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

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance pyriproxyfen. To assess the occurrence of pyriproxyfen residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Regulation (EC) No 1107/2009, the MRLs established by the Codex Alimentarius Commission as well as the import tolerances and European authorisations reported by Member States and the UK (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and most MRL proposals derived by EFSA still require further consideration by risk managers.

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Summary

Pyriproxyfen was renewed on 1 August 2020 by means of Commission Implementing Regulation (EU) 2020/968 in the framework of Regulation (EC) No 1107/2009 as implemented by Commission Implementing Regulations (EU) No 540/2011 and 541/2011.

As the basis for the MRL review, on 16 August 2021, EFSA initiated the collection of data for this active substance. In a first step, Member States and the UK were invited to submit by 20 September 2021 their national Good Agricultural Practices (GAPs) that are authorised nationally and the GAPs in non-EU countries for which import tolerances are authorised, in the format of specific GAP forms, allowing the designated rapporteur Member State, the Netherlands, to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States and the UK were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 23 December 2021. On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with an updated GAP overview file were provided by the RMS to EFSA on 17 March 2022. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States and the EURLs, and taking into account the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009 and the MRLs established by the Codex Alimentarius Commission, EFSA prepared in July 2022 a draft reasoned opinion, which was circulated to Member States and the EURLs for consultation via a written procedure. Comments received by 22 August 2022 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of pyriproxyfen in primary crops was investigated in fruits and pulses/oilseeds group only. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as pyriproxyfen (fruits and pulses/oilseeds) following foliar treatment. This residue definition is also applicable to root and tuber vegetables, provided that application is done to vegetables seedbeds (at BBCH 00 – early post-emergence), in line with the notified GAPs. For leafy crops, except tea, a data gap is set for representative metabolism studies. For tea, available metabolism studies on oranges’ leaves were used to derive the residue definition for risk assessment as the sum of pyriproxyfen and 4’-OH-pyriproxyfen, expressed as pyriproxyfen, while for enforcement the residue definition is confirmed as pyriproxyfen. Enforcement and risk assessment residue definitions as pyriproxyfen are applicable to rotational crops and processed commodities. Analytical methods are available for the enforcement of the proposed residue definition in all matrices and black tea at the LOQ of 0.01 mg/kg. Data gaps for ILV for all matrices and missing extraction efficiency for high oil and dry matrices were set by EFSA. According to the EURLs, the LOQ of 0.01 mg/kg is achievable in the four main matrix groups of plant origin by using multiresidue QuEChERS methods in routine analyses.

No data are available to derive MRL and risk assessment values for most commodities under evaluation, except for citrus and pome fruits, almonds, chestnuts, hazelnuts, pecans, pistachios, walnuts, pine nuts kernels, stone fruits, grapes, strawberries, olives, kaki/Japanese persimmons, tomatoes, sweet peppers, aubergines, cucurbits with edible peel, melons and watermelons, cottonseeds and tea, where the available data are considered sufficient to derive tentative MRL proposals as well as risk assessment values. Considering the general data gaps identified for missing metabolism study on leafy crops and analytical methods for all plant matrices, MRLs for all plant commodities under evaluation are tentative.

Pyriproxyfen is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for cattle (all diets and dairy only) and swine were found to exceed the trigger value of 0.004 mg/kg bw per day. Behaviour of residues was therefore assessed in these groups of livestock.

The metabolism of pyriproxyfen residues in livestock was investigated in lactating goats at dose rate covering the maximum dietary burdens calculated in this review. Although not required, studies on laying hens are also evaluated. According to the results of these studies and considering that at the calculated dietary burden for ruminants, transfer of total residues into milk and tissues was insignificant, a default residue definition as pyriproxyfen was proposed for enforcement and risk
assessment in livestock. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all animal matrices is available. According to the EURs, the same LOQ is achievable by using multiresidue QuEChERS methods in routine analyses.

For ruminants and swine, the metabolism study is sufficient to conclude that, at the calculated dietary burden, residues levels would remain below the enforcement LOQ of 0.01 mg/kg in milk and tissues. Therefore, MRLs and risk assessment values for the relevant commodities can be established at the LOQ level.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 3% of the ADI (Dutch toddler) and the highest acute exposure amounted to 2% of the acute reference dose (ARfD) (peaches).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for pyriproxyfen. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and the highest chronic exposure represented 3% of the ADI (Dutch toddler) and the highest acute exposure amounted to 2% of the ARfD (peaches).
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Background

Regulation (EC) No 396/2005\textsuperscript{1} (hereinafter referred to as ‘the Regulation’) establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide, within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Council Directive 91/414/EEC\textsuperscript{2}, a reasoned opinion on the review of the existing MRLs for that active substance.

Pyriproxyfen was renewed on 1 August 2020 by means of Commission Implementing Regulation (EU) 2020/968\textsuperscript{3} in the framework of Regulation (EC) No 1107/2009\textsuperscript{4} as implemented by Commission Implementing Regulations (EU) No 540/2011\textsuperscript{5} and 541/2011\textsuperscript{6}, EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, pyriproxyfen was evaluated by the Netherlands, designated as rapporteur Member State (RMS) in the framework of Regulation (EC) No 1107/2009. Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific output (EFSA, 2019b).

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

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

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

As the basis for the MRL review, on 16 August 2021, EFSA initiated the collection of data for this active substance. In a first step, Member States and UK\textsuperscript{7} were invited to submit by 20 September 2021 their Good Agricultural Practices (GAPs) that are authorised nationally and the GAPs in non-EU countries for which import tolerances (IT) are authorised, in the format of specific GAP forms. In the framework of this consultation, 19 Member States and the UK provided feedback on their national authorisations of pyriproxyfen. Based on the GAP data submitted, the designated RMS, the Netherlands, was asked to identify the critical GAPs to be further considered in the assessment, in the

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\textsuperscript{1} Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, pp. 1–16.

\textsuperscript{2} Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, pp. 1–32. Repealed by Regulation (EC) No 1107/2009.

\textsuperscript{3} Commission Implementing Regulation (EU) 2020/968 of 3 July 2020 renewing the approval of the active substance pyriproxyfen in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 213, 6.7.2020, pp. 7–11.

\textsuperscript{4} Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, pp. 1–50.

\textsuperscript{5} Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, pp. 1–186.

\textsuperscript{6} Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, pp. 187–188.

\textsuperscript{7} The United Kingdom withdrew from EU on 1 February 2020. In accordance with the Agreement on the Withdrawal of the United Kingdom from the EU, and in particular with the Protocol on IE/NI, the EU requirements on data reporting are also applicable to NI.
format of a specific GAP overview file. Subsequently, in a second step, Member States and the UK were requested to provide residue data supporting the critical GAPs by 23 December 2021.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked the Netherlands to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report together with an updated GAP overview file were provided by the RMS to EFSA on 17 March 2022. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information, and taking into account the MRLs established by the Codex Alimentarius Commission (CAC) (i.e. codex maximum residue limit; CXLs), EFSA prepared in July 2022 a draft reasoned opinion, which was circulated to Member States and the EURLs for commenting via a written procedure. All comments received by 22 August 2022 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Netherlands, 2022), taking into account also the information provided by Member States during the collection of data, and the EURLs report on analytical methods (EURLs, 2021) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the completeness check report (EFSA, 2022a) and the Member States consultation report (EFSA, 2022b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMO) and the PROFile as well as the GAP overview file listing all authorised uses and import tolerances are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMO is presented in Appendix C.

Terms of reference

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

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

The active substance and its use pattern

Pyriproxyfen is the ISO common name for 4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether (IUPAC).

The chemical structure of the active substance and its main metabolites are reported in Appendix F. Pyriproxyfen is approved for use in biocidal products as PT 18⁸ (insecticides, acaricides and products to control other arthropods) according to Commission Directive 2013/5/EU. Furthermore, pyriproxyfen is authorised as topical insecticide in veterinary medicinal products for dogs and no MRLs are set according to Commission Regulation (EU) No 37/2010⁹.

The EU MRLs for pyriproxyfen are established in Annexes IIIA of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for active substance were also established by the Codex Alimentarius Commission (CAC). An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

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⁸ Commission Directive 2013/5/EU of 14 February 2013 amending Directive 98/8/EC of the European Parliament and of the Council to include pyriproxyfen as an active substance in Annex I. OJ L 44, 15.2.2013, pp. 14–17.

⁹ Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. OJ L 15, 20.1.2010, pp. 1–72.
For the purpose of this MRL review, all the uses of pyriproxyfen currently authorised within the EU and in third countries as submitted by the Member States and the UK during the GAP collection have been reported by the RMS in the GAP overview file. The critical GAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAPs for pyriproxyfen are given in Appendix A.

Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Netherlands, 2022);
- the renewal assessment report (RAR) with its revisions prepared under Commission Regulation (EU) No 1141/2010 as amended by Commission Implementing Regulation (EU) No 380/2013 (Netherlands, 2017, 2019);
- the conclusion on the peer review of the pesticide risk assessment of the active substance pyriproxyfen (EFSA, 2019b);
- the Joint Meeting on Pesticide residues (JMPR) Evaluation reports (FAO, 1999, 2001, 2019);
- the previous reasoned opinions on pyriproxyfen (EFSA, 2013, 2016, 2022c).

The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a,b,c,d,e,f,g, 2000; 2010a,b, 2020b; OECD, 2011, 2013, 2018).

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

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of pyriproxyfen was investigated after foliar treatment in fruits and pulses/oilseeds (Netherlands, 2017) and assessed in the framework of the peer review for the renewal (EFSA, 2019b).
In all studies, pyriproxyfen was radiolabelled in the phenoxyphenyl and the pyridyl ring of the molecule.

After three foliar applications of 148 g a.s./ha on apple, the major component identified was the parent pyriproxyfen, representing 54% of the total radioactive residues (TRR) (0.1 mg eq./kg) for the pyridyl label and 52% of TRR (0.1 mg eq./kg) for the phenoxyphenyl label, while metabolite 4'-OH-PYR was present at 9–11% TRR (0.017–0.022 mg eq./kg) (EFSA, 2019b). In tomato, following the same application rate, parent represented 50–68% of the TRR (0.17–0.18 mg eq./kg), while metabolite PYPA was present at 11% of the TRR (0.04 mg eq./kg) with pyridyl label, not being quantified with phenoxyphenyl label. An overdosed metabolism study was also evaluated for tomato which did not lead to further characterisation of the residues (Netherlands, 2017; EFSA, 2019b).

After one foliar application of 225 g a.s./ha on oranges, the major component identified in the fruit was parent pyriproxyfen representing 45–48% TRR (0.04–0.1 mg eq./kg). In leaves, parent and metabolite 4'-OH-PYR represented the main components, amounting for 22–28% TRR (2 mg eq./kg) and 10–11% TRR (0.8–0.9 mg eq./kg), respectively (Netherlands, 2017; EFSA, 2019b).

A study in cucumber following topical treatment was available and used as a supportive information. When pyriproxyfen was applied directly to cucumber leaves, very little pyriproxyfen was observed to penetrate the leaf cuticle and translocate into the fruit. Residues in fruit after foliar application were all < 0.01 mg/kg equivalents. When applied directly onto cucumber fruit, more pyriproxyfen penetrated the fruit surface and data showed a similar metabolic pattern, with parent, 4'-OH-PYR (free and conjugated) and POPA constituting the main part of the residue.

After two foliar applications of 148 g a.s./ha on cottonseed, the major component identified was metabolite PYPAC, representing 13% TRR (0.02 mg eq./kg) with the phenoxyphenyl label, while parent pyriproxyfen was present at levels less than 4% TRR, in the seeds. Residue levels of pyriproxyfen in the gin trash were 34–42% TRR (0.8–1.5 mg eq./kg) (Netherlands, 2017; EFSA, 2019b).

The peer review for the renewal concluded that metabolism in fruits and pulses/oilseeds was sufficiently elucidated and the same conclusion is applicable here.

Besides fruits and oilseeds, uses on root crops and leafy vegetables, including tea, were submitted under this MRL review and they are not covered by the available metabolism studies. For root/tuber vegetables, the available rotational crops metabolism studies on radish (see Section 1.1.2) can be used as surrogate to support the metabolism on this crop group, along with the observed evidence of low translocation of residues (non-systemic active substance) and early treatment defined in the authorised GAPs (vegetables seedbeds: BBCH 00 – early post-emergence) for this crop group. This approach was agreed by the RMS in the completeness check report (EFSA, 2022a).

For indoor uses on leafy crops, EFSA is of the opinion that residues of pyriproxyfen following seedbed treatment cannot be disregarded if application is done at early post-emergence. Since no BBCH is reported in the GAPs for these uses, leaves of these crops might be directly exposed to pyriproxyfen and a no residue situation cannot be anticipated. Therefore, a metabolism study on at least one representative of leafy crops covering the authorised GAPs is required, what represents a data gap.

Tea is a permanent bushy woody crop, belonging to the leafy crop group. In a previous MRL application (EFSA, 2013), the metabolism data in orange leaves, supported by data in cucumber leaves, were used to address the metabolism of pyriproxyfen in tea leaves and the same approach is proposed here. A similar metabolic pathway is observed in fruits and leaves following foliar treatment with quantitative differences regarding concentrations of metabolite 4'-OH-PYR.

1.1.2. Nature of residues in rotational crops

Pyriproxyfen is authorised on crops that may be grown in rotation. The field DT₉₀ reported in the soil degradation studies evaluated in the framework of the peer review for renewal was 11–135 days (EFSA, 2019b), and thus, investigation of metabolic pattern in rotational crops is triggered.

One confined rotational crop study with pyriproxyfen radiolabelled on the phenoxyphenyl and pyridyl ring was available for this assessment. The study was peer reviewed in the framework of the renewal (Netherlands, 2017; EFSA, 2019b). Pyriproxyfen was applied once at a rate of 198 g a.s./ha onto bare soil. Crops were planted at nominal plant back interval (PBI) of 30 days after treatment (DAT). Crops planted at this interval consisted of leafy vegetable (lettuce), root/tuber crops (radish) and cereals (wheat).

The total radioactive residues were < 0.01 mg eq./kg in lettuce and radish root, 0.011 mg eq./kg in radish leaf. Residues in the different parts of wheat were at 0.011 mg eq./kg in forage,
0.081 mg eq./kg in grain, 0.059 mg eq./kg in straw and 0.082 mg eq./kg in chaff. In wheat grain, a major part of the radioactive residues was found to be incorporated into natural plant constituents (up to 88% TRR) while in wheat straw, the extracted radioactive residues were constituted of unidentified compounds, each below 10% TRR (< 0.01 mg/kg). Parent pyriproxyfen and its related metabolites were never detected in wheat grain and straw.

It is noted that the metabolites 4′-OH-PYR and PYPAC have very low to moderate persistence (maximum laboratory DT₉₀ of 148 and 179 days, respectively) and might be taken up by the succeeding crops. As their single residue fraction did not exceed 0.01 mg eq./kg in the rotational crops planted at 30-day PBI, it is not expected that residues > 0.01 mg eq/kg for 4′-OH-PYR and PYPAC would be observed in rotational crops planted at longer PBI. Based on this and the results from the soil dissipation studies (EFSA, 2019b), the peer review concluded that further studies addressing the fate of these two metabolites in rotational crops were not needed and a different residue definition for rotational crops was not set. The same conclusion is applicable here.

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities were made available and assessed in the frame of the peer review for the renewal (Netherlands, 2017; EFSA, 2019b). Studies were conducted with radiolabelled pyriproxyfen on the phenoxyphenyl ring simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6). Pyriproxyfen was stable to hydrolysis as the total recoveries of pyriproxyfen were between 93.2 and 93.9 (% TAR) in all three conditions (Netherlands, 2017; EFSA, 2019b).

1.1.4. Analytical methods for enforcement purposes in plant commodities

During the peer review for renewal, a multiresidue QuEChERS analytical method based on HPLC–MS/MS was validated in oranges (high acid content), apples (high water content), wheat grain (dry commodity), oilseed rape seeds (high oil content) and black tea (difficult matrix). The method is considered suitable for the enforcement of pyriproxyfen in high water, high oil and high acid content commodities, dry commodities and black tea with a limit of quantification (LOQ) of 0.01 mg/kg (Netherlands, 2017; EFSA, 2019b). Confirmation was done simultaneous to primary detection by monitoring two qualifier ions. However, an independent laboratory validation (ILV) is not available and is considered needed (data gap).

The EFSA conclusion on the renewal (EFSA, 2019b) set a data gap for extraction efficiency on high oil content and dry matrices. Since GAPs on crops belonging to these two categories were submitted under this MRL review (e.g. chestnuts, table olives, cottonseeds), the data gap is still relevant. Furthermore, data on extraction efficiency for tea are desirable.

During the completeness check, the EURLs provided validation data on multiresidue QuEChERS (GC- and LC–MS/MS) methods for enforcement of pyriproxyfen with an LOQ of 0.01 mg/kg in the four main matrix groups of plant origin in routine analysis. According to EURLs, the analytical standard of pyriproxyfen is commercially available as a racemate (EURLs, 2021).

1.1.5. Stability of residues in plants

The storage stability of pyriproxyfen and its metabolites PYPAC and DPH-PYR was investigated in the framework of the peer review for the renewal (EFSA, 2019b) and in new studies submitted under this review (Netherlands, 2022). The storage stability of pyriproxyfen was investigated in tomato, apple, apricot, cottonseeds, dry beans, potato, citrus fruits and grapes (EFSA, 2019b; Netherlands, 2022).

Residue levels of pyriproxyfen in samples of high-water content crops are stable for at least 12 months. It is noted that longer storage periods were observed for apples and apricots, i.e. 30 months. In samples of high acid content commodities, residues of pyriproxyfen are stable for up to 30 months. Available studies show that residues were stable for up to 9 months in high protein content crops. Finally, residues of pyriproxyfen were stable for a maximum of 2 months in honey.

The storage stability in high oil, high starch content and dry commodities cannot be demonstrated as data for one additional diverse crop from each of these groups is needed. However, based on the available evidence across the different crop groups, it can be concluded that residues of pyriproxyfen are stable for at least 9 months in all plant commodities, with the exception of honey.
It is noted that studies investigating the storage stability of metabolite 4′-OH-pyriproxyfen in tea (no group) are not available and are considered desirable.

1.1.6. Proposed residue definitions

The metabolism of pyriproxyfen was investigated in the fruits and pulses/oilseeds groups only and found to be similar in both. The metabolism in rotational crops is similar to the metabolism observed in primary crops and the processing of pyriproxyfen is not expected to modify the nature of residues.

As parent was found to be the major compound of the total residues in all investigated crops and all the metabolites identified at level > 10% TRR were concluded to be non-genotoxic (EFSA, 2019b), the peer review set the residue definition for monitoring and risk assessment as pyriproxyfen for fruits and pulses/oilseeds crops following foliar treatment. The same residue definitions are applicable here. However, unlike the peer review, where only fruit uses were evaluated, uses on root/tuber vegetables and leafy crops, including tea, were submitted under this MRL review and they are not covered by available metabolism studies. For root and tuber vegetables, the residue definitions for enforcement and risk assessment derived for fruits and oilseeds are applicable, provided that the active substance is applied according to the GAPs for this crop group. For leafy crops, except tea, a data gap is set. Finally, for tea, the risk assessment residue definition as the sum of pyriproxyfen and 4′-OH-pyriproxyfen, expressed as pyriproxyfen, derived in the framework of a previous MRL application (EFSA, 2013), is also proposed here. The enforcement residue definition for tea is confirmed as parent pyriproxyfen.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all matrices, including black tea, is available (EFSA, 2019b). However, the method is not considered sufficiently validated as ILV was missing and extraction efficiency was not addressed for high oil and dry matrices, what represent data gaps. According to EURLs, the LOQ of 0.01 mg/kg is achievable by using multiresidue methods in routine analyses. The analytical standard of pyriproxyfen is commercially available as a racemate (EURLs, 2021).

In addition, EFSA emphasises that pyriproxyfen is an isomeric mixture only produced as a racemate and a preferential metabolisation of the enantiomers in plants have not been investigated. However, in view of the large margin of safety in the exposure calculation, it can be reasonably assumed that the potential complete degradation of the racemic mixture to a potentially more toxic enantiomer in plant matrices will have a negligible impact on the consumer toxicological burden for the authorised uses evaluated in this review. In case future uses of active substance would lead to a higher consumer exposure, further information regarding the impact of plant metabolism on the isomer ratio might be required (EFSA, 2019d).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of pyriproxyfen residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Netherlands, 2022) as well as the residue trials evaluated in the framework of the peer review for the renewal (Netherlands, 2017; EFSA, 2019b) or in the framework of a previous MRL application (EFSA, 2013). All residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability of residues included in the residue definition for enforcement was demonstrated. Decline of residues during storage of the trial samples is therefore not expected.

The number of residue trials and extrapolations was evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2020b).

For citrus fruits, almonds, chestnuts, hazelnuts, pecans, pistachios, walnuts, pine nuts kernels, pome fruits, stone fruits, grapes, strawberries, olives, kaki/Japanese persimmons, tomatoes, sweet peppers, aubergines, cucurbits with edible and inedible peel, cottonseeds and tea, available residue trials are sufficient to derive tentative MRL and risk assessment values, taking note of the following considerations:

- Mandarins: Although MRL and risk assessment values can be derived from the southern data, four trials compliant with the northern GAP are still required.
• Apples: The number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for this crop. Therefore, one additional trial compliant with the northern outdoor use is still required. Furthermore, it is noted that the proposed tentative MRL might not cover apple varieties harvested at PHI shorter than 90 days.
• Pears: The number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case as all results were below LOQ. Further residue trials are therefore not required.
• Apricots: Although tentative MRL and risk assessment values can be derived from the southern outdoor data, four trials compliant with the northern outdoor use are still required.
• Peaches: Although tentative MRL and risk assessment values can be derived from the import tolerance GAP, four trials compliant with the northern outdoor use are still required.
• Cherries: The number of residue trials supporting the import tolerance GAP is not compliant with the data requirements for this crop. Therefore, one additional trial compliant with the import tolerance is still required. Moreover, eight trials compliant with the northern outdoor GAP are also required.
• Plums: The number of residue trials supporting the import tolerance GAP is not compliant with the data requirements for this crop. Thus, one additional trial compliant with the import tolerance is still required. Furthermore, the southern outdoor use is also supported by a reduced data set; however, considering that the import tolerance GAP is clearly more critical, no additional trials are required to support the southern outdoor use. Finally, eight trials compliant with the northern outdoor GAP are required.
• Table and wine grapes: The number of residue trials supporting the southern outdoor and import tolerance GAPs is not compliant with the data requirements for these crops. However, the reduced number of residue trials is considered acceptable in this case as all results were below LOQ. No trials are available to support the northern use of these crops, but in view of the < LOQ situation observed in southern and import tolerance uses and considering that NEU and SEU GAPs are identical and the import tolerance in place is clearly more critical, no additional trials are required to support the northern use of these crops.
• Strawberries: The number of residue trials supporting the indoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case as all results were below the LOQ of the method used in the trials (0.05 mg/kg); thus, no additional trials are required.
• Olives for oil production and table olives: The number of residue trials supporting the southern outdoor GAP is not compliant with the data requirement for these crops and no trials are available to support the northern GAP for olives for oil production. Considering that the active substance is not systemic, the application is done before flowering (BBCH 59) and the available trials on other orchards (apples and pears) show residue results below LOQ when application is done before flowering, EFSA is of the opinion that MRL and risk assessment values can be set at LOQ (0.01 mg/kg) and two additional trials (1 in case for table olives) are only desirable to support the southern use. Since no trials at all are available to support the northern use of these crops and the data set of trials performed in the northern zone for other orchards is more limited, EFSA considers that three trials compliant with the northern GAP for olives for oil production are still required.
• Tomatoes: The number of residue trials supporting the southern outdoor GAP is not compliant with the data requirement for this crop. However, considering that the indoor GAP is clearly more critical, no additional trials are required to support the southern outdoor GAP. Nonetheless, no trials at all are available to support the import tolerance GAP and eight trials compliant with the import tolerance are thus required.
• Sweet peppers/bell peppers: Although tentative MRL and risk assessment values can be derived from the indoor data, eight trials compliant with the southern outdoor use and eight compliant with the import tolerance in place are still required.
• Gherkins and courgettes: Although tentative MRL and risk assessment values can be derived from the indoor data, at least eight trials on courgettes compliant with the import tolerance GAP are required to support the import tolerance use of both crops.
• Cucurbits with inedible peel: Although tentative MRL and risk assessment values can be derived from the import tolerance limited data set for melons and watermelons, four additional
trials compliant with the import tolerance GAP are still required. Furthermore, eight trials compliant with the indoor GAP on melons, pumpkins and watermelons are required.

