CONCLUSION ON PESTICIDE PEER REVIEW

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

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SUMMARY

Quinmerac is one of the 84 substances of the third stage part B of the review programme covered by Commission Regulation (EC) No 1490/2002[3], as amended by Commission Regulation (EC) No 1095/2007[4]. In accordance with the Regulation, at the request of the Commission of the European Communities (hereafter referred to as 'the Commission'), the EFSA organised a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the United Kingdom, being the designated rapporteur Member State (RMS). The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of quinmerac in Annex I to Council Directive 91/414/EEC.

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

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

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 22 June 2009. The EFSA collated and forwarded all comments received to the Commission on 5 August 2009.

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

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of quinmerac as a herbicide on oilseed rape, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

1 On request from the European Commission, Question No EFSA-Q-2009-00785, issued on 26 February 2010.
2 Correspondence: praper@efsa.europa.eu
3 OJ L224, 21.08.2002, p.25
4 OJ L 246, 21.9.2007, p. 19
5 OJ L 333, 11.12.2008, p.11
6 OJ L 15, 18.01.2008, p.5
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There was a data gap identified in the section physical and chemical properties of the active substance.

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

In the residues area, for the specific use on oilseed rape, plant metabolism has been reasonably addressed. An outstanding issue in plant metabolism is clarification on the potential for opening of the quinoline ring structure. In rotational crops, significant residues may occur at shorter plant back intervals, and further data are required to address residue levels in these crops. This may have implications for the risk assessment but it is not a critical area of concern.

The fate and behaviour of quinmerac and its metabolites in the environment has been adequately investigated and end points have been derived, allowing the risk assessment to be completed at EU level.

The risk to birds and mammals from the representative formulation was not addressed. Furthermore, a critical area of concern was identified by EFSA regarding the long-term risk to earthworms from the soil metabolite BH 518-5, based on the indications of a high risk from existing data. For all other non-target organisms the risk from the representative use was assessed as low.

KEY WORDS

Quinmerac, peer review, risk assessment, pesticide, herbicide

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BACKGROUND

Legislative framework

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

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

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

Quinmerac is one of the 84 substances of the third stage part B of the review programme covered by Commission Regulation (EC) No 1490/2002, as amended by Commission Regulation (EC) No 1095/2007. In accordance with the Regulation, at the request of the Commission, the EFSA organised a peer review of the DAR provided by the designated rapporteur Member State, the United Kingdom, which was received by the EFSA on 18 April 2007 (The United Kingdom, 2007).

The peer review was initiated on 4 July 2007 by dispatching the DAR to Member States and the applicant BASF SE for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR.

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

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

Following the Commission Decision of 5 December 2008 (2008/934/EC)[10] concerning the non-inclusion of quinmerac in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant BASF SE made a resubmission application for the inclusion of quinmerac in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the issues identified in the DAR.

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

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicant for comments on 22 June 2009. In addition, the EFSA conducted a public consultation on the Additional Report. The EFSA collated and forwarded all comments received to the Commission on 5

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

August 2009. The collated comments were also forwarded to the RMS for compilation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 1 September 2009, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on quinmerac within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were required to be submitted by the applicant(s) in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicant in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the Commission on 14 September 2009; the applicant was also invited to give its view on the need for additional information. On the basis of the comments received, the applicant's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that there was no need for EFSA to organise a consultation with Member State experts and that no further information should be requested from the applicant.

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

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

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

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

- the comments received on the DAR and on the Additional Report,
- the Reporting Table (revision 1-1; 12 September 2009),
- the Evaluation Table (20 January 2010).

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

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Quinmerac is the ISO common name for 7-chloro-3-methylquinoline-8-carboxylic acid (IUPAC).

The representative formulated product for the evaluation was 'Butisan Top', a suspension concentrate (SC), containing 125 g/L quinmerac and 375 g/L metazachlor, registered under different trade names in Europe.

The representative use evaluated comprises foliar spraying against weeds in oilseed rape, one application every three years. Full details of the GAP can be found in the list of end points in Appendix A to this report.

CONCLUSIONS OF THE EVALUATION

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

The minimum purity of quinmerac is 980 g/kg. No FAO specifications exist.

A data gap was identified for the determination of the UV spectrum under acidic conditions.

The main data regarding the identity of quinmerac and its physical and chemical properties are given in Appendix A. Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible.

The compounds in the residue definition for food/feed of plant origin can be determined with HPLC-MS/MS. Analytical methods for food of animal origin are not required as there is no intake by livestock. HPLC-MS/MS methods are available to monitor the compounds in the residue definition for soil, and HPLC-UV methods are available for the compounds in the residue definition for water. Adequate analytical methods are available to monitor quinmerac residues in air. Since quinmerac is not classified as acute toxic or very toxic, analytical methods for the determination of residues of quinmerac in body fluids and/or tissues are not required.

2. Mammalian toxicity

Quinmerac is of low acute toxicity to rats by the oral, inhalation and dermal routes of exposure; it is not classifiable as a skin or eye irritant, or as a skin sensitiser. In short-term toxicity studies, the main effect was a reduction in red blood cell parameters in dogs: the relevant NOAEL is 7.9 mg/kg bw/day. Quinmerac is not genotoxic. In carcinogenicity studies, there was no evidence for quinmerac being oncogenic in rats or mice. The relevant NOAEL for long-term toxicity is 31 mg/kg bw/day (18-month mouse study, based on reduced body weight gain). Quinmerac did not affect reproductive parameters in a multigeneration study, but there was a reduction in the number of live pups born, reduced pup survival and other developmental effects (e.g. reduced body weight gain), which were considered to be a consequence of maternal toxicity. The relevant parental, reproductive and offspring NOAELs are 354 mg/kg bw/day, 323 mg/kg bw/day and 97 mg/kg bw/day, respectively. Quinmerac is not teratogenic, and developmental effects in rats and rabbits are a consequence of maternal toxicity: the relevant maternal and developmental NOAELs are 400 mg/kg bw/day in rats and 30 mg/kg bw/day in rabbits. Based on the findings of standard toxicology studies it is concluded that quinmerac is not neurotoxic. The ADI and AOEL are 0.08 mg/kg bw/day, based on applying a 100-fold assessment factor to the NOAEL of 7.9 mg/kg bw/day in the 12-month dog study. The ARfD is 0.3 mg/kg bw, based on applying a 100-fold assessment factor to the NOAEL of 30 mg/kg bw/day in the rabbit developmental toxicity study. The same reference values as for quinmerac can be applied to the metabolites BH 518-2 (expected to be of similar toxicity as quinmerac) and BH 518-5 (shown to be of similar/slightly lesser toxicity than quinmerac). Operator and worker exposure estimates are below the AOEL even without the use of PPE. Bystander exposure estimates are also below the AOEL.

3. Residues

The residue definition for plants is based on metabolism studies with pre- and post-emergence application to oilseed rape, sugar beet and wheat, and on rotational crop metabolism data in lettuce, radish and wheat. All metabolism studies were performed using quinmerac radiolabelled at a single site of the molecule. In various crops a major proportion of the total residue was present as unknown compounds that did not match with available reference standards containing the intact quinoline structure. Hence, a data gap was set to investigate the potential for opening of the quinoline ring structure and to address resulting metabolites. If detected at all, levels of unchanged quinmerac were generally less than 10% of the TRR at harvest of the mature crop. In both primary and rotational crops, the main component of the residue was the hydroxymethyl derivative BH 518-4, free and conjugated, and to a lesser extent the carboxylic acid derivative BH 518-2. The total radioactive residues in rape seeds were too low to enable exact metabolite quantification; however quinmerac, metabolite BH 518-1, BH 518-2 and BH 518-4 could be detected. The residue definition for risk assessment is therefore **the sum of quinmerac and its metabolites BH 518-2 and BH 518-4 (free and conjugated), expressed as quinmerac**, and for monitoring **the sum of quinmerac and its metabolites BH 518-2 and BH 518-4, expressed as quinmerac**.

Sufficient GAP conforming residue trials on winter and spring oilseed rape are available for the Northern EU region. The trials performed in the Southern EU region are not acceptable. Data on processed oilseed rape products were not required. Based on the acceptable residue trial data an MRL for oilseed rape seed has been proposed. The RMS stated that a storage stability study demonstrated that the total residue levels of quinmerac, metabolite BH 518-2 and BH 518-4 were stable for up to 24 months. The analytical method used in the residue trials did not analyse for conjugated residues according to the residue definition for risk assessment. In Addendum 5 (The United Kingdom, 2009b) it is proposed that a conversion factor of 2 could be applied in the risk assessment to take into account conjugated residues of metabolite BH 518-4. The approach of using a factor is considered acceptable given the very low intakes from oilseed rape seed. Data on immature oilseed rape foliage and on sugar beet root were used to derive the factor for seeds. The RMS considers this conversion factor only appropriate to the current use on oilseed rape with pre- and early post-emergent treatment. The proposal has not been peer reviewed.

In rotational crops significant amounts of relevant residues are taken up, in particular, at shorter plant back intervals up to 120 days. Hence, a data gap should be set for suitable rotational crop residue trial data. Ad interim, for a precautionary risk assessment, it might be acceptable to use the results of the rotational crop metabolism study, and to extrapolate to crops usually rotated with oilseed rape. Member States may choose to address the issue by a plant back restriction of 120 days or longer.

If only residues in the target crop are considered, the trigger for investigation of the nature and magnitude of residues in livestock is not exceeded. However, estimates of livestock exposure in Addendum 5 do not include potential residues in rotational crops. Hence it is currently not known whether the trigger value may be exceeded. Metabolism studies with quinmerac in lactating goats and in laying hens were evaluated in the Additional Report. Moreover, a ruminant feeding study was submitted but no detailed evaluation is available.

Using the UK consumption data for rapeseed oil all chronic and short-term intakes are less than 2% of the ADI and ARfD, respectively. Residues in rotational crops were not included in this assessment, nor were other European consumers (EFSA PRIMo 2.0) considered. For soil metabolites BH 518-2 and BH 518-5 exceeding 0.75 μg / L in the majority of the groundwater scenarios, consumer exposure via drinking water was calculated in Addendum 3 (The United Kingdom, 2009b) as less than 2 % of the ADI of quinmerac. The results of the consumer risk assessment must be considered along with the uncertainty in terms of residues in rotational crops not yet included in the estimates, and in terms of the data gap on the potential for 'ring-opened' metabolites. Even taking this into account, it is highly unlikely that the reference doses will be exceeded.

4. Environmental fate and behaviour

In principle, the use of 2-[^{14}C]-labelled quinmerac in the environmental fate and behaviour experiments does not guarantee that all potentially relevant metabolites would have been identified in the route of degradation studies. The applicant's view was that any metabolites potentially formed after opening of the quinoline ring (aniline and chloroaniline related metabolites) would be expected to exhibit very low or low persistence in soil. The applicant provided clarifications to support this case (see Reporting Table comment 4(50), EFSA, 2010); this information has not been evaluated and peer reviewed during this EU review exercise but is available to Member States. Additionally, the RMS highlighted that during soil incubation studies there is no evidence that the quinoline ring is opened up to 120 days.

