA 132465: 4-(2,4-Dichloro-phenyl)-5-[1,2,4]triazol-1-yl-pentan-2-ol

CGA 190503[3], CGA 127841[4] and their glucoside conjugates as well as penconazole. It was agreed that the provisional residue definition for risk assessment (fruit crops only) should be penconazole and free and conjugated CGA 132465, CGA 190503 and CGA 127841 expressed as penconazole. The residue definition for monitoring is penconazole with a conversion factor of 6 between monitoring and risk assessment residue definitions.

The residue trial data set was complete for grapes but a data gap for outdoor cucurbits in the North of Europe was identified. The stability of residues was demonstrated in freezer storage for a period of 16 months. Appropriate processing data are available.

Two rotational crop metabolism studies conducted at exaggerated rates showed that no significant residue would be expected in rotational crops. No livestock metabolism studies were supplied or required, as according to current guidance the representative crops under consideration are not fed to animals.

The chronic risk assessment showed a maximum intake of 2.9 % of the ADI for the French diet using the EFSA model. For the acute risk the highest intake was 13 % of the ARfD from the consumption of table grapes for the German diet using the EFSA model. The proposed MRLs are 0.2 mg/kg for grapes and 0.1 mg/kg for cucurbits.

In soil under aerobic conditions penconazole exhibits moderate to high persistence forming the major soil metabolites CGA 179944[5] (accounting for up to 18.9% of applied radioactivity (AR)) which exhibits low to moderate persistence and CGA 71019[6] (accounting for up to 38.6% of AR) which also exhibited low persistence. Mineralisation of both the phenyl and triazole rings to carbon dioxide accounted for 65 and 27 % of AR respectively after 546 and 364 days. The formation of unextractable residues accounted for 22 and 47 % of AR respectively after 364 and 336 days. A data gap was identified for the identification/characterisation of the unknown radioactivity U1 found in the aerobic soil degradation up to 17.3% of the applied radioactivity.

Penconazole is strongly adsorbed to soils and is unlikely to leach in soil. Column leaching studies have confirmed this, demonstrating that the parent compound is only recovered from the upper layers of the columns. Metabolite CGA 179944 exhibits very high mobility in soil and CGA 71019 exhibits very high to medium mobility in soil. There was no indication that adsorption of penconazole or that of its soil metabolites was pH dependent.

Penconazole does not degrade significantly via either hydrolysis or photolysis. The metabolites CGA 179944 and CGA 71019 were shown to be stable to hydrolysis under environmentally relevant conditions. The fate of penconazole in the aquatic environment therefore, will be principally determined by adsorption to the sediments and slow degradation therein. The terminal metabolite, carbon dioxide was a small sink in the material balance accounting for a maximum of 4.6-8.4% of

[3] CGA 190503: 2-(2,4-Dichloro-phenyl)-1-[1,2,4]triazol-1-yl-pentan-3-ol
[4] CGA 127841: 4-(2,4-Dichloro-phenyl)-5-[1,2,4]triazol-1-yl-pentan-1-ol
[5] CGA 179944 = 2-(2,4-dichloro-phenyl)-3-[1,2,4]triazol-1-yl-propionic acid
[6] CGA 71019 = 1*H*-1,2,4-triazole

AR at 678-706 days (study end). Unextracted sediment residues were also a sink representing 18-19 % of AR at study end. The necessary surface water and sediment exposure assessments were appropriately carried out using the agreed FOCUS scenarios approach for penconazole and metabolites CGA 179944 and CGA 71019 at steps 1-2. Additional FOCUSsw calculations for penconazole confirmed that the maximum Step 3 PECs are 85% (water) and 70% (sediment) lower than the Step 2 derived values.
The potential for groundwater exposure from the applied for intended uses by penconazole, CGA 71019 and CGA 179944 above the parametric drinking water limit of 0.1 µg/L, was concluded to be low for the intended uses covering only neutral and alkaline soil conditions. In addition, an assessment of the potential for groundwater exposure from the applied for intended uses on vines with highest rates and numbers of applications for some FOCUS scenarios is not available. For unknown U1, a data gap was identified for a groundwater exposure assessment. A second modelling with FOCUS PEARL model is also necessary.
It was concluded that penconazole is unlikely to be subject to long range atmospheric transport as a consequence of its likely indirect photooxidation intermediated transformation (half life estimated at 15.9 hours).

The representative uses of penconazole are applications to cucurbits and grapes. The first tier risk assessment indicated that a low risk is expected to birds and mammals. TERs for earthworm eating-birds and mammals meet the Annex VI trigger value of 5. The risk to birds and mammals from intake of contaminated drinking water from surface water or puddles was considered to be low.

The meeting agreed with the use of the toxicity data for the triazole metabolites from the report from PRAPeR 13 for the ecotoxicology and from the report from PRAPeR 14 for the mammalian endpoint.

The penconazole avian and mammalian databases were reviewed for effects indicative of potential endocrine activity. There are no relevant mediated effects below the threshold established by the current endpoints for the mammals. The expert meeting PRAPeR 48 agrees that some uncertainties remain on potential delayed reproductive effects on birds since these effects are not covered on the basis of the currently stated data requirements of Council Directive 91/414/EEC. More information should be requested at MS level.
Based on the information available penconazole is proposed to be classified as very toxic to aquatic organisms.
The first tier risk assessment indicated a low long term risk to fish and also a low acute risk to aquatic invertebrates, algae and sediment dwelling organisms. However, tier I risk assessment also indicated that there is a high acute risk to fish and a high long term risk to aquatic invertebrates and aquatic plants. The Annex VI triggers for acute and long term risk are met with the PECsw from FOCUS Step 2. The higher tier risk assessment indicated a low risk for all aquatic organisms, except for the

long term risk to aquatic invertebrates. However, with FOCUS Step 3 PECsw the TER value was above the Annex VI trigger values. The applicant and the RMS proposed that an appropriate FSDT study was required to address the potential endocrine-mediated effect in DMI fungicides since the FSDT will cover the sensitive time windows with respect to effect triggering and effect manifestation. The member state experts agreed with this proposal and also noted that member states should have the opportunity to ask for an appropriate test to address the endocrine effects.

The BCF of 320 was derived from a study with bluegill sunfish (*Lepomis machrochirus).*

The first tier risk assessment for metabolites indicated a low acute and long term risk to aquatic organisms for both metabolites CGA 71019 and CGA 179944.

Penconazole is of low toxicity to bees. Hazard Quotients (HQ) for oral and contact exposure were determined to be below the trigger values indicating a low risk for bees.

The risk to non-target arthropods was assessed as high for the in-field areas, however a potential for recolonisation from the off field areas had been demonstrated.

The acute and chronic TER values for penconazole and for both metabolites CGA 71019 and CGA 179944 were above the Annex VI trigger values indicating that the risk to earthworms is low.

Penconazole and the metabolite CGA 71019 were tested with *Folsomia candida,* and the active substance was tested for effects in a litter bag study. In conclusion, the risk of penconazole and the metabolite CGA 71019 to other non-target macro-organisms was considered to be low.

The results of the assessment of "Topas 10 EC" as well as the soil metabolites CGA 71019 and CGA 179944 indicate no adverse impact on soil non target organisms.

In a preliminary screening test "Topas 10 EC" had only a slight effect (< 50 % effect) on seedling emergence and vegetative vigour in 3 monocotyledons and 3 dicotyledons at rates up to 30 g a.s./ha. EFSA notes that the dose used in the screening test, 30 g a.s./ha, has not covered the higher proposed intended uses of 50 g a.s./ha.

No inhibitory effects of penconazole to respiration rates of activated sludge were observed up to 100 mg /L.

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

TABLE OF CONTENTS

BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000, as amended by Commission Regulation (EC) No 1095/2007, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Penconazole is one of the 84 substances of the third stage, part B, covered by the Regulation (EC) No 1490/2002 designating Germany as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Germany submitted the report of its initial evaluation of the dossier on penconazole, hereafter referred to as the draft assessment report, received by EFSA on 19 June 2007. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 11(2) of the Regulation (EC) No 1095/2007 the revised version of the draft assessment report was distributed for consultation on 1 October 2007 to the Member States and the main applicant Syngenta as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, EFSA identified and agreed on lacking information to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the requested information received from the notifier, a scientific discussion took place in expert meetings in May-June 2008. The reports of these meetings have been made available to the Member States electronically.

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

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

In accordance with Article 11c(1) of the amended Regulation (EC) No 1490/2002, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant endpoints for the active substance as well as the formulation is provided in appendix 1.

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

- the comments received,
- the resulting reporting table (revision 1-1, 29 February 2008)

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

- the reports of the scientific expert consultation,
- the evaluation table (revision 2-1, 17 September 2008).

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

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Penconazole is the ISO common name for (*RS*) 1-[2-(2,4-dichlorophenyl)pentyl]-1*H*-1,2,4-triazole (IUPAC).

Penconazole is a conazole fungicide; examples of other members of this class are fenbuconazole and myclobutanil. It causes inhibition of C-14-demethylase in sterol biosynthesis. It is a preventative and curative fungicide.

The representative formulated product for the evaluation was "Topas 10 EC", an emulsifiable concentrate (EC).

The evaluated representative uses are as a fungicide on cucurbits and grapes. Full details of the GAP can be found in the attached list of endpoints.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The specification for this active substance was not agreed by the section 1 meeting of experts. The original specification given in the DAR was based on 5-batch data from a full scale production source and 5-batch data from a pilot plant source. A revised technical specification was evaluated in addendum 2 Vol. 4 and was considered by the meeting of experts. This specification was also rejected by the meeting of experts. However the meeting of experts section 2 mammalian toxicology accepted this specification. It is noted that new full scale production 5-batch analyses are now available, however, in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies

after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No 1095/2007, the new studies could not be considered in the peer review.
At the moment no FAO specification exists. No relevant impurities were identified in the considered data.

Beside the specification, the assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of penconazole or the respective formulation. However, the following data gap was identified:

- Repeatability data for the impurity methods

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of penconazole in the technical material and in the representative formulation. The method for the impurities in the technical material needs further validation.
Therefore, enough data are available to ensure that quality control measurements of the plant protection product are possible.

Adequate methods are available to monitor all compounds given in the respective residue definition, i.e. penconazole; (wet, dry and oily food and feed matrices) and penconazole in soil, water and air. It is noted that the residue definition for soil and water is provisional.

Residues of penconazole in food of plant origin can be determined with a multi-method (The German S19 method has been validated). The LOQ is 0.01 mg/kg. The confirmatory method is LC/LC-MS/MS also with an LOQ of 0.01 mg/kg. For soil the primary method is LC-MS/MS with an LOQ of 0.01 mg/kg. Another method is also available: GC-NPD with an LOQ of 0.04 mg/kg. For surface and drinking/ground water a GC-MS method is available with an LOQ of 0.05 µg/L. The confirmatory method for drinking/ground water is GC-ECD with an LOQ of 0.1 µg/L; a data gap is identified for a confirmatory method for surface water. Air can be analysed by either GC-NPD or GC-MS with LOQs of 1 and 2 µg/m^3 respectively.

A method for products of animal origin is not required as MRLs will not be set (see section 3). Methods for body fluids and tissues are not required since penconazole is neither toxic nor very toxic.

2. Mammalian toxicology

Penconazole was discussed by the experts in mammalian toxicology in June 2008 (PRAPeR meeting 49, round 10, subgroup 2).

Based on the information provided in the addendum to Volume 4 (April 2008), the experts agreed that the toxicological batches were sufficiently representative of the technical specification. None of the impurities were considered as toxicologically relevant. However, it should be noted that the technical specification was not agreed by section 1.

Considering the composition of the toxicological batches as mentioned in Volume 4, the sum of the impurities and of the active substance was up to 911 g/kg. The part missing was explained by an impurity in the toxicological batches that no longer occurs in the current technical material.

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

Extensively absorbed from the gastro-intestinal tract (>80% based on urinary and biliary excretion within 48h), penconazole is widely distributed without bioaccumulation in body tissues. The urinary excretion is higher in females (70-85% via urine, 15-30% via faeces) than in males (45-60% via urine, 40-50% via faeces), and the biliary excretion is higher in males (55% vs 40% in females).

Penconazole is extensively metabolised, showing quantitative differences between males and females in metabolic pathways but a similar range of metabolites. The identified biotransformation reactions include cleavage of the carbon-nitrogen bond leading to the formation of 1,2,4-triazole, oxidations and conjugations.

2.2. Acute toxicity

Several species were used to determine the acute oral toxicity of penconazole (rat, hamster, rabbit and mouse). On one hand, the results in male rats and in rabbits ($200 < LD_{50} < 2000$ mg/kg bw) triggered the proposed classification **Xn, R22 Harmful if swallowed**. On the other hand, no mortality occurred after dermal exposure or exposure by inhalation in rats. Additionally it was not irritating to the eyes or the skin and did not induce skin sensitisation in guinea pigs (maximisation test).

2.3. Short term toxicity

The toxicological properties of penconazole upon short term oral treatment were investigated in the rat, the mouse and the dog, whereas the effects of repeated dermal application were evaluated in the rabbit. The liver was the main target organ following oral administration in all species investigated, with increased weight accompanied by histopathological alterations and clinical chemistry changes.

The **dog** was the most sensitive species with a NOAEL of 3 mg/kg bw/day based on reduced bodyweight gain and hepatotoxicity in the combined 90-d/1-yr study. In the **rat** studies (two 28-day studies by gavage, and three 90-day dietary studies), the overall NOAEL was 25 mg/kg bw/day based on decreased bodyweight gain and liver toxicity. Finally, the **mouse** was the less sensitive species

since the lowest NOAEL was 52 mg/kg bw/day based on hepatotoxicity in males in two 90-day studies.

In the 21-day **rabbit** dermal study, no sign of systemic toxicity was observed up to and including 2000 mg/kg bw/day becoming consequently the NOAEL.

2.4. GENOTOXICITY

Penconazole was negative in all mutagenicity tests performed. Tested *in vitro*, it induced neither gene mutations in bacterial or mammalian cells (Chinese hamster), nor chromosome aberrations in CHO cells, nor unscheduled DNA synthesis in rat hepatocytes. Furthermore a bone marrow micronucleus test revealed no evidence for clastogenic or aneugenic activity *in vivo*. It was concluded that penconazole had no genotoxic potential.

2.5. LONG TERM TOXICITY

The long term toxicity and carcinogenicity of penconazole have been investigated in rats (one 2-year study) and in mice (one 2-year and one 80-week studies).

In **rats** no relevant adverse health effect was observed because the dose levels chosen were too low. Only a slight increase in liver weight occurred, without any biochemical or histopathological correlate. Therefore the NOAEL for the rat was the highest dose tested, i.e. 15 mg/kg bw/day.

In **mice** significant hepatotoxic effects and bodyweight reductions were observed in the second study, whereas only minor changes without any macroscopic or microscopic pathology were observed in the first study. Following a comment during the peer-review, the overall NOAEL for the mouse was agreed to be 36 mg/kg bw/day considering the dose-spacing between both studies.

Taking into account a summary table on tumour incidences in the rat study (Addendum 1, April 2008), the negative genotoxicity package, the lack of any clear target organ toxicity which could lead to tumours in rats, and the negative results in the mouse studies, the experts agreed that penconazole had no carcinogenic potential and did not need to be tested at higher doses in rats.

2.6. REPRODUCTIVE TOXICITY

The adverse effects on the reproductive system were investigated in two multigeneration studies in rats and in four teratogenicity studies in rats and rabbits.

In the **first 2-generation study**, prolonged gestation and increased mortality of dams during parturition were observed at the high dose; whereas in the **second 2-generation study**, the overall mating index was slightly decreased for the first generation and the number of dams with a higher stillbirth rate was slightly increased. At the same dose level, maternal toxicity consisted of reduced bodyweight gain and liver effects while the toxicity for the offspring was manifested by a decreased growth during lactation. Taking into account that similar effects of dystocia (observed in the first study) could also be seen with other triazoles, the experts agreed that classification (**R62? Possible**

risk of impaired fertility) should be considered by EChA. The agreed NOAEL for the reproductive parameters, for the parents and for the offspring was 30 mg/kg bw/day.

In the **rat teratogenicity** studies, the maternal toxicity consisted in decreased food consumption and bodyweight gain as well as clinical signs and mortalities. The embryo-foetal toxicity included prenatal lethality, slight delay in growth and in skeletal development, and slight increase in the occurrence of cervical ribs at 300 mg/kg bw/day. The resulting maternal and developmental NOAEL was 100 mg/kg bw/day.
In the **rabbit teratogenicity** studies, the adverse effects in dams included clinical signs and reduced bodyweight gain at the high dose level resulting in an overall maternal NOAEL of 50 mg/kg bw/day. The premature parturition observed in all treated groups in the second study was not dose-related, not observed in the other developmental studies, and not accompanied by adverse effects on the foetuses. Therefore it was not considered as a relevant adverse effect. In the high dosed foetuses of the first rabbit study, an increased incidence of microphtalmia was observed, whereas in the second study no teratogenic effects were observed. The agreed developmental NOAEL was 50 mg/kg bw/day.
Looking at the overall picture of the foetal findings in the four developmental studies, the experts agreed that penconazole could produce developmental effects at high dose levels (e.g. cervical ribs in rats and microphthalmia in rabbits), and they proposed classification **Reprotoxic Category 3 R63 Possible risk of harm to the unborn child** to be confirmed by EChA.

2.7. NEUROTOXICITY

The available information on penconazole does not give any indication of neurotoxicity. Furthermore penconazole does not belong to a chemical class which is suspected to cause delayed neurotoxic effects, such as organophosphates or carbamates.

2.8. FURTHER STUDIES

2.8.1. Metabolites

During the PRAPeR 14 expert meeting on mammalian toxicology in January 2007, reference values were agreed for some triazole derivative metabolites based on a compilation of available data coming from different draft assessment reports. The agreed values were

- for 1,2,4- triazole:	ADI 0.02 mg/kg bw/d, based on the rat multigeneration study ARfD 0.06 mg/kg bw/d, based on the rat developmental study
- for triazolyl acetic acid:	the ADI and ARfD of 1,2,4-triazole were chosen due to the limited database available
- for triazolyl alanin:	ADI and ARfD 0.1 mg/kg bw/d, based on the rat developmental study

For penconazole, another triazole metabolite had to be considered: **triazolyl lactic acid** (or CGA 205369[7]). Considering the chemical structure and some information on the residue levels, the experts agreed that it had to be considered as a toxicologically relevant metabolite, but that it was not more toxic than penconazole and that the reference values of penconazole should be used in the absence of reproductive and developmental toxicity results (which seem to be the critical endpoint for triazole compounds). New toxicological data have been mentioned in the evaluation table, however, in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No 1095/2007, the new studies could not be considered in the peer review.
EFSA notes: It should be noted that this approach is not in line with what was agreed in January 2007 for triazole acetic acid (which is structurally closely related to triazole lactic acid).

