Modification of the existing maximum residue level for quizalofop (resulting from the use of quizalofop-P-ethyl) in caraway

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Nissan Chemical Europe S.A.S. submitted a request to the competent national authority in Finland to modify the existing maximum residue level (MRL) for quizalofop in caraway to accommodate the intended NEU use of quizalofop-P-ethyl for this commodity. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for caraway. Adequate analytical methods for enforcement are available to control the residues of quizalofop, resulting from the use of quizalofop-P-ethyl, on the commodity under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of quizalofop-P-ethyl according to the reported agricultural practice is unlikely to present a risk to consumer health.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Nissan Chemical Europe S.A.S. submitted an application to the competent national authority in Finland (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance quizalofop (resulting from the use of quizalofop-P-ethyl) in caraway. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 13 April 2021. To support the intended NEU use of quizalofop-P-ethyl in caraway, the EMS proposed to lower the existing MRL from 0.05* to 0.04 mg/kg based on new residues trials and analytical data.

It is noted that several tentative MRL proposals (including one for caraway) have been implemented in the MRL legislation by Commission Regulation (EU) No Reg. (EU) 2019/973 for ‘quizalofop, its salts, its esters (including propaquizafop) and its conjugates’; including footnotes, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRLs by 14 June 2021. In view of the above, EFSA initially put the assessment of the present application on hold to clarify first if such confirmatory data were already submitted to the Rapporteur Member State (RMS) or in the process of being submitted. After a clarification from the RMS and the Commission that such confirmatory data were not available, and considering that the deadline for their submission already expired, EFSA resumed the assessment of the current application and the evaluation report, as required by Article 10 of the MRL regulation on 7 October 2021.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments, including the review of the existing MRLs for all quizalofop-P ester variants according to Article 12 of Regulation (EC) No 396/2005 (MRL review), and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of quizalofop-P-ethyl following foliar applications was investigated in the framework of the peer review and the MRL review in crops belonging to the groups of fruit crops, root crops and pulses/oilseeds. Additionally, a new metabolism study in cereals was investigated in a subsequent MRL application. Considering the available metabolism studies of quizalofop-P-ethyl as well as metabolism studies of the other ester variants of quizalofop-P (quizalofop-P-tefuryl and propaquizafop), it was concluded that the metabolic patterns of all ester variants in plants were similar with the parent ester rapidly hydrolysed to the corresponding acid (quizalofop) which was always present at harvest. Other phenoxy metabolites than quizalofop were identified at harvest in lower amounts. The MRL review did not propose the inclusion of these metabolites in the residue definition for the time being but recommended to reconsider the toxicological relevance of these phenoxy metabolites under the renewal process.

Studies investigating the effect of processing on the nature of quizalofop-P-ethyl (hydrolysis studies) showed no degradation under conditions representative of pasteurisation and baking/brewing/boiling while for conditions simulating sterilisation, quizalofop-P-ethyl was partly hydrolysed to quizalofop. Since studies addressing the effect of processing on the nature of quizalofop demonstrated that quizalofop is hydrolytically stable, it was confirmed that the residue definitions for primary crops are also applicable to processed commodities.

From the available rotational crop metabolism studies performed with quizalofop-P-ethyl in sugar beets, lettuces, cotton seeds, peanuts and wheat, the MRL review concluded that metabolism in rotational crops proceeds in a similar pathway as in primary crops. No further data were required for the intended use on caraway assessed under this application.

Based on the metabolic pattern identified in metabolism studies with quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop, the results of hydrolysis studies with quizalofop-P-tefuryl and quizalofop-P-ethyl, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the residue definitions for plant products were proposed for all quizalofop ester variants as ‘the sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers)’ for both enforcement and risk assessment. These residue definitions are applicable to primary crops (all groups), rotational crops and processed products. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.
EFSA concluded that for the crop assessed in this application, metabolism of quizalofop-P-ethyl in primary and in rotational crops, and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definition is applicable.

A sufficiently validated analytical method based on high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) is available to quantify quizalofop-P-ethyl residues in caraway according to the enforcement and risk assessment residue definition. The method enables quantification of residues at or above 0.01 mg/kg in caraway (limit of quantification (LOQ)). As part of the current application, the applicant also provided a new cross-validation study which was deemed sufficient to demonstrate the extraction efficiency and hydrolysis of conjugates in high water and high oil matrices.

The available residue trials are sufficient to derive an MRL proposal of 0.04 mg/kg for caraway.

Specific studies investigating the magnitude of quizalofop-P-ethyl residues in processed commodities are not required for the present application, as significant residues are not expected for caraway and the contribution of caraway to the overall chronic exposure is below 0.01% of the acceptable daily intake (ADI).

The occurrence of quizalofop-P-ethyl residues in rotational crops was investigated in the framework of the EU pesticides peer review and the MRL review. Based on available confined rotational crop studies conducted at twice the intended application rate of quizalofop-P-ethyl in caraway, it is concluded that no residues are expected in rotational crops if quizalofop-P-ethyl is applied on caraway according to the intended good agricultural practice (GAP).

Residues of quizalofop-P-ethyl in commodities of animal origin were not assessed since caraway is not fed to livestock.

The toxicological profiles for the different quizalofop-P-ester variants (quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop) were derived in the framework of the EU pesticides peer review. Since all these different ester variants share the same residue definition based on quizalofop, EFSA considered for the consumer risk assessment the lowest toxicological reference values available (respectively, the ADI set for quizalofop-P-ethyl and the acute reference dose (ARfD) set for quizalofop-P-tefuryl) expressed as ‘quizalofop’, by correcting them by the different molecular weights. Consequently, the resulting values of 0.0083 mg/kg body weight (bw) per day and 0.08 mg/kg bw were used in the chronic and acute dietary exposure assessments, respectively. The metabolites included in the residue definition are deemed of similar toxicity than the parent active substance.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo).

The short-term exposure did not exceed the ARfD for the crop assessed in this application. It should be, however, noted that an establishment of an ARfD to quizalofop-P-ethyl was not considered necessary by the peer review (EFSA, 2009) and the ARfD used to evaluate the acute risk was the one set for quizalofop-P-tefuryl, recalculated as quizalofop equivalents.

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level of all quizalofop-P ester variants. EFSA updated the calculation with the STMR value derived from the residue trials submitted in support of this MRL application for caraway and other STMRs derived in another EFSA opinion published after the MRL review. The estimated long-term dietary intake accounted for 26% of the ADI (NL toddler diet). The contribution of residues expected in caraway to the overall long-term exposure is below 0.01% of the ADI.

EFSA concluded that the proposed use of quizalofop-P-ethyl on caraway will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

However, it should be noted that the MRL review recommended to reconsider the toxicological relevance of the phenoxy metabolites identified in primary and rotational crop metabolism studies under the renewal process, and therefore, the residue definitions and the consumer risk assessment may be reconsidered following the evaluation of this information. In addition, EFSA also highlighted that metabolism studies did not investigate the possible impact of plant metabolism on the isomer ratio of the active substance. Further investigation on this matter would in principle be required. EFSA would therefore recommend reconsidering also this point in the framework of the renewal of approval of the active substance.
EFSA proposes to amend the existing MRL as reported in the summary table below. Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|------------------------|-------------------------|------------------------|
| 0820030 | Caraway   | 0.05* (Ft)             | 0.04/Further risk managers’ consideration | The submitted data are sufficient to derive an MRL proposal for the NEU use. Risk for consumers unlikely. EFSA notes that the current MRL for quizalofop in caraway is set as tentative at 0.05* mg/kg, a higher level than the MRL of 0.04 mg/kg proposed in the present application. It is noted that an application to address all the Art.12 confirmatory data set for quizalofop has not been submitted yet and the deadline to provide such data is now expired. Nevertheless, the confirmatory data requirements on residue trials, analytical methods and storage stability for caraway could be considered as sufficiently addressed and the footnote can be removed for this crop. EFSA therefore considers the proposed MRL derived in the context of the present application as acceptable, also taking into account the availability of an enforcement method with an LOQ at 0.01 mg/kg for caraway. |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

(ft): Footnote in Commission Regulation (EU) 2019/973 for caraway: The European Food Safety Authority identified some information on residue trials, analytical methods and storage stability as unavailable for quizalofop-P-ethyl. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 14 June 2021, or, if that information is not submitted by that date, the lack of it.
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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for quizalofop (resulting from the use of quizalofop-P-ethyl) in caraway. The detailed description of the intended use of quizalofop-P-ethyl, which is the basis for the current MRL application, is reported in Appendix A.

Quizalofop-P-ethyl is the ISO common name for ethyl (2R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate (IUPAC). It is an ester variant of quizalofop-P. Quizalofop-P is the ISO common name for (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionic acid (IUPAC). The unresolved isomeric mixture of this substance has the common name quizalofop. Quizalofop-P belongs to the class of aryloxyphenoxypropionic herbicides which are taken up via leaves and hinder the synthesis of fatty acids by inhibition of the enzyme Acetyl-CoA carboxylase (ACCase). The chemical structures of the active substance, of other quizalofop ester variants and their main metabolites are reported in Appendix E.

Quizalofop-P (considered variants quizalofop-P-ethyl and quizalofop-P-tefuryl) was evaluated in the framework of Directive 91/414/EEC1 with Finland designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on oilseed rape, sugar/fodder beet, potatoes, peas, beans, linseed and sunflower. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2009). Quizalofop-P was approved2 for the use as herbicide on 1 December 2009.

