CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion regarding the peer review of the pesticide risk assessment of the active substance quizalofop-P (considered variants quizalofop-P-ethyl and quizalofop-P-tefuryl)

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SUMMARY

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

Finland being the designated rapporteur Member State submitted a DAR on the variant quizalofop-P-ethyl and a DAR on the variant quizalofop-P-tefuryl in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which were received by the EFSA on 1 February 2007 and 2 May 2007 respectively. The peer review was initiated on 24 October 2007 by dispatching the DARs for consultation of the Member States and the respective notifiers Nissan Chemical Europe SARL and Chemtura Europe Limited. Subsequently, the comments received on the DARs were examined and responded by the rapporteur Member State in the reporting tables. These tables were 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.

This conclusion was reached on the basis of the evaluation of the representative uses of quizalofop-P-ethyl as a herbicide on sugar beet and quizalofop-P-tefuryl as a herbicide on oilseed rape, sugar/fodder beet, potato, combining pea, field beans, linseed and sunflower. 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)

The representative formulated product for the evaluation of quizalofop-P-ethyl was 'Targa Super', an emulsifiable concentrate (EC). For quizalofop-P-tefuryl the representative formulation was 'Panarex' (also known as 'Pantera'), an emulsifiable concentrate (EC).

For food of plant and animal origin none of the methods supplied comply with the residue definition. For environmental matrices sufficient methods are available. Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that at least some quality control measurements of the plant protection products are possible. The specification for the ethyl variant was not accepted as further justification is required. Data gaps for surface tension and persistent foam were identified. For the tefuryl variant the specification was acceptable for section 1, although there is an outstanding question on the formation of the isomeric impurity of quizalofop. A data gap was identified for a method of analysis to separate the *R* and *S* isomers (note this is not the *R* and *S* isomers in the tefuryl part of the molecule). A data gap was also identified for kinematic viscosity for aspiration hazard classification.

Quizalofop-P-tefuryl tested in mammalian toxicology is "Harmful if swallowed" (Xn; R22 proposed based on oral Lethal Dose - LD_{50} 1012 mg/kg bw); it has low dermal and inhalation toxicity (LD_{50} >2000 mg/kg bw and Lethal Concentration - LC_{50} >3.9 mg/L air, respectively). Quizalofop-P-tefuryl is not a skin or eye irritant, but it is a skin sensitiser in Magnusson-Kligman test (Xn; R43 "May cause sensitisation by skin contact" was proposed). Short-term toxicity target organs were liver and testes. In rodents, the relevant No Observed Adverse Effect Level - NOAEL (rat study) was 1.7 mg/kg bw/day based on increased liver weights, accentuated lobulation of the liver and haematological and clinical chemistry findings at 33.4 mg/kg bw/day. Kidney, testis and body weights were decreased at 134 mg/kg bw/day. Quizalofop-P-tefuryl did not show genotoxic concern. In long-term toxicity studies the relevant NOAEL is 1.3 mg/kg bw/day. Quizalofop-P-tefuryl caused an increased incidence of rare renal squamous cell carcinoma, as well as a clear treatment related increase in the Leydig cell tumours in rats; the liver tumours occurring in rodents were not relevant to humans. On this basis Carc Cat, 3; R40 "Limited evidence of a carcinogenic effect" was proposed. In the two-generation rat study, the NOAEL for parental and offspring was 1.4 mg/kg bw/day based on increased liver weight and liver hypertrophy in adult males and females, vacuolar changes in pituitary in adult males, decreased body weights during lactation in F1 generation and decreased viability during early lactation. The NOAEL for reproduction was 16.9 mg/kg bw/day. In developmental toxicity studies in rats the maternal NOAEL was set at 10 mg/kg bw/day, whereas the developmental NOAEL was 30 mg/kg bw/day based on increased postimplantation loss per dam with concomitant lower number of viable foetuses and increased number of malformations at maternally toxic dose. In rabbits, the NOAEL was 20 mg/kg bw/day for maternal and developmental toxicity. However, the rabbit was not adequately tested but this was considered not to preclude concluding on the risk assessment. Due to the limitations of the studies, Repr. Cat. 3; R63? ("Possible risk of harm to the unborn child") was agreed for proposal to the European Chemicals Agency (ECHA). The Acceptable Daily Intake (ADI) is 0.013 mg/kg bw/day based on the NOAEL of the 2-year study in rats, SF 100.

The NOAEL of 1.7 mg/kg bw/day from the 90-day rat study was the most relevant NOAEL, also based on its dosing regime, and applying a 60% correction factor (limited oral absorption) and SF 100 resulted in an Acceptable Operator Exposure Level (AOEL) of 0.01 mg/kg bw/day. The Acute Reference Dose (ARfD) of 0.1 mg/kg bw was based on the maternal toxicity seen in the rat developmental study with a SF 100 applied. The estimated operator exposure exceeded the AOEL without the use of PPE, as well as with PPE but only with the UK POEM. The exposure was estimated below the AOEL (13%) applying the German model, with the use of gloves during mixing/loading and application and coverall and sturdy footwear during application. The exposure for workers re-entering the field for crop inspection and the bystander estimated exposure were estimated to be below the AOEL (for workers re-entering in ornamentals the use of gloves is needed).

Quizalofop-P-ethyl is "Harmful if swallowed" (Xn; R22 proposed based on oral LD_{50} 1182 mg/kg bw); dermal and inhalation acute toxicity is low (LD_{50} >5000 mg/kg bw and LC_{50} 5.8 mg/L air, respectively). Quizalofop-P-ethyl is not a skin or eye irritant, nor does it show any sensitisation potential. Target organ in repeat dose studies was shown to be the liver. The lowest short-term NOAEL for quizalofop-P-ethyl is 1.7 mg/kg bw/day in mice study after 13-week (90-day) dietary administration, whereas the relevant long-term NOAEL is 0.9 mg/kg bw/day (2-year study in rats). Quizalofop-P-ethyl did not exhibit genotoxic or carcinogenic properties relevant to humans. It is not a reproductive or developmental toxicant: the NOAEL for offspring is 2.4 mg/kg bw/day based on hepatoxicity; the parental NOAEL is 9.4 mg/kg bw/day based on slightly decreased body weight during premating period, whereas the reproductive NOAEL is 37.8 mg/kg bw/day, highest dose tested. The maternal and developmental NOAEL in rats is 30 mg/kg bw/day based on decreased body weight gain and food consumption, increased resorptions and skeletal variations at ≥100 mg/kg bw/day. In rabbits, no malformations were observed up to doses of 60 mg/kg bw/day, which represented the NOAEL for developmental toxicity, whereas the maternal NOAEL for dams was 30 mg/kg bw/day based on slightly decreased body weight and food consumption and decreased thymus and thyroid weights at 60 mg/kg bw/day. Quizalofop-P-ethyl does not have a potential to induce neurotoxicity in mammals. The Acceptable Daily Intake (ADI) is 0.009 mg/kg bw/day based on the 2-yr rat study with an SF 100; The Acceptable Operator Exposure Level (AOEL) is 0.01 mg/kg bw/day, based on the 90-day mouse study with an SF 100 (corrected for limited oral absorption of 67%). Due to the toxicological profile of quizalofop-P-ethyl, the Acute Reference Dose (ARfD) was not triggered. The operator exposure assessment was estimated to be below the AOEL (26%) with the use of Personal Protective Equipment (PPE, with the German model). The exposure for workers re-entering field for crop inspection and the bystander estimated exposure were estimated to be below the AOEL (for workers the use of gloves is needed).

For both quizalofop-P-ethyl and quizalofop-P-tefuryl, the metabolism in plants was investigated in potato, cotton and soya; the ethyl variant was additionally investigated in sugar beet. For quizalofop-P-tefuryl, one radioactive label was investigated and considering the insufficient metabolite characterisation in some studies, the meeting concluded that new studies labelled in a second position

need to be provided. For both variants, the metabolism proceeds primarily by the hydrolysis of the ester link to yield quizalofop (acid) followed by the loss of the propionyl moiety leading to the quizalofop-phenol metabolite. Further metabolism occurs by hydroxylation of the quinoxaline moiety giving the hydroxy-quizalofop, hydroxy-quizalofop-phenol and the dihydroxy-quizalofop-phenol. In addition, the presence of the quinoxaline and phenoxy metabolites indicated a cleavage of the parent molecule. Parts of these different metabolites were also found as conjugates.

The meeting discussed whether the phenoxy propionate and hydroxy-quizalofop-phenol metabolites which were observed in beet foliage and soya meal in similar amounts to the tefuryl ester or to quizalofop, have to be included in the plant residue definition and if they have to be taken into account in the animal feeding. Finally and provisionally, the experts decided not to include these compounds in the residue definition, awaiting a statement on their toxicological relevance, and proposed the following residue definition for monitoring and risk assessment for each individual ester variant:

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

Considering the metabolism studies performed with the three quizalofop ester variants, a common residue definition for monitoring and risk assessment was also 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 additional information. After the meeting and considering that conjugates were mainly detected in immature soya and cotton plants, the EFSA proposed not to include these conjugates in the residue definitions, especially for monitoring since the ethyl variant, tefuryl variant and quizalofop seem to be sufficient markers for the residues in plants.

In addition for quizalofop-P-ethyl, the meeting was of the opinion that the metabolism pattern has not been sufficiently described in root crops. No characterisations were performed in potato tubers and a substantial part of the extracted radioactivity was not identified in the sugar beet. Therefore, it was concluded that these studies were not sufficient to validate the proposed residue definition on the root/tuber plant group, especially on potato. However, and considering that no metabolites are expected at significant levels in sugar beet root, it was agreed that the proposed residue definition could be applied to beet root. The notifier was requested to provide further information concerning the unidentified fractions observed in the beet studies, unless a new metabolism study has to be submitted for tuber/root crops.

For quizalofop-P-ethyl, supervised residue trials were submitted to support a single representative use on sugar beet only. The trials performed with the highest LOQ of 0.10 mg/kg were removed from the data set and a MRL of 0.05 mg/kg was proposed for sugar beet roots. For quizalofop-P-tefuryl, a

sufficient number of residue trials were submitted to propose MRLs on potato, sugar beet, bean, pea, lentil, oilseed rape, linseed, soya and sunflower. Samples were analysed using a method quantifying separately the parent quizalofop-P-tefuryl and its free and conjugated metabolites (including quizalofop) which can be converted to 2-methoxy-6-chloroquinoxaline, but this method was only validated for the tefuryl variant and quizalofop. This method was considered as appropriate in the framework of this peer review since its scope is wider than the compounds included in the proposed residue definition.

The storage stability study showed that quizalofop-P-ethyl and quizalofop residues are stable for at least 16 months in beet matrices. However, an additional study on oil/protein matrices was requested in order to support the results of the rotational crop study. Quizalofop-P-tefuryl and quizalofop residues were shown to be stable up to 12 – 24 months in a wider range of plant matrices (soya beans, cotton seeds, rape seed oil and cake, potato tubers). A degradation from the ester quizalofop-P-tefuryl to quizalofop was observed in beet matrices after one month, but generally recoveries were more than 80% when both quizalofop-P-ethyl and quizalofop residues were added up. Clarifications were requested concerning the different analytical methods used in these storage stability studies and especially concerning the validation for "bound residues".

No processing study was provided for quizalofop-P-ethyl as no residues were detected in beet roots following the use of the active substance as stated in the critical GAP. For quizalofop-P-tefuryl, a standard hydrolytic study was provided but for the boiling condition only and a new study covering the full range of the processing conditions was requested. No processing factors could be derived from the rapeseed study since the residues detected in all processed fractions (crude oil, refined oil, pressed cake *etc*.) were considered to be not consistent with the initial levels observed in seeds. A new processing study was requested, unless clarifications could be provided. On potatoes, the residue levels were not affected in boiled potatoes but were increased in fried potatoes.

The compounds detected in the rotational crops studies performed with quizalofop-ethyl (racemate) and quizalofop-P-tefuryl were also present in the primary crops, suggesting a similar metabolic pathway in both primary and rotational crops. Considering the residue levels observed in these studies, it was concluded that no significant residues of quizalofop-ethyl, quizalofop-P-tefuryl and of their metabolites are expected in rotational crops.

The metabolism in animals was investigated using the racemate quizalofop-ethyl labelled on the phenyl and quinoxaline moieties in the goat study but only on the quinoxaline moiety in the hen study. This single radio-labelling was considered as sufficient in the scope of this peer review, since the intended use on sugar beet does not lead to significant intake by poultry. For quizalofop-P-tefuryl, the metabolism studies on goat and hen were conducted using a single label only. Considering that the characterisation/identification of the metabolites was insufficiently investigated in some animal matrices, a new study using a second labelling position was requested. Similar metabolic pathways

were observed for both ester variants, starting with rapid hydrolysis of the ester bond leading to the acid quizalofop and followed by hydroxylation or further hydrolysis giving the hydroxy-quizalofop and hydroxy-quizalofop-phenol, these metabolites being subject to conjugation. In the hen study, quizalofop-pentanoic acid was also observed as a major metabolite in liver and kidney. The very low proportion of quinoxaline metabolites (<1% TRR) indicated limited cleavage of the parent molecule. Considering the comparative metabolite distribution in rat and goat for quizalofop-P-ethyl, the experts discussed whether a supplementary metabolism study in pig should be requested. The metabolism in rat and ruminants was similar qualitatively but differences were observed quantitatively. Higher residues were detected in rat on an equivalent mg/kg bw basis, some differences being of a 10-fold magnitude. Before asking for a pig metabolism study, it was suggested to ask the notifiers to provide explanations for these quantitative differences. No comparison was possible for quizalofop-P-tefuryl since the dosages of the metabolites in rat and goat were performed at different time points. Finally and provisionally the meeting of experts proposed the following residue definitions for each individual variant:

- For monitoring: sum of quizalofop-ester and quizalofop expressed as quizalofop (sum of isomers).
- For risk assessment: sum of quizalofop-ester, quizalofop pentanoic acid and quizalofop, expressed as quizalofop (sum of isomers).

Considering the metabolism studies performed with the three ester variants, the meeting of experts concluded that the following common residue definitions can be proposed for propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl:

- For monitoring: sum of quizalofop-esters and quizalofop expressed as quizalofop (sum of isomers).
- For risk assessment: sum of quizalofop-esters, quizalofop pentanoic acid and quizalofop, expressed as quizalofop (sum of isomers).

These definitions should remain provisional, pending submission and the evaluation of the requested additional information and the statement on the toxicological relevance of some metabolites.

No feeding studies were submitted for quizalofop-P-ethyl and considering the metabolism studies performed with an exaggerated dose rate, it was concluded that no significant residues are expected in animal matrices resulting from the use of quizalofop-P-ethyl on sugar beet. Feeding studies in cow and hen were submitted for quizalofop-P-tefuryl. Taking into account the transfer in animal products and the theoretical animal burden resulting from the representative uses of quizalofop-P-tefuryl, residue levels above the LOQs are expected in ruminant kidney and in poultry liver, kidney and fat. MRLs were proposed for these animal products. The stability of the residues in products of animal origin was however considered as insufficiently demonstrated and the notifier was asked to provide new data.

Using the EFSA consumer model and considering the representative use of quizalofop-P-ethyl on sugar beet, no chronic concern was observed, the theoretical maximum daily intake (TMDI) being

less than 13% of the ADI (0.009 mg/kg bw/d). Considering the MRLs proposed for plant and animal products, no chronic and acute concerns were observed for quizalofop-P-tefuryl, the maximum TMDI using the EFSA model being 23% of the ADI (0.013 mg/kg bw/d) and the maximum international estimated short-term intake (IESTI), 31% of the ARfD (0.1 mg/kg bw/d).

Awaiting the additional information/clarification requested during the peer review process, provisional MRLs were proposed for sugar beet, potato, bean and pea (without pods), lentils, soybeans, oil seed rape and sunflower. MRLs were also proposed for products of animal origin, based on the quizalofop-P-tefuryl representative uses.

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 quizalofop-P-tefuryl exhibits very low persistence forming the major soil metabolites quizalofop (accounting for up to 101.5% of applied radioactivity (AR)) which exhibits low to high persistence, hydroxy-quizalofop (accounting for up to 21% AR) which exhibits low to medium persistence, dihydroxy-quinoxaline (accounting for up to 18% AR) which exhibits moderate to high persistence, and tetrahydrofurfuryl alcohol (accounting for up to 59% AR) which exhibits very low persistence. The metabolite tetrahydrofuroic acid (up to 9.3% AR) was present at levels that trigger a groundwater exposure assessment. Mineralisation of the phenyl ring, the furfuryl group or the quinoxaline group to carbon dioxide accounted for 2.3 – 70% AR after 30 – 120 days. The formation of unextractable residues was a significant sink, accounting for 15 – 50% AR after 30 – 120 days. Due to the rapid degradation of quizalofop-P-tefuryl in soil under aerobic conditions, batch equilibrium studies with the parent compound were not performed. A worst case value of 0 mL/g and 1/n = 1 was selected for use in FOCUS scenario calculations of groundwater exposure potential. Quizalofop and hydroxy-quizalofop exhibit low to high mobility in soil, and dihydroxy-quinoxaline exhibits low to very high mobility in soil. There was no indication in the available data that adsorption of either quizalofop-P-tefuryl or its identified soil metabolites is pH dependent.

In dark natural sediment water systems quizalofop-P-tefuryl degraded very rapidly to the metabolites quizalofop (max. 94% AR in water and max. 53% AR in the sediment) tetrahydrofurfuryl alcohol (max. 16.5% AR in the water), tetrahydrofuroic acid (max. 39.1% AR in the water), CQOP (max. 11.6% in the sediment) and dihydroxy-quinoxaline (max. 16.4% AR in the sediment). The necessary surface water and sediment exposure assessments were appropriately carried out using the agreed FOCUS scenarios approach for quizalofop-P-tefuryl. After the peer review for metabolites quizalofop and hydroxy-quizalofop, the EFSA performed new FOCUS SW calculations at Steps 1 and 2 using the endpoints agreed in the amalgamated list of endpoints. The recalculated initial predicted

environmental concentration in surface water (PEC_{sw}) was used in the toxicity exposure ratio (TER) calculations for these two metabolites. For metabolites CQOP, dihydroxy-quinoxaline, tetrahydrofuroic acid and tetrahydrofurfuryl alcohol no reliable PEC_{sw} and predicted environmental concentration in sediment (PEC_{sed}) were available. However, as the risk to aquatic organisms from exposure to CQOP, dihydroxy-quinoxaline, and tetrahydrofurfuryl alcohol is assessed to be low when the initial PEC values for quizalofop are used, no further assessment is required for these metabolites. No recalculations for tetrahydrofuroic acid were necessary. The potential for groundwater exposure from the applied for intended uses by quizalofop-P-tefuryl and its metabolites quizalofop, hydroxy-quizalofop, dihydroxy-quinoxaline, tetrahydrofurfuryl alcohol and tetrahydrofuroic acid 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.

In soil under aerobic conditions quizalofop-P-ethyl exhibits low to very low persistence, forming the major soil metabolites quizalofop (accounting for up to 84% AR) which exhibits low to high persistence, metabolite hydroxy-quizalofop accounting for up to 16% AR which exhibits low to medium persistence, and metabolite dihydroxy-quinoxaline accounting for up to 12% AR which exhibits moderate to high persistence. Mineralisation of the phenyl ring or the quinoxaline group to carbon dioxide accounted for 1.8 – 32% AR after 120 days. The formation of unextractable residues was a significant sink, accounting for 23 – 42% AR after 120 days. Quizalofop-P-ethyl exhibits low to slight mobility in soil. Quizalofop and hydroxy-quizalofop exhibit low to high mobility in soil, and dihydroxy-quinoxaline exhibits low to very high mobility in soil. There was no indication in the available data that adsorption of either quizalofop-P-tefuryl or its identified soil metabolites was pH dependent. In dark natural water/sediment systems quizalofop-P-ethyl degraded very rapidly to the metabolite quizalofop (max. 83% AR in water and max. 43% AR in the sediment). The necessary surface water and sediment exposure assessments were appropriately carried out using the agreed FOCUS scenarios approach with Steps 1 and 2 for quizalofop-P-tefuryl, quizalofop, hydroxy-quizalofop and dihydroxy-quinoxaline. The potential for groundwater exposure from the applied for intended uses by quizalofop-P-ethyl and its metabolites quizalofop, hydroxy-quizalofop, and dihydroxy-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.

Aquatic and terrestrial ecotoxicological endpoints for the common metabolites of propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl were assessed by Member State experts. Where more than one study was available for the same metabolite in the dossiers for propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl, the lower valid endpoint was agreed to be used in all relevant risk assessments.

The acute, short-term and long-term risk to birds from quizalofop-P-ethyl and quizalofop-P-tefuryl was assessed as low for the intended uses. For mammals, a revised long-term endpoint was agreed for quizalofop-P-ethyl in the meeting of experts. The acute and long-term risk to mammals from

quizalofop-P-ethyl and quizalofop-P-tefuryl was assessed as low for the intended uses. The risk to herbivorous birds and mammals from the common plant metabolites was considered to be low. The risk from consumption of contaminated drinking water was assessed as low for the intended uses of both ester variants. The risk from secondary poisoning was assessed as low for the intended uses of both ester variants and for the common metabolites.

Both quizalofop-P-ethyl and quizalofop-P-tefuryl was found to be very toxic to aquatic organisms, based on the lower acute endpoints for algae and fish respectively. The risk from both active substances was assessed as low for the intended uses, based on FOCUS Step 2 PEC calculations. The aquatic risk assessment for metabolites was revised, based on the agreed endpoints for metabolites and PEC values derived from the GAP of quizalofop-P-ethyl and quizalofop-P-tefuryl. Metabolite PEC values from the DAR of quizalofop-P-ethyl were used in the risk assessment, whereas EFSA did calculate new worst case PEC values for quizalofop-P-ethyl metabolites after the peer review. The risk to aquatic organisms from metabolites was assessed as low, based on FOCUS Step 2 and 3 for quizalofop-P-tefuryl and quizalofop-P-ethyl respectively. No risk from bio-accumulation was foreseen for quizalofop-P-ethyl and quizalofop-P-tefuryl or any of the metabolites. In the initial assessment for non-target arthropods a potential in-field risk was identified from the use of quizalofop-P-ethyl. Extended laboratory studies were provided for relevant non-target arthropod species. The risk was addressed for all tested species, except for *Typhlodromus pyri* where the meeting of experts agreed that the in-field risk still needed to be addressed. For the uses of quizalofop-P-tefuryl the initial assessment indicated a high risk to *T. pyri* and *Aphidius rhopalosiphi*, both in-field and off-field. Extended laboratory studies were provided to address the risk for relevant species. A data gap was, however, agreed in the meeting of experts for the notifier to address the risk to *Chrysoperla carnea*. The risk assessment for non-target plants from intended uses of quizalofop-P-ethyl indicated a need for no-spray buffer zones of 10 m to address the risk to the most sensitive plant species. No valid data were submitted to address the risk to non-target plants from the intended uses of quizalofop-P-tefuryl and a data gap was agreed during the peer review. A study was also required for quizalofop-P-tefuryl to address the risk to biological methods for sewage treatment. An assessment of the risk to biological methods for sewage treatment was provided in the DAR on quizalofop-P-ethyl, indicating a low risk. The risk to bees, earthworms, soil non-target micro- and macro-organisms was assessed as low for the intended uses of quizalofop-P-ethyl and quizalofop-P-tefuryl.

Key words: quizalofop-P, propaquizafop, 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. Quizalofop-P is one of the 84 substances of the third stage, part B, covered by the Regulation (EC) No 1490/2002 designating Finland as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Finland submitted the reports of its initial evaluations of the dossiers on the variants quizalofop-P-ethyl and quizalofop-P-tefuryl, hereafter referred to as the draft assessment reports, received by the EFSA on 1 February 2007 and 2 May 2007 respectively. Following an administrative evaluation, the draft assessment reports were distributed for consultation in accordance with Article 11(2) of the Regulation (EC) No 1095/2007 on 12 November 2007 to the Member States and on 24 October 2007 to the main notifiers Nissan Chemical Europe SARL and Chemtura Europe Limited (formally Crompton Europe Limited), as identified by the rapporteur Member State. A collaborative dossier with prospective notifier Makhteshim Agan was not submitted. Makhteshim Agan supplied a data package for the assessment of equivalence with the Nissan source of quizalofop-P-ethyl however the data package was not acceptable and the Makhteshim Agan source was not considered further.

The comments received on the draft assessment reports 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 expert 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 formulations

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 **peer review reports** comprising of the documents summarising and addressing the comments received on the initial evaluations provided in the rapporteur Member State's draft assessment reports:

- the comments received,
- the resulting reporting table for quizalofop-P-ethyl (revision 1-1; 11 April 2008),
- the resulting reporting tables for quizalofop-P-tefuryl (revision 1-1; 11 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,
- the evaluation table for quizalofop-P-ethyl (revision 2-1; 18 November 2008),
- the evaluation table for quizalofop-P-tefuryl (revision 2-1; 18 November 2008).

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

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Quizalofop-P is the ISO common name for (*R*)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionic acid (IUPAC). The unresolved isomeric mixture of this substance has the common name quizalofop. Due to the fact that quizalofop-P-ethyl and quizalofop-P-tefuryl are the variants that are manufactured and used in the formulated product, it should be noted that the evaluated data belong to the variants, unless otherwise specified.

A third ester variant of quizalofop-P with its own ISO common name, namely propaquizafop, is included in the third stage Part A of the review programme.

Quizalofop-P 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 products for the evaluation were 'Targa Super' for the ethyl variant and 'Panarex' (also known as 'Pantera') for the tefuryl variant, they are emulsifiable concentrate (EC) formulations.

The evaluated representative uses of quizalofop-P-ethyl are as a herbicide on sugar beet and quizalofop-P-tefuryl as a herbicide on oilseed rape, sugar/fodder beet, potato, combining pea, field beans, linseed and sunflower. Full details of the good agricultural practice (GAP) can be found in the attached list of endpoints.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

For quizalofop-P-ethyl no minimum purity of the active substance as manufactured can be given, because further justification of the technical specification is required. It was also noted that the volatile components need to be analysed and specified separately if they are present at >0.1% or if they are relevant. It is noted that new information is supplied in addendum 6 to Vol. 4, October 2008. This addendum was submitted after the peer review process and therefore it can not be taken in to account.

The minimum purity of quizalofop-P-tefuryl as manufactured should not be less than 795 g/kg. At present there are no FAO specifications for these compounds.

It should be noted for both variants that the *RS* configuration of the impurities is unknown. There was some evidence to suggest that, if present, the isomeric impurity of the variants could be significantly more toxic and therefore the level of these compounds in the technical material should be elucidated further.

Makhteshim Agan supplied a data package for the assessment of equivalence with the Nissan source of quizalofop-P-ethyl. The data package was not acceptable and therefore equivalence could not be concluded on. For this reason the Makhteshim Agan source will not be considered further. It is noted that new information is supplied in addendum 5 to Vol. 4, October 2008. This addendum was submitted after the peer review process and therefore it can not be taken in to account.

The content of quizalofop-P-ethyl in 'Targa Super' is 50 g/L pure. The content of quizalofop-P-tefuryl in 'Panarex' is 36.5 g/L pure. Originally the content of this formulation was 40 g/L however, this included isomers that are not covered by the ISO common name quizalofop-P.

For quizalofop-P-ethyl besides 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 this variant or the respective formulation. However, the following data gaps were identified:

- Surface tension at 25ºC.
- Persistent foam at the highest in use concentration.

For quizalofop-P-tefuryl, 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 this variant or the respective formulation. However, the following data gaps were identified:

- Kinematic viscosity at 40ºC.
- Analytical method for the active substance in the formulation capable of separating the *R* and *S* isomers.

The main data regarding the identity of quizalofop-P-ethyl and quizalofop-P-tefuryl and their physical and chemical properties are given in appendix 1.

Sufficient test methods and data relating to physical, chemical and technical properties are available for both variants. Furthermore, adequate analytical methods are available for determination of the variants in the technical materials and in the representative formulations as well as for determination of the respective impurities in the technical materials, with the exception of quizalofop-P-tefuryl in the representative formulation. Therefore, enough data are available to ensure that at least some quality control measurements of the plant protection products are possible.

For food of plant and animal origin, no methods are validated for the provisional residue definition, namely quizalofop and its esters expressed as quizalofop. For environmental matrices, methods are available that comply with the residue definition. The final residue definitions for soil were agreed as quizalofop. For water, the residue definition for quizalofop-tefuryl is quizalofop, for quizalofop-P-ethyl the residue definition is quizalofop-ethyl. For air, the residue definitions are quizalofop-ethyl or quizalofop-tefuryl. It was considered that chiral methods are not necessary as toxicities of the two quizalofop isomers are similar.

In the quizalofop-P-ethyl dossier, soil can be analysed by LC-MS/MS with a LOQ of 5 µg/kg. Surface and ground water are also analysed by LC-MS/MS with a LOQ of 0.05 µg/L. Air is analysed by LC-MS/MS with a LOQ of 0.5 µg/m^3.

In the quizalofop-P-tefuryl dossier, soil is analysed by GC-MS with a LOQ of 0.02 mg/kg. Surface water and drinking water are analysed by HPLC-UV with a LOQ of 0.1 µg/L and confirmation is via the UV spectrum. Air is analysed by HPLC-UV with a LOQ of 3.75 µg/m^3, for confirmation the water or soil method can be used.

Methods for products of animal origin are not required for the quizalofop-P-ethyl but for the quizalofop-P-tefuryl a data gap has been identified. Methods for body fluids and tissues are not required as neither variant is classified as toxic or very toxic.

2. Mammalian toxicology

Quizalofop-P-tefuryl and quizalofop-P-ethyl were discussed in the PRAPeR meeting of experts held in Parma in July 2008 (PRAPeR 54, subgroup 1). Quizalofop-P-tefuryl and quizalofop-P-ethyl are ester variants of the active substance quizalofop-P. During the meeting of experts there was a discussion on whether to express the reference values as 'quizalofop' only. It was noted that based on the available data the substances may not be toxicologically equivalent, although the quizalofop acid was quickly formed and was the main metabolite for both quizalofop-P-ethyl and quizalofop-P-tefuryl. The proposed classifications differed, with quizalofop-P-tefuryl having a more severe classification. It was agreed that quizalofop-P-ethyl and quizalofop-P-tefuryl should be considered as separate substances, but that the lowest reference value should be used for risk assessment if needed.

Quizalofop-P-tefuryl is a 50:50 mixture of two diastereoisomers. All the toxicokinetics and toxicity studies presented in the DAR were performed with the diastereomeric mixture.

The Member State experts discussed the potential for generation of hydroquinone in the mammalian metabolism and the possible impact on the overall assessment. Hydroquinone is classified as a genotoxic compound (Muta. Cat. 3; R68 "Possible risk of irreversible effects"). It was assumed that it is formed in mammalian metabolism, but due to the labelling position of the parent in the toxicokinetics study it could not be detected. In the rat metabolic pathway it is assumed to be formed and is therefore covered by the toxicity data package. The notifier provided information on batch analysis for batches tested in the mammalian toxicity section, including the relative amount of isomers with reference to the proposed specification. The rapporteur Member State reported that the batches tested were equivalent to the technical specification (the comparison information is presented in the revised Vol. 4 of June 2008). It was noted that three impurities are present at higher levels in the specification than in the batches tested for mammalian toxicity (overall 8% difference). It was also noted they are degraded to rat metabolites. A fourth impurity was structurally related to the parent and of no concern. Xylene was also proposed in the specification at 5% whereas it is in the batches tested in the mammalian toxicology package at 0.5%. Xylene was considered of relevance but not of toxicological concern given the level present. The meeting on physico-chemical properties highlighted the possible presence of the isomeric impurity of quizalofop-P-tefuryl, asking about its relevance. The PRAPeR 54 could not conclude based on the available information.

Quizalofop-P-ethyl is the active isomer (*R*(+)-enantiomer) of quizalofop-ethyl which is the racemic mixture of *R*(+)- and *S*(-)-enantiomers. Toxicokinetics, acute toxicity and short-term toxicity studies were performed using the racemate and *R*(+)-enantiomer, but long-term toxicity studies and reproductive toxicity studies were performed with the racemate only. The evaluation was mainly based on the results obtained using *R*(+)-enantiomer but the results from the long-term toxicity and reproductive toxicity studies conducted with the racemate were considered acceptable. The racemate was shown to be more toxic than the *R*(+)-enantiomer after a short-term exposure. However it was

assumed that the results obtained with the racemate reflect closely enough the toxicity of *R*(+)-enantiomer. In addition, *R*(+)-quizalofop was the only significant metabolite in the systemic circulation, indicating a predominant unidirectional metabolic conversion. However, the lower toxicity of *R*(+)-enantiomer during short-term exposure may indicate that higher doses of *R*(+)-enantiomer than those of the racemate could have been used in carcinogenicity, fertility and developmental toxicity studies.

During the meeting, Member State experts discussed the potential for the generation of hydroquinone in the mammalian metabolism of quizalofop-P-ethyl and the possible impact on the overall assessment. Hydroquinone is classified as a genotoxic compound. It was assumed that theoretically it was formed in mammalian metabolism, but the labelling position of the parent in the study meant it could not be detected. In the rat metabolic pathway it is assumed to be formed and is therefore covered by the toxicity data package. The relevance of the impurities detailed in rows 3, 4 and 6 of Table B.1.1.10-1 of Volume 4 of the DAR was considered in the meeting. These impurities were present at lower amounts in the toxicological batches than the specification. DEREK analysis raised no alerts for the impurities detailed in rows 3 and 6. Due to the structural similarity to quizalofop-P-ethyl of the impurity detailed in row 4, it raised an alert but was considered of equivalent toxicity. Therefore the impurity detailed in row 4 can be considered as not relevant but no conclusion can be reached on the relevance of the impurities detailed in rows 3 and 6.

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

- Metabolites with the chloroquinoxalin-phenoxy moiety: quizalofop, quizalofop-phenol and hydroxy-quizalofop.
- Metabolites with the chloroquinoxalin moiety: hydroxy quinoxaline and dihydroxychloroquinoxaline.
- Metabolites with the hydroxy-phenol moiety: ethyl-hydroxyphenoxy propionate (EPP)[2] and hydroxyphenoxy-propionic acid (PPA).[3]

Apart from quizalofop (acid) that was detected with the parent compounds at significant levels in different parts of the plant at interim and final harvests, the other metabolites were globally observed at low levels (<10% TRR), with some exceptions (e.g. EPP, *ca* 15% TRR, 0.065 mg/kg equiv. in sugar beet foliage, 92 days after a quizalofop-P-ethyl application).

All the metabolites were not considered to be of higher toxicity than the parent compounds, and were "covered" by the reference values set for their parent. All are rat metabolites except for EPP, which is very similar to the metabolite PPA that is present in rats at less than 10%. On this basis EPP is not of

[2] EPP: ethyl-2-(4-hydroxyphenoxy)propionate
[3] PPA: (*R*)-2-(4-hydroxyphenoxy)propionic acid

toxicological concern since it was not considered to be of higher toxicity than the parent compounds. It was not possible based on the available information to provide specific toxicological profiles for individual metabolites.

In the meeting it was not possible to conclude on the compliance of batches tested for mammalian toxicity to the proposed specification as information on the isomeric composition of the racemic mixture was not available.

The bridging of quizalofop-P-ethyl and quizalofop-ethyl was discussed. The data gap for isomeric composition of the racemate tested in toxicological studies could not be fulfilled by analytical data of those batches. The isomeric composition of the racemic mixture tested was most likely 50/50 based on the isomeric composition of the radiolabelled racemate presented in the DAR, and, as such, supporting the resolved isomer.

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

Based on the results of toxicokinetics studies, quizalofop-P-tefuryl shows a relatively rapid absorption, distribution and elimination mainly in faeces. Following a single oral dose, radioactivity was present in the urine within four hours after dosing. Based on the amount of radioactivity excreted in the urine, faeces and residue levels in the tissue, the absorption was estimated to be between 57 – 87% of the administered dose. The oral absorption value was discussed at the meeting. The rapporteur Member State considered that quizalofop-P-tefuryl was almost completely absorbed after oral administration. However, as no bile cannulated studies were available, the experts proposed to use the low dose figure, which resulted in 60% (rounded up from 58%) oral absorption. Quizalofop-P-tefuryl is rapidly distributed after single and multiple doses, with the highest tissue residues in fat, ovary, whole blood, kidneys and liver. No accumulation is observed. About 68 and 82% of the radioactivity is eliminated in males and females, respectively, within 48 hours. Quizalofop-P-tefuryl is extensively metabolised: the major route of metabolism is hydrolysis of the ester linkage to form quizalofop (acid) and tetrahydrofurfuryl alcohol (THFA).[4] Further metabolism occurs via hydroxylation and cleavage of the ether linkage yielding CHQ[5] and PPA. After a single dose, 10 – 15% of the administered dose was eliminated unchanged in the faeces.

Quizalofop-P-ethyl shows a relatively rapid absorption and distribution, and rather slow elimination in urine and faeces. Based on urinary (6, 14%) and biliary (52, 49%) excretion in rats after a single low dose, absorption was 67% in males and 89% in females. Following oral administration in the rat, 56 – 70% of quizalofop-P-ethyl was eliminated in 48 h. It is widely distributed. No potential of accumulation was found. Metabolism is extensive and involves initial de-ethylation to yield the major

[4] THFA: tetrahydrofuran-2-ylmethanol
[5] CHQ: 6-chloroquinoxalin-2-ol

metabolite, quizalofop (acid), followed by hydroxylation and bridge cleavage. Some conjugation also occurs.

2.2. ACUTE TOXICITY

Quizalofop-P-tefuryl is "Harmful if swallowed" (oral LD_{50} = 1012 mg/kg bw, R22 proposed); it has low dermal and inhalation toxicity (LD_{50} >2000 mg/kg bw and LC_{50} >3.9 mg/L, respectively). Quizalofop-P-tefuryl is not a skin or eye irritant, but it is a skin sensitiser in Magnusson-Kligman test (R43 "May cause sensitisation by skin contact" was proposed). The adequacy of the acute oral toxicity study in rats on which the classification R22 is proposed was discussed: the purity grade of technical material tested in this study was lower than the proposed one. The meeting agreed this would represent a worst case and confirmed R22 "Harmful if swallowed".

Quizalofop-P-ethyl is "Harmful if swallowed" (R22 proposed based on oral LD_{50} 1182 mg/kg bw); dermal and inhalation acute toxicity is low (LD_{50} >5000 mg/kg bw and LC_{50} 5.8 mg/L air, respectively). Quizalofop-P-ethyl is not a skin or eye irritant, nor does it show any sensitisation potential.

2.3. SHORT-TERM TOXICITY

Short-term toxicity of quizalofop-P-tefuryl was studied in rats, mice and dogs. Target organs were liver and testes. In rat toxicity studies, the relevant NOAEL was 25 ppm (corresponding to 1.7 mg/kg bw/day for males and 2.0 mg/kg bw/day for females) based on increased liver weights, accentuated lobulation of the liver of males and haematological and clinical chemistry findings at ≥500 ppm (33.4 mg/kg bw/day). Food consumption and body weights were markedly reduced at 2500 ppm (134 mg/kg bw/day) and kidney and testis weights were decreased at this dose level. At the same dose, testicular degeneration was seen in all males, vacuolar changes in the zona glomerulosa of the adrenal cortex were seen in both sexes, and hepatocellular hypertrophy was seen in all animals. In a mouse subchronic study the relevant NOAEL was 50 ppm (corresponding to 7 mg/kg bw/day for males and 9 mg/kg bw/day for females) based on increased liver and kidney weight, associated effects on clinical chemistry parameters and histopathological findings from 125 ppm onwards. The NOAEL from the dog subchronic study was 900 ppm (corresponding to 30 mg/kg bw/day) based on clinical signs, reduced body weight gain and food consumption in males, changes in haematological and serum chemistry parameters, increased liver weight and decreased testes/epididymides weights and macroscopic and microscopic tissue changes at 1800 ppm (51 mg/kg bw/day). In the testicular seminiferous tubules spermatogenic cells were absent. In a one-year dog study, the NOAEL was 750 ppm (corresponding to 26 mg/kg bw/day).

Subchronic toxicity of quizalofop-P-ethyl was studied in rats, mice and dogs. The target organ was shown to be the liver. The lowest short-term NOAEL for quizalofop-P-ethyl was 10 ppm (corresponding 1.7 mg/kg bw/day for males and 2.0 mg/kg bw/day for females; LOAEL 100 ppm,

14.6 and 24.5 mg/kg bw/day in males and females respectively) in mouse study after 13-week (90-day) dietary administration based on liver toxicity observed at and above 100 ppm. At 100 ppm, liver weight was increased and hepatocytic hypertrophy was seen; hepatocyte necrosis irreversible during the 4-week recovery period was present at 100 ppm and increased hepatic mitosis at and above 316 ppm.

In rats, liver changes were observed at and above 1280 ppm (80 – 90 mg/kg bw/day) with quizalofop-P-ethyl. Increased liver weight and associated change in serum enzyme activity and plasma proteins were reversible in the 6-weeks recovery period. The NOAEL was 128 ppm (7.7 and 9.0 mg/kg bw/day in male and females rats respectively) based on changes in body weight, clinical chemistry and liver weight at 1280 ppm.