When half-lives are normalized for temperature (EFSA, 2007) and moisture (FOCUS, 2000), quinmerac may be considered moderately persistent in soil under aerobic conditions on the basis of the complete data set. In soil, quinmerac either undergoes oxidation of the methyl moiety to yield the major soil metabolite BH 518-2, or, alternatively, oxidation in position 2 to yield the other major soil metabolite BH 518-5. In the resubmission dossier, the degradation of quinmerac and its metabolites in soil was reassessed following the recommendations of FOCUS kinetics (FOCUS, 2006). Based on normalized half-lives, metabolites BH 518-5 and BH 518-2 may be classified as moderately to very highly persistent in soil. Non-extractable radioactivity amounted to a maximum of 44.4 - 57.5 % AR, whereas mineralization was 19.1 % - 39.5 % after 120 days. Under anaerobic laboratory incubation conditions, quinmerac was highly persistent in soil, and no novel metabolites were identified. The contribution of photolysis is relatively low with respect to degradation under dark aerobic conditions, and no novel major metabolites were found.

Quinmerac exhibits high to very high mobility in soil (with adsorption being pH dependent). Metabolite BH 518-2 exhibits medium to very high mobility in soil (with adsorption being pH dependent). Metabolite BH 518-5 exhibits high mobility in soil (considered pH independent).

Dissipation of quinmerac under field conditions was investigated in a total of nine trials (6 in Germany, 2 in Spain and 1 in Sweden). Quinmerac was moderately persistent in these trials. These field half-lives have been normalized following FOCUS guidance (FOCUS, 2006).

PEC soil for quinmerac was calculated based on worst-case non-normalized field half-life (DT_{50} = 58 days). Maximum PEC soil for metabolites BH 518-2 and BH 518-5 were calculated based on initial PEC soil of quinmerac and the maximum formation observed in the aerobic degradation studies. In addition, for metabolite BH 518-5 accumulated PEC soil for application in consecutive years was provided by the applicant, based on what they claimed would represent a worst-case normalized half-life ($DT_{50\ soil}$ = 95.6 days). Longer half-lives are nevertheless observed in most of the experiments (when some decline was observed half-lives up to 154 days were calculated). It has been assumed to use a half-life of 1000 days for those experiments where no decline was observed. This resulted in a range of normalized half-lives in soil for metabolite BH 518-5 between 145.3 and > 1000 days (clarified by the RMS in the final list of end points in Appendix A). When these longer half-lives are applied to estimate the accumulated PEC in soil, EFSA obtained PEC soil for metabolite BH 518-5 in the range of 0.15 – 0.54 mg/kg. If the rotation (one application every three years) proposed in the GAP for oilseed rape is considered, the range of PEC soil values will be 0.125 - 0.23 mg/kg. These values were taken into consideration by EFSA when concluding on the earthworms risk assessment (see section 5). Agreed schemes for the assessment of the soil compartment involve the use of the worst-case half-life in the estimation of the PEC soil. This would correspond to the values calculated with a half-life of 1000 days. With the available information it is not possible to identify a less conservative realistic worst case.

Quinmerac is stable to hydrolysis at pH 5 to 9. Direct aqueous photolysis under artificial light simulating summer sunlight at 54°N indicated that quinmerac was slowly degraded.

The dissipation and degradation of [^{14}C] labelled quinmerac in aquatic systems was investigated in dark aerobic water sediment systems. Partition of quinmerac to the sediment was moderate (max. 19.7 – 35.2 % AR after 30 days). Quinmerac exhibited high persistence in the water/sediment systems. The only metabolite identified was BH 518-2 that reached a maximum of 9.5 % AR in the water phase at the end of the study in one of the experiments. After 100 days minimal mineralization was observed in both systems. Unextractable residue in sediment amounted to 15.8 – 26.7 % AR at the end of the study (100 days).

PEC_{SW} and PEC_{sed} values for quinmerac and its soil metabolites BH 518-2 and BH 518-5 were calculated with FOCUS SW scheme up to step 3 (FOCUS, 2001). For step 3 calculations worst-case second phase worst half-life of biphasic fitting of dissipation of quinmerac in the water phase of the water sediment systems was used as a surrogate for degradation half-life of quinmerac in water (DT_{50} = 138.8 days). The half-life in the sediment phase was assumed to be 1000 days as a worst case. This is a best-case assumption with respect to the mean of the whole microcosm system half-lives (mean $DT_{50whole\ system}$ = 333.5 days) or the mean of first-order whole system water/sediment systems (mean $DT_{50whole\ system}$ = 179.4 days), however it has been considered not to have a significant impact on the modelling results, since the worst-case concentrations at step 3 are derived in ditch scenarios that tend to be largely insensitive to the water phase degradation rates. However, the ecotoxicological risk assessment is driven by the toxicology of the formulation. Therefore, PEC_{SW} values, based on spray drift only, were used to finalize the risk assessment of the formulation.

Two lysimeter studies and a field leaching study in Germany are available. Among the lysimeter and field leaching studies only the lysimeter in oilseed rape may be considered fully relevant with respect to the representative use, since the other studies investigated spring application to sugar beet (see details in the list of end points in Appendix A).

The groundwater assessment has been completed using FOCUS PELMO and PEARL models (FOCUS, 2000; EFSA, 2004). The EU level groundwater exposure assessment is based on the RMS' calculations for the representative use in oilseed rape, assuming rotation and application once every three years (sorption pH dependence was assumed for the modelling with PEARL). For winter oilseed rape, the limit of 0.1 µg/L is exceeded by quinmerac in one out of the six scenarios. The limits of 0.1 µg/L and 0.75 µg/L were exceeded by metabolites BH 518-2 and BH 518-5 in various scenarios (see section 6.2).

5. Ecotoxicology

The environmental risk assessment of quinmerac was conducted according to current guidance documents (see References). Toxicity studies indicated a low acute toxicity of quinmerac to birds and mammals, and the risk from the representative use was assessed as low. The potential risk from the use of the representative formulation was not addressed for birds and mammals.

Based on the data available quinmerac was considered to be harmful to aquatic organisms, whereas the formulation (including metazachlor) was found to be very acutely toxic to aquatic organisms. The metabolites BH 518-2 and BH 518-5 were found to be of similar or less toxicity than the parent substance. Based on the standard formulation risk assessment (acute formulation toxicity data and drift exposure only), the risk to aquatic organisms from the representative formulation was assessed as low, provided a non-spray buffer zone of 15m was applied. The potential for bioaccumulation was assessed as low (logPow < 3).

HQ calculations based on acute oral and contact toxicity of quinmerac indicated a low risk to bees. Laboratory studies on non-target arthropods were provided for the two standard species *Typhlodromus pyri* and *Aphidius rhopalosiphi*. Additional tier 1 studies on *Chrysoperla carnea* and *Aleochara bilineata*, and extended laboratory studies on *T. pyri* and *A. rhopalosiphi* were provided, although not required. Based on the assessment of all studies, the in-field and off-field risk to non-target arthropods was considered as low.

The acute toxicity to earthworms was assessed for quinmerac, BAS 526 13 H and for the metabolites BH 518-2 and BH 518-5. For the latter metabolite also long-term toxicity was assessed. The acute risk to earthworms from the representative use of quinmerac was assessed as low. The long-term risk to earthworms from metabolite BH 518-5 could however not be finalised, due to uncertainties in the estimate of plateau PEC_{soil} (see section 4). The long-term risk to earthworms from the metabolite BH 518-5 would be assessed as high, if PEC_{soil} is based on a soil half-life of 1000 days (both with and without crop rotation). In fact, TERs for the long-term risk would breach the Annex VI trigger if PEC_{soil} is based on a soil half-life slightly exceeding 154 days without crop rotation. Therefore, for the soils where degradation of metabolite BH 518-5 was insufficient to estimate degradation half-lives, a high long-term risk to earthworms from metabolite BH 518-5 would be expected. Consequently, the long-term risk to earthworms from the soil metabolite BH 518-5 needs to be addressed further, based on the indications of a high risk from existing data. Information on the toxicity of metabolite BH 518-5 to collembola was available, although not required. The risk was assessed as low following an evaluation of the supplementary information. Additionally, the risk to soil processes from the representative use of quinmerac was assessed as low. No significant adverse effects on sewage treatment were expected.

Studies were evaluated on the effect of the plant protection product on a number of monocotyledon and dicotyledon non-target plant species. A low risk was indicated at 1m.

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

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Quinmerac	moderately persistent ($DT_{50\ norm\ 20\ °C,\ pF\ 2}$ = 12.3 – 27.3 d)	Risk to soil organisms assessed as low.
BH 518-2	moderately to highly persistent ($DT_{50\ norm\ 20\ °C,\ pF\ 2}$ = 16.1 – 126.4 d).	Risk to soil organisms assessed as low.
BH 518-5	high to very highly persistent ($DT_{50\ norm\ 20\ °C,\ pF\ 2}$ = 145.3 – > 1000 d)	Acute risk to soil organisms assessed as low. The long-term risk to earthworms needs to be addressed further, based on the indications of a high risk from existing data.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
Quinmerac	highly to very highly mobile in soil (K_{Foc} = 6.2 – 126 mL/g) pH dependence identified	FOCUS GW: yes, Winter oilseed rape: 0.1 µg/L is exceeded in one of the six scenarios. Spring oilseed rape: 0.1 µg/L is not exceeded in any of the three scenarios. Lysimeter: No.	Yes	Yes	Harmful to aquatic organisms. Risk to aquatic organisms assessed as low.
BH 518-2	medium to very highly mobile in soil (K_{Foc} = 28 – 211 mL/g) pH dependence identified	FOCUS GW: yes, Winter oilseed rape: 0.1 µg/L is exceeded in five of six scenarios (0.75 µg/L exceeded in three scenarios) Spring oilseed rape: 0.1 µg/L is exceeded in one or two out of three scenarios. Lysimeter: yes, max ann. av. = 6.5 µg / L	No	No (the same ADI and ARfD as for quinmerac can be used for consumers' risk assessment)	Harmful to aquatic organisms. Risk to aquatic organisms assessed as low.

BH 518-5	highly mobile in soil (K_{Foc} = 53 – 98 mL/g)	FOCUS GW: yes, 0.1 µg/L is exceeded by all six scenarios (0.75 µg/L exceeded in five scenarios) Spring oilseed rape: 0.1 µg/L is exceeded in all three scenarios (0.75 µg/L exceeded in two or three scenarios). Lysimeter: yes, max ann. av. = 0.74 µg / L	No	No (the same ADI and ARfD as for quinmerac can be used for consumers' risk assessment)	Harmful to aquatic organisms. Risk to aquatic organisms assessed as low.

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
Quinmerac	Harmful to aquatic organisms and risk assessed as low.
BH 518-2	Harmful to aquatic organisms and risk assessed as low.
BH 518-5	Harmful to aquatic organisms and risk assessed as low.

