CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion regarding the peer review of the pesticide risk assessment of propaquizafop (an ester variant of quizalofop-P)

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SUMMARY

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

Italy being the designated rapporteur Member State submitted the DAR on propaquizafop in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 22 September 2005. The peer review was initiated on 12 May 2006 by dispatching the DAR for consultation of the sole notifier Makhteshim Agan and the Member States. Subsequently, the comments received on the DAR were examined and responded by the rapporteur Member State in the reporting table. This table was evaluated by the EFSA to identify the remaining issues. The identified issues as well as further information made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in June – July 2008.

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

Propaquizafop is an ester variant of the active substance quizalofop-P[2] which is included in the third stage Part B of the review programme. The EFSA wrote a conclusion on quizalofop-P based on the DARs which were submitted on the ester variants quizalofop-P-ethyl[3] and quizalofop-P-tefuryl.[4]

This conclusion on propaquizafop was reached on the basis of the evaluation of the representative uses as a herbicide on sugar beet and oilseed rape. Full details of the good agricultural practice (GAP) can be found in the attached list of endpoints.

[1] OJ No L 224, 21.08.2002, p. 25, as amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19)
[2] (*R*)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionic acid
[3] ethyl (2*R*)-2-{4-[(6-chloroquinoxalin-2-yl)oxy]phenoxy}propanoate
[4] (*RS*)-tetrahydrofurfuryl (*R*)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate

The representative formulated product for the evaluation was 'Agil 100 EC', an emulsifiable concentrate (EC).

The meeting of experts was not able to conclude on the acceptability of any of the methods as none of the methods were capable of analysing for the original residue definition proposed in the DAR. As it is not possible to reconsider all the methods at this time no conclusion can be reached. A general data gap for reconsideration of the methods has been identified.

There are insufficient analytical methods as well as methods and data relating to physical, chemical and technical properties to ensure that quality control measurements of the plant protection product are possible. The specification of the technical material has not been accepted. The method of analysis for the formulation is identified as a data gap. The formulation was seen to perform poorly in some of the physical-chemical tests. And there are outstanding issues on possible relevant impurities.

In mammals, propaquizafop shows a low acute toxicity via the oral and dermal routes, as well as via inhalation; it is non-irritating to the skin and eyes. Skin sensitisation tests in guinea pigs gave positive results (R43 "May cause sensitisation by skin contact" was proposed). In repeated dose studies, liver was shown to be the target organ. The short-term toxicity No Observed Adverse Effect Levels (NOAELs) for rats and mice were 6.25 and 10 mg/kg bw/day, respectively, on the basis of liver effects (Lowest Observed Adverse Effect Levels - LOAELs 25 and 30 mg/kg bw/day, respectively); in long-term studies the relevant NOAELs were set at 5 mg/kg bw/day for rats and 1.5 mg/kg bw/day for mice (LOAELs 25 mg/kg bw/day and 7.5 mg/kg bw/day, respectively). Propaquizafop did not show any genotoxic potential. Increased incidences of hepatocellular adenomas and carcinomas were seen in both rats and mice. In one study in rats, an increase in Leydig cell tumours was also noted. Mechanistic studies performed in rats and mice indicate that propaquizafop acts as a peroxisome proliferator. Based on the occurrence of malignant tumours in two species (hepatocellular adenomas and carcinomas in rats and mice) and on an increased incidence of Leydig cell tumours in rats, proposal for classification and labelling of propaquizafop as Carc. Cat. 3 R40 ("Limited evidence of a carcinogenic effect") was considered and proposed during the meeting. In a multigeneration reproductive toxicity study, there were no treatment-related effects on mating performance, fertility index, gestation length or gestation index. The relevant reproductive NOAEL was 15 mg/kg bw/day, whereas the relevant maternal and offspring NOAEL were 3 mg/kg bw/day. In a rat developmental study, numbers of implantations, corpora lutea and viable foetuses were comparable among groups. No treatment-related skeletal malformations were observed in any dose group. The NOAEL for developmental toxicity was 20 mg/kg bw/day based on an increased incidence of dilated renal pelvis up to 50 mg/kg bw/day. The NOAEL for maternal toxicity was 50 mg/kg bw/day due to decreased body weight gain at 125 mg/kg bw/day. In rabbits, there were no treatment related malformations or developmental changes. The relevant maternal and developmental NOAELs were 6 mg/kg bw/day and 18 mg/kg bw/day, respectively. The Acceptable Daily Intake (ADI) of **0.015 mg/kg bw/day** was

based on the NOAEL of 1.5 mg/kg bw/day from the mouse long-term study (Safety Factor (SF): 100); the NOAEL of 6.25 mg/kg bw/day from the rat 90 day study was the basis for the Acceptable Operator Exposure Level (AOEL) of **0.04 mg/kg bw/day**, SF 100 and limited oral absorption (65%). Based on the acute toxicological profile of the propaquizafop, the Acute Reference Dose (ARfD) was not allocated. The operator, worker and bystander exposure assessment is below the AOEL even without the use of Personal Protective Equipment (PPE).

The metabolism of propaquizafop has been investigated in cotton, soybean, lettuce and sugar beet using ^{14}C-propaquizafop labelled on the phenyl and/or the quinoxaline moiety. The metabolism proceeds primarily with the hydrolysis of the ester link to yield quizalofop followed by the loss of the propionyl moiety leading to quizalofop-phenol[5], these metabolites being also observed as conjugates. Further metabolism occurs by hydroxylation of the quinoxaline moiety giving hydroxy-quizalofop[6] and hydroxy-quizalofop-phenol[7]. In addition and in a limited extent, the presence of quinoxaline metabolites and phenoxy acid metabolites indicated a cleavage of the oxygen bond of the molecule. In the sugar beet study, the metabolites quizalofop-phenol, hydroxy-quizalofop-phenol, hydroxy-quinoxaline[8] and dihydroxy-quinoxaline[9] were detected in leaves and roots in similar proportions to propaquizafop and quizalofop. However, taking into account the overall low residue levels expected in leaves and roots at harvest, these metabolites were not included in the plant residue definition. Finally, considering that the radioactivity was not sufficiently characterized in sugar beet and in cotton seeds the notifier was asked to provide clarifications on the uncharacterized radioactivity, otherwise a new metabolism studies on root crop on oilseed crop should be submitted. In conclusion and provisionally the experts proposed the following residue definition for monitoring and risk assessment:

"Sum of propaquizafop and quizalofop, expressed as quizalofop (sum of isomers)".

Considering the metabolism studies performed with the three quizalofop esters, a common residue definition for monitoring and risk assessment was proposed for propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl as:

"Sum of quizalofop-esters, quizalofop and quizalofop conjugates expressed as quizalofop (sum of isomers)".

These definitions should remain provisional, pending the submission and the evaluation of the requested information on the toxicological relevance of the phenoxy metabolites observed in the quizalofop-P-ethyl studies. After the meeting, the EFSA was however of the opinion that there is no need to include the conjugates in the residue definition for monitoring.

[5] 2-[4-(6-chloroquinoxalin-2-yloxy)phenol]
[6] (*R*)-2-[4-(6-chloro-3-hydroxyquinoxalin-2-yloxy)phenoxy]propionic acid
[7] 4-(3-hydroxy-6-chloroquinoxalin-2-yloxy)phenol
[8] 6-chloroquinoxalin-2-ol
[9] 6-chloroquinoxaline-2,3-diol

Supervised residue trials were submitted to support representative uses on rape seed and sugar beet. Samples were analysed using a method covering propaquizafop, quizalofop and quizalofop-phenol. Although this method was not strictly in line with the residue definition, results were considered as valid since the scope of this method was wider than the proposed residue definitions. The storage stability study showed the residues of propaquizafop, quizalofop and quizalofop-phenol to be stable under deep freeze storage conditions for at least 2 years in soya, rapeseed and tomato matrices. The behaviour of the residues in processing products was not investigated due to the low residue levels detected in the raw agricultural products.

A rotational crop study performed with ^{14}C-propaquizafop labelled on the quinoxaline moiety was provided. Propaquizafop was not observed in the different rotational plant parts investigated and the detected metabolites (quizalofop, quizalofop-phenol and their hydroxy derivatives) have also been identified in the primary crop studies, suggesting a similar metabolic pathway in both primary and rotational crops. Taking into account the residue levels observed in plants at harvest, it was concluded that no significant residues of propaquizafop or its metabolites are expected in rotational crops.

Metabolism studies in lactating goat and laying hen were provided. However, the meeting of experts concluded that no residue definitions can be established on the basis of these studies since the characterisation of the radioactivity was not sufficiently investigated in some matrices, especially in fat. However, and taking into account the low residues levels observed in rapeseed and sugar beet, the experts agreed that there is no need to set a residue definition in products of animal origin for propaquizafop at the moment. No feeding study was provided, the trigger value of 0.1 mg/kg in diet being not exceeded.

Considering the comparative metabolite distribution in rat and goat for quizalofop-P-ethyl and propaquizafop, the experts discussed whether a supplementary metabolism study on pig should be requested. The metabolism in rats and ruminants was similar qualitatively but differences were observed quantitatively. Higher residues were detected in rat on an equivalent mg/kg bw basis and the notifiers were asked to provide explanations for these quantitative differences. Such request is not relevant for propaquizafop at the moment, but this point would have to be considered if new uses beyond those supported in this review lead to a significant residue intake by animals.

No chronic risk for the consumer resulting from the use of propaquizafop according to the representative uses on sugar beet and oilseed rape is expected since the Theoretical Maximum Daily Intake (TMDI) using various calculation models was at most 21% of the ADI (0.015 mg/kg bw/d) using the UK model. No acute evaluation was performed as no ARfD was set for propaquizafop.

Based on the available supervised residue trials and the proposed residue definition a MRL of 0.05* mg/kg was proposed on sugar beet and rape seed, these MRLs being consistent with the proposals done for quizalofop-P-ethyl and quizalofop-P-tefuryl on these crops.

In the environmental fate and behaviour section, the data sets for the common metabolites quizalofop, hydroxy-quizalofop and dihydroxy-quinoxaline available in the DARs of propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl were combined in order to derive a single set of endpoints (amalgamated list of endpoints) for the fate properties of each metabolite to use in the environmental exposure assessment.

In soil under aerobic conditions propaquizafop exhibits very low persistence forming the major soil metabolite quizalofop (accounting for up to 88% of applied radioactivity (AR)) which exhibits low to high persistence, the metabolite hydroxy-quizalofop accounting for up to 33% AR which exhibits low to medium persistence, and the metabolite dihydroxy-quinoxaline accounting for up to 14% AR which exhibits moderate to high persistence. The metabolite hydroxy-quinoxaline (up to 8.8% AR) was present at levels that trigger a groundwater exposure assessment and exhibits moderate to medium persistence. Another minor non transient metabolite in soil (max. 5.4 – 5.7% AR in three consecutive sampling points) was quizalofop-phenol. Mineralisation of the hydroquinone ring or the quinoxaline group to carbon dioxide ranged from 22.6% AR (after 121 days) to 44.2% AR (after 119 days). The formation of unextractable residues was a significant sink, accounting for 36 – 39 % AR after 120 – 121 days. Due to the rapid degradation of propaquizafop in soil under aerobic conditions, batch equilibrium studies with the parent compound were not performed. An adsorption Koc of 2220 mL/g has been estimated for modelling purposes, based on the *n*-octanol/water partition coefficient Log K_{ow}. Quizalofop and hydroxy-quizalofop exhibit low to high mobility in soil, dihydroxy-quinoxaline exhibits low to very high mobility, and hydroxy-quinoxaline exhibits very low mobility in soil. Based on the adsorption properties of the minor non transient metabolite quizalofop-phenol (slight mobility to immobile) a groundwater exposure assessment for this metabolite was considered not necessary. There was no indication in the available data that adsorption of either propaquizafop or its identified soil metabolites was pH dependent.

In dark natural sediment water systems propaquizafop degraded very rapidly to the metabolites quizalofop (max. 90 % AR in water and max. 45% AR in the sediment), dihydroxy-quinoxaline (max. 10% in the sediment) and hydroxy-quizalofop (max. 11.2% AR in the sediment). The estimated rate of degradation in the aquatic system ($DT_{50\ system}$, $DT_{50\ water}$, $DT_{50\ sed}$) for propaquizafop and its metabolites quizalofop, hydroxy-quizalofop, dihydroxy-quinoxaline and hydroxy-quinoxaline are not peer reviewed and were not used in the risk assessment. The necessary surface water and sediment exposure assessments were appropriately carried out using the agreed FOCUS scenarios approach for hydroxy-quizalofop, dihydroxy-quinoxaline and hydroxy-quinoxaline (Steps 1 and 2) and for propaquizafop and quizalofop (up to Step 3). The initial predicted environmental concentrations in surface water (PEC_{sw}) and in sediment (PEC_{sed}) were used with the appropriate toxicity endpoints for the calculation of the toxicity exposure ratios (TERs).

The potential for groundwater exposure from the applied for intended uses by propaquizafop and its metabolites quizalofop, hydroxy-quizalofop, dihydroxy-quinoxaline, and hydroxy-quinoxaline above the parametric drinking water limit of 0.1 µg/L, was concluded to be low in geoclimatic situations that are represented by all pertinent FOCUS groundwater scenarios.

The lower metabolite toxicity endpoints available in the dossiers for propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl were used in the risk assessments of propaquizafop.

The acute and short-term risk to birds was assessed as low for the intended uses at tier one, as was the long-term risk to herbivorous birds. Further refinements were required to address the risk to insectivorous birds. The rapporteur Member State provided a refined risk assessment in an addendum after the expert meeting (Addendum, July 2008), based on yellow wagtail (*Motacilla flava*) as generic focal species feeding on a mixed small-large arthropod diet. A TER value of 14.8 was calculated using wet weight based proportion of different food types (PD) refinements, indicating a low long-term risk to insectivorous birds from the intended uses. The first tier acute and long-term TERs were above the Annex VI trigger for mammals, indicating a low risk from the intended uses. All TERs for secondary poisoning to birds and mammals were above the Annex VI trigger, indicating a low risk from all intended uses. The acute risk from consumption of contaminated drinking water was assessed for the puddle scenario. TERs were above the Annex VI trigger of 10 for both birds and mammals. The risk to herbivorous birds and mammals from plant metabolites was not addressed in the DAR or during the peer review. Mammal toxicity and metabolism data, however, suggest that the risk to herbivorous mammals was covered by the risk assessment for the parent substance. Propaquizafop was found to be very toxic to aquatic organisms, with fish being the most sensitive species tested. A comparable toxicity was identified for the macrophyte *Glyceria fluitans* exposed to the metabolite quizalofop. FOCUS Step 3 exposure refinements were required to identify a low risk to aquatic organisms. For use in sugar beet all FOCUS Step 3 scenarios indicated a low risk to aquatic organisms, whereas only 3 out of 5 scenarios for spring use in oilseed rape and 2 out of 6 in winter oilseed rape indicated a low risk to aquatic organisms. The risk to sediment dwellers and the risk from bioaccumulation were assessed as low. The risk to non-target arthropods needed to be refined further to address the in-field risk to *Aphidius rhopalosiphi*. A no-spray buffer zone of 5 m was required to identify a low risk to the non-target plants, based on the most sensitive vegetative vigour endpoint for oat.

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

Key words: propaquizafop, quizalofop-P, peer review, risk assessment, pesticide, herbicide

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BACKGROUND

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

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Italy submitted the report of its initial evaluation of the dossier on propaquizafop, hereafter referred to as the draft assessment report, received by the EFSA on 22 September 2005. Following an administrative evaluation, the draft assessment report was distributed for consultation in accordance with Article 11(2) of the Regulation (EC) No 1490/2002 on 12 May 2006 to the sole notifier Makhteshim Agan as identified by the rapporteur Member State and on 11 July 2006 to the Member States.

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

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

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

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

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

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

- the comments received;
- the resulting reporting table (revision 1-1; 9 April 2008);

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

- the reports of the scientific expert consultation;
- and the evaluation table (revision 2-1; 18 November 2008).

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

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Propaquizafop is the ISO common name for 2-isopropylidenamino-oxyethyl (*R*)-2-[4-(6-chloro-quinoxalin-2-yloxy)phenoxy]propionate (IUPAC).

Propaquizafop is an ester variant of the active substance quizalofop-P which is included in the third stage Part B of the review programme. The EFSA wrote a conclusion on quizalofop-P[10] based on the DARs which were submitted on the ester variants quizalofop-P-ethyl[11] and quizalofop-P-tefuryl[12].

Propaquizafop, belongs to the class of aryloxyphenoxypropionic herbicides (commonly called "FOPs") such as diclofop-P and fluazifop-P. They are taken up via leaves and hinder the *de novo* synthesis of fatty acids by inhibition of the enzyme acetyl-CoA carboxylase (ACCase).

The representative formulated product for the evaluation was 'Agil 100 EC', an emulsifiable concentrate (EC).

The evaluated representative uses are as a herbicide on sugar beet and oilseed rape. Full details of the good agricultural practice (GAP) can be found in the attached list of endpoints.

[10] (*R*)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionic acid
[11] ethyl (2*R*)-2-{4-[(6-chloroquinoxalin-2-yl)oxy]phenoxy}propanoate
[12] (*RS*)-tetrahydrofurfuryl (*R*)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

At the moment no minimum purity of propaquizafop as manufactured can be given because further clarification is needed. In addition, clarification is necessary with respect to the proposed maximum content of the significant impurities.

The technical material contains toluene, which has to be regarded as a relevant impurity. The maximum content in the technical material should not be greater than 5 g/kg.

It was noted that in previous technical material production, impurities CGA 320116 and CGA 328714 were present but they were not analysed for in the most recent production batches. The meeting of experts questioned what the change in manufacturing process was and the relevance of these two impurities. This issue needs to be addressed further and a data gap has been set. The meeting of experts also questioned what the change of manufacturing process was that resulted in the reduction of the levels of the relevant impurity Ro 41-5259.[13] The meeting of experts also considered that it would be necessary to analyse current production batches for this compound at an appropriately low level. The possible formation of nitrosamines during the manufacturing process also needs to be addressed.

The content of propaquizafop in the representative formulation is 100 g/L (pure).

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

- Hydrolysis study in accordance with EEC A7
- Oxidising properties of the Plant Protection Product (PPP)
- Surface tension of the formulation at 25 ºC for R65 classification
- Notifier to reformulate the PPP to comply with the general FAO specification for persistent foam or demonstrate under field conditions that the formation of foam is not an issue
- Notifier to reformulate the PPP so that a stable emulsion can be formed or demonstrate under field conditions this is not an issue
- Method of analysis for the formulation that is capable of separating the *R* and *S* isomers
- Storage stability study with analysis for *R* and *S* isomer before and after storage
- It should be explained why the high temperature of incineration is required for destruction of the active substance

[13] 2-isopropylideneamino-oxyethyl (*R*)-2-[4-(7-chloroquinoxalin-2-yloxy)phenoxy]propionate

The meeting of experts also wished to highlight that the formulation is not stable at low temperatures and this should be taken in to account. It should also be noted that the meeting of experts considered that the performance of the formulation is poor.

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

There are insufficient analytical methods as well as methods and data relating to physical, chemical and technical properties to ensure that quality control measurements of the plant protection product are possible.

The meeting of experts was not able to conclude on any of the analytical methods because none of them complied with the residue definitions proposed in the DAR. In addition, questions that were raised during the peer review process remain unanswered. It is likely that at least some new methods will be required as they will not only have to be validated for propaquizafop but also for the other esters of quizalofop-P. Consequently all the methods will have to be reconsidered and a data gap has been identified.

2. Mammalian toxicology

Propaquizafop was discussed in the PRAPeR meeting of experts held in Parma in July 2008 (PRAPeR 54 subgroup 1).

The meeting could not conclude on the compliance of batches tested in mammalian toxicity tests to the proposed specification as the impurity profile of key batches was not available. Due to the lack of toxicological information it was not possible to conclude on the relevance of some impurities (CGA 290292, CGA 287422, CGA 320116 and CGA 328714). Toluene was regarded as relevant, but of no concern at the amount presented in the specification (max. 5 g/kg). Concerning impurity Ro 41-5259, it was not possible to conclude because of missing information, however, due to its toxicological properties (mutagenic) this impurity should be considered relevant.

The meeting on residues sent a question about the toxicity of the common metabolites of propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl observed in the plant metabolism studies. In particular:

- Metabolites with the chloroquinoxalin-phenoxy moiety: quizalofop, quizalofop-phenol[14] and hydroxy-quizalofop.[15]

[14] 2-[4-(6-chloroquinoxalin-2-yloxy)phenol]
[15] (*R*)-2-[4-(6-chloro-3-hydroxyquinoxalin-2-yloxy)phenoxy]propionic acid

- Metabolites with the chloroquinoxalin moiety: hydroxy-quinoxalin and dihydroxychloroquinoxalin.

All the metabolites were not considered of higher toxicity than parent, and were "covered" by the reference values set for the parent. It was not possible based on the available information to provide specific toxicological profiles for individual metabolites.

2.1. ABSORPTION, DISTRIBUTION, EXCRETION AND METABOLISM (TOXICOKINETICS)

Propaquizafop is absorbed over a long period, and blood concentrations of radioactivity do not start to decline until approximately 8 – 10 hours after dosing. Propaquizafop and its metabolites are widely distributed into tissues, with the highest concentrations in liver and kidneys. No potential for accumulation was evidenced. Maximum excretion occurs during the first 48 hours after treatment. After repeated administration, tissue concentrations of radioactivity attained steady state after approximately 14 days after the end of treatment.

The main metabolic pathways of propaquizafop were by hydrolysis to propaquizafop acid, then undergoing subsequent hydroxylation, loss of the propionyl moiety, or loss of the phenoxy acid moiety. Some of the metabolites were formed by a combination of these pathways. Small amounts of unchanged propaquizafop were excreted in faeces.

During the PRAPeR meeting, the oral absorption value of propaquizafop was discussed. In the DAR the rapporteur Member State proposed an almost complete absorption. However, data on biliary and urinary excretion gave indications that 65 – 70% of administered dose was absorbed within 24 hours. The meeting considered 65% as more appropriate based on the available data.

2.2. ACUTE TOXICITY

Propaquizafop shows a low acute toxicity via the oral and dermal routes, as well as the inhalation route (oral LD_{50} 5000 mg/kg bw, dermal LD_{50} 2000 mg/kg bw, inhalation LC_{50}>2500 mg/m^3). Propaquizafop is non-irritating to the skin and eyes. Skin sensitisation tests in guinea pigs gave positive results (R43 "May cause sensitisation by skin contact" was proposed).

2.3. SHORT-TERM TOXICITY

Propaquizafop was tested in repeated dose studies in rats, mice and dogs. Liver was shown to be the target organ. The NOAELs for rats and mice on the basis of liver effects were 6.25 and 10 mg/kg bw/day, respectively (LOAELs 25 and 30 mg/kg bw/day). The dog was less sensitive and in a 1-year study no treatment-related effects were seen up to the highest dose level of 20 mg/kg bw/day. The meeting agreed that the 90-day dog study NOAEL was 40 mg/kg bw/day (LOAEL 60 mg/kg bw/day) and the 1-year dog study NOAEL was 20 mg/kg bw/day (the highest dose tested, considered the relevant NOEL in dog). Following dermal administration of propaquizafop to rats, a NOAEL of

250 mg/kg bw/day was established, based on signs of systemic toxicity, including the liver as target organ, at higher dose levels.

2.4. GENOTOXICITY

In cytogenetic tests with a pilot production batch propaquizafop showed positive results, due to the presence of a genotoxic impurity formed in the early manufacturing process, which was later modified in order to avoid its formation. Tested with batches representative of the proposed specification propaquizafop did not show any genotoxic potential.

2.5. LONG-TERM TOXICITY

In a chronic oral toxicity study, the liver was identified as the target organ (effects on liver enzymes, liver weights and non-neoplastic histopathological changes). Increased incidences of hepatocellular adenomas and carcinomas were seen in both rats and mice. In one study in rats, an increased incidence of Leydig cell tumors was also noted. Mechanistic studies performed in rats and mice indicate that propaquizafop acts as a peroxisome proliferator. Additionally, haematological investigations revealed changes of red cell parameters in rats and mice. There were increased kidney, heart and adrenal gland weights and decreased testes weights in high dose rats (100 mg/kg bw/day). Histopathological examinations showed angiectasis, purulent nephritis and papillary necrosis in kidneys. Leydig cell hyperplasia, aspermia, edema and tubular atrophy were seen in high dose male rats beside an increased incidence of Leydig cell tumours. In mice, there was also an increase of heart and adrenal gland weights at and above 30 mg/kg bw/day, and treatment-related histopathological findings of a chronic renal disease were seen at 300 mg/kg bw/day. On the basis of the available studies, the relevant NOAELs were set at 5 mg/kg bw/day for rats and 1.5 mg/kg bw/day for mice (LOAELs 25 mg/kg bw/day and 7.5 mg/kg bw/day, respectively).

Based on the occurrence of malignant tumours in two species (hepatocellular adenomas and carcinomas in rats and mice) and an increased incidence of Leydig cell tumours in rats, proposal for classification and labelling of propaquizafop as R40 “Limited evidence of a carcinogenic effect” was considered during the meeting. The proposed mechanism for liver tumours (peroxisome proliferation) is not relevant for humans, and these alone would not lead to R40. The mechanism for the formation of the Leydig cell tumours was unknown. The experts expressed some concerns regarding the notifier statement that these tumours were not relevant to humans. There were also no historical control data presented for these tumours. Therefore due to lack of information the meeting considered the Leydig cell tumours as relevant; and based on this, classification as R40, Carc. Cat. 3 was proposed.

2.6. REPRODUCTIVE TOXICITY

In a multigeneration reproductive toxicity study, there were no treatment-related effects on mating performance, fertility index, gestation length or gestation index for either the F0 or F1 generations for either pairing. Litter size, live birth, viability and lactation indices were comparable among groups for

all matings. The rate of physical and functional development of the F1A pups was not affected by treatment. In the F2A pups at 15 mg/kg bw/day, there was a delay in eye and ear opening. Histopathological findings of male and female adults revealed a slight increase in centrilobular hypertrophy and congestion at 15 mg/kg bw/day in both generations. Slightly increased renal calcification and haemosiderosis in the spleen were observed in females at the high dose. No changes in reproductive organs were noted. The relevant reproductive NOAEL was 15 mg/kg bw/day, whereas the relevant maternal and offspring NOAEL was 3 mg/kg bw/day.

In a rat developmental study, maternal body weight gain was decreased at 125 mg/kg bw/day during treatment, as well as body weights in 21-day old foetuses. Numbers of implantations, corpora lutea and viable foetuses were comparable among groups. No treatment-related skeletal malformations were observed in any dose group. Signs of delayed ossification were observed in foetuses of dams dosed with 125 mg/kg bw/day. At 125 mg/kg bw/day, peri- and early postnatal pup loss was observed, accompanied by increased gestation time. The NOAEL for developmental toxicity was 20 mg/kg bw/day based on an increased incidence of dilated renal pelvis up to 50 mg/kg bw/day. The NOAEL for maternal toxicity was 50 mg/kg bw/day due to decreased body weight gain at 125 mg/kg bw/day.

