Review of the existing maximum residue levels for triclopyr 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 triclopyr. To assess the occurrence of triclopyr residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC as well as the authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and all MRL proposals derived by EFSA still require further consideration by risk managers.

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Keywords: triclopyr, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, pyridine, herbicide, 3,5,6-trichloropyridinol (3,5,6-TCP)

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Review of the existing MRLs for triclopyr

Summary

Triclopyr was included in Annex I to Directive 91/414/EEC on 1 June 2007 by Commission Directive 2006/74/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. As triclopyr was approved before the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(2) of the aforementioned regulation. To collect the relevant pesticide residues data, EFSA asked Ireland, the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to Member States. A request for additional information was addressed to Member States in the framework of a completeness check period, which was initiated by EFSA on 26 November 2015 and finalised on 26 January 2016. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 13 April 2016.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the RMS and Member States, EFSA prepared in October 2016 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 21 November 2016 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of triclopyr was investigated in fruit crops (apples), root crops (radish) and grass crops (ryegrass). Triclopyr is the only significant residue observed in the three crop groups and it can be enforced with a limit of quantification (LOQ) of 0.01 mg/kg in high water content, high acid content, high oil content and dry commodities. Therefore, EFSA proposes to define the residue for enforcement and risk assessment as triclopyr in all commodities. A metabolism study for rotational crops indicated that residues uptake could only occur in cereals straw but, considering that rice is the only crop assessed in this review that could be rotated with cereals and that this practice is unusual, this was not deemed as a major concern.

The available residue trials were considered sufficient to derive tentative MRL proposals as well as risk assessment values for all commodities under evaluation, except for grapefruits, oranges, lemons and mandarins where residue trials compliant with the good agricultural practices (GAPs) were not available. The MRL proposals were tentative because of the data gaps concerning the storage stability of residues and/or because of the limited data sets of residue trials. As the chronic exposure does not exceed 10% of the acceptable daily intake (ADI) and since residues of triclopyr exceeding 0.1 mg/kg are not expected in the main commodities that could be subject to processing, investigation on the effect of processing on the nature and magnitude of the residue was not required.

The metabolism of triclopyr in animals was sufficiently investigated in ruminants and poultry. The available studies indicated that both triclopyr and its metabolite 3,5,6-trichloropyridinol (referred to as 3,5,6-TCP) should be considered for risk assessment purposes. However, considering that metabolite 3,5,6-TCP may also be generated from the use of two other active substances, chlorpyrifos and chlorpyrifos-methyl, and since different toxicological reference values were derived for triclopyr and 3,5,6-TCP, two separate residue definitions for risk assessment were derived. The first residue definition (specific to triclopyr) includes the parent compound only; triclopyr can be enforced in animal commodities with a LOQ of 0.01 mg/kg. The second residue definition is the sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP. Since this compound is not a specific metabolite of triclopyr, the first residue definition remains the most relevant for enforcement purpose but, as risk managers may consider that enforcement of metabolite 3,5,6-TCP is also necessary, an optional separate list of MRLs in livestock was also derived for the second residue definition. An analytical method was validated for analysis of 3,5,6-TCP and its conjugates with a LOQ of 0.01 mg/kg in animal commodities, but the efficiency of this hydrolysis step to release the conjugates has not been demonstrated.

Based on the available feeding studies, MRL and risk assessment values were derived for both proposed residue definitions, in dairy ruminants, meat ruminants and pigs. MRLs in poultry products are not required because poultry is not expected to be exposed to significant levels of triclopyr residues. It is highlighted that the final list of MRLs for the sum of 3,5,6-TCP and its conjugates also accommodates the use of chlorpyrifos and chlorpyrifos-methyl, which are the two other possible sources of 3,5,6-TCP in animal commodities. Based on a comparison of the respective dietary burdens for these substances, it was observed that the levels of 3,5,6-TCP in poultry are mainly driven by the...
dietary intake of chlorpyrifos-methyl. In ruminants (dairy and meat) and in pigs, however, the livestock dietary burden of triclopyr was identified as the main driver for the occurrence of 3,5,6-TCP. Therefore, the final MRLs for the sum of 3,5,6-TCP and its conjugates were derived from the respective data of these two substances.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For citrus fruits, where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 4.4% of the ADI (DE child) and the highest acute exposure amounted to 4.4% of the acute reference dose (ARfD) (oranges).

As different toxicological reference values were derived for the metabolite 3,5,6-TCP, a separate consumer risk assessment for 3,5,6-TCP and its conjugates was performed. In order to carry out a comprehensive consumer exposure calculation for metabolite 3,5,6-TCP, EFSA took into account residues arising from chlorpyrifos-methyl, chlorpyrifos and triclopyr. These chronic and acute exposure calculations were also performed using revision 2 of the EFSA PRIMo and the exposures calculated were compared with the toxicological reference values derived for the metabolite 3,5,6-TCP. The highest chronic exposure was calculated for German children, representing 6.0% of the ADI, and the highest acute exposure was calculated for bananas, representing 6.5% of the ARfD. Major uncertainties remain due to the data gaps identified for the metabolite 3,5,6-TCP but, this indicative exposure calculation did not indicate a risk to consumers and considering the large margin of safety, there are indications that metabolite 3,5,6-TCP is not of concern with regard to the use of triclopyr, chlorpyrifos and chlorpyrifos-methyl.
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Background

Regulation (EC) No 396/2005\(^1\) (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(2) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide by 1 September 2009, a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC\(^2\) before 2 September 2008. As triclopyr was included in Annex I to Council Directive 91/414/EEC on 1 June 2007 by means of Commission Directive 2006/74/EC,\(^3\) and has been deemed to be approved under Regulation (EC) No 1107/2009,\(^4\) in accordance with Commission Implementing Regulation (EU) No 540/2011,\(^5\) as amended by Commission Implementing Regulation (EU) No 541/2011,\(^6\) EFSA initiated the review of all existing MRLs for that active substance. As triclopyr shares a common metabolite with chlorpyrifos and chlorpyrifos-methyl, the review of MRLs for these three active substances has been carried out in parallel. For reasons of clarity, the outcome of the reviews was reported in three separate reasoned opinions.

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

Ireland, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for triclopyr and to prepare supporting evaluation reports (Ireland, 2009, 2010). The PROFile and the supporting evaluation reports were submitted to EFSA on 25 January 2010 and made available to Member States. A request for additional information was addressed to Member States in the framework of a completeness check period which was initiated by EFSA on 26 November 2015 and finalised on 26 January 2016. Additional evaluation reports were submitted by Belgium, France, Germany, Italy, Spain, the Netherlands and the European Union Reference Laboratories for Pesticide Residues (Netherlands, 2015, Belgium 2016, EURL 2016, France 2016, Germany 2016, Italy 2016, Spain 2016) and, after having considered all the information provided by the RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 13 April 2016. Further clarifications were sought from Member States via a written procedure in May 2016.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by Member States, EFSA prepared in October 2016 a draft reasoned

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1 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1 – 16.
2 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, OJ L 230, 19.8.1991, p. 1 – 32. Repealed by Regulation (EC) No 1107/2009.
3 Commission Directive 2006/74/EC of 21 August 2006 amending Council Directive 91/414/EEC to include dichlorprop-P, metconazole, pyrimethanil and triclopyr as active substances, OJ L 235, 30.8.2006, p. 17 – 22.
4 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1 – 50.
5 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1 – 186.
6 Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187 – 188.
opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 21 November 2016 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation reports submitted by Ireland (Ireland, 2009, 2010) and the evaluation reports submitted by Member States Belgium, France, Germany, Italy, Spain, the Netherlands and the European Union Reference Laboratories for Pesticide Residues (Netherlands, 2015, Belgium 2016, EURL 2016, France 2016, Germany 2016, Italy 2016, Spain 2016) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2016) and the Member States consultation report (EFSA, 2017a). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also, the chronic and acute exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) and the PROFile are key supporting documents and made publicly available.

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

Triclopyr is the ISO common name for 3,5,6-trichloro-2-pyridyloxyacetic acid (IUPAC).

Triclopyr belongs to the group of pyridine compounds which are used as herbicides. Triclopyr is taken up via leaves and roots and induces an epinastic response leading to chlorosis, cessation of normal growth and death of the target plant.

The chemical structure of the active substance and its main metabolites are reported in Appendix E.

Triclopyr was evaluated in the framework of Directive 91/414/EEC with Ireland designated as RMS. The representative uses supported for the peer review process comprise broadcast spraying or spot treatment to control a wide spectrum of broad-leaved weeds in pasture, forestry, grassland, railways and set-a-side. Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2006/74/EC, which entered into force on 1 June 2007. According to Regulation (EU) No 540/2011, triclopyr is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as herbicide only.

The EU MRLs for triclopyr are established in Annex IIIA of Regulation (EC) No 396/2005 and codex maximum residue limits (CXLs) for this active substance are not available. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

| Procedure                  | Legal implementation                  | Remarks                          |
|----------------------------|--------------------------------------|----------------------------------|
| MRL application (EFSA, 2009) | Commission Regulation (EU) No 750/2010(a) | Various commodities of animal origin |

(a): Commission Regulation (EU) No 750/2010 of 7 July 2010 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for certain pesticides in or on certain products. OJ L 220, 21.8.2010, p. 1–56.

For the purpose of this MRL review, the critical uses of triclopyr currently authorised within the EU, have been collected by the RMS and reported in the PROFile. The additional Good Agricultural Practices (GAPs) reported by Member States during the completeness check were also considered. With regard to the critical GAP currently authorised on citrus fruits, reference is made to the Member States consultation report (EFSA, 2017a) where Spain clarified the status of its authorisations for these crops: the current authorisation is a foliar spraying performed after the physiological fruit drop while
the assessment of the post-harvest drenching is still ongoing. Therefore, the post-harvest drenching was not considered in this review. The details of the authorised GAPs for triclopyr are given in Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

**Assessment**

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation reports accompanying the PROFile (Ireland, 2009, 2010), the draft assessment report (DAR) and its final addendum prepared under Council Directive 91/414/EEC (Ireland, 2003, 2005), the conclusion on the peer review of the pesticide risk assessment of the active substance triclopyr (EFSA, 2006), the previous reasoned opinion on triclopyr (EFSA, 2009), as well as the evaluation reports submitted during the completeness check (Netherlands, 2015, Belgium 2016, EURL 2016, France 2016, Germany 2016, Italy 2016 and Spain 2016). 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–g, 2000, 2010a,b, 2016; OECD, 2011).

Furthermore, as triclopyr shares a common metabolite with chlorpyrifos and chlorpyrifos-methyl, the review of MRLs for these three active substances has been carried out in parallel and data reported in the framework of chlorpyrifos and chlorpyrifos-methyl may have been relied upon (EFSA, 2017b,c). Where applicable, reference to the reasoned opinions for chlorpyrifos or chlorpyrifos-methyl is made.