Additional metabolites were assessed for their toxicological relevance.
CGA 127841[8] was also a major rat metabolite, and was considered as covered by the studies performed with penconazole. **CGA 132465**[9] and **CGA 190503**[10] were considered likely to be of the same or lower toxicity than penconazole, based on their structural similarity with the parent compound and some rat metabolites. A QSAR analysis with these two metabolites revealed the same structural alert for carcinogenicity as the parent compound, which showed no carcinogenic potential. Furthermore, CGA 132465 is also a minor rat metabolite found in urine.

2.8.2. Supplementary studies with penconazole

A supplementary study on liver enzyme induction in rats and mice was described in the DAR. The results suggested that in both species liver enlargement was due to a combination of both hyperplasia and hypertrophy of the hepatocytes.

2.9. MEDICAL DATA

During medical surveillance on manufacturing site personnel, no adverse health effects associated with the synthesis or formulation of penconazole have been reported. No cases of poisoning have been reported to the company or mentioned in the open literature.

[7] CGA 205369: 2-hydroxy-3-[1,2,4]triazol-1-yl-propionic acid
[8] CGA 127841: 4-(2,4-Dichloro-phenyl)-5-[1,2,4]triazol-1-yl-pentan-1-ol
[9] CGA 132465: 4-(2,4-Dichloro-phenyl)-5-[1,2,4]triazol-1-yl-pentan-2-ol
[10] CGA 190503: 2-(2,4-Dichloro-phenyl)-1-[1,2,4]triazol-1-yl-pentan-3-ol

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

The agreed **ADI** for penconazole was **0.03 mg/kg bw/day**, based on the combined 90-day/1-year dog study and using a safety factor of 100.

The agreed **AOEL** for penconazole was **0.03 mg/kg bw/day**, based on the combined 90-day/1-year dog study and using a safety factor of 100.

Initially in the DAR, the setting of an ARfD was not considered necessary. Nevertheless, based on effects on bodyweight occurring during the first days in the rabbit developmental study, the experts agreed to derive an **ARfD** of **0.5 mg/kg bw,** applying a safety factor of 100.

2.11. DERMAL ABSORPTION

Results of an *in vivo* study in rats and an *in vitro* study with rat and human epidermis were presented in the DAR. The tests were not performed with the representative formulation "Topas 10 EC" but with a similar formulation "Topas 100 EC" and were considered acceptable.

The agreed dermal absorption values through human skin *in vivo* were 5% for the dilution and 1% for the concentrate (as proposed in the DAR).

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product "Topas 10 EC" is an emulsifiable concentrate containing 100 g penconazole/L for use as fungicide in cucurbits (fields and glasshouses) and grapes (fields).

Operator exposure

According to the intended uses submitted by the applicant the maximum applied dose is 40 g a.s./ha for grapes and 50 g a.s./ha for cucurbits, with a minimum volume of 200 L/ha for grapes and 1000 L/ha for cucurbits. The exposure estimates according to the different scenarios are presented in the following table.

Estimated exposure presented as % of AOEL (0.03 mg/kg bw/day), according to calculations with the German and UK POEM model. The default for bodyweight of operator is 70 kg in the German model and 60 kg in the UK-POEM model.

Model	No PPE	With PPE[11]	With PPE[12]	With PPE[13]
Use in cucurbits: tractor boom sprayer				
German	6.1	4.9	n.a.	0.4
UK POEM	19.8	7.3	2.5	n.a.
Use in grapes: tractor mounted airblast sprayer				
German	9.4	9.0	n.a.	1.6
UK POEM	45.9	42.9	27.9	n.a.
Use in cucurbits: knapsack sprayer in greenhouse				
Mich study (1996)[14]	19.6	n.a.	n.a.	0.8
Use in cucurbits: spray lance with stationary tank in greenhouse				
Mich study (1996)	13.9	n.a.	n.a.	0.6

n.a. = not applicable.

According to the models applied, the exposure estimates are all below the AOEL for penconazole irrespective of the use or non-use of personal protective equipment.

Worker exposure

Workers may enter field cultivations of cucumbers and grapes after treatment to perform tasks such as crop inspections, pruning or harvesting. A conservative estimate of worker exposure has been provided with the generic re-entry exposure model by Krebs[15], resulting in 33.3% of the AOEL without personal protective equipment and 1.7% with the use of personal protective equipment.

EFSA notes: It is not expected that the worker exposure during **re-entry activities in greenhouses** will exceed the very conservative estimate obtained for the re-entry in field cultivations.

[11] PPE (personal protective equipment): gloves during mixing and loading
[12] PPE: gloves during mixing/loading and application
[13] PPE: gloves, standard protective garment and sturdy footwear during mixing/loading and application
[14] Mich, G. (1996): Operator Exposure in Greenhouses During Practical Use of Plant Protection Products; Project EF 94-02-03; June 6, 1996; ECON GmbH Ingelheim, conducted in Germany under the sponsorship of IVA.
[15] Krebs B, Maasfeld W, Schrader J, Wolf R, Hoernicke E, Nolting HG, Backhaus GF, Westphal D. Uniform Principles for Safeguarding the Health of Worker Re-entering Crop Growing Areas after Application of Plant Protection Products. Bulletin of the German Plant Protection Service, 2000, 52(1) 5-9.

Bystander exposure

Combining data from Ganzelmeier[16], US EPA[17] and Lloyd & Bell[18], the estimated bystander exposure during field applications (cucurbits or grapes) is below 1% of the AOEL.

EFSA notes: More recent measurements of Lloyd & Bell[19] can also be used and give an estimate of 2% of the AOEL.

3. Residues

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

Plant-uptake, distribution and metabolism of penconazole has been investigated in grapes, apples and tomatoes using the ^{14}C-triazole radiolabel and in the case of tomatoes and grapes also the ^{14}C-phenyl label. The meeting of experts PRAPeR 50 June 2008 considered that the grape studies were not acceptable due to various deficiencies. Therefore the grape studies will not be considered further.

The investigations showed that the nature of the residues was essentially the same in tomatoes and apples. The biotransformation of penconazole results from the oxidation of penconazole at the 1, 2 and 3 positions of the alkyl chain and subsequent conjugation to the o-glucosides. Label specific metabolites from the ^{14}C-triazole treatments resulted from the cleavage of the triazole moiety. No label specific metabolites to the phenyl part of the compound were identified.

The triazole moiety metabolites are an issue for all the triazole fungicides and will be dealt with in a separate exercise. For completeness, a general data gap was identified for this issue, which has been included in other triazole conclusions.

The hydroxylated metabolites, namely CGA 132465, CGA 190503 and CGA 127841, both free and as sugar conjugates were detected in both the tomato and apple studies and they are structurally very similar to penconazole. The meeting of experts of mammalian toxicology (PRAPeR 49; June 2008) were asked to consider the toxicity of these metabolites. The toxicology meeting reported that CGA 127841 was a major rat metabolite (20-40% of the TRR depending on the study); the other two metabolites CGA 132465 and CGA 190503 were not rat metabolites but were similar to rat

[16] Ganzelmeier H, Rautmann D, Spangenberg R, Streloke M, Herrmann M, Wenzelburger H-J, Walter HF Studies on the spray drift of plant protection products. Mitteilungen aus der Biologischen Bundensanstalt für Land- und Forstwirtschaft Berlin-Dahlem. Heft 305, 1995. Updated: BBA (2000:1).
[17] US Environmental Protection Agency
[18] Lloyd GA, Bell GJ (1983). Hydraulic nozzles: Comparative spray drift study. AHU report n°122.
[19] Lloyd GA, Bell GJ, Samuels SW, Cross JV, Berrie AM (1987). Orchard sprayers: comparative operator exposure and spray drift study. MAFF

metabolites and of course to penconazole and therefore they would have similar or lower toxicity compared to penconazole.

The report of the residue meeting of experts states that the residue definition for risk assessment should be penconazole, CGA 132465, CGA 190503 and CGA 127841 expressed as penconazole. EFSA believes that the meeting agreed upon "penconazole, and free and conjugated CGA 132465, CGA 190503 and CGA 127841 expressed as penconazole". The reason for this is that the conjugates are a major portion of the residue and it would make no sense not to include them. This residue definition is for fruiting crops only and must remain provisional because of the triazole metabolite issue.

For monitoring purposes the residue definition was agreed to be penconazole. A conversion factor of 6 (which will cover the conjugates as mentioned above) was also agreed on the basis of the metabolism data and on residue trial samples in a processing study, where penconazole was analysed, as well as on analysis with a total method for metabolites containing the dichlorbenzoic acid moiety. This will be a worst case conversion factor as other metabolites that are not in the residue definition will have been measured by this method.

The meeting of experts (residues and mammalian toxicology) considered that penconazole is made up of one pair of enantiomers (racemic mixture) and that the ADI/ARfD is set on this mixture. In the metabolism studies there was no investigation of the individual enantiomers so it is not known if the ratio is maintained in the plant. It was considered that if all the toxicity was coming from one enantiomer the risk assessment would only be affected by a factor of 2, which, for the representative uses, would not result in a significant change to the risk assessment.
The residue trials database for the grape use is complete with 8 trials in the north and south of Europe; in general there were higher residues in the southern trials with a HR of 0.17 mg/kg. For cucurbits with edible peel the data set was complete for the glasshouse use and the southern outdoor use with a HR of 0.03 mg/kg from the glasshouse trials. No trials were available for the outdoor use in the north of Europe and a data gap was identified. The same situation also applies for cucurbits with inedible peel where again the HR comes from the glasshouse treatment and there is a data gap identified for the outdoor use in the north of Europe.

In a freezer storage stability study it was shown that residues of penconazole are stable for a period of 16 months in both apples and grapes. The meeting of experts discussed the fact that there were no procedural recoveries reported in the study. The meeting concluded however, that the study could be accepted because the sample recoveries were high and there was no indication of instability. The meeting questioned how long the samples were stored for in the residue trials. Post meeting the rapporteur confirmed that the samples were not stored for more than 11 months, which is well within the period covered by the stability study.

In a simulated processing study it was demonstrated that penconazole was stable under the conditions of the test so it is unlikely that breakdown products will be formed during industrial or home processing and given the similarity of the metabolites EFSA believes that they would also behave in this way.

The need for fate of the residue on processing was triggered by the residue levels in grapes. In total 9 residue trials were processed covering the commodities juice, wine and raisins. The meeting of experts noted that the majority of the studies were on white wine which may not be the worst case for transfer to wine. The meeting agreed that the data were sufficient to set a transfer factor from grapes to wine and grapes to raisins and that a full balance study is not necessary in this case. It is expected that the metabolite will behave in the same way.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

Two confined rotational crop metabolism studies conducted at exaggerated rates showed low residues of triazole metabolites. There were no other significant metabolites found. Penconazole was only found at low levels in the 30-day samples but at field rates it will not be at detectable levels. The issue of the triazole metabolites as mentioned above will not be dealt with in this conclusion, but a general data gap will be made for all the triazoles. It can therefore be concluded, with the possible exception of the triazole metabolites, that no significant residues will occur in rotational crops.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

No metabolism studies were supplied or required as according to current guidance the representative crops under consideration are not fed to animals.

3.3. CONSUMER RISK ASSESSMENT

The chronic risk assessment showed a maximum intake of 2.9 % of the ADI for the French diet using the EFSA model. For the acute risk, the highest intake was 13 % of the ARfD from the consumption of table grapes for the German diet using the EFSA model.

3.4. PROPOSED MRLS

0.2 mg/kg is proposed for grapes and 0.1 mg/kg for cucurbits. No MRLs are proposed for products of animal origin as there are no intakes from the representative crops.

4. Environmental fate and behaviour

Penconazole was discussed at the PRAPeR experts‟ meeting for environmental fate and behaviour in May 2008 (PRAPeR 47) on the basis of the DAR and addendum 1 of April 2008.

The fate and behaviour characteristics of the major metabolite 1,2,4-triazole (a metabolite with the potential to be formed by several triazole moiety containing active substances) was also discussed at the PRAPeR experts‟ meeting for environmental fate and behaviour PRAPeR 12 in January 2007. Therefore the endpoints for metabolite 1,2,4-triazole, as agreed in PRAPeR 12, are included in the current conclusions for penconazole.

4.1. FATE AND BEHAVIOUR IN SOIL

The fate and behaviour of penconazole in soil was investigated using both ^{14}C-triazole labelled and ^{14}C-phenyl labelled test substance.

4.1.1. ROUTE OF DEGRADATION IN SOIL

Aerobic laboratory soil degradation studies demonstrated that penconazole is degraded under non-sterile incubation conditions to several metabolites and non-extractable residues and progressively but slowly mineralised to carbon dioxide.

Soil experiments (6 different soils: pH from 7.0 to 7.5; organic carbon content from 1.4% to 5.8%; clay content from 5.3% to 14.9%) were carried out under different aerobic conditions in the laboratory (20°C 40% maximum water holding capacity (MWHC), 20°C and 30% or 60% MWHC or 25°C and 75% field capacity) in the dark. One soil was additionally tested at 10°C and different application rates. Results indicated that degradation proceeds principally via oxidation of the aliphatic side chain yielding **CGA 179944**[20] (max 18.9% of AR at 364 days). Bridge cleavage leads either directly or via the intermediate CGA 142856[21] (<5% of AR) to **CGA 71019**[22] (max 38.6% of AR at 188 days). Finally, the last metabolic steps generate carbon dioxide (max 26.9% of AR after 364 days) and non-extractable (bound) residues (max. 47% of AR after 336 days). The phenyl portion of the molecule is rapidly metabolised to form bound residues (max 21.6% of AR after 364 days) and ultimately carbon dioxide (max. 65.4% of AR after 546 days).

Organic matter fractionation demonstrated that about two thirds of the non-extractable residues were associated with the humic and fulvic acid fractions, whilst one third was still bound to the insoluble humic fraction even after excessive extraction.

A data gap was identified at the experts‟ meeting PRAPeR 47 on the identification/characterisation of the unknown radioactivity of 17.3% AR observed after 182 days in the soil degradation study by Knoch (1993) and designated as U1. The experts did not accept the argumentation provided by the

[20] CGA 179944 = 2-(2,4-dichloro-phenyl)-3-[1,2,4]triazol-1-yl-propionic acid.
[21] CGA 142856 = 1,2,4-triazol-1-yl-acetic acid
[22] CGA 71019 = 1*H*-1,2,4-triazole

applicant on the possible identity of U1 being metabolite CGA 142856 and therefore it was agreed that a complete (PECsoil, PECsw and PECgw) assessment should be performed for U1.
Degradation under anaerobic conditions is characterized by a continuous formation of CGA 142856, a moderate plateau of non-extractable residues (19.6% of AR after 120 days) and a negligible formation of carbon dioxide (1.7% of AR after 120 days). CGA 71019 was the most prominent metabolite found at peak level of 27.2% of AR at 13 days.
Photolytic degradation of penconazole was investigated in a silt loam soil with ^{14}C-phenyl labelled penconazole. Under the experimental conditions, penconazole was slowly broken down by light with a half-life of 259 days corresponding to 269 days and 271 days at latitude 30ºN and 40ºN, respectively.

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

The rate of degradation of penconazole was examined under laboratory conditions in the same studies described in section 4.1.1. Under aerobic laboratory conditions, i.e. at 10 – 25 ºC and 30-75 % FC (field capacity) or 40% MWHC (maximum water holding capacity) penconazole was degraded with single first order (SFO) DT_{50} ranging from 55.3 days to 488 days (6 soils). Details of the fittings and plots of the degradation curves and residuals for each study were provided in Addendum 1. After normalisation to FOCUS reference conditions[23] (20°C and -10kPa soil moisture content) this range of single first order DT_{50} is 55.3-207 days. The experts from member states agreed that the geometric mean that is appropriate for use in FOCUS modelling is 117 days.
Soil degradation rates of metabolite CGA 179944 were available from two laboratory studies where parent penconazole was applied as well as from separate laboratory tests with the metabolite in three different soils. Based on the five values the range of DT_{50} values was 7.3 to 25.4 days. To reduce uncertainty in the evaluation of kinetical behaviour of the metabolite CGA 179944, RMS decided to consider only the three studies with CGA 179944 applied as parent. The resulting geometric mean DT_{50} value of this metabolite after standardisation was 13.1 days. However, concerns were raised on the narrow pH range (7.3-7.5) of the soils used to investigate the rate of degradation of CGA 179944. In view of the chemical structure of this metabolite (triazole propionic acid) the experts of the meeting considered that it is likely that the investigation of the degradation rate of CGA 179944 in more acidic soils would result in longer DT_{50} values. It was agreed that it can not be excluded that a longer DT_{50} value for this metabolite would affect the groundwater assessment resulting in concentrations above 0.1 µg/L in the most vulnerable FOCUS scenarios (estimated PECgw with current DT_{50} value of 10.1 days are up to 0.06 µg/L for the Piacenza scenario for vine, calculated with FOCUS PELMO model). Therefore a data gap was identified for additional soil laboratory DT_{50} values derived from acidic soils for metabolite CGA 179944 to finalize the assessment. It was also

[23] Using section 2.4.2 of the generic guidance for FOCUS groundwater scenarios (version 1.1 dated April 2002) with a Q10 value of 2.2 and Walker equation coefficient of 0.7.

agreed that based on the results of the studies requested in the data gap, a new groundwater assessment for metabolite CGA 179944 might be necessary. Because of the low toxicity of this metabolite to soil and aquatic organisms, the experts concluded that even in case the new soil DT_{50} values will be longer than the actual DT_{50} values, recalculations of PECsoil and PECsw for CGA 179944 are not needed.

For metabolite CGA 71019 an aerobic soil degradation study in three biologically active soils was performed. In agreement with the LoEP compiled for 1,2,4-triazole during PRAPeR 12, the SFO DT_{50} values normalised to FOCUS reference conditions are in the range 5.0-9.9 days (geometric mean = 8.2 days).

Field dissipation studies were undertaken at various sites on bare ground plots located in Germany (4 sites) and France (1 site). The studies were evaluated in the DAR with additional information and a new kinetic analysis for the French dissipation study reported in the addendum 1. The half-life of the parent compound was determined using non-linear regression and a single first order fit (SFO) and resulted to be the worst case SFO DT_{50} value (= 115 days) of the five field trials. The experts from member states agreed that this SFO DT_{50} value of 115 days is appropriate for PECsoil calculations for penconazole. The corresponding DT_{90f} values varied between 221 to 380 days.