- Cottonseeds: The number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ. Although tentative MRL and risk assessment values can be derived from the southern use, eight trials compliant with the import tolerance GAP are still required.

- Tea: Available residue trials were sufficient to derive tentative MRL for this crop. However, residue trials analysing simultaneously for enforcement and risk assessment residue definitions were not available and are desirable. In the absence of such trials, EFSA applied the CF derived from metabolism studies for risk assessment calculations.

For all other crops, residue trials are not available to support the reported GAPs. Therefore, MRL and risk assessment values could not be derived for these crops and the following data gaps were identified:

- Macadamias: Four trials compliant with the import tolerance GAP are required.
- Avocados: Four trials compliant with the import tolerance GAP are required.
- Mangoes: Four trials compliant with the import tolerance GAP are required.
- Granate apples/pomegranates: Four trials compliant with the southern outdoor GAP are required.
- Cherimoyas: Four trials compliant with the southern outdoor GAP are required.
- Potatoes: Eight trials compliant with the import tolerance GAP are required.
- Sweet potatoes and yams: Four trials on one of these crops compliant with the indoor GAP and four on sweet potatoes compliant with the import tolerance GAP are required.
- Other root and tuber vegetables except sugar beets: At least eight trials on carrots compliant with the indoor GAP are required to support the indoor use of the whole group of other root and tuber vegetables, except sugar beets.
- Garlic, onions and shallots: At least eight trials on onions compliant with the indoor GAP are required.
- Spring onions/green onions and Welsh onions, leeks: at least eight trials on leeks compliant with the indoor GAP are required.
- Okra/lady's fingers: Four trials compliant with the indoor GAP are required.
- Flowering brassica: Four trials on cauliflowers and four trials on broccoli compliant with the indoor GAP are required.
- Brussels sprouts: Four trials compliant with the indoor GAP are required.
- Head cabbage: Eight trials compliant the indoor GAP are required.
- Leafy brassica: At least four trials on kales compliant with the indoor GAP are required to support the indoor use of the leafy brassica group.
- Kohlrabies: Four trials compliant with the indoor GAP are required.
- Lettuces and salad plants: Eight trials on lettuces compliant with the indoor GAP are required. To support the indoor GAP of the other crops of the group, at least four trials on lettuce (open leaf varieties) compliant with the indoor GAP are needed.
- Spinach and similar leaves: Four trials on spinaches compliant with the indoor GAP are required.
- Watercresses: Four trials compliant with the indoor GAP are required.
- Witloofs/Belgian endives: Four trials compliant with the indoor GAP are required.
- Herbs and edible flowers: At least four trials on lettuces (open leaf varieties) compliant with the indoor GAP are needed to support the indoor use of the whole group.
- Beans and peas (with pods): Eight trials on beans with pods compliant with the indoor GAP are required to support both crops.
- Beans and peas (without pods): Eight trials on peas without pods compliant with the indoor GAP are required to support both crops.
- Lentils (fresh): Four trials compliant with the indoor GAP are required.
- Asparagus: Four trials compliant with the indoor GAP are required.
- Cardoons, celeries, Florence fennels, rhubarbs: At least four trials on celeries compliant with the indoor GAP are required to support the indoor use of the four crops.
- Globe artichokes: Four trials compliant with the indoor GAP are required.
- Bamboo shoots: Four trials compliant with the indoor GAP are required.
• Palm hearts: Four trials compliant with the indoor GAP are required.
• Beans (dry): Eight trials compliant with the import tolerance GAP are required.
• Soya beans: Eight trials compliant with the import tolerance GAP are required.

Moreover, no residue trials are available to support the authorisation on turnip top (feed item). Although no MRLs are currently set for feed items, four GAP compliant trials with the indoor GAP might still be required.

1.2.2. Magnitude of residues in rotational crops

The most critical GAP currently authorised on crops that can be rotated is 2 × 230 g a.s./ha, BBCH 50–89, PHI 3 (tomato, EU indoor). There were no studies investigating the magnitude of residues in rotational crops available for this review. Nevertheless, since application is done close to harvest (PHI 3) and considering foliar interception (up to 80% according to OECD, 2018), the amount of active substance effectively reaching the soil is considered to be covered by the rate of the above-mentioned confined rotational crop study (Section 1.1.2). It can be then concluded that residue levels of pyriproxyfen in rotational commodities are not expected to exceed 0.01 mg/kg, provided that it is applied in compliance with the GAPs reported in Appendix A.

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed on studies conducted on citrus, table and wine grapes, tomatoes and cottonseeds (EFSA, 2019b; Netherlands, 2022). An overview of all available processing studies is available in Appendix B.1.2.3. Robust processing factors (fully supported by data) could be derived for citrus (peeled, juice, wet and dry pomace, press cake and essential oil), orange marmalade, wine grape (juice, dry and wet pomace, wine), raisins and tomato (canned, puree, juice). Limited processing factors (not fully supported by data) were derived for tomato ketchup and cottonseeds (crude and refined oil, hulls and extracted meat).

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

1.2.4. Proposed MRLs

No data are available to derive MRL and risk assessment values for most commodities under evaluation, except for citrus and pome fruits, almonds, chestnuts, hazelnuts, pecans, pistachios, walnuts, pine nuts kernels, stone fruits, grapes, strawberries, olives, kaki/Japanese persimmons, tomatoes, sweet peppers, aubergines, cucurbits with edible peel, melons and watermelons, cottonseeds and tea, where the available data are considered sufficient to derive tentative MRL proposals as well as risk assessment values. A conversion factor of 1.4 from enforcement to risk assessment as derived from the metabolism studies on orange leaves was applied for tea, in the absence of residue trials analysing simultaneously for enforcement and risk assessment residue definitions.

Considering the general data gaps identified for missing metabolism study on leafy crops and analytical methods for all plant matrices, MRLs for all plant commodities under evaluation are tentative.

2. Residues in livestock

Pyriproxyfen is authorised for use on citrus and pome fruits, and cottonseeds that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. The dietary burdens calculated for cattle (all diets and dairy only) and swine were found to exceed the trigger value of 0.004 mg/kg body weight (bw) per day. Behaviour of residues was therefore assessed in these groups of livestock.

It is highlighted that for several feed items, no residue data were available (head cabbage, kale, potato, carrots, swedes, turnips, palm hearts, soya beans). The animal intake of pyriproxyfen residues via these commodities has therefore not been assessed assuming that uses on these crops will be withdrawn.
2.1. Nature of residues and methods of analysis in livestock

The metabolism of pyriproxyfen residues in livestock was investigated in lactating goats at dose rates covering the maximum dietary burdens calculated in this review (Netherlands, 2022). Although not triggered, studies on laying hens were also available and described here for completeness. The studies were assessed in the framework of the peer review for renewal (EFSA, 2019b). In all studies, pyriproxyfen was radiolabelled in the phenoxyphenyl and pyridyl ring of the molecule. An overview of the available metabolism studies is reported in Appendix B.2.1.1.

In lactating ruminants with the phenoxyphenyl label, the most relevant residue was 4'-OH-PYR (sulfate conjugates) with levels at 49% TRR (0.028 mg eq./kg) in milk, 25% TRR (0.123 mg eq./kg) in liver and 20% TRR (0.052 mg eq./kg) in kidney. A plateau was reached after approximately 4 days in milk, with a maximum of total radioactive residue of 0.058 mg eq./kg. Parent pyriproxyfen was predominant in muscle and fat, representing 44 and 79% of TRR (0.009 and 0.039 mg eq/kg), respectively. Other significant metabolites were 4'-OH-PYR (free) (14% TRR; 0.069 mg eq./kg) and POPA (16% TRR; 0.078 mg eq./kg) in liver and 5'-OH-PYR (sulfate) (15% TRR; 0.039 mg eq./kg) and POP (sulfate) (36% TRR; 0.094 mg eq./kg) in kidney.

With the pyridyl label, the most relevant residue in muscle and fat was parent pyriproxyfen, representing 20% TRR (0.002 mg eq./kg) and 56% TRR (0.039 mg eq./kg), respectively. Metabolite 4'-OH-PYR (sulfate conjugates) was predominant in milk, amounting to 35% TRR (0.042 mg eq/kg), and kidney, representing 22% TRR (0.064 mg eq./kg). Conjugates of metabolite 2,5-OH-PY and PYPA were also present at levels > 10% TRR in milk and kidney, respectively. No metabolite represented more than 10% TRR in liver, with this label.

In poultry and with both labels, parent pyriproxyfen was the most relevant residue in muscle, fat and eggs (34-94% TRR; 0.065-0.827 mg eq./kg). Conjugated 4'-OH-PYR was the predominant component of the residue in kidney and liver (12-39% TRR) and was also present in eggs (17-29% TRR). PYPAC and 2-OH-PY were also present at significant levels (> 10%) in liver, muscle and eggs with pyridyl label. In eggs, a plateau was reached after approximately 6 and 3 days in the yolk and white, respectively.

EFSA determines that the metabolism of pyriproxyfen in livestock is adequately elucidated, parent pyriproxyfen and metabolite 4'-OH-PYR (free and conjugated) are the most relevant components of the residues in livestock commodities. The peer review concluded that at the calculated dietary burden for ruminants, transfer of total residues into milk and tissues was insignificant and a default residue definition as pyriproxyfen was set for enforcement and risk assessment (EFSA, 2019b). The same conclusion is applicable to this MRL review. However, if missing data on the authorised uses are made available or if new uses are granted in the future, the inclusion of metabolite 4'-OH-PYR might be reconsidered.

For cattle and swine, the metabolism study (57-63 N compared to the maximum calculated dietary burden) is sufficient to conclude that residue levels would remain below the enforcement LOQ of 0.01 mg/kg in milk and tissues. Therefore, MRLs and risk assessment values for the relevant commodities can be established at the LOQ level. No MRLs are needed for poultry as they are not expected to be exposed to significant levels of pyriproxyfen residues at the current calculated dietary burden.

A sufficiently validated multiresidue QuEChERS analytical method, using LC–MS/MS, is available for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in tissues, eggs and milk (Netherlands, 2017; EFSA, 2019b). Extraction efficiency was addressed for tissues and eggs, but not for milk. It is, however, noted that no significant residues are expected to occur in milk, and thus, the evaluation of extraction efficiency in this matrix is considered only desirable. According to the EURLs, pyriproxyfen can be monitored in muscle, liver, milk and egg with an LOQ of 0.01 mg/kg, by using multiresidue QuEChERS-based methods, in routine analyses. The same LOQ is deemed achievable for kidney and fat (EURLs, 2021). Screening data show that pyriproxyfen can be monitored in muscle, milk, egg and honey with a screening detection limit (SDL) of 0.01 mg/kg. According to EURLs, the analytical standard of pyriproxyfen is commercially available as a racemate.

The storage stability of pyriproxyfen in livestock commodities has not been investigated, but it is not required for the current assessment since no residues above the LOQ are expected in animal commodities.

3. Consumer risk assessment

In the framework of this review, only the uses of pyriproxyfen reported by the RMS in Appendix A were considered; however, the use of pyriproxyfen was previously also assessed by the JMPR
(FAO, 1999, 2001, 2019). The CXLs, resulting from these assessments by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. To facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs.

3.1. Consumer risk assessment without consideration of the existing CXLs

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019a). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a (tentative) MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). For those commodities where data were insufficient to derive an MRL in Section 1, EFSA considered the existing EU MRL for an indicative calculation. All input values included in the exposure calculations are summarised in Appendix D.

The exposure values calculated were compared with the toxicological reference values for pyriproxyfen, set by European Commission (2020a). The highest chronic exposure was calculated for Dutch toddler, representing 3% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for peaches, representing 2% of the ARfD. Although major uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumer's health.

EFSA emphasises that the above assessment does not consider the possible impact of plant and livestock metabolism on the isomer ratio of pyriproxyfen and further investigation on this matter would in principle be required. EFSA notes that in view of the large margin of safety in the exposure calculations, the potential change of isomer ratios in the final residues is not expected to be of concern for the authorised uses reported in the framework of this review. In case future uses of pyriproxyfen would lead to a higher consumer exposure, further information regarding the impact of plant and/or livestock metabolism on the isomer ratio might be required (EFSA, 2019d).

3.2. Consumer risk assessment with consideration of the existing CXLs

To include the CXLs in the calculations of the consumer exposure, CXLs were compared with the EU MRL proposals in compliance with Appendix E and all data relevant to the consumer exposure assessment have been collected from JMPR evaluations. An overview of the input values used for this exposure calculation is also provided in Appendix D.

Chronic and acute exposure calculations were also performed using revision 3.1 of the EFSA PRIMo and the exposure values calculated were compared with the toxicological reference values derived for pyriproxyfen. The highest chronic exposure was calculated for Dutch toddler, representing 3% of the ADI, and the highest acute exposure was calculated for peaches, representing 2% of the ARfD. Although major uncertainties remain due to the data gaps identified for a certain number of these CXLs (general data gaps on analytical methods), this indicative exposure calculation did not indicate a risk to consumers.

Conclusions

The metabolism of pyriproxyfen in primary crops was investigated in fruits and pulses/oilseeds group only. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as pyriproxyfen (fruits and pulses/oilseeds) following foliar treatment. This residue definition is also applicable to root and tuber vegetables, provided that application is done to vegetables seedbeds (at BBCH 00 – early post-emergence), in line with the notified GAPs. For leafy crops, except tea, a data gap is set for representative metabolism studies. For tea, available metabolism studies on oranges' leaves were used to derive the residue definition for risk assessment as the sum of pyriproxyfen and 4'-OH-pyriproxyfen, expressed as pyriproxyfen, while for enforcement, the residue definition is confirmed as pyriproxyfen. Enforcement and risk assessment residue definitions as pyriproxyfen are applicable to rotational crops and processed commodities.

Analytical methods are available for the enforcement of the proposed residue definition in all matrices and black tea at the LOQ of 0.01 mg/kg. Data gaps for ILV for all matrices and missing extraction efficiency for high oil and dry matrices were set by EFSA. According to the EURLs, the LOQ of
0.01 mg/kg is achievable in the four main matrix groups of plant origin by using multiresidue QuEChERS methods in routine analyses.

No data are available to derive MRL and risk assessment values for most commodities under evaluation, except for citrus and pome fruits, almonds, chestnuts, hazelnuts, pecans, pistachios, walnuts, pine nuts kernels, stone fruits, melons, sweet peppers, aubergines, cucurbits with edible peel, tomatoes, strawberries, olives, kiwifruit, and dates. The available data are considered sufficient to derive tentative MRL proposals as well as risk assessment values. Considering the general data gaps identified for missing metabolism study on leafy crops and analytical methods for all plant matrices, MRLs for all plant commodities under evaluation are tentative.

Pyriproxyfen is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for cattle (all diets and dairy only) and swine were found to exceed the trigger value of 0.004 mg/kg bw per day. Behaviour of residues was therefore assessed in these groups of livestock.

The metabolism of pyriproxyfen residues in livestock was investigated in lactating goats at dose rate covering the maximum dietary burden calculated in this review. Although not required, studies on laying hens are also evaluated. According to the results of these studies and considering that at the calculated dietary burden for ruminants, transfer of total residues into milk and tissues was insignificant, a default residue definition as pyriproxyfen was proposed for enforcement and risk assessment in livestock. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all animal matrices is available. According to the EURLs, the same LOQ is achievable by using multiresidue QuEChERS methods in routine analyses.

For ruminants and swine, the metabolism study is sufficient to conclude that, at the calculated dietary burden, residues levels would remain below the enforcement LOQ of 0.01 mg/kg in milk and tissues. Therefore, MRLs and risk assessment values for the relevant commodities can be established at the LOQ level.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 3% of the ADI (Dutch toddler) and the highest acute exposure amounted to 2% of the ARfD (peaches).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for pyriproxyfen. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and the highest chronic exposure represented 3% of the ADI (Dutch toddler) and the highest acute exposure amounted to 2% of the ARfD (peaches).

**Recommendations**

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). All MRL values listed as ‘Recommended’ in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 2 footnotes for details). In particular, all tentative MRLs and existing EU MRLs need to be confirmed by the following data:

1. a representative study investigating primary crop metabolism in leafy crop group.
2. ILV for the available analytical method for all plant matrices.
3. Evaluation of extraction efficiency for high oil and dry matrices.
4. Full data set of GAP compliant residue trials to support the authorised uses on macadamias; avocados; mangoes; pomegranates; cherimoyas; potatoes; sweet potatoes and yams; other root and tuber vegetables, except sugar beets; bulb vegetables and leeks; okra; pumpkins, flowering, head and leafy brassica, and kohlrabies; lettuces and salad plants; spinach and similar leaves; watercresses; witloofs/Belgian endives; herbs and edible flowers; beans and peas (with pods); beans and peas (without pods); lentils; asparagus; cardoons, celery, Florence fennels and rhubarbs; globe artichokes; bamboo shoots; palm hearts; beans (dry); soya beans.
5. One additional GAP compliant residue trial to support the northern use of apples.
6) One additional GAP compliant residue trial to support the import tolerance in place for cherries and plums (one trial for each crop).
7) Four additional GAP compliant residue trials to support the import tolerance in place for watermelons.

It is highlighted, however, that some of the MRLs derived result from a GAP in one climatic zone only, whereas other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- Additional trials supporting the authorised GAPs on mandarins (NEU), apricots and peaches (NEU), cherries (NEU), plums (NEU), olives for oil production (NEU), tomatoes (IT), sweet peppers/bell peppers (SEU and IT), gherkins and courgettes (IT), melons and watermelons (EU indoor), cucurbits with inedible peel (EU indoor), cottonseeds (IT).

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level. Moreover, it must be noted that the investigation of possible risk to bees related to the use of pyriproxyfen is outside the scope of this reasoned opinion. The evaluation of the risk to honeybees was done in the framework of the renewal of the approval of pyriproxyfen at EU level (EFSA, 2019b). As laid down in the specific provisions of implementing regulation (EU) 2020/968, Member States shall include in the specific conditions a restriction of application to periods outside of the flowering of bee attractive crops. National competent authorities at Member State level should pay attention to the bee health and bee protection when granting authorisations for plant protection products.

EFSA also underlines that, according to the information provided by the EURLs, the analytical standard of pyriproxyfen is commercially available as a racemate.

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

- A minimum of eight trials analysing simultaneously for enforcement and risk assessment residue definitions and supporting the import tolerance GAP on tea.
- Two and one GAP compliant additional trial supporting the southern use of olives for oil production and table olives, respectively.
- Extraction efficiency for tea.
- Storage stability studies for metabolite 4'-OH-pyriproxyfen in tea.
- GAP compliant trials on turnip tops (feed item).
- To define a PHI for the authorised northern use on apples.

### Table 2: Summary table

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment |
|-------------|-----------|-------------------------|---------------------|-------------|---------|
| 110010      | Grapefruit| 0.6                     | 0.5                 | 0.7         | Further consideration needed[^a] data gap #2 |
| 110020      | Oranges   | 0.6                     | 0.5                 | 0.7         | Further consideration needed[^a] data gap #2 |
| 110030      | Lemons    | 0.6                     | 0.5                 | 0.7         | Further consideration needed[^a] data gap #2 |
| 110040      | Limes     | 0.6                     | 0.5                 | 0.7         | Further consideration needed[^a] data gap #2 |
| 110050      | Mandarins | 0.6                     | 0.5                 | 0.7         | Further consideration needed[^a] data gap #2 |
| 120010      | Almonds   | 0.05*                   | –                   | 0.01*       | Further consideration needed[^b] data gaps #2, 3 |
| 120040      | Chestnuts | 0.05*                   | –                   | 0.01*       | Further consideration needed[^b] data gaps #2, 3 |

