CONCLUSION ON PESTICIDE PEER REVIEW

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

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ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State Greece, for the pesticide active substance fenazaquin are reported. The context of the peer review was that required by Regulation (EC) No 1107/2009. The conclusions were reached on the basis of the evaluation of the representative uses of fenazaquin as an acaricide and insecticide on grapes, citrus, pome fruit, stone fruit and greenhouse ornamentals. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

KEY WORDS

Fenazaquin, peer review, risk assessment, pesticide, acaricide, insecticide

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SUMMARY

Regulation (EC) No 1107/2009 (hereinafter referred to as 'the Regulation') lays down, *inter alia*, the detailed rules as regards the procedure for the assessment of applications for amendment to the conditions of approval of active substances.

Fenazaquin was approved on 1 June 2011 by Commission Implementing Directive 2011/39/EU, following a peer review of the risk assessment as set out in the EFSA Conclusion on fenazaquin, published on 15 November 2010. It was a specific provision of the approval that only uses as an acaricide on ornamentals in greenhouses may be authorised. In accordance with Article 7 of Regulation (EC) No 1107/2009, Greece received an application from Gowan Comércio Internacional e Serviços Limitada on 19 September 2011 for amendment to the conditions of approval of the active substance fenazaquin to lift the restriction and allow uses on grapes and citrus (previously applied for uses) as well as uses on pome fruit and stone fruit (additional uses) to be authorised

The RMS provided its initial evaluation of the dossier in the form of an Addendum to the Draft Assessment Report, which was received by the EFSA on 14 February 2012. The peer review was initiated on 26 April 2012 by dispatching the DAR for consultation of the Member States and the applicant, SCC GmbH on behalf of Gowan Comércio Internacional e Serviços Limitada. EFSA also provided comments.

Following consideration of the comments received on the Addendum, it was concluded that there was no need to conduct an expert consultation, and that the EFSA should adopt a conclusion on whether fenazaquin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009, also taking into consideration recital (10) of the Regulation.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of fenazaquin as an acaricide and insecticide on grapes, citrus, pome fruit, stone fruit and greenhouse ornamentals, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

A data gap was identified for a search of the scientific peer-reviewed open literature relevant to the scope of the application for amendment to the conditions of approval.

No data gaps or areas of concern are identified in the area of identity, physical and chemical properties and analytical methods.

No areas of concern are identified in the area of mammalian toxicology. The data available are sufficient to carry out the required operator, worker and bystander exposure assessments to fenazaquin under the representative conditions of use.

No critical areas of concern are identified in the area of residues. The consumer risk was only provisionally assessed for the representative use in stone fruits considering only peaches, and for the metabolite TBPE in grape, pome fruit and stone fruit processed products due to lack of respective residue data. Data gaps were identified.

The data available on the fate and behaviour in the environment are sufficient to carry out the required environmental exposure assessments at EU level for the representative uses assessed. The potential for groundwater contamination consequent to the uses from fenazaquin or its metabolites 2-oxy-fenazaquin, 4-OHQ, and TBPE above the parametric drinking water limit of 0.1 µg/L was assessed as low.

The risk to aquatic organisms was assessed as high for all representative uses evaluated and a critical area of concern was identified. In addition, a restriction is proposed to mitigate the risk to bees.

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BACKGROUND

Regulation (EC) No 1107/2009[3] (hereinafter referred to as 'the Regulation') lays down, *inter alia*, the detailed rules as regards the procedure for the assessment of applications for amendment to the conditions of approval of active substances. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant(s) for comments on the initial evaluation in the Draft Assessment Report (DAR) provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

In accordance with Article 12 of the Regulation, EFSA is required to adopt a conclusion on whether an active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation (also taking into consideration recital (10) of the Regulation) within 120 days from the end of the period provided for the submission of written comments, subject to an extension of 30 days where an expert consultation is necessary, and a further extension of up to 150 days where additional information is required to be submitted by the applicant(s) in accordance with Article 12(3).

Fenazaquin was approved on 1 June 2011 by Commission Implementing Directive 2011/39/EU,[4] following a peer review of the risk assessment as set out in the EFSA Conclusion on fenazaquin, published on 15 November 2010 (EFSA, 2010). It was a specific provision of the approval that only use as an acaricide on ornamentals in greenhouses may be authorised. In accordance with Article 7 of Regulation (EC) No 1107/2009, Greece (hereinafter referred to as the rapporteur Member State, 'RMS') received an application from Gowan Comércio Internacional e Serviços Limitada on 19 September 2011 for amendment to the conditions of approval of the active substance fenazaquin to lift the restriction and allow uses on grapes and citrus (previously applied for uses) as well as uses on pome fruit and stone fruit (additional uses) to be authorised.

The RMS provided its initial evaluation of the dossier on fenazaquin in the form of an Addendum to the DAR, which was received by the EFSA on 14 February 2012 (Greece, 2012). The peer review was initiated on 26 April 2012 by dispatching the Addendum to Member States and the applicant, SCC GmbH on behalf of Gowan Comércio Internacional e Serviços Limitada, for consultation and comments. EFSA also provided comments. In addition, the EFSA conducted a public consultation on the Addendum. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 12(3) of the Regulation were considered in a telephone conference between the EFSA, the RMS, and the European Commission on 8 August 2012. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was concluded that additional information should be requested from the applicant and that there was no need to conduct an expert consultation.

The outcome of the telephone conference, together with the 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 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.

[3] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ No L 309, 24.11.2009, p. 1-50.

[4] Commission Implementing Directive 2011/39/EU of 11 April 2011 amending Council Directive 91/414/EEC to include fenazaquin as active substance and amending Commission Decision 2008/934/EC. OJ No L 97, 12.4.2011, p. 30-33.

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 February – March 2013.

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 an acaricide and insecticide on grapes, citrus, pome fruit, stone fruit and greenhouse ornamentals, 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, 2013) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the Addendum to the DAR,
- the Reporting Table (3 August 2012),
- the Evaluation Table (14 March 2013),
- the comments received on the assessment of the additional information (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the Addendum to the DAR including its Final Addendum (compiled version of January 2013 containing all individually submitted addenda (Greece, 2013)) 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

Fenazaquin is the ISO common name for 4-*tert*-butylphenethyl quinazolin-4-yl ether (IUPAC).

The representative formulated product for the evaluation was 'Magister 200 SC', a suspension concentrate (SC), containing 200 g/L fenazaquin, registered under different trade names in Europe.

The evaluated representative uses are as an acaricide and insecticide and comprise foliar spraying on grapes, citrus, pome fruit, stone fruit and greenhouse ornamentals. Full details of the representative uses can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

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

The minimum purity of fenazaquin technical material is 975 g/kg. No FAO specification exists.

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 fenazaquin or the representative formulation. The main data regarding the identity of fenazaquin and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of fenazaquin and the impurities in the technical material and for the determination of the active substance in the representative formulation.

Acceptable validated multi-residue methods are available to monitor fenazaquin in food of plant and animal origin. Adequate analytical methods are available for the monitoring of fenazaquin residues in the environmental matrices. Fenazaquin is classified as toxic; an adequate HPLC-MS/MS method exists for the determination of fenazaquin in liver, human plasma and urine.

2. Mammalian toxicity

Fenazaquin was discussed at the PRAPeR 81 experts' meeting held in September 2010.

During the acute toxicity studies fenazaquin was shown to be toxic if swallowed (R25/Acute Tox. 3 H301) and harmful by inhalation (R20/Acute Tox. 4 H332). Fenazaquin is of low acute dermal toxicity. Fenazaquin is not skin or eye irritating, and not a skin sensitiser (Maximisation test). The target organs after short-term repeated oral administration in hamsters were the liver (increased weight accompanied by hepatic enzyme induction and hepatic vacuolation) and the testes (decreased weight and testicular atrophy/hypospermatogenesis). In rats and dogs reduced food consumption resulted in decreased body weight gain and body weight (rat). The relevant short-term No Observed Adverse Effect Level (NOAEL) of 5 mg/kg bw per day was triggered by the effect on food consumption, body weight and body weight gain, based on the two dog studies (90-day and 1-year).

There is evidence that fenazaquin is mutagenic *in vitro*, inducing gene mutations, chromosome aberrations and polyploidy, mostly in the presence of metabolic activation. Fenazaquin was however not genotoxic in *in vivo* studies. Overall, fenazaquin is considered unlikely to be genotoxic *in vivo*.

After long-term repeated exposure in rats and hamsters, fenazaquin induced some of the same toxic effects observed in the short-term studies. In addition to the effects on food consumption and body weight parameters, changes in haematology and clinical chemistry parameters, alterations in organ weights, and increased incidence of focal hepatocellular atypia were observed. Fenazaquin exhibited

no carcinogenic potential in rats. A significantly increased incidence of adrenal cortical adenomas in female Syrian hamsters was observed at 35 mg/kg bw per day. The same tendency was not observed in male hamsters. The adrenal cortical carcinomas observed in females were however not statistically significantly increased compared to the controls and did not show a dose-response pattern. Adrenal cortical adenomas are known to be commonly occurring in aging Syrian hamsters (even though it is noted that it is difficult to quantify the contribution of the genetic and the exogenous factor). The available evidence is not sufficient to propose classification for carcinogenic potential. The relevant NOAEL for chronic toxicity was set at 0.46 mg/kg bw per day, based on increased incidence of focal hepatocellular atypia in the 2-year rat study.

In the two-generation rat study, no adverse effects in reproductive parameters were observed, resulting in a NOAEL for offspring and reproductive effects of 25 mg/kg bw per day. The NOAEL for parental toxicity was set at 5 mg/kg bw per day, based on excess salivation and decreased body weight in all parental animals at the highest dose. In the developmental studies in rats and rabbits there was no evidence of a teratogenic, embryotoxic or fetotoxic potential of fenazaquin. In rabbits the higher incidence of early resorptions at all doses tested was within the historical background and therefore was not regarded as adverse, resulting in a NOAEL for maternal and developmental toxicity of 60 mg/kg bw per day. Maternal toxicity in rats was manifested as decreased food consumption and body weight gain at 40 mg/kg bw per day, resulting in a NOAEL of 10 mg/kg bw per day (the developmental NOAEL is 40 mg/kg bw per day).

The Acceptable Daily Intake (ADI) is 0.005 mg/kg bw per day and the Acceptable Operator Exposure Level (AOEL) is 0.01 mg/kg bw per day, based on the long-term rat study and the 1-year dog study, respectively. The Acute Reference Dose (ARfD) of 0.1 mg/kg bw was based on the effects seen on dams in the rat developmental study. All reference values were derived by using a safety factor (SF) of 100. The AOEL value is corrected for the limited oral absorption (20 %).

Using the German model the estimated operator exposure levels for field applications (for both tractor-mounted and hand-held spraying) were below the AOEL only when considering the use of personal protective equipment (PPE). Based on data from EUROPOEM, operator exposure levels for indoor applications were below the AOEL when using gloves and coveralls (knapsack application), or gloves (automated gantry sprayer). According to EUROPOEM II data, worker exposure levels were below the AOEL immediately after treatment (2 hours) for citrus and grapes, even when no PPE is used. For ornamentals, worker exposure levels were below the AOEL considering the use of gloves when re-entering immediately after treatment (2 hours), or without PPE in case of re-entry 1 day after treatment. Bystander exposure levels are below the AOEL. No exposure assessment was provided for pome fruit and stone fruit.

The plant metabolite TBPE is of higher toxicity than fenazaquin due to its classification with R62: 'possible risk of impaired fertility', R48/22: 'danger of serious damage to health by prolonged exposure if swallowed' and R41: 'risk of serious damage to eyes' (European Chemicals Bureau (ECB), 28th ATP 2001). The experts agreed to set both reference values (ADI and ARfD) based on a 4-week rat study with the metabolite, resulting in a value of 0.002 mg/kg bw (per day). In addition to the standard SF of 100, an extra factor of 100 has been applied to cover the extrapolation to chronic toxicity and to take into account the uncertainties over the fertility effects and the damage after prolonged exposure (total SF 10000). Insufficient data were available to conclude on the toxicity of the plant metabolite M34 and the applicability of the reference values of the parent compound. Additional information on the toxicological properties of the plant metabolite 4-OHQ was submitted in the Addendum to the DAR in January 2012. An acute oral toxicity study was submitted indicating an estimated LD_{50} between 50.13 and 1220 mg/kg bw (95 % confidence interval), which was not suitable to define a conclusive LD_{50}; however this result, considered together with the relevant NOAEL of 100 mg/kg bw per day (highest dose tested in a subacute toxicity study in rodents), indicated that it is unlikely that 4-OHQ is of higher acute toxicity than fenazaquin. In addition, 4-OHQ showed negative in an Ames test. Overall it can be concluded that based on the available data 4-OHQ shows lower toxicity than fenazaquin.

3. Residues

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

The residue definition for fruit is based on a metabolism study with foliar application in grapes with ^{14}C-labelled fenazaquin. A major proportion of the total residue was present as parent fenazaquin. The levels of individual metabolites or fractions did not exceed 5 % of the TRR at harvest of the mature crop. There was indication of cleavage of the fenazaquin molecule at the ether bridge that lead to the generation of metabolites that either contained the quinazoline ring or the phenyl ring. Data on the toxicity of metabolite 4-OHQ indicated that the metabolite was less toxic than fenazaquin (see section 2). However, one of the metabolites found, TBPE, is of higher toxicity than fenazaquin (see section 2).

Under simulated processing conditions quinazoline ring labelled fenazaquin was degraded to a significant extent to 4-OHQ. The fate of the phenyl ring moiety under processing conditions has not been investigated. It is uncertain if TBPE will occur in grape, stone fruit and pome fruit processed products and further data are therefore still required.

It was agreed to define the residue for monitoring of fruit as the parent compound fenazaquin alone. For risk assessment, fenazaquin and TBPE were included in the residue definition for fruit. Following a risk based approach metabolite 4-OHQ has no longer been included. For fenazaquin and metabolite TBPE separate risk assessments are conducted due to the different toxicological reference values.

Fenazaquin exhibits moderate to high persistence in soil, and a potential transfer of residues from recycled soil and/or compost from the use on ornamentals in the greenhouse to edible crops cannot be assessed in the absence of data. Hence, where applicable, a restriction might be considered.

Based on metabolism studies in lactating goats the nature and magnitude of residues in animal matrices was assessed. For ruminant products, based on the representative uses, the residue for monitoring and risk assessment was defined as fenazaquin by default. An MRL of 0.01 mg/kg is proposed for fat. The representative uses did not trigger any assessment for poultry.

Sufficient GAP conforming residue trials are available on citrus (oranges and mandarins) analysing for fenazaquin and TBPE, and on processed citrus fruits analysing for fenazaquin, 4-OHQ and TBPE. The data on citrus permit sufficiently reliable estimates of livestock and consumer exposure. For grapes and pome fruits, a sufficient number of residue trials were submitted in which also the metabolites TBPE and 4-OHQ are determined. In addition, to support the use in stone fruits, residues trials in peaches were submitted but the data are insufficient to address the whole group of stone fruits. Therefore, a data gap for additional residue data in apricot was identified. The available residue trials and studies were supported by storage stability data and validated analytical methods, and they were considered suitable to propose MRLs for fenazaquin in citrus, pome fruit and grapes, and to conduct a consumer risk assessment for these uses. As for the representative use in stone fruits, an MRL can be proposed only for peaches and the risk for consumers was provisionally assessed for peaches alone.

