Review of the existing maximum residue levels for quinmerac according to Article 12 of Regulation (EC) No 396/2005

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance quinmerac. To assess the occurrence of quinmerac residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EC) No 33/2008, the European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

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Keywords: quinmerac, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, herbicide

Requestor: European Commission

Question number: EFSA-Q-2009-00072

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Acknowledgement: EFSA wishes to thank the rapporteur Member State, Estonia, for the preparatory work and Laszlo Bura, Viktoria Krivova, Silvia Ruocco and Viktor Toth for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Theobald A, Vagenende B and Verani A, 2020. Reasoned opinion on the review of the existing maximum residue levels for quinmerac according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(10):6257, 41 pp. https://doi.org/10.2903/j.efsa.2020.6257

ISSN: 1831-4732

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The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.
Summary

Quinmerac was included in Annex I to Directive 91/414/EEC on 1 May 2011 by Commission Directive 2010/89/EU, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011.

As quinmerac was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation.

As the basis for the MRL review, on 14 June 2019, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 15 July 2019 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State (RMS), Estonia, to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 1 November 2019. On the basis of all the data submitted by Member States and by the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with Pesticide Residues Intake Model (PRIMo) calculations and an updated GAP overview file, were provided by the RMS to EFSA on 27 January 2020. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States and the EURL, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EC) No 33/2008, EFSA prepared in June 2020 a draft reasoned opinion, which was circulated to Member States and EURL for consultation via a written procedure. Comments received by 17 July 2020 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of quinmerac in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement can be proposed as sum of quinmerac and its metabolites BH 518-2 and BH 518-4, expressed as quinmerac; while, for risk assessment, the residue is defined as the sum of quinmerac and its metabolites BH 518-2 and BH 518-4 (free and conjugated), expressed as quinmerac. These residue definitions are also applicable to processed commodities. Sufficiently validated analytical methods are available for the enforcement of the proposed residue definition in all four main plant matrices at the combined limit of quantification (LOQ) of 0.15 mg/kg. According to the EURLs, the combined LOQ of 0.1 mg/kg is achievable for the enforcement of the proposed residue definition in high water content, high acid content and dry commodities in routine analyses. In high oil content commodities, parent quinmerac can be enforced at the LOQ of 0.01 mg/kg, in routine analysis. Analytical standards for parent quinmerac and metabolite BH 518-2 are commercially available, but they are not available for metabolite BH 518-4.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all food commodities under evaluation. Tentative MRLs were derived for sugar and fodder beet tops, in view of the future need to set MRLs in feed items, noting that a data gap was identified for the lack of trials analysing simultaneously for enforcement and risk assessment residue definitions.

Quinmerac is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in all commodities of animal origin.

The metabolism of quinmerac residues in livestock was investigated in lactating goats and laying hens at dose rate covering the maximum dietary burdens calculated in this review. According to the results of these studies, the residue definition for enforcement and risk assessment in livestock commodities was proposed as quinmerac only. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.02 mg/kg in all matrices is available. According to EURLs, quinmerac can be monitored in liver and milk at the LOQ of 0.01 mg/kg. Furthermore, screening data generated by EURL showed that quinmerac can be monitored in muscle, milk and honey with a screening detection limit (SDL) of 0.01 mg/kg.
A livestock feeding study on lactating cows was used to derive MRL and risk assessment values in milk and tissues of ruminants. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. For poultry, the metabolism study was sufficient to conclude that, at the calculated dietary burden, residue levels would remain below the enforcement LOQ of 0.02 mg/kg in tissues and eggs. Since uncertainties remain due to the tentative conversion factors (CFs) applied for feed items, and the potential overestimation of the dietary burdens, MRLs for livestock commodities (ruminants and equine liver and kidney) above the LOQ of 0.02 mg/kg are also tentative.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. The highest chronic exposure was calculated for Dutch toddler, representing 3% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for beetroots, representing 3% of the acute reference dose (ARfD). Although some uncertainties were identified, these calculations indicate that the uses assessed under this review result in a consumer exposure far lower than the toxicological reference values, and thus are unlikely to pose a risk to consumer’s health.
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Background

Regulation (EC) No 396/2005¹ (hereinafter referred to as ‘the Regulation’) establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC² a reasoned opinion on the review of the existing MRLs for that active substance. Quinmerac was included in Annex I to Council Directive 91/414/EEC on 1 May 2011 by means of Commission Directive 2010/89/EU³ which has been deemed to be approved under Regulation (EC) No 1107/2009⁴, in accordance with Commission Implementing Regulation (EU) No 540/2011⁵, as amended by Commission Implementing Regulation (EU) No 541/2011⁶. Therefore, EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Commission Regulation (EC) No 33/2008⁷ quinmerac was evaluated by Estonia, designated as rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific output (EFSA, 2010). The approval of quinmerac is restricted to uses as herbicide. Furthermore, according to the provisions of the approval directive, confirmatory information was requested, among others, as regards the potential of plant metabolism to result in an opening of the quinoline ring and as regards residues in rotational crops as well as the long-term risk for earthworms due to the metabolite BH 518-5, to be submitted by 30 April 2013, and have been assessed by EFSA (2015).

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC repealed by Regulation (EC) No 1107/2009. It should be noted, however, that, in the framework of Regulation (EC) No 1107/2009, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU) and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC repealed by Regulation (EC) No 1107/2009 is therefore insufficient for the assessment of all existing MRLs for a given active substance.

To gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities;
- the analytical methods for enforcement of the proposed MRLs.

As the basis for the MRL review, on 14 June 2019, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 15 July 2019 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of

¹ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
² Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.
³ Commission Directive 2010/89/EU of 6 November 2010 amending Council Directive 91/414/EEC to include quinmerac as active substance and amending Decision 2008/934/EC. OJ L 320, 7.12.2010, p. 3–6.
⁴ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
⁵ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.
⁶ Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.
⁷ Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 9(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.1.2008, p. 5–12.
specific GAP forms. In the framework of this consultation, 19 Member States provided feedback on their national authorisations of quinmerac. Based on the GAP data submitted, the designated RMS Estonia was asked to identify the critical GAPs to be further considered in the assessment, in the format of a specific GAP overview file. Subsequently, in a second step, Member States were requested to provide residue data supporting the critical GAPs by 1 November 2019.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked quinmerac to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations and an updated GAP overview file, were submitted to EFSA on 27 January 2020. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information, EFSA prepared in June 2020 a draft reasoned opinion, which was circulated to Member States and EURL for commenting via a written procedure. All comments received by 17 July 2020 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Estonia, 2020), taking into account also the information provided by Member States during the collection of data (Germany, 2020), and the EURL report on analytical methods (EURL, 2019) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the completeness check report (EFSA, 2020a) and the Member States consultation report (EFSA, 2020b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) and the PROFile as well as the GAP overview file listing all authorised uses are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMo is presented in Appendix C.

Terms of Reference

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

The quinmerac and its use pattern

Quinmerac is the ISO common name for 7-chloro-3-methylquinoline-8-carboxylic acid (IUPAC). The chemical structure of the active substance and its main metabolites are reported in Appendix F.

The EU MRLs for quinmerac are established in Annex III of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for quinmerac are not available. There are no MRL changes occurred since the entry into force of the Regulation mentioned above.

For the purpose of this MRL review, all the uses of quinmerac currently authorised within the EU as submitted by the Member States during the GAP collection, have been reported by the RMS in the GAP overview file. The critical GAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAP for quinmerac are given in Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Estonia, 2020);
• the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (United Kingdom, 2007, 2009);
• the review report updated on the basis of the confirmatory data assessment carried out by EFSA (EFSA, 2015; European Commission, 2017a,b));
• the conclusion on the peer review of the pesticide risk assessment of the active substance quinmerac (EFSA, 2010);
• the review report on quinmerac (European Commission, 2017a,b);

The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2017a,b; OECD, 2011, 2013).

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

1. **Residues in plants**

1.1. **Nature of residues and methods of analysis in plants**

1.1.1. **Nature of residues in primary crops**

The metabolism of quinmerac was investigated after foliar treatment in tuber vegetables (sugar beet), pulses and oilseeds (rapeseeds) and cereals (wheat) (United Kingdom, 2007), and assessed in the framework of the peer review (EFSA, 2010). All studies were performed following pre- and post-emergence treatment. In all studies, quinmerac was radiolabelled in the quinoline ring of the molecule. The application rate used in the metabolism studies covered the critical GAPs (cGAPs) evaluated in this review for rapeseeds (2N), but not for sugar beet (0.5N). No uses were authorised for cereals at the time of this MRL review.

The metabolic pathway of quinmerac was found to be broadly comparable in the three crops investigated, with parent quinmerac found to be metabolised relatively rapidly. Following post-emergence application to rapeseeds and sugar beet, parent quinmerac declined from 80% to 90% of the total radioactive residues (TRR) (3.8–18.2 mg eq./kg) at 0–1 days after treatment (DAT) to less than 20% TRR (0.13–0.34 mg eq./kg) at 16–23 DAT, in foliage. At harvest of the mature crop, levels of quinmerac (free and conjugated) were below 10% TRR, or not detected at all. The same behaviour was observed after pre-emergence treatment. In wheat, levels of quinmerac, if detected, were always below 10% TRR.

The main component of the residue in the three crop categories investigated was the hydroxymethyl derivative BH 518-4, free and conjugated (up to 35% TRR, 0.006 mg eq./kg, in beets at harvest), and to a lesser extent, the carboxylic acid derivate BH 518-2 (up to 24% TRR, 0.004 mg eq./kg, in beets at harvest). The total radioactive residues in seeds were too low to enable metabolite quantification; nonetheless, quinmerac and metabolites BH 518-4 and BH 518-2 were detected.

Finally, albeit the metabolism study on sugar beets is underdosed when compared to the cGAP (0.5N), this is not expected to bias the results of the study. Overall, EFSA considers the metabolism of quinmerac in primary crops as sufficiently elucidated.

1.1.2. **Nature of residues in rotational crops**

Quinmerac is authorised on crops that may be grown in rotation. The field DT$_{90}$ reported in the soil degradation studies evaluated in the framework of the peer review was 193 days (EFSA, 2010). The soil metabolite BH 518-5 also exhibited field DT$_{90}$ longer than 100 days. An investigation of residues in rotational crops is thus required.

One confined rotational crop study with quinmerac radiolabelled on the quinoline ring of the molecule was available for this review (United Kingdom, 2007; EFSA, 2010). Quinmerac was applied at a rate of 500 g a.s./ha onto bare soil (0.5N compared to the most critical GAP under assessment for crops that can be rotated). Crops were planted at nominal plant back intervals (PBI) of 30, 120, 365

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8 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
days after treatment (DAT). Crops planted at each interval consisted of leafy vegetable (lettuce), roots and tuber vegetables (radish) and cereals (wheat).