[^a]: Enforcement residue definition: pyriproxyfen
| Code number | Commodity            | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review |
|-------------|----------------------|------------------------|---------------------|-----------------------|
| 120060      | Hazelnuts            | 0.05*                  | –                   | Further consideration needed[^b] data gap #2, 3 |
| 120070      | Macadamia           | 0.05*                  | –                   | Further consideration needed[^c] data gaps #2, 3, 4 |
| 120080      | Pecans               | 0.05*                  | –                   | Further consideration needed[^b] data gaps #2, 3 |
| 120090      | Pine nuts kernels   | 0.05*                  | –                   | Further consideration needed[^b] data gap #2, 3 |
| 120100      | Pistachios           | 0.05*                  | –                   | Further consideration needed[^b] data gaps #2, 3 |
| 120110      | Walnuts              | 0.05*                  | –                   | Further consideration needed[^b] data gaps #2, 3 |
| 130010      | Apples               | 0.2                    | –                   | Further consideration needed[^b] data gaps #2, 5 |
| 130020      | Pears                | 0.2                    | –                   | Further consideration needed[^b] data gap #2 |
| 130030      | Quinces              | 0.2                    | –                   | Further consideration needed[^b] data gap #2 |
| 130040      | Medlar               | 0.2                    | –                   | Further consideration needed[^b] data gap #2 |
| 130050      | Loquat               | 0.2                    | –                   | Further consideration needed[^b] data gap #2 |
| 140010      | Apricots             | 0.05*                  | –                   | Further consideration needed[^b] data gap #2 |
| 140020      | Cherries             | 1                      | –                   | Further consideration needed[^b] data gaps #2, 6 |
| 140030      | Peaches              | 0.5                    | –                   | Further consideration needed[^b] data gap #2 |
| 140040      | Plums                | 0.3                    | –                   | Further consideration needed[^b] data gaps #2, 6 |
| 151010      | Table grapes         | 0.05*                  | –                   | Further consideration needed[^b] data gap #2 |
| 151020      | Wine grapes          | 0.05*                  | –                   | Further consideration needed[^b] data gap #2 |
| 152000      | Strawberries         | 0.05*                  | –                   | Further consideration needed[^b] data gap #2 |
| 161030      | Table olives         | 0.05*                  | –                   | Further consideration needed[^b] data gaps #2, 3 |
| 161040      | Kumquats             | 0.05*                  | 0.5                 | Further consideration needed[^b] data gaps #2 |
| 161060      | Kaki/Japanese persimmon | 0.05*            | –                   | Further consideration needed[^b] data gap #2 |
| 163010      | Avocados             | 0.05*                  | –                   | Further consideration needed[^c] data gaps #2, 3, 4 |
| 163030      | Mangoes              | 0.05*                  | 0.02*               | Further consideration needed[^d] data gaps #2, 4 |
| 163040      | Papaya               | 0.3                    | 0.3                 | Further consideration needed[^d] data gaps #2 |
| 163050      | Pomegranate          | 0.05*                  | –                   | Further consideration needed[^c] data gaps #2, 4 |
| 163060      | Cherimoya            | 0.05*                  | –                   | Further consideration needed[^d] data gaps #2, 4 |
| Code number | Commodity               | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                  |
|-------------|-------------------------|-------------------------|----------------------|-------------|--------------------------|
| 163080      | Pineapples              | 0.05*                   | 0.01                 | 0.01*       | Further consideration needed | data gaps #2 |
| 211000      | Potatoes                | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 212020      | Sweet potatoes          | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 212030      | Yams                    | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 213010      | Beetroot                | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 213020      | Carrots                 | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 213030      | Celeriac                | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 213040      | Horseradish             | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 213050      | Jerusalem artichokes    | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 213060      | Parsnips                | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 213070      | Parsley root            | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 213080      | Radishes                | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 213090      | Salsify                 | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 213100      | Swedes                  | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 213110      | Turnips                 | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 220010      | Garlic                  | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 220020      | Onions                  | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 220030      | Shallots                | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 220040      | Spring onions           | 0.05*                   | –                    | 0.05        | Further consideration needed | data gaps #2, 4 |
| 231010      | Tomatoes                | 1                       | 0.4                  | 0.7         | Further consideration needed | data gap #2 |
| 231020      | Peppers                 | 1                       | 0.6                  | 0.6         | Further consideration needed | data gap #2 |
| 231030      | Aubergines (egg plants) | 1                       | 0.6                  | 0.6         | Further consideration needed | data gap #2 |
| 231040      | Okra, lady’s fingers    | 1                       | –                    | 1           | Further consideration needed | data gaps #2, 4 |
| 232010      | Cucumbers               | 0.1                     | 0.04                 | 0.04        | Further consideration needed | data gap #2 |
| 232020      | Gherkins                | 0.1                     | 0.04                 | 0.04        | Further consideration needed | data gap #2 |
| 232030      | Courgettes              | 0.05*                   | 0.04                 | 0.04        | Further consideration needed | data gap #2 |
| Code number | Commodity                        | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                                                                 |
|-------------|---------------------------------|-------------------------|----------------------|-------------|--------------------------------------------------------------------------|
| 233010      | Melons                          | 0.07                    | 0.07                 | 0.07        | Further consideration needed data gaps #2                                |
| 233020      | Pumpkins                        | 0.05*                   | –                    | 0.05        | Further consideration needed data gap #2, 4                               |
| 233030      | Watermelons                     | 0.05*                   | –                    | 0.02        | Further consideration needed data gaps #2, 7                               |
| 241010      | Broccoli                        | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 241020      | Cauliflower                     | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 242010      | Brussels sprouts                | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 242020      | Head cabbage                    | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 243010      | Chinese cabbage                 | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 243020      | Kale                            | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 244000      | Kohlrabi                        | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 251010      | Lamb’s lettuce                  | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 251020      | Lettuce                         | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 251030      | Escaroles (broad-leaf endive)   | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 251040      | Cress                           | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 251050      | Land cress                      | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 251060      | Rocket, Rucola                  | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 251070      | Red mustard                     | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 251080      | Leaves and sprouts of Brassica spp. | 0.05*               | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 252010      | Spinach                         | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 252020      | Purslane                        | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 252030      | Beet leaves (chard)             | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 254000      | Water cress                     | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 255000      | Witloof                         | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 256010      | Chervil                         | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 256020      | Chives                          | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| 256030      | Celery leaves                   | 0.05*                   | –                    | 0.05        | Further consideration needed data gaps #1, 2, 4                             |
| Code number | Commodity                  | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                                                                 |
|-------------|----------------------------|-------------------------|----------------------|-------------|-------------------------------------------------------------------------|
| 256040      | Parsley                    | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4              |
| 256050      | Sage                       | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4              |
| 256060      | Rosemary                   | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4              |
| 256070      | Thyme                      | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4              |
| 256080      | Basil                      | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4              |
| 256090      | Bay leaves (laurel)        | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4              |
| 256100      | Tarragon                   | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4              |
| 260010      | Beans (fresh, with pods)   | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #2, 4                 |
| 260020      | Beans (fresh, without pods)| 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #2, 4                 |
| 260030      | Peas (fresh, with pods)    | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #2, 4                 |
| 260040      | Peas (fresh, without pods) | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #2, 4                 |
| 260050      | Lentils (fresh)            | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #2, 4                 |
| 270010      | Asparagus                  | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4              |
| 270020      | Cardoons                   | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4              |
| 270030      | Celery                     | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4              |
| 270040      | Fennel                     | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4              |
| 270050      | Globe artichokes           | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4              |
| 270060      | Leek                       | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4              |
| 270070      | Rhubarb                    | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4              |
| 270080      | Bamboo shoots              | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4              |
| 270090      | Palm hearts                | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4              |
| 300010      | Beans (dry)                | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #2, 3, 4              |
| 401070      | Soya bean                  | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #2, 3, 4              |
| 401090      | Cotton seed                | 0.05*                   | 0.05                 | 0.05        | Further consideration needed\(^{(b)}\) data gaps #2, 3                 |
| 402010      | Olives for oil production  | 0.05*                   | –                    | 0.01*       | Further consideration needed\(^{(b)}\) data gaps #2, 3                 |
| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment |
|-------------|-----------|------------------------|---------------------|-------------|---------|
| 610000      | Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis) | 15 | – | 15 | Further consideration needed[^b^] data gap #2 |
| 1011010     | Swine meat | 0.05[^a^] | – | 0.01[^a^] | Recommended[^g^] |
| 1011020     | Swine fat (free of lean meat) | 0.05[^a^] | – | 0.01[^a^] | Recommended[^g^] |
| 1011030     | Swine liver | 0.05[^a^] | – | 0.01[^a^] | Recommended[^g^] |
| 1011040     | Swine kidney | 0.05[^a^] | – | 0.01[^a^] | Recommended[^g^] |
| 1012010     | Bovine meat | 0.05[^a^] | 0.01[^a^] | 0.01[^a^] | Recommended[^h^] |
| 1012020     | Bovine fat | 0.05[^a^] | 0.01[^a^] | 0.01[^a^] | Recommended[^h^] |
| 1012030     | Bovine liver | 0.05[^a^] | 0.01[^a^] | 0.01[^a^] | Recommended[^h^] |
| 1012040     | Bovine kidney | 0.05[^a^] | 0.01[^a^] | 0.01[^a^] | Recommended[^h^] |
| 1014010     | Goat meat | 0.05[^a^] | 0.01[^a^] | 0.01[^a^] | Recommended[^i^] |
| 1014020     | Goat fat | 0.05[^a^] | 0.01[^a^] | 0.01[^a^] | Recommended[^i^] |
| 1014030     | Goat liver | 0.05[^a^] | 0.01[^a^] | 0.01[^a^] | Recommended[^i^] |
| 1014040     | Goat kidney | 0.05[^a^] | 0.01[^a^] | 0.01[^a^] | Recommended[^i^] |
| 1015010     | Horse meat | 0.05[^a^] | – | 0.01[^a^] | Recommended[^j^] |
| 1015020     | Horse fat | 0.05[^a^] | – | 0.01[^a^] | Recommended[^j^] |
| 1015030     | Horse liver | 0.05[^a^] | – | 0.01[^a^] | Recommended[^j^] |
| 1015040     | Horse kidney | 0.05[^a^] | – | 0.01[^a^] | Recommended[^j^] |
| 1020010     | Cattle milk | 0.05[^a^] | – | 0.01[^a^] | Recommended[^j^] |
| 1020040     | Horse milk | 0.05[^a^] | – | 0.01[^a^] | Recommended[^j^] |
| –           | Other commodities of plant and/or animal origin | See Reg. (EU) 2020/856 | – | – | Further consideration needed[^j^] |

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

[^a^]: Indicates that the MRL is set at the limit of quantification.

(F): The residue definition is fat soluble.

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

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

(c): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination D-I in Appendix E).

(d): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the existing residue definition); there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix E).

(e): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); existing CXL is covered by the existing EU MRL (combination D-III in Appendix E).

(f): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the existing residue definition); GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination F-V in Appendix E).

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

(h): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination H-III in Appendix E).

(i): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E).

(j): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
References

EFSA (European Food Safety Authority), 2013. Reasoned Opinion on the modification of the existing MRL(s) for pyriproxyfen in stone fruits and tea. EFSA Journal 2013;11(12):3489, 26 pp. https://doi.org/10.2903/j.efsa.2013.3489

EFSA (European Food Safety Authority), 2016. Reasoned Opinion on the modification of the existing MRL(s) for pyriproxyfen in bananas. EFSA Journal 2016;14(2):4387, 18 pp. https://doi.org/10.2903/j.efsa.2016.4387

EFSA (European Food Safety Authority), Brancato, A, Brocca, D, Ferreira, L, Greco, L, Jarrah, S, Leuschner, R, Medina, P, Miron, I, Nougadere, A, Pedersen, R, Reich, H, Santos, M, Stanek, A, Tarazona, J, Theobald, A and Villamar-Bouza, L, 2018. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMO revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans J, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A, Verani A, 2019a. Pesticide Residue Intake Model- EFSA PRIMO revision 3.1 (update of EFSA PRIMO revision 3). EFSA supporting publication 2019:EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.EN-1605

EFSA (European Food Safety Authority), Abdourahime H, Anastassiadou M, Arena M, Auteri D, Barmaz S, Brancato A, Bura L, Carrasco Cabrera L, Chaideftou E, Chiusolo A, Court Marques D, Crivellente F, De Lentdecker C, Egsmose M, Fait G, Ferreira L, Gatto V, Greco L, Ippolito A, Istace F, Jarrah S, Kardassi D, Leuschner R, Löstá A, Lythgo C, Messinetti S, Miron I, Molnar T, Padovani L, Parra Morte JM, Pedersen R, Raczyk M, Reich H, Ruocco S, Saari KE, Santos M, Serafimova R, Sharp R, Stanek Alois, Streissl F, Sturma J, Szentes C, Terron A, Tiramani M, Vagenende B, Vainovska P and Villamar-Bouza L, 2019b. Conclusion on the peer review of the pesticide risk assessment of the active substance pyriproxyfen. EFSA Journal 2019;17(7):5732, 26 pp. https://doi.org/10.2903/j.efsa.2019.5732

EFSA (European Food Safety Authority), 2019c. Scientific Report on scientific support for preparing an EU position in the 51st Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2019;17(7):5797, 243 pp. https://doi.org/10.2903/j.efsa.2019.5797

EFSA (European Food Safety Authority), Bura L, Friel A, Magrans JO, Parra-Morte JM and Szentes C, 2019d. Guidance of EFSA on risk assessments for active substances of plant protection products that have stereoisomers as components or impurities and for transformation products of active substances that may have stereoisomers. EFSA Journal 2019;17(8):8004, 33 pp. https://doi.org/10.2903/j.efsa.2019.8004

EFSA (European Food Safety Authority), 2022a. Completeness check report on the review of the existing MRLs of pyriproxyfen prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 19 July 2022. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2022b. Member States consultation report on the review of the existing MRLs of pyriproxyfen prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 6 September 2022. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Castellan I, Ferreira L, Giner G, Greco L, Jarrah S, Leuschner R, Magrans J, Miron I, NaveS, Pedersen R, Reich H, Robinson T, Ruocco S, Santos M, Scarlato AP, Theobald A and Verani A, 2022c. Reasoned Opinion on the modification of the existing maximum residue levels for pyriproxyfen in apricots and peaches. EFSA Journal 2022;20(9):7567, 22 pp. https://doi.org/10.2903/j.efsa.2022.7567

EURLs (European Union Reference Laboratories for Pesticide Residues), 2021. Evaluation report prepared under EURLs (European Union Reference Laboratories to be considered for the review of the existing MRLs for pyriproxyfen. December 2021. Available online: www.efsa.europa.eu

European Commission, 1996. Appendix G. Livestock feeding studies. 7031/VI/95-rev 4, 22 July 1996.

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/VI/95-rev.3, 22 July 1997.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realisation of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 6, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2000. Residue analytical methods. For pre-registration data requirements for Annex II (part A, section 4) and Annex III (part A, section 5) of Council Directive 91/414. SANCO/3029/99-rev. 4. 11 July 2000.
European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2020a. Review report for the active substance pyriproxyfen. Finalised in the Standing Committee on Plants, Animals, Food and Feed on 19 May 2020 in view of the renewal of the approval of pyriproxyfen as active substance in accordance with Regulation (EC) No 1107/2009. SANTE/11426/2019-rev 2, 19 May 2020.

European Commission, 2020b. Appendix D. Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation on residue data on products from plant and animal origin. SANTE/2019/12752, 23 November 2020.

FAO (Food and Agriculture Organization of the United Nations), 1999. Pyriproxyfen. In: Pesticide residues in food – 1999. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 153.

FAO (Food and Agriculture Organization of the United Nations), 2001. Pyriproxyfen. In: Pesticide residues in food – 2000. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 153.

FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.

FAO (Food and Agriculture Organization of the United Nations), 2019. Pyriproxyfen. In: Pesticide residues in food – 2018. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 234.

Netherlands, 2017. Renewal Assessment Report (RAR) on the active substance pyriproxyfen prepared by the rapporteur Member State The Netherlands, in the framework of Commission Implementing Regulation (EU)No 844/2012, December 2017. Available online: www.efsa.europa.eu

Netherlands, 2019. Revised Renewal Assessment Report (RAR) on the active substance pyriproxyfen prepared by the rapporteur Member State The Netherlands, in the framework of Commission Implementing Regulation (EU) No 844/2012, March 2019. Available online: www.efsa.europa.eu

Netherlands, 2022. Evaluation report prepared under Article 12.1of Regulation (EC) No 396/2005. Review of the existing MRLs for pyriproxyfen, 17 March 2022 revised in May 2022. Available online: www.efsa.europa.eu

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org

OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 04 September 2013.

OECD (Organisation for Economic Co-operation and Development), 2018. Guidance Document on Residues in Rotational Crops. In: Series on Pesticides No 97. ENV/JM/MONO(2018)9, 22 May 2018.

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
CCPR Codex Committee on Pesticide Residues
CF conversion factor for enforcement residue definition to risk assessment residue definition
CXL codex maximum residue limit
DC dispersible concentrate
DAT days after treatment
DB dietary burden
DM dry matter
DT$_{90}$ period required for 90% dissipation (define method of estimation)
dw dry weight
EC emulsifiable concentrate
eq residue expressed as a.s. equivalent
EURoLs European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO Food and Agriculture Organisation of the United Nations

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Good Agricultural Practice
Gas chromatography
Gas chromatography with tandem mass spectrometry
Highest residue
International estimated daily intake
International estimated short-term intake
Independent laboratory validation
International Organisation for Standardisation
International Union of Pure and Applied Chemistry
Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
Organic carbon adsorption coefficient
Liquid chromatography
Liquid chromatography with tandem mass spectrometry
Liquid chromatography quadrupole time-of-flight mass spectrometry
Limit of quantification
Mosquito coil
Monitoring
Maximum residue level
Member States
Tandem mass spectrometry detector
National estimated daily intake
National estimated short-term intake
Northern Europe
National theoretical maximum daily intake
Organisation for Economic Co-operation and Development
Plant back interval
Processing factor
Preharvest interval
(EFSA) Pesticide Residues Intake Model
(EFSA) Pesticide Residues Overview File
Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
Risk assessment
Raw agricultural commodity
Residue definition
Rapporteur Member State
Directorate-General for Health and Consumers
Southern Europe
Simplified molecular-input line-entry system
Supervised trials median residue
Total applied radioactivity
Theoretical maximum daily intake
Total radioactive residue
World Health Organisation
Wettable powder
### Appendix A – Summary of authorised uses considered for the review of MRLs

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

| Crop and/or situation | MS or country | F or G or I(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|----------------|-------------------------------------|-------------|-------------|---------------------------------|--------------|---------|
|                        |               |                |                                     | Type(b)     | Conc. a.s.  | Range of growth stages & season(c) | Number min-max | Interval between application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit |             |
| Mandarins             | SI, F         |                | Lepidosaphes sp., Saissetia oleae, Aonidiella aurantii, Parlatoria oleae, Aspidiotus neri, Quadraspidiotus perniciosus | EC, 100 g/L | Foliar treatment – general | 0-59 | 1 | – | 80 g a.s./ha | | | |
| Apples                | AT, IE, F     |                | CARPPO, Cydia pomonella             | EC, 100 g/L | Foliar treatment – general (see also comment field) | 71-74 | 2 | 7 | – | – | 100 g a.s./ha | n.a. | max. 2 treatments per crop/year. 0.5 L PPP/ha/m crown height. PHI is not necessary as it is covered from the growth stage at last application and the growth stage at harvest. |
| Crop and/or situation | MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)
(d) | Remarks |
|-----------------------|---------------|-----------------------------------|-------------|-------------|-------------------------------|-----------|---------|
| Pears                 | AT, SI, IE, NL, CZ, UK, HU | PSYLP, Cacopsylla pyricola, insecticide, pear psyllas | EC 100 g/L | Foliar treatment – general (see also comment field) | 51–75 1 | – – | 100 g a.s./ha | n.a. | 0.5 L PPP/ha/m crown height. PHI is not necessary as it is covered from the growth stage at last application and the growth stage at harvest. Some countries placed restrictions on the label to prevent residues in honey, while other countries have not. |
| Quinces               | FR            | F                                 | EC 100 g/L | Foliar treatment – broadcast spraying | 59 1 | – – | 30 g a.s./ha | n.a. |
| Medlars               | FR            | F                                 | EC 100 g/L | Foliar treatment – broadcast spraying | 59 1 | – – | 30 g a.s./ha | n.a. |
| Loquats               | FR            | F                                 | EC 100 g/L | Foliar treatment – broadcast spraying | 59 1 | – – | 30 g a.s./ha | n.a. |
| Crop and/or situation | MS or country | F, G or T(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|--------------|-----------------------------------|-------------|-------------|-------------------------------|---------------|---------|
| Apricots              | SI F          |              | Quadraspidiotus perniciosus, Pseudaulacaspis pentagona, Parthenolecanium corni | EC 100 g/L  | Foliar treatment – general | 0-59 1                        | – – 50 g a.s./ha |         |
| Cherries              | SI F          |              | Quadraspidiotus perniciosus, Pseudaulacaspis pentagona, Parthenolecanium corni | EC 100 g/L  | Foliar treatment – general | 0-59 1                        | – – 50 g a.s./ha |         |
| Peaches               | SI F          |              | Quadraspidiotus perniciosus, Pseudaulacaspis pentagona, Parthenolecanium corni | EC 100 g/L  | Foliar treatment – general | 0-59 1                        | – – 50 g a.s./ha |         |
| Plums                 | SI F          |              | Quadraspidiotus perniciosus, Pseudaulacaspis pentagona, Parthenolecanium corni | EC 100 g/L  | Foliar treatment – general | 0-59 1                        | – – 50 g a.s./ha |         |
| Table grapes          | SI F          |              | Neopolvinaria innumerabilis, Pulvinaria vitis, Parthenolecanium corni, Planococcus ficus | EC 100 g/L  | Foliar treatment – general | 0-53 1                        | – – 80 g a.s./ha |         |
| Crop and/or situation | MS or country | F, G or I(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|-------------|-----------------------------------|-------------|-------------|-------------------------------|---------------|---------|
| Wine grapes           | SI F          | Neopulvinaria innumerabilis, Pulvinaria vitis, Parthenolecanium corni, Planococcus ficus | EC 100 g/L Foliar treatment – general | 0–53 1 | – – | 80 g a.s./ha | | |
| Olives for oil production | SI F | Saissetia oleae, Lichtensia viburni | EC 100 g/L Foliar treatment – general | 0–59 1 | – – | 40 g a.s./ha | | |

MS: Member State; a.s.: active substance; n.a.: not applicable; 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.
### A.2. Authorised outdoor uses in southern EU

