CONCLUSION ON PESTICIDE PEER REVIEW

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

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

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

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

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, the United Kingdom, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 20 July 2009.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 22 July 2009. The EFSA collated and forwarded all comments received to the Commission on 4 September 2009.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission requested the EFSA to deliver its conclusions on fenbuconazole.

1 On request from the European Commission, Question No EFSA-Q-2009-000863, issued on 18 March 2010.
2 Correspondence: praper@efsa.europa.eu
3 OJ L224, 21.08.2002, p.25
4 OJ L 246, 21.9.2007, p. 19
5 OJ L 333, 11.12.2008, p.11
6 OJ L 15, 18.01.2008, p.5
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The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of fenbuconazole as a fungicide on wheat, apples and grapes, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

The preferential metabolism/degradation of each enantiomer in plants, animals and the environment, and the possible impact on the toxicity, the consumer risk assessment, and the environment were not investigated in the studies submitted in the dossier and needs to be addressed.

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

No areas of concern were identified in the residue section. Based on the metabolism studies performed on cereal, pulses/oilseed and root crops, the residue for monitoring and risk assessment was defined as fenbuconazole only. No risk was identified for consumers, but this evaluation has to be considered provisional, since the contribution of the triazole derivative metabolites (TDMs) was not taken into account.

Concerning the environmental fate and behaviour of fenbuconazole, no specific data gaps other than addressing potential preferential enantio-selective degradation were identified. No areas of concern were identified with respect to the potential for groundwater contamination.

A potential high long-term risk to herbivorous mammals was identified in the first-tier risk assessment for all representative uses. However, considering the refinements accepted in the PRAPeR experts' meeting, the risk was considered sufficiently addressed for all uses, except for the use on vineyards at the application rate of 4 x 0.06 kg a.s./ha, where a high risk prevails for applications at early growth stages. A high risk was identified for aquatic organisms, and risk mitigation measures such as no-spray buffer zones are required.

KEY WORDS

Fenbuconazole, peer review, risk assessment, pesticide, fungicide

TABLE OF CONTENTS

BACKGROUND

Legislative framework

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

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

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

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

The peer review was initiated on 12 May 2006 by dispatching the DAR to the applicant Dow AgroSciences and on 24 May 2006 to the Member States for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The Reporting Table containing the RMS' evaluation of the comments in column 3 was further considered by the EFSA and the Member States in a written procedure in May - June 2007, resulting in a conclusion in column 4.

All points that were identified as unresolved at the end of the comment evaluation phase, and which required further consideration in the peer review process, were compiled by the EFSA in the format of an Evaluation Table. The issues identified in the Evaluation Table, as well as further information made available by the applicant upon request, were evaluated in a series of scientific meetings with Member State experts in October 2007 (PRAPeR 31-35). The outcome of the expert discussion phase was reported in the final column of the Evaluation Table.

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

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

Following the Commission Decision of 5 December 2008 (2008/934/EC)[10] concerning the non-inclusion of fenbuconazole in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Dow

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

AgroSciences made a resubmission application for the inclusion of fenbuconazole in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the issues identified in the PRAPeR expert meeting reports in the areas of physical and chemical properties, mammalian toxicology, residues and environmental fate and behaviour.

In accordance with Article 18, the United Kingdom, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report (The United Kingdom, 2009a). The Additional Report was received by the EFSA on 20 July 2009.

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicant for comments on 22 July 2009. In addition, the EFSA conducted a public consultation on the Additional Report. The EFSA collated and forwarded all comments received to the Commission on 4 September 2009. The collated comments were also forwarded to the RMS for compilation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 14 October 2009, the Commission requested the EFSA to deliver its conclusions on fenbuconazole within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were required to be submitted by the applicant in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicant in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the Commission on 28 September 2009; the applicant was also invited to give its view on the need for additional information. On the basis of the comments received, the applicant's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that there was no need for EFSA to organise a further consultation with Member State experts, however, it was agreed that further information should be requested from the applicant in the area of environmental fate and behaviour.

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

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in November – December 2009.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a fungicide on wheat, apples and grapes as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2010) comprises the following documents:

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

- the Reporting Tables (revision 1-1 of 2 July 2007 and revision 1-1 of 29 September 2009),
- the Evaluation Tables (revision 2-1 of 26 October 2007, and of 19 January 2010),
- the report(s) of the scientific consultation with Member State experts (where relevant).

Given the importance of the DAR and the Additional Report including its addendum (compiled version of November 2009 containing all individually submitted addenda) (The United Kingdom, 2009b) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Fenbuconazole is the ISO common name for (*R,S*) 4-(4-chlorophenyl)-2-phenyl-2-(1*H*-1,2,4-triazol-1-ylmethyl))butyronitrile (IUPAC).

The representative formulated products for the evaluation were 'Indar 5EW' an oil-in-water emulsion (EW), and 'Indar 5EC' an emulsifiable concentrate (EC), both containing 50 g/L fenbuconazole, registered under different trade names in Europe.

The representative uses evaluated comprise foliar spraying against scab and powdery mildew in apples, against black rot and powdery mildew in grapes, and against rusts and septoria in wheat. Full details of the GAP can be found in the list of end points in Appendix A of this conclusion.

CONCLUSIONS OF THE EVALUATION

It must be noted that fenbuconazole is a racemic mixture of enantiomers, but the possible preferential metabolism/degradation of each enantiomer in animals, plants and the environment was not investigated in the studies submitted in the dossier and was therefore not considered during the peer review. Moreover, the analytical methods used in the studies reported through all sections were not stereo-selective, and all values mentioned as "fenbuconazole" have to be considered as "sum of enantiomers". The possible impact of each individual enantiomer on the toxicity, the consumer risk assessment and the environment was not evaluated. A general data gap, applicable for sections 2, 3, 4 and 5, was therefore identified to address the impact of the isomeric composition of the substance.

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

The minimum purity of fenbuconazole is 965 g/kg. The active substance is a racemic mixture. No FAO specifications exist.

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 fenbuconazole or the respective formulations. The main data regarding the identity of fenbuconazole and its physical and chemical properties are given in Appendix A of this conclusion.

Adequate analytical methods are available for the determination of fenbuconazole in the technical material and in the representative formulation. Fenbuconazole residues in plants can be determined by GC-MS with LOQs of 0.01 mg/kg (grapes, orange, wheat grain, oilseed). In food/feed of animal origin residues of fenbuconazole can be monitored by GC-MS with LOQs of 0.05 mg/kg (milk, meat, kidney, liver, fat, eggs). Adequate analytical methods are available to monitor fenbuconazole residues in the environmental matrices. Since fenbuconazole is not classified as acute toxic or very toxic, analytical methods for the determination of residues of fenbuconazole in body fluids and/or tissues are not required.

2. Mammalian toxicity

Fenbuconazole is of low acute toxicity after oral or dermal exposure, or by inhalation. It is neither irritating to the skin or the eyes, nor skin sensitising. In short-term studies, the adverse effects were reduced body weight gain and liver changes. The lowest short-term NOAELs are 3.3 mg/kg bw/day (3-month dog study) and 0.62 mg/kg bw/day (12-month dog study). Fenbuconazole is not genotoxic *in vitro* or *in vivo*. In the long-term studies with rats and mice, the main target organ was the liver, with thyroid tumours in rats (through a rodent specific mechanism). The relevant long-term NOAELs are 3 mg/kg bw/day for rats, and 1.3 mg/kg bw/day for mice. In the rat multigeneration study, the parental and the reproductive NOAELs are 5.0 mg/kg bw/day, while the NOAEL for the offspring is 10.8 mg/kg bw/day. Based on the increased number of pups born dead, reduced litter size and decreased post-partum pup viability, the proposal to classify as **Xn; Repr. Cat. 3 R63 "Possible risk of harm to the unborn child"** was agreed by the PRAPeR 34 meeting of experts (October 2007). No teratogenic effects were observed in two developmental studies (rat and rabbit).

The metabolites 1, 2, 4-triazole, triazole alanine and triazole acetic acid are toxicologically relevant metabolites, for which reference values have already been agreed (PRAPeR 14, January 2007). The groundwater metabolites RH-9129 (Lactone A), RH-9130 (Lactone B) and RH-6467 were considered as relevant according to the current EU guideline (European Commission, 2003). The plant metabolite RH-4911 was also considered as relevant and of similar toxicity as fenbuconazole.

The Acceptable Daily Intake (**ADI**) of 0.006 mg/kg bw/day is derived from the 1-year dog study (safety factor 100). The Acceptable Operator Exposure Level (**AOEL**) of 0.02 mg/kg bw/day is based on the rat multigeneration study, with the application of a safety factor of 300, in order to provide a sufficient margin of safety (of 2500) with regard to the toxic effects observed in the multigeneration study. The Acute Reference Dose (**ARfD**) of 0.3 mg/kg bw is derived from the maternal effects seen in the rat developmental study, supported by the findings in the rabbit developmental study, and using a safety factor of 100. The estimated operator exposure is below the AOEL for all the representative uses; in apples and grapes with the use of personal protective equipment (PPE: at least gloves, coverall and sturdy footwear during application) and in wheat without the use of PPE. The estimated bystander exposure is below the AOEL. The predicted levels of exposure for workers re-entering treated crops to perform crop inspection or hand-harvesting operations are below the AOEL without the use of PPE.

3. Residues

The metabolism of fenbuconazole has been investigated using foliar applications on peaches, wheat, sugar beet and peanuts, representing the following crop groups: fruits, cereals, root vegetables and pulses/oilseeds. The metabolism was seen to be similar, the major constituents of the residue being unchanged fenbuconazole (12% to 83% of the TRR) and the triazole derivative metabolites (TDMs), in particular triazole alanine (RH-3968) that accounted for 47% to 88% of the TRR in cereal grains, peaches and peanuts. The parent compound was however not detected in peanut meat, where, in addition to triazole alanine, the hydroxy metabolite RH-4911 represented 30 % of the TRR (0.02 mg/kg). As the additional detected metabolites (lactone, ketone and hydroxy metabolites) were observed in clearly lesser amount than the parent substance, it was agreed to limit the residue definition for monitoring and risk assessment to fenbuconazole only. The residue definition for risk assessment needs however to be considered provisional, since the TDMs, sometimes present at much higher levels than fenbuconazole, were not considered. The metabolite profile in rotational crops is consistent with that observed in primary crops, and suggests that only TDMs residues are expected in rotational crops. It should be noted that the proposed residue definitions would eventually have to be reconsidered if additional uses are envisaged on oilseed/pulse crops, since the metabolite RH-4911 was observed above 0.01 mg/kg in the peanut nuts, but in a study performed at an exaggerated application rate of 2240 g a.s./ha. This metabolite, not observed in rats, was considered to be of similar toxicity as the parent compound by the PRAPeR 34 meeting of experts on mammalian toxicology, as it contains the intact triazole moiety.
A sufficient number of supervised residue trials have been reported to propose MRLs for apples, grapes and wheat. The samples were analysed for fenbuconazole and its lactone metabolites (RH-9129 and RH-9130), but no information was reported for the TDMs. The lactone metabolites were detected in significant levels in wheat straw only, representing about 50% of the parent levels. Fenbuconazole is not degraded under standard hydrolysis conditions, and transfer factors were proposed for apple, grape and wheat processed commodities.

Based on the studies performed at the exaggerated rate of 100 mg/kg feed, the residues in animal commodities were shown to be multi-components in nature and specific in each tissue, with the parent compound and metabolites RH-7968, RH-1311, 1,2,4-triazole and triazole alanine being the major constituents of the residues in goat tissues, and with the parent compound, RH-9129, RH-9130, 1,2,4-triazole and triazole alanine as the major ones in the hen tissues. However, and considering the new goat metabolism study performed at the more representative dose rate of 10 mg/kg feed (*c.a.* 6 -14N), these metabolites are not expected to be present at significant levels, and the residue definition for

monitoring and risk assessment was limited to the parent fenbuconazole only. Having regard to the animals' burden resulting from the representatives uses, a MRL of 0.05* mg/kg was proposed for ruminant products, and no MRLs were set for poultry tissues. As for plants, a final residue definition for risk assessment will need to consider the TDMs present in animal commodities as a result of the metabolism of the parent compound by animals, or of their direct transfer from feed items.
The consumer chronic and short-term intakes estimated using the WHO, UK or EFSA PRIMo models are less than 73% of the proposed ADI, and less than 22% of the ARfD. However, these estimations have to be considered as provisional as the contribution of the TDMs was not taken into account, since no information was provided on their possible residue levels in primary crops, rotational crops and in animal matrices.