In rabbits, body weight gain was reduced in the females of all dose groups during treatment. Total number of resorptions related to implantations were increased in all treatment groups, mainly during the embryonic developmental stage although without a clear dose related trend. There were no treatment related malformations or developmental changes reported in the study. The relevant maternal and developmental NOAELs were 6 mg/kg bw/day and 18 mg/kg bw/day, respectively.

2.7. NEUROTOXICITY

Propaquizafop is not considered to act on the nervous system. The results of the toxicity studies performed in different species receiving single and repeated doses of propaquizafop revealed no neurotoxic action.

2.8. FURTHER STUDIES

Impurity CGA 289740 induced a two-fold increase in revertants colonies in *S. typhimurium* TA98, only in the presence of exogenous metabolic activation. Due to the lack of any relationship with the dose applied, the biological significance of this finding is equivocal.

Impurity CGA 289742 did not induce gene mutations in the strains of *S. typhimurium* and *E. coli* tested.

2.9. MEDICAL DATA

Monitoring of workers' health and safety during the manufacturing and formulating processes of propaquizafop included periodical check of the workplace, checking protective equipment, periodic medical check-ups of the workers involved in the manufacturing process. There has been no evidence or indications of health effects due to propaquizafop. A literature search was performed concerning clinical cases, poisoning incidents, general population exposure, epidemiological studies: no data could be retrieved.

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

ADI

The meeting agreed with the proposal made by the rapporteur Member State to use the NOAEL of 1.5 mg/kg bw/day from the mouse long-term study as basis for setting the ADI, resulting in an ADI of **0.015 mg/kg bw/day** (SF 100).

AOEL

During the meeting the AOEL value was discussed. The relevance of the delayed eye opening seen in the rat reproductive study was considered. After further reflection the effect was not regarded as severe enough at this dose level to warrant setting an AOEL on this. The meeting therefore proposed to use the 6.25 mg/kg bw/day from the rat 90 day study, as the basis for the AOEL, this resulted in an AOEL of **0.04 mg/kg bw/day**, SF 100 and limited oral absorption (65%).

ARfD

The need for an ARfD was discussed during the meeting. Based on the acute toxicological profile of propaquizafop, it was agreed this reference value was not required.

2.11. DERMAL ABSORPTION

The rapporteur Member State proposed a default of 10%, based on limited data (no information is available for the dilution). An *in vitro* study was summarised using pig skin and rat skin. The experts had some doubts concerning the validity of the study. It was discussed whether the same values agreed for quizalofop-P-ethyl and quizalofop-P-tefuryl should be used. However, it was considered that the physical-chemical properties of propaquizafop were not sufficiently similar. The meeting agreed 10% could be used as default for the concentrate and dilution (based on physical-chemical properties) supported by the *in vitro* pig study.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

'Agil 100 EC' contains 100 g/L propaquizafop. It is used on sugar beet and oilseed rape (foliar spray). The maximum application rate is 0.2 kg a.s./ha in spray volume of 200 – 500 litres/ha.
Operator exposure assessment was performed with the German and the UK POEM models.

Operator exposure

Model	Application method (crop)	Systemic exposure (mg/kg bw/day)		% of systemic AOEL	
		No PPE	PPE	No PPE	PPE*
UK POEM	Tractor mounted, hydraulic boom and nozzles; 1 L wide neck container	0.2369	0.0284	592	71
UK POEM	Tractor mounted, hydraulic boom and nozzles; 5 L wide neck container	0.1036	0.0151	259	38
UK POEM	Tractor mounted, hydraulic boom and nozzles; 20 L wide neck container	0.0786	0.0126	196	31.5
German	Tractor mounted spray application	0.025	0.001	62.5	2.5

* PPE considered: UK POEM: gloves during mixing/loading and application. German model: gloves, standard protective equipment (SPE), sturdy footwear during mixing/loading and application.

The operator exposure assessment submitted by the rapporteur Member State showed exposure levels below the AOEL even without the use of PPE (German model) and was accepted at the meeting. No assessment was performed for hand held applications.

Worker exposure:

The "Uniform Principles for safeguarding workers" [Krebs, B. *et al*. Uniform Principles for Safeguarding the Health of Workers Re-entering Crop Growing Areas after Application of Plant Protection Products] were used to estimate exposures to the active substance for workers not wearing personal protective equipment. The Dislodgeable Foliar Residue (DFR) was estimated using the conservative default assumption that an application rate of 1 kg as/ha corresponds to an initial DFR of 1 µg/cm^2. A default transfer factor (TF) of 30000 cm^2/hr for a worker with no protective clothing was considered. Based on an 8-hour workday, the daily dermal exposures for a 60 kg worker were estimated to be 267 and 13% of the AOEL without and with PPE, respectively.

During the meeting it was noted that the worker exposure was performed with a TF of 30000 cm^2/hr which represents an extreme worst case based on the intended uses. It was agreed that it was not necessary to re-perform this. The meeting requested that this is made this clear in the EFSA conclusion.

EFSA note: As the TF of 30000 cm^2/hr considered was at least 6-fold the correct value, it can be estimated that exposure during re-entry activities after application of 'Agil 100 EC' is below the AOEL even for a worker without PPE (approximately 50% of the AOEL).

Bystander exposure:

A bystander exposure presented in the DAR was performed using Ganzelmeier[16] and this was agreed as acceptable. Bystander exposure was estimated assuming that bystanders stand 5 metres from the site of application. Worst-case bystander exposures were calculated using operator exposure estimates for field crop sprayer application to sugar beet and oilseed rape. On this basis, a bystander standing at 5 meters from the edge of a field being sprayed with 'Agil 100 EC' in the worst case would be exposed to a systemic dose 10% of the AOEL.

3. Residues

Propaquizafop was discussed at the PRAPeR experts' meeting for residues (PRAPeR 55, round 11) in July 2008. Propaquizafop is an ester variant of the active substance quizalofop-P, and two further ester variants of quizalofop-P were evaluated during this PRAPeR meeting, namely quizalofop-P-ethyl and quizalofop-P-tefuryl. During the peer review process, it was clear that, once quizalofop is formed after hydrolysis of the ester link, the metabolic pathways of these three esters in plants and animals are similar.

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

The metabolism of propaquizafop has been investigated in cotton, soybean, lettuce and sugar beet, representing three groups of crops; oilseed/pulse crops, leafy crops and root/tuber crops. Studies were performed using ^{14}C-propaquizafop either labelled on the phenyl or the quinoxaline moiety and with application rates representative of the supported uses (103 to 298 g a.s./ha).

The metabolism proceeds primarily by the hydrolysis of the ester link to yield quizalofop followed by loss of the propionyl moiety leading to the quizalofop-phenol metabolite, these metabolites being also observed as conjugated in soya and cotton. Further metabolism occurs by hydroxylation of the quinoxaline moiety giving the hydroxy-quizalofop and hydroxy-quizalofop-phenol[17] metabolites. In addition, and to a limited extent, the presence in low proportions of hydroxy-quinoxaline[18],

[16] Ganzelmeier H, Rautmann D, Spangenberg R, Streloke M, Herrmann M, Wenzelburger H-J, Walter HF (1995) Studies on the spray drift of plant protection products. *Mitteilungen aus der Biologischen Bundensanstalt für Land- und Forstwirtschaft Berlin-Dahlem. Heft 305, 1995.*

[17] 4-(3-hydroxy-6-chloroquinoxalin-2-yloxy)phenol

[18] 6-chloroquinoxalin-2-ol

dihydroxy-quinoxaline[19] and phenoxy acid[20] metabolites indicated a cleavage of the oxygen bond between the phenyl and quinoxaline parts of the molecule. Extensive incorporation of radioactivity in endogenous plant materials was also demonstrated in sugar beet. The plant metabolism was similar to rat metabolism and the metabolites formed in plants were covered by the toxicological studies.

The metabolite pattern was dominated by quizalofop, which generally represents the major constituent of the residue, accounting for 5% to 35% of the TRR at harvest, the parent compound being mainly observed in significant proportions in immature plant samples collected within 15 days following the application. However, propaquizafop was also present in mature soybean seeds and sugar beets roots in similar amount to quizalofop accounting for *c.a.* 7% of the TRR. In the sugar beet leaves and roots, the metabolites quizalofop-phenol, hydroxy-quizalofop-phenol and the hydroxyl-quinoxaline and dihydroxy-quinoxaline were detected in similar proportions to those of propaquizafop and quizalofop. However, given the overall low residue levels expected in leaves and roots at harvest when propaquizafop is applied according to the representative uses, the meeting was of the opinion not to include these metabolites in the residue definition. Considering that only a small part of the extracted radioactivity was characterized in leaves and roots and that only one label was investigated, the rapporteur Member State was asked to check if more information is available in the study report on the uncharacterized radioactivity, otherwise a new metabolism study on root crop using the phenyl label should be requested.

In the cotton study, the experts were of the opinion that the residues were not sufficiently investigated since only a small part of the extracted radioactivity was identified in the green plant parts and there was no characterisation of residues present in the seeds, where TRR accounted for 0.05 to 0.08 mg/kg. Consequently, the rapporteur Member State was asked whether more information is available in the metabolism study report concerning the residues in seeds and the extracted but not characterised radioactivity, otherwise a new study on oilseed crop should be requested with a special focus on the nature of the radioactivity in seeds. Moreover, the notifier was asked to clarify how the immature cotton plant samples were stored between sampling and analyses, since this information was missing from the report.

Finally, the meeting of experts discussed whether the unidentified polar metabolite M1 detected in lettuce and accounting for 23 to 30% TRR was sufficiently characterised. Taking into account the clarifications provided by the rapporteur Member State in the evaluation table, the meeting agreed that this metabolite results from incorporation of the ^{14}C in a high molecular plant constituent and that this metabolite is sufficiently characterised. In conclusion, and provisionally, the experts proposed for propaquizafop the following residue definitions for monitoring and risk assessment:

"Sum of propaquizafop and quizalofop, expressed as quizalofop (sum of isomers)".

[19] 6-chloroquinoxaline-2,3-diol
[20] (*R*)-2-(4-hydroxyphenoxy)-propionic acid

In addition and considering the metabolism studies performed with the three quizalofop esters, the meeting of experts concluded that a common residue definition for monitoring and risk assessment can be proposed for propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl as:

> "Sum of quizalofop-esters, quizalofop and quizalofop conjugates expressed as quizalofop (sum of isomers)".

This definition should remain provisional, pending the submission and the evaluation of the requested additional information on the toxicological relevance of the phenoxy metabolites observed in the quizalofop-P-ethyl studies. The EFSA is of the opinion that there is no need to include the quizalofop conjugates in the residue definition for monitoring (see EFSA conclusion on the peer review of quizalofop-P).

Supervised residue trials were submitted to support representative uses on rape seed and sugar beet in Northern and Southern Europe. Samples were analysed using a method covering propaquizafop, quizalofop and quizalofop-phenol. Although this method was not strictly in line with the residue definition, results obtained were considered as valid since MRL proposals were based on residue levels at or close to the LOQ and the scope of the analytical method was wider than the proposed residue definitions. In order to confirm the validity of the trials selected for the MRL setting, the rapporteur Member State was asked to report in an addendum the growth stage at each application for each individual trial. On rapeseed, 18 trials in compliance with the critical GAP were submitted for Northern Europe, the residues in seeds at harvest being in the range of 0.02 to <0.05 mg/kg. For Southern Europe, only two trials were provided, one conducted with a 1.8X application rate and residues below the LOQ. Taking into account the low residue situation and assuming that rapeseed is not a major crop in Southern EU, the experts concluded that no additional trials are needed on rapeseed. No data were available for whole rape plant, the notifier stating in the DAR that it was not intended to support a use on rape forage. On sugar beet, 37 trials in compliance with the critical GAP were provided for Northern and Southern Europe where residues in roots were consistently below the LOQ (<0.02 or <0.05 mg/kg) and in the range of <0.02 to 0.11 mg/kg in the leaves. The results of supervised residue trials can be considered as reliable on the basis of storage stability studies demonstrating that residues of propaquizafop, quizalofop and quizalofop-phenol were stable under deep freeze storage conditions for at least 2 years in soybean, rapeseed and tomato matrices. Considering the low residue levels detected in the raw agricultural products (<0.05 mg/kg) the behaviour of the residues in processing commodities was not investigated.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

A rotational crop study was performed using ^{14}C-propaquizafop labelled on the quinoxaline moiety and applied two times as a foliar treatment on soybean plants used as a primary crop (total dose 2.3X). Spring wheat, spinach and sugar beet were sown as rotational crops 30, 120 and 270 days after the soybean harvest. At harvest, total radioactive residues above 0.02 mg/kg were only detected in spinach and wheat chaff at day 30 (0.039 and 0.96 mg/kg respectively) and in wheat straw for each plant back interval (0.096 to 0.167 mg/kg). Propaquizafop was not observed in the plant parts

investigated and the detected metabolites (quizalofop, quizalofop-phenol and their hydroxy derivatives) have also been identified in the primary crop studies, suggesting a similar metabolic pathway in both primary and rotational crops. Considering the additional information provided by the rapporteur Member State in the evaluation table, it was agreed that a large portion of the radioactivity in straw (up to 56% TRR) was incorporated in the lignin fraction. Finally, it was concluded that no significant residues of propaquizafop or its metabolites are expected in rotational crops.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

Metabolism studies in lactating goat and laying hen have been provided. They were conducted using the parent compound, although the major residue the livestock are exposed to consists of quizalofop. Nevertheless, since these studies demonstrate that propaquizafop is rapidly metabolised to quizalofop, which was the major constituent of the residue in the investigated matrices, the use of propaquizafop was considered as acceptable. The meeting of experts concluded that no animal residue definitions can be established on the basis of these studies since the characterisation/identification of the radioactivity was not sufficiently investigated in different matrices. In the goat study, the nature of the residues was not determined in fat despite the fat soluble properties of the active substance and the significant level of 0.275 mg/kg. In milk, analyses were performed using a common moiety method that analysed propaquizafop, quizalofop and quizalofop-phenol as 6-chloro-2-methoxyquinoxaline and hence the exact nature of the residues remained unknown. In the same way, in the hen study, residues were not sufficiently identified in fat and egg yolk.

Finally, based on the representative uses supported by the notifier and the low residues levels observed in rape seed and sugar beet, the experts agreed that there is no need to set a residue definition for propaquizafop in animal products at present. However, it would be necessary to submit a new goat metabolism study to clarify the nature of the residues in milk and fat if further additional uses lead to an increase in the residue intake by animals.

Considering the table B.7.8.3 in the addendum 3 of June 2008 provided by the rapporteur Member State and summarizing the metabolite distribution in rat and goat for quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop, the experts discussed whether a metabolism study on pig should be requested. Comparison of metabolism was only possible for propaquizafop and quizalofop-P-ethyl since the dosages for quizalofop-P-tefuryl in rat were performed at different time points. Qualitatively, the metabolism in rats and ruminants was similar but differences were observed quantitatively. For both active substances, higher residues were detected in rat than in the goat on an equivalent mg/kg bw basis, some differences being of a 10-fold magnitude. As a result, it was concluded that MRLs set on the basis of ruminant feeding studies may not cover the residue levels that might be found in non-ruminant species. However, and before asking for a pig metabolism study, it was suggested to ask the notifiers to provide explanations for these quantitative differences and why they were of the opinion that these differences are of no concern. Concerning propaquizafop, the

notifier is informed that they would have to consider these requests if new uses beyond those supported in this review lead to a significant residue intake by animals.

No livestock feeding study was provided considering that the trigger value of 0.1 mg/kg in diet was not exceeded. Nevertheless, the rapporteur Member State was asked to recalculate the dietary burden by animals since it was not clear what "grains" refer to in the calculation presented in the DAR. The request made by one expert to include the rape forage in the animal burden calculation has not to be taken into account as it was clearly stated in the DAR that the notifier will not support such a use.

3.3. CONSUMER RISK ASSESSMENT

No chronic risk for the consumer resulting from the use of propaquizafop according to the representative uses on sugar beet and oilseed rape is expected since the Theoretical Maximum Daily Intake (TMDI) using various calculation models (WHO, UK, FR and DE) was at most 21% of the ADI (0.015 mg/kg bw/d) using the UK model. No acute risk evaluation was performed as the PRAPeR meeting 54 on mammalian toxicology concluded that the setting of an ARfD is not required for propaquizafop.

However the experts pointed out that it should be necessary to perform a combined consumer risk assessment which takes into account all the crops the different quizalofop esters are registered on and which considers the respective toxicological endpoints set for each individual ester.

3.4. PROPOSED MRLS

Based on the available supervised residue trials and the proposed residue definition, the following MRLs were proposed:

Sugar beet	0.05* mg/kg	
Rape seed	0.05* mg/kg	(restriction of use: No use on rape seed forage as animal feed)

* MRL is proposed at the LOQ

These MRLs are consistent with the proposals done for sugar beet and rape seed considering the quizalofop-P-ethyl and quizalofop-P-tefuryl GAP.

4. Environmental fate and behaviour

Propaquizafop was discussed at the PRAPeR experts' meeting for environmental fate and behaviour PRAPeR 52 (June 2008), on basis of the DAR (July 2005) and a revised DAR Vol3 B8 (March 2008). As indicated in the physical-chemical section, propaquizafop is an ester variant of the active substance quizalofop-P. During the peer review process, from a comparison of the routes of degradation of the ester variants propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl in the environmental compartments, it was clear that once quizalofop is formed, the degradation pathways

are very similar. In particular, the following major (>10% AR) metabolites[21] are common to two or all of the three ester variants in the different environmental compartments:

Quizalofop

aerobic soil degradation:	quizalofop-P-tefuryl, quizalofop-P-ethyl, propaquizafop
water:	quizalofop-P-tefuryl, quizalofop-P-ethyl, propaquizafop
sediment:	quizalofop-P-tefuryl, quizalofop-P-ethyl, propaquizafop

Hydroxy-quizalofop

aerobic soil degradation:	quizalofop-P-tefuryl, quizalofop-P-ethyl, propaquizafop
sediment:	propaquizafop

Dihydroxy-quinoxaline

aerobic soil degradation:	quizalofop-P-tefuryl, quizalofop-P-ethyl, propaquizafop
sediment:	quizalofop-P-tefuryl, propaquizafop

The EFSA and the Member States considered it fundamental for the exposure assessment to combine the three data sets for these metabolites available in the DARs on propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl in order to derive a single set of endpoints for the fate properties of each metabolite. This exercise was performed during the meeting of experts PRAPeR 52 and led to an agreed list of endpoints for metabolites quizalofop, hydroxy-quizalofop and dihydroxy-quinoxaline (referred to as the amalgamated list of endpoints in this conclusion). It was agreed that this amalgamated list of endpoints should be the basis for the exposure assessment of the above mentioned metabolites. It was decided also to draft two conclusions, one for propaquizafop and one for quizalofop-P-ethyl and quizalofop-P-tefuryl together. The present conclusion reflects the outcome of the consultation of experts where the consistency between the endpoints used for predicted environmental concentration (PEC) calculations reported in the propaquizafop DAR and the agreed endpoints was considered.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

The route of degradation of propaquizafop was investigated under aerobic conditions 20 – 22ºC and 40 – 60% maximum water holding capacity (MWHC) in five soils using two different labelling positions (hydroquinone or quinoxaline). The soils covered a range of characteristics (pH 5.0 to 7.7, organic carbon 0.78 to 3.2%, clay 4.2 to 26.8%) but no important differences in the route of degradation were observed. Some of the soils were also investigated under different incubation conditions (lower soil moisture content and/or lower temperature, and high application rate).

[21] A key to the different synonym names, systematic name and the proposed names used for the individual metabolites is included in Appendix 3.

Degradation of propaquizafop proceeded rapidly via biological hydrolysis of the ester group (sterile soils showed no degradation), to form the main metabolite quizalofop (max. 88% AR at 1d). Quizalofop dissipates via several oxidative steps yielding quizalofop-phenol, hydroxy-quizalofop, hydroxy-quinoxaline, hydroxy-quizalofop-phenol and dihydroxy-quinoxaline along with other several minor unidentified polar metabolites. Degradation of the hydroquinone ring also yielded phenoxy acid (<0.1% AR). The majority of the radioactivity was ultimately found as bound residues (up to 48.6% AR after 120 days) and carbon dioxide (up to 44.2% AR after 119 days).

Hydroxy-quizalofop and dihydroxy-quinoxaline exceeded 10% AR in two soils, reaching maxima of 32.6% AR (after 14 days) and 13.7% AR (after 56 days) respectively. Metabolite hydroxy-quinoxaline accounted for >5% AR at two consecutive sampling times (max. 6.7 – 8.8% AR at 7 – 14 days), triggering a groundwater assessment exposure. Quizalofop-phenol exceeded 5% AR on more than two consecutive occasions in soil at 20% MWHC, 20ºC, 40% MWHC and 8ºC; reaching a maximum of 6.2% AR (1 day). Taking into consideration that quizalofop-phenol is strongly adsorbed to soil particles (see section 4.1.3), the experts from the Member States agreed that an assessment of the potential for groundwater contamination of this metabolite is not necessary.

In a study on the anaerobic metabolism of propaquizafop, its degradation to quizalofop was so rapid during the aerobic phase that the parent compound almost disappeared at the onset of anaerobic conditions (1 – 4% AR). The anaerobic production of carbon dioxide was very low (1.7% AR and 1.7% AR after 61 and 62 days respectively). Degradation of quizalofop was not observed under anaerobic conditions and no metabolites were identified other than those already identified under aerobic conditions.

In a soil photolysis study, propaquizafop degraded rapidly under both light and dark conditions (a first-order DT_{50} value of 38.1 days under light conditions for the combined propaquizafop and quizalofop was determined). The degradation of quizalofop appeared to be enhanced in the irradiated samples suggesting that photodegradation of quizalofop occurs in soil.

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

The rate of degradation of propaquizafop under aerobic conditions was estimated from the results of the studies described in 4.1.1 above. In one study (Mamouni, 1999a), propaquizafop degraded rapidly forming quizalofop in all the soils and after three days it was detected only at very small quantities (<10% AR). Therefore an exact DT_{50} value was not calculated and DT_{50}/DT_{90} values were concluded to be less than 3 days in all soils. A worst case DT_{50} of 3 days at the FOCUS reference conditions[22] (20°C and -10 kPa soil moisture content) was assumed when deriving the appropriate DT_{50} value

[22] Using section 2.4.2 of the generic guidance for FOCUS groundwater scenarios, version 1.1 dated April 2002, utilising a Q10 of 2.2 and Walker equation coefficient of 0.7.

from the degradation rates dataset for FOCUS modelling. The data reported in the other two studies (Dieterle, 1987 and Dennis, 1991) were re-fitted to first-order kinetics using the least squares method to be compatible with the first-order degradation kinetics assumed by the FOCUS models. At temperatures in the range 20 – 22°C and moisture content between 35 and 40% MWHC, the DT_{50}/DT_{90} values for propaquizafop were in the ranges of 0.09 – 1.4 days and 2 – 56 days respectively.

The rate of degradation values of quizalofop, hydroxy-quizalofop and dihydroxy-quinoxaline were discussed at PRAPeR 52, taking into consideration the results of the studies presented in the DARs for propaquizafop (6 or 3 soils), quizalofop-P-tefuryl (8, 5 or 3 soils) and quizalofop-P-ethyl (6, 3 or 4 soils). With the exception of one study (reported in the quizalofop-P-ethyl DAR) conducted with dihydroxy-quinoxaline applied as the test substance on three soils, all DT_{50} values for these metabolites were estimated from the studies where the parent compounds were applied and these metabolites were present.

Propaquizafop and its principal metabolite quizalofop are stable under sterile soil conditions and it can be concluded that the aerobic metabolism of propaquizafop is due to biological activity.

The reliability of the un-normalised and normalised laboratory degradation rates for the major metabolite quizalofop was discussed at the meeting of experts. The estimated DT_{50} values were in the range 7 – 39 days (values from 6 different soils). The acceptable normalised DT_{50} values calculated with the appropriate normalisation method as recommended by FOCUS were provided during the meeting for all the metabolites. The agreed values are included in the list of endpoints, whereas the EFSA noted that in the final addendum to the DAR provided by the rapporteur Member State (July 2008), the incorrect values are still reported.

In addition, it was agreed that the use of the mean value of the DT_{50}s derived from the same soil tested with different application rates and different labelling positions should be considered in the assessment. The normalised DT_{50}s for quizalofop were 7 – 46 days (geometric mean from 6 soils is 16.7 days). From the amalgamated list of endpoints, the DT_{50} values for quizalofop with studies conducted at 10 – 22ºC ranged from 7 to 182 days (20 soils). After normalisation to FOCUS reference conditions this range of single first-order (SFO) DT_{50} values was essentially unchanged (7 – 181.5 days). The experts agreed that the median DT_{50} value of quizalofop that is appropriate for use in FOCUS modelling is 24.3 days.

The rates of degradation of metabolites hydroxy-quizalofop and dihydroxy-quinoxaline were determined in one of the studies discussed above where propaquizafop was applied as the test substance (3 soils). DT_{50} values were in the range of 12 – 21 days for hydroxy-quizalofop and 54 – 63 days for dihydroxy-quinoxaline.

From the amalgamated list of end points, the DT_{50} values for hydroxy-quizalofop with studies conducted at 10 – 20ºC ranged from 7 to 69.4 days (14 soils). After normalisation to FOCUS reference conditions this range of SFO DT_{50} is 10.7 – 53.3 days. The experts agreed that the median DT_{50} value of hydroxy-quizalofop that is appropriate for use in FOCUS modelling is 15.6 days.

For metabolite dihydroxy-quinoxaline when the amalgamated list of endpoints is considered the DT_{50} values ranged from 42 to 258 days (10 soils). After normalisation to FOCUS reference conditions this range of SFO DT_{50} values is 36 – 200 days. In conclusion, it was agreed that the DT_{50} value of hydroxy-quizalofop that is appropriate for FOCUS modelling is the median of 54.3 days.

The aerobic degradation of hydroxy-quinoxaline was determined in three soils at 20°C. The calculated DT_{50} values (46 – 71 days) when normalised to pF 2.0 are in the range 46 – 65 days (geometric mean that is appropriate for use in FOCUS modelling is 56 days).