The EU MRLs for quizalofop are established in Annex II of Regulation (EC) No 396/20053. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed on all quizalofop-P-ester variants (quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop) (EFSA, 2017) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued one reasoned opinion on the modification of MRLs for quizalofop-P-ethyl (EFSA, 2018b). The proposals from these reasoned opinions have been considered in recent MRL regulations.4

In accordance with Article 6 of Regulation (EC) No 396/2005, Nissan Chemical Europe S.A.S. submitted an application to the competent national authority in Finland (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for quizalofop (resulting from the use of quizalofop-P-ethyl) in caraway. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 13 April 2021. To accommodate for the intended use of quizalofop-P-ethyl, the EMS proposed to lower the existing MRL from 0.05* mg/kg (ft) to 0.04 mg/kg based on new residues data supporting the intended NEU use of quizalofop-P-ethyl in caraway.

It is noted that several tentative MRL proposals (including one for caraway) have been implemented in the MRL legislation by Commission Regulation (EU) No Reg. (EU) 2019/973,5 for ‘quizalofop, its salts, its esters (including propaquizafop) and its conjugates’; including footnotes, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 14 June 2021. In view of the above, EFSA initially put the assessment of the present application on hold in order to clarify first if such confirmatory data were already submitted to the rapporteur Member State (RMS) or were in the process of being submitted.

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1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1-32.
2 Commission Directive 2009/37/EC of 23 April 2009 amending Council Directive 91/414/EEC to include chlorimequat, copper compounds, propaquizafop, quizalofop-P, tebufluzuron and zeta-cypermethrin as active substances OJ L 104, 24.4.2009, p. 23-32.
3 Regulation (EC) No 396/2005 of the 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, 16.03.2005, p. 1–16.
4 For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/ eu-pesticides-database/active-substances/?event=27.
5 Footnote in Commission Regulation (EU) 2019/973 for caraway: The European Food Safety Authority identified some information on residue trials, analytical methods and storage stability as unavailable for quizalofop-P-ethyl. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 14 June 2021, or, if that information is not submitted by that date, the lack of it.
6 Commission Regulation (EU) 2019/973 of 13 June 2019 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bispyribac, denatonium benzoate, fenoxycarb, flurochloridone, quizalofop-P-ethyl, quizalofop-P-tefuryl, propaquizafop, tebufenozide in or on certain products.C/2019/4258. OJ L 157, 14.6.2019, p. 3-27.
After a clarification from the RMS and the Commission that such confirmatory data were not available, and considering that the deadline for their submission already expired, EFSA resumed the assessment of the current application and the evaluation report, as required by Article 10 of the MRL regulation on 7 October 2021.

EFSA based its assessment on the evaluation report submitted by the EMS (Finland, 2021), the DAR and its addendum (Finland, 2007, 2008) prepared under Council Directive 91/414/EEC, the Commission review report on quizalofop-P-ethyl (European Commission, 2010c), the conclusion on the peer review of the pesticide risk assessment of the active substance quizalofop-P-ethyl (EFSA, 2009), as well as the conclusions from the reasoned opinion on the MRL review according to Article 12 of Regulation No 396/2005 performed on all quizalofop-P-ester variants (quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop) (EFSA, 2017) and another EFSA opinion on quizalofop-P-ethyl (EFSA, 2018b).

For this application, the data requirements established in Regulation (EU) No 544/2011 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a-g, 2000, 2010a,b; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously is presented in Appendix B.

The evaluation report submitted by the EMS (Finland, 2021) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

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 quizalofop-P-ethyl in primary crops belonging to the groups of fruit crops (tomatoes), root crops (sugar beets and potatoes) and pulses/oilseeds (cotton and soya beans) has been investigated in the framework of the EU pesticides peer review (EFSA, 2009) and the MRL review (EFSA, 2017). Additionally, a new metabolism study in cereals (GM maize, containing the aryloxyalkanoate dioxygenase (aad-1) gene) was investigated in a subsequent MRL application (EFSA, 2018b). No additional metabolism studies were submitted in the framework of this MRL application.

Additionally, metabolism studies performed with other quizalofop-P ester variants (quizalofop-P-tefuryl and propaquizafop) have been considered in previous assessments and in the MRL review. The metabolic patterns of all three different ester variants in plants were similar with the parent ester rapidly hydrolysed to the corresponding acid (quizalofop), which was always present at harvest. In most cases, the amount of other metabolites than quizalofop was low at harvest, with exception of the metabolites phenoxy acid (PPA), phenoxy propionate (EPP), quizalofop-phenol (CQOP) and hydroxyquizalofop-phenol (CQOPOH). The MRL review did not propose the inclusion of these metabolites in the residue definition for the time being but recommended to reconsider the toxicological relevance of these phenoxy metabolites under the renewal process.

In the framework of the MRL review, it was also highlighted that metabolism studies did not investigate the possible impact of plant metabolism on the isomer ratio of the active substance. Further investigation on this matter would in principle be required. It is noted that the EFSA guidance on the risk assessment of compounds that may have stereoisomers has been issued (EFSA, 2019b). EFSA would therefore recommend reconsidering this point in the framework of the renewal of approval of the active substance.

For the intended use, the metabolic behaviour in primary crops is sufficiently addressed.
1.1.2. Nature of residues in rotational crops

Caraway can be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the peer review, quizalofop-P-ethyl has a low persistence in soil with a DT90 value under aerobic laboratory conditions of 1.1–3.5 days (Finland, 2007, EFSA, 2009). However, a significantly higher DT90 (603 days) was obtained for the free acid metabolite quizalofop. Therefore, further studies investigating the nature and magnitude of residues in rotational crops are required.

No new studies are submitted with the present application, but the metabolism of quizalofop-P-ethyl in rotational crops has been previously investigated in sugar beets, lettuces, cotton seeds, peanuts and wheat sown at 30 and 60 days after bare soil application at 308 g/ha (1.2 N compared to the maximum dose rate authorised for quizalofop-P-ethyl) of racemate quizalofop-P-ethyl labelled on either the quinoxaline or phenyl rings (Finland, 2007). According to the results of this study, residue levels were not significant (< 0.05 mg eq./kg) regardless of ageing period in soil in all crop parts analysed. It was also concluded that all compounds detected in the rotational crops were also present in primary crops suggesting a similar metabolic pathway between primary and rotational crops.

The same conclusion is also applicable to the present application since it is based on a use with an application rate of 150 g a.s./ha which is lower than the critical GAP considered in the MRL review.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of quizalofop was investigated in the framework of the MRL review for the variant quizalofop-P-tefuryl (EFSA, 2017) and a new study investigating the effect of processing for the variant quizalofop-P-ethyl was submitted with the current application (Finland, 2021).

The standard hydrolysis study investigated in the MRL review, showed that quizalofop is hydrolytically stable under conditions representative for pasteurisation, baking/brewing/boiling and sterilisation (EFSA, 2017).

In the new study provided as part of this MRL application, the hydrolytic stability of quizalofop-P-ethyl was investigated with 14C-phenoxy and 14C-quinoxalin radiolabelled active substance under conditions representative for pasteurisation, baking/brewing/boiling and sterilisation (Finland, 2021). No degradation of quizalofop-P-ethyl was detected under conditions representative of pasteurisation, and baking/brewing/boiling while for conditions simulating sterilisation, quizalofop-P-ethyl was partly hydrolysed to quizalofop at a maximum of 24% applied radioactivity with quizalofop being the remaining 76% of AR. Since quizalofop-P-ethyl and quizalofop were the main compounds detected, it was confirmed that the residue definitions for primary crops are also applicable to processed commodities.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of quizalofop residues from the use of the different quizalofop-P-ester variants were assessed during the EU peer review and in the framework of the MRL review (EFSA, 2009, 2017).

An analytical method for enforcement of quizalofop-P-ethyl (method AN41) was evaluated during the combined MRL review for quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop (EFSA, 2017). The method was considered as sufficiently validated for residues of quizalofop-P-ethyl and quizalofop for dry/high starch/high protein plant matrices (wheat grain and dry beans) and for plant matrices with high acid (oranges), high water (tomatoes) and high oil (cotton seeds) content. The method allows quantifying residues at or above the limit of quantification (LOQ) of 0.01 mg/kg for the total residue (sum of quizalofop-P-ethyl and quizalofop). An independent laboratory validation (ILV) for this method was successfully performed for the same four representative plant matrices. However, in the framework of the MRL review, it was noted that extraction efficiency and hydrolysis of conjugates was not demonstrated and that a validated analytical method for enforcement in complex matrices (such as herbal infusions and spices) was not available and it was required (EFSA, 2017).

As part of this application, the applicant provided a cross-validation study to demonstrate the extraction efficiency and hydrolysis of conjugates. The extraction efficiency was investigated in samples of oilseed rape whole plants (high water content) and seeds (high oil content). An exaggerated application rate (600 g a.s./ha) was applied to oilseed rape to generate treated samples with sufficient incurred residues in the whole plant and in seeds. Different solvents systems used in several analytical methods were applied showing comparable extractions of all analytical methods for the oilseed rape whole plant (high water matrix). Similar extraction was also observed in oilseed rape
seeds (high oil matrix) for the enforcement method AN41 compared with the metabolism studies methods RD051/RD2 and the pre-registration method C43766 (75% of the mean residues detected from the RD051/RD2 and C43766 methods before hydrolysis and 67% after hydrolysis) therefore demonstrating the equivalency of these methods.