4. Environmental fate and behaviour

Fenbuconazole exhibits moderate to very high persistence in soil under aerobic conditions (laboratory incubations). The main metabolites were the lactone RH-9129 (max. 9.7 % AR after 240 days), the ketone RH-6467 (max. 7.7 % AR after 120 days), and the major metabolite 1,2,4-triazole (max 12.4 to 15 %[11] AR). The first two metabolites appeared at levels above 5% AR for two consecutive data points, and therefore need to be further assessed for potential groundwater contamination (European Commission, 2003). Metabolite RH-9130 (diastereomer of RH-9129) was formed above 5 % in only one soil, at one sampling point, therefore, it does not need further assessment for potential groundwater contamination. FOCUS kinetics (FOCUS, 2006) has been followed to derive formation fractions and degradation half-lives for the metabolites requiring further assessment. Metabolites RH-9129 and RH-6467 may be considered to exhibit high persistence in soil. Metabolite 1,2,4-triazole exhibits low persistence in soil (evidence from laboratory incubations where 1,2,4-triazole was dosed). Mineralization after 90 days was very low for the triazole labelled experiments (0.7 % AR), and moderate for the phenyl labelled experiments (12 % AR). Unextracted radioactivity amounted to 15.2 - 45.5% after 90 - 96 days. Photolysis at the soil surface does not contribute significantly to the dissipation of fenbuconazole in soil. Field dissipation studies (German) and accumulation studies from the UK and California (USA) provide confirmation of the potentially very high persistence of fenbuconazole. Although some metabolites (RH-9129, RH-9130 and RH-6467) were analysed in these field studies, the data were not considered reliable due to the fact that the LOQ attained by the analytical methods employed was not sufficiently low (the LOQ for metabolites represented 15 - 33 % of the applied parent compound). Fenbuconazole is immobile to slightly mobile in soil. Metabolite 1,2,4-triazole exhibits medium to very high soil mobility. Metabolite RH-9129 exhibits slight mobility, and metabolite RH-6467 exhibits low mobility. There was no evidence of pH dependence of adsorption for any of these compounds. PEC in soil (see Appendix A) were calculated based on worst-case assumptions and a mean laboratory single first-order DT_{50} of 172 days, normalized only for temperature (20ºC) (considered more conservative than the worst-case field DT_{50} of 98 days). For some of the uses (apples and grapes) application programs exceeding the proposed application rates were simulated. Accumulation was considered in a separate calculation and the plateau values were determined to occur after four years.

In aerobic natural sediment water systems (laboratory incubations) fenbuconazole dissipated relatively rapidly from the water phase via partitioning to the sediment. However, fenbuconazole underwent minimal degradation in each system and represented 80.7 to 83.0 % AR at the end of the study. Eight metabolites were detected, but none exceeded 3.9 % AR. Mineralization was insignificant in both systems (0.3% at 105 days, study end). Unextracted sediment residues accounted for 6.6. to 12 % AR at study end. PEC_{SW} values were calculated according to the GAP proposed for each crop and each step of the FOCUS SW procedure (FOCUS, 2001; FOCUS, 2007). Based on the aquatic risk assessment, TER values did not meet the Annex VI triggers with the step 3 simulations for early applications to apples, late application to grapevines, and application to wheat. For these situations

* MRL is set at the limit of quantification (LOQ)
[11] From the rate of degradation study by Mamouni A, 1992 (The United Kingdom, 2005, Vol.3 B.8.1.2.1), Case for the identity being 1,2,4-triazole, see Addendum 1 to Vol3 B8 of the Additional Report (The United Kingdom, 2009b) .

buffer zones to reduce spray drift inputs were simulated. In order to perform the risk assessment of the formulation (more toxic than the active substance for aquatic species), PEC_{SW} values for the parent fenbuconazole were also calculated based on spray drift only (see Appendix A).
The groundwater contamination assessment follows the PPR panel opinions (EFSA 2004; EFSA, 2007), and addresses the potential groundwater contamination by fenbuconazole and metabolites RH-9129 and RH-6467, using FOCUS PELMO (3.2.2) and FOCUS PEARL (3.3.3) (FOCUS, 2000). 1,2,4-triazole was also assessed. The modelled application patterns followed the GAP proposed for the representative uses, or in some cases, patterns that represent even more worst-case situations. The results of the simulation indicate that 80th percentile annual average concentrations of fenbuconazole and the metabolites RH-9129, RH-6467 and 1,2,4-triazole would be well below the parametric drinking water limit of 0.1 µg/L over the 20 years simulation period. Therefore the potential for groundwater contamination from the representative uses is considered low for situations that are covered by the FOCUS groundwater scenarios.

5. Ecotoxicology

The acute, short-term and long-term risk to birds was assessed as low, as well as the acute risk to mammals. However, the long-term TER values for herbivorous mammals were significantly below the Annex VI trigger of 5 for all three representative uses, indicating a potential high long-term risk. A refined long-term risk assessment was provided in an annex to the DAR and in Addendum 2 of the Final Addendum (The United Kingdom, 2009b). The suggested refinement of residues in food items in orchards and vineyards was based on a DT_{50} of 6.7 days, which was agreed in the PRAPeR 33 meeting of experts for central European and southern European scenarios. In northern Europe there were some uncertainties, since the residue decline may take longer under cooler climatic conditions. The measured residues in cereals were accepted. The focal species *Microtus arvalis* (common vole) in apple orchards and vineyards, and *Apodemus sylvaticus* (wood mouse) in cereals were also agreed. The PD refinements were based on general considerations of food composition of common vole, but not from targeted studies in orchards or vineyards. Therefore the PD refinement is uncertain and was considered not necessary. A low risk to herbivorous mammals was demonstrated in the refined risk assessment for the uses in orchards, for the uses in vineyards (for the low application rate of 4 x 0.038 kg a.s/ha), and for the use in cereals. For the high application rate in vineyards the risk was assessed as low for late growth stages, but a high risk prevailed for applications during early growth stages of the grapevine.

Aquatic organisms including sediment-dwelling organisms (*Chironomus riparius*) were tested with the technical and formulated fenbuconazole. The test results showed a tendency of higher toxicity of fenbuconazole when formulated. Therefore the end points observed for the formulation were used in the risk assessment. The risk assessment was driven by the chronic risk. A high risk to aquatic organisms was identified for the uses in apples and grapevines. Risk mitigation measures comparable to no spray buffer zones of up to 25 m (70 g a.s./ha, apple orchards NE), 20 m (52.5 g a.s./ha, apple orchards SE), 10 m (60 g a.s./ha, grapevines NE), 5 m (38 g a.s./ha, grapevines SE), 3 m (75 g a.s./ha, cereals) are required. The risk from the soil metabolite 1,2,4-triazole is considered as low, since the TER values for fish, daphnids and algae based on FOCUS step1 PECsw were markedly above the Annex VI trigger values.
The whole body BCF for fish was determined as 160, which is above the trigger of 100 for not readily biodegradable substances. But since depuration is very fast (CT_{90} = 4.5 days), the risk from bioconcentration of fenbuconazole was considered to be low. No separate study on the bioconcentration potential of metabolite 1,2,4-triazole was conducted. But since metabolite 1,2,4-triazole is much more polar (log Kow = -1) than fenbuconazole, the potential for bioconcentration is lower than for fenbuconazole.

The risk to bees, non-target arthropods, earthworms, other non-target and soil-dwelling organisms including organic matter breakdown, non-target plants and biological methods of sewage treatment was assessed as low for the representative uses evaluated.

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

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
fenbuconazole	moderate to very high persistent ($DT_{50\ lab\ 20\ °C}$ = 33 – 590 days)	The risk to soil-dwelling organisms was assessed as low.
1,2,4-triazole	low persistent ($DT_{50\ lab\ 20\ °C}$ = 5.0 – 9.9 days)	The risk to soil-dwelling organisms was assessed as low.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
fenbuconazole	slightly mobile to immobile (K_{foc}= 2185 – 9043 mL/g)	FOCUS GW: No	Yes	Yes	Very toxic to aquatic organisms. A high risk was identified for surface water.
1,2,4-triazole	medium to very high mobity (K_{foc} = 43 – 202 mL / kg).	FOCUS GW: No	No data submitted	Yes ADI 0.02 mg/kg bw/day ARfD 0.06 mg/kg bw (PRAPeR 14, 2007)	More than 2 orders of magnitude less acutely toxic to aquatic organisms compared to fenbuconazole. The risk was assessed as low.

RH-9129	Slight mobility (K_{Foc} = 2375 – 3281 mL / g)	FOCUS GW: No	No data submitted	Yes	No data submitted
RH-6467	Low mobility (K_{Foc} = 938 - 1500 mL / g)	FOCUS GW: No	No data submitted	Yes	No data submitted

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
fenbuconazole (water and sediment)	Very toxic to aquatic organisms (LC_{50} fish = 0.68 mg a.s./L, EC_{50} daphnia = 2.3 mg a.s./L, EbC_{50} algae = 0.33 mg a.s./L). A high risk to aquatic organisms was identified. Risk mitigation measures are required.
1,2,4-triazole (water and sediment from drainage and run-off)	The toxicity to aquatic organisms was more than 2 orders of magnitude less compared to fenbuconazole and the risk to aquatic organisms was assessed as low.

6.4. Air

Compound (name and/or code)	**Toxicology**
fenbuconazole	Low acute toxicity by inhalation (LC_{50} >2.10 mg/L, maximum technically achievable)

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

- Fenbuconazole consists of 2 enantiomers. The preferential metabolism/degradation of each enantiomer in plants, animals, and the environment, as well as the possible impact on the toxicity, the consumer risk assessment and the environment needs to be addressed (relevant for all representative uses evaluated; data gap identified by EFSA during drafting of the conclusion; no submission date proposed; applicable to sections 2, 3, 4 and 5).

- Information allowing the assessment of consumer exposure to triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin (relevant for all representative uses evaluated; no submission date proposed by the applicant; refer to section 3).

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

- Use of personal protective equipment by the operators in order to have an estimated exposure level below the AOEL during the use on apples and grapes (see section 2).

- Risk mitigation measures comparable to no spray buffer zones of up to 25 m (70 g a.s./ha, apple orchards NE), 20 m (52.5 g a.s./ha, apple orchards SE), 10 m (60 g a.s./ha, grapevines NE), 5 m (38 g a.s./ha, grapevines SE), 3 m (75 g a.s./ha, cereals) are required to protect the aquatic environment (see section 5).

ISSUES THAT COULD NOT BE FINALISED

- Possible impact on the toxicity, the consumer risk assessment and the environment of the potential enantio-selective biologically mediated metabolism/degradation in plants, animals, and the environment needs to be addressed.

- The possible contribution of the TDMs residues present in primary crops, rotational crops and products of animal origin to the overall consumer exposure was not considered.

CRITICAL AREAS OF CONCERN

- None.