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 triclopyr was investigated in fruit crops (apples), root crops (radish) and grass crops (ryegrass) (Ireland, 2003). After foliar or soil application on apples, radioactive residues were very low in fruits (< 0.02 mg eq/kg) and the main residue was the parent compound, free and conjugated. Triclopyr was also the predominant compound in radish root, accounting for 75% of the total radioactive residues (TRR) (0.27 mg eq/kg) after foliar application and 64% of the TRR (3.2 mg eq/kg) after soil application. The polar metabolites observed in these studies were easily hydrolysed to triclopyr, and in lower amounts, to the metabolite 3,5,6-trichloropyridinol (referred to as 3,5,6-TCP) (0.13 mg eq/kg; < 3% TRR). In grass, the only residues identified after hydrolysis and enzymatic treatment was the parent triclopyr.

Based on these studies, EFSA concludes that the metabolism of triclopyr under preharvest treatments (foliar and soil application) is sufficiently elucidated and similar in the three investigated crop groups. Triclopyr is the major compound in all investigated commodities and is mainly present as a free acid. The only identified metabolite was 3,5,6-TCP, but this compound remained always below 10% of the TRR.

1.1.2. Nature of residues in rotational crops

According to the soil degradation studies evaluated in the framework of the peer review, DT$_{90}$ values of triclopyr and its relevant soil metabolite (3,5,6-TCP) range between 63 and 319 days which may exceed the trigger value of 100 days (EFSA, 2006, European Commission, 2006). Most of the crops evaluated in the framework of this MRL review are not expected to be grown in rotation. Orchard trees (apples, pears, apricots and peaches) and grass pastures are perennial crops and post-harvest GAPs are not of concern. Fields used for rice production can be rotated to other crops (mainly cereals) but this practice remains exceptional.

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7 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
A rotational crop study was evaluated during the peer review (Ireland, 2003). Turnips, lettuce, wheat and green beans were grown on a soil previously treated with triclopyr (0.56 kg a.s./ha), with the plant back interval of 36 days after treatment (DAT). Radioactivity was below 0.01 mg eq/kg in all investigated crops other than wheat straw where total radioactivity was 0.23 mg eq/kg. Thus, residues uptake is not expected in root crops, leafy crops, pulses and cereal grain. In cereal straw, the radioactivity consisted of very polar compounds that could not be hydrolysed to triclopyr or its known metabolites. However, the possible uptake of triclopyr residues in cereal straw is deemed of low concern considering that MRLs are not set for feed item, that the livestock dietary burden is mainly driven by grass (see also Section 2) and that the rotation of rice with other cereals is rather unusual. Thus, there is no need to further investigate residues in field rotational crops.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of residues was not investigated. However, the chronic exposure does not exceed 10% of the ADI (see also Section 3). Moreover, triclopyr residues observed in apples, pears, apricots and peaches are below 0.1 mg/kg. Processing studies are not applicable for the use on grass pasture since this commodity is not subject to hydrolysis before being fed to animals. With regard to the use in rice, only one trial result (0.21 mg/kg) out of 14 is above 0.1 mg/kg. Also, considering the outcome of the risk assessment, there is currently no need to investigate the effect of industrial and/or household processing.

1.1.4. Methods of analysis in plants

During the completeness check, an analytical method using high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) was reported by France (2016). This method is fully validated for the determination of triclopyr in commodities with high water content, high acid content and high oil content as well as in dry commodities, with a limit of quantification (LOQ) of 0.01 mg/kg. It is highlighted that this method used a radiolabelled internal standard. In addition, the EURLs also reported validation data for the QuEChERS methods also using HPLC–MS/MS. This method is applicable for the determination of triclopyr high water content, high acid content and dry commodities, also with a LOQ of 0.01 mg/kg (EURL, 2016).

Hence, it is concluded that triclopyr can be enforced with a LOQ of 0.01 mg/kg in high water content, high acid content, high oil content and dry commodities.

1.1.5. Stability of residues in plants

In the framework of the peer review, storage stability of triclopyr was demonstrated for a period of 48 months at –20°C in commodities with high water content (Ireland, 2003). However, concerns were identified regarding the validation of the method of analysis used in the study (EFSA, 2006). Since these data were not provided to EFSA, it is still considered as a data gap in the framework of the present review, and results of this study are considered on tentative basis only.

In addition, studies investigating the storage stability of triclopyr in dry and acidic commodities are not available. As authorisations were reported for commodities that belong to these categories (rice grain, citrus fruits), additional storage stability studies covering the storage conditions of the corresponding trial samples are required.

1.1.6. Proposed residue definitions

Triclopyr is the main residue observed in the three crop groups investigated. The metabolite 3,5,6-TCP was quantified in very low proportions in radish roots. It is also a soil metabolite but is very unlikely to be present in rotational crops, provided that triclopyr is applied in accordance with the authorised GAPs. Therefore, in line with the previous assessments (EFSA, 2006, 2009), EFSA proposes to define the residue for enforcement and risk assessment as triclopyr in all commodities.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of triclopyr residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation reports (Ireland, 2009, 2010), including residue
trials evaluated in the framework of the peer review (Ireland, 2003) or in the framework of a previous MRL application (EFSA, 2009), and additional data submitted during the completeness check (France, 2016; Germany, 2016; Spain, 2016). For many of the residue trials considered in this framework, the storage conditions were reported. However, as the storage stability was not investigated in dry and high acid content commodities and since it still needs to be confirmed for high water content commodities (see also Section 1.1.5), EFSA was not able to conclude on the full validity of the residue trials reported.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2016).

Residue trials are not available to support the authorisations on grapefruits, oranges, lemons and mandarins; only underdosed trials were reported by Spain (2016). Therefore, MRL or risk assessment values for these crops could not be derived by EFSA and the following data gaps were identified:

- Eight trials on oranges and/or mandarins, compliant with the southern outdoor GAP are required.
- For apricots, the number of residue trials reported is not compliant with the data requirements. Hence, the following data gap was identified by EFSA:
  - According to the current guidelines, a minimum of four trials performed on apricots are needed to derive a MRL for this crop. In the framework of the present review, only three trials compliant with GAP and one trial performed at a more critical GAP are available; these trials were all performed on peaches. Although all these trials show residue levels below the LOQ, EFSA is of the opinion that four additional trials on apricots and compliant with the southern outdoor GAP are still required.

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

- Apples and pears: The number of residue trials supporting the northern GAP on apples/pears (three trials) and the southern GAP on pears (four trials) is not compliant with the data requirements for these crops. However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and a no-residue situation is expected. Further residue trials are therefore not required.
- Peaches: Five trials on peach and three trials on apricots were reported. These trials were all performed with an overdosed rate compared to the GAP but four of these trials were performed with much longer preharvest interval (PHI) (from 67 to 135 days) compared to the others (PHI from 7 to 48 days). According to the GAP reported by Spain, triclopyr is applied at BBCH 71-73 but no PHI is defined. As the substance is applied during the development of the fruits, the definition of the PHI is in principle still needed. It is acknowledged that the period between BBCH 71-73 and fruit maturity may vary but it should still be possible to define the worst-case situation (i.e. the shorter PHI). This is considered as a minor deficiency. To cover this uncertainty, EFSA relied on the worst-case data set, which are the four trials performed with PHI 7–48 days. These trials all show residues below the LOQ. This result is consistent with the observation made in the metabolism studies performed with apples (see Section 1.1.1). Therefore, a no-residue situation is highly expected in peaches and further residue trials are not required.
- Grass: The southern trials were performed with a higher application rate (0.72–1.2 kg a.s./ha) compared to the critical southern GAP reported by France (application rate: 0.52 kg a.s./ha). However, the French proposal to scale the residue results by applying the proportionality principle was considered acceptable (France, 2016). Further residue trials are therefore not required.

1.2.2. Magnitude of residues in rotational crops

Significant residues in rotational crops are not expected for food commodities (see also Section 1.1.2). Field rotational crop studies are not required.
1.2.3. Magnitude of residues in processed commodities

There is currently no need to investigate the effect of industrial and/or household processing (see also Section 1.1.3).

1.2.4. Proposed MRLs

Consequently, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for grapefruits, oranges, lemons and mandarins where residue trials compliant with GAP were not available. All MRL proposals derived for plant commodities are tentative due to the data gaps concerning the storage stability of residues and/or missing residue trials. Tentative MRLs were also derived for grass in view of the future need to set MRLs in feed items.

2. Residues in livestock

Triclopyr is authorised for use on citrus fruits, apples and grass which might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock using the agreed European methodology (European Commission, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarised in Appendix C.1. The dietary burden values calculated for ruminants (dairy and meat) and for pigs were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in these groups of livestock.

It is highlighted that residue data were not available to support the GAP reported on citrus fruits (foliar treatment after physiological fruit drop). The animal intake of triclopyr residues via these commodities has therefore not been assessed. However, this is not expected to have a major impact on the outcome of the dietary burden considering the overwhelming contribution of grass.

2.1. Nature of residues and methods of analysis in livestock

In the framework of the peer review, the metabolism of triclopyr in livestock was investigated in lactating goats and in laying hens (Ireland, 2003). In the study performed with goats, the TRR accounted for 0.30–0.34 mg eq/kg in liver, kidney and fat. It mainly consisted of 3,5,6-TCP (91% TRR – 0.24 mg eq/kg) in liver, while both triclopyr (34–59% TRR) and 3,5,6-TCP (17–49% TRR) were significant in kidney and fat. Radioactivity was lower in muscle and the metabolite 3,5,6-TCP was the only component identified (0.02 mg eq/kg). In milk, the maximum TRR was at or below 0.21 mg eq/kg in each of the collected samples. Low concentrations of 3,5,6-TCP were found (≤ 0.004 mg eq/kg), while triclopyr represented the major fraction (≤ 0.162 mg eq/kg). Small quantities of polar conjugates were also found in milk (≤ 0.032 mg/kg). In hens, triclopyr was found to be the major residue identified, accounting for up to 90% of the total residue in liver and kidney. In the other tissues, residues were too low for identification.

Based on these studies, it is clear that triclopyr and 3,5,6-TCP (also including its conjugates) are both relevant in livestock commodities. No other metabolite was present in significant amounts.

During the completeness check, an analytical method using HPLC–MS/MS was reported by France (2016). This method is fully validated for the determination of triclopyr in all animal tissues, milk and eggs, with a LOQ of 0.01 mg/kg. This method was also validated for analysis of 3,5,6-TCP with a LOQ of 0.01 mg/kg. It is highlighted that this method used a radiolabelled internal standard. It is noted that, as metabolite 3,5,6-TCP is easily conjugated in livestock tissues, its analysis involves a hydrolysis step. However, the efficiency of this hydrolysis has not been validated.

The storage stability of triclopyr was demonstrated for a period of 12 months at −20°C in muscle, fat, liver, kidney and milk, and for a period of 30 months in eggs (Ireland, 2003). The storage stability of the metabolite 3,5,6-TCP was investigated in the framework of an MRL application for chlorpyrifos-methyl (EFSA, 2011). This metabolite was shown to be stable in beef muscle, liver, kidney and fat matrices for a period of 15 months and in milk and cream for 12 months, when stored deep frozen at −20°C. This study is also considered adequate to address storage stability of 3,5,6-TCP conjugates because a possible decline of such conjugates would only be expected to release 3,5,6-TCP.