Residues in radish and wheat declined over time, while residues in lettuce did not show a consistent pattern over time. Following a PBI of 30 days, the total radioactive residues in wheat grain, lettuce (head) and radish (root) ranged from 0.031 to 0.302 mg eq./kg; residues were highest in wheat grain. Following a PBI of 120 days, the total residue levels decreased from 0.010 to 0.115 mg eq./kg. A further decrease was seen at PBI of 365 days, with total radioactive residues of 0.005–0.033 mg eq./kg. Residues were considerably higher in wheat foliage (0.029–0.863 mg eq./kg), straw (0.049–2.291 mg eq./kg) and chaff (0.062–0.684 mg eq./kg); levels in feed items also decreased with the increasing length of the plant back period.

Parent quinmerac was not found in any crop at any PBI. Major metabolites were BH 518-4 (≤ 36% TRR, 0.83 mg eq./kg in wheat straw) and its conjugate (≤ 69% TRR, 0.15 mg eq./kg in radish roots), BH 518-2 (16% TRR, 0.36 mg eq./kg in wheat straw) and three unidentified metabolites, accounting (individually) for up to 47% TRR. These unknown metabolites represented a major proportion of TRR in lettuce leaves (42%, 0.014 mg eq./kg, PBI 365), radish leaves (29%, < 0.01 mg eq./kg, PBI 120) and wheat straw (36%, 0.05 mg eq./kg, PBI 120). For some matrices, unidentified metabolites accounted for 100% of the extractable radioactive residues. The soil metabolite BH 518-5 was not taken up.

The metabolism and distribution of quinmerac in rotational crops followed a similar pathway to the one observed in primary crops, but it resulted to be more extensive. In view of the presence of three unknown metabolites representing more than 10% TRR (> 0.01 mg eq./kg) in leafy crops and cereals’ forage and straw, EFSA determines that the characterisation of these metabolites is desirable.

1.1.3. Nature of residues in processed commodities

One study investigating the nature of residues in processed commodities was available in the DAR and assessed in the peer review (United Kingdom, 2007; EFSA, 2010). The study was conducted with quinmerac radiolabelled on the quinoline ring simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6). The recovery of applied radioactivity following treatment was higher than 96% and, therefore, it is concluded that quinmerac is stable to hydrolysis under standard conditions of pasteurisation, baking/brewing/boiling and sterilisation (United Kingdom, 2007; EFSA, 2010).

1.1.4. Methods of analysis in plants

During the peer review, a hyphenated analytical method based on high-performance liquid chromatography (HPLC) coupled to tandem mass spectrometry (MS/MS) detection was validated for the determination of parent quinmerac and metabolites BH 518-2 and BH 518-4, as free forms, in high water (sugar beets), high acid (orange), high oil content (rapeseed) and dry commodities (wheat grain), with a limit of quantification (LOQ) of 0.05 mg/kg, for each analyte (United Kingdom, 2009; EFSA, 2010). An independent laboratory validation (ILV) was also available for the four main matrix groups. Validation data also exist for wheat straw (no group), with the same LOQ, for each analyte (United Kingdom, 2009; EFSA, 2010).

Under the framework of this MRL review, an HPLC-MS/MS method was made available for the determination of parent quinmerac and metabolites BH 518-2 and BH 518-4, as free forms, in the four main matrices (lettuce, orange, rapeseeds, wheat grain) (Estonia, 2020). The LOQ was reported to be 0.05 mg/kg, for each analyte. The ILV was provided for high water content and dry commodities. As the principle of the primary method is the same for the four main matrices, the ILV is also acceptable for high oil and high acid content commodities. Hence, EFSA considers the method as sufficiently validated.

During the Member States consultation, the EURLs provided validation results of a single residue method (QuEChERS-based) using liquid chromatography with tandem mass spectroscopy (LC-MS/MS), with a combined LOQ of 0.1 mg/kg for the enforcement of the sum of parent quinmerac, and metabolites BH 518-2 and BH 518-4 in high water content, high acid content and dry commodities in routine analysis. According to EURLs, validation results for high oil content commodities were only available for parent quinmerac at the LOQ of 0.01 mg/kg. Recoveries obtained for BH 518-2 and BH 518-4 were too low, though those of BH 518-4 were consistent. Analytical standards are commercially available for parent quinmerac and metabolite BH 518-2, but not for the metabolite BH 518-4 (EURL, 2019).
1.1.5. Stability of residues in plants

The storage stability of quinmerac was investigated in the framework of the peer review (EFSA, 2010), and in studies submitted as confirmatory data (United Kingdom, 2015). The storage stability of quinmerac was studied in high oil content (rapeseeds) and high water content (sugar beets) matrices (United Kingdom, 2009, 2015; EFSA, 2010). In both studies, the levels of quinmerac and the metabolites BH 518-2 and BH 518-4 were determined using an ELISA method, which determines the total residue of quinmerac and its two metabolites, without differentiating among the individual chemical species.

In high water content and high oil content commodities, the available studies demonstrated storage stability for total residues of quinmerac (defined as the total levels of quinmerac, BH 518-2 and BH 518-4) for a period of 24 months, when stored at −20°C. It is noted that at the time of this MRL review, only uses on high water content and high oil content commodities were authorised. If additional uses on high acid content, high protein and high starch content commodities or specific matrices are proposed in the future, further storage stability studies might be required.

1.1.6. Proposed residue definitions

The metabolism of quinmerac was similar in all crops assessed. The metabolism in rotational crops exhibited a similar pathway to the metabolism in primary crops, but it showed to be more extensive. Processing of quinmerac is not expected to modify the nature of residues.

Metabolites BH 518-4 and BH 518-2 were found to be the main components of the residue in primary and rotational crops; however, since a major proportion of the total residue were unknown compounds that did not match with available reference standards containing the intact quinoline structure, a data gap was set in the EFSA conclusion (EFSA, 2010) to investigate the potential for opening of the quinoline ring structure and corollary, to address resulting metabolites. In the framework of confirmatory data, a non-good laboratory practice (GLP) cell culture experimental study and a reasoned case were submitted to demonstrate the opening of the quinoline ring. It was reported that the generation of metabolites with a structure different from the parent and identified metabolites is unlikely to occur. There was no indication for ring opening from the available data and information (EFSA, 2015). Consequently, the residue definition for monitoring for commodities of plant origin was confirmed as proposed during the peer review, i.e., the sum of quinmerac and its metabolites BH 518-2 and BH 518-4, expressed as quinmerac (European Commission, 2017a,b). This residue definition is considered valid in this MRL review. It is noted that the residue definition for enforcement set in Regulation (EC) No 396/2005 is not identical to the proposed residue definition.

An analytical method for the enforcement of the proposed residue definition at the combined LOQ of 0.15 mg/kg in all four main plant matrices is available (EFSA, 2010; Estonia, 2020). According to the EURLs, the combined LOQ of 0.1 mg/kg is achievable for the enforcement of the proposed residue definition in high water content, high acid content and dry commodities, by using single residue methods (QuEChERS-based) in routine analyses. In high oil content commodities, parent quinmerac can be monitored in routine analysis at the LOQ of 0.01 mg/kg, whereas validation experiments with the metabolites are pending. Analytical standards for parent quinmerac and metabolite 518-2 are commercially available, but not for metabolite BH 518-4 (EURL, 2019).

For risk assessment, three major uncharacterised metabolites were detected at significant levels (> 0.01 and > 0.05 mg eq./kg, but below the combined LOQ for enforcement set at 0.15 mg/kg) in rotated leafy crops and cereal straw and forage, in the confined study conducted with bare soil (see Section 1.1.2). Considering the potential occurrence of these metabolites in rotational crops, the consumer exposure is unlikely to lead to a toxicological concern, and therefore, their inclusion in the residue definition for risk assessment is dismissed. Hence, the residue for risk assessment in plant commodities defined by the peer review as the sum of quinmerac and its metabolites BH 518-2 and BH 518-4 (free and conjugated), expressed as quinmerac, is still considered valid in this MRL review.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of quinmerac residues resulting from the reported GAPs, EFSA considered all the residue trials reported by the RMS in its evaluation report (Estonia, 2020), as well as the supporting trials submitted by Member States (Germany, 2020). All residue trial samples considered in
this framework were stored in compliance with the conditions for which storage stability of residues was demonstrated. Decline of residues during storage of the trial samples is therefore not expected.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017a,b).

For all crops, available residue trials are sufficient to derive tentative MRL and risk assessment values, taking note of the following considerations:

- **Rapeseeds/canola seeds:** the number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and a no residues situation is expected. Regarding the southern outdoor GAP, compliant trials are not available. Nonetheless, in view of the results of the metabolism studies conducted with rapeseeds and considering that northern and southern outdoor GAPs are similar, and a no residues situation was observed in the northern trials, significant residues are not expected in rapeseeds according to this use. Residue trials analysing for the conjugated residues included in the residue definition for risk assessment are not available. Nevertheless, as the compounds analysed were all below the LOQ and, according to the metabolism study, the conjugates are expected to be present at the same level as the other compounds, additional trials analysing simultaneously for enforcement and risk assessment residue definitions are only desirable.

- **Sunflower seeds:** the number of residue trials supporting the northern and southern outdoor GAPs is not compliant with the data requirement for this crop. However, the reduced number of residue trials (extrapolated from rapeseeds) is considered acceptable in this case as all results (both, northern and southern) were below the LOQ and a no residues situation is expected. Residue trials analysing for the conjugated residues included in the residue definition for risk assessment are not available. Nevertheless, as the compounds analysed were all below the LOQ and, according to the metabolism study, the conjugates are expected to be present at the same level as the other compounds, additional trials analysing simultaneously for enforcement and risk assessment residue definitions are only desirable.

- **Soyabeans:** the number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials (extrapolated from rapeseeds) is considered acceptable in this case as all results were below the LOQ and a no residues situation is expected. Residue trials analysing for the conjugated residues included in the residue definition for risk assessment are not available. Nevertheless, as the compounds analysed were all below the LOQ and, according to the metabolism study, the conjugates are expected to be present at the same level as the other compounds, additional trials analysing simultaneously for enforcement and risk assessment residue definitions are only desirable.

- **Mustard seeds, gold of pleasure seeds and borage seeds:** no significant residues are expected for the northern and southern use of these crops. Residue trials analysing for the conjugated residues included in the residue definition for risk assessment are not available. Nevertheless, as the compounds analysed were all below the LOQ and, according to the metabolism study, the conjugates are expected to be present at the same level as the other compounds, additional trials analysing simultaneously for enforcement and risk assessment residue definitions are only desirable.