REFERENCES

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APPENDICES

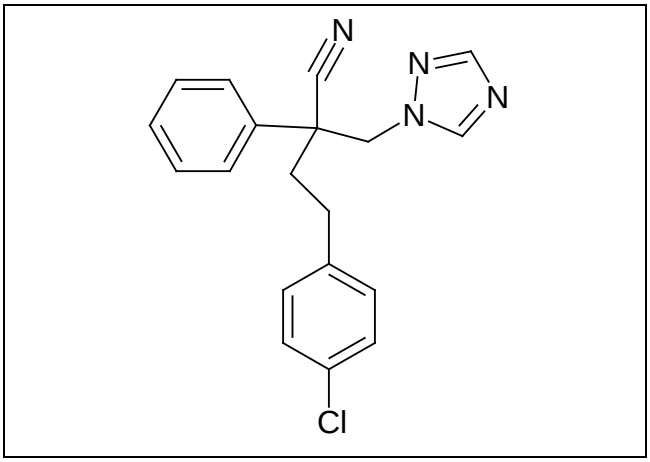
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

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

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	*(R,S)* 4-(4-chlorophenyl)-2-phenyl-2-(1*H*-1,2,4-triazol-1-ylmethyl))butyronitrile
Chemical name (CA) ‡	α-[2-(4-chlorophenyl)ethyl]-α-phenyl-1*H*-1,2,4-triazole-1-propanenitrile
CIPAC No ‡	694
CAS No ‡	114369-43-6
EC No (EINECS or ELINCS) ‡	406-140-2
FAO Specification (including year of publication) ‡	Not available
Minimum purity of the active substance as manufactured ‡	965 g/kg (50:50 racemic mixture)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula ‡	$C_{19}H_{17}ClN_4$
Molecular mass ‡	336.8 g/mol

Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	126.5-127.0 °C (98.5%)
Boiling point (state purity) ‡	Not measurable
Temperature of decomposition (state purity)	No evidence of major exothermic decomposition below 360°C (98.5%)
Appearance (state purity) ‡	Off-white to white powder (technical material as manufactured purity in range 97.7 – 99.3%)
Vapour pressure (state temperature, state purity) ‡	3.40 x 10^{-7} Pa at 25°C (99.97%)
Henry's law constant ‡	3.01 x 10-5 Pa m3 mol-1
Solubility in water (state temperature, state purity and pH) ‡	Column elution method (20°C): pH 4: 2.57 mg/L (99.6%) pH 7: 2.47 mg/L (99.6%) pH 10: 2.17 mg/L (99.6%)
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20°C in g/L (97.5%) Acetone: >250 g/L 1,2-dichloroethane: >250 g/L Ethyl acetate: 132 g/L Methanol: 60.9 g/L Octanol: 8.43 g/L Xylene: 26.0 g/L n-heptane: 0.068 g/L
Surface tension ‡ (state concentration and temperature, state purity)	69.5mN/m at 22°C (90 % saturated solution) (technical material as manufactured purity in range 94 – 99%)

Partition co-efficient ‡ (state temperature, pH and purity)	log $P_{O/W}$ = 3.23 at 25 °C (99.5%) at 20 °C (shake flask method): pH 4: 3.79 (99.8%) pH 7: 3.79 (99.8%) pH 10: 3.76 (99.8%)
Dissociation constant (state purity) ‡	Not applicable. The compound does not contain ionisable protons.
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	λ_{max} (nm); ε (L.mol^{-1}.cm^{-1}) basic 217 nm 12100 neutral 195 nm 35600 acidic 200 nm 20600 (99.8%) No absorbance at λ > 290 nm.
Flammability ‡ (state purity)	Not highly flammable (technical material as manufactured purity in range 94 – 99%)
Explosive properties ‡ (state purity)	Not explosive (99.1%)
Oxidising properties ‡ (state purity)	Not oxidising (99.1%)

Summary of representative uses evaluated for fenbuconazole

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. as g/l (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)		
Apples	Northern Zone (UK)	Indar 5EW	F	Apple Scab and Powdery Mildew	EW	50	Low volume Air-assisted Spray Method	Bud burst to end of extension shoot growth / ripening fruit Spring / Summer	4	11	0.014 - 0.035	200-500	0.070	28	Number of applications restricted to 4 per season for resistance management reasons
Apples	Southern Zone (France)	Indar 5EW	F	Apple Scab	EW	50	High volume Air-assisted Spray Method	Bud burst to end of extension shoot growth / ripening fruit Spring/ Summer	4	10	0.0035	500-1500	<0.052	28	Number of applications restricted to 4 per season for resistance management reasons
Grapes FB0269	Northern Zone (UK/France)	Indar 5EW	F	Powdery Mildew Black rot Brenner	EW	50	High volume Air-assisted Spray	From 3 leaves unfurled (GS 09) to fruit ripening	4	10	0.0038	400 1600	0.015 0.060	21	Number of applications restricted to 4 per season for resistance management reasons
							Low volume Air-assisted Spray	From 3 leaves unfurled (GS 13) up to fruit set (GS 71) After berry pea size (GS 75)	4	10	0.0095 - 0.025	150-400 500	0.038 0.060	21	Number of applications restricted to 4 per season for resistance management reasons
Grapes FB0269	Southern Zone (France)	Indar 5EW	F	Powdery Mildew	EW	50	Low Volume Air-assisted Spray	Ripening fruit Spring / Summer	4	10-14	0.0095 - 0.025	150-400	0.038	28	Number of applications restricted to 4 per season for resistance management reasons
Grapes FB0269	Southern Zone (Italy)	Indar 5EW	F	Powdery Mildew	EW	50	High volume Air-	Ripening fruit Spring / Summer	4	10	0.003	1000	0.03 min.	28	Number of applications restricted to 4 per

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. as g/l (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)		
							assisted Spray								season for resistance management reasons
Wheat	Northern Zone (UK)	Indar 5EC	F	Septoria, Rusts	EC	50	Low Volume Overall boom sprayer	Apply upto and including (GS 59) Spring / Summer	2	14-28	0.0375	200	0.075	N/A	
Wheat GC06542	Southern Zone (France)	Indar 5EC	F	Rust and Septoria	EC	50	Low Volume Overall boom spray	GS 55	2	20-30	0.0375	200	0.075	45	

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

Methods of Analysis

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

Technical as (analytical technique)	GC-FID
Impurities in technical as (analytical technique)	GC-FID, titrimetric.
Plant protection product (analytical technique)	GC-FID

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Fenbuconazole (sum of enantiomers)
Food of animal origin		Fenbuconazole (sum of enantiomers)
Soil		Fenbuconazole (sum of enantiomers)
Water	surface	Fenbuconazole (sum of enantiomers)
	drinking/ground	Fenbuconazole (sum of enantiomers)
Air		Fenbuconazole (sum of enantiomers)

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Fenbuconazole: GC-MS LOQ = 0.01 mg/kg Validated for grape, orange, wheat grain, oilseed. ILV for orange & oilseed.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Fenbuconazole: GC-MS LOQ = 0.05 mg/kg. Validated for milk, meat, kidney, liver, fat, eggs ILV for beef fat & milk.
Soil (analytical technique and LOQ)	Fenbuconazole: GC-MS LOQ = 0.05 mg/kg.
Water (analytical technique and LOQ)	Fenbuconazole: LC-MS/MS LOQ = 0.05µg/L
Air (analytical technique and LOQ)	Fenbuconazole: GC-NPD LOQ = 0.9µg/m^3
Body fluids and tissues (analytical technique and LOQ)	Not required

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

	RMS/peer review proposal
Active substance	No classification required.

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Absorption was rapid and almost complete (>88%).
Distribution ‡	Widely distributed. Highest levels in liver, kidneys and adrenals.
Potential for accumulation ‡	No evidence for bioaccumulation.
Rate and extent of excretion ‡	Rapidly excreted (>75% in 24 hours, ≈10% via urine and ≥80% via bile by 48 hours).
Metabolism in animals ‡	Extensively metabolised, mainly by oxidation, hydrolysis and conjugation (3-7% of unchanged parent in faeces). Ca 2.5% of the dose was cleaved.
Toxicologically relevant compounds ‡ (animals and plants)	Parent and triazole derivative metabolites (TDMs).
Toxicologically relevant compounds ‡ (environment)	Parent and 1,2,4-triazole

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	>2000 mg/kg bw	-
Rat LD_{50} dermal ‡	>5000 mg/kg bw	-
Rat LC_{50} inhalation ‡	>2.10 mg/L (4h, nose only, maximum technically achievable)	-
Skin irritation ‡	Not irritant	-
Eye irritation ‡	Not irritant	-
Skin sensitisation ‡	Non-sensitising (Buehler test and M & K test)	-

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Reduced bodyweight gain, liver effects (clinical chemistry, increased liver weight, hepatocellular hypertrophy).	
Relevant oral NOAEL ‡	5.7 mg/kg bw/d (3-mo rat) 3.3 mg/kg bw/d (3-mo dog) 0.62 mg/kg bw/d (12-mo dog)	
Relevant dermal NOAEL ‡	1000 mg/kg bw/day (top dose tested).	
Relevant inhalation NOAEL ‡	No data – not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

No evidence of genotoxicity in the available studies.	-

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

Target/critical effect ‡	Reduced bodyweights, liver and secondary thyroid effects in rats. Liver effects in mice.	
Relevant NOAEL ‡	3 mg/kg bw/d (104-wk rat) 1.3 mg/kg bw/d (78-wk mouse)	
Carcinogenicity ‡	The increased incidence of thyroid tumours in rats (rodent specific) and hepatocellular carcinomas in mice (common in mice at prolonged high doses of xenobiotics) is unlikely to pose a carcinogenic risk to humans.	-

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Dystocia, increased numbers of pups born dead, reduced litter size and decreased post-partum pup viability.	**R63**
Relevant parental NOAEL ‡	5.0 mg/kg bw/d (80 ppm)	
Relevant reproductive NOAEL ‡	5.0 mg/kg bw/d (80 ppm)	
Relevant offspring NOAEL ‡	10.8 mg/kg bw/d (80 ppm)	

Developmental toxicity

Developmental target / critical effect ‡	Developmental toxicity: - reduced litter size, increased resorptions, increased incidence of partial or unossified sternebrae (rat) - increased incidence of abortions and resorptions (rabbit) Maternal toxicity: reduced bodyweight gains (rat), mortality and reduced food consumption (rabbit). No teratogenic effects (rat & rabbit).	
Relevant maternal NOAEL ‡	30 mg/kg bw/d (rat & rabbit)	
Relevant developmental NOAEL ‡	75 mg/kg bw/d (rat) 45 mg/kg bw/d (rabbit)	

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 ‡	Thyroid function and hepatic clearance of thyroxine in male rats – hepatic metabolism and biliary excretion of L-thyroxine increased, serum T4 decreased and serum TSH increased in response to fenbuconazole treatment. Cell proliferation and enzyme induction in the liver of female mice – fenbuconazole induced liver effects in mice with a non-linear dose-response relationship.
Studies performed on metabolites or impurities ‡	RH 9129 (Fenbuconazole lactone A):- - Oral LD_{50} (mice) >5000 mg/kg bw - Negative Ames test RH 9130 (Fenbuconazole lactone B):- - Oral LD_{50} (mice) >5000 mg/kg bw - Negative Ames test
Reference values agreed in PRAPeR 14 (January 2007) for three triazole metabolites	1,2,4-triazole: ADI 0.02 mg/kg bw/d; ARfD 0.06 mg/kg bw Triazole alanine: ADI 0.1 mg/kg bw/d; ARfD 0.1 mg/kg bw Triazole acetic acid: ADI 0.02 mg/kg bw/d; ARfD 0.06 mg/kg bw

Medical data ‡ (Annex IIA, point 5.9)

There are no reports of adverse reactions to fenbuconazole during manufacture or use.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.006 mg/kg bw/day	1 year dog	100
AOEL ‡	0.02 mg/kg bw/day	Multigeneration study in the rat	300
ARfD ‡	0.3 mg/kg bw	Developmental rat	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

Representative formulation: 'Indar 5EW' (oil in water (EW) formulation containing 50 g/l fenbuconazole)	Concentrate: 4% Spray dilutions: 30% Based on *in vitro* human skin study performed with 'Indar 5EW'.