Hence both triclopyr and 3,5,6-TCP should be considered for risk assessment purposes. However, considering that metabolite 3,5,6-TCP may also be generated from the use of two other active substances, chlorpyrifos and chlorpyrifos-methyl, and different toxicological reference values were derived for triclopyr and 3,5,6-TCP (EFSA, 2014), two separate risk assessments should be carried out,
noting that the assessment of 3,5,6-TCP and its conjugates should also take into consideration the use of chlorpyrifos and chlorpyrifos-methyl.

For monitoring purposes, since 3,5,6-TCP is not specific to triclopyr, the parent compound remains the most relevant marker compound but, if risk managers consider that enforcement of the metabolite 3,5,6-TCP is also necessary, an optional separate list of MRLs may be derived when combining the assessments of chlorpyrifos, chlorpyrifos-methyl and triclopyr at a later stage. Both residue definitions are not fat soluble.

2.2. Magnitude of residues in livestock

In the framework of the peer review, two non-Good Laboratory Practice (GLP) feeding studies performed with dairy and meat ruminants were assessed (Ireland, 2003). Although these studies are not GLP compliant, they should be considered because they were conducted prior to GLP implementation.

In the first study, triclopyr was administered to lactating cows using five different dosing levels ranging from 0.36 to 36.4 mg/kg body weight (bw) per day. In the second study, calves were dosed with triclopyr at dose levels ranging from 0.3 to 31 mg/kg bw.

The study performed on dairy cow was used to derive MRL and risk assessment values in milk. The studies performed on dairy cow and calves could both be used to derive MRLs and risk assessment values in tissues of ruminants. However, as the study performed on calves results in higher residue levels, this study was preferred in order to ensure a more conservative calculation. This is also in line with the previous assessment of EFSA (2009). In both studies, samples of milk and tissues were separately analysed for triclopyr and its metabolite 3,5,6-TCP (free and conjugated). These samples were stored in compliance with the demonstrated storage conditions. A decline of residues during storage of the samples is therefore not expected.

Hence, the available studies were considered sufficient to derive MRL and risk assessment values (for both proposed residue definitions) for dairy ruminants, meat ruminants and pigs, resulting from the use of triclopyr. These proposals were derived in compliance with the latest recommendations on this matter (FAO, 2009). MRLs in poultry products are not required because poultry is not expected to be exposed to significant levels of triclopyr residues.

3. Consumer risk assessment

As different toxicological reference values were derived for triclopyr and for the metabolite 3,5,6-TCP, EFSA performed separate consumer risk assessments for triclopyr (resulting from the use of triclopyr only) and for 3,5,6-TCP and its conjugates (resulting from the use of chlorpyrifos, chlorpyrifos-methyl and triclopyr).

3.1. Consumer risk assessment for triclopyr

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix D. 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 citrus fruits, where data were not available to derive a 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 C.2.

The calculated exposure values were compared with the toxicological reference values for triclopyr, derived by EFSA (2006) under Directive 91/414/EEC. The highest chronic exposure was calculated for German children, representing 4.4% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for oranges, representing 4.4% of the acute reference dose (ARfD). Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumers.

3.2. Consumer risk assessment for the metabolite 3,5,6-trichloropyridinol

Metabolite 3,5,6-TCP is not specific to triclopyr as it is also a major metabolism product of two other active substances: chlorpyrifos and chlorpyrifos-methyl. Hence, in order to carry out a
comprehensive consumer exposure calculation for metabolite 3,5,6-TCP, EFSA took into account residues arising from triclopyr, chlorpyrifos and chlorpyrifos-methyl. In plant commodities, this metabolite is mainly expected to occur following the use of chlorpyrifos or chlorpyrifos-methyl. For these two compounds, the consumer risk assessment of the parent compounds already revealed a possible risk to consumers which could not be further refined by EFSA, and several fall-back GAPs were suggested by EFSA (EFSA, 2017b,c). Hence, for each plant commodity, the input value for 3,5,6-TCP is based on the highest residue level observed following the use of either chlorpyrifos or chlorpyrifos-methyl, assuming that the fall-back GAPs suggested by EFSA are implemented and that the two active substances are not used together on the same crop. Nevertheless, for several plant commodities assessed in the reasoned opinions of chlorpyrifos and chlorpyrifos-methyl, data were not available to derive MRL and risk assessment values for metabolite 3,5,6-TCP. As there are no MRLs currently established for this metabolite, it was not possible to consider these commodities in the present risk assessment. For citrus fruits and bananas, the relevant peeling factor was applied.

For animal commodities, it appears that levels of 3,5,6-TCP in dairy and meat ruminants as well as in pigs are mainly driven by the dietary intake of triclopyr (see Table 2). Therefore, risk assessment values derived in Section 3.2 of the present reasoned opinion were used as input values for the present exposure calculation in ruminants and swine. In poultry, however, the livestock dietary burden of chlorpyrifos-methyl was identified as the main driver for the occurrence of 3,5,6-TCP (see Table 2). Therefore, risk assessment values for 3,5,6-TCP were derived from the reasoned opinion of chlorpyrifos-methyl (EFSA, 2017c).

Table 2: Overview of dietary burden calculations for metabolite 3,5,6-TCP\(^{(e),(f)}\)

| Maximum dietary burden (mg/kg bw per day) | Triclopyr\(^{(a)}\) | Chlorpyrifos-methyl\(^{(b)}\) | Chlorpyrifos\(^{(c)}\) |
|----------------------------------------|---------------------|--------------------------|---------------------|
|                                       | Parent 3,5,6-TCP    | Sum as 3,5,6-TCP\(^{(d)}\) | Parent 3,5,6-TCP    |
| Dairy ruminants                        | 2.8                 | 0.11                     | 0.03                |
|                                        |                     | 0.37                     | 0.09                |
|                                        | 2.2                 | 0.21                     | 0.22                |
|                                        |                     | 0.44                     | 0.36                |
| Meat ruminants                         | 3.3                 | 0.25                     | 0.06                |
|                                        |                     | 0.44                     | 0.11                |
|                                        | 0.27                | 0.01                     | 0.01                |
|                                        |                     | 0.01                     | 0.01                |
| Poultry                                | 0.46                | 0.20                     | 0.04                |
|                                        | 0.36                | 0.07                     | 0.04                |
|                                        |                     | 0.07                     | 0.07                |

(a): Dietary burden was calculated in the present reasoned opinion.
(b): Dietary burden was calculated in the present reasoned opinion of chlorpyrifos-methyl (EFSA, 2017c).
(c): Dietary burden was calculated in the reasoned opinion of chlorpyrifos (EFSA, 2017b).
(d): Sum of the dietary burden of parent compound (expressed as 3,5,6-TCP equivalent) and of the dietary burden calculated for 3,5,6-TCP (based on the use of the parent compound).
(e): For each animal category/active substance, value in bold refers to dietary burden resulting from the sum of parent compound and metabolite 3,5,6-TCP, expressed as 3,5,6-TCP equivalent.
(f): For each animal category, the underlined value indicate the highest dietary burden value (expressed as 3,5,6-TCP equivalent) observed from comparison between triclopyr, chlorpyrifos-methyl and chlorpyrifos.

All input values included in the exposure calculations are summarised in Appendix C.3.

This chronic and acute exposure calculations were also performed using revision 2 of the EFSA PRIMO and the exposure values calculated were compared with the toxicological reference values derived for the metabolite 3,5,6-TCP (EFSA, 2014). The highest chronic exposure was calculated for German children, representing 6.0% of the ADI, and the highest acute exposure was calculated for bananas, representing 6.5% of the ARfD.

It is highlighted that major uncertainties remain due to the data gaps identified for the metabolite 3,5,6-TCP. However, this indicative exposure calculation did not indicate a risk to consumers and considering the large margin of safety, there are indications that metabolite 3,5,6-TCP is not of concern with regard to the use of triclopyr, chlorpyrifos and chlorpyrifos-methyl.

Conclusions

The metabolism of triclopyr was investigated in fruit crops (apples), root crops (radish) and grass crops (ryegrass). Triclopyr is the only significant residue observed in the three crop groups and it can be enforcing with a LOQ of 0.01 mg/kg in high water content, high acid content, high oil content and dry...
commodities. Therefore, EFSA proposes to define the residue for enforcement and risk assessment as triclopyr in all commodities. A metabolism study for rotational crops indicated that residues uptake could only occur in cereals straw but, considering that rice is the only crop assessed in this review that could be rotated with cereals and that this practice is unusual, this was not deemed as a major concern.

The available residue trials were considered sufficient to derive tentative MRL proposals as well as risk assessment values for all commodities under evaluation, except for grapefruits, oranges, lemons and mandarins where residue trials compliant with GAP were not available. The MRL proposals were tentative because of the data gaps concerning the storage stability of residues and/or because of the limited datasets of residue trials. As the chronic exposure does not exceed 10% of the ADI and since residues of triclopyr exceeding 0.1 mg/kg are not expected in the main commodities that could be subject to processing, investigation on the effect of processing on the nature and magnitude of the residue was not required.

The metabolism of triclopyr in animals was sufficiently investigated in ruminants and poultry. The available studies indicated that both triclopyr and its metabolite 3,5,6-TCP should be considered for risk assessment purposes. However, considering that metabolite 3,5,6-TCP may also be generated from the use of two other active substances, chlorpyrifos and chlorpyrifos-methyl, and since different toxicological reference values were derived for triclopyr and 3,5,6-TCP, two separate residue definitions for risk assessment were derived. The first residue definition (specific to triclopyr) includes the parent compound only; triclopyr can be enforced in animal commodities with a LOQ of 0.01 mg/kg. The second residue definition is the sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP. Since this compound is not a specific metabolite of triclopyr, the first residue definition remains the most relevant for enforcement purpose but, as risk managers may consider that enforcement of metabolite 3,5,6-TCP is also necessary, an optional separate list of MRLs in livestock was also derived for the second residue definition. An analytical method was validated for analysis of 3,5,6-TCP and its conjugates with a LOQ of 0.01 mg/kg in animal commodities, but the efficiency of this hydrolysis step to release the conjugates has not been demonstrated.

Based on the available feeding studies, MRL and risk assessment values were derived for both proposed residue definitions in dairy ruminants, meat ruminants and pigs. MRLs in poultry products are not required because poultry is not expected to be exposed to significant levels of triclopyr residues. It is highlighted that the final list of MRLs for the sum of 3,5,6-TCP and its conjugates also accommodates the use of chlorpyrifos and chlorpyrifos-methyl, which are the two other possible sources of 3,5,6-TCP in animal commodities. Based on a comparison of the respective dietary burdens for these substances, it was observed that the levels of 3,5,6-TCP in poultry are mainly driven by the dietary intake of chlorpyrifos-methyl. In ruminants (dairy and meat) and in pigs, however, the livestock dietary burden of triclopyr was identified as the main driver for the occurrence of 3,5,6-TCP. Therefore, the final MRLs for the sum of 3,5,6-TCP and its conjugates were derived from the respective data of these two substances.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For citrus fruits, where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 4.4% of the ADI (DE child) and the highest acute exposure amounted to 4.4% of the ARfD (oranges).