Several long-term soil residue trials were performed in grapes and in apple or pear orchards applying various penconazole formulations according to common agricultural practice. Soil samples were analysed for penconazole, CGA 71019 and for total residues hydrolysable to 1,2,4-triazole (expressed as penconazole equivalents). The trials demonstrated that the soil accumulation potential of the parent compound and its major degradates, CGA 71019 is generally low. Repeated applications over many years in most studies do not, on average, lead to soil concentrations in the upper 10 cm layer above 0.1 mg as/kg for penconazole and above 0.01 mg/kg for the metabolite. The maximum accumulation of penconazole residues was found in a long-term study in an apple orchard where an accumulation factor of 4.75 was derived. For this study no final conclusion on the kinetics of soil accumulation and the resulting soil accumulation factor could be drawn and therefore an accumulation potential of penconazole in soil could not be definitely excluded. The member state experts agreed that as the risk assessment for soil organisms was performed using the revised calculated PECsoil values with the worst case degradation rates, this uncertainty on soil accumulation potential does not affect the outcomes of the risk assessment.

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

The adsorption/desorption of penconazole was investigated in 8 soils in satisfactory batch adsorption experiments. Calculated adsorption K_foc values varied from 786 to 4120 mL/g, (1/n 0.75 – 0.89), indicating that penconazole is low-slightly mobile in soil. There was no evidence of a correlation of adsorption with soil pH.

The adsorption/desorption of metabolite CGA 179944 was investigated in four soils in satisfactory guideline batch adsorption experiments. Calculated adsorption K_foc values were 10-17 mL/g (1/n

0.71 – 0.93), indicating that metabolite CGA 179944 exhibits very high mobility in soil. There was no evidence of a correlation of adsorption with pH.

The adsorption/desorption of metabolite CGA 71019 was investigated in four soils in satisfactory guideline batch adsorption experiments. Calculated adsorption K_foc values as agreed in PRAPeR 12 discussion on triazole containing active substances were 43-202 mL/g (1/n 0.827 – 1.016), indicating that metabolite CGA 71019 exhibits medium-very high mobility in soil. There was no evidence of a correlation of adsorption with pH.

The low mobility of the parent penconazole was confirmed in two different column leaching studies (7 soils). In the first study more than 90% of the recovered radioactivity was retained in the top 4 cm layers in all four soils tested. Most of this radioactivity (>98%) was extractable and consisted mainly of intact penconazole. The radioactivity found in the leachates was always 0.5% in the first study and < 2% of the applied amount in the second study.

The maximum predicted environmental concentration (PECsoil) for penconazole and its soil metabolites were recalculated (see addendum 1) considering the worst case degradation rates and the worst case application pattern (cucurbits, 4 x 50 g a.s./ha).

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

Penconazole was stable under sterile aqueous hydrolysis conditions at 25°C at pH 5, 7 and 9 and at 50°C at pH 4, 7 and 9. The metabolites CGA 179944 and CGA 71019 were shown to be stable to hydrolysis under environmentally relevant conditions. Data on the direct aqueous photolysis of penconazole or its degradates are not required since the molar absorption coefficient ε is < 10 L mol^{-1} cm^{-1}. A ready biodegradability test (OECD 301/B) indicated that penconazole is „not readily biodegradable" using the criteria defined by the test.

In dark water-sediment studies (two systems studied at 20°C in the laboratory, sediment pH 7.3-7.6, water pH 7.7-7.9 sediment OC content 2.1 and 2.82%) penconazole dissipated primarily by partitioning to the sediment with single first order DT_{50} of 1.9-3.4 days where it subsequently degraded (whole system pseudo first order DT_{50} 505->706 days, DT_{90} > 678 days) forming the major metabolite CGA 179944 that was present in the water phase (max. 17.3 % of AR after 365 days) and only accounted for a maximum of 4.8% of AR in the sediment. The terminal metabolite, CO_2, accounted for only 4.6-8.4 % of AR after 678-706 days (study end). Residues not extracted from sediment by acetonitrile/water were a significant sink representing 17.6-18.7% of AR at study end. The rates of disappearance of penconazole from the water phase were very rapid: the DT_{50} and DT_{90} values were determined to be 2.2 and 7.4 days for the river system, respectively. Corresponding values for the pond system were 3.3 and 11 days, respectively. For a compound so rapidly adsorbed to sediment the total system half-life is an approximate value to also represent the sediment degradation half-life. Therefore, for environmental assessment the longest value determined at 20ºC is recommended for use, i.e. 706 days. The half-life of CGA 179944 in the river system was

estimated to be about 235 days. No calculation was possible for the dissipation of this metabolite from the pond system due to the low amounts formed.

FOCUS surface water Step 1 and Step 2 were performed for penconazole and its soil metabolites CGA 179944 and CGA 71019. The relevant results from the FOCUSsw Step 3 modelling were presented in addendum 1 based on the worst case GAP for fruiting vegetables in Southern Europe. During the meeting of experts it was noted that the crop interception used in FOCUS Step 2 calculation was incorrect (25% should have been used instead of 50% for cucurbits). It was considered that the calculated difference between FOCUS Step 2 and Step 3 results would be lower than 85%. However, it was agreed that the conclusion on the risk assessment for aquatic invertebrates would not change if the correct crop interception factor at Step 2 would have been used. On balance it was concluded that at Step 3 the maximum surface water and sediment PEC from single or multiple applications for the worst case GAP was approximately 85% and 70% lower than the values at Step 2. Therefore it is confirmed that the TER for invertebrates" chronic effects will be greatly in excess of 10 for this worst case use.

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

Groundwater modelling using the FOCUS PELMO (3.3.2) model was conducted to assess the potential leaching of penconazole and its soil metabolites CGA 179944 and CGA 71019 following application to vines and fruiting vegetables. The experts from member states discussed in detail the input parameters that should be used in the modelling. For the parent penconazole and metabolite CGA 71019, the soil DT_{50}, the K_{oc} and 1/n values used in the available groundwater modelling were slightly different from the values that the experts considered appropriate (see addendum 3, July 2008). The EFSA agrees with the RMS that a new modelling with the correct input values would not lead to additional information in comparison to the results provided in the DAR. With regard to metabolite CGA 179944, a data gap was identified for degradation rates derived from acidic soils (refer to section 4.1.2) and therefore the current groundwater assessment covers only neutral and alkaline soil conditions. Additionally, as the highest concentrations for metabolite CGA 179944 for the Piacenza scenario were close to the trigger of 0.1 µg/L for both the intended uses, an additional groundwater modelling with FOCUS PEARL was required. Because of the data gap on degradation rates for metabolite CGA 179944, it was not possible to provide a peer-reviewed modelling with a second model based on agreed input parameters. It was also noted by the experts that as the FOCUS groundwater scenarios do not mimic specific fields, and nor are they necessarily representative of the agriculture at the location after which they are named or in the Member States where they are located, PECgw calculations with all the FOCUS scenarios relevant to the vines use, irrespective to the country indicated in the representative uses table, should be performed (i.e. modelling with Piacenza, Sevilla, Porto and Thiva scenarios with an application rate of 25 g/ha with 4 applications and modelling with Châteaudun, Hamburg and Kremsmünster scenarios with an application rate of 40

g/ha with 3 applications are necessary). Therefore a final groundwater assessment for penconazole and its metabolites can not be concluded.

4.3. FATE AND BEHAVIOUR IN AIR

The vapour pressure of penconazole (3.66 x 10^{-4} Pa at 25°C) means that penconazole would be classified under the national scheme of The Netherlands as very slightly volatile, indicating that only limited losses due to volatilisation would be expected.

Calculations using the method of Atkinson for indirect photooxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half-life estimated at about 16 hours (assuming an atmospheric hydroxyl radical concentration of $0.5x10^6$ radicals cm^{-3}) indicating that the small proportion of applied penconazole that does volatilise would be unlikely to be subject to long range atmospheric transport.

5. Ecotoxicology

Penconazole was discussed at the expert meeting PRAPeR 48 in May 2008.

The intended uses evaluated for penconazole is a fungicide with 1-4 applications in cucurbits (max. 0.05 kg a.s./ha) and 1-4 applications in grapes (max 0.04 kg a.s./ha) with an interval between applications of one or two weeks, respectively.

General comment: the endpoints for the relevant metabolite CGA 71019 were discussed and agreed in the PRAPeR experts‟ meetings for ecotoxicology (PRAPeR 13) and mammalian toxicology (PRAPeR 14) in January 2007. The PRAPeR 48 experts‟ meeting agreed to use the same endpoints for this relevant metabolite in the risk assessment for penconazole.

5.1. RISK TO TERRESTRIAL VERTEBRATES

The risk to birds and mammals was assessed for standard species in accordance with the Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC (SANCO/4145/2000) using the leafy crops and orchard vines and hop scenarios.

First tier calculations considering insectivorous birds for grapes and insectivorous and medium herbivorous birds for cucurbits resulted in TER values above the Annex VI trigger values.

The resulting TER_A and TER_{lt} for herbivorous mammals were 121 and 7.4, respectively. Both acute and long-term TER values were above the Annex VI trigger values, indicating that low risk is expected for mammals.

Acute and long term TER values for the metabolites were estimated to be above the Annex VI trigger values.

Penconazole has a log Kow = 3.72. The risk from secondary poisoning of earthworm eating birds and mammals was estimated using the approach outlined in SANCO/4145/2000. The TER values for

cucurbits, grapevine (NEU) and grape (SEU) for birds are 173, 347 and 283, respectively. The TER values were 95, 190 and 155 for cucurbits, grapes NEU and grapes SEU for mammals. The TER values meet the Annex VI trigger of 5.

For fish-eating birds and mammals a high risk was concluded based on the BCF of 320 derived from a study with bluegill *Lepomis machrochirus*. TER values were in a range from 121-282 for birds and 136-310 for mammals. The PEC_{sw} used in the calculations are from the FOCUS Step 2. The risk to birds from intake of contaminated drinking water from surface water or puddles was considered to be low.

The penconazole avian and mammalian databases were reviewed for effects indicative of potential endocrine activity. There are no relevant mediated effects below the threshold established by the current endpoints for the mammals. The PRAPeR 48 meeting of experts agreed that some uncertainties remains on potential delayed reproductive effects on birds since these effects are not covered on the basis of the currently stated data requirements of Council Directive 91/414/EEC. In case of Annex I inclusion more information should be requested at MS level.

In conclusion, a low risk was identified in the tier I risk assessment for birds and mammals.

5.2. RISK TO AQUATIC ORGANISMS

Based on the information available penconazole is proposed to be classified as very toxic to aquatic organisms.

The relevant endpoint for the metabolites CGA 71019 to aquatic organisms was discussed in the PRAPeR 48. The meeting agreed with the use of the 96 h LC_{50} = 498 mg/L for the acute toxicity of fish for the relevant metabolite CGA 71019 from the original DAR, and the endpoints included in the 1,2,4-triazole (PRAPeR 13) for the other aquatic organisms.

The first tier risk assessment indicated a low long term risk to fish and a low acute risk to aquatic invertebrates, algae and the sediment dwelling organisms. However, tier I risk assessment also indicated that there is high acute risk to fish and a high long term risk to aquatic invertebrates and also to aquatic plants. In order to meet the Annex VI trigger for acute and long term risk it was necessary to use the PECsw from FOCUS Step 2 except for the long term risk to aquatic invertebrates. More realistic exposure at FOCUS Step 3 provided a TER value above the Annex VI trigger value.

The experts at the PRAPeR 48 meeting discussed the testing strategy of addressing the potential endocrine disrupting properties of penconazole. The experts noticed that no appropriate information is available to address this point with regard to potential effects on fish. The applicant and the RMS proposed that an appropriate FSDT study was required to address the potential endocrine-mediated effect in DMI fungicides since the FSDT will cover the sensitive time windows with respect to effect triggering and effect manifestation. The member states experts agreed with this proposal and also noted that member states should have the opportunity to ask for an appropriate test to address the

endocrine effects. Furthermore, a preliminary risk assessment on the basis of the existing ELS test was considered possible by the RMS. The comparison of the most sensitive endpoints between FFLC tests and other chronic fish studies for several DMI fungicides allows the evaluation of re-mating uncertainties in case where no FFLC was available. It was concluded that an uncertainty factor of 5 on the most sensitive endpoint chronic fish studies should be used (similar case was discussed for tebuconazole, triadimenol, tetraconazole and fenbuconazole). This preliminary risk assessment indicated a low risk to fish in all intended uses.

The BCF of 320 was derived from a study with bluegill *Lepomis machrochirus.*

The first tier risk assessment for metabolites indicated a low acute and long term risk for both metabolites CGA 71019 and CGA 179944.

5.3. RISK TO BEES

Penconazole is of low toxicity for bees. LD_{50} from acute oral toxicity tests with the preparation ranged from > 112 to > 178 µg /bee and the LD_{50} from the contact tests with the preparation are always > 30 µg/bee. Hazard Quotients (HQ) were estimated to be in a range from < 2.3 to < 4.4 for the oral exposure and < 16.4 for the contact exposure. As a conclusion a low risk is expected to bees for the use of penconazole.

5.4. RISK TO OTHER ARTHROPOD SPECIES

The laboratory studies show that a 79 % mortality was observed for *Typhlodromus pyri* and 59 % was observed for *Aphidius rophalosiphi* at 100g a.s./ha. Furthermore, laboratory studies at 10g a.s./ha caused no mortality on *Poecilus cupreus* and to *Orius laevigatus.* 24 % mortality was observed in the *Aphidius matricariae* at 12 g a.s./ha.

The expert meeting agreed with the RMS‟ proposal in the DAR to estimate the HQ for soil and foliar exposure taking into account the different degradation rates in soil and in plant. The HQ in-field for cucurbit for *A. rhopalosiphi* were < 1.88 for foliar and < 2.21 for soil. For the *T. pyri* the HQ in-field were <9.4 for soil and < 11.4 for foliar.

The HQ off-field for cucurbits, which is the worst case, were < 0.55 at 3 m for *T. pyri* and < 0.11 for *A. rophalosiphi.* Therefore low risk is identified for the off-field areas.

In agreement with the ESCORT 2, extended laboratory tests on natural substrate were performed with *T. pyri, O. laevigatus, C. carne* and with *C. septempunctata.* In these studies the more sensitive species *T. pyri* showed a reduction of fecundity of 55 %, these effects were above the trigger value of 50%.

There were two higher tier studies, a semi-field study with *A. rhophalosiphi* and a field study with *Phytoseiidae*. The results of both of these studies showed that no adverse effects were observed on reproduction of *A. rophalosiphi* and no adverse effects were observed in *T. pyri.*

Further refinement of the in-field risk assessment was conducted by considering recolonisation from the off-field areas. Risk to off-field NTA has been demonstrated to be low and it was shown that in-

field penconazole residues will degrade to a level allowing potential for re-colonisation from off-field areas within 25 days for foliar-dwellers and 257 days for soil-dwellers.

5.5. RISK TO EARTHWORMS

The acute toxicity of penconazole, "Topas 10 EC" formulation, and both of the relevant metabolites CGA 71019 and CGA 179944 to earthworms is low. The $NOEC_{corr}$ for reproduction effect was determined to be NOEC > 5 mg a.s./kg soil for the preparation "Topas 10 EC" and NOEC 56days = 1.0 mg a.s./kg soil for the metabolite CGA 71019 (agreed endpoint in PRAPeR 13).

TER values were estimated for the worst case scenario cucurbits, using the PEC plateau of 0.14 mg/ kg for penconazole and 0.002 and 0.015 mg /kg for the CGA 71019 and CGA 179944, respectively. TER values are above the Annex VI trigger values for acute and chronic effects indicating a low risk to earthworms.

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

Penconazole has a soil DT_{90} of 630 days. Therefore penconazole and the metabolite CGA 71019 were tested for effects on *Folsomia candida,* and penconazole was tested for effects on litter bag study.
The chronic TERs were calculated using the PEC_{soil} plateau values, and were above the Annex VI trigger values.
The litter bag study with the preparation showed that there were no significant effects over 365 days on straw decomposition for litter bags buried in soil.

In conclusion, the risk is considered to be low for penconazole and the metabolite CGA 71019 to other non-target macro-organisms.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The results of the assessment of "Topas 10 EC" as well as the soil metabolites CGA 71019 and CGA 179944 indicate that no adverse impact on soil non-target organisms and their function in soil systems is expected from use on cucurbits and grapes. No effects of > 25 % were observed for penconazole in soil nitrification /respiration at concentrations of 0.32 mg a.s./kg.
No effects > 25 % were observed for the metabolites CGA 71019 and CGA 179944 at concentrations of 0.353 mg /kg and 0.2 mg /kg, respectively.

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

In a preliminary screening test "Topas 10 EC" at rates up to 30 g as /ha had only a slight effect (< 50 % effect) on seedling emergence and vegetative vigour in three monocotyledons and three dicotyledons.

EFSA notes that the dose used in the screening test, 30 g as /ha, has not covered the higher proposed intended uses of 50 g a.s./ha. A data requirement is proposed to provide a risk assessment that covers the full intended uses.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

No inhibitory effects of penconazole to respiration rates of activated sludge was observed up to 100 mg /L. The EC_{50} is > 100 mg /L and the NOEC = 32 mg/L.

6. Residue definitions

Soil

Definition for risk assessment:	penconazole, CGA 71019, CGA 179944, unknown U1
Definition for monitoring:	penconazole (provisional as a data gap was identified for unknown U1)

Water

Ground water

Definition for exposure assessment:	penconazole, CGA 71019, CGA 179944, unknown U1
Definition for monitoring:	penconazole (provisional as a data gap was identified for metabolites CGA 179944 and CGA 71019, and unknown U1)

Surface water

Water

Definition for risk assessment:	penconazole, CGA 179944, originating from soil via runoff and drainage: CGA 71019 and unknown U1
Definition for monitoring:	penconazole (provisional as a data gap was identified for unknown U1)

Sediment

Definition for risk assessment:	penconazole
Definition for monitoring:	penconazole

Air

Definition for risk assessment:	penconazole
Definitions for monitoring:	penconazole

Food of plant origin

Definition for risk assessment:	penconazole and free and conjugated CGA 132465, CGA 190503 and CGA 127841 expressed as penconazole (provisional fruit crops only).
Definition for monitoring:	penconazole

Food of animal origin

Definition for risk assessment:	not necessary no animal intakes for the representative crops.
Definition for monitoring:	not necessary no animal intakes for the representative crops.