Using the European chronic consumption data in the EFSA PRIMo rev.2 for grapes, citrus fruit, pome fruit, peaches and ruminant fat, the TMDI calculated with the MRLs is 103 % ADI while the NEDI using median residue levels is 37 % of the ADI of 0.005 mg/kg bw per day fenazaquin for the most critical consumer category (German child). Stone fruits other than peaches were not included in these estimates. In the acute risk assessment using the ARfD of 0.1 mg/kg bw for fenazaquin and the HR values observed in the supervised residue trials, the highest IESTI corresponds to 9 % of the ARfD for apples.

As for TBPE, the TMDI is 9 % of the ADI of 0.002 mg/kg bw per day for TBPE for the most critical consumer category (German child). As for TBPE, the IESTI was at the maximum 66 % of the ARfD of 0.002 mg/kg bw for TBPE for oranges with residues at the LOQ of 0.01 mg/kg. Again, stone fruits

other than peaches were also not included in the estimates for TBPE. Moreover, in the absence of appropriate studies, the assessment does not consider the TBPE levels potentially occurring in grape, stone fruit and pome fruit processed products.

4. Environmental fate and behaviour

In soil laboratory incubations under aerobic conditions in the dark, fenazaquin exhibits moderate to high persistence, forming the minor (<10 % applied radioactivity (AR)) metabolite 2-oxy-fenazaquin (max. 9.1 % AR at 180 d, exhibiting moderate to medium persistence). This metabolite triggers consideration for groundwater exposure assessment.[5] Mineralisation of the phenyl ring and phenyl-quinazoline ring radiolabels to carbon dioxide accounted for 38 % AR and 10 % AR after 180 and 110 days, respectively. The formation of unextractable residues for these radiolabels accounted for 14 – 27 % AR and 25 % AR after 180 and 56 days, respectively. In anaerobic laboratory incubations novel metabolites were not formed. Under the conditions of a laboratory soil photolysis study, degradation of fenazaquin was enhanced compared to that which occurred in the dark with the major (>10 % AR) metabolites 4-OHQ (max. 36.7 % AR at 30 days) and TBPE (17.9 % AR at 30 days) being formed. The rates of degradation of 4-OHQ and TBPE were determined in two separate studies in three soils, indicating that these two metabolites are of very low persistence in soil (DT_{50} << 2 hours for 4-OHQ and << 4 hours for TBPE). Fenazaquin and its metabolite 2-oxy-fenazaquin are considered immobile in soil. 4-OHQ exhibited medium mobility. TBPE exhibited high to medium mobility. There was no evidence that the mobility of these compounds was pH dependent. The behaviour of fenazaquin under realistic outdoor conditions was investigated in seven field trials located in Germany (five sites) and Italy (two sites). The dissipation half-lives (not normalised single first-order, SFO, DT_{50}) estimated for fenazaquin in field ranged from 13 to 48 days, indicating that fenazaquin is moderately persistent in soil under field conditions.

In laboratory incubations in dark aerobic natural sediment water systems, fenazaquin rapidly dissipated from the water phase by degradation to metabolites, mineralisation to CO_2 (max. 17.9 % AR after 100 days) and by adsorption to the sediment (unextractable sediment fraction up to 16 % AR after 60 – 100 days). Two major degradation products were detected in the sediment phase and identified as 2-oxy-fenazaquin and 4-(2-(4-(1,1-dimethylethanoic acid)phenyl)ethoxy)quinazoline, accounting for up to 19.8 % AR (30 days) and 10.3 % AR (100 days), respectively. Fenazaquin degraded rapidly in distilled water under natural sunlight in the laboratory. Three degradation products were detected and identified as 4-OHQ (max. 32.4 % AR), TBPE (max. 18.6 % AR), and 4-tert-butylstyrene (max. 9.2 % AR). The degradation products 4-OHQ and TBPE were only formed under artificial and sterile conditions of the photolysis and hydrolysis study, and did not occur at significant amounts under more realistic conditions, in the water/sediment study. Therefore, it is very unlikely that these degradation products will be formed at significant amounts under realistic outdoor conditions, and thus they were considered as not relevant.

For the representative uses on grapes and citrus, the necessary surface water and sediment exposure assessments (predicted environmental concentrations (PEC)) were appropriately carried out using the FOCUS (2001) step 1 and step 2 approach for fenazaquin and metabolites 4-(2-(4-(1,1-dimethylethanoic acid)phenyl)ethoxy)quinazoline, 2-oxy-fenazaquin, TBPE and 4-OHQ. FOCUS step 3 calculations were completed for fenazaquin. To introduce mitigation of exposure from fenazaquin, step 4 calculations following the principles of the FOCUS (2007) guidance were provided.[6] For grapes and citrus buffer zones of 10 m and 35 m were assumed, respectively. However, for citrus the buffer of 35 m exceeds the upper limit for spray drift mitigation (maximum 95 % drift reduction) prescribed by FOCUS (2007) guidance. In the post approval application for amendment to the approval conditions to lift the restriction on greenhouse uses on ornamentals only, new FOCUS PECsw calculations for fenazaquin at step 3 and step 4 were provided in the ecotoxicology section of the

[5] According to European Commission (2003), as this metabolite exceeded 5 % AR at more than two consecutive sampling times.
[6] Step 3 and 4 simulations correctly utilised the agreed Q10 of 2.58 (following EFSA PPR (2007)) and Walker equation coefficient of 0.7.

Addendum to the DAR of January 2013 (Post Annex I inclusion). As the step 4 calculations were performed again with buffer zones larger than 35 m (35, 40, 45 and 50 m) the resulting PECs can not be used in the risk assessment. For the representative greenhouse use (ornamentals), PECsw initial was calculated assuming a 0.1 % emission of fenazaquin from greenhouses being re-deposited on adjacent surface water bodies. This approach has been accepted by Member State experts as an assumption that can be used in EU level surface water exposure assessments for greenhouse uses and is referred to in FOCUS (2008) guidance as being appropriate, except when applications are made with ultra low-volume application techniques when 0.2 % emission is prescribed. An exposure assessment of fenazaquin to sewage treatment plants following the greenhouse use on ornamentals was provided (Addendum 1 to the Additional Report, July 2010; Greece, 2010). PECsw of fenazaquin estimated by using the PC program USES 4.0 were considered satisfactory.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (2000) scenarios and the model PELMO 3.3.2 for fenazaquin and its metabolites 2-oxy-fenazaquin, TBPE and 4-OHQ.[7] Three separate simulations were conducted for each scenario: one simulation considered the leaching behaviour of fenazaquin and its soil metabolite 2-oxy-fenazaquin. The PECgw calculations for the metabolites TBPE and 4-OHQ were conducted separately due to the fact that these two metabolites were only formed at relevant amounts due to photolysis, and not in biologically active systems. For the simulation, 4-OHQ and TBPE were treated as the parent, but the application rates related to fenazaquin were corrected by their maximum occurrence in soil and their molecular weight ratio metabolite/parent. The potential for groundwater exposure from the representative uses assessed, by fenazaquin or these metabolites above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by the pertinent FOCUS groundwater scenarios.

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

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a, b, c), SETAC (2001), EFSA (2009), EFSA PPR (2005) and HARAP (1998).

The acute, short-term and long-term risk to birds was assessed as low. The acute and long-term TERs for mammals were below the Annex VI triggers in a first-tier risk assessment according to the guidance (European Commission, 2002c). The RMS recalculated the TER values according to the PPR opinion on the science behind the guidance document on the risk assessment for birds and mammals (EFSA PPR, 2008). The resulting TERs exceeded the Annex VI trigger values, indicating a low risk to mammals for the outdoor uses. No risk assessment for birds and mammals was conducted for the use on ornamentals in greenhouse. It was considered that no birds or mammals would be exposed inside the greenhouse. The risk to earthworm-eating and fish-eating birds and mammals was assessed as low for the representative uses.

Fenazaquin is very toxic to aquatic organisms. No full FOCUS step 3 scenarios resulted in TERs above the Annex VI triggers with end points from the standard ecotoxicity dataset, indicating the need for further refinement of the aquatic risk assessment. The refined risk assessment including time weighted average PECsw values and the end point from a mesocosm study was questioned during the commenting period and discussed in the PRAPeR 80 meeting of experts (August 2010). The use of time weighted average values was rejected in the meeting of experts due to lack of information on the time to onset of effects. The experts agreed on a NOEC of 0.3 µg a.s./L from the mesocosm study together with an assessment factor of 2. TERs for aquatic invertebrates were provided using the above agreed approach in the Addendum submitted for the post approval application for amendment to the approval conditions. The risk to aquatic invertebrates was indicated as low for the representative uses

[7] Simulations complied with EFSA PPR (2004) and correctly utilised the agreed Q10 of 2.58 (following EFSA PPR (2007)) and Walker equation coefficient of 0.7.

in grapes, with the application of mitigation measures comparable to no-spray buffer zone of 20 m (grapes in Northern Europe) and 25 m (grapes in Southern Europe). These no-spray buffer zones could be reduced to 15 m and 20 m for grapes in Northern and Southern Europe, respectively, when the TER for aquatic invertebrates were calculated according to the geometric mean EC_{50} (PPR Opinion (EFSA PPR, 2005)). The risk was low also for the greenhouse uses. However, a high risk to aquatic invertebrates for the representative uses in citrus and orchards could not be excluded (i.e. a low risk could only be achieved with buffer zones larger than 35 m which exceeds 95 % maximum spray drift mitigation (see section 4)). Since several acute toxicity data were available for fish, in accordance with the PPR Opinion (EFSA PPR, 2005), the third most sensitive species was selected for risk assessment. Therefore, the end point driving the refined aquatic risk assessment was the acute 96 h LC_{50} for fish of 4.7 µg a.s./L. Using this value a high risk was indicated for all representative uses. In the Addendum submitted for the post approval application, a re-assessment of the data set was carried out by using different approaches to further refine the risk to fish. For example the TERs were calculated according to the lowest available endpoint (i.e. LC_{50} of 3.2 µg a.s./L on *Perca fluviatilis*) and compared with the assessment factor of 10 following the recommendations from the HARAP workshop (HARAP, 1998). The TERs were also calculated according to alternative methods that were discussed in the PPR Opinion (EFSA PPR, 2005). Based on the HARAP approach, the risk was indicated as low for greenhouse uses and for grapes in Northern and Southern Europe with no-spray buffer zones of 15 m and 20 m, respectively, while it was indicated as high with the methods 2, 3 and 4 of the EFSA PPR (2005) for both greenhouse uses and grapes (including mitigation measures of 20 m and 25 m for Northern and Southern Europe, respectively). It was noted that with methods 3 and 4 of the EFSA PPR (2005), the risk was low by considering, along with mitigation measures, levels of protection of 95 % or 90 %. A high risk to fish for the representative uses in citrus and orchards could not be excluded (i.e. a low risk was achieved with buffer zones larger than 35 m). It is highlighted that the HARAP approach has not been validated. Furthermore, specific levels of protection are not agreed in the aquatic risk assessment. Therefore, given that a high acute risk to fish was indicated with the PPR Panel Opinion in some cases, overall a high acute risk to fish could not be excluded for all of the representative uses. The data gap identified in the previous peer review is considered still open.

The toxicity of the metabolites 4-(2-(4-(1,1-dimethylethanoic acid)phenyl)ethoxy)quinazoline, TBPE and 4-OHQ to aquatic organisms was significantly lower compared to fenazaquin and the risk was assessed as low. The risk to sediment-dwelling organisms was assessed as low for 2-oxy-fenazaquin. No data on sediment-dwelling organisms were made available for 4-(2-(4-(1,1-dimethylethanoic acid)phenyl)ethoxy)quinazoline, but given its low toxicity to daphnids, the risk to sediment-dwelling organisms is considered as low.

The standard HQ value for the acute risk to bees for contact exposure exceeded the HQ trigger of 50 on the basis of end points from exposure to technical fenazaquin. The toxicity of the formulated product to bees was markedly lower. However, some adverse effects were observed in a study at an application rate of 87 g a.s./ha, while no adverse effects were detected in another study where a rate of 300 g a.s./ha was applied. Overall, uncertainties remained with regard to the potential adverse effects on bees, therefore a restriction was proposed in the meeting of experts to avoid the application of fenazaquin to crops when in flower.

The HQ values calculated for the in-field and off-field risk were less than 2 for *A. rhopalosiphi* for the use on grapes and citrus. *Typhlodromus pyri* was very sensitive in the standard glass plate test, leading to 100 % mortality at the lowest tested application rate of 2 g fenazaquin/ha. The HQ values based on the tested rate of 2 g fenazaquin/ha were markedly above the trigger of 2, suggesting a potential high risk to predatory mites. In extended laboratory studies the mortality was less than 50 % when exposed to dried residues after application of 150 to 252 g fenazaquin/ha. The studies confirmed that predatory mites were the most sensitive species. The LR_{50} in the extended laboratory study with *T. pyri* was determined as 58.8 mg fenazaquin/ha. Other predatory mites (*Phytoseiulus persimilis, Metaseiulus occidentalis, Amblyseius californicus*) were also very sensitive in the extended laboratory studies (LR_{50} values of 3 – 36 mg fenazaquin/ha). Field studies in apple orchards with *T. pyri* showed that recovery/recolonisation is possible within one year. Application rates of 150 and 225 g fenazaquin/ha

had a severe impact on adult mites, but the numbers of juveniles increased from day 14 on until the end of observation on day 40. Although the number of adults and juveniles were still significantly lower than in the controls, it gives an indication that there is potential for recovery. In another field trial, where 117 – 250 and 234 – 500 g fenazaquin/ha was applied, the abundance of *T. pyri* began to increase two months after application of the product (application beginning of June). However, the abundance of mites did not reach the abundance in the controls (reduction in abundance of 13 – 58 % after 63 – 90 days). Two field studies were conducted in vineyards at a lower application rate of 100 g fenazaquin/ha. The predatory mite *Zetzellia mali* was not affected and *T. pyri* reached 50 % of the abundance of the control 28 days after the application. The difference in abundance was only 11 % at day 35 after treatment. Overall, it is concluded that the representative use on citrus is likely to cause high initial mortality rates in predatory mites. The field trials in apple orchards give an indication that recovery within 1 year is possible. The lower application rates in vineyards lead to less reduction in abundance, and recovery is likely to take place within 1 year. No risk assessment for non-target arthropods was conducted for the use in greenhouse. The risk to non-target arthropods outside the greenhouse is considered to be low because of negligible exposure. However, if non-target arthropods (predatory mites) would be used as biological control agents in the greenhouse, then it is expected that there would be a high mortality of beneficials after application of fenazaquin.

The risk to earthworms, other soil-dwelling macroorganisms, soil microorganisms, and biological methods of sewage treatment was assessed as low for all representative uses evaluated.