6.4. Air

Compound (name and/or code)	**Toxicology**
Quinmerac	Not acutely toxic via inhalation.

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

- UV spectrum under acidic conditions (relevant for the representative use evaluated; data gap identified during the peer review, submission date proposed by the applicant: unknown, see section 1)
- Potential opening of the quinoline ring and subsequent metabolisation to be further investigated (relevant for the representative use evaluated; data gap identified during the peer review, information is available but could not be considered in the peer review in accordance with the relevant legislation, see section 3).
- Rotational crop residue trials data for plant back intervals up to 120 days (relevant for the representative use evaluated; data gap identified during the peer review, submission date proposed by the applicant: unknown, see section 3).
- The potential risk from use of the representative formulation needs to be addressed for birds and mammals (relevant for the representative use evaluated; data gap identified during the peer review, some information is available (see Reporting Table comment 5(1)) and section 5).
- The long-term risk to earthworms from the soil metabolite BH 518-5 needs to be addressed (relevant for the representative use evaluated; data gap identified by EFSA after the peer review, submission date proposed by the applicant: unknown, see sections 4 and 5).

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

- One application (250 g a.s/ha) every three years has been assumed in the risk assessment performed (see section 4). A more frequent or higher rate use would likely to increase the concerns with respect to potential groundwater contamination by quinmerac and its metabolites.
- Use of quinmerac should be avoided in conditions and soils vulnerable to groundwater contamination.
- Member States may choose to overcome the data gap on rotational crop residue trials with a plant back restriction of at least 120 days (see section 3).
- Non-spray buffer zone of 15 m is required to address the risk to aquatic organisms (see section 5).

ISSUES THAT COULD NOT BE FINALISED

- Significant residues are likely to occur in rotational crops at shorter plant back intervals up to 120 days. Without rotational crop residue trials MRLs could not be proposed for succeeding crops.
- The consumer risk assessment is not finalised because of the issues of unidentified, potentially 'ring-opened' metabolites with a very different structure to the parent quinmerac, and of rotational crop residues.
- The potential risk from use of the representative formulation for birds and mammals could not be finalised.
- The long-term risk to earthworms from the soil metabolite BH 518-5 could not be finalised.

CRITICAL AREAS OF CONCERN

- The long-term risk to earthworms from the soil metabolite BH 518-5 needs to be addressed further, as there are indications of a high risk from the existing data (environmental fate and behaviour data indicated that PECsoil is likely to be higher, and therefore there is a high likelihood this would lead to a TER value below the Annex VI trigger; see sections 4 and 5).

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APPENDICES

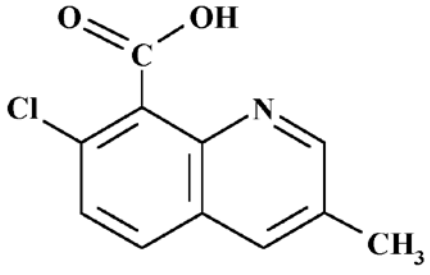
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

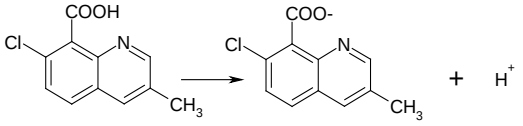
Active substance (ISO Common Name) ‡	Quinmerac
Function (*e.g.* fungicide)	Herbicide

Rapporteur Member State	UK
Co-rapporteur Member State	None

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	7-chloro-3-methylquinoline-8-carboxylic acid
Chemical name (CA) ‡	7-chloro-3-methyl-8-quinolinecarboxylic acid
CIPAC No ‡	563
CAS No ‡	90717-03-6
EC No (EINECS or ELINCS) ‡	402-790-6
FAO Specification (including year of publication) ‡	Not available
Minimum purity of the active substance as manufactured ‡	980 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	No relevant impurities
Molecular formula ‡	$C_{11}H_8Cl\ NO_2$
Molecular mass ‡	221.6 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	252.3-253.8°C (100%)
Boiling point (state purity) ‡	No boiling point observed, the compound decomposes
Temperature of decomposition (state purity)	260°C (100%)
Appearance (state purity) ‡	Pure: White crystalline solid (100%) Technical: White coarse grained powder (100%)
Vapour pressure (state temperature, state purity) ‡	< 1 x 10^{-10} Pa at 20°C (100%)
Henry's law constant ‡	< 1.0 x 10^{-10} Pa m^3 mol^{-1}
Solubility in water (state temperature, state purity and pH) ‡	213 mg/l at 20°C and pH 3.7 (100%) 107 g/L at 20°C and pH 7 (100%) 157 g/l at 20°C and pH 11 (100%)
Solubility in organic solvents ‡ (state temperature, state purity)	The pure a.i. (100%) is nearly insoluble in most of the tested solvents. The different solubilities (in g/l solvent @ 20°C) are: n-heptane: 0.0 toluene: <0.1 dichloromethane: 2.2 methanol: 1.9 acetone: 1.5 ethyl acetate: 0.4
Surface tension ‡ (state concentration and temperature, state purity)	72.2 mN/m at 0.1 % (w/w), 20°C (100%)
Partition co-efficient ‡ (state temperature, pH and purity)	pH 4: log P_{OW} 1.17 pH 7: log P_{OW} - 1.41 pH 10: log P_{OW} - 4.41 Test performed at 21°C (99.4%)
Dissociation constant (state purity) ‡	At 20 °C the pKa is 4.31 (99.4%) at 25 °C the pKa is 4.29 (99.4%) 

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Methanol solution λ_{max} (nm)□ 222 4.0 x 10^4 254 3.2 x 10^3 274 4.0 x 10^3 300 2.6 x 10^3 311 3.3 x 10^3 325 3.7 x 10^3 345 22 Open for spectrum in acidic conditions
Flammability ‡ (state purity)	Not highly flammable. Not classified. (100%)
Explosive properties ‡ (state purity)	Non-explosive (theoretical consideration)
Oxidising properties ‡ (state purity)	Non-oxidising (theoretical consideration)

Summary of representative uses evaluated (quinmerac)*

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)		
Oilseed rape	Germany, Austria United Kingdom, Sweden	Butisan Top/ Katamaran	F	Weeds (general)	SC	125g/l quinmerac 375 g/l metazachlor	SP	00-18	1 Every three years	Not applicable	0.063-0.250	100-400	0.250	-2	Pre-emergence to early post-emergence. Crop rotation resulting on use restricted to one every three years has been assumed in the assessment. [1]

[1] A high long-term risk to earthworms from metabolite BH 518-5 has been identified for soils where the degradation half-life exceeds 154 days without crop rotation.

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

Methods of Analysis

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

Technical as (analytical technique)	Quinmerac in technical material was determined by CIPAC method 563/TC/M/3.
Impurities in technical as (analytical technique)	Impurities in technical material were determined by HPLC-UV, GC-FID, GC-MS and IC.
Plant protection product (analytical technique)	Quinmerac in the plant protection product was determined by HPLC-DAD.

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Quinmerac and its metabolites BH518-2 and BH 518-4 expressed as quinmerac.
Food of animal origin		Not required as intakes by animals are below the trigger value and no MRL's will be set.
Soil		Quinmerac and its metabolites BH518-2 and BH 518-5
Water	surface	Quinmerac and its metabolites BH518-2 and BH 518-5
	drinking/ground	Quinmerac and its metabolites BH518-2 and BH 518-5
Air		Quinmerac

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC/MS/MS. Acceptable validation data were submitted for wheat, sugar beet and orange, therefore the following crop groupings have been addressed: cereals, high fat and high acid matrices. The limit of determination for all matrices and analytes was 0.05 mg/kg.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required.
Soil (analytical technique and LOQ)	HPLC-MS/MS, with LOQs of 0.01 mg/kg for quinmerac and its metabolites BH518-2 and BH 518-5.
Water (analytical technique and LOQ)	HPLC-UV, with LOQs of 0.05 µg/kg for quinmerac and its metabolites BH518-2 and BH 518-5 in surface and drinking water.
Air (analytical technique and LOQ)	HPLC/UV, with a LOQ of 0.0023 µg/L for quinmerac.

Body fluids and tissues (analytical technique and LOQ)	Not required as quinmerac is not classified as toxic.

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

	RMS/peer review proposal
Active substance	Not classified

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Rapid, 60% in 0-8h urine; Tmax 0.5h at 15 mg/kg bw Extensive, 80-90% (based on urinary excretion within 48h of single or repeat dose of 15 mg/kg bw). Lower absorption at higher dose level (600 mg/kg bw/d).
Distribution ‡	At 4h post dose, highest systemic concentrations in blood, plasma and kidneys
Potential for accumulation ‡	Evidence suggests no significant potential for bioaccumulation at low dose levels
Rate and extent of excretion ‡	>85% of acute dose excreted within 24h, mainly via urine (>75% of dose)
Metabolism in animals ‡	Limited metabolism (80-90% of low dose excreted unchanged), involving oxidation and glucuronidation. 2 unconjugated metabolites: BH 518-2 and BH 518-4.
Toxicologically relevant compounds ‡ (animals and plants)	Parent and/or metabolites account for toxicity to rats. No plant metabolites of particular toxicological concern for human health have been identified.
Toxicologically relevant compounds ‡ (environment)	quinmerac

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	>5000 mg/kg bw	
Rat LD_{50} dermal ‡	>2000 mg/kg bw	
Rat LC_{50} inhalation ‡	>5.4 mg/L air /4h (nose only)	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Slightly irritating (no classification proposed)	
Skin sensitisation ‡	Non-sensitiser (Magnusson & Kligman)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Red blood cells (dog)	
Relevant oral NOAEL ‡	1-year dog: 7.9 mg/kg bw/day	

Relevant dermal NOAEL ‡	28-day rat : 1000 mg/kg bw/day	
Relevant inhalation NOAEL ‡	No data available - not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

Quinmerac is not genotoxic	

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

Target/critical effect ‡	Body weight (rats and mice)	
Relevant NOAEL ‡	18-month mouse: 31 mg/kg bw/day	
Carcinogenicity ‡	Quinmerac is unlikely to pose a carcinogenic risk to humans	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	Reduced number of live pups and reduced pup survival in the presence of a slight reduction in parental body weight gain (parental bodyweight gain reduced by <10% at this dose of 4,000 ppm and hence regarded as not adverse)	
Relevant parental NOAEL ‡	4,000 ppm (354 mg/kg bw/day)	
Relevant reproductive NOAEL ‡	4,000 ppm (323 mg/kg bw/day)	
Relevant offspring NOAEL ‡	1,000 ppm (97 mg/kg bw/day = parental intake for F0 dams)	

Developmental toxicity

Developmental target / critical effect ‡	Slight reduction in foetal bodyweight in presence of maternal toxicity (rabbit); at higher dose in rabbit absent foetal gall bladder and fewer viable foetuses in presence of marked maternal toxicity	
Relevant maternal NOAEL ‡	Rat: 400 mg/kg bw/day Rabbit: 30 mg/kg bw/day	
Relevant developmental NOAEL ‡	Rat: 400 mg/kg bw/day Rabbit: 30 mg/kg bw/day	

Note: NOAELs of potential relevance to ecotoxicological assessment of effect of quinmerac on population viability = rat (323 mg/kg bw/day), rabbit (150 mg/kg bw/day or possibly as a worst-case 100 mg/kg bw/day)

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available - not required. No concern from other studies.	
Repeated neurotoxicity ‡	No data available - not required. No concern from other studies.	
Delayed neurotoxicity ‡	No data available - not required.	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data available - not required.
Studies performed on metabolites or impurities ‡	**Metabolite BH 518-2**: Although positive in an Ames test at a high dose (overall a relatively weak response), further data indicate that this metabolite is not of genotoxic concern (negative *in vitro* cytogenetics and mouse lymphoma assays and negative *in vivo* bone marrow micronucleus assay). **Metabolite BH 518-5**: studies in rats (acute oral, 90-day diet, developmental toxicity) indicate that this metabolite is of similar/slightly lesser toxicity than quinmerac. No evidence for genotoxic activity (negative Ames test, inconclusive V79/HPRT assay, negative *in vivo* bone marrow assay) supported by negative genotoxicity data for quinmerac (structurally similar). **Impurity 1**: negative Ames test **Impurity 2:** *In vitro* and *in vivo* data indicate that this impurity is not of genotoxic concern.