Additionally, this new study demonstrates that conjugates are efficiently released upon hydrolysis using the analytical method for enforcement AN41. As shown by the study, higher levels of quizalofop were detected in seeds after hydrolysis with a 39.6% increase compared to the quizalofop levels measured before hydrolysis (average of three trials). This increase following the hydrolysis step is in line with the one observed in the two methods used in metabolism studies RD051/RD2 (average of 39.5% increase of quizalofop after hydrolysis). It is therefore concluded that the enforcement method AN41 will hydrolyse conjugates with the same efficiency as the methods used in the metabolism studies.

Regarding the confirmatory data request of a validated analytical method for enforcement in complex matrices (such as herbal infusions and spices), the EMS considers that such method is not indispensable within the framework of this application since the analytical method AN41 has been successfully validated in four different matrices and taking into account the insignificant contribution of caraway seeds to the overall dietary exposure. EFSA agrees with the EMS’ view, also considering that caraway seeds are mostly composed of fatty acids and oils, hence the validation of the analytical method AN41 in four different matrices (including high oil matrix) – in addition to caraway being a minor crop with insignificant contribution to the dietary exposure – is sufficient reasons to consider the present analytical method AN41 sufficiently suitable for the crop under assessment.

Regarding the achievable LOQ for caraway, EFSA notes that a validated analytical method for enforcement in complex matrices is still not available. However, additional recovery data were generated for caraway with the enforcement method AN41, which was also used for the analysis of the residue trials, achieving an LOQ of 0.01 mg/kg for this commodity (Finland, 2021). EFSA considered the confirmatory data requirements on analytical methods as sufficiently addressed for caraway.

### 1.1.5. Storage stability of residues in plants

The storage stability of residues of the different quizalofop-P-ester variants, including quizalofop-P-ethyl, in plants stored under frozen conditions was investigated in the framework of the MRL review (EFSA, 2017). Stability of quizalofop-P-ethyl and quizalofop residues was demonstrated for at least 12 months when stored at −18°C in samples of crops classified as matrices with high water content (snap beans), high acid content (oranges), high oil content (cotton seeds and rape seeds) and dry matrices (wheat grain, GM maize).

EFSA notes that storage stability in complex matrices (such as herbal infusions and spices) has not been demonstrated yet. However, considering that in the available residue trials on caraway, samples of caraway seeds were stored frozen for a maximum of 62 days prior to extraction and storage stability was demonstrated in four different main matrices for at least 12 months (including high oil matrix), it is very unlikely that any degradation would occur in such a short time.

Therefore, the integrity of the caraway seed samples is considered sufficiently demonstrated for the present application. EFSA considered the confirmatory data requirements on storage stability as sufficiently addressed for caraway.

### 1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definition was proposed in the framework of the MRL review, for both enforcement and risk assessment ‘sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers)’.

The same residue definition is applicable to rotational crops and processed products for all groups. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition. Taking into account the proposed use assessed in this application, EFSA concluded that this residue definition is appropriate, and no modification is required.

However, EFSA notes that the MRL review recommended to reconsider the toxicological relevance of the phenoxo metabolites identified in primary and rotational crop metabolism studies under the renewal process, and therefore, the above residue definition may be reconsidered following the
evaluation of this information. In addition, EFSA highlighted that the metabolism studies did not investigate the possible impact of plant metabolism on the isomer ratio of the active substance. Further investigation on this matter would in principle be required. EFSA would therefore recommend reconsidering also this point in the framework of the renewal of approval of the active substance.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of this MRL application, the applicant submitted residue trials performed in caraway seeds. The residue trial samples were analysed for the parent compound and the metabolites included in the residue definitions for enforcement and risk assessment.

According to the assessment of the EMS (Finland, 2021), the methods used were sufficiently validated and fit for purpose. The samples of these residue trials were stored under conditions for which integrity of the samples can be considered as sufficiently demonstrated (see Section 1.1.5).

Caraway

**NEU outdoor GAP:** $1 \times 150$ g a.s./ha, $BBCH = 11–60$, $PHI = 56$ days

The applicant provided four residue trials conducted in Finland over the period 2015–2016 to determine the residues of quizalofop in caraway after the application of quizalofop-P-ethyl according to the intended GAP as reported in Appendix A. All residue trials were considered independent as they were performed in different geographical locations and over two different growing seasons.

EFSA notes that sampling of seeds occurred at 57, 66, 67 and 73 days after the application. Therefore, for three of these trials, the preharvest interval (PHI) is within the $\pm 25\%$ tolerance rule (42–70 days for a PHI of 56 days) while for one trial only (trial number ONE0316-02), the PHI of 73 days slightly exceeds this tolerance rule. This minor deviation was justified since a PHI of 73 days was considered necessary for this trial to ensure the sampling at harvest matches the maturity of the crop. EFSA agrees to accept this minor deviation and considers the independency and number of trials sufficient to derive an MRL proposal of 0.04 mg/kg for caraway in support of the intended NEU use of quizalofop-P-ethyl.

EFSA considered the confirmatory data on residue trials as sufficiently addressed for caraway.

1.2.2. Magnitude of residues in rotational crops

The possible transfer of quizalofop residues to crops that are grown in crop rotation has been assessed in the EU pesticides peer review and in the MRL review (EFSA, 2009, 2017) for the different ester variants of quizalofop-P, including quizalofop-P-ethyl.

The MRL review concluded that significant residues of quizalofop-P ester variants (including quizalofop-P-ethyl) and their metabolites are not expected to be present in rotational crops based on the confined rotational crop studies conducted at 2.8N (propaquizafop), 1.2N (quizalofop-P-ethyl) and 2.5N (quizalofop-P-tefuryl) and the maximum application rates supported in the framework of the MRL review, provided that these quizalofop ester variants are applied according to the existing GAPs considered in the MRL review.

Since the maximum annual application rate for the crop under consideration (i.e. 150 g a.s./ha) is lower than the application rate tested in the rotational crop study, it is concluded that no residues are expected, provided that the active substance is applied according to the intended GAP.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies for the crop under assessment are not available and are not required since residues in caraway do not exceed the trigger value of 0.1 mg/kg and the contribution of caraway to overall chronic exposure is less than 0.01% of the ADI.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal for quizalofop in caraway in support of the intended NEU use of quizalofop-P-ethyl as well as risk assessment values for the commodity under evaluation (see Appendix B.4).
EFSA notes that the current MRL for quizalofop in caraway is set as tentative at 0.05 mg/kg (FT)\textsuperscript{5}, a higher level than the MRL of 0.04 mg/kg proposed in the present application. It is noted that an application to address all the Art.12 confirmatory data set for quizalofop has not been submitted yet and the deadline to provide such data is now expired. Nevertheless, the confirmatory data requirements on residue trials, analytical methods and storage stability for caraway could be considered as sufficiently addressed and the footnote can be removed for this crop. EFSA, therefore, considers the proposed MRL derived in the context of the present application as acceptable, also taking into account the availability of an enforcement method with an LOQ at 0.01 mg/kg for caraway.

In Section 3, EFSA assessed whether residues on this crop resulting from the intended use are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as caraway seeds are not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019a). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for the different quizalofop-P-ester variants (quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop) were derived in the framework of the EU pesticides peer review (EFSA, 2009; European Commission, 2010c). The metabolites included in the risk assessment residue definition were deemed of similar toxicity than the parent active substance. Since all these different ester variants share the same residue definition based on quizalofop, EFSA considered for the consumer risk assessment the lowest toxicological reference values available (respectively, the ADI set for quizalofop-P-ethyl and the ARfD set for quizalofop-P-tefuryl) expressed as 'quizalofop' by correcting them by the different molecular weights. Consequently, the resulting values of 0.0083 mg/kg bw per day and 0.08 mg/kg bw were used in the chronic and acute dietary exposure assessment, respectively.

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed only for the commodity assessed in this application in accordance with the internationally agreed methodology (FAO, 2016). The calculations were based on the highest residue (HR) derived from supervised field trials and the complete list of input values can be found in Appendix D.1.

The short-term exposure did not exceed the ARfD for the crop assessed in this application (see Appendix B.3). It should be, however, noted that an establishment of an ARfD for quizalofop-P-ethyl was not considered necessary by the peer review (EFSA, 2009) and the ARfD used in this application to evaluate the acute risk was the one set for quizalofop-P-tefuryl, recalculated as quizalofop equivalent (0.08 mg/kg bw).

Long-term (chronic) dietary risk assessment

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level of all quizalofop-P ester variants (EFSA, 2017). EFSA updated the calculation with the STMR value derived from the residue trials submitted in support of this MRL application for caraway and other STMRs derived in an EFSA opinion published after the MRL review (EFSA, 2018b). The input values used in the exposure calculations are summarised in Appendix D.1. The estimated long-term dietary intake accounted for 26% of the ADI (NL toddler diet). The contributions of residues expected in caraway assessed in the present MRL application to the overall long-term exposure is insignificant. The ADI used in this application to evaluate the chronic risk is based on the lowest ADI of 0.009 mg/kg bw per day derived for quizalofop-P-ethyl (EFSA, 2009) and recalculated as quizalofop equivalent (0.0083 mg/kg bw per day).