Although not required, a number of field dissipation studies using EC formulations of propaquizafop were conducted in Switzerland and Germany. The soils used ranged from a sandy clay loam to a sandy loam (OC 1.5 – 4.2%, pH 5.8 – 8.0). Propaquizafop was applied to oilseed rape at a rate of 0.2 kg a.s./ha at one site in Switzerland (Vouvry) and to bare soil at a rate of 0.4 – 0.5 kg a.s./ha at the remaining sites. At the majority of sites, residues of propaquizafop and its metabolites, quizalofop and quizalofop-phenol were considered together and expressed as propaquizafop equivalents. The experts from the Member States agreed with the rapporteur Member State that the residue data expressed as propaquizafop equivalents are not appropriate to derive $DT_{50\ field}$ values to be considered for the environmental risk assessment.

Only soil samples from the Vouvry site were analysed for residues of quizalofop. For this metabolite the DT_{50} and DT_{90} values, calculated according to Timme and Frehse best-fit calculations, of 31 and 103 days respectively, were obtained. Reliable field DT_{50} values for metabolites quizalofop and hydroxy-quizalofop were derived from one study presented in the DAR of quizalofop-P-ethyl. The valid SFO $DT_{50\ field}$ values agreed by the experts were in the range 33.6 – 39.8 days for quizalofop (1 site in Germany, 1 site in France and 1 site in Spain) and 32.2 days (1 site in Germany) for hydroxy-quizalofop.

The predicted environmental concentrations in soil (PEC_{soil}) for propaquizafop were calculated based on standard equations recommended by FOCUS modelling work group. For propaquizafop the longest normalised DT_{50} value from laboratory studies of 2.1 days (SQRT 1.5^{th} order kinetics) was derived from the longest DT_{50} value (1.8 d) of one of the replicates from the same soil with different application rate/radiolabel position. For PEC_{soil} calculations for metabolite quizalofop, the worst-case normalised DT_{50} value from laboratory studies of 45.3 days was used. The following worst-case not normalised laboratory DT_{50} values were used as input values for the metabolites: 21 days for hydroxy-quizalofop, 63 days for dihydroxy-quinoxaline and 71 days for hydroxy-quinoxaline. For the three

metabolites quizalofop, hydroxy-quizalofop and dihydroxy-quinoxaline, the appropriate DT_{50} values to be used in PEC_{soil} calculations were discussed at the meeting PRAPeR 52 on the basis of the amalgamated list of endpoints. It was agreed in PRAPeR 52 that the longest normalised soil DT_{50} value from the laboratory studies should be used: 182 days for quizalofop, 53.3 days for hydroxy-quizalofop and 200 days for dihydroxy-quinoxaline. As the TER values were based on the corresponding initial PEC_{soil} values, the experts concluded that the available PEC_{soil} values for quizalofop, hydroxy-quizalofop and dihydroxy-quinoxaline at the later time points should not be considered in the risk assessment. For metabolite hydroxy-quinoxaline as a worse case DT_{50} value was used in the calculations, PEC_{soil} values at the later time points can be considered valid.

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

As propaquizafop is highly unstable in soil, its adsorption and desorption characteristics could not be determined. An adsorption Koc of 2220 mL/g has been estimated for modelling purposes, based on the *n*-octanol/water partition coefficient Log K_{ow}.

The sorption of quizalofop was investigated in four soils. $K_f$oc values were 347 – 472 mL/g, with 1/n values of 0.82 – 0.88. Taking into consideration the reliable adsorption coefficients for quizalofop reported in the quizalofop-P-tefuryl (7 soils) and quizalofop-P-ethyl (8 soils) DARs, the agreed $K_f$oc median value for quizalofop is 356 mL/g and the median 1/n is 0.8. Quizalofop is therefore classified as exhibiting low to high mobility in soil. There was no evidence of a correlation of adsorption with pH.

The sorption of metabolites quizalofop-phenol, hydroxy-quizalofop and dihydroxy-quinoxaline was directly measured in three soils using the batch equilibrium sorption technique. The following adsorption $K_f$oc values were obtained: 2433 – 7741 mL/g (1/n values 0.83 – 1.12) for quizalofop-phenol; 74 – 141 mL/g (1/n values of 0.94 – 1.07) for hydroxy-quizalofop; 371 – 609 mL/g (1/n values of 0.59 – 0.66) for dihydroxy-quinoxaline. Satisfactory batch adsorption experiments reported in the quizalofop-P-tefuryl DAR (3 soils) and in the quizalofop-P-ethyl DAR (3 soils) were also considered by PRAPeR 52 to derive the appropriate endpoint for metabolites hydroxy-quizalofop and dihydroxy-quinoxaline. On the basis of the results obtained, hydroxy-quizalofop is classified as having low to high mobility in soil ($K_f$oc or Koc 74.4 – 1567 mL/g; 1/n 0.8 – 1.07). There was no evidence of a correlation of adsorption with pH. The experts agreed that the median $K_f$oc value of 141.1 mL/g (median 1/n 1.0) is appropriate for FOCUS modelling. Taking into consideration the amalgamated list of endpoints, dihydroxy-quinoxaline is classified as having low to very high mobility in soil ($K_f$oc or Koc 48 – 1468 mL/g; 1/n 0.59 – 1.0). There was no evidence of a correlation of adsorption with pH. The experts agreed that the median $K_f$oc value of 547.7 mL/g (median 1/n 0.7) is appropriate for FOCUS modelling.

In the groundwater exposure assessment reported in the DAR, the adsorption properties of hydroxy-quinoxaline was estimated using the software programme PCKOCWIN (Koc = 522.4 mL/g). The experts from the Member States considered this value acceptable.

The mobility of propaquizafop was assessed in two column leaching studies. In the first study, four typical agricultural soils with a range of characteristics (pH 5.5 – 8.0, organic matter 0.6 – 1.5%, texture: clay loam – sandy loam) were used. In the second study, three German standard soils (pH 6.0 – 6.6, organic carbon 0.5 – 2.6%, texture: sand – sandy loam) were used. In the former study, after application of ca. 50 cm simulated rainfall over a 7 day period, the vast majority of radioactivity was retained within the upper 0 – 15 cm of the sandy loam, clay loam and loamy sand soil columns (85 – 98%). In the silt loam soil column, the distribution of applied radioactivity, by comparison, was slightly more uniform, with 49% of the applied radioactivity retained in the upper 0 – 15 cm. In the second study, the percentage of applied radioactivity in the soil was not determined. The hydrolysis product quizalofop was the major degradation product identified in the soil (max. 59% of total extracted radioactivity in the sample at 10 – 15 cm depth). Further degradation of quizalofop by hydrolysis to quizalofop-phenol (max. 15.9% of total extracted radioactivity in the sample at 15 – 20 cm depth) and hydroxylation to hydroxy-quizalofop (max. 55.5% of total extracted radioactivity in the sample at 5 – 10 cm depth) also took place. In both the studies the amount of radioactivity detected in the column leachates at the end of leaching was very low (0.034 – 4.07% AR).

Two aged column leaching studies, with aerobically aged propaquizafop, were conducted using treated BBA 2.1 standard sand (aged for 76 days), Dielsdorf sandy loam soil (aged for 31 days) and Steinmaur loam soil (aged for 30 days). The principal degradation products of propaquizafop, quizalofop (max. 52.9%) and hydroxy-quizalofop (max. 19.3%), along with quizalofop-phenol (max. 5.5%) occurred in the aged residue soil samples. Trace amounts of hydroxy-quizalofop-phenol (max. 0.6%) were also detected in the upper sections of the soil columns (0 – 6 cm depth) after leaching. After application of 20 – 51 cm simulated rainfall, the vast majority of radioactivity was retained in the upper sections of the soil columns (ca. 85% AR, 0 – 12 cm depth) and the column leachates contained only 0.1 – 0.4% AR.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

The rate of hydrolysis of propaquizafop is pH dependent, increasing under alkaline conditions. Half-lives of 10.5 days, 32 days and 12.9 hours at pH 5, 7 and 9 respectively, were measured. A hydrolysis study for the main hydrolysis products of propaquizafop was not considered necessary since the results of the laboratory water-sediment dissipation study are more representative of the aquatic environment. The formation of the hydroxylamine derivative occurred only at pH 5.0.

In a photolysis study using artificial irradiation, no difference between light and dark conditions was observed in the degradation of propaquizafop. Several degradation products were observed, including quizalofop (max. 16.4% AR after 11 days) and quizalofop-phenol (max. 36% AR after 11 days). Further information on the radiation intensity of the xenon lamp used in the study was submitted by the notifier and discussed at the meeting of experts. It was agreed that the information provided on the aqueous photolysis study was inadequate for the calculation of reliable photolytic half-lives. Therefore, a data gap was identified. Results from two separate studies on phototransformation of propaquizafop and quizalofop in water by direct irradiation were available. The measured quantum yield of photolysis was 1.11 x 10^{-5} and 1.15 x 10^{-5} for propaquizafop and quizalofop respectively. Annual average DT_{50} values were calculated at latitude of 50°N, giving 32 and 26 days for propaquizafop and quizalofop respectively.

Based on the results obtained in a biodegradation test (OECD 301B), propaquizafop is not a readily biodegradable substance.

Relevant information on the fate of propaquizafop was obtained from a sediment/water study in two systems. In this study propaquizafop was rapidly hydrolysed to quizalofop, which was initially predominantly detected in the water phase (84.6 – 90.2% AR, day 1 – 2) and then gradually partitioned into sediment up to levels of 40.5 – 45.4% AR after 14 – 28 days. Quizalofop was degraded in the water phase to yield a number of metabolites including hydroxy-quizalofop, dihydroxy-quinoxaline, hydroxy-quinoxaline, quizalofop-phenol and hydroxy-quizalofop-phenol, none of which exceeded 4.1% AR. Further degradation of quizalofop in the sediment phase yielded the metabolites dihydroxy-quinoxaline and hydroxy-quizalofop, which reached maxima of 10% AR and 11.2% AR respectively. Several other metabolites were detected in the sediments, including hydroxy-quinoxaline (max. 6.4% AR), quizalofop-phenol (max. 5.2% AR) and hydroxy-quizalofop-phenol (max. 7.1% AR). Terminal products were carbon dioxide (max. 38% AR) and bound residues in the sediment (max. 46%). The rate of degradation ($DT_{50\ system}$, $DT_{50\ water}$, $DT_{50\ sed}$) for propaquizafop and its metabolites were provided in the "Predicted environmental concentrations in surface water" (PEC) section of the DAR. Surface water modelling was conducted using the FOCUS surface water models and scenarios. The simulations were based on application of the product 'Agil 100 EC' (100 g/L EC formulation) to sugar beet and spring and winter oilseed rape in Northern and Southern Europe at a maximum single application of 0.2 kg a.s./ha, in accordance with the proposed EU GAP. The peer review considered the information provided on the kinetic modelling of data from the water/sediment study inadequate. Thorough descriptions of the kinetic analysis of the total system as well as of the water/sediment compartments were provided by the notifier but were not available for the experts of PRAPeR 52. Therefore, all the DT_{50} values derived from the water/sediment study are not peer reviewed and should not be used for risk assessment. As a consequence, all the PEC_{sw} and PEC_{sed} values at the later time points are considered not reliable. Nevertheless, initial PEC_{sw} and PEC_{sed} at Step 1 for hydroxy-quizalofop, dihydroxy-quinoxaline and hydroxy-quinoxaline and up to Step 3 for propaquizafop and quizalofop were used with the appropriate toxicity endpoints for the

calculation of the TERs. The required information on the conceptual compartments model utilised by the Model Maker application was provided in the final addendum (July 2008). Although the data ($DT_{50,\ system}$ for propaquizafop, quizalofop, hydroxy-quizalofop, dihydroxy-quinoxaline, hydroxy-quinoxaline, quizalofop-phenol and hydroxy-quizalofop-phenol; $DT_{50,\ water}$ and $DT_{50,\ sediment}$ for propaquizafop and quizalofop) are not peer reviewed, the EFSA considered the assessment acceptable.

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

Simulations of the leaching behaviour of propaquizafop and its soil metabolites quizalofop, hydroxy-quizalofop, dihydroxy-quinoxaline and hydroxy-quinoxaline were conducted using the FOCUS PELMO model version 3.3.2. The simulations were based on a single maximum application of 0.2 kg a.s./ha to sugar beet and spring and winter oilseed rape in accordance with the proposed EU GAP, using the relevant FOCUS groundwater scenarios. The approach used to model metabolites as applied substances was considered inappropriate by the experts. However, based on the available PEC_{gw} results for these metabolites, it was agreed that it is unlikely that the assessment would change if the simulations were to take into consideration the formation of the metabolites in deeper soil layers.

The selection of the input parameters for the metabolites quizalofop, dihydroxy-quinoxaline and hydroxy-quizalofop was discussed at the meeting of experts PRAPeR 52. According to the amalgamated list of endpoints the normalised (20ºC and pF 2) soil DT_{50} values to be used for modelling purposes are: 24.3 days for quizalofop (median of 20 values), 54.3 days for dihydroxy-quinoxaline (median of 10 values) and 15.6 days for hydroxy-quizalofop (median of 14 values). In addition, the agreed K_{oc} values are: 356 mL/g for quizalofop (median of 19 values), 548 mL/g for dihydroxy-quinoxaline (median of 9 values) and 141 mL/g for hydroxy-quizalofop (median of 9 values). Although the input parameters used in the available modelling were slightly different from these agreed values, the experts concluded that the modelling presented by the notifier was acceptable and no recalculations of PEC_{gw} are needed. The predicted 80^{th} percentile annual average concentrations of propaquizafop and its metabolites were <0.01 µg/L in groundwater at 1 m depth for all scenarios and crop types simulated.

4.3. FATE AND BEHAVIOUR IN AIR

The vapour pressure of propaquizafop is low (4.4×10^{-10} Pa at 25ºC). In a volatility study from plant surfaces, no significant volatilisation of propaquizafop sprayed under controlled climatic conditions was found within 24 hours of application. Modelling calculations with PELMO covering the range of intended uses, indicated that propaquizafop has a very low potential to volatilise from topsoil. It can therefore be concluded that the tendency of propaquizafop to partition into air from other environmental compartments is low and exposure to air is expected to be negligible.

Rate constants of the reaction of propaquizafop and its principal metabolite quizalofop with hydroxyl radicals ($1.5x10^6$ radicals cm^{-3}) were estimated using the Atkinson procedure, resulting in DT_{50} values of 0.6 days and 0.7 days for propaquizafop and quizalofop respectively. Therefore the low amounts of propaquizafop, which may enter the atmosphere, would be unlikely to be subject to long-range atmospheric transport.

5. Ecotoxicology

Propaquizafop was discussed in the meeting of ecotoxicology experts PRAPeR 53 (subgroup 1) in July 2008 on the basis of the DAR (July 2005), the addenda of August 2006 and July 2008 and the corrigendum of July 2008. Propaquizafop is the active substance in the herbicide 'Agil 100 EC' (100 g/L). The representative field uses were in sugar beet (1 x 200 g a.s./ha) and oilseed rape (1 x 200 g a.s./ha).

Quizalofop-P-tefuryl, quizalofop-P-ethyl and propaquizafop are ester variants of the active substance quizalofop-P. These three ester variants have different toxicities based on their lipophilic properties (bioavailability). Aquatic and terrestrial toxic endpoints for the common metabolites of propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl were assessed by Member State experts at PRAPeR 53. Where more than one study was available for the same metabolite in the three dossiers, the lower valid endpoint was agreed to be used in all relevant risk assessments. The agreed endpoints were made available to Member States electronically via the CIRCA website.

The risk assessment was conducted according to the following guidance documents: Risk Assessment for Birds and Mammals, SANCO/4145/2000, September 2002; Aquatic Ecotoxicology, SANCO/3268/2001 rev.4 final, October 2002; Terrestrial Ecotoxicology, SANCO/10329/2002 rev.2 final, October 2002; Risk Assessment for non-target arthropods, ESCORT 2, March 2000, SETAC.

In view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, the new studies on algae and higher aquatic plants could not be considered in the peer review.

5.1. RISK TO TERRESTRIAL VERTEBRATES

The acute and short-term LD_{50} values for birds were >2000 mg a.s./kg bw and 827 mg a.s./kg bw/d. Member State experts agreed to use the reproductive NOEC of 20.2 mg/kg bw/day for bobwhite quail (*Colinus virginianus*) for the long-term risk assessment. In the first tier risk assessment the acute and short-term TERs for herbivorous and insectivorous birds were above the Annex VI triggers of 10. The long-term TER value for herbivorous birds was also above the Annex VI trigger of 5, but further refinements were required to address the long-term risk to insectivorous birds. More justification was required during the peer review to accept the proportion of diet obtained in the treated area (PT)

refinements presented in the DAR. The experts suggested to refine the long-term risk assessment based on the yellow wagtail (*Motacilla flava*) as focal species and a mixed diet of 11% small and 89% large arthropods (by wet weight). The rapporteur Member State provided a refined risk assessment in an addendum after the expert meeting (Addendum, July 2008). A TER value of 14.8 was calculated using wet weight based proportion of different food types (PD) refinements, indicating a low long-term risk to insectivorous birds from the intended uses.

The lowest acute endpoint for mammals was observed in a test with mouse (LD_{50} = 3009 mg a.s./kg bw), indicating a low acute toxicity to mammals. A NOAEL of 15 mg a.s./kg bw/d, derived from a two-generation rat study, was used for the long-term risk assessment. The first tier acute and long-term TERs were above the Annex VI trigger for mammals, indicating a low risk from the intended uses.

A log P_{ow} of 4.78 for propaquizafop triggered a risk assessment for secondary poisoning of fish- and earthworm-eating birds and mammals. TER calculations for earthworm-eating birds and mammals were corrected in the addendum from July 2008, based on correct PEC_{soil} values. All TERs for secondary poisoning were above the Annex VI trigger, indicating a low risk from all intended uses. The potential for bio-accumulation and food chain behaviour of the metabolites not assessed in the DAR nor commented during the peer review. The EFSA notes however, that such an assessment was provided in the DAR for quizalofop-P-ethyl. A log P_{ow} of 2.22 for the main metabolite (quizalofop) suggested little potential for bioaccumulation. Following structure-activity relationship considerations and metabolism studies in rat, laying hen and lactating goat no bioaccumulation was expected for hydroxy-quizalofop or dihydroxy-quinoxaline.

The acute risk from consumption of contaminated drinking water from puddles or reservoirs held in the axils of leaves was assessed following the existing guidance document (SANCO 4145/2000). TERs were above the Annex VI trigger of 10 for both birds and mammals.

The risk from plant metabolites to herbivorous birds and mammals was not addressed in the DAR nor commented during the peer review. The EFSA notes however, that such an assessment was provided in the DAR for quizalofop-P-ethyl. There it was noted that the main metabolite was quizalofop, for which the ecotoxicology testing indicated comparable or lower toxicity compared to quizalofop-P-ethyl. Moreover, the low risk posed by quizalofop-P-ethyl to avian species could be extrapolated to quizalofop. Furthermore, the available data confirmed that metabolism in the rat and hen was comparable. Therefore the toxicity of the quizalofop was considered to be assessed as an integral aspect of the studies conducted with the quizalofop-P-ethyl. In conclusion toxicity tests with quizalofop in avian species were considered unnecessary. The EFSA consider this assessment to address the concerns also for propaquizafop.

5.2. RISK TO AQUATIC ORGANISMS

The lowest endpoints for technical propaquizafop was observed for fish with an acute $LC_{50, 96h}$ of 0.19 mg a.s./L and a chronic $NOEC_{21d}$ of 0.019 mg a.s./L. The acute toxicity of the formulation (LC_{50} = 0.11 mg a.s./L) was comparable to the toxicity of propaquizafop, based on active substance content. The rapporteur Member State proposed to classify propaquizafop as very toxic to aquatic organisms (R50). Only one algae study was considered valid in the DAR. A second algae study was subsequently submitted to the rapporteur Member State by the notifier, and assessed in the addendum of August 2006. The new study was not considered in the peer review in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007. The rapporteur Member State requested an additional formulation study with *Lemna gibba,* as the formulation toxicity was found to be 14 times higher for algae (*Pseudokirchneriella subcapitata*) compared to the toxicity from the technical substance on its own. A formulation study was subsequently submitted to the rapporteur Member State by the notifier and assessed in the addendum from August 2006. The new study was not considered in the peer review in view of the restrictions laid down in Commission Regulation (EC) No. 1095/2007. No studies were required for sediment dwellers.

On the basis of available toxicity data and FOCUS Step 1 and 2 exposure values, TERs above the Annex VI trigger were derived for the acute and chronic risk to invertebrates, algae and *Lemna* for all intended uses. Further refinements were required to address the acute and chronic risk to fish. At FOCUS Step 3, acute TERs were above the Annex VI trigger for all scenarios for use in sugar beet. The TER trigger was respected in the D4, D5 and R1 scenarios but not in the D1 and D3 scenarios for use in spring oilseed rape. In winter oilseed rape the TER trigger was respected in the D4 and R1 scenarios but not in the D2, D3, D5 and R3 scenarios. Chronic TERs for fish were above the Annex VI trigger for all scenarios, based on FOCUS Step 3 values for all intended uses. It was not possible to draw a final conclusion on the risk to aquatic organisms until the additional plant studies had been included in the assessment. In case of Annex I inclusion the preliminary conclusion indicates however, that further refinements of the acute risk assessment for fish would be required for Member States having geo-climatic conditions represented by the FOCUS water body scenarios which failed to meet the Annex VI trigger for the spring and winter use in oilseed rape.

Aquatic toxicity data were available for the metabolites quizalofop, hydroxy-quizalofop, dihydroxy-quinoxaline, hydroxy-quinoxaline and quizalofop-phenol. The lower toxicity endpoint for each metabolite was used, as agreed in the meeting of experts (see above in section 5). All toxicity data indicated that the toxicity of these metabolites to aquatic organisms is lower than the active substance, except for quizalofop which was a factor of 15 more toxic to higher plants. The higher toxicity of the metabolite quizalofop compared to the active substance propaquizafop may be attributed to the fact that quizalofop is the substance expected to cause the herbicidal effect. It may however, also in part result from the different higher plants tested. *Lemna gibba* was used in the toxicity test with

propaquizafop, whereas the non-standard test species *Glyceria fluitans* was used in the study with quizalofop.

Surface water modelling was available for the four major metabolites quizalofop, hydroxy-quizalofop, dihydroxy-quizalofop and hydroxy-quinoxaline. The risk assessment resulted in TERs above the Annex VI trigger for all metabolites for all intended uses except for quizalofop, based on FOCUS Step 1 exposure data. A further refined risk assessment at FOCUS Step 3 provided TERs above the Annex VI trigger for all scenarios and all indented uses. No risk assessment was provided on basis of the toxicity data available for quizalofop-phenol, as this was considered a minor metabolite in the aquatic environment (see section 4.2).

The risk to sediment dwellers from the four major metabolites which may partition to sediment was considered to be low in the DAR. It was pointed out that the acute toxicity of the four metabolites was lower than that of the parent compound (>10-fold difference) for fish, *Daphnia* and algae. Acute TER values, based on *Daphnia* toxicity data for quizalofop, hydroxy-quizalofop, dihydroxy-quinoxaline, and hydroxy-quinoxaline and the maximum concentrations expected in the sediment were several orders above the Annex VI trigger, indicating a negligible level of acute risk also for sediment-dwelling organisms. The available DT_{50} values for the metabolites in sediment (from 41 to 80 d) indicate that they could persist long enough to be of concern for chronic toxicity; nevertheless due to the low acute toxicity to *Daphnia*, it was considered in the DAR that the chronic risk was low. This assessment was never challenged during the peer review. The EFSA did however provide a risk assessment for quizalofop and dihydroxy-quinoxaline when writing the conclusion; based on worst case FOCUS Step 2 PEC_{sw} values for quizalofop and FOCUS Step 1 PEC_{sed} for dihydroxy-quinoxaline. Toxicity endpoints for *Chironomous riparius* for quizalofop (water-spiked study) and dihydroxy-quinoxaline (sediment-spiked study) are available from the quizalofop-P-ethyl and quizalofop-P-tefuryl DARs (see above in section 5). TERs were several orders of magnitude above the Annex VI trigger, supporting the conclusion that a low risk from the major metabolites was expected for sediment dwellers.

A bio-concentration study was provided (log P_{ow} = 4.78) and assessed as valid by the rapporteur Member State. The risk of bioaccumulation in aquatic food chains was assessed as low, based on a BCF of 583 (whole fish) and an elimination half-life of 2.6 h (whole fish).

It was not possible to finalise the risk assessment to aquatic organisms before the missing studies on aquatic plants had been included in the assessment. Based on the data available, it was possible to identify a low risk for all scenarios from uses in sugar beet. Risk assessment for uses in oilseed rape (spring and winter) also indicated a low risk for some scenarios. However further refinements of the acute risk assessment for fish would be required for Member States having geo-climatic conditions represented by the FOCUS water body scenarios which failed to meet the Annex VI trigger for the

spring and winter use in oilseed rape. The risk for all metabolites was addressed, indicating a low risk for all intended uses. The risk from bioaccumulation in fish was assessed as low.

5.3. RISK TO BEES

Hazard quotients calculated for both oral and contact exposure for formulated propaquizafop (which was slightly more toxic than the technical substance) were well below the trigger of 50, indicating a low risk to bees from the intended uses. The results from the semi-field cage tests, in which foraging bees were exposed to treatments applied to a crop in full flower, confirm this low risk. Overall, it was concluded that the intended uses of 'Agil 100 EC' would pose a low risk to honey bees.

5.4. RISK TO OTHER ARTHROPOD SPECIES

The hazard quotients for *Typhlodromus pyri* (HQs <2) indicate a low risk to arthropods for in-field and off-field environments. For *Aphidius rhopalosiphi*, there was 100% mortality on glass plate at an application rate of 150 g a.s./ha (lower than the GAP use of 200 g a.s./ha). Extended laboratory studies were provided for both *A. rhopalosiphi* and *T. pyri*. There were no significant effects on survival or reproduction with *T. pyri*. There were no effects on survival with *A. rhopalosiphi*, whereas there were effects above the trigger value of 50% (66%) on reproduction at the field rate (<50% effect at 1 m drift rate). In the DAR these effects were considered to be short lived as they were seen on fresh residues and propaquizafop foliar residues were expected to decline rapidly. The higher tier risk assessment was discussed in the meeting of Member State experts. The experts concluded that the notifier should further address the in-field risk to *A. rhopalosiphi*, either by an estimation of the foliage half-life of propaquizafop based on measured residues or by providing an aged residue study with *A. rhopalosiphi.* Following the recommendations of ESCORT 2, laboratory studies were provided for *Chrysoperla carnea*, *Coccinella septempunctata* and *Aleochara bilineata*, together with a study on *Poecilus cupreus* (ESCORT 1 recommended species). The studies on these additional species all indicate effects on survival or reproduction of less than the ESCORT 2 trigger of 50% at the recommended field rate, indicating a low risk to these additional species. However, a final conclusion on the risk to non-target arthropods was pending further studies to fully address the in-field risk to *A. rhopalosiphi*.