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

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
fenazaquin	Moderate to high persistence. Single first-order DT_{50} 34.2 – 104.1 days (20ºC pF 2 soil moisture). European field dissipation studies, single first-order DT_{50} 12.9 – 48.2 days.	Low risk to earthworms. The end point driving the risk assessment for earthworms, reproductive NOEC = 0.62 mg a.s./kg soil (regulatory concentration including a safety factor of 5 = 0.124). The risk to collembola and soil micro-organisms was assessed as low.
2-oxy-fenazaquin (max. 9.1 % AR at 180d)	Moderate to medium persistence. Single first-order DT_{50} 11 – 98.7 days (20ºC pF 2 soil moisture).	Low risk to earthworms. The risk to collembola and soil micro-organisms was assessed as low.
4-OHQ (soil photolysis metabolite)	Very low persistence. Single first-order DT_{50} <<2 hours (20ºC pF 2 soil moisture).	Low risk to earthworms. The risk to collembola and soil micro-organisms was assessed as low.
TBPE (soil photolysis metabolite)	Very low persistence. Single first-order DT_{50} <<4 hours (20ºC pF 2 soil moisture).	Low risk to earthworms. The risk to collembola and soil micro-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
fenazaquin	Immobile K_{Foc} 16020 – 42695 mL/g	No	Yes	Yes	Very toxic to aquatic organism, the risk in surface water was assessed as high.
2-oxy-fenazaquin	Immobile K_{doc} 54840– 107735 mL/g	No	No data submitted. No data needed.	No data available, not needed. (it is noted that based on the acute toxicity profile of fenazaquin it should be regarded as relevant if leaching above the trigger value).	Data on effects on *Chironomus riparius* are available and the risk was assessed as low.
4-OHQ (soil photolysis metabolite)	Medium mobility K_{Foc} 173 – 294 mL/g	No	No data submitted. No data needed.	Not needed. (based on the available acute toxicity, subacute toxicity and Ames tests, it is unlikely it has higher toxicity than fenazaquin).	Data on effects on *Daphnia* and fish are available and the risk was assessed as low.

TBPE (soil photolysis metabolite)	High to medium mobility K_{doc} 131 – 217 mL/g	No	No data submitted. No data needed.	Not needed. (It is noted that based on its toxicological profile – R48 and R62- it should be regarded as relevant if leaching above the trigger value).	Data on effects on *Daphnia* and fish are available and the risk was assessed as low.

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
fenazaquin	Very toxic to aquatic organisms, refined acute fish end point of 4.7 µg a.s./L was driving the aquatic risk assessment (regulatory concentration including a safety factor of 100 = 0.047 µg a.s./L). A high risk to aquatic organisms was indicated.
2-oxy-fenazaquin (sediment)	Toxic to aquatic organisms. Only one toxicity value available, 96h acute toxicity to *Chironomus riparius*, EC_{50} >3 mg a.s./L (regulatory concentration including a safety factor of 100 = 30 µg/L). The risk to *Chironomus riparius* was assessed as low.
4-(2-(4-(1,1-dimethylethanoic acid)phenyl)ethoxy)quinazoline (sediment)	Very toxic to aquatic organisms, end point driving the aquatic risk assessment for this metabolite: fish acute LC_{50} = 0.77 mg a.s./L (regulatory concentration including a safety factor of 100 = 7.7 µg/L. The risk to fish was assessed as low. No data on sediment-dwelling organisms were made available, but given its low toxicity to daphnids, the risk to sediment-dwellers is considered as low.

6.4. Air

Compound (name and/or code)	Toxicology
fenazaquin	Rat LC_{50} inhalation > 1.9 mg/L air nose only exposure (Xn; R20: 'Harmful by inhalation')

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

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

- A search of the scientific peer-reviewed open literature relevant to the scope of the application for amendment to the conditions of approval, dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of dossier, to be conducted and reported in accordance with the Guidance of EFSA on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011).

- At least four residue trials in apricots analysing for the full residue definition for risk assessment and for monitoring (relevant for the representative uses in stone fruits; submission date proposed by the applicant: unknown; see section 3).

- Data in grape processed products, analysing for TBPE (relevant for the representative uses on wine and table grapes; submission date proposed by the applicant: spring 2013; see section 3).

- Data in stone fruit and pome fruit processed products, analysing for the full residue definition for risk assessment (relevant for the representative uses on stone fruit and pome fruit submission date proposed by the applicant: unknown; see section 3).

- The risk assessment for aquatic organisms needs further refinement (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).

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

- Operator exposure is below the AOEL if personal protective equipment (PPE) is worn according to the German model (see section 2).

- As for the ornamentals in greenhouse, it is suggested that management measures should establish conditions of use to avoid exposure to residues of fenazaquin with respect to crops for human and animal consumption. Such measures may consider the need to

    - preclude disposal of contaminated soil and plant material (including recycled/composted material) in the environment;

    - avoid the use of recycled/composted material to grow edible crops (see section 3).

- Fenazaquin should not be applied to crops when in flower which could attract foraging bees (see section 5).

9. Concerns

9.1. Issues that could not be finalised

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

1. The consumer risk assessment is not finalised for fenazaquin in stone fruit other than peaches and does not consider the TBPE levels potentially occurring in stone fruit raw commodities other than peaches, and in processed products of grape, stone fruit and pome fruit.

9.2. Critical areas of concern

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

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

2. A high risk to aquatic organisms was indicated. No full FOCUS step 4 scenarios resulted in TERs above the Annex VI trigger including risk mitigation and refined end points.

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

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

Representative use		Grapes (Table and Wine) Southern Europe	Grapes (Table and Wine) Northern Europe	Citrus Southern Europe	Pome fruit (apples, pears) Central, Northern Europe	Pome fruit (apples, pears) Southern Europe	Stone Fruits Southern Europe	Ornamentals
Operator risk	Risk identified							
	Assessment not finalised							
Worker risk	Risk identified							
	Assessment not finalised							
Bystander risk	Risk identified							
	Assessment not finalised							
Consumer risk	Risk identified							
	Assessment not finalised	X[1]	X[1]		X[1]	X[1]	X[1]	
Risk to wild non target terrestrial vertebrates	Risk identified							
	Assessment not finalised							
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified							
	Assessment not finalised							
Risk to aquatic organisms	Risk identified	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]
	Assessment not finalised							
Groundwater exposure active substance	Legal parametric value breached							
	Assessment not finalised							
Groundwater exposure metabolites	Legal parametric value breached							
	Parametric value of 10µg/L[(a)] breached							
	Assessment not finalised							
Comments/Remarks								

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

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APPENDICES

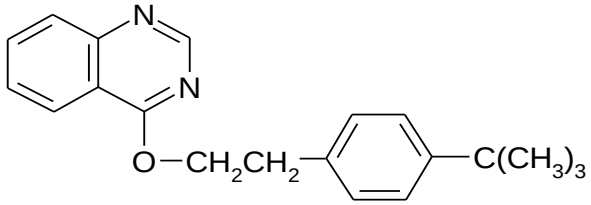
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

Active substance (ISO Common Name) ‡	Fenazaquin
Function (*e.g.* fungicide)	Acaricide and insecticide

Rapporteur Member State	Hellas
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	4-*tert*-butylphenethyl quinazolin-4-yl ether
Chemical name (CA) ‡	4-[2-[4-(1,1-dimethylethyl)phenyl]ethoxy]quinazoline
CIPAC No ‡	693
CAS No ‡	120928-09-8
EC No (EINECS or ELINCS) ‡	410-580-0 (ELINCS)
FAO Specification (including year of publication) ‡	Not available
Minimum purity of the active substance as manufactured ‡	975 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula ‡	$C_{20}H_{22}N_2O$
Molecular mass ‡	306.4 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Melting point: 80.5 C ±0.1 (99 % pure)
Boiling point (state purity) ‡	Decomposition occurred before boiling.
Temperature of decomposition (state purity)	Decomposition at approx. 307 °C (99 % pure)
Appearance (state purity) ‡	pure active substance (no data on purity): white crystalline solid
	technical active substance (no data on purity): white to tan, crystalline solid
Vapour pressure (state temperature, state purity) ‡	1.9×10^{-5} Pa at 25 °C (99.4 % technical)
Henry's law constant ‡	$H=5.71 \times 10^{-2}$ Pa m^3 mol^{-1}
Solubility in water (state temperature, state purity and pH) ‡	In distilled water: 0.102 mg/L at 20°C (99.2 % technical)
	At 20°C (99.2 % technical): **PH 5: 0.102 MG/L** pH 7: 0.102 mg/L pH 9: 0.135 mg/L
Solubility in organic solvents ‡ (state temperature, state purity)	hexane: <10 g/L toluene: 40-50 g/L chloroform: >1000 g/L methanol: 67-80 g/L ethyl acetate: >90 g/L acetonitrile: 40-50 g/L (all values in g/L solvent, at 25°C) (98.9 % technical) acetone: to be confirmed by testing
Surface tension ‡ (state concentration and temperature, state purity)	65.7 mN/m at 20°C and concentration 58 µg/L 72.3 mN/m at 20°C and concentration 29 µg/L (99.2 % technical)
Partition co-efficient ‡ (state temperature, pH and purity)	Log P_{ow} = 5.51±0.17 at 21°C (pH ranged 5.3-5.9) (99.2 % technical)
	Effect of pH was not investigated, since there is no dissociation in water in the environmentally relevant pH-range.
Dissociation constant (state purity) ‡	pKa = 2.44 (SD=0.22) at 22°C (99.2 % technical)
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	In methanol (pH 7.83) (99.2 % technical) λmax (nm) ε (Lx mol-1x cm-1) 215.8 5.15×10^4 262.6 1.24×10^4 In acetonitrile (pH not stated) (99 % pure) λ (nm) ε (Lx $mol^{-1} \times cm^{-1}$) 200 3.8239×10^4 215 4.1588×10^4 263 0.6257×10^4 297 0.3360×10^4 308 0.3448×10^4
Flammability ‡ (state purity)	Not highly flammable (99.2 % technical) Not auto-flammable (99.2 % technical)

Explosive properties ‡ (state purity)	Not explosive (99.2 % technical)
Oxidising properties ‡ (state purity)	Not oxidising (99.2 % technical)

Summary of representative uses evaluated (*fenazaquin*)*

Crop and/ or situation (a)	Member State, Country or Region	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg a.s./hL (l) min – max	water L/ha min – max	kg a.s./ha (l) min – max		
Grapes (Table and Wine)	Southern Europe	Magister 200 SC	F	*Panonychus ulmi, Tetranychus urticae, Calipitrimerus vitis, Eotetranychus carpini Eriophyes vitis*	SC	200 g/L	spraying	when first symptoms or pests appear	1	nr	0.0075 - 0.015	800 - 1600	0.12	35	
Grapes (Table and Wine)	Northern Europe	Magister 200 SC	F	*Panonychus ulmi, Tetranychus urticae, Calipitrimerus vitis, Eotetranychus carpini*	SC	200 g/L	spraying	when first symptoms or pests appear	1	nr	0.032 - 0.044	180 - 250	0.08	28	
Citrus	Southern Europe	Magister 200 SC	F	*Panonynchus citri, Tetranychus urticae, Aleurothrixus floccosus*	SC	200 g/L	spraying	when first symptoms or pests appear	1	nr	0.005 - 0.01	2000 - 4000	0.2	28	
Pome fruit (apples, pears)	Central, Northern Europe	Magister 200	F	Apple: *Tetranychus urticae Panonychus ulmi Aculus schlechtendali* Pear: *Tetranychus urticae Panonychus ulmi Aculus schlechtendali Eriophyes pyri Epytrimerus pyri*	SC	200 g/L	Foliar application	when first symptoms or pests appear	1	nr	0.01- 0.015	670- 2000	0.1-0.2	21	
				Pear: *Psylla pyri*							0.013- 0.02	1000- 1500	0.2	21	

Crop and/ or situation	Member State, Country or Region	Product name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)	Remarks
Pome fruit (apples, pears)	Southern Europe	Magister 200	F	*Apple:* *Tetranychus urticae* *Panonychus ulmi* *Aculus schlechtendali* *Pear:* *Tetranychus urticae* *Panonychus ulmi* *Aculus schlechtendali* *Eriophyes pyri* *Epytrimerus pyri*	SC	200 g/L	Foliar application	nr	1	nr	0.01-0.015	670-2000	0.1-0.2	21	
				Pear: *Psylla pyri*							0.013-0.02	1000-1500	0.2		
Stone Fruit	Southern Europe	Magister 200	F	*Tetranychus urticae* *Panonychus ulmi* *Aculus fockeui*	SC	200 g/L	Foliar application	when first symptoms or pests appear	1	nr	0.01-0.015	670-2000	0.1-0.2	14	
Ornamentals	Europe	Magister 200 SC	G	*Panonychus ulmi,* *Tetranychus urticae* *Polyphagtarsonemius latus;* *Phytonemus pallidus*	SC	200 g/L	spraying	when first symptoms or pests appear	1	nr	0.01	3000	0.3	nr	

nr: not relevant

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

Methods of Analysis

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

Technical as (analytical technique)	HPLC-UV_{280nm} method. Acceptable, fully validated method.
Impurities in technical as (analytical technique)	Details in Annex C of Additional Report.
Plant protection product (analytical technique)	HPLC-UV method. Acceptable, fully validated method.

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		fenazaquin
Food of animal origin		ruminants: fenazaquin
Soil		fenazaquin
Water	surface	fenazaquin
	drinking/ground	fenazaquin
Air		fenazaquin
Body fluids and tissues		fenazaquin

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	**The DFG method S19 using HPLC-MS/MS-** **Lakaschus, S. (2006) (Doc. No. 432-018):** Substrates: orange and grapes Analysis: HPLC-MS/MS Determined analyte: fenazaquin LOQ: 0.01 mg/kg for each substrate Method fully validated. The HPLC-MS/MS with second mass transition was used as confirmatory method (Lakaschus, S. (2006), Doc. No. 432-018). ILV data were provided (Wolf (2007), Doc. No. 432-020). Lakaschus, S. (2006) (Doc. No. 432-019) Analysis: HPLC-MS/MS Determined analyte: 4-OHQ LOQ: 0.01 mg/kg (grapes, wine, juice, raisins, dry pomace) **HPLC-MS/MS method based on QuEChERS method (German version EN 15662:2008)** **Wiesner, F & Breyer N. (2012) (Doc. No. 432-027):** Substrates: tomato (high water content), lemon (high acid content), oilseed rape seeds (high oil content) and dry bean (dry commodity) Analysis: HPLC-MS/MS Determined analyte: fenazaquin LOQ: 0.01 mg/kg for each substrate Method fully validated in crops with high water content, high acid content, high oil content and in dry commodity. The HPLC-MS/MS with second mass transition was used as confirmatory method (Wiesner, F & Breyer N. (2012),

	Doc. No. 432-027). ILV data were provided for tomato and oilseed rape seeds (Knoch (2012), Doc. No. 432-030).
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	**HPLC-MS/MS method based on QuEChERS method (German version EN 15662:2008)** **Wiesner, F & Breyer N. (2012) (Doc. No. 433-004):** Substrates: meat, fat, liver, milk, egg Analysis: HPLC-MS/MS Determined analyte: fenazaquin LOQ: 0.01 mg/kg for each substrate Method fully validated. The HPLC-MS/MS with second mass transition was used as confirmatory method (Wiesner, F & Breyer N. (2012), Doc. No. 433-004). ILV data were provided for meat and milk (Knoch (2012), Doc. No. 433-005).
Soil (principle of method and LOQ)	**Düsterloh, K. (2008) (Doc. No. 434-005):** Substrates: soil (sandy loam) Analysis: HPLC-MS/MS Determined analyte: fenazaquin LOQ: 0.05 mg/kg Method fully validated. The HPLC-MS/MS with second mass transition was used as confirmatory method (Düsterloh, K. (2008), Doc. No. 434-005)
Water (principle of method and LOQ)	**Wolf, S., (2003) (Doc. No.: 435-006):** Substrates: Drinking, ground and surface water Analysis: GC-NPD Determined analyte: fenazaquin LOQ: 0.05 µg/L for all substrates Method fully validated. Confirmatory method (GC-MS with a different column) was provided [Wolf, S. (2003, with report amendment 2007) (Doc.No. 435-008)]
Air (principle of method and LOQ)	**Wolf, S. (2007)(Doc. No. 436-003):** Substrates: air Analysis: HPLC-MS/MS Determined analyte: fenazaquin LOQ: 0.15 µg/m^3 Method fully validated. The HPLC-MS/MS with second mass transition was used as confirmatory method (Wolf, S. (2007), Doc. No. 436-003).
Body fluids and tissues (principle of method and LOQ)	**Wolf, S. (2006)(Doc. No. 433-003):** Substrates: human plasma, urine, liver Analysis: HPLC-MS/MS Determined analyte: fenazaquin LOQ=0.01 mg/kg (liver) LOQ=0.01 mg/L (human plasma, urine)

	Method fully validated. The HPLC-MS/MS with second mass transition was used as confirmatory method (Wolf, S. (2006), Doc. No. 433-003).