Based on the risk assessment results, EFSA concluded that the long-term and short-term intake of residues occurring in food from the existing uses of quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop and from the intended use of quizalofop-P-ethyl in caraway, is unlikely to present a risk to consumer health.
However, it should be noted that the MRL review recommended to reconsider the toxicological relevance of the phenoxy metabolites identified in primary and rotational crop metabolism studies under the renewal process, and therefore, the residue definitions and the consumer risk assessment may be reconsidered following the evaluation of this information. In addition, EFSA also highlighted that metabolism studies did not investigate the possible impact of plant metabolism on the isomer ratio of the active substance. Further investigation on this matter would in principle be required. EFSA would therefore recommend reconsidering also this point in the framework of the renewal of approval of the active substance.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for caraway.

EFSA concluded that the proposed use of quizalofop-P-ethyl on caraway will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

However, it should be noted that the MRL review recommended to reconsider the toxicological relevance of the phenoxy metabolites identified in primary and rotational crop metabolism studies under the renewal process, and therefore, the residue definitions and the consumer risk assessment may be reconsidered following the evaluation of this information. In addition, EFSA also highlighted that metabolism studies did not investigate the possible impact of plant metabolism on the isomer ratio of the active substance. Further investigation on this matter would in principle be required. EFSA would therefore recommend reconsidering also this point in the framework of the renewal of approval of the active substance.

EFSA considered the confirmatory data requirements on residue trials, analytical methods and storage stability could be considered as sufficiently addressed for caraway and the related footnote in Regulation can be removed for this crop.

The MRL recommendations are summarised in Appendix B.4.

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**Abbreviations**

- **a.s.** active substance
- **ADI** acceptable daily intake
- **ARfd** acute reference dose
- **BBCH** growth stages of mono- and dicotyledonous plants
- **Bw** body weight
- **CAC** Codex Alimentarius Commission
- **CAS** Chemical Abstract Service
- **CCPR** Codex Committee on Pesticide Residues
- **CEN** European Committee for Standardisation (Comité Européen de Normalisation)
- **CF** conversion factor for enforcement to risk assessment residue definition
- **DAR** draft assessment report
- **DAT** days after treatment
- **DT₉₀** period required for 90% dissipation (define method of estimation)
- **EMS** evaluating Member State
- **Eq** residue expressed as a.s. equivalent
- **EURL** EU Reference Laboratory (former Community Reference Laboratory (CRL))
- **FAO** Food and Agriculture Organization of the United Nations
- **GAP** Good Agricultural Practice
- **GC** gas chromatography
- **GC-MS** gas chromatography with mass spectrometry
- **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
HPLC-UVD  high performance liquid chromatography with ultra-violet detector
HR  highest residue
IEDI  international estimated daily intake
IESTI  international estimated short-term intake
ILV  independent laboratory validation
ISO  International Organisation for Standardisation
IUPAC  International Union of Pure and Applied Chemistry
LOQ  limit of quantification
MRL  maximum residue level
MS  Member States
MS  mass spectrometry detector
MS/MS  tandem mass spectrometry detector
MW  molecular weight
NEU  northern Europe
OECD  Organisation for Economic Co-operation and Development
PBI  plant back interval
PHI  preharvest interval
P<sub>ow</sub>  partition coefficient between n-octanol and water
PRIMo  (EFSA) Pesticide Residues Intake Model
QuEChERS  Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA  risk assessment
RAC  raw agricultural commodity
RD  residue definition
RMS  rapporteur Member State
RPF  relative potency factor
SANCO  Directorate-General for Health and Consumers
SC  suspension concentrate
SCPAFF  Standing Committee on Plants, Animals, Food and Feed (formerly: Standing Committee on the Food Chain and Animal Health; SCFCAH)
SEU  southern Europe
SG  water-soluble granule
SL  soluble concentrate
SP  water-soluble powder
STMR  supervised trials median residue
WHO  World Health Organization
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F, G or I<sup>(a)</sup> | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|--------------------------|--------------------------|-----------------------------------|-------------|-----------------------------|---------------------------|---------|---------|
| Caraway               | NEU                      | F                        | Annual and perennial grasses      | EC 50 g/L   | Foliar treatment – broadcast spraying | BBCH 11 - 60 | 1 n.a. | 25-75   | 200-300 | 0.075-0.150 | kg a.i./ha | 56      |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; EC: Emulsifiable concentrate.

(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)(a) | Comment/Source |
|----------------------------------|-------------|---------|----------------|-------------------|----------------|
| Fruit crops                      | Tomatoes(b) | Foliar, 1 × 167–173 g a.s./ha | 0, 12 and 105 | (EFSA, 2017; EFSA, 2018b for a study in GM maize) |
| Root crops                       | Sugar beets(b) | Foliar, 1 × 280 g a.s./ha | 31, 60 and 90 | 28 |
| Root crops                       | Potatoes(c) | Foliar, 1 × 6 g a.s./ha | 14 |
| Root crops                       | Sugar beets(c) | Foliar, 1 × 316 g a.s./ha | 31 |
| Pulses/oilseeds                  | Cotton(e) | Foliar, 1 × 260 g a.s./ha | 0, 7, 21 and 42 |
| Pulses/oilseeds                  | Soya beans(e) | Foliar, 1 × 273–287 g a.s./ha | 0, 7, 21 and 42 |
| Pulses/oilseeds                  | Soya beans(f) | Foliar, 1 × 280 g a.s./ha | 0, 7, 14, 29 and 63 |
| Pulses/oilseeds                  | Soya beans(g) | Foliar, 1 × 340 g a.s./ha (R/S); 1 × 160 g a.s./ha (R + S) | 1, 14 and 105 |
| Cereals                          | GM maize(b) (aad-1 gene) | 1 × 98 g a.s./ha | 48 (forage); 72 (grain, cobs, stover/fodder) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Sugar beets(e) | Bare soil, 308 g a.s./ha | 30, 60 | EFSA (2017) |
| Leafy crops                         | Lettuces(h) | Bare soil, 308 g a.s./ha | 30, 60 |  |
| Pulses and oilseeds                 | Cotton seeds(e) | Bare soil, 308 g a.s./ha | 30, 60 |  |
| Cereal (small grain)                | Wheat(e) | Bare soil, 308 g a.s./ha | 30, 60 |  |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)     | Yes        | Finland (2021) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes |  |
| Sterilisation (20 min, 120°C, pH 6)     | No (quizalofop-P-ethyl was partly hydrolysed to quizalofop) |  |
A standard hydrolysis study performed with quizalofop-P-terfuryl was assessed in the framework of the MRL review demonstrating that quizalofop is not expected to degrade hydrolytically under conditions representative of three different processing practices (EFSA, 2017). A new study performed with quizalofop-P-ethyl was also submitted with this application. As quizalofop-P-ethyl and quizalofop were the main compounds detected in the buffer solutions in conditions simulating pasteurisation, baking/brewing/boiling and sterilisation, it can be concluded that the residue definitions for primary crops are also applicable to processed commodities.

### Table: Can a general residue definition be proposed for primary crops?

| Question                                                                 | Yes | EFSA (2017) |
|-------------------------------------------------------------------------|-----|-------------|
| Rotational crop and primary crop metabolism similar?                    | Yes | EFSA (2017) |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | Yes | EFSA (2017) |

### Table: Plant residue definition for monitoring (RD-Mo)

- MRL review (EFSA, 2017) and Regulation (EU) 2019/973:
  - Sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers)

### Table: Plant residue definition for risk assessment (RD-RA)

- MRL review (EFSA, 2017):
  - Sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers)

### Table: Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

- HPLC–MS/MS, high water, high acid, high oil content and dry commodities. The method is validated for analysis of quizalofop-P-ethyl and quizalofop (through hydrolysis). LOQ 0.01 mg/kg expressed as total residues (‘sum of quizalofop-P-ethyl and quizalofop’); ILV available (EFSA, 2017).
  - Extraction efficiency and hydrolysis step demonstrated in oil seed rape whole plant (high water) and seeds (high oil) (Finland, 2021).
  - Fully validated analytical method in complex matrices is still missing and desirable (relevant for the authorisations of quizalofop-P-ethyl on herbal infusions and spices) (EFSA, 2017). This data gap identified in the MRL review is not considered indispensable within the framework of this application since the analytical method AN41 has been successfully validated in four matrices and additional recovery data were generated for caraway demonstrating that an LOQ of 0.01 mg/kg is achievable for this commodity.