- **Sugar beets, and by extrapolation, beetroots and fodder beets:** northern residue trials were performed with one instead of four applications. However, this is deemed acceptable in this case, as the first three applications are foreseen to be done early in the season and no impact on the final residue levels is thus expected. Residue trials analysing for the conjugated residues included in the residue definition for risk assessment are not available. In roots, considering that the compounds analysed were all below the LOQ and, according to the metabolism study, the conjugates are expected to be present at the same level as the other compounds, additional trials analysing simultaneously for enforcement and risk assessment residue definitions are only desirable. In tops, although all compounds analysed were below the LOQ, according to the metabolism study, levels of conjugates are expected to be higher than the free forms, and therefore, residue trials analysing simultaneously for enforcement and risk assessment residue definitions are still required.
1.2.2. Magnitude of residues in rotational crops

A field rotational crop study, assessed in the framework of confirmatory data, was available for this review (EFSA, 2015; United Kingdom, 2015). Three field trials were conducted in northern Europe and one trial in the south. In all four trials, quinmerac was applied once at 250 g a.s./ha to bare soil (0.25N of the maximum seasonal application rate currently authorised on crops that can be rotated). Representative rotational crops of carrots/radish, cauliflower/broccoli and spinach/lettuce were planted at plant back intervals of 30, 60 and 90 days. Wheat was planted at plant back intervals of 30 and 60 days only. Longer PBIs were not assayed. Rotational crops were sampled between 45 and 362 DAT. Samples were stored frozen for up to 23 months before analysis, in compliance with the conditions for which storage stability of residues was demonstrated for high water content commodities; nevertheless, storage stability data are still needed to demonstrate the validity of the results of the rotated cereals. Samples were analysed for residues of parent quinmerac and its metabolites BH 518-2 and BH 518-4. The LOQ of the method used in the study was 0.01 mg/kg (for each analyte), except for wheat straw and whole plant, for which the LOQ was 0.05 mg/kg (for each analyte). The analytical method does not determine conjugates.

No residues of quinmerac or metabolite BH 518-2 above the LOQ (0.01 mg/kg) were found in any of the samples taken from all the PBIs. Residues of the metabolite BH 518-4 were found in spinach leaves (mature) at all PBIs (0.087 mg/kg for 30 PBI; 0.017 mg/kg for 60 PBI; 0.033 for 90 PBI). In the other crops, residues of metabolites BH 518-4 were below the LOQ (0.01 mg/kg) in all samples, except for immature plants taken at 30 PBI (up to 91 DAT), namely cauliflower and broccoli whole plants (0.017 mg/kg), wheat whole plant (0.089 mg/kg) and radish whole plant (0.021 mg/kg).

Detectable amounts of quinmerac and its metabolites BH 518-2 and BH 518-4 are expected to be below 0.01 mg/kg, each, at plant back intervals longer than 30 days in succeeding root and tuber vegetables, and cereals (to be confirmed by storage stability data). For rotated leafy crops, residues of metabolite BH 518-4 higher than 0.01 mg/kg cannot be excluded at any PBI. Bearing in mind that the study is underdosed compared to the most critical GAP currently authorised and that PBIs longer than 90 days were not investigated, residues of metabolite BH 518-4 cannot be excluded in rotated leafy crops. Consequently, additional field crops studies covering the most critical GAP currently authorised on sugar beets are still required (data gap). In the new studies, storage stability data on high protein content commodities should be provided. Member States granting authorisations for quinmerac may choose to avoid the presence of significant residues in rotational crops by taking the appropriate risk mitigation measures (e.g., define plant back interval of at least 180 days, based on the field DT90).

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed in one study conducted on rapeseeds (United Kingdom, 2007, EFSA, 2010). No residues of quinmerac or its metabolites BH 518-2 and BH 518-4 were detected in the raw agricultural commodity (seeds) or in the processed commodities (crude oil, refined oil, press cake). It can be concluded that no significant concentration of residues of quinmerac or its metabolites occurred in the processed fractions of oilseed rape.

Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals for all food commodities under evaluation. Tentative MRLs were also derived for sugar and fodder beet tops, in view of the future need to set MRLs in feed items.

Regarding risk assessment values, residue trials analysing simultaneously for enforcement and risk assessment residue definitions were not available for any crop under evaluation. The tentative worst-case conversion factor (CF) of 2, as proposed in the addendum of the DAR (United Kingdom, 2009), was applied to rapeseeds, and by extrapolation to all oil seeds and soyabean under evaluation, for the risk assessment to take into account the conjugated residues. For beetroots, sugar beet and fodder beet roots, a tentative CF of 1 derived from the metabolism study on sugar beet was applied for risk assessment, while for sugar beet tops and fodder beet tops, a tentative CF of 3 was applied, also derived from the metabolism studies.
Specific MRLs for rotational crops are not needed, provided that Member States will take adequate risk mitigation measures (e.g. define plant back interval) in order to avoid significant residues to occur in rotational crops.

2. Residues in livestock

Quinmerac is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D.1. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in all commodities of animal origin. Nonetheless, considering that the dietary burden is driven by the input values of high LOQ (0.15 mg/kg), and by the application of additional conservative conversion factors, the calculated livestock exposure is expected to be overestimated and should be reconsidered once the pending residue trials on sugar beet tops will be submitted.

It is highlighted that the calculation did not consider residues from rotational crops, as it is assumed that risk mitigation measures, that will avoid the uptake of residues in succeeding crops, will be taken by MSs when granting national authorisations.

2.1. Nature of residues and methods of analysis in livestock

The metabolism of quinmerac residues in livestock was investigated in lactating goats and laying hens at dose rate covering the maximum dietary burdens calculated in this review (United Kingdom, 2007). These studies were included in the DAR, but not peer reviewed. In all studies, quinmerac was radiolabelled in the quinoline ring of the molecule.

The study performed on lactating goats indicated that quinmerac was rapidly excreted. Highest residue levels were found in kidney (0.805 mg eq./kg) and liver (0.161 mg eq./kg), whilst limited transfer is expected in milk, fat and muscle (< 0.02 mg eq./kg).

Liver and kidney residues were largely extractable, with the radioactivity found to consist of unchanged quinmerac (85%–95% TRR, 0.137–0.749 mg eq./kg), with a small proportion (3.6% TRR, 0.03 mg eq./kg) of conjugated quinmerac, also identified in kidney. Radioactivity levels in milk were low (0.015 mg eq./kg) and rapidly reached a plateau (at 32 h following first dose). Most of the radioactivity in milk (77.5%) was associated with the whey fraction. Further characterisation of residues from milk, fat and muscle was not accomplished due to the low sample radioactivity.

In laying hen, residue levels were generally low. Highest residues were found in eggs (0.014 mg eq./kg), followed by fat (0.013 mg eq./kg). Levels in liver and muscle were very low (< 0.01 mg eq./kg), and radioactive residues were not further characterised. In eggs, the only identified radioactive component was unchanged quinmerac (88% TRR, 0.012 mg eq./kg), while in fat, besides parent (13% TRR, < 0.01 mg eq./kg), two unidentified metabolites were also isolated, accounting for 58% (< 0.01 mg eq./kg) and 11% TRR (< 0.01 mg eq./kg). Given the low radioactivity in fat, further characterisation of these metabolites was not performed.

EFSA concludes that the metabolism of quinmerac in livestock is adequately elucidated, and unchanged quinmerac (free) is the most relevant component of the residue in livestock commodities. It is noted that some uncertainty remains as the metabolism of the plant metabolite BH 518-4 was not investigated in livestock. Nevertheless, considering its expected level in the feed items according to the authorised uses, no further study is required.

An analytical method using HPLC-MS/MS was sufficiently validated for the determination of quinmerac and its metabolites BH 518-2 and BH 518-4 in all animal tissues, milk and eggs, with an LOQ of 0.02 mg/kg, for each analyte individually. The method does not determine conjugates.

The storage stability of quinmerac was demonstrated for a period of 3 months at –18°C in muscle, fat, liver, kidney and milk (United Kingdom, 2007). No studies are available for eggs, but they are not required since residues are expected to remain below the LOQ for enforcement (see Section 2.2.)

As parent quinmerac (free) was found to be a sufficient marker in all livestock commodities, the residue definition for enforcement is proposed as quinmerac. The residue is not fat soluble. For risk assessment, in view of the current authorised uses and the resulting dietary burdens calculated, EFSA suggests including only parent quinmerac, in its free form, in the residue definition. These residue definitions were agreed by the rapporteur Member State, Estonia, in its evaluation report, and they are applicable to all livestock commodities.
An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.02 mg/kg in all animal matrices is available (Estonia, 2020). The ILV was available for muscle and fat, but since the principle of the primary method is the same for all livestock matrices, the ILV is also acceptable for liver-kidney and milk. According to EURLs, quinmerac (free) can be monitored in liver and milk in routine analysis at the LOQ of 0.01 mg/kg. The same LOQ is supposed to be achievable also for the other main groups of animal products (egg, muscle, kidney, fat). Furthermore, screening validation data generated by EURL showed that quinmerac can be monitored in muscle, milk and honey with a screening detection limit (SDL) of 0.01 mg/kg. Validation data on metabolites BH 518-2 and BH 518-4 were also made available for this review, indicating that they can be monitored in milk at LOQ = 0.05 mg/kg (each) (EURL, 2019).

2.2. Magnitude of residues in livestock

Feeding studies were performed with dairy cows, and submitted in the DAR (United Kingdom, 2007). The studies were not peer reviewed. In these studies, quinmerac was administered using three different dosing levels at 0.032, 0.091 and 0.313 mg/kg body weight (bw) per day. This study was used to derive MRL and risk assessment values in milk and tissues of ruminants. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. In this study, samples of tissues and milk were analysed for quinmerac. The storage period of the samples was covered by the conditions for which storage stability was demonstrated; thus, decline of residues during storage of the trial samples is not expected.

Based on these studies, MRL and risk assessment values were derived for all commodities of meat ruminants and pigs, in compliance with the latest recommendations on this matter (FAO, 2009). It is noted that significant levels of quinmerac are only expected in cattle liver. For sheep liver, and cattle and sheep kidney, MRLs are proposed at the LOQ of the feeding study (0.05 mg/kg), since considering also the metabolism studies, residues between the LOQ for enforcement (0.02 mg/kg) and the LOQ of the feeding study (0.05 mg/kg) cannot be excluded in these commodities. For milk, fat and muscle, in view of the results of the metabolism and feeding studies, it is expected that residues will remain below the LOQ for enforcement (0.02 mg/kg), and thus, the MRL is proposed at the level of this LOQ. MRLs for swine tissues are also proposed at the LOQ for enforcement since residues are expected to remain below 0.02 mg/kg at the calculated dietary burden.

For poultry, the metabolism study (performed at 61N rate compared to the maximum dietary burden) is sufficient to conclude that residue levels would remain below the enforcement LOQ of 0.02 mg/kg in muscle, fat, liver and eggs. No livestock feeding study is thus needed and MRLs and risk assessment values for the relevant commodities in poultry can be established at the enforcement LOQ level.