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

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
penconazole	Moderate to high persistence Single first order DT_{50} 55.3-173 days (20°C, PF2 soil moisture)	Low risk was identified for the earthworms
CGA 179944	Low to moderate persistence Single first order DT_{50} 4.5-15.5 days (20°C, PF2 soil moisture)	*Eisineia fetida* 14 days LC_{50} > 1000 mg /kg dw soil (750kg /ha) Low risk was identified for the earthworms.
CGA 71019	Low persistence Single first order DT_{50} 5.0-9.9 days (20°C, PF2 soil moisture)	*Eisineia fetida* 14 days LC_{50} > 1000 mg /kg dw soil(750kg /ha) *Eisinea fetida* 8 weeks NOEC = 1 mg/kg dw soil Low risk was identified for the earthworms.
Unknown U1	Data gap	No data available

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
penconazole	low to slight mobility K_{foc} 786-4120 mL/g	No, but a data gap for FOCUS GW modelling with Piacenza, Sevilla, Porto and Thiva scenarios with an application rate of 25 g/ha with 4 applications and modelling with Châteaudun, Hamburg and Kremsmünster scenarios with an application rate of 40 g/ha with 3 applications has been identified	Yes	Yes	Yes
CGA 179944	very high mobility K_{foc} 10-17 mL/g	No, but actual PECgw assessment covers only neutral and alkaline soil conditions) Data gap for FOCUS GW modelling with Piacenza, Sevilla, Porto and Thiva scenarios with an application rate of 25 g/ha with 4	Not	Minor rat metabolite. No toxicological data available. Might be required pending on modelling results.	Not relevant

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
		applications and modelling with Châteaudun, Hamburg and Kremsmünster scenarios with an application rate of 40 g/ha with 3 applications			
CGA 71019	High to very high mobility K_{foc} 43-120 mL/g	No, but a data gap for FOCUS GW modelling with Piacenza, Sevilla, Porto and Thiva scenarios with an application rate of 25 g/ha with 4 applications and modelling with Châteaudun, Hamburg and Kremsmünster scenarios with an application rate of 40 g/ha with 3 applications has been identified	Not	Yes* Reprotoxic Cat.3 ADI = 0.02 mg/kg bw/d ARfD = 0.06 mg/kg bw/d	Not relevant
Unknown U1	Data gap	Data gap	No data available	No data available. Might be required pending on identification and modelling results.	No data available

* see PRAPeR meeting 14, January 2007

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
penconazole	The risk was assessed as low for the intended uses in grapes and cucurbits.
CGA 179944	The CGA 179944 metabolite is very toxic to aquatic organisms. The risk was assessed as low for the intended uses in grapes and cucurbits. Selenastrum capricornutum 72 h E_bC_{50}= 45 mg /L
CGA 71019	The CGA 71019 metabolite is very toxic to aquatic organisms. The risk was assessed as low for the intended uses in grapes and cucurbits. Selenastrum capricornutum 72 h E_bC_{50}= 8.2 mg /L
Unknown U1	No data available

Air

Compound (name and/or code)	Toxicology
penconazole	low acute toxicity by inhalation (LC_{50} >4.05 mg/L/4h)

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

- A new specification with supporting 5-batch data for all sources has been identified as a data gap (relevant for all uses evaluated, data gap identified by PRAPeR meeting of experts May 2008, data submitted May 2008 but not peer reviewed, refer to chapter 1).
- Repeatability data for the impurity method of analysis has been identified as a data gap (relevant for all uses evaluated, data gap identified by PRAPeR meeting of experts May 2008, proposed submission date unknown, refer to chapter 1).
- A confirmatory method for surface water has been identified as a data gap (relevant for all uses evaluated, data gap identified by PRAPeR meeting of experts May 2008, proposed submission date unknown, refer to chapter 1).
- New toxicological data for the (plant) metabolite triazolyl lactic acid (relevant for all uses evaluated, data already submitted to the RMS but not evaluated due to Commission Regulation No 1095/2007, refer to chapter 2.8)
- 4 trials on cucurbits edible peel and 4 trials on cucurbits inedible peel have been identified as a data gap (relevant for the cucurbit uses, for the outdoor use in the north of Europe; data gap identified in the DAR, proposed submission date unknown, refer to chapter 3)
- Information allowing the assessment of consumer exposure to triazole metabolite derivatives in primary crops, rotational crops and products of animal origin (relevant for all uses evaluated; no submission date proposed by the applicant; data gap identified by PRAPeR meeting of experts June 2008; refer to chapter 3)
- The identification/characterisation of the unknown radioactivity U1 found in the aerobic soil degradation and a complete (PECsoil, PECsw and PECgw) assessment have been identified as a data gap (relevant for all uses evaluated; no submission date proposed by the applicant; data gap identified by PRAPeR meeting of experts May 2008; refer to chapter 4.1.1)
- Degradation rates data in soil for metabolite CGA 179944 derived from acidic soils have been identified as a data gap (relevant for all uses evaluated; no submission date proposed by the applicant; data gap identified by PRAPeR meeting of experts May 2008; refer to chapter 4.1.2)
- Pending on the results of the new aerobic rate of degradation studies required for metabolite CGA 179944 with acidic soils, a new groundwater assessment for the leaching potential of this metabolite may be necessary (relevant for all uses evaluated; no submission date proposed by the applicant; data gap identified by PRAPeR meeting of experts May 2008; refer to chapter 4.1.2)
- FOCUS groundwater modelling for all the FOCUS scenarios relevant to vines uses with the highest application rate has been identified as a data gap (relevant for all uses evaluated; no submission date proposed by the applicant; data gap identified by PRAPeR meeting of experts May 2008; refer to chapter 4.2.2)

- A second FOCUS groundwater modelling for metabolite CGA 179944 with FOCUS PEARL model has been identified as a data gap (relevant for all uses evaluated; no submission date proposed by the applicant; data gap identified by member state /ESFA comments on the DAR, May 2008; refer to chapter 4.2.2)
- Potential delayed reproductive effects on birds since these effects are not covered on the basis of the currently stated data requirements of Council Directive 91/414/EEC. In case of Annex I inclusion more information should be requested at Member State level. (relevant for all uses evaluated; no submission date proposed by the applicant; data gap was identified during the PRAPeR 48 meeting of experts; refer to chapter 5.1)
- An appropriate test to address the potential endocrine effects of penconazole in fish is required (relevant for all uses evaluated; no submission date proposed by the applicant; data gap was identified during the PRAPeR 48 meeting of experts; refer to point 5.2)
- A risk assessment for non-target plants that covers the full intended uses is required (relevant for all representative uses evaluated; submission date proposed by the applicant unknown; data gap was identified by EFSA after the PRAPeR meeting of experts; refer to point 5.8)

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

This conclusion was reached on the basis of the evaluation of the representative uses as a fungicide on cucurbits and grapes. Full details of the GAP can be found in the attached list of endpoints.
The representative formulated product for the evaluation was "Topas 10 EC", an emulsifiable concentrate (EC).

Adequate methods are available to monitor all compounds given in the respective residue definition. Residues of penconazole in food of plant origin can be determined with a multi-method (The German S19 method has been validated). For the other matrices only single methods are available to determine residues of penconazole. A data gap was identified for a confirmatory method for surface water. It is noted that the residue definition for soil and water is provisional.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible. It is noted however, that further validation data are required for the impurity method and that there is no supported technical specification.

The toxicological studies on the metabolism of penconazole have shown an extensive oral absorption, a wide distribution in the body and an excretion mainly via urine. According to the results of acute oral toxicity testing, the agreed classification was **Xn, R22 Harmful if swallowed**. The main target

organ in short term toxicity studies was the liver, and the dog was the most sensitive species. No genotoxic potential was observed during *in vitro* or *in vivo* tests, and no carcinogenicity was observed in rats or mice after long term exposure. In the reproductive toxicity studies, an increased incidence of dystocia was considered as an effect already observed with other triazoles, and to be forwarded to EChA for a decision upon classification (R62?- "Possible risk of impaired fertility"). Developmental effects were observed in the teratogenicity studies, and the classification **Reprotoxic Category 3 R63 Possible risk of harm to the unborn child** was proposed by the experts. Several plant metabolites were considered to be of the same or lower toxicity than penconazole. The Acceptable Daily Intake (ADI) and the Acceptable Operator Exposure Level (AOEL) were both 0.03 mg/kg bw/day based on the combined 90-day/1-year dog study. The Acute Reference Dose (ARfD) was 0.5 mg/kg bw based on early bodyweight changes in the rabbit developmental study. These reference values were all derived with the use of a safety factor of 100. The dermal absorption values were 5% for the dilution and 1% for the concentrate. The exposure estimates in different scenarios (field or greenhouse use) were all below the AOEL even without the use of personal protective equipment.

The metabolism of penconazole was tested in grapes, tomatoes and apples where triazole- and phenyl labelled compound was applied. The meeting of experts considered that the grape data were not acceptable and they were not considered further. The apple and tomato data were acceptable and showed the same metabolic profile. The main metabolism route is oxidation at the 1, 2 and 3 positions on the alkyl chain. The triazole moiety metabolites are an issue for all the triazole fungicides and will be dealt with in a separate exercise. For completeness, a general data gap was identified for this issue which has been used in other triazole conclusions. No phenyl-ring-only metabolites were seen. The significant residues at harvest consisted of CGA 132465, CGA 190503, CGA 127841 and their glucoside conjugates as well as penconazole. It was agreed that the provisional residue definition for risk assessment (fruit crops only) should be penconazole and free and conjugated CGA 132465, CGA 190503 and CGA 127841 expressed as penconazole. The residue definition for monitoring is penconazole with a conversion factor of 6 between monitoring and risk assessment residue definitions.

The residue trial data set was complete for grapes but a data gap for outdoor cucurbits in the North of Europe was identified. The stability of residues was demonstrated in freezer storage for a period of 16 months. Appropriate processing data are available.

Two rotational crop metabolism studies conducted at exaggerated rates showed that no significant residue would be expected in rotational crops. No livestock metabolism studies were supplied or required as according to current guidance the representative crops under consideration are not fed to animals.

The chronic risk assessment showed a maximum intake of 2.9 % of the ADI for the French diet using the EFSA model. For the acute risk the highest intake was 13 % of the ARfD from the consumption of table grapes for the German diet using the EFSA model. The proposed MRLs are 0.2 mg/kg for grapes and 0.1 mg/kg for cucurbits.

The information available on the fate and behaviour in the environment is sufficient to carry out an appropriate environmental exposure assessment at EU level with the notable exception that the assessment of the potential for groundwater exposure by penconazole and its soil metabolites cannot be finalised. The PECgw assessment originally provided in the DAR with the indication of no leaching for the active substance, CGA 71019 and CGA 179944 can only cover neutral and alkaline soil conditions. A data gap was also identified for the identification/characterisation of the unknown radioactivity U1 found in the aerobic soil degradation up to 17.3% of the applied radioactivity and for a complete (PECsoil, PECsw and PECgw) assessment for this unknown U1.

The risk to birds and mammals is considered to be low for the use in cucurbits and grapes. The risk from secondary poisoning of earthworm-eating birds and mammals was considered low. The risk to bird and mammals from intake of contaminated drinking water from surface water or puddles was considered to be low. The metabolites CGA 71019 and CGA 179944 have a low risk to birds and mammals. The penconazole avian and mammalian databases were reviewed for effects indicative of potential endocrine activity.

Based on the information available penconazole is proposed to be classified as very toxic to aquatic organisms. The first tier risk assessment indicated a low long term risk to fish and also a low acute risk for aquatic invertebrates, algae and for the sediment dwelling organisms. However, tier I risk assessment also indicated that there is high acute risk to fish and a high long term risk to aquatic invertebrates and also to aquatic plants. In order to meet the Annex VI trigger for acute and long term risk it was necessary to use the PECsw from Step 2. The higher tier risk assessment indicated a low risk for all the aquatic organisms, except for the long term risk to aquatic invertebrates exposed to the preparation, which, under more realistic exposure, at PECsw Step 3, provided a TER value above the Annex VI trigger value.

The BCF of 320 was derived from a study with bluegill *Lepomis machrochirus.*

The first tier risk assessment for metabolites indicated a low acute and long term risk for both metabolites CGA 71019 and CGA 179944.

Penconazole is of low toxicity to bees. Hazard Quotients (HQ) for oral and contact exposure were determined to be below the trigger values indicating a low risk for bees.

The risk to non-target arthropods was assessed as high for the in-field areas, however a potential for recolonisation from the off-field areas had been demonstrated.

The acute and chronic TER values for penconazole and for both metabolites CGA 71019 and CGA 179944 were above the Annex VI triggers values indicating that the risk to earthworms is low.

Penconazole and the metabolite CGA 71019 were tested with *Folsomia candida,* and the active substance was tested for effects in a litter bag study. In conclusion, the risk from penconazole and the metabolite CGA 71019 to other non-target macro-organisms was considered to be low.

The results of the assessment of “Topas 10 EC” as well as the soil metabolites CGA 71019 and CGA 179944 indicate no adverse impact on soil non-target organisms.

In a preliminary screening test "Topas 10 EC" had only a slight effect (< 50 % effect) on seedling emergence and vegetative vigour in three monocotyledons and three dicotyledons at rates up to 30g a.s. /ha.

Particular conditions proposed to be taken into account to manage the risk(s) identified
None.

Critical areas of concern

- The specification has not been finalised
- The groundwater exposure assessment has not been finalised as the assessment for unknown metabolite U1 is needed and FOCUS groundwater modelling for all the FOCUS scenarios relevant to vines uses with the highest application rate is missing.

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

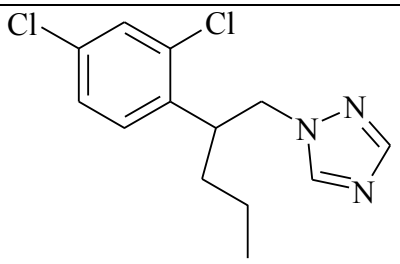
(Abbreviations used in this list are explained in appendix 2)

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

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

Rapporteur Member State	Federal Republic of Germany
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	(*RS*) 1-[2-(2,4-dichlorophenyl)pentyl]-1*H*-1,2,4-triazole
Chemical name (CA) ‡	1-[2-(2,4-dichlorophenyl)pentyl]-1H-1,2,4-triazole
CIPAC No ‡	446
CAS No ‡	66246-88-6
EC No (EINECS or ELINCS) ‡	266-275-6
FAO Specification (including year of publication) ‡	Not available
Minimum purity of the active substance as manufactured ‡	Open
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula ‡	$C_{13}H_{15}Cl_2N_3$
Molecular mass ‡	284.2 g/mol
Structural formula ‡	

Appendix 1 – list of endpoints

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	60.3 to 61.0 °C (99.5 %)
Boiling point (state purity) ‡	none observed up to 360 °C (99.5 %)
Temperature of decomposition (state purity)	none observed up to 360°C (99.5 %)
Appearance (state purity) ‡	PAS (99.5 %): odourless white powder TAS (96.1 %): weak smelling off-white powder with lumps
Vapour pressure (state temperature, state purity) ‡	3.66 * 10^{-4} Pa at 25 °C (99.5 %)
Henry"s law constant ‡	6.6 * 10^{-4} Pa m^3 mol^{-1} (20 °C)
Solubility in water (state temperature, state purity and pH) ‡	pH 6.7: 0.073 g/Lat 20 °C (99.5 %) pH has no effect on the water solubility in the range 4 to 10
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 25 °C in g/L (96.1 %)) *n*-hexane 24 toluene > 500 dichloromethane > 500 methanol > 500 acetone > 500 ethyl acetate > 500 *n*-octanol 400
Surface tension ‡ (state concentration and temperature, state purity)	59.7 - 62.8 mN/ m (0.1g/L suspension) (96.1 %) 67.5 - 71.4 mN/ m (0.01g/L suspension) 90 % of saturated solution is equivalent to a concentration of 0.066 g/L. As the values for a 1.5fold higher concentrated solution are around the threshold value it is assumed that the substance must not be regarded as surface active.
Partition co-efficient ‡ (state temperature, pH and purity)	log $P_{O/W}$ = 3.72 at 25 °C (distilled water, pH 5.65, 99.5%)
Dissociation constant (state purity) ‡	pKa1 = 1.51, at 20 °C (99.5 %)

Appendix 1 – list of endpoints

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	wavelength λ_{max} [nm] / molar absorption coefficient ε [$L_*mol^{-1}_*cm^{-1}$] (99.5 %) neutral: MeOH 220 10564 273 437 281 401 acid: 0.1 M aqueous HCl/methanol (9 + 91) 220 10741 273 410 281 376 basic: 0.1 M aqueous NaOH/methanol (9 + 91) 224 9607 273 453 281 417 No absorption maximum above 290 nm was observed (ε < 10 at 295 nm).
Flammability ‡ (state purity)	Penconazole is not highly flammable. (96.1%). No self-ignition was observed between room-temperature and the melting point.
Explosive properties ‡ (state purity)	No explosive properties were detected (thermal and mechanical impact). (96.1%).
Oxidising properties ‡ (state purity)	Not considered as oxidising substance (96.1%).