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

	RMS/peer review proposal
Active substance	None

Impact on Human and Animal Health

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

Rate and extent of absorption ‡	20 % (based on radioactivity detected in urine, organ/tissues and carcass 168 hours post-dosing; single oral low dose rat study). No biliary data were available.
Distribution ‡	Widely distributed: highest concentration in fat, bone, and the female genital organs (single low or high dose level and repeated low dosing groups), lungs (repeated low dose group) and liver and spleen (single oral high dose group).
Potential for accumulation ‡	No evidence for accumulation.
Rate and extent of excretion ‡	Rapid and extensive (>75 % within 48 hours), mainly *via* faeces (72 - 89 %) and minor in urine (16 - 21 %).
Metabolism in animals ‡	Extensively metabolised, involved oxidation and hydrolysis reactions. Major identified metabolites were the urinary AN-1 (4.2-5.8 % of the dose) and the faecal F-2 (11.9-19.9 % of the dose), F-3 (4.7-10.5 % of the dose), and F-1 (3.5-8.4 % of the dose). The parent compound was detected mostly in faeces (1.0-15.0 % of the administered dose) and at minor amounts in urine (< 0.5 % of the dose).
Toxicologically relevant compound ‡ (animals and plants)	Fenazaquin and TBPE
Toxicologically relevant compounds ‡ (environment)	**Fenazaquin**

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	134 mg/kg bw	T; R25
Rabbit LD_{50} dermal ‡	> 5000 mg/kg bw	
Rat LC_{50} inhalation ‡	>1.9 mg/L air	Xn; R20
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non-irritant	
Skin sensitisation ‡	Non sensitizer (M&K)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Hamster: liver (increased weight, hepatic enzyme induction, hepatic vacuolation), testes (decreased weight, atrophy/ hypospermatogenesis) Rat/dog: reduced food consumption, body weight gain, body weight (rat).	
Relevant oral NOAEL ‡	1-year & 90-day dog: 5 mg/kg bw per day 90-day rat: 10 mg/kg bw per day 90-day hamster: 25 mg/kg bw per day	
Relevant dermal NOAEL ‡	28-day, rabbit: 1000 mg/kg bw per day	
Relevant inhalation NOAEL ‡	No data - not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

In vitro genotoxic potential The substance is unlikely to be genotoxic *in vivo*	

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

Target/critical effect ‡	Rat: Liver/increased incidence of focal hepatocellular atypia. Hamster: haematology parameters, clinical chemistry parameters, organ weight changes.
Relevant NOAEL ‡	0.46 mg/kg bw per day (2-year rat study) 2 mg/kg bw per day (18-month hamster study)
Carcinogenicity ‡	Adrenal cortical adenomas in female hamster at 35 mg/kg bw per day (high dose). Classification not warranted based on available evidence.

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Excess salivation, decreased parental body weight at the parental toxic dose of 25 mg/kg bw per day in the rat. No effects on the reproductive parameters.	
Relevant parental NOAEL ‡	5 mg/kg bw per day	
Relevant reproductive NOAEL ‡	25 mg/kg bw per day	
Relevant offspring NOAEL ‡	25 mg/kg bw per day	

Developmental toxicity

Developmental target / critical effect ‡	No evidence of developmental toxicity (rat, rabbit) at maternal toxic doses (decreased food consumption, body weight gain)	
Relevant maternal NOAEL ‡	Rat: 10 mg/kg bw per day Rabbit: 60 mg/kg bw per day	

Relevant developmental NOAEL ‡	Rat: 40 mg/kg bw per day Rabbit: 60 mg/kg bw per day	

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 ‡	LD_{50} acute intraperitoneal: 77 mg/kg bw (fenazaquin)
Studies performed on metabolites or impurities ‡	**TBPE** TBPE is classified as R62, R48/22 and R41 (28th ATP). LD_{50} oral >2000 mg/kg bw, LD_{50} dermal >2000 mg/kg bw, severely irritant to eyes and slightly irritant to skin, not a skin sensitizer. oral NOAEL (4-week study, rat): 20 mg/kg bw per day Negative in *in vitro* bacterial mutation assay Agreed ADI and ARfD for the metabolite TBPE are both 0,002 mg/kg bw(/day). **4-OHQ** LD50 oral: between 50.13 to 1220 mg/kg bw (95 % confidence interval) Oral NOAEL (4-week study, rat): 100 mg/kg bw per day Ames test: negative. **M34**: Insufficient data are available to conclude on the applicability of the reference values of the parent compound .

Medical data‡ (Annex IIA, point 5.9)

Limited. No evidence of toxicological concern from the medical surveillance of manufacturing plant personnel.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.005 mg/kg bw per day	2-year oral rat study	100
AOEL ‡	0.01 mg/kg bw per day	1-year oral dog study	100*

ARfD ‡

0.1 mg/kg bw	Developmental rat study	100

* Correction for low oral absorption (20 %)

Dermal absorption‡ (Annex IIIA, point 7.3)

Magister 200 SC

2 % for the undiluted formulation and 14 % for the spray dilution (*in vitro* human data from the comparative *in vitro* human/rat study)

Exposure scenarios (Annex IIIA, point 7.2)

Operator

Field application via tractor air-assisted sprayer

Pome fruit and stone fruit

No exposure assessment provided.

Citrus (Southern EU) [0.2 kg a.s./ha, 2000 L/ha]

	UK POEM	German	
No PPE:	390 %	383 %	of the AOEL
PPE(gloves):	210 %	350 %	of the AOEL
PPE*:	-	58 %	of the AOEL

Grapes (Southern EU) [0.12 kg a.s./ha, 800 L/ha]

	UK POEM	German	
No PPE:	492 %	230 %	of the AOEL
PPE(gloves):	310 %	210 %	of the AOEL
PPE*:	-	35 %	of the AOEL

Grapes (Northern EU) [0.08 kg a.s./ha, 180 L/ha]

	UK POEM	German	
No PPE:	1320 %	153 %	of the AOEL
PPE(gloves):	910 %	140 %	of the AOEL
PPE*:	-	23 %	of the AOEL

Field application via knapsack sprayer

Citrus (Southern EU) [0.2 kg a.s./ha]

	German	
No PPE:	290 %	of the AOEL
PPE*:	14 %	of the AOEL

Grapes (Southern EU) [0.12 kg a.s./ha]

	German No PPE: 175 % of the AOEL PPE°: 80 % of the AOEL **Grapes (Northern EU)** [0.08 kg a.s./ha] **German** No PPE: 115 % of the AOEL PPE°: 50 % of the AOEL * gloves during M/L, and gloves, coverall and sturdy footwear during application ° gloves during M/L and application **Ornamentals (Southern EU)** [0.3 kg a.s./ha, 3000 L/ha] ***Indoor application via automated gantry spayer*** **EUROPOEM** No PPE: 304 % of the AOEL PPE(gloves): 38 % of the AOEL ***Indoor application via knapsack spayer*** **EUROPOEM Dutch model** No PPE: 261 % 1243 % of the AOEL PPE(gloves&coverall): 16 % 163 % of the AOEL
Workers	According to the EUROPOEM II data estimated re-entry exposure is below the AOEL 2 hours after treatment for citrus (72 % of AOEL) and grapes (44 % of AOEL), even without PPE. For ornamentals the re-entry exposure is below AOEL with the use of gloves 2 hours post dosing, or without PPE 1 day after treatment (64 %). No exposure assessment provided for pome fruit and stone fruit.
Bystanders	Bystander exposure levels were below the AOEL (<5 %). No exposure assessment provided for pome fruit and stone fruit.

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

	RMS/peer review proposal
Fenazaquin	**T** ‘‘Toxic’’ (ECB, 28thATP) **R25** ‘‘Toxic if swallowed’’ **R20 ‘‘Harmful by Inhalation’’**

Residues

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

Plant groups covered	Fruits (Grapes)
Rotational crops	Not applicable to orchard or vineyard uses. Note: Residues can be persistent in soil; as for the use on ornamentals in greenhouse, restrictions might be necessary for the use of recycled soil or plant material to grow edible crops.
Metabolism in rotational crops similar to metabolism in primary crops?	Not assessed, study not triggered.
Processed commodities	Hydrolysis study at pH 4 and 90°C, pH 5and 100°C, pH 6 and 120°C
Residue pattern in processed commodities similar to residue pattern in raw commodities?	No Fenazaquin is significantly degraded to 4-OHQ [more than 60 % AR at pH 4 and 90°C]. Fate of phenyl ring moiety not investigated.
Plant residue definition for monitoring	Fruit crop group: Fenazaquin
Plant residue definition for risk assessment	For fruit RAC and their processed products: Fenazaquin TBPE
Conversion factor (monitoring to risk assessment)	Open.

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

Animals covered	Lactating goats
Time needed to reach a plateau concentration in milk and eggs	Plateau is reached within 4 days
Animal residue definition for monitoring	Fenazaquin (ruminants)
Animal residue definition for risk assessment	Fenazaquin (ruminants)
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	Yes (log P_{ow}=5.51)

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

Not relevant, provided edible crops are not grown on soil or recycled soil and plant material from the use on ornamentals.

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

Fenazaquin residues in oranges and grapes are stable for periods of storage at <-15°C for at least 12 months. TBPE is stable in grapes, raisins and orange pulp for at least 18 months, and in orange peel for at least 12 months under frozen conditions. 4-OHQ residues in fortified matrices of grapes, raisins, and citrus (orange peel and pulp) are stable under frozen conditions for at least 18 months.

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Fenazaquin: Yes (0.148 mg/kg dairy cattle; 0.443 mg/kg beef cattle) TBPE: No 4-OHQ: No	No	No
Potential for accumulation (yes/no):	Yes	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No*	No	No
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	Not applicable	Not applicable	Not applicable
Liver	Not applicable	Not applicable	Not applicable
Kidney	Not applicable	Not applicable	Not applicable
Fat	Not applicable	Not applicable	Not applicable
Milk	Not applicable		
Eggs		Not applicable	

*estimated fenazaquin levels in fat on the basis of the goat metabolism study over 5 days were between 0.0021 and 0.0028 mg/kg; considering uncertainty of these estimates due to extrapolation from much higher dose rates and only 2 test animals used, a highest residue of 0.01 mg/kg was derived for fat (= proposed MRL).

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Citrus fruits (mandarins)	Southern Europe	Fenazaquin (whole fruit): 1x 0.04, 1x 0.05, 1x 0.07, 1x 0.10, 1x 0.11, 1x 0.14, 1x 0.20, 1x 0.22, 1x 0.23, 1x 0.24, 1x 0.30, 1x 0.40		0.5	0.40	0.17
		TBPE: 4x <0.003 (pulp) 3x <0.003, 1x 0.003 (peel)			0.003	0.003
Citrus fruits (oranges)	Southern Europe	Fenazaquin (whole fruit): 2x 0.05, 1x 0.06, 3x 0.07, 1x 0.09, 4x 0.14, 1x 0.19, 1x 0.23		0.5	0.23	0.09
		TBPE: 4x <0.003 (pulp) 4x <0.003 (peel)			0.003	0.003
		Based on residue trials (processing studies) with same PHI, but with a higher application rate (1x 1 kg a.s./ha) than the representative cGAP (2x 0.2 kg a.s.//ha). Results indicative. 4-OHQ (whole fruit prior processing): 1x <0.01, 1x 0.01, 2x 0.02	If levels were higher for washed oranges, they were considered as the critical residue values. Under cGAP criteria 4-OHQ residues are not expected to exceed 0.01 mg/kg.			
Pome fruits (apples)	Southern Europe	Fenazaquin (whole fruit): 2x0.01, 4x0.02, 2x0.03, 0.04, 0.06, 2x 0.07		0.15	0.07	0.03
		TBPE: 8x<0.01 4-OHQ: 8x<0.01				
Pome fruits (apples)	Northern Europe	Fenazaquin (whole fruit): < 0.01, 0.01, 3x0.02, 0.03, 0.04, 4x0.08, 0.09		0.2	0.09	0.04

		TBPE: 8x<0.01 4-OHQ: 8x<0.01				
Peaches	Southern Europe	Fenazaquin: 0.01, 3x0.02, 2x0.03, 2x0.04, 2x0.05, 0.06, 0.10* TBPE: 8x<0.01 4-OHQ: 8x<0.01	No trials were performed on apricots. Therefore extrapolation to the whole group of stone fruits is not possible.	0.15	0.1	0.04
Grapes (table and wine)	Southern Europe	Fenazaquin: 2x 0.01, 1x 0.02, 3x 0.04, 1x 0.05, 3x 0.06, 1x 0.07, 2x 0.09, 1x 0.10, 1x 0.11, 1x 0.13 New trials: Fenazaquin: 3x<0.01, 0.01, 3x0.02, 0.03 TBPE: 8x<0.01 4-OHQ: 8x<0.01		0.2	0.13	0.04
Grapes (table and wine)	Northern Europe	Fenazaquin: 4x <0.01, 4x 0.01, 2x 0.02, 2x 0.03, 2x 0.04, 2x 0.05, 1x 0.06 New trials: Fenazaquin: 0.01, 3x0.02, 0.03, 2x0.04, 0.05 TBPE: 8x<0.01 4-OHQ: 8x<0.01		0.09	0.06	0.02