Medical data ‡ (Annex IIA, point 5.9)

No evidence of toxicological concern from medical surveillance of manufacturing personnel, field trial personnel or a laboratory technician.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.08 mg/kg bw/day	Dog, 1-year	100
AOEL ‡	0.08 mg/kg bw/day	Dog, 1-year	100
ARfD ‡	0.3 mg/kg bw	Rabbit, developmental toxicity	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

(BAS 526 13 H)	Concentrate: 2% Spray dilution: 5% *In vivo* rat study with 12.5% SC formulation

Exposure scenarios (Annex IIIA, point 7.2)

Operator	**German model**: (oilseed rape through tractor-mounted or trailed field crop sprayers) systemic exposure equivalent to 14 % of the systemic AOEL (no PPE) **UK POEM**: systemic exposure equivalent to 21% of the systemic AOEL (operator wearing gloves when handling the concentrate and gloves when handling contaminated surfaces during application).
Workers	German worker re-entry model: systemic exposure equivalent to 8% of the proposed systemic AOEL (no PPE).
Bystanders	Published surrogate data (vapour exposure): systemic exposure equivalent to 11% of the systemic AOEL. Bystander exposure study for field crop sprayers (spray drift exposure): systemic exposure equivalent to 0.6% of the AOEL. Children's exposure: estimates based on published spray drift deposition values and published EPA residential exposure values: 0.1% of the systemic AOEL.

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

	RMS/peer review proposal
Substance classified (quinmerac)	R52/R53

Residues

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

Plant groups covered	Rape, sugar beet, wheat
Rotational crops	Radish, lettuce, wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	-
Residue pattern in processed commodities similar to residue pattern in raw commodities?	-
Plant residue definition for monitoring	Quinmerac + BH 518-2 + BH 518-4 (expressed as quinmerac)
Plant residue definition for risk assessment	Quinmerac and its metabolites BH 518-2 and BH 518-4 (free and conjugated), expressed as quinmerac.
Conversion factor (monitoring to risk assessment)	Not peer reviewed - RMS proposal 2.0 Note: this conversion factor is only appropriate for pre-emergence or early post-emergence oilseed rape uses (see Addendum 5, The United Kingdom, 2009b).

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

Animals covered	Goat, hen
Time needed to reach a plateau concentration in milk and eggs	32 hours (milk)
Animal residue definition for monitoring	Not required due to low predicted intakes and low residue levels
Animal residue definition for risk assessment	Not required due to low predicted intakes and low residue levels
Conversion factor (monitoring to risk assessment)	-
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No

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

	Rotational crop metabolism data indicate that significant residues will occur in rotational crops. Rotational crop residue trials required (data gap – RMS proposed plant back restriction of 120 days)

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

Adequate stability demonstrated following freezer storage for up to 24 months in oilseed rape.

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	No[11]	No[11]	-
Potential for accumulation (yes/no):	No	No	-
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No	No	-
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	<0.05	-	-
Liver	<0.05	-	-
Kidney	<0.05	-	-
Fat	<0.05	-	-
Milk	<0.01		
Eggs		-	

[11] Estimates do not consider potential residues in rotational crops. Assessment not finalised.

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Oilseed rape (winter)	Northern	16 x <0.05		0.1	<0.05	<0.05
Oilseed rape (spring)	Northern	3 x <0.05; 1x 0.07; 1 x 0.13		0.2	0.13	<0.05

NOTE: the residue values above have been determined using the monitoring residue definition; therefore the risk assessment has used these values multiplied by the proposed conversion factor.

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

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

Note: Assessment not finalised.

Estimates do not consider potential residues in rotational crops.

Additional contribution from groundwater used as drinking water < 2% ADI

ADI	0.08 mg/kg bw/day
TMDI (% ADI) according to WHO European diet	n.a.
TMDI (% ADI) according to national (to be specified) diets	<1% (UK)
IEDI (WHO European Diet) (% ADI)	n.a.
NEDI (specify diet) (% ADI)	n.a.
Factors included in IEDI and NEDI	n.a.
ARfD	0.3 mg/kg bw
IESTI (% ARfD)	n.a.
NESTI (% ARfD) according to national (to be specified) large portion consumption data	< 2% (UK)
Factors included in IESTI and NESTI	n.a.

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	
Rapeseed oil	1	~1	~1	
Rapeseed meal	1	~1	~1	

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

Oilseed rape	0.2 mg/kg

MRLs for rotational crops could not be proposed due to lack of rotational crop residue trials.

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

Environmental fate and behaviour

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

Mineralization after 100 days ‡	19.1 – 39.5 % AR after 120 d, [^{14}C-quinmerac]-label (n[12]= 4)
Non-extractable residues after 100 days ‡	44.4 – 57.5 % AR after 120 d, [^{14}C-quinmerac]-label (n= 4)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	BH 518-2 – 3.0 – 29.1 % AR at 7 - 30 d (n= 7) BH 518-5 – 6.0 – 27.2 % AR at 91 d (n= 7) [^{14}C-quinmerac]-label

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

Anaerobic degradation ‡ note: radio-labelled study conducted with initial 21 day aerobic phase, followed by anaerobic phase to 120 days total study duration

Mineralization after 100 days	1.9 % AR after 120 d, [^{14}C-quinmerac]-label (n= 1)
Non-extractable residues after 100 days	25.4 % AR after 120 d, [^{14}C-quinmerac]-label (n= 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	BH 518-2 – 18.5 % AR at 62 d (41 days after start of anaerobic phase) (n= 1) BH 518-5 – 4.5 % AR at 30 d (9 days after start of anaerobic phase) (n= 1)

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Continuous irradiation, equivalent to 2x the average daily irradiation at 40˚N, 15 days duration. Maximum level of total metabolites 4.3% AR at 1 – 3 DAT.

[12] n corresponds to the number of soils.

Quinmerac	Aerobic conditions					
Soil type	pH (water)	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	χ^2 error value	Method of calculation
Bruch West	8.2	20˚C/40% MWHC	21 days/70 days	19.7	3.25	SFO
Bruch West	8.2	10˚C/40% MWHC	104 days/346 days	37.7	3.37	SFO
Geomean Bruch West				**27.3**		
Li 35b	7.3	20˚C/40% MWHC	17 days/57 days	**16.7**	1.55	SFO
LUFA 2.2	6.5	20˚C/40% MWHC	16 days/54 days	**14.7**	3.78	SFO
LUFA 3A	8.2	20˚C/40% MWHC	16 days/52 days	**12.5**	3.0	SFO
Woburn	6.2	5˚C/60% FC	75 days	14.1	6.79	SFO
"	"	10˚C/60% FC	38 days	11.4	7.75	SFO
"	"	15˚C/60% FC	23 days	11.0	10.7	SFO
"	"	10˚C/40% FC	52 days	11.8	7.93	SFO
"	"	10˚C/80% FC	37 days	13.5	11.35	SFO
"	"	10˚C/60% FC 1/20 dose	40 days	12.0	6.93	SFO
Geomean Woburn				**12.3**		
Broom's Barn	7.5	5˚C/60% FC	139 days	28.7	5.26	SFO
"	"	10˚C/60% FC	76 days	25.1	4.13	SFO
"	"	15˚C/60% FC	43 days	22.8	5.0	SFO
"	"	10˚C/40% FC	85 days	21.3	6.35	SFO
"	"	10˚C/60% FC 1/20 dose	51 days	16.8	9.02	SFO
Geomean Broom's Barn				**22.6**		
Shuttleworth	6.8	5˚C/60% FC	67 days	12.9	3.96	SFO
"	"	10˚C/60% FC	35 days	10.8	7.21	SFO
"	"	15˚C/60% FC	22 days	10.7	10.77	SFO
"	"	10˚C/40% FC	66 days	15.3	5.26	SFO
"	"	10˚C/80% FC	69 days	25.9	20.85	SFO

"	"	10˚C/60% FC 1/20 dose	28 days	8.7	14.42	SFO
Geomean Shuttleworth				**13.1**		
Geometric mean				17.4 days		

Note, where more than one result was available for a particular soil, a geometric mean for the individual soil was calculated. Overall geometric mean calculated from mean values from the individual soils.

BH 518-2	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10k Pa	χ^2 error value	Method of calculation
Woburn	6.2	5°C / 60% FC	1000	0.32	1000		No decline at study end, default DT_{50} + Notifier ff used.
"	"	10°C / 60% FC	58.6	0.47	17.5		Notifier derived values
"	"	15°C / 60% FC	30.3	0.47	14.5	SFO	SFO
"	"	10°C / 40% FC	185.9	0.50	37.9	SFO	SFO
"	"	10°C / 80% FC	72.3	0.42	26.4	SFO	SFO
"	"	10°C / 60% FC	31.1	0.25	8.4	SFO	Modelled from peak at d 48
Geomean Woburn					**35.9**		
Broom's Barn	7.5	5°C / 60% FC	1000	0.65	1000	SFO	Default DT_{50} + Notifier ff used.
"	"	10°C / 60% FC	386.6	0.53	128.10	SFO	SFO
"	"	15°C / 60% FC	73.9	0.58	39.3		SFO
"	"	10°C / 40% FC	369.0	0.55	92.0		SFO
"	"	10°C / 80% FC	1000	0.40	1000		Default DT_{50} + Notifier ff used.
"	"	10°C / 60% FC	26.6	0.30	8.8		SFO
Geomean Broom's Barn					**126.4**		
Shuttleworth	6.8	5°C / 60% FC	239.8	0.49	45.8		SFO
"	"	10°C / 60% FC	43.7	0.59	13.4		SFO
"	"	15°C / 60% FC	23.4	0.55	11.5		SFO
"	"	10°C / 40% FC	36.8	0.57	8.5		SFO

BH 518-2	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10k Pa	χ^2 error value	Method of calculation
"	"	10°C / 80% FC	78.9	0.42	29.6		SFO
"	"	10°C / 60% FC	31.5	0.18	9.7		SFO
Geomean Shuttleworth					**16.1**		
Bruch West	8.2	20˚C/40% MWHC	12.7	0.526	11.9		KingGUI
Bruch West	8.2	10˚C/40% MWHC	77.2	0.757	27.9		KingGUI
Geomean Bruch West					**18.2**		
Li 35b	7.3	20˚C/40% MWHC	47.7	0.531	46.7		KingGUI
LUFA 2.2	6.5	20˚C/40% MWHC	12.3	0.395	11.1		KingGUI
LUFA 3A	8.2	20˚C/40% MWHC	nc	0.703	nc		KingGUI
					29.7 days		

Note, where more than one result was available for a particular soil, a geometric mean for the individual soil was calculated. Overall geometric mean calculated from mean values (bold figures) for the individual soils.