Appendix 1 – list of endpoints

Summary of representative uses evaluated (*Penconazole*)*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d - f)	Conc. of as (i)	method kind (f - h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hL min - max (l)	water L/ha min - max	kg as/ha min - max (l)		
Cucurbit group	Northern and Southern Europe	Topas 10 EC	F/ G	*Erysiphe spp.* *Sphaerotheca spp.*	EC	100	Foliar spray	from BBCH 14 at first sign of disease	1 - 4	7 days		1000 - 1500	0.05	3	[1]
Grapes	Northern Europe	Topas 10 EC	F	*Uncinula necator*	EC	100	Foliar spray	from BBCH 57 at first sign of disease	1 - 4	10 to 14 days		400 - 1000	0.025	30	high volume air assisted sprayer [1]
Grapes	Northern Europe	Topas 10 EC	F	*Uncinula necator*	EC	100	Foliar spray	from BBCH 57 at first sign of disease	1 - 4	10 to 14 days		200 - 400	0.025	30	low volume mist blower [1]
Grapes	Southern Europe	Topas 10 EC	F	*Uncinula necator*	EC	100	Foliar spray	from BBCH 57 at first sign of disease	1 – 3	7 to 14 days		400 - 1000	0.04	14	high volume air assisted sprayer [1]
Grapes	Southern Europe	Topas 10 EC	F	*Uncinula necator*	EC	100	Foliar spray	from BBCH 57 at first sign of disease	1 – 3	7 to 14 days		200 - 400	0.04	14	low volume mist blower [1]

[1] Data gaps identified in fate and behaviour section (ground water assessment exposure has not been finalised)

Appendix 1 – list of endpoints

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

Appendix 1 – list of endpoints

Methods of Analysis

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

Technical as (analytical technique)	GC/FID on packed column
Impurities in technical as (analytical technique)	GC/FID on packed column, validation data required
Plant protection product (analytical technique)	HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	Penconazole
Food of animal origin	Not relevant
Soil	Penconazole
Water	Penconazole
Air	Penconazole

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	GC-MSD (primary and ILV) 0.01 mg/kg (lettuce, apple, wheat grain, sunflower seed) LOQ for ILV 0.05 mg/kg LC/LC-MS/MS (confirmatory) 0.01 mg/kg (cucumber, grapes, ,melon peel, melon flesh, peppers, strawberries, toma- toes)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not relevant, since no residue definition is proposed
Soil (analytical technique and LOQ)	LC-MS/MS 0.01 mg/kg GC-NPD 0.04 mg/kg
Water (analytical technique and LOQ)	GC-MSD 0.05 µg/L (drinking-,surface water) GC-ECD 0.1 µg/L (drinking-, ground water) Open confirmatory method for surface water
Air (analytical technique and LOQ)	GC-NPD 1 µg/m³ GC-MSD 2 µg/m³

Appendix 1 – list of endpoints

Body fluids and tissues (analytical technique and LOQ)	Not relevant, since penconazole is neither classified as toxic (T) nor as very toxic (T^+)

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

	RMS/peer review proposal
Active substance	None

Appendix 1 – list of endpoints

Impact on Human and Animal Health

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

Rate and extent of absorption ‡	ca. 85 % within 48h based on urinary and biliary excretion; AUC in males 2-fold > females
Distribution ‡	Widely distributed
Potential for accumulation ‡	No evidence of accumulation
Rate and extent of excretion ‡	> 95 % within 72 h, faster in females than in males Mainly via urine (F: ca. 70 - 85 %, M: ca. 45 - 60 %)
Metabolism in animals ‡	> 95 %, main pathways include cleavage of parent resulting in free [1H]-1,2,4-triazole, and oxidative degradation of pentyl chain yielding various oxidation products and their respective glucuronides
Toxicologically relevant compounds ‡ (animals and plants)	Parent and metabolites (1,2,4-triazole, triazolyl alanine, triazolyl acetic acid, triazole lactic acid)
Toxicologically relevant compounds ‡ (environment)	Parent and metabolites (1,2,4-triazole, triazolyl alanine, triazolyl acetic acid, triazole lactic acid)

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	< 2000 mg/kg bw	**R22**
Rabbit LD_{50} oral	971 mg/kg bw	**R22**
Rat LD_{50} dermal ‡	> 3000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 4.05 mg/L/4 h (nose-only, dust, maximum attainable concentration)	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non-irritant	
Skin sensitisation (test method used and result) ‡	Non-sensitising (M&K)	

Appendix 1 – list of endpoints

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Liver (organ wt and histopathology), body weight
Relevant oral NOAEL ‡	3 mg/kg bw/d (90-d/1-yr, dog) 25 mg/kg bw/d (90-d rat, overall NOAEL) 52 mg/kg bw/d (90-d mouse, overall NOAEL)
Relevant dermal NOAEL ‡	2000 mg/kg bw/d (15 doses over 21 d, rabbit)
Relevant inhalation NOAEL ‡	No data, not required

Genotoxicity (Annex IIA, point 5.4)

No genotoxic potential.

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

Target / critical effect ‡	Liver (organ wt., hepatocyte vacuolisation)
Relevant NOAEL ‡	36 mg/kg bw/d (18-mo mouse) 15 mg/kg bw/d (2-yr rat)
Carcinogenicity ‡	No carcinogenic potential.

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Prolonged pregnancy/delayed parturition, increase in parturition mortality (dams and foetuses) at parental toxic doses[24]
Relevant parental NOAEL ‡	30 mg/kg bw/d
Relevant reproductive NOAEL ‡	30 mg/kg bw/d
Relevant offspring NOAEL ‡	30 mg/kg bw/d

Developmental toxicity

Developmental target / critical effect	Red. foetal wt., delayed ossification and skeletal variations, bilateral microphthalmia in one rabbit strain, all findings at maternal toxic doses **R63**[25]
Relevant maternal NOAEL ‡	50 mg/kg bw/d (rabbit) 100 mg/kg bw/d (rat)
Relevant developmental NOAEL	50 mg/kg bw/d (rabbit) 100 mg/kg bw/d (rat)

[24] *R62? Possible risk of impaired fertility* has to be considered by EChA
[25] *R63 Possible risk of harm to the unborn child* has to be confirmed by EChA

Appendix 1 – list of endpoints

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity	No data, not required
Repeated neurotoxicity ‡	No data, not required
Delayed neurotoxicity ‡	No data, not required

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data, not required
Studies performed on metabolites or impurities ‡ :	1,2,4-triazole, triazolyl alanine, triazolyl acetic acid have been previously discussed by PRAPeR 14 (January 2007):
Effect on hepatic drug metabolising enzyme activity	14-d gavage study in rats and mice Pronounced induction of several hepatic xenobiotic metabolising enzymes, liver enlargement $NOEL_{Rat}$ < 10 mg/kg bw/d $NOEL_{Mouse}$ = 10 mg/kg bw/d

Medical data ‡ (Annex IIA, point 5.9)

No detrimental health effects in manufacturing staff, no cases of poisoning

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.03 mg/kg bw/d	90-d and 1-yr dog	100
AOEL systemic ‡	0.03 mg/kg bw/d	90-d and 1-yr dog	100
ARfD ‡	0.5 mg/kg bw	Rabbit developmental (maternal NOAEL)	100

Dermal absorption ‡ (Annex IIIA, point 7.3

Formulation (TOPAS 100 EC)	Concentrate: < 1 %, spray dilution: ca. 5 % (in vivo rat, in vitro comparison of rat and human skin)

Appendix 1 – list of endpoints

Exposure scenarios (Annex IIIA, point 7.2)

Operator (exposure estimates in % of AOEL)	Field crop spray in cucurbits	No PPE	PPE (gloves mix/loading)
	German model	6.1	4.9
	UK POEM	19.8	7.3
	Tractor-mounted spray in grapes		
	German model	9.4	9.0
	UK POEM	45.9	42.9
	Cucurbits in greenhouses (Mich)		
	Knapsack sprayer	19.6	0.8
	Spray lance, stationary tank	13.9	0.6
Workers	Worst case exposure estimate for re-entry is 33.3 % of the AOEL syst.		
Bystanders	Estimated exposure is <1% of the AOEL		

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data	Xn; R22 Harmful if swallowed Reprotox Cat.3, R63 Possible risk of harm to the unborn child

Appendix 1 – list of endpoints

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

Plant groups covered	Apples, tomatoes
Rotational crops	Lettuce, radish, spring wheat, winter wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Simulation of industrial processing or household preparation (pasteurisation; baking, brewing and boiling; sterilisation)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes.
Plant residue definition for monitoring	Penconazole
Plant residue definition for risk assessment	Penconazole + CGA 132465 + CGA 190503 + CGA 127841 and the conjugates of the metabolites, expressed as penconazole (provisional)
Conversion factor (monitoring to risk assessment)	6

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

Animals covered	No animal metabolism studies were submitted.
Time needed to reach a plateau concentration in milk and eggs	Not applicable
Animal residue definition for monitoring	No proposal for the residue definition on animal commodities has been made, because no residues will be expected in animal products and the setting of MRLs in animal products is not relevant.
Animal residue definition for risk assessment	See above
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Not applicable
Fat soluble residue: (yes/no)	Not applicable

Appendix 1 – list of endpoints

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

Residues transferred into all investigated rotational crops with higher residues resulting from the ^{14}C-triazolyl treatments and only very low residues resulting from the ^{14}C-phenyl treatments. Main metabolites resulted from the cleavage of the triazole moiety. Penconazole and metabolites resulting from the oxidation on the alkyl chain were determined only in trace amounts.

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

Stable in crops of high water content for at least 16 months under freezer storage conditions (- 20 °C).

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	No	No	No
Potential for accumulation (yes/no):	N/A	N/A	N/A
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	N/A	N/A	N/A
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	N/A	N/A	N/A
Liver	N/A	N/A	N/A
Kidney	N/A	N/A	N/A
Fat	N/A	N/A	N/A
Milk	N/A		
Eggs		N/A	

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Appendix 1 – list of endpoints

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Grapes	Northern	< 0.01 (2), 0.01, < 0.02 (4), 0.02 mg/kg	Calculation of the MRL is based on residue data from S-EU	0.2	0.02	0.02
	Mediterranean	< 0.01, 0.02 (3), 0.03 (2), 0.04, 0.17 mg/kg			0.17	0.025
Cucurbits with edible peel	Mediterranean, field-use	< 0.01, 0.01, < 0.02 mg/kg	Calculation of the MRL is based on residue data from greenhouse uses	0.1	N/A	N/A
	Northern and Mediterranean, greenhouse	< 0.01, 0.01 (2), < 0.02 (2), 0.02 (2), 0.03 (3) mg/kg			0.03	0.02
Cucurbits with inedible peel	Mediterranean, field-use	< 0.02 (2), 0.03 (2) mg/kg	Calculation of the MRL is based on residue data from greenhouse uses	0.1	N/A	N/A
	Northern and Mediterranean, greenhouse	0.01 (2), 0.02 (2), 0.03, 0.04 (2), 0.05, 0.06 mg/kg			0.06	0.03

Appendix 1 – list of endpoints

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

Appendix 1 – list of endpoints

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

ADI	0.03 mg/kg bw/day
ITMDI (EFSA model) (% ADI)	Max. 2.9 % (French diet, all populations)
NTMDI (German Diet, VELS project) (% ADI)	1.1 %
IEDI (WHO European Diet) (% ADI)	Not applicable
NEDI (German Diet) (% ADI)	Not applicable
Factors included in IEDI and NEDI	None
ARfD	0.5 mg/kg bw/day
Acute exposure (EFSA model) (% ARfD)	Table grapes: 13 % ARfD (German diet) Wine grapes: 4.8 % ARfD (UK adult) Cucumbers: 2.1 % ARfD (Dutch children) Gherkins: <1 % ARfD (Dutch children) Courgettes: 1.7 % ARfD (UK toddler) Melons: 11 % ARfD (Belgian children) Pumpkins: 3.8 % ARfD (Dutch adults) Watermelons: 8.8 % ARfD (Dutch children)
Factors included in IESTI and NESTI	Not applicable

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Grapes/ must	2	0.26	N/A	
Grapes/ juice	4	0.51	N/A	
Grapes/ wine	4	0.23	N/A	
Grapes/ raisins	4	3.5	N/A	
Grapes/ wet pomace	6	3.8	N/A	
Grapes/ dry pomace	4	18	N/A	

Appendix 1 – list of endpoints

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

Plant matrices (penconazole)	0.2 mg/kg for grapes 0.1 mg/kg for cucurbits
Animal matrices (penconazole)	None

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

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

Mineralisation after 100 days ‡	Triazole label (0.2-6% AR after 84-120 days, n=6): *Study 1, n=2, 20°C* 2.8 and 5.4 % AR after 120d, 6.8 and 9.6% AR after 188 d *Study 2, n=1, 20°C, 40% MWC* 2.9% AR after 120 days, 4.1% AR after 210 days *Study 3, n=1, (4 subprojects)* *Subproject 1: 10°C, 60%FC* 0.4% AR after 105 days, 0.9% AR after 364 days *Subproject 2: 20°C, 60%FC* 3.5% AR after 105 days, 11% AR after 364 days *Subproject 3: 20°C, 30%FC* 0.2% AR after 105 days, 0.7% AR after 364 days *Subproject 4: 20°C, 65%FC, low dose* 6.4% AR after 105 days 26.9% AR after 364 days *Study 6, n=1, 15°C* 0.3% AR after 84d, 1.4% AR after 546d *Study 7, n=1, 25°C* 1.4% AR after 84 days, 3.9% AR after 336 days Phenyl Label (15-19% AR after 84-182 days, n=2): *Study 4, n=1, 25°C, 65%FC* 19.3% AR after 84 days, 65.4% AR after 546 days *Study 5, n=1, 15°C* 15.3% AR after 182d, 31% after 364d
Non-extractable residues after 100 days ‡	Triazole label (6-25% AR after 84-120 days, n=6: *Study 1, n=2, 20°C* 17.1 and 25.5 % AR after 120d, 27.3 and 35.8%

Appendix 1 – list of endpoints

	after 188d *Study 2, n=1, 20°C, 40% MWC* 25.4% AR after 120 days, 35.1% AR after 210days *Study 3, n=1, (4 subprojects)* *Subproject 1: 10°C, 60%FC* 5.5% AR after 105 days, 10.9% AR after 364 days *Subproject 2: 20°C, 60%FC* 14.5% AR after 105 days, 23.7% AR after 364 days *Subproject 3: 20°C, 30%FC* 4.9% AR after 105 days, 15.8% AR after 364 days *Subproject 4: 20°C, 65%FC, low dose* 18.4% AR after 105 days 40.2% AR after 364 days *Study 6, n=1, 15°C* 9.4% AR after 84d, 43.3% AR after 546d *Study 7, n=1, 25°C* 15.2% AR after 84 days, 47% AR after 336days Phenyl Label (13-15% AR after 84-182 days, n=2): *Study 4, n=1, 25°C, 65%FC* 13.3% AR after 84 days, 20.6% AR after 546days *Study 5, n=1, 15°C* 14.6% after182d, 21.6% after 364d
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	CGA 71019: 2.5-38.6 % AR at 7-188 d [^{14}C-triazole] label CGA 179944: 0-18.9 % AR at 7-364 d [^{14}C-triazole] label U1: 17.3 % AR (182 d, subproject 2)

Appendix 1 – list of endpoints

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

Anaerobic degradation ‡

Mineralisation after 100 days	Study 1 -anaerobic <LD after 120 days [^{14}C-triazole]-label -77d aerobic pre-incubation, anaerobic incubation 1.7 % AR after 120 days [^{14}C-triazole]-label Study 2 (30d aerobic/ 50d anaerobic) 0.5 % AR after 84 days [^{14}C-triazole]-label (n=1) Study with metabolite CGA71019 1.3 % AR after 126days [^{14}C-triazole]-label (n=1)
Non-extractable residues after 100 days	Study 1 -Anaerobic 8.3 % AR after 120 days [^{14}C-triazole]-label -77d aerobic pre-incubation, anaerobic incubation 19.6 % AR after 120 days [^{14}C-triazole]-label Study 2 (aerobic/ anaerobic) 8.6 % AR after 84 days [^{14}C-triazole]-label (n=1) (Study with metabolite CGA71019 16.3 % AR after 126days [^{14}C-triazole]-label (n=1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Study 1 -77d aerobic pre-incubation, anaerobic incubation CGA 71019: 27.2 % at 13 days d [^{14}C-triazole] label CGA 142856: 5.2 % AR d145 Study 2 (30d aerobic/ 50d anaerobic) CGA 71019: 5.2 % AR d 84

Soil photolysis ‡

Appendix 1 – list of endpoints

Soil photolysis ‡ Mineralisation after 30 d non-extractable residues after 30 d	 4.3 %AR (29 days) 4.2 % AR (29 days)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	no degradation products > 10 % detected

Appendix 1 – list of endpoints

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type (site)	X[26]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d) (report)	DT_{50} (d) 20 °C pF2/10kPa	χ^2 Error %	Model, Kinetics; Method of calculation
Silt loam (Weide, CH)		7.5	20 °C / 40 % MWHC	158 /524	158	2.92	SFO
Sandy loam (Pappelacker, CH)		7.4	20 °C / 40 % MWHC	55.3 / 184	55.3	4.06	SFO
Loam (Gartenacker, CH)		7.2	20 °C / 40 % MWHC	79.6 / 264	79.6	4.61	SFO
Silt loam (Itingen III, CH)	*0.838 ppm*	7.4	10 °C / 60 % FC	488 / 1620	(155)	2.95	SFO
Silt loam (Itingen III, CH)	*0.838 ppm*	7.4	20 °C / 60 % FC	142 / 471	(99.3)	7.63	SFO
Silt loam (Itingen III, CH)	*0.838 ppm*	7.4	20 °C / 30 % FC	480 / 1493	(207)	3.44	SFO
Silt loam (Itingen III, CH)	0.084 ppm	7.4	20 °C / 60 % FC	138 / 458	(96.5) geo mean of 4 replicates: 132	6.52	SFO
Silt loam (Le Barges, CH) Phenyl label		7.0	25 °C / 75 % FC	155 / 514	(188)	9.69	SFO
Silt loam (Le Barges, CH) Phenyl label		7.0	15 °C / 75 % FC	study not reliable **	--	--	SFO

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

Appendix 1 – list of endpoints

Silt loam (Le Barges, CH) Triazole Label	7.0	15 °C / 75 % FC	289 / 959	(159) geo mean of 2 replicates: 173	4.81	SFO
Silt loam (Le Barges, CH) Triazol label	7.3	25 °C / 75 % FC	134 / 444	163	2.53	SFO
Geometric mean/median (DT_{50})				**117 / 145**		

n.d. not determined n.g. not given
** based only on 3 sampling points, therefore not considered when calculating the average for this soil

CGA 71019 1,2,4-triazole	Aerobic conditions						
Soil type (site)	X	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d) (report)	DT_{50} (d) 20 °C pF 2/10 kPa	St. (r^2)	Model, Kinetics; Method of calculation
Sandy loam (Laacherhof, D)		6.4	20 °C / 40 % MWHC	6.3 / 20.8*	5.0**	n.g.	SFO
Loamy sand (Hanhofen, D)		5.8	20 °C / 40 % MWHC	9.9 / 32.7*	9.9**	n.g.	SFO
Silt loam (Laacherhof, D)		6.7	20 °C / 40 % MWHC	12.3 / 40.6*	8.2**	n.g.	SFO
Geometric mean/median (DT_{50})					**8.2 / 7.4****		

* calc. by the RMS n.g. not given
** agreed values from PRAPeR 12

CGA 179944	Aerobic conditions						
Soil type (site)	X	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d) (report)	DT_{50} (d) 20 °C pF 2/10 kPa	St. (r^2)	Model, Kinetics; Method of calculation
CGA 17944 as metabolite in studies with penconazole							

Appendix 1 – list of endpoints

Silt loam (Weide, CH)		7.5	20 °C / 40 % MWHC	7.3 / 24.2	(4.5*)**	0.965	SFO
Sandy loam (Pappelacker, CH)		7.4	20 °C / 40 % MWHC	8.6 / 28.4	(5.8*)**	0.983	SFO
CGA 179944 as parent							
Silt loam (Weide, CH)		7.5	20 °C / 40 % MWHC	25.4 / 84.5	15.5*	0.953	SFO
Sandy loam (Pappelacker, CH)		7.4	20 °C / 40 % MWHC	21.3 / 70.8	14.3*	0.956	SFO
Silt loam (Gartenacker,CH)		7.3	20 °C / 40 % MWHC	16.7 / 55.4	10.2*	0.981	SFO
Geometric mean/median (DT_{50})					**13.1 / 14.3**		

* calc. by RMS n.g. not given
** not considered when calculating the average

A **data gap** has been identified in PRAPeR 42 for degradation rates data in soil for metabolite CGA 179944 derived from acidic soils

Field studies ‡									
Parent	Aerobic conditions								
Soil type (all bare soils).	Location	X	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
loam	Schornbusch, D		6.6	0 - 20	67[1)]	221	0.9254	n. calc.	SFO
loamy sand	Meissner-Vockerode, D		5.7	0 - 20	84[1)]	290	0.7607	n. calc.	SFO
sand	Weeze-Wemb, D		5.8	0 - 20	84[1)]	279	0.8129	n. calc.	SFO
loamy silt	Plattling-See, D		6.9	0 - 20	107[2)]	355	0.634	n. calc.	1st

Appendix 1 – list of endpoints

Field studies ‡									
Parent	Aerobic conditions								
Soil type (all bare soils).	Location	X	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
clay loam	Codognan, F		7.7	0 - 20	(96[2)/ 3)]) 115 22	(319) 380 320707	0.714 Chi^2= 21.7% 0.95 Chi^2= 9.4	n. calc.	1st SFO FOMC[4)]
Geometric mean/median (DT50, n = 5)					**90/ 84** [5)]				

n.calc. not calculated 1) Origin software (Microcal, version 5) 2) linear recression (MS Excel) 3)without day 240, 4) alphaP= 0.168, betaP=0.361, Pini= 0.159 5) considering the SFO DT_{50} of 115 d from Codognon, F

pH dependence ‡ (yes / no) (if yes type of dependence)	no
Soil accumulation and plateau concentration ‡	In total 6 studies were available. 5 of the studies do not show accumulation. However, in one of the study soil accumulation cannot be definitely excluded since for the first 4 years of the 10-years study where penconazole was applied no residues were analysed.