As different toxicological reference values were derived for the metabolite 3,5,6-TCP, a separate consumer risk assessment for 3,5,6-TCP and its conjugates was performed. In order to carry out a comprehensive consumer exposure calculation for metabolite 3,5,6-TCP, EFSA took into account residues arising from chlorpyrifos-methyl, chlorpyrifos and triclopyr. These chronic and acute exposure calculations were also performed using revision 2 of the EFSA PRIMo and the exposures calculated were compared with the toxicological reference values derived for the metabolite 3,5,6-TCP. The highest chronic exposure was calculated for German children, representing 6.0% of the ADI, and the highest acute exposure was calculated for bananas, representing 6.5% of the ARfD. Major uncertainties remain due to the data gaps identified for the metabolite 3,5,6-TCP but, this indicative exposure calculation did not indicate a risk to consumers and considering the large margin of safety, there are indications that metabolite 3,5,6-TCP is not of concern with regard to the use of triclopyr, chlorpyrifos and chlorpyrifos-methyl.

**Recommendations**

Considering that two separate residue definitions were derived for enforcement purposes, two lists of MRLs are proposed:
Main residue definition (1): triclopyr. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see Table 3). None of the MRL values listed in the table are recommended for inclusion in Annex II to the Regulation as they are not sufficiently supported by data (see Table 3 footnotes for details).

Optional residue definition (2): sum of 3,5,6-trichloropyridinol (3,5,6-TCP) and its conjugates, expressed as 3,5,6-TCP. MRLs derived for this residue definition take into account all sources of 3,5,6-TCP in plant and animal commodities (chlorpyrifos-methyl, chlorpyrifos and triclopyr). As the metabolite 3,5,6-TCP is not specific to triclopyr and due to the several data gaps identified, this list of MRLs is proposed on a tentative basis only. The indicative risk assessment for this compound showed a large margin of safety. However, if risk managers consider that enforcement of metabolite 3,5,6-TCP is necessary, an optional separate list of MRLs is derived below.

Regarding the main residue definition, certain tentative MRLs still need to be confirmed by the following data:

- validation of the method of analysis used in the study investigating the storage stability of triclopyr in high water content commodities;
- studies investigating the storage stability of triclopyr in dry and acidic commodities (covering the storage conditions of the corresponding trial samples);
- additional residue trials supporting the GAPs on citrus fruits and apricots.

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.

In addition, one minor deficiency was also identified which is not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data is therefore considered desirable but not essential:

- A PHI should preferably be defined for the critical GAP on peaches.

For the optional residue definition, the proposed MRLs also took into consideration the reasoned opinions of chlorpyrifos (for plant commodities) and chlorpyrifos-methyl (for plant and livestock commodities). For each plant commodity, the MRL proposal for the sum of 3,5,6-TCP and its conjugates is based on the most critical GAP between chlorpyrifos-methyl and chlorpyrifos, assuming that the fall-back GAPs suggested by EFSA are implemented and that the two active substances are not used together on the same crop. The outcome of these comparisons is reported in the summary table below (Table 3). For animal commodities, MRLs in ruminants (dairy and meat) and pigs are derived from the dietary burden calculated for triclopyr, while MRLs in poultry are derived from the reasoned opinion of chlorpyrifos-methyl (identified as the main driver of residues intake in this group of livestock). Since the analytical method for enforcement of the metabolite 3,5,6-TCP (and its conjugates) in plant and animal commodities was not fully validated, the MRLs for the optional residue definition are considered tentative. In addition, specific data gaps for the metabolite 3,5,6-TCP were also identified in the assessments of chlorpyrifos and chlorpyrifos-methyl. Therefore, if risk managers intend to set MRLs for this compound, the following data should be required (in addition to the above mentioned data gap):

- full validation of the analytical method for enforcement of the conjugates in plant and livestock commodities (the efficiency of the hydrolysis step still needs to be demonstrated);
- residue trials analysing 3,5,6-TCP and supporting the GAP of chlorpyrifos-methyl on currants.

Table 3: Summary table

| Code number | Commodity      | Existing EU MRL (mg/kg) | Outcome of the review | MRL (mg/kg) | Comment                              |
|-------------|----------------|-------------------------|-----------------------|-------------|--------------------------------------|
|             | Enforcement residue definition (existing): triclopyr |                         |                       |             |                                      |
| 110010      | Grapefruit     | 0.1*                    | Further consideration needed(6) |
| 110020      | Oranges        | 0.1*                    | Further consideration needed(6) |
| 110030      | Lemons         | 0.1*                    | Further consideration needed(6) |
| Code number | Commodity     | Existing EU MRL (mg/kg) | Outcome of the review |
|-------------|---------------|-------------------------|-----------------------|
| 110050      | Mandarins     | 0.1*                    | Further consideration needed<sup>(a)</sup> |
| 130010      | Apples        | 0.1*                    | Further consideration needed<sup>(a)</sup> |
| 130020      | Pears         | 0.1*                    | Further consideration needed<sup>(a)</sup> |
| 140010      | Apricots      | 0.1*                    | Further consideration needed<sup>(a)</sup> |
| 140030      | Peaches       | 0.1*                    | Further consideration needed<sup>(a)</sup> |
| 500060      | Rice grain    | 1                       | Further consideration needed<sup>(a)</sup> |
| 1011010     | Swine muscle  | 0.05*                   | Recommended<sup>(c)</sup> |
| 1011020     | Swine fat     | 0.05*                   | Recommended<sup>(c)</sup> |
| 1011030     | Swine liver   | 0.05*                   | Recommended<sup>(c)</sup> |
| 1011040     | Swine kidney  | 0.05*                   | Recommended<sup>(c)</sup> |
| 1012010     | Bovine muscle | 0.05*                   | Recommended<sup>(c)</sup> |
| 1012020     | Bovine fat    | 0.05*                   | Recommended<sup>(c)</sup> |
| 1012030     | Bovine liver  | 0.05*                   | Recommended<sup>(c)</sup> |
| 1012040     | Bovine kidney | 0.2                     | Recommended<sup>(c)</sup> |
| 1013010     | Sheep muscle  | 0.05*                   | Recommended<sup>(c)</sup> |
| 1013020     | Sheep fat     | 0.05*                   | Recommended<sup>(c)</sup> |
| 1013030     | Sheep liver   | 0.05*                   | Recommended<sup>(c)</sup> |
| 1013040     | Sheep kidney  | 0.2                     | Recommended<sup>(c)</sup> |
| 1014010     | Goat muscle   | 0.05*                   | Recommended<sup>(c)</sup> |
| 1014020     | Goat fat      | 0.05*                   | Recommended<sup>(c)</sup> |
| 1014030     | Goat liver    | 0.05*                   | Recommended<sup>(c)</sup> |
| 1014040     | Goat kidney   | 0.2                     | Recommended<sup>(c)</sup> |
| 1020000     | Milk of ruminants | 0.05*         | Recommended<sup>(c)</sup> |
|             | Other commodities of plant and/or animal origin | See Reg. (EC) No 750/2010 | Further consideration needed<sup>(d)</sup> |