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17

(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use

(c) Highest residue

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

Fenazaquin

ADI	0.005 mg/kg bw per day
TMDI (% ADI) according to WHO European diet	EFSA PRIMo rev.2: 31% (WHO Cluster diet B) All other WHO cluster diets use up less of the ADI.
TMDI (% ADI) according to national (to be specified) diets	EFSA PRIMo rev.2: 103% (German child) All other national diets use up less of the ADI.
IEDI (WHO European Diet) (% ADI)	9% (WHO Cluster diet B)
NEDI (specify diet) (% ADI)	37% (German child)
Factors included in IEDI and NEDI	Not applicable
ARfD	0.1 mg/kg bw
IESTI (% ARfD)	EFSA PRIMo rev.2: Pome fruit: Highest intake 9% (UK infant) from apples Table grapes: 8% (DE) Peaches: 6% (DE)
Factors included in IESTI	Not applicable

TBPE

ADI	0.002 mg/kg bw per day
TMDI (% ADI) according to WHO European diet	EFSA PRIMo rev.2: 3% (WHO Cluster diet B) All other WHO cluster diets use up less of the ADI.
TMDI (% ADI) according to national (to be specified) diets	EFSA PRIMo rev.2: 9% (German child) All other national diets use up less of the ADI.
IEDI (WHO European Diet) (% ADI)	Not necessary
NEDI (specify diet) (% ADI)	Not necessary
Factors included in IEDI and NEDI	Not applicable
ARfD	0.002 mg/kg bw
IESTI (% ARfD)	EFSA PRIMo rev.2: Citrus fruits: Highest intake 66 % (UK infant) from oranges Table grapes: 33% (DE) Pome fruit: Highest intake 49% (UK infant) from apples Peaches: 22% (DE) Consumption of wine grapes and other citrus and pome fruits is estimated to use up less of the ARfD.
Factors included in IESTI	Not applicable

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

Fenazaquin

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Citrus Fruits				
Peel / pulp distribution	12	3.5 (peel) 0.07 (pulp)	Not applicable	Not applicable
Juice	4	0.07	Not applicable	Not applicable
Marmalade	4	0.48	Not applicable	Not applicable
Canned oranges	4	0.04	Not applicable	Not applicable
Wet pomace	1	2	Not applicable	Not applicable
Dry pomace	1	8.4	Not applicable	Not applicable
Grapes				
Raisins	4	2.2	Not applicable	Not applicable
Wine	4	0.02	Not applicable	Not applicable
Juice	4	0.14	Not applicable	Not applicable
Pome fruit Processing data still required. (data gap)				
Stone fruit Processing data still required. (data gap)				

TBPE

Reliable processing factors for **citrus fruit** cannot be derived since residues were not quantifiable (<LOQ) in raw and processed citrus commodities.

Processing data in **pome fruit, stone fruit and grapes** still required.(data gap)

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

Citrus Fruits	0.5 mg/kg
Pome Fruits	0.2 mg/kg
Peaches	0.15 mg/kg
Table grapes	0.2 mg/kg
Wine grapes	0.2 mg/kg
Products of animal origin: Fat	0.01 mg/kg

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

Fate and Behaviour in the Environment

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

Mineralization after 100 days ‡	38 % AR after 180 d, [^{14}C-phenyl]-label (n[8]= *4*) 10 % AR after 110 d, [^{14}C-phenyl]-label , [^{14}C-quinazoline]-label (n= *1)* Sterile conditions: n.d. after 180 d (n= 4)
Non-extractable residues after 100 days ‡	14-27 % AR after 180 d, [^{14}C-phenyl]-label (n= 4) 24.6 % AR after *56* d, [^{14}C-phenyl]-label , [^{14}C-quinazoline]-label (n= *1*) Sterile conditions: 3.4 % AR after *180* d (n= 4)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	None of the metabolites exceeds 10% AR 2-oxy-fenazaquin: 9.1 % at 180 d and 13.9 % at 90d under sterile conditions (n= 4)

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

Anaerobic degradation ‡ Mineralization after 100 days	Mineralisation: 2.4 - 6.1% AR after 60 to 90 days (n=3)
Non-extractable residues after 100 days	9.2-24.2 % after *60* d, [^{14}C-phenyl]-label , [^{14}C-quinazoline]-label (n= *3*)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Up to 17 degradation products formed during aerobic pre-incubation of 30 days. None of them exceeded 7%.
Soil photolysis ‡ Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	4-OHQ 0.4-36.7 % at *30* d [^{14}C-quinazoline]-label (n= *1*) TBPE – 1.4-17.9 % at *30* d (n= *1*) DT_{50} (net photolysis) = 15 days

[8] n corresponds to the number of soils.

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	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (χ^2)	Method of calculation
Sandy clay loam	7.4	20 °C / 40 %	55.5/184.3	34.4	3.8	SFO
Clayish soil	7.0	20 °C / 40 %	58.9/195.6	34.2	5.3	SFO
Silty sand	6.5	20 °C / 40 %	121.1/402.4	104.1	3.4	SFO
Loamy sand	6.3	20 °C / 40 %	90.1/299.2	69.4	1.8	SFO
Geometric mean/median			-	54.0		

Laboratory studies ‡

2-oxy-fenazaquin	Aerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (χ^2)	Method of calculation
Sandy clay loam	7.4	20 °C / 40 %	30.1/100 (f. f. 0.256±0.15)	18.7	19.5	SFO
Clayish soil	7.0	20 °C / 40 %	18.9/62.7 (f. f. 0.198±0.79)	11.0	21.2	SFO
Silty sand	6.5	20 °C / 40 %	108.1/359.1 (f.f. 0.207±0.08)	93.0	25	SFO
Loamy sand	6.3	20 °C / 40 %	128.2/425.9 (f. f. 0.123±0.07)	98.7	15.4	SFO
Geometric mean/median			-	37.1		

The laboratory DT50 and kinetic formation fractions for 2-oxy-fenazaquin from fenazaquin have some uncertainty, but this is acceptable in this case due to the high adsorption of 2-oxy-fenazaquin.

Laboratory studies ‡

4-OHQ	Aerobic conditions					
Soil type	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Silt loam	5.74	20 °C / pF2	-	<<2hrs	-	SFO
Loam	7.27	20 °C / pF2	-	<<2hrs	-	SFO
Sandy loam	6.40	20 °C / pF2	-	<<2hrs	-	SFO

Geometric mean/median		-	<<2hrs		

Laboratory studies ‡

TBPE	Aerobic conditions					
Soil type	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Silt loam	5.74	20 °C / pF2	-	<<4hrs	-	SFO
Loam	7.27	20 °C / pF2	-	<<4hrs	-	SFO
Sandy loam	6.40	20 °C / pF2	-	<<4hrs	-	SFO
Geometric mean/median			-	<<4hrs		

Field studies ‡

Parent	Aerobic conditions							
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	DT_{50} (d) Norm.	Method of calculation
Silt loam	Lauter, Germany	5.9	20	27.1	90	26.5	-	SFO
Silty clay loam	Landsberg, Germany	7.0	20	48.2	160	26	-	SFO
Silt loam	Grebin, Germany	5.0	20	33.7	112	17.4	-	SFO
Loamy silt	Herford-Eickum, Germany	5.8	20	31.7	105	24.2	-	SFO
Loamy sand	Adelshausen Germany	6.4	20	12.9	42.7	21.8	-	SFO
Loamy	Grugno, Parma, Italy	8.06	25	43.6	145	4.1	-	SFO
Clay loam	Fognamo, Parma, Italy	7.93	25	16.3	54.2	24.4	-	SFO
Geometric mean/median				-	-	-	-	-

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	Not required

Laboratory studies ‡

Parent	Anaerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (χ^2)	Method of calculation
Loamy sand	5.7	20 °C / 50 %	264 (quinazoline) 320 (phenyl) / 870 (quinazoline) >1000 (phenyl)	-	4.8 (quinazoline) 2.9 (phenyl)/ 2.9	SFO
Geometric mean/median		-	-	-	-	-

Laboratory studies ‡

Parent	Photolysis in soil					
Soil type	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (χ^2)	Method of calculation
Sandy loam	7.00	25 °C / 40%	24.6/81.6(C-quinazoline) 26.1/86.6 (C-phenyl		5.9 5.7	SFO
Geometric mean/median			-			

4-OHQ	Photolysis in soil					
Soil type	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (χ^2)	Method of calculation
Sandy loam	7.00	25 °C / 40%	36.7/121.9 (C-quinazoline) (f.f. 1.0±0.29) 9.6/31.7 (C-phenyl(f.f. 0.989±0.404)		10.8 8.3	SFO
Geometric mean/median			-			

TBPE	Photolysis in soil					
Soil type	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (χ^2)	Method of calculation

Sandy loam	7.00	25 °C / 40%	9.6/31.7 (C-phenyl(f.f. 0.989±0.404)		8.3	SFO
Geometric mean/median			-			

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sand	0.3	7.7	-	-	54	17915	0.917
Sandy loam	0.8	5.7	-	-	128	16020	0.896
Loam	1.0	6.5	-	-	294	29365	0.887
Clay loam	1.2	6.9	-	-	512	42695	0.890
Arithmetic mean/median					-	26499	0.9
pH dependence (yes or no)			No				

2-oxy fenazaquin ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Silt loam	2.1	5.7	1163	54840	-		-
Loam	2.7	7.3	2688	98814	-		-
Sandy loam	1.0	6.4	1066	107735	-		-
Arithmetic mean/median				87129	-	-	-
pH dependence (yes or no)			No				

4-OHQ ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Silt loam	2.1	5.7	-	-	-	173	0.79
Loam	2.7	7.3	-	-	-	215	0.73
Sandy loam	1.0	6.4	-	-	-	294	0.57
Arithmetic mean/median					-	227	0.70
pH dependence (yes or no)			No				

TBPE ‡							
Soil Type	OC %	Soil pH	Kd	Koc	Kf	Kfoc	1/n

			(mL/g)	(mL/g)	(mL/g)	(mL/g)	
Silt loam	2.1	5.7	3.33	157	-		-
Loam	2.7	7.3	3.56	131	-		-
Sandy loam	1.0	6.4	2.13	217	-		-
Arithmetic mean/median				168	-		-
pH dependence (yes or no)			No				

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

Column leaching ‡	Eluation: 393 mL distilled water Time period (d): 2 d
	Leachate: 0.05 - 0.24 % total residues/radioactivity in leachate 0.05-0.24 % ^{14}C-Fenazaquin 93.42-97.35% of total residues/radioactivity retained in top *5* cm
Aged residues leaching ‡	Aged for (d): 30 and 60 d Eluation: 393 mL distilled water or 508 mm 0.01 M $CaCl_2$
	68.8 - 83.03 % total residues/radioactivity retained in top 0-5 cm
	Leachate: 0.25 - 2.4 % total residues/radioactivity in leachate
Lysimeter/ field leaching studies ‡	Not required

PEC (soil) (Annex IIIA, point 9.1.3)

Parent	DT_{50} (d): 121 days
Method of calculation	Kinetics: SFO
Metabolites formation fractions	2-oxy-fenazaquin = kinetic formation of 0.256 resulting in 9.1% observed TBPE = 17.9% observed 4-OHQ = 36.6% observed

Application data	Crop: grapes, citrus, ornamentals Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % deposition rate: 60% grapes, 30% citrus, Number of applications: 1 Interval (d): - Application rates: 1 x 0.12 kg a.s./ha grapes, Southern Europe 1 x 0. 2 kg a.s./ha citrus 1 x 0.3 kg a.s./ha ornamentals

PECs(mg/kg) **Fenazaquin**		Grapes (vine) (1 x 0.12 kg a.s./ha, 40 % Interception)		Citrus (1 x 0.2 kg a.s./ha, 70 % Interception)	
		Single application Actual	Single application Time weighted average	Single application Actual	Single application Time weighted average
Initial		0.096	-	0.080	-
Short term	24h	0.095	0.096	0.080	0.080
	2d	0.095	0.095	0.079	0.080
	4d	0.094	0.095	0.078	0.079
Long term	7d	0.092	0.094	0.077	0.078
	28d	0.082	0.089	0.068	0.074
	50d	0.072	0.083	0.060	0.070
	100d	0.054	0.073	0.045	0.061

PECs initial (mg/kg) Fenazaquin for ornamentals = 0.2 mg/kg

PECs(mg/kg) **Degradation products**	Grapes (vine)			Citrus		
	2-oxy fenazaquin	TBPE	4-OHQ	2-oxy fenazaquin	TBPE	4-OHQ
Initial	0.015	0.010	0.017	0.013	0.008	0.014

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: 9.6 days at 25 °C sterile (1st order, r^2=0.9986) 4-OHQ: 79.3 % AR (within 20 d) TBPE: 82.2% AR (within 20 d)
	pH 7: 130 days at 25°C (1st order, poor correlation), 354 days 4-OHQ: 13.8 % AR (within 34 d) TBPE: 14.3% AR (within 34 d)
	pH 9: 219 days at 25°C (1st order, poor correlation)
Photolytic degradation of active substance and metabolites above 10 % ‡	DT_{50} : 15 days Natural light, 40°N; at 25°C 4-OHQ 32.4% TBPE 18.6% 4-tert-butylstyrene 9.2%
Quantum yield of direct phototransformation in water at Σ > 290 nm	8.0· 10^{-4} mol · Einstein $^{-1}$
Readily biodegradable ‡ (yes/no)	No.