| Crop and/or situation | MS or country | F, G or Y(а) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|--------------|------------------------------------|-------------|------------|-------------------------------|---------------|---------|
|                       |               |              |                                    | Type(b) Conc. a.s. | Method kind | Number min-max | Interval between application (min) | a.s./ha | Water L/ha | Rate and unit |               |          |
| **Grapefruits**       | ES, EL, IT    | F            | Scales                             | EC 100 g/L | Foliar treatment – broadcast spraying | 85–89 | 1 | – | – | 225 g a.s./ha | 28 |          |
| **Oranges**           | ES, EL, IT    | F            | Scales                             | EC 100 g/L | Foliar treatment – broadcast spraying | 85–89 | 1 | – | – | 225 g a.s./ha | 28 |          |
| **Lemons**            | ES, EL, IT    | F            | Scales                             | EC 100 g/L | Foliar treatment – broadcast spraying | 85–89 | 1 | – | – | 225 g a.s./ha | 28 |          |
| **Limes**             | ES, IT        | F            | Scales                             | EC 100 g/L | Foliar treatment – broadcast spraying | 85–89 | 1 | – | – | 225 g a.s./ha | 28 |          |
| **Mandarins**         | PT, ES, EL, IT| F            | Scales                             | EC 100 g/L | Foliar treatment – broadcast spraying | 85–89 | 1 | – | – | 225 g a.s./ha | 28 |          |
| **Almonds**           | PT, ES        | F            | Scales                             | EC 100 g/L | Foliar treatment – broadcast spraying | 0–59 | 1 | – | – | 50 g a.s./ha | n.a. |          |
| **Chestnuts**         | ES            | F            |                                    | EC 100 g/L | Foliar treatment – broadcast spraying | 59 | 1 | – | – | 50 g a.s./ha | n.a. |          |
| **Hazelnuts**         | ES            | F            |                                    | EC 100 g/L | Foliar treatment – broadcast spraying | 59 | 1 | – | – | 50 g a.s./ha | n.a. |          |
| **Pecans**            | ES            | F            |                                    | EC 100 g/L | Foliar treatment – broadcast spraying | 59 | 1 | – | – | 50 g a.s./ha | n.a. |          |
| Crop and/or situation | MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate | PHI (days) | Remarks |
|-----------------------|--------------|-----------------------------------|-------------|-------------|------------------|-----------|---------|
| Pine nut kernels      | ES F         | EC 100 g/L Foliar treatment – broadcast spraying | EC     | 59 1 n.a. | 30 g a.s./ha | n.a. | From the beginning of infestation until BBCH59 (fall-back GAP). |
| Pistachios            | ES F         | EC 100 g/L Foliar treatment – broadcast spraying | EC     | 59 1 n.a. | 50 g a.s./ha | n.a. | Restriction on the label to prevent residues in honey. |
| Walnuts               | ES F         | EC 100 g/L Foliar treatment – broadcast spraying | EC     | 59 1 n.a. | 50 g a.s./ha | n.a. | From the beginning of infestation until BBCH59. |
| Apples                | IT F         | EC 100 g/L Foliar treatment – broadcast spraying | EC     | 59 1 n.a. | 60 g a.s./ha | n.a. | From the beginning of infestation until BBCH59. |
| Pears                 | BG, HR F     | EC 100 g/L Foliar treatment – broadcast spraying | EC     | 59 1 n.a. | 60 g a.s./ha | n.a. | From the beginning of infestation until BBCH59. |
| Quinces               | IT F         | EC 100 g/L Foliar treatment – broadcast spraying | EC     | 59 1 n.a. | 60 g a.s./ha | n.a. | From the beginning of infestation until BBCH59. |
| Medlars               | IT F         | EC 100 g/L Foliar treatment – broadcast spraying | EC     | 59 1 n.a. | 60 g a.s./ha | n.a. | From the beginning of infestation until BBCH59. |
| Loquats               | IT F         | EC 100 g/L Foliar treatment – broadcast spraying | EC     | 59 1 n.a. | 60 g a.s./ha | n.a. | From the beginning of infestation until BBCH59. |
| Crop and/or situation | MS or country | Pests or Group of pests controlled | Preparation | Type | Conc. a.s. | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-----------------------------------|-------------|------|-----------|-------------|-----------------------------|-------------|---------|
|                        |               |                                    |             |      |           | Range of growth stages & season | Number min-max | Interval between application (min) | a.s./hL | Water L/ha | Rate and unit |               |
| Apricots               | IT            | F Scales                          | EC          | 100 g/L | Foliar treatment – broadcast spraying | 59 | 1 | – | – | 60 g a.s./ha | 14 |
| Cherries               | IT            | F Scales                          | EC          | 100 g/L | Foliar treatment – broadcast spraying | 59 | 1 | – | – | 60 g a.s./ha | n.a. |
| Peaches                | ES, IT        | F Scales                          | EC          | 100 g/L | Foliar treatment – broadcast spraying | 75 | 1 | – | – | 60 g a.s./ha | 14 |
| Plums                  | ES, IT        | F Scales                          | EC          | 100 g/L | Foliar treatment – broadcast spraying | 75 | 1 | n.a. | – | 60 g a.s./ha | 14 |
|                        |               |                                    |             |      |           | From the beginning of infestation until BBCH75. Restriction on the label to prevent residues in honey. |               | |
| Table grapes           | IT            | F Planococcus, Parthenolecanium, Other scales | EC          | 100 g/L | Foliar treatment – general (see also comment field) | 8–53 | 1 | – | – | 80 g a.s./ha | n.a. |
| Wine grapes            | IT            | F Planococcus, Parthenolecanium, Other scales | EC          | 100 g/L | Foliar treatment – general (see also comment field) | 8–53 | 1 | – | – | 80 g a.s./ha | n.a. | Tractor mounted sprayer or handheld sprayer. |
| Crop and/or situation | MS or country | F, G or T(a) | Pests or Group of pests controlled | Preparation | Conc. a.s. | Type(b) | Application | Application rate a.s./ha | PHI (days)(d) | Rate and unit | Remarks |
|-----------------------|---------------|---------------|-----------------------------------|-------------|------------|---------|------------|-------------------------|--------------|-------------|---------|
| Table olives          | IT            | F             | Scales                            | EC          | 100 g/L    | Foliar treatment – broadcast spraying | 59          | 1            | n.a.               | 45 g a.s./ha | n.a.        | From the beginning of infestation until BBCH59. |
| Kaki                  | PT, ES        | F             | Scales                            | EC          | 100 g/L    | Foliar treatment – broadcast spraying | 51–59       | 1            | n.a.               | 50 g a.s./ha | n.a.        |                     |
| Granate apples        | ES            | F             | Scales                            | EC          | 100 g/L    | Foliar treatment – broadcast spraying | 59          | 1            | n.a.               | 50 g a.s./ha | n.a.        |                     |
| Cherimoyas            | PT            | F             | Scales                            | EC          | 100 g/L    | Foliar treatment – broadcast spraying | 49          | 1            | n.a.               | 50 g a.s./ha | n.a.        | preflowering       |
| Tomatoes              | IT            | F             | White fly                         | EC          | 100 g/L    | Foliar treatment – broadcast spraying | 88          | 1–2          | 10                 | 112.5 g a.s./ha | 3           | From the beginning of infestation until BBCH88. Restriction on the label to prevent residues in honey. |
| Sweet peppers         | PT, ES        | F             | White fly                         | EC          | 100 g/L    | Foliar treatment – broadcast spraying | 89          | 1            | n.a.               | 112.5 g a.s./ha | 3           | Spain has a restriction on the label to prevent residues in honey, Portugal is considering it. |
| Crop and/or situation | MS or country | F, G or I<sup>(a)</sup> | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI<sup>(d)</sup> | Remarks |
|-----------------------|---------------|--------------------------|-----------------------------------|-------------|-----------------|-------------------------------|----------------|---------|
| Aubergines            | IT            | F                        | White fly                         | EC          | 100 g/L         | Foliar treatment – broadcast spraying | 112.5 g a.s./ha | 3       |
|                       |               |                          |                                   |             |                 |                               |                | From the beginning of infestation until BBCH88. Restriction on the label to prevent residues in honey. |
| Cottonseeds           | ES            | F                        | White fly                         | EC          | 100 g/L         | Foliar treatment – broadcast spraying | 75 g a.s./ha   | n.a.    |
|                       |               |                          |                                   |             |                 |                               |                | About 90% of the bolls have attained their final size. |
| Olives for oil        | IT            | F                        | Scales                            | EC          | 100 g/L         | Foliar treatment – broadcast spraying | 45 g a.s./ha   | n.a.    |
| production            |               |                          |                                   |             |                 |                               |                |                                                   |

MS: Member State; a.s.: active substance; n.a.: not applicable; 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.
### A.3. Authorised indoor uses in EU

| Crop and/or situation | MS or country | F, G or T<sup>(a)</sup> | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|---------------|--------------------------|----------------------------------|-------------|----------------|-------------------------------|-----------------|---------|
| Strawberries          | FR, EL        | I                        | White flies                      | EC 100 g/L  | Foliar treatment – broadcast spraying | 2 10             | 25 g a.s./ha                   | 3      |
| Sweet potatoes        | ES            | I                        |                                  | EC 100 g/L  | Foliar treatment – broadcast spraying | 1                | 30 g a.s./ha                   | n.a.  |
| Yams                  | ES            | I                        |                                  | EC 100 g/L  | Foliar treatment – broadcast spraying | 1                | 30 g a.s./ha                   | n.a.  |
| Beetroots             | ES            | I                        |                                  | EC 100 g/L  | Foliar treatment – broadcast spraying | 1                | 30 g a.s./ha                   | n.a.  |

<sup>(a)</sup> Pesticides not yet authorised for use in EU: T (traces), X (exempt)

<sup>(b)</sup> Type: EC (emulsifiable concentrate), WG (wettable granule), WP (water dispersible powder), WP (water dispersible powder, nanoformulation), WDG (water dispersible granule), SC (suspension concentrate), SL (suspension lotion), WP (water dispersible powder), EC (emulsifiable concentrate)

<sup>(c)</sup> Range of growth stages & season

<sup>(d)</sup> PHI: Precautionary Handling Interval

n.a.: Not applicable

Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation.
| Crop and/or situation | MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------|-----------------------------------|-------------|-------------|-------------------------------|------------|---------|
| Carrots               | ES I         | Pests or Group of pests controlled | EC 100 g/L  | Foliar treatment – broadcast spraying | 30 g a.s./ha | n.a. | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Celeriacs             | ES I         | Pests or Group of pests controlled | EC 100 g/L  | Foliar treatment – broadcast spraying | 30 g a.s./ha | n.a. | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Horseradishes        | ES I         | Pests or Group of pests controlled | EC 100 g/L  | Foliar treatment – broadcast spraying | 30 g a.s./ha | n.a. | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Crop and/or situation | 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 |
|-----------------------|---------------|------------------------|-----------------------------------|-------------|----------------|-------------------------------|-----------------|---------|
| Jerusalem artichokes  | ES            | I                      | EC                                | 100 g/L     | Foliar treatment – broadcast spraying | 1               | 30 g a.s./ha                 | n.a.     | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Parsnips              | ES            | I                      | EC                                | 100 g/L     | Foliar treatment – broadcast spraying | 1               | 30 g a.s./ha                 | n.a.     | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Parsley roots         | ES            | I                      | EC                                | 100 g/L     | Foliar treatment – broadcast spraying | 1               | 30 g a.s./ha                 | n.a.     | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Crop and/or situation | 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 |
|-----------------------|---------------|--------------------------|------------------------------------|-------------|---------------------------|-----------------------------|-------------------|---------|
| Radishes              | ES            | I                        | EC 100 g/L                        | Foliar treatment – broadcast spraying | 1           | –                          | 30 g a.s./ha    | n.a.    | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Salsifies             | ES            | I                        | EC 100 g/L                        | Foliar treatment – broadcast spraying | 1           | –                          | 30 g a.s./ha    | n.a.    | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Swedes                | ES            | I                        | EC 100 g/L                        | Foliar treatment – broadcast spraying | 1           | –                          | 30 g a.s./ha    | n.a.    | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Crop and/or situation | 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 |
|-----------------------|---------------|-------------------------|-----------------------------------|-------------|-----------------|-------------------------------|-----------------|---------|
| Turnips               | ES            | I                       | EC                                | 100 g/L     | Foliar treatment – broadcast spraying | 1 a.s./hL min–max | 30 g a.s./ha | n.a. Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Garlic                | ES            | I                       | EC                                | 100 g/L     | Foliar treatment – broadcast spraying | 1 a.s./hL min–max | 30 g a.s./ha | n.a. Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Onions                | ES            | I                       | EC                                | 100 g/L     | Foliar treatment – broadcast spraying | 1 a.s./hL min–max | 30 g a.s./ha | n.a. Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
### Crop and/or situation
| Crop and/or situation | MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-----------------------------------|-------------|-------------|---------------------------------|------------|---------|
| **Shallots**          | ES            | I                                 | EC 100 g/L  | Foliar treatment – broadcast spraying | 1           | –       | –       | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| **Spring onions**     | ES            | I                                 | EC 100 g/L  | Foliar treatment – broadcast spraying | 1           | –       | –       | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| **Tomatoes**          | BG, AT, PT, BG, PL, PL, IE, CZ, UK, ES, HU, IT, SI, IT | I white fly (TRIAVA), Greenhouse white fly, white fly (Trialeurodes vaporariorum), White flies (Bremisia, Trialeurodes) | EC 100 g/L  | Foliar treatment – broadcast spraying | 50–89 1–2 10 | –       | 230 g a.s./ha | 3 |
| **Sweet peppers**     | PL            | I White fly                       | EC 100 g/L  | Foliar treatment – broadcast spraying | 11–88 2 10 | –       | –       | 112.5 g a.s./ha | 3 |
| Crop and/or situation | MS or country | Pests or Group of pests controlled | Preparation | Application | PHI (days) | Remarks |
|-----------------------|---------------|-----------------------------------|-------------|-------------|-----------|---------|
| Aubergines            | PT, PL, ES    | I White fly                       | EC 100 g/L  | Foliar treatment – broadcast spraying | 11–89 2 10 | – – 112.5 g a.s./ha 3 |
| Okra                  | ES            | I                                 | EC 100 g/L  | Foliar treatment – broadcast spraying | 1         | – – 30 g a.s./ha n.a. |
| Cucumbers             | BG, AT, PT, PL, IE, CZ, UK, ES, HU | I white fly (TRIAVA), white fly, Greenhouse white fly, white fly (Trialeurodes vaporariorum) | EC 100 g/L  | Foliar treatment – broadcast spraying | 50–89 1–2 | – – 112.5 g a.s./ha 3 |
| Gherkins              | BG, ES        | I                                 | EC 100 g/L  | Foliar treatment – broadcast spraying | 50–89 2 10 | – – 112.5 g a.s./ha 3 |
| Courgettes            | IT            | I White fly                       | EC 100 g/L  | Foliar treatment – broadcast spraying | 88 1–2 14 | – – 112.5 g a.s./ha 3 |

Remarks:
- Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation.
| Crop and/or situation | MS or country | F, G or I(\(a\)) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|--------------|------------------|-----------------------------------|-------------|------------|-------------------------------|---------------|---------|
|                       |              |                  |                                   | Type(\(b\)) | Conc. a.s. | Method kind | Range of growth stages & season(\(c\)) | Number min-max | Interval between application (min) | Rate and unit |            |
| Melons                | ES           | I                |                                   | EC          | 100 g/L   | Foliar treatment – broadcast spraying | 1             | –       | –       | 30 g a.s./ha | n.a.       | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Pumpkins              | ES           | I                |                                   | EC          | 100 g/L   | Foliar treatment – broadcast spraying | 1             | –       | –       | 30 g a.s./ha | n.a.       | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Watermelons           | ES           | I                |                                   | EC          | 100 g/L   | Foliar treatment – broadcast spraying | 1             | –       | –       | 30 g a.s./ha | n.a.       | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Crop and/or situation | MS or country | F, G or I\(^{(a)}\) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)\(^{(d)}\) | Remarks |
|-----------------------|--------------|----------------|----------------------------------|-------------|-------------|-------------------------------|----------------|---------|
| Broccoli              | ES           | I              | Foliar treatment – broadcast spraying | EC          | 100 g/L     | 1                             | 30 g a.s./ha   | n.a.    |
|                       |              |                |                                  |             |             |                               |                |         |
| Cauliflowers          | ES           | I              | Foliar treatment – broadcast spraying | EC          | 100 g/L     | 1                             | 30 g a.s./ha   | n.a.    |
|                       |              |                |                                  |             |             |                               |                |         |
| Brussels sprouts      | ES           | I              | Foliar treatment – broadcast spraying | EC          | 100 g/L     | 1                             | 30 g a.s./ha   | n.a.    |
|                       |              |                |                                  |             |             |                               |                |         |

\(^{(a)}\) MS, G, or I indicates the monsoon, greenhouse, indoor conditions.

\(^{(b)}\) Type: EC (emulsifiable concentrate).

\(^{(c)}\) Range of growth stages & season: BBCH 00 – early post-emergence.

\(^{(d)}\) PHI: Pre- harvesting interval.
| Crop and/or situation | MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------|----------------------------------|-------------|-------------|-------------------------------|------------|---------|
| Head cabbages         | ES I         | EC                               | 100 g/L Foliar treatment – broadcast spraying | 1 | a.s./ha | n.a. | n.a. | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Chinese cabbages      | ES I         | EC                               | 100 g/L Foliar treatment – broadcast spraying | 1 | a.s./ha | n.a. | n.a. | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Kales                 | ES I         | EC                               | 100 g/L Foliar treatment – broadcast spraying | 1 | a.s./ha | n.a. | n.a. | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Crop and/or situation | MS or country | F, G or I<sup>(a)</sup> | Pests or Group of pests controlled | Preparation Type<sup>(b)</sup> | Conc. a.s. | Method kind | Range of growth stages & season<sup>(c)</sup> | Number min-max | Interval between application (min) | a.s./ L min-max | Water L/ha min-max | Rate and unit | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|---------------|-------------------------|-----------------------------------|-----------------------------|------------|-------------|--------------------------------|----------------|-------------------------|----------------|----------------|---------------|-------------|----------|
| Kohlrabies            | ES            | I                       | EC                               | 100 g/L                     | Foliar treatment – broadcast spraying | 1          | –               | –                        | 30 g a.s./ha     | n.a.                    | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Lamb’s lettuces       | ES            | I                       | EC                               | 100 g/L                     | Foliar treatment – broadcast spraying | 1          | –               | –                        | 30 g a.s./ha     | n.a.                    | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Lettuces              | ES            | I                       | EC                               | 100 g/L                     | Foliar treatment – broadcast spraying | 1          | –               | –                        | 30 g a.s./ha     | n.a.                    | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Crop and/or situation | 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 |
|-----------------------|--------------|-----------------|-----------------------------------|-------------|-------------|-------------------------------|-----------------|---------|
| Escaroles             | ES           | I               | EC                                | Foliar treatment – broadcast spraying | 1           | a.s./hL min-max | Water L/ha min-max | Rate and unit |         |
| Land cresses          | ES           | I               | EC                                | Foliar treatment – broadcast spraying | 1           | a.s./hL min-max | Water L/ha min-max | Rate and unit |         |
| Cresses               | ES           | I               | EC                                | Foliar treatment – broadcast spraying | 1           | a.s./hL min-max | Water L/ha min-max | Rate and unit |         |

<sup>(a)</sup> MS or country: EU, F, G or I.

<sup>(b)</sup> Type: a.s., hL.

<sup>(c)</sup> Method kind: Foliar treatment – broadcast spraying.

<sup>(d)</sup> Remarks: Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation.
| Crop and/or situation | MS or country | F, G or I | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHl (days) | Remarks |
|-----------------------|---------------|-----------|-----------------------------------|-------------|-------------|-------------------------------|------------|---------|
| Roman rocket          | ES            | I         |                                   | EC          | 100 g/L     | Foliar treatment – broadcast spraying | 1          | – – 30 g a.s./ha | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Red mustards          | ES            | I         |                                   | EC          | 100 g/L     | Foliar treatment – broadcast spraying | 1          | – – 30 g a.s./ha | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Baby leaf crops       | ES            | I         |                                   | EC          | 100 g/L     | Foliar treatment – broadcast spraying | 1          | – – 30 g a.s./ha | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Crop and/or situation | MS or country | F, G or I(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|--------------|-----------------------------------|-------------|------------|-------------------------------|--------------|---------|
| Spinaches             | ES I          | EC 100 g/L   | Foliar treatment – broadcast spraying | EC          | 1          | 30 g a.s./ha                  | n.a.         | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Purslanes             | ES I          | EC 100 g/L   | Foliar treatment – broadcast spraying | EC          | 1          | 30 g a.s./ha                  | n.a.         | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Chards                | ES I          | EC 100 g/L   | Foliar treatment – broadcast spraying | EC          | 1          | 30 g a.s./ha                  | n.a.         | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Crop and/or situation | MS or country | F, G or I(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|------------------------|--------------|-------------|-----------------------------------|-------------|------------|-------------------------------|---------------|---------|
| Watercresses           | ES I         | I           | EC 100 g/L Foliar treatment – broadcast spraying | 1           | –          | 30 g a.s./ha                  | n.a.          | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Witloofs               | ES I         | I           | EC 100 g/L Foliar treatment – broadcast spraying | 1           | –          | 30 g a.s./ha                  | n.a.          | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Chervil                | ES I         | I           | EC 100 g/L Foliar treatment – broadcast spraying | 1           | –          | 30 g a.s./ha                  | n.a.          | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Crop and/or situation | MS or country | F, G or I(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|--------------|--------------|-----------------------------------|-------------|-------------|-------------------------------|---------------|---------|
| **Chives**            | ES           | I            |                                   | EC          | Foliar treatment – broadcast spraying | 100 g/L a.s./ha | 1 | n.a. | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| **Celery leaves**     | ES           | I            |                                   | EC          | Foliar treatment – broadcast spraying | 100 g/L a.s./ha | 1 | n.a. | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| **Parsley**           | ES           | I            |                                   | EC          | Foliar treatment – broadcast spraying | 100 g/L a.s./ha | 1 | n.a. | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Crop and/or situation | MS or country | F, G or I(a) | Pests or Group of pests controlled | Preparation | Type(b) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit | PHI (days)(d) | Remarks |
|----------------------|--------------|-------------|-----------------------------------|-------------|---------|------------|-------------|------------------------------------|----------------|-------------------------------|----------------|----------------|----------------|-------------|---------|
| Sage                 | ES           | I           | EC                                | 100 g/L     | Foliar treatment – broadcast spraying | 1           | –          | –                                  | 30 g a.s./ha   | n.a.                          | n.a.          | n.a.          | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Rosemary             | ES           | I           | EC                                | 100 g/L     | Foliar treatment – broadcast spraying | 1           | –          | –                                  | 30 g a.s./ha   | n.a.                          | n.a.          | n.a.          | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Thyme                | ES           | I           | EC                                | 100 g/L     | Foliar treatment – broadcast spraying | 1           | –          | –                                  | 30 g a.s./ha   | n.a.                          | n.a.          | n.a.          | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Crop and/or situation | MS or country | F, G or I(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|--------------|-----------------------------------|-------------|------------|-------------------------------|----------------|---------|
| Basil                 | ES            | I            | EC 100 g/L Foliar treatment – broadcast spraying | 1           | –          | 30 g a.s./ha                  | n.a.           | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Laurel                | ES            | I            | EC 100 g/L Foliar treatment – broadcast spraying | 1           | –          | 30 g a.s./ha                  | n.a.           | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Tarragon             | ES            | I            | EC 100 g/L Foliar treatment – broadcast spraying | 1           | –          | 30 g a.s./ha                  | n.a.           | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Crop and/or situation | 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 |
|-----------------------|---------------|--------------------------|-----------------------------------|-------------|----------------|-------------------------------|----------------|---------|
| Beans (with pods)     | ES            | I                        | EC                                | 100 g/L EC  | Foliar treatment – broadcast spraying | 1               | 30 g a.s./ha                 | n.a.       | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Beans (without pods)  | ES            | I                        | EC                                | 100 g/L EC  | Foliar treatment – broadcast spraying | 1               | 30 g a.s./ha                 | n.a.       | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Peas (with pods)      | ES            | I                        | EC                                | 100 g/L EC  | Foliar treatment – broadcast spraying | 1               | 30 g a.s./ha                 | n.a.       | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Crop and/or situation | 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 |
|-----------------------|---------------|-------------------------|----------------------------------|-------------|-----------------|-------------------------------|-----------------|---------|
| Peas (without pods)   | ES            | I                       | 100 g/L Foliar treatment – broadcast spraying | EC          | 1               | 30 g a.s./ha                 | n.a.            | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Lentils (fresh)       | ES            | I                       | 100 g/L Foliar treatment – broadcast spraying | EC          | 1               | 30 g a.s./ha                 | n.a.            | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Asparagus             | ES            | I                       | 100 g/L Foliar treatment – broadcast spraying | EC          | 1               | 30 g a.s./ha                 | n.a.            | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Crop and/or situation | MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-----------------------------------|-------------|-------------|-------------------------------|------------|---------|
| Cardoons | ES | I | EC 100 g/L | Foliar treatment – broadcast spraying | 1 | 30 g a.s./ha | n.a. | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Celeries | ES | I | EC 100 g/L | Foliar treatment – broadcast spraying | 1 | 30 g a.s./ha | n.a. | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Florence fennels | ES | I | EC 100 g/L | Foliar treatment – broadcast spraying | 1 | 30 g a.s./ha | n.a. | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Crop and/or situation | MS or country | F, G or I | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------|-----------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
| Globe artichokes      | ES           | I         | EC 100 g/L Foliar treatment – broadcast spraying | EC          | 1          | 30 g a.s./ha n.a.             | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Leeks                 | ES           | I         | EC 100 g/L Foliar treatment – broadcast spraying | EC          | 1          | 30 g a.s./ha n.a.             | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Rhubarbs              | ES           | I         | EC 100 g/L Foliar treatment – broadcast spraying | EC          | 1          | 30 g a.s./ha n.a.             | Vegetable seedbeds only (BBCH 00 – early post-emergence). Apply at the beginning of infestation. |
| Crop and/or situation | MS or country | F, G or I (a) | Pests or Group of pests controlled | Preparation | Method kind | Application | Application rate per treatment |
|-----------------------|--------------|--------------|-----------------------------------|-------------|-------------|-------------|----------------------------------|
|                       |              |              |                                   | Type (b)    | Conc. a.s.  | Range of growth stages & season (c) | PHI (days) (d) | Remarks                              |
| **Bamboo shoots**     | ES           | I            | ES I EC 100 g/L Foliar treatment – broadcast spraying | EC          | 100 g/L    | 71–89 1–2 14 | 30 g a.s./ha n.a. Vegetable seedbeds only. Apply at the beginning of infestation. |
| **Palm hearts**       | ES           | I            | ES I EC 100 g/L Foliar treatment – broadcast spraying | EC          | 100 g/L    | 71–89 1–2 14 | 30 g a.s./ha n.a. Vegetable seedbeds only. Apply at the beginning of infestation. |

MS: Member State; a.s.: active substance; n.a.: not applicable; 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.