**Enforcement residue definition (existing):** –

**Enforcement residue definition (proposed):** sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP
| Code number | Commodity | Existing EU MRL (mg/kg) | Outcome of the review |
|-------------|-----------|------------------------|-----------------------|
| 152000      | Strawberries | – 0.3 | Further consideration needed(6) |
| 1540120     | Cranberries | – – | Further consideration needed(9) |
| 154030      | Currants (red, black and white) | – – | Further consideration needed(9) |
| 161040      | Kumuquats | – – | Further consideration needed(9) |
| 162010      | Kiwi | – 0.05 | Further consideration needed(6) |
| 163020      | Bananas | – 1.5 | Further consideration needed(6) |
| 211000      | Potatoes | – 0.1 | Further consideration needed(6) |
| 213010      | Beetroot | – – | Further consideration needed(9) |
| 213020      | Carrots | – – | Further consideration needed(9) |
| 213080      | Radishes | – – | Further consideration needed(9) |
| 220010      | Garlic | – – | Further consideration needed(9) |
| 220020      | Onions | – – | Further consideration needed(9) |
| 220030      | Shallots | – – | Further consideration needed(9) |
| 220040      | Spring onions | – – | Further consideration needed(9) |
| 231010      | Tomatoes | – 0.15 | Further consideration needed(6) |
| 231020      | Peppers | – 0.01* | Further consideration needed(6) |
| 231030      | Aubergines (egg plants) | – 0.15 | Further consideration needed(6) |
| 233010      | Melons | – 0.02 | Further consideration needed(6) |
| 233020      | Pumpkins | – 0.02 | Further consideration needed(6) |
| 233030      | Watermelons | – 0.02 | Further consideration needed(6) |
| 234000      | Sweet corn | – – | Further consideration needed(9) |
| 241010      | Broccoli | – 0.01* | Further consideration needed(6) |
| 241020      | Cauliflower | – 0.01* | Further consideration needed(6) |
| 242010      | Brussels sprouts | – 0.01* | Further consideration needed(6) |
| 242020      | Head cabbage | – 0.01* | Further consideration needed(6) |
| 243010      | Chinese cabbage | – – | Further consideration needed(9) |
| 243020      | Kale | – 0.01* | Further consideration needed(6) |
| 244000      | Kohlrabi | – 0.01* | Further consideration needed(6) |
| 251010      | Lamb’s lettuce | – – | Further consideration needed(9) |
| 251020      | Lettuce | – – | Further consideration needed(9) |
| 251030      | Scarole (broad-leaf endive) | – – | Further consideration needed(9) |
| 251060      | Rocket, rucola | – – | Further consideration needed(9) |
| 252010      | Spinach | – 0.03 | Further consideration needed(9) |
| 260010      | Beans (fresh, with pods) | – 0.01* | Further consideration needed(6) |
| 260020      | Beans (fresh, without pods) | – – | Further consideration needed(9) |
| 260030      | Peas (fresh, with pods) | – – | Further consideration needed(9) |
| 260040      | Peas (fresh, without pods) | – – | Further consideration needed(9) |
| 270010      | Asparagus | – – | Further consideration needed(9) |
| 270050      | Globe artichokes | – – | Further consideration needed(9) |
| 300010      | Beans (dry) | – 0.01* | Further consideration needed(6) |
| 300030      | Peas (dry) | – – | Further consideration needed(9) |
| 300040      | Lupins (dry) | – 0.01* | Further consideration needed(6) |
| 401030      | Poppy seed | – 0.3 | Further consideration needed(9) |
| 401050      | Sunflower seed | – 0.01* | Further consideration needed(6) |
| 401060      | Rape seed | – 0.3 | Further consideration needed(9) |
| 401070      | Soya bean | – – | Further consideration needed(9) |
| 401080      | Mustard seed | – 0.3 | Further consideration needed(9) |
| Code number | Commodity                  | Existing EU MRL (mg/kg) | MRL (mg/kg) | Outcome of the review                                           |
|-------------|----------------------------|-------------------------|-------------|----------------------------------------------------------------|
| 401090      | Cotton seed               | –                       | 0.09        | Further consideration needed\(^{(f)}\)                         |
| 401130      | Gold of pleasure          | –                       | 0.3         | Further consideration needed\(^{(f)}\)                         |
| 402010      | Olives for oil production | –                       | 0.01\(^{*}\)| Further consideration needed\(^{(f)}\)                     |
| 500010      | Barley grain              | –                       | 1.5         | Further consideration needed\(^{(f)}\)                         |
| 500020      | Buckwheat grain           | –                       |            | Further consideration needed\(^{(f)}\)                         |
| 500030      | Maize grain               | –                       | 0.02        | Further consideration needed\(^{(f)}\)                         |
| 500040      | Millet grain              | –                       |            | Further consideration needed\(^{(f)}\)                         |
| 500050      | Oats grain                | –                       | 1.5         | Further consideration needed\(^{(f)}\)                         |
| 500060      | Rice grain                | –                       |            | Further consideration needed\(^{(f)}\)                         |
| 500070      | Rye grain                 | –                       | 0.4         | Further consideration needed\(^{(f)}\)                         |
| 500080      | Sorghum grain             | –                       |            | Further consideration needed\(^{(f)}\)                         |
| 500090      | Wheat grain               | –                       | 0.4         | Further consideration needed\(^{(f)}\)                         |
| 610000      | Tea                       | –                       |            | Further consideration needed\(^{(f)}\)                         |
| 620000      | Coffee beans              | –                       |            | Further consideration needed\(^{(f)}\)                         |
| 810000      | Spices (seeds)            | –                       |            | Further consideration needed\(^{(f)}\)                         |
| 820000      | Spices (fruits and berries)| –                      |            | Further consideration needed\(^{(f)}\)                         |
| 840000      | Spices (roots and rhizome)| –                      |            | Further consideration needed\(^{(f)}\)                         |
| 900010      | Sugar beet (root)         | –                       | 0.1         | Further consideration needed\(^{(f)}\)                         |
| 1011010     | Swine muscle              | –                       | 0.01\(^{*}\)| Further consideration needed\(^{(f)}\)                     |
| 1011020     | Swine fat (free of lean meat)| –                    | 0.015       | Further consideration needed\(^{(f)}\)                         |
| 1011030     | Swine liver               | –                       | 0.15        | Further consideration needed\(^{(f)}\)                         |
| 1011040     | Swine kidney              | –                       | 0.15        | Further consideration needed\(^{(f)}\)                         |
| 1012010     | Bovine muscle             | –                       | 0.06        | Further consideration needed\(^{(f)}\)                         |
| 1012020     | Bovine fat                | –                       | 0.09        | Further consideration needed\(^{(f)}\)                         |
| 1012030     | Bovine liver              | –                       | 1           | Further consideration needed\(^{(f)}\)                         |
| 1012040     | Bovine kidney             | –                       | 1           | Further consideration needed\(^{(f)}\)                         |
| 1013010     | Sheep muscle              | –                       | 0.06        | Further consideration needed\(^{(f)}\)                         |
| 1013020     | Sheep fat                 | –                       | 0.09        | Further consideration needed\(^{(f)}\)                         |
| 1013030     | Sheep liver               | –                       | 1           | Further consideration needed\(^{(f)}\)                         |
| 1013040     | Sheep kidney              | –                       | 1           | Further consideration needed\(^{(f)}\)                         |
| 1014010     | Goat muscle               | –                       | 0.06        | Further consideration needed\(^{(f)}\)                         |
| 1014020     | Goat fat                  | –                       | 0.09        | Further consideration needed\(^{(f)}\)                         |
| 1014030     | Goat liver                | –                       | 1           | Further consideration needed\(^{(f)}\)                         |
| 1014040     | Goat kidney               | –                       | 1           | Further consideration needed\(^{(f)}\)                         |
| 1016010     | Poultry muscle            | –                       | 0.03        | Further consideration needed\(^{(f)}\)                         |
| 1016020     | Poultry fat               | –                       | 0.03        | Further consideration needed\(^{(f)}\)                         |
| 1016030     | Poultry liver             | –                       | 0.03        | Further consideration needed\(^{(f)}\)                         |
| 1020010     | Cattle milk               | –                       | 0.015       | Further consideration needed\(^{(f)}\)                         |
| 1020020     | Sheep milk                | –                       | 0.015       | Further consideration needed\(^{(f)}\)                         |
| 1020030     | Goat milk                 | –                       | 0.015       | Further consideration needed\(^{(f)}\)                         |
| 1030000     | Birds’ eggs               | –                       | 0.03        | Further consideration needed\(^{(f)}\)                         |
| –           | Other commodities of plant and/or animal origin | – | – | Further consideration needed\(^{(f)}\)                         |

MRL: maximum residue level.

\(^{*}\): Indicates that the MRL is set/proposed at the limit of quantification.

(a): 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 C-I in Appendix D).

(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; no CXL is available (combination E-I in Appendix D).
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**Abbreviations**

3,5,6-TCP 3,5,6-trichloropyridinol  
a.i. active ingredient  
a.s. active substance  
ADl acceptable daily intake  
AR applied radioactivity  
ARFD acute reference dose  
BBCH growth stages of mono- and dicotyledonous plants  
bw body weight
cGAP  critical GAP
CXL  codex maximum residue limit
DAR  draft assessment report
DAT  days after treatment
DB  dietary burden
DM  dry matter
DT₉₀  period required for 90% dissipation (define method of estimation)
EMS  evaluating Member State
eq  residue expressed as a.s. equivalent
EURLs  European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO  Food and Agriculture Organization of the United Nations
GAP  Good Agricultural Practice
GLP  Good Laboratory Practice
HPLC–MS/MS  high-performance liquid chromatography with tandem mass spectrometry
HR  highest residue
IEDI  international estimated daily intake
IESTI  international estimated short-term intake
ILV  independent laboratory validation
ISO  International Organisation for Standardization
IUPAC  International Union of Pure and Applied Chemistry
JMPR  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)
LOQ  limit of quantification
Mo  monitoring
MRL  maximum residue level
MS  Member States
NEU  northern European Union
OECD  Organisation for Economic Co-operation and Development
PBI  plant back interval
PF  processing factor
PHI  preharvest interval
PRIMO  (EFSA) Pesticide Residues Intake Model
PROFile  (EFSA) Pesticide Residues Overview File
QuEChERS  Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
Rₑr  statistical calculation of the MRL by using a non-parametric method
Rₘₐₓ  statistical calculation of the MRL by using a parametric method
RA  risk assessment
RAC  raw agricultural commodity
RD  residue definition
RMS  rapporteur Member State
SANCO  Directorate-General for Health and Consumers
SEU  southern European Union
SMILES  simplified molecular-input line-entry system
STMR  supervised trials median residue
TRR  total radioactive residue
WHO  World Health Organization
### Appendix A – Summary of authorised uses considered for the review of MRLs

#### Critical outdoor GAPs for northern Europe

| Crop | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Method | Growth stage | Application | PHI or waiting period (days) | Comments |
|------|-----------------|--------|----------------|-------------------------|-----------------|-------------|--------|--------------|-------------|-----------------------------|----------|
| Apples | *Malus domesticus* | NEU | Outdoor | BE, DE, NL | Early fruit fall | ST | 100 g/kg | Foliar treatment – spraying | 1 | 20 g a.i./ha | 21 |
| Pears | *Pyrus communis* | NEU | Outdoor | BE, DE, FR, NL | Early fruit fall | ST | 100 g/kg | Foliar treatment – spraying | 1 | 20 g a.i./ha | 21 |
| Grass | Not specified | NEU | Outdoor | IE, UK | Broad leaved weeds, bushwood | EC | 480 g/L | Foliar treatment – spraying | 35–92 | 1 | 960 g a.i./ha | 7 |

#### Critical outdoor GAPs for southern Europe

| Crop | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Method | Growth stage | Application | PHI or waiting period (days) | Comments |
|------|-----------------|--------|----------------|-------------------------|-----------------|-------------|--------|--------------|-------------|-----------------------------|----------|
| Grapefruit | *Citrus paradisi* | SEU | Outdoor | ES | Growth regulator | TB | 10% (v/v) | Foliar treatment – general (see also comment field) | 95–99 | 1 | 3.8 g a.i./ha | Spraying after physiological fruit drop. Assessment of a GAP with post-harvest drenching in currently on-going in ES |
### Critical outdoor GAPs for southern Europe

| Crop   | Common name   | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation      | Content Type | Method                  | Growth stage From BBCH | Number | Interval (days) Min. | Max. | Rate | PHI or waiting period (days) | Comments (max. 250 characters) |
|--------|---------------|-----------------|--------|----------------|--------------------------|-----------------|-------------------|---------------|------------------------|-------------------------|--------|------------------------|-----|------|--------------------------|--------------------------------|
| Oranges| Citrus sinensis | SEU Outdoor ES | Growth regulator | TB 10 % (v/v) | Foliar treatment – general (see also comment field) | 95 99 1 3.8 g a.i./ha | 21 Apr | A PHI should preferably be defined |
| Lemons | Citrus limon  | SEU Outdoor ES | Growth regulator | TB 10 % (v/v) | Foliar treatment – general (see also comment field) | 95 99 1 3.8 g a.i./ha | n.a.   | See grapefruits |
| Mandarins | Citrus reticulata | SEU Outdoor ES | Growth regulator | TB 10 % (v/v) | Foliar treatment – general (see also comment field) | 95 99 1 3.8 g a.i./ha | n.a.   | See grapefruits |
| Pears  | Pyrus communis | SEU Outdoor FR  | Early fruit fall | ST 100 g/kg | Foliar treatment – spraying | 1 10 20 g a.i./ha | 21    | |
| Apricots | Prunus armeniaca | SEU Outdoor FR | Growth regulator | ST 100 g/kg | Foliar treatment – spraying | 1 9.6 12 g a.i./ha | 40    | |
| Peaches | Prunus persica | SEU Outdoor ES | Growth regulator | ST 100 g/kg | Foliar treatment – spraying | 4 g a.i./ha | A PHI should preferably be defined |
| Rice   | Oryza sativa  | SEU Outdoor IT  | Broad leaved weeds, bushwood | EC 668 g/L | Foliar treatment – spraying | 21 32 1 668 g a.i./ha | n.a.  | |
### Critical outdoor GAPs for southern Europe

| Crop          | Scientific name       | Region     | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Method | Growth stage | Application | PHI or waiting period (days) | Comments (max. 250 characters) |
|---------------|-----------------------|------------|----------------|-------------------------|----------------|-------------|--------|--------------|-------------|-----------------------------|---------------------------------|
| Grass         | Not specified         | SEU        | Outdoor        | FR                      | Broad leaved weeds, bushwood | EC 480 g/L    | Foliar treatment – spraying | 1          | 518 g a.i./ha       | 15                             |                                 |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; BBCH: growth stages of mono- and dicotyledonous plants; PHI: preharvest interval; a.i.: active ingredient.
# Appendix B – List of end points