Since uncertainties remain due to the tentative CFs applied for plants, and the potential overestimation of the animal burden, MRLs above the LOQ of 0.02 mg/kg for livestock commodities (ruminants’ liver and kidney) are proposed on a tentative basis. MRLs for these commodities of animal origin might need to be reconsidered when residue trials analysing simultaneously for enforcement and risk assessment plants’ residue definitions will be made available.

3. Consumer risk assessment

In the framework of this review, only the uses of quinmerac reported by the RMS in Appendix A were considered. Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 3.1 of the EFSA PRIMO (EFSA, 2018, 2019). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a tentative MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). All input values included in the exposure calculations are summarised in Appendix D.2.

The exposure values calculated were compared with the toxicological reference values for quinmerac derived by EFSA (2010). The highest chronic exposure was calculated for Dutch toddler, representing 3% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for beetroot, representing 3% of the ARfD. It should be underlined that the calculation does not consider residues in rotational crops, as it is assumed that risk mitigation measures will be taken by MSs when granting national authorisations. Although uncertainties remain due to the data gaps
identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumer’s health.

Conclusions

The metabolism of quinmerac in plants was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement can be proposed as sum of quinmerac and its metabolites BH 518-2 and BH 518-4, expressed as quinmerac; while for risk assessment, the residue is defined as the sum of quinmerac and its metabolites BH 518-2 and BH 518-4 (free and conjugated), expressed as quinmerac. These residue definitions are also applicable to processed commodities. Sufficiently validated analytical methods are available for the enforcement of the proposed residue definition in all four main plant matrices at the combined LOQ of 0.15 mg/kg. According to the EURLs, the combined LOQ of 0.1 mg/kg is achievable for the enforcement of the proposed residue definition in high water content, high acid content and dry commodities in routine analyses. In high oil content commodities, parent quinmerac can be enforced at the LOQ of 0.01 mg/kg in routine analysis. Analytical standards for parent quinmerac and metabolite BH 518-2 are commercially available, but they are not available for metabolite BH 518-4.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all food commodities under evaluation. Tentative MRLs were derived for sugar and fodder beet tops, in view of the future need to set MRLs in feed items, noting that a data gap was identified for the lack of trials analysing simultaneously for enforcement and risk assessment residue definitions.

Quinmerac is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in all commodities of animal origin.

The metabolism of quinmerac residues in livestock was investigated in lactating goats and laying hens at dose rate covering the maximum dietary burdens calculated in this review. According to the results of these studies, the residue definition for enforcement and risk assessment in livestock commodities was proposed as quinmerac only. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.02 mg/kg in all matrices is available. According to EURLs, quinmerac can be monitored in liver and milk at the LOQ of 0.01 mg/kg. Furthermore, screening data generated by EURL showed that quinmerac can be monitored in muscle, milk and honey with a screening detection limit (SDL) of 0.01 mg/kg.

A livestock feeding study on lactating cows was used to derive MRL and risk assessment values in milk and tissues of ruminants. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. For poultry, the metabolism study was sufficient to conclude that, at the calculated dietary burden, residue levels would remain below the enforcement LOQ of 0.02 mg/kg in tissues and eggs. Since uncertainties remain due to the tentative CFs applied for feed items, and the potential overestimation of the dietary burdens, MRLs for livestock commodities (ruminants and equine liver and kidney) above the LOQ of 0.02 mg/kg are also tentative.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. The highest chronic exposure was calculated for Dutch toddler, representing 3% of the ADI, and the highest acute exposure was calculated for beetroots, representing 3% of the ARfD. Although some uncertainties were identified, these calculations indicate that the uses assessed under this review result in a consumer exposure far lower than the toxicological reference values, and thus are unlikely to pose a risk to consumer’s health.

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 1). All MRL values listed as ‘Recommended’ in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 1 footnotes for details). All tentative MRLs need to be confirmed by the following data:
Residue trials analysing simultaneously for enforcement and risk assessment residue definitions for sugar beet and fodder beet tops (relevant for liver and kidney from ruminant and equine commodities).

Once this information will be made available, dietary burdens calculation and MRLs thereof might need to be reconsidered.

EFSA identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- Characterisation of the three major unknown metabolites detected in the confined rotational crop study.
- Representative field rotational crops studies covering the most critical GAPs on crops that can be rotated considered in this review. In the new studies, storage stability data on high protein content commodities should be provided.

Member States granting authorisations for quinmerac may choose to take appropriate risk mitigation measures (e.g. define plant back interval of at least 180 days) in order to avoid the significant presence of quinmerac and its metabolites in rotational crops.

Minor deficiencies were also identified in the assessment, but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore desirable considered but not essential:

- Residue trials analysing simultaneously for enforcement and risk assessment residue definitions for beetroots, rapeseeds/canola seeds, soyabeans and mustard, sunflower, gold of pleasure and borage seeds.

EFSA also underlines that, according to the information provided by the EURLs, the analytical standard for metabolite BH 518-4 is not commercially available (EURL, 2019).

### Table 1: Summary table

| Code number | Commodity     | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|---------------|-------------------------|----------------------|-----------------------|---------|
|             |               |                         |                      |                       |         |
| **Enforcement residue definition (existing):** quinmerac |               |                         |                      |                       |         |
| 213010      | Beetroot      | 0.1*                    | –                    | 0.15*                 | Recommended<sup>(a)</sup> |
| 401050      | Sunflower seed| 0.1*                    | –                    | 0.15*                 | Recommended<sup>(a)</sup> |
| 401060      | Rape seed     | 0.1*                    | –                    | 0.15*                 | Recommended<sup>(a)</sup> |
| 401070      | soyabeans     | 0.1*                    | –                    | 0.15*                 | Recommended<sup>(a)</sup> |
| 401080      | Mustard seed  | 0.1*                    | –                    | 0.15*                 | Recommended<sup>(a)</sup> |
| 401120      | Borage seed   | 0.1*                    | –                    | 0.15*                 | Recommended<sup>(a)</sup> |
| 401130      | Gold of pleasure | 0.1*                | –                    | 0.15*                 | Recommended<sup>(a)</sup> |
| 900010      | Sugar beet (root) | 0.5                  | –                    | 0.15*                 | Recommended<sup>(a)</sup> |
| **Enforcement residue definition (proposed):** sum of quinmerac and its metabolites BH 518-2 and BH 518-4, expressed as quinmerac | | | | | |
| 1011010     | Swine meat    | 0.05*                   | –                    | 0.02*                 | Recommended<sup>(a)</sup> |
| 1011020     | Swine fat (free of lean meat) | 0.05*       | –                    | 0.02*                 | Recommended<sup>(a)</sup> |
| 1011030     | Swine liver   | 0.05*                   | –                    | 0.02*                 | Recommended<sup>(a)</sup> |
| 1011040     | Swine kidney  | 0.05*                   | –                    | 0.02*                 | Recommended<sup>(a)</sup> |
| 1012010     | Bovine meat   | 0.05*                   | –                    | 0.02*                 | Recommended<sup>(a)</sup> |
| 1012020     | Bovine fat    | 0.05*                   | –                    | 0.02*                 | Recommended<sup>(a)</sup> |
| 1012030     | Bovine liver  | 0.05*                   | –                    | 0.07                  | Further consideration needed<sup>(b)</sup> |
| 1012040     | Bovine kidney | 0.05*                   | –                    | 0.05                  | Further consideration needed<sup>(b)</sup> |
| 1013010     | Sheep meat    | 0.05*                   | –                    | 0.02*                 | Recommended<sup>(a)</sup> |
| 1013020     | Sheep fat     | 0.05*                   | –                    | 0.02*                 | Recommended<sup>(a)</sup> |
| 1013030     | Sheep liver   | 0.05*                   | –                    | 0.05                  | Further consideration needed<sup>(b)</sup> |

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| Code number | Commodity            | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review MRL (mg/kg) | Comment                                      |
|-------------|----------------------|-------------------------|----------------------|----------------------------------|----------------------------------------------|
| 1013040     | Sheep kidney         | 0.05*                   | –                    | 0.05                             | Further consideration needed (b)             |
| 1014010     | Goat meat            | 0.05*                   | –                    | 0.02*                            | Recommended (a)                              |
| 1014020     | Goat fat             | 0.05*                   | –                    | 0.02*                            | Recommended (a)                              |
| 1014030     | Goat liver           | 0.05*                   | –                    | 0.05                             | Further consideration needed (b)             |
| 1014040     | Goat kidney          | 0.05*                   | –                    | 0.05                             | Further consideration needed (b)             |
| 1015010     | Horse meat           | 0.05*                   | –                    | 0.02*                            | Recommended (a)                              |
| 1015020     | Horse fat            | 0.05*                   | –                    | 0.02*                            | Recommended (a)                              |
| 1015030     | Horse liver          | 0.05*                   | –                    | 0.07                             | Further consideration needed (b)             |
| 1015040     | Horse kidney         | 0.05*                   | –                    | 0.05                             | Further consideration needed (b)             |
| 1016010     | Poultry meat         | 0.05*                   | –                    | 0.02*                            | Recommended (a)                              |
| 1016020     | Poultry fat          | 0.05*                   | –                    | 0.02*                            | Recommended (a)                              |
| 1016030     | Poultry liver        | 0.05*                   | –                    | 0.02*                            | Recommended (a)                              |
| 1020010     | Cattle milk          | 0.05*                   | –                    | 0.02*                            | Recommended (a)                              |
| 1020020     | Sheep milk           | 0.05*                   | –                    | 0.02*                            | Recommended (a)                              |
| 1020030     | Goat milk            | 0.05*                   | –                    | 0.02*                            | Recommended (a)                              |
| 1020040     | Horse milk           | 0.05*                   | –                    | 0.02*                            | Recommended (a)                              |
| 1030000     | Birds’ eggs          | 0.05*                   | –                    | 0.02*                            | Recommended (a)                              |
| – Other commodities of plant and/or animal origin | See Reg. (EC) 149/ 2008 | –                    | –                                | Further consideration needed (c)             |

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination H-I in Appendix E).
(b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination F-I in Appendix E).
(c): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).