### A.4. Import tolerance

| Crop and/or situation | MS or country | F, G or I (a) | Pests or Group of pests controlled | Preparation | Method kind | Application | Application rate per treatment |
|-----------------------|--------------|--------------|-----------------------------------|-------------|-------------|-------------|----------------------------------|
|                       |              |              |                                   | Type (b)    | Conc. a.s.  | Range of growth stages & season (c) | PHI (days) (d) | Remarks                              |
| **Macadamias**        | AU           | F            | Pink wax scale DC 124 g/L Foliar treatment – broadcast spraying | DC          | 124 g/L    | 71–89 1–2 14 | 99.2 g a.s./ha 28 max. Individual rate = 4.96 g/100 L |
| Crop and/or situation | MS or country | Prep. or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-----------------------------------|-------------|-------------|-------------------------------|------------|---------|
| **Cherries**          | US            | *Lecanium* scale, san jose scale, suppression of peach twig borer, oriental fruit moth | EC 330 g/kg | Foliar treatment – general (see also comment field) | n.a. 3 14 | 128.5 g a.s./ha | 14 | Apply at dormant, delayed dormant |
| **Peaches**           | US            | *Lecanium* scale, san jose scale, suppression of peach twig borer, oriental fruit moth | EC 330 g/kg | Foliar treatment – general (see also comment field) | n.a. 3 14 | 128.5 g a.s./ha | 14 | Apply at dormant, delayed dormant |
| Crop and/or situation | MS or country | F, G or I | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) |
|-----------------------|---------------|-----------|-----------------------------------|-------------|-------------|-----------------------------|------------|
|                       |               |           |                                   | Type(b)     | Conc. a.s.  | Method kind                  |                         |            |
|                       |               |           |                                   | Range of growth stages & season(c) | Number min-max | Interval between application (min) | a.s./L min-max | Water L/ha min-max | Rate and unit |            |
|                       |               |           |                                   |                         |            |                                     |                         |                   |              |            |
| Plums                 | US            | F         | Lecanium scale, san jose scale, suppression of peach twig borer, oriental fruit moth, suppression of peach twig borer, oriental fruit moth | EC          | 330 g/kg | Foliar treatment – general (see also comment field) | n.a.        | 3              | 14 | – | – | 128.5 g a.s./ha | 14 | Apply at dormant, delayed dormant |
| Table grapes          | AU            | F         | Light brown apple moth           | DC          | 124 g/L | Foliar treatment – broadcast spraying | 53-61       | 1-2             | 7 | – | – | 99.2 g a.s./ha | n.a. | Latest time of application E-L 25 for export (BBCH 61), E-L 31 (BBCH 75) domestic. |
| Wine grapes           | AU            | F         | Light brown apple moth           | DC          | 124 g/L | Foliar treatment – broadcast spraying | 53-61       | 1-2             | 7 | – | – | 99.2 g a.s./ha | n.a. | Latest time of application E-L 25 for export (BBCH 61), E-L 31 (BBCH 75) domestic. |
| Avocados              | AU            | F         | Fruit spotting bug               | DC          | 124 g/L | Foliar treatment – broadcast spraying | 69-89       | 1-2             | 14 | – | – | 99.2 g a.s./ha | 28 | max. Individual rate = 4.96 g/100 L |
| Mangoes               | AU            | F         | Mediterranean fruit fly          | DC          | 124 g/L | Foliar treatment – broadcast spraying | n.a. to 89  | 1-2             | 14 | – | – | 99.2 g a.s./ha | 28 | max. Individual rate = 4.96 g/100 L |
| Potatoes              | BR            | F         | Insects                          | DC          | 124 g/L | Foliar treatment – broadcast spraying | n.a.        | 1-3             | 7 | – | – | 37.2 g a.s./ha | 7 |            |
| Crop and/or situation | MS or country | F, G or I | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|-----------|-----------------------------------|-------------|------------|-------------------------------|-----------|---------|
| Sweet potatoes        | BR F          | Insects   | DC 124 g/L Foliar treatment – broadcast spraying | n.a. 1-3 7 | – – | 37.2 g a.s./ha 7 | PHI = 30 days |
| Tomatoes              | BR F          | Insects   | DC 124 g/L Foliar treatment – broadcast spraying | n.a. 1-3 7 | – – | 62.4 g a.s./ha 7 | max. Individual rate = 6.2 g/100 L |
| Sweet peppers         | BR F          | Insects   | DC 124 g/L Foliar treatment – broadcast spraying | n.a. 1-3 7 | – – | 62.4 g a.s./ha 7 | max. Individual rate = 6.2 g/100 L |
| Gherkins              | BR F          | Insects   | DC 124 g/L Foliar treatment – broadcast spraying | n.a. 1-3 7 | – – | 62.4 g a.s./ha 7 | max. Individual rate = 6.2 g/100 L |
| Courgettes            | BR F          | Insects   | DC 124 g/L Foliar treatment – broadcast spraying | n.a. 1-3 7 | – – | 62.4 g a.s./ha 7 | max. Individual rate = 6.2 g/100 L |
| Melons                | BR F          | Insects   | DC 124 g/L Foliar treatment – broadcast spraying | n.a. 1-3 7 | – – | 37.2 g a.s./ha 14 |
| Watermelons           | BR F          | Insects   | DC 124 g/L Foliar treatment – broadcast spraying | n.a. 1-3 7 | – – | 37.2 g a.s./ha 14 |
| Beans (dry)           | BR F          | Insects   | DC 124 g/L Foliar treatment – broadcast spraying | n.a. 1-3 7 | – – | 37.2 g a.s./ha 14 |
| Soya beans            | BR F          | Insects   | DC 124 g/L Foliar treatment – broadcast spraying | n.a. 1-3 7 | – – | 37.2 g a.s./ha 28 | PHI = 30 days |
| Cottonseeds           | BR F          | Insects   | DC 124 g/L Foliar treatment – broadcast spraying | n.a. 1-3 7 | – – | 37.2 g a.s./ha 7 |
| Crop and/or situation | MS or country | F, G or I(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|--------------|-----------------------------------|-------------|------------|-------------------------------|--------------|---------|
| Tea                   | JP            | F            | Mulberry scale                    | MC          | 90 g/kg    | Foliar treatment – general (see also comment field) n.a. 1 | –            | 900 g a.s./ha 28 Application from January to March |

MS: Member State; a.s.: active substance; n.a.: not applicable; EC: emulsifiable concentrate; DC: dispersible concentrate; MC: mosquito coil.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I). CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017.
(b): 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 analytical methods for enforcement purposes in plant commodities

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|---------------|----------------|
| Fruit crops                       |             |         |                |               |                |
|                                   | Apple       | Foliar: 3 × 148 g a.s./ha and 3 × 593 g a.s./ha | 45 DAT<sub>3</sub> | Radiolabelled active substance: Phenoxyphenyl-<sup>14</sup>C label and pyridyl-<sup>14</sup>C label pyriproxyfen (Netherlands, 2017; EFSA, 2019b). Study on orange leaves (supported by cucumber leaves) used as surrogate to support metabolism in tea (EFSA, 2013). |
|                                   | Tomato      | Foliar: 3 × 148 g a.s./ha and 3 × 593 g a.s./ha | 7 DAT<sub>3</sub> |               |
|                                   | Orange      | Foliar: 1 × 225 g a.s./ha | 28 |               |
|                                   | Cucumber    | Foliar and fruit topical treatment: 1 × 200 μg/leaf and 1 × 30 μg/fruit | Leaves: 0, 1, 3, 7, 14, 21 Fruit: 0, 3, 7 |               |
| Pulses/oilseeds                   |             |         |                |               |                |
|                                   | Cotton      | Foliar: 2 × 148 g a.s./ha | 28 DAT<sub>2</sub> | Radiolabelled active substance: Phenoxyphenyl-<sup>14</sup>C label and pyridyl-<sup>14</sup>C label pyriproxyfen (Netherlands, 2017; EFSA, 2019b). |
| Root/tuber crops                  |             |         |                |               |                |
|                                   |             |         |                |               | No study available and not required in view of the early treatment, low translocation of residues and results of confined metabolism studies with rotational crops (radish). |
| Leafy crops                       |             |         |                |               | No study available, but required (data gap), except for tea. |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Radish      | Bare soil: 1 × 198 g a.s./ha | 30 | Radiolabelled active substance: Phenoxyphenyl-<sup>14</sup>C label and pyridyl-<sup>14</sup>C label pyriproxyfen (Netherlands, 2017; EFSA, 2019b). |
| Leafy crops                         | Lettuce     | Bare soil: 1 × 198 g a.s./ha | 30 |               |
| Cereal (small grain)                | Wheat       | Bare soil: 1 × 198 g a.s./ha | 30 |               |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|-----------------------------------------|------------|---------|----------------|
|                                        | Pasteurisation (20 min, 90°C, pH 4) | Yes | Parent pyriproxyfen (93.9% TAR) [U- phenoxyphenyl-<sup>14</sup>C] pyriproxyfen (Netherlands, 2017; EFSA, 2019b). |
|                                        | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | Parent pyriproxyfen (93.6% TAR) [U- phenoxyphenyl-<sup>14</sup>C] pyriproxyfen (Netherlands, 2017; EFSA, 2019b). |
|                                        | Sterilisation (20 min, 120°C, pH 6) | Yes | Parent pyriproxyfen (93.2% TAR) [U- phenoxyphenyl-<sup>14</sup>C] pyriproxyfen (Netherlands, 2017; EFSA, 2019b). |
|                                        | Other processing conditions | – | – |
### Review of the existing MRLs for pyriproxyfen

| Question                                                                 | No                                                                 | Metabolism studied in fruits and pulses/oilseeds groups only                                                                 |
|--------------------------------------------------------------------------|--------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| Can a general residue definition be proposed for primary crops?           | No                                                                 | No                                                                                                                      |
| Rotational crop and primary crop metabolism similar?                      | Yes                                                                | Yes                                                                                                                      |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | Yes                                                                | Yes                                                                                                                      |
| Plant residue definition for monitoring (RD-Mo)                          | Fruits, pulses/oilseeds, root and tuber (vegetables seedbeds: BBCH 00 – early post-emergence) and tea, following foliar treatment: pyriproxyfen | Fruits, pulses/oilseeds, root and tuber (vegetables seedbeds: BBCH 00 – early post-emergence) and tea, following foliar treatment: pyriproxyfen |
|                                                                          | Leafy crops, except tea: data gap                                   | Leafy crops, except tea: data gap                                                                                      |
| Plant residue definition for risk assessment (RD-RA)                     | Fruits, pulses/oilseeds, root and tuber (vegetables seedbeds: BBCH 00 – early post-emergence) and tea, following foliar treatment: pyriproxyfen | Fruits, pulses/oilseeds, root and tuber (vegetables seedbeds: BBCH 00 – early post-emergence) and tea, following foliar treatment: pyriproxyfen |
|                                                                          | Leafy crops, except tea: data gap                                   | Leafy crops, except tea: data gap                                                                                      |
|                                                                          | Tea – foliar treatment: sum of pyriproxyfen and 4’-OH-pyriproxyfen, expressed as pyriproxyfen | Tea – foliar treatment: sum of pyriproxyfen and 4’-OH-pyriproxyfen, expressed as pyriproxyfen |

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

- High water content, high oil content, high acid content, dry commodities and no group (Netherlands, 2017):
  - Multiresidue QuEChERS (HPLC-MS/MS).
  - LOQ = 0.01 mg/kg for pyriproxyfen in four main plant matrices and black tea (no group).
  - Confirmation by monitoring 2 qualifier ions.
  - No ILV available (data gap).
  - Extraction efficiency addressed for high water and high acid content crops; data gap for high oil content and dry commodities; desirable for tea.

- Multiresidue QuEChERS (GC- and LC-MS/MS) for enforcement of pyriproxyfen with LOQ = 0.01 mg/kg in four main matrix groups of plant origin in routine analysis (EURLs, 2021).

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

| Plant products (available studies) | Category             | Commodity       | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|----------------------|-----------------|--------|-----------------|-------------------|----------------|
|                                   |                      |                 |        |                 |                   |                |
| **High water content**            |                      | Tomato          | –18    | 12 Months       | pyriproxyfen      | EFSA (2019b)   |
|                                   |                      | Apple           | –18    | 6 Months        | pyriproxyfen      | Netherlands (2022) |
|                                   |                      | Apricot         | –18    | 30 Months       | pyriproxyfen      | Netherlands (2022) |
| **High oil content**              |                      | Cottonseeds     | –20    | 13 Months       | pyriproxyfen      | EFSA (2019b)   |
|                                   |                      |                 | –20    | 12.5 Months     |                   |                |
| **High protein content**          |                      | White beans (dry) | –18    | 9 Months       | pyriproxyfen      | Netherlands (2022) |
| **High starch content**           |                      | Potato          | –18    | 9 Months        | pyriproxyfen      | Netherlands (2022) |
| **High acid content**             |                      | Orange          | –20    | 4 Months        | pyriproxyfen      | EFSA (2019b)   |
|                                   |                      |                 | –18    | 30 Months       | pyriproxyfen      | Netherlands (2022) |
|                                   |                      | Mandarins       | –18    | 30 Months       | pyriproxyfen      | Netherlands (2022) |
|                                   |                      | Grapes          | –18    | 30 Months       | pyriproxyfen      | Netherlands (2022) |
|                                   |                      | Citrus           | –18    | 9 Months        | pyriproxyfen      | Netherlands (2022) |
| **Processed products**            |                      | Cotton crude oil | –20    | 1 Months       | pyriproxyfen      | EFSA (2019b)   |
|                                   |                      |                 | –20    | 1 Months        |                   |                |
|                                   |                      | Cotton gin trash | –20    | 7.5 Months     | pyriproxyfen      | EFSA (2019b)   |
|                                   |                      |                 | –20    | 6.5 Months      | DPH-PYR           |                |
|                                   |                      | Tomato juice    | –18    | 6 Months        | pyriproxyfen      | Netherlands (2022) |
|                                   |                      | Tomato canned   | –18    | 6 Months        | pyriproxyfen      | Netherlands (2022) |
|                                   |                      | Tomato ketchup  | –18    | 6 Months        | pyriproxyfen      | Netherlands (2022) |
|                                   |                      | Tomato wet pomace | –18    | 6 Months       | pyriproxyfen      | Netherlands (2022) |
| **Others**                        |                      | honey           | –18    | < 2 Months      | pyriproxyfen      | Netherlands (2022) |
### B.1.2. Magnitude of residues in plants

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

| Commodity               | Region\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                                                                                                                                 | Calculated MRL (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) | CF\(^{(d)}\) |
|-------------------------|------------------|---------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|------------------------|-------------|
| **Mandarins**           | NEU              | –                                                             | No GAP compliant trials available.                                                                                                                                                                         |                        |                      |                        |             |
| Oranges                 | SEU              | 2 × 0.10; 2 × 0.13; 0.14; 2 × 0.17; 0.18; 0.20; 0.25; 3 × 0.28; 0.30; 0.33; 0.47 | Combined residue data set on oranges \((n = 8)\) and mandarins \((n = 8)\) compliant with GAP, evaluated in the peer review (Netherlands, 2017; EFSA, 2019b). Extrapolation to whole citrus fruits group applicable. MRL\(_{OECD} = 0.66\) | 0.70\(^{(e)}\) (tentative) | 0.47 | 0.19 | 1 |
| Grapefruits             |                  |                                                               |                                                                                                                                                                                                             |                        |                      |                        |             |
| Lemons                  |                  |                                                               |                                                                                                                                                                                                             |                        |                      |                        |             |
| Limes                   |                  |                                                               |                                                                                                                                                                                                             |                        |                      |                        |             |
| Mandarins               | SEU              | 13 × < 0.01                                                   | Combined residue data set on apple \((n = 9)\) and apricot \((n = 4)\) compliant with GAP on tree nuts, except four trials on apples performed at BBCH 72–75 (deemed acceptable as residues < LOQ) (Netherlands, 2022). Extrapolation to tree nuts applicable. MRL\(_{OECD} = 0.01\) | 0.01\(^{(e)}\) (tentative) | 0.01 | 0.01 | 1 |
| Almonds                 | SEU              | 13 × < 0.01                                                   | Combined residue data set of overdosed (1.6N) trials on apples \((n = 9)\) and apricots \((n = 4)\). Four trials on apples performed at BBCH 72–75. Extrapolation to pine nut kernels acceptable as all residues < LOQ (Netherlands, 2022). MRL\(_{OECD} = 0.01\) | 0.01\(^{(e)}\) (tentative) | 0.01 | 0.01 | 1 |
| Chestnuts               |                  |                                                               |                                                                                                                                                                                                             |                        |                      |                        |             |
| Hazelnuts/cobnuts       |                  |                                                               |                                                                                                                                                                                                             |                        |                      |                        |             |
| Pecans                  |                  |                                                               |                                                                                                                                                                                                             |                        |                      |                        |             |
| Pistachios              |                  |                                                               |                                                                                                                                                                                                             |                        |                      |                        |             |
| Walnuts                 |                  |                                                               |                                                                                                                                                                                                             |                        |                      |                        |             |
| Pine nut kernels        | SEU              | 13 × < 0.01                                                   | Combined residue data set of overdosed (1.6N) trials on apples \((n = 9)\) and apricots \((n = 4)\). Four trials on apples performed at BBCH 72–75. Extrapolation to pine nut kernels acceptable as all residues < LOQ (Netherlands, 2022). MRL\(_{OECD} = 0.01\) | 0.01\(^{(e)}\) (tentative) | 0.01 | 0.01 | 1 |
| Macadamias              | Import (AU)      | –                                                             | No GAP compliant trials available.                                                                                                                                                                         |                        |                      |                        |             |
| Apples                  | NEU              | 4 × < 0.01; 0.01; 0.02; 0.03                                    | Reduced data set of trials on apples performed at treatment interval longer than 7 days. Residue results were selected at the longest PHI (> 93 days) (Netherlands, 2022). MRL\(_{OECD} = 0.05\) | 0.05\(^{(e),(f)}\) (tentative) | 0.03 | 0.01 | 1 |
|                        | SEU              | 9 × < 0.01                                                   | Trials on apples performed at application rate within 25% deviation \((n = 5)\), evaluated in the peer review (Netherlands, 2017; EFSA, 2019b), and trials performed at more critical BBCH \((n = 4)\), deemed acceptable as all residues < LOQ (Netherlands, 2022). Extrapolation to pears, quinces, medlars and loquats applicable. MRL\(_{OECD} = 0.01\) | 0.01\(^{(e)}\) (tentative) | 0.01 | 0.01 | 1 |
| Commodity                  | Region<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                                                                                                                                 | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|---------------------------|-----------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------------|---------------------------|--------------|
| Pears                     | NEU                   | 4 × < 0.01                                                    | Reduced data set of trials on pears compliant with GAP, deemed acceptable as all residues < LOQ (Netherlands, 2022). MRL<sub>OECD</sub> = 0.01                                                              | 0.01<sup>(e)</sup>     | 0.01                     | 0.01                       | 1             |
|                           | SEU                   | 9 × < 0.01                                                    | Trials on apples performed at application rate within 25% deviation (n = 5), evaluated in the peer review (Netherlands, 2017; EFSA, 2019b), and trials performed at more critical BBCH (n = 4), deemed acceptable as all residues < LOQ (Netherlands, 2022). Extrapolation to pears, quinces, medlars and loquats applicable. MRL<sub>OECD</sub> = 0.01 | 0.01<sup>(e)</sup>     | 0.01                     | 0.01                       | 1             |
| Quinces                   | NEU                   | 4 × < 0.01                                                    | Combined data set of 2 overdosed trials on apple (1.6 N) and 2 overdosed trials on pears (3.3 N), all performed at BBCH < 60, deemed acceptable as all residues < LOQ (Netherlands, 2022). MRL<sub>OECD</sub> = 0.01 | 0.01<sup>(e)</sup>     | 0.01                     | 0.01                       | 1             |
| Medlars                   |                       |                                                               |                                                                                                                              |                        |                          |                            |               |
| Loquats/Japanese medlars  |                       |                                                               |                                                                                                                              |                        |                          |                            |               |
|                           | SEU                   | 9 × < 0.01                                                    | Trials on apples performed at application rate within 25% deviation (n = 5), evaluated in the peer review (Netherlands, 2017; EFSA, 2019b), and trials performed at more critical BBCH (n = 4), deemed acceptable as all residues < LOQ (Netherlands, 2022). Extrapolation to pears, quinces, medlars and loquats applicable. MRL<sub>OECD</sub> = 0.01 | 0.01<sup>(e)</sup>     | 0.01                     | 0.01                       | 1             |
| Apricots                  | NEU                   | –                                                             | No GAP compliant trials available.                                                                                                                                                                         | –                      | –                        | –                          | –             |
|                           | SEU                   | 4 × 0.02; 0.03; 2 × 0.04; 0.11; 0.17; 0.24                  | Combined residue data set of trials on apricots (n = 4) and peaches (n = 6) compliant with GAP (Netherlands, 2022; EFSA, 2022c). MRL<sub>OECD</sub> = 0.38 | 0.40<sup>(e)</sup>     | 0.24                     | 0.04                       | 1             |
| Peaches                   | NEU                   | –                                                             | No GAP compliant trials available.                                                                                                                                                                         | –                      | –                        | –                          | –             |
|                           | SEU                   | 4 × 0.02; 0.03; 2 × 0.04; 0.11; 0.17; 0.24                  | Combined residue data set of trials on apricots (n = 4) and peaches (n = 6) compliant with GAP (Netherlands, 2022; EFSA, 2022c). MRL<sub>OECD</sub> = 0.38 | 0.40<sup>(e)</sup>     | 0.24                     | 0.04                       | 1             |
| Import (US)               |                       | 0.035; 2 × 0.12; 0.14; 0.16; 0.17; 0.18; 0.19; 0.20         | Trials on peaches compliant with GAP, evaluated in the framework of previous MRL application (EFSA, 2013). MRL<sub>OECD</sub> = 0.44                                                                 | 0.50<sup>(e)</sup>     | 0.20                     | 0.16                       | 1             |
| Commodity             | Region<sup>a</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR<sup>b</sup> (mg/kg) | STMR<sup>c</sup> (mg/kg) | CF<sup>d</sup> |
|----------------------|---------------------|---------------------------------------------------------------|-------------------------------------------------------------------------------|------------------------|------------------------|--------------------------|----------|
| Cherries (sweet)     | NEU                 | –                                                             | No GAP compliant trials available.                                             |                        |                        |                          |          |
| SEU                  | 8 × < 0.01          | Combined data set of trials on apples (n = 4) and apricots (n = 4) performed at application rate within 25% deviation of GAP on cherries. MRL<sub>OECD</sub> = 0.01 | 0.01<sup>e</sup> (tentative)                                                  | 0.01                   | 0.01                   | 1                        |          |
| Import (US)          | 2 × 0.16; 0.24; 0.26; 0.35; 0.59; 0.62 | Reduced data set of trials on cherries compliant with GAP, evaluated in a previous MRL application (EFSA, 2013). MRL<sub>OECD</sub> = 1.11 | 1.50<sup>e,f</sup> (tentative)                                               | 0.62                   | 0.26                   | 1                        |          |
| Plums                | NEU                 | –                                                             | No GAP compliant trials available.                                             |                        |                        |                          |          |
| SEU                  | 2 × < 0.01; 0.01; 0.013; 0.02; 0.03 | Reduced data set of trials on plums compliant with GAP (Netherlands, 2022). No additional trials are required since the import tolerance GAP is clearly more critical. MRL<sub>OECD</sub> = 0.05 | 0.05<sup>e</sup> (tentative)                                                  | 0.03                   | 0.01                   | 1                        |          |
| Import (US)          | 0.025; 0.03; 0.04; 3 × 0.045; 0.20 | Reduced data set of trials on plums compliant with GAP, evaluated in previous MRL application (EFSA, 2013). MRL<sub>OECD</sub> = 0.31 | 0.30<sup>e,f</sup> (tentative)                                               | 0.20                   | 0.05                   | 1                        |          |
| Table grapes Wine grapes | NEU                 | –                                                             | No GAP compliant trials available and not required since < LOQ situation is observed for SEU and import tolerance, NEU and SEU GAPs are identical and import GAP is clearly more critical. |                        |                        |                          |          |
| SEU                  | 5 × < 0.01          | Reduced data set of trials on grapes (table and wine) performed at application rates within 25% deviation, deemed acceptable as all residues < LOQ (Netherlands, 2022). MRL<sub>OECD</sub> = 0.01 | 0.01<sup>e</sup> (tentative)                                                  | 0.01                   | 0.01                   | 1                        |          |
| Import (AU)          | 5 × < 0.01          | Reduced data set of trials on grapes (table and wine) performed at application rates within 25% deviation, deemed acceptable as all residues < LOQ (Netherlands, 2022). MRL<sub>OECD</sub> = 0.01 | 0.01<sup>e</sup> (tentative)                                                  | 0.01                   | 0.01                   | 1                        |          |
| Strawberries         | EU                  | 7 × < 0.05          | Reduced and overdosed (2 N, 4 trials) data set of trials on strawberries deemed acceptable as all residues < 0.05 mg/kg (Netherlands, 2022). MRL<sub>OECD</sub> = 0.05 | 0.05<sup>e</sup> (tentative)                                                  | 0.05                   | 0.05                   | 1                        |          |
| 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) | CF(d) |
|------------------------------------------------|-----------|---------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|--------------|----------------|-------|
| Olives for oil production, table olives       | NEU       | –                                                             | No GAP compliant trials available. GAP authorised for olives for oil production only. |                        |              |                |       |
|                                               | SEU       | $2 \times < 0.01$                                              | Reduced data set of trials on table olives (Netherlands, 2022) deemed acceptable as a.s. is not systemic, application is done before flowering (BBCH 59) and trials on other orchards show residue results $< \text{LOQ}$. | $0.01^\text{(e)}$ (tentative) | 0.01         | 0.01           | 1     |
| Kaki/Japanese persimmons                      | SEU       | $9 \times < 0.01$                                              | Trials on apples compliant with GAP, except 4 trials performed at BBCH 72–75, deemed acceptable as all residues $< \text{LOQ}$ (Netherlands, 2022). Extrapolation to kaki applicable. MRL$_{\text{OECD}} = 0.01$ | $0.01^\text{(e)}$ (tentative) | 0.01         | 0.01           | 1     |
| Avocados                                      | Import (AU)| –                                                             | No GAP compliant trials available.                                               |                        |              |                |       |
| Mangoes                                        | Import (AU)| –                                                             | No GAP compliant trials available.                                               |                        |              |                |       |
| Granate apples/pomegranates                   | SEU       | –                                                             | No GAP compliant trials available.                                               |                        |              |                |       |
| Cherimoyas                                    | SEU       | –                                                             | No GAP compliant trials available.                                               |                        |              |                |       |
| Potatoes                                      | Import (BR)| –                                                             | No GAP compliant trials available.                                               |                        |              |                |       |
| Sweet potatoes Yams                           | EU        | –                                                             | No GAP compliant trials available.                                               |                        |              |                |       |
| Sweet potatoes Yams                           | Import (BR)| –                                                             | No GAP compliant trials available.                                               |                        |              |                |       |
| Beetroots Carrots Celeriacs/turnip rooted celeries Horseradishes Jerusalem artichokes Parsnips Parsley roots/ Hamburg roots parsley Radishes Salsifies Swedes/rutabagas Turnips | EU        | –                                                             | No GAP compliant trials available.                                               |                        |              |                |       |
| Garlic Onions Shallots                        | EU        | –                                                             | No GAP compliant trials available.                                               |                        |              |                |       |
| Spring onions/green onions and Welsh onions Leeks | EU        | –                                                             | No GAP compliant trials available.                                               |                        |              |                |       |
| 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) | CF(d) |
|------------------------|-----------|-----------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|---------------|----------------|-------|
| Tomatoes               | SEU       | 0.08; 0.10; 0.11; 0.12; 0.14; 0.16; 0.20                         | Reduced data set of trials on tomatoes compliant with GAP, evaluated in the peer review (EFSA, 2019b). No additional trials are required since the import tolerance GAP is clearly more critical. MRL\textsubscript{OECD} = 0.39 | 0.40(e) (tentative)   | 0.20          | 0.12           | 1     |
|                        | EU        | **Unscaled:** 0.05; 0.06; 0.08; 0.09; 2 × 0.11; 0.17; 0.18 **Scaling factor:** 2 **Scaled:** 0.10; 0.13; 0.16; 0.19; 2 × 0.23; 0.35; 0.38 | Underdosed trials on tomatoes (0.5 N) evaluated in the peer review (EFSA, 2019b). Proportionality applied (Netherlands, 2022). MRL\textsubscript{OECD} = 0.66 | 0.70(e) (tentative)   | 0.38          | 0.21           | 1     |
| Import (BR)            | –         | No GAP compliant trials available.                              |                                                                                 | –                      | –             | –              | –     |
| Sweet peppers/bell peppers | SEU       | –                                                               | No GAP compliant trials available.                                              | –                      | –             | –              | –     |
|                        | EU        | 0.07; 0.11; 0.12; 0.13; 0.21; 0.25; 0.26(g); 0.28              | Trials on peppers compliant with GAP (Netherlands, 2022). MRL\textsubscript{OECD} = 0.54 | 0.60(e) (tentative)   | 0.28          | 0.17           | 1     |
| Import (BR)            | –         | No GAP compliant trials available.                              |                                                                                 | –                      | –             | –              | –     |
| Aubergines/eggplants  | SEU       | 0.08; 0.10; 0.11; 0.12; 0.14; 0.16; 0.20                         | Trials on tomatoes compliant with GAP, evaluated in the peer review (EFSA, 2019b). Extrapolation to aubergines applicable. MRL\textsubscript{OECD} = 0.39 | 0.40(e) (tentative)   | 0.20          | 0.12           | 1     |
|                        | EU        | 0.05; 0.06; 0.08; 0.09; 2 × 0.11; 0.17; 0.18                   | Trials on tomatoes compliant with GAP on aubergines (EFSA, 2019b). MRL\textsubscript{OECD} = 0.32 | 0.40(e) (tentative)   | 0.18          | 0.10           | 1     |
| Import (BR)            | –         | No GAP compliant trials available.                              |                                                                                 | –                      | –             | –              | –     |
| Okra/lady’s fingers   | EU        | –                                                               | No GAP compliant trials available.                                              | –                      | –             | –              | –     |
| Cucumbers Gherkins Courgettes | EU | 7 × < 0.01; 0.02                                               | Trials on cucumber compliant with GAP (Netherlands, 2022). Extrapolation to gherkins and courgette applicable. MRL\textsubscript{OECD} = 0.03 | 0.03(e) (tentative)   | 0.02          | 0.01           | 1     |
| Import (BR)            | –         | No GAP compliant trials available.                             | Only relevant for gherkins and courgettes.                                     | –                      | –             | –              | –     |
| Melons Watermelons Pumpkins | EU   | –                                                               | No GAP compliant trials available.                                              | –                      | –             | –              | –     |
|                        | Import (BR)| 2 × < 0.005; 0.007; 0.013(g)                                             | Reduced data set of trials on melons compliant with GAP (Netherlands, 2022). Extrapolation to watermelon applicable. No GAP authorised for pumpkins. MRL\textsubscript{OECD} = 0.02 | 0.02(e),(f) (tentative) | 0.01          | 0.01           | 1     |
| Broccoli Cauliflowers | EU        | –                                                               | No GAP compliant trials available.                                              | –                      | –             | –              | –     |
| Brussels sprouts      | EU        | –                                                               | No GAP compliant trials available.                                              | –                      | –             | –              | –     |
### 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) CF(d)