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
### Stability of residues in plants

| Plant product (available studies) | Category | Commodity       | T (°C) | Stability period | Value | Unit  | Compounds covered                          | Comment/Source                                                                                                                                                                                                 |
|----------------------------------|----------|-----------------|--------|-----------------|-------|-------|-------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                  | High water content | Snap beans     | –20    | 28              | (a)   | Months | quizalofop-P-ethyl and quizalofop-P      | Since conjugates may only degrade to the acid form, the reported storage stability studies are expected to cover all compounds included in the residue definition, including conjugates. (EFSA, 2017)               |
|                                  | High oil content    | Cotton seeds   | –20    | 28              | (a)   | Months |                                           |                                                                                                                                                    |
|                                  |                      | Rape seeds     | –20    | 28              | (a)   | Months |                                           |                                                                                                                                                    |
|                                  | Dry/High starch     | Wheat grain    | –18    | 12              | (a)   | Months |                                           |                                                                                                                                                    |
|                                  |                      | GM maize grain | –20    | 13              | (a)   | Months |                                           |                                                                                                                                                    |
|                                  | High acid content   | Oranges        | –18    | 12              | (a)   | Months |                                           |                                                                                                                                                    |
|                                  | Processed products  | GM maize oil   | –20    | 13              | (b)   | Months |                                           |                                                                                                                                                    |
|                                  |                      | GM maize flour | –20    | 13              | (b)   | Months |                                           |                                                                                                                                                    |
|                                  |                      | GM maize starch| –20    | 13              | (b)   | Months |                                           |                                                                                                                                                    |
|                                  | Others              | GM maize stover| –20    | 13              | (a)   | Months |                                           |                                                                                                                                                    |
|                                  |                      | GM maize forage| –20    | 13              | (a)   | Months |                                           |                                                                                                                                                    |

GM: genetically modified.

(a): Storage stability refers to the total residues of quizalofop-P-ethyl and quizalofop.

(b): Storage stability demonstrated individually for quizalofop-P-ethyl and quizalofop.
## Modification of the existing MRLs for quizalofop-P-ethyl in caraway

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

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

| Commodity     | Region/(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) |
|---------------|------------|------------------------------------------------------------------|----------------------------------|------------------------|---------------|-----------------|
| Caraway seeds | NEU        | Mo/RA: $2 \times < 0.01; 2 \times 0.02$                         | Residue trials on caraway compliant with GAP. MRL<sub>OECD</sub> = 0.04 | 0.04                   | 0.02          | 0.02            |

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

*: Indicates that the MRL is proposed at the limit of quantification.
B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | No | Based on the confined rotational crop studies conducted at 2N compared to the maximum application rate supported in the framework of this application, significant residues of quizalofop-P-ethyl and its metabolites are not expected to be present in rotational crops, provided that quizalofop-P-ethyl is applied according to the intended GAP. |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Not triggered | Not available and not required. |

GAP: Good Agricultural Practice.

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application and not required.

B.2. Residues in livestock

Not relevant.
B.3. Consumer risk assessment

| ARfD | 0.08 mg/kg bw (EFSA, 2017) |
|------|-----------------------------|
|      | ARfD is based on the lowest ARfD of 0.1 mg/kg bw derived for quizalofop-P-tefuryl (European Commission, 2010c) and recalculated as quizalofop equivalent (EFSA, 2017). |
| Highest IESTI, according to EFSA PRIMo | Caraway: < 0.01% of ARfD |
| Assumptions made for the calculations | The short-term exposure assessment was calculated only for caraway using as input value the highest residue level derived from the submitted residue trials assessed under the present MRL application. |
|      | Calculations performed with PRIMo revision 3.1. |

| ADI | 0.0083 mg/kg bw per day (EFSA, 2017) |
|-----|-------------------------------------|
|      | ADI is based on the lowest ADI of 0.009 mg/kg bw per day derived for quizalofop-P-ethyl (European Commission, 2010c) and recalculated as quizalofop equivalent (EFSA, 2017). |
| Highest IEDI, according to EFSA PRIMo | 26% ADI (NL toddler) |
| Contribution of crops assessed: | Caraway: < 0.01 % of ADI |
| Assumptions made for the calculations | The long-term exposure assessment was calculated by updating the input values for the risk assessment derived in the MRL review (EFSA, 2017) and the subsequent MRL application (EFSA, 2018b) with the median residue level for caraway derived from the submitted residue trials assessed under the present MRL application. |
|      | Calculations performed with PRIMo revision 3.1. |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue; CXL: codex maximum residue limit.

MW quizalofop = 344.8; MW quizalofop-P-ethyl = 372.8; MW quizalofop-P-tefuryl = 428.8.
### B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-------------------|-----------|------------------------|------------------------|------------------------|
| 0820030           | Caraway   | 0.05* (Ft)             | 0.04                   | Further risk managers’ considerations |

**Enforcement residue definition:** Quizalofop (sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers))

The submitted data are sufficient to derive an MRL proposal for the NEU use. Risk for consumers unlikely. EFSA notes that the current MRL for quizalofop in caraway is set as tentative at 0.05* mg/kg, a higher level than the MRL of 0.04 mg/kg proposed in the present application. It is noted that an application to address all the Art.12 confirmatory data set for quizalofop has not been submitted yet and the deadline to provide such data is now expired. Nevertheless, the confirmatory data requirements on residue trials, analytical methods and storage stability for caraway could be considered as sufficiently addressed and the footnote can be removed for this crop. EFSA therefore considers the proposed MRL derived in the context of the present application as acceptable, also taking into account the availability of an enforcement method with an LOQ at 0.01 mg/kg for caraway.

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MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.

<sup>(a)</sup> Commodity code number according to Annex I of Regulation (EC) No 396/2005.

<sup>*</sup> Indicates that the MRL is set at the limit of analytical quantification (LOQ).
Modification of the existing MRLs for quizalofop-P-ethyl in caraway

Appendix C – Pesticide Residue Intake Model (PRIMo)

The toxicological reference values for the different quizalofop-P-ester variants were derived in the framework of the EU simplified risk assessment guidance. The toxicological reference values (ADI and ARfD) were set at the lowest toxicological reference values available (respectively the ADI set for quizalofop-P-ethyl and the ARfD set for quizalofop-P-tefuryl) expressed as ‘quizalofop’ by correcting them by the different molecular weights of the respective variants.

Details – chronic risk assessment

ADI (mg/kg bw per day): 0.08
ARfD (mg/kg bw): 0.0083

Source of ADI: EC assessment/children
Source of ARfD: EC assessment/adults

Year of evaluation: 2010

EFSA PRIMo revision 3.1; 2021/01/06

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of quizalofop is unlikely to present a public health concern.

DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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## Results for all crops

| Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|-----------------------|--------------------------|---------------------|-----------------------|-----------------------|--------------------------|---------------------|
| 26% Broccoli/boiled  | 0.45/0.26             | 16                       | 0.45/0.26           | 14% Cauliflowers  | 0.45/0.26             | 14                       | 0.45/0.26           |
| 21% Cauliflowers/boiled  | 0.45/0.26             | 16                       | 0.45/0.26           | 14% Cauliflowers  | 0.45/0.26             | 14                       | 0.45/0.26           |
| 17% Escarole/broad-leaved endive/boiled  | 0.20/0.26             | 13                       | 0.20/0.26           | 8% Escarole/broad-leaved endive  | 0.20/0.26             | 8                       | 0.20/0.26           |
| 13% Potatoes/boiled  | 0.10/0.08             | 7.5                      | 0.10/0.08           | 8% Parsnips/boiled   | 0.20/0.1             | 8                       | 0.20/0.1             |
| 6% Parsnips/boiled  | 0.20/0.1             | 5.1                      | 0.20/0.1            | 5% Parsnips/boiled  | 0.20/0.1             | 5                       | 0.20/0.1             |
| 3% Sugar beets (root)/sugar  | 0.06/0.46             | 4.4                      | 0.06/0.46           | 3% Sugar beets (root)/sugar  | 0.06/0.46             | 3                       | 0.06/0.46           |
| 3% Sugar beets (root)/sugar  | 0.06/0.46             | 4.4                      | 0.06/0.46           | 3% Sugar beets (root)/sugar  | 0.06/0.46             | 3                       | 0.06/0.46           |
| 3% Beetroot/boiled  | 0.20/0.1             | 2.8                      | 0.20/0.1            | 3% Scallops/boiled  | 0.05/0.05            | 2.9                       | 0.05/0.05           |
| 3% Scallops/boiled  | 0.05/0.05            | 2.9                      | 0.05/0.05           | 3% Scallops/boiled  | 0.05/0.05            | 2.9                       | 0.05/0.05           |

## Conclusion

No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short-term intake of residues of quizalofop is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.
# Appendix D – Input values for the exposure calculations