## B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) |
|-----------------------------------|-------------|---------|----------------|----------------|
| Fruit crops                       | Apples      | Foliar, 1 × 650 g a.s./ha | 21 |
|                                   |             | Soil, 2 × 1.1 kg a.s./ha   | 14 |
| Root crops                        | Radishes    | Foliar, 1 × 27 g a.s./ha   | 8  |
|                                   |             | Soil, 1 × 1.1 kg a.s./ha   | 7  |
| Cereals/grass crops               | Rye grass   | Foliar, 1 × 2.24 kg a.s./ha| 0, 3, 7, 14, 30, 60, 91 |
|                                   |             | Foliar, 1 × 4.5 kg a.s./ha | 91 |

Source: Ireland (2003)

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) |
|--------------------------------------|-------------|---------|----------------|-----------|
| Root/tuber crops                     | Turnips     | Bare soil, 0.56 kg a.s./ha | 36 |
| Leafy crops                          | Lettuce     | Bare soil, 0.56 kg a.s./ha | 36 |
| Cereal (small grain)                 | Wheat       | Bare soil, 0.56 kg a.s./ha | 36 |
| Pulses/oilseeds                      | Green beans | Bare soil, 0.56 kg a.s./ha | 36 |

Source: Ireland (2003)

| Processed commodities (hydrolysis study) | Conditions | Investigated? |
|------------------------------------------|------------|---------------|
|                                          | Pasteurisation (20 min, 90°C, pH 4) | No |
|                                          | Baking, brewing and boiling (60 min, 100°C, pH 5) | No |
|                                          | Sterilisation (20 min, 120°C, pH 6) | No |
|                                          | Study is not available and not required | |

Source: Ireland (2003)
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category               | Commodity | T (°C) | Stability (months/years) |
|-----------------------------------|------------------------|-----------|--------|-------------------------|
|                                   | High water content     | Grass     | –20    | 48 months\(^{(a)}\)     |
|                                   | Dry                    | –         | –      | (b)                     |
|                                   | High acid content      | –         | –      | (b)                     |

**Source:** Ireland (2003)

- (a): Storage stability demonstrated in grass for a period of 4.2 years should still be confirmed by additional data ‘full details of the validation of the method of analysis used in this study’ (EFSA, 2006).
- (b): Studies in dry and high acid content commodities are not available but required.

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| Conversion factor (monitoring to risk assessment) |
|-------------------------------------------------|
| Not relevant                                    |

|Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) |
|------------------------------------------------------------------------------------------|
| HPLC-MS/MS (France, 2016):                                                                 |
|   • Validated in high water (grass forage), high acid (orange, lemons), high oil (sunflower, soybean grain) and dry (rice grain) commodities and in grass straw |
|   • ILV available for dry and high water content commodities                              |
|   • Method validated for two different mass transitions                                    |
|   • LOQ: 0.01 mg/kg                                                                       |
| HPLC-MS/MS (EURL, 2016):                                                                  |
|   • QuEChERS method is fully validated for high water, high acid and dry commodities, also with a LOQ of 0.01 mg/kg |

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## B.1.2. Magnitude of residues in plants

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

| Crop           | Region/indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg)<sup>(b)</sup> | STMR (mg/kg)<sup>(c)</sup> |
|----------------|-----------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|--------------------------|--------------------------|
| Grapefruit     | SEU                         | No trials compliant with GAP                                                                 |                                            |                       |                          |                          |
| Orange Lemons  |                             |                                                                                                 |                                            |                       |                          |                          |
| Mandarins      |                             |                                                                                                 |                                            |                       |                          |                          |
| Apples         | NEU                         | 3 $\times$ < 0.05                                                                               | Trials performed on apples and compliant with GAP on apples and pears (France, 2016; Germany, 2016) | 0.05 (tentative)<sup>(d)</sup> | 0.05                     | 0.05                     |
| Pears          | SEU                         | 4 $\times$ < 0.01                                                                               | Trials performed on apples are compliant with the GAP for pears (France, 2016). No southern use on apples | 0.01* (tentative)<sup>(d)</sup> | 0.01                     | 0.01                     |
| Apricots       | SEU                         | Peaches: 4 $\times$ < 0.05 Apricots: –                                                           | 3 trials compliant with GAP; 1 trial performed with a more critical GAP: 1 $\times$ 30 g a.s./ha; PHI 28 d, acceptable since residues < 0.05 mg/kg (Ireland, 2010). In the absence of trials performed on apricots, the MRL proposal is tentative | 0.05 (tentative)<sup>(d),<f>(f)</sup> | 0.05                     | 0.05                     |
| Peaches        | SEU                         | 4 $\times$ < 0.05                                                                               | Trials performed on peaches with an overdosed rate (8–30 g a.s./ha instead of 4 g a.s./ha) and different PHI (from 7 to 48 days) (Ireland, 2010). No significant residues are expected | 0.05 (tentative)<sup>(d)</sup> | 0.05                     | 0.05                     |
| Rice grain     | SEU                         | 7 $\times$ < 0.1; 0.02; 0.016; 0.052; 0.054; 0.06; 0.08; 0.21                                      | Trials compliant with GAP (Ireland, 2009; France, 2016) | MRL<sub>OECD</sub> = 0.27 | 0.3 (tentative)<sup>(e)</sup> | 0.21                     | 0.10                     |
| Grass          | NEU                         | 1.6; 2.5; 7; 7.8; 11.4<sup>(g)</sup>; 11.7; 15.4                                               | Trials compliant with GAP (Ireland, 2009) | MRL<sub>OECD</sub> = 28.3 | 30 (tentative)<sup>(d)</sup> | 15.4                     | 7.8                      |
|                | SEU                         | 4.3; 4.5; 8.4; 13.3                                                                             | Trials were performed with higher application rates (0.72–1.2 kg a.s./ha) but results were scaled to the GAP (France, 2016) | R<sub>per</sub> = 24.2 | R<sub>max</sub> = 29.4 | MRL<sub>OECD</sub> = 24.5 |
|                |                             |                                                                                                 |                                            |                       | 30 (tentative)<sup>(d)</sup> | 13.3                     | 6.45                     |

### Residue definition for enforcement and risk assessment: triclopyr
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GAP: Good Agricultural Practice; MRL: maximum residue level; a.s.: active substance; PHI: preharvest interval; OECD: Organisation for Economic Co-operation and Development; \( R_{\text{ox}} \): statistical calculation of the MRL by using a non-parametric method; \( R_{\max} \): statistical calculation of the MRL by using a parametric method.

*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue.
(c): Supervised trials median residue.
(d): MRL proposal is tentative because the storage stability in high water content commodities is not fully addressed.
(e): MRL proposal is tentative because the storage stability in dry commodities was not investigated.
(f): MRL proposal is tentative because additional trials are required.
(g): Sampling only available at 10 days instead of 7 days (slight deviation) is considered acceptable considering that residues are in the same range.
B.1.2.2. Residues in succeeding crops

Confined rotational crop study (quantitative aspect)  
Radioactivity was below 0.01 mg eq/kg in all investigated crops other than wheat straw where total radioactivity was 0.23 mg eq/kg. Residues uptake is not expected in food commodities (root crops, leafy crops, pulses and cereal grain). The possible uptake in cereal straw is deemed of low concern considering that MRLs are not set for feed item, that the livestock dietary burden is mainly driven by grass and that the rotation of rice with other cereals is rather unusual.

Field rotational crop study  
Not available and not required

B.1.2.3. Processing factors

| Processed commodity | Number of studies\(^{(a)}\) | Processing factor (PF) |
|--------------------|--------------------------|------------------------|
|                    | Individual values | Median PF |

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

B.2. Residues in livestock

| Livestock | Median dietary burden (mg/kg bw per day) | Maximum dietary burden (mg/kg bw per day) | Highest contributing commodity\(^{(a)}\) | Max dietary burden (mg/kg DM) | Trigger exceeded (Y/N) |
|-----------|------------------------------------------|------------------------------------------|---------------------------------------|-----------------------------|------------------------|
| Dairy ruminants | 1.42                                      | 2.8                                      | Grass (fresh)                        | 77.8                        | Y                      |
| Meat ruminants  | 1.67                                      | 3.3                                      | Grass (fresh)                        | 76.7                        | Y                      |
| Poultry      | 0                                         | 0                                        | Not relevant                         | 0                           | N                      |
| Pigs         | 0.23                                      | 0.46                                     | Grass silage                         | 11.6                        | Y                      |

bw: body weight; DM: dry matter.
\(^{(a)}\): Calculated for the maximum dietary burden.

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 per day) | Duration (days) | N rate/comment |
|-------------------------------|----------|-------------------------|-----------------|----------------|
|                               | Laying hen | 0.57\(^{(a)}\)   | 10              | Not relevant (no dietary burden in poultry) |
|                               | Lactating goat | 14.3\(^{(b)}\) | 3               | 5.1N/dairy ruminants 4.3N/meat ruminants |

Source: Ireland (2003)
\(^{(a)}\): Nominal dose of 9 mg/kg feed; theoretical administered dose converted in mg/kg bw per day assuming a feed intake of 0.12 kg DM/day and a standard body weight of 1.9 kg.
\(^{(b)}\): Nominal dose of 500 mg/kg feed; theoretical administered dose converted in mg/kg bw per day assuming a feed intake of 2 kg DM/day and a standard body weight of 70 kg.
### B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal     | Commodity               | T (°C) | Stability (months/years) |
|-------------------------------------|------------|-------------------------|--------|-------------------------|
|                                     | Beef       | Muscle, fat, liver,     | −20    | 12 months               |
|                                     | Laying hen | Eggs                    | −20    | 30 months               |
|                                     | Cow        | Milk                    | −20    | 12 months               |

**Triclopyr**

**3,5,6-trichloropyridinol (3,5,6-TCP) and its conjugates** *(a)*

| Animal     | Commodity               | T (°C) | Stability (months/years) |
|------------|-------------------------|--------|-------------------------|
| Beef       | Muscle, fat, liver,     | −20    | 15 months               |
| Cow        | Milk and cream          | −20    | 12 months               |

*(a)*: As the possible decline of conjugates is expected to proceed through 3,5,6-TCP, conjugates are also covered.
### B.2.2. Magnitude of residues in livestock

#### B.2.2.1. Summary of the residue data from livestock feeding studies (for triclopyr)

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1 N | MRL proposal (mg/kg) |
|------------------|-----------------------------------------------|------------------------|---------------------|
|                  | Mean | Highest | STMR (mg/kg)<sup>(b)</sup> | HR (mg/kg)<sup>(c)</sup> |
| **Dairy ruminants**<sup>(d)</sup> | Closest feeding level<sup>(e)</sup> (3.64 mg/kg bw; 1.3 N rate) | | |
| Milk<sup>(e)</sup> | < 0.01 | n.a. | < 0.01 | < 0.01 | 0.01* |
| **Meat ruminants**<sup>(f)</sup> | Closest feeding level<sup>(g)</sup> (3.10 mg/kg bw; 0.94 N rate) | | |
| Muscle | < 0.05 | < 0.05 | 0.03 | 0.05 | 0.06 |
| Fat | < 0.05 | < 0.05 | 0.03 | 0.05 | 0.06 |
| Liver | < 0.05 | < 0.05 | 0.03 | 0.05 | 0.06 |
| Kidney | 0.05 | 0.06 | 0.03 | 0.08 | 0.08 |
| **Poultry** | MRLs are not required for triclopyr since there is no intake of triclopyr residues in poultry |
| **Pig**<sup>(h)</sup> | Closest feeding level<sup>(i)</sup> (3.10 mg/kg bw; 6.7 N rate) | | |
| Muscle | < 0.05 | < 0.05 | < 0.01 | < 0.01 | 0.01* |
| Fat | < 0.05 | < 0.05 | < 0.01 | < 0.01 | 0.01* |
| Liver | < 0.05 | < 0.05 | < 0.01 | < 0.01 | 0.01* |
| Kidney | 0.05 | 0.06 | < 0.01 | < 0.01 | 0.01* |

MRL: maximum residue level; bw: body weight.