| Commodity | Region | Residue levels observed | Comments/Source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|-----------|--------|-------------------------|-----------------|------------------------|---------------|-----------------|-------|
| Head cabbages | EU | – | No GAP compliant trials available. | – | – | – | – |
| Chinese cabbages/pe-tsai Kales | EU | – | No GAP compliant trials available. | – | – | – | – |
| Kohlrabies | EU | – | No GAP compliant trials available. | – | – | – | – |
| Lamb’s lettuces/corn salads | EU | – | No GAP compliant trials available. | – | – | – | – |
| | Lettuces leaved endives | | | | | | |
| | Cresses and other sprouts and shoots | | | | | | |
| | Land cresses | | | | | | |
| | Roman rocket/rucola | | | | | | |
| | Red mustards | | | | | | |
| | Baby leaf crops (including brassica species) | | | | | | |
| Spinaches Purslanes Chards/beet leaves | EU | – | No GAP compliant trials available. | – | – | – | – |
| Watercresses | EU | – | No GAP compliant trials available. | – | – | – | – |
| Witloofs/Belgian endives | EU | – | No GAP compliant trials available. | – | – | – | – |
| Chervil Chives Celery leaves Parsley Sage Rosemary Thyme Basil and edible flowers Laurel/bay leave Tarragon | EU | – | No GAP compliant trials available. | – | – | – | – |
| Commodity                  | Region<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|---------------------------|----------------------|----------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|--------------------------|-----------------------------|--------------|
| Beans and peas (with pods)| EU                   | –                                                              | No GAP compliant trials available.                                              | –                      | –                        | –                           | –            |
| Beans and peas (without pods)| EU             | –                                                              | No GAP compliant trials available.                                              | –                      | –                        | –                           | –            |
| Lentils (fresh)           | EU                   | –                                                              | No GAP compliant trials available.                                              | –                      | –                        | –                           | –            |
| Asparagus                 | EU                   | –                                                              | No GAP compliant trials available.                                              | –                      | –                        | –                           | –            |
| Cardoons                  | EU                   | –                                                              | No GAP compliant trials available.                                              | –                      | –                        | –                           | –            |
| Celeris                   | EU                   | –                                                              | No GAP compliant trials available.                                              | –                      | –                        | –                           | –            |
| Florence fennels          | EU                   | –                                                              | No GAP compliant trials available.                                              | –                      | –                        | –                           | –            |
| Rhubarbs                  | EU                   | –                                                              | No GAP compliant trials available.                                              | –                      | –                        | –                           | –            |
| Globe artichokes          | EU                   | –                                                              | No GAP compliant trials available.                                              | –                      | –                        | –                           | –            |
| Bamboo shoots             | EU                   | –                                                              | No GAP compliant trials available.                                              | –                      | –                        | –                           | –            |
| Palm hearts               | EU                   | –                                                              | No GAP compliant trials available.                                              | –                      | –                        | –                           | –            |
| Beans (dry)               | Import (BR)          | –                                                              | No GAP compliant trials available.                                              | –                      | –                        | –                           | –            |
| Soya beans                | Import (BR)          | –                                                              | No GAP compliant trials available.                                              | –                      | –                        | –                           | –            |
| Cottonseeds               | SEU                  | 4 × < 0.01                                                     | Reduced data set of trials on cottonseeds compliant with GAP, deemed acceptable since all residues < LOQ (Netherlands, 2022). MRL<sub>OECD</sub> = 0.01 | 0.01 (tentative)       | 0.01                     | 0.01                        | 1            |
|                           | Import (BR)          | –                                                              | No GAP compliant trials available.                                              | –                      | –                        | –                           | –            |
| Tea                       | Import (JP)          | Mo: 0.10; 0.14; 2.10; 2.80; 2.90; 4.80; 5.90; 6.20; 6.60 RA: <sup>(h)</sup> | Trials on tea performed at PHI within 25% deviation, evaluated in previous MRL application (EFSA, 2013). MRL<sub>OECD</sub> = 13.51 | 15.00 (tentative)      | 6.60                      | 2.90                        | 1.40<sup>(i)</sup> |
| Turnip tops               | EU                   | –                                                              | No GAP compliant trials available.                                              | –                      | –                        | –                           | –            |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level.

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

Mo: Residue levels expressed according to the monitoring residue definition; RA: Residue levels expressed according to risk assessment residue definition.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials, Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(e): Tentative MRL in the absence of sufficiently validated analytical methods.
(f): Tentative MRL in the absence of sufficient number of GAP-compliant trials.
(g): Selected value corresponds to higher residue levels observed at a longer PHI.
(h): No residue data for metabolites included in the RD-RA available.
(i): In the absence of residue data for metabolites included in the RD-RA, a CF of 1.4 was applied for tea as derived from metabolism studies on orange leaves.
B.1.2.2. Residues in rotational crops

Overall summary

Residues in rotational and succeeding crops expected based on confined rotational crop study?

no

The total radioactive residues were < 0.01 mg eq/kg in lettuce and radish root, 0.011 mg eq/kg in radish leaves and wheat forage and accounted for up to 0.081 mg eq/kg in wheat grain, 0.059 mg eq/kg in wheat straw and 0.082 mg eq/kg in wheat chaff. In wheat grain, the major part of the radioactive residues was found to be incorporated into natural plant constituents (up to 88% TRR) whilst in wheat straw, the extracted radioactive residues were constituted of unidentified compounds, each below 10% TRR (< 0.01 mg/kg). Parent pyriproxyfen and/or its related metabolites were never detected in wheat grain and straw. Further studies addressing the fate of respectively 4'-OH-PYR and PYPAC residues in rotational crops are also not required.

Residues in rotational and succeeding crops expected based on field rotational crop study?

no

There were no studies investigating the magnitude of residues in rotational crops available for this review. Nevertheless, considering the maximum application rate of GAPs under assessment (2 × 230 g a.s./ha) and foliar interception, the amount of active substance effectively reaching the soil is considered to be covered by the rate of the available confined rotational crop study. Residue levels of pyriproxyfen in the edible part of crops that can be rotated are not expected to exceed 0.01 mg/kg, provided that active substance is applied in compliance with the GAPs reported in Appendix A.

B.1.2.3. Processing factors

| Processed commodity            | Number of valid studies<sup>(a)</sup> | Individual values | Processing Factor (PF) | Median PF | Comment/Source |
|-------------------------------|-------------------------------------|-------------------|------------------------|-----------|----------------|
| Citrus, peeled                | 18                                  | < 0.01; 2 x < 0.02; 2 x < 0.03; 4 x < 0.04; 2 x < 0.05; 2 x < 0.06; 2 x < 0.07; 2 x < 0.08; < 0.1; 0.1 | < 0.05   | EFSA (2019b)   |
| Citrus, juice                 | 2                                   | < 0.02; 0.16      |                         | 0.16      | EFSA (2019b)   |
| Citrus, wet pomace            | 2                                   | 1.27; 1.85        |                         | 1.56      | EFSA (2019b)   |
| Citrus, dry pomace            | 2                                   | 3.75; 4.0         |                         | 3.88      | EFSA (2019b)   |
| Oranges, marmalade            | 2                                   | 0.13; 0.18        |                         | 0.16      | EFSA (2019b)   |
| Citrus, press cake            | 2                                   | 7.29; 10.0        |                         | 8.65      | EFSA (2019b)   |
| Citrus, essential oil         | 2                                   | 110; 176          |                         | 143       | EFSA (2019b)   |
| Table grapes, dried (raisins) | 2                                   | 0.29; 0.49        |                         | 0.39      | Netherlands (2022) |
| Processed commodity                       | Number of valid studies<sup>(a)</sup> | Processing Factor (PF) | Median PF | Comment/Source                  |
|------------------------------------------|---------------------------------------|------------------------|-----------|---------------------------------|
|                                          | Individual values                     |                        |           |                                 |
| Wine grapes, juice                       | 7                                     | < 0.03; < 0.12; 2 × < 0.18; < 0.36; < 0.67; < 0.91 | 0.18      | Netherlands (2022)               |
| Wine grapes, dry pomace                  | 7                                     | 2 × 10; 11; 12; 14; 32; 36 | 12        | Netherlands (2022)               |
| Wine grapes, wet pomace                  | 3                                     | 2 × 2.9; 3.1           | 2.9       | Netherlands (2022)               |
| Wine grapes, wine                        | 3                                     | < 0.12; < 0.36; < 0.91 | 0.36      | Netherlands (2022)               |
| Tomatoes, canned                         | 3                                     | < 0.12; < 0.17; < 0.20 | 0.17      | EFSA (2019b); Netherlands (2022) |
| Tomatoes, puree                          | 3                                     | 0.31; 0.67; 1.8        | 0.67      | EFSA (2019b); Netherlands (2022) |
| Tomato, ketchup                          | 1                                     | 0.67                   | 0.67      | Tentative<sup>(b)</sup> (EFSA, 2019b) |
| Tomato, juice                            | 3                                     | < 0.12; < 0.17; < 0.20 | 0.17      | EFSA (2019b), Netherlands (2022) |
| Cottonseeds, crude oil                   | 1                                     | 0.2                    | 0.2       | Tentative<sup>(b)</sup> (EFSA, 2019b) |
| Cottonseeds, refined oil                 | 1                                     | 0.2                    | 0.2       | Tentative<sup>(b)</sup> (EFSA, 2019b) |
| Cottonseeds, hulls                       | 1                                     | < 0.2                  | < 0.2     | Tentative<sup>(b)</sup> (EFSA, 2019b) |
| Cottonseeds, extracted meal              | 1                                     | < 0.2                  | < 0.2     | Tentative<sup>(b)</sup> (EFSA, 2019b) |

PF: Processing factor (=Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo).

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

<sup>(b)</sup>: A tentative PF is derived based on a limited data set.
B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) | Comments |
|---------------------------|-----------------------------|---------------------------|---------------------------|------------------------|----------|
|                           | mg/kg bw per day            | mg/kg DM                  |                           |                        |          |
|                           | Median | Maximum | Median | Maximum |                      |          |
| Cattle (all)              | 0.006  | 0.006   | 0.16   | 0.16    | Dairy cattle          | Citrus, dried pulp | Yes      |          |
| Cattle (dairy only)       | 0.006  | 0.006   | 0.16   | 0.16    | Dairy cattle          | Citrus, dried pulp | Yes      |          |
| Sheep (all)               | 0.001  | 0.001   | 0.01   | 0.01    | Lamb                  | Apple, pomace wet  | No       |          |
| Sheep (ewe only)          | 0      | 0       | 0.01   | 0.01    | Ram/Ewe               | Apple, pomace wet  | No       |          |
| Swine (all)               | 0.003  | 0.003   | 0.12   | 0.12    | Swine (breeding)      | Citrus, dried pulp | Yes      |          |
| Poultry (all)             | 0      | 0       | 0      | 0       | Turkey                | Cotton, meal       | No       |          |
| Poultry (layer only)      | 0      | 0       | 0      | 0       | Poultry layer         | Cotton, meal       | No       |          |
| Fish                      | –      | –       | –      | –       | –                     | –                  | –        |          |

Bw: body weight; DM: dry matter.

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

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

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

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

| Livestock (available studies) | Animal     | Dose (mg/kg bw/d) | Duration (days) | Comment/Source                                                                 |
|-------------------------------|------------|-------------------|-----------------|--------------------------------------------------------------------------------|
|                               | Laying hen | 0.78              | 8               | Not triggered for the current authorised uses. Phenoxyphenyl- 14C and Pyridyl-14C label. |
|                               | Lactating ruminants | 0.34 | 5 | Goat: 57N compared to the maximum dietary burden calculated for cattle (all diets and dairy only). Pyridyl-14C label |
|                               |            | 0.38              | 5               | Goat: 63N compared to the maximum dietary burden calculated for cattle (all diets and dairy only). Phenoxyphenyl- 14C label |
|                               | Pig        | –                 | –               | Not available and not required (extrapolated from ruminants)                     |
|                               | Fish       | –                 | –               | –                                                                                |
B.2.1.2. Stability of residues in livestock

No storage stability studies are available and are not required.
### B.2.2. Magnitude of residues in livestock

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

Calculations performed with Animal model 2017.\(^\text{11}\)

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) |
|------------------|---------------------------------------------|-----------------------|----------------------|
|                  | Mean | Highest\(^a\) | STMR\(_{Mo}\)\(^b\) | HR\(_{Mo}\)\(^c\) |
| Cattle (all)     |      |               |                      |                     |
| Muscle           | n.r. | 0.019         | < 0.01               | < 0.01              | 0.01*               |
| Fat              | n.r. | 0.069         | < 0.01               | < 0.01              | 0.01*               |
| Liver            | n.r. | 0.83          | < 0.01               | < 0.01              | 0.01*               |
| Kidney           | n.r. | 0.29          | < 0.01               | < 0.01              | 0.01*               |
| Cattle (dairy only) |    |               |                      |                     |
| Milk             | n.r. | 0.12          | < 0.01               | < 0.01              | 0.01*               |
| Sheep (all)      |      |               |                      |                     |
| Muscle           | –    | –             | –                    | –                   |                     |
| Fat              | –    | –             | –                    | –                   |                     |
| Liver            | –    | –             | –                    | –                   |                     |
| Kidney           | –    | –             | –                    | –                   |                     |
| Sheep (ewe only) |      |               |                      |                     |
| Milk             | –    | n.a.          | –                    | –                   |                     |
| Swine (all)\(^e\) |    |               |                      |                     |
| Muscle           | n.r. | 0.019         | < 0.01               | < 0.01              | 0.01*               |
| Fat              | n.r. | 0.069         | < 0.01               | < 0.01              | 0.01*               |
| Liver            | n.r. | 0.83          | < 0.01               | < 0.01              | 0.01*               |
| Kidney           | n.r. | 0.29          | < 0.01               | < 0.01              | 0.01*               |
| Poultry (all)    |      |               |                      |                     |
| Muscle           | –    | –             | –                    | –                   |                     |
| Fat              | –    | –             | –                    | –                   |                     |
| Liver            | –    | –             | –                    | –                   |                     |
| Poultry (layer only) |   |               |                      |                     |
| Eggs             | –    | –             | –                    | –                   |                     |

Bw: body weight; n.r.: not reported.

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

\(^a\): Total radioactive residues in the metabolism study (mg eq/kg). Highest level of the two labels reported.

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

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

\(^d\): Feeding level tested in the metabolism study and N dose rate related to the maximum dietary burden.

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

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\(^\text{11}\) [https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en](https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en)
B.3. Consumer risk assessment

B.3.1. Consumer risk assessment without consideration of the existing CXLs

**ARfD**

| CXL | Description |
|-----|-------------|
| 1 mg/kg bw (European commission, 2020a) |

**Highest IESTI, according to EFSA PRIMo (rev.3.1)**

| CXL | Description |
|-----|-------------|
| Peaches: 2% of ARfD |

**NESTI (% ARfD)**

| CXL | Description |
|-----|-------------|
| Not assessed in this review. |

**Assumptions made for the calculations**

The calculation is based on the highest residue levels expected in raw agricultural commodities, except for citrus fruits where the derived peeling factor was applied and cotton seeds, olives for oil production, tea, and milk where the calculation was based on the median residue levels expected in raw commodity. The CF of 1.4 for risk assessment was applied to tea. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation.

**ADI**

| CXL | Description |
|-----|-------------|
| 0.05 mg/kg bw per day (European Commission, 2020a) |

**TMDI according to EFSA PRIMo**

| CXL | Description |
|-----|-------------|
| Not assessed in this review. |

**NTMDI, according to (to be specified)**

| CXL | Description |
|-----|-------------|
| Not assessed in this review. |

**Highest IEDI, according to EFSA PRIMo (rev.3.1)**

| CXL | Description |
|-----|-------------|
| 3% ADI (Dutch toddler) |

**NEDI (% ADI)**

| CXL | Description |
|-----|-------------|
| Not assessed in this review. |

**Assumptions made for the calculations**

The calculation is based on the median residue levels derived for raw agricultural commodities, except for citrus fruits where the derived peeling factor was applied. The CF of 1.4 for risk assessment was applied to tea. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.