Dogs were exposed to quizalofop-ethyl for 26 or 52 weeks: very slight effects were seen up to 400 ppm (12 – 15 mg/kg bw/day). The endpoints and the NOAELs of the two dog studies were discussed in the meeting. The 26-week study NOAEL was 3.2 mg/kg bw/day and the 1-year study was 13.4 mg/kg bw/day. The shorter study had a lower NOAEL because of a finding (increased blood urea nitrogen - BUN) not seen in the longer study. The liver weight increase at the top dose was not considered adverse in the 52-week study by the rapporteur Member State, and this was questioned by the experts. The meeting agreed that the NOAEL for both studies is 100 ppm, for the 26-week study based on increased BUN, and liver weight increase for the 52-week study, leading to NOAEL values of 3.2 and 3.4 mg/kg bw/day, respectively.

2.4. GENOTOXICITY

Genotoxicity of quizalofop-P-tefuryl was tested in five *in vitro* and three *in vivo* tests. An *in vitro* mammalian gene mutation test gave an equivocal result in the absence of metabolic activation; the *in vitro* chromosome aberration test and an *in vivo* micronucleus assay were considered not adequate by the rapporteur Member State in the DAR. Quizalofop-P-tefuryl gave a negative result in an *in vivo* UDS assay with rat hepatocytes and in an acceptable micronucleus assay in mouse bone marrow. The meeting of experts agreed that the overall profile does not indicate genotoxic concerns.

Genotoxicity of quizalofop-P-ethyl was negative in all tests which were adequately performed (Ames test, *in vitro* mammalian cell gene mutation tests, and *in vitro* UDS assay). The adequacy of the genotoxicity tests to address the aneugenic and clastogenic potential of quizalofop-P-ethyl was discussed at the meeting. In the DAR the rapporteur Member State considered that the aneugenic properties of quizalofop-P-ethyl were not properly assessed, and requested a new *in vivo* study (either a micronucleus or a chromosome aberration test). A new study was submitted but in view of the restrictions concerning the acceptance of newly submitted studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, it could not be considered in the peer review. The study has been evaluated by the rapporteur Member State. The meeting questioned

whether a further *in vivo* study was really required, and agreed that given the data already available the compound did not exhibit genotoxic properties and therefore the data gap was not confirmed.

2.5. LONG-TERM TOXICITY

The chronic toxicity and carcinogenicity of quizalofop-P-tefuryl was studied in rats and mice. The liver was the main target organ. In rats, changes in haematological and clinical chemistry parameters were observed. Hypertrophy, hyperplasia of hepatocytes, bile stasis and hepatocellular adenomas and carcinomas were observed in both sexes at ≥750 ppm (corresponding to 39.5 and 48.7 mg/kg bw/day in males and females, respectively). The incidence of hepatocellular adenoma was increased at ≥750 ppm in both sexes and the incidence of hepatocellular carcinomas was increased in high dose males (1500/1250 ppm). Follicular epithelial hypertrophy was observed in thyroid at ≥750 ppm in both sexes, likely secondary to the hepatic changes. Testis weights were reduced at the interim sacrifice of the high dose level; degeneration of the seminiferous tubules with secondary aspermia in the epididymis was noted in the testis of the high dose males (also in satellite group at 12 months). Increased incidence of Leydig cell tumours was observed at mid and high dose levels.

The mechanism of hepatocellular tumour induction is likely by peroxisome proliferation and the resulting oxidative stress. There is a clear no-effect level for this effect and the mechanism is usually considered irrelevant for humans. A high incidence of Leydig cell tumours was observed at the same dose levels as hepatocellular tumours. However, the number and area of peroxisomes were not studied from testes samples and mechanism of Leydig tumour induction remained unclear. The NOAEL level was considered to be 25 ppm (equivalent to 1.3 and 1.7 mg/kg bw/day for male and female rats, respectively).

In mice, the liver was the main target organ. Liver and kidney weights increased at ≥125 ppm (corresponding to 21.7 and 26.2 mg/kg bw/day in males and females respectively) and enlarged livers were evident in several high dose animals at necropsy. There was a dose-related increase in diffuse hepatic pigment accumulation at ≥125 ppm. Hepatocellular or testicular tumours were not observed. In the PRAPeR meeting, Member State experts discussed whether the low survival rate in mice at 125 ppm could have an impact on the assessment of carcinogenic potential of quizalofop-P-tefuryl. Further information was presented by the rapporteur Member State in addendum 1. It was agreed that the animals survived long enough to develop tumours. Based on the liver weight findings in the males at 60 ppm, the NOAEL was 10 ppm, corresponding to 1.7 mg/kg bw/day. The relevance of the increased incidence of rare renal squamous cell carcinoma was considered during the meeting of experts. The rapporteur Member State reported that only a few animals were involved, but the incidences of renal squamous cell carcinoma were outside the historical control range (it was noted that this is also a very rare tumour). The meeting concurred that the tumours may be treatment related, and relevant to humans. Furthermore, classification with R40 “Limited evidence of a carcinogenic effect” was discussed. There was a clear treatment related increase in the Leydig cell tumours in rats; the liver tumours were not relevant to humans (as the mechanism of peroxisome

proliferation was not relevant to humans), but the tumours in the testes were, as the mechanism for these was not known. Furthermore, also the renal carcinomas were considered relevant to humans. On this basis classification with R40 was proposed.

In a 2-year study in rats with quizalofop-ethyl, increased liver weights and hepatocyte hypertrophy were seen at and above 100 ppm and cytoplasmic eosinophilia of centrilobular hepatocytes was seen at 400 ppm. The NOAEL for this liver effect was 25 ppm (corresponding to 0.9 and 1.1 mg/kg bw/day for males and females, respectively) and was confirmed during the experts' meeting. The adequacy of the rat carcinogenicity study (because of low survival rate) for the assessment of carcinogenicity was discussed. It was noted that in controls the survival was also reduced. There were no treatment related clinical signs to account for the mortalities observed in male rats. Significant carcinogenicity was not observed in the surviving male rats. Considering all the information available (negative genotoxicity, mechanism of action of liver tumours), no concern was expressed by the group over the reduced survival rates for carcinogenicity assessments concerned.

In mice, increased liver weights and hepatocyte/sinusoidal/macrophage pigment deposition were seen at 80 ppm as well as diffuse hepatocyte enlargement at 320 ppm. In addition, increased incidence of testicular atrophy was seen at and above 80 ppm. The NOAEL in mice was 10 ppm (1.6 and 1.9 mg/kg bw/day for males and females, respectively). A few liver tumours were seen in rats and mice. In female rats, the incidence of malignant liver cell tumours was slightly higher than in controls without statistical significance. After re-evaluation, two of the hepatocellular carcinomas were classified as adenomas and the difference in the incidences decreased and was considered unremarkable. In high dose male mice, the incidence of malignant liver cell tumours was slightly higher than in the concurrent control but within historical control values. Thus, there was no definite carcinogenic effect of quizalofop-P-ethyl at these dose levels. The NOAEL and the relevance of ovarian cysts in the long-term mice study was discussed at a meeting of experts. The increase in ovary weight was present already at the lowest dose tested of 2 ppm. The meeting agreed there is no dose related effect (resulting in increased ovarian cysts) and also no treatment relation. The NOAEL was therefore confirmed as 10 ppm (1.6 mg/kg bw/day) based on liver and testis findings.

2.6. REPRODUCTIVE TOXICITY

The reproductive toxicity of quizalofop-P-tefuryl was investigated in one two-generation study and in two developmental toxicity studies. In the two-generation rat study, the parental and offspring NOAEL was 25 ppm (corresponding to 1.4 mg/kg bw/day for F0 males and 2.1 mg/kg bw/day for F0 females) based on increased liver weight and liver hypertrophy in adult males and females, vacuolar changes in pituitary in adult males, decreased body weights during lactation in F1 generation at 300 ppm and decreased viability during early lactation at 900 ppm. The NOAEL for reproduction was 300 ppm (corresponding to 16.9 mg/kg bw/day for F0 males and 24.5 mg/kg bw/day for F0 females) based on decreased viability index in F1 and F2 generation at 900 ppm and decreased male fertility index during F2 matings and slightly prolonged copulation period during F2a mating. Increased liver

weight at ≥300 ppm was correlated with the hepatocyte hypertrophy and was most severe in high dose F0 males. Malformations were seen in pups at 52 – 76 mg/kg bw/day, but the main malformation (hydrocephaly) was not observed in rat developmental toxicity study in the same rat strain at 100 mg/kg bw/day. Decreased fertility was observed at the same slightly toxic dose level. Quizalofop-P-tefuryl caused degeneration of seminiferous tubules and aspermia in subchronic rat and dog studies and in chronic toxicity study in rats where also Leydig cell tumours were induced. Leydig cell tumours were observed at ≥39.2 mg/kg bw/day and degeneration and aspermia at doses of 51 – 134 mg/kg bw/day.

In developmental toxicity studies in rats, the maternal and developmental NOAEL proposed by the rapporteur Member State was 30 mg/kg bw/day based on increased mortality, clinical signs and decreased maternal body postimplantation loss and malformations at 100 mg/kg bw/day. At this dose anogenital staining was also observed and considered relevant. It was noted that almost half the test animals died or were sacrificed at the highest test dose, indicating a steep dose response. Therefore it was agreed to set the maternal NOAEL at 10 mg/kg bw/day, whereas the developmental NOAEL in rats was 30 mg/kg bw/day based on increased postimplantation loss per dam with concomitant lower number of viable foetuses and increased number of malformations at maternally toxic dose.

In rabbits, the NOAEL was 20 mg/kg bw/day for maternal and developmental toxicity. In the meeting it was discussed if the developmental toxicity had been adequately studied. In the DAR the rapporteur Member State considered the rabbit study not acceptable because it only went up to 20 mg/kg bw/day where no effects were observed. Therefore it could only be concluded that the active was not teratogenic up to this dose level. Based on this limited dose range the validity of this study was questioned. It was agreed that the rabbit was not adequately tested and there was a requirement for a further rabbit study done to the current guidelines (i.e. up to maternal toxicity). However, it was considered that this did not preclude concluding on the risk assessment of this substance, as there were clear no effect levels and margins of safety would be sufficient, and the study would not be used for setting reference values, but experts agreed that R63? ("Possible risk of harm to the unborn child") should be proposed to European Chemicals Agency (ECHA), because of the limitations of the studies.

EFSA note after PRAPeR meeting: the need for this additional study to be confirmed by ECHA when considering the classification of quizalofop-P-tefuryl.

The reproduction toxicity of quizalofop-ethyl was investigated in one two-generation reproduction study and in two prenatal toxicity studies and one range-finding rabbit study. In the two-generation toxicity study with quizalofop-ethyl, the NOAEL for offspring was 25 ppm (2.4 mg/kg bw/day for males and 2.6 mg/kg bw/day for females) based on hepatotoxicity; the parental NOAEL was 100 ppm (9.4 and 10.2 mg/kg bw/day in males and females respectively) based on decreased body weight

during premating period, whereas the reproductive NOAEL was 400 ppm (37.8 mg/kg bw/day, highest dose tested).

In a developmental toxicity study in rats, quizalofop-ethyl caused increased resorptions and skeletal variations at the maternally toxic dose. The developmental NOAEL from the rat study was discussed at the meeting. It was commented that the NOAEL of the study was based on an increased incidence of 14th rib, which may not be an adverse effect. However in the DAR, 30 mg/kg bw/day was proposed as the developmental NOAEL (based also on resorptions, in addition to skeletal variations at the maternally toxic dose). No historical background data were available for these findings. The meeting confirmed the developmental and maternal NOAEL at 30 mg/kg bw/day based on decreased bodyweight and food consumption (maternal) and on resorptions and changed ossification (developmental).

In rabbits, no malformations were observed up to doses of 60 mg/kg bw/day, which represented the NOAEL for developmental toxicity, whereas the maternal NOAEL for dams was 30 mg/kg bw/day based on decreased body weight and food consumption and decreased thymus and thyroid weights at 60 mg/kg bw/day. This study was not accepted by the rapporteur Member State because there was only marginal maternal toxicity and no foetal findings at the highest dose level (60 mg/kg bw/day) studied. The meeting agreed that developmental data were available in rats and rabbits, both valid with determinable NOAELs, with no evidence of teratogenicity. The dosing regime in the rabbit study was considered acceptable. The NOAELs proposed by the rapporteur Member State were confirmed by the meeting: 30 mg/kg bw/day for maternal toxicity and 60 mg/kg bw/day for developmental toxicity. There was no requirement for a further study.

2.7. NEUROTOXICITY

Quizalofop-P-tefuryl is not chemically or structurally related to organophosphates or other chemicals capable of inducing delayed neurotoxicity. However, a specific acute neurotoxicity study in the rat has been conducted with quizalofop-P-tefuryl (NOAEL 400 mg/kg bw in males and >800 mg/kg bw in females).

Quizalofop-P-ethyl does not have a chemical structure related to those substances capable of inducing delayed neurotoxicity. It was therefore considered that it does not have a potential to induce neurotoxicity in mammals and no studies are required. In some experiments investigating the general pharmacological effects of quizalofop-ethyl at 500 mg/kg bw, a slight inhibition of the central nervous system was observed in mice (reduced motor activity, retarded pinna reflex and hypothermia). It was presumed that quizalofop-ethyl might possess little inhibitory effect on the central nervous system in mice.

2.8. FURTHER STUDIES

Tetrahydrofurfuryl alcohol (THFA), the alcohol resulting from the major initial route of metabolism/degradation (ester hydrolysis) of quizalofop-P-tefuryl, is moderately toxic by the oral (LD_{50} 1600 mg/kg), intravenous and intraperitoneal route. It is a moderate to severe eye irritant and is irritating to skin and mucous membranes.

The acute oral LD_{50} of quizalofop (acid) to rats was calculated to be 1330 and 1520 mg/kg bw for males and females respectively, and in mice it was 1160 and 1115 mg/kg bw for males and females.

The acute oral LD_{50} of quizalofop-phenol in rats and mice was found to be greater than 5000 mg/kg bw, as well as the acute oral LD_{50} of PPA and hydroxy quinoxaline in rats.

Quizalofop-ethyl seems to cause hypothermia and it was demonstrated to reduce rectal temperature. Intravenous dose of 10 – 30 mg/kg caused pronounced dysfunction of the brain in the spontaneous EEG and a transient condition like a coma.

2.9. MEDICAL DATA

According to medical surveillance on manufacturing personnel, workers involved in the production of quizalofop-P-tefuryl were healthy and have not shown any acute or chronic medical problems. According to the notifier, no clinical cases or poisoning cases have been reported. In addition, no epidemiological assessment or observation on experience of the general population have been reported.

There were no adverse health effects attributable to quizalofop-P-ethyl in workers of Onoda Plant manufacturing pesticide products, between years 1998 – 2002. Also companies that have dealt with quizalofop-P-ethyl technical and its formulated products, both in the USA and Europe, have not reported any abnormal symptoms in the health of researchers and workers relating to use of quizalofop-P-ethyl. According to the notifier, no clinical or poisoning cases have been reported. In addition, no epidemiological assessment or observation on experience of the general population has been reported.

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

The reference values for quizalofop-P-tefuryl and quizalofop-P-ethyl were confirmed during the meeting of experts.

Quizalofop-P-tefuryl

ADI

The NOAEL of the 2-year study in rats was agreed as the basis for setting the ADI of 0.013 mg/kg bw/day, SF 100. The meeting agreed all the moieties would be covered by the toxicological testing and hence would contribute to the toxicological profile, and would be covered by this ADI (including esters released).

AOEL

The proper endpoints/dose levels for setting of the AOEL were discussed. The rapporteur Member State proposed an AOEL of 0.014 mg/kg bw/day, based on the rat multi-generation study with a SF 100. The meeting agreed that the NOAEL of 1.7 mg/kg bw/day from the 90-day rat study was the most relevant NOAEL, also based on its dosing regime, and applying a 60% correction factor (limited oral absorption) and SF 100 resulted in an AOEL of 0.01 mg/kg bw/day.

ARfD

The setting of an ARfD value was discussed. It was suggested to base the ARfD on maternal toxicity seen in the rat developmental study (NOAEL 10 mg/kg bw/day agreed by the experts). But this NOAEL was based on the clinical finding of anogenital staining, mainly occurring later during gestation, and only in few animals earlier. It was noted however, that a steep dose response was observed in this study. After further discussion, it was concurred that this was the only relevant study for setting an ARfD. The ARfD agreed therefore was 0.1 mg/kg bw (based on clinical findings), with an SF 100 applied.

Quizalofop-P-ethyl

ADI

The experts' meeting agreed on an ADI of 0.009 mg/kg bw/day based on the 2-year rat study (using the racemic mixture) with SF 100.

AOEL

The meeting agreed that the AOEL is 0.01 mg/kg bw/day, based on the 90-day mouse study (performed with the *R*(+) enantiomer) and SF 100 (corrected for limited oral absorption of 67%).

ARfD

The meeting considered whether an ARfD was required. Based on the low acute toxicological profile of the active substance, it was agreed that an ARfD was not triggered.

2.11. DERMAL ABSORPTION

An *in vitro* test performed with [^{14}C]-quizalofop-P-tefuryl applied to rat skin, as undiluted 'Panarex' test preparation and as the in use spray dilution, was summarised in the DAR. More details were given in an addendum to the DAR discussed during the PRAPeR meeting 59. In the DAR, the

proposed values were 12.19% for the concentrate and 25.09% for the dilution. It was noted that in this study, 20 tape strips were done and these have all been disregarded. It was concluded that only the first 5 tapes should be disregarded (instead of 2 as usually done, as in this study they were considered in groups of 5). Including these tapes, the dermal absorption values increased to 18% for the concentrate and 28% for the dilution.

As for quizalofop-P-ethyl, in the DAR the proposed values were 4% for concentrate and 12% for dilution. A pig study was performed using a different formulation type (a SC rather than an EC) and this is generally only regarded as supporting evidence. For this reason it was considered not a valid study on which to base dermal absorption. It was clarified in the DAR that for the *in vivo* rat study, the skin deposition was taken into account. However, it was noted that there were no recovery data for this study. In this case it was discussed whether the values from quizalofop-P-tefuryl could be used. It was discussed whether the physico-chemical properties and formulations were comparable. It was agreed this was the case and so the dermal absorption values agreed for quizalofop-P-ethyl are 18% for concentrate and 28% for the dilution.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

OPERATOR EXPOSURE

Quizalofop-P-tefuryl

The notified product 'Panarex' is a herbicide formulated as an emulsifiable concentrate (EC) containing 36.5 g/L of quizalofop-P-tefuryl. It is intended for application to field crops including potatoes, sugar beet, peas, beans, soyabeans, oilseed rape and sunflowers. It is effective on a wide range of annual and perennial grasses. 'Panarex' is applied by spray application with a standard tractor-mounted boom sprayer fitted with hydraulic nozzles. One application is recommended per season. The use rate is 0.5 – 2.5 L of formulated product/ha (0.02 – 0.10 kg a.s./ha) in a spray volume of 200 to 400 litres of water/hectare. The product is packed in 1 and 5 litre containers with the openings of 24 and 50 mm, respectively.

During the PRAPeR meeting the rapporteur Member State was asked to re-calculate operator, worker and bystander exposure using revised dermal absorption figures and the new AOEL value. The recalculations are presented below.

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 boom spraying, hydraulic nozzles, potatoes	0.2480	0.0306	2480	306
German	Tractor mounted boom spraying, hydraulic nozzles, potatoes	0.0288	0.0013	288	13

* UK POEM: gloves during mixing/loading and application.

German model: gloves during mixing/loading and application, coverall and sturdy footwear during application.

The estimated operator exposure exceeded the AOEL without the use of PPE, as well as with PPE but only with the UK POEM. The exposure was estimated to be below the AOEL (13%) applying the German model, with the use of gloves during mixing/loading and application and coverall and sturdy footwear during application. It is noted that all other scenarios are covered by the potato scenario.

Quizalofop-P-ethyl

'Targa Super' is a herbicide formulated as an emulsifiable concentrate (EC) containing 50 g/L of quizalofop-P-ethyl. It is intended to be used on sugar beet using a tractor-mounted boom sprayer with hydraulic nozzles. Recommended application rate is one application per season of 1 to 4 L of product/ha (0.05 – 0.2 kg a.s./ha) in a spray volume of 200 to 400 litres of water/hectare. The container sizes of 'Targa Super' are 5 and 20 litres.

In the expert meeting it was noted that the rapporteur Member State should re-calculate exposure estimates with the standard input parameters for the respective models (UK or German) and the revised dermal absorption values agreed and compare the results with the revised AOEL of 0.01 mg/kg bw/day. The results are reported below.

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 boom sprayer	0.2549	0.0371	2549	371
German	Tractor mounted boom sprayer	0.0574	0.00264	574	26

* UK POEM: gloves during mixing/loading and application.

German model: Gloves during mixing/loading/application, coverall and sturdy footwear during application.

The operator exposure assessment was estimated to be below the AOEL (26%) with the use of PPE (German model). The AOEL was exceeded for exposure estimates with the German model (no PPE applied) and with UK POEM (either with or without PPE).

WORKER EXPOSURE

Quizalofop-P-tefuryl

The re-entry exposure was calculated using algorithm and default values recommended by the Reentry Working Group (EUROPOEM 2, Re-entry Working Group Report, December 2002). The estimation of dermal re-entry exposure is based on the amount of active substance on the crop foliage. Because no specific Dislodgeable Foliar Residue (DFR) value was present for quizalofop-P-tefuryl the default value of 0.003 mg/cm^2 was used (EUROPOEM 2; Re-entry Working Group Report, December 2002). Transfer coefficient (TC) value of 2500 cm^2/h for bare hands was used for vegetables and 5000 cm^2/h for ornamentals. Work rate was assumed to be 2 h/day (crop inspection). The application rate for sugar beet is 0.10 kg a.s./ha. The worker is assumed to weight 60 kg and the dermal absorption is 28%. Exposure through inhalation was considered negligible outdoors.

The exposure for workers re-entering field for crop inspection was estimated to be 70% of the AOEL for vegetables and 140% of the AOEL for ornamentals.

EFSA note after the PRAPeR meeting: the rapporteur Member State further refined the calculation for re-entry activities in the ornamentals scenario considering a reduced TC of 1400 cm^2/h, accounting for 90% reduction of TC hands for use of gloves. The assessment, estimating an exposure of 39% of the AOEL, has not been peer reviewed. However it is agreed that the use of gloves is expected to reduce exposure below the AOEL.

Quizalofop-P-ethyl

The re-entry exposure was calculated using algorithm and default values recommended by the Reentry Working Group (EUROPOEM 2, Re-entry Working Group Report, December 2002). The estimation of dermal re-entry exposure is based on the amount of active substance on the crop foliage. Because no specific Dislodgeable Foliar Residue (DFR) value was present for quizalofop-P-ethyl the default value of 0.003 mg/cm^2 was used (EUROPOEM 2; Re-entry Working Group Report, December 2002). Transfer coefficient value of 2500 cm^2/h for bare hands was used. Work rate was assumed to be 2 h/day (crop inspection). The application rate for sugar beet is 0.20 kg a.s./ha. The worker was assumed to weight 60 kg and the dermal absorption is 28%. Exposure through inhalation was considered negligible outdoors. The exposure for workers re-entering field for crop inspection was estimated to be 140% of the AOEL

EFSA note after the PRAPeR meeting: the rapporteur Member State further refined the calculation considering a reduced TC of 520 cm^2/h, accounting for 90% reduction of TC hands for use of gloves. The assessment, estimating an exposure of 29% of the AOEL, has not been peer reviewed. However it is agreed that the use of gloves is expected to reduce exposure below the AOEL.

BYSTANDER EXPOSURE

Quizalofop-P-tefuryl

The bystander exposure was evaluated by calculating the realistic worst case scenario of potential exposure to quizalofop-P-tefuryl while spraying potatoes with tractor mounted boom sprayer fitted with hydraulic nozzles. This scenario was considered to cover also all other crops. Exposure time was considered to be one hour, which is a conservative assumption. The drift values recommended by the Bystander Working Group (EUROPOEM 2, Bystander Working Group Report, December 2002) were used for calculations. Absorption via dermal route was assumed to be 28% and via inhalation 100% and a body weight of 60 kg was assumed. Area of unprotected skin was assessed to be 2 m^2. The bystander estimated exposure is 7% of the proposed AOEL.

Quizalofop-P-ethyl

The bystander exposure was evaluated by calculating the realistic worst case scenario of potential exposure to quizalofop-P-ethyl while spraying sugarbeet with tractor mounted boom sprayer. Exposure time was considered to be one hour. The drift values recommended by the Bystander Working Group (EUROPOEM 2, Bystander Working Group Report, December 2002) were used for calculations. Absorption via dermal route was assumed to be 28% and via inhalation 100% and a body weight of 60 kg was assumed. Area of unprotected skin was assessed to be 2 m^2. The bystander estimated exposure represented 14% of the proposed AOEL.

3. Residues

Quizalofop-P-tefuryl and quizalofop-P-ethyl were discussed at the PRAPeR experts' meeting for residues (PRAPeR 55, round 11) in July 2008. Both compounds are ester variants of the active substance quizalofop-P. A third ester variant, propaquizafop, was also evaluated during this PRAPeR meeting as an active substance. 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 variants in plants and animals are similar.

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

Plant metabolism

In plant, the metabolism of quizalofop-P-tefuryl has been investigated in potato, cotton and soybean, using ^{14}C-label on the quinoxaline moiety only. No study was performed with a radioactive label on the phenyl or furfuryl moiety. Considering this point and the fact that identification of the metabolites was not sufficiently investigated in some studies, the meeting of experts concluded that new studies using a second radioactive position have to be provided, unless the notifier has access to the plant metabolism studies done with an other variant. The quizalofop-P-tefuryl studies were generally conducted with exaggerated application rates representing 3 to 6 times the normal rate and, in order to facilitate the identification, some experiments were even performed with a 20x to 30x dose level.

For quizalofop-P-ethyl, metabolism was also investigated in potato, cotton, soybean and additionally in sugar beet. Studies were performed using ^{14}C-quizalofop-P-ethyl (*R* enantiomer) or ^{14}C-quizalofop-ethyl (racemate *R*/*S*) either labelled on the phenyl or the quinoxaline moiety. On soybean, and in order to compare the metabolic fate of the different isomers in the plant, studies were also conducted using ^{14}C-quizalofop-ethyl (racemate *R*/*S*), ^{14}C-quizalofop-P-ethyl (*R* enantiomer) and ^{14}C-quizalofop-*S*-ethyl[6] (*S* enantiomer) respectively. Due to their low application rates (*c.a.* 6 g/ha), two studies performed on sugar beet and potato with quizalofop-ethyl were disregarded by the meeting and considered as informative only. The other studies were conducted using application rates representative of the supported uses (140 – 280 g a.s./ha).

For both variants, the metabolism proceeds primarily by the hydrolysis of the ester link to yield quizalofop (acid) followed by the loss of the propionyl moiety leading to the quizalofop-phenol metabolite. Further metabolism occurs by hydroxylation of the quinoxaline moiety giving the hydroxy-quizalofop, hydroxy-quizalofop-phenol and the dihydroxy-quizalofop-phenol. In addition, the presence of the quinoxaline and phenoxy metabolites indicated a cleavage of the parent molecule. However and due to the single label, the phenoxy metabolites were not seen in the quizalofop-P-tefuryl studies. Some of these metabolites were also found to be conjugated.

[6] Quizalofop-S-ethyl: ethyl (2*S*)-2-{4-[(6-chloroquinoxalin-2-yl)oxy]phenoxy}-propanoate

Parent esters were always detected in immature plant parts collected within 10 to 20 days after the last application but they were generally not detected or in low proportions in the mature plants at harvest, except for quizalofop-ethyl in beet leaves and in soya straw where it accounted for 20% (0.12 mg/kg) and 47% (0.13 mg/kg) of the TRR respectively. However, this high proportion of quizalofop-ethyl in soya straw observed in one study was not confirmed in two other studies conducted with similar PHI and application rates, where esters were either not detected or limited to 15% TRR. Quizalofop was always present at harvest, accounting for 3 – 6% TRR in cotton seed and foliage, 5 – 21% in soya beans and straw, 3 – 14% in beet roots and leaves and 38 – 59% in potato tubers. Quizalofop was also observed as glutathion conjugate in the mature potato tubers (6 – 10% TRR). The other identified metabolites were globally present in low proportions except for:

- the hydroxy-quizalofop-phenol accounting for 20% TRR in the soya meal (0.17 mg/k, 6x study),
- hydroxy-quinoxaline which represented more than 10% TRR in cotton seeds (0.01 mg/kg) and soya hulls (0.85 mg/kg) in the quizalofop-P-tefuryl studies performed at a 6x dose level,
- the phenoxy propionate metabolite that accounted as free and conjugate for 16.2% of the TRR (0.065 mg/kg) in the sugar beet leaves (considering the corrected figures reported in table B.7.1.1-7 provided by the rapporteur Member State in the quizalofop-P-ethyl addendum 4 of September 2008).

The meeting discussed whether the phenoxy propionate and hydroxy-quizalofop-phenol metabolites observed in beet foliage and soya meal, in similar amounts to the parent ester or to quizalofop, have to be included in the plant residue definition and whether they have to be taken into account in the animal feeding. Finally, the experts decided to ask the notifier to provide a statement on the toxicological relevance of these metabolites and a message was addressed to the PRAPeR meeting on mammalian toxicology on this point. Finally and provisionally, awaiting toxicological information on these metabolites, the meeting decided not to include these compounds in the plant residue definition.

In conclusion and **provisionally**, awaiting the requested information and clarification, the meeting proposed the following plant residue definition for monitoring and risk assessment for each individual variant:

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

In addition, and considering the metabolism studies performed with the three quizalofop variants, 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 some metabolites.

After the meeting and considering that the conjugates were mainly detected in soya (Vithala *et al*., 1998, tefuryl variant study) and in cotton (Koeppe *et al*., 1990, ethyl variant study) on immature plants and for pre harvest intervals of 7 and 21 days which are not in compliance with the representative GAP where the PHI are at least 60 days, the **EFSA was of the opinion that there is no need to include the conjugates in the residue definitions**, **especially for monitoring**. Moreover, conjugates were generally not detected in plant parts collected at maturity except in potato tubers but in low proportions in comparison to the quizalofop (6 – 10% besides 38 – 58%) and to a lesser extent in sugar beet foliage (<9% TRR). Even if the further additional information/clarification requested on the uncharacterised radioactivity shows that conjugates are part of the residues, the parent esters and quizalofop both seem to be sufficient markers for the residues in plant since they accounted together generally for *c.a.* 20% of the total radioactivity in plant at maturity, except in the cotton seeds (5% TRR).

In addition for quizalofop-P-ethyl, the meeting concluded that the metabolism pattern has not been sufficiently described in root crops. No characterisations were performed in potato tubers due to the low application rate (*c.a.* 6 g/ha) and in the sugar beet study performed with a sufficient application rate (280 g/ha), a substantial part of the extracted radioactivity (43% TRR) was not identified. Therefore, the meeting concluded that these metabolism studies were not sufficient to validate the proposed residue definition on the root/tuber plant group, especially on potatoes. However, and considering that no metabolites are expected at significant levels in sugar beet roots, it was agreed that the proposed residue definition could be applied on beet root only. Consequently, the notifier was requested to provide further information concerning the unidentified fractions observed in the beet studies, unless a new metabolism study has to be submitted for root crops.

Concerning the metabolism study performed on soya and using the racemate (*R*/*S*), the *S* and *R* enantiomers respectively, some differences were observed in the metabolic fate but not to the extent that it could be concluded that the different enantiomers have different metabolic pathways. Globally, the metabolic pathways have to be considered as similar. The chiral residue analyses showed that no chiral inversions were observed in the samples collected 1 and 14 days after application. At harvest, 15 weeks after treatment, there was some evidence of an overall chiral inversion from the *S* to the *R* enantiomer, this inversion being more important for quizalofop than for quizalofop-ethyl. To a lesser extent, a slight inversion from *S* to *R* was also observed but for the ethyl variant only.

Supervised residue trials

For the ethyl variant, residue trials were submitted to support a single representative use on sugar beet. Samples were analysed using different methods quantifying quizalofop-P-ethyl and quizalofop either separately or both compounds together as quizalofop and achieving a large range of individual LOQs from 0.005 mg/kg to 0.10 mg/kg. Studies using analytical methods not sufficiently validated were removed from the data set. No residues were detected in roots at harvest and a value of 0.10 mg/kg based on the highest LOQ was initially proposed as a MRL in the DAR. After discussion, the

meeting was of the opinion to remove the three studies performed with these highest LOQ and proposed to set the MRL at a value of 0.05 mg/kg for sugar beet roots since a sufficient number of studies was available.

For quizalofop-P-tefuryl, numerous residue trials were submitted to support the uses on potato, sugar beet, bean, pea, lentil, oilseed rape, linseed, soya and sunflower. Samples were analysed using a method quantifying separately the parent quizalofop-P-tefuryl and its metabolites (including quizalofop) free and conjugated that could be converted to 2-methoxy-6-chloroquinoxaline (MCQ) and achieving individual LOQs of 0.02 mg/kg (0.04 mg/kg for the total residues). The total residue was expressed as tefuryl variant equivalent and not as quizalofop equivalent. However, fortifications were performed for the parent and for quizalofop only and this method has to be considered as not validated for the other metabolites. Moreover, it is not clear which metabolites could be effectively analysed in addition to quizalofop. Therefore in the quizalofop-P-tefuryl DAR, "metabolites residues" have to be understood as "quizalofop residues plus other metabolites, free and conjugated, containing the chloroquinoxaline moiety". Nevertheless, this method was considered as appropriate in the framework of this peer review since its scope may be wider than the compounds included in the residue definition. The additional information provided in the evaluation table and concerning the growth stages at last application was considered as insufficiently detailed and the rapporteur Member State was asked to provide new tables detailing for each individual trial the growth stage at last application and the values selected for the MRL calculations. Therefore, the MRLs proposed for the different crops have to be considered as provisional awaiting the requested clarifications. The parent quizalofop-P-tefuryl was never detected (<0.02 mg/kg), even at interim sampling times. Positive residues were exclusively found as "metabolites". The supervised residue trials confirmed the metabolism study results where the tefuryl variant was never detected in the mature plant parts investigated, except in soya hulls but in low proportions.

Storage stability studies

A storage stability study performed on sugar beet roots and beet tops spiked with quizalofop-P-ethyl and quizalofop has been submitted. While some concerns on the analytical method were highlighted, it was agreed that there was enough evidence to conclude that residues of quizalofop-P-ethyl and quizalofop are stable for at least 16 months in beet matrices when stored in frozen conditions at -20°C. However, the meeting was of the opinion that an additional storage stability study on oil/protein matrices should be requested in order to support the results of the rotational crop study. This new study has been submitted but could not be considered by the peer review in view of the restrictions concerning the acceptance of new (newly submitted) studies after the submission of the DAR to EFSA, as laid down in the Commission Regulation (EC) No. 1095/2007.

For quizalofop-P-tefuryl the storage stability study was performed on a wider range of commodities since information was provided on soya beans, cotton seeds, rape seed oil and cake, potato tubers, sugar beet roots and sugar beet tops, spiked with quizalofop-P-tefuryl and quizalofop. Three different

analytical methods were used, the methods XM-12A and XM-12B being variants of the original method XM-12 validated in 1992 for the active substance quizalofop and "bound residues". The experts were unable to understand how these methods could have been validated for "bound residues" and asked the notifier to clarify the differences between the three analytical methods and for an explanation concerning the "known levels of bound residues in treated samples". Residues were stable for up to 12 months in potato, rapeseed oil and rapeseed cake and up to 24 months in rapeseed, soya and cotton seeds. In contrast, quizalofop-P-tefuryl residues were shown to be degraded in sugar beet roots and tops after a storage period exceeding one month, although such degradation has not been observed in the quizalofop-P-ethyl study using similar conditions. However, the missing residues were recovered as quizalofop and after 231 days recoveries were more than 80% of the spiked levels when both quizalofop-P-ethyl and quizalofop residues were added up. These results indicate that in some matrices and under some circumstances that could not be clarified, the ester residues may be degraded to the acid form during the storage and therefore, routine analytical methods have to take into account both the variants and the acid in order to effectively consider the total residues.

Processing study

No processing study was provided for quizalofop-P-ethyl and the meeting agreed that it was not necessary to request such a study as no residues are expected in beet roots following the use of the active substance as stated in the critical GAP.

For quizalofop-P-tefuryl, a standard hydrolytic processing study was provided for the boiling conditions only; pasteurisation and sterilisation being missing. The meeting concluded that a new study covering the full range of the processing conditions has to be requested. In addition, the experts discussed whether the processing studies performed on rapeseed could be considered as acceptable since the residue levels in pressed cakes from two different experiments seem to be inconsistent with the initial seed residue levels. The meeting agreed that these differences could be explained by the low levels observed in the processed fractions. Nevertheless, the notifier was asked to clarify the low residue levels detected in all processed fractions (crude oil, refined oil, pressed cake *etc*.) which seem to be inconsistent with the initial residue levels observed in seeds. Depending on the clarification that could be provided, a new processing study on rape seed should be necessary. Moreover, the notifier should consider that the nature of the residues in processed commodities was not sufficiently investigated and the analytical method not validated for oil. On potatoes, the residue levels were not affected in boiled potatoes but were increased in fried potatoes.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

A rotational crop study performed with the racemate quizalofop-ethyl labelled on either the quinoxaline or phenyl moieties has been submitted. Application was performed at a rate of 308 g/ha (1.5x) and cotton, lettuce, beet, wheat and peanuts were sown as rotational crops after an ageing period of 30 and 62 days. Residues in crops at harvest were generally low, below 0.05 mg/kg (with

many values <0.02 mg/kg) regardless of the ageing period. For the plant back interval of 62 days, maximum levels were observed in wheat straw (0.025 – 0.045 mg/kg) and in peanut shell (0.084 – 0.090 mg/kg). Quizalofop-ethyl, quizalofop, quizalofop-phenol and the breakdown metabolites hydroxy-quinoxaline, dihydroxy-quinoxaline, hydroxy-phenoxy-propionic acid and hydroxy-phenoxy propioniate were identified in the rotational plant parts analysed, these compounds being generally detected in proportions below 10% of the TTR and levels below 0.01 mg/kg, except in the 30 day aged soil where quizalofop and the dihydroxy-quinoxaline metabolite accounted for 27 – 35% of the TRR in the beet roots (0.005 – 0.009 mg/kg) and 15% TRR in the beet foliage (0.007 mg/kg).

For quizalofop-P-tefuryl, the rotational crop study was performed with the ^{14}C-quinoxaline label only and using an application rate of 250 g/ha (2.5x). Wheat, turnips and lettuce were sown as rotational crops after ageing periods of 1, 4, 8 and 12 months, but the crops planted one month after treatment were lost due to crop failure. As previously for the ethyl variant, no significant residues were observed in crops at harvest, the maximum radioactivity being observed in straw (*c.a.* 0.02 mg/kg), irrespective of the plant back intervals.

Overall it was concluded that all the compounds detected in the rotational crops were also present in the primary crops, suggesting a similar metabolic pathway in primary and in rotational crops and that significant residues of quizalofop-ethyl, quizalofop-P-tefuryl and of their metabolites are not expected in rotational crops.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

Animal metabolism study

The quizalofop-P-ethyl studies were conducted using the racemate quizalofop-ethyl labelled on the phenyl and quinoxaline moieties in the goat study, and on the quinoxaline moiety only in the hen study. This single radio-labelling was considered as sufficient in the scope of this peer review since the intended use on sugar beet does not lead to significant intake by poultry. However, the meeting of experts underlined that the need of a second labelling should be reconsidered if further uses lead to an increase of the residue burden in animal diets. Goats and hens were dosed during 5 days at a rate of 50 mg/kg feed instead of the 10 mg/kg feed usually recommended, but it was agreed that this dose rate was acceptable since it allowed for better identification of the metabolites.

For quizalofop-P-tefuryl, the metabolism studies on goat and hen were conducted using a single label on the quinoxaline moiety only, the animals being dosed during three consecutive days and using an exaggerated dose rate of 15 mg/kg bw/d (equivalent to 323 mg/kg feed for goat). The meeting agreed that a study with a second labelling position on quizalofop-P-tefuryl or with another variant has to be requested. The 1991 goat study was considered as informative only since the total radioactive recovery was low (53%) and the conclusions of the meeting were based on the second study performed in 2004.

Both variants were rapidly excreted in urine and faeces. Less than 2.6% of the administered radioactivity was recovered in goat milk and tissues and less than 1% in eggs and hen tissues. Similar metabolic pathways were observed for both variants, starting with rapid hydrolysis of the ester bond leading to the acid quizalofop and followed by hydroxylation or further hydrolyses giving hydroxy-quizalofop and hydroxyl-quizalofop-phenol, these metabolites being subject to conjugations. In the hen and for both variants, quizalofop-pentanoic acid was also observed as a major metabolite in liver and kidney. The very low proportion of quinoxaline metabolites (<1% TRR) indicated limited cleavage of the parent molecule.