5.5. RISK TO EARTHWORMS

The lowest acute and chronic toxicity endpoints for the metabolites common to propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl were used in the earthworm risk assessment, as agreed during the meeting of experts (see above in section 5). The risk assessment was only updated in appendix 1. Propaquizafop and the soil metabolites quizalofop, dihydroxy-quinoxaline and hydroxy-quizalofop were of low acute toxicity to earthworms ($LC50_{14d}$ from 948 to >1000 mg a.s./kg soil). The representative formulation was more acutely toxic to earthworms ($LC50_{14d}$ = 54.6 mg a.s./kg soil). The acute TERs based on maximum initial PEC_{soil} values and toxicity correction (log P_{ow} >2) were several orders of magnitude above the Annex VI trigger of 10. Chronic toxicity data were

provided for the formulation and the soil metabolite quizalofop. TERs above the Annex VI trigger indicated a low chronic risk to earthworms. In conclusion a low risk to earthworms was expected from all intended uses.

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

Propaquizafop rapidly degrades in soil but the main metabolite quizalofop has a $DT_{90\ field}$ = 103 days and field dissipation studies for the sum of propaquizafop and metabolites residues indicated $DT_{90\ field}$ values in the range of 215 to 392 days. Consequently, a laboratory study with collembola (*Folsomia candida*) was conducted to address the effects on other soil non-target macro-organisms. A TER was derived for propaquizafop, based on the 28-day NOEC (divided by 2) and the worst case initial soil PEC value. In addition, a risk assessment was performed for the metabolites quizalofop, hydroxy-quizalofop, dihydroxy-quinoxaline, and hydroxy-quinoxaline, assuming toxicities ten times higher than that of propaquizafop. All of the TER values were greater than the trigger of 5, indicating a low risk to soil macro-organisms.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

No effects of >25 % on soil respiration and nitrification were observed in tests with propaquizafop up to a concentration of 1500 mg a.s./kg soil dw. Quizalofop and the other metabolites were likely to have been formed in the test systems and hence were also addressed. Since no effects were observed at a concentration significantly above the calculated maximum PEC_{soil} it was concluded that the risk to soil non-target micro-organisms was low for the representative uses evaluated.

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

Second tier laboratory assays were provided for the four dicotyledonous species *Brassica napus* (oilseed rape), *Daucus carota* (carrot), *Lactuca sativa* (lettuce), *Pisum sativum* (pea), in addition two monocotyledonous species *Allium cepa* (onion) and *Avena sativa* (oat). Oat was distinctly more sensitive than any of the other plant species ($EC_{50\ vegetative\ vigour}$ = 26 g a.s./ha). TER values, calculated from EC_{50} values, from seedling emergence tests with pre-emergent application were all above the Annex VI trigger of 5 based on PEC values form spray drift at 1 m distance. All TER values, based on EC_{50} values from vegetative vigor tests with post-emergent application were above the Annex VI trigger, except for the lowest vegetative vigour endpoint for oats (TER = 4.8). It was agreed during the meeting of Member State experts that a refined risk assessment should be provided, based on an in-field no-spray buffer zone of 5 m. The rapporteur Member State provided the refined risk assessment in the addendum from July 2008. In conclusion the risk to non-target plants was assessed to be low if appropriate mitigation measures were provided, e.g. in-field no-spray buffer zone of 5 m.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

Propaquizafop up to a concentration of 100 mg a.s./L (the highest concentration tested) did not adversely affect the biodegradation activity of sewage micro-organisms. It was not expected that the

concentrations of propaquizafop in biological sewage treatment plants would reach a concentration of more than 100 mg a.s./L if the product were to be applied according to the GAP and therefore the risk to biological methods of sewage treatment was considered to be low.

6. Residue definitions

Soil

Definition for risk assessment:	propaquizafop; quizalofop; hydroxy-quizalofop; dihydroxy-quinoxaline
Definition for monitoring:	propaquizafop

Water

Ground water

Definition for exposure assessment:	propaquizafop; quizalofop; hydroxy-quizalofop; dihydroxy-quinoxaline; quizalofop-phenol; hydroxy-quinoxaline
Definition for monitoring:	propaquizafop

Surface water

Definition for risk assessment:	propaquizafop; quizalofop; from soil runoff/drainage: hydroxy-quizalofop, dihydroxy-quinoxaline
Definition for monitoring:	quizalofop (as the $DT_{90water/sed}$ value for propaquizafop is less than 3 days, this metabolite is indicated as a good indicator for monitoring purposes)

Air

Definition for risk assessment:	propaquizafop
Definition for monitoring:	propaquizafop

Food of plant origin

Definition for risk assessment:	Sum of propaquizafop and quizalofop, expressed as quizalofop (sum of isomers)
Definition for monitoring:	Sum of propaquizafop and quizalofop, expressed as quizalofop (sum of isomers)

Food of animal origin

Definition for risk assessment:	not necessary
Definition for monitoring:	not necessary

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

Soil

Compound (name and/or code)	**Persistence**	**Ecotoxicology**
Propaquizafop	Very low persistence Laboratory DT_{50} < 3 d; DT_{90} < 3 – 56 days (best-fit linear regression analysis) (20 – 22°C, 40 – 60% MWHC soil moisture)	The risk to earthworms, soil non-target macro and micro-organisms was assessed as low.
Quizalofop	Low to high persistence Single first-order labDT_{50} 7 – 182 days (20 – 22°C, different soil moisture conditions in the range 40 – 55% MWHC)	The risk to earthworms and soil non-target macro-organisms was assessed as low.
Hydroxy-quizalofop	Low to medium persistence Single first-order labDT_{50} 7 – 69.4 days (20°C, different soil moisture conditions in the range 40 – 49% MWHC)	The risk to earthworms and soil non-target macro-organisms was assessed as low.
Dihydroxy-quinoxaline	Moderate to high persistence Single first-order labDT_{50} 42 – 258 days (20°C, different soil moisture conditions in the range 40 – 70% MWHC)	The risk to earthworms, soil non-target macro and micro-organisms was assessed as low.
Hydroxy-quinoxaline*	Moderate to medium persistence Single first-order labDT_{50} 46 – 71 days (20°C, 40% MWHC soil moisture)	The risk to earthworms and soil non-target macro-organisms was assessed as low.

* Minor non-transient soil metabolite (maximum 8.8% AR)

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
Propaquizafop	Adsorption properties cannot be determined (K_{oc} = 2220 mL/g based on log K_{ow})	No	Yes	Yes	Yes
Quizalofop	Low to high mobility K_{foc} 133 – 1791 mL/g	No	Yes	Rat metabolite; higher toxicity than the parent not expected. No further data needed.	Yes
Hydroxy-quizalofop	Low to high mobility K_{oc}/K_{foc} 74 – 1567 mL/g	No	No	Rat metabolite; higher toxicity than the parent not expected. No further data needed.	No
Dihydroxy-quinoxaline	Low to very high mobility K_{oc}/K_{foc} 48 – 1468 mL/g	No	No	Rat metabolite; higher toxicity than the parent not expected. No further data needed.	No

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
Hydroxy-quinoxaline	Low mobility K_{oc} 522.4 mL/g (estimated using the software programme PCKOCWIN)	No	No	Rat metabolite; higher toxicity than the parent not expected. No further data needed.	No
Quizalofop-phenol (minor non transient metabolite in soil)	Slight mobility to immobile K_{foc} 2433 – 7741 mL/g	Based on the adsorption properties, no PEC_{gw} >0.1 µg/L 1 m depth for the representative uses is expected (agreed in PRAPeR 52)	No	Rat metabolite; higher toxicity than the parent not expected. No further data needed.	No

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Propaquizafop	Very toxic to aquatic organisms. The risk to aquatic organisms was assessed as low.
Quizalofop (water and sediment)	Harmful to aquatic organisms. The risk to aquatic organisms was assessed as low.
Hydroxy-quizalofop (only sediment)	Not toxic to aquatic organisms. The risk to aquatic organisms was assessed as low.
Dihydroxy-quinoxaline (only sediment)	Harmful to aquatic organisms. The risk to aquatic organisms was assessed as low.
Hydroxy-quinoxaline*	Harmful to aquatic organisms. The risk to aquatic organisms was assessed as low.

* Minor soil metabolite (maximum 8.8%)

Air

Compound (name and/or code)	Toxicology
Propaquizafop	LC_{50} >2500 mg/m^3 – Low acute inhalation toxicity

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

- The specification for the active substance and impurities is not justified by the available data. This includes the specification for the *S* isomer which was a separate data gap in the evaluation table (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- The change in the manufacturing process that resulted in impurities CGA 320116 and CGA 328714 no longer being produced should be explained in detail (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- The change in the manufacturing process that reduced the level of impurity Ro 41-5259 should be described in detail, including the date the process changed. In addition, this impurity should be analysed in the current production batches with a validated method of analysis (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- The possibility of nitrosamine formation during the manufacturing process should be addressed in full (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- Hydrolysis study in accordance with EEC A7 (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- Oxidising properties of the PPP (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- Surface tension of the formulation at 25ºC for R65 classification (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- It must be demonstrated under field conditions that the persistent foam is not an issue (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- It must be demonstrated under field conditions that the emulsion stability is not an issue (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- The high temperature of incineration of the active substance should be justified (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- For the formulation, a new method of analysis is required that separates the *R* and *S* isomers (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).

- Storage stability study with analysis of the *R* and *S* isomer content (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- The methods of analysis for monitoring in food, feed and the environment needs to be reconsidered with the revised residue definitions (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- To provide clarification on the extracted but not characterised/identified radioactivity in cotton seeds (Dieterle P.Ch., 1990), otherwise a metabolism study in one oilseed crop with special focus on the nature of residues in seeds is requested (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 3.1.1).
- To clarify the conditions the samples were stored between sampling and analyses in the cotton metabolism study (Dieterle P.Ch., 1990) (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 3.1.1).
- To provide clarification on the extracted but not characterised/identified radioactivity in the sugar beet roots and leaves (Rumbeli, R., 1991), otherwise a new metabolism study using the phenyl label is requested or to present a justification why such a study is not necessary (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 3.1.1).
- Photolytic half-lives for propaquizafop and quizalofop are not available (relevant for all uses evaluated, data gap identified by meeting of experts PRAPeR 52, not essential to finalise the risk assessment, proposed submission date unknown, refer to section 4.2.1).
- Degradation rates ($DT_{50\ system}$, $DT_{50\ water}$, $DT_{50\ sed}$) for propaquizafop and its metabolites quizalofop, hydroxy-quizalofop, dihydroxy-quinoxaline and hydroxy-quinoxaline derived from the water/sediment study (information available in the final addendum to the DAR, July 2008, not peer reviewed, refer to section 4.2.1).
- An second algae toxicity study is required (relevant for all representative uses evaluated; level 4 data requirement identified by the rapporteur Member State, data gap confirmed in meeting of experts (PRAPeR 53); the study was submitted to the rapporteur Member State and assessed in the addendum from August 2006, but not included in the peer review in view of the restrictions laid down in Commission Regulation (EC) No. 1095/2007.; refer to section 5.2).
- A formulation study on *Lemna gibba* is required (relevant for all representative uses evaluated; level 4 data requirement identified by the rapporteur Member State, data gap confirmed in meeting of experts (PRAPeR 53); the study was submitted to the rapporteur Member State and assessed in the addendum from August 2006, but not included in the peer review due to regulation 1095/2007; refer to section 5.2).
- A study to estimate the foliage half-life of propaquizafop or an aged residue study with *A. rhopalosiphi* is needed to address the in-field risk to non-target arthropods (relevant for all

representative uses evaluated; agreed at the meeting of Member State experts (PRAPeR 53); proposed submission date unknown; refer to section 5.4).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

This conclusion was reached on the basis of the evaluation of the representative uses as a herbicide on sugar beet and oilseed rape. Full details of the GAP can be found in the attached list of endpoints. The representative formulated product for the evaluation was 'Agil 100 EC', an emulsifiable concentrate (EC).

The meeting of experts were not able to conclude on the acceptability of any of the methods as none of the methods were capable of analysing for the original residue definition proposed in the DAR. As it is not possible to reconsider all the methods at this time no conclusion can be reached. A general data gap for reconsideration of the methods has been identified.

There are insufficient analytical methods as well as methods and data relating to physical, chemical and technical properties to ensure that quality control measurements of the plant protection product are possible. The specification of the technical material has not been accepted. The method of analysis for the formulation is identified as a data gap. The formulation was seen to perform poorly in some of the physical-chemical tests. And there are outstanding issues on possible relevant impurities.

In mammals, propaquizafop shows a low acute toxicity via the oral and dermal routes, as well as via inhalation; it is non-irritating to the skin and eyes. Skin sensitisation tests in guinea pigs gave positive results (R43 "May cause sensitisation by skin contact" was proposed). In repeated dose studies, liver was shown to be the target organ. The short-term toxicity No Observed Adverse Effect Levels (NOAELs) for rats and mice on the basis of liver effects were 6.25 and 10 mg/kg bw/day, respectively (Lowest Observed Adverse Effect Levels - LOAELs 25 and 30 mg/kg bw/day); in long-term studies the relevant NOAELs were set at 5 mg/kg bw/day for rats and 1.5 mg/kg bw/day for mice (LOAELs 25 mg/kg bw/day and 7.5 mg/kg bw/day, respectively). Propaquizafop did not show any genotoxic potential. Increased incidences of hepatocellular adenomas and carcinomas were seen in both rats and mice. In one study in rats, an increased incidence of Leydig cell tumors was also noted. Mechanistic studies performed in rats and mice indicate that propaquizafop acts as a peroxisome proliferator. Based on the occurrence of malignant tumours in two species (hepatocellular adenomas and carcinomas in rats and mice) and the increased incidence of Leydig cell tumours in rats, proposal for classification and labelling of propaquizafop as Carc. Cat. 3 R40 ("Limited evidence of a carcinogenic effect") was considered and proposed during the meeting. In a multigeneration reproductive toxicity study, there were no treatment-related effects on mating performance, fertility index, gestation length or gestation index. The relevant reproductive NOAEL

was 15 mg/kg bw/day, whereas the relevant maternal and offspring NOAEL was 3 mg/kg bw/day. In a rat developmental study, numbers of implantations, corpora lutea and viable foetuses were comparable among groups. No treatment-related skeletal malformations were observed in any dose group. The NOAEL for developmental toxicity was 20 mg/kg bw/day based on an increased incidence of dilated renal pelvis up to 50 mg/kg bw/day. The NOAEL for maternal toxicity was 50 mg/kg bw/day due to decreased body weight gain at 125 mg/kg bw/day. In rabbits, there were no treatment related malformations or developmental changes. The relevant maternal and developmental NOAELs were 6 mg/kg bw/day and 18 mg/kg bw/day, respectively. The Acceptable Daily Intake (ADI) of 0.015 mg/kg bw/day was based on the NOAEL of 1.5 mg/kg bw/day from the mouse long-term study (SF 100). The NOAEL of 6.25 mg/kg bw/day from the rat 90 day study was the basis for the Acceptable Operator Exposure Level (AOEL) of 0.04 mg/kg bw/day, SF 100 and limited oral absorption (65%). Based on the acute toxicological profile of propaquizafop, the Acute Reference Dose (ARfD) was not allocated. The operator, worker and bystander exposure assessment is below the AOEL even without the use of Personal Protective Equipment (PPE).

The metabolism of propaquizafop has been investigated in cotton, soybean, lettuce and sugar beet using ^{14}C-propaquizafop labelled on the phenyl and/or the quinoxaline moiety. The metabolism proceeds primarily with the hydrolysis of the ester link to yield quizalofop followed by the loss of the propionyl moiety leading to quizalofop-phenol, these metabolites being also observed as conjugates. Further metabolism occurs by hydroxylation of the quinoxaline moiety giving hydroxy-quizalofop and hydroxy-quizalofop-phenol. In addition and in a limited extent, the presence of quinoxaline metabolites and phenoxy acid metabolites indicated a cleavage of the oxygen bond of the molecule. In the sugar beet study, the metabolites quizalofop-phenol, hydroxy-quizalofop-phenol, hydroxy-quinoxaline and dihydroxy-quinoxaline were detected in leaves and roots in similar proportions to propaquizafop and quizalofop. However, taking into account the overall low residue levels expected in leaves and roots at harvest, these metabolites were not included in the plant residue definition. Finally, considering that the radioactivity was not sufficiently characterized in sugar beet and in cotton seeds the notifier was asked to provide clarifications on the uncharacterized radioactivity unless new metabolism studies on root crop on oilseed crop should be submitted. In conclusion and provisionally the experts proposed the following residue definition for monitoring and risk assessment:

"Sum of propaquizafop and quizalofop, expressed as quizalofop (sum of isomers)"

Considering the metabolism studies performed with the three quizalofop esters, a common residue definition for monitoring and risk assessment was proposed for propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl as:

"Sum of quizalofop-esters, quizalofop and quizalofop conjugates expressed as quizalofop (sum of isomers)"

These definitions should remain provisional, pending the submission and the evaluation of the requested information on the toxicological relevance of the phenoxy metabolites observed in the

quizalofop-P-ethyl studies. After the meeting, the EFSA was of the opinion that there is no need to include the conjugates in the residue definition for monitoring.

Supervised residue trials were submitted to support representative uses on rape seed and sugar beet. Samples were analysed using a method covering propaquizafop, quizalofop and quizalofop-phenol. Although this method was not strictly in line with the residue definition, results were considered as valid since the scope of this method was wider than the proposed residue definitions. The storage stability study showed the residues of propaquizafop, quizalofop and quizalofop-phenol to be stable under deep freeze storage conditions for at least 2 years in soya, rapeseed and tomato matrices. The behaviour of the residues in processing products was not investigated due to the low residue levels detected in the raw agricultural products.

A rotational crop study performed with ^{14}C-propaquizafop labelled on the quinoxaline moiety was provided. Propaquizafop was not observed in the different rotational plant parts investigated and the detected metabolites (quizalofop, quizalofop-phenol and their hydroxy derivatives) have also been identified in the primary crop studies, suggesting a similar metabolic pathway in both primary and rotational crops. Taking into account the residue levels observed in plants at harvest, it was concluded that no significant residues of propaquizafop or its metabolites are expected in rotational crops.

Metabolism studies in lactating goat and laying hen were provided. However, the meeting of experts concluded that no residue definitions can be established on the basis of these studies since the characterisation of the radioactivity was not sufficiently investigated in some matrices, especially in fat. However, and taking into account the low residues levels observed in rapeseed and sugar beet, the experts agreed that there is no need to set a residue definition in products of animal origin for propaquizafop at present. No feeding study was provided, the trigger value of 0.1 mg/kg in diet being not exceeded.

Considering the comparative metabolite distribution in rat and goat for quizalofop-P-ethyl and propaquizafop, the experts discussed whether a supplementary metabolism study on pig should be requested. The metabolism in rats and ruminants was similar qualitatively but differences were observed quantitatively. Higher residues were detected in rat on an equivalent mg/kg bw basis and the notifiers were asked to provide explanations for these quantitative differences. Such a request is not relevant for propaquizafop at present, but this point would have to be considered if new uses beyond those supported in this review lead to a significant residue intake by animals.

No chronic risk for the consumer resulting from the use of propaquizafop according to the representative uses on sugar beet and oilseed rape is expected since the Theoretical Maximum Daily Intake (TMDI) using various calculation models was at most 21% of the ADI (0.015 mg/kg bw/d) using the UK model. No acute evaluation was performed as no ARfD was set for propaquizafop.

Based on the available supervised residue trials and the proposed residue definition a MRL of 0.05* mg/kg was proposed on sugar beet and rape seed, these MRLs being consistent with the proposals done for quizalofop-P-ethyl and quizalofop-P-tefuryl on these crops.

The information available on the fate and behaviour in the environment is sufficient to carry out an appropriate environmental exposure assessment for propaquizafop at the EU level. Degradation rates ($DT_{50\ system}$, $DT_{50\ water}$, $DT_{50\ sed}$) for propaquizafop and its metabolites derived from the water/sediment study were not peer reviewed. However, a low risk assessment to aquatic organisms was identified based on the maximum PEC values. For the applied for intended uses, the potential for groundwater exposure by propaquizafop and its metabolites quizalofop, hydroxy-quizalofop, dihydroxy-quinoxaline, and hydroxy-quinoxaline above the parametric drinking water limit of 0.1 µg/L is low.

The lower metabolite ecotoxicity endpoints available in the dossier for propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl were used in the risk assessments of propaquizafop. The acute and short-term risk to birds was assessed as low for the intended uses at tier one, as was the long-term risk to herbivorous birds. Further refinements were required to address the risk to insectivorous birds. The rapporteur Member State provided a refined risk assessment in an addendum after the expert meeting (Addendum, July 2008), based on yellow wagtail (*Motacilla flava*) as generic focal species feeding on a mixed small/large arthropod diet. A TER value of 14.8 was calculated using wet weight based PD refinements, indicating a low long-term risk to insectivorous birds from the intended uses. The first tier acute and long-term TERs were above the Annex VI trigger for mammals, indicating a low risk from the intended uses. All TERs for secondary poisoning to birds and mammals were above the Annex VI trigger, indicating a low risk from all intended uses. The acute risk from consumption of contaminated drinking water was assessed for the puddle scenario. TERs were above the Annex VI trigger of 10 for both birds and mammals. The risk to herbivorous birds and mammals from plant metabolites was not addressed in the DAR or during the peer review. Mammal toxicity and metabolism data for quizalofop-P-ethyl, however, suggests that the risk to herbivorous mammals from plant metabolites was covered by the risk assessment for quizalofop-P-ethyl. Propaquizafop was found to be very toxic to aquatic organisms, with fish as the most sensitive species tested. A comparable toxicity was identified for the macrophyte *Glyceria fluitans* exposed to the metabolite quizalofop. FOCUS Step 3 exposure refinements were required to identify a low risk to aquatic organisms. For use in sugar beet all FOCUS Step 3 scenarios indicated a low risk to aquatic organisms, whereas only 3 out of 5 scenarios for spring use in oilseed rape and 2 out of 6 in winter oilseed rape indicated a low risk to aquatic organisms. The risk to sediment dwellers and the risk from bioaccumulation were assessed as low. The risk to non-target arthropods needed to be refined further to address the in-field risk to *Aphidius rhopalosiphi*. A no-spray buffer zone of 5 m was required to identify a low risk to the non-target plants, based on the most sensitive vegetative vigour endpoint for oat.

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

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

- An in-field no-spray buffer zone of 5 m was required for all intended uses to conclude a low risk to non-target plants.

CRITICAL AREAS OF CONCERN

- The specification has not been agreed
- The acceptability of monitoring methods has not been concluded.
- It was not possible to finalise the risk assessment for aquatic organisms.
- It was not possible to finalise the in-field risk assessment for non-target arthropods.

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

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

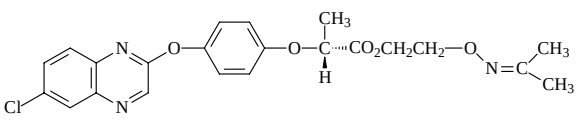
(Abbreviations used in this list are explained in appendix 2)

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

Active substance (ISO Common Name) ‡	Propaquizafop (a variant of quizalofop-P)
Function (*e.g.* fungicide)	Herbicide

Rapporteur Member State	Italy
Co-rapporteur Member State	none

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	2-isopropylidenamino-oxyethyl (*R*)-2-[4-(6-chloro-quinoxalin-2-yloxy)phenoxy]propionate
Chemical name (CA) ‡	(*R*)-2-[4-[(6-chloro-2-quinoxalinyl)oxy]phenoxy]-propionic acid 2-[[(1-methylethylidene)amino]oxy]ethyl ester
CIPAC No ‡	713
CAS No ‡	111479-05-1
EC No (EINECS or ELINCS) ‡	not available
FAO Specification (including year of publication) ‡	not available
Minimum purity of the active substance as manufactured ‡	Open
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Toluene maximum content 5 g/kg Open for the other relevant impuritity Ro 41-5259
Molecular formula ‡	$C_{22}H_{22}ClN_3O_5$
Molecular mass ‡	443.9 g/mol
Structural formula ‡	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	66.3ºC (purity 99.9%)
Boiling point (state purity) ‡	Not applicable
Temperature of decomposition (state purity)	260ºC (purity 99.1%)
Appearance (state purity) ‡	Off white powder (purity 99.1%)
	Orange to brown mixture of fine powder and granular material (purity: technical material)
Vapour pressure (state temperature, state purity) ‡	4.395 x 10^{-10} Pa at 25ºC (99.9%)
Henry's law constant ‡	9.2 x 10^{-8} Pa m^3/mol @ 20ºC
Solubility in water (state temperature, state purity and pH) ‡	Propaquizafop – 0.63 mg/L at 20°C (pH = 6.8) (99.9%)
	Quizalofop-P – 7500 mg/L at 20°C (pH = 7) (98.3%)
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 25ºC (94.2%) Acetone >500 g/l Dichloromethane >500 g/l Ethyl acetate >500 g/l Hexane 11 g/l Methanol 76 g/l Octanol 30 g/l Toluene >500 g/l
Surface tension ‡ (state concentration and temperature, state purity)	53.3-55.4 mN/m at 20°C (filtered of 10.0 g/L suspensions) (94.2%)
Partition co-efficient ‡ (state temperature, pH and purity)	Propaquizafop - log $P_{O/W}$ = 4.78 at 25 °C (pH neutral) (99.9 %)
	Quizalofop-P - log $P_{O/W}$ = 1.518 at 20 °C (pH = 4.6) (98.3 %)
Dissociation constant (state purity) ‡	Propaquizafop - pKa_1 = -2.3 (99.9%) Quizalofop-P - pKa_1 = 6.14 (98.3%) There is no dissociation between pH 4 and 9.

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	- Propaquizafop - UV/Vis: Molar adsorption coefficients (ε) were found at the following wavelength maxima (λ_{max}) (99.1%) Neutral 235.0 nm ε = 30500 334.0 nm ε = 5850 Acidic 235.0 nm ε = 30000 334.0 nm ε = 5810 Alkaline 235.0 nm ε = 29700 334.0 nm ε = 5790 No absorbance found between 400 and 750 nm
Flammability ‡ (state purity)	Not flammable, no self-ignition (94.2%)
Explosive properties ‡ (state purity)	Not explosive (94.2 %)
Oxidising properties ‡ (state purity)	Not oxidising (94.2 %)

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Summary of representative uses evaluated (*Propaquizafop*)*

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 (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL (l) min – max	water L/ha min – max	g as/ha (l) min – max		
e.g.															
Sugar beet	Northern and Southern Europe	Agil 100 EC	F	Monocotyl weeds	EC	100 g/L	Foliar spray	Post-em: crop GS: BBCH 12-39 weed GS: BBCH 12-29	1	n/a	40-100	200-500	200	n/a	2.0 litre product/ha
Oilseed rape	Northern and Southern Europe	Agil 100 EC	F	Monocotyl weeds	EC	100 g/L	Foliar spray	Post-em: Spring, crop GS: BBCH 21-39 weed GS: BBCH 13-29 Autumn, crop GS: BBCH 13-29 weed GS:	1	n/a	40-100	200-500	200	n/a	[1][2]

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

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 (for explanation see the text in front of this section)			PHI (days)	Remarks
(a)			(b)	(c)	Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL (l) min – max	water L/ha min – max	g as/ha (l) min – max	(m)	
								BBCH 12-25							

[1] The risk assessment has revealed data gap(s) in section 1.
[2] The risk assessment has revealed a risk (exceedance of relevant threshold) in section 5.