BH 518-5	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10k Pa	χ^2 error value	Method of calculation
Woburn	6.2	5°C / 60% FC	1000	0.14	1000		Default DT50 + Notifier ff used.
"	"	10°C / 60% FC	1000	0.18	1000		Default DT50 + Notifier ff used.
"	"	15°C / 60% FC	321.5	0.15	154.3		SFO
"	"	10°C / 40% FC	1000	0.26	1000		Default DT50 + Notifier ff used.
"	"	10°C / 80% FC	188.7	0.21	69.0		SFO
"	"	10°C / 60% FC	186.9	0.47	55.9		SFO

BH 518-5	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10k Pa	χ^2 error value	Method of calculation
Geomean Woburn					**290.0**		
Broom's Barn	7.5	5°C / 60% FC	1000	0.07	1000		Default DT50 + Notifier ff used.
"	"	10°C / 60% FC	1000	0.09	1000		Default DT50 + Notifier ff used.
"	"	15°C / 60% FC	1000	0.08	1000		Default DT50 + Notifier ff used.
"	"	10°C / 40% FC	1000	0.10	1000		Default DT50 + Notifier ff used.
"	"	10°C / 80% FC	1000	0.09	1000		Default DT50 + Notifier ff used.
"	"	10°C / 60% FC	288.5	0.26	95.6		SFO
Geomean Broom's Barn					**676.2**		
Shuttleworth	6.8	5°C / 60% FC	256.5	0.22	49.0		SFO
"	"	10°C / 60% FC	201.9	0.21	61.9		SFO
"	"	15°C / 60% FC	162.3	0.19	79.9		SFO
"	"	10°C / 40% FC	1000	0.35	1000		Default DT50 + Notifier ff used.
"	"	10°C / 80% FC	1000	0.23	1000		Default DT50 + Notifier ff used.
"	"	10°C / 60% FC	126.6	0.43	38.8		SFO
Geomean Shuttleworth					**145.3**		
Bruch West	8.2	20˚C/40% MWHC	>1000	0.162	>1000		Default DT50 + Notifier ff used.
Bruch West	8.2	10˚C/40% MWHC	nc	-	nc		
Geomean Bruch West					**1000**		
Li 35b	7.3	20˚C/40% MWHC	>1000	0.236	>1000		Default DT50 + Notifier ff used.
LUFA 2.2	6.5	20˚C/40% MWHC	>1000	0.235	>1000		Default DT50 + Notifier ff used.
LUFA 3A	8.2	20˚C/40% MWHC	>1000	0.115	>1000		Default DT50 + Notifier ff used.
					601.5 days		

Note, where more than one result was available for a particular soil, a geometric mean for the individual soil was calculated. Overall geometric mean calculated from mean values (bold figures) for the individual soils.

Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH (CaCl)	Depth (cm)	$DisT_{50}$ (d) actual	$DisT_{90}$ (d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
Sand, bare soil	Utrera, Spain		6.5	50	17	57	0.879	11.80	PEARL; Inverse modelling.
Sandy silt loam, bare soil	Manzanilla, Spain		7.5	50	12	40	0.989	9.04	PEARL; Inverse modelling
Sandy loam, bare soil	Grossharrie, Germany		6.0	50	13	43	0.849	5.78	PEARL; Inverse modelling
Sandy loam, bare soil	Bjarred, Sweden		6.1	50	33	110	0.885	13.80	PEARL; Inverse modelling
Loess, bare soil	Gut Holzen, Germany		6.4	100	27	90	0.919	4.62	PEARL; Inverse modelling
Loam, bare soil	Kircheim, Germany		5.5	100	58	193	0.997	12.80	PEARL; Inverse modelling
Sandy loam, bare soil	Limburgerhof, Germany		6.5	100	30	100	0.957	19.2	PEARL; Inverse modelling
Sandy loam, bare soil	Havixbeck, Germany		6.6	100	38	126	0.921	8.9	PEARL; Inverse modelling
Geometric mean								9.8	

BH 518-2	Aerobic conditions								
Soil type	Location		pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (r2)	DT_{50} (d) Norm.	Method of calculation
Sandy loam, bare soil	Grossharrie, Germany		6.0	50	22	72	0.849	-	ModelMaker

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

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	X[13]	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Bruch West		8.0	20˚C/40% MWHC for first 21 days, then flooded up to 120 days	DT_{50} 402 days for anaerobic phase	Not appropriate	0.821	SFO
Li35b		6.7	20˚C/40% MWHC, anaerobic conditions established by flushing with nitrogen	DT_{50} 250 days	Not appropriate	0.775	SFO

Laboratory studies ‡

Quinmerac	Soil photolysis						
Soil type	X[14]	pH ($CaCl_2$)	t. °C / % MWHC/illumination	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam		7.3-(1.5)	22/40% MWHC/15 days continuous, equiv. 30 days natural spring sunlight at 40°N)	*40 experimental days* Stated to be equivalent of 80 d 12h light at 40°N Dark control DT_{50} 231d/ no degradation (RMS calculation)	-	0.0.71	SFO

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

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Quinmerac ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Borstel, Loamy sand	1.3	5.7			0.31	23.7	0.81
Stetten, Clay loam	1.0	7.5			0.06	6.2	0.86
Venningen, Sandy clay loam	1.1	7.3			0.12	11.2	0.89
Forst, Sandy loam	1.4	6.9			0.20	13.9	0.88
Birkenheide, Loamy sand	1.0	6.5			0.17	16.5	0.87
LUFA soil 2.1, Sand	0.5	6.1			0.10	17.7	0.95
Standard soil 2.1, N/S	0.47	6.0	0.869	184.8			-
Standard soil 2.2, N/S	2.55	6.0	1.739	68.2			-
Standard soil 2.3, N/S	0.74	6.6	0.519	70.1			-
Pfungstadt, N/S	1.20	7.7	0.230	19.2			-
SB 2.1, Sand	0.5	6.0			0.63	126.0	0.75
SB 2.2, Loamy sand	2.6	6.0			1.08	41.5	0.84
SB 2.3, Sandy loam	0.7	6.6			0.65	92.9	0.93
Bruch-Ost, Loam	3.1	7.0			1.20	38.7	0.96
Bruch-West, Loam	2.9	7.3			0.95	32.8	0.96
Pfungstadt, Clay loam	1.2	7.7			0.59	49.2	0.91
Arithmetic mean/median							
pH dependence, Yes or No			Yes; note that mean values of Koc and 1/n are not appropriate for modelling				

BH518-2 ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Standard soil 2.1, Sand	0.7	6.2			1.37	211	1.14
Standard soil 2.2, Loamy sand	2.4	5.8			1.49	62	0.98
Standard soil 2.3, Sandy loam	1.0	5.9			0.51	54	1.28
Limburgerhof Bruch Ost, Sandy loam	3.1	7.0			0.85	28	0.88
Arithmetic mean/median							
pH dependence (yes or no)			Yes; note that mean values of Koc and 1/n are not appropriate for modelling				

BH518-5 ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n

Standard soil 2.1, Sand	0.7	6.2			0.43	66	0.79
Standard soil 2.2, Loamy sand	2.4	5.8			2.36	98	0.83
Standard soil 2.3, Sandy loam	1.0	5.9			0.49	53	0.77
Limburgerhof Bruch Ost, Sandy loam	3.1	7.0			2.38	77	0.83
Arithmetic mean/median					1.42	73.5	0.81
pH dependence (yes or no)			No				

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

Column leaching ‡	Not submitted, not required
Aged residues leaching ‡	Not submitted, not required
Lysimeter/ field leaching studies ‡	Location: Julich, Germany Study type: lysimeter Soil properties: sandy loam, pH = 6.9, OC= 1.15, MWHC = Dates of application: May 1990 Crop: /Interception estimated: sugar beet, pre-emergence (0% interception) Number of applications: 1 year, 1 applications per year Duration: 2 years Application rate: 224.6 g/ha/year Average annual rainfall (mm): 840 mm year 1, 780 mm year 2 Average annual leachate volume (mm): 59.5 mm year 1, 261.2 mm year 2. % radioactivity in leachate (maximum/year): 2.83 % AR in year 1, 0.88 % AR in year 2 Individual annual maximum concentrations: <0.02 µg/L quinmerac; 8.25 µg/L BH 518-2 during year 1; <0.01 µg/l µg/L BH 518-5. Unidentified radioactivity, no of components not

	investigated, 6.32 µg/L parent equivalents. Individual annual average concentrations (e.g. 1st, 2nd, 3rd yr):< 0.02 µg/L quinmerac; 6.49 µg/L BH 518-2 year 1 and 0.25 µg/l year 2; <0.01 µg/l µg/L BH 518-5. Unidentified radioactivity, no of components not investigated, 4.89 µg/L parent equivalents year 1, 0.49 µg/l year 2. Amount of radioactivity in the soils at the end of the study = 31.8 AR; 0.4 % AR as parent, 0.7 % AR as BH 518-5
Lysimeter/ field leaching studies ‡	Location: Schmallenberg, Germany Study type: lysimeter Soil properties: sandy loam, pH = 5.7, OC= 1.5, MWHC = not stated Dates of application: September 1990 Crop: /Interception estimated: winter oilseed rape, crop growth stage at treatment not recorded Number of applications: 1 year, 1 application per year Duration: 2 years Application rate: 240 g/ha/year Average annual rainfall (mm): 731 mm year 1, 1062 mm year 2 Average annual leachate volume (mm): 292 mm year 1, 426 mm year 2. % radioactivity in leachate (maximum/year): Not stated Individual annual maximum concentrations: 0.14 µg/L quinmerac during year 1; 5.49 µg/L BH 518-2 during year 1; 1.47 µg/l µg/L BH 518-5 during year 2. Unidentified radioactivity, no of components not investigated, 5.05 µg/L parent equivalents in 1st year. Individual annual average concentrations: 0.06 µg/L quinmerac year 1, 0.05 µg/l quinmerac year 2; 2.35 µg/L BH 518-2 year 1 and 0.79 µg/l year 2; 0.04 µg/l µg/L BH 518-5 year 1 and 0.74 µg/l year 2. Unidentified radioactivity, no of components not investigated, 2.0 µg/L parent equivalents year 1, 0.6 µg/l year 2. Amount of radioactivity in the soils at the end of the study = 54.3% AR; 1.4 % AR as parent, 9.6 % AR as BH 518-5