In the goat studies and for both variants, quizalofop was the major residue detected, accounting for 21 – 61% TRR in liver, 48 – 83% in kidney, 78 – 81% in muscle and up to 81% in milk. The esters quizalofop-ethyl and quizalofop-P-tefuryl were only observed in milk in low proportions (maximum 8% TRR). Some discrepancies were however observed concerning the nature of the residue in fat since it was shown to be entirely constituted of quizalofop (of which 67% TRR as conjugate) in the tefuryl variant study; whereas quizalofop accounted for only 15 – 25% in the ethyl variant study, a large part of the radioactivity remaining not characterised. The meeting of experts recognised that the residues were not sufficiently investigated in fat in this late study since only a small part of the radioactivity was characterised and the notifier was requested to provide additional information concerning the nature of the residues in fat. Additional metabolites were also identified in the goat tissues but in lower proportions. In the tefuryl variant study, hydroxy-quizalofop and quizalofop-phenol were detected in kidney and liver (respectively 13% and 19% TRR) and hydroxy-quizalofop-phenol in kidney only (6% TRR). These metabolites were not identified in the ethyl variant study where the only additional metabolite identified was quizalofop-methyl observed up to 25% TRR in milk.

The metabolism was more complex in hen. For both variants, quizalofop was the major residue in kidney (32 – 41% TRR) and eggs and mainly as glycerol conjugate (87% TRR) in the quizalofop-P-tefuryl study. Quizalofop pentanoic acid was shown to be the major metabolite in liver (57 – 83% TRR) and accounted for 16 – 29% in kidney. The parent ester was only detected as a major component in fat in the quizalofop-P-ethyl study (55% TRR) but no information was provided in the tefuryl study since fat was not analysed. In addition in the quizalofop-P-ethyl study, quizalofop-methyl was observed in kidney, this metabolite being considered as an analytical artefact by the notifier. The meeting of experts was not of this opinion and concluded that quizalofop-methyl should be considered as the other metabolites since it was observed in hen, goat and sugar beet matrices while these different substrates were analysed using different analytical methods.

Considering table B.7.8.3 in 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 supplementary metabolism study in pig should be requested. Comparison of the biodistribution of radioactivity 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 goat on an equivalent mg/kg bw basis, some differences being of a 10-fold magnitude. As a result, it was concluded that the MRLs set on the basis of ruminant feeding studies may not cover the residues 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.

Finally, the meeting of experts concluded that the residue definitions for animal products should be proposed as **provisional** only, awaiting the additional information requested especially on the nature of residue in fat, on the quantitative differences observed in rat and ruminant and on phenol metabolites observed in the sugar beet metabolism study. Provisionally, the following residue definitions were proposed for each individual quizalofop variant:

- For monitoring: sum of quizalofop-ester and quizalofop expressed as quizalofop (sum of isomers).
- For risk assessment: sum of quizalofop-ester, quizalofop pentanoic acid and quizalofop, expressed as quizalofop (sum of isomers).

In addition and considering the metabolism studies performed with the three variants, the meeting of experts concluded that the following common residue definitions can be proposed for propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl as:

- For monitoring: sum of quizalofop-esters and quizalofop expressed as quizalofop (sum of isomers).
- For risk assessment: sum of quizalofop-esters, quizalofop pentanoic acid and quizalofop, expressed as quizalofop (sum of isomers).

This definition should remain provisional, pending the submission and the evaluation of the requested additional information and the statement on the toxicological relevance of some metabolites.

Feeding study

For quizalofop-P-ethyl, no feeding studies were submitted although animal burden calculations indicated that the trigger value of 0.10 mg/kg in feed was exceeded when calculations are expressed on the dry matter basis. However, considering the metabolism studies performed with an exaggerated 50x dose rate, it was concluded that no significant residues are expected in animal matrices, milk and eggs on the basis of the representative use in sugar beet, and the meeting agreed that no feeding study is necessary. Nevertheless, the meeting informs the notifier that taking into account the possible additional uses of quizalofop-P-ethyl on other crops used to feed animals, such studies could be requested in the future.

For quizalofop-P-tefuryl, a feeding study was submitted for cow where animals were dosed over 28 days at levels of 1.1, 3.1 and 10.2 mg/kg feed (equivalent to 0.025, 0.081 and 0.276 mg/kg bw) the highest dose level corresponding to approximately 3 times the maximum theoretical residue intake calculated on the representative uses. Samples were analysed using the XAM-31 method quantifying the tefuryl ester and the metabolites (quizalofop included), free and conjugated that could be converted to 2-methoxy-6-chloroquinoxaline. However, as for plant, this method was only validated for quizalofop-P-tefuryl and for quizalofop. Moreover, the stability of the residues in products of animal origin (both poultry and ruminant) was considered as insufficiently demonstrated as the initial residue levels before freezing were not determined and the notifier was asked to provide new data supporting the stability of residues in animal matrices.

In milk, residues above the LOQ (0.01 mg/kg) were only detected in the medium and highest dose groups with maximum levels of 0.014 and 0.030 mg/kg respectively. In tissues, all residue were <0.02 mg/kg except in kidney where residues were detected in all dose groups (0.04 to 0.38 mg/kg) and in liver for the higher dose group (0.04 mg/kg). For poultry, the feeding study was carried out using the dose levels of 0.2, 0.6 and 2.0 mg/kg feed (approximately 0.013, 0.038 and 0.125 mg/kg bw) over 28 days, the higher level being approximately a 5x dose level. No residues were detected in eggs except for the highest dose level where the maximum residue was 0.022 mg/kg. In tissues, residues above the LOQ of 0.02 mg/kg were observed in the medium and highest dose groups accounting for 0.047 – 0.095 mg/kg in liver, 0.067 – 0.143 in kidney and 0039 – 0.122 mg/kg in fat. Taking into account the transfer observed in these feeding studies and considering the theoretical animal burden resulting from the representative uses of quizalofop-P-tefuryl, residues levels above the LOQs are expected in ruminant kidney and in poultry liver, kidney and fat. MRLs were proposed for these animal products.

3.3. CONSUMER RISK ASSESSMENT

After the meeting the rapporteur Member State reconsidered the consumer risk assessments taking into account the changes proposed by the PRAPeR meeting on mammalian toxicology.

- Quizalofop-P-ethyl: ADI: 0.009 mg/kg bw/d ARfD: not necessary
- Quizalofop-P-tefuryl: ADI: 0.013 mg/kg bw/d ARfD: 0.1 mg/kg bw/d

For quizalofop-P-ethyl, taking into account the representative use on sugar beet and the MRL of 0.05 mg/kg, the maximum TMDI is 13% of the ADI for the UK toddler, using the EFSA model. For quizalofop-P-tefuryl, and considering the MRLs proposed for plant and animal products in section 3.4 below, the maximum TMDI using the EFSA model is 23% of the ADI for the WHO cluster E, and the maximum IESTI is 31% of the ARfD for potatoes. In addition the meeting of experts concluded on the need for an overall risk assessment taking into account exposure resulting from the uses of the three different variants, quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop, and taking into account their respective toxicological endpoints.

3.4. PROPOSED MRLS

The MRL proposed for plant and animals products have to be considered as provisional awaiting the additional information/clarification that were requested during the peer review process.

Plant products

Sugar beet roots	0.05 mg/kg	(for both variants)
Potato	0.2 mg/kg	quizalofop-P-tefuryl GAP only
Bean (without pods)	0.2 mg/kg	quizalofop-P-tefuryl GAP only
Pea (without pods)	0.2 mg/kg	quizalofop-P-tefuryl GAP only
Lentils	0.2 mg/kg	quizalofop-P-tefuryl GAP only
Soybeans	0.2 mg/kg	quizalofop-P-tefuryl GAP only
Oil seed rape	2.0 mg/kg	quizalofop-P-tefuryl GAP only
Linseed	0.2 mg/kg	quizalofop-P-tefuryl GAP only
Sunflowers	2.0 mg/kg	quizalofop-P-tefuryl GAP only

For animal products, the following MRLs are proposed based on the representative uses of quizalofop-P-tefuryl only:

Ruminants

Kidney:	0.20 mg/kg
Milk:	0.01* mg/kg
Other ruminant products:	0.02* mg/kg

Poultry

Meat:	0.02* mg/kg
Fat	0.05 mg/kg
Liver	0.05 mg/kg
Kidney	0.10 mg/kg
Egg	0.01* mg/kg

* MRL is proposed at the LOQ

4. Environmental fate and behaviour

Quizalofop-P-tefuryl was discussed at the PRAPeR experts' meeting for environmental fate and behaviour PRAPeR 52 (June 2008), on basis of the DAR (March 2007), addendum 1 and corrigendum 1 (June 2008). Quizalofop-P-ethyl was also discussed at the PRAPeR experts' meeting for environmental fate and behaviour PRAPeR 52 (June 2008), on basis of the DAR (January 2007), addendum 2 and corrigendum 1 (June 2008).

Quizalofop-P-tefuryl and quizalofop-P-ethyl are ester variants of the active substance quizalofop-P. As indicated in the physical-chemical section, a third ester variant of quizalofop is the active substance propaquizafop. 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% of the applied radioactivity (AR)) metabolites[7] are common to two or all of the three of the 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 State experts considered it fundamental for the exposure assessment to combine the three single 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. 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 quizalofop-P-tefuryl and quizalofop-P-ethyl DARs and the agreed endpoints was considered.

Quizalofop-P-ethyl is the *R*(+) enantiomer of quizalofop-ethyl (racemic mixture of *R*(+) and *S*(-) enantiomers). The dossier concerning the environmental fate and behaviour of quizalofop-P-ethyl consists of a series of laboratory studies and field experiments performed using the *R*(+) enantiomer, the *S*(-) enantiomer or the racemic mixture. In this section the aim has been to conduct the evaluation

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

based on the results obtained using the *R*(+) enantiomer. However, since according to the open literature enantiomers (optical isomers) have the same physical and chemical properties, also those studies conducted with the racemic mixture have been accepted if studies with the *R*(+) enantiomer have not been available or their number limited.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

Quizalofop-P-tefuryl

Soil experiments (ten different soils) were carried out under aerobic conditions in the laboratory (20 – 25°C and 75% 1/3 bar moisture holding capacity (MHC) or 40% – 45% maximum water holding capacity (MWHC)) in the dark. Due to some deficiencies in the method of characterization/identification of the extractable radioactivity, the aerobic soil degradation study by Dzialo (1991) was considered not valid by the experts of PRAPeR 52 to assess the route of degradation of quizalofop-P-tefuryl. The formation of non extractable residues was a sink for the applied phenyl ring-^{14}C-radiolabel (32 – 47% AR after 120 days), for the applied ^{14}C-furfuryl-radiolabel (15 – 32% AR after 30 days) and for the applied ^{14}C-phenylquinoxaline-radiolabel (40 – 50% AR after 120 days). Mineralisation to carbon dioxide accounted for 22 – 34% AR (^{14}C-phenyl label at 120d), 57 – 70% AR (^{14}C-furfuryl label at 30d) and 2.3 – 26% AR (^{14}C-quinoxaline label at 120d). The major (>10% AR) extractable breakdown products present were quizalofop (max. 102% AR at 1 day), hydroxyl-quizalofop (max. 21% AR at 7 days), dihydroxy-quinoxaline (max. 18% AR at 28 days) and tetrahydrofurfuryl alcohol (max. 59% AR at 1 day). A metabolite accounting for >5% AR at two consecutive sampling times was tetrahydrofuroic acid (max. 9.3 – 7.6% AR at 1 – 3 days). The Member State experts agreed that for this metabolite, a groundwater exposure assessment was triggered on the basis of these soil metabolism studies (see section 4.2.2). The metabolite hydroxyl quinoxaline occurred at levels close to 5% AR from day 21 to day 120. The experts discussed the need for a ground water contamination risk assessment for this metabolite. Taking into consideration the low levels of hydroxy-quinoxaline in the soil degradation studies, the low application rate of the parent compound and the FOCUS GW modelling results for the same metabolite presented in the propaquizafop dossier, it was concluded that no further assessment for hydroxy-quinoxaline is necessary.

The aerobic soil degradation of ^{14}C-phenylquinoxaline-labelled quizalofop-P-tefuryl was investigated also at 5°C in one soil. Results indicated that the only degradation product identified other than quizalofop was hydroxy-quinoxaline which accounted for up to 5% of the AR after 125 days. No significant volatile radioactivity (<0.01% AR) was trapped.

Quizalofop-P-tefuryl degraded rapidly in a sandy loam soil under anaerobic conditions at 25ºC. The major degradation product identified in both soil and the aqueous phase was quizalofop. No

significant degradation of quizalofop was observed during the study. Bound residues increased with time and no significant quantity of volatile radioactivity was produced.

In a laboratory soil photolysis study, the amount of extractable quizalofop-P-tefuryl represented 36.6% AR and 15.5% AR in the irradiated and dark samples at the end of the study (132 hours). The major metabolite was identified as quizalofop (max. 32.4% AR and 72.0% AR after 96 hours in the irradiated and dark samples, respectively). The DT_{50} value of quizalofop-P-tefuryl at 25°C was calculated to be 4.8 days for the irradiated samples and 2.3 days for the dark control samples.

Quizalofop-P-ethyl

The route of degradation of quizalofop-P-ethyl in soil was investigated at 20°C under dark aerobic conditions in three studies with a total of four soils (pH 6.6 – 7.9; OC 1.8 – 4.6%; clay 10 – 33.6%) with ^{14}C-quizalofop-P-ethyl radiolabelled at the phenyl ring and at the benzene portion of the quinoxaline ring. The formation of residues not extracted by acetonitrile:water (including Soxhlet) were a sink for the applied phenyl ring-^{14}C-radiolabel (39.6 – 42% AR after 120 days) and for the applied quinoxaline ring-^{14}C-radiolabel (23% AR after 120 days). The amounts of carbon dioxide ranged from 1.8% (quinoxaline label) AR to 32% AR (phenyl label) by the end of the study.

In the soil environment quizalofop-P-ethyl degrades largely to the major (>10% AR) metabolite quizalofop by hydrolysis of the ester. Further hydrolysis of the side chain occurs resulting in the minor metabolite quizalofop-phenol (max. 3.0% AR at 7d). Hydroxylation of the quinoxaline ring occurs to give the major metabolite hydroxy-quizalofop. Cleavage of the ether linkage leads to the formation of series of degradates containing either the quinoxaline ring or the phenyl ring. Both series of degradates are further degraded to carbon dioxide.

Quizalofop has been identified in all of the studies with the maximum percentage formed ranging from 67% AR to 84% AR after 1 – 7 days. The major metabolite hydroxy-quizalofop occurred up to 15.7% AR after 120 days and dihydroxy quinoxaline has been found up to 12.3% AR after 184 days. Four minor metabolites have been identified on occasions: CQOP, CQO, EPP and PPA at maximum percentages of <5% AR.

In addition to investigations with quizalofop-P-ethyl (*R*(+) enantiomer), the behaviour of the racemate (*R*/*S*)-quizalofop-ethyl and *S*(-)-quizalofop-ethyl has been studied. The dominant enantiomeric conversion was from the *S*(-) enantiomer to the *R*(+) enantiomer.

The metabolism of quizalofop-P-ethyl under anaerobic conditions has shown that hydroxy-quizalofop is rapidly formed reaching a maximum of 94% AR after 30 days. Another metabolite (PPA) can be formed under such conditions up to levels of 11.7% AR after 90 days. Very little mineralisation to carbon dioxide was observed, with carbon dioxide accounting for max. 0.7% AR at the study end (120

days). The amount of soil bound residues increased slowly over the period of the study up to 6.6% AR after 120 days.

Quizalofop-P-ethyl was shown to be susceptible to photolysis (the half-life was approximately 40 days). The only significant degradation product (except carbon dioxide: 22.3% AR at 32d) was quizalofop formed by hydrolysis (max. 7.2% AR in the irradiated sample at 15d). Minor amounts of CQO, dihydroxy-quinoxaline and other unidentified decomposition products were detected, but individually were no greater than 5% AR.

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

Quizalofop-P-tefuryl

The rate of degradation of quizalofop-P-tefuryl under aerobic conditions was estimated from the results of the studies described in 4.1.1 above (eight different soils). Single first-order (SFO) DT_{50} values were less than 1 day (0.10 – 0.90 days) and the DT_{90} values ranged from 0.30 to 1.16 days. After normalisation to FOCUS reference conditions[8] (20°C and -10kPa soil moisture content) this range of DT_{50} is 0.04 – 0.62 days (geometric mean that is appropriate for use in FOCUS modelling 0.16 days, see addendum 1 to the DAR (16 June 2008; pages 33 – 35) where the derivation of these values is clarified.

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 quizalofop-P-tefuryl (8 or 5 or 3 soils), quizalofop-P-ethyl (6 or 3 or 4 soils) and propaquizafop (6 or 3 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 the DT_{50} values for these metabolites were estimated from the studies where the parent compounds were applied and these metabolites were present.

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 the range of SFO DT_{50} values is basically the same (7 – 181.5 days). The experts agreed that the DT_{50} value of quizalofop that is appropriate for use in FOCUS modelling is the median 24.3 days.

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} values 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.

[8] 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.

The DT_{50} values for dihydroxy-quinoxaline with studies conducted at 20ºC 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). The experts agreed that the median DT_{50} value of hydroxy-quizalofop that is appropriate for use in FOCUS modelling is 54.3 days.

The rate of degradation of tetrahydrofurfuryl alcohol was estimated from the same studies discussed above where quizalofop-P-tefuryl radiolabelled in the furfuryl group was applied (20ºC and 45% MWHC). The DT_{50} values were less than 1 day: 0.44 – 0.75 days (values from three different soils). After normalisation to FOCUS reference conditions this range of single first-order DT_{50} values is 0.44 – 0.66 day (geometric mean that is appropriate for use in FOCUS modelling 0.54 days).

The field dissipation of quizalofop-P-tefuryl and its degradation products quizalofop, hydroxy-quinoxaline and CQOP was studied at six sites in Canada. Quizalofop-P-tefuryl was applied to bare soil as a single application at rates of 450 or 900 g/ha (equivalent to 4.5 or 9 times the maximum proposed rate). Quizalofop-P-tefuryl was rapidly dissipated in soil under field conditions and it was detected only in the top horizon (0 – 15 cm). Further details on the kinetic method used to calculate field DT_{50} values were provided in addendum 1. Experts from the Member States considered this method based on the instructions of Environment Canada not appropriate and therefore the endpoints derived from the field studies should not be used in the assessment at the EU level. It was also concluded that as the field studies are not triggered (DT_{50lab} for quizalofop-P-tefuryl <60 days) the additional information provided in addendum 1 on the representativeness of the Canadian field studies for European agro-climatic conditions was not relevant to finalise the assessment of quizalofop-P-tefuryl for Annex I inclusion.

Reliable field DT_{50} values for metabolites quizalofop and hydroxy-quizalofop were derived from one study presented in the DAR of quizalofop-P-ethyl and one study available in the DAR of propaquizafop (for quizalofop only). The valid values $DT_{50field}$ agreed by the experts were in the range 31.6 – 39.8 days for quizalofop (one site in Germany, one site in France, one site in Spain and one site in Switzerland) and 32.2 days (one site in Germany) for hydroxy-quizalofop.

PEC values in soil of quizalofop-P-tefuryl and its soil metabolites quizalofop, hydroxy-quizalofop, dihydroxy-quinoxaline and tetrahydrofurfuryl alcohol were calculated based on standard equations recommended by the FOCUS modelling group. The proposed application rate was a single 100 g a.s./ha application, the maximum application rate recommended for use as a post-emergence spray on oilseed rape, sugar and fodder beet, potatoes, peas, beans, linseed and sunflowers and other pulse crops. The lowest crop interception factor of 15% recommended for the crops mentioned in the list of intended uses was considered. In the original DAR the worst case field DT_{50} values for quizalofop-P-tefuryl (1 day) and for quizalofop (77 days) and the maximum normalised laboratory DT_{50} values for hydroxy-quizalofop (39.9 days), dihydroxy-quinoxaline (157.2 days) and tetrahydrofurfuryl alcohol

(0.66 days) were used as input parameters. At the experts' meeting it was noted that the field DT_{50} values were considered not acceptable and that the normalised laboratory DT_{50} values used for hydroxy-quizalofop and dihydroxy-quinoxaline were lower than the maximum values agreed in the amalgamated endpoints list. However, as the ecotoxicological risk assessment for soil organisms was based on initial predicted environmental concentrations in soil (PEC_{soil}), re-calculations of PEC_{soil} based on the agreed DT_{50} values are not necessary.

Quizalofop-P-ethyl

The degradation rate of quizalofop-P-ethyl was investigated in the same degradation studies used to establish soil metabolism at 20ºC and in two additional studies with two soils at 10ºC and 40% MWHC. The parent and two metabolites (quizalofop and hydroxy-quizalofop) model was implemented within Model Manager using simple first-order (SFO) kinetics. Although the degradation of quizalofop-P-ethyl follows bi-phasic kinetics in the laboratory studies, it was agreed that the very rapid initial degradation to quizalofop ensures that SFO kinetics are a good representation of the data sets. For the four experiments performed at 20°C with quizalofop-P-ethyl (*R*(+)), data from kinetic modelling experiments showed that the DT_{50} for quizalofop-P-ethyl ranged from 0.33 to 1.10 days, and the DT_{90} value ranged from 1.1 to 3.5 days. The rate of metabolism at 10°C was found to be similar with DT_{50} values of 0.3 and 0.52 days. After normalisation to FOCUS reference conditions[9] (20°C and -10kPa soil moisture content) this range of single first-order DT_{50} values is 0.1 – 1.1 days (geometric mean that is appropriate for use in FOCUS modelling 0.4 days).

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 quizalofop-P-ethyl (6 or 3 or 4 soils), quizalofop-P-tefuryl (8 or 5 or 3 soils) and propaquizafop (6 or 3 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 the DT_{50} values for these metabolites were estimated from the studies where the parent compounds quizalofop-P-ethyl, quizalofop-P-tefuryl or propaquizafop were applied and these metabolites were present.

In the quizalofop-P-ethyl DAR, the DT_{50} value (182 days) derived for quizalofop from study FD13 was not considered acceptable. Following the evaluation of the study report (FD21) with the kinetic reassessment of the degradation data, the Member State experts concluded that this value should be included in the risk assessment. It was also agreed that, in line the FOCUS degradation Work Group kinetics recommendations, all the calculated DT_{50} values with the confidence interval with negative values were not considered reliable (the DT_{50} values of 217.1 days and 50.9 days for hydroxy-quizalofop from the silty clay loam and the clay loam soils from study FD14) and should not be used for risk assessment.

[9] 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 0.7.

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 SFO DT_{50} is basically the same (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.

From the amalgamated list of endpoints, 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} values 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.

A degradation rate study conducted with dihydroxy-quinoxaline with three soils was available in the quizalofop-P-ethyl DAR (SFO DT_{50} 42 – 53 days). In the original DAR these values were not taken into account, but only the DT_{50} value (55.5 days) obtained in study FD13 conducted with quizalofop-P-ethyl was used as an input parameter in FOCUS modelling for dihydroxy-quinoxaline. The experts considered the amalgamated list of endpoints, where the DT_{50} values for dihydroxy-quinoxaline with studies conducted at 20ºC ranged from 42 to 258 days (10 soils). After normalisation to FOCUS reference conditions this range of SFO DT_{50} is 36 – 200 days. In conclusion, it was agreed that since the median DT_{50} value of hydroxy-quizalofop which is appropriate for use in FOCUS modelling is 54.3 days, recalculations of predicted environmental concentrations in surface water (PEC_{sw}), sediment (PEC_{sed}) and ground water (PEC_{gw}) with the agreed endpoints are not necessary.

Further details on the formation fractions calculated for the metabolites in the kinetics assessment were provided in addendum 2.

The field dissipation of quizalofop-P-ethyl was assessed at four European sites. The sites were representative of sugar beet crop production areas and were in the United Kingdom, Germany, southern France and Spain. At each site a single application of quizalofop-P-ethyl was made to bare soil at a nominal application rate of 200 g a.s./ha to two plots. Quizalofop-P-ethyl, quizalofop and hydroxy-quizalofop were detected only in the top horizon (0 – 10 cm). No residues above the limit of quantitation were detected in the 10 – 20 cm horizon.

The parent and two metabolites model was implemented within Model Manager using simple first-order (SFO) kinetics. The estimated DT_{50} for quizalofop-P-ethyl were in the range 0.55 – 8.2 days. Quizalofop was estimated to dissipate with reliable DT_{50} values within the range 33.6 to 40 days and hydroxy quizalofop with a field DT_{50} derived from the German trial of 32.2 days. The Member State experts agreed on the exclusion of the DT_{50} values derived from the UK field site (for quizalofop and hydroxy-quizalofop) and from the French and Spanish sites (for hydroxy-quizalofop) as no valid 95% confidence intervals could be determined.

The PEC_{soil} of quizalofop-P-ethyl was calculated based on standard equations recommended by FOCUS modelling work group. The following soil DT_{50} values were used as input parameters: for quizalofop-P-ethyl, the worst-case non-normalised DT_{50} value from field studies (8.25 days, from the Spanish site), for the metabolites quizalofop and hydroxy-quizalofop the worst-case non-normalised DT_{50} values from field studies (39.8 days and 32.2 days, respectively, from the German trial), for metabolite dihydroxy-quinoxaline the worst-case normalised laboratory DT_{50} value of 102 days. 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 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 toxicity exposure ratio (TER) values were based on the corresponding initial PEC_{soil} values, the experts concluded that the available PEC_{soil} values for the later time points should not be considered for risk assessment but no recalculations are necessary.

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

Quizalofop-P-tefuryl

Due to the rapid degradation of quizalofop-P-tefuryl in soil under aerobic conditions, batch equilibrium studies with the parent compound were not performed. Worst case values of 0 mL/g and 1/n = 1 were considered for use in FOCUS scenario calculations of groundwater exposure potential. The major degradation product, quizalofop, was selected as the most appropriate test substance for use in the adsorption/desorption batch equilibrium tests. In studies using a range of seven soils from the USA and Canada and a pond sediment, calculated adsorption $K_f oc$ values ranged from 133 to 477 mL/g (1/n 0.69 – 0.89) in the agricultural soils and 1254 mL/g (1/n 0.72) in the pond sediment. Taking into consideration the reliable adsorption coefficients for quizalofop reported in the DARs of quizalofop-P-ethyl (eight soils) and propaquizafop (four soils), the agreed $K_f oc$ median value for quizalofop is 356 mL/g and the median 1/n is 0.8. There was no evidence of a correlation of adsorption with pH.

Soil adsorption/desorption studies on the metabolite hydroxy-quizalofop using three soils were available in the quizalofop-P-tefuryl DAR. Satisfactory batch adsorption experiments reported in the quizalofop-P-ethyl DAR (three soils) and in the propaquizafop DAR (three soils) were also considered by PRAPeR 52 to derive the appropriate endpoint for this metabolite. On the basis of the results obtained, hydroxy-quizalofop is classified as having low to high mobility in soil ($K_f oc$/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.

Soil adsorption/desorption studies on metabolite dihydroxy-quinoxaline using three soils were available in the quizalofop-P-tefuryl DAR. Satisfactory batch adsorption experiments reported in the quizalofop-P-ethyl DAR (three soils) and in the propaquizafop DAR (three soils) were also considered by PRAPeR 52 to derive the appropriate endpoint for this metabolite. On the basis of the results obtained, dihydroxy-quinoxaline is classified as having low to very high mobility in soil ($K_f$oc/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 a column leaching study conducted with ^{14}C-quizalofop-P-tefuryl labelled in the quinoxaline group, only 0.1 – 0.8% of the AR was found in the leachate. Quizalofop-P-tefuryl accounted for up to 4.2% AR on the column top and was not found in the leachate. Quizalofop was found to be the major component of the radioactivity in all soil segments analysed (total of 71.1% AR) and the only compound found in the leachate (0.7% AR).

Two aged (29 days and 133 days) residues column leaching studies were available. Results indicated that the main metabolite quizalofop was the only compound found in the leachate (≤0.8% AR). Quizalofop-P-tefuryl or other metabolites were not found in leachate. The majority of the AR remained in the top segments of the columns (80% AR or 91% AR retained in the top 7.6 cm or 6.3 cm). In the second study conducted with the soil aged for 133 days, of the 38.7% of the radioactivity applied to the column which was extractable, 20.2% AR was found to be dihydroxy-quinoxaline, 6.9% AR was identified as hydroxy-quizalofop and 4.3% AR was quizalofop.

Quizalofop-P-ethyl

The adsorption/desoprtion characteristics of quizalofop-P-ethyl, quizalofop, hydroxy-quizalofop and dihydroxy-quinoxaline were investigated using conventional batch equilibrium methods. In four Japanese soils ^{14}C-quizalofop-P-ethyl adsorption $K_f$oc values ranged from 1024 to 3078 mL/g (arithmetic mean 1816 mL/g; 1/n: 0.83 – 0.88, arithmetic mean 0.86), indicating low to slight mobility in soil for the parent compound. There was no evidence of a correlation of adsorption with pH. Although the pH range (5.3 – 6.4) of the soils tested was narrow, the experts noted that the available data would indicate even higher Koc values at higher soil pH and therefore no further assessment on soil adsorption properties of quizalofop-P-ethyl was considered necessary.

For the major soil degradation product quizalofop, in addition to the Koc values derived from the study conducted with quizalofop-P-ethyl, a satisfactory batch adsorption experiment using ^{14}C-quizalofop with four soils was available. Calculated adsorption $K_f$oc values ranged from 212 to 1791 mL/g. Taking into consideration the reliable adsorption coefficients for quizalofop reported in the quizalofop-P-tefuryl (eight soils) and propaquizafop (four soils) DARs, the agreed $K_f$oc median value for quizalofop is 356 mL/g and the median 1/n is 0.8. There was no evidence of a correlation of adsorption with pH.

Soil adsorption/desorption studies on metabolite hydroxy-quizalofop using three soils were available in the quizalofop-P-ethyl DAR ($K_f$oc 129 – 1567 mL/g). Satisfactory batch adsorption experiments reported in the quizalofop-P-tefuryl DAR (three soils) and in the propaquizafop DAR (three soils) were also considered by PRAPeR 52 to derive the appropriate endpoint for this metabolite. On the basis of the results obtained, hydroxy-quizalofop is classified as having low to high mobility in soil ($K_f$oc/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.

Soil adsorption/desorption studies on metabolite dihydroxy-quinoxaline using three soils were available in the quizalofop-P-ethyl DAR ($K_f$oc 48 – 694 mL/g). Satisfactory batch adsorption experiments reported in the quizalofop-P-tefuryl DAR (three soils) and in the propaquizafop DAR (three soils) were also considered by PRAPeR 52 to derive the appropriate endpoint for this metabolite. On the basis of the results obtained, dihydroxy-quinoxaline is classified as having low to very high mobility in soil ($K_f$oc/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.

A lysimeter study using two UK soils was reported in the DAR. However, information provided on the test design, the method of analysis and on the recharge from the lysimeter was considered unsatisfactory. Although some clarifications were provided in addendum 2, the Member State experts concluded that the study can be considered to provide only supportive information.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

Quizalofop-P-tefuryl

Quizalofop-P-tefuryl rapidly degraded in hydrolysis studies conducted at 22 – 25ºC under alkaline conditions (DT_{50} 7.2 – 7.8 hours, pH 8.9 – 9.1). It was more stable in neutral and acidic solutions where the half-life values were 4.3 – 18.2 days (pH 7) and 8.2 – 277 days (pH 5.1). Hydrolytic degradation proceeded via ester hydrolysis to form quizalofop (the information on the amount of quizalofop formed was not reported). The metabolite quizalofop was stable under sterile hydrolysis conditions at 50°C at pH 4, 7 and 9.

In two photolytic degradation studies, quizalofop-P-tefuryl was rapidly degraded in aqueous solutions at pH 5 with the DT_{50} values of 1.1 – 2.4 days. In one of the two studies, the photodegradation product quinoxaline-2-carboxylic acid was found up to 11.3% AR at the study end (32.2 hours). Information to address the leaching potential to groundwater for this metabolite was provided by the notifier and included in addendum 1. Even though the reported information on the modelling

conducted was considered inadequate for a regulatory submission, the Member State experts concluded that based on this conservative simulation, it is likely that the potential for contamination of groundwater above the parametric drinking water limit of 0.1 µg/L for this metabolite is low.

Based on the results obtained in a biodegradation test, quizalofop-P-tefuryl is not a readily biodegradable substance.

In dark water-sediment studies (six systems studies at 20ºC in the laboratory with quizalofop-P-tefuryl labelled in the quinozaline group or the phenyl ring or in the furfuryl group; water pH 7.6 – 8.4, sediment pH 7.0 – 7.3, organic carbon content 0.9 – 5.3%) quizalofop-P-tefuryl rapidly degraded (whole system DT_{50} and DT_{90} <1 day). The rates of disappearance of quizalofop-P-tefuryl from the water phase were very rapid: the DT_{50} and DT_{90} values were determined to be 2.4 – 3.1 hours in two systems. Five major metabolites were formed: **quizalofop** (max. 85.0 – 93.9% AR at 8 hours or 1 day after treatment, in water and max. 35.8 – 53.2% AR at 14d in the sediment) **CQOP** (max. 11.6% AR at 28d in the sediment), **dihydroxy-quinoxaline** (max. 16.4% AR at 62d in the sediment), **tetrahydrofurfuryl alcohol** (max. 16.5% AR at 1d in the water) and **tetrahydrofuroic acid** (max. 39.1% AR at 1d in the water). The terminal metabolite, carbon dioxide, accounted for up to 80.7% AR of the furfuryl group-^{14}C-radiolabel by 28 days. Residues not extracted from sediment accounted for 14.8 – 42.1% AR at 7 – 98 days.

For the metabolite quizalofop, the SFO $DT_{50\ whole\ system}$ for quizalofop was estimated to be in the range 25 – 35 days and SFO $DT_{50\ water}$ was 10 days (2 systems). Reliable data on degradation of quizalofop in two water/sediment systems at 10ºC were also available from the quizalofop-ethyl DAR (120 days and 88 days). An extrapolation of these values to 20ºC (54 days and 40 days) was performed on the basis of the default Q10 factor of 2.2 used in environmental exposure assessment to account for the impact of different temperatures.[10] Although this approach was not objected to by the experts, it is the EFSA's opinion that it should be applicable only to derive soil degradation rates since the Q10 factor has been derived from soil measurements. However, as in this case the inclusion of the values from the quizalofop-ethyl DAR leads to a worst case (geometric mean value $DT_{50\ whole\ system}$ of 35 days), the EFSA considers the values acceptable.

The estimated SFO $DT_{50\ whole\ system}$ values for metabolite CQOP were 40 – 42 days (two systems). The metabolites tetrahydrofurfuryl alcohol and tetrahydrofuroic acid degraded rapidly in the water and sediment with first-order whole system DT_{50} of 0.3 – 0.4 days and 1.3 – 1.6 days, respectively. No reliable water and sediment DT_{50} for the metabolite dihydroxy-quinoxaline could be derived.

The potential for surface water contamination following recommended application of quizalofop-P-tefuryl was determined using FOCUS surface water concentrations (Steps 1 and 2). Annual

[10] FOCUS (1997). Soil persistence models and EU registration.

applications were evaluated at the maximum proposed application rate of 100 g a.s./ha assuming minimal crop cover for early post-emergence applications on potatoes. Results of PEC_{sw} and PEC_{sed} at Step 2 calculated for autumn (October – February) applications are reported in the list of endpoints. Because the degradation of quizalofop-P-tefuryl occurs very quickly also quizalofop was considered as the active substance. The PEC_{sw} and PEC_{sed} were re-calculated by the rapporteur Member State in the DAR for quizalofop-P-tefuryl and its major degradation products: quizalofop, hydroxy-quizalofop, dihydroxy-quinoxaline, CQOP, tetrahydrofurfuryl alcohol and tetrahydrofuroic acid. The normalised soil DT_{50} and the K_{oc} input values for the parent compound were 0.14 day and 1 L/kg, respectively. While writing the conclusion, the EFSA noted that the re-calculations for the metabolites provided by the rapporteur Member State had some deficiencies. The EFSA performed new FOCUS SW calculations at Steps 1 and 2 for quizalofop and hydroxy-quizalofop with the agreed endpoints (for quizalofop: K_{oc} 356 L/kg, $DT_{50\ water}$ 35 days; $DT_{50\ sed}$ 35 days; soil DT_{50} 24.3 days; for hydroxy-quizalofop: K_{oc} 141 L/kg, $DT_{50\ water}$ 300 days; $DT_{50\ sed}$ 300 days; soil DT_{50} 15.6 days) for autumn application to potatoes. The recalculated initial PEC_{sw} of 7.41 µg/L for quizalofop is slightly lower than the value of 7.47 µg/L used by the rapporteur Member State to calculate the TER for aquatic organisms. On the contrary, the max. PEC_{sed} was slightly higher (25.8 µg/kg compared to 21.35 µg/kg as calculated by the rapporteur Member State). The recalculated maximum initial PEC_{sw} and PEC_{sed} for hydroxy-quizalofop were 1.45 µg/L and 2.04 µg/kg, respectively. For metabolites CQOP, dihydroxy-quinoxaline and tetrahydrofurfuryl alcohol, the worst case TER calculations were performed using the maximum initial PEC values for quizalofop. Overall, the new exposure assessment confirmed that the risk to aquatic organisms from exposure to quizalofop, hydroxy-quizalofop, CQOP, dihydroxy-quinoxaline, tetrahydrofurfuryl alcohol and tetrahydrofuroic acid is low (see section 5.2).

At the meeting of experts it was agreed that FOCUS SW calculations at Step 3 are not needed as safe uses were determined based on the results at Step 2 for all the TERs. However it was also concluded that based on the available assessment, it is not evident which (if any) geoclimatic conditions represented by Step 3 scenarios would result in higher concentrations.

Quizalofop-P-ethyl

The hydrolysis of quizalofop-P-ethyl is dependent on pH and temperature. The substance was stable in acidic conditions (DT_{50} >1 year, pH 4) and unstable in alkaline conditions (DT_{50} <2.4 hours, pH 9). The half-life values at pH 7 were 3.7 days (50ºC) and 10.7 days (40ºC). The main hydrolysis product, quizalofop, is considered hydrolytically stable at 22ºC.

Quizalofop-P-ethyl degraded slowly under photolytic conditions in aqueous solution. The major photodegradation product was shown to be volatile material and the majority of it was confirmed to be carbon dioxide. Other metabolites were determined at levels <3% AR. The theoretical lifetimes of quizalofop-P-ethyl were calculated to range from 11 days in summer at 30ºN to 273 days in winter at 60ºN.

Based on the results obtained in biodegradation test (OECD 301B) quizalofop-P-ethyl is not a readily biodegradable substance.

In water/sediment systems at 10ºC, quizalofop-P-ethyl rapidly degraded (DT_{50} of 1.2 – 1.9 days and DT_{90} of 3.9 – 6.3 days in the total system) in both the water and sediment phases to yield the major degradate, quizalofop (max. 68 – 83% AR at 7d in water and max. 21 – 43% AR at 28d in the sediment). Quizalofop degraded at a slower rate with a DT_{50} of 88 – 119 days and DT_{90} of 144 – 181 days in the total system. An extrapolation of these values to 20ºC was performed on the basis of the default Q10 factor of 2.2 used in environmental exposure assessment to account for the impact of different temperatures.[11] Although this approach was not objected to by the experts, it is the EFSA's opinion that it should be applicable only to derive soil degradation rates since the Q10 factor has been derived from soil measurements. Reliable data on degradation of quizalofop in four water/sediment systems at 20ºC were also available from the quizalofop-tefuryl DAR (SFO $DT_{50\ whole\ system}$ in the range 25 – 35 days). On balance, as the inclusion of the values from the quizalofop-ethyl DAR leads to a worst case (geometric mean value $DT_{50\ whole\ system}$ of 35 days in the amalgamated list of endpoints for FOCUS modelling), the EFSA considers the assessment acceptable in this case.

A number of degradation products other than quizalofop including hydroxy-quizalofop, CQOP, PPA, EPP were detected at levels <6% AR. At the end of water/sediment studies carbon dioxide accounted for 22 – 23% AR and unextractable residues for 32 – 38% AR.

Occasionally in some samples in water/sediment studies, <1% inversion of quizalofop-P-ethyl (*R*(+)-enantiomer) to the *S*(-)-enantiomer was detected. Also some inversion (<4%) of quizalofop-acid to the *S*(-)-enantiomer occurred.

Predicted environmental concentrations for contamination of surface waters (PEC_{sw}) of quizalofop-P-ethyl and its metabolites quizalofop, hydroxy-quizalofop and dihydroxy-quinoxaline were calculated using the computer program 'Steps 1 – 2 in FOCUS' recommended by the EU FOCUS Working Group on Surface Water Scenarios (2001). The proposed application rate was a single 200 g a.s./ha application to sugar beet, at an earliest growth stage of approximately BBCH 15 (a crop interception factor of 20% was used). Application was considered to occur throughout Europe, and within the 'March – May' interval. In Northern Europe, the runoff/drainage input therefore was 2% of the remaining soil residue; in Southern Europe, this was 4% (Step 2 calculations).