*	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

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Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Methods of Analysis

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

Technical as (analytical technique)	HPLC/UV
Impurities in technical as (analytical technique)	HPLC/UV; GC/FID
Plant protection product (analytical technique)	Open

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	Sum propaquizafop + quizalofop expressed as quizalofop
Food of animal origin	Not necessary considering the supported uses evaluated in this peer review
Soil	Propaquizafop
Water surface	Propaquizafop
drinking/ground	Propaquizafop
Air	Propaquizafop

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Open
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Open

Soil (analytical technique and LOQ)	Open
Water (analytical technique and LOQ)	Open

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

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Air (analytical technique and LOQ)	Open
Body fluids and tissues (analytical technique and LOQ)	Not required [substance is not classified as toxic (T) or very toxic (T^+)]

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

	RMS/peer review proposal
Active substance	None

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Propaquizafop was absorbed over a long period (Cmax 8-12 h), with an oral absorption value of 65%.
Distribution ‡	Generally distributed with highest levels in blood, liver and kidney
Potential for accumulation ‡	None
Rate and extent of excretion ‡	Rapidly excreted in faeces and urine
Metabolism in animals ‡	Extensively metabolised. Major metabolites are the free acid of the parent compound and further oxidation products
Toxicologically relevant compounds ‡ (animals and plants)	Propaquizafop
Toxicologically relevant compounds ‡ (environment)	Propaquizafop

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	5000 mg/kg bw	
Rat LD_{50} dermal ‡	2000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 2500 mg/m^3	
Skin irritation ‡	Non-irritating	
Eye irritation ‡	Non-irritating	
Skin sensitisation ‡	Sensitizer (Magnusson & Kligman)	R43; Xn

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Hepatotoxicity	
Relevant oral NOAEL ‡	6.25 mg/kg bw/day (rat) 10 mg/kg bw/day (mouse) 20 mg/kg bw/day (dog)	
Relevant dermal NOAEL ‡	250 mg/kg bw/day (rat)	

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Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Relevant inhalation NOAEL ‡	N/A	

Genotoxicity ‡ (Annex IIA, point 5.4)

	Non-genotoxic	

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

Target/critical effect ‡	Hepatotoxicity	
Relevant NOAEL ‡	1.5 mg/kg bw/day (18 months - mouse) 5 mg/kg bw/day (2 years - rat)	
Carcinogenicity ‡	Rat and mouse hepatic neoplasms (peroxisome proliferator); Leydig cell tumour production	R40

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Increased resorption rat/delayed eye opening in the offspring	
Relevant parental NOAEL ‡	3 mg/kg bw/day	
Relevant reproductive NOAEL ‡	15 mg/kg bw/day	
Relevant offspring NOAEL ‡	3 mg/kg bw/day	

Developmental toxicity

Developmental target / critical effect ‡	Increased number of resorption rabbit	
Relevant maternal NOAEL ‡	6 mg/kg bw/day (rabbit) 50 mg/kg bw/day (rat)	
Relevant developmental NOAEL ‡	18 mg/kg bw/day (rabbit) 20 mg/kg bw/day (rat)	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	Not a neurotoxicant	

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Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Repeated neurotoxicity ‡	Not a neurotoxicant	
Delayed neurotoxicity ‡	Not a neurotoxicant	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Peroxisome proliferator (rat and mouse)
Studies performed on metabolites or impurities ‡	Metabolite CGA 289740 induced a two-fold increase in revertants colonies in S. typhimurium TA98, only in the presence of exogenous metabolic activation. Due to the lack of any relationship with the dose applied, the biological significance of this finding is equivocal. Metabolite CGA 289742 did not induce gene mutations in the strains of S. typhimurium and E. coli tested

Medical data ‡ (Annex IIA, point 5.9)

	No manufacturing incidents reported. Manufactured in closed systems.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.015 mg/kg bw/day	Chronic mouse	100
AOEL ‡	0.04 mg/kg bw/day	90 day rat (oral absorption rate 65%)	100
ARfD ‡	Not necessary		

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (e.g. name 50 % EC)	10% for the concentrate and for the dilution as default dermal absorption value

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Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Exposure scenarios (Annex IIIA, point 7.2)

Operator	% use of AOEL from use of German model: Without PPE: 62.5 With PPE (gloves, standard protective equipment, sturdy footwear during mixing/loading and application): 2.5 % use of AOEL from use of UK model: Without PPE: 196 (20 L), 259 (5 L), 592 (1 L) With gloves during mixing/loading and application: 31.5 (20 L), 38 (5 L), 71 (1 L)
Workers	German Uniform principles: Without PPE: ~50 % of the AOEL
Bystanders	Using Ganzelmeyer spray drift values: All crop scenarios: 10 % of the AOEL

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

	RMS/peer review proposal
Substance classified (name)	Xn; R43; R40

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

Plant groups covered	Leafy vegetable (lettuce), Root/tuber crops (sugar beet) and Oilseeds (cotton seed, soybeans) foliar treatment
Rotational crops	Spring wheat, spinach and sugar beet
Metabolism in rotational crops similar to metabolism in primary crops?	Yes.
Processed commodities	Not applicable
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Sum propaquizafop and quizalofop expressed as quizalofop (sum of isomers) (Provisional)
Plant residue definition for risk assessment	Sum propaquizafop and quizalofop expressed as quizalofop (sum of isomers) (Provisional)
Conversion factor (monitoring to risk assessment)	Not relevant

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

Animals covered	Goats and hens
Time needed to reach a plateau concentration in milk and eggs	Study No. 047880 H. Ellgehausen, 1985a - Milk Plateau level (0.46 – 0.95 mg/kg) at 3-4 days. Study No. 047891 H. Ellgehausen, 1985b - Milk Plateau level (0.42 – 0.71 mg/kg) at 3-4 days.
Animal residue definition for monitoring	Not necessary considering the supported uses evaluated in this peer review
Animal residue definition for risk assessment	Not necessary considering the supported uses evaluated in this peer review
Conversion factor (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	No: Quantitative differences were observed. Clarification was requested from the applicant (PRAPeR 55).
Fat soluble residue: (yes/no)	To be reconsidered on the basing of the new goat metabolism study requested during the PRAPeR 55

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Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

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

	Spring wheat, spinach and sugar beet

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

	Residue of propaquizafop, quizalofop and quizalofop-phenol stable during frozen storage for at least 2 years in soybean, rapeseed, tomato, sugar beet (leaves and roots) and carrots.

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

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

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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	Trials results relevant to the representative uses (a)	Recommendation /comments	MRL estimated from trials according to the representative use	HR (mg/kg) (c)	STMR (mg/kg) (b)
Sugar beet	Northern (Field)	Rate: 200 g ai/ha; 1 application; PHI = 49-171days **Roots**: 19x <0.02, 10x <0.05 **Leaves**: 15x <0.02, 2x 0.02, 2x 0.03, 0.04, 6x <0.05, 2x 0.06, 0.11		0.05	0.05	0.02
	Southern (Field)	Rate: 0.2 kg ai/ha; 1 application; PHI = 60-153 days **Roots**: 6x <0.02, 2x <0.05 **Leaves**: 2x <0.02, 0.04, <0.05, 0.05		0.05	0.05	0.02
Oilseed rape	Northern (Field)	Rate: 0.2 kg ai/ha; 1 application; PHI = 71-270 days **Seeds:** 2x 0.02, 2x 0.03, 14x < 0.05		0.05	0.05	0.05
	Southern (Field)	Rate: 0.2 kg ai/ha; 1 application; PHI = 157 and 211 days **Seeds:** 2x <0.05		0.05	0.05	0.05

(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

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

ADI	0.015 mg/kg bw/day
TMDI (% ADI) according to WHO European diet	<1% ADI for adults
TMDI (% ADI) according to national (to be specified) diets	calculated with MRL of 0.05 mg/kg **UK PSD Consumer Model** Maximum TMDI 21% of the ADI for Toddler **BBA German model, the TMDI predicted is**: <1% of the ADI for 4 - 6 year old female children **French model, the TMDI predicted is:** <1%% of the ADI for adults
IEDI (WHO European Diet) (% ADI)	Not considered necessary
NEDI (specify diet) (% ADI)	None
Factors included in IEDI and NEDI	None
ARfD	Not necessary
IESTI (% ARfD)	None
NESTI (% ARfD) according to national (to be specified) large portion consumption data	None
Factors included in IESTI and NESTI	None

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Not relevant	Not relevant	Not relevant	Not relevant	Not relevant

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

Sugar beet	0.05* mg/kg
Oilseed rape	0.05* mg/kg

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Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

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

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Fate and behaviour

FOREWORD:
Propaquizafop is an ester variant of the active substance quizalofop-P. There are other two other esters of the same active substance, namely quizalofop-P-tefuryl and quizalofop-P-ethyl, which were notified 3B active substances.
During the peer review process, from a comparison of the routes of degradation of the three active substances in the environmental compartments it was clear that, once quizalofop is formed, the degradation pathways are very similar. In particular, the following major (> 10% AR) metabolites are in common to two or all the three active substances in the different environmental compartments:
-quizalofop
aerobic soil degradation: quizalofop-P-tefuryl, quizalofop-P-ethyl, propaquizafop
water: quizalofop-P-tefuryl, quizalofop-P-ethyl, propaquizafop
sediment: quizalofop-P-tefuryl, quizalofop-P-ethyl, propaquizafop
-hydroxy-quizalofop
aerobic soil degradation: quizalofop-P-tefuryl, quizalofop-P-ethyl, propaquizafop
sediment: propaquizafop
-dihydroxy-quinoxaline
aerobic soil degradation: quizalofop-P-tefuryl, quizalofop-P-ethyl, propaquizafop
sediment: quizalofop-P-tefuryl, propaquizafop

The EFSA and the Member States considered fundamental for the exposure assessment to combine the three single data sets for these metabolites available in the DARs in order to derive a single set of endpoints for the fate properties of each metabolite. This exercise was performed during the meeting of experts PRAPeR 52 and leaded to an agreed list of endpoints for metabolites quizalofop, hydroxy-quizalofop and dihydroxy-quinoxaline (named as "amalgamated LoEP" in this conclusion). It was agreed that this amalgamated list of endpoints should be the basis for the exposure assessment of the above mentioned metabolites. It was decided also to draft two conclusions, one for propaquizafop and one for quizalofop-P-ethyl and quizalofop-P-tefuryl together. The present report reflects the outcome of the consultation of experts where the consistency between the endpoints used for predicted environmental concentrations (PEC) calculations reported in the propaquizafop DAR and the agreed endpoints was considered.

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

Mineralization after 100 days ‡	27.7-44.2% AR after 119-120 d, [^{14}C- quinoxaline]-label (n= *3*) 28.3-28.4% AR after 120 d, [^{14}C- hydroquinone]-label (n= *2*) 22.6 % AR after *121* d, [^{14}C- quinoxaline]-label (n= *1*) Sterile conditions: no data available
Non-extractable residues after 100 days ‡	39.9-48.6% AR after 120 d, [^{14}C- quinoxaline]-label

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	(n= *3*) 36-39.4% AR after 120 d, [^{14}C- hydroquinone]-label (n= *2*) 43.6 % AR after *121* d, [^{14}C- quinoxaline]-label (n= *1*) Sterile conditions: no data available
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	quizalofop (CGA 287422)- 71.3-87.9 % AR at 1-3 d (n= 6; 20ºC 40% MWC; 22ºC 35% MWC). hydroxy quizalofop (CGA 294972)- 16.1-32.6% AR at 30-14 d (n= 3; 20ºC 40% MWC; 22ºC 35% MWC). dihydroxy quinoxaline (CGA 294970)– 13.7% AR at 56 d (n= 3; 20ºC 40% MWC). hydroxy quinoxaline (CGA 290291) – 6.7-8.8% AR at 7-14 d (n= 3; 20ºC 40% MWC). quizalofop-phenol (CGA 129674) – 5.4-5.7% AR at 1-7 d (n= 6; 20ºC 40% MWC). [^{14}C- quinoxaline] & [^{14}C- hydroquinone] labels

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

Anaerobic degradation ‡

Mineralization after 100 days	1.7-1.9 % AR at 62-61 d, [^{14}C- hydroquinone] label (n= 2) Sterile conditions: no data available
Non-extractable residues after 100 days	30.7-34.4 % AR at 29-0 d, [^{14}C- hydroquinone] label (n= 2) Sterile conditions: no data available
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	quizalofop (CGA 287422)- 31.4-38.8 % AR at 29 -0 d (n= 2) hydroxy quizalofop (CGA 294972)- 12.1-17.0 % AR at 62-29 d (n= *2*) [^{14}C- hydroquinone] label

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Quizalofop max 38.6% AR at 31 d (n=1) Quizalofop-phenol max 3.5% AR at 31 d (n=1)

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

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

Laboratory studies ‡

Propaquizafop	Aerobic conditions						
Soil type	OC %	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Loam (Mamouni 1999a) / **PROP**	2.02	7.18#	20 °C / 40 %	<3/<3			
Loamy sand (Mamouni 1999a) / **PROP**	0.78	7.43#	20 °C / 40 %	<3/<3			
Sandy loam (Mamouni 1999a) / **PROP**	1.3	5.01#	20 °C / 40 %	<3/<3			
Sandy loam (Dieterle 1987a) / **PROP**	2.5	6.9	22 °C / 60 %	1.4 / 56$			Best-fit linear regression analysis
Loam (Dieterle 1987a) / **PROP**	3.2	7.5	22 °C / 60 %	1.2 / 51$			Best-fit linear regression analysis
Loam (Dennis 1991b) / **PROP**	2.7	7.7	20 °C / 40 %	0.09 / 2@			Best-fit linear regression analysis
Geomean/median*				1.3/2.2			

= pH in KCl
$ = geomean of three values for the same soil (different application rate and radiolabel position) sandy loam DT_{50}/ DT_{90} (d)= 1.1/87, 1.8/149, 1.2/31; loam soil DT_{50}/ DT_{90} (d) = 1.0/82, 1.8/50, 0.8/22.
@ = geomean of two values for the same soil (different application rate) DT_{50}/ DT_{90} (d) = 0.09/2, 0.09/2.
* = a worst case DT_{50} value of 3 d was considered for the 3 soils of the Mamouni 1999a study

PROP = the study presented in the DAR of propaquizafop

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Met: Quizalofop	Aerobic conditions							
Soil type /Origin	OC (%)	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	Molar f. f. k_{dp}/k_f from ester precursors	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy l. (Dzialo, 2004, phenyl-l.)/**TEF**	1.0	6.3	20 °C / 45 %	55.9 / 185.6	*	49.2 *****	0.993	SFO, ModelMaker
Sand (Dzialo, 2004, phenyl-label) /**TEF**	1.2	6.2	20 °C / 45 %	18.7 / 62.0	*	18.7 *****	0.984	SFO, ModelMaker
Loam (Dzialo, 2004, phenyl-label) /**TEF**	0.90	5.9	20 °C / 45 %	42.4 / 141.0	*	41.05 *****	0.969	SFO, ModelMaker
Clay l. (Dzialo, 2004, phenyl-label) /**TEF**	1.0	7.6	20 °C / 45 %	22.5 / 74.6	*	21.04 *****	0.984	SFO, ModelMaker
Sandy loam (Völkel, 1998, quinoxaline-label) /**TEF**	1.4	6.3	20 °C / 40 %	14.1 / 47.0	1	14.0 *****	0.967	SFO, ModelMaker
Silty clay l. (Völkel, 1998, quinoxaline-label) /**TEF**	3.1	7.4	20 °C / 40 %	59.4 / 197.4	1	45.7 ****	0.961	SFO, ModelMaker
Sandy loam (Völkel, 1998, quinoxaline-label) /**TEF**	1.4	8.2	20 °C / 40 %	14.5 / 48.2	1	14.1 *****	0.968	SFO, ModelMaker
Loam (Völkel, 1998, quinoxaline-label) /**TEF**	1.8	5.0	20 °C / 40 %	10.4 / 34.5	1	8.0 *****	0.951	SFO, ModelMaker
Sandy loam (study FD7) /**ET**	2.1	7.5	10 °C / 40 %	54.5 / 181	0.925	24.8	0.970	SFO, ModelManager
Sandy loam (Study FD8) /**ET**	1.8	7.1	20 °C / 40 %	28.0 / 93.0	0.880	28.0	0.976	SFO, ModelManager

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Met: Quizalofop	Aerobic conditions							
Soil type /Origin	OC (%)	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	Molar f. f. k_{dp}/k_f from ester precursors	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam (Study FD9) /**ET**	2.5	7.1	10 °C / 40 %	74.3 / 247	0.863	33.8	0.961	SFO, ModelManager
Sandy loam (Study FD13) / **ET** ****	3.3	6.6	20 °C / 49 %	182/603	0.701	181.5	0.966	SFO, ModelManager
Silty clay loam (Study FD14) /**ET**	3.6	6.7	20 °C / 65 %	23.7 / 78.7	0.758	23.7	0.934	SFO, ModelManager
Clay loam (Study DF14) /**ET**	4.6	7.9	20 °C / 47 %	39.6 / 132	0.806	39.6	0.980	SFO, ModelManager
Loam (Mamouni 1999a) / **PROP**	2.02	7.18 #	20 °C / 40 %	7 / 24	*	7	0.9985	SFO
Loamy sand (Mamouni 1999a) / **PROP**	0.78	7.43 #	20 °C / 40 %	10 / 34	*	10	0.996	SFO
Sandy loam (Mamouni 1999a) / **PROP**	1.3	5.01 #	20 °C / 40 %	14 / 45	*	11.6	0.9894	SFO
Sandy loam (Dieterle 1987a) / **PROP**	2.5	6.9	22 °C / 60 %	39/128.4$	*	46.0		FO, ModelMaker
Loam (Dieterle 1987a) / **PROP**	3.2	7.5	22 °C / 60 %	31/102.6$	*	36.3		FO, ModelMaker
Loam (Dennis 1991b) / **PROP**	2.7	7.7	20 °C / 40 %	14.8 / 48.7@	*	16.0		FO, ModelMaker
Loam (Dennis 1991a) / **PROP**	2.7	7.7	Not considered for the risk assessment (see DAR p. 342) (same soil as Dennis 1999b)					

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Met: Quizalofop	Aerobic conditions							
Soil type /Origin	OC (%)	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	Molar f. f. k_{dp}/k_f from ester precursors	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
median						**24.25**		

* = Not available
** = Formation fraction from Quizalofop-P-tefuryl was assumed to be 1.0
*** = Mean formation fraction from Quizalofop-P-ethyl was informed to be 0.834
**** = Not considered acceptable in the DAR
***** = Values re-normalised to reference conditions based on the measured moisture content (in the DAR the moisture correction was made using default values)
# = pH in KCl
$ = geomean of three values for the same soil (different application rate and radiolabel position) sandy loam DT_{50}/ DT_{90} (d)= 30/98, 45/148, 44/146; loam soil DT_{50}/ DT_{90} (d) = 24/81, 38/127, 32/105.
@ = geomean of two values for the same soil (different application rate) DT_{50}/ DT_{90} (d) = 22/74, 10/32.

TEF = the study presented in the DAR of quizalofop-P-tefuryl
ET = the study presented in the DAR of quizalofop-P-ethyl
PROP = the study presented in the DAR of propaquizafop

Note: concerning the longest lab soil DT50 for quizalofop (182days) is was agreed during the expert meeting that no accumulation calculation was necessary considering the results from the available field studies (longest DT50 around 40 days) and the large number of lab studies with shorter DT50.

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Met: hydroxy-quizalofop	Aerobic conditions							
Soil type	OC (%)	pH (w)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	Molar f. f. k_{dp}/k_f from quizalofop	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy l. (Dzialo, 2004, phenyl-l.)/**TEF**	1.0	6.3	20 °C / 45 %	39.8 / 132.1	*	35.02 *****	0.993	SFO, ModelMaker
Sand (Dzialo, 2004, phenyl-label) /**TEF**	1.2	6.2	20 °C / 45 %	7.0 / 23.3	*	7.00 *****	0.984	SFO, ModelMaker
Loam (Dzialo, 2004, quinoxal.-label)/**TEF**	0.90	5.9	20 °C / 45 %	17.3 / 57.4	*	16.71 *****	0.969	SFO, ModelMaker
Clay l. (Dzialo, 2004, phenyl-label) /**TEF**	1.0	7.6	20 °C / 45 %	15.4 / 51.2	*	14.43 *****	0.984	SFO, ModelMaker
Sandy loam (Völkel, 1998, quinoxaline-label) /**TEF**	1.4	6.3	20 °C / 40 %	11.2 / 37.2	0.36	11.1 *****	0.967	SFO, ModelMaker
Silty clay l. (Völkel, 1998, quinoxaline-label) /**TEF**	3.1	7.4	20 °C / 40 %	69.4 / 230.4	0.36	53.3 *****	0.961	SFO, ModelMaker
Sandy loam (Völkel, 1998, quinoxaline-label) /**TEF**	1.4	8.2	20 °C / 40 %	12.3 / 40.9	0.36	11.9 *****	0.968	SFO, ModelMaker
Loam (Völkel, 1998, quinoxaline-label) /**TEF**	1.8	5.0	20 °C / 40 %	14.2 / 47.1	0.36	11.0 *****	0.951	SFO, ModelMaker
Sandy loam (Study FD8) /**ET**	1.8	7.1	20 °C / 40 %	45.8 / 152	0.32	45.8	0.986	SFO, ModelManager

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Met: hydroxy-quizalofop	Aerobic conditions							
Soil type	OC (%)	pH (w)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	Molar f. f. k_{dp}/k_f from quizalofop	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam (Study FD13) /**ET**	3.3	6.6	20 °C / 49 %	40.7 / 210	0.756	40.7	0.746	SFO, ModelManager
Sandy loam (Study FD9)**** /**ET**	2.5	7.1	10 °C / 40 %	47.5 / 158	0.436	21.7	0.967	SFO, ModelManager
Loam (Mamouni 1999a) / **PROP**	2.02	7.18 #	20 °C / 40 %	21 / 68	**	21	0.969	SFO
Loamy sand (Mamouni 1999a) / **PROP**	0.78	7.43 #	20 °C / 40 %	12 / 39	**	12	0.970	SFO
Sandy loam (Mamouni 1999a) / **PROP**	1.3	5.01 #	20 °C / 40 %	13 / 43	**	10.7	0.984	SFO
median						**15.6**		

* = not available
**= no formation fraction, DT50 equates to observed decline after maximum formation.
**** = the results of study FD9 were erroneously not reported in the LoEP presented in the DAR
***** = values re-normalised to reference conditions based on the measured moisture content (in the DAR the moisture correction was made using default values)
# = pH in KCl

TEF = the study presented in the DAR of quizalofop-P-tefuryl
ET = the study presented in the DAR of quizalofop-P-ethyl
PROP = the study presented in the DAR of propaquizafop

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Met: Dihydroxy quinoxaline	Aerobic conditions							
Soil type	OC (%)	pH (w)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	Molar f. f. k_{dp}/k_f from quizalofop	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam (Völkel, 1998, quinoxaline-label) /**TEF**	1.4	6.3	20 °C / 40 %	106.7 / 354.4	0.1 quizalofop	105.9 **	0.967	SFO, ModelMaker
Sandy loam (Völkel, 1998, quinoxaline-label) /**TEF**	1.4	8.2	20 °C / 40 %	68.9 / 228.8	0.1 quizalofop	66.7 **	0.968	SFO, ModelMaker
Loam (Völkel, 1998, quinoxaline-label) / **TEF**	1.8	5.0	20 °C / 40 %	258.1 / 857.5	0.1 quizalofop	199.9 **	0.951	SFO, ModelMaker
Sandy loam (Study FD13) /**ET**	3.3	6.6	20 °C / 49 %	55.5 / 184	1 hydroxy-quizalofop	55.5	0.587	SFO, ModelManager
Clay (Study FD17) /**ET**	5.2	7.9	20 °C / 44 %	102 / 337	****	102	0.996	SFO
Sandy loam (Study FD17) /**ET**	2.8	6.5	20 °C / 46 %	53 / 175	****	53	0.997	SFO
Silty clay loam (Study FD17) /**ET**	4.1	6.6	20 °C / 70 %	42 / 139	****	42	0.998	SFO
Loam (Mamouni 1999a) / **PROP**	2.02	7.18 #	20 °C / 40 %	54/180	*	36	.874	SFO
Loamy sand (Mamouni 1999a) / **PROP**	0.78	7.43 #	20 °C / 40 %	58/190	*	37	.95	SFO
Sandy loam (Mamouni 1999a) / **PROP**	1.3	5.01 #	20 °C / 40 %	63/209	*	40.6	.935	SFO

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Met: Dihydroxy quinoxaline	Aerobic conditions							
Soil type	OC (%)	pH (w)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	Molar f. f. k_{dp}/k_f from quizalofop	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
median						**54.3**		

* = no formation fraction, DT50 equates to observed decline after maximum formation.
** = Values re-normalised to reference conditions based on the measured moisture content (in the DAR the moisture correction was made using default values)
*** = Formation fraction from hydroxy-quizalofop of 1.0 % was used
**** = The study was conducted using dihydroxy-quinoxaline
# = pH in KCl

TEF = the study presented in the DAR of quizalofop-P-tefuryl
ET = the study presented in the DAR of quizalofop-P-ethyl
PROP = the study presented in the DAR of propaquizafop

Met: Hydroxy quinoxaline	Aerobic conditions						
Soil type	OC %	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Loam (Mamouni 1999a) / **PROP**	2.02	7.18#	20 °C / 40 %	46/154	46	0.832	SFO
Loamy sand (Mamouni 1999a) / **PROP**	0.78	7.43#	20 °C / 40 %	65/217	65	0.967	SFO
Sandy loam (Mamouni 1999a) / **PROP**	1.3	5.01#	20 °C / 40 %	71/235	59	0.947	SFO
geomean					56		

= pH in KCl

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

PROP = the study presented in the DAR of propaquizafop

Field studies ‡ no reliable data available for propaquizafop

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
No data available									
Geometric mean/median									

Field studies

Met: Quizalofop	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	OC (%)	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
Sandy loam, oil seed rape / **PROP**	Switzerland	3.0	7.9	10	31	103	n.a.	N.a.	1st order Timme and Frehse best-fit
Loamy sand, bare soil /**ET**	Germany	0.5	6.3	30	39.8	132	0.932	N.a.	SFO, ModelManager
Silty clay loam, bare soil /**ET**	France	1.2	7.8	30	33.6	112	0.953	N.a.	SFO, ModelManager
Silty loam sand, bare soil /**ET**	Spain	1.8	5.6	30	37.6	125	0.899	N.a.	SFO, ModelManager
Geometric mean/median									

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

N.a. = Not available
TEF = the study presented in the DAR of Quizalofop-P-tefuryl
ET = the study presented in the DAR of Quizalofop-P-ethyl
PROP = the study presented in the DAR of propaquizafop

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

Met: Hydroxy-quizalofop	Aerobic conditions								
Soil type	Location	OC (%)	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
Loamy sand, bare soil / **ET**	Germany	0.5	6.3	30	32.2	107	0.861	N.a.	SFO, ModelManager

ET = the study presented in the DAR of quizalofop-P-ethyl

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Propaquizafop
ADSORPTION KOC: As propaquizafop is highly unstable in soil, its adsorption and desorption characteristics cannot be determined). Estimated value based on log Kow, according to Briggs 1989, was 2220 mL/g
ADSORPTION KD : not determined

Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Arithmetic mean/median							

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

pH dependence (yes or no)	

Met: Quizalofop							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay /**TEF**	4.8	5.9			3.99	141	0.88
Sand /**TEF**	0.1	6.2			0.19	321	0.89
Sandy loam /**TEF**	3.1	6.3			8.69	477	0.78
Loam /**TEF**	0.8	6.7			0.62	133	0.85
Clay loam /**TEF**	5.1	8.1			4.9	332	0.71
Loam /**TEF**	0.1	6.1			10.6	356	0.69
Silty clay loam (pond sediment) /**TEF**	0.8	6.7			9.5*	1254*	0.72*
Sandy clay loam /**ET**	0.5	6.4			1.73	346	0.79
Sand /**ET**	2.0	5.3			4.23	212	0.79
Silty loam /**ET**	5.1	6.0			40.0	783	0.86
Light clay /**ET**	5.9	5.3			33.3	564	0.87
Loamy sand /**ET**	0.5	4.3			125	1782	0.8
Loamy sand /**ET**	7.0	3.1			9	1791	0.8
Clay /**ET**	3.9	6.0			8	214	0.8
Clay loam /**ET**	3.2	7.4			9	275	0.7
Sand /**PROP**	0.5	6.0			2.36	472	0.88
Silt loam /**PROP**	1.8	5.6			6.24	347	0.842
Clay-clay loam /**PROP**	2.4	7.3			9.29	387	0.822
Loam /**PROP**	1.2	6.9			5.27	439	0.855
median						356	0.811
pH dependence, Yes or No			No dependence				

* = This value has been considered as an outlier and it has not been taken into account in the calculation of the mean values. The test soil was a pond sediment, not an agricultural soil.