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Scenario		Models (estimated exposure in % AOEL)	
			UK POEM	German BBA
	Apples – low volume	No PPE	690	145
		PPE	420* + closed cab: 15	25**
	Apples – high volume	No PPE	350	110
		PPE	230* + closed cab: 125	19**
	Grapes – high volume	No PPE	395#	120
		PPE	262# *	20**
	Grapes – low volume	No PPE	485	75
		PPE	295*	13**
	Wheat	No PPE	415	75
		PPE	65*	15**
	Apples – handheld – low volume	No PPE	920	105
		PPE	170***	50**
	Apples – handheld – high volume	No PPE	495	105
		PPE	90***	50**
Workers	Estimated exposure (% AOEL) by EUROPOEM + DFR measurements: - during harvest of apples, without PPE: 70% -during harvest of grapes, without PPE: 18% - during inspection of grapes, without PPE: 28%			
Bystanders	The estimated bystander exposure by spray drift is 33% of the AOEL.			

PPE (personal protective equipment): *gloves during mixing/loading and application; **: gloves, coverall and sturdy footwear during application; ***: gloves during mixing/loading, gloves and impermeable coveralls during application.

It is noted that these values do not correspond to the miscalculated values as proposed in the Reporting Table of 29 September 2009 (in 2(2)), but were corrected by EFSA when writing the conclusion.

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

	RMS/peer review proposal
Fenbuconazole	Xn, Reprotox Cat.3 R63: Possible risk of harm to the unborn child

Residues

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

Plant groups covered	Fruit (peach), Cereal (wheat), Root & tubers (sugar beet), Pulse/Oilseed (peanut)
Rotational crops	Leafy (lettuce, collard), root (turnip, radish, carrot) and cereal (wheat, barley, sorghum).
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Fenbuconazole
Residue pattern in processed commodities similar to residue pattern in raw commodities?	No breakdown observed during hydrolysis
Plant residue definition for monitoring	Fenbuconazole (sum of enantiomers)
Plant residue definition for risk assessment	Fenbuconazole (sum of enantiomers) (Provisional, pending information on residue levels and outcome of a global risk assessment on TDMs). An additional residue definition is needed for TDMs, harmonized for all active substances of the triazole chemical class.
Conversion factor (monitoring to risk assessment)	None

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

Animals covered	Goat, hen
Time needed to reach a plateau concentration in milk and eggs	Milk: plateau not reached after 7 days Eggs: plateau reached after 6 to 7 days
Animal residue definition for monitoring	Fenbuconazole (sum of enantiomers)
Animal residue definition for risk assessment	Fenbuconazole (sum of enantiomers) (Provisional, pending information on residue levels and outcome of a global risk assessment on TDMs). An additional residue definition is needed for TDMs, harmonized for all active substances of the triazole chemical class.
Conversion factor (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No: (log $P_{o/w}$ >3, but metabolism and feeding studies show no accumulation).

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

Metabolism profile similar to primary crop. TDMs residues expected to be present in significant levels in rotational/succeeding crops.

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

Fruit crops: 4.5 years, Cereals: 3 years, Nuts: 4.5 years and Processed fruit products: 1 year, when stored frozen at <-10°C. Milk: 4 months, Eggs: 2.5 months, other animal products: 2-4 months, when stored at <-10°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)	Yes 0.72 and 1.78 mg/kg DM (dairy/beef cattle)	No 0.02 mg/kg DM	No
Potential for accumulation (yes/no):	No	No	-
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues	Yes	No	-
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : (Max) mg/kg		
Muscle	<0.01 mg/kg (3.6N)	A study on poultry was conducted; however intakes by poultry are not significant	-
Liver	0.093 mg/kg (3.6N)		-
Kidney	<0.01 mg/kg (3.6N)		-
Fat	<0.01 mg/kg (3.6N)		-
Milk	<0.01 mg/kg (3.5N)		
Eggs			

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/ Southern Region	Trials results relevant to the representative uses (a)	Recommendation/ comments	MRL from trials according to the representative use	HR (c)	STMR (b)
Wheat grain	N	26x <0.02		0.02* (LOQ)	<0.02	0.02
	S	6x <0.02		0.02* (LOQ)	<0.02	0.02
Wheat straw	N	0.20, 0.39, 0.41, 0.75, 0.79, 0.85, 0.89, 2x 0.95, 1.05, 1.26, 2.35		-	2.35-	0.87
	S	0.05, 0.539, 1.59, 2.89		-	2.89	1.06
Apple	N	3x 0.02, 4x 0.03, 2x 0.04, 3x 0.05, 2x 0.06.	R_{max} = 0.08 R_{ber} = 0.10	0.1	0.06	0.04
	S	<0.01, 2x 0.01, 2x 0.013, 0.017, 0.02, 0.034, 2x 0.04, 0.057, 2x 0.06	R_{max} = 0.08 R_{ber} = 0.10	0.1	0.06	0.02
Grape	N	0.15, 0.27, 0.30, 2x 0.36, 0.37, 0.48, 0.54, 0.61, 0.68	R_{max} = 0.89 R_{ber} = 1.12	1.0	0.68	0.37
	S	0.026, 0.038, 0.046, 0.047, 0.05, 0.068, 0.077, 0.107	R_{max} = 0.14 R_{ber} = 0.15	0.2	0.107	0.05

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

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

Note: Triazole derivative metabolites (TDMs) not taken into account in the consumer risk assessment.

ADI	0.006 mg/kg bw/day
TMDI (% ADI) according to WHO European diet	Maximum TMDI: 0.0017 mg/kg bw/day (28%), Cluster diet B
TMDI (% ADI) EFSA PRIMo model	Maximum TMDI: 73% ADI (FR all population)
IEDI (WHO European Diet) (% ADI)	Not calculated – see TMDI.
NEDI (UK diet) (% ADI)	UK diet: Critical consumer, toddler: NEDI = 0.0014 mg/kg bw/d (23% ADI).
Factors included in IEDI and NEDI	Processing factor of 0.08 for wine from grapes
ARfD	0.3 mg/kg bw/day
IESTI (% ARfD) EFSA PRIMo model	Maximum IESTI: 22% ARfD (table grapes, DE child)
NESTI (% ARfD) according to UK diets, large portion consumption data	UK diet: Critical consumer, toddler consuming table grape: 0.0415 mg/kg bw/d (14% ARfD).
Factors included in IESTI and NESTI	None

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

Crop/ process/processed product	Number of studies	Processing factors		Amount transferred (%)
		Transfer factor	Yield factor	
Apple/ washed apples	1	1.08	-	-
Apple/ wet pomace	1	2.50	-	-
Apple/ apple juice	1	0.16	-	-
Grape/ wine	6	0.08	-	-
Wheat/flour	2	0.20	-	-
Peach/ peach puree	2	0.19	-	-
Plum/prune	10	2.80	-	-

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

Plant products

Apple	0.1 mg/kg
Grape	1.0 mg/kg
Wheat grain	0.02* mg/kg

Ruminant products[12]	0.05* mg/kg

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

[12] The initial proposal for ruminant products was 0.05 mg/kg for liver and 0.01*mg/kg for meat, fat, kidney and milk, but an overall MRL of 0.05*mg/kg was finally proposed during the written procedure, since the analytical method for monitoring was validated with an LOQ of 0.05 mg/kg only. This is of no consequence on the consumer risk assessment.

Fate and behaviour in the environment

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

Mineralization after 100 days ‡	0.7 % after 90 d, [^{14}C-TR]-label (n = 5) 12 % after 90 d, [^{14}C-PH]-label (n = *2*) (studies at 20-25°C) Sterile conditions: no degradation after 363 d (n = 2)
Non-extractable residues after 100 days ‡	45.5 % after 96 d, [^{14}C-TR]-label (n = 5) 15.2 % after 90 d, [^{14}C-PH]-label (n = 2) (studies at 20-25°C)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	RH-0118 (1,2,4-triazole) peaked at 12.4% AR after 363 d [^{14}C-TR] label (25°C) and up to 15 % after 70 – 92 d [^{14}C-TR] label. RH-9129 peaked at 9.7% after 240 d [^{14}C-TR] label (25°C) (>5% on more than 2 time points) RH-6467 peaked at 7.7% after 120 d [^{14}C-PH] label (25°C) (>5% on more than 2 time points)

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

Anaerobic degradation ‡

Mineralization after 100 days	no collection of volatile products was made
Non-extractable residues after 100 days	18.6 % after 60 d, [^{14}C-TR]-label (n = 2) 19.0 % after 60 d, [^{14}C-PH]-label (n = *2*) (studies at 25°C)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	None

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	None

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	X[13]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa†	St. (r^2)	Method of calculation
Sandy loam		4.9*	25°C / 75% FC	367 / 1219	590	8.4	SFO
Silty clay loam		6.4*	25°C / 75% FC	261 / 868	258	4.3	SFO
Sandy loam		4.8	20°C / 40% MWHC	33 / 109	33	6.9	SFO
Sandy loam		6.0	20°C / 40% MWHC	71 / 235	67	3.9	SFO
Silt loam		7.4	20°C / 40% MWHC	260 / 865	240	3.4	SFO
Geometric mean					152 d		

*method of pH determination not reported

† normalised to 20°C using Q10 factor of 2.58

A geometric mean DT_{50} normalised to 20°C only (no soil moisture corrections) was 172 d (used for PECsoil calculations)

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

RH-9129	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa†	St. (chi^2)	Method of calculation
Silty clay loam		4.9	25 / 75% FC	144.4/479.7	0.436	131.4**	7.5*	SFO
Silty clay loam		4.9	25 / 75% FC	122.4/406.6	0.326			SFO
Sandy loam		6.4	25 / 75% FC	69.3/230.2	0.259	103.9**	30.4*	SFO

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

RH-9129	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa†	St. (chi^2)	Method of calculation
Sandy loam		6.4	25 / 75% FC	60.4/200.6	0.241			SFO
Geometric mean/median					0.315*	N/A		

* arithmetic mean
** geomean of individual soil types
† normalised to 20°C using Q10 factor of 2.58
N/A: not applicable, only data from 2 soils available, worst-case value used in exposure assessment.

RH-6467	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa†	St. (chi^2)	Method of calculation
Silty clay loam		4.9	25 / 75% FC	94.9/315.3	0.291	101.1	40.0	SFO
Silty clay loam		4.9	25 / 75% FC	110.2/366.1	0.208			SFO
Sandy loam		6.4	25 / 75% FC	178.3/592.3	0.355	244.2	33.3	SFO
Sandy loam		6.4	25 / 75% FC	129.7/430.9	0.393			SFO
Geometric mean/median					0.312*	N/A		

* arithmetic mean
** geomean of individual soil types
† normalised to 20°C using Q10 factor of 2.58
N/A: not applicable, only data from 2 soils available, worst-case value used in exposure assessment.