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

| CXL | Description |
|-----|-------------|
| Not assessed in this review. |

**Metabolite(s)**

| CXL | Description |
|-----|-------------|
| Not assessed in this review. |

**ADI (mg/kg bw per day)**

| CXL | Description |
|-----|-------------|
| Not assessed in this review. |

**Intake of groundwater metabolites (% ADI)**

| CXL | Description |
|-----|-------------|
| Not assessed in this review. |
### B.3.2. Consumer risk assessment with consideration of the existing CXLs

| ARfD | 1 mg/kg bw (European Commission, 2020a) |
|------|----------------------------------------|
| Highest IESTI, according to EFSA PRIMO (rev.3.1.) | Peaches: 2% of ARfD |
| NESTI (% ARfD) | Not assessed in this review. |
| Assumptions made for the calculations | For those commodities having a CXL higher than the EU MRL proposal, median residue levels applied in the EU scenario were replaced by the median residue levels derived by JMPR. The CF of 1.4 for risk assessment was applied to tea. |

| ADI | 0.05 mg/kg bw per day (European Commission, 2020a) |
|-----|--------------------------------------------------|
| TMDI according to EFSA PRIMO | Not assessed in this review. |
| NTMDI, according to (to be specified) | Not assessed in this review. |
| Highest IEDI, according to EFSA PRIMO (rev.3.1) | 3% ADI (Dutch toddler) |
| NEDI (% ADI) | Not assessed in this review. |
| Assumptions made for the calculations | For those commodities having a CXL higher than the EU MRL proposal, median residue levels applied in the EU scenario were replaced by the median residue levels derived by JMPR. The CF of 1.4 for risk assessment was applied to tea. |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMO: (EFSA) Pesticide Residues Intake Model; NESTI: national estimated short-term intake; CXL: codex maximum residue limit; CF: conversion factor; MRL: maximum residue level.

ADI: acceptable daily intake; bw: body weight; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake; IEDI: international estimated daily intake; PRIMO: (EFSA) Pesticide Residues Intake Model; NEDI: national estimated daily intake; CXL: codex maximum residue limit; CF: conversion factor; MRL: maximum residue level.
## B.4. Proposed MRLs

| Code number | Commodity       | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Outcome of the review | Comment            |
|-------------|-----------------|-------------------------|----------------------|-------------|-----------------------|---------------------|
| 110010      | Grapefruit      | 0.6                     | 0.5                  | 0.7         | Further consideration needed | data gap #2, 3   |
| 110020      | Oranges         | 0.6                     | 0.5                  | 0.7         | Further consideration needed | data gap #2, 3   |
| 110030      | Lemons          | 0.6                     | 0.5                  | 0.7         | Further consideration needed | data gap #2, 3   |
| 110040      | Limes           | 0.6                     | 0.5                  | 0.7         | Further consideration needed | data gap #2, 3   |
| 110050      | Mandarins       | 0.6                     | 0.5                  | 0.7         | Further consideration needed | data gap #2, 3   |
| 120010      | Almonds         | 0.05*                   | –                    | 0.01*       | Further consideration needed | data gap #2, 3   |
| 120040      | Chestnuts       | 0.05*                   | –                    | 0.01*       | Further consideration needed | data gap #2, 3   |
| 120060      | Hazelnuts       | 0.05*                   | –                    | 0.01*       | Further consideration needed | data gap #2, 3   |
| 120070      | Macadamia       | 0.05*                   | –                    | 0.05        | Further consideration needed | data gap #2, 3, 4 |
| 120080      | Pecans          | 0.05*                   | –                    | 0.01*       | Further consideration needed | data gap #2, 3   |
| 120090      | Pine nuts kernels | 0.05*               | –                    | 0.01*       | Further consideration needed | data gap #2, 3   |
| 120100      | Pistachios      | 0.05*                   | –                    | 0.01*       | Further consideration needed | data gap #2, 3   |
| 120110      | Walnuts         | 0.05*                   | –                    | 0.01*       | Further consideration needed | data gap #2, 3   |
| 130010      | Apples          | 0.2                     | –                    | 0.05        | Further consideration needed | data gap #2, 5   |
| 130020      | Pears           | 0.2                     | –                    | 0.01*       | Further consideration needed | data gap #2      |
| 130030      | Quinces         | 0.2                     | –                    | 0.01*       | Further consideration needed | data gap #2      |
| 130040      | Medlar          | 0.2                     | –                    | 0.01*       | Further consideration needed | data gap #2      |
| 130050      | Loquat          | 0.2                     | –                    | 0.01*       | Further consideration needed | data gap #2      |
| 140010      | Apricots        | 0.05*                   | –                    | 0.4         | Further consideration needed | data gap #2      |
| 140020      | Cherries        | 1                       | –                    | 1.5         | Further consideration needed | data gap #2, 6   |
| 140030      | Peaches         | 0.5                     | –                    | 0.5         | Further consideration needed | data gap #2      |
| 140040      | Plums           | 0.3                     | –                    | 0.3         | Further consideration needed | data gap #2, 6   |
| 151010      | Table grapes    | 0.05*                   | –                    | 0.01*       | Further consideration needed | data gap #2      |
| 151020      | Wine grapes     | 0.05*                   | –                    | 0.01*       | Further consideration needed | data gap #2      |

**Enforcement residue definition:** pyriproxyfen
| Code number | Commodity                        | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                                      |
|-------------|----------------------------------|-------------------------|---------------------|-------------|----------------------------------------------|
| 152000      | Strawberries                     | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gap #2 |
| 161030      | Table olives                     | 0.05*                   | –                   | 0.01*       | Further consideration needed[^6] data gaps #2, 3 |
| 161040      | Kumquats                         | 0.05*                   | 0.5                 | 0.5         | Further consideration needed[^5] data gaps #2 |
| 161060      | Kaki/Japanese persimmon          | 0.05*                   | –                   | 0.01*       | Further consideration needed[^5] data gap #2 |
| 163010      | Avocados                         | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 3 |
| 163030      | Mangos                           | 0.05*                   | 0.02*               | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| 163040      | Papaya                           | 0.3                     | 0.3                 | 0.3         | Further consideration needed[^6] Data gaps #2 |
| 163060      | Cherimoya                        | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| 163080      | Pineapples                       | 0.05*                   | 0.01                | 0.01*       | Further consideration needed[^6] Data gaps #2 |
| 211000      | Potatoes                         | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| 212020      | Sweet potatoes                   | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| 212030      | Yams                             | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| 213010      | Beetroot                         | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| 213020      | Carrots                          | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| 213030      | Celeriac                         | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| 213040      | Horseradish                      | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| 213050      | Jerusalem artichokes             | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| 213060      | Parsnips                         | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| 213070      | Parsley root                     | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| 213080      | Radishes                         | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| 213090      | Salsify                          | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| 213100      | Swedes                           | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| 213110      | Turnips                          | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| 220010      | Garlic                           | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| 220020      | Onions                           | 0.05*                   | –                   | 0.05        | Further consideration needed[^6] data gaps #2, 4 |
| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Outcome of the review |
|-------------|-----------|------------------------|---------------------|-------------|----------------------|
| 220030      | Shallots  | 0.05*                  | –                   | 0.05        | Further consideration needed (c) data gaps #2, 4 |
| 220040      | Spring onions | 0.05*                | –                   | 0.05        | Further consideration needed (c) data gaps #2, 4 |
| 231010      | Tomatoes  | 1                      | 0.4                 | 0.7         | Further consideration needed (a) data gap #2 |
| 231020      | Peppers   | 1                      | 0.6                 | 0.6         | Further consideration needed (a) data gap #2 |
| 231030      | Aubergines (egg plants) | 1                | 0.6                 | 0.6         | Further consideration needed (f) data gap #2 |
| 231040      | Okra, lady’s fingers | 1                  | –                   | 1           | Further consideration needed (f) data gaps #2, 4 |
| 232010      | Cucumbers | 0.1                    | 0.04                | 0.04        | Further consideration needed (f) data gap #2 |
| 232020      | Gherkins  | 0.1                    | 0.04                | 0.04        | Further consideration needed (f) data gap #2 |
| 232030      | Courgettes | 0.05*                | 0.04                | 0.04        | Further consideration needed (f) data gap #2 |
| 233010      | Melons    | 0.07                   | 0.07                | 0.07        | Further consideration needed (f) data gaps #2 |
| 233020      | Pumpkins  | 0.05*                  | –                   | 0.05        | Further consideration needed (c) data gaps #2, 4 |
| 233030      | Watermelons | 0.05*                | –                   | 0.02        | Further consideration needed (a) data gaps #2, 7 |
| 241010      | Broccoli  | 0.05*                  | –                   | 0.05        | Further consideration needed (c) data gaps #2, 4 |
| 241020      | Cauliflower | 0.05*                | –                   | 0.05        | Further consideration needed (c) data gaps #2, 4 |
| 242010      | Brussels sprouts | 0.05*            | –                   | 0.05        | Further consideration needed (c) data gaps #1, 2, 4 |
| 242020      | Head cabbage | 0.05*               | –                   | 0.05        | Further consideration needed (c) data gaps #1, 2, 4 |
| 243010      | Chinese cabbage | 0.05*              | –                   | 0.05        | Further consideration needed (c) data gaps #1, 2, 4 |
| 243020      | Kale      | 0.05*                  | –                   | 0.05        | Further consideration needed (c) data gaps #1, 2, 4 |
| 244000      | Kohlrabi  | 0.05*                  | –                   | 0.05        | Further consideration needed (c) data gaps #1, 2, 4 |
| 251010      | Lamb’s lettuce | 0.05*              | –                   | 0.05        | Further consideration needed (c) data gaps #1, 2, 4 |
| 251020      | Lettuce   | 0.05*                  | –                   | 0.05        | Further consideration needed (c) data gaps #1, 2, 4 |
| 251030      | Escaroles (broad-leaf endive) | 0.05*         | –                   | 0.05        | Further consideration needed (c) data gaps #1, 2, 4 |
| 251040      | Cress     | 0.05*                  | –                   | 0.05        | Further consideration needed (c) data gaps #1, 2, 4 |
| 251050      | Land cress | 0.05*                | –                   | 0.05        | Further consideration needed (c) data gaps #1, 2, 4 |
| 251060      | Rocket, Rucola | 0.05*              | –                   | 0.05        | Further consideration needed (c) data gaps #1, 2, 4 |
| 251070      | Red mustard | 0.05*               | –                   | 0.05        | Further consideration needed (c) data gaps #1, 2, 4 |
| Code number | Commodity                              | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                                      |
|-------------|----------------------------------------|-------------------------|----------------------|-------------|----------------------------------------------|
| 251080      | Leaves and sprouts of Brassica spp.    | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 252010      | Spinach                                | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 252020      | Purslane                               | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 252030      | Beet leaves (chard)                    | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 254000      | Water cress                            | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 255000      | Witloof                                | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 256010      | Chervil                                | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 256020      | Chives                                 | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 256030      | Celery leaves                          | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 256040      | Parsley                                | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 256050      | Sage                                   | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 256060      | Rosemary                               | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 256070      | Thyme                                  | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 256080      | Basil                                  | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 256090      | Bay leaves (laurel)                    | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 256100      | Tarragon                               | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 260010      | Beans (fresh, with pods)               | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #2, 4 |
| 260020      | Beans (fresh, without pods)            | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #2, 4 |
| 260030      | Peas (fresh, with pods)                | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #2, 4 |
| 260040      | Peas (fresh, without pods)             | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #2, 4 |
| 260050      | Lentils (fresh)                        | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #2, 4 |
| 270010      | Asparagus                              | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 270020      | Cardoons                               | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 270030      | Celery                                 | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 270040      | Fennel                                 | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| 270050      | Globe artichokes                       | 0.05*                   | –                    | 0.05        | Further consideration needed\(^{(c)}\) data gaps #1, 2, 4 |
| Code number | Commodity                              | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                                                                 |
|-------------|----------------------------------------|-------------------------|----------------------|-------------|-------------------------------------------------------------------------|
| 270060      | Leek                                   | 0.05*                   | –                    | 0.05        | Further consideration needed<sup>(c)</sup> data gaps #1, 2, 4           |
| 270070      | Rhubarb                                | 0.05*                   | –                    | 0.05        | Further consideration needed<sup>(c)</sup> data gaps #1, 2, 4           |
| 270080      | Bamboo shoots                          | 0.05*                   | –                    | 0.05        | Further consideration needed<sup>(c)</sup> data gaps #1, 2, 4           |
| 270090      | Palm hearts                            | 0.05*                   | –                    | 0.05        | Further consideration needed<sup>(c)</sup> data gaps #1, 2, 4           |
| 300010      | Beans (dry)                            | 0.05*                   | –                    | 0.05        | Further consideration needed<sup>(c)</sup> data gaps #2, 3, 4           |
| 401070      | Soya bean                              | 0.05*                   | –                    | 0.05        | Further consideration needed<sup>(c)</sup> data gaps #1, 2, 4           |
| 401090      | Cotton seed                            | 0.05* 0.05             | 0.05                 |             | Further consideration needed<sup>(f)</sup> data gaps #2, 3              |
| 402010      | Olives for oil production              | 0.05*                   | –                    | 0.01*       | Further consideration needed<sup>(b)</sup> data gaps #2, 3              |
| 610000      | Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis) | 15 | – | 15 | Further consideration needed<sup>(b)</sup> data gap #2 |
| 1011010     | Swine meat                             | 0.05*                   | –                    | 0.01*       | Recommended<sup>(g)</sup>                                               |
| 1011020     | Swine fat (free of lean meat)          | 0.05*                   | –                    | 0.01*       | Recommended<sup>(g)</sup>                                               |
| 1011030     | Swine liver                            | 0.05*                   | –                    | 0.01*       | Recommended<sup>(g)</sup>                                               |
| 1011040     | Swine kidney                           | 0.05*                   | –                    | 0.01*       | Recommended<sup>(g)</sup>                                               |
| 1012010     | Bovine meat                            | 0.05* 0.01*             | 0.01*                |             | Recommended<sup>(h)</sup>                                               |
| 1012020     | Bovine fat                             | 0.05* 0.01*             | 0.01*                |             | Recommended<sup>(h)</sup>                                               |
| 1012030     | Bovine liver                           | 0.05* 0.01*             | 0.01*                |             | Recommended<sup>(h)</sup>                                               |
| 1012040     | Bovine kidney                          | 0.05* 0.01*             | 0.01*                |             | Recommended<sup>(h)</sup>                                               |
| 1014010     | Goat meat                              | 0.05* 0.01*             | 0.01*                |             | Recommended<sup>(i)</sup>                                               |
| 1014020     | Goat fat                               | 0.05* 0.01*             | 0.01*                |             | Recommended<sup>(i)</sup>                                               |
| 1014030     | Goat liver                             | 0.05* 0.01*             | 0.01*                |             | Recommended<sup>(i)</sup>                                               |
| 1014040     | Goat kidney                            | 0.05* 0.01*             | 0.01*                |             | Recommended<sup>(i)</sup>                                               |
| 1015010     | Horse meat                             | 0.05*                   | –                    | 0.01*       | Recommended<sup>(g)</sup>                                               |
| 1015020     | Horse fat                              | 0.05*                   | –                    | 0.01*       | Recommended<sup>(g)</sup>                                               |
| 1015030     | Horse liver                            | 0.05*                   | –                    | 0.01*       | Recommended<sup>(g)</sup>                                               |
| 1015040     | Horse kidney                           | 0.05*                   | –                    | 0.01*       | Recommended<sup>(g)</sup>                                               |
| 1020010     | Cattle milk                            | 0.05*                   | –                    | 0.01*       | Recommended<sup>(g)</sup>                                               |
| 1020040     | Horse milk                             | 0.05*                   | –                    | 0.01*       | Recommended<sup>(g)</sup>                                               |
|             | Other commodities of plant and/or animal origin | See Reg. (EU) 2020/856 | – | – | Further consideration needed<sup>(j)</sup> |

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

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

(F): The residue definition is fat soluble.

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

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

(c): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination D-I in Appendix E).
(d): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the existing residue definition); there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix E).
(e): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); existing CXL is covered by the existing EU MRL (combination D-III in Appendix E).
(f): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the existing residue definition); GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination F-V in Appendix E).
(g): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination H-I in Appendix E).
(h): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination H-III in Appendix E).
(i): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E).
(j): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
## Appendix C – Pesticide Residue Intake Model (PRIMo)

- **PRIMo(EU)**

### Pyriproxyfen (F)

| Volume | Type | Reference Value | Year of Evaluation | Year of Evaluation |
|--------|------|-----------------|-------------------|-------------------|
| LOQs (mg/kg) | 0.01 | | 2020 | 2020 |

### Toxicological reference values

- **ADI (mg/kg bw per day):**
  - Source of ADI: 2020
- **ARfD (mg/kg bw):**
  - Source of ARfD: 2020

### Pyramid methodology (ED/TMDI)

#### Exposure

| Commodity | Group of Commodities | Exposure (µg/kg bw per diet) | % of ADI | MS Diet | No of diets exceeding the ADI: --- |
|-----------|----------------------|-----------------------------|---------|---------|-------------------------------------|
| Potatoes  | GEMS/Food G06        | 3%                          | 1.59    | DE child| 2%                                  |
| Tea (dried leaves of Camellia sinensis) | GEMS/Food G07 | 2%                          | 1.06    | FR adult| 2%                                  |
| Tomatoes  | GEMS/Food G10        | 2%                          | 1.12    | IE adult| 2%                                  |
| Milk: Cattle | GEMS/Food G11      | 2%                          | 1.06    | FR child 3 yr | 2% |
| Soyabeans | GEMS/Food G12       | 2%                          | 1.06    | SE general| 2% |
| Sweet peppers/bell peppers | GEMS/Food G15 | 2%                          | 1.12    | NL child | 2% |

#### Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of pyriproxyfen (F) is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD.

### Acute risk assessment/children

| Commodity | MRL/input (mg/kg) | Exposure (µg/kg bw) |
|-----------|------------------|---------------------|
| Peaches   | 0.5/0.24         | 23                  |
| Tomatoes  | 0.7/0.38         | 22                  |
| Sweet peppers/bell peppers | 0.6/0.28 | 17                  |
| Peaches   | 0.6/0.24         | 8                   |
| Potatoes  | 0.05/0.05        | 7.7                 |
| Cherries (sweet) | 1.5/0.62 | 7.6                 |
| Tea (dried leaves of Camellia sinensis) | 15/4.06 | 6.2                 |
| Apricots  | 0.4/0.24         | 5.0                 |
| Mangoes   | 0.05/0.05        | 3.2                 |
| Potatoes  | 0.05/0.05        | 3.2                 |
| Peaches   | 0.5/0.24         | 2.8                 |
| Pumpkins/boiled | 0.05/0.05 | 2.8                 |
| Cauliflowers/boiled | 0.05/0.05 | 2.8                 |
| Peaches   | 0.5/0.24         | 2.8                 |
| Broccoli/boiled | 0.05/0.05 | 2.8                 |
| Cauliflowers/boiled | 0.05/0.05 | 2.8                 |
| Peaches   | 0.5/0.24         | 2.8                 |
| Broccoli/boiled | 0.05/0.05 | 2.8                 |

### Acute risk assessment/adults/general population

| Commodity | MRL/input (mg/kg) | Exposure (µg/kg bw) |
|-----------|------------------|---------------------|
| Peaches   | 0.5/0.24         | 23                  |
| Tomatoes  | 0.7/0.38         | 22                  |
| Sweet peppers/bell peppers | 0.6/0.28 | 17                  |
| Peaches   | 0.6/0.24         | 8                   |
| Potatoes  | 0.05/0.05        | 7.7                 |
| Cherries (sweet) | 1.5/0.62 | 7.6                 |
| Tea (dried leaves of Camellia sinensis) | 15/4.06 | 6.2                 |
| Apricots  | 0.4/0.24         | 5.0                 |
| Mangoes   | 0.05/0.05        | 3.2                 |
| Potatoes  | 0.05/0.05        | 3.2                 |
| Peaches   | 0.5/0.24         | 2.8                 |
| Pumpkins/boiled | 0.05/0.05 | 2.8                 |
| Cauliflowers/boiled | 0.05/0.05 | 2.8                 |
| Peaches   | 0.5/0.24         | 2.8                 |
| Broccoli/boiled | 0.05/0.05 | 2.8                 |

### Conclusion

No exceedance of the toxicological reference value was identified for any unprocessed commodity.