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

TEF = the study presented in the DAR of Quizalofop-P-tefuryl
ET = the study presented in the DAR of Quizalofop-P-ethyl
PROP = the study presented in the DAR of propaquizafop

Met: Hydroxy-quizalofop							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam /**TEF**	2.3	5.6	2.8	122			1
Loam /**TEF**	1.3	7.4	2.2	172			1
Clay loam /**TEF**	4.7	7.5	8.6	184			1
Loamy sand /**ET**	7.0	3.1			110	1567	0.8
Clay loam /**ET**	3.2	7.4			10	302	0.8
Clay /**ET**	3.9	6.0			5	129	0.8
Sandy silt loam /**PROP**	2.3	7.5			1.7	74.4	1.07
Sandy loam /**PROP**	1.0	7.5			0.8	78.5	1.06
Sandy loam /**PROP**	1.1	5.2			1.6	141.1	0.94
median						141.1	1.00
pH dependence (yes or no)			No dependence				

TEF = the study presented in the DAR of quizalofop-P-tefuryl
ET = the study presented in the DAR of quizalofop-P-ethyl
PROP = the study presented in the DAR of propaquizafop

Met: Dihydroxy quinoxaline							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam /**TEF**	2.3	5.6	11.0	480			1
Loam /**TEF**	1.3	7.4	11.5	901			1
Clay loam /**TEF**	4.7	7.5	68.6	1468			1
Loamy sand /**ET**	7.0	3.1			3	48	0.8
Clay loam /**ET**	3.2	7.4			22	694	0.7
Clay /**ET**	3.9	6.0			14	370	0.7

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Sandy silt loam /**PROP**	2.3	7.5			8.5	370.6	0.63
Sandy loam /**PROP**	1.0	7.5			5.5	547.7	0.59
Sandy loam /**PROP**	1.1	5.2			6.7	609.2	0.66
median						547.7	0.70
pH dependence (yes or no)			No dependence in the environmentally relevant soil pH range				

TEF = the study presented in the DAR of quizalofop-P-tefuryl
ET = the study presented in the DAR of quizalofop-P-ethyl
PROP = the study presented in the DAR of propaquizafop

Met: Quizalofop-phenol							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy silt loam /**PROP**	2.3	7.5			56.0	2433.1	1.02
Sandy loam /**PROP**	1.0	7.5			49.5	4945.2	0.83
Sandy loam /**PROP**	1.1	5.2			85.1	7740.8	1.12
median						4945.2	1.02
pH dependence (yes or no)			No dependence				

PROP = the study presented in the DAR of propaquizafop

Met: Hydroxy-quinoxaline
ADSORPTION KOC: Estimated value using th software programme PCKOCWIN (Version 1.66, EPA 2000), was 522.4 mL/g

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

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

Column leaching ‡	Eluation (mm): 504 mm (soils n=4) Time period (d): 7 d (soils n=4) Eluation (mm): 200 mm (soils n=3) Time period (d): 2 d (soils n=3)
	Leachate: 0.034-4.07 % total residues/radioactivity in leachate Levels of radioactivity present in the leachates were too low to permit chromatographic investigations as to the nature of the material present 17 to 62 % total residues/radioactivity retained in top 10 cm.
Aged residues leaching ‡	Aged for (d): 76 d (soil n=1) Time period (d): 2 d (soil n=1) Eluation (mm): 200 mm(soil n=1) Aged for (d): 30-31 d (soils n=2) Time period (d): 4-5 d (soils n=2) Eluation (mm): 508 mm(soils n=2)
	Analysis of soil residues post ageing (soil residues pre-leaching): 1.2-30 % propaquizafop, 31.1-52.9 % quizalofop, 7.5-19.3 % hydroxy-quizalofp, 0.5-5.5 % quizalofop-phenol
	Leachate: 0.1-0.4 % total residues/radioactivity in leachate Levels of radioactivity present in the leachates were too low to permit chromatographic investigations as to the nature of the material present >80 % total residues/radioactivity retained in top 12 cm
Lysimeter/ field leaching studies ‡	No data available. These studies were not performed because no evidence of leaching from laboratory experiments or computer modelling simulations was observed.

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

PEC (soil) (Annex IIIA, point 9.1.3)

Propaquizafop	
Parent: Propaquizafop Method of calculation	DT_{50} (d): 2.1 days Kinetics: SQRT 1.5th order Field or Lab: representative worst case from laboratory studies normalised to pF2 and to 20°C[1]
Application data	Crop: sugar beet and oilseed rape Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: 50 Number of applications: 1 Application rate(s): 200 g as/ha

[1]from normalisation of DT_{50} = 1.8 d (single DT_{50} value before averaging the values from the same soil with different radiolabeling position and/or application rate). As the rsik to soil organism was performed on the basis of the initial PEC value, deviations on the selection of the appropriate soil DT_{50} does not influence the final assessment in this case.

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.13			
Short term 24h	0.08	0.11		
2d	0.07	0.09		
4d	0.05	0.08		
Long term 7d	0.04	0.07		
28d	0.02	0.04		
50d	0.01	0.03		
100d	0.009	0.02		

Plateau concentration	Not required

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Met: Quizalofop				
Metabolite Quizalofop Method of calculation			Molecular weight relative to the parent: 344.8 g/mol It was agreed during the expert meeting PRAPeR 52 that the longest lab soil DT_{50} for quizalofop of 182 days, from the amalgamated list of endpoints, should be used for PECsoil calculations. PEC_{ini} value was used in the risk assessment for soil organism.	
Application data			Application rate assumed: 68.3 g as/ha (assumed quizalofop is formed at a maximum of 87.9 % of the applied dose) or formation fraction (if sequential modelling is employed)	
$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.09			
Plateau concentration	Not required			

Met: Hydroxy-quizalofop	
Metabolite Hydroxy propaquizafop acid Method of calculation	Molecular weight relative to the parent: 360.8 g/mol PEC_{ini} value was used in the risk assessment for soil organism. It was agreed during the expert meeting PRAPeR 52 that the longest lab soil DT_{50} for hydroxy-quizalofop of 53.3 days, from the amalgamated list of endpoints, should be used for PEC_{soil} calculations.
Application data	Application rate assumed: 11.14 g as/ha (assumed hydroxy propaquizafop acid is formed at a maximum of 32.6 % of the applied dose) or

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

		formation fraction (if sequential modelling is employed)		
PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.04			
Plateau concentration	Not required			

Met: Dihydroxy quinoxaline				
Metabolite Dihydroxy quinoxaline Method of calculation		Molecular weight relative to the parent: 196.6 g/mol PEC_{ini} value was used in the risk assessment for soil organism. It was agreed during the expert meeting PRAPeR 52 that the longest lab soil DT_{50} for dihydroxy-quinoxaline of 200 days, from the amalgamated list of endpoints, should be used for PECsoil calculations.		
Application data		Application rate assumed: 14.44 g as/ha (assumed dihydroxy quinoxaline is formed at a maximum of 13.7 % of the applied dose) or formation fraction (if sequential modelling is employed)		
PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.008			
Plateau concentration	Not required			

Met: Hydroxy quinoxaline	
Metabolite Hydroxy quinoxaline Method of calculation	Molecular weight relative to the parent: 180.6 g/mol DT_{50} (d): 71 days[1]

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

		Kinetics: SFO Field or Lab: representative worst case from laboratory studies.		
Application data		Application rate assumed: 3.58 g as/ha (assumed hydroxy quinoxaline is formed at a maximum of 8.8 % of the applied dose) or formation fraction (if sequential modelling is employed)		
PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.005			
Short term 24h	0.005	0.005		
2d	0.005	0.005		
4d	0.005	0.005		
Long term 7d	0.004	0.005		
28d	0.004	0.004		
50d	0.003	0.004		
100d	0.002	0.003		
	Plateau concentration	Not required		

[1]The appropriate DT_{50} value that should be used for PECsoil calculations should be 65 days (longest not normalised lab DT_{50}).

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: 10.5 d at 25 °C Met Aminooxyethyl ester: 74.9 % AR (21 d)
	pH 7: 32.0 days at 25 °C Met quizalofop: 49.9 % AR (30 d)
	pH 9: 0.54 days at 25 °C Met quizalofop: 80.5 % AR (21 d)

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Photolytic degradation of active substance and metabolites above 10 % ‡	**A data gap for photolytic half-lives for propaquizafop and quizalofop was identified in PRAPeR 52 meeting (not essential to finalise the assessment)** Natural light, 50°N; DT_{50} 32 days (annual averaged DT_{50} calculated with monthly averaged sun intensities) Propaquizafop acid (CGA 287422): 19.9-16.4% AR (3-11 d) Natural light, 50°N; DT_{50} 26 days Hydroxy ether (CGA 129674): 15-36.6% AR (7-11 d) Estimated DT_{50} at 50°N 32 days annual averaged DT_{50} calculated with monthly averaged sun intensities)
Quantum yield of direct phototransformation in water at Σ > 290 nm	Propaquizafop: 1.11 x 10^{-5} mol Einstein $^{-1}$ quizalofop (CGA 287422): 1.15 x 10^{-5} mol Einstein $^{-1}$
Readily biodegradable ‡ (yes/no)	Not ready biodegradable.

Degradation in water / sediment

Propaquizafop	**PROP:** Distribution: max. in water 75.7 % AR after 0 d. Max. sed. 20.03 % AR after 0 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. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
River, (quinoxal. l.) /**PROP**	7.05		20	< 1		< 1		< 1		
Pond, (quinoxal. l.) /**PROP**	6.77		20	< 1		< 1		< 1		
Geometric mean/median										

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Quizalofop	**TEF**: Distribution: max. in water 94 % AR after 1 d. Max. sed. 53 % AR after 14 d **ET:** Distribution: max. in water 83 % AR after 7 d. Max. sed. 43 % AR after 28 d **PROP:** Distribution: max. in water 90.2 % AR after 1 d. Max. sed. 45.4 % AR after 28 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	r^2	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
River, (phenyl-quinoxal. l.) /**TEF**	8.1	7.3	20	27–88	0.970	10–33	0.991	*	*	SFO
Pond, (phenyl-quinoxal. l.) /**TEF**	7.9	7.0	20	34–114	0.970	9.9 – 33	0.975	*	*	SFO
River, (phenyl. l.) /**TEF**	7.7	7.3	20	25–84	0.908	*	*	*	*	SFO
Pond, (phenyl l.) /**TEF**	7.6	7.1	20	35– 117	0.979	*	*	*	*	SFO
Mill Stream Pond /**ET**	8.3	7.9	10	54-83***	0.983	50-62***	0.987	61-104***	0.992	One comp. model
Iron Hatch Stream /**ET**	8.3	8.2	10	40-66***	0.991	38-53***	0.998	47-89***	0.965	One comp. model
Geometric mean				35		-		-		

* = not available ** = not performed *** = at 20 °C, not normalised in the DAR, dissipation in both experiments were biphasic (both phases individually 1st order) with the first phase being the slow phase and the calculated DT50 were before the inflection point (102 days in the 10 °C study)

TEF = the study presented in the DAR of quizalofop-P-tefuryl
ET = the study presented in the DAR of quizalofop-P-ethyl
PROP = thedata presented in the addendum to the DAR of propaquizafop are not peer reviewed

Note: data from the propaquizafop was excluded because is not peer reviewed

For the metabolites quizalofop, hydroxy-quizalofop, dihydroxy-quinoxaline, hydroxy-quinoxaline, quizalofop-phenol and dihydroxy-quinoxaline degradation rates from the water/sediment study are available in the final addendum to the DAR but are not peer reviewed.

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Dihydroxy quinoxaline	**PROP:** Distribution: max. in water 3.7 % AR after 119 d. Max. sed. 10 % AR after 56 d

Hydroxy propaquizafop acid	**PROP:** Distribution: max. in water 4.1 % AR after 56 d. Max. sed. 11.2 % AR after 56 d

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
River, (quinoxal. l.) /**PROP**	7.05		37.5% after 239 d	45.2% after 119 d	40% after 239 d
Pond, (quinoxal. l.) /**PROP**	6.77		31.6% after 239 d	46% after 239 d	46% after 239 d

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

Parent: Propaquizafop Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: Version 1.1 Molecular weight (g/mol): 443.9 Water solubility (mg/L): 0.63 mg/kg K_{OC} (L/kg): 2220 (estimated using Briggs equation from log Kow) DT_{50} soil (d): 3 days (Lab worst case value, as exact value could not be determined using 1st order kinetics. DT_{50} and DT_{90} <3 days. Degradation rates from the water/sediment study are available in the final addendum to the DAR but are not peer reviewed. Crop interception (%): Sugar beet and winter oil seed rape, minimal crop cover selected. For spring

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

	oil seed rape average crop cover selected. 0 % partitioning to top x cm layer of sediment, entry route as for surface water, pattern of decline reflecting that measured in the sediment/water study
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: SWASH v1.1, MACRO in FOCUS v4.4.2, PRZM in FOCUS v1.5.6, TOXSWA v2.1.1 Vapour pressure: 4.395 x 10^{-10} Pa (25°C) Kom/Koc: 2220 (estimated using Briggs equation from log Kow) 1/n: 0.9 (default)
Application rate	Crop: Sugar beet Crop interception: (adjusted within the model) Number of applications: 1 Interval (d): Not applicable Application rate(s): 200 g as/ha Application window: Step 1 and 2: March-May Step 3 -14 days from emergence date

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Propaquizafop Sugar beet	0 h	18.6744		373.7374	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU Propaquizafop Sugar beet	0 h	1.8393		23.7309	
Southern EU Propaquizafop Sugar beet	0 h	2.1381		47.4617	

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3 Propaquizafop Sugar beet	Ditch	0 h	1.045		0.094	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D4 Propaquizafop Sugar beet	Pond	0 h	0.042		0.006	
D4 Propaquizafop Sugar beet	Stream	0 h	0.877		0.036	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R1 Propaquizafop Sugar beet	Pond	0 h	0.042		0.007	
R1 Propaquizafop Sugar beet	Stream	0 h	0.723		0.064	
R3 Propaquizafop Sugar beet	Stream	0 h	1.021		0.110	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Application rate	Crop: Spring oilseed rape Crop interception: (adjusted within the model) Number of applications: 1 Interval (d): not applicable Application rate(s): 200 g as/ha Application window: Step 1 and 2: March-May Step 3 -14 days from emergence date

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Propaquizafop Spring oil seed rape	0 h	18.6744	---	373.7374	---

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU Propaquizafop Spring oil seed rape	0 h	1.8393	---	8.8991	---
	24 h				
	2 d				
	4 d				
	7 d				
	14 d				
	21 d				
	28 d				
	42 d				
Southern EU Propaquizafop Spring oil seed rape	0 h	1.8393	---	17.7982	---
	24 h				
	2 d				
	4 d				
	7 d				
	14 d				
	21 d				
	28 d				
	42 d				

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D1 Propaquizafop Spring oil seed rape	Ditch	0 h	1.277		0.159	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D1 Propaquizafop Spring oil seed rape	Stream	0 h	1.117		0.137	
D3 Propaquizafop Spring oil seed rape	Ditch	0 h	1.262		0.181	
D4 Propaquizafop Spring oil seed rape	Pond	0 h	0.044		0.006	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D4 Propaquizafop Spring oil seed rape	Stream	0 h	1.047		0.061	
D5 Propaquizafop Spring oil seed rape	Pond	0 h	0.044		0.007	
D5 Propaquizafop Spring oil seed rape	Stream	0 h	0.990		0.022	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R1 Propaquizafop Spring oil seed rape	Pond	0 h	0.044		0.008	
R1 Propaquizafop Spring oil seed rape	Stream	0 h	0.832		0.073	

Application rate	Crop: Winter oilseed rape Crop interception: (adjusted within the model) Number of applications: 1 Interval (d): not applicable

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Application rate(s): 200 g as/ha Application window: Step 1 and 2: March-May Step 3 -14 days from emergence date

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Propaquizafop Winter oil seed rape	0 h	18.6744	---	373.7374	---

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU Propaquizafop Winter oil seed rape	0 h	2.0044	---	44.4954	---
Southern EU	0 h	1.8393	---	35.5963	---

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Propaquizafop Winter oil seed rape					

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
			Actual	TWA	Actual	TWA
D2	Ditch	0 h	1.278		0.174	

Propaquizafop
Winter oil seed rape

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
			Actual	TWA	Actual	TWA
D2 Propaquizafop Winter oil seed rape	Stream	0 h	1.138		0.155	
D3 Propaquizafop Winter oil seed rape	Ditch	0 h	1.266		0.120	
D4	Pond	0 h	0.044		0.005	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
			Actual	TWA	Actual	TWA
Propaquizafop Winter oil seed rape						

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
			Actual	TWA	Actual	TWA
D4 Propaquizafop Winter oil seed rape	Stream	0 h	1.092		0.102	
D5 Propaquizafop Winter oil seed rape	Pond	0 h	0.044		0.005	
D5 Propaquizafop	Stream	0 h	1.178		0.120	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
			Actual	TWA	Actual	TWA
Winter oil seed rape						
R1 Propaquizafop Winter oil seed rape	Pond	0 h	0.044		0.005	
R1 Propaquizafop Winter oil seed rape	Stream	0 h	0.835		0.064	
R3 Propaquizafop	Stream	0 h	1.167		0.446	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
			Actual	TWA	Actual	TWA
Winter oil seed rape						

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Metabolite Quizalofop (CGA 287422) Parameters used in FOCUSsw step 1 and 2	Molecular weight: 344.8 Water solubility (mg/L): 7500 Soil or water metabolite: Both Koc (L/kg): 411.3 mL/g Mean value (n=4)* DT_{50} soil (d): 27 days Mean of recalculated Lab value (n=11). Values normalised where necessary in accordance with FOCUS)** Degradation rates from the water/sediment study presented in the propaquizafop DAR are available in the final addendum but are not peer reviewed. From the amalgamated LoEP, the geometric mean DT_{50} water/sediment system is 35 days Crop interception (%): Sugar beet and winter oil seed rape, minimal crop cover selected. For spring oil seed rape average crop cover selected. Maximum occurrence observed (% molar basis with respect to the parent) Soil: 87.9% Water: 90.2% Sediment: -
Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure: 5.7195×10^{-8} (estimated using MPBPWIN v1.422 (US EPA, 2000) Koc: 411.3 mL/g Mean value (n=4) 1/n: 0.85 Mean (n=4) Metabolite kinetically generated in simulation (yes/no): No Formation fraction in soil (k_{dp}/k_f): Not determined

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Application rate	Crop: sugar beet Number of applications: 1 Interval (d): not applicable Application rate(s): 140 g as/ha (adjusted accordingly, assuming the maximum percentage formation of 90.2%, and taking account of the difference in molecular weight between parent) Depth of water body: 30 cm Application window: Step 1 and 2: March-May Step 3 -14 days from emergence date
Main routes of entry	Spray drift; runoff

Based on the amalgamated list of endpoints for quizalofop metabolite, it was agreed during the experts' meeting PRAPeR 52 that the following :
*median Koc value of 356 L/kg, and the median 1/n value of 0.81
**median lab normalised soil DT_{50} of 24.3 days,
should be used for FOCUS modelling.
It was agreed that re-calculations are not required in this case.

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Quizalofop (CGA 287422) Sugar beet	0h	30.6853		120.9081	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU Quizalofop (CGA 287422) Sugar beet	0 h	5.1313		20.1931	
Southern EU Quizalofop (CGA 287422) Sugar beet	0 h	9.3757		37.3205	

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3 Quizalofop (CGA 287422) Sugar beet	Ditch	0 h	0.733		0.362	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D4 Quizalofop (CGA 287422) Sugar beet	Pond	0 h	0.0303		0.102	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D4 Quizalofop (CGA 287422) Sugar beet	Stream	0 h	0.616		0.0406	
R1 Quizalofop (CGA 287422) Sugar beet	Pond	0 h	0.106		0.401	
R1 Quizalofop (CGA 287422) Sugar beet	Stream	0 h	1.115		0.442	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R3 Quizalofop (CGA 287422) Sugar beet	Stream	0 h	1.559		0.986	

Application rate	Crop: Spring oilseed rape Number of applications: 1 Interval (d): not applicable Application rate(s): 140 g as/ha (adjusted accordingly, assuming the maximum percentage formation of 90.2%, and taking account of the difference in molecular weight between parent) Depth of water body: 30 cm Application window: Step 1 and 2: March-May Step 3 -14 days from emergence date
Main routes of entry	Spray drift; runoff

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Quizalofop (CGA 287422) Spring Oilseed rape	0h	30.6853		120.9081	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU Quizalofop (CGA 287422) Spring Oilseed rape	0 h	2.4785		9.5315	
Southern EU Quizalofop (CGA 287422) Spring Oilseed rape	0 h	4.0702		15.9285	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D1 Quizalofop (CGA 287422) Spring Oilseed rape	Ditch	0 h	0.973		2.352	
D1 Quizalofop (CGA 287422) Spring Oilseed rape	Stream	0 h	0.786		0.728	
D3 Quizalofop	Ditch	0 h	0.886		0.438	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
(CGA 287422) Spring Oilseed rape						
D4 Quizalofop (CGA 287422) Spring Oilseed rape	Pond	0 h	0.0310		0.104	
D4 Quizalofop (CGA 287422) Spring Oilseed rape	Stream	0 h	0.735		0.062	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D5 Quizalofop (CGA 287422) Spring Oilseed rape	Pond	0 h	0.0315		0.115	
D5 Quizalofop (CGA 287422) Spring Oilseed rape	Stream	0 h	0.695		0.0208	
R1 Quizalofop (CGA 287422) Spring Oilseed rape	Pond	0 h	0.0970		0.384	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R1 Quizalofop (CGA 287422) Spring Oilseed rape	Stream	0 h	1.115		0.440	

Application rate	Crop: Winter oilseed rape Number of applications: 1 Interval (d): not applicable Application rate(s): 140 g as/ha (adjusted accordingly, assuming the maximum percentage formation of 90.2%, and taking account of the difference in molecular weight between parent) Depth of water body: 30 cm Application window: Step 1 and 2: October-February Step 3 -14 days from emergence date
Main routes of entry	Spray drift; runoff

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Quizalofop (CGA 287422) Winter Oilseed rape	0h	30.6853		120.9081	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU Quizalofop (CGA 287422) Winter Oilseed rape	0 h	8.8452		35.1383	
Southern EU Quizalofop (CGA 287422) Winter Oilseed rape	0 h	7.2535		28.7224	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D2 Quizalofop (CGA 287422) Winter Oilseed rape	Ditch	0 h	0.942		2.049	
D2 Quizalofop (CGA 287422) Winter Oilseed rape	Stream	0 h	0.819		1.688	
D3 Quizalofop	Ditch	0 h	0.889		0.581	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
(CGA 287422) Winter Oilseed rape						
D4 Quizalofop (CGA 287422) Winter Oilseed rape	Pond	0 h	0.104		0.598	
D4 Quizalofop (CGA 287422) Winter Oilseed rape	Stream	0 h	0.767		0.304	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D5 Quizalofop (CGA 287422) Winter Oilseed rape	Pond	0 h	0.0349		0.190	
D5 Quizalofop (CGA 287422) Winter Oilseed rape	Stream	0 h	0.827		0.200	
R1 Quizalofop (CGA 287422) Winter Oilseed rape	Pond	0 h	0.0339		0.201	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R1 Quizalofop (CGA 287422) Winter Oilseed rape	Stream	0 h	0.681		0.183	
R3 Quizalofop (CGA 287422) Winter Oilseed rape	Stream	0 h	1.962		1.302	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Metabolite Hydroxy-quizalofop (CGA 294972) Parameters used in FOCUSsw step 1 and 2	Molecular weight: 360.8 g/mol Water solubility (mg/L): 36.3 (estimated using EPIWIN v3.1, EPA, 2000) Soil or water metabolite: Both Koc (L/kg): 98 (mean, n=3)* DT_{50} soil (d): 10 days (Mean lab value normalised in accordance with FOCUS)** Degradation rates from the water/sediment study are available in the final addendum to the DAR but are not peer reviewed. Crop interception (%):Sugar beet and winter oil seed rape, minimal crop cover selected. For spring oil seed rape average crop cover selected Maximum occurrence observed (% molar basis with respect to the parent) Soil: 32.6% Water: <5% Sediment: 11.2%
Parameters used in FOCUSsw step 3 (if performed)	Not applicable
Application rate	Crop: sugar beet Number of applications: 1 Interval (d): not applicable Application rate(s): 200 g as/ha Depth of water body: 30 cm Application window: March-May
Main routes of entry	Spray drift; runoff

Based on the amalgamated list of endpoints for hydroxy-quizalofop metabolite, it was agreed during the experts' meeting PRAPeR 52 that::
*the median Koc value of 141 L/kg,
**the median lab normalised soil DT_{50} of 15.6 days,
should be used for FOCUS modelling.
It was agreed that re-calculations are not required in this case.