Degradation in water / sediment

Parent	Distribution (max. in water 62.6 after 0 d. Max. sed 54.3 % after 60 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (χ^2)	DT_{50} - DT_{90} sed	St. (r^2)	Method of calculation
Sandy loam sediment	7.14	5.7	20	41.9* (C-quinazoline label) 42.8* (C-phenyl label)	- -		12.5 10.1	- -	- -	SFO SFO
Clay loam sediment	7.24	6.3	20	119* (C-quinazoline label) 140* (C-phenyl label)	- -		3.6 4.9	- -	- -	SFO SFO
Geometric mean/median				-		-		-		-

*recalculated DT_{50} values with Modelmaker

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)
Sandy loam sediment	7.14	5.7	17.9 % after 100 days	15.7 % after 60 days	11.8% after 100 days

Clay loam sediment	7.24	6.3	6.4 % after 100 days	16.1 % after 100 days	16.1 % after 100 days

Major metabolites in water sediment sudy:

2-oxy-fenazaquin: (Max. occurrence water/sediment study) 21.2%, 19.8% AR (30 d) in the sediment

4-(2-(4-(1,1-dimethylethanoic acid) phenyl) ethoxy) quinazoline: (Max. occurrence water/sediment study) 11.5%, 10.3 % AR (100 d) in the sediment

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

Parent Parameters used in FOCUSsw 2	Molecular weight (g/mol): 306.4 Water solubility (mg/L): 0.1 K_{OC} (L/kg):26499 DT_{50} soil (d): 54.9 days (geomean lab) DT_{50} water/sediment system (d): 73.9 days (geomean of entire system) DT_{50} water (d): 73.9 days DT_{50} sediment (d): 1000 days Crop interception (%): Vine 40%, Citrus 70%
4-(2-(4-(1,1-dimethylethanoic acid) phenyl) ethoxy) quinazoline Parameters used in FOCUSsw 2	K_{OC} (L/kg):0 DT_{50} soil (d): 1000 days DT_{50} water/sediment system (d): 1000 days DT_{50} water (d): 1000 days DT_{50} sediment (d): 1000 days Max. occurrence water/sediment study = 11.5% Max. occurrence soil = 2.1%
2-oxy-fenazaquin Parameters used in FOCUSsw 2	K_{OC} (L/kg):9586 DT_{50} soil (d): 37.1 days DT_{50} water/sediment system (d): 1000 days DT_{50} water (d): 1000 days DT_{50} sediment (d): 1000 days Max. occurrence water/sediment study = 21.2% Max. occurrence soil = 9.1%
TBPE Parameters used in FOCUSsw 2	K_{OC} (L/kg):168 DT_{50} soil (d): 0.17 days DT_{50} water/sediment system (d): 1000 days DT_{50} water (d): 1000 days DT_{50} sediment (d): 1000 days Max. occurrence water/sediment study = 82.2% Max. occurrence soil = 17.9%
4-OHQ Parameters used in FOCUSsw 2	K_{OC} (L/kg):227 DT_{50} soil (d): 0.08 days DT_{50} water/sediment system (d): 1000 days

	DT_{50} water (d): 1000 days DT_{50} sediment (d): 1000 days Max. occurrence water/sediment study = 79.3% Max. occurrence soil = 36.6%
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: Vapour pressure: 1.9 x 10^{-5} Koc: 26499 1/n: 0.9 Q10=2.58
Application rate	Crop: Vine, Citrus, Ornamentals Crop interception: Vine 40%, Citrus 70% Number of applications: *1* Interval (d): - Application rate(s): 1 x 0.12 kg a.s./ha in grapes (vine), 1 x 0.2 kg a.s./ha in citrus

FOCUS STEP 1

Results of the Step 1 exposure assessment were not reported. The risk assessment started with the more realistic Step 2 scenario.

FOCUS STEP 2

Fenazaquin

PECsw (µg/L)	**Grapes (1 x 0.12 kg a.s./ha)**		**Citrus (1 x 0.2 kg a.s./ha)**	
	Actual	TWA	Actual	TWA
0d	1.080	-	10.483	
1d	0.376	0.728	3.652	7.068
2d	0.150	0.496	1.458	4.811
4d	0.305	0.324	0.735	2.868
7d	0.278	0.306	0.490	1.867
14d	0.276	0.291	0.487	1.177
21d	0.274	0.286	0.484	0.947
28d	0.272	0.283	0.481	0.831
42d	0.269	0.279	0.474	0.713
50d	0.267	0.277	0.471	0.674
100d	0.255	0.269	0.449	0.567

Degradation products

PECsw (µg/L) Initial	Grapes (1 x 0.12 kg a.s./ha)	Citrus (1 x 0.2 kg a.s./ha)
	(4-(2-(4-(1,1-dimethyl ethanoic acid) phenyl) ethoxy) quinazoline)	
	0.357	1.504
	2-oxy fenazaquin	
	0.241	2.339
	TBPE	
	0.516	5.014
	4-OHQ	
	0.408	3.965

Step 2 scenarios, Fenazaquin:

PECsed (µg/kg)	Grapes (1 x 0.12 kg a.s./ha)		Citrus (1 x 0.2 kg a.s./ha)	
	Actual	TWA	Actual	TWA
0d	74.329	-	131.227	
1d	74.260	74.294	131.105	131.166
2d	74.191	74.260	130.983	131.105
4d	74.053	74.191	130.740	130.983
7d	73.846	74.087	130.375	130.801
14d	73.366	73.847	129.528	130.376
21d	72.890	73.607	128.686	129.953
28d	72.416	73.368	127.850	129.531
42d	71.478	72.894	126.194	128.694
50d	70.948	72.625	125.257	128.219
100d	67.720	70.973	119.559	125.303

Step 2 scenarios, degradation products:

PECsed (µg/kg) Initial	Grapes (1 x 0.12 kg a.s./ha)	Citrus (1 x 0.2 kg a.s./ha)
	(4-(2-(4-(1,1-dimethyl ethanoic acid) phenyl) ethoxy) quinazoline)	
	0.000	0.000
	2-oxy fenazaquin	
	7.599	21.151
	TBPE	
	0.706	6.858
	4-OHQ	
	0.709	6.886

Step 3 scenarios, Fenazaquin

PECsw (µg/L)	Step 3 scenarios: Grapes					
	D6: Thiva, ditch		R1: Weiherbach, pond		R1: Weiherbach, stream	
	Actual	TWA	Actual	TWA	Actual	TWA
0d	0.641	-	0.022	-	0.473	-
1d	0.009	0.250	0.021	0.021	0.000	0.078
2d	0.000	0.126	0.020	0.021	0.000	0.039
4d	0.000	0.063	0.019	0.020	0.000	0.020
7d	0.000	0.036	0.017	0.019	0.000	0.011
14d	0.000	0.018	0.013	0.017	0.000	0.006
21d	0.000	0.012	0.010	0.015	0.000	0.004
28d	0.000	0.009	0.008	0.013	0.000	0.003
42d	0.000	0.006	0.005	0.011	0.000	0.002
50d	0.000	0.005	0.004	0.010	0.000	0.002
100d	0.000	0.003	0.002	0.006	0.000	0.001

Step 3 scenarios, Fenazaquin

PECsw (µg/L)	Step 3 scenarios: Grapes					
	R2: Porto, stream		R3: Bologna, stream		R4: Roujan, stream	
	Actual	TWA	Actual	TWA	Actual	TWA
0d	0.628	-	0.671	-	0.473	-
1d	0.000	0.053	0.000	0.202	0.000	0.078
2d	0.000	0.026	0.000	0.101	0.000	0.039
4d	0.000	0.013	0.000	0.051	0.000	0.019
7d	0.000	0.008	0.000	0.029	0.000	0.011
14d	0.007	0.004	0.000	0.015	0.000	0.006
21d	0.000	0.003	0.000	0.011	0.000	0.004
28d	0.000	0.002	0.000	0.008	0.000	0.003
42d	0.000	0.001	0.000	0.005	0.000	0.002
50d	0.000	0.001	0.000	0.005	0.000	0.002
100d	0.000	0.001	0.000	0.002	0.000	0.001

Step 3 scenarios, Fenazaquin

PECsw (µg/L)	Step 3 scenarios: Citrus			
	D6: Thiva, ditch		R4: Roujan, stream	
	Actual	TWA	Actual	TWA
0d	7.147	-	5.399	-
1d	6.416	6.766	0.000	0.875
2d	5.761	6.421	0.000	0.438
4d	4.376	5.756	0.000	0.219
7d	2.021	4.649	0.000	0.125
14d	0.236	2.718	0.000	0.063
21d	0.135	1.867	0.000	0.042
28d	0.119	1.432	0.000	0.031
42d	0.007	0.965	0.000	0.021
50d	0.014	0.812	0.000	0.018
100d	0.039	0.425	0.000	0.010

Step 3 scenarios, Fenazaquin

PECsed (µg/kg)	Step 3 scenarios: Grapes					
	D6: Thiva, ditch		R1: Weiherbach, pond		R1: Weiherbach, stream	
	Actual	TWA	Actual	TWA	Actual	TWA
0d	0.193	-	0.325	-	0.314	-
1d	0.192	0.193	0.325	0.325	0.314	0.314
2d	0.190	0.192	0.325	0.325	0.313	0.314
4d	0.188	0.191	0.325	0.325	0.312	0.313
7d	0.184	0.189	0.325	0.325	0.310	0.312
14d	0.175	0.185	0.323	0.325	0.306	0.310
21d	0.167	0.180	0.320	0.325	0.302	0.308
28d	0.160	0.176	0.317	0.324	0.298	0.307
42d	0.147	0.169	0.310	0.323	0.292	0.305
50d	0.141	0.165	0.306	0.322	0.288	0.304
100d	0.116	0.147	0.285	0.314	0.300	0.300

Step 3 scenarios, Fenazaquin

PECsed (µg/kg)	Step 3 scenarios: Grapes					
	R2: Porto, stream		R3: Bologna, stream		R4: Roujan, stream	
	Actual	TWA	Actual	TWA	Actual	TWA
0d	0.942	-	0.317	-	1.689	-
1d	0.941	0.942	0.316	0.317	1.688	1.688
2d	0.941	0.941	0.315	0.316	1.687	1.688
4d	nc	0.940	0.312	0.315	1.684	1.687
7d	nc	0.938	0.309	0.313	1.681	1.685
14d	nc	0.920	0.301	0.309	1.673	1.681
21d	nc	0.886	0.293	0.305	1.665	1.681
28d	nc	0.870	0.286	0.301	1.658	1.680
42d	nc	0.853	0.273	0.294	1.644	1.675
50d	nc	0.849	0.266	0.290	1.637	1.672
100d	nc	0.829	0.231	0.269	nc	1.638

nc not calculated: simulated period was too short for calculation of PECsed

Step 3 scenarios, Fenazaquin

PECsed (µg/kg)	Step 3 scenarios: Citrus			
	D6: Thiva, ditch		R4: Roujan, stream	
	Actual	TWA	Actual	TWA
0d	26.086	-	3.142	-
1d	26.045	26.083	3.140	3.141
2d	25.943	26.071	3.137	3.140
4d	25.642	26.025	3.132	3.138
7d	25.105	25.909	3.125	3.134
14d	23.852	25.500	3.133	3.126
21d	22.592	25.013	3.117	3.126
28d	21.056	24.498	3.100	3.122
42d	18.587	23.316	3.070	3.110
50d	17.581	22.638	3.054	3.102
100d	13.679	19.370	nc	3.047

nc not calculated: simulated period was too short for calculation of PECsed

Step 4 scenarios, Fenazaquin

Initial predicted surface water concentrations derived from FOCUS Step 4 calculations for application of 1 x 80 g ai/ha to grapes in Northern Europe

FOCUS Scenario	Water body type	Step 4			
		buffer zone [m]	PEC [µg/L]	buffer zone [m]	PEC [µg/L]
D6 (Thiva)	Ditch	20	**0.100**	25	**0.071**
R1 (Weiherbach)	Pond	20	0.015	25	0.012
R1 (Weiherbach)	Stream	20	0.086	25	0.061
R2 (Porto)	Stream	20	0.119	25	0.084
R3 (Bologna)	Stream	20	**0.125**	25	**0.089**
R4 (Roujan)	Stream	20	0.088	25	0.063

Step 4 scenarios, Fenazaquin
Initial predicted surface water concentrations derived from FOCUS Step 4 calculations for application of 1 x 120 g ai/ha to grapes in Southern Europe

FOCUS Scenario	Water body type	Step 4			
		buffer zone [m]	PEC [µg/L]	buffer zone [m]	PEC [µg/L]
D6 (Thiva)	Ditch	20	**0.151**	25	**0.107**
R1 (Weiherbach)	Pond	20	0.022	25	0.017
R1 (Weiherbach)	Stream	20	0.129	25	0.092
R2 (Porto)	Stream	20	0.179	25	0.127
R3 (Bologna)	Stream	20	**0.188**	25	**0.133**

R4 (Roujan)	Stream	20	0.133	25	0.095

Value in **bold** used for the risk assessment

PECsw initial (µg/l) ornamentals = 0.1 µg/L (resulting from assuming emission to surface water 0.1% of applied amount, i.e. 0.3 a.s.kg/ha for a standard water body of 30 cm depth).

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model used: PELMO 3.3.2 Scenarios (list of names): Châteaudun, Hamburg, Kremsműnster, Okehampton, Piacenza, Porto, Sevilla, Thiva. Crop: 1 x 0.12 kg a.s./ha in vine (grapes) 1 x 0.20 kg a.s./ha in citrus 1 x 0.30 kg a.s./ha in ornamentals (vines as surrogate for ornamentals) **Parent** DT_{50lab} 54.9 d K_{OC}: parent, 26499, $^1/_n$= 0.9 Q10 = 2.58 **2-oxy-fenazaquin** DT_{50lab} 37.1 d, kinetic ff from fenazaquin 0.196 K_{OC}: 9586, $^1/_n$= 1.0, Q10 = 2.58 **TBPE** DT_{50lab} 0.17 d K_{OC}: 168, $^1/_n$= 1.0, Q10 = 2.58, simulation run as if applied as parent, with application rate calculated assuming the maximum molar formation fraction of 17.9% **4-OHQ** DT_{50lab} 0.08 d K_{OC}: 227, $^1/_n$= 1.0, Q10 = 2.58, simulation run as if applied as parent, with application rate calculated assuming the maximum molar formation fraction of 36.6%
Application rate	Application rate: 1 x 0.12 kg a.s./ha in vine (grapes) 1 x 0.20 kg a.s./ha in citrus 1 x 0.30 kg a.s./ha in ornamentals No. of applications: 1 Time of application: at early growth stages: crop interception values utilised were 40% for grapes, 70% for citrus and 50% for ornamentals.

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

Maximum concentration	< 0.001 µg/L for fenazaquin and its metabolites 2-oxy-fenazaquin, TBPE and 4-OHQ
Average annual concentration	80th percentile annual average concentration < 0.001 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	active substance: 3.0 x 10^{-3} molecules degraded/photon
Photochemical oxidative degradation in air ‡	DT_{50} of 3.321 hours derived by the Atkinson model (AOPWIN version 1.90). OH (12 or 24 h) concentration assumed = 1.5 x 10^{6} molecules/cm^{3} considering 12 hours irradiation per day
Volatilisation ‡	from plant surfaces (BBA guideline): <0.4 % after 24 hours
	from soil surfaces (BBA guideline): < 1.0% after 24 hours
Metabolites	-

PEC (air)

Method of calculation	The volatility of fenazaquin is negligible. Moreover, its reactivity with OH radicals in the troposphere is predicted to be extremely rapid.Thus, it is unlikely that significant residues will occur in the air.