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

n.a. not applicable.

<sup>(a)</sup>: Closest feeding level and N dose rate related to the maximum dietary burden.

<sup>(b)</sup>: Mean residue level, recalculated at the 1 N rate for the median dietary burden.

<sup>(c)</sup>: Highest residue level for tissues and eggs and mean residue level for milk, recalculated at the 1 N rate for the maximum dietary burden.

<sup>(d)</sup>: Study performed on dairy cow: feeding level was recalculated as mg/kg bw considering the average feed daily consumption (20 kg/day) and weight (550 kg) of cow.

<sup>(e)</sup>: Only the milk samples collected from day 6 to day 13 were considered (plateau level).

<sup>(f)</sup>: Study performed on calves: feeding level was recalculated as mg/kg bw considering the average feed daily consumption (6.8 kg/day) and weight (220 kg) of calves.

<sup>(g)</sup>: Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs.

#### B.2.2.2. Summary of the residue data from livestock feeding studies (sum of 3,5,6-TCP and its conjugates, expresses as 3,5,6-TCP)

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1 N | MRL proposal (mg/kg) |
|------------------|-----------------------------------------------|------------------------|---------------------|
|                  | Mean | Highest | STMR (mg/kg)<sup>(b)</sup> | HR (mg/kg)<sup>(c)</sup> |
| **Dairy ruminants**<sup>(d)</sup> | Based on the dietary burden of triclopyr (2.8 mg/kg bw) and the feeding study analysing for 3,5,6-TCP | | |
| Closest feeding level<sup>(e)</sup> (3.64 mg/kg bw; 1.3 N rate) | | | |
| Milk<sup>(e)</sup> | 0.01 | n.a. | 0.01 | 0.01 | 0.015 (tentative)<sup>(h)</sup> |
| **Meat ruminants**<sup>(f)</sup> | Based on the dietary burden of triclopyr (3.3 mg/kg bw) and the feeding study analysing for 3,5,6-TCP | | |
| Closest feeding level<sup>(g)</sup> (3.10 mg/kg bw; 0.94 N rate) | | | |
| Muscle | < 0.05 | < 0.05 | 0.03 | 0.05 | 0.06 (tentative)<sup>(h)</sup> |
### Animal commodity

| Residues at the closest feeding level (mg/kg) | Estimated value at 1 N | MRL proposal (mg/kg) |
|---------------------------------------------|------------------------|---------------------|
| Mean | Highest | STMＲ (mg/kg) | HR (mg/kg) | |
| Fat | 0.07 | 0.08 | 0.04 | 0.09 | 0.09 (tentative) |
| Liver | 0.78 | 0.89 | 0.42 | 0.95 | 1 (tentative) |
| Kidney | 0.58 | 0.85 | 0.31 | 0.90 | 1 (tentative) |

### Poultry

MRLs are not required for triclopyr since there is no intake for triclopyr residues in poultry

### Pig

Based on the dietary burden of triclopyr (0.46 mg/kg bw) and the feeding study analysing for 3,5,6-TCP

Closest feeding level(a) (3.10 mg/kg bw; 6.7 N rate)

| Commodity | Mean | Highest | STMＲ (mg/kg)(b) | HR (mg/kg)(c) | MRL proposal (mg/kg) |
|-----------|------|---------|-----------------|--------------|---------------------|
| Muscle | < 0.05 | < 0.05 | < 0.01 | < 0.01 | 0.01* (tentative) |
| Fat | 0.07 | 0.08 | 0.01 | 0.01 | 0.015 (tentative) |
| Liver | 0.78 | 0.89 | 0.06 | 0.13 | 0.15 (tentative) |
| Kidney | 0.58 | 0.85 | 0.04 | 0.13 | 0.15 (tentative) |

MRL: maximum residue level; bw: body weight.
*: Indicates that the MRL is proposed at the limit of quantification.

(a): Closest feeding level and N dose rate related to the maximum dietary burden.
(b): Mean residue level, recalculated at the 1 N rate for the median dietary burden.
(c): Highest residue level for tissues and eggs and mean residue level for milk, recalculated at the 1N rate for the maximum dietary burden.

B.3. Consumer risk assessment

#### B.3.1. Consumer risk assessment for triclopyr

| Parameter | Value |
|-----------|-------|
| ADI       | 0.03 mg/kg bw per day (EFSA, 2006) |
| Highest IEDI, according to EFSA PRIMO | 4.4% ADI (DE, child) |

Assumptions made for the calculations

- The calculation is based on the median residue levels in the raw agricultural commodities
- For those commodities where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation
- The contributions of commodities where no GAP was reported in the framework of this review, were not included in the calculation

| Parameter | Value |
|-----------|-------|
| ARID      | 0.3 mg/kg bw (EFSA, 2006) |
| Highest IESTI, according to EFSA PRIMO | 4.4% ARID (oranges) |

Assumptions made for the calculations

- The calculation is based on the highest residue levels in the raw agricultural commodities
- For those commodities where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation
B.3.2. Consumer risk assessment for the metabolite 3,5,6-trichloropyridinol (3,5,6-TCP)

| ADI | 0.03 mg/kg bw per day (EFSA, 2014) |
|-----|-----------------------------------|
| Highest IEDI, according to EFSA PRIMo | 6.0% ADI (DE, child) |

Assumptions made for the calculations:

The calculation is based on the median residue levels arising from the use of chlorpyrifos, chlorpyrifos-methyl and triclopyr. For plant commodities, the highest residue level resulting from the use of chlorpyrifos or chlorpyrifos-methyl was considered, assuming that the two active substances are not used together on the same crop. For those crops where an acute concern was identified for chlorpyrifos or chlorpyrifos-methyl and for which it was possible to identify a fall-back GAP (see scenario EU2 in the respective reasoned opinions), EFSA directly considered the 3,5,6-TCP residue levels resulting from these fall-back GAPs. For citrus fruits and bananas, the relevant peeling factor was applied.

The plant commodities, where data were not available to derive MRLs and risk assessment values for the metabolite 3,5,6-TCP (see chlorpyrifos and chlorpyrifos-methyl), were not considered because there are no MRLs currently defined for 3,5,6-TCP.

For animal commodities, median residue levels derived, taking into account the three active substances, were considered.

The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation.

ARfD | 0.25 mg/kg bw (EFSA, 2014) |
|-----|-------------------------|
| Highest IESTI, according to EFSA PRIMo | 6.5% ARfD (bananas) |

Assumptions made for the calculations:

The calculation is based on the highest residue levels arising from chlorpyrifos, chlorpyrifos-methyl and triclopyr. For plant commodities, the most critical GAP between chlorpyrifos and chlorpyrifos-methyl was considered, assuming that the two active substances are not used together on the same crop. For those crops where an acute concern was identified for chlorpyrifos or chlorpyrifos-methyl and for which it was possible to identify a fall-back GAP (see scenario EU2 in the respective reasoned opinions), EFSA directly considered the 3,5,6-TCP residue levels resulting from these fall-back GAPs. For citrus fruits and bananas, the relevant peeling factor was applied.

The plant commodities, where data were not available to derive MRLs and risk assessment values for the metabolite 3,5,6-TCP (see chlorpyrifos and chlorpyrifos-methyl), were not considered because there are no MRLs currently defined for 3,5,6-TCP.

For animal commodities, highest residue levels derived taking into account the three active substances were considered.

The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation.

B.4. Proposed MRLs

| Code number | Commodity | Existing EU MRL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|-------------------------|-----------------------|---------|
|             |           |                         | MRL (mg/kg)           |         |
| **Enforcement residue definition (existing): triclopyr** |            |                         |           |         |
| **Enforcement residue definition (proposed): triclopyr** |            |                         |           |         |
| 110010 | Grapefruit | 0.1* | 0.1 | Further consideration needed<sup>a</sup> |
| 110020 | Oranges | 0.1* | 0.1 | Further consideration needed<sup>a</sup> |
| 110030 | Lemons | 0.1* | 0.1 | Further consideration needed<sup>a</sup> |
### Review of the existing MRLs for triclopyr

| Code number | Commodity       | Existing EU MRL (mg/kg) | MRL (mg/kg) | Comment                        |
|-------------|-----------------|-------------------------|-------------|--------------------------------|
| 110050      | Mandarins       | 0.1*                    | 0.1         | Further consideration needed(*) |
| 130010      | Apples          | 0.1*                    | 0.05        | Further consideration needed(*) |
| 130020      | Pears           | 0.1*                    | 0.05        | Further consideration needed(*) |
| 140010      | Apricots        | 0.1*                    | 0.05        | Further consideration needed(*) |
| 140030      | Peaches         | 0.1*                    | 0.05        | Further consideration needed(*) |
| 500060      | Rice grain      | 1                       | 0.3         | Further consideration needed(*) |
| 1011010     | Swine muscle    | 0.05*                   | 0.01*       | Recommended(c)                 |
| 1011020     | Swine fat       | 0.05*                   | 0.01*       | Recommended(c)                 |
| 1011030     | Swine liver     | 0.05*                   | 0.01*       | Recommended(c)                 |
| 1011040     | Swine kidney    | 0.05*                   | 0.01*       | Recommended(c)                 |
| 1012010     | Bovine muscle   | 0.05*                   | 0.06        | Recommended(c)                 |
| 1012020     | Bovine fat      | 0.05*                   | 0.06        | Recommended(c)                 |
| 1012030     | Bovine liver    | 0.05*                   | 0.06        | Recommended(c)                 |
| 1012040     | Bovine kidney   | 0.2                     | 0.08        | Recommended(c)                 |
| 1013010     | Sheep muscle    | 0.05*                   | 0.06        | Recommended(c)                 |
| 1013020     | Sheep fat       | 0.05*                   | 0.06        | Recommended(c)                 |
| 1013030     | Sheep liver     | 0.05*                   | 0.06        | Recommended(c)                 |
| 1013040     | Sheep kidney    | 0.2                     | 0.08        | Recommended(c)                 |
| 1014010     | Goat muscle     | 0.05*                   | 0.06        | Recommended(c)                 |
| 1014020     | Goat fat        | 0.05*                   | 0.06        | Recommended(c)                 |
| 1014030     | Goat liver      | 0.05*                   | 0.06        | Recommended(c)                 |
| 1014040     | Goat kidney     | 0.2                     | 0.08        | Recommended(c)                 |
| 1020000     | Milk of ruminants | 0.05*               | 0.01*       | Recommended(c)                 |