## D.1 Consumer risk assessment

| Commodity                  | Existing/proposed MRL (mg/kg) | Source                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|--------------------------------|-------------------------|-------------------------|-----------------------|
|                            |                                |                         | Input value (mg/kg)     | Comment               |
|                            |                                |                         |                         | Input value (mg/kg)   | Comment <sup>(a)</sup> |
| Risk assessment residue definition: Quizalofop (sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers)) | | | | |
| Grapefruits                | 0.02*                          | EFSA (2017)             | 0.01                    | STMR-RAC              |
| Oranges                    | 0.02*                          | EFSA (2017)             | 0.01                    | 0.01 STMR-RAC         |
| Lemons                     | 0.02*                          | EFSA (2017)             | 0.01                    | 0.01 HR-RAC           |
| Limes                      | 0.02*                          | EFSA (2017)             | 0.01                    | 0.01 HR-RAC           |
| Mandarins                  | 0.02*                          | EFSA (2017)             | 0.01                    | 0.01 HR-RAC           |
| Other citrus fruit         | 0.02*                          | EFSA (2017)             | 0.01                    | 0.01 HR-RAC           |
| Almonds                    | 0.01*                          | EFSA (2017)             | 0.01                    | 0.01 HR-RAC           |
| Brazil nuts                | 0.01*                          | EFSA (2017)             | 0.01                    | 0.01 HR-RAC           |
| Cashew nuts                | 0.01*                          | EFSA (2017)             | 0.01                    | 0.01 HR-RAC           |
| Chestnuts                  | 0.01*                          | EFSA (2017)             | 0.01                    | 0.01 HR-RAC           |
| Coconuts                   | 0.01*                          | EFSA (2017)             | 0.01                    | 0.01 HR-RAC           |
| Hazelnuts/cobnuts          | 0.01*                          | EFSA (2017)             | 0.01                    | 0.01 HR-RAC           |
| Macadamia                  | 0.01*                          | EFSA (2017)             | 0.01                    | 0.01 HR-RAC           |
| Pecans                     | 0.01*                          | EFSA (2017)             | 0.01                    | 0.01 HR-RAC           |
| Pine nut kernels           | 0.01*                          | EFSA (2017)             | 0.01                    | 0.01 HR-RAC           |
| Pistachios                 | 0.01*                          | EFSA (2017)             | 0.01                    | 0.01 HR-RAC           |
| Walnuts                    | 0.01*                          | EFSA (2017)             | 0.01                    | 0.01 HR-RAC           |
| Other tree nuts            | 0.01*                          | EFSA (2017)             | 0.01                    | 0.01 HR-RAC           |
| Apples                     | 0.02*                          | EFSA (2017)             | 0.02                    | 0.02 HR-RAC           |
| Pears                      | 0.02*                          | EFSA (2017)             | 0.02                    | 0.02 HR-RAC           |
| Quinces                    | 0.02*                          | EFSA (2017)             | 0.02                    | 0.02 HR-RAC           |
| Medlar                     | 0.02*                          | EFSA (2017)             | 0.02                    | 0.02 HR-RAC           |
| Loquats/Japanese medlars    | 0.02*                          | EFSA (2017)             | 0.02                    | 0.02 HR-RAC           |
| Other pome fruit           | 0.02*                          | EFSA (2017)             | 0.02                    | 0.02 STMR-RAC         |
| Apricots                   | 0.02*                          | EFSA (2017)             | 0.02                    | 0.02 HR-RAC           |
| Cherries (sweet)           | 0.02*                          | EFSA (2017)             | 0.02                    | 0.02 HR-RAC           |
| Peaches                    | 0.02*                          | EFSA (2017)             | 0.02                    | 0.02 HR-RAC           |
| Plums                      | 0.02*                          | EFSA (2017)             | 0.02                    | 0.02 HR-RAC           |
| Other stone fruit          | 0.02*                          | EFSA (2017)             | 0.02                    | 0.02 STMR-RAC         |
| Table grapes               | 0.02*                          | EFSA (2017)             | 0.02                    | 0.02 HR-RAC           |
| Wine grapes                | 0.02*                          | EFSA (2017)             | 0.02                    | 0.02 HR-RAC           |
| Strawberries               | 0.02*                          | EFSA (2017)             | 0.02                    | 0.02 HR-RAC           |
| Blackberries               | 0.02*                          | EFSA (2017)             | 0.02                    | 0.02 HR-RAC           |
| Dewberries                 | 0.02*                          | EFSA (2017)             | 0.02                    | 0.02 HR-RAC           |
| Raspberries (red and yellow)| 0.02*                          | EFSA (2017)             | 0.02                    | 0.02 HR-RAC           |
| Kumquats                   | 0.01*                          | EFSA (2017)             | 0.01                    | 0.01 STMR-RAC         |
| Potatoes                   | 0.1                            | EFSA (2017)             | 0.04                    | 0.08 STMR-RAC         |
| Beetroot                   | 0.06                           | EFSA (2017)             | 0.04                    | 0.05 STMR-RAC         |
| Carrots                    | 0.2                            | EFSA (2017)             | 0.06                    | 0.1 STMR-RAC          |