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Hydroxy-quizalofop (CGA 294972) Sugar beet	0h	15.7908		15.3108	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU Hydroxy-quizalofop (CGA 294972) Sugar beet	0 h	2.0438		1.9820	
Southern EU Hydroxy-quizalofop (CGA 294972) Sugar beet	0 h	3.9382		3.8243	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA

Application rate	Crop: Spring oilseed rape Number of applications: 1 Interval (d): Not applicable Application rate(s): 200 g as/ha Depth of water body: 30 cm Application window: March-May
Main routes of entry	Spray drift; runoff

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Hydroxy-quizalofop (CGA 294972) Spring oilseed rape	0h	15.7908		15.3108	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.8598		0.8305	
Hydroxy-quizalofop (CGA 294972)					
Spring oilseed rape					
Southern EU	0 h	1.5702		1.5214	
Hydroxy-quizalofop (CGA 294972)					
Spring oilseed rape					

Application rate	Crop: Winter oilseed rape Number of applications: 1 Interval (d): not applicable Application rate(s): 200 g as/ha Depth of water body: 30 cm Application window: October-February
Main routes of entry	Spray drift; runoff

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Hydroxy-quizalofop (CGA 294972) Winter oilseed rape	0h	15.7908		15.3108	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU Hydroxy-quizalofop (CGA 294972) Winter oilseed rape	0 h	3.7014		3.5940	
Southern EU Hydroxy-quizalofop (CGA 294972) Winter oilseed rape	0 h	2.9910		2.9031	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA

Metabolite Dihydroxy quinoxaline (CGA 294970) Parameters used in FOCUSsw step 1 and 2	Molecular weight: 196.6 Water solubility (mg/L): 494 estimated using EPIWIN v 3.1 (EPA, 2000) Soil or water metabolite: Both Koc (L/kg): 509.2 (mean, n=3)* DT_{50} soil (d): 39 days (Lab mean (n=3), after normalisation in accordance with FOCUS)** Degradation rates from the water/sediment study are available in the final addendum to the DAR but are not peer reviewed. Crop interception (%):Sugar beet and winter oil seed rape, minimal crop cover selected. For spring oil seed rape average crop cover selected Maximum occurrence observed (% molar basis with respect to the parent) Soil: 13.7 Water: <5% Sediment: 10%
Parameters used in FOCUSsw step 3 (if performed)	Not applicable
Application rate	Crop: sugar beet Number of applications: 1 Interval (d): not applicable Application rate(s): 200 g as/ha Depth of water body: 30 cm Application window: March-May
Main routes of entry	Spray drift; runoff

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Based on the amalgamated list of endpoints for dihydroxy-quinoxaline metabolite, it was agreed during the experts' meeting PRAPeR 52 that:
*the median Koc value of 547.7 L/kg,
**the median lab normalised soil DT_{50} of 54.3 days,
should be used for FOCUS modelling.
It was agreed that re-calculations are not required in this case.

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Dihydroxy quinoxaline (CGA 294970) Sugar beet	0h	2.4908		12.2683	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU Dihydroxy quinoxaline (CGA 294970) Sugar beet	0 h	0.4132		2.0487	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	0.7722		3.8610	
Dihydroxy quinoxaline (CGA 294970)					
Sugar beet					

Application rate	Crop: Spring oilseed rape Number of applications: 1 Interval (d): not applicable Application rate(s): 200 g as/ha Depth of water body: 30 cm Application window: March-May
Main routes of entry	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Dihydroxy quinoxaline (CGA 294970) Spring oilseed rape	0h	2.4908		12.2683	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU Dihydroxy quinoxaline (CGA 294970) Spring oilseed rape	0 h	0.1888		0.9161	
Southern EU Dihydroxy quinoxaline (CGA 294970) Spring oilseed rape	0 h	0.3234		1.5956	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA

Application rate	Crop: Winter oilseed rape Number of applications: 1 Interval (d): not applicable Application rate(s): 200 g as/ha Depth of water body: 30 cm Application window: October-February
Main routes of entry	Spray drift; runoff

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Dihydroxy quinoxaline (CGA 294970) Winter oilseed rape	0h	2.4908		12.2683	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.7273		3.6344	
Dihydroxy quinoxaline (CGA 294970)					
Winter oilseed rape					
Southern EU	0 h	0.5927		2.9548	
Dihydroxy quinoxaline (CGA 294970)					
Winter oilseed rape					

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Metabolite Hydroxy quinoxaline (CGA 290291) Parameters used in FOCUSsw step 1 and 2	Molecular weight: 180.6 Water solubility (mg/L): 1009 estimated using EPIWIN v 3.1 (EPA, 2000) Soil or water metabolite: both Koc/Kom (L/kg): 522.4 estimated usingPCKOCWIN v 1.66 DT_{50} soil (d): 41 days (Lab mean (n=3) after normalisation in accordance with FOCUS) Degradation rates from the water/sediment study are available in the final addendum to the DAR but are not peer reviewed. Crop interception (%):Sugar beet and winter oil seed rape, minimal crop cover selected. For spring oil seed rape average crop cover selected Maximum occurrence observed (% molar basis with respect to the parent) Soil: 8.8 Water: - < 5 Sediment: 6.4
Parameters used in FOCUSsw step 3 (if performed)	Not applicable
Application rate	Crop: sugar beet Number of applications: 1 Interval (d): not applicable Application rate(s): 200 g as/ha Depth of water body: 30 cm Application window: March-May
Main routes of entry	Spray drift; runoff

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Hydroxy quinoxaline (CGA 290291) Sugar beet	0h	1.4548		7.3496	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU Hydroxy quinoxaline (CGA 290291) Sugar beet	0 h	0.2415		1.2237	
Southern EU Hydroxy quinoxaline (CGA 290291) Sugar beet	0 h	0.4519		2.3090	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA

Application rate	Crop: Spring oilseed rape Number of applications: 1 Interval (d): not applicable Application rate(s): 200 g as/ha Depth of water body: 30 cm Application window: March-May
Main routes of entry	Spray drift; runoff

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Hydroxy quinoxaline (CGA 290291) Spring oilseed rape	0h	1.4548		7.3496	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.1100		0.5454	
Hydroxy quinoxaline (CGA 290291)					
Spring oilseed rape					
Southern EU	0 h	0.1889		0.9524	
Hydroxy quinoxaline (CGA 290291)					
Spring oilseed rape					

Application rate	Crop: Winter oilseed rape Number of applications: 1 Interval (d): not applicable Application rate(s): 200 g as/ha Depth of water body: 30 cm Application window: October- February
Main routes of entry	Spray drift; runoff

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Hydroxy quinoxaline (CGA 290291) Winter oilseed rape	0h	1.4548		7.3496	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU Hydroxy quinoxaline (CGA 290291) Winter oilseed rape	0 h	0.4256		2.1734	
Southern EU Hydroxy quinoxaline (CGA 290291) Winter oilseed rape	0 h	0.3467		1.7664	

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – PELMO 3.3.2 Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: PELMO 3.3.2 Scenarios (list of names): -sugar beet: Chateaudun, Hamburg, Jokioinen, Kremsmunster, Okehampton, Piacenza, Porto, Sevilla, Thiva. - spring oilseed rape: Jokioinen, Okehampton, Piacenza, - winter oilseed rape: Chateaudun, Hamburg, Kremsmunster, Okehampton, Piacenza, Porto, Crops: sugar beet, spring and winter oilseed rape Crop interception: sugar beet 20%, oilseed rape (spring) 80%, oilseed rape (winter) 40%. Parent: Propaquizafop DT_{50lab}: 3 d (max worse case assumption of 1.8 d normalisation to pF2, 20 °C with Q10 of 2.2). K_{OC}: 2200 ml/g (estimated), $^1/_n$= 0.9 (default) Metabolite Quizalofop (CGA 287422): DT_{50lab}: 27 d Recalculated mean (n=11) normalised to pF2 and 20°C with Q10 of 2.2. K_{OC}: 411.3 ml/g, $^1/_n$= 0.85 Mean (n=4) Metabolite hydroxy propaquizafop acid (CGA 294972): DT_{50lab}: 10 d mean (n=3) normalised to pF2. K_{OC}: 98 ml/g, $^1/_n$= 1.02 Mean (n=3) Metabolite dihydroxy quinoxaline (CGA 294970): DT_{50lab}: 39 d mean (n=3) normalised to pF2. K_{OC}: 509.2 ml/g, $^1/_n$= 0.63 Mean (n=3) Metabolite hydroxy quinoxaline (CGA 290291): DT_{50lab}: 41 d mean (n=3) normalised to pF2. K_{OC}: 522.4 ml/g estimated PCKOCWIN Ver 1.66 USEPA, $^1/_n$= 0.9 (default) Metabolite quizalofop-phenol (CGA 129674):

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

	Taking into consideration that quizalofop-phenol is strongly adsorbed to soil particles (Koc = 2433-7741 mL/g), the experts from MS in PRAPeR 52 agreed that in this case the potential for groundwater contamination of this metabolite is not necessary.
Application rate	Application rate: 200 g/ha. No. of applications: 1 Time of application (month or season): Sugar beet: 15th March Spring oilseed rape : 15 March Winter oilseed rape: 30th November:

[1] Based on the amalgamated list of endpoints for QUIZ, QUIZ-OH and CHHQ metabolites, it was agreed during the expert meeting PRAPeR 52 that the following input values should be used in FOCUS modelling:
Quizalofop:
- DT_{50}lab: 24.3 d (median, normalisation to 10 kPa/ pF2 and 20 °C with Q10 of 2.2).
- Koc: 356, 1/n: 081 (median values)

Hydroxy-quizalofop:
- DT_{50}lab: 15.6 d (median, normalisation to 10 kPa/ pF2 and 20 °C with Q10 of 2.2).
- Koc: 141, 1/n: 1.0 (mean value from two soils at environmentally relevant pHs, 6.0 and 7.4)

Dihydroxy-quinoxaline:
- DT_{50}lab: 54.3 d (median, normalisation to 10 kPa/ pF2 and 20 °C with Q10 of 2.2).
- Koc: 548, 1/n: 0.70 (the worst case value)

However, based on the available PECgw results and due to the fact that the used input parameters are generally worst cases, the experts agreed that no PECgw recalculations are necessary for the applied for intended uses.

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

	Scenario	Propaquizafop (µg/L)	Metabolite (µg/L)			
			Quizalofop	Hydroxy-quizalofop	Dihydroxy quinoxaline	Hydroxy quinoxaline
Pelmo / Sugar beet	Chateaudun	<0.001	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmunster	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	<0.001

	Scenario	Propaquizafop (µg/L)	Metabolite (µg/L)			
			Quizalofop	Hydroxy-quizalofop	Dihydroxy quinoxaline	Hydroxy quinoxaline
Pelmo / Oliseed rape (Spring)	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001	<0.001

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

	Scenario	Propaquizafop (µg/L)	Metabolite (µg/L)			
			Quizalofop	Hydroxy-quizalofop	Dihydroxy quinoxaline	Hydroxy quinoxaline
Pelmo / Oliseed rape (Winter)	Chateaudun	<0.001	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	0.002	<0.001	<0.001
	Kremsmunster	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	0.003	<0.001	<0.001
	Piacenza	<0.001	<0.001	0.007	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001	<0.001

PEC$_{(gw)}$ From lysimeter / field studies

No data required

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

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

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

Direct photolysis in air ‡	Not studied -
Quantum yield of direct phototransformation	Propaquizafop: 1.11 x 10^{-5} Quizalofop (CGA 287422):1.15 x 1^{-5}
Photochemical oxidative degradation in air ‡	Propaquizafop: DT_{50} of 0.6 d Quizalofop (CGA 287422): 0.7 d derived by the Atkinson model (version 1.82). OH (12 or 24 h) concentration assumed = 5 x 10^5 cm^{-3}
Volatilisation ‡	from plant surfaces (BBA guideline): insignificant

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

	losses within hours
	from soil surfaces (BBA guideline): <0.1% of the applied does
Metabolites	None

PEC (air)

Method of calculation	Not applicable

PEC$_{(a)}$

Maximum concentration	Negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	The residue definition of propaquizafop includes both R and S isomers as there is no current method available to separate the isomers. The same applies to quizalofop. Soil: propaquizafop; quizalofop (CGA 287422); dihydroxy quinoxaline (CGA 294970); hydroxy - quizalofop (CGA 294972). Groundwater: propaquizafop; quizalofop (CGA 287422); dihydroxy quinoxaline (CGA 294970); hydroxy-quizalofop (CGA 294972); quizalofop-phenol (CGA 129674); Hydroxy quinoxaline(CGA 290291). Surface water: propaquizafop; quizalofop (CGA 287422); (from soil run off and drainage) dihydroxy quinoxaline (CGA 294970); hydroxy-quizalofop (CGA 294972). Sediment: propaquizafop; dihydroxy quinoxaline (CGA 294970); hydroxy-quizalofop (CGA 294972; quizalofop (CGA 287422). Air: propaquizafop.

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

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

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

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

Candidate for R53

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

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

Species	Test substance	Time scale	Endpoint[1] (mg/kg bw/day)	Endpoint[1] (mg/kg feed)
Birds ‡				
Bobwhite Quail	a.s.	Acute	LD50>2000 mg a.s./kg bw	not relevant*
Japanese quail	Preparation	Acute (limit test)	LD50 > 2000 mg form/Kg bw	not relevant*
	Metabolite 1	Acute	no data available – not required	
Mallard duck	a.s.	Short-term	LC50>827[+]	>6593 mg
Bobwhite quail	a.s.	Long-term	NOEC ≥20.2	≥250 mg
Mammals ‡				
Mouse	a.s.	Acute	3009 mg a.s./kg bw	not relevant*
	Preparation	Acute	no data available – not required	no data available – not required
	Metabolite 1	Acute	no data available – not required	no data available – not required
Rat (two-generation)	a.s.	Long-term (NOAEL)	15 mg a.s./kg bw/d	Not #
[1] Lowest endpoint in cases of several studies * Single oral dose, unit "mg/kg feed" not relevant [+] corrected according to Evaluation Table, Open point 5.2 # Diets were adjusted weekly based on the previous week's body weights, hence recalculation to endpoint in "(mg/kg feed)" not appropriate				
Additional higher tier studies ‡				

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

Leafy crops (sugar beet, oilseed rape), 0.2 kg a.s./ha

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Medium herbivorous	Acute	13.2	>152	10
Small insectivorous	Acute	10.8	>185	10
Medium herbivorous	Short-term	6.1	>131	10
Small insectivorous	Short-term	6.0	>134	10
Medium herbivorous	Long-term	3.2	6.2	5
Small insectivorous	Long-term	6.0	**3.3**	5
Higher tier refinement (Birds) Open point in the Evaluation table				
	Acute	not needed	not needed	10
	Short-term	not needed	not needed	10
Small insectivorous	Long-term	1.362	14.8	5
Tier 1 (Mammals)				
Medium herbivorous	Acute	4.9	614	10
Medium herbivorous	Long-term	1.2	13	5
Higher tier refinement (Mammals)				
	Acute	not needed	not needed	10
	Long-term	not needed	not needed	5

Risk to birds and mammals from consumption of contaminated drinking water

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Small insectivorous	Acute	54	>37	10
Tier 1 (Mammals)				
Small insectivorous	Acute	3009	94	10

Risk to birds and mammals from secondary poisoning

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Earthworms eating	Long-term	0.598	33.8	5
Fish eating	Long-term	7.71	2620	5
Tier 1 (Mammals)				
Earthworms eating	Long-term	0.343	43.7	5
Fish eating	Long-term	4.77	314	5

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

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

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity (mg a.s./L)
Laboratory tests ‡				
Fish				
Mirror carp *Cyprinus carpio*	Propaquizafop technical	96 hr (flow-through)	Mortality, LC_{50}	0.19
Rainbow trout *Oncorhynchus mykiss*	Propaquizafop technical	28 d (ELS) Flow through	Growth NOEC	**0.019**
Common carp *Cyrpinus carpio*	Preparation	96 hr (flow-through)	Mortality, LC_{50}	**0.11**
	Preparation	28 d (flow-through)	Growth NOEC	No data available – not required
Rainbow trout *Oncorhynchus mykiss*	Quizalofop	96 hr Static test	Mortality, LC_{50}	>100 nom[a]
Rainbow trout *Oncorhynchus mykiss*	Quizalofop	28 d (flow-through)	NOEC	46.2 mm[b]
Rainbow trout *Oncorhynchus mykiss*	Hydroxy quizalofop	96 hr Static test	Mortality, LC_{50}	>100 mm[a]
Rainbow trout *Oncorhynchus mykiss*	Dihydroxy quinoxaline	96 hr Static test	Mortality, LC_{50}	>11.2 mm[a]
Rainbow trout *Oncorhynchus mykiss*	Quizalofop phenol	96 hr Static test	Mortality, LC_{50}	1.3 mm[a]
Rainbow trout *Oncorhynchus mykiss*	Hydroxy quinoxaline	96 hr Static test	Mortality, LC_{50}	15.6 mm[a]
Aquatic invertebrates				
Daphnia magna	Propaquizafop technical	48 h (static)	Immobilisation, EC_{50}	>0.9
Daphnia magna	Propaquizafop technical	21 d (flow-through)	Reproduction, NOEC	**0.44**
Daphnia magna	Propaquizafop, formulated as a 100g/l EC	48 h (static)	Immobilisation, EC_{50}	**0.24**

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity (mg a.s./L)
	Preparation	21 d (static)	Reproduction, NOEC	No data available – not required
Daphnia magna	Quizalofop	48 h (static)	Immobilisation, EC_{50}	57.7 mm[b]
Daphnia magna	Quizalofop	21 d (semistatic)	Reproduction, NOEC	0.82 mm[b]
Daphnia magna	Hydroxy quizalofop	48 h (static)	Immobilisation, EC_{50}	>100 nom[a]
Daphnia magna	Dihydroxy quinoxaline	48 h (static)	Immobilisation, EC_{50}	>9.8 mm[a]
Daphnia magna	Quizalofop phenol	48 h (static)	Immobilisation, EC_{50}	2.8 mm[a]
Daphnia magna	Hydroxy quinoxaline	48 h (static)	Immobilisation, EC_{50}	>19.2 mm[a]
Sediment dwelling organisms				
	a.s.	28 d (static)	NOEC	No data available – not required
Chironomus riparius	Metabolite Quizalofop	28 d (static) Water spiked sys.	NOEC	35.7 nom[b]
Chironomus riparius	Metabolite Quizalofop phenol	28 d (static) Sediment spiked sys.	NOEC	10 nom[b] (mg a.s./kg)
Chironomus riparius	Metabolite Dihydroxy quinoxaline	28 d (static) Sediment spiked sys.	NOEC	> 1.48 mm[c] (mg a.s./kg)
Algae				
Pseudokirchneriella subcapitata	Propaquizafop, technical	72 h (static)	Biomass: 96h E_bC_{50} Growth rate: 96h E_rC_{50}	>2.1 >2.1
Second algae species [1]		72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	Not available Required at MS level [2]

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity (mg a.s./L)
Scenedesmus subspicatus	Preparation	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.27 **0.15**
Pseudokirchneriella subcapitata	Metabolite Quizalofop	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	54.5 mm[b]
Pseudokirchneriella subcapitata	Metabolite Hydroxy quizalofop	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>100 nom[a] >100 nom
Scenedesmus subspicatus	Metabolite Dihydroxy quinoxaline	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>8.6 mm[a] >8.6 mm
Scenedesmus subspicatus	Metabolite Quizalofop phenol	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	4.5 nom[a] Growth rate not reported
Scenedesmus subspicatus	Metabolite Hydroxy quinoxaline	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>18.8 mm[a] >18.8 mm
Higher plant				
Lemna gibba	Propaquizafop technical	7 d test (static)	Fronds, EC_{50}	>**1.4**
Lemna gibba	Preparation	14 d (static)	Fronds, EC_{50}	Not available Required at MS level[2]
Lemna gibba	Metabolite Quizalofop	14 d (static)	Fronds, EC_{50} NOEC	28 nom[c] 3.2 nom
Glyceria fluitans	Metabolite Quizalofop	14 d (static)	Fronds, EC_{50} NOEC	> 0.190[a] 0.094
Microcosm or mesocosm tests Not required. A low level of risk to aquatic organisms expected following the recommended use of products containing propaquizafop, based on the current GAP.				

1) A test on a second algal species was a level 4 requirement (open point 5.5, Evaluation Table)
2) A test on higher plant with the formulation on MS level was a level 4 requirement (open point 5.5, Evaluation Table)
a) Endpoint from propaquizafop DAR
b) Endpoint from quizalofop-P-ethyl DAR

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

c) Endpoint from quizalofop-P-tefuryl DAR

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

FOCUS Step1

200 g a.s.-ha (all uses)

Test substance [1]	Organism	Toxicity endpoint (mg/L) [1]	Time scale	PEC_i (µg/L)	TER	Annex VI Trigger
Product	Fish	0.11	Acute	18.67	**5.9**	100
a.s.	Fish	0.019	Chronic	18.67	**1**	10
Product	Aquatic invertebrates	0.24	Acute	18.67	**12.9**	100
a.s.	Aquatic invertebrates	0.44	Chronic	18.67	23.6	10
Product	Algae		Chronic	18.67		10
a.s.	Higher plants	>1.4	Chronic	18.67	>75	10
Quizalofop	Fish	>100	Acute	30.69	>3258	100
Quizalofop	Fish	46.2	Chronic	30.69	1505 [2]	10
Quizalofop	Aquatic invertebrates	57.7	Acute	30.69	1880	100
Quizalofop	Aquatic invertebrates	0.82	Chronic	30.69	27 [2]	10
Quizalofop	Algae	54.5	Acute	30.69	1776	10
Quizalofop	Higher plants (*G. fluitans)*	0.094	Chronic	30.69	**3.1**	10
Quizalofop	Higher plants (Lemna)	3.2	Chronic	30.69	104	10
Quizalofop	Sediment dwellers	35.7	Chronic	30.69	1163	10
Hydroxy quizalofop	Fish	>100	Acute	15.79	>6333	100
Hydroxy quizalofop	Aquatic invertebrates	>100	Acute	15.79	>6333	100
Hydroxy quizalofop	Algae	>100	Acute	15.79	>6333	10
Dihydroxy quinoxaline	Fish	>11.2	Acute	2.49	>4498	100

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Test substance [1]	Organism	Toxicity endpoint (mg/L) [1]	Time scale	PEC_i (µg/L)	TER	Annex VI Trigger
Dihydroxy quinoxaline	Aquatic invertebrates	>9.8	Acute	2.49	>3936	100
Dihydroxy quinoxaline	Algae	>8.6	Acute	2.49	>3454	10
Dihydroxy quinoxaline	Sediment dwellers	>1.48[3] mg/kg	Chronic	12.3 mg/kg	120	10
Quizalofop phenol	Considered minor metabolite (see definition of the residue above)					
Hydroxy quinoxaline	Fish	15.6	Acute	1.45	10759	100
Hydroxy quinoxaline	Aquatic invertebrates	>19.2	Acute	1.45	>13241	100
Hydroxy quinoxaline	Algae	>18.8	Acute	1.45	>12966	10

[1] Lowest endpoint (active substance or preparation)
Values in bold are lower than Annex VI 91/414/EEC triggers (10 or 100), indicating that further assessment is required

[2] TER calculated using PEC_i

[3] Sediment spiked study

FOCUS Step 2

Sugar beet, 200 g a.s./ha, BBCH 12 -39, Northern and Southern Europe

Test substance [1]	N/S	Organism	Toxicity endpoint (mg/L) [1]	Time scale	PEC max (µg/L)	TER	Annex VI Trigger
Product	N	Fish	0.11	Acute	1.84	**59.8**	100
a.s.	N	Fish	0.019	Chronic	1.84	**10.3**	10
Product	N	Daphnia	0.24	Acute	1.84	130.4	100
a.s.	N	Daphnia	0.44	Chronic	1.84	239.1	10
Product	N	Algae		Chronic	1.84		10
a.s.	N	Higher plants	>1.4	Chronic	1.84	>761	10
Quizalofop	N	Higher plants	0.094	Chronic	5.13	18	10
Product	S	Fish	0.11	Acute	2.14	**51.4**	100
a.s.	S	Fish	0.019	Chronic	2.14	**8.9**	10

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Test substance [1]	N/S	Organism	Toxicity endpoint (mg/L) [1]	Time scale	PEC max (µg/L)	TER	Annex VI Trigger
Product	S	Daphnia	0.24	Acute	2.14	112.1	100
a.s.	S	Daphnia	0.44	Chronic	2.14	205.6	10
Product	S	Algae		Chronic	2.14		10
a.s.	S	Higher plants	>1.4	Chronic	2.14	>654	10
Quizalofop	S	Higher plants	0.094	Chronic	9.38	**10**	10

[1] Lowest endpoint (active substance or preparation)
Values in bold are lower than Annex VI 91/414/EEC triggers (10 or 100), indicating that further assessment is required

Spring oilseed rape (spring), 200 g a.s./ha, BBCH 21 -39, Northern and Southern Europe

Test substance [1]	N/S	Organism	Toxicity endpoint (mg/L) [1]	Time scale	PEC max (µg/L)	TER	Annex VI Trigger
Product	N	Fish	0.11	Acute	1.84	**59.8**	100
a.s.	N	Fish	0.019	Chronic	1.84	**10.3**	10
Product	N	Daphnia	0.24	Acute	1.84	130.4	100
a.s.	N	Daphnia	0.44	Chronic	1.84	239.1	10
Product	N	Algae		Chronic	1.84		10
a.s.	N	Higher plants	>1.4	Chronic	1.84	>761	10
Quizalofop	N	Higher plants	0.094	Chronic	2.48	38	10
Product	S	Fish	0.11	Acute	1.84	**59.8**	100
a.s.	S	Fish	0.019	Chronic	1.84	**10.3**	10
Product	S	Daphnia	0.24	Acute	1.84	130.4	100
a.s.	S	Daphnia	0.44	Chronic	1.84	239.1	10
Product	S	Algae		Chronic	1.84		10
a.s.	S	Higher plants	>1.4	Chronic	1.84	>761	10
Quizalofop	S	Higher plants	0.094	Chronic	4.07	23	10