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 58 days Kinetics: SFO Field or Lab: representative worst-case from field studies, non-normalised.
Application data	Crop: oilseed rape Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: Pre-emergence therefore no crop interception Number of applications: 1 Interval (d): not relevant Application rate(s): 250 g as/ha

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average
Initial		0.333	
Short term	24h	0.329	0.331
	2d	0.325	0.329
	4d	0.318	0.325
Long term	7d	0.307	0.320
	28d	0.239	0.283
	50d	0.183	0.251
	100d	0.101	0.194

Metabolite BH 518-2 Method of calculation	Molecular weight relative to the parent: 1.135x parent DT_{50} (d): DT_{50} not used as only initial concentration used in risk assessment Kinetics: - Field or Lab: -.
Application data	Application rate assumed: 120.3 g as/ha (assumed BH 518-2 is formed at a maximum of 42.4 % AR 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		0.160			
Short term	24h				
	2d				
	4d				
Long term	7d				
	28d				
	50d				
	100d				

Metabolite BH 518-5 Method of calculation	Molecular weight relative to the parent: 1.072x parent DT_{50} (d): 145 - 1000 days* Kinetics: SFO Field or Lab: representative worst-case from field studies.
Application data	Application rate assumed: 93.0 g as/ha (assumed BH 518-5 is formed at a maximum of 34.7 % AR 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		0.124 (initial PEC)			
Short term	24h				
	2d				
	4d				
Long term	7d				
	28d				
	50d				
	100d				

* Longer half-lives than the originally used by the applicant have been agreed during the peer review. Adequate end points and PEC soil accumulation calculations that take into consideration these longer half lives need to be agreed and produced to finalize the chronic risk assessment for earthworms.

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	Less than 2% degradation during 15 days at 22˚C at pH 5, 7 and 9. Quinmerac considered stable to hydrolysis.
Photolytic degradation of active substance and metabolites above 10 % ‡	Study conducted at pH 5, 7 and 9. DT_{50} : 57 d at pH 5, 131 d at pH 7, 117 d at pH 9 Artificial light, DT_{50} values are for continuous illumination, equivalent to summer sunlight intensity at approx. 54˚N No identified metabolites >10% AR
Quantum yield of direct phototransformation in water at Σ > 290 nm	3.92 x 10^{-5} mol/Einstein $^{-1}$ at pH 5 1.55 x 10^{-5} mol/Einstein $^{-1}$ at pH 7 1.30 x 10^{-5} mol/Einstein $^{-1}$ at pH 9
Readily biodegradable ‡ (yes/no)	No data submitted, substance considered not ready biodegradable.

Degradation in water / sediment (standard dark water/sediment study)

Parent	Distribution: max in water 96.7% AR after 0 d. Max. sed 19.7 - 35.2 % AR after 30 d									
Water / sediment system	pH water phase	pH sed (h_2o)	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
Swiss Lake	6.7	5.8	20	163.0 d/541.3 d	0.905	99.4d/330.1 d	0.860	Not calc		SFO
Millstream Pond	8.3	7.2	20	195.8 d/650.3 d	0.950	77.9 d/258.8 d	0.759	Not calc		SFO
Geometric mean/median										

BH 518-2	Distribution: max in water 1.2 – 9.5% AR after 100 days. Max. sed 3.6 % AR after 120 d. Note that no DT_{50} calculations were possible.				
Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after 100 d. (end of the study).	Non-extractable residues in sed. max x % after 100 d	Non-extractable residues in sed. max x % after 100 d (end of the study)
Swiss Lake	6.7	5.8	3.8	26.7	26.7
Millstream Pond	8.3	7.2	2.0	15.8	15.8

Results also submitted for 2 microcosm systems in glasshouse under natural illumination (plus supplementary illumination up to 16 hours/day). Water depth approx. 85cm with 15cm sediment. In these systems the partition of quinmerac to sediment was very low (max. 7.5 % AR after 352 d). Muhlenteich system water DT_{50} 328 – 374 days, whole system DT_{50} 388 – 430 days. Altensenner See system water DT_{50} 156 – 322 days, whole system DT_{50} 167 – 349 days (overall whole system arithmetic mean 333.5 d).

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

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS Step 1-2 calculator: Version 1.1 Molecular weight (g/mol): 221.64 Water solubility (mg/L): 220 K_{OC}/K_{OM} (L/kg): 35.1 DT_{50} soil (d): 10.4 for recalculation of Step 3. Steps 1 & 2 not recalculated in addenda so original DT_{50} value of 12 days (SFO, field normalised to reference conditions) used. DT_{50} water/sediment system (d): 179.4 (representative worst-case from sediment water studies) DT_{50} water (d): 179.4 DT_{50} sediment (d): 179.4 Crop interception (%): 0
Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure: 1 x 10^{-10} Pa Kom/Koc: 20.34/35.06 1/n: 0.86 DT_{50} soil (d): 10.4 for recalculation of Step 3. $DT_{50\ water}$ (d): 138.8 d $DT_{50\ sediment}$ (d): 1000 d
Application rate	Crop: winter and spring oilseed rape Crop interception: set internally by FOCUS models Number of applications: 1 Interval (d): - Application rate(s): 250 g as/ha Application window:

spring oilseed rape		
D1	13th May	12th June
D3	4th April	4th May
D4	25th April	25th May
D5	9th March	8th April
R1	4th April	4th May

winter oilseed rape		
D2	9th September	9th October
D3	27th August	26th September
D4	28th August	27th September
D5	14th September	14th October
R1	29th August	28th September
R3	29th September	29th October

FOCUS STEP 1 Quinmerac Winter oilseed rape	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	81.91	---		
	24 h	81.49	81.70		
	2 d	81.18	81.52		
	4 d	80.55	81.19		
	7 d	79.63	80.72		
	14 d	77.50	79.64		
	21 d	75.43	78.58		
	28 d	73.42	77.54		
	42 d	69.55	75.52		

Note that PECsed not required for risk assessment, therefore results not given

FOCUS STEP 1 Quinmerac Spring oilseed rape	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	81.91	---		
	24 h	81.49	81.70		
	2 d	81.18	81.52		
	4 d	80.55	81.19		
	7 d	79.63	80.72		
	14 d	77.50	79.64		
	21 d	75.43	78.58		
	28 d	73.42	77.54		
	42 d	69.55	75.52		

Note that PECsed not required for risk assessment, therefore results not given

FOCUS STEP 2 Quinmerac Winter oilseed rape	Day after overall maximum	PEC_{SW} (µg/L) N Europe		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	14.83	---		
	24 h	14.74	14.79		
	2 d	14.69	14.75		
	4 d	14.57	14.69		
	7 d	14.41	14.60		
	14 d	14.02	14.41		
	21 d	13.65	14.22		
	28 d	13.28	14.03		
	42 d	12.58	13.66		
Southern EU	0 h	21.15	---		
	24 h	21.04	21.09		
	2 d	20.96	21.05		
	4 d	20.80	20.96		
	7 d	20.56	20.84		
	14 d	20.01	20.56		
	21 d	19.47	20.29		
	28 d	18.95	20.02		
	42 d	17.96	19.50		

Note that PECsed not required for risk assessment, therefore results not given

FOCUS STEP 2 Quinmerac Spring oilseed rape	Day after overall maximum	PEC_{SW} (µg/L) N Europe		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	14.83	---		
	24 h	14.74	14.79		
	2 d	14.69	14.75		
	4 d	14.57	14.69		
	7 d	14.41	14.60		
	14 d	14.02	14.41		
	21 d	13.65	14.22		
	28 d	13.28	14.03		

FOCUS STEP 2 Quinmerac Spring oilseed rape	Day after overall maximum	PEC_{SW} (µg/L) N Europe		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	42 d	12.58	13.66		
Southern EU	0 h	27.47	---		
	24 h	27.33	27.40		
	2 d	27.23	27.34		
	4 d	27.02	27.23		
	7 d	26.71	27.07		
	14 d	25.99	26.71		
	21 d	25.30	26.36		
	28 d	24.62	26.01		
	42 d	23.33	25.33		

Note that PECsed not required for risk assessment, therefore results not given

Note that Step 3 not required for risk assessment, global max PECsw values given for information only

FOCUS STEP 3 Quinmerac	Date applied	PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual	TWA
Winter Oilseed rape				
D2 ditch		*30.639*	*10.542*	
D2 stream		19.377	3.609	
D3 ditch		1.600	0.535	
D4 pond		0.292	0.760	
D4 stream		1.371	0.259	
D5 pond		0.189	0.471	
D5 stream		1.479	0.255	
R1 pond		0.055	0.088	
R1 stream		1.048	0.085	
R3 stream		7.177	0.800	
Spring oilseed rape				

FOCUS STEP 3 Quinmerac	Date applied	PEC_{SW} (µg/L) Actual	PEC_{SED} (µg/kg) Actual	TWA
D1 ditch		*1.745*	*0.844*	
D1stream		1.349	0.471	
D3 ditch		1.585	0.260	
D4 pond		0.056	0.097	
D4 stream		1.272	0.054	
D5 pond		0.056	0.096	
D5 stream		1.241	0.028	
R1 pond		0.055	0.102	
R1 stream		1.044	0.079	

Metabolite BH 518-2	
Parameters used in FOCUSsw step 1 and 2	Molecular weight: 251.63 Water solubility (mg/L): 1000 (assumption, not measured) Soil or water metabolite: major soil, minor water Koc/Kom (L/kg): 28 DT_{50} soil (d): 29.7 days DT_{50} water/sediment system (d): 1000 (no degradation assumed) DT_{50} water (d): 1000 (no degradation assumed) DT_{50} sediment (d): 1000 (no degradation assumed) Crop interception (%): 0 Maximum occurrence observed (% molar basis with respect to the parent) Water/sediment: 13.1 Soil: 42.4
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Crop: winter and spring oilseed rape Number of applications: 1 Interval (d): - Application rate(s): 250 g as/ha
Main routes of entry	

FOCUS STEP 1 BH 518-2	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	39.01	---		
	24h	38.97	38.99		
	2d	38.95	38.98		
	4d	38.89	38.95		
	7d	38.81	38.91		
	14d	38.62	38.81		
	21d	38.44	38.72		
	28d	38.25	38.62		
	42d	37.88	38.44		