*EFSA (2017) = EFSA Scientific Committee on Plants, Animals, and Food Security (2017).*
| Commodity                                    | Existing/proposed MRL (mg/kg) | Source          | Chronic risk assessment | Acute risk assessment |
|----------------------------------------------|-------------------------------|-----------------|-------------------------|-----------------------|
| Celeriacs/turnip-rooted celeries             | 0.08                          | EFSA (2017)     | 0.02 STMR-RAC           | 0.06 HR-RAC           |
| Horseradishes                                | 0.08                          | EFSA (2017)     | 0.02 STMR-RAC           | 0.06 HR-RAC           |
| Jerusalem artichokes                         | 0.08                          | EFSA (2017)     | 0.02 STMR-RAC           | 0.06 HR-RAC           |
| Parsnips                                     | 0.2                           | EFSA (2017)     | 0.06 STMR-RAC           | 0.1 HR-RAC            |
| Parsley roots/Hamburg roots parsley          | 0.2                           | EFSA (2017)     | 0.06 STMR-RAC           | 0.1 HR-RAC            |
| Radishes                                     | 0.2                           | EFSA (2017)     | 0.06 STMR-RAC           | 0.1 HR-RAC            |
| Salsifies                                    | 0.2                           | EFSA (2017)     | 0.06 STMR-RAC           | 0.1 HR-RAC            |
| Swedes/rutabagas                             | 0.06                          | EFSA (2017)     | 0.04 STMR-RAC           | 0.05 HR-RAC           |
| Turnips                                      | 0.08                          | EFSA (2017)     | 0.03 STMR-RAC           | 0.04 HR-RAC           |
| Other root and tuber vegetables              | 0.2                           | EFSA (2017)     | 0.06 STMR-RAC           |                       |
| Garlic                                       | 0.04                          | EFSA (2017)     | 0.04 STMR-RAC           | 0.04 HR-RAC           |
| Onions                                       | 0.04                          | EFSA (2017)     | 0.04 STMR-RAC           | 0.04 HR-RAC           |
| Shallots                                     | 0.04                          | EFSA (2017)     | 0.04 STMR-RAC           | 0.04 HR-RAC           |
| Tomatoes                                     | 0.05                          | EFSA (2017)     | 0.01 STMR-RAC           | 0.05 HR-RAC           |
| Aubergines/egg plants                        | 0.05                          | EFSA (2017)     | 0.01 STMR-RAC           | 0.05 HR-RAC           |
| Broccoli                                     | 0.4                           | EFSA (2017)     | 0.06 STMR-RAC           | 0.26 HR-RAC           |
| Cauliflowers                                  | 0.4                           | EFSA (2017)     | 0.06 STMR-RAC           | 0.26 HR-RAC           |
| Other flowering brassica                     | 0.4                           | EFSA (2017)     | 0.06 STMR-RAC           |                       |
| Head cabbages                                | 0.6                           | EFSA (2017)     | 0.05 STMR-RAC           | 0.2 HR-RAC            |
| Lamb's lettuce/corn salads                   | 0.2                           | EFSA (2017)     | 0.2 STMR-RAC            | 0.2 HR-RAC            |
| Lettuces                                     | 0.2                           | EFSA (2017)     | 0.2 STMR-RAC            | 0.2 HR-RAC            |
| Escaroles/broad-leaved endives               | 0.2                           | EFSA (2017)     | 0.2 STMR-RAC            | 0.2 HR-RAC            |
| Cress and other sprouts and shoots           | 0.2                           | EFSA (2017)     | 0.2 STMR-RAC            | 0.2 HR-RAC            |
| Land cress                                   | 0.2                           | EFSA (2017)     | 0.2 STMR-RAC            | 0.2 HR-RAC            |
| Roman rocket/rucola                          | 0.2                           | EFSA (2017)     | 0.2 STMR-RAC            | 0.2 HR-RAC            |
| Red mustards                                 | 0.2                           | EFSA (2017)     | 0.2 STMR-RAC            | 0.2 HR-RAC            |
| Baby leaf crops (including brassica species) | 0.2                           | EFSA (2017)     | 0.2 STMR-RAC            | 0.2 HR-RAC            |
| Other lettuce and other salad plants         | 0.2                           | EFSA (2017)     | 0.2 STMR-RAC            |                       |
| Spinaches                                    | 0.2                           | EFSA (2017)     | 0.02 STMR-RAC           | 0.12 HR-RAC           |
| Chards/beet leaves                           | 0.04                          | EFSA (2017)     | 0.04 STMR-RAC           | 0.04 HR-RAC           |
| Chervil                                      | 0.2                           | EFSA (2017)     | 0.05 STMR-RAC           | 0.12 HR-RAC           |
| Chives                                       | 0.2                           | EFSA (2017)     | 0.05 STMR-RAC           | 0.12 HR-RAC           |
| Celery leaves                                | 0.2                           | EFSA (2017)     | 0.05 STMR-RAC           | 0.12 HR-RAC           |
| Parsley                                      | 0.2                           | EFSA (2017)     | 0.05 STMR-RAC           | 0.12 HR-RAC           |
| Sage                                         | 0.2                           | EFSA (2017)     | 0.05 STMR-RAC           | 0.12 HR-RAC           |
| Rosemary                                     | 0.2                           | EFSA (2017)     | 0.05 STMR-RAC           | 0.12 HR-RAC           |
| Thyme                                        | 0.2                           | EFSA (2017)     | 0.05 STMR-RAC           | 0.12 HR-RAC           |
| Basil and edible flowers                     | 0.2                           | EFSA (2017)     | 0.05 STMR-RAC           | 0.12 HR-RAC           |
| Commodity                          | Existing/proposed MRL (mg/kg) | Source            | Chronic risk assessment | Acute risk assessment |
|-----------------------------------|-------------------------------|-------------------|-------------------------|-----------------------|
| Laurel/bay leaves                 | 0.2                           | EFSA (2017)       | 0.05 STMR-RAC           | 0.12 HR-RAC           |
| Tarragon                          | 0.2                           | EFSA (2017)       | 0.05 STMR-RAC           | 0.12 HR-RAC           |
| Other herbs                       | 0.2                           | EFSA (2017)       | 0.05 STMR-RAC           |                       |
| Beans (with pods)                 | 0.3                           | EFSA (2017)       | 0.02 STMR-RAC           | 0.17 HR-RAC           |
| Beans (without pods)              | 0.2                           | EFSA (2017)       | 0.04 STMR-RAC           | 0.07 HR-RAC           |
| Peas (with pods)                  | 0.03                          | EFSA (2017)       | 0.01 STMR-RAC           | 0.02 HR-RAC           |
| Peas (without pods)               | 0.2                           | EFSA (2017)       | 0.03 STMR-RAC           | 0.11 HR-RAC           |
| Lentils (fresh)                   | 0.2                           | EFSA (2017)       | 0.03 STMR-RAC           | 0.11 HR-RAC           |
| Florence fennels                  | 0.01*                         | EFSA (2017)       | 0.01 STMR-RAC           | 0.01 HR-RAC           |
| Beans                             | 0.2                           | EFSA (2017)       | 0.05 STMR-RAC           | 0.05 STMR-RAC         |
| Lentils                           | 0.2                           | EFSA (2017)       | 0.05 STMR-RAC           | 0.05 STMR-RAC         |
| Peas                              | 0.2                           | EFSA (2017)       | 0.05 STMR-RAC           | 0.05 STMR-RAC         |
| Linseeds                          | 0.3                           | EFSA (2017)       | 0.1 STMR-RAC            | 0.1 STMR-RAC          |
| Poppy seeds                       | 0.7                           | EFSA (2017)       | 0.2 STMR-RAC            | 0.2 STMR-RAC          |
| Sunflower seeds                   | 0.8                           | EFSA (2017)       | 0.12 STMR-RAC           | 0.12 STMR-RAC         |
| Rapeseeds/canola seeds            | 2                             | EFSA (2017)       | 0.23 STMR-RAC           | 0.23 STMR-RAC         |
| Soya beans                        | 0.2                           | EFSA (2017)       | 0.04 STMR-RAC           | 0.04 STMR-RAC         |
| Mustard seeds                     | 0.7                           | EFSA (2017)       | 0.2 STMR-RAC            | 0.2 STMR-RAC          |
| Cotton seeds                      | 0.1                           | EFSA (2017)       | 0.04 STMR-RAC           | 0.04 STMR-RAC         |
| Maize/corn                        | 0.02                          | EFSA (2018b)      | 0.02 STMR-RAC           | 0.02 STMR-RAC         |
| Rice                              | 0.05*                         | EFSA (2017)       | 0.05 STMR-RAC           | 0.05 STMR-RAC         |
| Chamomile                         | 0.8                           | EFSA (2017)       | 0.03 STMR-RAC           | 0.46 HR-RAC           |
| Hibiscus/roseelle                 | 0.8                           | EFSA (2017)       | 0.03 STMR-RAC           | 0.46 HR-RAC           |
| Rose                              | 0.8                           | EFSA (2017)       | 0.03 STMR-RAC           | 0.46 HR-RAC           |
| Jasmine                           | 0.8                           | EFSA (2017)       | 0.03 STMR-RAC           | 0.46 HR-RAC           |
| Lime/linden                       | 0.8                           | EFSA (2017)       | 0.03 STMR-RAC           | 0.46 HR-RAC           |
| Other herbal infusions (dried flowers) | 0.8                       | EFSA (2017)       | 0.03 STMR-RAC           |                       |
| Strawberry leaves                 | 0.8                           | EFSA (2017)       | 0.03 STMR-RAC           | 0.46 HR-RAC           |
| Rooibos                           | 0.8                           | EFSA (2017)       | 0.03 STMR-RAC           | 0.46 HR-RAC           |
| Mate/maté                         | 0.8                           | EFSA (2017)       | 0.03 STMR-RAC           | 0.46 HR-RAC           |
| Other herbal infusions (dried leaves) | 0.8                       | EFSA (2017)       | 0.03 STMR-RAC           |                       |
| Anise/aniseed                     | 0.05*                         | EFSA (2017)       | 0.05 STMR-RAC           | 0.05 HR-RAC           |
| Black caraway/black cumin         | 0.05*                         | EFSA (2017)       | 0.05 STMR-RAC           | 0.05 HR-RAC           |
| Celery seed                       | 0.05*                         | EFSA (2017)       | 0.05 STMR-RAC           | 0.05 HR-RAC           |
| Coriander seed                    | 0.05*                         | EFSA (2017)       | 0.05 STMR-RAC           | 0.05 HR-RAC           |
| Cumin seed                        | 0.05*                         | EFSA (2017)       | 0.05 STMR-RAC           | 0.05 HR-RAC           |
| Dill seed                         | 0.05*                         | EFSA (2017)       | 0.05 STMR-RAC           | 0.05 HR-RAC           |
| Fennel seed                       | 0.05*                         | EFSA (2017)       | 0.05 STMR-RAC           | 0.05 HR-RAC           |
| Fenugreek                         | 0.05*                         | EFSA (2017)       | 0.05 STMR-RAC           | 0.05 HR-RAC           |
| Nutmeg                            | 0.05*                         | EFSA (2017)       | 0.05 STMR-RAC           | 0.05 HR-RAC           |
| Other spices (seeds)              | 0.05*                         | EFSA (2017)       | 0.05 STMR-RAC           |                       |
| Allspice/pimento                  | 0.05*                         | EFSA (2017)       | 0.05 STMR-RAC           | 0.05 HR-RAC           |
| Sichuan pepper                    | 0.05*                         | EFSA (2017)       | 0.05 STMR-RAC           | 0.05 HR-RAC           |
| Commodity                     | Existing/proposed MRL (mg/kg) | Source         | Chronic risk assessment | Acute risk assessment |
|-------------------------------|-------------------------------|----------------|-------------------------|-----------------------|
|                               |                               |                | Input value (mg/kg)     | Comment (mg/kg)       |
|                               |                               |                | Comment                 | Input value (mg/kg)   | Comment (a) |
| Caraway                       | 0.04                          | Proposed       | 0.02                    | STMR-RAC              | 0.02          | HR-RAC |
| Cardamom                      | 0.05* EFSA (2017)             | 0.05 STMR-RAC  | 0.05                    | HR-RAC                |
| Juniper berry                 | 0.05* EFSA (2017)             | 0.05 STMR-RAC  | 0.05                    | HR-RAC                |
| Peppercorn (black, green and white) | 0.05* EFSA (2017)         | 0.05 STMR-RAC  | 0.05                    | HR-RAC                |
| Vanilla pods                  | 0.05* EFSA (2017)             | 0.05 STMR-RAC  | 0.05                    | HR-RAC                |
| Tamarind                      | 0.05* EFSA (2017)             | 0.05 STMR-RAC  | 0.05                    | HR-RAC                |
| Other spices (fruits)         | 0.05* EFSA (2017)             | 0.05 STMR-RAC  | 0.05                    | HR-RAC                |
| Sugar beet roots              | 0.06 EFSA (2017)              | 0.04 STMR-RAC  | 0.05                    | HR-RAC                |
| Chicory roots                 | 0.08 EFSA (2017)              | 0.02 STMR-RAC  | 0.06                    | HR-RAC                |
| Swine: Muscle/meat            | 0.02* EFSA (2017)             | 0.02 STMR-RAC  | 0.02                    | HR-RAC                |
| Swine: Fat tissue             | 0.02* EFSA (2017)             | 0.02 STMR-RAC  | 0.02                    | HR-RAC                |
| Swine: Liver                  | 0.02* EFSA (2017)             | 0.02 STMR-RAC  | 0.02                    | HR-RAC                |
| Swine: Kidney                 | 0.1 EFSA (2017)               | 0.07 STMR-RAC  | 0.1                     | HR-RAC                |
| Swine: Edible offals (other than liver and kidney) | 0.1 EFSA (2017) | 0.07 STMR-RAC | 0.1                     | HR-RAC                |
| Bovine: Muscle/meat           | 0.02* EFSA (2017)             | 0.02 STMR-RAC  | 0.02                    | HR-RAC                |
| Bovine: Fat tissue            | 0.02* EFSA (2017)             | 0.02 STMR-RAC  | 0.02                    | HR-RAC                |
| Bovine: Liver                 | 0.03 EFSA (2017)              | 0.02 STMR-RAC  | 0.03                    | HR-RAC                |
| Bovine: Kidney                | 0.3 EFSA (2017)               | 0.16 STMR-RAC  | 0.22                    | HR-RAC                |
| Bovine: Edible offals (other than liver and kidney) | 0.3 EFSA (2017) | 0.16 STMR-RAC | 0.22                    | HR-RAC                |
| Sheep: Muscle/meat            | 0.02* EFSA (2017)             | 0.02 STMR-RAC  | 0.02                    | HR-RAC                |
| Sheep: Fat tissue             | 0.02* EFSA (2017)             | 0.02 STMR-RAC  | 0.02                    | HR-RAC                |
| Sheep: Liver                  | 0.03 EFSA (2017)              | 0.03 STMR-RAC  | 0.03                    | HR-RAC                |
| Sheep: Kidney                 | 0.3 EFSA (2017)               | 0.17 STMR-RAC  | 0.24                    | HR-RAC                |
| Sheep: Edible offals (other than liver and kidney) | 0.3 EFSA (2017) | 0.17 STMR-RAC | 0.24                    | HR-RAC                |
| Goat: Muscle/meat             | 0.02* EFSA (2017)             | 0.02 STMR-RAC  | 0.02                    | HR-RAC                |
| Goat: Fat tissue              | 0.02* EFSA (2017)             | 0.02 STMR-RAC  | 0.02                    | HR-RAC                |
| Goat: Liver                   | 0.03 EFSA (2017)              | 0.03 STMR-RAC  | 0.03                    | HR-RAC                |
| Goat: Kidney                  | 0.3 EFSA (2017)               | 0.17 STMR-RAC  | 0.24                    | HR-RAC                |
| Goat: Edible offals (other than liver and kidney) | 0.3 EFSA (2017) | 0.17 STMR-RAC | 0.24                    | HR-RAC                |
| Equine: Muscle/meat           | 0.02* EFSA (2017)             | 0.02 STMR-RAC  | 0.02                    | HR-RAC                |
| Equine: Fat tissue            | 0.02* EFSA (2017)             | 0.02 STMR-RAC  | 0.02                    | HR-RAC                |
| Equine: Liver                 | 0.03 EFSA (2017)              | 0.02 STMR-RAC  | 0.03                    | HR-RAC                |
| Equine: Kidney                | 0.3 EFSA (2017)               | 0.16 STMR-RAC  | 0.22                    | HR-RAC                |
| Equine: Edible offals (other than liver and kidney) | 0.3 EFSA (2017) | 0.16 STMR-RAC | 0.22                    | HR-RAC                |
| Poultry: Muscle/meat          | 0.02* EFSA (2017)             | 0.02 STMR-RAC  | 0.02                    | HR-RAC                |
| Poultry: Fat tissue           | 0.04 EFSA (2017)              | 0.03 STMR-RAC  | 0.03                    | HR-RAC                |
| Poultry: Liver                | 0.04 EFSA (2017)              | 0.03 STMR-RAC  | 0.03                    | HR-RAC                |
| Commodity                        | Existing/proposed MRL (mg/kg) | Source          | Chronic risk assessment | Acute risk assessment |
|---------------------------------|-------------------------------|-----------------|-------------------------|-----------------------|
|                                 |                               |                 | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment<sup>(a)</sup> |
| Poultry: Kidney                 | 0.04                          | EFSA (2017)     | 0.03                    | STMR-RAC              | 0.03               | HR-RAC                  |
| Poultry: Edible offals (other than liver and kidney) | 0.04                          | EFSA (2017)     | 0.03                    | STMR-RAC              | 0.03               | HR-RAC                  |
| Other farmed animals: Muscle/meat | 0.02*                         | EFSA (2017)     | 0.02                    | STMR-RAC              | 0.02               | HR-RAC                  |
| Other farmed animals: Fat tissue | 0.02*                         | EFSA (2017)     | 0.02                    | STMR-RAC              | 0.02               | HR-RAC                  |
| Other farmed animals: Liver     | 0.03                          | EFSA (2017)     | 0.02                    | STMR-RAC              | 0.03               | HR-RAC                  |
| Other farmed animals: Kidney    | 0.3                           | EFSA (2017)     | 0.16                    | STMR-RAC              | 0.22               | HR-RAC                  |
| Other farmed animals: Edible offals (other than liver and kidney) | 0.3                           | EFSA (2017)     | 0.16                    | STMR-RAC              | 0.22               | HR-RAC                  |
| Milk: Cattle                    | 0.015                         | EFSA (2017)     | 0.01                    | STMR-RAC              | 0.01               | STMR-RAC                |
| Milk: Sheep                     | 0.015                         | EFSA (2017)     | 0.01                    | STMR-RAC              | 0.01               | STMR-RAC                |
| Milk: Goat                      | 0.015                         | EFSA (2017)     | 0.01                    | STMR-RAC              | 0.01               | STMR-RAC                |
| Milk: Horse                     | 0.015                         | EFSA (2017)     | 0.01                    | STMR-RAC              | 0.01               | STMR-RAC                |
| Milk: Others                    | 0.015                         | EFSA (2017)     | 0.01                    | STMR-RAC              | 0.01               | STMR-RAC                |
| Eggs: Chicken                   | 0.01*                         | EFSA (2017)     | 0.01                    | STMR-RAC              | 0.01               | HR-RAC                  |
| Eggs: Duck                      | 0.01*                         | EFSA (2017)     | 0.01                    | STMR-RAC              | 0.01               | HR-RAC                  |
| Eggs: Goose                     | 0.01*                         | EFSA (2017)     | 0.01                    | STMR-RAC              | 0.01               | HR-RAC                  |
| Eggs: Quail                     | 0.01*                         | EFSA (2017)     | 0.01                    | STMR-RAC              | 0.01               | HR-RAC                  |
| Eggs: Others                    | 0.01*                         | EFSA (2017)     | 0.01                    | STMR-RAC              | 0.01               | STMR-RAC                |