Appendix 1 – list of endpoints

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Sand, Collombey (VS, CH)	1.29	7.8	n.calc.#	n.calc.#	10.03	786	0.89
Sandy clay loam (Vetroz, VS, CH)	3.29	6.7	n.calc.#	n.calc.#	69.80	2149	0.75
Loam (Les Evouettes, VS, CH)	2.12	6.1	n.calc.#	n.calc#	33.45	1602	0.77
Sand (Lakeland, FL, USA)	0.71	6.3	n.calc.#	n.calc#	24.42	3508	0.86
Clay loam (California)	1.12	7.8	n.calc.#	n.calc.#	11.2	998	0.798
Sandy loam (California)	0.77	4.9	n.calc.#	n.calc.#	31.3	4120	0.844
Silt loam (Arkansas)	0.29	5.9	n.calc.#	n.calc#	7.28	2510	0.801
Loam (New York)	1.82	6.5	n.calc.#	n.calc#	35.9	1970	0.816
Arithmetic mean/median					**27.9 / 27.9**	**2205 / 2060**	**0.82 / 0.81**
pH dependence, Yes or No			No				

not relevant

CGA 179944 ‡							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Silt loam (Weide, CH)	2.14	7.5	n.calc.#	n.calc.#	0.36	17	0.89
Silt loam (Vetroz, CH)	5.0	7.2	n.calc.#	n.calc.#	0.55	11	0.93
Loam (Gartenacker, CH)	2.59	7.13	n.calc.#	n.calc#	0.26	10	0.84
Loamy sand (Borstel, D)	1.5	5.8	n.calc.#	n.calc#	0.19	12	0.71
Arithmetic mean/median					**0,34 / 0,31**	**12,5 / 11,5**	**0,84 / 0,87**
pH dependence (yes or no)			No				

#: not relevant

CGA 710019 ‡
1,2,4-triazole

Appendix 1 – list of endpoints

Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Silty Clay (Alpaugh)	0.71	8.8	n.calc.#	n.calc.#	0.833	120**	0.897**
Clay Loam (Hollister)	1.77	6.9	n.calc.#	n.calc.#	0.748	43**	0.827**
Sand (Lakeland)	0.12	4.8	n.calc.#	n.calc #	0.234	202	0.885
Silty Clay Loam (Lawrenceville)	0.71	7.0	n.calc.#	n.calc #	0.722	104**	0.922**
Sandy Loam (Pachappa)	0.82	6.9	n.calc.#	n.calc #	0.720	89**	1.016**
Arithmetic mean/median*					**0.756***	**89*/****	**0.91*****
pH dependence (yes or no)			No				

#: not relevant * Mean values do not include the value for Lakeland soil due to its exceptionally low organic matter content
** agreed values from PRAPeR 12

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

Column leaching ‡	Eluation (mm): 200 mm (n = 4), 393 (n = 3) Time period (d): 2 d
	Eluation (mm): 200 mm: << 0.1 % Eluation (mm): 393 mm: < 2 % (LOQ = 3 µg/L) metabolites were not studied total residues/radioactivity retained in the soil column: 75 – 96 %
Aged residues leaching ‡	no studies performed
Lysimeter/ field leaching studies ‡	no studies performed

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 115 days Kinetics: SFO Worst case value from Field studies.

Appendix 1 – list of endpoints

Application data	Crop: cucurbits* Growth stage: at first signs of disease (earliest application at BBCH 14) Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 50 (all applications) Number of applications: 4 Interval (d): 7 Application rate(s): 4 x 50 g as/ha (worst case rate)

* For the PEC-calculation only the worst case application pattern (cucurbits) was used.

Appendix 1 – list of endpoints

PEC(s) (mg/kg)	application Actual (after 4th annual application)	application Time weighted average	Multiple application Actual (time period of multiple years)	Multiple application Time weighted average
Initial	**0.125**		0.141	
1	0.125	0.125	0.140	0.140
2 d	0.124	0.124	0.139	0.140
4 d	0.122	0.124	0.137	0.139
Long term 7 d	0.120	0.123	0.136	0.138
21	0.110	0.117	0.126	0.133
28 d	0.105	0.115	0.121	0.131
50 d	0.093	0 0.108	0.108	0.108
100 d	0 0.068	0.096	0.084	0.084
Plateau concentration				Min. plateau concentration in soil over 5 cm is 0.016 mg as/kg (according to the estimation 100% of the final plateau was reached after 10 years) Max. plateau concentration over 5 cm is 0.141 mg as/kg

Appendix 1 – list of endpoints

Metabolite CGA 179944			Molecular weight (g/mol): 286.1	
Method of calculation			Molecular weight relative to the parent: 1.01 DT_{50} (d): 15.5 Kinetics: SFO worst case value from lab studies.	
Application data			Application rate assumed: 4 x 50 g as/ha (assumed CGA 179944 worst case formation fraction 100%)	
$PEC_{(s)}$ (mg/kg)	application Actual (after 4th annual application)	application Time weighted average	Multiple application Actual (time period of multiple years)	Multiple application Time weighted average
Short term 24 h	0.013	0.013	0.015	0.015
2 d	0.013	0.013	0.015	0.015
4 d	0.013	0.013	0.015	0.015
Long term 7 d	0.013	0.013	0.015	0.015
28 d	0.012	0.013	0.014	0.015
50 d	0.011	0.013	0.013	0.015
100 d	0.008	0.012	0.010	0.014
Plateau concentration				not relevant

Appendix 1 – list of endpoints

Metabolite CGA 71019			Molecular weight (g/mol): 69.1	
Method of calculation			Molecular weight relative to the parent: 0.243 DT_{50} (d): 9.9 Kinetics: SFO worst case value from lab studies.	
Application data			Application rate assumed: 4 x 50 g as/ha (assumed CGA 71019 worst case formation fraction 100%))	
PEC(s) (mg/kg)	Actual (after 4th annual	Time weighted	Multiple Actual (time period of	Multiple Time weighted
Short term 24 h	0.002	0.002	0.002	0.002
2 d	0.002	0.002	0.002	0.002
4 d	0.002	0.002	0.002	0.002
Long term 7 d	0.002	0.002	0.002	0.002
28 d	0.002	0.002	0.002	0.002
50 d	0.002	0.002	0.002	0.002
100 d	0.001	0.002	0.002	0.002

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	parent stable at pH 4, 7, 9 (up to 50 °C, 7 d) parent stable at pH 5, 7, 9 (up to 25 °C, 30 d) CGA 179944: stable at pH 4, 7, 9 (50 °C, 5 d) CGA 71019: stable at pH 5,7,9 (25 °C, 30 d)
Photolytic degradation of active substance and metabolites above 10 % ‡	Data on the direct aqueous photolysis of penconazole or its degradates is not required since the molar absorption coefficient ε is < 10 $L.mol^{-1}.cm^{-1}$
Quantum yield of direct phototransformation in water at Σ > 290 nm	not relevant
Readily biodegradable ‡ (yes/no)	no

Appendix 1 – list of endpoints

Degradation in water / sediment										
Parent	max. in water: 97 % after 0 h, max. in sediment: 92.7 % after 56 d									
Water / sediment system	pH water phase	pH sed.	t. °C	DT_{50} - DT_{90} whole sys. (d)	St. (r^2)	DT_{50} - DT_{90} water (d)	St. (r^2)	DT_{50} - DT_{90} sed. (d)	St. (r^2)	Method of calculation
river (Rhine, CH)	7.7	7.3	20	534 / 1668 505 / > 678	n.g.	2 / 48 2.2 / 7.4	n.g.	505 / > 678	n.g.	Timme/Frehse series 1st order
pond (Juden weiher, CH)	7.9	7.6	20	1362 / 4495 > 706 / > 706	n.g.	2 / 49 3.3 / 11.0	n.g.	> 706 / > 706	n.g.	Timme/Frehse series 1st order
Geometric mean/median DT_{50}				853 / 948 597 / 606		2 / 2 2.7 / 2.8		597 / 606		Timme/Frehse series 1st order

n.g. not given

CGA 179944*	max in water: 17.3 % after 365d, max in sediment: 4.8 % after 365d

* DT_{50} of this metabolite was estimated to be 235 d (based on the river system). More detailed information is not available due limitation of the data set

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
River (Rhine, CH)	7.7	7.3	3.6 % after 365 d 8.4% after 678d	2.1 % after 120 d 4.3 % after 365 d	17.6% after 678d
pond (Judenweiher, CH)	7.9	7.6	3.5 % after 365 d 4.6% after 706d	5.3 % after 120 d 9.1 % after 365 d	18.7% after 706d

Appendix 1 – list of endpoints

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

Parent Parameters used in $FOCUS_{sw}$ step 1 and 2	Version control no. of FOCUS calculator: 1.1. Molecular weight (g/mol): 284.2 Water solubility (mg/L): 73 K_{fOC} (L/kg): 2205 (mean) DT_{50} soil (d): 113.8 days (Lab, in accordance with FOCUS SFO)* DT_{50} water/sediment system (d): (representative worst case from sediment water studies) DT_{50} water (d): 706 d DT_{50} sediment (d): 706 DT_{50} system (d): 706 Crop interception (%): 50 %** (step 2 only, earliest application at BBCH 14 in cucurbits)
Parameters used in $FOCUS_{sw}$ step 3 (if performed)	Version control no. of FOCUS calculator: 1.1. Vapour pressure: $3.66 * 10^{-4}$ Pa K_{fOC}: (L/kg): 2205 (mean) 1/n: 0.82 DT_{50} soil (d): 113.8 days (Lab, in accordance with FOCUS SFO)* DT_{50} water (d): 1000 d DT_{50} sediment (d): 706 Crop interception (%): n.a. (determined by program for scenario "fruiting vegetables in Southern Europe", first application at BBCH 10)
Application rate	Crop: vines and cucurbits Number of applications: 4 Interval (d): 7 d Application rate(s): 50 g as/ha (cucurbits, worst case application rate) Application window: June to September and March –May
Main routes of entry	drift and runoff/drainage

* Applicant selected arithmetic mean. Formally correct value would have been geometric mean (103 d) but applicant"s selection is more conservative
** At Step 2, correct value for crop interception for earliest application at BBCH 14 in cucurbits should be 25% (no impact on the actual risk assessment)

Appendix 1 – list of endpoints

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Parent (4 x 50 g/ha in cucurbits)	0 h	18.8		383	
	24 h	not given	18.1	not given	378
	2 d	not given	17.7	not given	380
	4 d	not given	17.5	not given	381
	7 d	not given	17.4	not given	381
	14 d	not given	17.3	not given	380
	21 d	not given	17.2	not given	379
	28 d	not given	17.2	not given	378
	42 d	not given	17.1	not given	375

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Parent Northern EU (4 x 50 g/ha in cucurbits)	0 h	1.97		41.0	
	24 h	not given*	not given*	not given*	not given*
	2 d	not given*	not given*	not given*	not given*
	4 d	not given*	not given*	not given*	not given*
	7 d	not given*	not given*	not given*	not given*
	14 d	not given*	not given*	not given*	not given*
	21 d	not given*	not given*	not given*	not given*
	28 d	not given*	not given*	not given*	not given*
	42 d	not given*	not given*	not given*	not given*
Southern EU (4 x 50 g/ha in cucurbits)	0 h	3.52		75.2	
	24 h	not given	3.46	not given	75.1
	2 d	not given	3.43	not given	75.1
	4 d	not given	3.42	not given	75.0
	7 d	not given	3.41	not given	74.9
	14 d	not given	3.39	not given	74.7
	21 d	not given	3.38	not given	74.4
	28 d	not given	3.37	not given	74.1

Appendix 1 – list of endpoints

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	42 d	not given	3.34	not given	73.6

* not relevant because Southern EU condition represents worst case situation

FOCUS step 3 modelling for intended uses in cucurbits (SEU) as worst case GAP (see step 2 results)

FOCUS STEP 3	Time	D6 ditch	R2 stream	R3 stream	R4 stream
Maximum PECsw, 4 x 50 g/ha in cucurbits (7 day interval)					
Water (µg as/L)	Global Maximum	0.212	0.184	0.393	0.556
Sediment (µg as/kg)	Global Maximum	0.224	20.076	6.785	4.421
Maximum PEC_{sw}, 1 x 50 g/ha in cucurbits					
Water (µg as/L)	Global Maximum	0.315	0.275	0.292	0.207
Sediment (µg as/kg)	Global Maximum	0.233	6.597	1.799	1.294

Metabolite CGA 71019

Parameters used in $FOCUS_{sw}$ step 1 and 2

Molecular weight: 69.1
Water solubility (mg/L): 730000
Soil or water metabolite: soil and water
K_{oc} (L/kg): (if necessary, soil metabolites): 89
DT_{50} soil (d): 11.8 days (Lab)
DT_{50} water/sediment system (d): (representative worst case from sediment water studies)
DT_{50} water (d): 300 d (worst case default)
DT_{50} sediment (d): 300 d (worst case default)
Crop interception (%): 50 (Step 2 only)
Maximum occurrence observed (% molar basis with respect to the parent):
Water/sediment: 5.6
Soil: 68

Appendix 1 – list of endpoints

Application rate	Crop: vines and cucurbits Number of applications: 4 Interval (d): 7 d Application rate(s): 50 g as/ha (cucurbits, worst case application rate) Application window: June to September and March –May
Main routes of entry	drift and runoff/drainage

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Metabolite CGA 71019 (4 x 50 g/ha in cucurbits)	0 h	5.62		4.99	
	24 h	not given	5.61	not given	4.98
	2 d	not given	5.60	not given	4.98
	4 d	not given	5.59	not given	4.97
	7 d	not given	5.57	not given	4.96
	14 d	not given	5.53	not given	4.92
	21 d	not given	5.48	not given	4.88
	28 d	not given	5.44	not given	4.84
	42 d	not given	5.35	not given	4.76

Appendix 1 – list of endpoints

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Metabolite CGA 71019 Northern EU (4 x 50 g/ha in cucurbits)	0 h	0.28		0.248	
	24 h	not given*	not given*	not given*	not given*
	2 d	not given*	not given*	not given*	not given*
	4 d	not given*	not given*	not given*	not given*
	7 d	not given*	not given*	not given*	not given*
	14 d	not given*	not given*	not given*	not given*
	21 d	not given*	not given*	not given*	not given*
	28 d	not given*	not given*	not given*	not given*
	42 d	not given*	not given*	not given*	not given*
Southern EU (4 x 50 g/ha in cucurbits)	0 h	0.544		0.483	
	24 h	not given	0.543	not given	0.482
	2 d	not given	0.543	not given	0.482
	4 d	not given	0.541	not given	0.481
	7 d	not given	0.540	not given	0.479
	14 d	not given	0.535	not given	0.475
	21 d	not given	0.531	not given	0.471
	28 d	not given	0.527	not given	0.468
	42 d	not given	0.518	not given	0.460

* not relevant because Southern EU condition represents worst case situation

Appendix 1 – list of endpoints

Metabolite CGA 179944 Parameters used in $FOCUS_{sw}$ step 1 and 2	Molecular weight: 286.1 Water solubility (mg/L): 400000 Soil or water metabolite: soil and water K_{oc} (L/kg): (if necessary, soil metabolites): 12.5 DT_{50} soil (d): 24 days (Lab) DT_{50} water/sediment system (d): (representative worst case from sediment water studies) DT_{50} water (d): 235 d (worst case default) DT_{50} sediment (d): 235 d (worst case default) Crop interception (%): 50 (Step 2 only) Maximum occurrence observed (% molar basis with respect to the parent): Water/sediment: 17.3 Soil: 18.9
Application rate	Crop: vines and cucurbits Number of applications: 4 Interval (d): 7 d Application rate(s): 50 g as/ha (cucurbits, worst case application rate) Application window: June to September and March –May
Main routes of entry	drift and runoff/drainage

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Metabolite CGA 179944 (4 x 50 g/ha in cucurbits)	0 h	12.8		1.59	
	24 h	not given	12.8	not given	1.58
	2 d	not given	12.8	not given	1.58
	4 d	not given	12.7	not given	1.58
	7 d	not given	12.7	not given	1.58
	14 d	not given	12.5	not given	1.57
	21 d	not given	12.4	not given	1.55
	28 d	not given	12.3	not given	1.53
	42 d	not given	12.0	not given	1.50

Appendix 1 – list of endpoints

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Metabolite CGA 179944 Northern EU (4 x 50 g/ha in cucurbits)	0 h	1.05		0.13	
	24 h	not given*	not given*	not given*	not given*
	2 d	not given*	not given*	not given*	not given*
	4 d	not given*	not given*	not given*	not given*
	7 d	not given*	not given*	not given*	not given*
	14 d	not given*	not given*	not given*	not given*
	21 d	not given*	not given*	not given*	not given*
	28 d	not given*	not given*	not given*	not given*
	42 d	not given*	not given*	not given*	not given*
Southern EU (4 x 50 g/ha in cucurbits)	0 h	1.89		0.235	
	24 h	not given	1.89	not given	0.235
	2 d	not given	1.88	not given	0.235
	4 d	not given	1.88	not given	0.234
	7 d	not given	1.87	not given	0.233
	14 d	not given	1.85	not given	0.231
	21 d	not given	1.83	not given	0.228
	28 d	not given	1.81	not given	0.226
	42 d	not given	1.78	not given	0.221

* not relevant because Southern EU condition represents worst case situation

Appendix 1 – list of endpoints

PEC ground water (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter) **	Modelling using FOCUS model(s), with appropriate $FOCUS_{gw}$ scenarios, according to FOCUS guidance. Model(s) used: (with version control no.(s)) FOCUS PELMO 3.3.2 Scenarios (list of names): C – Châteaudun P – Piacenza O – Porto S – Sevilla T - Thiva Crop: cucurbits (tomatoes used as surrogate with crop interception: 50 %) vines (crop interception: 40 %) Arithmetic mean or median parent DT_{50lab}: 113.8 d* (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.2). K_{OC}: parent, arithmetic mean or median: 2205 $^1/_n = 0.82$. Median CGA 179944 DT_{50lab}: 10.1 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.2). K_{OC}: CGA 179944, arithmetic mean: 12.5 L/kg[*2], $^1/_n = 0.84$. Formation fraction (parent → CGA 179944): 0.76. Arithmetic mean CGA 71019 DT_{50lab}: 6.4 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.2). K_{OC}: CGA 71019, arithmetic mean: 89 L/kg[*2], $^1/_n = 0.92$. Formation fraction (CGA 179944 → CGA 71019): 1.0
Application rate	Application rate: tomatoes: 4 x 50 g /ha. vines: 4 x 25 g/ha (North: C,H,K) vines 3 x 40 g/ha (South: P,S,O,T) No. of applications: 3/4 (all scenarios modelled with minimum application interval of 7 d) Time of application (month or season): spring/summer

* Applicant selected arithmetic mean. Formally correct value would have been geometric mean (103 d) but applicant"s selection is more conservative

Appendix 1 – list of endpoints

** based on the original PECgw assessment from DAR since input parameter values were not significantly different from the values agreed upon at the PRAPeR Expert Meeting 47 (see Addendum 2 for comparison), and a final PECgw assessment is not possible (see **data gap** on CGA 179944 for acidic soil conditions and identity/ characterisation of unknown U1); this PECgw assessment covers only non-acidic soil condition scenarios

A **data gap** was identified in PRAPeR 42 for FOCUS groundwater modelling for all the FOCUS scenarios relevant to vines uses with the highest application rate (i.e. modelling with Piacenza, Sevilla, Porto and Thiva scenarios with an application rate of 25 g/ha with 4 applications and modelling with Châteaudun, Hamburg and Kremsmünster scenarios with an application rate of 40 g/ha with 3 applications) and for a second modelling with FOCUS PEARL.