Note that PECsed not required for risk assessment, therefore results not given

FOCUS STEP 2 BH 518-2	Day after overall maximum	PEC_{SW} (µg/L) Winter OSR		PEC_{SW} (µg/L) Spring OSR	
		Actual	TWA	Actual	TWA
Northern EU	0 h	7.38	---	7.38	---
	24 h	7.37	7.37	7.37	7.37
	2 d	7.36	7.37	7.36	7.37
	4 d	7.35	7.36	7.35	7.36
	7 d	7.34	7.36	7.34	7.36
	14 d	7.30	7.34	7.30	7.34
	21 d	7.27	7.32	7.27	7.32
	28 d	7.23	7.30	7.23	7.30
	42 d	7.16	7.27	7.16	7.27
Southern EU	0 h	10.90	---	14.42	---
	24 h	10.89	10.89	14.41	14.42
	2 d	10.88	10.89	14.40	14.41
	4 d	10.87	10.88	14.38	14.40
	7 d	10.84	10.87	14.35	14.38
	14 d	10.79	10.84	14.28	14.35
	21 d	10.74	10.82	14.21	14.31
	28 d	10.69	10.79	14.14	14.28
	42 d	10.58	10.74	14.00	14.21

Note that PECsed not required for risk assessment, therefore results not given

Metabolite BH 518-5 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 237.64 Water solubility (mg/L): 1000 (assumption, not measured) Soil or water metabolite: major soil, minor water Koc/Kom (L/kg): 73.5 DT_{50} soil (d): 601.5 days DT_{50} water/sediment system (d): 1000 (no degradation assumed) DT_{50} water (d): 1000 (no degradation assumed) DT_{50} sediment (d): 1000 (no degradation assumed) Crop interception (%): 0 Maximum occurrence observed (% molar basis with respect to the parent) Water/sediment: 0.01 Soil: 34.7
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Crop: winter and spring oilseed rape Number of applications: 1 Interval (d): - Application rate(s): 250 g as/ha
Main routes of entry	

FOCUS STEP 1 BH 518-5	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	29.89			
	24h	29.87	29.88		
	2d	29.85	29.87		
	4d	29.81	29.85		
	7d	29.74	29.82		
	14d	29.60	29.74		
	21d	29.46	29.67		
	28d	29.31	29.60		
	42d	29.03	29.46		

Note that PECsed not required for risk assessment, therefore results not given

FOCUS STEP 2 BH 518-5	Day after overall maximum	PEC_{SW} (µg/L) Winter OSR		PEC_{SW} (µg/L) Spring OSR	
		Actual	TWA	Actual	TWA
Northern EU	0 h	5.95	---	5.95	---
	24 h	5.95	5.95	5.95	5.95
	2 d	5.94	5.95	5.94	5.95
	4 d	5.93	5.94	5.93	5.94
	7 d	5.92	5.94	5.92	5.94
	14 d	5.89	5.92	5.89	5.92
	21 d	5.86	5.91	5.86	5.91
	28 d	5.84	5.89	5.84	5.89
	42 d	5.78	5.86	5.78	5.86
Southern EU	0 h	8.93	---	11.90	---
	24 h	8.92	8.92	11.89	11.90
	2 d	8.91	8.92	11.88	11.89
	4 d	8.90	8.91	11.87	11.88
	7 d	8.88	8.90	11.84	11.87
	14 d	8.84	8.88	11.79	11.84
	21 d	8.80	8.86	11.73	11.81
	28 d	8.75	8.84	11.67	11.79
	42 d	8.67	8.80	11.56	11.73

Note that PECsed not required for risk assessment, therefore results not given

FORMULATION PECsw

Spray drift PECsw values for the formulation at 1, 5 and 10m have been calculated. This is because the notified formulation (which also contains another active substance, metazachlor), appears to be more toxic than technical quinmerac.

The formulation is applied once at a dose of 2.0 l/ha. The density of the formulation is 1.15 g/cm^3. Thus the mass of formulation
applied is 2.3 kg/ha.

Assumptions:
30cm deep static water body
2.77% drift at 1m
0.57% drift at 5m
0.29% drift at 10m
0.20% at 15m

Initial PECsw values are:
21.237 µg/l at 1m
4.370 µg/l at 5m
2.223 µg/l at 10m

	1.533 µg/l at 15m

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model, with appropriate FOCUSgw scenarios, according to FOCUS guidance. FOCUS-PELMO 3.3.2 and FOCUS-PEARL 3.3.3 Scenarios: Winter oilseed rape – Chateaudun, Hamburg, Kremsmunster, Okehampton, Piacenza, Porto Spring oilseed rape: Jokioinen, Okehampton, Porto Crop: Winter and spring oilseed rape Geometric mean parent $DT_{50field}$ 10.4 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58). Rate constant for parent split 0.490 to BH 518-2, 0.234 to BH 518-5 and 0.276 to sink. K_{OC}: parent, arithmetic mean of soils with pH ≥ 6.5 35.1 ml/g, $^1/_n$= 0.86. For pH dependent setting in PEARL $K_{f,om,ac}$ =364.6 $K_{f,om,ba}$ =17.4 Pka = 4.31 ΔpH = 0.316 **BH518-2:** Geometric mean DT_{50lab} 29.7 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58) Koc: worst-case 28 ml/g, 1/n 0.88 **BH518-5:** Geometric mean DT_{50lab} 601.5 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58) Koc: mean 73.5 ml/g, 1/n 0.80 For field and lysimeter studies See above under Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2 for lysimeter study results
Application rate	Application rate: 250 g a.s./ha. No. of applications: 1/crop, rotation 1 in 3 Time of application: 6 days before emergence; 0% crop interception

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

FOCUS PELMO W OSR	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			BH 518-2	BH 518-5
	Chateaudun	<0.001	0.265	2.675
	Hamburg	0.001	0.970	2.580
	Kremsmunster	<0.001	0.518	2.083
	Okehampton	0.001	0.773	1.854
	Piacenza	**0.200**	**2.147**	2.935
	Porto	<0.001	0.032	0.587

FOCUS PELMO S OSR	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			BH 518-2	BH 518-5
	Jokioinen	<0.001	0.077	**3.154**
	Okehampton	<0.001	0.374	2.848
	Porto	<0.001	<0.001	1.136

FOCUS PEARL W OSR	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			BH 518-2	BH 518-5
	Chateaudun	<0.001	0.563	**3.215**
	Hamburg	<0.001	1.257	2.683
	Kremsmunster	0.008	0.728	2.204
	Okehampton	<0.001	0.919	2.010
	Piacenza	**0.211**	**2.143**	2.629
	Porto	<0.001	0.055	0.617

FOCUS PEARL S OSR	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			BH 518-2	BH 518-5
	Jokioinen	<0.001	0.300	2.358
	Okehampton	<0.001	0.432	1.939
	Porto	<0.001	0.003	0.585

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

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	Quinmerac 3.92×10^{-5} mol/Einstein $^{-1}$ at pH 5 1.55×10^{-5} mol/Einstein $^{-1}$ at pH 7 1.30×10^{-5} mol/Einstein $^{-1}$ at pH 9
Photochemical oxidative degradation in air ‡	DT_{50} of ≤ 39 hours derived by the Atkinson calculation (AOPWIN software not used). OH (24 h) concentration assumed = 5×10^5 cm^{-3}
Volatilisation ‡	Not submitted, not required
	Henry's Law constant $<1 \times 10^{-10}$ $Pa.m^3/mol$
Metabolites	None

PEC (air)

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

$PEC_{(a)}$

Maximum concentration	expected to be negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: quinmerac, BH 518-2, BH 518-5 Surface Water: quinmerac, BH 518-2, BH 518-5 (by drainflow/run-off) Sediment: not required Ground water: quinmerac, BH 518-2, BH 518-5 Air: quinmerac

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

Soil (indicate location and type of study)	None submitted

Surface water (indicate location and type of study)	None submitted
Ground water (indicate location and type of study)	None submitted
Air (indicate location and type of study)	None submitted

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

Candidate to R53

Ecotoxicology

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Bobwhite quail (*Colinus virginianus*)	a.s.	Acute	> 2000	
Bobwhite quail (*Colinus virginianus*)	a.s.	Short-term	> 933	
Japanese quail *(Coturnix coturnix)*	a.s.	Long-term	173	
Mammals ‡				
Rat/mouse	a.s.	Acute	> 5000	
Rabbit	a.s.	Long-term	100	
Additional higher tier studies ‡				
Not necessary				

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

Crop and application rate

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Medium herbivorous bird	Acute	16.53	> 121	10
Insectivorous bird	Acute	13.52	> 147.9	10
Medium herbivorous bird	Short-term	7.60	> 122.8	10
Insectivorous bird	Short-term	7.54	> 123.7	10
Medium herbivorous bird	Long-term	4.00	43.3	5
Insectivorous bird	Long-term	7.54	22.9	5
Higher tier refinement (Birds)				
Not necessary				
Tier 1 (Mammals)				
Medium herbivorous mammal	Acute	6.09	> 821	10
Medium herbivorous mammal	Long-term	1.47	68.0	5

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Higher tier refinement (Mammals)				
Not necessary				
Drinking water assessment (puddles – leaf axils assessment not applicable to crop)				
Indicator species	Time scale	PEC mg/L	TER	Annex VI Trigger
Small granivorous bird	Acute	0.35	>12422	10
Small granivorous bird	Long-term	0.35	>1075	5
Small granivorous mammal	Acute	0.35	>59524	10
Small granivorous mammal	Long-term	0.35	1190	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)	End point	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
Rainbow trout *(Oncorhynchus mykiss)*	a.s.	96 hr (flow-through)	Mortality, EC_{50}	86.8
Rainbow trout *(Oncorhynchus mykiss)*	a.s.	28 d (static)	Growth NOEC	3.16
Rainbow trout *(Oncorhynchus mykiss)*	Preparation	96 hr (flow-through)	Mortality, EC_{50}	22 (2.75 a.s. equivalent*)
Rainbow trout *(Oncorhynchus mykiss)*	BH 518-2	96 hr (flow-through)	Mortality, EC_{50}	> 100
Rainbow trout *(Oncorhynchus mykiss)*	BH 518-5	96 hr (flow-through)	Mortality, EC_{50}	> 100
Rainbow trout *(Oncorhynchus mykiss)*	BH 518-2	28 d(flow-through)	Growth NOEC	0.32 (no study, assumed 10* more toxic than quinmerac)
Rainbow trout *(Oncorhynchus mykiss)*	BH 518-5	28 d(flow-through)	Growth NOEC	5
Aquatic invertebrate				
Daphnia magna	a.s.	48 h (static)	Mortality, EC_{50}	> 100
Daphnia magna	a.s.	21 d (static)	Reproduction, NOEC	100

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Daphnia magna	Preparation	48 h (static)	Mortality, EC_{50}	> 100 (> 12.5 a.s. equivalent*)
Daphnia magna	BH 518-2	48 h (static)	Mortality, EC_{50}	> 100
Daphnia magna	BH 518-5	48 h (static)	Mortality, EC_{50}	> 100
Daphnia magna	BH 518-2	21 d (static)	Reproduction, NOEC	25
Daphnia magna	BH 518-5	21 d (static)	Reproduction, NOEC	25
Sediment dwelling organisms				
Not necessary (NOEC Daphnia >0.1 mg a.s./L).				
Algae				
Anabena flos-aquae	a.s.	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	> 100 (E_bC_{50}, E_rC_{50})
Pseudokirchneriella subcapitata	Preparation	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.022 (0.00275 a.s. equivalent*) 0.043 (0.00538 a.s. equivalent*)
Pseudokirchneriella subcapitata	BH 518-2	72 h (static)	Biomass: E_bC_{50}	700
Pseudokirchneriella subcapitata	BH 518-5	72 h (static)	Biomass: E_bC_{50}	160
Higher plant				
Lemna gibba	a.s.	7 d (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	96 > 100
Lemna gibba	Preparation	7 d (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	16.7 (2.0875 a.s. equivalent*) 82.0 (10.25 a.s. equivalent*)
Lemna gibba	BH 518-2	7 d (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	> 100 > 100
Lemna gibba	BH 518-5	7 d (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	> 100 > 100
Microcosm or mesocosm tests				
Not required				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

*The formulation's metazachlor component is likely to be responsible for its higher toxicity when compared to quinmerac.