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PeF: Peeling factor.

(a): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.
**Appendix E – Used compound codes**

| Code/trivial name(a) | Chemical name/SMILES notation/InChiKey(b) | Structural formula(c) |
|----------------------|-------------------------------------------|-----------------------|
| Quizalofop-P-ethyl   | ethyl (2R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate<br>\(\text{O} = \text{C(\text{OCC}[\text{C}@\text{H}](\text{C})\text{Oc1ccc(cc1)}}\text{Oc2cncc3cc(Cl)c3nn2})\) OSUHJPCHFDQAIT-GFCCVEGCSA-N | ![Structural formula of Quizalofop-P-ethyl](image1) |
| Quizalofop-P-tefuryl  | (RS)-tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate<br>\(\text{O} = \text{C(\text{OCC1CCO})([\text{C}@\text{H})(\text{C})\text{Oc4ccc(Oc2cncc3cc(Cl)c3nn2})\text{ccc4})}\) BBKDWPHJZANJGB-IKJXHCRLSA-N | ![Structural formula of Quizalofop-P-tefuryl](image2) |
| Propaquizafop        | 2-isopropylideneminoxyethyl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate<br>\(\text{C/C(=\text{N})\text{OCCOC(=\text{O})[\text{C}@\text{H}](\text{C})\text{Oc1ccc(cc1)}}\text{Oc2cncc3cc(Cl)c3nn2})\) FROBCXTULYFHEJ-OAHLLOKOSA-N | ![Structural formula of Propaquizafop](image3) |
| Quizalofop-P         | (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionic acid<br>\(\text{O} = \text{C(\text{O})([\text{C}@\text{H})(\text{C})\text{Oc1ccc(cc1)}}\text{Oc2cncc3cc(Cl)c3nn2})\) ABOOPXYCKNDNJ-SNVBAGLBSA-N | ![Structural formula of Quizalofop-P](image4) |
| Quizalofop           | (RS)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionic acid<br>\(\text{O} = \text{C(\text{O})(\text{C})\text{Oc1ccc(cc1)}}\text{Oc2cncc3cc(Cl)c3nn2})\) ABOOPXYCKNDNJ-UHFFFAOYSA-N | ![Structural formula of Quizalofop](image5) |
| Phenoxy propionate (EPP) | 2-(4-hydroxyphenoxy)-2-methylbutanoate<br>\(\text{[O-]}\text{C(=\text{O})C(C)Oc1ccc(O)cc1}\) CFECBHTYUULLL-UHFFFAOYSA-M | ![Structural formula of Phenoxy propionate](image6) |
| Phenoxy acid Hydroxyphenoxypionic acid (PPA) | (R)-2-(4-hydroxyphenoxy)propionic acid<br>\(\text{C[\text{C}@\text{H}](\text{Oc1ccc(O)cc1})\text{C(=\text{O})}}\) AQIHDXGKQHFBNW-ZCFIWIBLSA-N | ![Structural formula of Phenoxy acid](image7) |
| Quizalofop-phenol Hydroxy ether (CQOP) | 4-(6-chloroquinoxalin-2-yloxy)phenol<br>\(\text{Oc1ccc(cc1)}\text{Oc2cncc3cc(Cl)c3nn2}\) UVYFSLAJRJHGB-UHFFFAOYSA-N | ![Structural formula of Quizalofop-phenol](image8) |
| Code/trivial name<sup>(a)</sup> | Chemical name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-----------------------------|-------------------------------------------------|---------------------------------|
| Hydroxy-quizalofop-phenol (CQPOH) Dihydroxy ether | 7-chloro-3-(4-hydroxyphenoxy) quinoxalin-2(1H)-one Oc1ccc(cc1)Oc2nc3ccc(Cl)cc3nc2O SUDISTHTCZHOSE-UHFFFAOYSA-N | ![Structural formula](image) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

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

<sup>(b)</sup> ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 Jun 2020).

<sup>(c)</sup> ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 Mar 2021).