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Abbreviations

- a.i. active ingredient
- a.s. Quinmerac
- ADI acceptable daily intake
- ARFD acute reference dose
- BBCH growth stages of mono- and dicotyledonous plants
- bw body weight
- CAS Chemical Abstract Service
- CF conversion factor for enforcement residue definition to risk assessment residue definition
- cGAP critical GAP
- CIRCA (EU) Communication & Information Resource Centre Administrator
- CS capsule suspension
- CV coefficient of variation (relative standard deviation)
- CXL codex maximum residue limit
- DAR draft assessment report
- DAT days after treatment
DB dietary burden
DM dry matter
DS powder for dry seed treatment
DT\textsubscript{90} period required for 90\% dissipation (define method of estimation)
EC emulsifiable concentrate
EMS evaluating Member State
EUURLs European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO Food and Agriculture Organization of the United Nations
FID flame ionisation detector
GAP Good Agricultural Practice
GLP Good Laboratory Practice
HPLC high-performance liquid chromatography
HPLC-MS high-performance liquid chromatography with mass spectrometry
HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
ISO International Organisation for Standardization
IUPAC International Union of Pure and Applied Chemistry
LC liquid chromatography
LC-MS/MS liquid chromatography with tandem mass spectrometry
LOQ limit of quantification
Mo Monitoring
MRL maximum residue level
MS Member States
MS mass spectrometry detector
MS/MS tandem mass spectrometry detector
MW molecular weight
NEU northern European Union
OECD Organisation for Economic Co-operation and Development
PBI plant back interval
PF processing factor
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
PROFile (EFSA) Pesticide Residues Overview File
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RAC raw agricultural commodity
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SC suspension concentrate
SEU southern European Union
SMILES simplified molecular-input line-entry system
SP water soluble powder
STMR supervised trials median residue
TMDI theoretical maximum daily intake
TRR total radioactive residue
UV ultraviolet (detector)
WHO World Health Organization
## Appendix A – Summary of authorised uses considered for the review of MRLs

### A.1. Authorised outdoor uses in northern EU

| Crop and/or situation | MS or country | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-------------|-------------|---------------------------------|------------|---------|
|                       |               | Type(b)     | Conc. a.s.  | Method kind                      | Range of growth stages & season(c) | Number min-max | Interval between application (min) | Water L/ha min-max | Rate and unit |         |
| Beetroots             | LT            | SC          | 10 g/L      | Foliar treatment – general (see also comment field) | 10–19 | 3 | 5 | – | – | 80 g a.i./ha | n.a. | Residue results extrapolated from sugar beets |
| Sunflower seeds       | DE            | SC          | 250 g/L     | Foliar treatment – broadcast spraying | 10–14 | 1 | – | – | – | 250 g a.i./ha | n.a. | – |
| Rapeseeds             | DE, UK, SE, EE, AT, FI | SC | 250 g/l | Foliar treatment – spraying | 30–50 | 1 | – | – | – | 250 g a.i./ha | n.a. | – |
| Soyabeans             | DE            | SC          | 250 g/L     | Foliar treatment – broadcast spraying | 10–25 | 1 | – | – | – | 250 g a.i./ha | n.a. | Application after emergence |
| Mustard seeds         | DE, FR        | SC          | 100 g/L     | Foliar treatment – general | 10–18 | 1 | – | – | – | 250 g a.i./ha | n.a. | – |
| Crop and/or situation | MS or country | F | G or T | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|---|--------|----------------------------------|-------------|-------------|-------------------------------|--------------|---------|
| Borage seeds | UK | F | | Foliar treatment – spraying | SC | 125 g/l | 250 g a.i./ha | n.a. | UK use is on corn growell to which borage MRL applies. Use was granted based on extrapolation from oilseed rape assessment at COP (conference of the parties of the UN) 2013/00549 (W001606000). month replanting restriction |
| Gold of pleasure seeds | FR, CZ | F | Weeds (general) | SC | 100 g/L | 250 g a.i./ha | n.a. |  |
| Sugar beets | FR | F | Weeds (general) | SC | 100 g/L | 250 g a.i./ha | 90 | ‘Possible split application 1 pre-emergence of 2–2.5 L/ha and/or 1–4 applications of 0.5–1.25 L/ha post-emergence Do not apply this product more than 1 every 3 years’ |
| Fodder beets | FR | F | Weeds (general) | SC | 101 g/L | 250 g a.i./ha | 91 | – |
## A.2. Authorised outdoor uses in southern EU

| Crop and/or situation | MS or country | F G or I (a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|---------------|-------------|-----------------------------------|-------------|------------|--------------------------------|----------------|---------|
|                       |               |             |                                   |             |            |                                |                |         |
| **Sunflower seeds**   | FR            | F           | Weeds (general)                   | SC          | 100 g/L    | Foliar treatment – general (see also comment field) | 0–9             | 1       |
|                       |               |             |                                   |             |            |                                | 200 g a.i./ha   | 90      |         |
| **Rapeseeds**         | IT            | F           | Weeds general                     | SC          | 250 g/L    | Foliar treatment – broadcast spraying | 30–50           | 1       |
|                       |               |             |                                   |             |            |                                | 250 g a.i./ha   | n.a.    |         |
| **Mustard seeds**     | BG            | F           | SE 167 g/L                        | Foliar treatment – general (see also comment field)   | 0–18       | 1       |                                | 250 g a.i./ha   | n.a.    |
|                       |               |             |                                   |             |            |                                |                 |         |
|                       | BG, FR        | F           | Weeds (general)                   | SC          | 167 g/L    | Foliar treatment – general      | 0–18           | 1       |
|                       |               |             |                                   |             |            |                                | 250 g a.i./ha   | n.a.    |         |

**MS:** Member State.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to 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.
(d): PHI = minimum preharvest interval.
Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Root crops                        | Sugar beet  |         | Foliar pre-emergence: 1 × 500 g a.s./ha | 22, 38, 74, 155 | Radiolabelled active substance: 14C-quinoline-quinmerac (EFSA, 2010) |
|                                   |             |         | Foliar post-emergence: 1 × 250 g a.s./ha | 1, 16, 38, 119  |                |
| Cereals/grass                     | Wheat       |         | Foliar pre-emergence: 1 × 1,000 g a.s./ha | 21, 52, 114     |                |
|                                   |             |         | Foliar post-emergence: 1 × 500 g a.s./ha | 1, 27, 78       |                |
| Pulses/oilseeds                   | Rapeseed    |         | Foliar pre-emergence: 1 × 1,000 g a.s./ha | 25, 38, 51, 106 |                |
|                                   |             |         | Foliar post-emergence: 1 × 500 g a.s./ha | 0, 9, 23, 76    |                |
| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
| Root/tuber crops                  | Radish      |         | Bare soil: 1 × 500 g a.s./ha | 30, 120, 365 | Radiolabelled active substance: 14C-quinoline-quinmerac (EFSA, 2010) |
| Leafy crops                       | Lettuce     |         | Bare soil: 1 × 500 g a.s./ha | 30, 120, 365 |                |
| Cereal (small grain)              | Wheat       |         | Bare soil: 1 × 500 g a.s./ha | 30, 120, 365 |                |
| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
| Pasteurisation (20 min, 90°C, pH 4) | Yes | EFSA (2010) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | EFSA (2010) |
| Sterilisation (20 min, 120°C, pH 6) | Yes | EFSA (2010) |
Can a general residue definition be proposed for primary crops?

Yes

Rotational crop and primary crop metabolism similar?

Yes

The metabolism and distribution of quinmerac in rotational crops followed a similar pathway to the one observed in primary crops, but it resulted to be more extensive. Three unidentified metabolites were detected at levels > 0.01 and > 0.05 mg/kg in lettuces leaves and wheat straw (but below the enforcement LOQ of 0.15 mg/kg) in the underdosed confined rotational crop study. It is desirable to further characterise these three metabolites.

Residue pattern in processed commodities similar to residue pattern in raw commodities?

Yes

Plant residue definition for monitoring (RD-Mo)

Sum of quinmerac and its metabolites BH 518-2 and BH 518-4, expressed as quinmerac

Plant residue definition for risk assessment (RD-RA)

Sum of quinmerac and its metabolites BH 518-2 and BH 518-4 (free and conjugated), expressed as quinmerac

Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)

High water, high oil, high acid and dry matrices (EFSA, 2010; Estonia, 2020):

- Single residue method HPLC–MS/MS
- LOQ = 0.05 mg/kg for parent quinmerac and metabolites BH 518-2 and BH 518-4, individually
- Confirmation by monitoring one additional MRM transition
- ILV (HPLC–MS/MS) available
- QuEChERS-based single residue method for enforcement of parent quinmerac and metabolites BH 518-2 and BH 518-4 in routine analysis, with a combined LOQ = 0.1 mg/kg in high water content, high acid content and dry commodities. LOQ = 0.01 mg/kg for enforcement of (only) parent quinmerac in high oil content commodities, in routine analysis (EURL, 2019).

Wheat straw (no group) (EFSA, 2010):

- Single residue method HPLC–MS/MS
- LOQ = 0.05 mg/kg for parent quinmerac and metabolites BH 518-2 and BH 518-4, individually
- Confirmation by monitoring one additional MRM transition
- ILV (HPLC–MS/MS) available

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|------------------|-------------------|---------------|
| Plant products                    |          |           |        |                  |                   |               |
|                                    | High water content | Sugar beets | –20     | 24 Months | Total level of Quinmerac, BH 518-2 and BH 518-4 | EFSA (2010), United Kingdom (2015) |
|                                    | High oil content   | Rapeseeds  | –20     | 24 Months | Total level of Quinmerac, BH 518-2 and BH 518-4 | EFSA (2010), United Kingdom (2015) |
|                                    | High protein content | –          | –       | –       | – | Not available and not required |
|                                    | High starch content   | –          | –       | –       | – | Not available and not required |
|                                    | High acid content     | –          | –       | –       | – | Not available and not required |
|                                    | Processed products    | –          | –       | –       | – | Not available and not required |
|                                    | Others                | –          | –       | –       | – | Not available and not required |