$PEC_{(a)}$

Maximum concentration	Negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil:	Fenazaquin, 4-OHQ (soil photolysis), TBPE (soil photolysis) and 2-oxy-fenazaquin
	Surface water:	Fenazaquin
	Sediment:	Fenazaquin, 2-oxy-fenazaquin, 4-(2-(4-(1,1-dimethylethanoic acid)phenyl)ethoxy)quinazoline
	Ground water:	Fenazaquin, 2-oxy-fenazaquin, 4-OHQ, TBPE
	Air:	Fenazaquin

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

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

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

Not readily biodegradable

Ecotoxicology

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

Acute toxicity to mammals	Oral technical: LD_{50}: 134 mg/kg bw (rat, male)
Long term (2-generation) toxicity to mammals	Reproduction: NOEL: 25 mg/kg bw/d (rat)
Acute toxicity to birds	Technical: LD_{50} 1747 mg a.s./kg bw (Bobwhite quail) LD_{50} >2000 mg a.s./kg bw (Mallard duck)
Dietary toxicity to birds (sort-term)	Technical: LC_{50} >1169 mg a.s./kg bw/d (5204 mg as/kg $_{food}$) (Bobwhite quail)
Reproductive toxicity to birds	Technical: NOEC 80.3 mg a.s./kg bw/d (953 ppm) (Bobwhite quail)

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

Application rate (kg a.s./ha)	Crop	Category	Time-scale	TER	Annex VI Trigger
		Birds			
0.2	citrus	Insectivorous bird	Acute	162	10
0.2	citrus	Insectivorous bird	short-term	>194	10
0.2	citrus	Insectivorous bird	long-term	13.3	5
0.2	citrus	Earthworm-eating bird	long-term	84.7	5
0.2	citrus	Fish-eating bird	long-term	780	5
		Mammals			
0.2	citrus	Small herbivorous mammal	Acute	Tier 1: **5.67** Refined 11.31	10
0.12	grapes	Small herbivorous mammal	Acute	Tier 1: **9.43** Refined 11.31	10
0.2	citrus	Small herbivorous mammal	long-term	Tier 1: **3.7** Refined 7.44	5
0.12	grapes	Small herbivorous mammal	long-term	Tier 1: 6.2 Refined 7.44	5
0.2	citrus	Earthworm-eating mammal	long-term	20.74	5
0.2	citrus	Fish-eating mammal	long-term	391	5

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

Group	Test substance	Time-scale	Endpoint	Toxicity (mg a.s/L)
Laboratory tests				
Fish *Oncorhynchus mykiss*	Technical	Acute flow through	96h LC_{50}	0.0038
Oncorhynchus mykiss	Technical	Acute static without	96h LC_{50}	0.0066
		and with sediment	96h LC_{50}	0.0119
Lepomis macrochirus	Technical	Acute flow through	96h LC_{50}	0.0341
Rhodeus amarus	Technical	Acute semi static	96h LC_{50}	0.0363
Pimephales promelas	Technical	Acute semi static	96h LC_{50}	0.0042
Oryzias latipes	Technical	Acute semi static	96h LC_{50}	0.0136
Gasterosteus aculeatus	Technical	Acute semi static	96h LC_{50}	0.0082
Danio rerio	Technical	Acute semi static	96h LC_{50}	0.0080
Perca fluviatilis	Technical	Acute semi static	96h LC_{50}	0.0032
Leucaspius delineatus	Technical	Acute semi static	96h LC_{50}	0.0047
Poecilia reticulate	Technical	Acute semi static	96h LC_{50}	0.0590
Oncorhynchus mykiss	Formulation	Acute flow through	96h LC_{50}	0.045
Oncorhynchus mykiss	4-(2-(4-(1,1-dimethyl ethanoic acid) phenyl) ethoxy) quinazoline	Acute semi static	96h LC_{50}	0.77
Oncorhynchus mykiss	TBPE	Acute semi static	96h LC_{50}	13.3
Oncorhynchus mykiss	4-OHQ	Acute static	96h LC_{50}	91
Oncorhynchus mykiss	Technical	Chronic ELS flow-through	63d NOEC	0.00096
Oncorhynchus mykiss	Formulation	Chronic flow-through	21d NOEC	0.0065
Invertebrates *Daphnia magna*	Technical	Acute static	48h EC_{50}	0.0041
Daphnia magna	Technical	Acute static without	48h EC_{50}	0.0057
		and with sediment	48h EC_{50}	0.0127
Crassostrea virginica	Technical	Acute flow through	96h EC_{50}	0.0054
Crangon crangon	Technical	Acute semi static	96h EC_{50}	0.015
Daphnia magna	Formulation	Acute static	48h EC_{50}	0.000467
Planorbarius corneus	Formulation	Acute semi static	96h EC_{50}	> 1.101
Hydropsyche spec	Formulation	Acute semi static	96h EC_{50}	0.204
Notonecta maculate	Formulation	Acute semi static	48h EC_{50}	>0.04875

Ephemera danica	Formulation	Acute semi static	96h EC_{50}	> 0.804
Chironomus riparius	Formulation	Acute semi static	48h EC_{50}	0.0261
Asellus aquaticus	Formulation	Acute semi static	96h EC_{50}	0.00386
Gammarus pulex	Formulation	Acute semi static	96h EC_{50}	0.00416
Daphnia magna	4-(2-(4-(1,1-dimethyl ethanoic acid) phenyl) ethoxy) quinazoline	Acute static	48h EC_{50}	2.34
Daphnia magna	TBPE	Acute semi static	48h EC_{50}	3.86
Daphnia magna	4-OHQ	Acute static	48h EC_{50}	>100
Daphnia magna	Technical	Chronic semi static	21d NOEC	0.0014
Daphnia magna	Formulation	Chronic flow through	21d NOEC	0.0002
Chironomus riparius	Technical	Chronic static	28d NOEC	0.0025 (equal to 18.8 µg a.s./kg sediment)
Chironomus riparius	2-oxy-fenazaquin	Acute semi static	96h EC_{50}	>3
Algae *S. capricornutum*	Technical	Acute static	72h EC_{50}	>0.208
S. capricornutum	Formulation	Acute static	72h EbC_{50}	15.8
S. capricornutum.	4-(2-(4-(1,1-dimethyl ethanoic acid) phenyl) ethoxy) quinazoline	Chronic	72h EbC_{50}	8.73
Microcosm or mesocosm tests				
Invertebrate Community	Formulation	Static	8 weeks NOEC	0.0003

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

FOCUS Step 3

Scenario Water body type	Test organism	Time scale	Toxicity endpoint (µg/L)	Buffer zone [m]	$PEC_{initial,sw}$ µg a.s./L	TER	Annex VI trigger
Grapes (Northern Europe): 1 application 80 g a.s./ha							
Laboratory study							
D6 ditch	*D. magna*	48h	0.467	3.5	1.320	**0.35**	100
R1 pond	*D. magna*	48h	0.467	6.0	0.046	**10.15**	100
R1 stream	*D. magna*	48h	0.467	4.0	0.940	**0.50**	100
R2 stream	*D. magna*	48h	0.467	4.0	1.298	**0.36**	100
R3 stream	*D. magna*	48h	0.467	4.0	1.365	**0.34**	100
R4 stream	*D. magna*	48h	0.467	4.0	0.967	**0.48**	100
D6 ditch	*D. magna*	21d	0.2	3.5	1.320	**0.15**	10
R1 pond	*D. magna*	21d	0.2	6.0	0.046	**4.35**	10
R1 stream	*D. magna*	21d	0.2	4.0	0.940	**0.21**	10
R2 stream	*D. magna*	21d	0.2	4.0	1.298	**0.15**	10
R3 stream	*D. magna*	21d	0.2	4.0	1.365	**0.15**	10
R4 stream	*D. magna*	21d	0.2	4.0	0.967	**0.21**	10
Grapes (Southern Europe): 1 application 120 g a.s./ha							
D6 ditch	*D. magna*	48h	0.467	3.5	1.983	**0.24**	100
R1 pond	*D. magna*	48h	0.467	6.0	0.070	**6.67**	100
R1 stream	*D. magna*	48h	0.467	4.0	1.413	**0.33**	100
R2 stream	*D. magna*	48h	0.467	4.0	1.950	**0.24**	100
R3 stream	*D. magna*	48h	0.467	4.0	2.050	**0.23**	100
R4 stream	*D. magna*	48h	0.467	4.0	1.453	**0.32**	100
D6 ditch	*D. magna*	21d	0.2	3.5	1.983	**0.10**	10
R1 pond	*D. magna*	21d	0.2	6.0	0.070	**2.86**	10
R1 stream	*D. magna*	21d	0.2	4.0	1.413	**0.14**	10
R2 stream	*D. magna*	21d	0.2	4.0	1.950	**0.10**	10
R3 stream	*D. magna*	21d	0.2	4.0	2.050	**0.10**	10
R4 stream	*D. magna*	21d	0.2	4.0	1.453	**0.14**	10
Citrus: 1 application 200 g a.s./ha							
Laboratory study							
D6 ditch	*D. magna*	48h	0.467	3.5	7.147	**0.07**	100
R4 stream	*D. magna*	48h	0.467	4.0	5.399	**0.09**	100
D6 ditch	*D. magna*	21d	0.2	3.5	7.147	**0.03**	10
R4 stream	*D. magna*	21d	0.2	4.0	5.399	**0.04**	10
Orchards: 1 application 200 g a.s./ha							
D3 ditch	*D. magna*	48h	0.467	3.5	7.106	**0.07**	100
D4 pond	*D. magna*	48h	0.467	6.0	0.315	**1.48**	100
D4 stream	*D. magna*	48h	0.467	4.0	6.857	**0.07**	100
D5 pond	*D. magna*	48h	0.467	6.0	0.315	**1.48**	100
D5 stream	*D. magna*	48h	0.467	4.0	7.696	**0.06**	100
R1 pond	*D. magna*	48h	0.467	6.0	0.314	**1.49**	100
R1 stream	*D. magna*	48h	0.467	4.0	5.446	**0.09**	100
R2 stream	*D. magna*	48h	0.467	4.0	7.187	**0.06**	100
R3 stream	*D. magna*	48h	0.467	4.0	7.642	**0.06**	100
R4 stream	*D. magna*	48h	0.467	4.0	5.444	**0.09**	100
D3 ditch	*D. magna*	21d	0.2	3.5	7.106	**0.03**	10
D4 pond	*D. magna*	21d	0.2	6.0	0.315	**0.63**	10
D4 stream	*D. magna*	21d	0.2	4.0	6.857	**0.03**	10
D5 pond	*D. magna*	21d	0.2	6.0	0.315	**0.63**	10
D5 stream	*D. magna*	21d	0.2	4.0	7.696	**0.03**	10
R1 pond	*D. magna*	21d	0.2	6.0	0.314	**0.64**	10

R1 stream	*D. magna*	21d	0.2	4.0	5.446	**0.04**	10
R2 stream	*D. magna*	21d	0.2	4.0	7.187	**0.03**	10
R3 stream	*D. magna*	21d	0.2	4.0	7.642	**0.03**	10
R4 stream	*D. magna*	21d	0.2	4.0	5.444	**0.04**	10

FOCUS Step 4

Scenario Water body type	Test organism	Time scale	Toxicity endpoint (µg/L)	Buffer zone [m]	$PEC_{initial,sw}$ µg a.s./L	TER	Annex VI trigger
Grapes (Northern Europe): 1 application 80 g a.s./ha							
Laboratory study							
D6 ditch	*D. magna*	48h	0.467	20	0.100	**4.67**	100
R1 pond	*D. magna*	48h	0.467	20	0.015	**31.13**	100
R1 stream	*D. magna*	48h	0.467	20	0.086	**5.43**	100
R2 stream	*D. magna*	48h	0.467	20	0.119	**3.92**	100
R3 stream	*D. magna*	48h	0.467	20	0.123	**3.74**	100
R4 stream	*D. magna*	48h	0.467	20	0.088	**5.31**	100
D6 ditch	*D. magna*	21d	0.2	20	0.100	**2.00**	10
R1 pond	*D. magna*	21d	0.2	20	0.015	13.33	10
R1 stream	*D. magna*	21d	0.2	20	0.086	**2.33**	10
R2 stream	*D. magna*	21d	0.2	20	0.119	**1.68**	10
R3 stream	*D. magna*	21d	0.2	20	0.123	**1.60**	10
R4 stream	*D. magna*	21d	0.2	20	0.088	**2.27**	10
D6 ditch	Mesocosm	8 weeks	0.3	20	0.100	3.00	2
R1 pond	Mesocosm	8 weeks	0.3	20	0.015	20.00	2
R1 stream	Mesocosm	8 weeks	0.3	20	0.086	3.49	2
R2 stream	Mesocosm	8 weeks	0.3	20	0.119	2.52	2
R3 stream	Mesocosm	8 weeks	0.3	20	0.123	2.44	2
R4 stream	Mesocosm	8 weeks	0.3	20	0.088	3.41	2
Grapes (Southern Europe): 1 application 120 g a.s./ha							
D6 ditch	*D. magna*	48h	0.467	25	0.107	**4.36**	100
R1 pond	*D. magna*	48h	0.467	25	0.017	**27.47**	100
R1 stream	*D. magna*	48h	0.467	25	0.092	**5.08**	100
R2 stream	*D. magna*	48h	0.467	25	0.127	**3.68**	100
R3 stream	*D. magna*	48h	0.467	25	0.133	**3.51**	100
R4 stream	*D. magna*	48h	0.467	25	0.095	**4.92**	100
D6 ditch	*D. magna*	21d	0.2	25	0.107	**1.87**	10
R1 pond	*D. magna*	21d	0.2	25	0.017	11.76	10
R1 stream	*D. magna*	21d	0.2	25	0.092	**2.17**	10
R2 stream	*D. magna*	21d	0.2	25	0.127	**1.57**	10
R3 stream	*D. magna*	21d	0.2	25	0.133	**1.50**	10
R4 stream	*D. magna*	21d	0.2	25	0.095	**2.11**	10
D6 ditch	Mesocosm	8 weeks	0.3	20	0.107	2.80	2
R1 pond	Mesocosm	8 weeks	0.3	20	0.017	17.65	2
R1 stream	Mesocosm	8 weeks	0.3	20	0.092	3.26	2
R2 stream	Mesocosm	8 weeks	0.3	20	0.127	2.36	2
R3 stream	Mesocosm	8 weeks	0.3	20	0.133	2.26	2
R4 stream	Mesocosm	8 weeks	0.3	20	0.095	3.16	2

Glasshouse

Scenario Water body type	Test organism	Time scale	Toxicity endpoint (µg/L)	Buffer zone [m]	$PEC_{initial,sw}$ µg a.s./L	TER	Annex VI trigger
Laboratory study							
Glasshouse	*D. magna*	48h	0.467	-	0.1	**4.7**	100
Glasshouse	*D. magna*	21d	0.2	-	0.1	**2**	100
Glasshouse	*C. riparius*	28d	2.5***	-	0.1	25	10
Glasshouse	Mesocosm	8 weeks	0.3	-	0.1	3	2

* worst-case scenario
** endpoint expressed in µg a.s./kg sediment
*** endpoint expressed in µg a.s./L used in the TER calculation

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

FOCUS Step 4

Scenario Water body type	Test organism	Time scale	Toxicity endpoint (µg/L)	Buffer zone [m]	$PEC_{initial,sw}$ µg a.s./L	TER	Annex VI trigger
O.mykiss: TERs not reported because based on not acceptable buffer zones							
Ornamental : 1 application 300 g a.s./ha							
Glasshouse	*O.mykiss*	48h	3.8	-	0.1	**38**	100
Glasshouse	*O.mykiss*	63d	0.96	-	0.1	**9.6** (10, rounded)	10

Refined acute risk assessment for fish according to Opinion of the PPR EFSA (EFSA Journal 2005).