The input values for quizalofop-P-ethyl were based on the normalised geometric mean soil $DT_{50\ lab}$ of 0.4d, a worst case $DT_{50\ water}$ of 100 days and $DT_{50\ sed}$ of 0.7 day.

[11] FOCUS (1997). Soil persistence models and EU registration.

The input values for quizalofop, hydroxy-quizalofop and dihydroxy-quinoxaline were not consistent with the endpoints as agreed in the amalgamated list of endpoints compiled in PRAPeR 52; however, as the values (soil DT_{50}, $DT_{50\ water}$, $DT_{50\ sed}$, K_{oc}) used in the modelling represented worst cases, the experts considered the assessment acceptable.

FOCUS SW simulations at Step 3 for quizalofop-P-ethyl and quizalofop were also provided in addendum 2. The experts confirmed that for use of the active substance the risk is considered low with TER values based on Step 2 calculations, since the PEC at Step 3 resulted in lower values than those at Steps 1 and 2. Maximum PEC_{sw} and PEC_{sed} values at Step 3 were used to refine the risk assessment for higher plants for quizalofop.

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

Quizalofop-P-tefuryl

The leaching potential of quizalofop-P-tefuryl and its soil degradation products quizalofop, hydroxy-quizalofop, dihydroxy-quinoxaline and tetrahydrofurfuryl alcohol was estimated using the FOCUS PELMO 3.3.2 model. The simulations were carried out following application of quizalofop-P-tefuryl to sugar beet and potato (nine FOCUS scenarios) and oil seed rape (Châteaudun, Hamburg, Kremsmünster, Okehampton, Piacenza and Porto scenarios). For quizalofop-P-tefuryl and metabolite tetrahydrofurfuryl alcohol, it was assumed that there was no adsorption (K_{oc}= 0). 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 pF2) 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 should be: 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) for these metabolites. 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.

Parent quizalofop-P-tefuryl and its metabolites quizalofop, hydroxy-quizalofop and dihydroxy-quinoxaline were calculated to be present in leachate leaving the top 1 m soil layer at 80th percentile annual average concentrations of <0.0001µg/L. The predicted 80th percentile groundwater concentrations of tetrahydrofurfuryl alcohol for application to oil seed rape were ≤0.023 µg/L.

The notifier addressed the leaching potential of the minor non transient metabolite tetrahydrofuroic acid based on a conservative ground water risk assessment (K_{oc} of 0 mL/g, formation fraction of 100%; see addendum 1 to the DAR, pages 36 – 37). Even though the reported information on the modelling conducted was considered inadequate for a regulatory submission, the Member State

experts concluded that the potential for contamination of groundwater above the parametric drinking water limit of 0.1 µg/L for tetrahydrofuroic acid is low.

Quizalofop-P-ethyl

Groundwater modelling to estimate the concentration of quizalofop-P-ethyl and its metabolites quizalofop, hydroxy-quizalofop and dihydroxy-quinoxaline in groundwater recharge (PEC_{gw}) was undertaken with the FOCUS groundwater scenarios using the computer simulation models PELMO (FOCUS version 3.3.2) and MACRO (FOCUS version 4.4.2). PELMO was used to estimate PEC_{gw} at all nine scenarios; MACRO was used to estimate PEC_{gw} at the Châteaudun scenario to assess the importance of leaching resulting from preferential flow through cracked soil.

The proposed application rate was a single 200 g a.s./ha application to sugar beet, PHI 110 days (at an earliest growth stage of approximately BBCH 15). A crop interception of 20% was used to represent the minimum interception likely at the time of application, according to FOCUS guidance. As the application 'season' is quite long in some scenarios, simulation runs were conducted at two times approximating to the earliest and latest possible dates. These were 14 days after emergence and 110 days before harvest.

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 pF2) 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 should be: 356 mL/g for quizalofop (median of 19 values, 1/n 0.81), 548 mL/g for dihydroxy-quinoxaline (median of 9 values, 1/n 0.7) and 141 mL/g for hydroxy-quizalofop (median of 9 values, 1/n 1.0) for these metabolites. In general, the input parameters used in the available modelling were worse cases than these agreed values, and therefore the experts concluded that the modelling presented by the notifier was acceptable for the EU level assessment.

For quizalofop-P-ethyl, quizalofop and hydroxy-quizalofop, all predicted concentrations (using both models, at both application times) were <0.001 µg/L. For dihydroxy-quinoxaline the predicted concentrations were <0.080 µg/L. Results indicated that for the applied for intended uses, the potential for groundwater exposure by quizalofop-P-ethyl and its metabolites quizalofop, hydroxy-quizalofop and dihydroxy-quinoxaline above the parametric drinking water limit of 0.1 µg/L, is low.

4.3. FATE AND BEHAVIOUR IN AIR

Quizalofop-P-tefuryl

The vapour pressure of quizalofop-P-tefuryl is low (<7.9 $x10^{-6}$ Pa at 25ºC). Thus it is highly probable that this substance will not evaporate in significant amounts. On the basis of Henry's law constant (9.0 x 10^{-4} Pa x m^3 x mol^{-1}) quizalofop-P-tefuryl has no tendency to volatilize from aqueous solution.

Calculations using the method of Atkinson (using the software AOPWIN) for indirect photo oxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half-life estimated at about 2.7 hours (assuming an atmospheric hydroxyl radical concentration of $1.5x10^6$ radicals cm^{-3}) indicating that quizalofop-P-tefuryl that will volatilise would be unlikely to be subject to long-range atmospheric transport.

Quizalofop-P-ethyl

The vapour pressure of quizalofop-P-ethyl is low (1.1×10^{-7} Pa at 20ºC). In addition, it has been estimated that the vapour pressure of the main metabolite quizalofop at 20ºC is less than 1.1×10^{-7} Pa. Thus it is very probable that these substances will not evaporate in significant amounts. On the basis of Henry's law constant (6.7×10^{-5} Pa x m^3 x mol^{-1}) quizalofop-P-ethyl has no tendency to volatilize from aqueous solution.

In volatilization studies, quizalofop-P-ethyl was sprayed onto plants and soil. Little (<0.3%) or no radioactivity was found in the traps and the AR could be accounted for on the soil (>100%) and plants (95.8%).

Calculations using the method of Atkinson for indirect photooxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half-life estimated at 4.5 hours (assuming an atmospheric hydroxyl radical concentration of $1.5x10^6$ radicals cm^{-3}), indicating the small proportion of applied quizalofop-P-ethyl that will volatilise would be unlikely to be subject to long-range atmospheric transport.

5. Ecotoxicology

Quizalofop-P-ethyl was discussed in the meeting of ecotoxicology experts PRAPeR 53 (subgroup 1) in July 2008, on the basis of the DAR (January, 2007), addendum 2 (June 2008) and addendum 4 (September 2008). Quizalofop-P-ethyl is the active substance in the herbicide 'Targa Super' (50g/L). The representative field use was in sugar beets (1 x 200 g a.s./ha).

Quizalofop-P-tefuryl was also discussed in the meeting of ecotoxicology experts PRAPeR 53 (subgroup 1) in July 2008, on the basis of the DAR (March, 2007), addendum 1 (June 2008) and addendum 2 (September 2008). Quizalofop-P-tefuryl is the active substance in the herbicide 'Panarex'. The representative field uses were in spring and winter oilseed rape, sugar beet, potato, peas, beans, linseed and sunflower (1 x 100 g a.s./ha).

Quizalofop-P-tefuryl and quizalofop-P-ethyl are ester variants of the active substance quizalofop-P. A third ester variant of quizalofop-P is the active substance propaquizafop. These three ester variants have different toxicities based on their lipophilic properties (bioavailability). Aquatic and terrestrial

toxic endpoints for the common metabolites of propaquixafop, 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.

It was noted by the experts in the meeting on physico-chemical properties that none of the environmental monitoring methods were capable of separating the *R* and the *S* isomers. In response, it was considered by the experts on ecotoxicology that if the mammalian toxicity studies indicated that the toxicity of the isomers was comparable, then there was no concern for the ecotoxicology section. Based on the toxicity data available for the racemate and *R*(+)-enantiomer it was agreed by the experts on toxicology that the toxicity data could be considered as comparable.

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.

5.1. RISK TO TERRESTRIAL VERTEBRATES

Quizalofop-P-ethyl

Birds

The acute and short-term toxicity studies for birds indicated a low toxicity to bobwhite quail (*Colinus virginianus*) and mallard duck (*Anas platyrhynchos*). A reproductive NOEC of 58 mg/kg bw/day for mallard duck was used for the long-term risk assessment. TERs in a first tier risk assessment were all above the Annex VI trigger, indicating a low acute, short-term and long-term risk to birds for all intended uses.

Mammals

The lowest acute endpoint for mammals was observed in a test with rat (LD_{50} = 1182 mg a.s./kg bw), supporting a low acute toxicity to mammals. Based on content of active substance, the formulation was found to be more acutely toxic to rats than the technical active substance. The meeting of experts agreed not to require an acute risk assessment, based on the acute formulation toxicity. The rapporteur Member State proposed a NOAEL of 2.4 mg a.s./kg bw/d from the two-generation rat study as the long-term endpoint, based on weight effects on the liver. The meeting of Member State experts did not consider the organ weight changes to have a significant effect on reproductive capacity of mammals. It was agreed to base the long-term risk assessment on a NOAEL of 9.45 mg a.s./kg bw/d, based on body weight reductions. The first tier acute and long-term TERs were above the Annex VI trigger for mammals, indicating a low risk from the intended use.

Plant metabolites

The risk from plant metabolites to herbivorous birds and mammals was considered in the quizalofop-P-ethyl DAR. 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 quizalofop was considered to be assessed as an integral aspect of the studies conducted with quizalofop-P-ethyl. In conclusion, toxicity tests with quizalofop in avian species were considered unnecessary.

Secondary poisoning

A log P_{ow} of 4.61 for quizalofop-P-ethyl triggered a risk assessment for secondary poisoning of fish- and earthworm-eating birds and mammals. A risk assessment of secondary poisoning for birds was provided in the DAR and updated in addendum 4 (September 2008), based on the revised long-term mammalian NOAEL. All TERs for secondary poisoning were above the Annex VI trigger, indicating a low risk from the intended use in sugar beet.

The potential for bio-accumulation and food chain behaviour of the metabolites was assessed in the quizalofop-P-ethyl DAR. 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 hydroxyl quizalofop or dihydroxy quinoxaline.

Contaminated drinking water

Revised acute risk assessments for birds and mammals consuming contaminated drinking water were provided in addendum 2 (June 2008) and addendum 4 (September 2008) respectively, based on the worst case scenario of a 10 g bird or mammal. TERs were above the Annex VI trigger of 10 for both birds and mammals, indicating a low risk for the intended use.

Quizalofop-P-tefuryl

Birds

The lowest acute and short-term toxicity endpoints for the birds tested were a LD_{50} of >2150 mg a.s./kg bw and a LC_{50} of 258.6 mg a.s./kg bw/d for bobwhite quail (*Colinus virginianus*) and mallard duck (*Anas platyrhynchos*) respectively. A reproductive NOEC of 68.7 mg/kg bw/day for mallard duck was used for the long-term risk assessment. TERs in a first tier risk assessment were all above the Annex VI trigger, indicating a low acute, short-term and long-term risk to birds for all intended uses.

Mammals

The lowest acute endpoint for mammals was observed in a test with rat (LD_{50} = 1012 mg a.s./kg bw), supporting a low acute toxicity to mammals. A NOAEL of 16.9 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.

Plant metabolites

In the DAR of quizalofop-P-tefuryl no assessment of the risk from plant metabolites to herbivorous birds or mammals was provided. It was agreed by the Member State experts that the risk should be addressed by the notifier. After the peer review, the EFSA however suggests that the risk to herbivorous birds and mammals has been addressed adequately by the assessment provided in the DAR for quizalofop-P-ethyl (see above).

Secondary poisoning

The log P_{ow} of 4.32 for quizalofop-P-tefuryl triggered a risk assessment for secondary poisoning of fish- and earthworm-eating birds and mammals. A risk assessment of secondary poisoning for birds was provided in the DAR, and for mammals in addendum 2 (September 2008). All TERs for secondary poisoning were several orders of magnitude above the Annex VI trigger, indicating a low risk from all intended uses.

No assessment of secondary poisoning by metabolites was provided by the notifier for quizalofop-P-tefuryl. This was not commented on during the peer review. The EFSA considered the risk from bioaccumulation of metabolites in birds and mammals to have been addressed by the assessment provided in the DAR of quizalofop-P-ethyl (see above).

Contaminated drinking water

A risk assessment for birds and mammals consuming contaminated drinking water was not included in the DAR, but was provided in addendum 1 (June 2008). Member State experts noted that only an acute risk assessment was required, and the risk assessment should be based on the exposure of a 10 g bird or mammal (first tier worst case scenario) to contaminated drinking water from puddles or reservoirs held in leave axils. A revised acute TER calculation was provided in addendum 2 (September 2008) for mammals, based on a 10 g mammal. TERs were above the Annex VI trigger of 10 for both birds and mammals, indicating a low risk from consumption of contaminated drinking water for all intended uses.

5.2. RISK TO AQUATIC ORGANISMS

Quizalofop-P-ethyl

The lowest short-term toxicity for technical quizalofop-P-tefuryl was observed for algae with an acute $E_bC_{50,\ 72h}$ of 0.021 mg a.s./L. It was proposed to classify quizalofop-P-tefuryl as very toxic to aquatic organisms (R50). The formulation was also very toxic to algae. The level of toxicity for the

formulation was comparable to the toxicity of quizalofop-P-ethyl based on content of active substance. Chronic toxicity studies were available for fish and daphnia. The chronic toxicity was at the same level as the acute toxicity. Due to the fast hydrolysis of quizalofop-P-ethyl seen in the *Lemna* study, the meeting of Member State experts recommended to use the mean measured concentration to derive an endpoint. On the basis of the toxicity data available and FOCUS Step 2 exposure values TERs were above the Annex VI trigger for quizalofop-P-ethyl.

Metabolites

In the DAR on quizalofop-P-ethyl, an aquatic risk assessment was provided for the water body metabolites quizalofop and dihydroxy quinoxaline and for the sediment metabolite quizalofop phenol. In the meeting of Member State experts, the aquatic toxicity endpoints for the metabolites were revised to ensure that the more toxic endpoint available was used (see section 5 above). All metabolite toxicity data indicated a lower toxicity to aquatic organisms than quizalofop-P-ethyl, except for quizalofop which was a factor of 6 more toxic to *Glyceria fluitans* compared to the toxicity of the active substance (to *Lemna gibba*). An open point was agreed for the rapporteur Member State to update the risk assessment in line with the common metabolite toxicity endpoints. The rapporteur Member State, however, considered that a revision would not result in a more scientifically valid risk assessment, based on the fact that the exposure had not changed and the large margin of safety indicated by the existing TERs (see evaluation table; open point: 5.11). The EFSA did, nevertheless, revise the risk assessment to aquatic organisms while drafting the conclusion. The new aquatic TERs for metabolites are provided in appendix 1 for all the metabolites considered to be relevant for water (quizalofop, hydroxy quizalofop and dihydroxyl quinoxaline) and sediment (quizalofop). The TERs were above the Annex VI trigger for aquatic organisms and sediment dwellers for all these metabolites, based on FOCUS Step 2 PEC values provided in the DAR. The only exception was the assessment for the most sensitive endpoint of quizalofop (*G. fluitans*) where further refinement was required to identify a low risk. All TERs were above the Annex VI trigger when the assessment was based on FOCUS Step 3 scenarios.

A bio-concentration study for quizalofop-P-ethyl was provided (log P_{ow} = 4.61) 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 380 (whole fish); and after 14 days of depuration, less than 1% of the day 28 exposure levels remained in whole fish. Quizalofop was considered not to bio-accumulate, with a log P_{ow} of 2.22; as were the other metabolites.

In conclusion, the risk to aquatic organisms was assessed to be low from the intended use of quizalofop-P-ethyl in sugar beet.

Quizalofop-P-tefuryl

The lowest acute endpoints for technical quizalofop-P-tefuryl was observed for fish with an acute $LC_{50,\ 96h}$ of 0.23 mg a.s./L. It was proposed to classify quizalofop-P-tefuryl as very toxic to aquatic

organisms (R50). Chronic toxicity studies with fish and daphnia were not required for the active substance, due to the fast DT_{50} in water and only one application. The formulation was very toxic to algae ($L_bC_{50,\ 72h}$ = 0.01 mg a.s./L). Based on the content of active substance, the formulation appeared to be more toxic than the technical quizalofop-P-tefuryl. On the basis of the toxicity data available and FOCUS Step 2 exposure values, TERs were above the Annex VI trigger for quizalofop-P-tefuryl.

Metabolites

In the DAR on quizalofop-P-tefuryl, an aquatic risk assessment was provided for the water body metabolites quizalofop and tetrahydrofurfuryl alcohol, and for the sediment metabolites quizalofop phenol and dihydroxyl quinoxaline. In the meeting of Member State experts, the aquatic toxicity endpoints for the metabolites were revised to ensure that the more toxic endpoint available was used (see section 5 above). All metabolite toxicity data indicated a lower toxicity to aquatic organisms than the active substance itself, except for quizalofop which was a factor of 22x more toxic to *Glyceria fluitans* compared to the toxicity of the active substance (to *Lemna gibba*). An open point was agreed for the rapporteur Member State to update the risk assessment. The rapporteur Member State, however, considered that a revision would not result in a more scientifically valid risk assessment, based on the fact that the exposure had not changed and the large margin of safety indicated by the existing TERs (see evaluation table; open point: 5.11). EFSA did, nevertheless, revise the risk assessment to aquatic organisms while drafting the conclusion, as the PEC values for quizalofop and hydroxyl quizalofop were recalculated by EFSA after the peer review. No reliable PEC_{sw} values were available for any of the other metabolites (see section 4.2). The new aquatic TERs for metabolites are provided in appendix 1 for all the metabolites considered to be relevant for water (quizalofop, hydroxy quizalofop, tetrahydrofurfuryl alcohol and tetrahydrofuroic acid) and sediment (quizalofop, quizalofop phenol and dihydroxyl quinoxaline). For the metabolites where no exposure could be recalculated, the PEC_{sw} or PEC_{sed} for quizalofop was used as a worst case exposure. The TERs were above the Annex VI trigger for aquatic organisms and sediment dwellers for all the metabolites. It was, however, not possible to assess the risk to aquatic organisms from the metabolite tetrahydrofuroic acid, as no aquatic toxicity data were available. Nonetheless, the EFSA considered the risk to be low, based on the fact that tetrahydrofurfuryl alcohol was considered to be of low toxicity to aquatic organisms ($L(E)C_{50}$ >100 mg/L), tetrahydrofuroic acid was considered to be included in the metabolic pathway of tetrahydrofurfuryl alcohol and the TER indicated a safety margin of several orders of magnitude.

A bio-concentration study for quizalofop-P-tefuryl was provided (log P_{ow} = 4.32) 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 340 (whole fish) and an elimination half-life of less than 1 day. Quizalofop was considered not to bio-accumulate, with a log P_{ow} of 2.22; as were the other metabolites (see section 5.1).

In conclusion the risk to aquatic organisms was assessed to be low from the intended uses of quizalofop-P-tefuryl.

5.3. RISK TO BEES

Quizalofop-P-ethyl

The potential risk to honey bees from exposure to quizalofop-P-ethyl was assessed on the basis of the contact and oral hazard quotients (HQ). These were derived as the ratio between the maximum application rate expressed in terms of active ingredient (200 g a.s./ha) and the lowest contact and oral LD_{50} values expressed as µg of active ingredient per bee. The hazard quotients for acute oral and contact toxicity based on an application rate of 100 g a.s./ha, were below the trigger value of 50 for both quizalofop-P-tefuryl and the formulated product 'Targa Super', indicating a low risk to bees.

Quizalofop-P-tefuryl

The potential risk to honey bees from exposure to quizalofop-P-tefuryl was assessed on the basis of the contact and oral hazard quotients. The hazard quotients for acute oral and contact toxicity were below the trigger value of 50 for both quizalofop-P-tefuryl and the formulated product, indicating a low risk to bees.

5.4. RISK TO OTHER ARTHROPOD SPECIES

Quizalofop-P-ethyl

In the laboratory glass plate test, *Typhlodromus pyri* was the most sensitive with respect to survival (LR_{50} = 25 g a.s./ha). *Aphidius rhopalosiphi* was slightly less sensitive (LR_{50} = 48.5 g a.s./ha). Reproduction was not affected to the same extent as mortality in both species. In a risk assessment, the in-field hazard quotient (HQ) was above the trigger for both species, whereas the off-field HQ indicated a low risk to non-target arthropods. Extended laboratory studies were provided for *T. pyri* and *A. rhopalosiphi*. Both species tested were exposed to residues on leaf immediately after spray application. The studies indicated 83% mortality for *T. pyri* at the intended application rate, whereas the effect on mortality and reproduction on *A. rhopalosiphi* was below 50% at the intended use rate. For the beetles *Aleochara bilineata* and *Poecilus cupreus*, there was no reduction in reproduction in the former or mortality in the latter at 100 g a.s./ha. For *Chrysoperla carnea*, no effects on survival, fecundity or fertility was observed at 200 g a.s./ha. It was concluded in the DAR that the risk to non-target arthropods was addressed. The meeting of Member State experts, however, agreed on a data gap for the notifier to further address the in-field risk to *T. pyri*, e.g. by estimation of the foliage DT_{50} of quizalofop-P-ethyl or by an aged residue study. The notifier did provide a refinement in addendum 4 (September 2008). Available residue data from sugar beet foliage indicated DT_{50} and DT_{90} values of 10.4 and 34.7 days respectively. Given a field application rate of 200 g a.s./ha, a relatively fast disappearance of quizalofop-P-ethyl and a LR_{50} of 106.9 g a.s./ha derived from the extended laboratory study, it was considered possible for *T. pyri* to re-colonise the in-field area within 1 year. The rapporteur Member State accepted the response of the notifier. The EFSA also agrees to the

assessment, but it was noted, however, that the data gap would have to remain, as the assessment has not been peer reviewed.

In conclusion, the off-field risk to non-target arthropods was assessed as low, whereas further refinement was required to address the in-field risk.

Quizalofop-P-tefuryl

The mortality was 100% to *Typhlodromus pyri* and *Aphidius rhopalosiphi* in standard laboratory tests at the intended use rate (100 g a.s./ha). To fulfil Annex II and III requirements, the most relevant species for the intended uses of the formulation on arable crops were considered to be ground dwelling organisms. Tier 1 laboratory studies on *Poecilus cupreus* and *Pardosa sp.* exposed to a single dose at the highest proposed application rate, indicated no mortality to *Poecilus cupreus* and only low mortality in the study to *Pardosa* (10% after 14 days). Nor was any mortality observed in a study with *Agonum dorsale* at 100 g a.s./ha. The same exposure to *Chrysoperla carnea*, however, indicated a mortality of 83.9%. In-field and off-field hazard quotients for *T. pyri* and *A. rhopalosiphi* and effects above 50% for *C. carnea* at intended use rate indicated a need for further higher tier testing. Tier 2 studies were provided for *T. pyri* indicating effects on mortality and reproduction of 51% and 32.2% respectively at the intended use rate. An extended laboratory study with *Aleochara bilineata* exposed on soil, and aged residue studies with *Aphidius colemani* and *C. carnea* exposed on bean leaves were provided and accepted in the DAR. For the aged residue study, *A. colemani* was considered to be a more appropriate test species than *A. rhopalosiphi*. It was not considered practical to test *A. rhopalosiphi* on cereal plants as quizalofop-P-tefuryl is phytoxtoxic to cereal plants at very low rates of application, and both species were considered to have the same sensitivity to plant protection products. At exposure rates of 90 g a.s./ha, none of the higher tier studies indicated effects on mortality or reproduction exceeding 50%. The rapporteur Member State considered that the more sensitive species *A. rhopalosiphi*, *T. pyri* and *C. carnea* were of less risk as these are predators and their prey would not be present in the crop at the time of application. The more relevant ground-dwelling predators, *P. cupreus*, *Pardosa sp.*, *A. dorsale* and *A. bilineata* species were less affected and in the higher tier tests, the effect to *T. pyri*, *A. colemani* and *C. carnea* were transient and without long-term effects. On this basis, the rapporteur Member State considered the risk to non-target arthropods as low.

The meeting of experts, however, did not accept the aged residue study with *C. carnea* due to the high control mortality (>50% in one of five control groups). A data gap was identified for the notifier to address the risk to *C. carnea.* Furthermore, the EFSA considered that the risk to *T. pyri* would have to be addressed further to identify a low risk, as the effect on mortality was above 50% in an extended laboratory study at the application rate proposed in the GAP.

5.5. RISK TO EARTHWORMS

Quizalofop-P-ethyl

The acute studies in earthworms indicated a low toxicity from quizalofop-P-ethyl, hydroxy quizalofop and dihydroxy quinoxaline. The acute toxicity of the formulation indicated a slightly higher toxicity. The toxicity endpoint used in the risk assessment was corrected to take account of the log P_{ow} greater than 2. The TER calculations were based on initial worst case PEC_{soil} calculations. All TERs were above the Annex VI trigger, indicating a low risk to earthworms from the intended use.

Quizalofop-P-tefuryl

The acute studies in earthworms indicated a low toxicity from quizalofop-P-tefuryl, hydroxy quizalofop and dihydroxy quinoxaline. The acute toxicity of the formulation indicated a slightly higher toxicity. No toxicity data were available for quizalofop or tetrahydrofurfuryl alcohol. Their potential impact was considered to be covered in the study with quizalofop-P-tefuryl. The toxicity endpoint used in the risk assessment was corrected to take account of the log P_{ow} greater than 2. The TER calculations were based on initial worst case PEC_{soil} calculations. All TERs were above the Annex VI trigger, indicating a low risk to earthworms from the intended uses.

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

Quizalofop-P-ethyl

DT_{90} values ranging from 1.2 to 4 days showed that quizalofop-P-tefuryl would not persist in soil. Accordingly, the risk to soil non-target macro-organisms could be considered as low and as such no further testing was required. In addition to these findings, studies conducted with earthworms and soil micro-organisms indicated a low risk following exposure to quizalofop-P-ethyl. Furthermore, earthworm studies were conducted with the metabolites hydroxy quizalofop and dihydroxy quinoxaline, which allow the same conclusion to be drawn, that these metabolites do not pose a high risk to soil non-target macro-organisms.

Quizalofop-P-tefuryl

DT_{90} values ranging from 0.30 to 1.16 days showed that quizalofop-P-tefuryl would not persist in soil. Accordingly, the risk to soil non-target macro-organisms could be considered as low and as such no further testing was required. In addition to these findings, studies conducted with earthworms and soil micro-organisms indicated a low risk following exposure to quizalofop-P-tefuryl. Furthermore, the earthworm studies conducted with the metabolites hydroxy quizalofop and dihydroxy quinoxaline allow the same conclusion to be drawn, that these metabolites do not pose a high risk to soil non-target macro-organisms.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

Quizalofop-P-ethyl

Two studies were submitted, but only one study was considered to be acceptable by the rapporteur Member State. No effects of >25% on soil respiration and nitrification were observed in tests with quizalofop-P-ethyl at a soil concentration of 1.23 mg a.s./kg, i.e. 5.7 times the expected maximum concentration in soil. Quizalofop and the other metabolites were considered 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.

Quizalofop-P-tefuryl

No effects of >25% on soil respiration and nitrification were observed in tests with quizalofop-P-tefuryl at five times the expected maximum soil concentration. Quizalofop and the other metabolites were considered 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)

Quizalofop-P-ethyl

The effect of the formulated product 'Targa Super' on seedling emergence and growth and vegetative vigour of non-target terrestrial plants (10 species) was investigated. Quizalofop-P-ethyl did not affect the germination of any species tested. In the test conducted with seedlings, mortality and phytotoxic (>15%) effects were seen in *Zea mays* and *Avena sativa*, mortality was also observed in *Brassica oleracea*. Seedling growth rate was affected in *Z. mays*, *A. sativa* and *B. oleracea* with EC_{50} values of 52.31, 59.29 and 113.54 g a.s./ha respectively. All other species were unaffected with NOECs greater than the highest dose rate used (*ca* 100 g a.s./ha). The results of the vegetative vigour study confirmed the relative sensitivity of *Z. mays* and *A. sativa* to quizalofop-P-ethyl as mortality and phytotoxicity was observed. EC_{50} values for growth were 5.46 and 15.29 g a.s./ha respectively. Vegetative vigour was unaffected in all other species at the intended application rate. A risk assessment was provided for the two most sensitive species, *Z.mays* and *A. sativa*. No-spray buffer zones of 10 m were required to identify TER values above the Annex VI trigger for the most sensitive species (*Z. mays*).

Quizalofop-P-tefuryl

A herbicide screening test for quizalofop-P-tefuryl provided by the notifier was not considered valid for the risk assessment by the rapporteur Member State. The biological activity of the quizalofop-P-tefuryl and the four soil metabolites phenoxy acid, dihydroxy quinoxaline, quizalofop phenol and tetrahydrofurfuryl alcohol was tested on three grass species and a bean species. Quizalofop-P-tefuryl (34 g a.s./ha) showed a 100% biological control on grasses but no effects beans. The metabolites had

no effect on the biological activity. The study was not considered valid for a risk assessment. No risk assessment was provided as no valid studies were submitted. Since quizalofop-P-tefuryl is a herbicide, laboratory assays (dose-response tests) should be conducted to address the risk to non-target plants.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

Quizalofop-P-ethyl

Based on the data available with an EC_{50} above 100 mg a.s./L, no risk was expected for sewage sludge micro-organisms.

Quizalofop-P-tefuryl

The notifier did not submit any studies to address the effect on biological methods of sewage treatment, as quizalofop-P-tefuryl was considered to be readily degraded by soil micro-organisms and it was not expected to have any adverse effects on sewage treatment plants. The rapporteur Member State, however, considered that a study was needed. This view was supported by the Member State experts and a data gap was agreed for the notifier to provide a study on effects on sewage treatment plants.

6. Residue definitions

Quizalofop-P-tefuryl

Soil

Definition for risk assessment:	quizalofop-P-tefuryl, quizalofop, tetrahydrofurfuryl alcohol, hydroxy-quizalofop, dihydroxy-quinoxaline
Definition for monitoring:	quizalofop (as ten out of eleven soil DT_{90} values for quizalofop-P-tefuryl are less than 3 days, this metabolite is indicated as a good indicator for monitoring purposes)

Water

Ground water

Definition for exposure assessment:	quizalofop-P-tefuryl, quizalofop, tetrahydrofurfuryl alcohol, hydroxy-quizalofop, dihydroxy-quinoxaline, tetrahydrofuroic acid
Definition for monitoring:	quizalofop (as the $DT_{90\ water}$ value for quizalofop-P-tefuryl is less than 3 days, this metabolite is indicated as a good indicator for monitoring purposes)

Surface water

Definition for risk assessment:

Water:	quizalofop-P-tefuryl, quizalofop, tetrahydrofurfuryl alcohol, tetrahydrofuroic acid; (from soil surface runoff and drainage) hydroxy-quizalofop
Sediment:	quizalofop-P-tefuryl, quizalofop, dihydroxy-quinoxaline, CQOP

Definition for monitoring: quizalofop (as the $DT_{90\ water}$ value for quizalofop-P-tefuryl is less than 3 days, this metabolite is indicated as a good indicator for monitoring purposes)

Air

Definition for risk assessment: quizalofop-tefuryl

Definitions for monitoring: quizalofop-tefuryl

Quizalofop-P-ethyl

Soil

Definition for risk assessment: quizalofop-P-ethyl; quizalofop; hydroxy-quizalofop, dihydroxy-quinoxaline

Definition for monitoring: quizalofop (as five out of six DT_{90} values for quizalofop-P-ethyl are less than 3 days, this metabolite is indicated as a good indicator for monitoring purposes)

Water

Ground water

Definition for exposure assessment: quizalofop-P-ethyl; quizalofop; hydroxy-quizalofop, dihydroxy-quinoxaline

Definition for monitoring: quizalofop-ethyl

Surface water

Definition for risk assessment: quizalofop-P-ethyl; quizalofop; from soil surface runoff/drainage: hydroxy-quizalofop, dihydroxy-quinoxaline

Definition for monitoring: quizalofop-ethyl

Air

Definition for risk assessment: quizalofop-ethyl

Definitions for monitoring: quizalofop-ethyl

Quizalofop-P-tefuryl and quizalofop-P-ethyl

Food of plant origin (for both ester variants)

Definition for risk assessment:	**Provisional;** Sum of quizalofop-esters, quizalofop and quizalofop conjugates expressed as quizalofop (sum of isomers)
Definition for monitoring:	**Provisional;** Sum of quizalofop-esters, quizalofop and quizalofop conjugates expressed as quizalofop (sum of isomers) (The EFSA is however of the opinion that there is no need to include the conjugates in the residue definition for monitoring, both parent ester and quizalofop being sufficient markers for the residues in plant products).

Food of animal origin (for both ester variants)

Definition for risk assessment:	**Provisional;** sum of quizalofop-esters, quizalofop pentanoic acid, and quizalofop, expressed as quizalofop (sum of isomers)
Definition for monitoring:	**Provisional;** sum of quizalofop-esters and quizalofop expressed as quizalofop (sum of isomers)

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

Quizalofop-P-tefuryl

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Quizalofop-P-tefuryl	Very low persistence Single first-order laboratory DT_{50} 0.1 – 0.9 d; DT_{90} 0.2 – 3.1 d (20°C, 40 – 45% MWHC soil moisture)	The risk to earthworms and soil non-target 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 micro-organisms was assessed as low, as it was considered to be covered by the assessment of quizalofop-P-tefuryl.
Tetrahydrofurfuryl alcohol	Very low persistence Single first-order labDT_{50} 0.44 – 0.75 day (20°C, 45% MWHC soil moisture)	The risk to earthworms and soil non-target micro-organisms was assessed as low, as it was considered to be covered by the assessment of quizalofop-P-tefuryl.
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 was assessed as low. The risk to soil non-target micro-organisms was assessed as low, as it was considered to be covered by the assessment of quizalofop-P-tefuryl.
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 was assessed as low. The risk to soil non-target micro-organisms was assessed as low, as it was considered to be covered by the assessment of quizalofop-P-tefuryl.

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
Quizalofop-P-tefuryl	Adsorption properties cannot be determined (K_{oc} = 0 used in the modelling)	No	Yes	Yes	Yes
Quizalofop	Low to high mobility K_{foc} 133 – 1791 mL/g	No	Yes	No information available. Rat metabolite; higher toxicity than the parent not expected. No further data needed	Yes
Tetrahydrofurfuryl alcohol	Data not available (Koc = 0 used in the modelling)	No	No	Moderately toxic by oral route; moderate to severe eye irritant, skin irritant. 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-quizalofop	Low to high mobility K_{oc}/K_{foc} 74 – 1567 mL/g	No	No	No information available. 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	No information available. Rat metabolite; higher toxicity than the parent not expected. No further data needed	No
Tetrahydrofuroic acid	Data not available (Koc = 0 used in the modelling)	No	No	No information available. Likely rat metabolite; higher toxicity than the parent not expected. No further data needed	No

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Quizalofop-P-tefuryl	Very toxic to aquatic organisms. The risk to aquatic organisms was assessed as low.

Compound (name and/or code)	Ecotoxicology
Quizalofop	Harmful to aquatic organisms. The risk to aquatic organisms was assessed as low.
CQOP (only sediment)	The risk to *Chironomus riparius* was assessed as low based on worst case PEC_{sed} calculations for quizalofop provided by the EFSA after the peer review.
Dihydroxy-quinoxaline (only sediment)	The risk to *Chironomus riparius* was assessed as low based on worst case PEC_{sed} calculations for quizalofop provided by the EFSA after the peer review.
Tetrahydrofurfuryl alcohol (only water)	Not toxic to aquatic organisms. The risk to aquatic organisms was assessed as low, based on worst case PEC_{sw} calculations for quizalofop provided by the EFSA after the peer review.
Tetrahydrofuroic acid (only water)	No toxicity data available. The risk to aquatic organisms was assessed as low, based on the assessment of tetrahydrofurfuryl alcohol (tetrahydrofuroic acid was considered a metabolic breakdown product of tetrahydrofurfuryl alcohol; tetrahydrofurfuryl alcohol was identified as not toxic to aquatic organisms (EC_{50} >100 mg a.s./L); TER value for tetrahydrofurfuryl alcohol was several orders of magnitude above the Annex VI trigger).
Hydroxy-quizalofop (from soil via runoff and drainage)	Aquatic toxicity data for hydroxyl quizalofop were available in the DAR of quizalofop-P-ethyl. The risk to aquatic organisms was assessed as low, based on FOCUS Step 2 PEC_{sw} calculations provided by the EFSA after the peer review.

Air

Compound (name and/or code)	Toxicology
Quizalofop-P-tefuryl	Low toxicity via inhalation

Quizalofop-P-ethyl

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Quizalofop-P-ethyl	Low to very low persistence Single first-order laboratory DT_{50} 0.33 – 1.1 d; DT_{90} 1.1 – 3.5 d (20°C, different soil moisture conditions in the range 40 – 65% MWHC)	The risk to earthworms and soil non-target 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 was assessed as low. Risk to soil non-target micro-organisms was regarded as low due to the low amount.
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 was assessed as low. Risk to soil non-target micro-organisms was regarded as low due to the low amount.
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 was assessed as low. Risk to soil non-target micro-organisms was regarded as low due to the low amount.

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
Quizalofop-P-ethyl	Low to slight mobility K_{foc} 1024 – 3078 mL/g	No	Yes	Yes	Yes
Quizalofop	Low to high mobility K_{foc} 133 – 1791 mL/g	No	Yes	Acute oral LD_{50} of quizalofop to rats 1330 mg/kg bw, and in mice 1115 mg/kg bw. 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	No information available. 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	No information available. Rat metabolite; higher toxicity than the parent not expected. No further data needed	No

Surface water and sediment

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

Air

Compound (name and/or code)	Toxicology
Quizalofop-P-ethyl	Low acute toxicity via inhalation

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

Ethyl variant

- The specification is not supported by the available data and must be justified further (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, new information was provided in addendum 6 to volume 4 dated October 2008, refer to section 1).
- The volatile components should be specified individually if they are present at >0.1% or if they are relevant (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- It should be addressed if the isomeric impurity of quizalofop is present in the technical material (relevant for all uses evaluated, data gap identified by the EFSA September 2008, proposed submission date unknown, refer to section 1).
- Surface tension at 25ºC (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- Persistent foam should be tested at the highest in use concentration (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- Validated method of analysis for food of plant origin (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- To provide information concerning the nature of the unidentified compounds or unidentified radioactive fractions detected in the sugar beet metabolism study (Stevenson I.E., 1991; 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 information on the toxicological relevance of the phenoxy metabolites observed as free and conjugated in the sugar beet metabolism study (Stevenson I.E., 1991) and especially the phenoxy propionate metabolite that may exceed 0.05 mg/kg in leaves at harvest (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 a storage stability study for oil/protein matrices in order to support the results of the rotational crop study (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 3.1.2).
- To clarify, in the goat and hen metabolism studies, the nature of the residues in fat since only a small part was characterised or identified (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 3.2).
- To provide an explanation on the quantitative differences observed in the bio-distribution of the residues in rat and ruminants. If it cannot be concluded that these quantitative differences are of no concern, a metabolism study in pig should be requested (relevant for all uses evaluated, data

gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 3.2).

- Further refinements are required to address the in-field risk to *Typhodromus pyri* (relevant for all representative uses evaluated, data gap identified in PRAPeR 53expert meeting; a response addressing the in-field risk to *T. pyri* was provide by the notifier in addendum 4 (September 2008), the rapporteur Member State and the EFSA agrees to the assessment but the data gap remains as it has not been peer reviewed; refer to section 5.4).