### B.1.2. Magnitude of residues in plants

#### B.1.2.1. Summary of residues data from the supervised residue trials – Primary crops

| Commodity | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|-----------|------------------|---------------------------------------------------------------|-----------------|------------------------|--------------|-----------------|------|
| Rapeseeds/canola seeds | NEU | Mo: 7 < 0.15 RA: – | Trials on rapeseed compliant with GAP (Germany, 2020). Reduced data set deemed acceptable as no residues are expected. Extrapolation to sunflower seeds, soybeans, mustard seeds, borage seeds and gold of pleasure seeds is acceptable (less cGAP) MRL_OECD = 0.15 | 0.15* | 0.15 | 0.15 | 2.00(e) |
|             | SEU | Mo: – RA: – | The absence of GAP complaint trials accepted in view of results of the northern trials (similar GAP) and the metabolism studies on rapeseeds (post-emergence) showing that no residues are expected | 0.15* | 0.15 | 0.15 | 2.00(e) |
| Commodity | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|-----------|-----------------|-----------------------------------------------------------------|-----------------|------------------------|--------------|-----------------|------|
| Mustard seeds  
Sunflower seeds  
Gold of pleasure seeds | NEU | **Mo**: 7 × < 0.15  
**RA**: – | Trials on rapeseed compliant with GAP (Germany, 2020). Reduced data set deemed acceptable as no residues are expected (also considering the metabolism study on rapeseed). Extrapolation to sunflower seeds, soyabean, mustard seeds, borage seeds and gold of pleasure seeds is acceptable (less cGAP)  
MRL\textsubscript{OECD} = 0.15 | 0.15* | 0.15 | 0.15 | 2.00(e) |
| | SEU | **Mo**: 4 × < 0.15  
**RA**: – | Trials on rapeseed compliant with GAP on mustard and gold of pleasure seeds (Estonia, 2020). Reduced data set deemed acceptable for extrapolation to sunflower seeds as residues were below LOQ and a less cGAP is authorised for sunflower seeds  
MRL\textsubscript{OECD} = 0.15 | 0.15* | 0.15 | 0.15 | 2.00(e) |
| Soyabeans  
Borage seeds | NEU | **Mo**: 7 × < 0.15  
**RA**: – | Trials on rapeseed compliant with GAP (Germany, 2020). Reduced data set deemed acceptable as no residues are expected (also considering the metabolism study on rapeseed). Extrapolation to sunflower seeds, soyabean, mustard seeds, borage seeds and gold of pleasure seeds is acceptable (less cGAP)  
MRL\textsubscript{OECD} = 0.15 | 0.15* | 0.15 | 0.15 | 2.00(e) |
| Sugar beet roots  
Beetroots  
Fodder beet roots | NEU | **Mo**: 8 × < 0.15  
**RA**: – | Trials on sugar beets (Estonia, 2020) performed with 1 instead of 4 applications, deemed acceptable as the first applications are foreseen to be done early in the season and no impact in the final residue levels is thus expected. Extrapolation to beetroots and fodder beet roots is applicable  
MRL\textsubscript{OECD} = 0.15 | 0.15* | 0.15 | 0.15 | 1.00(f) |
| Sugar beet tops  
Fodder beet tops | NEU | **Mo**: 8 × < 0.15  
**RA**: – | Trials on sugar beets (Estonia, 2020) performed with 1 instead of 4 applications, deemed acceptable as the first applications are foreseen to be done early in the season and no impact in the final residue levels is thus expected. Extrapolation to fodder beet tops is applicable  
MRL\textsubscript{OECD} = 0.15 | 0.15(g)  
(tentative) | 0.15 | 0.15 | 3.00(h) |
B.1.2.2. Residues in rotational crops

**Overall summary**

| Question                                                                 | Answer 1                                                                 | Answer 2                                                                 |
|-------------------------------------------------------------------------|--------------------------------------------------------------------------|---------------------------------------------------------------------------|
| Residues in rotational and succeeding crops expected based on confined rotational crop study? | yes                                                                      | In the available confined rotational crop study conducted with bare soil at 0.5N compared to the most cGAP that can be rotated assessed in this review, metabolites BH 518-4 and its conjugate, BH 518-2, and three unidentified metabolites were detected at significant levels in rotated crops at all plant back intervals. |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | inconclusive                                                              | Residues of metabolite BH 518-4 cannot be excluded in rotated leafy crops, mostly considering that the available field rotational crop study was underdosed (0.28X) compared to the most cGAP that can be rotated, assessed in this review. |

cGAP: critical Good Agricultural Practice;
B.1.2.3. Processing factors

| Processed commodity | Number of valid studies(a) | Processing Factor (PF) Individual values | Median PF | Comment/Source |
|---------------------|-----------------------------|------------------------------------------|-----------|----------------|
| Rapeseed crude oil, refined oil and press cake | – | – | – | One processing study on residue levels of quinmerac and its metabolites BH 518-2 and BH 518-4 in rapeseeds crude oil, refine oil, and cake is available. No residues of quinmerac or its metabolites in the RAC and processed commodities were detected |

PF: Processing factor (\(=\)Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo); CFp: Conversion factor for risk assessment in processed commodity (\(=\)Residue level in processed commodity expressed according to RD-RA/Residue level in processed commodity expressed according to RD-Mo).

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) | Comments |
|----------------------------|-----------------------------|---------------------------|----------------------------|------------------------|----------|
|                           | mg/kg bw per day (Median, Maximum) | mg/kg DM (Median, Maximum) |                           |                        |          |
| Cattle (all)              | 0.046 (0.046, 1.18)          | 1.18 (1.18)               | Dairy cattle               | Beet, mangel fodder    | Yes      | –        |
| Cattle (dairy only)       | 0.046 (0.046, 1.18)          | 1.18 (1.18)               | Dairy cattle               | Beet, mangel fodder    | Yes      | –        |
| Sheep (all)               | 0.023 (0.023, 0.54)          | 0.54 (0.54)               | Lamb                       | Beet, sugar tops       | Yes      | –        |
| Sheep (ewe only)          | 0.017 (0.017, 0.51)          | 0.51 (0.51)               | Ram/Ewe                    | Beet, sugar tops       | Yes      | –        |
| Swine (all)               | 0.013 (0.013, 0.58)          | 0.58 (0.58)               | Swine (breeding)           | Beet, mangel fodder    | Yes      | –        |
| Poultry (all)             | 0.016 (0.016, 0.23)          | 0.23 (0.23)               | Poultry layer              | Beet, sugar tops       | Yes      | –        |
| Poultry (layer only)      | 0.016 (0.016, 0.23)          | 0.23 (0.23)               | Poultry layer              | Beet, sugar tops       | Yes      | –        |
| Fish                      | –                            | –                         | –                          | –                      | –        |          |

(a): When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

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**B.2.1. Nature of residues and methods of analysis in livestock**

### B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

| Livestock (available studies) | Animal | Dose (mg/kg bw/d) | Duration (days) | Comment/Source |
|-------------------------------|--------|------------------|----------------|----------------|
| Laying hen                    | 0.97   | 8                | 61N compared to the maximum dietary burden calculated for layer poultry. Radiolabelled active substance: ¹⁴C-quinoline-quinmerac (United Kingdom, 2007) |
| Lactating goat                | 0.78   | 5                | 17N compared to the maximum dietary burden calculated for dairy cattle. Radiolabelled active substance: ¹⁴C-quinoline-quinmerac (United Kingdom, 2007) |
| Pig                           | –      | –                | Not available and not required (extrapolated from ruminants) |

**Time needed to reach a plateau concentration in milk and eggs (days)**

| Livestock (available studies) | Animal | Dose (mg/kg bw/d) | Duration (days) | Comment/Source |
|-------------------------------|--------|------------------|----------------|----------------|
| Laying hen                    | 0.97   | 8                | 61N compared to the maximum dietary burden calculated for layer poultry. Radiolabelled active substance: ¹⁴C-quinoline-quinmerac (United Kingdom, 2007) |
| Lactating goat                | 0.78   | 5                | 17N compared to the maximum dietary burden calculated for dairy cattle. Radiolabelled active substance: ¹⁴C-quinoline-quinmerac (United Kingdom, 2007) |
| Pig                           | –      | –                | Not available and not required (extrapolated from ruminants) |

**Metabolism in rat and ruminant similar**

- Yes

**Can a general residue definition be proposed for animals?**

- Yes

**Animal residue definition for monitoring (RD-Mo)**

- Quinmerac

**Animal residue definition for risk assessment (RD-RA)**

- Quinmerac

**Fat soluble residues**

- No

**Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)**

- Milk, eggs, muscle, fat, kidney and liver (Estonia, 2020):
  - Single residue method HPLC–MS/MS
  - LOQ 0.02 mg/kg for parent quinmerac and metabolites BH 518-2 and BH 518-4, individually.
  - Confirmation by monitoring 1 additional MRM transition.
  - ILV (HPLC–MS/MS) available for muscle and fat.
  - FA-QuEChERS (LC–MS/MS) for enforcement of parent quinmerac (free) in milk and liver with LOQ = 0.01 mg/kg, in routine analysis. QuEChERS-citrate (LC–MS-qToF) for screening of parent quinmerac (free) with screening detection limit (SDL) = 0.01 mg/kg in muscle, milk and honey. FA-QuEChERS (LC–MS/MS) for enforcement of metabolites BH 518-2 and BH 518-4 in milk, with LOQ = 0.05 mg/kg (EURL, 2019)

**Log K<sub>ow</sub>** = –1.41 (21°C, pH 7) 77.5% radioactivity in milk was associated with the whey fraction.
### B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-------------------------------------|--------|-----------|--------|------------------|-------------------|----------------|
|                                     | Bovine | Muscle    | –18    | 3 Months         | Quinmerac         | United Kingdom (2007) |
|                                     | Bovine | Fat       | –18    | 3 Months         | Quinmerac         | United Kingdom (2007) |
|                                     | Bovine | Liver     | –18    | 3 Months         | Quinmerac         | United Kingdom (2007) |
|                                     | Bovine | Kidney    | –18    | 3 Months         | Quinmerac         | United Kingdom (2007) |
|                                     | Bovine | Milk      | –18    | 3 Months         | Quinmerac         | United Kingdom (2007) |
|                                     | Poultry | Eggs | – | – | – | Not available and not required |

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### B.2.2. Magnitude of residues in livestock