Method 2

TER values for the 3rd most sensitive species Sunbleak (*L. delineatus)*

Crop	Buffer zone (m)	LC_{50} (µg/L)	TER (FOCUS worst case drainage scenario)	TER (FOCUS worst case run-off scenario)	Trigger
Grapes (NE)	25	4.7	**66.2**	**52.8**	100
Glasshouse*	1		**47**		100

* PECsw calculated for stagnant water body of 30 cm depth

Toxicity/exposure ratios for aquatic organisms exposed to 4-(2-(4-(1,1-dimethyl ethanoic acid) phenyl) ethoxy) quinazoline (Annex IIIA, point 10.2)

Application rate [kg a.s./ha]	Crop	Organism	Time-scale	Distance [m]	PEC_{sw} µg a.s./L	TER	Annex VI Trigger
Laboratory standard tests							
0.12	Grapes (Southern Europe) (covering Northern Europe)	*Oncorhynchus mykiss*	96 h	3	0.357	2157	100
		Daphnia magna	48 h	3	0.357	6443	100
		Selenastrum capricornutum	72 h	3	0.357	24370	10
0.2	Citrus (covering orchards)	*Oncorhynchus mykiss*	96 h	3	1.504	512	100
		Daphnia magna	48 h	3	1.504	1529	100
		Selenastrum capricornutum	72 h	3	1.504	5805	10
0.3	Ornamentals-glasshouse	*Oncorhynchus mykiss*	96 h	1	0.01	77000	100
		Daphnia magna	48 h	1	0.01	234000	100
		Selenastrum capricornutum	72 h	1	0.01	873000	10

Toxicity/exposure ratios for aquatic organisms exposed to 2-oxy-fenazaquin (Annex IIIA, point 10.2)

Application rate [kg a.s./ha]	Crop	Organism	Time-scale	Distance [m]	PEC_{sw} µg a.s./L	TER	Annex VI Trigger
Laboratory standard tests							
0.12	Grapes (Southern Europe) (covering Northern Europe)	*Chironomus riparius*	48 h	3	0.241	>12448	100
0.2	Citrus (covering orchards)	*Chironomus riparius*	48 h	3	2.339	2383	100
0.3	Ornamentals-glasshouse	*Chironomus riparius*	48 h	1	0.02	150000	100

Toxicity/exposure ratios for aquatic organisms exposed to TBPE (Annex IIIA, point 10.2)

Application rate [kg a.s./ha]	Crop	Organism	Time-scale	Distance [m]	PEC_{sw} µg a.s./L	TER	Annex VI Trigger
Laboratory standard tests							
0.12	Grapes (Southern Europe) (covering Northern Europe)	*Oncorhynchus mykiss*	96 h	3	0.516	25775	100
		Daphnia magna	48 h	3	0.516	7364	100
0.2	Citrus (covering orchards)	*Oncorhynchus mykiss*	96 h	3	5.014	2653	100
		Daphnia magna	48 h	3	5.014	779	100
0.3	Ornamentals-glasshouse	*Oncorhynchus mykiss*	96 h	1	0.05	266000	100
		Daphnia magna	48 h	1	0.05	77200	100

Toxicity/exposure ratios for aquatic organisms exposed to 4-OHQ (Annex IIIA, point 10.2)

Application rate [kg a.s./ha]	Crop	Organism	Time-scale	Distance [m]	PEC_{sw} µg a.s./L	TER	Annex VI Trigger
Laboratory standard tests							
0.12	Grapes (Southern Europe) (covering Northern Europe)	*Oncorhynchus mykiss*	96 h	3	0.408	223039	100
		Daphnia magna	48 h	3	0.408	>245098	100
0.2	Citrus (covering orchards)	*Oncorhynchus mykiss*	96 h	3	3.965	22951	100
		Daphnia magna	48 h	3	3.965	>25221	100
0.3	Ornamentals-glasshouse	*Oncorhynchus mykiss*	96 h	1	0.04	2275000	100
		Daphnia magna	48 h	1	0.04	2500000	100

Bioconcentration

Bioconcentration factor (BCF)	699 and 878
Annex VI Trigger for the Bioconcentration factor	100/1000
Clearance time (CT_{50}) (CT_{90})	>98 % after 14 d

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

Acute oral toxicity	Technical:	48 h LD_{50} 4.29 µg a.s./bee
	Technical:	48 h LD_{50} 7.35 µg a.s./bee
	Formulation:	72 h LD_{50} >100 µg formulation/bee
Acute contact toxicity	Technical:	48 h LD_{50} 1.21 µg a.s/bee
	Technical:	48 h LD_{50} 8.18 µg a.s/bee
	Formulation:	48 h LD_{50} >100 µg formulation/bee

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

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
0.20	citrus	oral	47	50
0.2	citrus	contact	**165**	50
Field or semi-field tests The formulations containing 200 g/L fenazaquin were applied at the application rates of 87 and 300 g a.s./ha. No adverse effects on bees were observed regarding flight activity, bee brood and mortality at 300 g a.s./ha, but some adverse effects were observed at the application rate of 87 g a.s./ha.				

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

Test species	Application rate [g a.s./ha]	Endpoint		HQ value			Annex VI Trigger
		LR_{50} [g a.s./ha]	Sublethal effects	In field*	Off field		
					Grape**	Citrus***	
Laboratory studies (Tier 1)							
Aphidius rhopalosiphi parasitoid	Lab. test	187.25	No significant effects up to 75 g a.s./ha	1.06	Early appl. 0.02 Late appl. 0.05 (3m)	0.17 (3m bufferzone)	2
Typhlodromus pyri Predatory mite	Lab. test	< 2	nd	> 100	(3m bufferzone) Early appl.>1.62 Late appl.> 4.8 (5m bufferzone) Early appl.>0,71 Late appl.>2,17 (10m bufferzone) Early appl.>0,234 Late appl.> 0,738	>15.7 (3m bufferzone) >3,6 (10m bufferzone)	2
Coccinella septempunctata	Lab. test	< 21.9	22.2% at 21.9 g a.s./ha	>9.13			50%
Extended laboratory studies							
Typhlodromus pyri		(LR_{50} = 58.8 mg a.s./ha)	nd				2
Phytoseiulus persimilis *Metaseiulus occidentalis* *Amblyseius californicus*	0.48 - 4500	(LR_{50} = 3) (LR_{50} = 3) (LR_{50} = 36)	nd				2
Coccinella septempunctata	150	14 %	No significant effects at 150 g a.s./ha				50 %
Aphidius colemani Aged residue	252	5 %	No significant effects				50 %
Bembidion lampros Aged residue	252	2 %[3]	No significant effects at 252 g a.s./ha				50 %
Pardosa ssp. Aged residue	252	13.5 %[3]	nd				50 %
Typhlodromus pyri Aged residue	150	25 % (day 15)	nd				50 %
Field studies							

Typhlodromus pyri (apples)	150 225	No significant effects after 14 days (57 % nymphs) No significant effects after 28 days (59 % adults)	No significant effects after 14 days Significant effects up to 40 days				
Typhlodromus pyri (apples) (1.trial)	117-250 234-500	Significant effects after 90 days (55 %) Significant effects after 90 days (58 %)	nd				
Typhlodromus pyri (apples) (2.trial)	117-250 234-500	No significant effects after 72 days (31%) No significant effects after 72 days (48 %)	nd				
Typhlodromus pyri (apples) (3.trial)	117-250 234-500	Significant effects after 63 days (22 %) Significant effects after 63 days (13 %)	nd				
Typhlodromus pyri (apples) (4.trial)	117-250 234-500	No significant effects after 45 days (46 %) No significant effects after 45 days (39 %)	nd				
Typhlodromus pyri (grapes)	100	11 % after 35 days	nd				
Zetzellia mali Predatory mite (grapes)	100	No effect after 7 days of exposure	nd				

* calculation based on the max. application rate of 200 g a.s./ha and a MAF = 1

** calculation based on the max. application rate of 120 g a.s./ha, a MAF = 1 and a drift value of 2.7% (early) and 8.02% (late)

*** calculation based on the max. application rate of 200 g a.s./ha, a MAF = 1 and a drift value of 15.73% (late application)

nd not determined

[3] mortality was determined after 5 days of exposure, animals were exposed to direct spray run-off

Effects on earthworms and other non-target macro-organisms (Annex IIA, point 8.4; Annex IIIA, point 10.6/Annex IIA, point 8.6; Annex IIIA, point 10.5)

Acute toxicity	Technical: *E. foetida* 14 days LC_{50} 26.5 mg a.s./kg soil (corrected 13.25 mg a.s./kg soil). Technical: *Folsomia candida* 14 days LC_{50} >1000 mg a.s./kg soil (corrected >500 mg a.s./kg soil). Product: *E. foetida* 14 day LC_{50} 21.8 mg a.s./kg soil (corrected 10.9 mg a.s./kg soil) Metabolites: *E. foetida* 14 days LC_{50} >1000 mg 2-oxy-fenazaquin/kg soil (corrected 500 mg metabolite/kg soil) *E. foetida* 14 days LC_{50} >1000 mg 4-OHQ/kg soil (corrected 500 mg metabolite/kg soil) *E. foetida* 14 days LC_{50} 265 mg TBPE/kg soil (corrected 132.5 mg metabolite/kg soil) Metabolites: *Folsomia candida* 14 days LC_{50} >1000 mg 2-oxy-fenazaquin/kg soil (corrected 500 mg metabolite/kg soil) *Folsomia candida* 14 days LC_{50} >1000 mg 4-OHQ/kg soil (corrected 500 mg metabolite/kg soil) *Folsomia candida* 14 days LC_{50} 169 mg TBPE/kg soil (corrected 84.5 mg metabolite/kg soil)
Reproductive toxicity	Product: *E. foetida* 8-week NOEC= 1.25 mg a.s./kg soil (corrected 0.62 mg a.s./kg soil) Product: *Folsomia candida* 28 d NOEC= 23 mg a.s./kg soil dry weight (corrected 12.5 mg a.s./kg soil)

Application rate (kg a.s./ha)	Crop	Species	Test substance	Time-scale	TER	Annex VI Trigger
0.12	Grapes	*E. foetida*	Fenazaquin	14 days	114	10
0.12	Grapes	*E. foetida*	Fenazaquin	56 days	6.5	5
0.3	Ornamentals – glasshouse	*E. foetida*	Fenazaquin	14 days	54.5	10
0.3	Ornamentals – glasshouse	*E. foetida*	Fenazaquin	56 days	**3.1***	5
0.12	Grapes	*E. foetida*	2-oxy-fenazaquin	14 days	>33333	10
0.12	Grapes	*E. foetida*	4-OHQ	14 days	>29412	10
0.12	Grapes	*E. foetida*	TBPE	14 days	13250	10
0.12	Grapes	*Folsomia candida*	Fenazaquin product	28 days	130	5
0.3	Ornamentals – glasshouse	*Folsomia candida*	Fenazaquin	28 days	62.5	5
0.12	Grapes	*Folsomia candida*	Fenazaquin	14 days	>5208	10
0.12	Grapes	*Folsomia candida*	2-oxy-fenazaquin	14 days	>29412	10
0.12	Grapes	*Folsomia candida*	4-OHQ	14 days	8450	10

0.12	Grapes	*Folsomia candida*	TBPE	14 days	>33333	10

*based on this TER the risk to earthworms for the glasshouse use in ornamentals would need to be further considered in case the exposure cannot be avoided.

Field study
No study is available and not required.

Effects on soil micro-organism (Annex IIA, point 8.5; Annex IIIA, point 10.7)

Nitrogen mineralization	< 25% effect at concentrations up to 0.75 kg a.s./ha
Carbon mineralization	< 25% effect at concentrations up to 0.75 kg a.s./ha

2-oxy-fenazaquin

Nitrogen mineralization	< 25% effect up to at least 0.21 kg test item /ha
Carbon mineralization	< 25% effect up to at least 0.21 kg test item /ha

TBPE

Nitrogen mineralization	< 25% effect up to at least 0.11 kg test item /ha
Carbon mineralization	< 25% effect up to at least 0.11 kg test item /ha

4-OHQ

Nitrogen mineralization	< 25% effect up to at least 0.18 kg test item /ha
Carbon mineralization	< 25% effect up to at least 0.18 kg test item /ha

Effects on other non-target organisms believed to be at risk (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Seed germination	No effects < 0.6 mg a.s./L
Seedling emergence and vegetative vigour	No effects < 0.897 kg a.s./ha
Postemergence vegetative vigour	No effects < 0.897 kg a.s./ha

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha) vegetative vigour	ER_{50} (g/ha) emergence	Exposure[1] (g/ha)	TER	Trigger[2]
All tested species	Fenazaquin		>897 (a.s.)	58.4 (a.s.)	15.36 (3 m)	5
All tested species	Fenazaquin	>897 (a.s.)		58.4 (a.s.)	15.36 (3 m)	5

[1] based on Ganzelmeier drift data and deposition after volatilisation
[2] according to SANCO/10329/2002 (European Commission, 2002a)

Ecotoxicologically relevant compounds

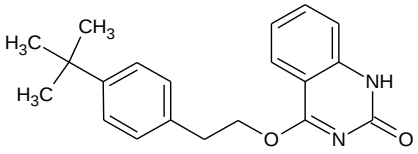
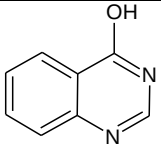
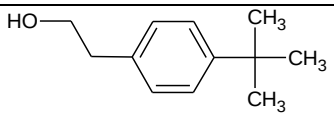
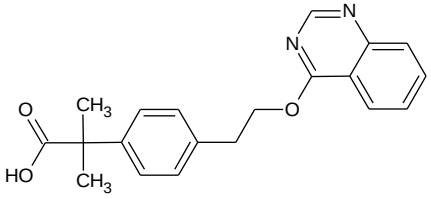
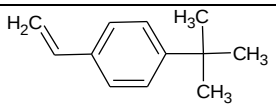
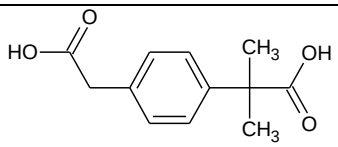
Compartment	

soil	Fenazaquin, 2-oxy-fenazaquin
water	Fenazaquin
sediment	Fenazaquin, 4-(2-(4-(1,1-dimethylethanoic acid) phenyl) ethoxy) quinazoline (sediment), 2-oxy-fenazaquin

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

Respiration inhibition test	No effects up to at least 100 mg a.s./L

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula**
2-oxy-fenazaquin	4-[2-(4-*tert*-butylphenyl)ethoxy]quinazolin-2(1*H*)-one	
4-OHQ 4-hydroxyquinazoline	quinazolin-4-ol	
TBPE 2,4-TBPE 4-(1,1-dimethylethyl)benzene ethanol	2-(4-*tert*-butylphenyl)ethanol	
4-(2-(4-(1,1-dimethylethanoic acid) phenyl) ethoxy) quinazoline	2-methyl-2-{4-[2-(quinazolin-4-yloxy)ethyl]phenyl}propanoic acid	
4-tert-butylstyrene	1-*tert*-butyl-4-ethenylbenzene	
M34	2-[4-(carboxymethyl)phenyl]-2-methylpropanoic 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
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstract Service
CFU	colony forming units
ChE	cholinesterase
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
ECB	European Chemicals Bureau
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
ELS	early-life-stage
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
f.f.	formation fraction
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram

GAP	good agricultural practice
GC	gas chromatography
GC-NPD	gas chromatography with nitrogen phosphorus selective detection
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high performance liquid chromatography – mass spectrometry
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UV	high pressure liquid chromatography with ultraviolet detector
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_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
n.d.	not determined
NESTI	national estimated short-term intake
ng	nanogram
nm	nanometre

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