Field studies ‡

Fenbuconazole	Aerobic conditions								
Soil type (ADAS) (bare soil).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
Sandy loam	Germany		6.3	15	98	-	0.816		SFO for the first part of a bi-phasic decay curve. DT_{90} considered to be > 1 year
Sandy loam	Germany		4.7	15	73	-	0.875		
Silty clay loam	Germany		6.7	15	6	-	0.860		
Sand	Germany		4.7	15	66	-	0.775		
Arithmetic mean					61				

pH dependence ‡ (yes / no) (if yes type of dependence)	No

Soil accumulation and plateau concentration ‡	Plateau concentration of 0.28 mg/kg (residue before next application) was reached after 5 years (5 x 136 g/ha monthly intervals per annum) in field accumulation studies.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Fenbuconazole ‡							
Soil Type (USDA)	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay	0.23	5.3	-	-	5.07	2185	0.927
Loam	1.39	7.2	-	-	75.21	5402	1.005
Sand	0.29	7.3	-	-	7.56	2608	1.222
Sandy loam	1.28	5.4	-	-	115.4	9043	1.004
Silty clay loam	0.70	7.0	-	-	20.08	2885	0.845
Arithmetic mean					45	4425	1.001
pH dependence, Yes or No			No				

Metabolite 1,2,4-triazole ‡							
Soil Type (USDA)	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Silty clay	0.70	8.8	-	-	0.833	120	0.897
Clay loam	1.74	6.9	-	-	0.748	43	0.827
Sand	0.12	4.8	-	-	0.234	202	0.885
Silty clay loam	0.70	7.0	-	-	0.722	104	0.922
Sandy loam	0.81	6.9	-	-	0.720	59	1.016
Arithmetic mean (of 4 values excluding the very low OC sand that was considered not representative of agricultural soils)					0.756	89	0.916
pH dependence (yes or no)			No				

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

Metabolite RH-6467‡							
Soil Type (USDA)	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loam	1.0	5.8	-	-	14	1400	0.91
Sandy loam	0.9	7.7	-	-	12	1333	0.93
Sandy loam	3.2	5.9	-	-	30	938	0.90
Loamy sand	0.8	7.9	-	-	12	1500	0.92
Arithmetic mean					17	1293	0.92

pH dependence (yes or no)	No

Metabolite RH-9129‡							
Soil Type (USDA)	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loam	1.0	5.8	-	-	24	2400	0.89
Sandy loam	0.9	7.7	-	-	24	2667	0.96
Sandy loam	3.2	5.9	-	-	105	3281	0.93
Loamy sand	0.8	7.9	-	-	19	2375	0.91
Arithmetic mean					43	2681	0.92
pH dependence (yes or no)			No				

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

Column leaching ‡	None required None submitted
Lysimeter/ field leaching studies ‡	None required None submitted

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 172 days Kinetics: SFO Lab: geomean from lab studies corrected to 20 °C, considered more conservative compared to the longest field value.
Application data	Crop: apples, grapevine and wheat Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: 50% interception for foliar applications Number of applications: Apples: 10 x 70g a.s./ha; Grapevines: 2 x 37 g a.s./ha followed by 6 x 60 g a.s./ha; Wheat: 2 x 75 g a.s./ha. No application interval assumed since soil loading considered cumulative based on DT_{50} of 172 d

PEC$_{(s)}$ (mg/kg)	Apples		Grapevines		Wheat	
	Actual	TWA	Actual	TWA	Actual	TWA
Initial	0.467	0.467	0.289	0.289	0.100	0.100
Short term 24h	0.465	0.466	0.288	0.289	0.100	0.100
2d	0.463	0.465	0.287	0.288	0.099	0.100
4d	0.459	0.463	0.285	0.287	0.098	0.099
Long term 7d	0.454	0.460	0.281	0.285	0.097	0.099
28d	0.417	0.441	0.258	0.274	0.089	0.095
50d	0.382	0.423	0.237	0.262	0.082	0.091
100d	0.312	0.384	0.193	0.238	0.067	0.082
Plateau concentration	0.38 mg/kg after 4 yr (calculated)					

Metabolite 1,2,4-triazole Method of calculation	Molecular weight relative to the parent: 69.1 g/mol (1,2,4-triazole); 336.8 g/mol (fenbuconazole)
Application data	Application rate assumed: Apples: 700g a.s./ha; Grapevines: 434g as/ha; Wheat: 150g a.s./ha. (assumed 1,2,4-triazole is formed at a maximum of 14.9 % AR after 70 d)
PECsoil initial	Apple: 0.012mg/kg Grapevine: 0.007mg/kg Wheat: 0.003mg/kg
Maximum accumulated PECsoil (based on 5 x 136g a.s./ha applied annually to apples)	0.029 mg/kg

Metabolite RH-9129 Method of calculation	Molecular weight relative to the parent: 353.8 g/mol (RH-9129); 336.8 g/mol (fenbuconazole)
Application data	Application rate assumed: Apples: 700g a.s./ha; Grapevines: 434g as/ha; Wheat: 150g a.s./ha. (assumed RH-9129 is formed at a maximum of 9.7% of the applied dose)
PECsoil initial	Apple: 0.048mg/kg Grapevine: 0.029mg/kg Wheat: 0.010mg/kg
Maximum accumulated PECsoil (based on 5 x 136g a.s./ha applied annually to apples)	0.098mg/kg

Metabolite RH-6467 Method of calculation	Molecular weight relative to the parent: 350.8 g/mol (RH-6467); 336.8 g/mol (fenbuconazole)
Application data	Application rate assumed: Apples: 700g a.s./ha; Grapevines: 434g as/ha; Wheat: 150g a.s./ha. (assumed RH-6467 is formed at a maximum of 5.6% of the applied dose)
PECsoil initial	Apple: 0.027mg/kg Grapevine: 0.017mg/kg Wheat: 0.006mg/kg
Maximum accumulated PECsoil (based on 5 x 136g a.s./ha applied annually to apples)	0.056mg/kg

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5, 7 and 9: fenbuconazole was stable to hydrolysis at 25 ºC
Photolytic degradation of active substance and metabolites above 10 % ‡	Artificial light, equivalent to midsummer sunlight at 40°N for 30 d Fenbuconazole was stable to photolytic degradation (pH 7)
Quantum yield of direct phototransformation in water at Σ > 290 nm	None required, none submitted.
Readily biodegradable ‡ (yes/no)	No

Degradation in water / sediment

Parent	Distribution: Water: 96% after 0 d, 0.4-3.6% after 105 d. Maximum of 87.5% in sediment after 30 d									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50} whole sys.	St. (r^2)	$DissT_{50}$ water	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Rhine river	8.5	7.7	20	509	0.824	5	0.980	Not calculated	-	SFO
Rheinfelden pond	8.1	7.15	20	451	0.927	3	0.994		-	SFO
Geometric mean/median				-		-		-		-

Metabolites	No major metabolites				
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)
Rhine river	8.5	7.7	0.3% at end of study (105 d)	4.7% after 60 d	6.6% at end of study (105 d)
Rheinfelden pond	8.1	7.15	0.3% at end of study (105 d)	8.2 after 60 d	12.0 at end of study (105 d)

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

Parent	Version control no. of FOCUS calculator: 1.1
Parameters used in FOCUSsw step 1 and 2	Molecular weight: 336.8 g/mol Water solubility: 0.2 mg/l Koc: 4425 ml/g DT_{50} soil (d): 150 days (Mean from Lab. Corrected

	to 20°C and pF 2 assuming SFO) DT_{50} water/sediment system (d): 480 d (Mean DT_{50} from two water sediment systems) DT_{50} water (d): 480 d DT_{50} sediment (d): 480 d Crop interception (%): Average crop canopy values
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: FOCUS SWASH 1.1 FOCUS MACRO 4.4.2 FOCUS PRZM SW 3.21.a FOCUS TOXSWA 2.1.1 As Step2 with following additions and amendments:- Vapour pressure: 5 x 10^{-6} Pa DT_{50} water (d): 999 d (worst-case) 1/n = 1
Application rate	Crop: Pome fruit; grapevines and winter wheat Crop interception: FOCUS Default at Step 3 Number of applications: Pome fruit: 4 x 70 g a.s. from 1st April with an 11 d interval; Grapevines: 4 x 60 g a.s./ha from 1st June with a 10 d interval; Winter wheat: 2 x 75g a.s./ha from 1st May with a 14 d interval.
Main routes of entry	29.197% drift at 3m (pome fruit) 8.028% drift at 3m (grapevine) 2.759% drift from 1m (winter wheat) 10 % runoff/drainage (at FOCUSsw Step 1) 4 % runoff/drainage (at FOCUSsw Step 2)

Use	PECsw (µg/l)		PECsed (µg/kg dry weight)	
FOCUS Step 1	**Max.**	**21 d TWA**	**Max.**	**21 d TWA**
Apples (early appl.) NE	40.8	17.8	772	758
Wheat (winter or spring var.) NE & SE	8.6	7.4	692	680
Vines (late appl.) NE	18.0	12.5	553	545
Total load PECsw[1]	120.58	-	-	-
FOCUS Step 2				
Apples (early appl.) NE	8.8	4.7	202	199
Wheat (winter or spring var.) SE	1.6	1.5	68.6	67.6
Vines (late appl.) NE	2.1	1.8	80	78.8
Total load PECsw[1]	15.71	-	-	-
FOCUS Step 3				
Apples (early appl.) R3 Stream at 4m	6.225	-	-	-
Apples (early appl.) D4 Pond at 6m	-	0.676	-	-
Apples (early appl.) D5 Pond at 6m	-	-	8.074	8.072
Winter wheat D1 Ditch at 1m	0.697	0.470	4.499	4.260
Vines (late appl.) D6 Ditch at 3.5m	1.078	0.605	5.334	4.751
FOCUS Step 4				
[2]Apples (early appl.) D4 Stream at 10m	3.019	-	-	-
Apples (early appl.) D4 Pond at 12m	-	0.332	-	-
Apples (early appl.) D5 Pond at 12m	-	-	3.971	3.970
Vines (late appl.) D6 Ditch at 6m	0.497	0.279	2.461	2.192
Wheat D1 Ditch at 3m	0.325			

[1]based on loadings resulting from early applications to apples in NE as a worst-case
[2]worst-case PECsw for apples relative to distance

PECsw via spray drift only (for aquatic risk assessment with formulation endpoints)

Use	Maximum initial PECsw (µg/l) (spray drift only)	Maximum initial PECsw (µg/l) (spray drift only, increased no spray buffer zone)
Apples (70 g/ha; early appl., **NE**)	6.09 (3m)	0.33 (25m)
Apples (52.5 g/ha; early appl., **SE**)	4.57 (3m)	0.46 (20m)
Vines (60 g/ha; late appl., **NE**)	1.28 (3m)	0.23 (10m)
Vines (38 g/ha; late appl., **SE**)	0.81 (3m)	0.39 (5m)
Wheat (75 g/ha, **NE** and **SE**)	0.48 (1m)	0.13 (5m)

Metabolites

Parameter	1,2,4-triazole
Mol wt. (g/mol)	69.1
Water solubility (mg/l)	1000*
Max. observed in soil studies (%)	12.4
Max. observed in water/sediment	0

studies	
K_{foc} (ml/g)	89
DT_{50} soil (d)	7.7
DT_{50} water/sediment (d)	999*
DT_{50} water (d)	999*
DT_{50} sediment (d)	999*
Application	Single application of 7.12g/ha based on total dose of parent of 4 x 70g a.s./ha used on pome fruit

*worst-case assumptions

Use (parent applied on pome fruit)	**Maximum initial PECsw (µg/l)**	**Maximum initial PECsed (µg/kg dry weight)**
Step 1: NE	2.12	1.89
Step 2: NE (Mar – May)	0.30	0.26
Step 2: SE (Mar – May)	0.59	0.53

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	<u>For FOCUS gw modelling, values used –</u> Modelling using FOCUS model(s), with appropriate FOCUS gw scenarios, according to FOCUS guidance. Model(s) used: FOCUS PELMO (v3.3.2), FOCUS PEARL (v3.3.3) Scenarios (list of names): All 9 FOCUS scenarios Crop: pome fruit, grapevine and spring and winter wheat Geometric mean parent DT_{50lab} 152 d *RH-9129 DT_{50lab} 131 d *RH-6467 DT_{50lab} 244 d (normalised to 10kPa or pF2, 20°C with Q10 of 2.58) Geometric mean 1,2,4-triazole DT_{50lab} 7.4 d (normalised to 10kPa or pF2, study performed at 20°C) Mean parent Kfoc: 4425 ml/g Mean parent 1/n: 1.001 Mean RH-9129 Kfoc: 2681 ml/g Mean RH-9129 1/n: 0.92 Mean RH-6467 Kfoc: 1293 ml/g 1,2,4-triazole Kfoc: 89 ml/g Mean 1,2,4-triazole 1/n: 0.92 Formation fraction: RH-9129 = 0.315 Formation fraction: RH-6467 = 0.312 Formation fraction: 1,2,4-triazole = 1 * max values of geometric mean from same soils
Application rate	Application rate: Apples: 10 x 70 g a.s./ha from 1st April at 11 d intervals, 50% crop interception; Grapevines: 2 x 37g a.s./ha from 1st May with a 10

d interval for early season use followed by 6 x 60 g a.s./ha from 1st June at 10 d intervals for late season use, crop interception assumed to be 50% early and 60% late; Wheat: 2 x 75 g a.s./ha from 1st May at 14 d intervals, crop interception assumed to be 50%