#### B.2.2.1. Summary of the residue data from livestock feeding studies

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) |
|------------------|---------------------------------------------|-----------------------|---------------------|
|                  | Mean | Highest | STMR<sub>Mo</sub> | HR<sub>Mo</sub> | |
| Muscle | catt(0.032 mg/kg bw; 0.7 N rate)<sup>(c)</sup> | <0.05 | <0.05 | <0.02<sup>(d)</sup> | <0.02<sup>(d)</sup> | 0.02* |
| Fat | catt(0.032 mg/kg bw; 0.7 N rate)<sup>(c)</sup> | <0.05 | <0.05 | <0.02<sup>(d)</sup> | <0.02<sup>(d)</sup> | 0.02* |
| Liver | catt(0.032 mg/kg bw; 0.7 N rate)<sup>(c)</sup> | <0.05 | <0.05 | 0.06 | 0.06 | 0.07 (tentative)<sup>(e)</sup> |
| Kidney | catt(0.032 mg/kg bw; 0.7 N rate)<sup>(c)</sup> | <0.05 | <0.05 | <0.05 | <0.05 | 0.05 (tentative)<sup>(e)</sup> |
| Milk (dairy only) | catt(0.032 mg/kg bw; 0.7 N rate)<sup>(c)</sup> | <0.02 | n.a. | <0.02<sup>(d)</sup> | <0.02<sup>(d)</sup> | 0.02* |
| Muscle | sheep(0.032 mg/kg bw; 1.4 N rate)<sup>(c)</sup> | <0.05 | <0.05 | <0.02<sup>(d)</sup> | <0.02<sup>(d)</sup> | 0.02* |
| Fat | sheep(0.032 mg/kg bw; 1.4 N rate)<sup>(c)</sup> | <0.05 | <0.05 | <0.02<sup>(d)</sup> | <0.02<sup>(d)</sup> | 0.02* |
| Liver | sheep(0.032 mg/kg bw; 1.4 N rate)<sup>(c)</sup> | <0.05 | <0.05 | <0.05 | <0.05 | 0.05 (tentative)<sup>(e)</sup> |
| Kidney | sheep(0.032 mg/kg bw; 1.4 N rate)<sup>(c)</sup> | <0.05 | <0.05 | <0.05 | <0.05 | 0.05 (tentative)<sup>(e)</sup> |
| Milk (ewe only) | sheep(0.032 mg/kg bw; 1.9 N rate)<sup>(c)</sup> | <0.02 | n.a. | <0.02<sup>(d)</sup> | <0.02<sup>(d)</sup> | 0.02* |
| Muscle | swine(0.032 mg/kg bw; 2.4 N rate)<sup>(d)</sup> | <0.05 | <0.05 | <0.02<sup>(d)</sup> | <0.02<sup>(d)</sup> | 0.02* |
| Fat | swine(0.032 mg/kg bw; 2.4 N rate)<sup>(d)</sup> | <0.05 | <0.05 | <0.02<sup>(d)</sup> | <0.02<sup>(d)</sup> | 0.02* |
| Liver | swine(0.032 mg/kg bw; 2.4 N rate)<sup>(d)</sup> | <0.05 | <0.05 | <0.05 | <0.05 | 0.02* |
| Kidney | swine(0.032 mg/kg bw; 2.4 N rate)<sup>(d)</sup> | <0.05 | <0.05 | <0.05 | <0.05 | 0.02* |
| Muscle | poultry (all) | n.r.| <0.01 | <0.01 | <0.01 | 0.02* |
| Fat | poultry (all) | n.r.| <0.01 | <0.01 | <0.01 | 0.02* |
| Liver | poultry (all) | n.r.| <0.01 | <0.01 | <0.01 | 0.02* |
| Eggs | poultry (all) | n.r.| <0.01 | <0.01 | <0.01 | 0.02* |

*: Indicates that the MRL is proposed at the limit of quantification.

n.a.: not applicable.
n.r.: not reported.

(a): Median residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.

(b): Highest residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.

(c): Closest feeding level and N dose rate related to the maximum dietary burden.

(d): Based on the metabolism and feeding studies levels are expected to remain below the enforcement LOQ set at 0.02 mg/kg.

(e): Tentative MRL due to data gap identified in CFs for risk assessment applied in plants, leading to the potential overestimation of the dietary burdens.

(f): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

(g): Feeding level tested in the metabolism study and N dose rate related to the maximum dietary burden.
B.3. Consumer risk assessment

| ARfD | 0.3 mg/kg bw (EFSA, 2010) |
|------|--------------------------|
| Highest IESTI, according to EFSA PRIMo (rev.3.1) | Beetroots: 3% of ARfD |
| NESTI (% ARfD) | Not assessed in this review |
| Assumptions made for the calculations | The calculation is based on the highest residue levels expected in raw agricultural commodities, multiplied by the following tentative CF for risk assessment: --beetroots, sugar beet and fodder beet roots: 1 --sugar beet tops and fodder beet tops: 3 --rapeseeds, mustard seeds, sunflower seeds, gold of pleasure seeds, borage seeds and soyabeans: 2 |

ARfD: acute reference dose; bw: body weight; NESTI: national estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; IESTI: international estimated short-term intake.

| ADI | 0.08 mg/kg bw per day (EFSA, 2010) |
|-----|-------------------------------|
| TMDI according to EFSA PRIMo | Not assessed in this review. |
| NTMDI, according to (to be specified) | Not assessed in this review. |
| Highest IEDI, according to EFSA PRIMo (rev.3.1) | 3% ADI (NL toddler) |
| NEDI (% ADI) | Not assessed in this review. |
| Assumptions made for the calculations | The calculation is based on the median residue levels derived for raw agricultural commodities, multiplied by the tentative conversion factor for risk assessment (see above). The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation. |

ADI: acceptable daily intake; bw: body weight; NEDI: national estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake.

Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/02/2003).

| Metabolite(s) | Not assessed in this review. |
|---------------|----------------------------|
| ADI (mg/kg bw per day) | Not assessed in this review. |
| Intake of groundwater metabolites (% ADI) | Not assessed in this review. |
### B.4. Proposed MRLs

| Code number | Commodity            | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment          |
|-------------|----------------------|-------------------------|----------------------|-----------------------|------------------|
|             | **Enforcement residue definition (existing): quinmerac** |                          |                      |                       |                  |
| 213010      | Beetroot             | 0.1*                    | –                    | 0.15*                 | Recommended (a)  |
| 401050      | Sunflower seed       | 0.1*                    | –                    | 0.15*                 | Recommended (a)  |
| 401060      | Rape seed            | 0.1*                    | –                    | 0.15*                 | Recommended (a)  |
| 401070      | Soyabean             | 0.1*                    | –                    | 0.15*                 | Recommended (a)  |
| 401080      | Mustard seed         | 0.1*                    | –                    | 0.15*                 | Recommended (a)  |
| 401120      | Borage               | 0.1*                    | –                    | 0.15*                 | Recommended (a)  |
| 401130      | Gold of pleasure     | 0.1*                    | –                    | 0.15*                 | Recommended (a)  |
| 900010      | Sugar beet (root)    | 0.5                     | –                    | 0.15*                 | Recommended (a)  |

| Code number | Commodity            | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment          |
|-------------|----------------------|-------------------------|----------------------|-----------------------|------------------|
|             | **Enforcement residue definition (proposed): sum of quinmerac and its metabolites BH 518-2 and BH 518-4, expressed as quinmerac** |                          |                      |                       |                  |
| 1011010     | Swine meat           | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1011020     | Swine fat (free of lean meat) | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1011030     | Swine liver          | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1011040     | Swine kidney         | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1012010     | Bovine meat          | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1012020     | Bovine fat           | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1012030     | Bovine liver         | 0.05*                   | –                    | 0.05                  | Further consideration needed (b) |
| 1012040     | Bovine kidney        | 0.05*                   | –                    | 0.05                  | Further consideration needed (b) |
| 1013010     | Sheep meat           | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1013020     | Sheep fat            | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1013030     | Sheep liver          | 0.05*                   | –                    | 0.05                  | Further consideration needed (b) |
| 1013040     | Sheep kidney         | 0.05*                   | –                    | 0.05                  | Further consideration needed (b) |
| 1014010     | Goat meat            | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1014020     | Goat fat             | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1014030     | Goat liver           | 0.05*                   | –                    | 0.05                  | Further consideration needed (b) |
| 1014040     | Goat kidney          | 0.05*                   | –                    | 0.05                  | Further consideration needed (b) |
| 1015010     | Horse meat           | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1015020     | Horse fat            | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1015030     | Horse liver          | 0.05*                   | –                    | 0.07                  | Further consideration needed (b) |
| 1015040     | Horse kidney         | 0.05*                   | –                    | 0.05                  | Further consideration needed (b) |
| 1016010     | Poultry meat         | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1016020     | Poultry fat          | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1016030     | Poultry liver        | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1020010     | Cattle milk          | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1020020     | Sheep milk           | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1020030     | Goat milk            | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1020040     | Horse milk           | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |
| 1030000     | Birds’ eggs          | 0.05*                   | –                    | 0.02*                 | Recommended (a)  |

| Code number | Commodity            | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment          |
|-------------|----------------------|-------------------------|----------------------|-----------------------|------------------|
|             | Other commodities of plant and/or animal origin | See Reg. (EC) 149/2008 | –                    | Further consideration needed (c) |                  |

**MRL:** maximum residue level; **CXL:** codex maximum residue limit.

*: Indicates that the MRL is set at the limit of quantification.
(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination H-I in Appendix E).

(b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination F-I in Appendix E).

(c): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
### Appendix C – Pesticide Residue Intake Model (PRIMo)

**PRIMo(EU)**

### Input values

#### Source of ARfD
- EFSA

#### Details – chronic risk assessment
- Toxicological reference values
- Input values

#### Details – acute risk assessment
- Supplementary results – chronic risk assessment

#### Details – acutestock assessment/children
- Normal mode
- Chronic risk assessment: JMPR methodology (IEDI/TMDI)

#### Calculated exposure (% of ADI)
- Normal mode
- Exposure resulting from commodities not under assessment

#### Year of evaluation
- EFSA PRIMo revision 3.1; 2019/03/19

#### Comments
- EFSA
- Source of ARfD:
- ADI (mg/kg bw per day):
- Source of ARfD:
- EFSA
- EFSA PRIMo revision 3.1; 2019/03/19

#### Input values

- Quinmerac
  - LOQs (mg/kg) range from: 0.02 to: 0.15
  - ADI (mg/kg bw per day): 0.3

#### Year of evaluation

- Year of evaluation:
- No of diets exceeding the ADI: ---

#### Exposure resulting from commodities not under assessment

| Commodity/group of commodities | Normal Mode | IEDI/TMDI |
|-------------------------------|------------|------------|
| Sugar beet roots             | 2.0%       | 1.47%      |
| Rapeseeds/canola seeds       | 1.2%       | 0.95%      |
| Milk: Cattle                 | 1.0%       | 0.8%       |
| Sugar beet roots             | 1.0%       | 0.8%       |
| Beetroots                    | 1.0%       | 0.6%       |

#### Calculated exposure (% of ADI)

- Normal mode
- Exposure resulting from commodities not under assessment

#### Conclusion

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Quinmerac is unlikely to present a public health concern.