Tefuryl variant

- It should be addressed if the isomeric impurity of quizalofop is present in the technical material (relevant for all uses evaluated, data gap identified by EFSA September 2008, proposed submission date unknown, refer to section 1).
- Determination of the kinematic viscosity at 40ºC (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- Analytical method for the active substance in the formulation that is capable of separating 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).
- Validated method of analysis for food of plant and animal origin (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- Formal data gap: new developmental toxicity study in rabbit according to the current guidelines (relevant for all uses evaluated, data gap identified by the rapporteur Member State and confirmed during PRAPeR 59 meeting, proposed submission date unknown, refer to section 2.6). It is noted that this study would not impact on the overall risk assessment; gap to be reconsidered by ECHA when assessing quizalofop-P-tefuryl for classification and labelling purposes.
- Validated method of analysis for food commodities (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 1).
- To provide two plant metabolism studies with an additional labelling position on quizalofop-P-tefuryl or with another variant (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 a statement on the toxicological relevance of the hydroxy-quizalofop-phenol metabolite observed at significant levels in the soya meal and why the notifier considers that this metabolite has not to be included in the residue definition (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 differences between the three analytical methods XM-12, XM-12A and XM-12B used in the plant storage stability study and to explain what "known levels of bound residues in treated samples" means (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 a standard hydrolytic processing study covering the full range of the processing conditions: boiling, pasteurisation and sterilisation (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 low transfer of residues observed in the rapeseed processing study in all processed products (crude oil, refined oil and pressed cake) and not consistent with the residue level observed in seeds. In case of insufficient explanation, a new processing study in oilseed rape is requested (relevant for all uses evaluated, data gap identified by the meeting of experts June 2008, proposed submission date unknown, refer to section 3.1.1).
- A goat metabolism study with an additional labelling position on quizalofop-P-tefuryl or with another variant is required (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 3.2).
- Justification that a metabolism study in pig is not required since quantitative differences were observed in the bio-distribution of the residues in rat and ruminants for other ester variants (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 3.2).
- To provided a storage stability study for products of animal origin (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to section 3.2).
- The risk to *Chrysoperla carnea* needs to be addressed further (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).
- The risk to *Typlodromus pyri* needs to be addressed further (relevant for all representative uses evaluated, data gap identified by EFSA after the peer review, proposed submission date unknown, refer to section 5.4).
- A study to address the effect on biological methods of sewage treatment is required (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State in the DAR and agreed at the meeting of Member State experts (PRAPeR 53), proposed submission date unknown, refer to section 5.9).
- Laboratory assays (dose-response tests) are required to address the risk to non-target plants (relevant for all representative uses evaluated, data gap identified by the rapporteur Member State in the DAR, proposed submission date unknown, refer to section 5.8).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

This conclusion was reached on the basis of the evaluation of the representative uses of quizalofop-P-ethyl as a herbicide on sugar beet and quizalofop-P-tefuryl as a herbicide on oilseed rape, sugar/fodder beet, potato, combining pea, field beans, linseed and sunflower. Full details of the GAP can be found in the attached list of endpoints.

The representative formulated product for the evaluation of quizalofop-P-ethyl was 'Targa Super', an emulsifiable concentrate (EC). For the quizalofop-P-tefuryl, the representative formulation was 'Panarex' (also known as 'Pantera'), an emulsifiable concentrate (EC).

For food of plant and animal origin, none of the methods supplied comply with the residue definition. For environmental matrices sufficient methods are available.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that at least some quality control measurements of the plant protection products are possible. The specification for the ethyl variant was not accepted as further justification is required. Data gaps for surface tension and persistent foam were identified. For the tefuryl variant, the specification was acceptable for section 1, although there is an outstanding question on the formation of the isomeric impurity of quizalofop. A data gap was identified for a method of analysis to separate the *R* and *S* isomers (note this is not the *R* and *S* isomers in the tefuryl part of the molecule). A data gap was also identified for kinematic viscosity for aspiration hazard classification.

Tested in mammalian toxicology, quizalofop-P-tefuryl is "Harmful if swallowed" (Xn; R22 proposed based on oral Lethal Dose – LD_{50} 1012 mg/kg bw); it has low dermal and inhalation toxicity (LD_{50} >2000 mg/kg bw and Lethal Concentration – LC_{50} >3.9 mg/L air, respectively). Quizalofop-P-tefuryl is not a skin or eye irritant, but it is a skin sensitiser in the Magnusson-Kligman test (Xn; R43 "May cause sensitisation by skin contact" was proposed). Short-term toxicity target organs were liver and testes. In rodents, the relevant No Observed Adverse Effect Level – NOAEL (rat study) was 1.7 mg/kg bw/day based on increased liver weights, accentuated lobulation of the liver and haematological and clinical chemistry findings at 33.4 mg/kg bw/day. Kidney, testis and body weights were decreased at 134 mg/kg bw/day. Quizalofop-P-tefuryl did not show genotoxic concern. In long-term toxicity studies the relevant NOAEL is 1.3 mg/kg bw/day. Quizalofop-P-tefuryl caused an increased incidence of rare renal squamous cell carcinoma, as well as a clear treatment related increase in the Leydig cell tumours in rats; the liver tumours occurring in rodents were not relevant to humans. On this basis, Carc. Cat. 3; R40 "Limited evidence of a carcinogenic effect" was proposed. In the two-generation rat study, the NOAEL for parental and offspring was 1.4 mg/kg bw/day based on increased liver weight and liver hypertrophy in adult males and females, vacuolar changes in

pituitary in adult males, decreased body weights during lactation in F1 generation and decreased viability during early lactation. The NOAEL for reproduction was 16.9 mg/kg bw/day. In developmental toxicity studies in rats the maternal NOAEL was set at 10 mg/kg bw/day, whereas the developmental NOAEL was 30 mg/kg bw/day based on increased postimplantation loss per dam with concomitant lower number of viable foetuses and increased number of malformations at maternally toxic dose. In rabbits, the NOAEL was 20 mg/kg bw/day for maternal and developmental toxicity. However, the rabbit was not adequately tested but this was considered not to preclude concluding on the risk assessment. Due to the limitations of the studies Repr. Cat. 3; R63? ("Possible risk of harm to the unborn child") was agreed for proposal to the European Chemicals Agency (ECHA). The Acceptable Daily Intake (ADI) is 0.013 mg/kg bw/day based on the NOAEL of the 2-year study in rats, SF 100. The NOAEL of 1.7 mg/kg bw/day from the 90-day rat study was the most relevant NOAEL, also based on its dosing regime, and applying a 60% correction factor (limited oral absorption) and SF 100 resulted in an Acceptable Operator Exposure Level (AOEL) of 0.01 mg/kg bw/day. The Acute Reference Dose (ArfD) of 0.1 mg/kg bw was based on the maternal toxicity seen in the rat developmental study with a SF 100 applied. The estimated operator exposure exceeded the AOEL without the use of PPE, as well as with PPE but only with the UK POEM. The exposure was estimated below the AOEL (13%) applying the German model, with the use of gloves during mixing/loading and application and coverall and sturdy footwear during application. The exposure for workers re-entering the field for crop inspection and the bystander estimated exposure were estimated to be below the AOEL (for workers re-entering ornamentals the use of gloves is needed).

Quizalofop-P-ethyl is "Harmful if swallowed" (Xn; R22 proposed based on oral LD_{50} 1182 mg/kg bw); dermal and inhalation acute toxicity is low (LD_{50} >5000 mg/kg bw and LC_{50} 5.8 mg/L air, respectively). Quizalofop-P-ethyl is not a skin or eye irritant, nor does it show any sensitisation potential. The target organ in repeat dose studies was shown to be the liver. The lowest short-term NOAEL for quizalofop-P-ethyl is 1.7 mg/kg bw/day in mice study after 13-week (90-day) dietary administration, whereas the relevant long-term NOAEL is 0.9 mg/kg bw/day (2-year study in rats). Quizalofop-P-ethyl did not exhibit genotoxic or carcinogenic properties relevant to humans. It is not a reproductive or developmental toxicant: the NOAEL for offspring is 2.4 mg/kg bw/day based on hepatoxicity; the parental NOAEL is 9.4 mg/kg bw/day based on slightly decreased body weight during premating period, whereas the reproductive NOAEL is 37.8 mg/kg bw/day, highest dose tested. The maternal and developmental NOAEL in rats is 30 mg/kg bw/day based on decreased body weight gain and food consumption, increased resorptions and skeletal variations at ≥100 mg/kg bw/day. In rabbits, no malformations were observed up to doses of 60 mg/kg bw/day, which represented the NOAEL for developmental toxicity, whereas the maternal NOAEL for dams was 30 mg/kg bw/day based on slightly decreased body weight and food consumption, and decreased thymus and thyroid weights at 60 mg/kg bw/day. Quizalofop-P-ethyl does not have a potential to induce neurotoxicity in mammals. The Acceptable Daily Intake (ADI) is 0.009 mg/kg bw/day based on the 2-year rat study with a SF 100. The Acceptable Operator Exposure Level (AOEL) is 0.01 mg/kg

bw/day, based on the 90-day mouse study with an SF 100 (corrected for limited oral absorption of 67%). Due to the toxicological profile of quizalofop-P-ethyl, the Acute Reference Dose (ArfD) was not triggered. The operator exposure assessment was estimated to be below the AOEL (26%) with the use of Personal Protective Equipment (PPE, with the German model). The exposure for workers re-entering field for crop inspection and the bystander estimated exposure were estimated to be below the AOEL (for workers the use of gloves is needed).

For both quizalofop-P-ethyl and quizalofop-P-tefuryl, the metabolism in plants was investigated in potato, cotton, soya and additionally in sugar beet but for the ethyl variant only. One radioactive label was investigated for quizalofop-P-tefuryl and considering the insufficient metabolite characterisation in some studies, the meeting concluded that new studies using a second radioactive position need to be provided. For both variants, the metabolism proceeds primarily by the hydrolysis of the ester link to yield quizalofop (acid) followed by the loss of the propionyl moiety leading to the quizalofop-phenol metabolite. Further metabolism occurs by hydroxylation of the quinoxaline moiety giving the hydroxy-quizalofop, hydroxy-quizalofop-phenol and the dihydroxy-quizalofop-phenol. In addition, the presence of the quinoxaline and phenoxy metabolites indicated a cleavage of the parent molecule. Some of these metabolites were also found to be conjugated.

The meeting discussed whether the phenoxy propionate and hydroxy-quizalofop-phenol metabolites observed in beet foliage and soya meal in similar amounts to the tefuryl ester or to quizalofop, have to be included in the plant residue definition and if they have to be taken into account in the animal feeding. Finally and provisionally, the experts decided not to include these compounds in the residue definition, awaiting a statement on their toxicological relevance and proposed the following residue definition for monitoring and risk assessment for each individual variant:

> "Sum of quizalofop-ester, quizalofop and quizalofop conjugates 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 also 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 additional information. After the meeting and considering that conjugates were mainly detected in immature soya and cotton plants, the EFSA proposed not to include these conjugates in the residue definitions, especially for monitoring since the ethyl variant, tefuryl variant and quizalofop seem to be sufficient markers for the residues in plants.

In addition for quizalofop-P-ethyl, the meeting was of the opinion that the metabolism pattern has not been sufficiently described in root crops. No characterisations were performed in potato tubers and a substantial part of the extracted radioactivity was not identified in sugar beet. Therefore, it was

concluded that these studies were not sufficient to validate the proposed residue definition on the root/tuber plant group, especially on potato. However and considering that no metabolites are expected at significant levels in sugar beet root, it was agreed that the proposed residue definition could be applied to beet root. The notifier was requested to provide further information concerning the unidentified fractions observed in the beet studies, unless a new metabolism study has to be submitted for tuber/root crops.

For quizalofop-P-ethyl, supervised residue trials were submitted to support a single representative use on sugar beet. The trials performed with the highest LOQ of 0.10 mg/kg were removed from the data set and a MRL of 0.05 mg/kg was proposed for sugar beet roots. For quizalofop-P-tefuryl, a sufficient number of residue trials were submitted to propose MRLs on potato, sugar beet, bean, pea, lentil, oilseed rape, linseed, soya and sunflower. Samples were analysed using a method quantifying separately the parent quizalofop-P-tefuryl and its metabolites (including quizalofop) free and conjugated that could be converted to 2-methoxy-6-chloroquinoxaline, but this method was only validated for the tefuryl variant and quizalofop. This method was considered as appropriate in the framework of this peer review since its scope is wider than the compounds included in the proposed residue definition.

The storage stability study showed that quizalofop-P-ethyl and quizalofop residues are stable for at least 16 months in beet matrices. However, an additional study on oil/protein matrices was requested in order to support the results of the rotational crop study. Quizalofop-P-tefuryl and quizalofop residues were shown to be stable up to 12 – 24 months in a wider range of plant matrices (soya beans, cotton seeds, rape seed oil and cake, potato tubers). A degradation from the ester quizalofop-P-tefuryl to quizalofop was observed in beet matrices after one month, but generally recoveries were more than 80% when both quizalofop-P-ethyl and quizalofop residues were added up. Clarifications were requested concerning the different analytical methods used in these storage stability studies and especially concerning the validation for “bound residues”.

No processing study was provided for quizalofop-P-ethyl as no residues were detected in beet roots following the use of the active substance as stated in the critical GAP. For quizalofop-P-tefuryl, a standard hydrolytic study was provided but for the boiling condition only and a new study covering the full range of the processing conditions was requested. No processing factors could be derived from the rapeseed study since the residues detected in all processed fractions (crude oil, refined oil, pressed cake *etc*.) were considered to be inconsistent with the initial levels observed in seeds. A new processing study was requested, unless clarifications could be provided. On potatoes, the residue levels were not affected in boiled potatoes but were increased in fried potatoes.

The compounds detected in the rotational crops studies performed with quizalofop-ethyl (racemate) and quizalofop-P-tefuryl were also present in the primary crops, suggesting a similar metabolic

pathway in both primary and rotational crops. Considering the residue levels observed in these studies, it was concluded that no significant residues of quizalofop-ethyl, quizalofop-P-tefuryl and of their metabolites are expected in rotational crops.

The metabolism in animals was investigated using the racemate quizalofop-ethyl labelled on the phenyl and quinoxaline moieties in the goat study but on the quinoxaline moiety only in the hen study. This single radio-labelling was considered as sufficient in the scope of this peer review, since the intended use on sugar beet does not lead to significant intake by poultry. For quizalofop-P-tefuryl, the metabolism studies on goat and hen were conducted using a single label only. Considering that the characterisation/identification of the metabolites was insufficiently investigated in some animal matrices, a new study using a second labelling position was requested. Similar metabolic pathways were observed for both variants, starting with a rapid hydrolysis of the ester bond leading to the acid quizalofop and followed by hydroxylation or further hydrolysis giving hydroxy-quizalofop and hydroxy-quizalofop-phenol, these metabolites being subject to conjugations. In the hen study, quizalofop-pentanoic acid was also observed as a major metabolite in liver and kidney. The very low proportion of quinoxaline metabolites (<1% TRR) indicated limited cleavage of the parent molecule. Considering the comparative metabolite distribution in rat and goat for quizalofop-P-ethyl, 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, some differences being of a 10-fold magnitude. Before asking for a pig metabolism study, it was suggested to ask the notifiers to provide explanations for these quantitative differences. No comparison was possible for quizalofop-P-tefuryl since the dosages of the metabolites in rat and goat were performed at different time points. Finally and provisionally the meeting of experts proposed the following residue definitions for each individual variant:

- For monitoring: sum of quizalofop-ester and quizalofop expressed as quizalofop (sum of isomers).
- For risk assessment: sum of quizalofop-ester, quizalofop pentanoic acid and quizalofop, expressed as quizalofop (sum of isomers).

Considering the metabolism studies performed with the three different variants, the meeting of experts concluded that the following common residue definitions can be proposed for propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl:

- For monitoring: sum of quizalofop-esters and quizalofop expressed as quizalofop (sum of isomers).
- For risk assessment: sum of quizalofop-esters, quizalofop pentanoic acid and quizalofop, expressed as quizalofop (sum of isomers).

These definitions should remain provisional, pending the submission and the evaluation of the requested additional information and the statement on the toxicological relevance of some metabolites.

No feeding studies were submitted for quizalofop-P-ethyl and considering the metabolism studies performed with an exaggerated dose rate, it was concluded that no significant residues are expected in animal matrices resulting from the use of quizalofop-P-ethyl on sugar beet. Cow and hen feeding studies were submitted for quizalofop-P-tefuryl. Taking into account the transfer in animal products and the theoretical animal burden resulting from the representative uses of quizalofop-P-tefuryl, residue levels above the LOQs are expected in ruminant kidney and in poultry liver, kidney and fat. MRLs were proposed for these animal products. The stability of the residues in products of animal origin was however considered as insufficiently demonstrated and the notifier was asked to provide new data.

Using the EFSA consumer model and considering the representative use of quizalofop-P-ethyl on sugar beet, no chronic concern was observed, the Theoretical Maximum Daily Intake (TMDI) being less than 13% of the ADI (0.009 mg/kg bw/d). Considering the MRLs proposed for plant and animal products, no chronic and acute concerns were observed for quizalofop-P-tefuryl, the maximum TMDI using the EFSA model being 23% of the ADI (0.013 mg/kg bw/d) and the maximum IESTI, 31% of the ArfD (0.1 mg/kg bw/d).

Awaiting the additional information/clarification requested during the peer review process, provisional MRLs were proposed for sugar beet, potato, bean and pea (without pods), lentils, soybeans, oil seed rape and sunflower. MRLs were also proposed for products of animal origin, based on the quizalofop-P-tefuryl representative uses.

The information available on the fate and behaviour in the environment is sufficient to carry out an appropriate environmental exposure assessment for quizalofop-P-tefuryl at the EU level. For the applied for intended uses, the potential for groundwater exposure by quizalofop-P-tefuryl and its metabolites quizalofop, hydroxy-quizalofop, dihydroxy-quinoxaline, tetrahydrofurfuryl alcohol and tetrahydrofuroic acid above the parametric drinking water limit of 0.1 µg/L, is low.

The information available on the fate and behaviour in the environment is sufficient to carry out an appropriate environmental exposure assessment for quizalofop-P-ethyl at the EU level. For the applied for intended uses, the potential for groundwater exposure by quizalofop-P-tefuryl and its metabolites quizalofop, hydroxy-quizalofop, and dihydroxy-quinoxaline above the parametric drinking water limit of 0.1 µg/L, is low.

Aquatic and terrestrial toxic endpoints for the common metabolites of propaquixafop, 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 acute, short-term and long-term risk to birds from quizalofop-P-ethyl and quizalofop-P-tefuryl was assessed as low for the intended uses. For mammals, a revised long-term endpoint was agreed for quizalofop-P-ethyl in the meeting of experts. The acute and long-term risk to mammals from quizalofop-P-ethyl and quizalofop-P-tefuryl was assessed as low for the intended uses. The risk to herbivorous birds and mammals from the common plant metabolites was considered to be low. The risk from consumption of contaminated drinking water was assessed as low for the intended uses of both ester variants. The risk from secondary poisoning was assessed as low for the intended uses of both ester variants and for the common metabolites.

Both quizalofop-P-ethyl and quizalofop-P-tefuryl were found to be very toxic to aquatic organisms, based on the lower acute endpoints for algae and fish respectively. The risk from quizalofop-P-ethyl and quizalofop-P-tefuryl was assessed as low for the intended uses, based on FOCUS Step 2 PEC calculations. The aquatic risk assessment for metabolites was revised, based on the agreed endpoints for metabolites and PEC values derived from the GAP of quizalofop-P-ethyl and quizalofop-P-tefuryl. Metabolite PEC values from the DAR of quizalofop-P-ethyl were used in the risk assessment, whereas the EFSA did calculate new worst case PEC values for quizalofop-P-ethyl metabolites after the peer review. The risk to aquatic organisms from metabolites was assessed as low, based on FOCUS Step 2 and 3 for quizalofop-P-tefuryl and quizalofop-P-ethyl respectively. No risk from bio-accumulation was foreseen for quizalofop-P-ethyl and quizalofop-P-tefuryl or any of the metabolites. In the initial assessment for non-target arthropods a potential in-field risk was identified from the use of quizalofop-P-ethyl. Extended laboratory studies were provided for relevant non-target arthropod species. The risk was addressed for all tested species, except for *Typhlodromus pyri* where the meeting of experts agreed that the in-field risk still needed to be addressed. For the uses of quizalofop-P-tefuryl the initial assessment indicated a high risk to *T. pyri* and *Aphidius rhopalosiphi*, both in-field and off-field. Extended laboratory studies were provided to address the risk for relevant species. A data gap was however agreed in the meeting of experts for the notifier to address the risk to *Chrysoperla carnea*. The risk assessment for non-target plants from intended uses of quizalofop-P-ethyl indicated a need for no-spray buffer zones of 10 m to address the risk to the most sensitive plant species. No valid data were submitted to address the risk to non-target plants from the intended uses of quizalofop-P-tefuryl. A data gap was agreed during the peer review. A study was also required for quizalofop-P-tefuryl to address the risk to biological methods for sewage treatment. Such assessment was addressed in the DAR of quizalofop-P-ethyl, indicating a low risk.

The risk to bees, earthworms, soil non-target micro- and macro-organisms was assessed as low for the intended uses of quizalofop-P-ethyl and quizalofop-P-tefuryl.

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

- Use of PPE is needed to lower operator exposure during application to ornamentals with the tefuryl formulation, and for all uses with the quizalofop-P-ethyl formulation.

- A no-spray buffer zone of 10 m was required for uses of quizalofop-P-ethyl to identify a low risk to the most sensitive non-target plants.

Critical areas of concern

- Specification for quizalofop-P-ethyl can not be finalised.
- Methods of analysis for food of plant origin are not available.
- Methods of analysis for food of animal origin are not available (tefuryl variant only).
- It was not possible to finalise the risk assessment to non-target arthropods for use of quizalofop-P-ethyl and quizalofop-P-tefuryl.
- No data were available to address the risk to non-target plants for use of quizalofop-P-tefuryl.
- No data were available to address the risk to biological methods of sewage treatment for use of quizalofop-P-tefuryl.

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

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

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

Identity, Physical and Chemical Properties, Details of Uses, Further Information (ethyl & tefuryl –variants)

Active substance (ISO Common Name) ‡	Quizalofop-P (unless otherwise stated the following data relate to the variant quizalofop-P-ethyl)
Active substance (ISO Common Name) ‡	Quizalofop-P (unless otherwise stated the following data relate to the variant quizalofop-P-tefuryl)
Function (*e.g.* fungicide)	Herbicide

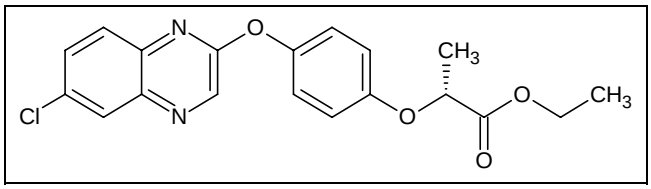
Rapporteur Member State	Finland
Co-rapporteur Member State	-

Identity (Annex IIA, point 1) (ethyl-variant)

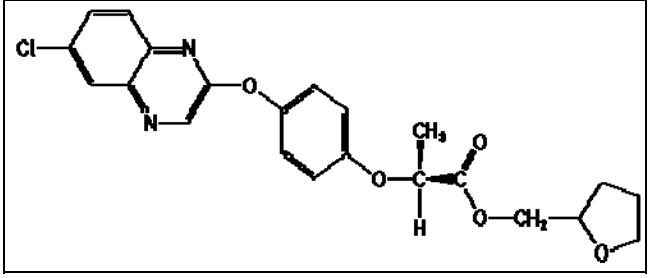
Chemical name (IUPAC) ‡	ethyl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy] propionate
Chemical name (CA) ‡	propanoic acid, 2-[4-[(6-chloro-2-quinoxalinyl)oxy] phenoxy]-, ethyl ester, (R)- (9CI)
CIPAC No ‡	641 (Quizalofop-P) 641.202 (Quizalofop-P-ethyl)
CAS No ‡	100646-51-3
EC No (EINECS or ELINCS) ‡	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	Open
Molecular formula ‡	$C_{19}H_{17}ClN_2O_4$
Molecular mass ‡	372.81 g/mol

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

Structural formula ‡



Identity (Annex IIA, point 1) (tefuryl-variant)

CHEMICAL NAME (IUPAC) ‡	(*RS*)-Tetrahydrofurfuryl (*R*)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate
CHEMICAL NAME (CA) ‡	(*RS*)-Tetrahydrofurfuryl (*R*)-2-[4-[(6-chloro-2-quinoxalinyl)oxy]phenoxy]propanoate
CIPAC NO ‡	641 (Quizalofop-P) 641.226 (Quizalofop-P-tefuryl)
CAS NO ‡	119738-06-6
EC NO (EINECS OR ELINCS) ‡	94-06-0565-00
FAO SPECIFICATION (INCLUDING YEAR OF PUBLICATION) ‡	Not established
Minimum purity of the active substance as manufactured ‡	795 g/kg, racemic, RR/SR ratio 50/50
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Open
MOLECULAR FORMULA ‡	$C_{22}H_{21}ClN_2O_5$
MOLECULAR MASS ‡	428.9
Structural formula ‡	

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

Physical and chemical properties (Annex IIA, point 2) (ethyl-variant)

Melting point (state purity) ‡	75 °C (99.6 %)
Boiling point (state purity) ‡	Substance decomposes before boiling. (99.6 %)
Temperature of decomposition (state purity)	Substance decomposes between 320 – 445 °C. (99.6 %)
Appearance (state purity) ‡	Pure: white crystalline solid (99.6 %) Technical: very pale yellow crystalline solid (98.4 %)
Vapour pressure (state temperature, state purity) ‡	$1.1 \cdot 10^{-7}$ Pa at 20 °C extrapolated (99.0 %)
Henry's law constant ‡	$6.7 \cdot 10^{-5}$ Pa m^3 mol^{-1} at 20 °C
Solubility in water (state temperature, state purity and pH) ‡	0.61 mg/l at 20 °C in deionized water (99.9 %) (pH is not applicable)
Solubility in organic solvents ‡ (state temperature, state purity)	**Solvent:** **Solubility** (99.6 %)**:** acetone >250 g/l at 22-23 °C 1,2-dichloroethane >1000 g/l at 22-23 °C ethyl acetate >250 g/l at 22-23 °C n-heptane 7.2 g/l at 20 °C methanol 35 g/l at 20 °C xylene >250 g/l at 22-23 °C
Surface tension ‡ (state concentration and temperature, state purity)	Not applicable, the water solubility of the active substance is ≤ 1 mg/l at 20 °C.
Partition co-efficient ‡ (state temperature, pH and purity)	log P_{ow} = 4.61 at 23 °C (99.0 %)
Dissociation constant (state purity) ‡	The structure, low water solubility and theoretical assessment of the pKa indicate that quizalofop-P-ethyl does not dissociate.

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

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	UV/VIS absorption measured in neutral, acidic and basic methanolic solutions at 21 °C. (99.6 %) Maximum absorption at neutral: λ_{max} = 343.4 nm ε = 6342 l · mol^{-1} · cm^{-1} λ_{max} = 333.3 nm ε = 6463 l · mol^{-1} · cm^{-1} λ_{max} = 234.7 nm ε = 33498 l · mol^{-1} · cm^{-1} acid, pH < 2: λ_{max} = 342.5 nm ε = 6356 l · mol^{-1} · cm^{-1} λ_{max} = 334.3 nm ε = 6431 l · mol^{-1} · cm^{-1} λ_{max} = 234.8 nm ε = 32833 l · mol^{-1} · cm^{-1} basic, pH > 10: λ_{max} = 343.4 nm ε = 6242 l · mol^{-1} · cm^{-1} λ_{max} = 333.5 nm ε = 6299 l · mol^{-1} · cm^{-1} λ_{max} = 234.4 nm ε = 32459 l · mol^{-1} · cm^{-1}
Flammability ‡ (state purity)	Not highly flammable. (98.4 %)
Explosive properties ‡ (state purity)	Not explosive. (98.4 %)
Oxidising properties ‡ (state purity)	Not oxidizing. (98.4 %)

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

Physical and chemical properties (Annex IIA, point 2) (tefuryl-variant)

Melting point (state purity) ‡	58.3°C (99.0 %)
Boiling point (state purity) ‡	Substance decomposes before boiling at 213 °C. (96.9%)
Temperature of decomposition (state purity)	Substance decomposes before boiling at 213 °C. (96.9%)
Appearance (state purity) ‡	Pure: White solid powder. (99.96 %) Technical: Orange waxy solid (89.2 %)
Vapour pressure (state temperature, state purity) ‡	< 7.9 x 10^{-6} Pa at 25 °C (97.43 %)
Henry's law constant ‡	< 9.0 x 10^{-4} Pa m^3 mol^{-1} at 25 °C
Solubility in water (state temperature, state purity and pH) ‡	3.15 mg/l at 25 °C, pH 4.37 (97.43 %) 3.13 mg/l at 25 °C, pH 7.00 (97.43 %)
Solubility in organic solvents ‡ (state temperature, state purity)	**Solvent:** **Solubility:** acetone 221 g/l at 20 °C 1,2-dichloroethane 558 g/l at 20 °C ethyl acetate 461 g/l at 20 °C methanol 64 g/l at 25 °C toluene 652 g/l at 25 °C hexane 12 g/l at 25 °C n-octanol 71 g/l at 25°C
Surface tension ‡ (state concentration and temperature, state purity)	69.3 mN/m at 21°C, 1.73 mg/l aqueous solution (95.8%)
Partition co-efficient ‡ (state temperature, pH and purity)	log P_{ow} = 4.32 at 25°C (Milli-Q™ water) (99.5 %)
Dissociation constant (state purity) ‡	pK_a = - 1.25 at 25 °C for quizalofop-P-tefuryl (97.7 %)

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

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	UV/VIS measured in neutral, acidic and basic methanolic solutions at 23 °C. (99.5 %) Maximum absorption at neutral: λ_{max} = 238 nm ε = 15171 l · mol^{-1} · cm^{-1} λ_{max} = 334 nm ε = 5782 l · mol^{-1} · cm^{-1} acid: λ_{max} = 238 nm ε = 15169 l · mol^{-1} · cm^{-1} λ_{max} = 334 nm ε = 5815 l · mol^{-1} · cm^{-1} basic: λ_{max} = 238 nm ε = 15081 l · mol^{-1} · cm^{-1} λ_{max} = 334 nm ε = 5733 l · mol^{-1} · cm^{-1}
Flammability (state purity) ‡	Not flammable. (96.9 %)
Explosive properties (state purity) ‡	Not explosive. (95.8 %)
Oxidising properties (state purity) ‡	Not oxidizing. (Expert statement)

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

Summary of representative uses evaluated (quizalofop-P-ethyl)*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL min – max (l)	water L/ha min – max	g as/ha min – max (l)		
Sugar beet	Southern EU	Targa Super	F	Annual grasses	EC	50 g/L	Spray	BBCH 13-39	1	-	12.5-62.5	200-400	50-125	60	[1], [2]
Sugar beet	Northern EU	Targa Super	F	Annual grasses	EC	50 g/L	Spray	BBCH 13-39	1	-	12.5-62.5	200-400	50-125	110	[1], [2]
Sugar beet	Southern EU	Targa Super	F	Perennial grasses	EC	50 g/L	Spray	BBCH 13-39	1	-	25-100	200-400	100-200	60	[1], [2]
Sugar beet	Northern EU	Targa Super	F	Perennial grasses	EC	50 g/L	Spray	BBCH 13-39	1	-	25-100	200-400	100-200	110	[1], [2]

[1] The specification is not finalised
[2] Monitoring methods for food commodities are not available

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

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

Summary of intended uses evaluated (quizalofop-P-tefuryl)*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hl min – max (l)	water l/ha min – max	kg as/ha min – max (l)		
Winter sown oilseed rape	North and South Europe	Pantera/ Panarex	F	Volunteer Cereals Cereals cover crops drilled to provide protection from 'Wind Blow'	EC	36.5 g/l	Spraying Tractor-mounted	2 leaves (GS12) to stem elongation (GS 39) Autumn to Summer	1	Not applicable	0.0050 - 0.015	200 - 400	0.02 – 0.03	60	[1]
				Blackgrass Wild Oats	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Autumn to Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03 – 0.05	60	[1]
				Perennial Rye Grass from Seed	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to late tillering (GS 29) Autumn to Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03 – 0.05	60	[1]
				Bentgrass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 29) Autumn to Summer	1	Not applicable	0.015 – 0.035	200 - 400	0.06 – 0.07	60	[1]
				Italian Rye Grass Perennial Rye Grass (established plants)	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Autumn to Summer	1	Not applicable	0.0150 – 0.04	200 - 400	0.06 – 0.08	60	[1]

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

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hl min – max (l)	water l/ha min – max	kg as/ha min – max (l)		
				Common Couch Grass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Autumn to Summer	1	Not applicable	0.0175 – 0.05	200 - 400	0.07 – 0.10	60	[1]
				Onion Couch	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Autumn to Summer	1	Not applicable	0.0125 – 0.03	200 - 400	0.05 – 0.06	60	[1]
Spring sown oilseed rape	North and South Europe	Pantera/ Panarex	F	Volunteer Cereals Cereals cover crops drilled to provide protection from 'Wind Blow'	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Spring & Summer	1	Not applicable	0.0050 - 0.015	200 - 400	0.02 – 0.03	60	[1]
				Blackgrass Wild Oats	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Spring & Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03– 0.05	60	[1]
				Perennial Rye Grass from Seed	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to late tillering (GS 29) Spring & Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03 – 0.05	60	[1]
				Bentgrass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.015 – 0.035	200 - 400	0.06 – 0.07	60	[1]

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

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hl min – max (l)	water l/ha min – max	kg as/ha min – max (l)		
				Italian Rye Grass Perennial Rye Grass (established plants)	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0150 - 0.040	200 - 400	0.06 – 0.08	60	[1]
				Common Couch Grass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0175 - 0.050	200 - 400	0.07 – 0.10	60	[1]
				Onion Couch	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0125 - 0.030	200 - 400	0.05 – 0.06	60	[1]
Sugar & Fodder Beet	North and South Europe	Pantera/ Panarex	F	Volunteer Cereals Cereals cover crops drilled to provide protection from 'Wind Blow'	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Spring & Summer	1	Not applicable	0.0050 - 0.015	200 - 400	0.02 – 0.03	60	[1]
				Blackgrass Wild Oats	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Spring & Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03– 0.05	60	[1]
				Perennial Rye Grass from Seed	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to late tillering (GS 29) Spring & Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03 – 0.05	60	[1]

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

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hl min – max (l)	water l/ha min – max	kg as/ha min – max (l)		
				Bentgrass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0150 - 0.035	200 - 400	0.06 – 0.07	60	[1]
				Italian Rye Grass Perennial Rye Grass (established plants)	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0150 - 0.040	200 - 400	0.06 – 0.08	60	[1]
				Common Couch Grass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0175 - 0.050	200 - 400	0.07 – 0.10	60	[1]
				Onion Couch	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0125 - 0.030	200 - 400	0.05 – 0.06	60	[1]
Potatoes	North and South Europe	Pantera/ Panarex	F	Volunteer Cereals Cereals cover crops drilled to provide protection from 'Wind Blow'	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Spring & Summer	1	Not applicable	0.0050 - 0.015	200 - 400	0.02 – 0.03	60	[1]
				Blackgrass Wild Oats	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Spring & Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03– 0.05	60	[1]

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

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hl min – max (l)	water l/ha min – max	kg as/ha min – max (l)		
				Perennial Rye Grass from Seed	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to late tillering (GS 29) Spring & Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03 – 0.05	60	[1]
				Bentgrass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0150 - 0.035	200 - 400	0.06 – 0.07	60	[1]
				Italian Rye Grass Perennial Rye Grass (established plants)	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0150 - 0.040	200 - 400	0.06 – 0.08	60	[1]
				Common Couch Grass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0175 - 0.050	200 - 400	0.07 – 0.10	60	[1]
				Onion Couch	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0125 - 0.030	200 - 400	0.05 – 0.06	60	[1]
Combining peas	North and South Europe	Pantera/ Panarex	F	Volunteer Cereals Cereals cover crops drilled to provide protection from 'Wind Blow'	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Autumn to Summer	1	Not applicable	0.0050 - 0.015	200 - 400	0.02 – 0.03	60	[1]

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

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hl min – max (l)	water l/ha min – max	kg as/ha min – max (l)		
				Blackgrass Wild Oats	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Autumn to Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03– 0.05	60	[1]
				Perennial Rye Grass from Seed	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to late tillering (GS 29) Autumn to Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03 – 0.05	60	[1]
				Bentgrass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 29) Autumn to Summer	1	Not applicable	0.0150 - 0.035	200 - 400	0.06 – 0.07	60	[1]
				Italian Rye Grass Perennial Rye Grass (established plants)	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Autumn to Summer	1	Not applicable	0.0150 - 0.040	200 - 400	0.06 – 0.08	60	[1]
				Common Couch Grass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Autumn to Summer	1	Not applicable	0.0175 - 0.050	200 - 400	0.07 – 0.10	60	[1]
				Onion Couch	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Autumn to Summer	1	Not applicable	0.0125 - 0.030	200 - 400	0.05 – 0.06	60	[1]

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

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					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hl min – max (l)	water l/ha min – max	kg as/ha min – max (l)		
Winter sown Field Beans	North and South Europe	Pantera/ Panarex	F	Volunteer Cereals Cereals cover crops drilled to provide protection from 'Wind Blow'	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Autumn to Summer	1	Not applicable	0.0050 - 0.015	200 - 400	0.02 – 0.03	60	[1]
				Blackgrass Wild Oats	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Autumn to Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03– 0.05	60	[1]
				Perennial Rye Grass from Seed	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to late tillering (GS 29) Autumn to Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03 – 0.05	60	[1]
				Bentgrass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 29) Autumn to Summer	1	Not applicable	0.0150 - 0.035	200 - 400	0.06 – 0.07	60	[1]
				Italian Rye Grass Perennial Rye Grass (established plants)	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Autumn to Summer	1	Not applicable	0.0150 - 0.040	200 - 400	0.06 – 0.08	60	[1]
				Common Couch Grass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Autumn to Summer	1	Not applicable	0.0175 - 0.050	200 - 400	0.07 – 0.10	60	[1]

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

Crop and/ or situation	Member State or Country	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)	kg as/hl min – max (l)	water l/ha min – max	kg as/ha min – max (l)	(m)	
				Onion Couch	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Autumn to Summer	1	Not applicable	0.0125 - 0.030	200 - 400	0.05 – 0.06	60	[1]
Spring sown Field Beans	North and South Europe	Pantera/ Panarex	F	Volunteer Cereals Cereals cover crops drilled to provide protection from 'Wind Blow'	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Spring & Summer	1	Not applicable	0.0050 - 0.015	200 - 400	0.02 – 0.03	60	[1]
				Blackgrass Wild Oats	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Spring & Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03– 0.05	60	[1]
				Perennial Rye Grass from Seed	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to late tillering (GS 29) Spring & Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03 – 0.05	60	[1]
				Bentgrass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0150 - 0.035	200 - 400	0.06 – 0.07	60	[1]
				Italian Rye Grass Perennial Rye Grass (established plants)	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0150 - 0.040	200 - 400	0.06 – 0.08	60	[1]

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

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					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hl min – max (l)	water l/ha min – max	kg as/ha min – max (l)		
				Common Couch Grass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0175 - 0.050	200 - 400	0.07 – 0.10	60	[1]
				Onion Couch	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0125 - 0.030	200 - 400	0.05 – 0.06	60	[1]
Winter sown linseed and sunflowers	North and South Europe	Pantera/ Panarex	F	Volunteer Cereals Cereals cover crops drilled to provide protection from 'Wind Blow'	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Autumn to Summer	1	Not applicable	0.0050 - 0.015	200 - 400	0.02 – 0.03	60	[1]
				Blackgrass Wild Oats	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Autumn to Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03– 0.05	60	[1]
				Perennial Rye Grass from Seed	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to late tillering (GS 29) Autumn to Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03 – 0.05	60	[1]
				Bentgrass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 29) Autumn to Summer	1	Not applicable	0.0150 - 0.035	200 - 400	0.06 – 0.07	60	[1]

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					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hl min – max (l)	water l/ha min – max	kg as/ha min – max (l)		
				Italian Rye Grass Perennial Rye Grass (established plants)	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Autumn to Summer	1	Not applicable	0.0150 - 0.040	200 - 400	0.06 – 0.08	60	[1]
				Common Couch Grass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Autumn to Summer	1	Not applicable	0.0175 - 0.050	200 - 400	0.07 – 0.10	60	[1]
				Onion Couch	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Autumn to Summer	1	Not applicable	0.0125 - 0.030	200 - 400	0.05 – 0.06	60	[1]
Spring sown linseed and sunflowers	North and South Europe	Pantera/ Panarex	F	Volunteer Cereals Cereals cover crops drilled to provide protection from 'Wind Blow'	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Spring & Summer	1	Not applicable	0.0050 - 0.015	200 - 400	0.02 – 0.03	60	[1]
				Blackgrass Wild Oats	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Spring & Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03 – 0.05	60	[1]
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				Bentgrass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0150 - 0.035	200 - 400	0.06 – 0.07	60	[1]
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				Common Couch Grass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0175 - 0.050	200 - 400	0.07 – 0.10	60	[1]
				Onion Couch	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0125 - 0.030	200 - 400	0.05 – 0.06	60	[1]
Other Pulse crops	North and South Europe	Pantera/ Panarex	F	Volunteer Cereals Cereals cover crops drilled to provide protection from 'Wind Blow'	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Spring & Summer	1	Not applicable	0.0050 - 0.015	200 - 400	0.02 – 0.03	60	[1]
				Blackgrass Wild Oats	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 39) Spring & Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03– 0.05	60	[1]

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

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hl min – max (l)	water l/ha min – max	kg as/ha min – max (l)		
				Perennial Rye Grass from Seed	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to late tillering (GS 29) Spring & Summer	1	Not applicable	0.0075 - 0.025	200 - 400	0.03 – 0.05	60	[1]
				Bentgrass	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS12) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0150 - 0.035	200 - 400	0.06 – 0.07	60	[1]
				Italian Rye Grass Perennial Rye Grass (established plants)	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0150 - 0.040	200 - 400	0.06 – 0.08	60	[1]
				Common Couch Grass	EC)	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0175 - 0.050	200 - 400	0.07 – 0.10	60	[1]
				Onion Couch	EC	36.5 g/l	Spraying Tractor mounted	2 leaves (GS14) to stem elongation (GS 29) Spring & Summer	1	Not applicable	0.0125 - 0.030	200 - 400	0.05 – 0.06	60	[1]

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

[1] [2] Monitoring methods for food commodities are not available

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse 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
(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) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

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

Methods of Analysis (ethyl-variant)

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

Technical as (analytical technique)	Chiral column HPLC-UV
Impurities in technical as (analytical technique)	Chiral column HPLC-UV and reversed phase column HPLC-UV
Plant protection product (analytical technique)	Chiral column HPLC-UV

Methods of Analysis (tefuryl-variant)

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

Technical as (analytical technique)	Chiral column HPLC-UV for the enantiomers
Impurities in technical as (analytical technique)	Reversed phase column HPLC-UV
Plant protection product (analytical technique)	Open

Analytical methods for residues (Annex IIA, point 4.2) (ethyl-variant)

Residue definitions for monitoring purposes (ethyl-variant)

Food of plant origin		Sum of quizalofop esters, quizalofop and quizalofop conjugates expressed as quizalofop (sum of isomers) (provisional)
Food of animal origin		Sum of quizalofop-esters and quizalofop expressed as quizalofop (sum of isomers) (provisional)
Soil		Quizalofop
Water	surface	Quizalofop-ethyl
	drinking/ground	Quizalofop-ethyl
Air		Quizalofop-ethyl

Analytical methods for residues (Annex IIA, point 4.2) (tefuryl-variant)

Residue definitions for monitoring purposes (tefuryl-variant)

Food of plant origin	Sum of quizalofop esters, quizalofop and quizalofop conjugates expressed as quizalofop (sum of isomers) (provisional)
Food of animal origin	Sum of quizalofop-esters and quizalofop expressed as quizalofop (sum of isomers) (provisional).
Soil	Quizalofop

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

Water	surface	Quizalofop
	drinking/ground	Quizalofop
Air		Quizalofop-tefuryl

Monitoring/Enforcement methods (ethyl-variant)

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)	No MRL is proposed.
Soil (analytical technique and LOQ)	LC-MS/MS 5 µg/kg quizalofop
Water (analytical technique and LOQ)	LC-MS/MS 0.05 µg/l for quizalofop-ethyl in drinking and ground water.
Air (analytical technique and LOQ)	LC-MS/MS 0.5 µg/m^3 for quizalofop-ethyl
Body fluids and tissues (analytical technique and LOQ)	Quizalofop-P-ethyl is not classified as toxic or very toxic.