A short-term intake of residues of pyriproxyfen (P) is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD was identified.
### Pyriproxyfen (F)

#### Input values

**LOQs (mg/kg) range from:**
- Numeric value: 0.01 to 0.01

#### Supplementary results – chronic risk assessment

| Source of ADI | Source of ARfD |
|---------------|----------------|
| EC            |                |

#### Details – acute risk assessment/adults

**Details – chronic risk assessment**

**ADI (mg/kg bw per day):**
- Numeric value: 1

**ARfD (mg/kg bw):**
- Numeric value: 0.5

#### Year of evaluation

- Numeric value: 2020

#### Comments

- **Normal mode**

#### Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of pyriproxyfen (F) is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

### Results for children

| Commodity                        | MRL/input for RA | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|----------------------------------|------------------|---------------------|-----------------------|
| Peaches                          | 0.50/0.24        | 2.2                 | 0.6%                  |
| Tomatoes                         | 0.70/0.38        | 22                  | 0.6%                  |
| Sweet peppers/bell peppers       | 0.63/2.49        | 11                  | 0.5%                  |
| Plums                            | 0.30/0.2         | 8.4                 | 0.4%                  |
| Apricots                         | 0.43/0.24        | 8.4                 | 0.4%                  |
| Potatoes                         | 0.05/0.03        | 7.7                 | 0.4%                  |
| Cherries (sweet)                 | 1.55/0.62        | 7.6                 | 0.3%                  |
| Tea (crushed leaves of Camellia sinensis) | 154/6.2       | 6.2                 | 0.2%                  |
| Aubergines/egg plants            | 0.45/2.4         | 5.9                 | 0.2%                  |
| Mangoes                          | 0.05/0.03        | 3.9                 | 0.2%                  |
| Apple                            | 0.05/0.03        | 3.2                 | 0.1%                  |
| Carrots                          | 0.05/0.05        | 3.4                 | 0.1%                  |
| Oranges                          | 0.07/0.02        | 3.1                 | 0.1%                  |
| Cauliflowers                     | 0.05/0.05        | 2.9                 | 0.1%                  |
| Peaches/canned                   | 0.50/0.24        | 6.2                 | 0.3%                  |
| Pumpkins/boiled                  | 0.05/0.05        | 2.8                 | 0.2%                  |
| Witloofs/boiled                  | 0.05/0.05        | 4.4                 | 0.2%                  |
| Broccoli/boiled                  | 0.05/0.05        | 3.9                 | 0.2%                  |
| Cauliflowers/boiled              | 0.05/0.05        | 3.5                 | 0.2%                  |
| Potatoes/juice                   | 0.05/0.05        | 4.7                 | 0.2%                  |
| Brewers/tossed                   | 0.05/0.05        | 2.9                 | 0.1%                  |
| Peaches/juice                    | 0.50/0.16        | 2.7                 | 0.1%                  |
| Turnips/boiled                   | 0.05/0.05        | 2.5                 | 0.1%                  |
| Parsnips/boiled                  | 0.05/0.05        | 2.5                 | 0.1%                  |
| Celeriacs/boiled                 | 0.05/0.05        | 2.5                 | 0.1%                  |
| Carrots/boiled                   | 0.05/0.05        | 2.5                 | 0.1%                  |
| Broccoli/boiled                  | 0.05/0.05        | 2.5                 | 0.1%                  |
| Cauliflowers/boiled              | 0.05/0.05        | 2.9                 | 0.1%                  |
| Cauliflowers/boiled              | 0.05/0.05        | 3.4                 | 0.2%                  |
| Turnips/boiled                   | 0.05/0.05        | 2.9                 | 0.1%                  |

### Results for adults

| Commodity                        | MRL/input for RA | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|----------------------------------|------------------|---------------------|-----------------------|
| Peaches                          | 0.50/0.24        | 6.2                 | 0.2%                  |
| Tomatoes                         | 0.70/0.38        | 6.0                 | 0.6%                  |
| Sweet peppers/bell peppers       | 0.63/2.49        | 5.4                 | 0.5%                  |
| Plums                            | 0.30/0.2         | 4.6                 | 0.4%                  |
| Apricots                         | 0.43/0.24        | 4.5                 | 0.4%                  |
| Potatoes                         | 0.05/0.03        | 3.6                 | 0.4%                  |
| Cherries (sweet)                 | 0.43/0.24        | 2.6                 | 0.3%                  |
| Tea (crushed leaves of Camellia sinensis) | 154/6.2       | 2.1                 | 0.2%                  |
| Aubergines/egg plants            | 0.05/0.05        | 1.7                 | 0.1%                  |
| Mangoes                          | 0.05/0.05        | 1.5                 | 0.1%                  |
| Apple                            | 0.05/0.05        | 1.4                 | 0.1%                  |
| Carrots                          | 0.05/0.05        | 1.3                 | 0.1%                  |
| Oranges                          | 0.05/0.05        | 1.3                 | 0.1%                  |
| Cauliflowers                     | 0.05/0.05        | 1.2                 | 0.1%                  |
| Peaches/canned                   | 0.50/0.03        | 2.0                 | 0.1%                  |
| Pumpkins/boiled                  | 0.05/0.05        | 1.9                 | 0.1%                  |
| Witloofs/boiled                  | 0.05/0.05        | 1.7                 | 0.1%                  |
| Broccoli/boiled                  | 0.05/0.05        | 1.6                 | 0.1%                  |
| Peaches/juice                    | 0.05/0.05        | 1.5                 | 0.1%                  |
| Brewers/tossed                   | 0.05/0.05        | 1.1                 | 0.1%                  |
| Turnips/boiled                   | 0.05/0.05        | 0.91                | 0.1%                  |
| Parsnips/boiled                  | 0.05/0.05        | 0.87                | 0.1%                  |
| Celeriacs/boiled                 | 0.05/0.05        | 0.85                | 0.1%                  |
| Carrots/boiled                   | 0.05/0.05        | 0.82                | 0.1%                  |

### Conclusion:

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

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Review of the existing MRLs for pyriproxyfen
Appendix D – Input values for the exposure calculations

### D.1. Livestock dietary burden calculations

| Feed commodity                  | Median dietary burden | Maximum dietary burden |
|---------------------------------|-----------------------|------------------------|
|                                 | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment                |
| Cotton undelinted seed          | 0.01*                 | STMR                   | 0.01*                 | STMR                   |
| Apple pomace, wet               | 0.05                  | STMR × default PF (5)²(a) | 0.05                  | STMR × default PF (5)²(a) |
| Citrus dried pulp               | 0.74                  | STMR × PF (3.9)        | 0.74                  | STMR × PF (3.9)        |
| Cotton meal                     | 0.002                 | STMR × PF (0.2)        | 0.002                 | STMR × PF (0.2)        |

Risk assessment residue definition: pyriproxyfen

STMR: supervised trials median residue; PF: processing factor.
*: Indicates that the input value is proposed at the limit of quantification.
(a): In the absence of processing factors supported by data, the default processing factor of 5 was included in the calculation to consider the potential concentration of residues in these commodities.

### D.2. Consumer risk assessment without consideration of the existing CXLs

| Commodity                        | Chronic risk assessment | Acute risk assessment |
|----------------------------------|-------------------------|-----------------------|
|                                  | Input value (mg/kg)     | Comment               | Input value (mg/kg)     | Comment               |
|                                  |                         |                       |                        |                       |
| Citrus fruits                    | 0.01                    | STMR × PF (0.05) (tentative) | 0.024                  | HR × PF (0.05) (tentative) |
| Tree nuts, except macadamia     | 0.01*                   | STMR (tentative)      | 0.01*                  | HR (tentative)        |
| Macadamia                       | 0.05                    | EU MRL (tentative)    | 0.05                   | EU MRL (tentative)    |
| Apples                           | 0.01                    | STMR (tentative)      | 0.03                   | HR (tentative)        |
| Pome fruits, except apples       | 0.01*                   | STMR (tentative)      | 0.01*                  | HR (tentative)        |
| Apricots                         | 0.035                   | STMR (tentative)      | 0.24                   | HR (tentative)        |
| Cherries (sweet)                 | 0.26                    | STMR (tentative)      | 0.62                   | HR (tentative)        |
| Peaches                          | 0.16                    | STMR (tentative)      | 0.24                   | HR (tentative)        |
| Plums                            | 0.045                   | STMR (tentative)      | 0.20                   | HR (tentative)        |
| Grapes                           | 0.01*                   | STMR (tentative)      | 0.01*                  | HR (tentative)        |
| Strawberries                     | 0.05                    | STMR (tentative)      | 0.05                   | HR (tentative)        |
| Table olives                     | 0.01*                   | STMR (tentative)      | 0.01*                  | HR (tentative)        |
| Kaki/Japanese persimmons         | 0.01*                   | STMR (tentative)      | 0.01*                  | HR (tentative)        |
| Avocados                         | 0.05                    | EU MRL (tentative)    | 0.05                   | EU MRL (tentative)    |
| Mangoes                          | 0.05                    | EU MRL (tentative)    | 0.05                   | EU MRL (tentative)    |
| Granate apples/pomegranates      | 0.05                    | EU MRL (tentative)    | 0.05                   | EU MRL (tentative)    |
| Cherimoyas                       | 0.05                    | EU MRL (tentative)    | 0.05                   | EU MRL (tentative)    |
| Potatoes                         | 0.05                    | EU MRL (tentative)    | 0.05                   | EU MRL (tentative)    |
| Sweet potatoes                   | 0.05                    | EU MRL (tentative)    | 0.05                   | EU MRL (tentative)    |
| Yams                             | 0.05                    | EU MRL (tentative)    | 0.05                   | EU MRL (tentative)    |
| Other root and tuber vegetables, except sugar beets | 0.05 | EU MRL (tentative) | 0.05 | EU MRL (tentative) |
| Bulb vegetables                  | 0.05                    | EU MRL (tentative)    | 0.05                   | EU MRL (tentative)    |
| Tomatoes                         | 0.21                    | STMR (tentative)      | 0.38                   | HR (tentative)        |
| Sweet peppers/bell peppers       | 0.17                    | STMR (tentative)      | 0.28                   | HR (tentative)        |
### Review of the existing MRLs for pyriproxyfen

| Commodity                        | Chronic risk assessment | Acute risk assessment |
|----------------------------------|-------------------------|-----------------------|
|                                  | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Aubergines/eggplants             | 0.12                    | STMR (tentative)      | 0.20                | HR (tentative)        |
| Okra/lady's fingers              | 1                       | EU MRL (tentative)    | 1                   | EU MRL (tentative)    |
| Cucurbits with edible peel       | 0.01                    | STMR (tentative)      | 0.02                | HR (tentative)        |
| Melons, watermelons              | 0.006                   | STMR (tentative)      | 0.013               | HR (tentative)        |
| Pumpkins                         | 0.05                    | EU MRL (tentative)    | 0.05                | EU MRL (tentative)    |
| Flowering brassica               | 0.05                    | EU MRL (tentative)    | 0.05                | EU MRL (tentative)    |
| Head brassica                    | 0.05                    | EU MRL (tentative)    | 0.05                | EU MRL (tentative)    |
| Leafy brassica                   | 0.05                    | EU MRL (tentative)    | 0.05                | EU MRL (tentative)    |
| Kohlrabies                       | 0.05                    | EU MRL (tentative)    | 0.05                | EU MRL (tentative)    |
| Lettuces and salad plants        | 0.05                    | EU MRL (tentative)    | 0.05                | EU MRL (tentative)    |
| Spinaches and similar leaves     | 0.05                    | EU MRL (tentative)    | 0.05                | EU MRL (tentative)    |
| Watercress                       | 0.05                    | EU MRL (tentative)    | 0.05                | EU MRL (tentative)    |
| Witloofs/Belgian endives         | 0.05                    | EU MRL (tentative)    | 0.05                | EU MRL (tentative)    |
| Herbs and edible flowers         | 0.05                    | EU MRL (tentative)    | 0.05                | EU MRL (tentative)    |
| Legume vegetables                | 0.05                    | EU MRL (tentative)    | 0.05                | EU MRL (tentative)    |
| Stem vegetables                  | 0.05                    | EU MRL (tentative)    | 0.05                | EU MRL (tentative)    |
| Beans (dry)                      | 0.05                    | EU MRL (tentative)    | 0.05                | EU MRL (tentative)    |
| Soya beans                       | 0.05                    | EU MRL (tentative)    | 0.05                | EU MRL (tentative)    |
| Cottonseeds                      | 0.01*                   | STMR (tentative)      | 0.01*               | STMR (tentative)      |
| Olives for oil production        | 0.01*                   | STMR (tentative)      | 0.01*               | STMR (tentative)      |
| Swine muscle                     | 0.01*                   | 0.8 STMR muscle + 0.2 STMR fat | 0.01* | 0.8 HR muscle + 0.2 HR fat |
| Swine fat tissue                 | 0.01*                   | STMR                  | 0.01*               | HR                    |
| Swine liver                      | 0.01*                   | STMR                  | 0.01*               | HR                    |
| Swine kidney                     | 0.01*                   | STMR                  | 0.01*               | HR                    |
| Bovine and equine muscle         | 0.01*                   | STMR                  | 0.01*               | HR                    |
| Bovine equine fat tissue         | 0.01*                   | STMR                  | 0.01*               | HR                    |
| Bovine equine liver              | 0.01*                   | STMR                  | 0.01*               | HR                    |
| Bovine equine kidney             | 0.01*                   | STMR                  | 0.01*               | HR                    |
| Cattle and horse milk            | 0.01*                   | STMR                  | 0.01*               | STMR                  |

**Risk assessment residue definition 2:** sum of pyriproxyfen and 4’-OH-pyriproxyfen, expressed as pyriproxyfen

| Commodity                        | Input value (mg/kg)     | Comment               |
|----------------------------------|-------------------------|-----------------------|
| Tea                              | 4.06                    | STMR<sub>M0</sub> × CF (1.4) | 4.06 | STMR<sub>M0</sub> × CF (1.4) |

*STMR: supervised trials median residue; PF: processing factor; CF: conversion factor; HR: highest residue; MRL: maximum residue level.*

*Indicates that the input value is proposed at the limit of quantification.

### D.3. Consumer risk assessment with consideration of the existing CXLs

| Commodity                        | Chronic risk assessment | Acute risk assessment |
|----------------------------------|-------------------------|-----------------------|
|                                  | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Risk assessment residue definition 1: pyriproxyfen |
| Citrus fruits                    | 0.01                    | STMR × PF (0.05) (tentative) | 0.024 | HR × PF (0.05) (tentative) |
| Tree nuts, except macadamia      | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Macadamia                        | 0.05                    | EU MRL (tentative)    | 0.05                | EU MRL (tentative)    |
| Commodity               | Chronic risk assessment |          | Acute risk assessment |          |
|------------------------|-------------------------|----------|-----------------------|----------|
|                        | **Input value** (mg/kg) | **Comment** | **Input value** (mg/kg) | **Comment** |
| Apples                 | 0.01                    | STMR (tentative) | 0.03                    | HR (tentative) |
| Pome fruits, except apples | 0.01*                  | STMR (tentative) | 0.01*                   | HR (tentative) |
| Apricots               | 0.035                   | STMR (tentative) | 0.24                    | HR (tentative) |
| Cherries (sweet)       | 0.26                    | STMR (tentative) | 0.62                    | HR (tentative) |
| Peaches                | 0.16                    | STMR (tentative) | 0.24                    | HR (tentative) |
| Plums                  | 0.045                   | STMR (tentative) | 0.20                    | HR (tentative) |
| Grapes                 | 0.01*                   | STMR (tentative) | 0.01*                   | HR (tentative) |
| Strawberries           | 0.05                    | STMR (tentative) | 0.05                    | HR (tentative) |
| Table olives           | 0.01*                   | STMR (tentative) | 0.01*                   | HR (tentative) |
| Kumquats               | 0.12                    | STMR (CXL) (tentative) | 0.53                    | HR (CXL) (tentative) |
| Kaki/Japanese persimmons | 0.01*                  | STMR (tentative) | 0.01*                   | HR (tentative) |
| Avocados               | 0.05                    | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Mangoes                | 0.05                    | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Papaya                 | 0.04                    | STMR (CXL) (tentative) | 0.15                    | HR (CXL) (tentative) |
| Granate apples/pomegranates | 0.05              | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Cherimoyas             | 0.05                    | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Pineapples             | 0.01                    | STMR (CXL) (tentative) | 0.01                    | HR (CXL) (tentative) |
| Potatoes               | 0.05                    | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Sweet potatoes         | 0.05                    | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Yams                   | 0.05                    | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Other root and tuber vegetables, except sugar beets | 0.05 | EU MRL (tentative) | 0.05 | EU MRL (tentative) |
| Bulb vegetables        | 0.05                    | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Tomatoes               | 0.21                    | STMR (tentative) | 0.38                    | HR (tentative) |
| Sweet peppers/bell peppers | 0.17                  | STMR (tentative) | 0.28                    | HR (tentative) |
| Aubergines/eggplants   | 0.17                    | STMR (CXL) (tentative) | 0.28                    | HR (CXL) (tentative) |
| Okra/lady’s fingers    | 1                      | EU MRL (tentative) | 1                       | EU MRL (tentative) |
| Cucubirts with edible peel | 0.01                | STMR (CXL) (tentative) | 0.02                    | HR (CXL) (tentative) |
| Melons                 | 0.016                   | STMR (CXL) (tentative) | 0.035                   | HR (CXL) (tentative) |
| Pumpkins               | 0.05                    | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Watermelons            | 0.006                   | STMR (tentative) | 0.013                   | HR (tentative) |
| Flowering brassica     | 0.05                    | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Head brassica          | 0.05                    | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Leafy brassica         | 0.05                    | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Kohlrabies             | 0.05                    | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Lettuces and salad plants | 0.05                | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Spinaches and similar leaves | 0.05            | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Watercress             | 0.05                    | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Witloofs/Belgian endives | 0.05                 | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Herbs and edible flowers | 0.05                   | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Legume vegetables      | 0.05                    | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Stem vegetables        | 0.05                    | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Beans (dry)            | 0.05                    | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Soyabeans              | 0.05                    | EU MRL (tentative) | 0.05                    | EU MRL (tentative) |
| Cotton seeds           | 0.01*                   | STMR (CXL) (tentative) | 0.01                    | STMR (CXL) (tentative) |
## Commodity

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|-----------------------|
|                            | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Olives for oil production  | 0.01* STMR (tentative)  | 0.01* STMR (tentative) |
| Swine muscle               | 0.01* 0.8 STMR muscle + 0.2 STMR fat | 0.01* 0.8 HR muscle + 0.2 HR fat |
| Swine fat tissue           | 0.01* STMR              | 0.01* HR              |
| Swine liver                | 0.01* STMR              | 0.01* HR              |
| Swine kidney               | 0.01* STMR              | 0.01* HR              |
| Bovine and equine muscle   | 0.01* STMR              | 0.01* HR              |
| Bovine equine fat tissue   | 0.01* STMR              | 0.01* HR              |
| Bovine equine liver        | 0.01* STMR              | 0.01* HR              |
| Bovine equine kidney       | 0.01* STMR              | 0.01* HR              |
| Goat muscle                | 0.01* 0.8 STMR (CXL) muscle + 0.2 STMR (CXL) fat | 0.01* 0.8 HR (CXL) muscle + 0.2 HR (CXL) fat |
| Goat fat                   | 0.01* STMR (CXL)        | 0.01* HR (CXL)        |
| Goat liver                 | 0.01* STMR (CXL)        | 0.01* HR (CXL)        |
| Goat kidney                | 0.01* STMR (CXL)        | 0.01* HR (CXL)        |
| Cattle and horse milk      | 0.01* STMR              | 0.01* STMR            |

**Risk assessment residue definition 2**: sum of pyriproxyfen and 4’-OH-pyriproxyfen, expressed as pyriproxyfen.

| Commodity | Input value (mg/kg) | Comment |
|-----------|---------------------|---------|
| Tea       | 4.06 STMR$_{std}$ × CF (1.4) | 4.06 STMR$_{std}$ × CF (1.4) |

STMR: supervised trials median residue; PF: processing factor; HR: highest residue; MRL: maximum residue level; CXL: codex maximum residue limit.

*: Indicates that the input value is proposed at the limit of quantification.
Appendix E – Decision tree for deriving MRL recommendations

1. **Evaluation of the GAPs and available residues data at EU level**
   - GAP or DB ≤ 0.1 mg/kg QM in EU?
     - Yes
     - Is RD-RA derived for this commodity?
       - Yes
         - MRL fully supported by data?
           - Yes
             - MRL And RA derived in section 3?
               - Yes
               - MRL fully supported by data?
                 - No
                 - No
   - No
     - No
     - No

2. **Consumer risk assessment for GAPs evaluated at EU level - EU scenarios**
   - Not considered for the RA
   - Not considered for the RA
   - Current EU MRL is included in the RA.
   - Tentative median/highest values are included in the RA.
     - Yes
     - Risk identified?
       - Yes
       - Fail-back MRL available?
         - Yes
         - MRL is recommended.
         - No
         - No
       - No
       - No
   - No
   - No
   - No
   - Risk identified?
     - Yes
     - Fail-back MRL available?
       - Yes
       - MRL is recommended.
       - No
       - No
   - No
   - No

3. **Recommendations resulting from EU authorisations and import tolerances**
   - (A) Specific LOQ or default MRL?
   - (B) Specific LOQ or default MRL?
   - (C) Specific LOQ or default MRL?
   - (D) Maintain current EU MRL?
   - (E) Specific LOQ or default MRL?
   - (F) Establish tentative EU MRL?
   - (G) Specific LOQ or default MRL?
   - (H) MRL is recommended.

Comparison with CXLs
Comparison of the EU recommendation with the existing CXL

- CXL available? (Yes/No)
  - RD comparable? (Yes/No)
    - CXL higher? (Yes/No)
      - CXL available?
        - RD comparable?
          - CXL higher?
            - Yes: Maintain EU recommendation indicating CXL is not safe for consumer.
            - No: Maintain EU recommendation indicating that CXL is covered.
        - No: Maintain EU recommendation indicating CXL is not compatible.
  - No: Maintain current CXL or EU recommendation.

Consumer risk assessment with consideration of the existing CXL

- CXL supported by data? (Yes/No)
  - Yes: Codex median/highest residues are included in the RA.
  - No: Input values for the RA remain unchanged.

Recommendations with consideration of the existing CXL

- Maintain EU recommendation indicating that no CXL is available.
- Maintain EU recommendation indicating CXL is not compatible.
- Maintain EU recommendation indicating that CXL is covered.
- Maintain current CXL or EU recommendation.
- Maintain EU recommendation; higher CXL is not safe for consumer.
- Maintain EU recommendation; higher CXL is not safe for consumer.
### Appendix F – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|----------------------|----------------------------------------|-----------------------|
| Pyriproxyfen         | 4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether  
                      CC(COc1ccc(Oc2ccccc2)cc1)Coc1ccccn1  
                      NHDHVHZCFYRSB-UHFFFAOYSA-N  
|                      |                                        |                       |
| PYPAC                | 2-[[pyridin-2-yl]oxy]propanoic acid  
                      CC(Oc1ccccn1)C(=O)O  
                      INLOHUIHTHYO0-UHFFFAOYSA-N  
|                      |                                        |                       |
| 4′-OH-pyriproxyfen   | 4-(4-[[pyridin-2-yl]oxy]propoxy)phenoxyphenyl  
                      | i-D-glucopyranosiduronic acid  
                      | CC(Oc1ccccn1)COC1cccc(cc1)Oc1cccc(cc1)O[C@@H]1O[C@@H]([C@H]([O][C@H])([O][C@H])1O)C(=O)O  
                      | KADFZEVUCBZCAR-LEMJXWAQSA-N  
| glucuronide          |                                        |                       |
| 2,5-OH-PY            | pyridine-2,5-diol  
                      | Oc1cnc(O)ccc1  
                      | CHGPEDOMXOLANF-UHFFFAOYSA-N  
|                      |                                        |                       |
| 4′-OH-PYR            | 4-(4-(2-(pyridin-2-yloxy)propoxy)phenoxy)phenol  
                      | Oc1cccc(cc1)Oc1cccc(cc1)OCC(C)Oc1ccccn1  
                      | LRAGDWMWQLALS-UHFFFAOYSA-N  
|                      |                                        |                       |
| 4′-OH-PYR sulfate     | 4-(4-(2-(pyridin-2-yloxy)propoxy)phenoxy)phenyl  
                      | hydrogen sulfate  
                      | O=S(=O)(O)Oc1cccc(cc1)Oc1cccc(cc1)OCC(C)Oc1ccccn1  
                      | HDDYYMKTLYSP-UHFFFAOYSA-N  
| conjugates           |                                        |                       |
| 5′′-OH-PYR           | 6-[[1-(4-phenoxyphenoxy)propan-2-yl]oxy]pyridin-3-ol  
                      | KQTSOUNGTZTUPO-UHFFFAOYSA-N  
                      | CC(COC1cccc(Oc2ccccc2)cc1)Coc1ccccc1n1  
| POPA                 | 1-(4-phenoxyphenoxy)propan-2-ol  
                      | CC(O)COC1cccc(cc1)Oc1ccccc1  
                      | RVAHBQJLFMRF-E-UHFFFAOYSA-N  

| Code/trivial name<sup>(a)</sup> | IUPAC name/SIMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|---------------------------------|------------------|
| PYPA                          | 2-(pyridin-2-yloxy)propan-1-ol  | ![Structural formula](image1) |
|                               | CC(CO)Oc1ccccc1                 |                  |
|                               | XYMSWYULCWKBKHX-UHFFFFAOYSA-N   |                  |
| POP sulfate conjugates        | 4-phenoxyphenyl hydrogen sulfat | ![Structural formula](image2) |
|                               | OS(=O)(=O)Oc1cccc(cc1)Oc1ccccc1|                  |
|                               | BGBLXCAVHFWLJR-UHFFFFAOYSA-N   |                  |
| 2-OH-PY                       | pyridin-2-ol                    | ![Structural formula](image3) |
|                               | Oc1ccccc1                       |                  |
|                               | UBQKCCHYAOITMY-UHFFFFAOYSA-N   |                  |
| DPH-PYR                       | 4-(2-(pyridin-2-yloxy)propoxy)phenol | ![Structural formula](image4) |
|                               | Oc1ccc(cc1)OCC(C)Oc1ccccc1     |                  |
|                               | OEEXMCPZWLJVE-UHFFFFAOYSA-N   |                  |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123,232, 07 July 2021).
(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123,835, 28 August 2021).