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

FOCUS PELMO 3.3.2 Cucurbits	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			CGA 179944	CGA 71019
	Châteaudun	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	0.039	< 0.001
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001

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

FOCUS PELMO 3.3.2 Vines	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			CGA 179944	CGA 71019
	Châteaudun	< 0.001	0.007	< 0.001
	Hamburg	< 0.001	0.016	< 0.001
	Kremsmünster	< 0.001	0.006	< 0.001
	Piacenza	< 0.001	0.060	< 0.001
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	0.003	< 0.001

$PEC_{(gw)}$ From lysimeter / field studies

Compound	1st year	2nd year	3rd year
Annual average (µg/L)	no studies performed	no studies performed	no studies performed

Appendix 1 – list of endpoints

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

Direct photolysis in air ‡	not studied
Quantum yield of direct phototransformation	not studied
Photochemical oxidative degradation in air ‡	DT_{50} of 47.7 hours (1.99 d) derived by the Atkinson model (version v1.91). OH (24 h) concentration assumed = 0.5 10^{6}/ cm^{-3} DT_{50} of 15.9 hours (1.32 d) derived by the Atkinson model (version v1.85). OH (12 h) concentration assumed = 1.5 10^{6}/ cm^{-3} (USA)
Volatilisation ‡	No reliable data available
	No reliable data available
Metabolites	None

PEC_{air}

Method of calculation	not performed*

$PEC_{(a)}$

Maximum concentration	not calculated*

* Volatilisation from treated leaves after application of A-6209 G may occur.
It is a justified assumption that these air-borne residues are removed efficiently from air via degradation of penconazole residues by OH-radicals which proceeds with a DT_{50} value in the range of 1.32 to 1.99 d depending on the scenario chosen.. Therefore, it is not expected that penconazole would be present in air for extended time periods or be transported over significant distances.
The effective predicted environmental concentration in air (PEC_a) is therefore negligible.

Appendix 1 – list of endpoints

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: penconazole CGA 71019 CGA 179944 Surface Water: penconazole CGA 179944 was formed in amounts > 10 % in water Ground water: penconazole CGA 179944 CGA 71019 Air: penconazole

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

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

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

R53 – Penconazole can be classified as ”not readily biodegradable”:

Appendix 1 – list of endpoints

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

Species	Test substance	Time scale	Endpoint (mg/kg bw/d)	Endpoint (mg/kg feed)
Birds ‡				
Anas platyrhynchos	Penconazole	Acute	LD_{50} > 1590	Not relevant
	Preparation	Acute	No data submitted – justification accepted	
Colinus virginianus	Metabolite CGA 131013	Acute	> 1342	> 5000
Anas platyrhynchos	Penconazole	Short-term	LD_{50} > 1845	LC_{50} > 5620
Anas platyrhynchos	Penconazole	Long-term	NOEL 28.6 *	NOEL 300
Coturnix coturnix	Metabolite 1,2,4-triazole = CGA 71019	Long-term	NOEL > 316	Literature data, not validated
Mammals ‡				
Rabbit	Penconazole	Acute	LD_{50} 971	Not relevant
Rat	Preparation	Acute	LD_{50} 2574 (257 mg as)	Not relevant
Rat	Metabolite triazolyl alanine (CGA 131013)	Acute	LD_{50} > 5000	Not relevant
Rat	Metabolite triazolyl acetic acid (CGA 142856)	Acute	LD_{50} > 5000	Not relevant
Rat	Penconazole	Long-term, 2-generation repro study	NOAEL 20	NOEC 250
Rat	Metabolite triazolyl alanine (CGA 131013)	Long-term, 2-generation repro study	NOAEL 100	NOEC 2000
Additional higher tier studies ‡ No data submitted – justification accepted. Not relevant				

Appendix 1 – list of endpoints

* recalculated to 100% purity of the a.s. since purity lower than stated by the specification

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

Birds: worst case exposure: cucurbits, Northern and Southern Europe, 4 × 0.05 kg as/ha, 7 day interval
Mammals: worst case exposure: grapevine, Southern Europe, 3 × 0.04 kg as/ha, 7 day interval

Parent				
Indicator species/Category[2]	Time scale	ETE (mg/kg/day)	TER	Annex VI Trigger[3]
Tier 1 (Birds)				
Medium herbivorous bird	Acute	5.95	> 267	10
Insectivorous bird	Acute	2.70	> 589	10
Medium herbivorous bird	Short-term	3.34	> 552	10
Insectivorous bird	Short-term	1.51	> 1223	10
Medium herbivorous bird	Long-term	1.77	16	5
Insectivorous bird	Long-term	1.51	19	5
Higher tier refinement (Birds)				
Not required	Acute			10
Not required	Short-term			10
Not required	Long-term			5
Tier 1 (Mammals)				
Small herbivorous mammal	Acute	8.03	121	10
Small herbivorous mammal	Long-term	2.71	7.4	5
Higher tier refinement (Mammals)				
Not required	Acute			
Not required	Long-term			

Appendix 1 – list of endpoints

Metabolite CGA 131013 (ETE assumed to be 68 % of the maximum value estimated for parent)				
Indicator species/Category[2]	Time scale	ETE (mg/kg/day)	TER	Annex VI Trigger[3]
Tier 1 (Birds)				
Medium herbivorous bird	Short-term	2.27	> 591	10
Higher tier refinement (Birds)				
Not required	Short-term			10
Tier 1 (Mammals)				
Small herbivorous mammal	Acute	4.82	1037	10
Small herbivorous mammal	Long-term	1.84	54	5
Higher tier refinement (Mammals)				
Not required	Acute			
Not required	Long-term			

Long-term risk to birds from secondary poisoning occurring by feeding on earthworms exposed to penconazole residues			
Parameter	**Cucurbits**	**Grapevine (NEU)**	**Grapevine (SEU)**
PEC_{soil} (mg as/kg) [1)]	0.1244 / 0.141 [3)]	0.0622	0.0764
BCF [2)]	1.21	1.21	1.21
PEC_{worm} (mg as/kg bw)	0.15 / 0.17 [3)]	0.075	0.092
NOEL mg as/kg bw/d	28.6	28.6	28.6
TER	173 / 152 [3)]	347	283
Trigger	5	5	5

1. based on maximum predicted penconazole concentration in soil following multiple application assuming 50 % foliar interception
2. BCF = C_{worm}/C_{soil} = (0.84 + 0.01 K_{ow}) / (f_{oc} * K_{oc}). Penconzole K_{ow} = 5248; f_{oc} = 0.02; K_{oc} = 2205.
3. for worst case GAP in addition based on maximum predicted concentration in soil following multiple application assuming 50 % foliar interception and potential accumulation after multiple year application

Appendix 1 – list of endpoints

Long-term risk to birds from secondary poisoning by feeding on fish exposed to penconazole residues				
Parameter	**Cucurbits (NEU)**	**Cucurbits (SEU)**	**Grapevine (NEU)**	**Grapevine (SEU)**
PECsw (µg as/L) [1)]	1.97	3.52	1.51	2.35
BCF [2)]	320	320	320	320
PEC_{fish} (mg as/kg bw)	0.630	1.13	0.483	0.752
NOEL mg as/kg bw/d	28.6	28.6	28.6	28.6
TER	216	121	282	181
Trigger	5	5	5	5

1. maximum predicted penconazole concentration in water following the final application (FOCUS Step 2).
2. whole fish BCF from bioaccumulation study (Suprenant, 1988 IIA 8.2.3/01, chapter B.9.2.1.3).

Estimated concentrations of penconazole in spray dilutions and potential drinking water intake levels for birds						
Crop	**Application volume (L/ha)**	**Spray dilution**		**Potential exposure ($PEC_{drinking\ water}$)**	**ETE [2)]**	**TER [3)]**
		Application rate (kg as/ha)	**Maximum in-use spray concentration (mg/L) [1)]**	**Correction factor 1/5 (mg/L)**	**(mg a.s./kg bw/day)**	**Trigger: 10**
Cucurbit	1000 - 1500	0.05	50	10	2.70	589
Grape NEU	200 - 1000	0.025	125	25	6.75	236
Grape SEU	200 - 1000	0.04	200	40	10.78	147

1. minimum water volumes are used in the calculations as a worst case
2. ETE calculated according to Guidance Document on Risk Assessment for Birds and Mammals for a 10 g bird as worst case (see chapter 4) with total water ingestion rate = 0.0027 L/d
3. based on acute oral LD_{50} value of > 1590 mg/kg body weight (*Anas platyrhynchus*)

Appendix 1 – list of endpoints

Long-term risk to mammals from secondary poisoning occurring by feeding on earthworms exposed to penconazole residues			
Parameter	**Cucurbits**	**Grapevine (NEU)**	**Grapevine (SEU)**
PEC_{soil} (mg as/kg)[1]	0.1244 / 0.141 [3]	0.0622	0.0764
BCF [2]	1.21	1.21	1.21
PEC_{worm} (mg as/kg bw)	0.15 / 0.17 [3]	0.075	0.092
NOEL mg as/kg bw/d	20	20	20
TER	95 / 83 [3]	190	155
Trigger	5	5	5

1. based on maximum predicted penconazole concentration in soil following multiple application assuming 50 % foliar interception
2. BCF = C_{worm}/C_{soil} = (0.84 + 0.01 K_{ow}) / (f_{oc} * K_{oc}). Penconzole K_{ow} = 5248; f_{oc} = 0.02; K_{oc} = 2205.
3. for worst case GAP in addition based on maximum predicted concentration in soil following multiple application assuming 50 % foliar interception and potential accumulation after multiple year application

Long-term risk to mammals from secondary poisoning by feeding on fish exposed to penconazole residues				
Parameter	**Cucurbits (NEU)**	**Cucurbits (SEU)**	**Grapevine (NEU)**	**Grapevine (SEU)**
PECsw (µg as/L) [1]	1.97	3.52	1.51	2.35
BCF [2]	320	320	320	320
PEC_{fish} (mg as/kg bw)	0.630	1.13	0.483	0.752
NOEL mg as/kg bw/d	20	20	20	20
TER	244	136	310	205
Trigger	5	5	5	5

1. maximum predicted penconazole concentration in water following the final application (FOCUS Step 2).
2. whole fish BCF from bioaccumulation study (Suprenant, 1988 IIA 8.2.3/01, chapter B.9.2.1.3).

Appendix 1 – list of endpoints

Estimated concentrations of penconazole in spray dilutions and potential drinking water intake levels for mammals						
Crop	**Application volume (L/ha)***	**Spray dilution**		**Potential exposure ($PEC_{drinking\ water}$)**	**ETE [2)]**	**TER [3)]**
		Application rate (kg as/ha)	**Maximum in-use spray concentration [1)] (mg/L)**	**Correction factor 1/5 (mg/L)**	**(mg a.s./kg bw/day)**	**Trigger: 10**
Cucurbit	1000 - 1500	0.05	50	10	1.43	679
Grape NEU	200 - 1000	0.025	125	25	3.58	271
Grape SEU	200 - 1000	0.04	200	40	5.73	170

1. minimum water volumes are used in the calculations as a worst case
2. ETE calculated according to Guidance Document on Risk Assessment for Birds and Mammals for a 25 g mammal as worst case (see chapter 4) with total water ingestion rate 0.00358 L/day
3. based on acute oral LD_{50} value of 971 mg/kg body weight (rabbit)

Appendix 1 – list of endpoints

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] (µg/L)
Laboratory tests ‡				
Fish				
Oncorhynchus mykiss	Penconazole	96 hr acute (static)	Mortality, LC_{50}	1130 $_{mm}$ [3)]
Pimephales promelas	Penconazole	Chronic 30 d (flow-through) ELS	NOEC [2)]	320 $_{mm}$ [3)]
Oncorhynchus mykiss	Preparation	96 hr (static)	Mortality, LC_{50}	6800 product $_{mm}$ (680 as)
Oncorhynchus mykiss	Preparation	Long-term 21 d (flow-through)	NOEC	240 as $_{mm}$ 2400 product $_{mm}$
Oncorhynchus mykiss	Metabolite CGA 71019	96 hr acute (static)	Mortality, LC_{50}	498000 $_{mm}$ [4)]
Oncorhynchus mykiss	Metabolite CGA 71019	Long-term 28 d (semi-static)	NOEC, Behaviour	3200 $_{mm}$
Oncorhynchus mykiss	Metabolite CGA 179944	96 hr acute (static)	Mortality, LC_{50}	85000 $_{mm}$
Aquatic invertebrate				
Daphnia magna	Penconazole	48 hr (static)	Mortality, EC_{50}	6750 $_{nom}$
Daphnia magna	Penconazole	21 d (semi-static)	Reproduction, NOEC	60 $_{mm}$ [3)]
Daphnia magna	Preparation	48 hr (static)	Mortality, EC_{50}	36000 product 3880 as $_{mm}$
Daphnia magna	Preparation	21 d (semi-static)	Reproduction, NOEC	320 product 32 as $_{mm}$
Daphnia magna	Metabolite 1,2,4-triazole (CGA 71019)	48 hr (static)	Mortality, EC_{50}	> 100000 $_{mm}$
Daphnia magna	Metabolite 179944	48 hr (static)	Mortality, EC_{50}	> 120000 $_{mm}$
Sediment dwelling organisms				

Appendix 1 – list of endpoints

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (µg/L)
Chironomus riparius	Penconazole	28 d (static)	NOEC water NOEC sediment	800 $_{mm}$ (2000 $_{nom}$) 25200 µg/kg sediment $_{nom}$
Algae				
Selenastrum capricornutum	Penconazole	72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	2000 $_{mm}$ 4900 $_{mm}$
Scenedesmus subspicatus	Preparation	72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	390 as $_{mm}$ 3900 product 790 as $_{mm}$ 7900 product
Selenastrum capricornutum	Metabolite 1,2,4-triazole (CGA 71019)	72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	8200 $_{mm}$ **5)** 22500 $_{mm}$ **5)**
Selenastrum capricornutum	Metabolite CGA 179944	72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	45600 $_{mm}$ 57900 $_{mm}$
Higher plant				
Lemna gibba	Penconazole	14 (static)	Dry weight Biomass: E_bC_{50} Frond number EC_{50} NOEC	96 $_{nom}$ **3)** 190 $_{nom}$ **3)** 96 $_{nom}$ **3)**
Microcosm or mesocosm tests				
Not performed, not relevant				

[1] indicate whether based on nominal ($_{nom}$ = analytically confirmed) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether endpoints are presented as units of preparation or as. No indication means effects related to compound indicated in column "Test substance".