Monitoring/Enforcement methods (tefuryl-variant)

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)	GC-MS 0.02 mg/kg quizalofop
Water (analytical technique and LOQ)	HPLC-UV 0.1 µg/l for quizalofop in surface water and drinking water
Air (analytical technique and LOQ)	HPLC-UV 3.75 µg/m^3 for quizalofop-P-tefuryl
Body fluids and tissues (analytical technique and LOQ)	Quizalofop-P-tefuryl is not classified as toxic or very toxic.

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

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

	RMS/peer review proposal
quizalofop-P-ethyl	None

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

	RMS/peer review proposal
quizalofop-P-tefuryl	None

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

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	**Quizalofop-P-ethyl**: Racemate: Male: 67%; female: 89%. Based on urinary (6, 14%) and biliary (52, 49%) excretion within 48 h and residues in liver (2, 4%) and carcass (8, 23%) at 48 h. **Quizalofop-P-tefuryl**: Males: 58%; females: 61%. Based on urinary (12, 36%) excretion within 168 h and faecal elimination (43, 36%) after 24 h and total tissue residues (3, 1%) at 168 h.
Distribution ‡	**Quizalofop-P-ethyl**: Uniformly distributed **Quizalofop-P-tefuryl**: Widely distributed; highest residues in fat, ovary, whole blood, carcass, kidney and liver at 168 h.
Potential for accumulation ‡	**Quizalofop-P-ethyl**: No evidence for accumulation, although the elimination from the fat very seem to be slow. **Quizalofop-P-tefuryl**: No evidence for accumulation, although total elimination half-life was slightly longer than 24 hours in males.
Rate and extent of excretion ‡	**Quizalofop-P-ethyl**: Elimination: 56-70% within 48 h. Urinary excretion was 43-54% in females and 26-28% in males within 7 days and elimination via faeces 44-57% in females and 64-69% in males after a low dose. **Quizalofop-P-tefuryl**: Elimination: 68% in males and 82% in females within 48 h. Urinary excretion was 35-48% in females and 12-41% in males within 7 days after a low or high dose administration and elimination via faeces was 38-59% in females and 38-80% in males.
Metabolism in animals ‡	**Quizalofop-P-ethyl**: Extensively metabolised (>90% of radioactivity in plasma was associated with quizalofop acid); de-ethylation, hydroxylation, bridge cleavage. **Quizalofop-R-tefuryl**: Extensively metabolised (less than 15% of administered dose in excreta was parent compound). Rapidly hydrolysed to its acid form in the stomach or gastrointestinal tract (38-58% of dose in excreta was acid form). Further metabolism: hydroxylation, hydrolysis, conjugation.

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

Toxicologically relevant compounds ‡ (animals and plants)	Parent compound and metabolites
Toxicologically relevant compounds ‡ (environment)	Parent compound and metabolites

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	**Quizalofop-P-ethyl**: 1182 mg/kg bw (females) **Quizalofop-P-tefuryl**: 1012 mg/kg bw (combined for both sexes)	R22 R22
Rat LD_{50} dermal ‡	**Quizalofop-P-ethyl**: Racemate: > 5000 mg/kg bw **Quizalofop-P-tefuryl**: > 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	**Quizalofop-P-ethyl**: Racemate: 5.8 mg/L air/4 h (nose-only) **Quizalofop-P-tefuryl**: > 3.9 mg/L air/4 h (nose-only)	
Skin irritation ‡	**Quizalofop-P-ethyl**: Racemate: Non-irritant **Quizalofop-P-tefuryl**: Non-irritant	
Eye irritation ‡	**Quizalofop-P-ethyl**: Racemate: Slightly irritating transiently (no classification proposed) **Quizalofop-P-tefuryl**: Slightly irritating (no classification proposed)	
Skin sensitisation ‡	**Quizalofop-P-ethyl**: Not sensitising (M & K, Racemate: Buehler) **Quizalofop-P-tefuryl**: Sensitiser (sensitising in M & K, non-sensitising in Buehler)	R43

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

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	**Quizalofop-P-ethyl**: Liver (hepatotoxicity; rat, mouse) **Quizalofop-P-tefuryl**: Liver (hepatotoxicity; rat, mouse, dog), testes (dog, rat, mouse)	
Relevant oral NOAEL ‡	**Quizalofop-P-ethyl**: 90-day mouse: 1.7 mg/kg bw/day **Quizalofop-P-tefuryl**: 90-day rat: 1.7 mg/kg bw/day (liver weight, haematology and clinical chemistry).	
Relevant dermal NOAEL ‡	**Quizalofop-P-ethyl**: 2000 mg/kg bw/day **Quizalofop-P-tefuryl**: No data – not required	
Relevant inhalation NOAEL ‡	No data – not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

Quizalofop-P-ethyl: no genotoxic potential **Quizalofop-P-tefuryl**: no genotoxic potential	

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

Target/critical effect ‡	**Quizalofop-P-ethyl**: Racemate: Liver (hepatotoxicity; rat, mice), testes (decreased weight, atrophy; mice) **Quizalofop-P-tefuryl**: Liver (hepatotoxicity; rat, mice)	
Relevant NOAEL ‡	**Quizalofop-P-ethyl**: Racemate: 0.9 mg/kg bw/day; 2-year, rat 1.6 mg/kg bw/day; 18-month, mouse **Quizalofop-P-tefuryl**: 1.3 mg/kg bw/day; 2-year, rat 1.7 mg/kg bw/day; 18-month, mouse	
Carcinogenicity ‡	**Quizalofop-P-ethyl**: Racemate: no carcinogenic effect. **Quizalofop-P-tefuryl**: Liver tumours, Leydig cell tumours and renal squamous cell carcinoma in rats	R40

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

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	**Quizalofop-P-ethyl**: Racemate: No critical effect. Some incidental observations in early survival of pups and growth reduction at parental slightly toxic dose (decreased body weight) **Quizalofop-P-tefuryl**: Decreased fertility at systemically toxic dose levels.	
Relevant parental NOAEL ‡	**Quizalofop-P-ethyl**: Racemate: 9.4 mg/kg bw/day (decreased body weight) **Quizalofop-P-tefuryl**: 1.4 mg/kg bw/day (liver toxicity, vacuolar changes in pituitary)	
Relevant reproductive NOAEL ‡	**Quizalofop-P-ethyl**: Racemate 37.8 mg/kg bw/day **Quizalofop-P-tefuryl**: 16.9 mg/kg bw/day (decreased number of live pups, decreased male fertility index, slightly increased copulatory interval)	
Relevant offspring NOAEL ‡	**Quizalofop-P-ethyl**: Racemate: 2.4 mg/kg bw/day (25 ppm) for hepatotoxicity **Quizalofop-P-tefuryl**: 1.4 mg/kg bw/day (25 ppm; decreased body weights at 300 ppm)	

Developmental toxicity

Developmental target / critical effect ‡	**Quizalofop-P-ethyl**: Racemate: Rat: Resorptions, skeletal variations at maternally toxic dose (e.g., 30% bw gain reduction, 19% increased liver weight) **Quizalofop-P-tefuryl**: Rat: Increased postimplantation loss, lower number of viable foetuses, increased malformations at maternally highly toxic dose (e.g., mortality, clinical signs, no weight gain during administration period)	

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

Relevant maternal NOAEL ‡	**Quizalofop-P-ethyl**: Racemate: Rat: 30 mg/kg bw/day Rabbit: 30 mg/kg bw/day. **Quizalofop-P-tefuryl**: Rat: 10 mg/kg bw/day Rabbit: 20 mg/kg bw/day. The rabbit was not adequate tested. A new study required – too low dose levels	
Relevant developmental NOAEL ‡	**Quizalofop-P-ethyl**: Racemate: Rat: 30 mg/kg bw/day Rabbit: 60 mg/kg bw/day **Quizalofop-P-tefuryl**: Rat: 30 mg/kg bw/day Rabbit: 20 mg/kg bw/day	R63?

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	**Quizalofop-P-ethyl**: No data – not required **Quizalofop-P-tefuryl**: NOAEL 400 mg/kg for males and >800 mg/kg for females	
Repeated neurotoxicity ‡	No data – not required	
Delayed neurotoxicity ‡	No data – not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	**Quizalofop-P-ethyl**: No data – not required **Quizalofop-P-tefuryl**: Proposed mechanism for liver tumours in rats was peroxisome proliferation. Mechanisms for Leydig cell tumours and renal squamous cell carcinoma were not studied.
Studies performed on metabolites or impurities ‡	**Quizalofop-P-ethyl**: LD_{50} for quizalofop acid was 1330–1520 mg/kg bw and for metabolites quizalofop-phenol, phenoxy acid and CQO >5000 mg/kg bw **Quizalofop-P-tefuryl**: No data – not required

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

Medical data ‡ (Annex IIA, point 5.9)

No detrimental effects on health in manufacturing personnel. **Quizalofop-P-ethyl**: One case report has been published where a 75-years old farmer developed an obstructive cholestasis after exposure to quizalofop-P-ethyl. **Quizalofop-P-tefuryl**: No clinical cases or poisoning cases have been reported.

Summary (Annex IIA, point 5.10)		Value	Study	Safety factor
ADI ‡ *)	**Quizalofop-P-ethyl** **Quizalofop-P-tefuryl**	0.009 mg/kg bw/day 0.013 mg/kg bw/day	Rat, 2-year study	100
AOEL ‡ *)	**Quizalofop-P-ethyl** **Quizalofop-P-tefuryl**	0.01 mg/kg bw/day [a)] 0.01 mg/kg bw/day [b)]	Mouse, 90-d study Rat, 90-d study	100
ARfD ‡ *)	**Quizalofop-P-ethyl** **Quizalofop-P-tefuryl**	Not triggered 0.1 mg/kg bw	- Rat, developmental toxicity study (maternal toxicity)	100

*) Reference values for quizalofop variants (quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop) are expressed as the separate substance, but the lowest value should be used for risk assessment if needed.
a) 67% correction factor for limited enteral absorption
b) 60% correction factor for limited enteral absorption

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation Targa Super 50 g/L EC Pantera 40 g/L EC	**Quizalofop-P-ethyl**: 18% for the concentrate and 28% for the dilution based on data on quizalofop-P-tefuryl, which were considered comparable. **Quizalofop-P-tefuryl**: 18% for the concentrate and 28% for the dilution.

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

Exposure scenarios (Annex IIIA, point 7.2)

Operator	**Quizalofop-P-ethyl**: Targa Super 50 g/L EC Exposure is below the AOEL if PPEs are used (German model). Without PPE / With PPE Tractor mounted equipment Boom sprayer (sugar beet) German model 574% / 26% UK-POEM 2549% / 371% **Quizalofop-P-tefuryl**: Pantera 40 g/L EC Exposure is below the AOEL if PPEs are used (German model). Without PPE / With PPE Tractor mounted equipment Boom sprayer (potato) German model 288% / 13% UK-POEM 2480% / 306%
Workers	Exposure is below the AOEL if gloves are used and also without gloves for vegetables treated with quizalofop-P-tefuryl. Without gloves / With gloves **Quizalofop-P-ethyl**: Sugar beet 140% / 29*% **Quizalofop-P-tefuryl**: Vegetables 70% / - Ornamentals 140% / 39*%
Bystanders	Exposure is low (14% of AOEL for quizalofop-P-ethyl and 7% of AOEL for quizalofop-P-tefuryl).

*__EFSA note:__ *this estimate has been submitted after the PRAPeR meeting of experts. The approach adopted by RMS for re-calculations considering the use of PPE was not agreed during the meeting, however it is agreed that the use of gloves is expected to reduce exposure below the AOEL*

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

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

	RMS/peer review proposal
Substance classified (name)	**Quizalofop-P-ethyl**: R22 “Harmful if swallowed” **Quizalofop-P-tefuryl**: R22 “Harmful if swallowed” R40 “Limited evidence of a carcinogenic effect” R43 “May cause sensitization by skin contact” R63? “Possible risk of harm to the unborn child”

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

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

Plant groups covered	**Q-P-E:** Sugar beet only, further metabolism studies are required for extrapolation to other root crops (PRAPeR 55). **Q-P-T:** Root crops (Potato), Pulse/oilseed crops (cotton, soya)
Rotational crops	**Q-P-E:** Wheat (C), red beet (R) and cotton and peanuts (P/O), and lettuce (L) **Q-P-T:** Lettuce (L), turnip roots (R), turnip tops(), wheat (C)
Metabolism in rotational crops similar to metabolism in primary crops?	**Q-P-E:** Yes **Q-P-T:** Yes
Processed commodities	**Q-P-E:** Not available **Q-P-T:** Potato (R), oilseed rape (P/O)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	**Q-P-E:** Not available **Q-P-T:** Has only been studied indirectly by using prolonged times at 50°C. A new standard hydrolytic processing study is requested
Plant residue definition for monitoring	**Provisional for Q-P-E and Q-P-T:** sum of quizalofop-ester, quizalofop and quizalofop conjugates, expressed as quizalofop (sum of isomers). Nevertheless after the meeting EFSA is of the opinion that conjugates do not need to be included in the definition for monitoring (see conclusion)
Plant residue definition for risk assessment	**Provisional for Q-P-E and Q-P-T:** sum of quizalofop-ester, quizalofop and quizalofop conjugates, expressed as quizalofop (sum of isomers).
Conversion factor (monitoring to risk assessment)	To be reconsidered if conjugates are not included in the residue definition for monitoring

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

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

Animals covered	Lactating goat, laying hen
Time needed to reach a plateau concentration in milk and eggs	Eggs: 14 days Milk: 4 days
Animal residue definition for monitoring	**Rrovisional for Q-P-E and Q-P-T:** Sum of quizalofop-ester and quizalofop expressed as quizalofop (sum of isomers)
Animal residue definition for risk assessment	**Rrovisional for Q-P-E and Q-P-T:** Sum of quizalofop-ester; quizalofop-pentanoic acid and quizalofop expressed as quizalofop (sum of isomers)
Conversion factor (monitoring to risk assessment)	Not discussed and them not proposed. This point has to be reconsidered
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)	Yes for Quizalofop-P-ethyl (log P_{ow} 4.61) and for Quizalofop-P-tefuryl (log P_{ow} 4.32) The PRAPeR 55 was unable to state on the fat soluble property for quizalofop (log P_{ow} 2.22) awaiting clarification on the nature of residue in fat.

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

<0.05 mg/kg as parent equivalents

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

Q-P-E: Quizalofop-P-ethyl and quizalofop stable up to 16 months in beet matrices **Q-P-T:** Quizalofop-P-tefuryl and quizalofop are stable up to 12 months in potato, rapeseed oil and cake and up to 24 months in rapeseed, cotton and soya seeds. Degradation from the tefuryl ester to quizalofop has been observed in sugar beet matrices after one month but total residues (tefuryl ester + quizalofop) were stable up to 8 months.

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

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

The following values refer to Q-P-T. (For **Q-P-E** feeding studies were not considered as necessary by PRAPeR 55)	**Ruminant:**	**Poultry:**	**Pig:**
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes 3.4 mg/kg	Yes 0.43 mg/kg	Yes 2.8 mg/kg
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Yes	Yes	Yes PRAPeR 55 asked applicant for clarification
Values refer to Q-P-T.	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
	10.2 mg/kg DM	2.0 mg/kg DM	
Muscle	<0.02	<0.02	
Liver	0.044	0.095	
Kidney	0.38	0.143	
Fat	0.02	0.122	
Milk	0.02		
Eggs		0.022	

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

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 Southern Field or glasshouse	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according the representative uses	HR (c)	STMR (b)
Quizalofop-P-ethyl: Analyses performed using a mehod dosing the ethyl ester and quizalofop either separately or togheter as quizalofop						
Sugar beet	Northern	5x <0.005 (3x <0.1)	3 trials performed with the LOQ of 0.1 mg/kg not taken into account for MRL calculation	0.05	0.005	0.005
	Southern	3x <0.005, 0.006, 0.009, 2x 0.01,		0.05	0.01	0.006
Quizalofop-P-tefuryl: Analyses performed using a mehod dosing the tefuryl ester and its metabolites (including quizalofop), free and conjugate that could be converted to MCQ*						
Potatoes	Northern	5 x 0.04, 3x 0.05, 0.06, 0.10	MRL of 0.2 mg/kg proposed on the basis of the Northern trials.	0.2	0.10	0.05
	Southern	8 x 0.04		0.1	0.04	0.04
Sugar beet (roots)	Northern	7x 0.04, 0.06	South and North combined: HR 0.06, STMR 0.04. Results consistent with ethyl ester trials.	0.05	0.06	0.04
	Southern	8x 0.04		0.05	0.04	0.04
Bean (spring field bean)	Northern	3x 0.04, 0.07	A global MRL of 0.2 mg/kg is proposed for bean, pea (without pods) and lentils	0.2	0.07	0.04
Bean (winter field bean)	Southern	0.04, 0.06, 0.09, 0.12, 0.16		0.2	0.15	0.04
Pea	North & South	4x 0.04, 2 x 0.05, 0.11, 0.15		0.2	0.15	0.045
lentils	Southern	0.04, 0.06		/	/	/
Linseed	Northern	4x 0.04, 0.07, 0.09, 0.10, 0.11, 0.12		0.2	0.12	0.07
Soybean	Southern	6x 0.04, 0.05, 2x 0.09, 0.18		0.2	0.18	0.04
Oilseed rape(spring)	Northern	0.04, 0.09, 0.11, 0.18, 0.21, 0.22, 0.23, 0.25, 0.27, 0.35, 0.42		1.0	0.42	0.22
	Southern	0.04, 2x0.05, 0.09, 0.24, 0.28, 0.43, 0.73, 1.18, 1.45		2.0	1.45	0.26
Oilseed rape (winter)	Southern	2x 1.19		2.0	0.19	
Sunflower	Southern	2x 0.04, 0.09, 0.12, 0.16, 0.19, 0.31, 0.62, 1.03		2.0	1.03	0.16

(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

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

(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
* **MCQ:** 2-methoxy-6-chloroquinoxaline

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

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

ADI	**Q-P-E:** 0.009 mg/kg bw/d **Q-P-T:** 0.013 mg/kg bw/d Toxicological end-points are not identical
TMDI (% ADI) according to WHO European diet	**Q-P-T:** 20.9%ADI
TMDI (% ADI) maximum TMDI according to EFSA model rev2	**Q-P-E:** 13% ADI (UK toddler) **Q-P-T:** 23% ADI (WHO cluster E)
IEDI (WHO European Diet) (% ADI)	
NEDI (specify diet) (% ADI)	
Factors included in IEDI and NEDI	Not necessary at this stage since Q-P-T residue analyses include the conjugates. This point should be reconsidered if the RD for monitoring does not take into account these conjugates as proposed by EFSA or if additional metabolites need to be included in the RD following the receipt of the requested information on the toxicological relevance of some metabolites.
ARfD	**Q-P-E:** ARfD not necessary **Q -P-T:** ARfD 0.1 mg/kg
IESTI (% ARfD) according to EFSA model rev2	**Q-P-E:** not relevant **Q-P-T:** Higest IESTI 31% ARfD (Potatoes)
NESTI (% ARfD) according to national (to be specified) large portion consumption data	**Q-P-E:** not relevant **Q-P-T:** Maximum NESTI UK model : 37% ARfD (potato chips, Toddler)
Factors included in IESTI and NESTI	**Q-P-T**: For fried potatoes, prosessing factor is 2.

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

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	
10% ADI trigger exceeded A standard hydrolytic processing study on the nature of residues has been identified as a data gap for **Q-P-T**.				
Q-P-T : Potato/frying in oil	1	2		
Q-P-T: Oilseed / processing to oil and cake A study was provided but clarification was requested since results seem not consistent				

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

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

Plant products
Provisional, awaiting confirmation that in the selected residue trials the growth stages at last application was in compliance with the GAPs as stated in the intended uses.

Potato	0.2 mg/kg (Q-P-T GAPs only)
Sugar beet / fodder beet	0.05 mg/kg (Q-P-T & Q-P-E GAPs)
Beans and peas (without pods)	0.2 mg/kg (Q-P-T GAPs only)
Lentils	0.2 mg/kg (Q-P-T GAPs only)
Soybeans	0.2 mg/kg (Q-P-T GAPs only)
Oil seed rape	2.0 mg/kg (Q-P-T GAPs only)
Linseed	0.2 mg/kg (Q-P-T GAPs only)
Sunflowers	2.0 mg/kg (Q-P-T GAPs only)

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

Products of animal origin (MRLs based on quizalofop-P-tefuryl GAPs only)
Provisional, awaiting requested additional information

Ruminants

Kidney	0.20 mg/kg
Milk	0.01* mg/kg
Others	0.02* mg/kg

Poultries

Meat	0.02* mg/kg
Fat	0.05 mg/kg
Liver	0.05 mg/kg
Kidney	0.10 mg/kg
Egg	0.01* mg/kg

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

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

FOREWORD:

Quizalofop-P-tefuryl and quizalofop-P-ethyl are esters of the same active substance quizalofop, and have only one ISO name (quizalofop-P). In addition, a third variant of quizalofop is propaquizafop, a notified 3A active substance for which the designated rapporteur Member State is Italy. During the peer review process, it was clear from a comparison of the route of degradation of the 3 active substances in the environmental compartments that once quizalofop is formed, the degradation pathways are very similar. In particular, the following major (> 10% AR) metabolites are in common to 2 or all the 3 active substances:

-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

A key to the different synonym names, systematic name and the proposed names used for the individual metabolites are included in Appendix III.

The EFSA and the MS 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 LoEP 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 PEC (Predicted Environmental Concentrations) calculations reported in the quizalofop-P-tefuryl and quizalofop-P-ethyl DARs and the agreed endpoints was considered.

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

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

Parent Quizalofop-P-ethyl:

Mineralization after 100 days ‡	-1.8 % AR after 120 d, [^{14}C-Quinoxaline]-label (n^{12}= 1), 20°C -25.3-31.6 % AR after 120 d, [^{14}C-Phenyl]-label (n= 3), 20°C
Non-extractable residues after 100 days ‡	-22.9 % AR after 120 d, [^{14}C-Quinoxaline]-label (n= 1), 20°C -39.6-42.0 % AR after 120 d, [^{14}C-Phenyl]-label (n= 3), 20°C
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	- quizalofop maximum 67.0-83.8 % AR at 1-7 d (n=4) -Hydroxy-quizalofop, maximum ~~9.9~~ 12.0-15.7 % AR at 60-~~184~~ 120 d (n= 4) [^{14}C-Quinoxaline] & [^{14}C-Phenyl] labels -dihydroxy-quinoxaline, maximum 12.3 % AR at 184 d (n=1) [^{14}C-Quinoxaline]-label

Parent Quizalofop-P-tefuryl:

Mineralization after 100 days ‡	-22-34 % AR after 120 d, [^{14}C-phenyl]-label (n= 4), 20°C -57-70 % AR after 30 d, [^{14}C-furfuryl]-label (n=3), 20°C -2.3-26 % AR after 120-125 d, [^{14}C-quinoxaline]-label (n= 4), 20-25°C
Non-extractable residues after 100 days ‡	-32-47 % AR after 120 d, [^{14}C-phenyl]-label (n= 4), 20°C -15-32 % AR after 30 d, [^{14}C-furfuryl]-label (n=3), 20°C -40-50 % AR after 120-125 d, [^{14}C-quinoxaline]-label (n= 4), 20-25°C

[12] n corresponds to the number of soils.

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

Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	-quizalofop, maximum 68.6-102 % AR at 1-7 d (n= 10) - Hydroxy-quizalofop, maximum 4.8-21 % AR at 7-14 d (n= 8) -dihydroxy-quinoxaline, maximum 1.2-18 % AR at 28-250 d (n=5) - hydroxy-quinoxaline (CHQ), maximum 2.0-5.8 % AR at 24-64 d (n=5)[1] [^{14}C-phenyl] & [^{14}C-quinoxaline]-labels -tetrahydrofurfuryl alcohol, maximum 37-59 % AR at 1 d (n=3) [^{14}C-furfuryl]-label -tetrahydrofuroic acid, > % AR at 2 consecutive sampling points (9.34% AR at 1d, 7.6% AR at 3d) [^{14}C-furfuryl]-label

1= Metabolite hydroxy-quinoxaline accounted more than 5 % in soil degradation studies only once (5.8 %, day 64). Thus the assessment of the leaching potential in ground water is not triggered. However, the two preceding samples were close to 5 % (4.96 %, day 21 and 4.97, day 28) and therefore the PRAPeR 52 meeting considered that this was clearly a border line case. No further ground water assessment was, however, not required because based on the information presented in propaquizafop dossier the risk of leaching was expected to be low. The maximum amount of CHQ in the soil degradation studies of quizalofop-P-ethyl was 1.8 %.

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

Anaerobic degradation ‡

Parent Quizalofop-P-ethyl:

Mineralization after 100 days	0.7 % AR after 120 d, [^{14}C-Phenyl]-label (n= 1), 20^{o}C Sterile conditions: no data available
Non-extractable residues after 100 days	6.5 % AR after 120 d, [^{14}C-Phenyl]-label (n= 1), 20^{o}C

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

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	-quizalofop, maximum, total system 94.2 % AR at 30 d (n= 1) -phenoxy acid, maximum, total system 11.7 % AR at 90 d (n= 1) [^{14}C-Phenyl]-label
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No degradation products exceeding 10 % AR except CO_2 (CO_2 maximum 13.4-22.3 % AR at 32 d (n= 1)) [^{14}C-Phenyl] & [^{14}C-Quinoxaline] labels (24-28^{o}C, natural sunlight, Delaware, USA) (DT_{50} (parent) 39-43 d, dark samples: DT_{50} (parent) 222-597 d based on only 3 sampling points)

Parent Quizalofop-P-tefuryl:

Mineralization after 100 days	0.2 % AR after 63 d, [^{14}C-quinoxaline]-label (n= 1), 25 ^{o}C Sterile conditions: no data available
Non-extractable residues after 100 days	57 % AR after 63 d, [^{14}C-quinoxaline]-label (n= 1), 25 ^{o}C
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	- quizalofop maximum 33 % AR at 15 d, [^{14}C-quinoxaline]-label (n= 1)
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	quizalofop, maximum 32 % AR at 96 d (n= 1) No other degradation products exceeding 10 % AR [^{14}C-quinoxaline]-label (25 ^{o}C, Xenon arc burner, 12 hour light/dark) (DT_{50} (parent) 114 h, dark samples: DT_{50} 55 h)

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

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

Laboratory studies ‡

Parent Quizalofop-P-ethyl	Aerobic conditions (studies conducted with R(+) enantiomer)						
Soil type	OC (%)	pH (w)	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam (Study FD7)	2.1	7.5	10 °C / 40 %	0.30 / 1.0	0.1	0.993	SFO, ModelManager
Sandy loam (Study FD8)	1.8	7.1	20 °C / 40 %	0.33 / 1.1	0.3	0.994	SFO, ModelManager
Sandy loam (Study FD9)	2.5	7.1	10 °C / 40 %	0.52 / 1.7	0.2	0.928	SFO, ModelManager
Sandy loam (Study FD13)	3.3	6.6	20 °C / 49 %	1.1 / 3.5	1.1	0.941	SFO, ModelManager
Silty clay loam (Study FD14)	3.6	6.7	20 °C / 65 %	0.66 / 2.2	0.7	0.992	SFO, ModelManager
Clay loam (Study DF14)	4.6	7.9	20 °C / 47 %	0.54 / 1.8	0.5	0.997	SFO, ModelManager
Geometric mean/median					0.4 / 0.4		

Laboratory studies ‡

Parent Quizalofop-P-tefuryl	Aerobic conditions						
Soil type	OC (%)	pH (w)	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam (Dzialo, 2004, phenyl-label)	1.0	6.3	20 °C / 45 %	0.30 / 0.99	0.26[1]	0.993	SFO, ModelMaker

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

Sand (Dzialo, 2004, phenyl-label)	1.2	6.2	20 °C / 45 %	0.23 / 0.77	0.23[2]	0.984	SFO, ModelMaker
Loam (Dzialo, 2004, phenyl.-label)	0.90	5.9	20 °C / 45 %	0.35 / 1.16	0.34	0.969	SFO, ModelMaker
Clay loam (Dzialo, 2004, phenyl.-label)	1.0	7.6	20 °C / 45 %	0.15 / 0.51	0.14[3]	0.984	SFO, ModelMaker
Sandy loam (Dzialo et al., 2004, furfuryl-label)	1.0	6.3	20 °C / 45 %	0.25 / 0.84	0.22[1]	0.988	SFO, ModelMaker
Sand (Dzialo et al., 2004, furfuryl-label)	1.2	6.2	20 °C / 45 %	0.25 / 0.82	0.25[2]	0.995	SFO, ModelMaker
Clay loam (Dzialo et al., 2004, furfuryl-label)	1.4	7.5	20 °C / 45 %	0.18 / 0.60	0.15[3]	0.989	SFO, ModelMaker
Sandy loam (Völkel, 1998, quinoxaline-label)	1.4	6.3	20 °C / 40 %	0.1 / 0.4	0.11	0.967	SFO, ModelMaker
Silty clay loam (Völkel, 1998, quinoxaline-label)	3.1	7.4	20 °C / 40 %	0.1 / 0.2	0.04	0.961	SFO, ModelMaker
Sandy loam (Völkel, 1998, quinoxaline-label)	1.4	8.2	20 °C / 40 %	0.9 / 3.1	0.62	0.968	SFO, ModelMaker
Loam (Völkel, 1998, quinoxaline-label)	1.8	5.0	20 °C / 40 %	0.1 / 0.3	0.06	0.951	SFO, ModelMaker
Geometric mean / arithmetic mean / median					0.16 /0.22 / 0.19 (n=8)		

1 = The studies were carried out with same soil (sandy loam). Therefore the geomean DT_{50} value (0.24 days) for that soil was used in geometric mean / arithmetic mean / median calculations presented in the LoEP.

2 = The studies were carried out with same soil (sand). Therefore the geomean DT_{50} value (0.24 days) for that soil was used in geometric mean / arithmetic mean / median calculations presented in the LoEP.

3 = The studies were carried out with same soil (clay loam). Therefore the geomean DT_{50} value (0.14 days) for that soil was used in geometric mean / arithmetic mean / median calculations presented in the LoEP.

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

Metabolite 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

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

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)					
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)

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

[#] = 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) it was agreed during the PRAPeR 52 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.

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

Metabolite 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
Sandy loam (Study FD13) /**ET**	3.3	6.6	20 °C / 49 %	40.7 / 210	0.756	40.7	0.746	SFO, ModelManager

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

Metabolite 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 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

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

Metabolite: 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	0.874	SFO
Loamy sand (Mamouni 1999a) / **PROP**	0.78	7.43 #	20 °C / 40 %	58/190	*	37	0.95	SFO
Sandy loam (Mamouni 1999a) / **PROP**	1.3	5.01 #	20 °C / 40 %	63/209	*	40.6	0.935	SFO

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

Metabolite: 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-P-acid 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

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

Met tetrahydrofurfuryl alcohol	Aerobic conditions							
Soil type	OC (%)	pH (w)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy l. (Dzialo et al., 2004, furfuryl-l.) /**TEF**	1.0	6.3	20 °C / 45 %	0.75 / 2.51	*	0.66	0.988	SFO, ModelMaker
Sand (Dzialo et al., 2004, furfuryl-label) /**TEF**	1.2	6.2	20 °C / 45 %	0.44 / 1.47	*	0.44	0.995	SFO, ModelMaker
Clay loam (Dzialo et al., 2004, furfuryl-l.) /**TEF**	1.4	7.5	20 °C / 45 %	0.62 / 2.06	*	0.53	0.989	SFO, ModelMaker
Geometric mean / arithmetic mean / median						0.54 / 0.54 / 0.53		

* = not available
TEF = the study presented in the DAR of Quizalofop-P-tefuryl

Field studies ‡

Parent Quizalofop-P-ethyl	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
Loamy sand, bare soil	Germany	0.5	6.3	30	1.2	3.8	1.00	N.a.	SFO, ModelManager
Silty clay loam, bare soil	France	1.2	7.8	30	0.55	1.8	1.00	N.a.	SFO, ModelManager

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

Field studies ‡

Parent Quizalofop-P-ethyl	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
Silty loam sand, bare soil	Spain	1.8	5.6	30	8.2	27.4	0.961	N.a.	SFO, ModelManager
Geometric mean/median					1.8 / 1.5	5.7 / 4.8			

N.a. = Not available

Field studies ‡

Parent Quizalofop-P-tefuryl	Aerobic conditions

Experts at the PRAPeR 52 meeting did not agree with the kinetic evaluation provide by the applicant. Consequently the endpoints from the field study should not be used for risk assessment.

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

Field studies ‡

Met quizalofop	Aerobic conditions								
Soil type	Location	OM (%)	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (r2)	DT_{50} (d) Norm.	Method of calculation
Loamy sand, bare soil /**ET**	Germany	0.5 (OC)	6.3	30	39.8	132	0.932	N.a.	SFO, ModelManager
Silty clay loam, bare soil /**ET**	France	1.2 (OC)	7.8	30	33.6	112	0.953	N.a.	SFO, ModelManager
Silty loam sand, bare soil /**ET**	Spain	1.8 (OC)	5.6	30	37.6	125	0.899	N.a.	SFO, ModelManager
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
Geometric mean / arithmetic mean / median					35.3 / 35.5 / 35.6	117 / 118 / 119			

* = not available
** = a best fit residue decline was drawn through the residue values
*** = this value has been considered as an outlier and it has not been taken into account in the calculation of the mean values

N.a. = Not available
ET = the study presented in the DAR of quizalofop-P-ethyl
TEF = the study presented in the DAR of quizalofop-P-tefuryl (Experts at the PRAPeR 52 meeting did not agree with the kinetic evaluation provide by the applicant. Consequently the endpoints from the field study should not be used for risk assessment.)

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

Field studies

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

Parent Quizalofop-P-ethyl:

pH dependence ‡ / (yes / no) (if yes type of dependence)	No clear dependence (However, in hydrolysis studies the parent substance rapidly hydrolysed in alkaline conditions, see route and rate of degradation in water.)
Soil accumulation and plateau concentration ‡	In field dissipation studies mean residues of Quizalofop-P-ethyl declined to <LOQ (5 µg/kg) 3-28 days after application of 200 g/ha. Accumulation factor: not relevant.

Parent Quizalofop-P-tefuryl:

pH dependence ‡ (yes / no) (if yes type of dependence)	No clear dependence (However, in hydrolysis studies the parent substance rapidly hydrolysed in alkaline conditions, see route and rate of degradation in water.)
Soil accumulation and plateau concentration ‡	In field dissipation studies mean residues of Quizalofop-P-tefuryl declined to <LOD (20 µg/kg) 3-31 days after application of 450 or 900 g/ha. Accumulation factor: not relevant.

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

Laboratory studies ‡

Parent Quizalofop-P-ethyl	Anaerobic conditions						
Soil type	OC (%)	pH (w)	t. °C / % MWHC *	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam / loamy sand	2.5	7.1	20 °C / *	0.3 / 1.2 (total system)	N.a.	N.a.	Two and one compartment model (SAS)
Geometric mean/median							

* = Water saturated soil

Met Quizalofop	Anaerobic conditions							
Soil type	OC (%)	pH (w)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam / loamy sand (total sys.)/**ET**	2.5	7.1	20 °C / *	253 / 880	N.a.	N.a.	N.a.	Two and one compartment model (SAS)
Geometric mean/median								

* = Water saturated soil
ET = the study presented in the DAR of Quizalofop-P-ethyl

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

Laboratory studies ‡

Parent Quizalofop-P-tefuryl* **	Anaerobic conditions						
Soil type	OM (%)	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam	3.1	6.3	25 °C/*	0.63 d / **	0.9 d (20 °C)*	0.710	Linear regression analysis
Geometric mean/median							

* = The samples were flooded with water
** = Not available
*** = The amount of the main metabolite quizalofop was approximately 30 % of the applied radioactivity in all samples analysed during the test period (63 days). Thus no significant degradation of Quizalofop-P-tefuryl was observed.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent Quizalofop-P-ethyl ‡							
Soil Type	OC %	Soil pH (w)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy clay loam	0.5	6.4			15.4	3078	0.88
Sand	2.0	5.3			24.3	1214	0.87
Silty loam	5.1	6.0			99.3	1948	0.84
Light clay	5.9	5.3			60.4	1024	0.83
Arithmetic mean/median					49.9 / 42.4	1816 / 1581	0.86 / 0.86
pH dependence, Yes or No			No				

Studies on adsorption and desorption of parent substance, **Quizalofop-P-tefuryl**, were not performed. Due to the rapid degradation of Quizalofop-P-tefuryl the major degradation product, quizalofop, was selected as the most appropriate test substance for use in adsorption/desorption studies.

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

Met: Quizalofop							
Soil Type	OM %	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 (OC)	6.4			1.73	346	0.79
Sand /**ET**	2.0 (OC	5.3			4.23	212	0.79
Silty loam /**ET**	5.1 (OC	6.0			40.0	783	0.86
Light clay /**ET**	5.9 (OC)	5.3			33.3	564	0.87
Loamy sand /**ET**	0.5 (OC)	4.3			125	1782	0.8
Loamy sand /**ET**	7.0 (OC)	3.1			9	1791	0.8
Clay /**ET**	3.9 (OC)	6.0			8	214	0.8
Clay loam /**ET**	3.2 (OC)	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 in the DAR (test soil was a pond sediment, not an agricultural soil). However, based on the discussion of the experts' meeting PRAPeR 52 the values should be included in the risk assessment.

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

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

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

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

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
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

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

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

Parent Quizalofop-P-ethyl:

Column leaching ‡	Not available. Not considered necessary, reliable adsorption/desorption data available.
Aged residues leaching ‡	Not available. Not considered necessary, reliable adsorption/desorption data available.
Lysimeter/ field leaching studies ‡	A lysimeter study with 2 UK soils is available. Experts of PRAPeR 52 considered this study as providing supportive information only.

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

Parent Quizalofop-P-tefuryl:

Column leaching ‡	Eluation (mm): 508 mm Time period (d): approximately 1 d
	Leachate: 0.1-0.8 % applied radioactivity in leachate 0 % active substance, 0.7 % Quizalofop-P-acid 48.9 % total radioactivity retained in top 6 cm Koc 21211 (the equation used for calculation was not presented in OECD guideline)
Aged residues leaching ‡ Study 1 (Dzialo, 1992)	Aged for (d): 29 d at 25 °C Time period (d): not reported Eluation (mm): 500 mm
	Analysis of soil residues post ageing (soil residues pre-leaching): 0 % active substance, 70 % Quizalofop-P-acid, 0.03 % CO_2 80.3 % applied radioactivity retained in top 7.6 cm
	Leachate: 0.8 % total applied radioactivity in leachate.
Aged residues leaching ‡ Study 2 (Völkel, 1998)	Aged for (d): 133 d at 20 °C Time period (d): 2 d Eluation (mm): 200 mm
	Analysis of soil residues post ageing (soil residues pre-leaching): 77.8 % in soil and 18.1 % as CO_2 91.3 % applied radioactivity retained in top 6.3 cm (20.2% AR as dihydroxy-quinoxaline, 6.9% AR as hydroxy-quizalofop, 4.3% AR as quizalofop and 53.5% AR as bound residues)
	Leachate: No radioactivity (<0.16 µg quizalofop-P-tefuryl equivalents/L) in leachate
Lysimeter/ field leaching studies	Not available. Not considered necessary.