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The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Quinmerac is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Unprocessed Commodities

| Highest % of ARfD/ADI | Commodity            | MRL/input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodity            | MRL/input (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|----------------------|-------------------|---------------------|-----------------------|----------------------|-------------------|---------------------|
| 3%                    | Beetroots            | 0.15/0.15         | 8.6                 | 1%                    | Beetroots            | 0.15/0.15         | 3.5                 |
| 0.8%                  | Milk: Cattle         | 0.02/0.02         | 2.5                 | 0.8%                  | Soyabeanse          | 0.15/0.3          | 1.7                 |
| 0.3%                  | Sunflower seeds      | 0.15/0.3          | 0.96                | 0.3%                  | Milk: Cattle         | 0.02/0.02         | 0.77                |
| 0.2%                  | Soyabeanse           | 0.15/0.3          | 0.69                | 0.2%                  | Milk: Goat          | 0.02/0.02         | 0.37                |
| 0.2%                  | Bovine: Liver        | 0.01/0.06         | 0.52                | 0.1%                  | Milk: Sheep         | 0.02/0.02         | 0.30                |
| 0.2%                  | Milk: Goat           | 0.02/0.02         | 0.48                | 0.1%                  | Sunflower seeds     | 0.15/0.3          | 0.30                |
| 0.1%                  | Rapeseeds/canola seeds | 0.15/0.3  | 0.41                | 0.09%                 | Bovine: Liver       | 0.07/0.06         | 0.28                |
| 0.1%                  | Poultry: Muscles/meat | 0.02/0.02 | 0.34                | 0.08%                 | Poultry: Muscles/meat | 0.02/0.02         | 0.23                |
| 0.1%                  | Mustard seeds        | 0.15/0.3          | 0.31                | 0.07%                 | Mustard seeds       | 0.15/0.3          | 0.21                |
| 0.09%                 | Eggs: Chicken        | 0.02/0.02         | 0.25                | 0.05%                 | Rapeseeds/canola seeds | 0.15/0.3         | 0.16                |
| 0.09%                 | Seme: Muscles/meat   | 0.02/0.02         | 0.24                | 0.05%                 | Storage seeds       | 0.15/0.3          | 0.15                |
| 0.09%                 | Bovine: Kidney       | 0.05/0.05         | 0.19                | 0.05%                 | Sheep: Liver        | 0.05/0.05         | 0.14                |
| 0.05%                 | Bovine: Muscles/meat | 0.02/0.02         | 0.14                | 0.04%                 | Bovine: Muscles/meat | 0.02/0.02         | 0.11                |
| 0.04%                 | Equine: Muscles/meat | 0.02/0.02         | 0.12                | 0.04%                 | Bovine: Kidney       | 0.05/0.05         | 0.11                |
| 0.04%                 | Sheep: Muscles/meat  | 0.02/0.02         | 0.11                | 0.03%                 | Seme: Muscles/meat  | 0.02/0.02         | 0.10                |

### Processed Commodities

| Highest % of ARfD/ADI | Processed commodity | MRL/input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Processed commodity | MRL/input (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|---------------------|-------------------|---------------------|-----------------------|---------------------|-------------------|---------------------|
| 6%                    | Sugar beets (root)sugar | 0.15/0.15         | 6.7                 | 2%                    | Sugar beets (root)sugar | 0.15/0.15         | 5.8                 |
| 2%                    | Beetroots/baked     | 0.15/0.15         | 6.7                 | 2%                    | Beetroots/baked     | 0.15/0.15         | 5.8                 |
| 0.4%                  | Soyabeanse/soya drink | 0.15/0.3          | 1.3                 | 0.9%                  | Sunflower seeds/canola | 0.15/0.6          | 0.70                |
| 0.2%                  | Soyabeanse/baked    | 0.15/0.13         | 0.44                | 0.1%                  | Rapeseeds/canola    | 0.15/0.6          | 0.18                |

Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short-term intake of residues of Quinmerac is unlikely to present a public health risk for processed commodities, no exceedance of the ARfD/ADI was identified.

Show results for all crops

No exceedance of the toxicological reference value was identified for any unprocessed commodity.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

| Feed commodity                  | Median dietary burden | Maximum dietary burden |
|---------------------------------|-----------------------|------------------------|
|                                 | Input value (mg/kg)   | Comment                | Input value (mg/kg) | Comment                |
| Beet, mangel fodder             | 0.45                  | STMR<sub>med</sub> × CF (3)<sup>(a)</sup> | 0.45                  | STMR<sub>med</sub> × CF (3)<sup>(a)</sup> |
| Beet, sugar tops                | 0.45                  | STMR<sub>med</sub> × CF (3)<sup>(a)</sup> | 0.45                  | STMR<sub>med</sub> × CF (3)<sup>(a)</sup> |
| Soyabeans seed                  | 0.3                   | STMR<sub>med</sub> × CF (2)<sup>(a)</sup> | 0.3                   | STMR<sub>med</sub> × CF (2)<sup>(a)</sup> |
| Beet, sugar dried pulp          | 0.15<sup>*</sup>       | STMR<sub>med</sub> × CF (1)<sup>(a),(b)</sup> | 0.15<sup>*</sup>       | STMR<sub>med</sub> × CF (1)<sup>(a),(b)</sup> |
| Beet, sugar ensiled pulp        | 0.15<sup>*</sup>       | STMR<sub>med</sub> × CF (1)<sup>(a),(b)</sup> | 0.15<sup>*</sup>       | STMR<sub>med</sub> × CF (1)<sup>(a),(b)</sup> |
| Beet, sugar molasses            | 0.15<sup>*</sup>       | STMR<sub>med</sub> × CF (1)<sup>(a),(b)</sup> | 0.15<sup>*</sup>       | STMR<sub>med</sub> × CF (1)<sup>(a),(b)</sup> |
| Canola (Rape seed) meal         | 0.3                   | STMR<sub>med</sub> × CF (2)<sup>(a),(b)</sup> | 0.3                   | STMR<sub>med</sub> × CF (2)<sup>(a),(b)</sup> |
| Rape meal                       | 0.3                   | STMR<sub>med</sub> × CF (2)<sup>(a),(b)</sup> | 0.3                   | STMR<sub>med</sub> × CF (2)<sup>(a),(b)</sup> |

**Risk assessment residue definition:** sum of quinmerac and its metabolites BH 518-2 and BH 518-4 (free and conjugated), expressed as quinmerac

| STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
|<sup>*</sup>: Indicates that the input value is proposed at the limit of quantification.
|<sup>(a)</sup>: The tentative conversion factors applied to plant commodities for risk assessment were included in the calculation.
|<sup>(b)</sup>: For sugar beet by-products and canola/rapeseed, soyabeans and sunflower meal and soyabeans hulls, no default processing factor was applied because residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

D.2. Consumer risk assessment

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|-----------------------|
|                            | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| **Risk assessment residue definition 1:** sum of quinmerac and its metabolites BH 518-2 and BH 518-4 (free and conjugated), expressed as quinmerac |
| Beetroots                  | 0.15<sup>*</sup>        | STMR<sub>med</sub> × CF (1) | 0.15<sup>*</sup> | STMR<sub>med</sub> × CF (1) |
| Sunflower seeds            | 0.3                    | STMR<sub>med</sub> × CF (2) | 0.3                    | STMR<sub>med</sub> × CF (2) |
| Rapeseeds/canola seeds     | 0.3                    | STMR<sub>med</sub> × CF (2) | 0.3                    | STMR<sub>med</sub> × CF (2) |
| Soyabeans                  | 0.3                    | STMR<sub>med</sub> × CF (2) | 0.3                    | STMR<sub>med</sub> × CF (2) |
| Mustard seeds              | 0.3                    | STMR<sub>med</sub> × CF (2) | 0.3                    | STMR<sub>med</sub> × CF (2) |
| Borage seeds               | 0.3                    | STMR<sub>med</sub> × CF (2) | 0.3                    | STMR<sub>med</sub> × CF (2) |
| Gold of pleasure seeds     | 0.3                    | STMR<sub>med</sub> × CF (2) | 0.3                    | STMR<sub>med</sub> × CF (2) |
| Sugar beet roots           | 0.15<sup>*</sup>        | STMR<sub>med</sub> × CF (1) | 0.15<sup>*</sup> | STMR<sub>med</sub> × CF (1) |

**Risk assessment residue definition 2:** quinmerac

| Swine meat                  | 0.02<sup>*</sup>        | STMR | 0.02<sup>*</sup> | HR |
| Swine fat                   | 0.02<sup>*</sup>        | STMR | 0.02<sup>*</sup> | HR |
| Swine liver                 | 0.02<sup>*</sup>        | STMR | 0.02<sup>*</sup> | HR |
| Swine kidney                | 0.02<sup>*</sup>        | STMR | 0.02<sup>*</sup> | HR |
| Bovine and equine meat      | 0.02<sup>*</sup>        | STMR | 0.02<sup>*</sup> | HR |
| Bovine and equine fat       | 0.02<sup>*</sup>        | STMR | 0.02<sup>*</sup> | HR |
| Bovine and equine liver     | 0.06                   | STMR (tentative) | 0.06                   | HR (tentative) |
| Commodity                  | Chronic risk assessment | Acute risk assessment |
|---------------------------|-------------------------|-----------------------|
|                           | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment   |
| Bovine and equine kidney  | 0.05                    | STMR (tentative)      | 0.05                | HR (tentative) |
| Sheep and goat meat       | 0.02*                   | STMR                  | 0.02*               | HR         |
| Sheep and goat fat        | 0.02*                   | STMR                  | 0.02*               | HR         |
| Sheep and goat liver      | 0.05                    | STMR (tentative)      | 0.05                | HR (tentative) |
| Sheep and goat kidney     | 0.05                    | STMR (tentative)      | 0.05                | HR (tentative) |
| Poultry meat              | 0.02*                   | STMR                  | 0.02*               | HR         |
| Poultry fat               | 0.02*                   | STMR                  | 0.02*               | HR         |
| Cattle and horse milk     | 0.02*                   | STMR                  | 0.02*               | STMR       |
| Sheep and goat milk       | 0.02*                   | STMR                  | 0.02*               | STMR       |
| Birds eggs                | 0.02*                   | STMR                  | 0.02*               | HR         |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
*: Indicates that the input value is proposed at the limit of quantification.
Appendix E – Decision tree for deriving MRL recommendations
### Appendix F – Used compound codes

| Code/Trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|--------------------------------|--------------------------------------------------|---------------------------------|
| Quinmerac                     | 7-chloro-3-methylquinoline-8-carboxylic acid     | ![Quinmerac structural formula](image) |
|                               | O=C(O)c1c(Cl)ccc2cc(cnc12)C(nc12)=O             |                                 |
|                               | ALZOLUNSQWINIR-UHFFFAOYSA-N                      |                                 |
| BH 518-2                      | 7-chloroquinoline-3,8-dicarboxylic acid          | ![BH 518-2 structural formula](image) |
|                               | O=C(O)c1c(Cl)ccc2cc(cnc12)C(=O)O                 |                                 |
|                               | ZYIDIAPHYHJMCU-UHFFFAOYSA-N                      |                                 |
| BH 518-4                      | 7-chloro-3-(hydroxymethyl)quinoline-8-carboxylic acid | ![BH 518-4 structural formula](image) |
|                               | O=C(O)c1c(Cl)ccc2cc(cnc12)CO                    |                                 |
|                               | JHTYXALVKFBXHL-UHFFFAOYSA-N                     |                                 |
| BH 518-5                      | 7-chloro-2-hydroxy-3-methylquinoline-8-carboxylic acid | ![BH 518-5 structural formula](image) |
|                               | O=C(O)c1c(Cl)ccc2cc(Cc12)(O)cnc12              |                                 |
|                               | UHQUQQVAUMGZJE-UHFFFAOYSA-N                     |                                 |

<sup>(a)</sup>: The metabolite name in bold is the name used in the conclusion.

<sup>(b)</sup>: ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).

<sup>(c)</sup>: ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).