[2] There is concern about a relevant endocrine potential of penconazole (Zarn, Bruschweiler and Schlatter, EHP 2003, 111(3):255-61; classification as "HPV and/or persistent and/or exposure expected in humans and wildlife, with insufficient data" in a working document of the EU Commission on the implementation of the community strategy on endocrine disruptors (EU Commission, 2004). Further data on the potential endocrine activity in fish is required for the final risk assessment[3] endpoints re-calculated to 100% purity of active substance to account for low purity of test material

[4] endpoint agreed at PRAPeR 13

[5] endpoint agreed at PRAPeR 13 Meeting and amended at PRAPeR 43 Meeting

Appendix 1 – list of endpoints

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

FOCUS Step1

Worst case exposure: cucurbits, Northern and Southern Europe, 4 × 0.05 kg as/ha, 7 day interval

Test substance	Organism	Toxicity endpoint (µg as/L)	Time scale	$PEC_{sw}i$ µg/L	PEC_{twa}	TER	Annex VI Trigger[1]
as	Fish	1130	Acute	18.76	-	69	100
as	Fish	360	Long-term	18.76	-	19	10
as	Aquatic invertebrates	6750	Acute	18.76	-	360	10
as	Aquatic invertebrates	60	Long-term	18.76	-	4	10
as	Algae	2000	Long-term	18.76	-	107	10
as	Aquatic plants	96	Long-term	18.76	-	6	10
as	Sediment-dwelling organisms	800 µg/L 25200 µg/kg sed.	Long-term	18.76 $PEC_{sed\ i}$: 383 µg/kg	-	43 66	10
Metabolite CGA 71019	Fish	498000	Acute	5.614	-	89000	100
Metabolite CGA 71019	Fish	3200	Long-term	5.614	-	570	10
Metabolite CGA 71019	Aquatic invertebrates	100000	Acute	5.614	-	18000	100
Metabolite CGA 71019	Algae	8200	Long-term	5.614	-	1588	10
Metabolite 179944	Fish	85000	Acute	12.8	-	6600	100
Metabolite 179944	Aquatic invertebrates	> 120000	Acute	12.8	-	9400	100
Metabolite 179944	Algae	45600	Long-term	12.8	-	3600	10

Appendix 1 – list of endpoints

Test substance	Organism	Toxicity endpoint (µg as/L)	Time scale	$PEC_{sw}i$ µg/L	PEC_{twa}	TER	Annex VI Trigger[1]
Preparation	Fish	680	acute	18.76 (as)	-	36	100
Preparation	Fish	240	Long-term	18.76 (as)	-	13	10
Preparation	Aquatic invertebrates	3880	Acute	18.76 (as)	-	207	100
Preparation	Aquatic invertebrates	32	Long-term	18.76 (as)	-	2	10
Preparation	Algae	390	Long-term	18.76 (as)	-	21	10

FOCUS Step 2

Worst case exposure: Cucurbits, Southern Europe, 4 × 0.05 kg as/ha, 7 day interval

Test substance	N/S[1]	Organism[2]	Toxicity endpoint (µg as/L)	Time scale	PEC_{max}[3] µg/L	TER	Annex VI Trigger[4]
as	S	Fish	1130	Acute	3.52	321	100
as	S	Aquatic invertebrates	60	Long-term	3.52	17	10
as	S	Aquatic plants	96	Long-term	3.52	27	10
Preparation	S	Fish	680	Acute	3.52 (as)	193	100
Preparation	S	Aquatic invertebrates	32	Long-term	3.52 (max) 3.38 (twa)	9 9.5 [4)]	10

[1)] indicate whether Northern or Southern
[2)] include critical groups which fail at Step 1.
[3)] indicate whether maximum or twa values have been used.
[4)] under more realistic exposure conditions (FOCUS Step 3) maximum PECsw and PECsed values are approximately 85% and 70% lower than modelled maximum values for Step 2. Therefore the TER will exceed Annex VI trigger 10.

Appendix 1 – list of endpoints

	Active substance	Metabolite 1,2,4-triazole (CGA 71019)
logPow	3.72	- 1.0
Bioconcentration factor (BCF)[1] ‡	320	Not relevant
Annex VI Trigger for the bioconcentration factor	100	
Clearance time (days) (CT_{50})	< 3 d (TAR)	
(CT_{90})	7 d	
Level and nature of residues (%) in organisms after the 14 day depuration phase	120 µg as/kg Whole fish	

[1] only required if log Pow >3.

* based on total ^{14}C or on specific compounds

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
as ‡	-	-
Preparation (units refer to the preparation)	> 178	> 30
Preparation (units refer to the preparation)	> 112	> 30
Preparation (units refer to the preparation)	> 116	> 30
Metabolite 1	-	-
Field or semi-field tests		
not required		

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

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

Cucurbit group; 0.5 L/ha

Test substance	Route	Hazard quotient	Annex VI Trigger
as	contact	-	50
as	oral	-	50
Preparation	contact	< 16.4	50
Preparation	oral	< 2.8	50

Appendix 1 – list of endpoints

Test substance	Route	Hazard quotient	Annex VI Trigger
Preparation	contact	< 16.4	50
Preparation	oral	< 4.4	50
Preparation	contact	< 16.4	50
Preparation	oral	< 4.3	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	Endpoint	Effect (LR_{50} g/ha[1])
Typhlodromus pyri ‡	Preparation TOPAS 100 EC A-6209 G	Mortality	10 g as/ha: 43 % 50 g as/ha: 69 % 100 g as/ha: 79 %
		Fecundity	10 g as/ha: 72 % 50 g as/ha: not determined 100 g as/ha: not determined
Aphidius rhopalosiphi ‡	Preparation TOPAS 100 EC A-6209 G	Mortality	10 g as/ha: -2 % 50 g as/ha: 28 % 100 g as/ha: 59 %
		Fecundity	10 g as/ha: 56 % 50 g as/ha: 84 % 100 g as/ha: not determined

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

Hazard quotients for other arthropods (HQ approach)

Crop and application rate: In-field worst case exposure: cucurbits, 4 × 0.05 kg as/ha, 7 day interval
Off-field worst case exposure: grapevines Southern Europe 3 × 0.04 kg as/ha, 7 day interval, 3 m distance

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field [1]	Trigger
Preparation	*Typhlodromus pyri*	> 10	< 9.40 soil < 11.04 foliar	< 0.55 foliar (3 m)	2
Preparation	*Aphidius rhopalosiphi*	> 50	< 1.88 soil < 2.21 foliar	< 0.11 foliar (3 m)	2

[1] indicate distance assumed to calculate the drift rate

Appendix 1 – list of endpoints

Toxicity/exposure ratios for other arthropods (TER approach)

Test substance	Species	Effect (LR50 g /ha)	TER off-field [1, 2]	Trigger value
Standard laboratory test				
A-6209 G	*Typhlodromus pyri*	> 10 g as/ha	Cucurbits: > 24(1 m) Grapevine (NE): > 14 (3 m) Grapevine (SE): > 9.2 (3 m)	10
A-6209 G	*Aphidius rhopalosiphi*	> 50 g as/ha	Cucurbits: > 122 (1 m) Grapevine (NE): > 68 (3 m) Grapevine (SE): > 46 (3 m)	10
Extended laboratory test				
A-6209 G	*Typhlodromus pyri*	> 9.6 g as/ha	Grapevine (SE): > 8.8 (3 m)	5

1 TER approach used by the German Federal Environmental Agency (Schulte et al., 1999: UWSF 11(5) 261-266).
PEC off-crop = Application rate × drift factor/VDF(5). Application rate includes MAF for multiple applications. Without VDF if product is sprayed on plants
2 Semi-field and field study indicate acceptable effects on sublethal parameters for both species at PECoff-field

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g as/ha)[1, 2]	Endpoint	% adverse effect[3]	Trigger value
Further laboratory tests - inert substrate, further test organisms						
Aphidius matricariae	adult	TOPAS A-6209 G; glass plates; 24 h (mortality), 11 d (parasitised aphids)	12 g as/ha	Mortality / parasitized aphids	12.5 / 24.5	50 %
P. cupreus	adult	Preparation TOPAS 100 EC A-6209 G; quartz sand; 14 d	10 g as/ha 50 g as/ha 100 g as/ha	Mortality / food consumption	0 / 9.6 0 / 15.7 0 / - 16.9	50 %
Orius laevigatus	2nd instar larvae	Preparation TOPAS 100 EC A-6209 G; glass cage; 9 d (mortality); further 10 d (reproduction)	10 g as/ha 50 g as/ha 100 g as/ha	Mortality / reproduction	No effect on mortality and reproduction at every concentration (test not valid)	50 %

Appendix 1 – list of endpoints

Species	Life stage	Test substance, substrate and duration	Dose (g as/ha)[1, 2]	Endpoint	% adverse effect[3]	Trigger value
Extended laboratory tests - natural substrate; fresh residues						
Typhlodromus pyri	juveniles	Preparation TOPAS A-6209 G; leaves; 18 d	9.6 g as/ha	Mortality Fecundity	31.5 55	50 %
Orius laevigatus	Nymph (second instar)	Preparation CGA71818 CG 100 (A-6209 G); leaves (*Phaseolus vulgaris*; 22 d	200 g as/ha 100 g as/ha	Mortality (9 DAT) / fecundity	7 / no effect 0 / no effect	50 %
Chrysoperla carnea	Larvae	Preparation CGA71818 CG 100 (A-6209 G); leaves (*Phaseolus vulgaris*; 27 d	200 g as/ha 100 g as/ha 50 g as/ha 5.54 g as/ha	Mortality / fecundity	5 / no effect 12 / no effect 11 / no effect 11 / no effect	50 %
Coccinella septempunctata	Larvae	Preparation CGA71818 CG 100 (A-6209 G); plants were sprayed; leaves tested (*Phaseolus vulgaris*); 14 d	200 g as/ha 100 g as/ha 50 g as/ha 5.54 g as/ha	Mortality / egg production	10.2 / no effect 19.0 / no effect 7.5 / no effect 2.4 / no effect	50 %

[1] indicate whether initial or aged residues

[2] for preparations indicate whether dose is expressed in units of as or preparation

[3] indicate when the effect is not adverse

Appendix 1 – list of endpoints

Field or semi-field tests
Aphidius rhophalosiphi: semi-field Test design: A. rhophalosiphi wasps were released into exposure test units consisting of summer barley planted in plastic containers and covered with a fine mesh netting (nominal test concentrations: 2.5 g as/ha; 15.2 g as/ha; 75.9 g as/ha; 135 g as/ha). The test units were kept under natural semi-field conditions. Aphids (Rhopalosiphum padi) were used as hosts for the parasitoids. After 48 h exposure in the field, the barley plants with the aphids were transferred to an environmental chamber. The number of parasitised aphids (mummies) were assessed 11 and 10 days later. Results: No adverse effect on reproduction (parasitation capacity) of Aphidius rhophalosiphi and no repellent effect were observed in any treatment with A 6209 G. Acari: Phytoseiidae: field study Test design: Potential effects of multiple applications of the fungicides TOPAS 100 EC (A-6209G) to predatory mite populations were studied in a Dutch apple orchard. The pesticide was applied at the highest recommended field rate of about 50 g as/ha and at a 20 % drift rate of about 10 g as/ha. Application was performed 5 times with a 11 - 13 day spray interval. From each plot 180 sampling units (flower clusters plus leaves at the first 2 samples and leaves at lager samples) were collected at 7 sampling dates to assess predatory mite densities and species composition. In addition 30 leaves were collected on 6 occasions to generate information on life stage distribution and prey occurrence. Samples were taken 9 and 5 days before the first application, just before the second and fourth application and about 1, 4 and 7 weeks after the last application. Results: No statistically significant adverse effects on predatory mites were observed in the TOPAS 100 EC 8A-6209G) treated plots.

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

Test organism	Test substance	Time scale	Endpoint[1]
Earthworms			
Eisenia fetida	as ‡ Penconazole	Acute 14 days	LC_{50corr} > 331.5 [3]mg as/kg dw soil (248.6 [3]kg as/ha)
Eisenia fetida	as ‡ Penconazole	Chronic 8 weeks	See preparation
Eisenia fetida	Preparation TOPAS A-6209 G	Acute 14 days	LC_{50corr} > 50 mg as/kg dw soil (37.5 kg as/ha)

Appendix 1 – list of endpoints

Test organism	Test substance	Time scale	Endpoint[1]
Eisenia fetida	Preparation TOPAS A-6209 G	Chronic 8 weeks	$NOEC_{corr}$ = ≥ 0.17 mg as/kg d.w.soil (125 g as/ha)
Eisenia fetida	Preparation TOPAS A-6209 G	Chronic 8 weeks	$NOEC_{corr}$ = 5 mg as/kg dw soil (3.75 kg as/ha)
Eisenia fetida	Metabolite CGA 71019	Acute 14 days	LC_{50} > 1000 mg/kg dw soil (750 kg/ha)
Eisenia fetida	Metabolite CGA 71019	Chronic 8 weeks	NOEC = 1 mg/kg dw soil
Eisenia fetida	Metabolite CGA 179944	Acute 14 days	LC_{50} > 1000 mg/kg dw soil (750 kg/ha)
Eisenia fetida	Metabolite CGA 179944	Chronic	Not relevant
Other soil macro-organisms			
Soil mite	as ‡	Chronic	Not relevant
	Preparation	Chronic	Not relevant
	Metabolite		Not relevant
Collembola			
	as ‡ Penconazole	Chronic 4 weeks	See preparation
Folsomia candida	Preparation TOPAS A-6209 G	Chronic 4 weeks	$NOEC_{corr}$ = 49.4 mg as/kg dw soil (37.05 kg as/ha)
Folsomia candida	Metabolite CGA 71019	Chronic 4 weeks	NOEC = 1.8 mg as/kg dw soil (1.35 kg as/ha)
	Metabolite CGA 179944	Chronic	Not relevant
Soil micro-organisms			
Nitrogen mineralisation	Preparation TOPAS A-6209 G	28 days	3 % effect at day 28 at 0.32 mg as/kg dw soil (240 mg as/ha)
	Metabolite CGA 71019	28 days	2 % effect at day 28 at 0.35 mg/kg dwsoil (263 mg/ha)
	Metabolite CGA 179944	28 days	8 % effect at day 28 at 0.20 mg/kg dw soil (150 mg/ha)
Dehydrogenase activity	Preparation TOPAS A-6209 G	28 days	5 % effect at day 28 at 0.32 mg as/kg dw soil (240 mg as/ha)

Appendix 1 – list of endpoints

Test organism	Test substance	Time scale	Endpoint[1]
Carbon mineralisation	Metabolite CGA 71019	28 days	0 % effect at day 28 at 0.35 mg/kg dw soil (263 mg/ha)
	Metabolite CGA 179944	28 days	0 % effect at day 28 at 0.20 mg/kg dw soil (150 mg/ha)
Field studies[2]			
Litter bag: A plateau concentration of 0.073 mg penconazole/kg followed by a further application of 50 g as/ha, had no significant effect upon decomposition of wheat straw in litter-bags.			

1 indicate where endpoint has been corrected due to log $P_{o/w}$ > 2.0 (e.g. LC_{50corr})

2 litter bag, field arthropod studies not included at 8.3.2/10.5 above and earthworm field studies

3 endpoints re-calculated to 100% purity of active substance to account for low purity of test material

Toxicity/exposure ratios for soil organisms

Crop and application rate

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia fetida	as ‡ Penconazole	Acute 14 days	PEC_{accu} 0.141 mg/kg	> 2351	10
Eisenia fetida	as ‡ Penconazole	Chronic 8 weeks	PEC_{accu} 0.1414 mg/kg	See preparation	5
Eisenia fetida	Preparation TOPAS A-6209 G	Acute 14 days	PEC_{accu} 0.1414mg/kg	>355	10
Eisenia fetida	Preparation TOPAS A-6209 G	Chronic 8 weeks	PEC_{accu} 0.1414 mg/kg	>35.5	5
Eisenia fetida	Metabolite CGA 71019	Acute 14 days	PEC_{accu} 0.002 mg/kg	> 500000	10
Eisenia fetida	Metabolite CGA 71019	Chronic 8 weeks	PEC_{accu} 0.002 mg/kg	500	5

Appendix 1 – list of endpoints

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Eisenia fetida	Metabolite CGA 179944	Acute 14 days	PEC_{accu} 0.015mg/kg	> 66666	10
Eisenia fetida	Metabolite CGA 179944	Chronic	Not relevant	Not relevant	5
Other soil macro-organisms					
Collembola	Preparation TOPAS A-6209 G	Chronic 4 weeks	PEC_{accu} 0.1414mg/kg	350	5
	Metabolite CGA 71019	Chronic 4 weeks	PEC_{accu} 0.002 mg/kg	900	5

[1] $PEC_{max.\ plateau\ (accu)}$ after last application in ´cucurbits, SEU, NEU´ considering accumulation after multi-year use) were used

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

Preliminary screening data

The preparation TOPAS (A-6209 G) at rates up to 300 g formulation/ha (30 g as/ha) had at most only slight effects (less than 50 % by visual rating) on seedling emergence and vegetative vigour in three monocotyledons and 3 dicotyledons.

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
	as ‡ and Preparation	Not relevant	Not relevant			

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)
[2] for preparations indicate whether dose is expressed in units of as or preparation

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

Not relevant

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

Test type/organism	endpoint
Activated sludge	EC_{50} = >100 mg as/L, NOEC = 32 mg/L
Pseudomonas sp.	Not relevant

Appendix 1 – list of endpoints

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

Compartment	
soil	Parent (Penconazole)
water	Parent (Penconazole)
sediment	Parent (Penconazole)
air	Parent (Penconazole)
groundwater	Parent (Penconazole)

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

	RMS/peer review proposal
Active substance	N, R50 (aquatic plants)/R53 dangerous to the environment very toxic to aquatic organisms, may cause long-term effects

	RMS/peer review proposal
Preparation	N, R51/R53 dangerous to the environment toxic to aquatic organisms, may cause long-term effects

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
BCF	bioconcentration factor
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
d	day
DAR	draft assessment report
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
DMI	demethylase inhibitor
ε	decadic molar extinction coefficient
EChA	European Chemicals Agency
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
ELS	early life stages
ER50	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FC	field capacity
FFLC	fish full life cycle test
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FSDT	fish sexual development test
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GC-NPD	gas chromatography with nitrogen phosphorous detector
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage

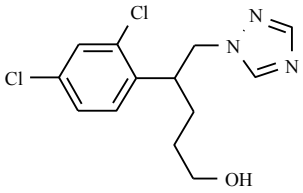
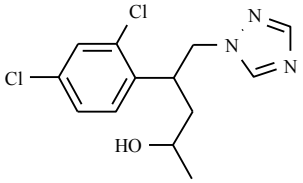
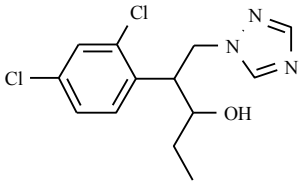
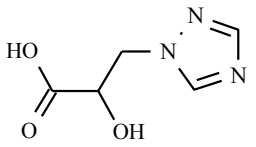
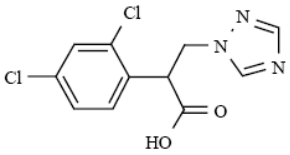
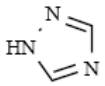
Appendix 2 – abbreviations used in the list of endpoints

h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography
	or high performance liquid chromatography
HQ	hazard quotients
HR	highest residue
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
K_{ow}	octanol-water partition coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
MWHC	maximum water holding capacity
NESTI	national estimated short term intake
NEU	Northern Europe
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NTA	non-target-arthropods
OC	organic carbon content
Pa	Pascal
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil

Appendix 2 – abbreviations used in the list of endpoints

PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RMS	Rapporteur Member State
SEU	Southern Europe
SFO	single first-order
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
CGA 127841	4-(2,4-Dichloro-phenyl)-5-[1,2,4]triazol-1-yl-pentan-1-ol	
CGA 132465	4-(2,4-Dichloro-phenyl)-5-[1,2,4]triazol-1-yl-pentan-2-ol	
CGA 190503	2-(2,4-Dichloro-phenyl)-1-[1,2,4]triazol-1-yl-pentan-3-ol	
CGA 205369	2-hydroxy-3-[1,2,4]triazol-1-yl-propionic acid (triazolyl lactic acid)	
CGA 179944	2-(2,4-dichloro-phenyl)-3-[1,2,4]triazol-1-yl-propionic acid	
CGA 71019	1*H*-1,2,4-triazole	
CGA 142856	1,2,4-triazol-1-yl-acetic acid