[1] Lowest endpoint (active substance or preparation)
Values in bold are lower than Annex VI 91/414/EEC triggers (10 or 100), indicating that further assessment is required

Winter oilseed rape (autumn), 200 g a.s./ha, BBCH 13 -29, Northern and Southern Europe

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Test substance [1]	N/S	Organism	Toxicity endpoint (mg/L) [1]	Time scale	PEC max (µg/L)	TER	Annex VI Trigger
Product	N	Fish	0.11	Acute	2.00	**55**	100
a.s.	N	Fish	0.019	Chronic	2.00	**9.5**	10
Product	N	Daphnia	0.24	Acute	2.00	120	100
a.s.	N	Daphnia	0.44	Chronic	2.00	220	10
Product	N	Algae		Chronic	2.00		10
a.s.	N	Higher plants	>1.4	Chronic	2.00	>700	10
Quizalofop	N	Higher plants	0.094	Chronic	8.85	11	10
Product	S	Fish	0.11	Acute	1.84	**59.8**	100
a.s.	S	Fish	0.019	Chronic	1.84	**10.3**	10
Product	S	Daphnia	0.24	Acute	1.84	130.4	100
a.s.	S	Daphnia	0.44	Chronic	1.84	239.1	10
Product	S	Algae		Chronic	1.84		10
a.s.	S	Higher plants	>1.4	Chronic	1.84	>761	10
Quizalofop	S	Higher plants	0.094	Chronic	7.25	13	10

[1] Lowest endpoint (active substance or preparation)
Values in bold are lower than Annex VI 91/414/EEC triggers (10 or 100), indicating that further assessment is required

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3 (Propaquizafop)

Crop: Sugar beet, 0.2 kg a.s./ha, BBCH 12 -39

Test substance [1]	Scenario	Water body type	Test organism	Time scale	Toxicity endpoint (mg a.s./L) [1]	PEC max (µg a.s./L)	TER	Annex VI trigger
Formulation	D3	Ditch	Fish	Acute	0.11	1.045	105	100
a.s.	D3	Ditch	Fish (ELS)	Chronic	0.019	1.045	18	10
Formulation	D4	Pond	Fish	Acute	0.11	0.042	2619	100
a.s.	D4	Pond	Fish (ELS)	Chronic	0.019	0.042	452	10
Formulation	D4	Stream	Fish	Acute	0.11	0.877	125	100
a.s.	D4	Stream	Fish (ELS)	Chronic	0.019	0.877	22	10
Formulation	R1	Pond	Fish	Acute	0.11	0.042	2619	100
a.s.	R1	Pond	Fish (ELS)	Chronic	0.019	0.042	452	10
Formulation	R1	Stream	Fish	Acute	0.11	0.723	152	100
a.s.	R1	Stream	Fish (ELS)	Chronic	0.019	0.723	26	10
Formulation	R3	Stream	Fish	Acute	0.11	1.021	108	100
a.s.	R3	Stream	Fish (ELS)	Chronic	0.019	1.021	19	10

[1] Lowest endpoint (active substance or preparation)
Values in bold are lower than Annex VI 91/414/EEC triggers (10 or 100), indicating that further assessment is required

Crop: Spring oilseed rape, 0.2 kg a.s./ha, BBCH 21 -39

Test substance [1]	Scenario	Water body type	Test organism	Time scale	Toxicity endpoint (mg a.s./L) [1]	PEC max (µg a.s./L)	TER	Annex VI trigger
Formulation	D1	Ditch	Fish	Acute	0.11	1.277	**86**	100
a.s.	D1	Ditch	Fish (ELS)	Chronic	0.019	1.277	15	10
Formulation	D1	Stream	Fish	Acute	0.11	1.117	**98**	100
a.s.	D1	Stream	Fish (ELS)	Chronic	0.019	1.117	17	10
Formulation	D3	Ditch	Fish	Acute	0.11	1.262	**87**	100
a.s.	D3	Ditch	Fish (ELS)	Chronic	0.019	1.262	15	10

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Test substance [1]	Scenario	Water body type	Test organism	Time scale	Toxicity endpoint (mg a.s./L) [1]	PEC max (µg a.s./L)	TER	Annex VI trigger
Formulation	D4	Pond	Fish	Acute	0.11	0.044	2500	100
a.s.	D4	Pond	Fish (ELS)	Chronic	0.019	0.044	432	10
Formulation	D4	Stream	Fish	Acute	0.11	1.047	105	100
a.s.	D4	Stream	Fish (ELS)	Chronic	0.019	1.047	18	10
Formulation	D5	Pond	Fish	Acute	0.11	0.044	2500	100
a.s.	D5	Pond	Fish (ELS)	Chronic	0.019	0.044	432	10
Formulation	D5	Stream	Fish	Acute	0.11	0.99	111	100
a.s.	D5	Stream	Fish (ELS)	Chronic	0.019	0.99	19	10
Formulation	R1	Pond	Fish	Acute	0.11	0.044	2500	100
a.s.	R1	Pond	Fish (ELS)	Chronic	0.019	0.044	432	10
Formulation	R1	Stream	Fish	Acute	0.11	0.832	132	100
a.s.	R1	Stream	Fish (ELS)	Chronic	0.019	0.832	23	10

[1] Lowest endpoint (active substance or preparation)
Values in bold are lower than Annex VI 91/414/EEC triggers (10 or 100), indicating that further assessment is required

Crop: Winter oilseed rape, 0.2 kg a.s./ha, BBCH 13 -29

Test substance [1]	Scenario	Water body type	Test organism	Time scale	Toxicity endpoint (mg a.s./L) [1]	PEC max (µg a.s./L)	TER	Annex VI trigger
Formulation	D2	Ditch	Fish	Acute	0.11	1.278	**86**	100
a.s.	D2	Ditch	Fish (ELS)	Chronic	0.019	1.278	15	10
Formulation	D2	Stream	Fish	Acute	0.11	1.138	**97**	100
a.s.	D2	Stream	Fish (ELS)	Chronic	0.019	1.138	17	10
Formulation	D3	Ditch	Fish	Acute	0.11	1.266	**87**	100
a.s.	D3	Ditch	Fish (ELS)	Chronic	0.019	1.266	15	10
Formulation	D4	Pond	Fish	Acute	0.11	0.044	2500	100
a.s.	D4	Pond	Fish (ELS)	Chronic	0.019	0.044	432	10

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Test substance [1]	Scenario	Water body type	Test organism	Time scale	Toxicity endpoint (mg a.s./L) [1]	PEC max (µg a.s./L)	TER	Annex VI trigger
Formulation	D4	Stream	Fish	Acute	0.11	1.092	101	100
a.s.	D4	Stream	Fish (ELS)	Chronic	0.019	1.092	17	10
Formulation	D5	Pond	Fish	Acute	0.11	0.044	2500	100
a.s.	D5	Pond	Fish (ELS)	Chronic	0.019	0.044	432	10
Formulation	D5	Stream	Fish	Acute	0.11	1.178	**93**	100
a.s.	D5	Stream	Fish (ELS)	Chronic	0.019	1.178	16	10
Formulation	R1	Pond	Fish	Acute	0.11	0.044	2500	100
a.s.	R1	Pond	Fish (ELS)	Chronic	0.019	0.044	432	10
Formulation	R1	Stream	Fish	Acute	0.11	0.835	132	100
a.s.	R1	Stream	Fish (ELS)	Chronic	0.019	0.835	23	10
Formulation	R3	Stream	Fish	Acute	0.11	1.167	**94**	100
a.s.	R3	Stream	Fish (ELS)	Chronic	0.019	1.167	16	10

[1] Lowest endpoint (active substance or preparation)
Values in bold are lower than Annex VI 91/414/EEC triggers (10 or 100), indicating that further assessment is required

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3: Metabolite Quizalofop (CGA 287422,)

Crop: Sugar beet, 0.2 kg a.s./ha, BBCH 12 -39

Test substance [1]	Scenario	Water body type	Test organism	Time scale	Toxicity endpoint (mg/L) [1]	PECmax (µg/L)	TER	Annex VI trigger
Quizalofop	D3	Ditch	Higher plants	Chronic	0.094	0.733	128	10
Quizalofop	D4	Pond	Higher plants	Chronic	0.094	0.0303	3102	10
Quizalofop	D4	Stream	Higher plants	Chronic	0.094	0.616	153	10
Quizalofop	R1	Pond	Higher plants	Chronic	0.094	0.106	887	10
Quizalofop	R1	Stream	Higher plants	Chronic	0.094	1.115	84	10
Quizalofop	R3	Stream	Higher plants	Chronic	0.094	1.559	60	10

Crop: Spring oilseed rape, 0.2 kg a.s./ha, BBCH 21 -39

Test substance [1]	Scenario	Water body type	Test organism	Time scale	Toxicity endpoint (mg/L) [1]	PECmax (µg/L)	TER	Annex VI trigger
Quizalofop	D1	Ditch	Higher plants	Chronic	0.094	0.973	97	10
Quizalofop	D1	Stream	Higher plants	Chronic	0.094	0.786	120	10
Quizalofop	D3	Ditch	Higher plants	Chronic	0.094	0.886	106	10
Quizalofop	D4	Pond	Higher plants	Chronic	0.094	0.0310	3032	10
Quizalofop	D4	Stream	Higher plants	Chronic	0.094	0.735	128	10
Quizalofop	D5	Pond	Higher plants	Chronic	0.094	0.315	298	10
Quizalofop	D5	Stream	Higher plants	Chronic	0.094	0.695	135	10
Quizalofop	R1	Pond	Higher	Chronic	0.094	0.097	969	10

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Test substance [1]	Scenario	Water body type	Test organism	Time scale	Toxicity endpoint (mg/L) [1]	PECmax (µg/L)	TER	Annex VI trigger
			plants					
Quizalofop	R1	Stream	Higher plants	Chronic	0.094	1.115	84	10

Crop: Winter Oilseed rape 0.2 kg a.s./ha, BBCH 13 -29

Test substance [1]	Scenario	Water body type	Test organism	Time scale	Toxicity endpoint (mg/L) [1]	PECmax (µg/L)	TER	Annex VI trigger
Quizalofop	D2	Ditch	Higher plants	Chronic	0.094	0.92	102	10
Quizalofop	D2	Stream	Higher plants	Chronic	0.094	0.819	115	10
Quizalofop	D3	Ditch	Higher plants	Chronic	0.094	0.889	106	10
Quizalofop	D4	Pond	Higher plants	Chronic	0.094	0.104	904	10
Quizalofop	D4	Stream	Higher plants	Chronic	0.094	0.767	123	10
Quizalofop	D5	Pond	Higher plants	Chronic	0.094	0.0349	2693	10
Quizalofop	D5	Stream	Higher plants	Chronic	0.094	0.827	114	10
Quizalofop	R1	Pond	Higher plants	Chronic	0.094	0.0339	2773	10
Quizalofop	R1	Stream	Higher plants	Chronic	0.094	0.681	138	10
Quizalofop	R3	Stream	Higher plants	Chronic	0.094	1.962	48	10

[1] Lowest endpoint (active substance or preparation)

FOCUS Step 4 (Not needed)

Crop and application rate -

Scenario	Water body type	Test organism	Time scale	Toxicity endpoint	Buffer zone distance	PEC	TER	Annex VI trigger

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Scenario	Water body type	Test organism	Time scale	Toxicity endpoint	Buffer zone distance	PEC	TER	Annex VI trigger

Bioconcentration				
	Active substance	Metab. 1	Metab. 2	Metab. 3
$logP_{O/W}$	4.78 ± 0.07 at 25°C			
Bioconcentration factor (BCF) ‡	64, 1243 and 583 (muscle, viscera and whole fish) *			
Annex VI Trigger for the bioconcentration factor	100			
Clearance time (days) (CT_{50})	33 hours (muscle); 2.6 hours (whole fish)			
(CT_{90})	Not reported			
Level and nature of residues (%) in organisms after the 14 day depuration phase	< 10%			

* based on total ^{14}C

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
Propaquizafop ‡	>20	>200
Preparation 100 g/L EC	>189 µg product/bee; (approximately >18.9 µg a.s./bee).	>189 µg product/bee; (approximately >18.9 µg a.s./bee).
Metabolite	No data available – not required	No data available – not required
Field or semi-field tests No data available – not required		

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

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

Application rate: 200g a.s./ha (all uses)

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	<1	50
a.s.	oral	<10	50
Preparation	Contact	<10.6	50
Preparation	oral	<10.6	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	Endpoint	Effect (LR_{50} g a.s./ha)
Typhlodromus pyri ‡	Propaquizafop (100 g/l EC formulation)	Mortality	>8 (4% mortality at exposure equivalent to 4% spray-drift)
Typhlodromus pyri ‡	Propaquizafop (100 g/l EC formulation)	Mortality	200
Aphidius rhopalosiphi ‡	Propaquizafop (100 g/l EC formulation)	Mortality	< 150 (100% mortality)

Application rate: 200g a.s./ha (all uses)

Test substance	Species	Effect (LR_{50} g a.s./ha)	HQ in-field	HQ off-field [1]	Trigger
100 g/l EC formulation	*Typhlodromus pyri*	200	1	0.028	2
100 g/l EC formulation	*Aphidius rhopalosiphi*	< 150	Not determined. (>2 assumed)	Not determined.	2

[1] drift rate calcualated at 1m distance

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (ga.s./ha)	Endpoint	% effect	Trigger value
Chrysoperla carnea	Adults	Propaquizafop (100 g/l EC formulation) Glass plate test 3 weeks	200	mortality & reproduction	Corrected mortality: 12 Reduction in reproductive capacity: 0	50 %
Coccinella septempunctata	Adults	Propaquizafop (100 g/l EC formulation) Glass plate test 3 weeks	200	mortality & reproduction	Corrected mortality: 23 Reduction in reproductive capacity: 6.1	50 %
Poecilus cupreus	Adults	Propaquizafop (100 g/l EC formulation) Sand 14 days	200	Mortality and feeding	Corrected mortality: 3% Reduction in feeding rate: 19%	50 %
Aleochara bilineata	Adults	Propaquizafop (100 g/l EC formulation) Sand 29 days	200	Reproduction	Reduction in reproductive capacity: 17%	50 %
Typhlodromus pyri	Proto-nymphs	Propaquizafop (100 g/l EC formulation) Bean leaves 7 days	200	Mortality and reproduction	Corrected mortality: 3.2% Reduction in reproductive capacity: 15%	50%

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Species	Life stage	Test substance, substrate and duration	Dose (ga.s./ha)	Endpoint	% effect	Trigger value
Aphidius rhopalosiphi	Adults	Propaquizafop (100 g/l EC formulation) Barley Seedlings 14 days	150	Mortality & reproduction	Corrected mortality: 6.7 Reduction in reproductive capacity: 59	50%
Aphidius rhopalosiphi	Adults	Propaquizafop (100 g/l EC formulation) Barley seedlings 14 days	28	Mortality & reproduction	Corrected mortality: 8 Reduction in reproduction: 34	50%
			200	Mortality & reproduction	Corrected mortality: 0 Reduction in reproduction: 66	50%

Field or semi-field tests
No data available – not required

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

Test organism	Test substance	Time scale	Endpoint
Earthworms			
Eisenia foetida	Propaquizafop technical ‡	Acute 14 days	14 day LC_{50} >1000 mg a.s./kg soil (corrected to >500 mg a.s./kg soil)
Eisenia foetida	a.s. ‡	Chronic 8 weeks	No data available – not required
Eisenia foetida	Propaquizafop 100g/l formulation	Acute	14 day LC_{50}: 54.6 mg a.s./kg soil (corrected to 27 mg a.s./kg soil)

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Test organism	Test substance	Time scale	Endpoint
Eisenia foetida	Propaquizafop 100g/l formulation)	Chronic (28 days)	3.9 mg a.s./kg soil (corrected to 1.95 mg a.s./kg soil).
Eisenia foetida	Quizalofop	Acute	14 day LC_{50}: 948 mg/kg dw soil (corrected to 474 mg a.s./kg soil
Eisenia foetida	Quizalofop	Chronic	NOEC > 50 mg/kg dw soil
Eisenia foetida	Dihydroxy quinoxaline (CGA 294970)	Acute	14 day LC_{50}: >1000 mg/kg soil (corrected to >500 mg a.s./kg soil)
Eisenia foetida	Hydroxy quizalofop (CGA 294972)	Acute	14 day LC_{50}: >1000 mg/kg soil (corrected to >500 mg a.s./kg soil)
Other soil macro-organisms			
Soil mite	a.s. ‡	No data available - not required	
	Preparation	No data available - not required	
	Metabolite	No data available - not required	
Collembola			
	a.s. ‡	No data available - not required	
Folsomia candida	Propaquizafop 100g/l formulation	28 day	NOEC: 5.4 mg a.s./kg soil: (corrected to 2.7 mg a.s./kg soil)
	Metabolite	No data available -	Assumed to be 10 times more toxic than parent compound
Soil micro-organisms			
Nitrogen mineralisation	Propaquizafop technical ‡	28 days	Deviation from the control <25% after 28 days incubation up to 1.5 Kg/ha (equivalent to 2.0 mg a.s./Kg soil).

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Test organism	Test substance	Time scale	Endpoint
	Propaquizafop technical ‡	56 days	Deviation from the control <25% after 56 days incubation at 0.750 Kg/ha (equivalent to 1.0 mg/ kg dry soil)
	Propaquizafop (100 g/l EC formulation)	90 days	Deviation from the control <25% after 90 days incubation at 1.25 Kg/ha (equivalent to 1.7 mg a.s./Kg soil).
	Metabolite Dihydroxy quinoxaline (CGA 294970)	28 days	Deviation from the control <25% after 28 days incubation at 0.53 mg/kg dry soil
Carbon mineralisation	Propaquizafop technical ‡	28 days	Deviation from the control <25% after 28 days incubation up to 1.5 Kg/ha (equivalent to 2.0 mg a.s./Kg soil).
	Metabolite	No data available – not required	
Field studies No data available – not required			

Toxicity/exposure ratios for soil organisms

Application rate: 200g a.s./ha (all uses)

Test organism	Test substance	Time scale	Soil PEC (max)	TER	Trigger
Earthworms					
Eisenia foetida	Propaquizafop technical	Acute	0.13 mg/ kg soil	>3486	10
Eisenia foetida	a.s. ‡	Chronic	0.13 mg/ kg soil	not calculable	5
Eisenia foetida	Formulated propaquizafop (100 g a.s./L)	Acute	0.13 mg kg soil	212	10
Eisenia foetida	Preparation	Chronic	0.13 mg kg soil	15	5

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

Test organism	Test substance	Time scale	Soil PEC (max)	TER	Trigger
Eisenia foetida	Metabolite Quizalofop (287422)	Acute	0.09 mg/ kg soil	5266	10
Eisenia foetida	Metabolite Quizalofop (287422)	Chronic	0.09 mg/ kg soil	278	
Eisenia foetida	Dihydroxy quinoxaline (CGA 294970)	Acute	0.008 mg/ kg soil	>62500	10
Eisenia foetida	Hydroxy quizalofop (CGA 294972)	Acute	0.04 mg/ kg soil	>12500	10
Eisenia foetida	Hydroxy quinoxaline (CGA 290291)	Acute	0.005 mg/ kg soil	>10000*	10
* Value calculated assuming the metabolite is 10 times more toxic than parent compound					
Other soil macro-organisms					
Collembola	a.s. ‡			Not calculable	
	Preparation	Chronic	0.13 mg kg soil	21	5
	Quizalofop (CGA 287422)	Chronic	0.09 mg kg soil	6.0*	5
	Dihydroxy quinoxaline (CGA 294970)	Chronic	0.008 mg kg soil	34*	5
	Hydroxy quizalofop (CGA 294972)	Chronic	0.04 mg kg soil	6.8*	5
	Hydroxy quinoxaline CGA 290291	Chronic	0.005 mg kg soil	54*	5

*TER were calculated assuming that the metabolites ares 10 times more toxic than parent compound. The corrected $NOEC_c$ value was used to calculate the TERs with the exception of the Quizalofop (CGA 287422) where the uncorrected NOEC was used as the $logK_{ow}$ is 1.51.

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

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

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g a.s./ha) vegetative vigour	ER_{50} (g/ha) emergence/survival	Exposure (g/ha)[2]	TER	Trigger
Pre emergent application						
Lettuce	Preparation Agil 100 EC	>400	>400	400	>72	
Oilseed rape	Preparation Agil 100 EC	>400	>400	400	>72	
Carrot	Preparation Agil 100 EC	>400	>400	5.54	>72	5
Pea	Preparation Agil 100 EC	>400	>400	5.54	>72	5
Oat	Preparation Agil 100 EC	>400	>400	5.54	>72	5
Onion	Preparation Agil 100 EC	>400	>400	5.54	>72	5
Post-emergent application						
Oat[3]	Preparation Agil 100 EC	26.6	34.4	5.54	4.8	5
Oat	Preparation Agil 100 EC	26.6	34.4	1.14[4]	23	5

[2] Exposure calculated using spray drift value of 2.77% (according to Rautmann *et al.* (2001).
[3] most sensitive species
[4] Based on a no-spry buffer zone of 5 m.

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

Appendix 1 – amalgamated list of endpoints for the active substance and the representative formulation

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

No data available - justification provided

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

Test type/organism	Endpoint
Activated sludge	EC_{50} >100 mg/l
Pseudomonas sp	no data available – not required

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

Compartment	
soil	Propaquizafop.
water	Propaquizafop.
sediment	
groundwater	Propaquizafop.

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

	RMS/peer review proposal
Active substance	

	RMS/peer review proposal
Preparation	

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

Appendix 2 – abbreviations

APPENDIX 2 – ABBREVIATIONS

ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
AV	avoidance factor
BCF	bioconcentration factor
bw	body weight
CAS	Chemical Abstract Service
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
DFR	dislodgeable foliar residue
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
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre

Appendix 2 – abbreviations

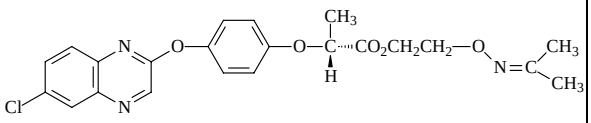
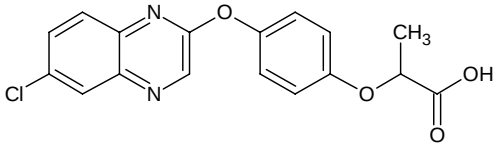
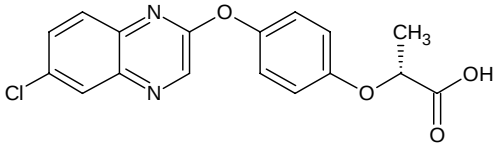
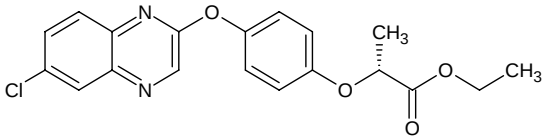
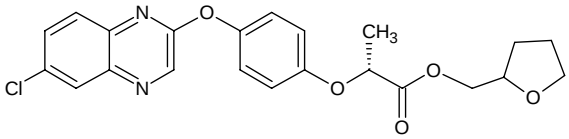
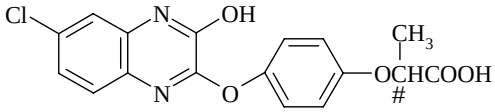
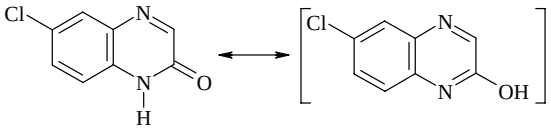
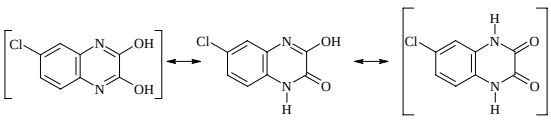
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HQ	hazard quotient
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
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
PHI	pre-harvest interval
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
r^2	coefficient of determination
RPE	respiratory protective equipment

Appendix 2 – abbreviations

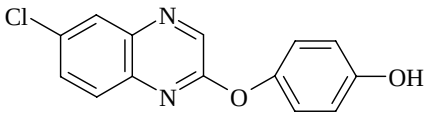
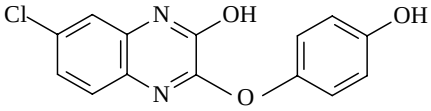
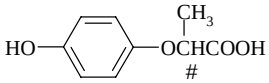
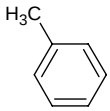
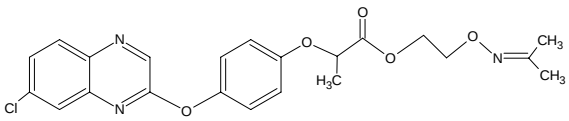
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TF	transfer factor
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TWA	time weighted average
UV	ultraviolet
W/S	water/sediment
WG	water dispersible granule
WHO	World Health Organisation
yr	year

Appendix 3 – used compound code(s)

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
Propaquizafop	2-isopropylideneamino-oxyethyl (*R*)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate	
Quizalofop QUIZ	2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionic acid	
Quizalofop-P CGA 287422	(*R*)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionic acid	
Quizalofop-P-ethyl	ethyl (2*R*)-2-{4-[(6-chloroquinoxalin-2-yl)oxy]phenoxy}propanoate	
Quizalofop-P-tefuryl	(*RS*)-tetrahydrofurfuryl (*R*)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate	
Hydroxy-quizalofop QUIZ-OH Hydroxy-propaquizafop acid CGA 294972	(*R*)-2-[4-(6-chloro-3-hydroxyquinoxalin-2-yloxy)phenoxy]propionic acid	 # chiral centre
Hydroxy-quinoxaline CHQ CGA 290291 CQO	6-chloroquinoxalin-2-ol	
Dihydroxy-quinoxaline Dihydroxychloroquinoxalin CHHQ CGA 294970	6-chloroquinoxaline-2,3-diol	

Appendix 3 – used compound code(s)

Code/Trivial name*	Chemical name	Structural formula
Quizalofop-phenol CQOP Hydroxy ether CGA 129674	2-[4-(6-chloroquinoxalin-2-yloxy)phenol]	
Hydroxy-quizalofop-phenol CHQOP Dihydroxy ether CGA 294971	4-(3-hydroxy-6-chloroquinoxalin-2-yloxy)phenol	
Phenoxy acid Ro 16-2752 PPA	(*R*)-2-(4-hydroxyphenoxy)-propionic acid	 # chiral centre
Toluene		
Ro 41-5259 7-chloro isomer of propaquizafop	2-isopropylideneamino-oxyethyl (*R*)-2-[4-(7-chloroquinoxalin-2-yloxy)phenoxy]propionate	

* The metabolite name in bold is the name used in the conclusion.