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

FOCUS Step1

Oilseed rape 1 x 250 g a.s./ha (using worst-case PECs from winter and spring OSR, North and South Europe)

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i	PEC_{twa}	TER	Annex VI Trigger[1]
Quinmerac	Fish	86.8	Acute	0.0819		1060	100
Quinmerac	Fish	3.16	Chronic	0.0819		39	10
Quinmerac	Aquatic invertebrates	>100	Acute	0.0819		>1221	100
Quinmerac	Aquatic invertebrates	100	Chronic	0.0819		1221	10
Quinmerac	Algae	>100	Chronic	0.0819		>1221	10
Quinmerac	Higher plants	96	Chronic	0.0819		1172	10
Quinmerac	Sediment-dwelling organisms	The Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev 4, p 16) (European Commission, 2002b) states that studies on sediment-dwelling organisms are not required if the NOEC from a chronic study on Daphnia is > 0.1 mg a.s./L. The study by Jatzek (2003) gives an end point of 100 mg a.s./L. A study on sediment dwellers is therefore not required.					
BH 518-2	Fish	> 100	Acute	0.039		> 2564	100
BH 518-2	Invertebrates	> 100	Acute	0.039		> 2564	100
BH 518-2	Algae	700	Acute	0.039		17949	10
BH 518-2	Higher plants	> 100	Acute	0.039		> 2564	10
BH 518-2	Fish	0.32[2]	Chronic	0.039		**8.2**	10
BH 518-2	Invertebrates	25	Chronic	0.039		641	10
BH 518-5	Fish	> 100	Acute	0.030		> 3333	100
BH 518-5	Invertebrates	> 100	Acute	0.030		> 3333	100
BH 518-5	Algae	160	Acute	0.030		5333	10
BH 518-5	Higher plants	> 100	Acute	0.030		> 3333	10
BH 518-5	Fish	5	Chronic	0.030		167	10
BH 518-5	Invertebrates	25	Chronic	0.030		833	10

[1]If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
[2]No study. Assumed 10x more toxic than parent as worst-case.

FOCUS Step 2

Winter and spring oilseed rape, 1 application, 250 g a.s./ha, growth stages 00 – 18.

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC max	TER	Annex VI Trigger
BH 518-2	Fish	0.32	Chronic	0.012	27	10

Product - spray drift only, acute risk only

Organism	**LC/EC50 (mg formulation/L)**	**PEC[1] (mg formulation/L) (see B.8.5.2c)**	**Distance (m)[2]**	**TER**	**Annex VI trigger**
Fish	22	0.0212	1	1038	100
Invertebrates	> 100	0.0212	1	> 4717	100
Algae	0.022	0.0212	1	**1.0**	10
Algae	0.022	0.0044	5	**5.0**	10
Algae	0.022	0.0022	10	10.0	10
Aquatic higher plants	0.0167	0.0212	1	**0.8**	10
Aquatic higher plants	0.0167	0.0044	5	**3.8**	10
Aquatic higher plants	0.0167	0.0022	10	**7.6**	10
Aquatic higher plants	0.0167	0.0015	15	11.1	10

[1] Exposure based on spray drift input.
[2] 2.77% spray-drift assumed at 1m, 0.57% at 5m, 0.29% at 10m and 0.20% at 15m

Bioconcentration				
	Active substance	Metabolite 1	Metabolite 2	Metabolite 3
$logP_{O/W}$	- 1.47	N/A	N/A	N/A
Bioconcentration factor (BCF)[1]	Not required			

[1]only required if log $P_{O/W}$ >3.

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. ‡	> 108.51	> 100.0
Preparation[1]	> 85.27	> 100
Field or semi-field tests		
Not required		

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

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

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	< 2.5	50
a.s.	Oral	< 2.3	50
Preparation	Contact	< 2.5	50
Preparation	Oral	< 2.9	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha[1])
Typhlodromus pyri ‡	Quinmerac	Mortality	> 500
Aphidius rhopalosiphi ‡	Quinmerac	Mortality	> 500

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

Crop and application rate

Test substance	Species	Effect (LR_{50})	HQ in-field	HQ off-field at 1m	Trigger
Quinmerac	*Typhlodromus pyri*	> 500 g/ha	<0.5	< 0.014	2
Quinmerac	*Aphidius rhopalosiphi*	> 500 g/ha	<0.5	< 0.014	2
BAS 526 13 H	*Typhlodromus pyri*	> 4.0 L/ha	< 0.5	< 0.022	2
BAS 526 13 H	*Aphidius rhopalosiphi*	> 2.5 L/ha	< 0.8	< 0.014	2

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	End point	Trigger value
Typhlodromus pyri	Protonymph	BAS 526 13 H, bean leaves, 14 days	2.0 L/ha	LR_{50} > 2.0 L/ha	50 %
Aphidius rhopalosiphi	Adult	BAS 526 13 H, barley seedlings, 48 h	2.0 L/ha	LR_{50} > 2.0 L/ha	50 %
Chrysoperla carnea	Larvae	BAS 526 13 H, glass	2.0 L/ha	LR_{50} > 2.0 L/ha	50%
Aleochara bilineata	Adult	BAS 526 13 H, sand	2.0 L/ha	ER_{50} > 2.0 L/ha (repro)	50%

[1]indicate whether initial or aged residues
[2]for preparations indicate whether dose is expressed in units of a.s. or preparation
[3]indicate if positive percentages relate to adverse effects or not

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	End point[1]
Earthworms			
Eisenia fetida	Quinmerac	Acute 14 days	> 1000 mg a.s./kg
No chronic study required for quinmerac or BH 518-2 – DT_{50} > 100 and < 365 days, one application proposed.			
Eisenia fetida	BAS 526 13 H	Acute 14 days	142 mg a.s./kg
Eisenia fetida	BH 518-2	Acute 14 days	> 1000 mg/kg
Eisenia fetida	BH 518-5	Acute 14 days	> 1000 mg/kg
A study was submitted for BH 518-5, as its DT_{90} is > 365 days.			
Eisenia fetida	BH 518-5	Chronic 56 days	0.775 mg/kg (NOEC)
Other soil macro-organisms			
Collembola			
Folsomia candida	BH 518-5	Chronic	1000 mg/kg (NOEC)
Soil micro-organisms			
Nitrogen mineralisation	Quinmerac	28 days	<25% effect at day 28 at 16.5 mg a.s./kg d.w.soil
Nitrogen mineralisation	BAS 526 13 H	28 days	<25% effect at day 28 at 1.92 mg a.s./kg d.w.soil
Nitrogen mineralisation	BH 518-2	28 days	<25% effect at day 28 at 0.83 mg a.s./kg d.w.soil
Nitrogen mineralisation	BH 518-5	28 days	<25% effect at day 28 at 0.42 mg a.s./kg d.w.soil
Carbon mineralisation	Quinmerac	28 days	+27.8% effect at day 28 at 16.5 mg a.s./kg d.w.soil
Carbon mineralisation	BAS 526 13 H	28 days	<25% effect at day 28 at 1.92 mg a.s./kg d.w.soil
Carbon mineralisation	BH 518-2	28 days	<25% effect at day 28 at 0.83 mg a.s./kg d.w.soil
Carbon mineralisation	BH 518-5	28 days	<25% effect at day 28 at 0.42 mg a.s./kg d.w.soil
Field studies[2]			
Not required			

[1]indicate where end point 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

Toxicity/exposure ratios for soil organisms

Crop and application rate

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia fetida	Quinmerac	Acute	0.333	> 3003	10
Eisenia fetida	BAS 526 13 H	Acute	0.333	426.4	10
Eisenia fetida	BH 518-2	Acute	0.16	> 6250	10
Eisenia fetida	BH 518-5	Acute	0.14	> 7143	10
Eisenia fetida	BH 518-5	Chronic	0.14	5.5	5
Other soil macro-organisms					
Folsomia candida	BH 518-5	28 days	0.14	7143	10

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

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

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

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
Lettuce *(Lactuca sativa)*	BAS 526 13 H	50.5 g a.s./ha		6.925 g a.s./ha (1m, at 2.77% drift)	7.29	5

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

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

None required

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

Test type/organism	end point
Activated sludge	EC_{50} 870 mg a.s./L (quinmerac)
Pseudomonas sp	EC_{10} > 1000 mg a.s./L (BH 518-2, BH 518-5)

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

Compartment	
soil	Quinmerac, BH 518-2, BH 518-5
water	Quinmerac, BH 518-2, BH 518-5

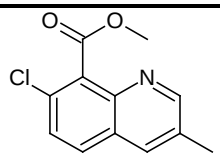
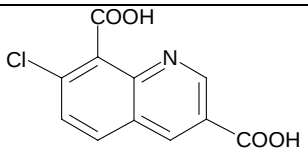
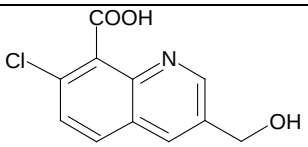
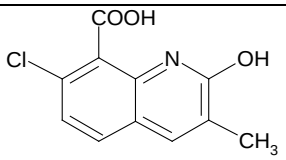
sediment	
groundwater	

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	R52/R53

	RMS/peer review proposal
Preparation	R50/R53

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula
BH 518-1	methyl 7-chloro-3-methylquinoline-8-carboxylate	
BH 518-2	7-chloroquinoline-3,8-dicarboxylic acid	
BH 518-4	7-chloro-3-(hydroxymethyl)quinoline-8-carboxylic acid	
BH 518-5	7-chloro-2-hydroxy-3-methylquinoline-8-carboxylic acid	

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

** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

ABBREVIATIONS

1/n	slope of Freundlich isotherm
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstract Service
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
EPA	Environmental Protection Agency
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
F	field
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector

GC-MS	gas chromatography-mass spectrometry
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GM	geometric mean
GS	growth stage
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HPLC-DAD	high pressure liquid chromatography with diode array detector
HQ	hazard quotient
IC	ion chromatography
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
N	North
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration

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