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

	Scenario	Fenbuconazole (µg/L)	Metabolite (µg/L)		
			1,2,4-triazole	RH-9129	RH-6467
PELMO/Apples	Chateaudun	<0.001	<0.001	0.001	0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001	<0.001
	Kremsmunster	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001	0.019
	Porto	<0.001	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001

	Scenario	Fenbuconazole (µg/L)	Metabolite (µg/L)		
			1,2,4-triazole	RH-9129	RH-6467
PEARL/Apples	Chateaudun	<0.001	<0.001	<0.001	0.002
	Hamburg	<0.001	<0.001	<0.001	0.002
	Jokioinen	<0.001	<0.001	<0.001	< 0.001
	Kremsmunster	<0.001	<0.001	<0.001	< 0.001
	Okehampton	<0.001	<0.001	<0.001	0.002
	Piacenza	<0.001	<0.001	<0.001	0.067
	Porto	<0.001	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	0.001
	Thiva	<0.001	<0.001	<0.001	0.004

	Scenario	Fenbuconazole (µg/L)	Metabolite (µg/L)		
			1,2,4-triazole	RH-9129	RH-6467
PELMO/Vines	Chateaudun	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001
	Jokioinen	-	-	-	-
	Kremsmunster	<0.001	<0.001	<0.001	<0.001
	Okehampton	-	-	-	-
	Piacenza	<0.001	<0.001	<0.001	0.015
	Porto	<0.001	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001

	Scenario	Fenbuconazole (µg/L)	Metabolite (µg/L)		
			1,2,4-triazole	RH-9129	RH-6467
PEARL/Vines	Chateaudun	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001
	Jokioinen	-	-	-	-
	Kremsmunster	<0.001	<0.001	<0.001	<0.001
	Okehampton	-	-	-	-
	Piacenza	<0.001	<0.001	<0.001	0.045
	Porto	<0.001	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	0.003

FOCUS PELMO and PEARL modelling – Wheat	All scenario results were < 0.1 µg/L for fenbuconazole RH-9129, RH-6467and 1,2,4-triazole

PEC$_{(gw)}$ From lysimeter / field studies – None submitted, none required

Parent	1st year	2nd year	3rd year
Annual average (µg/L)			

Metabolite X	1st year	2nd year	3rd year
Annual average (µg/L)			

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

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	Not studied - no data requested
Photochemical oxidative degradation in air ‡	DT_{50} of 13.1 h based on an OH radical concentration of 1.5 x 10^6 cm^{-3} on a 12h day basis derived by the Atkinson method of calculation.
Volatilisation ‡	Negligible from soil and plant surfaces over 24 hrs
Metabolites	None determined

PEC (air)

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

$PEC_{(a)}$

Maximum concentration	Negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: fenbuconazole, 1,2,4-triazole Surface Water: fenbuconazole, 1,2,4-triazole may enter via runoff/drainage Sediment: fenbuconazole, 1,2,4-triazole Ground water: fenbuconazole, 1,2,4-triazole, RH-9129 and RH-6467 Air: fenbuconazole

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

Soil (indicate location and type of study)	N\A
Surface water (indicate location and type of study)	Fenbuconazole was found to be included in only one surface water monitoring programme in France, which covered 6 sites in 2000 with a total of 26 samples. It was detected (> 0.05µg/L) in eight samples from four sites, with a maximum concentration in surface water of 0.28µg/L.
Ground water (indicate location and type of study)	N\A
Air (indicate location and type of study)	N\A

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

With regard to fate and behaviour data	Candidate for R53 (not ready biodegradable)

Ecotoxicology

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Bobwhite quail (*Colinus virginianus*)	a.s.	Acute	>2150	-
Bobwhite quail (*Colinus virginianus*)	a.s.	Short-term	NOEL[a]: 111	2110 (mallard) 4050 (bobwhite quail)
Mallard duck (*Anas platyrhynchos*)	a.s.	Long-term	21	150
Mammals ‡				
Rat	a.s.	Acute	>5000	-
	a.s.	Long-term	5	80

[a] Due to reduced food consumption seen in the short-term dietary study with the a.s., it was not possible to determine an accurate dietary LDD_{50} (or $LD50_{st}$) in terms of mg a.s./kg bw/day, therefore the NOEC from the study has been converted into a $NOEL_{st}$ and is used. This is in line with current guidance but it should be noted that this will provide a more precautionary and conservative estimate of short-term risk

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

Application rate (kg as/ha)		Bird or mammal category	Timescale	ETE[a] mg a.s./kg bw/day	TER	Ann.VI trigger
4 x 0.07	apples	small insectivorous bird	acute	3.79	>567	10
4 x 0.07	apples	small insectivorous bird	short term dietary	2.11	53	10
4 x 0.07	apples	small insectivorous bird	long term/ reproductive	2.11	9.95	5
4 x 0.06	vines	small insectivorous bird	acute	3.24	>664	10
4 x 0.06	vines	small insectivorous bird	short term dietary	1.81	61	10
4 x 0.06	vines	small insectivorous bird	long term/ reproductive	1.81	11.6	5

Toxicity/exposure ratios for terrestrial vertebrates – continued

2 x 0.075	wheat	large herbivorous bird	acute	4.69	>458	10
2 x 0.075	wheat	small insectivorous bird	acute	4.06	>530	10
2 x 0.075	wheat	large herbivorous bird	short term dietary	2.51	44	10
2 x 0.075	wheat	small insectivorous bird	short term dietary	2.26	49	10
2 x 0.075	wheat	large herbivorous bird	long term/ reproductive	1.33	15.8	5
2 x 0.075	wheat	small insectivorous bird	long term/ reproductive	2.26	9.3	5
4 x 0.07	apples	small herbivorous mammal	acute	12.4	>403	10
4 x 0.07	apples	small herbivorous mammal	long term/ reproductive	4.24	**1.2**[b]	5
4 x 0.06	vines	small herbivorous mammal	acute	11.05	>452	10
4 x 0.06	vines	small herbivorous mammal	long term/ reproductive	3.81	**1.3**[b]	5
2 x 0.075	wheat	small herbivorous mammal	acute	14.8	>338	10
2 x 0.075	wheat	small insectivorous mammal	acute	0.66	>7576	10
2 x 0.075	wheat	small herbivorous mammal	long term/ reproductive	4.2	**1.2**[b]	5
2 x 0.075	wheat	small insectivorous mammal	long term/ reproductive	0.24	21	5

[a] The ETE (Estimated Theoretical Exposure) is calculated in terms of daily dose according to the equations given in the EC Guidance Document on Risk Assessment for Birds and Mammals (SANCO/4145/2000, European Commission, 2002).

[b] Higher tier risk assessments for small herbivorous mammals were conducted and the refined TERs (which are very close to or greater than 5) are considered acceptable. See below and refer to DAR Vol. 3, Section B.9.3.4.1 and Appendix 10 to Vol. 3 Section B.9 for further details.

Higher tier refinement (long term risk, herbivorous mammals)
See Appendix 10 to Vol. 3 of the DAR for the applicant's case regarding refinements for TER_{LT} for herbivorous mammals. See also Addendum 2 to the DAR. The revised foliar DT_{50} of 6.7 days was agreed. Refinements of concentrations in food items (C) were also agreed based on cereals residue trial summarised in Section B.7.6 (mean cereal residue at relevant growth stages of 1.64-8 mg a.s./kg).

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

Timescale/Species	Test substance	Duration/ method	Endpoint	Toxicity (mg a.s./l)
Acute				
cold water fish *Oncorhynchus mykiss*	technical fenbuconazole	96 h, static	LC_{50}	1.5[1]
warm water fish *Lepomis machrochirus*	technical fenbuconazole	96 h, static	LC_{50}	0.68[1]
invertebrate *Daphnia magna*	technical fenbuconazole	48 h, flow-through	EC_{50}	2.3[2]
marine invertebrate *Americamysis bahia*	technical fenbuconazole	96 h, flow-through	EC_{50}	0.75[2]
green alga *Pseudokirchneriella subcapitata*	technical fenbuconazole	72 h, static	E_bC_{50} (cell count)	0.33[3]
cold water fish *Oncorhynchus mykiss*	'Indar 5EC'	96 h, flow-through	LC_{50}	0.06[1] (a.s. ≡)
cold water fish *Oncorhynchus mykiss*	'Indar 5EW'	96 h, flow-through	LC_{50}	0.29[1] (a.s. ≡)
warm water fish *Lepomis machrochirus*	'Indar 5EW'	96 h, static	LC_{50}	0.62[2] (a.s. ≡)
green alga *Scenedesmus subspicatus*	'Indar 5EC'	96 h, static	E_bC_{50} E_rC_{50}	0.16[2] (96 h 0.41[2] (72 h) (a.s. ≡)
green alga *Scenedesmus subspicatus*	'Indar 5EW'	96 h, static	E_bC_{50} E_rC_{50}	0.13[2] 0.31[2] (72 h, a.s. ≡)

Toxicity to aquatic organisms - cont.d

Chronic				
cold water fish *Oncorhynchus mykiss*	technical fenbuconazole	21 d, semi-static, growth	NOEC	0.32[2]
warm water fish *Pimephales promelas*	technical fenbuconazole	33 d, flow-through, ELS	NOEC	0.082[1]
warm water fish *Pimephales promelas*	technical fenbuconazole	33 d, flow-through, life cycle	NOEC	0.023[2]
invertebrate *Daphnia magna*	technical fenbuconazole	21 d, semi-static	NOEC	0.078[1]
cold water fish *Oncorhynchus mykiss*	'Indar 5EC'	21 d, flow through, growth	NOEC	0.005[1] (a.s. ≡)
invertebrate *Daphnia magna*	'Indar 5EC'	21 d, semi-static	NOEC	0.012[2] (a.s. ≡)
Sediment-dwelling invertebrate *Chironomus riparius*	technical fenbuconazole	31 d, static, in presence of sediment	NOEC	1.73[3] aqueous phase, 8.0[1] mg/kg in sediment
Fish bioconcentration study				
Lepomis machrochirus	technical fenbuconazole	28 h, flow-through	BCF whole fish: 160 clearance ½ life: 1.4 d	>10
Microcosm or mesocosm tests				
None submitted				

[1] Based on mean measured test concentrations.
[2] Based on nominal test concentrations.
[3] Based on initial measured test concentrations.

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

FOCUS Step 1 acute TERs for aquatic life

Apples (early application in NE at 4 x 70 g a.s./ha gives maximum PEC) - see Tables B.8.54 and B.8.61 in DAR						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)[2]	TERa	Annex VI Trigger
'Indar 5EW'	Fish	Acute	0.29[1]	0.0408	7.1	100
'Indar 5EW'	Aquatic invertebrates	Acute	0.52[1]	0.0408	12.7	100
'Indar 5EW'	Algae	Acute[3]	0.13[1]	0.0408	3.2	10
Grapevines (late application in NE at 4 x 60 g a.s./ha gives maximum PEC) - see Tables B.8.54 and B.8.61 in DAR						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)[2]	TERa	Annex VI Trigger
'Indar 5EW'	Fish	Acute	0.29[1]	0.018	16.1	100
'Indar 5EW'	Aquatic invertebrates	Acute	0.52[1]	0.018	28.9	100
'Indar 5EW'	Algae	Acute[3]	0.13[1]	0.018	7.2	10
Wheat (application to winter or spring var.s in NE & SE at 2 x 75 g a.s./ha) - see Tables B.8.54 and B.8.61 in DAR						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)[2]	TERa	Annex VI Trigger
'Indar 5EC'	Fish	Acute	0.06[1]	0.0086	**6.98**	100
'Indar 5EC'	Aquatic invertebrates	Acute	0.31[1]	0.0086	**36.0**	100
'Indar 5EC'	Algae	Acute[3]	0.158[1]	0.0086	18.4	10

[1] Active substance equivalent endpoint from formulation toxicity study
[2] Worst-case maximum initial surface water PECs from Table B.8.61
[3] More correctly a short term or chronic endpoint since it covers multiple generations.