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

PEC (soil) (Annex IIIA, point 9.1.3)

Quizalofop-P-ethyl

Parent Method of calculation	DT_{50} (d): 8.25 days Kinetics: SFO Field or Lab: worst case from field studies.
Application data	Crop: sugar beet Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 20 % Number of applications: 1 Interval (d): a single application/year Application rate(s): 200 g as/ha

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.2133			
Short term 24h	0.1961	0.2046		
2d	0.1803	0.1964		
4d	0.1524	0.1812		
Long term 7d	0.1185	0.1613		
28d	0.0203	0.0821		
50d	0.0032	0.0500		
100d	<0.0001	0.0254		
Plateau concentration	Not necessary (<0.0001 mg/kg after 100 days)			

Metabolite Quizalofop Method of calculation	Molecular weight relative to the parent: no molecular weight correction (Quizalofop-acid was determined in absolute concentrations in the study) DT_{50} (d): 39.8 days[1] Kinetics: SFO, ModelMaker (PEC values were derived directly from ModelMaker output) Field or Lab: worst case from field studies.
Application data	Application rate assumed: 200 g as/ha (formation fraction 0.629, from Quizalofop-P-acid)

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

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.1207			
Plateau concentration	Not necessary (not persistent in soil)			

[1]It was agreed during the expert meeting that the longest lab soil DT_{50} for quizalofop-acid (182 days, amalgamated list of endpoints) should be used for PECsoil calculations. Initial PECsoil values were used in the risk assessment.

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

Metabolite hydroxy-quizalofop Method of calculation	Molecular weight relative to the parent: No molecular weight correction (3-OH-Quizalofop-acid was determined in absolute concentrations in the study) DT_{50} (d): 32.2 days[1] Kinetics: SFO, ModelMaker (PEC values were derived directly from ModelMaker output) Field or Lab: field study, which resulted in worst case value for the primary metabolite
Application data	Application rate assumed: 200 g as/ha (formation fraction 0.114, from Quizalofop-acid)

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.0051			
Plateau concentration	Not necessary (not persistent in soil)			

[1]It was agreed during the expert meeting that the longest lab soil DT_{50} for 3-OH-quizalofop-acid (53.3 days, amalgamated list of endpoints) should be used for PECsoil calculations. Initial PECsoil values were used in the risk assessment.

Metabolite dihydroxy-quinoxaline Method of calculation	Molecular weight relative to the parent: 0.527 (=196.6/372.8) DT_{50} (d): 102 days[1] Kinetics: SFO, ModelMaker (PEC values were derived directly from ModelMaker output) Field or Lab: worst case from laboratory study
Application data	Application rate assumed: 200 g as/ha (100 % from 3-OH-Quizalofop-acid)

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

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.0040			
Plateau concentration	Not necessary (not persistent in soil)			

[1]It was agreed during the expert meeting that the longest lab soil DT_{50} for 3-OH-CQO (200 days, amalgamated list of endpoints) should be used for PECsoil calculations. Initial PECsoil values were used in the risk assessment.

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

Quizalofop-P-tefuryl

Parent Method of calculation	DT_{50} (d): 1 day Kinetics: SFO Field or Lab: representative worst case from field studies[1].
Application data	Crop: potatoes Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 15 % Number of applications: 1 Interval (d): a single application/year Application rate(s): 100 g as/ha

[1] PRAPeR 52 considered the field DT_{50} not reliable; however, as the field DT_{50} represent a worst case for the degradation of quizalofop-P-tefuryl, the assessment was considered acceptable.

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.113			
Short term 24h	0.057	0.082		
2d	0.028	0.061		
4d	0.007	0.038		
Long term 7d	<0.001	0.023		
28d	<0.001	0.006		
50d	<0.001	0.003		
100d	<0.001	0.002		
Plateau concentration	Not necessary (<0.001 mg/kg after 7 days)			

Metabolite quizalofop Method of calculation	Molecular weight relative to the parent: 0.804 (=344.75 : 428.9)
Application data	Application rate assumed: 80.4 g as/ha (assumed quizalofop is formed at a maximum of 100 % of the applied dose)

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

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.091			
Plateau concentration	Not necessary (not persistent in soil)			

It was agreed during the expert meeting that the longest normalised soil DT_{50} lab for quizalofop (182 days, agreed amalgamated list of endpoints) should be used for PECsoil calculations. Therefore the PECsoil values for the later time points were decided to remove from the LoEP.

Metabolite hydroxy-quizalofop Method of calculation	Molecular weight relative to the parent: 0.841 (=360.8 : 428.9)
Application data	Application rate assumed: 17.7 g as/ha (assumed hydroxy-quizalofop is formed at a maximum of 21 % of the applied dose)

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.020			
Plateau concentration	Not necessary (not persistent in soil)			

It was agreed during the expert meeting that the longest lab soil DT_{50} for hydroxy-quizalofop (53.3 days, agreed amalgamated list of endpoints) should be used for PECsoil calculations. Therefore the PECsoil values for the later time points were decided to remove from the LoEP.

Metabolite dihydroxy-quinoxaline Method of calculation	Molecular weight relative to the parent: 0.458 (=196.59 : 428.9)
Application data	Application rate assumed: 8.2 g as/ha (assumed dihydroxy-quinoxaline is formed at a maximum of 18 % of the applied dose)

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

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.009			
Plateau concentration	Not necessary (not persistent in soil)			

It was agreed during the expert meeting that the longest lab soil DT_{50} for dihydroxy-quinoxaline (200 days, agreed amalgamated list of endpoints) should be used for PECsoil calculations. Therefore the PECsoil values for the later time points were decided to remove from the LoEP.

Metabolite tetrahydrofurfuryl alcohol Method of calculation	Molecular weight relative to the parent: 0.238 (=102.1 : 428.9) DT_{50} (d): 0.66 days Kinetics: SFO Field or Lab: maximum normalised laboratory DT_{50}.
Application data	Application rate assumed: 14.0 g as/ha (assumed tetrahydrofurfuryl alcohol is formed at a maximum of 59 % of the applied dose)

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.016			
Short term	24h	0.006	0.010		
	2d	0.002	0.007		
	4d	<0.001	0.004		
Long term	7d	<0.001	0.002		
	28d	<0.001	<0.001		
	50d	<0.001	<0.001		
	100d	<0.001	<0.001		
Plateau concentration		Not necessary (not persistent in soil)			

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

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

Parent Quizalofop-P-ethyl:

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 4: stable at 50 °C (Met Quizalofop: stable at 22 °C)
	pH 7: DT_{50} 3.67 days at 50 °C (1^{st} order, r^2=0.999) pH 7: DT_{50} 10.7 days at 40 °C (1^{st} order, r^2=0.999) pH 7: DT_{50} 59.8 days at 25 °C (calculated by Arrhenius method using 40 and 50 °C values) Met Quizalofop 21.1 % AR (30 d) Met Quizalofop stable at 22 °C
	pH 9: unstable at 50 °C (DT_{50} <2.4 h) Met Quizalofop: 78.3 % AR (7 d) Met Quizalofop stable at 22 °C
Photolytic degradation of active substance and metabolites above 10 % ‡	DT_{50} : 38.3 days (continuous light) (Natural light, 40 °N; DT_{50} 40.2 days) No metabolite occurred at levels >10 % AR. Estimated DT_{50} at 30 °N in summer: 11 days Estimated DT_{50} at 60 °N in winter: 273 days
Quantum yield of direct phototransformation in water at Σ > 290 nm	$3.0 \cdot 10^{-5}$ mol · Einstein $^{-1}$
Readily biodegradable ‡ (yes/no)	Not a readily biodegradable substance

Parent Quizalofop-P-tefuryl:

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5.1: 8.2 days at 22 °C (regression analysis) (study 1) (Met I: Quizalofop-P-acid (the amount was not informed), stable at 50 °C, pH 4) pH 5.1: 277 days at 25 °C (1^{st} order, r^2=0.8820) (study 2)

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

	pH 7.0: 18.2 days at 22 °C (regression analysis) (study 1) (Met I: Quizalofop-P-acid (the amount was not informed), stable at 50 °C, pH 7.0) pH 7.0: 4.3 days at 25 °C (1st order, r^2=0.9275) (study 2)
	pH 9.1; 7.2 hours at 22 °C (regression analysis) (study 1) (Met I: Quizalofop-P-acid (the amount was not informed), stable at 50 °C, pH 9.0) pH -8.9: 8.7 hours at 25 °C (1st order, r^2=0.9894) (study 2)
Photolytic degradation of active substance and metabolites above 10 % ‡	DT_{50} : 25.3 h (Xenon arc lamp, 600 W/m^2) Met CQOP: 11.3 % AR (32.2 h) (study 1) DT_{50} : 2.4 h (Xenon burner) No metabolite occurred at levels >10 % AR (study 2)
Quantum yield of direct phototransformation in water at Σ > 290 nm	$1.2 \cdot 10^{-4}$ mol · Einstein $^{-1}$
Readily biodegradable ‡ (yes/no)	No

Degradation in water / sediment

Parent Quizalofop-P-ethyl	Distribution (eg max in water 58-62 % after 0-0.25 d. Max. sed 20-29 % 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
Mill Stream Pond	8.3	7.9	10	1.2-3.9 d	0.997	1.2-4.0 d	0.955	1.0-3.3 d	0.635	One comp. model
Iron Hatch Stream	8.3	8.2	10	1.9-6.3 d	0.996	2.0-6.8 d	0.984	1.2-4.0 d	0.945	One comp. model
Geometric mean				1.51-4.96		1.55-5.22		1.10-3.63		

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

Mineralization and non extractable residues / **Parent Quizalofop-P-ethyl**					
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)
Mill Stream Pond	8.3	7.9	21.9 % after 158 days	31.6 % after 158 days	31.6 % after 158 days
Iron Hatch Stream	8.3	8.2	22.7 % after 158 days	37.9 % after 158 days	37.9 % after 158 days

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

Degradation in water / sediment

Parent Quizalofop-P-tefuryl	Distribution (max in water 95.4 % after 0 d. Max. sed 2.9 % 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, [^{14}C-phenyl-quinoxal.]-label	8.1	7.3	20	2.5 - 8.3 h	0.991	2.4-8.1 h	0.991	*	*	SFO
Pond, [^{14}C-phenyl-quinoxal.]-label	7.9	7.0	20	3.2 - 10.5 h	0.978	3.1-10.4 h	0.977	*	*	SFO
River, [^{14}C-phenyl]-label	7.7	7.3	20	2.0 h** - <24 h	*	*	*	*	*	SFO
Pond, [^{14}C-phenyl]-label	7.6	7.1	20	2.0 h** - <24 h	*	*	*	*	*	SFO
River, [^{14}C-5-furfuryl]-label	7.6	7.3	20	4.8 - 12 h	0.998	*	*	*	*	SFO
Pond, [^{14}C-5-furfuryl]-label	8.4	7.1	20	0.24 - 0.72 h	0.990	*	*	*	*	SFO
Geometric mean/median				1.8 h (0.08 d) / 2.0 h ***		2.7 h (0.11 d) - 9.2 h****		*		

* = not available
** = the value was presented in PEC_{SW} calculation report (Gurney, 2004), it was not presented in water/sediment study report (Diehl, 2004)
*** = the DT_{50} values only
**** = the geometric mean values only

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

Mineralization and non-extractable residues / **Parent Quizalofop-P-tefuryl**					
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,[^{14}C-phenyl-quinoxal.]-label	8.1	7.3	14. 9 % after 98 days	34.6 % after 98 days	34.6 % after 98 days
Pond, [^{14}C-phenyl-quinoxal.]-label	7.9	7.0	10.3 % after 98 days	42.1 % after 98 days	42.1 % after 98 days
River, [^{14}C-phenyl]-label	7.7	7.3	45.7 % after 102 days	28.8 % after 60-102 days	28.8 % after 102 days
Pond, [^{14}C-phenyl]-label	7.6	7.1	45.3 % after 150 days	26.7 % after 150 days	26.7 % after 150 days
River, [^{14}C-5-furfuryl]-label	7.6	7.3	80.7 % after 28 days	18.3 % after 7 days	10.8 % after 28 days
Pond, [^{14}C-5-furfuryl]-label	8.4	7.1	77.8 % after 28 days	14.8 % after 7 days	11.1 % after 28 days

* = not available ** = not performed

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

Degradation in water / sediment

Met Quizalofop	**TEF**: Distribution: max. in water 94 % after 1 d. Max. sed. 53 % after 14 d **ET:** Distribution: max. in water 83 % after 7 d. Max. sed. 43 % 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. (d)	St. (r^2)	DT_{50}-DT_{90} water (d)	St. (r^2)	DT_{50}-DT_{90} sed (d)	St. (r^2)	Method of calculation
River, (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 d – 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/median				35/35-90/86		21/24-43/43		54/54-96/97		

* = 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 = data from the propaquizafop was excluded because is not peer reviewed

For the metabolite dihydroxy-quinoxaline no dissipation values on the water sediment degradation are available from the quizalofop-P-tefuryl DAR. In the final addendum to the propaquizafop DAR (July 2008) DT_{50}-DT_{90} for the whole system for dihydroxy-quinoxaline were provided but are not peer reviewed.

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

Met CQOP	**TEF:** Distribution: max. in water 1.1 % after 8 h. Max. sed. 11.6 % 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	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
River (phenyl l.) /**TEF**	7.7	7.3	20	40 - **	0.908	*	*	*	*	SFO
Pond (phenyl l.) /**TEF**	7.6	7.1	20	42–141	0.979	*	*	*	*	SFO
Geometric mean				41–141 d		*		*		
Met tetrahydrofurfuryl alcohol	**TEF**: Distribution (max in water 16.5 % after 1 d. Max. sed 0.2 % after 0 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys. (d)	St. (r^2)	DT_{50}-DT_{90} water (d)	St. (r^2)	DT_{50}-DT_{90} sed (d)	St. (r^2)	Method of calculation
River, [^{14}C-5-furfuryl]-label /**TEF**	7.6	7.3	20	0.3 – 0.9 d	0.998	*	*	*	*	SFO
Pond, [^{14}C-5-furfuryl]-label /**TEF**	8.4	7.1	20	0.4 – 1.4 d	0.990	*	*	*	*	SFO
				0.35–1.1 d		*		*		
Met tetrahydrofuroic acid	**TEF:** Distribution (max in water 39.1 % after 1 d. Max. sed 1.6 % after 0 d)									
River, [^{14}C-5-furfuryl]-label	7.6	7.3	20	1.3 – 4.3 d	0.998	*	*	*	*	SFO
Pond, [^{14}C-5-furfuryl]-label	8.4	7.1	20	1.6 – 5.5 d	0.990	*	*	*	*	SFO
				1.4 – 4.9 d		*		*		

* = not available ** = not performed *** = at 20 °C, not normalised in the DAR

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

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

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

Quizalofop-P-ethyl

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 1.1 Molecular weight (g/mol): 372.81 Water solubility (mg/L): 0.61 K_{OC} (L/kg): 1816 DT_{50} soil (d): 0.4 days (lab., in accordance with FOCUS SFO) DT_{50} water (d): 100 DT_{50} sediment (d): 0.7 (mean of two values in the total water/sediment system adjusted to 20 oC utilising a Q10 of 2.2) Crop interception (%): 20 Runoff/drainage input used in modelling: - 2 % of remaining soil residue in Northern Europe - 4 % of remaining soil residue in Southern Europe
Parameters used in FOCUSsw step 3 (if performed)	All values were those used for Step 2 unless: Crop washoff factor: 0.01 cm^{-1} (not used previously)
Application rate	Crop: sugar beet Crop interception: 20 % Number of applications: 1 Interval (d): - Application rate(s): 200 g as/ha Application window: - Step 2: BBCH 10-19 (March – May) - Step 3: BBCH 13-39, with PHI 60 in Southern Europe or 110 in Northern Europe Early: 30-day application window commencing 14 days after emergence Late: 30-day application window commencing 60 days before harvest

FOCUS STEP 1 Scenario	Step 1 PEC values were not reported.

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

FOCUS STEP 2 Scenario	Time after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	1.8393		2.4179	
	24 h	0.9648	1.4021	1.9040	2.1610
	2 d	0.5997	1.0922	1.2889	1.8787
	4 d	0.2566	0.7502	0.7437	1.4196
	7 d	0.0335	0.4737	0.1259	0.9646
	14 d	0.0005	0.2409	0.0020	0.4977
	21 d	<0.0001	0.1607	<0.0001	0.3319
	28 d	<0.0001	0.1205	<0.0001	0.2490
	42 d	<0.0001	0.0803	<0.0001	0.1660
Southern EU	0 h	1.8393		2.4179	
	24 h	0.9648	1.4021	1.9040	2.1610
	2 d	0.5997	1.0922	1.2889	1.8787
	4 d	0.2596	0.7505	0.7643	1.4360
	7 d	0.0344	0.4748	0.1294	0.9782
	14 d	0.0005	0.2416	0.0021	0.5049
	21 d	<0.0001	0.1611	<0.0001	0.3368
	28 d	<0.0001	0.1208	<0.0001	0.2526
	42 d	<0.0001	0.0806	<0.0001	0.1684

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

FOCUS STEP 3 Scenario	Water body	Maximum PEC_{SW} (µg/L)	Maximum PEC_{SED} (µg/kg)
D3,early	Ditch	1.044	0.412
D3, late	Ditch	1.048	0.450
D4, early	Pond	0.0421	0.0492
D4, late	Pond	0.0421	0.0396
D4, early	Stream	0.877	0.0448
D4, late	Stream	0.865	0.0382
R1, early	Pond	0.0421	0.0465
R1, late	Pond	0.0421	0.0340
R1, early	Stream	0.722	0.0947
R1, late	Stream	0.725	0.0982
R3, early	Stream	1.020	0.217
R3, late	Stream	1.022	0.185

Metabolite Quizalofop Parameters used in FOCUSsw step 1 and 2	Molecular weight: 344.75 Water solubility (mg/L): not reported Soil or water metabolite: soil and water metabolite Koc (L/kg): 245* DT_{50} soil (d): 30.9** (lab., in accordance with FOCUS SFO) DT_{50} water (d): 1000*** DT_{50} sediment (d): 100*** Crop interception (%): 20 Maximum in soil: 83.8 % Maximum in water/sediment: 97.9 %
Parameters used in FOCUSsw step 3 (if performed)	All values were those used for Step 2 unless: DT_{50} soil (d): 29.4 (re-calculated value, refer to reporting table 4 (63) Water solubility (g/l): 8.5 (not used previously) Vapour pressure (Pa): 1.1 x 10^{-7} (not used previously) Crop washoff factor (cm^{-1}): 0.04 (not used previously) 1/n = 0.75****

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

Application rate	Crop: sugar beet Number of applications: 1 Interval (d): - Application rate(s): 200 g as/ha Depth of water body: 30 cm - Step 2: Application window: BBCH 10-19 (March – May) - Step 3: BBCH 13-39, with PHI 60 in Southern Europe or 110 in Northern Europe Early: 30-day application window commencing 14 days after emergence Late: 30-day application window commencing 60 days before harvest
Main routes of entry	Spray drift at the time of application and a single input representing a runoff, erosion or drainage event four days after application

Based on the amalgamated list of endpoints for quizalofop metabolite, it was agreed during the experts' meeting PRAPeR 52 that:
*the median Koc value of 356 L/kg,
**the median lab normalised soil DT_{50} of 24.3 days,
***the geomean whole system DT_{50} of 35 days
****the median 1/n value of 0.81
should be used for FOCUS modelling. However, as the used input parameters are worst cases, the experts concluded that no PECsw/sed recalculations are necessary.

FOCUS STEP 1 Scenario	Step 1 PEC values were not reported.

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

FOCUS STEP 2 Scenario	Time after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	7.0564		16.8936	
	24 h	6.9385	6.9975	16.8560	16.8748
	2 d	6.9231	6.9641	16.8186	16.8561
	4 d	6.8923	6.9359	16.7439	16.8186
	7 d	6.8465	6.9074	16.6324	16.7627
	14 d	6.7406	6.8504	16.3753	16.6331
	21 d	6.6364	6.7964	16.1222	16.5049
	28 d	6.5338	6.7435	15.8730	16.3780
	42 d	6.3334	6.6401	15.3860	16.1281
Southern EU	0 h	12.7533		30.7544	
	24 h	12.6314	12.6923	30.6861	30.7202
	2 d	12.6033	12.6548	30.6178	30.6861
	4 d	12.5473	12.6151	30.4819	30.6180
	7 d	12.4638	12.5681	30.2790	30.5161
	14 d	12.2712	12.4677	29.8109	30.2803
	21 d	12.0815	12.3705	29.3501	30.0468
	28 d	11.8947	12.2748	28.8964	29.8158
	42 d	11.5298	12.0870	28.0099	29.3608

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

FOCUS STEP 3 Scenario	Water body	Maximum PEC_{SW} (µg/L)	Maximum PEC_{SED} (µg/kg)
D3,early	Ditch	0.968	0.527
D3, late	Ditch	0.972	0.699
D4, early	Pond	0.0404	0.293
D4, late	Pond	0.0391	0.274
D4, early	Stream	0.814	0.0670
D4, late	Stream	0.802	0.0382
R1, early	Pond	0.139	0.888
R1, late	Pond	0.0928	0.842
R1, early	Stream	1.588	0.664
R1, late	Stream	0.673	0.270
R3, early	Stream	2.492	1.534
R3, late	Stream	2.984	2.168

Metabolite hydroxy-quizalofop Parameters used in FOCUSsw step 1 and 2	Molecular weight: 360.75 Water solubility (mg/L): not reported Soil or water metabolite: soil metabolite Koc (L/kg): 216* DT_{50} soil (d): 45.8** (lab., in accordance with FOCUS SFO) DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Crop interception (%): 20 Maximum in soil: 15.7 % Maximum in water/sediment: 3.0 %
Parameters used in FOCUSsw step 3 (if performed)	PEC_{SW} values were not calculated using step 3.
Application rate	Crop: sugar beet Number of applications: 1 Interval (d): - Application rate(s): 200 g as/ha Depth of water body: 30 cm Application window: BBCH 10-19 (March -May)
Main routes of entry	Spray drift at the time of application and a single input representing a runoff, erosion or drainage event four days after application

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

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. However, as the used input parameters are worst cases, the experts concluded that no PECsw/sed recalculations are necessary.

FOCUS STEP 1 Scenario	Step 1 PEC values were not reported.

FOCUS STEP 2 Scenario	Time after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	1.2291		2.6459	
	24 h	1.2249	1.2270	2.6440	2.6449
	2 d	1.2241	1.2258	2.6422	2.6440
	4 d	1.2224	1.2245	2.6385	2.6422
	7 d	1.2199	1.2231	2.6331	2.6395
	14 d	1.2139	1.2200	2.6203	2.6331
	21 d	1.2081	1.2170	2.6076	2.6267
	28 d	1.2022	1.2140	2.5950	2.6204
	42 d	1.1906	1.2082	2.5699	2.6077
Southern EU	0 h	2.4136		5.2025	
	24 h	2.4086	2.4111	5.1989	5.2007
	2 d	2.4069	2.4094	5.1953	5.1989
	4 d	2.4036	2.4073	5.1881	5.1953
	7 d	2.3986	2.4046	5.1773	5.1899
	14 d	2.3869	2.3987	5.1522	5.1773
	21 d	2.3754	2.3928	5.1273	5.1648
	28 d	2.3639	2.3870	5.1025	5.1523
	42 d	2.3411	2.3755	5.0532	5.1275

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

FOCUS STEP 3 Scenario	PEC values were not calculated using step 3.

Metabolite dihydroxy-quinoxaline Parameters used in FOCUSsw step 1 and 2	Molecular weight:196.6 Water solubility (mg/L): not reported Soil or water metabolite: soil metabolite Koc/Kom (L/kg): 48* DT_{50} soil (d): 55.5** (lab., in accordance with FOCUS SFO) DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Crop interception (%): 20 Maximum in soil: 12.3 % Maximum in water/sediment: 3-OH-CQO was not formed in the water/sediment system. As a value of >0 is required, an arbitrary value of 1 was used.
Parameters used in FOCUSsw step 3 (if performed)	PEC_{SW} values were not calculated using step 3.
Application rate	Crop: sugar beet Number of applications: 1 Interval (d): - Application rate(s): 200 g as/ha Depth of water body: 30 cm Application window: BBCH 10-19 (March –May)
Main routes of entry	Spray drift at the time of application and a single input representing a runoff, erosion or drainage event four days after application.

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. However, as the used input parameters are worst cases, the experts concluded that no PECsw/sed recalculations are necessary.

FOCUS STEP 1 Scenario	Step 1 PEC values were not reported.

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

FOCUS STEP 2 Scenario	Time after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.6279		0.3011	
	24 h	0.6272	0.6276	0.3009	0.3010
	2 d	0.6268	0.6273	0.3007	0.3009
	4 d	0.6259	0.6268	0.3002	0.3007
	7 d	0.6246	0.6262	0.2996	0.3003
	14 d	0.6216	0.6247	0.2982	0.2996
	21 d	0.6186	0.6231	0.2967	0.2989
	28 d	0.6156	0.6216	0.2953	0.2982
	42 d	0.6097	0.6186	0.2924	0.2967
Southern EU	0 h	1.2465		0.5978	
	24 h	1.2454	1.2459	0.5974	0.5976
	2 d	1.2445	1.2455	0.5970	0.5974
	4 d	1.2428	1.2446	0.5961	0.5970
	7 d	1.2402	1.2433	0.5949	0.5963
	14 d	1.2342	1.2403	0.5920	0.5949
	21 d	1.2283	1.2373	0.5892	0.5935
	28 d	1.2223	1.2343	0.5863	0.5920
	42 d	1.2105	1.2283	0.5806	0.5892

FOCUS STEP 3 Scenario	PEC values were not calculated using step 3.

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

Quizalofop-P-tefuryl

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 1.1 Molecular weight (g/mol): 428.9 Water solubility (mg/L): 3.75 K_{OC} (L/kg): 1 DT_{50} soil (d): 0.14[1] days (lab, geom. mean, FOCUS SFO) DT_{50} water/sediment system (d): 0.08 (geom. mean) DT_{50} water (d): 0.08 DT_{50} sediment (d): 0.08 Runoff/drainage input used in modelling (autumn applications): - 5 % of remaining soil residue in Northern Europe - 4 % of remaining soil residue in Southern Europe Spray drift: 2.759 % of application
Parameters used in FOCUSsw step 3 (if performed)	PEC values were not calculated using step 3
Application rate	Crop: potatoes Crop interception: 15 % Number of applications: 1 Interval (d): - Application rate(s): 100 g as/ha Application window: minimal crop cover, BBCH 10-19 (Oct.-Feb.)

[1]The appropriate DT_{50} soil to be use in the modelling should be 0.16 d.

FOCUS STEP 1	Not reported

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

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.92		<0.01	
	24 h	<0.01	0.46	<0.01	<0.01
	2 d	<0.01	0.23	<0.01	<0.01
	4 d	<0.01	0.12	<0.01	<0.01
	7 d	<0.01	0.07	<0.01	<0.01
	14 d	<0.01	0.03	<0.01	<0.01
	21 d	<0.01	0.02	<0.01	<0.01
	28 d	<0.01	0.02	<0.01	<0.01
	42 d	<0.01	0.01	<0.01	<0.01
Southern EU	0 h	0.92		<0.01	
	24 h	<0.01	0.46	<0.01	<0.01
	2 d	<0.01	0.23	<0.01	<0.01
	4 d	<0.01	0.12	<0.01	<0.01
	7 d	<0.01	0.07	<0.01	<0.01
	14 d	<0.01	0.03	<0.01	<0.01
	21 d	<0.01	0.02	<0.01	<0.01
	28 d	<0.01	0.02	<0.01	<0.01
	42 d	<0.01	0.01	<0.01	<0.01

FOCUS STEP 3	PEC values were not calculated using step 3

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

Metabolite quizalofop Parameters used in FOCUSsw step 1 and 2 Recalculations performed after the peer review by EFSA using the agreed endpoints in PRAPeR 52	Molecular weight: 344.8 Water solubility (mg/L): 1000 Soil or water metabolite: soil and water metabolite Koc/Kom (L/kg): (if necessary, soil metabolites) 356 (median from the amalgamated LoEP) DT_{50} soil (d): 24.3 d(lab., median from the amalgamated LoEP, FOCUS SFO) DT_{50} water/sediment system (d): 35 (median from the amalgamated LoEP) DT_{50} water (d): 35 DT_{50} sediment (d): 35 Crop interception (%): 15 % Maximum in soil: 100 % Maximum in water/sediment: 100 % (quizalofop was considered as the active substance)
Parameters used in FOCUSsw step 3 (if performed)	PEC values were not calculated using step 3
Application rate	Crop: potatoes Number of applications: 1 Interval (d): - Application rate(s): 80.4 g as/ha (=344.8 : 428.9 x 100 g/ha) Depth of water body: 30 cm Application window: BBCH 10-19 (Oct.-Feb.)
Main routes of entry	Spray drift (% application): 2.759 Runoff/drainage input used in modelling (autumn applications): - 5 % in Northern Europe - 4 % in Southern Europe

FOCUS STEP 1	Not reported

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

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	7.41		25.76	
	24 h	7.21	7.31	25.67	25.72
	2 d	7.07	7.22	25.16	25.57
	4 d	6.79	7.08	24.19	25.12
	7 d	6.40	6.87	22.79	24.42
	14 d	5.57	6.42	19.84	22.85
	21 d	4.85	6.02	17.27	21.41
	28 d	4.22	5.65	15.04	20.09
	42 d	3.20	4.99	11.40	17.77
Southern EU	0 h	6.03		20.86	
	24 h	5.86	5.95	20.45	20.65
	2 d	5.74	5.87	20.05	20.45
	4 d	5.52	5.75	19.27	20.05
	7 d	5.20	5.58	18.16	19.48
	14 d	4.53	5.22	15.81	18.22
	21 d	3.94	4.89	13.76	17.06
	28 d	3.43	4.59	11.98	16.01
	42 d	2.60	4.06	9.08	14.16

FOCUS STEP 3	PEC values were not calculated using step 3

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

Metabolite CQOP Parameters used in FOCUSsw step 1 and 2	Molecular weight: 272.7 Maximum in soil: 3.7 % Maximum in water/sediment: 11.6 % Reliable PECsw and PECsed not available. Risk assessment to aquatic organisms was based on the worst case intial PECsed value of quizalofop (25.76 µg/Kg).
Parameters used in FOCUSsw step 3 (if performed)	PEC values were not calculated using step 3
Metabolite hydroxy-quizalofop Parameters used in FOCUSsw step 1 and 2 Recalculations performed by EFSA after the peer review using the agreed endpoints in PRAPeR 52	Molecular weight: 360.5 Maximum in soil: 20.5 % Maximum in water/sediment: 12.3 % Koc/Kom (L/kg): (if necessary, soil metabolites) 141 (median from the amalgamated LoEP) DT_{50} soil (d): 15.6 d(lab., median from the amalgamated LoEP, FOCUS SFO) DT_{50} water/sediment system (d): ~~30~~ 300 (default, worst case) DT_{50} water (d): ~~30~~ 300 (default, worst case) DT_{50} sediment (d): ~~30~~ 300 (default, worst case) Assumed active substance and its amount in calculations: quizalofop, 80.4 g/ha
Parameters used in FOCUSsw step 3 (if performed)	PEC values were not calculated using step 3
Application rate	Crop: potatoes Number of applications: 1 Interval (d): - Application rate(s): 80.4 g as/ha (=344.8 : 428.9 x 100 g/ha) Depth of water body: 30 cm Application window: BBCH 10-19 (Oct.-Feb.)
Main routes of entry	Spray drift: 2.759 d Runoff and drainage: 5% (Northern Europe, autumn application)

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

FOCUS STEP 1	Not reported

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	1.45		2.04	
	24 h	1.45	1.45	2.03	2.04
	2 d	1.44	1.45	2.03	2.03
	4 d	1.44	1.44	2.02	2.03
	7 d	1.43	1.44	2.01	2.02
	14 d	1.40	1.43	1.97	2.01
	21 d	1.38	1.41	1.94	1.99
	28 d	1.36	1.40	1.91	1.97
	42 d	1.31	1.38	1.85	1.94

Metabolite dihydroxy-quinoxaline Parameters used in FOCUSsw step 1 and 2	Molecular weight: 196.6 Maximum in soil: 18.1 % Maximum in water/sediment: 16.7 % Reliable PECsw and PECsed not available. Risk assessment to aquatic organisms was based on the worst case intial PECsed value of quizalofop (25.76 µg/Kg).
Parameters used in FOCUSsw step 3 (if performed)	PEC values were not calculated using step 3

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

Metabolite tetrahydrofurfuryl alcohol Parameters used in FOCUSsw step 1 and 2	Molecular weight: 102.1 Maximum in soil: 59.0 % Maximum in water/sediment: 16.5 % Reliable PECsw and PECsed not available. Risk assessment to aquatic organisms was based on the worst case intial PECsw value of quizalofop (7.41 µg/L).
Parameters used in FOCUSsw step 3 (if performed)	PEC values were not calculated using step 3
Application rate	Crop: potatoes Number of applications: 1 Interval (d): - Application rate(s): parent 100 g/ha Depth of water body: 30 cm Application window: BBCH 10-19 (Oct.-Feb.)

Metabolite tetrahydrofuroic acid Parameters used in FOCUSsw step 1 and 2	Molecular weight: 116.1 Maximum in soil: 9.3 % Maximum in water/sediment: 39.1 % Reliable PECsw and PECsed not available. Data not required (see section 5.2)

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

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

Quizalofop-P-ethyl

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used[1] – Model(s) used: PELMO (FOCUS version 3.3.2) and MACRO (FOCUS version 4.4.2) Scenarios: using PELMO all nine FOCUS scenarios, using MACRO the Châteaudun scenario Crop: sugar beet Input values: **Parent:** - DT_{50lab}: 0.4 d (geometric mean and median, normalisation to 10 kPa/ pF2 and 20 °C with Q10 of 2.2). - K_{OC}: 1816, $^1/_n$: 0.86 (arithmetic mean) - water solubility: 0.61 mg/L - vapour pressure: 1.1 x 10^{-7} Pa - plant uptake factor: 0.5 **Quizalofop-acid:** - DT_{50lab}: 30.9 (median, normalisation to 10 kPa/ pF2 and 20 °C with Q10 of 2.2). - K_{OC}: 245, $^1/_n$: 0.75 (mean value from two soils at environmentally relevant pHs, 6.0 and 7.4) - plant uptake factor: 0.5 - formation fraction: 0.834 (from Quizalofop-P-ethyl) **3-OH-Quizalofop-acid:** - DT_{50lab}: 45.8 d (the worst case value from two soils accepted, normalisation to 10 kPa/ pF2 and 20 °C with Q10 of 2.2). - K_{OC}: 216, $^1/_n$: 0.80 (mean value from two soils at environmentally relevant pHs, 6.0 and 7.4) - plant uptake factor: 0.5 - formation fraction: 0.407 (from Quizalofop-acid) **3-OH-CQO:** - DT_{50lab}: 55.5 d (median, normalisation to 10 kPa/ pF2 and 20 °C with Q10 of 2.2). - K_{OC}: 48, $^1/_n$: 0.80 (the worst case value) - plant uptake factor: 0.5 - formation fraction: 1.0 (from 3-OH-Quizalofop-acid)

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

	For field and lysimeter studies Location: UK, Cottenham and Icklingham Study type (e.g.lysimeter, field): lysimeter Soil properties: - Cottenham: sandy loam/loamy sand, pH 5.0, OC 1.4 % - Icklingham: sand/loamy sand, pH 5.7, OC 0.8 % (MWHC was not available) Dates of application: 9 February 1987 Crop: bare soil Number of applications: one application, 510 g/ha Duration: 12 months Average annual rainfall (mm): 855.1 mm Average annual leachate volume (mm): not available (amounts presented in figures)
Application rate	Application rate: 200 g/ha, sugar beet. No. of applications: 1 Time of application: the earliest possible date 14 days after emergence and the latest possible date 110 days before harvest

[1] Based on the amalgamated list of endpoints for quizalofop, hydroxy-quizalofop and dihydroxy-quinoxaline 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, as the used input parameters are generally worst cases, the experts agreed that no PECgw recalculations are necessary for the applied for intended uses.

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

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

(14 days after emergence / 110 days before harvest)

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Quizalofop-acid	3-OH-Quizalofop-acid	3-OH-CQO
PELMO / Sugar beet	Chateaudun	<0.001 / <0.001	<0.001 / <0.001	<0.001 / <0.001	0.005 / 0.005
	Hamburg	<0.001 / <0.001	<0.001 / <0.001	<0.001 / <0.001	0.008 / 0.008
	Jokioinen	<0.001 / <0.001	<0.001 / <0.001	<0.001 / <0.001	<0.001 / <0.001
	Kremsmunster	<0.001 / <0.001	<0.001 / <0.001	<0.001 / <0.001	0.002 / 0.002
	Okehampton	<0.001 / <0.001	<0.001 / <0.001	<0.001 / <0.001	0.005 / 0.005
	Piacenza	<0.001 / <0.001	<0.001 / <0.001	<0.001 / <0.001	0.073 / 0.080
	Porto	<0.001 / <0.001	<0.001 / <0.001	<0.001 / <0.001	<0.001 / <0.001
	Sevilla	<0.001 / <0.001	<0.001 / <0.001	<0.001 / <0.001	<0.001 / <0.001
	Thiva	<0.001 / <0.001	<0.001 / <0.001	<0.001 / <0.001	<0.001 / <0.001

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

(14 days after emergence / 110 days before harvest)

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Quizalofop-acid	3-OH-Quizalofop-acid	3-OH-CQO
MACRO / Sugar beet	Chateaudun	0 / 0	8×10^{-20}/2×10^{-18}	7×10^{-9}/5×10^{-8}	0.029 / 0.031

$PEC_{(gw)}$ From lysimeter

Parent	1st year	2nd year	3rd year
Annual average (µg/L)	Not detected	Not analysed	Not analysed

Quizalofop-acid	1st year	2nd year	3rd year
Annual average (µg/L)	Not detected	Not analysed	Not analysed

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

Quizalofop-P-tefuryl

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Model used: PELMO 3.3.2 Scenarios and crops: - sugar beet and potatoes using all nine FOCUS scenarios - oil seed rape using Chateaudun, Hamburg, Kremsmünster, Okehampton, Piacenza and Porto scenarios - crop interception: no interception of plant canopy was assumed Input values[1]: **Parent:** - DT_{50lab}: 0.2 d (arithmetic mean, normalisation to 10 kPa/pF2 and 20 °C) - K_{OC}: 0, $^1/_n$= 1 **quizalofop:** - DT_{50lab}: 20.0 d (arithmetic mean, normalisation to 10 kPa/pF2 and 20 °C) - K_{OC}: 293, $^1/_n$= 0.8 (arithmetic means) **hydroxy-quizalofop:** - DT_{50lab}: 15.1 d (arithmetic mean, normalisation to 10 kPa/pF2 and 20 °C) - K_{OC}: 159 (arithmetic mean), $^1/_n$= 1 (linear ads. coeff.) **dihydroxy-quinoxaline:** - DT_{50lab}: 91.8 d (arithmetic mean, normalisation to 10 kPa/pF2 and 20 °C) - K_{OC}: 950 (arithmetic mean), $^1/_n$= 1 (linear ads. coeff.) **tetrahydrofurfuryl alcohol:** - DT_{50lab}: 0.44 d (geometric mean, normalisation to 10 kPa/pF2 and 20 °C) - K_{OC} 0, $^1/_n$= 0.9 Field or lysimeter studies were not conducted
Application rate	Application rate: 100 g/ha. No. of applications: 1 Time of application: - sugar beet: March (Porto) – November (Sevilla) - potatoes: February (Sevilla) – June (Hamburg, Jokioinen, Kremsmünster) - oil seed rape (October - November)

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

[1] The input parameters used in the modelling for quizalofop, hydroxy-quizalofop and dihydroxy-quinoxaline were slightly different from the endpoints agreed in the amalgamated LoEP for these metabolites. However, the experts of PRAPeR 52 considered that it is unlikely that these differences would lead to significant differences in the PECgw results.