FOCUS Step 2 acute TERs for aquatic life

Apples (early application in NE at 4 x 70 g a.s./ha gives maximum PEC) - see Tables B.8.54 and B.8.61 in DAR						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)[2]	TERa	Annex VI Trigger
'Indar 5EW'	Fish	Acute	0.29[1]	0.0088	32.95	100
'Indar 5EW'	Aquatic invertebrates	Acute	0.52[1]	0.0088	59.1	100
'Indar 5EW'	Algae	Acute	0.13[1]	0.0088	14.8	10
Grapevines (late application in NE at 4 x 60 g a.s./ha gives maximum PEC) - see Tables B.8.54 and B.8.61 in DAR						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)[2]	TERa	Annex VI Trigger
'Indar 5EW'	Fish	Acute	0.29[1]	0.0027	107.4	100
'Indar 5EW'	Aquatic invertebrates	Acute	0.52[1]	0.0027	192.6	100
'Indar 5EW'	Algae	Acute	0.13[1]	0.0027	48.1	10
Wheat (application to winter or spring var.s in SE at 2 x 75 g a.s./ha gives maximum PEC) - see Tables B.8.54 and B.8.61 in DAR						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)[2]	TERa	Annex VI Trigger
'Indar 5EC'	Fish	Acute	0.06[1]	0.0016	**37.5**	100
'Indar 5EC'	Aquatic invertebrates	Acute	0.31[1]	0.0016	193.75	100

[1] Active substance equivalent endpoint from formulation toxicity study
[2] Worst-case maximum initial surface water PECs from Table B.8.61

FOCUS Step 3 acute TERs for aquatic life based on minimum default spray drift distances for each crop

Apples (early application in NE at 4 x 70 g a.s./ha and 4 m drift to R3 stream gives maximum PEC) - see Tables B.8.55 and B.8.61 in DAR						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)[2]	TERa	Annex VI Trigger
'Indar 5EW'	Fish	Acute	0.29[1]	0.006225	46.6	100
'Indar 5EW'	Aquatic invertebrates	Acute	0.52[1]	0.006225	83.5	100
Wheat (application to winter sown crops in SE at 2 x 75 g a.s./ha and 1 m drift to D1 ditch gives maximum PEC) - see Tables B.8.57 and B.8.61 in DAR						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)[2]	TERa	Annex VI Trigger
'Indar 5EC'	Fish	Acute	0.06[1]	0.000697	**86.1**	100

[1] Active substance equivalent endpoint from formulation toxicity study
[2] Worst-case maximum initial surface water PECs from Table B.8.61

FOCUS Step 4 acute TERs for aquatic life, determined as for Step 3 but with additional buffer zone distances

Apples (early application in NE at 4 x 70 g a.s./ha and 10 m drift to D4 stream provides worst-case initial PEC relative to buffer distance) - see Table B.8.60 in DAR						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)	TERa	Annex VI Trigger
'Indar 5EW'	Fish	Acute	0.29[1]	0.003019[2]	96	100
'Indar 5EW'	Aquatic invertebrates	Acute	0.52[1]	0.003019[2]	172	100
Wheat (application to winter sown crops in SE at 2 x 75 g a.s./ha and 3 m drift to D1 ditch gives maximum initial PEC) see Tables B.8.60a and B.8.61 in DAR						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)	TERa	Annex VI Trigger
'Indar 5EC'	Fish	Acute	0.06[1]	0.000325[3]	185	100

[1] Active substance equivalent endpoint from formulation toxicity study
[2] Relative worst-case initial surface water PEC (D4 stream, 10 m buffer) from Table B.8.60
[3] Worst-case maximum initial surface water PEC from Table B.8.61

Chronic toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, 10.2)

FOCUS Step 1 chronic TERs for aquatic life

Apples (early application in NE at 4 x 70 g a.s./ha gives maximum PEC) - see Tables B.8.54 and B.8.61 in DAR						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)[2]	TERlt	Annex VI Trigger
'Indar 5EC'[1]	Fish	Chronic	0.005[1]	0.0408	0.12	10
'Indar 5EC'[1]	Aquatic invertebrates	Chronic	0.012[1]	0.0408	0.29	10
fenbuconazole	Sediment dwelling invertebrates	Chronic	0.173 8.0[3]	0.1206[4] 0.772[5]	1.4 10.4	10
Grapevines (late application in NE at 4 x 60 g a.s./ha gives maximum PEC) - see Tables B.8.54 and B.8.61 in DAR						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)[2]	TERlt	Annex VI Trigger
'Indar 5EC'[1]	Fish	Chronic	0.005[1]	0.018	0.28	10
'Indar 5EC'[1]	Aquatic invertebrates	Chronic	0.012[1]	0.018	0.67	10
Wheat (application to winter or spring var.s in NE & SE at 2 x 75 g a.s./ha) - see Tables B.8.54 and B.8.61 in DAR						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)[2]	TERlt	Annex VI Trigger
'Indar 5EC'	Fish	Chronic	0.005[1]	0.0086	**0.58**	10
'Indar 5EC'	Aquatic invertebrates	Chronic	0.012[1]	0.0086	**1.4**	10

[1] The lowest active substance equivalent endpoints from 'Indar 5EC' toxicity studies are used for all assessments.
[2] Worst-case maximum initial surface water PECs from Table B.8.61.
[3] Sediment phase effects endpoint in mg a.s./kg.
[4] Total Load PECsw - see Section B.8.5.2.
[5] Maximum PECsed in mg a.s./kg dry weight.

Note: The sediment dweller risk assessment is only conducted for the apple use as this covers the less worst-case uses on vines and cereals.

FOCUS Step 2 chronic TERs for aquatic life

Apples (early application in NE at 4 x 70 g a.s./ha gives maximum PEC) - see Tables B.8.54 and B.8.61						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)[2]	TERlt	Annex VI Trigger
'Indar 5EC'[1]	Fish	Chronic	0.005[1]	0.0088	0.56	10
'Indar 5EC'[1]	Aquatic invertebrates	Chronic	0.012[1]	0.0088	1.4	10
fenbuconazole	Sediment dwelling invertebrates	Chronic	0.173	0.01571[3]	11	10
Grapevines (late application in SE at 4 x 60 g a.s./ha gives max PEC) - see Tables B.8.54, B.8.61						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)[2]	TERlt	Annex VI Trigger
'Indar 5EC'[1]	Fish	Chronic	0.005[1]	0.0027	1.9	10
'Indar 5EC'[1]	Aquatic invertebrates	Chronic	0.012[1]	0.0027	4.4	10
Wheat (application to winter or spring var.s in SE at 2 x 75 g a.s./ha gives maximum PEC) - see Tables B.8.54 and B.8.61						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)[2]	TERlt	Annex VI Trigger
'Indar 5EC'	Fish	Chronic	0.005[1]	0.0016	**3.1**	10
'Indar 5EC'	Aquatic invertebrates	Chronic	0.012[1]	0.0016	**7.5**	10

[1] The lowest active substance equivalent endpoints from 'Indar 5EC' toxicity studies are used for all assessments.
[2] Worst-case maximum initial surface water PECs from Table B.8.61.
[3] Total Load PECsw - see Section B.8.5.2.

Note: The sediment dweller risk assessment is only conducted for the apple use as this covers the less worst-case uses on vines and cereals.

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3 chronic TERs for aquatic life based on minimum default spray drift distances for each crop

Apples (early application in NE at 4 x 70 g a.s./ha and 4 m drift to R3 stream gives maximum PEC) - see Tables B.8.55 and B.8.61						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)[2]	TERlt	Annex VI Trigger
'Indar 5EC'[1]	Fish	Chronic	0.005[1]	0.006225	0.8	10
'Indar 5EC'[1]	Aquatic invertebrates	Chronic	0.012[1]	0.006225	1.9	10
Grapevines (late application in SE at 4 x 60 g a.s./ha to D6 ditch at 3.5 m drift gives maximum PEC) - see Tables B.8.56 and B.8.61						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)[2]	TERlt	Annex VI Trigger
'Indar 5EC'[1]	Fish	Chronic	0.005[1]	0.001078	4.6	10
'Indar 5EC'[1]	Aquatic invertebrates	Chronic	0.012[1]	0.001078	11	10
Wheat (application to winter sown crops in SE at 2 x 75 g a.s./ha and 1 m drift to D1 ditch gives maximum PEC) - see Tables B.8.57 and B.8.61						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)[2]	TERlt	Annex VI Trigger
'Indar 5EC'	Fish	Chronic	0.005[1]	0.000697	**7.4**	10
'Indar 5EC'[1]	Aquatic invertebrates	Chronic	0.012[1]	0.000697	17	10

[1] The lowest active substance equivalent endpoints from 'Indar 5EC' toxicity studies are used for all assessments.
[2] Worst-case maximum initial surface water PECs from Table B.8.61.

FOCUS Step 4 chronic TERs for aquatic life, as for Step 3 but with additional buffer zone distances

Apples (early application in NE at 4 x 70 g a.s./ha and 10 m drift to D4 stream provides worst-case initial PEC relative to buffer distance) - see Table B.8.60 in DAR						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)	TERlt	Annex VI Trigger
'Indar 5EC'[1]	Fish	Chronic	0.005[1]	0.003019[2]	1.66[4]	10
'Indar 5EC'[1]	Aquatic invertebrates	Chronic	0.012[1]	0.003019[2]	3.97[4]	10
Grapevines (late application in SE at 4 x 60 g a.s./ha to D6 ditch at 6 m drift gives maximum initial PEC) - see Tables B.8.59 and B.8.61 in DAR						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)	TERlt	Annex VI Trigger
'Indar 5EC'[1]	Fish	Chronic	0.005[1]	0.000497[3]	10.1	10
Wheat (application to winter sown crops in SE at 2 x 75 g a.s./ha and 3 m drift to D1 ditch gives maximum initial PEC) see Tables B.8.60a and B.8.61 in DAR						
Test substance	Organism	Timescale	Toxicity endpoint (mg/l)	PECsw (mg/l)	TERlt	Annex VI Trigger
'Indar 5EC'	Fish	Chronic	0.005[1]	0.000325[3]	15.4	10

[1] The lowest active substance equivalent endpoints from 'Indar 5EC' toxicity studies are used for all assessments.
[2] Relative worst-case initial surface water PEC (D4 stream, 10 m buffer) from Table B.8.60.
[3] Worst-case maximum initial surface water PECs from DAR Table B.8.61.
[4] These chronic TERs are still below the Annex VI trigger of 10 indicating that further refinement steps or larger buffer zones are required to protect against chronic effects in this 'worst-case' FOCUS scenario. See below:

Due to the use of a chronic formulation endpoint and because the major route of entry for fenbuconazole to surface water is via spray drift it is considered appropriate to also determine risks and buffer zones required to protect against spray-drift-only. The following buffer zone calculations are provided for key uses:

Buffer zone distances calculated for fenbuconazole using the SWASH spray drift calculator and chronic fish toxicity data on the EC formulation

Use	Maximum initial PECsw (µg a.s./l) (spray drift only based on default distances)	TER_{LT} (based on chronic fish NOEC of 5 µg a.s./l)	Maximum initial PECsw (µg a.s./l) (spray drift only, increased buffer zone)	TER_{LT} (based on chronic fish NOEC of 5 µg a.s./l)
Apples (70 g/ha; early appl., **NE**)	6.09 (3m)	**0.82**	0.326 (25m)	15.3
Apples (52.5 g/ha; early appl., **SE**)	4.57 (3m)	**1.1**	0.46 (20m)	10.9
Grapevines (60 g/ha; late appl., **NE**)	1.28 (3m)	**3.9**	0.23 (10m)	21.7
Grapevines (38 g/ha; late appl., **SE**)	0.81 (3m)	**6.2**	0.39 (5m)	12.8
Wheat (75 g/ha, **NE** and **SE**)	0.48 (1m)	10.4	-	-

TERs compare initial 'spray-drift-only' PECsw values against the worst-case chronic formulation NOEC of 0.005 mg a.s./l (for fish using 'Indar 5 EC' data). Values in **bold** fail the relevant Annex VI trigger of 10.

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)
Preparation ('Indar 5EC')	>95 µg formulation/bee, ≡ >5.2 µg a.s./bee	>100 µg formulation/bee, ≡ >5.5 µg a.s./bee
Semi-field or field tests		
Two cage studies were conducted using 'Indar 5EC' at 75 g a.s./ha and 150 g a.s./ha. No noticeable effect on mortality, no abnormal behaviour of the bees (no disorientation effects) and no negative influence on development of the bee brood. Fenbuconazole has no properties which would indicate that it has any residual or brood toxicity.		

Hazard quotients for honeybees (Annex IIIA, point 10.4)

Crop use	Maximum application rate (g a.s./ha)	48 h acute LD50 (µg a.s./bee)	Hazard quotient	Annex VI trigger
Apples	70	Oral: >5.2	QHO: <13.46	50
		Contact: >5.5	QHC: <12.73	50
Grapevines	60	Oral: >5.2	QHO: <11.54	50
		Contact: >5.5	QHC: <10.91	50
Wheat	75	Oral: >5.2	QHO: <14.42	50
		Contact: >5.5	QHC: <13.64	50

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

Species and life stage	Test type, substrate & duration	Endpoint	Dose (kg a.s./ha)	Effect	Annex VI Trigger
Laboratory tests on arthropods					
Aphidius rhopalosiphi (parasitic wasp) adults	Tier I, glass plate, 48h exposure + 24h fecundity, 'Indar 5EW'	Mortality & parasitism	0.063 0.136	M = 0.0%, P = 11.1% M = 0.0%, P = -1.4%	30% effect
Aphidius rhopalosiphi adults	Extended lab on barley seedlings for 24h, 'Indar 5EW'	Mortality & parasitism	0.150 0.680	M = 6.9%, P = -15.2% M = 6.9%, P = 18.3%	30% effect
Typhlodromus pyri (predatory mite) proto-nymphs	Tier I, glass plate, 7d exposure + 7d fecundity, 'Indar 5EW'	Mortality & fecundity	0.063	M = 0.0%, F = 9.0%	30% effect
Poecilus cupreus (ground beetle) adults	Tier I, quartz sand for 15d, 'Indar 5EC'	Mortality & food consumption	0.080	M = 0.0%, FC = -32.3%	30% effect
Coccinella septempuncatata (ladybird, foliage dweller) larvae	Tier I, glass plate until adult emergence, 'Indar 5EW'	Mortality & fecundity	0.066	M = 2.8%, F = -17.4%	30% effect

Effects on non-target arthropods - continued

Chrysoperla carnea[1] (lacewing, foliage dweller) larvae	Tier I, glass plate until pupation, 'Indar 5EW'[1]	Mortality & fecundity	0.066	M = 14.1%, F = -94.9%[1]	30% effect
Chrysoperla carnea[1] (lacewing, foliage dweller) larvae	Tier I, glass plate until pupation, 'Indar 5EC'[1]	Mortality & fecundity	0.080	M = 0.0%, F = -19.1%[1]	30% effect
Chrysoperla carnea larvae	Extended lab, on french bean leaves until pupation, 'Indar 5EW'	Mortality & fecundity	0.150 0.238 0.680	M = 0.0%, F = 19% M = 0.0%, F = 37% M = 0.0%, F = 16% effects on fecundity not clearly dose related or statistically significant (p >0.05)	30% effect
Field tests on arthropods					
Typhlodromus pyri (grapevines)	Field test in vines using 'Indar 5EW'. Nine applications at 0.051 kg a.s./ha (= 0.495 kg a.s./ha/yr) caused a maximum reduction in population size of 6.0 % compared to the control. Nine applications at 0.105 kg a.s./ha (= 0.945 kg a.s./ha/yr) caused a maximum reduction in population size of 13% compared to the control. Neither reduction was statistically significant from the control (p >0.05).				-

This substance was considered against ESCORT 1 criteria.
M = corrected mortality, P = parasitism by surviving females, F = fecundity of surviving females, FC = food consumption.
Note: Only increased mortality is shown. Negative effect values indicate an increase compared to the control.
[1] Endpoints from the glass plate studies with *C. carnea* should not be considered in isolation (studies were not in compliance with current guidelines re: validity criteria and no toxic reference was included).

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

Test organism	Test substance	Time scale	End point (mg a.s./kg d.w. soil)
Earthworms			
Eisenia fetida	a.s. ‡	Acute 14-days	LC50: >100 corrected to take account of Log K_{ow} of fenbuconazole = >50
Eisenia fetida	Preparation ('Indar 5EW')	Acute 14-days	LC50: 451 mg form.n/kg soil, ≡ 23, corrected to take account of Log K_{ow} of fenbuconazole = **11.5**
Eisenia fetida	Preparation ('Indar 5EW')	Chronic 28-days	NOEC: 181 mg form.n/kg soil, ≡ 10, corrected to take account of Log K_{ow} of fenbuconazole = **5**
Eisenia fetida	Metabolite 1,2,4-triazole	Acute	LC50: >1000 mg/L (taken from report of PRAPeR Expert Meeting 13)
Eisenia fetida	Metabolite 1,2,4-triazole	Chronic	NOEC of 1.0 mg/kg (taken from report of PRAPeR Expert Meeting 13)
Soil micro-organisms			
Nitrogen mineralisation	a.s. ‡		No significant effect >25% at up to 1.49 mg a.s./kg soil (actual 15% at 28d)
	Preparation ('Indar 5EW')		No significant effect >25% at equivalent of up to 6.35 mg a.s./kg soil (actual 12% at 28d)
Carbon mineralisation	a.s. ‡		No significant effect >25% at up to 1.49 mg a.s./kg soil (actual 17% at 28d)
	Preparation ('Indar 5EW')		No significant effect >25% at equivalent of up to 6.35 mg a.s./kg soil (actual 12% at 28d)

Field studies
A litter bag study conducted according to EPFES[14] guidelines and at a maximum soil concentration of 0.64 mg a.s./kg soil was submitted. This is considered adequate to cover typical concentrations in soil resulting from use on apples, grapevines and wheat - and indicates a no significant difference >10% in organic matter breakdown between control and treated plots. Based also on the low risk to earthworms, soil non-target arthropods and microbial processes, the risk to soil macro-organisms involved in organic matter breakdown is considered to be low.

[14] Effects of Plant Protection Products on Functional Endpoints in Soil

Toxicity/exposure ratios for earthworms

Crop use	Application rate (kg as/ha)	Time-scale	TER[1]	Annex VI trigger
Apples	2 x 0.7	acute	12	10
Grapevines	4 x 0.06	acute	30	10
Wheat	2 x 0.75	acute	46	10
Apples	2 x 0.7	chronic	5.2	5
Grapevines	4 x 0.06	chronic	13	5
Wheat	2 x 0.75	chronic	20	5

[1] TER is based on lowest toxicity value on the 'Indar 5EW' formulation which is also corrected by a factor of 2 to account for the log Kow of fenbuconazole (3.23). The PEC used is a worst-case maximum based on the accumulated baseline plateau concentration in soil plus the total in-year application for each crop.

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

The effects of fenbuconazole (applied as 'Indar 5EW') on seedling emergence, subsequent plant development and vegetative vigour were investigated in two glasshouse studies on a total of 10 monocotyledonous and dicotyledonous crop plants. None of the species tested showed any significant adverse pre-or post-emergence effects >50% after application of fenbuconazole at up to 204 g a.s./ha. A low off-field risk to non-target terrestrial plants is predicted.

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

Test type/organism	end point
Activated sludge	EC_{50}: >20 mg a.s./L

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

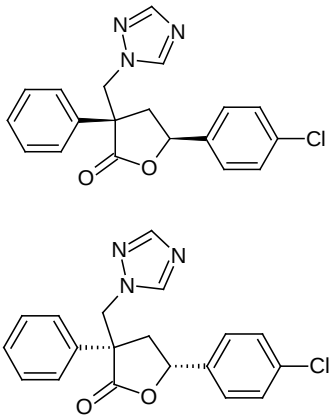
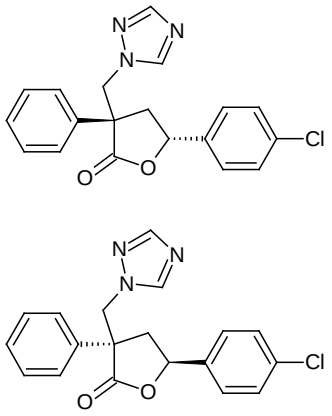
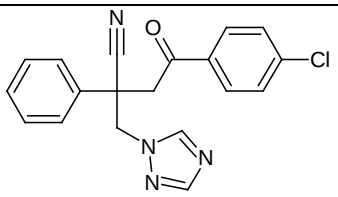
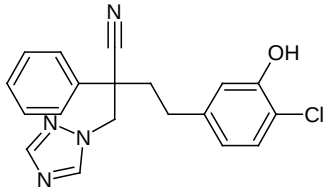
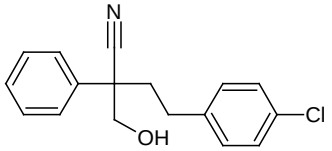
Compartment	
soil	fenbuconazole, 1,2,4-triazole
water	fenbuconazole, 1,2,4-triazole
sediment	fenbuconazole, 1,2,4-triazole
groundwater	fenbuconazole

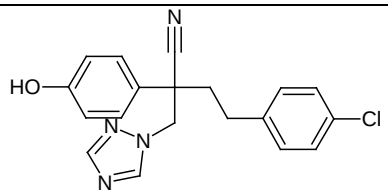
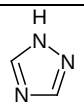
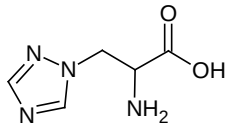
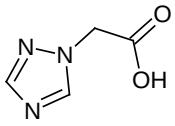
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	N, R50/R53, S60/S61

	RMS/peer review proposal
Preparation ('Indar 5EW' and 'Indar 5EC')	N, R51/R53, S35/S57

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula**
RH-9129 Lactone Lactone A	(3*RS*,5*SR*)-5-(4-chlorophenyl)-3-phenyl-3-(1*H*-1,2,4-triazol-1-ylmethyl)dihydrofuran-2(3*H*)-one	
RH-9130 Lactone Lactone B	(3*RS*,5*RS*)-5-(4-chlorophenyl)-3-phenyl-3-(1*H*-1,2,4-triazol-1-ylmethyl)dihydrofuran-2(3*H*)-one	
RH-6467 Ketone	(2*RS*)-4-(4-chlorophenyl)-4-oxo-2-phenyl-2-(1*H*-1,2,4-triazol-1-ylmethyl)butanenitrile	
RH-4911 Hydroxy-phenyl	(2*RS*)-4-(4-chloro-3-hydroxyphenyl)-2-phenyl-2-(1*H*-1,2,4-triazol-1-ylmethyl)butanenitrile	
RH-7968	(2*RS*)-4-(4-chlorophenyl)-2-(hydroxymethyl)-2-phenylbutanenitrile	

RH-1311 4-phenol	(2*RS*)-4-(4-chlorophenyl)-2-(4-hydroxyphenyl)-2-(1*H*-1,2,4-triazol-1-ylmethyl)butanenitrile	
1,2,4-triazole	1*H*-1,2,4-triazole	
RH-3968 **Triazole alanine** (TA)	3-(1*H*-1,2,4-triazol-1-yl)-DL-alanine	
RH-4098 **Triazole acetic acid** (TAA)	1*H*-1,2,4-triazol-1-ylacetic acid	

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

ABBREVIATIONS

1/n	slope of Freundlich isotherm
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
AV	avoidance factor
BCF	bioconcentration factor
bw	body weight
CAS	Chemical Abstract Service
CFU	colony forming units
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
EC	emulsifiable concentrate
EChA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-NPD	gas chromatography with nitrogen phosphorous detector
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GM	geometric mean
GS	growth stage

h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	inter laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value

PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PPR	Scientific Panel on Plant Protection Products and their Residues
PT	proportion of diet obtained in the treated area
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
Rf	retention factor
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TDMs	Triazole Derivative Metabolites
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLC	thin layer chromatography
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TWA	time weighted average
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year