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

	Scenario	Parent (µg/L)	Metabolite (µg/L)			
			quizalofop	hydroxy-quizalofop	dihydroxy-quinoxaline	tetrahydrofurfuryl alcohol
PELMO 3.3.2/sugar beet and potatoes	Chateaudun	0.000	0.000	0.000	0.000	0.000
	Hamburg	0.000	0.000	0.000	0.000	0.000
	Jokioinen	0.000	0.000	0.000	0.000	0.000
	Kremsmünster	0.000	0.000	0.000	0.000	0.000
	Okehampton	0.000	0.000	0.000	0.000	0.000
	Piacenza	0.000	0.000	0.001	0.000	0.000 (p),0.002 (s)
	Porto	0.000	0.000	0.000	0.000	0.000
	Sevilla	0.000	0.000	0.000	0.000	0.000 (p),0.003 (s)
	Thiva	0.000	0.000	0.000	0.000	0.000

p = potatoes
s = sugar beet

	Scenario	Parent (µg/L)	Metabolite (µg/L)			
			quizalofop	hydroxy-quizalofop	dihydroxy-quinoxaline	tetrahydrofurfuryl alcohol
PELMO 3.3.2 / oil seed rape	Chateaudun	0.000	0.000	0.000	0.000	0.000
	Hamburg	0.000	0.000	0.000	0.000	0.019
	Jokioinen	-	-	-	-	-
	Kremsmunster	0.000	0.000	0.000	0.000	0.004
	Okehampton	0.000	0.000	0.001	0.000	0.002
	Piacenza	0.000	0.000	0.001	0.000	0.023
	Porto	0.000	0.000	0.000	0.000	0.001
	Sevilla	-	-	-	-	-
	Thiva	-	-	-	-	-

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

The applicant addressed the leaching potential of metabolite tetrahydrofuroic acid (max. in soil 9.3 % AR, max. DT50 3.2 d) based on a conservative ground water risk assessment (Koc of 0 mL/g, formation fraction of 100 %). Even though the reported information on the modelling conducted was considered inadequate for a regulatory submission, the PRAPeR 52 meeting concluded that the potential for contamination of groundwater above the parametric drinking water limit of 0.1 µg/L for tetrahydrofuroic acid is low.

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

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

Parent Quizalofop-P-ethyl:

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	3.0 x 10^{-5} mol x Einstein^{-1} at pH 5 and 25 ^{o}C
Photochemical oxidative degradation in air ‡	DT_{50} of 4.5 hours calculated assuming a hydroxyl radical concentration of 1.5 x 10^{6} per cm^{3}
Volatilisation ‡	from plant surfaces: none in a 24 hour period
	from soil surfaces: <0.3 % applied radioactivity in a 24 hour period
Metabolites	None

Parent Quizalofop-P-tefuryl:

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	$1.2 \cdot 10^{-4}$ mol · Einstein $^{-1}$
Photochemical oxidative degradation in air ‡	DT_{50} of 2.7 hours calculated assuming a hydroxyl radical concentration of 1.5 x 10^{6} per cm^{3}
Volatilisation ‡	from plant and soil surfaces: not studied - no data requested (significant volatilization is not expected)
Metabolites	None

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

Residues requiring further assessment

Parent Quizalofop-P-ethyl:

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: Quizalofop-P-ethyl, Quizalofop, Hydroxy-Quizalofop and dihydroxy-quinoxaline Surface water: Quizalofop-P-ethyl and quizalofop; (from soil surface and runoff) hydroxy-quizalofop and dihydroxy-quinoxaline Sediment: Quizalofop-P-ethyl and Quizalofop Ground water: ~~none~~ quizalofop-P-ethyl, quizalofop, hydroxy-quizalofop and dihydroxy-quinoxaline Air: Quizalofop-P-ethyl

Parent Quizalofop-P-tefuryl:

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: Quizalofop-P-tefuryl, quizalofop, tetrahydrofurfuryl alcohol, Hydroxy-Quizalofop (hydroxy-quizalofop) and dihydroxy-quinoxaline Surface Water: Quizalofop-P-tefuryl, quizalofop, tetrahydrofurfuryl alcohol and tetrahydrofuroic acid (hydroxy-quizalofop from soil surface runoff and drainage) Sediment: Quizalofop-P-tefuryl, quizalofop, CQOP, dihydroxy-quinoxaline Ground water:quizalofop-P-tefuryl, quizalofop, tetrahydrofurfuryl alcohol, hydroxy-quizalofop (hydroxy-quizalofop), dihydroxy-quinoxaline and tetrahydrofuroic acid Air: Quizalofop-P-tefuryl

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

Parent Quizalofop-P-ethyl:

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 detects in water in Holland during 1999 (National monitoring program)
Air (indicate location and type of study)	No data available

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

Parent Quizalofop-P-tefuryl:

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

Quizalofop-P-tefuryl and Quizalofop-P-ethyl:

Candidate for R53

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

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

Species	Test substance	Time scale	Endpoint (mg/kg bw/day)	Endpoint (mg/kg feed)
Birds ‡				
Bobwhite quail (*Colinus virginianus*)	a.s. (Quizalofop-ethyl)	Acute		LD_{50} > 2000
Bobwhite quail	a.s. (Quizalofop-P-tefuryl)	Acute		LD_{50} > 2150
Mallard duck (*Anas platyrhynchos*)	a.s. (Quizalofop-ethyl)	Acute		LD_{50} > 2000
Mallard duck	a.s. (Quizalofop-P-ethyl)	Acute		LD_{50} > 2000
Mallard duck	a.s. (Quizalofop-P-tefuryl)	Acute		LD_{50} > 2150
Bobwhite quail	a.s. (Quizalofop-ethyl)	Short-term	LC_{50} > 1123	LC_{50} > 5000
Bobwhite quail	a.s. (Quizalofop-P-tefuryl)	Short-term	LC_{50} > 486.6	LC_{50} > 5000
Mallard duck	a.s. (Quizalofop-ethyl)	Short-term	LC_{50} > 1258	LC_{50} > 5000
Mallard duck	a.s. (Quizalofop-P-tefuryl)	Short-term	LC_{50} > 258.6	LC_{50} > 5000
Bobwhite quail	a.s. (Quizalofop-P-ethyl)	Long-term	NOEC = 87.6	NOEC = 1000
Bobwhite quail	a.s. (Quizalofop-P-tefuryl)	Long-term	NOEC = 69.4	NOEC = 625
Mallard duck	a.s. (Quizalofop-P-ethyl)	Long-term	NOEC = 58.0	NOEC = 500
Mallard duck	a.s. (Quizalofop-P-tefuryl)	Long-term	NOEC = 68.7	NOEC = 625

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

Mammals ‡				
Rat	a.s. (Quizalofop-P-ethyl)	Acute	LD_{50} = 1182	
	a.s. (Quizalofop-P-tefuryl)	Acute	LD_{50} = 1012	
	Preparation Targa super (a.s. Quizalofop-P-ethyl)	Acute	LD_{50} = 2551 (127.6 mg a.s/kg bw)	
	Metabolite	Acute	-	-
	a.s. (Quizalofop-P-ethyl)	Long-term	NOAEL = 9.45	
	a.s. (Quizalofop-P-tefuryl)	Long-term	NOAEL = 16.9	
Additional higher tier studies ‡: Not required				

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

Quizalofop-P-ethyl (Sugar beet, 200 g a.s./ha)

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Leafy crops/herbivorous bird	Acute	13.22	151	10
Leafy crops/insectivorous bird	Acute	10.82	185	10
Leafy crops/herbivorous bird	Short-term	6.08	185	10
Leafy crops/insectivorous bird	Short-term	6.03	186	10
Leafy crops/herbivorous bird	Long-term	3.22	18	5
Leafy crops/insectivorous bird	Long-term	6.03	9.6	5
Earthworm eating bird	Long-term	1.23	47	5
Fish eating bird	Long-term	0.013	4531	5
Exposure via drinking water	Acute	54	>37	10

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

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Mammals)				
Leafy crops/herbivorous mammal	Acute	4.87	243	10
Leafy crops/herbivorous mammal	Long-term	1.19	**7.96**	5
Fish eating mammal	Long-term	0.008	304	5
Earthworm eating mammal	Long-term	1.57	**6.0**	5
Exposure via drinking water	Acute	31.38	38	10
Higher tier refinement (Mammals)				

[1] in higher tier PT and PD refinement has been taken into account
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

Quizalofop-P-tefuryl (Leafy crops, 0.1 kg a.s./ha)

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Leafy crops/herbivorous bird	Acute	6.61	325	10
Leafy crops/insectivorous bird	Acute	5.41	398	10
Exposure via drinking water	Acute	27	>79	10
Leafy crops/herbivorous bird	Short-term	3.04	85	10
Leafy crops/insectivorous bird	Short-term	3.02	86	10
Leafy crops/herbivorous bird	Long-term	1.61	43	5
Leafy crops/insectivorous bird	Long-term	3.02	23	5
Fish eating birds	Long-term	0.0014	49086	5
Earthworm eating birds	Long-term	0.0044	15618	5

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

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Higher tier refinement (Birds)	Not required			
	Acute			10
	Short-term			10
	Long-term			5
Tier 1 (Mammals)				
Leafy crops/medium herbivorous mammal	Acute	2.44	415	10
Exposure via drinking water	Acute	15.69	64	10
Leafy crops/medium herbivorous mammal	Long-term	0.59	29	5
Fish eating mammal	Long-term	0.000884	19118	5
Earthworm eating mammal	Long-term	0.0056	3018	5
Higher tier refinement (Mammals)	Not required			
	Acute			10
	Long-term			5

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

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

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
Bluegill sunfish (*Lepomis macrochirus*)	a.s. (Quizalofop-P-ethyl)	96 hr (flow-through)	Mortality, LC_{50}	**0.21** (mm)
Bluegill sunfish (*Lepomis macrochirus*)	a.s. (Quizalofop-P-tefuryl)	96 hr (flow-through)	Mortality, LC_{50}	0.23 (mm)
Rainbow trout (*Oncorhynchus mykiss*)	a.s. (Quizalofop-P-ethyl)	21 d (semistatic)	Growth NOEC	**0.044** (mm)

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

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (mg/L)
Rainbow trout (*Oncorhynchus mykiss*)	a.s. (Quizalofop-P-tefuryl)	Chronic study	NOEC	n.a. Not required[3]
Rainbow trout (*Oncorhynchus mykiss*)	Preparation (a.s. Quizalofop-P-ethyl)	96 hr (static)	Mortality, LC_{50}	0.21 (nom)[2] 4.2 mg prep./L
Rainbow trout (*Oncorhynchus mykiss*)	Preparation (a.s. Quizalofop-P-tefuryl)	96 hr (flow-through)	Mortality, LC_{50}	0.36 (mm)[2] 8.2 mg prep./L
Rainbow trout *Oncorhynchus mykiss*	Quizalofop	96 hr Static test	Mortality, LC_{50}	**>100** nom[a]
Rainbow trout *Oncorhynchus mykiss*	Quizalofop	28 d (flow-through)	Growth 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]
	Metabolite tetrahydrofurfuryl alcohol	96 h (semi-static)	Mortality, LC_{50}	>100 (mm)[c]
Aquatic invertebrate				
Daphnia magna	a.s. (Quizalofop-P-ethyl)	48 h (semistatic)	Mortality, EC_{50}	**0.29** (mm)
Daphnia magna	a.s. Quizalofop-P-tefuryl	48 h (flow-through)	Mortality, EC_{50}	>1.5 (mm)
Daphnia magna	a.s. (Quizalofop-P-ethyl)	21 d (semistatic)	Reproduction, NOEC	**0.023** (mm)

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

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (mg/L)
Daphnia magna	a.s. (Quizalofop-P-tefuryl)	Chronic study	NOEC	n.a. Not required[3]
Daphnia magna	Preparation (a.s. Quizalofop-P-ethyl)	48 h (static)	Mortality, EC_{50}	0.35 (nom)[2] 6.87 mg prep./L
Daphnia magna	Preparation (a.s. Quizalofop-P-tefuryl)	48 h (semi-static)	Mortality, EC_{50}	**0.21** (mm)[2] 4.8 mg prep./L
Daphnia magna	Preparation	21 d (static)	Reproduction, NOEC	No study provided. No study needed.
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]
Daphnia magna	Metabolite (tetrahydrofurfuryl alcohol)	48 h (static)	Mortality, EC_{50}	>100 (mm)[c]
Sediment dwelling organisms				
Chironomus riparius	a.s.	28 d (static)	NOEC	No study provided. No study needed.
Chironomus riparius	Metabolite Quizalofop	28 d (static) Water spiked sys.	NOEC	**35.7** nom[b]

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

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (mg/L)
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	a.s. (Quizalofop-P-ethyl)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	**0.021** (mm) 0.069 (mm)
Pseudokirchneriella subcapitata	a.s. (Quizalofop-P-tefuryl)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>1.9 (mm) >1.9 (mm)
Navicula pelliculosa	a.s. (Quizalofop-P-tefuryl)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.60 (mm) 1.3 (mm)
Pseudokirchneriella subcapitata	Preparation (a.s. Quizalofop-P-ethyl)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} Biomass: E_bC_{50} Growth rate: E_rC_{50}	**0.024** $(mm)^2$ 0.060 $(mm)^2$ 1.1 mg prep./L 0.45 mg prep./L
Pseudokirchneriella subcapitata	Preparation (a.s. Quizalofop-P-tefuryl)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} Biomass: E_bC_{50} Growth rate: E_rC_{50}	**0.01** $(mm)^2$ 0.03 $(mm)^2$ 0.31 mg prep./L 0.65 mg prep./L
Navicula pelliculosa	Preparation (a.s. Quizalofop-P-tefuryl)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.44 $(mm)^2$ 0.57 $(mm)^2$ 10.9 mg prep./L 14.3 mg prep./L
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

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

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (mg/L)
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
Scenedesmus subspicatus	Metabolite (tetrahydrofurfuryl alcohol)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>100 (mm)[c] >100 (mm)[c]
Higher plant				
Lemna gibba	a.s. (Quizalofop-P-ethyl)	7 d (static)	Fronds, EC_{50}	**0.098** (nom)
Lemna gibba	a.s. (Quizalofop-P-tefuryl)	14 d (static)	Fronds, EC_{50} Fronds, NOEC	2.1 (nom) 0.38 (nom)
	Preparation (a.s. Quizalofop-P-tefuryl)	14 d (static)	Fronds, EC_{50}	No study provided. Not required.
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				

n.a. = not available
[1] Indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). Endpoints used in aquatic risk assessment are highlighted in bold.
[2] Endpoint is presented as units of a.s.
[3] DT_{50} in water less than two days and only one application
a) Endpoint from propaquizafop DAR
b) Endpoint from quizalofop-P-ethyl DAR
c) Endpoint from quizalofop-P-tefuryl DAR

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

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

FOCUS Step 2

Quizalofop-P-ethyl: Sugar beet, 0.2 kg as/ha, growth stage between 10 and 19, the worst case 'Southern Europe' maximum PEC_{sw} and PEC_{sed} values.

Test substance	N/S	Organism	Toxicity endpoint (µg/L)	Time scale	PEC_{max} (µg/L)	TER	Annex VI Trigger
a.s.	S	Fish	209	Acute	1.84	114	100
a.s.	S	Fish	44	Chronic	1.84	24	10
a.s.	S	Aquatic invertebrates	290	Acute	1.84	158	100
a.s.	S	Aquatic invertebrates	23	Chronic	1.84	13	10
a.s.	S	Algae	21	Chronic	1.84	11	10
a.s.	S	Higher plants	98.1	Chronic	1.84	53	10
Quizalofop	S	Fish (*O. mykiss*)	>100,000	96 h	12.75	7843	100
Quizalofop	S	Fish (*O. mykiss*)	46200	28 d	12.75	3624	10
Quizalofop	S	Aquatic invertebrates (*D. magna*)	57,700	48 h	12.75	4525	100
Quizalofop	S	Aquatic invertebrates (*D. magna*)	820	21 d	12.75	64.3	10
Quizalofop	S	Sediment dwelling organisms (*C. riparius*)	35,700	28 d	12.75	2800	10
Quizalofop	S	Algae (*S. subcapitata*)	54,500	72 h	12.75	4275	10
Quizalofop	S	Higher plant (*L. gibba)*	3,200	14 d	12.75	251	10
Quizalofop	S	Higher plant (*G. fluitans*)	94	14 d	12.75	**7.4**	10
Dihydroxy quinoxaline	S	*Rainbow trout* Oncorhynchus mykiss	>11,200	96 h	1.25	8,960	10
Dihydroxy quinoxaline	S	*Daphnia magna*	9,800	48	1.25	7,840	10
Dihydroxy quinoxaline	S	*Scenedesmus subspicatus*	8,600	72	1.25	6,880	10
Hydroxy quizalofop	S	Fish (*O. mykiss*)	>100,000	96 h	2.41	41494	100
Hydroxy quizalofop	S	Aquatic invertebrates (*D. magna*)	>100,000	48 h	2.41	41494	100

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

Test substance	N/S	Organism	Toxicity endpoint (µg/L)	Time scale	PEC_{max} (µg/L)	TER	Annex VI Trigger
Hydroxy quizalofop	S	Algae (*S. subcapitata*)	>100,000	72 h	2.41	41494	10
Preparation (a.s. Quizalofop-P-ethyl)	S	Algae	24	Chronic	1.84	13	10

FOCUS Step 3

Quizalofop-P-ethyl: Sugar beet, 0.2 kg as/ha, growth stage between 10 and 19.

Test substance	Scenario/water body	Organism	Toxicity endpoint (µg/L)	Time scale	PEC	**TER**	Annex VI Trigger
Quizalofop	D3,early/ditch	Higher plant (*G. fluitans*)	94	14 d	0.968	97.11	10
	D3, late/ditch				0.972	96.71	10
	D4, early/pond				0.0404	2326.73	10
	D4, late/pond				0.0391	2404.09	10
	D4, early/stream				0.814	115.48	10
	D4, late/stream				0.802	117.21	10
	R1, early/pond				0.139	676.26	10
	R1, late/pond				0.0928	1012.93	10
	R1, early/stream				1.588	59.19	10
	R1, late/stream				0.673	139.67	10
	R3, early/stream				2.492	37.72	10
	R3, late/stream				2.984	31.50	10

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

FOCUS Step 2

Quizalofop-P-tefuryl, potatoes, 100 g as/ha, BBCH 10-19, crop interception 15 %, Northern Europe (Oct.-Feb.), worst case maximum PEC_{SW} and PEC_{SED} values

Test substance	N/S	Organism	Toxicity endpoint (µg/L)	Time scale	PEC	TER	Annex VI Trigger
a.s.	N	Fish	230	Acute	0.92	250	100
a.s.	N	Aquatic invertebrates	>1500	Acute	0.92	1630	100
a.s.	N	Algae	600	Chronic	0.92	652	10
a.s.	N	Higher plants	380	Chronic	0.92	413	10
Quizalofop	N	Fish (*O. mykiss*)	>100,000	96 h	7.41[2]	>13495.28	100
Quizalofop	N	Fish (*O. mykiss*)	46200	28 d	7.41[2]	6234.82	10
Quizalofop	N	Aquatic invertebrates (*D. magna*)	57,700	48 h	7.41[2]	7786.77	100
Quizalofop	N	Aquatic invertebrates (*D. magna*)	820	21 d	7.41[2]	110.66	10
Quizalofop	N	Sediment dwelling organisms (*C. riparius*)	35,700	28 d	7.41[2]	4817.81	10
Quizalofop	N	Algae (*S. subcapitata*)	54,500	72 h	7.41[2]	7354.93	10
Quizalofop	N	Higher plant (*L. gibba)*	3,200	14 d	7.41[2]	431.85	10
Quizalofop	N	Higher plant (*G. fluitans*)	94	14 d	7.41[2]	12.69	10
Tetrahydrofurfuryl alcohol	N	Fish (*O. mykiss*)	>100,000	96 h	7.41[3]	13,495	100
Tetrahydrofurfuryl alcohol	N	Aquatic invertebrates (*D. magna*)	>100,000	48 h	7.41[3]	13,495	100
Tetrahydrofurfuryl alcohol	N	Algae (*S. subcapitata*)	>100,000	72 h	7.41[3]	13,495	10
Hydroxy quizalofop	N	Fish (*O. mykiss*)	>100,000	96 h	1.45[4]	7x10[4]	100

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

Test substance	N/S	Organism	Toxicity endpoint (µg/L)	Time scale	PEC	TER	Annex VI Trigger
Hydroxy quizalofop	N	Aquatic invertebrates (*D. magna*)	>100,000	48 h	1.45[4]	7x10[4]	100
Hydroxy quizalofop	N	Algae (*S. subcapitata*)	>100,000	72 h	1.45[4]	7x10[4]	10
Quizalofop phenol	N	Sediment dwelling organisms	10,000 (µg/kg)	28 d	25.8[5] (µg/kg)	388	10
Dihydroxy quinoxaline	N	Sediment dwelling organisms	1,480 (µg/kg)	28 d	25.8[5] (µg/kg)	57.4	10
Preparation	N	Aquatic invertebrates	210[1]	48 h	0.92	228	100
Preparation	N	Algae	10[1]	72 h	0.92	10.9	10

[1] endpoint is presented as units of a.s.
[2] A new FOCUS Step 2 PECsw for quizalofop was calculated by EFSA after the peer-review
[3] No reliable FOCUS PEC_{sw}. were available. Initial PEC_{sw} at Step 2 for quizalofop (as re-calculated by EFSA after the peer review with the agreed endpoints) was used as worst case value.
[4] No reliable FOCUS PEC_{sw}. were available. FOCUS Step 2 PEC_{sw} for Tetrahydrofurfuryl alcohol was estimade by EFSA.
[5] No reliable FOCUS PEC_{sw}. were available. Initial PEC_{sw} at Step 2 for quizalofop (as re-calculated by EFSA after the peer review with the agreed endpoints) was used as worst case value.

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

Refined aquatic risk assessment using higher tier FOCUS modelling: Not needed

	Active substance (Quizalofop-P-ethyl)	Active substance (Quizalofop-P-tefuryl)	Metabolite (Quizalofop-P-acid)
$logP_{O/W}$	4.61	4.32	2.22**
Bioconcentration factor (BCF)[1] ‡	380*	27 (maximum fillet)* 340 (maximum whole fish)* 600 (maximum viscera)*	
Annex VI Trigger for the bioconcentration factor	100	100	
Clearance time (days) (CT_{50})	Not calculated	0.94 ± 0.27	
(CT_{90})	Not calculated	<3	
Level and nature of residues (%) in organisms after the 14 day depuration phase	< 1 % of day 28 exposure levels remained in whole fish	<1 % of day 28 exposure levels remained in whole fish (this radioactivity was not analysed)	

[1] only required if log $P_{O/W}$ >3.
* based on total ^{14}C
** Endpoint from the study of Quizalofop-P-ethyl DAR

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

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

Test substance	Acute oral toxicity (LD_{50} µg a.s./bee)	Acute contact toxicity (LD_{50} µg a.s./bee)
a.s. (Quizalofop-P-ethyl)	> 100	> 100
a.s. (Quizalofop-P-tefuryl)	-	>100
Preparation (expressed in units of a.s Quizalofop-P-ethyl)	10.4	> 25
Preparation (expressed in units of a.s Quizalofop-P-tefuryl)	16.8	>40
Metabolite	No study submitted, not required	No study submitted, not required
Field or semi-field tests: not required		

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

Sugar beet, , 0.2 kg as/ha

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s. (Quizalofop-P-ethyl)	Contact	< 2	50
a.s. (Quizalofop-P-tefuryl)	Contact	<1	50
a.s. (Quizalofop-P-ethyl)	oral	< 2	50
a.s. (Quizalofop-P-tefuryl)	oral	-	50
Preparation (a.s. Quizalofop-P-ethyl)	Contact	< 8	50
Preparation (a.s. Quizalofop-P-tefuryl)	Contact	<2.5	50
Preparation (a.s. Quizalofop-P-ethyl)	oral	19	50
Preparation (a.s. Quizalofop-P-tefuryl)	oral	6.0	50

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

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	50 g/L EC (a.s. Quizalofop-P-ethyl)	Mortality	25
Typhlodromus pyri	40 g/L EC (a.s. Quizalofop-P-tefuryl)	Mortality	< 100 (100% mortality at 100g a.s./ha)
Aphidius rhopalosiphi	50 g/L EC (a.s. Quizalofop-P-ethyl)	Mortality	48.5
Aphidius rhopalosiphi	40 g/L EC (a.s. Quizalofop-P-tefuryl)	Mortality	< 100 (100% mortality at 100g a.s./ha)

Sugar beet, 200 g a.s./ha

Test substance	Species	Effect (LR_{50} g a.s./ha)	HQ in-field	HQ off-field[1]	Trigger
50 g/L EC (a.s. Quizalofop-P-ethyl)	*Typhlodromus pyri*	25	**8**	0.22	2
40 g/L EC (a.s. Quizalofop-P-tefuryl)	*Typhlodromus pyri*	< 100	**> 1**	> 0.0277	2
50 g/L EC (a.s. Quizalofop-P-ethyl)	*Aphidius rhopalosiphi*	48.5	**4.12**	0.11	2
40 g/L EC (a.s. Quizalofop-P-tefuryl)	*Aphidius rhopalosiphi*	< 100	**> 1**	> 0.0277	2

[1] distance assumed to calculate the drift rate = 1 m

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

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	Endpoint	% effect[1]	Trigger value
P. cupreus	Adult	EXP 30650 (49.0 g a.s./L), sand, 16 d	98 g a.s./ha (initial residues)	Mortality	0[3]	50 %
P. cupreus	Adult	40 g/L EC, sand, 14 d	100 (ir)	Mortality	0[2]	50 %
Pardosa Sp.	Adult	40 g/L EC, sand, 14 d	100 (ir)	Mortality	10[2]	50 %
Agonum dorsale	Adult	40 g/L EC, sand, 14 d	100 (ir)	Mortality	0[2]	50 %
A. bilineata	Adult	EXP 30650 (49.0 g a.s./L), sand, 36 d	100 g a.s./ha (initial residues)	Mortality Reproduction	0[3] -1.6	50 %
C. carnea	Larvae	EXP 30650B (53.8 g a.s./L), glass plate	200 g a.s./ha (initial residues)	Mortality Eggs/female/d	10[3] -11	50 %
C. carnea	First instar	40 g/L EC, glass plate	100 (ir)	Mortality Reproduction	83.9[2] -1.1	50 %
Aphidius rhopalosiphi	Adult	50 g/L EC, barley plants, 48 h	2, 10, 20, 100 and 200	Survival & fecundity	No adverse effects on mortality. [3] No statistically significant fecundity. Reduction in reproduction <26 % in all groups	50 %
A. bilineata	Adult	40 g/L EC, soil, 28 d	90 (ir)	Mortality Reproduction	0[2] 2.6	50 %
A. colemani	Adult	40 g/L EC, bean leaves, 14 d	90 (ar)	Mortality Reproduction	0[2] 46.3	50 %

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

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	Endpoint	% effect[1]	Trigger value
Tyhlodromus pyri	Protonymph	50 g/l EC, bean leaves, 7 d	6.25, 12.5, 25, 50, 100, 200	Survival and reproduction	LR_{50}: 106.9 g a.i./ha[3] No statistically significant reduction in reproduction at ≤100g a.s./ha, 80 % reduction in mortality at 200 g a.s./ha	50 %
T. pyri	Proto-nymph	40 g/L EC, bean leaves, 48 h	4 (ir) 4 (ir) 50 (ir) 50 (ir) 100 (ir)	Mortality Reproduction Mortality Reproduction Mortality	6.7[2] 14.5 28.9 32.3 51.1	50 %

[1] Positive effect indicate adverse effect, negative result indicate higher reproduction when compared to controls.
[2] Endpoint from quizalofop-P-tefuryl DAR
[3] Endpoint from quizalofop-P-ethyl DAR

Field or semi-field tests: 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[1]
Earthworms			
Eisenia foetida	a.s. Quizalofop-P-ethyl	Acute 14 days	LC_{50corr} > 500 mg a.s./kg d.w.soil
	a.s. Quizalofop-P-tefuryl	Acute 14 days	LC_{50corr} >500 mg a.s./kg d.w.soil
	a.s.	Chronic 8 weeks	Not submitted. Not required

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

Test organism	Test substance	Time scale	Endpoint[1]
	Preparation (a.s. Quizalofop-P-ethyl)	Acute 14 days	LC_{50corr} = 18.5 mg a.s./kg d.w.soil
	Preparation (a.s. Quizalofop-P-tefuryl)	Acute 14 days	LC_{50corr} 16.95 mg a.s./kg d.w.soil
	Preparation	Chronic	Not submitted. Not required
Eisenia foetida	Quizalofop	Acute	14 day LC_{50}: 948 mg/kg dw soil[3] (corrected to 474 mg a.s./kg soil
Eisenia foetida	Quizalofop	Chronic	NOEC > 50 mg/kg dw soil[3] (corrected to 25 mg/kg)
Eisenia foetida	Dihydroxy quinoxaline	Acute	14 day LC_{50}: >1000 mg/kg soil[3] [4] (corrected to >500 mg a.s./kg soil)
Eisenia foetida	Hydroxy quizalofop	Acute	14 day LC_{50}: >1000 mg/kg soil[3] [4] (corrected to >500 mg a.s./kg soil)
Other soil macro-organisms			
Soil mite	a.s. ‡		Not submitted. Not required.
	Preparation		Not submitted. Not required.
	Metabolite 1		Not submitted. Not required.
Collembola			
	a.s. ‡	Chronic	Not submitted. Not required
	Preparation		Not submitted. Not required.
	Metabolite 1		Not submitted. Not required.
Soil micro-organisms			
Nitrogen mineralisation	Preparation (Targa, a.s. Quizalofop-P-ethyl)		No effect at day 60 at 1.23 mg a.s./kg d.w.soil (925 g a.s/ha)
	Preparation (40 g/L EC, a.s. Quizalofop-P-tefuryl)		Max. effect/proposed field rate: +11.1 % deviation from control at day 28 at 0.133 mg a.s./kg d.w.soil (mg 100 a.s./ha) (not statistically significant)
	Metabolite		Not submitted. Not required.

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

Test organism	Test substance	Time scale	Endpoint[1]
Carbon mineralisation	Preparation (Targa, a.s. Quizalofop-P-ethyl)		No effect at day 60 at 1.23 mg a.s./kg d.w.soil (925 g a.s/ha)
	Preparation (40 g/L EC, a.s. Quizalofop-P-tefuryl)		Max. effect/proposed field rate: +13.6 % deviation from control at day 29 at 0.133 mg a.s./kg d.w.soil (mg 100 a.s./ha) (not statistically significant)
	Metabolite		Not submitted. Not required.
Field studies[2]: Not submitted. Not required.			

[1] indicate where endpoint has been corrected due to log Pow >2.0 (e.g. LC_{50corr})
[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies
[3] Endpoint from the study of Quizalofop-P-ethyl DAR
[4] Endpoint from the study of Quizalofop-P-tefuryl DAR

Toxicity/exposure ratios for soil organisms

Toxicity/exposure ratios for soil organisms

Quizalofop-P-ethyl: Sugar beet, , 0.2 kg as/ha

Test organism	Test substance	Time scale	Soil $PEC_{initial}$ (mg a.s./kg)	TER	Trigger
Earthworms					
	a.s. ‡	Acute	0.2133	2344	10
	a.s. ‡	Chronic	-	-	5
	Preparation	Acute	0.2133	87	10
	Preparation	Chronic	-	-	5
	quizalofop	Acute	0.1207	3927	10
	quizalofop	Chronic	0.1207	207	5
	Hydroxy quizalofop	Acute	0.0051	>196078	
	Dihydroxy quinoxaline	Acute	0.0040	>250000	

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

Test organism	Test substance	Time scale	Soil $PEC_{initial}$ (mg a.s./kg)	TER	Trigger
Other soil macro-organisms					
Soil mite	a.s. ‡	-	-	-	-
	Preparation	-	-	-	-
	Metabolite 1	-	-	-	-
Collembola	a.s. ‡	-	-	-	-
	Preparation	-	-	-	-
	Metabolite 1	-	-		-

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

Quizalofop-P-tefuryl, potatoes, 100 g a.s./ha

Test organism	Test substance	Time scale	Soil $PEC_{initial}$ (mg a.s./kg)	TER	Trigger
Earthworms					
	a.s. ‡	Acute	0.113	4425	10
	a.s. ‡	Chronic	-	-	5
	Preparation	Acute	0.113	150	10
	Preparation	Chronic	-	-	5
	Metabolite dihydroxy-quinoxaline	Acute	0.009	>111111	10
	Metabolite hydroxy-quizalofop	Acute	0.020	>50000	5

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

Test organism	Test substance	Time scale	Soil $PEC_{initial}$ (mg a.s./kg)	TER	Trigger
Other soil macro-organisms					
Soil mite	a.s. ‡	-	-	-	-
	Preparation	-	-	-	-
	Metabolites	-	-	-	-
Collembola	a.s. ‡	-	-	-	-
	Preparation	-	-	-	-
	Metabolites	-	-	-	-

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

Quizalofop-P-ethyl: Laboratory dose response tests

Most sensitive species	Test substance	Testing endpoint	ER_{50} (g a.s./ha)	Distance (m)	Exposure[1] (g a.s./ha)	TER	Trigger
Zea mays	Targa Super (a.s. Quizalofop-P-ethyl)	seedling emergence	52.31	1	5.54	9.4	5
		vegetative vigour	5.46	1	5.54	**1.0**	5
				5	1.14	**4.8**	5
				10	0.58	9.4	5
Avena sativa	Targa Super (a.s. Quizalofop-P-ethyl)	seedling emergence	59.29	1	5.54	10.7	5
		vegetative vigor	15.29	1	5.54	**2.8**	5
				5	1.14	13.4	5

[1] Exposure has been estimated based on Ganzelmeier drift data

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

Not required

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

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

Test type/organism	endpoint
Activated sludge (a.s Quizalofop-P-ethyl)	EC_{50} for respiration > 100 mg a.s./L

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

Compartment	
soil	-
water	-
sediment	-
groundwater	-

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

	RMS/peer review proposal
Active substance	N, R50/53

	RMS/peer review proposal
Preparation	N, R50/53

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

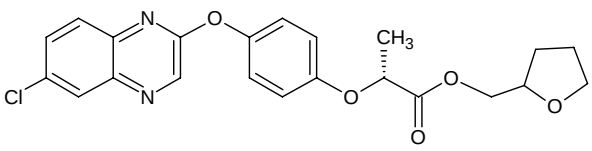
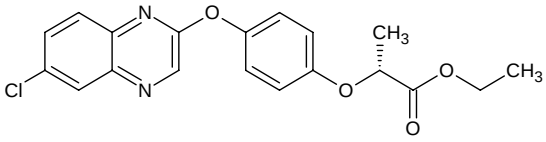
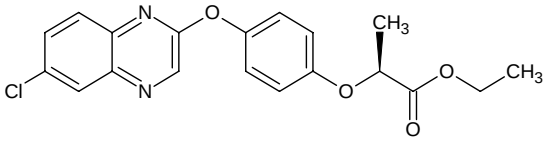
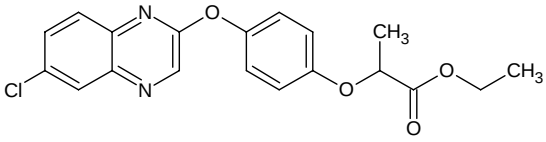
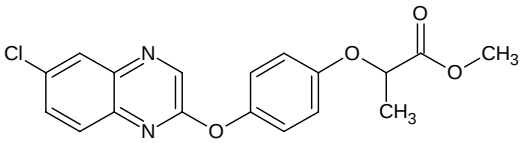
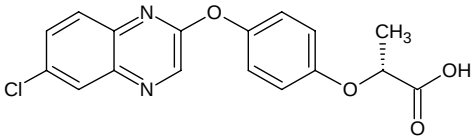
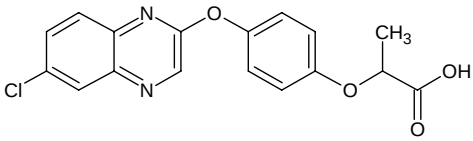
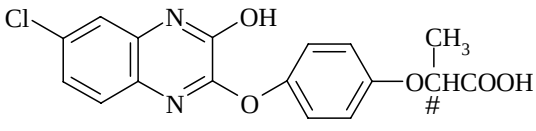
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HQ	hazard quotient
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
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
MHC	moisture holding capacity
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

Appendix 2 – abbreviations

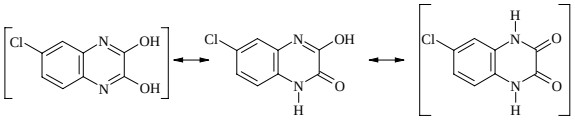
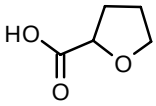
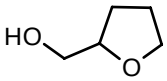
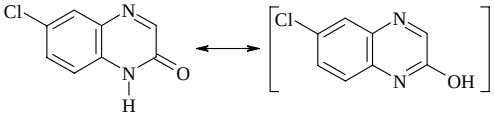
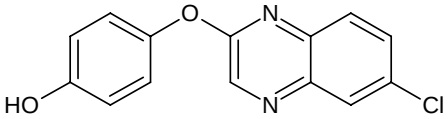
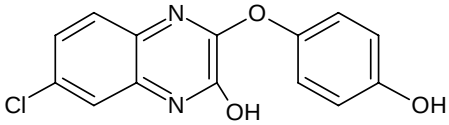
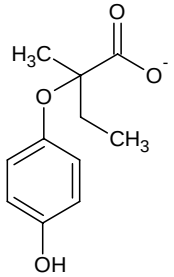
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
FTF	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)

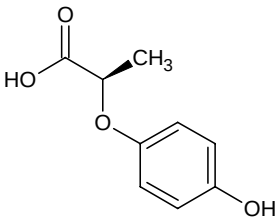
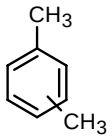
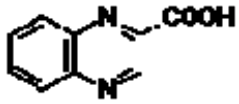
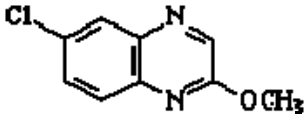
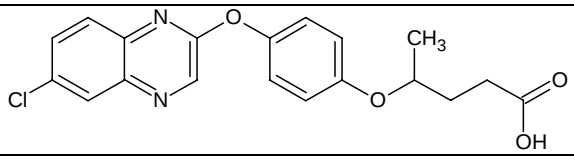
APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
Quizalofop-P-tefuryl	(*RS*)-tetrahydrofurfuryl (*R*)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate	
Quizalofop-P-ethyl	ethyl (2*R*)-2-{4-[(6-chloroquinoxalin-2-yl)oxy]phenoxy}-propanoate	
Quizalofop-S-ethyl	ethyl (2*S*)-2-{4-[(6-chloroquinoxalin-2-yl)oxy]phenoxy}-propanoate	
Quizalofop-ethyl	ethyl-2-{4-[(6-chloroquinoxalin-2-yl)oxy]phenoxy}-propanoate	
Quizalofop-methyl ME-DPX-Y6202	methyl 2-{4-[(6-chloroquinoxalin-2-yl)oxy]phenoxy}-propanoate	
Quizalofop-P CGA 287422	(*R*)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionic acid	
Quizalofop QUIZ Quizalofop acid Propaquizafop acid	2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionic acid	
Hydroxy-quizalofop QUIZ-OH Hydroxy-quizalofop acid 3-OH-Quizalofop-acid OH-Quizalofop Hydroxy propaquizafop acid	2-[4-(6-Chloro-3-hydroxyquinoxalin-2-yloxy)phenoxy]propionic acid	 # chiral centre

Appendix 3 – used compound code(s)

Code/Trivial name*	Chemical name	Structural formula
Dihydroxychloroquinoxalin Dihydroxy quinoxaline Hydroxy Phenol 2 CHHQ	6-chloroquinoxaline-2,3-diol	
THFAC Tetrahydrofuroic acid	tetrahydrofuran-2-carboxylic acid	
THFA Tetrahydrofurfuryl alcohol 2-Hydroxymethyl tetrahydrofurane	tetrahydrofuran-2-ylmethanol	
CHQ Hydroxy quinoxaline CQO Phenol 2 6-Chloro-2-hydroxyquinoxaline	6-chloroquinoxalin-2-ol	
Quizalofop-phenol Phenol 1 Hydroxyl ether CQOP QHQ	4-(6-chloroquinoxalin-2-yloxy)phenol	
Hydroxy-quizalofop-phenol	7-chloro-3-(4-hydroxyphenoxy)-quinoxalin-2-ol	
Dihydroxy-quizalofop-phenol	–	See hydroxy-quizalofop-phenol, the position of the additional hydroxy group is unknown.
EPP Ethyl-hydroxyphenoxy propionate Phenol 3	Ethyl-2-(4-hydroxyphenoxy)-propionate	

Appendix 3 – used compound code(s)

Code/Trivial name*	Chemical name	Structural formula
PPA Phenoxy acid Hydroxyphenoxy-propionic acid Phenol 4	(*R*)-2-(4-hydroxyphenoxy)propionic acid	
Hydroquinone Quinol	Benzene-1,4-diol	
Xylene	–	
Q2C-ACID	Quinoxaline-2-carboxylic acid	
MCQ	2-methoxy-6-chloroquinoxaline	
Quizalofop-pentanoic acid	4-{4-[(6-chloroquinoxalin-2-yl)oxy]phenoxy}pentanoic acid	

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