**Enforcement residue definition (existing):**

**Enforcement residue definition (proposed):** sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP

| Code number | Commodity       | Enforcement residue definition (proposed) | Comment                        |
|-------------|-----------------|-------------------------------------------|--------------------------------|
| 1011010     | Swine muscle    | –                                         | Further consideration needed(*) |
| 1011020     | Swine fat       | –                                         | Further consideration needed(*) |
| 1011030     | Swine liver     | –                                         | Further consideration needed(*) |
| 1011040     | Swine kidney    | –                                         | Further consideration needed(*) |
| 1012010     | Bovine muscle   | –                                         | Further consideration needed(*) |
| 1012020     | Bovine fat      | –                                         | Further consideration needed(*) |
| 1012030     | Bovine liver    | –                                         | Further consideration needed(*) |
| 1012040     | Bovine kidney   | –                                         | Further consideration needed(*) |
| 1013010     | Sheep muscle    | –                                         | Further consideration needed(*) |
| 1013020     | Sheep fat       | –                                         | Further consideration needed(*) |
| 1013030     | Sheep liver     | –                                         | Further consideration needed(*) |
| 1013040     | Sheep kidney    | –                                         | Further consideration needed(*) |
| 1014010     | Goat muscle     | –                                         | Further consideration needed(*) |
| 1014020     | Goat fat        | –                                         | Further consideration needed(*) |
| 1014030     | Goat liver      | –                                         | Further consideration needed(*) |
| 1014040     | Goat kidney     | –                                         | Further consideration needed(*) |
| 1020000     | Milk of ruminants | –                                     | Further consideration needed(*) |
### Review of the existing MRLs for triclopyr

| Code number | Commodity                                | Existing EU MRL (mg/kg) | Outcome of the review | MRL (mg/kg) | Comment                                      |
|-------------|------------------------------------------|-------------------------|-----------------------|-------------|----------------------------------------------|
| –           | Other commodities of plant and/or animal origin | –                       | –                     | –           | Further consideration needed<sup>(d)</sup>   |

**MRL**: maximum residue level.

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

(a): 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 C-I in Appendix D).

(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; no CXL is available (combination E-I in Appendix D).

(c): 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 G-I in Appendix D).

(d): There are no relevant authorisations or import tolerances on triclopyr 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 D).
Appendix C – Input values for the exposure calculations

### C.1. Livestock dietary burden calculations

| Feed commodity       | Median dietary burden | Maximum dietary burden |
|----------------------|-----------------------|------------------------|
|                      | Input value (mg/kg)   | Comment                | Input value (mg/kg) | Comment                |
| Grass (fresh)        | 7.8 STMR              |                        | 15.4 HR             |                        |
| Grass silage         | 7.8 STMR              |                        | 15.4 HR             |                        |
| Apple pomace         | 0.13 STMR × 2.5\(^{(a)}\) | 0.13 STMR × 2.5\(^{(a)}\) |                |                        |
| Grass hay            | 31.2 STMR × 4\(^{(a)}\) | 61.6 HR × 4\(^{(a)}\) |                |                        |

**Risk assessment residue definition:** triclopyr

**STMR:** supervised trials median residue; **HR:** highest residue; **PF:** processing factor.

\(^{(a)}\): For fruit pomace and grass hay, in the absence of processing factors supported by data, default processing factors of 2.5 and 4 were respectively included in the calculation to consider the potential concentration of residues in these commodities.

### C.2. Consumer risk assessment for triclopyr

| Commodity       | Chronic risk assessment | Acute risk assessment |
|-----------------|-------------------------|-----------------------|
|                 | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
|                  |                         |                       |                     |                       |
| Oranges          | 0.1 EU MRL              | 0.1 EU MRL            |                     |                       |
| Grapefruits      | 0.1 EU MRL              | 0.1 EU MRL            |                     |                       |
| Lemons           | 0.1 EU MRL              | 0.1 EU MRL            |                     |                       |
| Mandarins        | 0.1 EU MRL              | 0.1 EU MRL            |                     |                       |
| Apples           | 0.05 STMR (tentative)   | 0.05 HR (tentative)   |                     |                       |
| Pears            | 0.05 STMR (tentative)   | 0.05 HR (tentative)   |                     |                       |
| Apricots         | 0.05 STMR (tentative)   | 0.05 HR (tentative)   |                     |                       |
| Peaches          | 0.05 STMR (tentative)   | 0.05 HR (tentative)   |                     |                       |
| Rice grain       | 0.10 STMR (tentative)   | 0.21 HR (tentative)   |                     |                       |
| Swine meat       | 0.01* STMR muscle       | 0.01* HR muscle       |                     |                       |
| Swine fat        | 0.01* STMR              | 0.01* HR              |                     |                       |
| Swine liver      | 0.01* STMR              | 0.01* HR              |                     |                       |
| Swine kidney     | 0.01* STMR              | 0.01* HR              |                     |                       |
| Ruminant meat    | 0.027 STMR muscle       | 0.050 HR muscle       |                     |                       |
| Ruminant fat     | 0.027 STMR              | 0.050 HR              |                     |                       |
| Ruminant liver   | 0.027 STMR              | 0.050 HR              |                     |                       |
| Ruminant kidney  | 0.029 STMR              | 0.075 HR              |                     |                       |
| Milk             | 0.01* STMR              | 0.01* HR              |                     |                       |

**MRL:** maximum residue level; **STMR:** supervised trials median residue; **HR:** highest residue.

\(^{*}\): Indicates that the input value is proposed at the limit of quantification.

### C.3. Consumer risk assessment for the metabolite 3,5,6-trichloropyridinol (3,5,6-TCP)

| Commodity       | Chronic risk assessment | Acute risk assessment |
|-----------------|-------------------------|-----------------------|
|                 | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
|                 |                         |                       |                     |                       |
| Grapefruit      | 0.02 STMR (chlorpyrifos) × PF | 0.05 HR (chlorpyrifos) × PF |                     |                       |
| Oranges         | 0.02 STMR (chlorpyrifos-methyl) × PF | 0.06 HR (chlorpyrifos-methyl) × PF |                     |                       |
| Commodity       | Chronic risk assessment | Acute risk assessment |
|-----------------|-------------------------|-----------------------|
|                 | Input value (mg/kg)     | Comment               | Input value (mg/kg)     | Comment               |
| Lemons          | 0.02                    | STMR (chlorpyrifos-methyl) × PF | 0.06                    | HR (chlorpyrifos-methyl) × PF |
| Limes           | 0.02                    | STMR (chlorpyrifos) × PF | 0.05                    | HR (chlorpyrifos) × PF |
| Mandarins       | 0.02                    | STMR (chlorpyrifos-methyl) × PF | 0.06                    | HR (chlorpyrifos-methyl) × PF |
| Almonds         | 0.01*                   | STMR (chlorpyrifos)    | 0.01*                   | HR (chlorpyrifos)    |
| Chestnuts       | 0.01*                   | STMR (chlorpyrifos)    | 0.01*                   | HR (chlorpyrifos)    |
| Hazelnuts       | 0.01*                   | STMR (chlorpyrifos)    | 0.01*                   | HR (chlorpyrifos)    |
| Walnuts         | 0.01*                   | STMR (chlorpyrifos)    | 0.01*                   | HR (chlorpyrifos)    |
| Apples          | 0.04                    | STMR (chlorpyrifos-methyl) | 0.10                    | HR (chlorpyrifos-methyl) |
| Pears           | 0.04                    | STMR (chlorpyrifos-methyl) | 0.15                    | HR (chlorpyrifos-methyl) |
| Quinces         | 0.04                    | STMR (chlorpyrifos-methyl) | 0.10                    | HR (chlorpyrifos-methyl) |
| Medlar          | 0.01*                   | STMR (chlorpyrifos)    | 0.01*                   | HR (chlorpyrifos)    |
| Apricots        | 0.01*                   | STMR (chlorpyrifos)    | 0.01*                   | HR (chlorpyrifos)    |
| Cherries        | 0.05                    | STMR (chlorpyrifos-methyl) | 0.18                    | HR (chlorpyrifos-methyl) |
| Peaches         | 0.05                    | STMR (chlorpyrifos-methyl) | 0.11                    | HR (chlorpyrifos-methyl) |
| Plums           | 0.01*                   | STMR (chlorpyrifos)    | 0.03                    | HR (chlorpyrifos)    |
| Table grapes    | 0.08                    | STMR (chlorpyrifos-methyl) | 0.23                    | HR (chlorpyrifos-methyl) |
| Wine grapes     | 0.08                    | STMR (chlorpyrifos-methyl) | 0.23                    | HR (chlorpyrifos-methyl) |
| Strawberries    | 0.10                    | STMR (chlorpyrifos-methyl) | 0.16                    | HR (chlorpyrifos-methyl) |
| Currants (red, black and white) | – | No data available | – | No data available |
| Kiwi            | 0.05                    | STMR (chlorpyrifos-methyl) | 0.05                    | HR (chlorpyrifos-methyl) |
| Bananas         | 0.11                    | STMR (chlorpyrifos) × PF | 0.20                    | HR (chlorpyrifos) × PF |
| Potatoes        | 0.01*                   | STMR (chlorpyrifos-methyl) | 0.06                    | HR (chlorpyrifos-methyl) |
| Beetroot        | –                       | No data available      | –                       | No data available      |
| Carrots         | –                       | No data available      | –                       | No data available      |
| Radishes        | –                       | No data available      | –                       | No data available      |
| Garlic          | –                       | No data available      | –                       | No data available      |
| Onions          | –                       | No data available      | –                       | No data available      |
| Shallots        | –                       | No data available      | –                       | No data available      |
| Spring onions   | –                       | No data available      | –                       | No data available      |
| Tomatoes        | 0.04                    | STMR (chlorpyrifos-methyl) | 0.06                    | HR (chlorpyrifos-methyl) |
| Peppers         | 0.01*                   | STMR (chlorpyrifos)    | 0.01*                   | HR (chlorpyrifos)    |
| Aubergines (egg plants) | 0.04 | STMR (chlorpyrifos-methyl) | 0.06                    | HR (chlorpyrifos-methyl) |
| Melons          | 0.02                    | STMR (chlorpyrifos)    | 0.02                    | HR (chlorpyrifos)    |
| Pumpkins        | 0.02                    | STMR (chlorpyrifos)    | 0.02                    | HR (chlorpyrifos)    |
| Watermelons     | 0.02                    | STMR (chlorpyrifos)    | 0.02                    | HR (chlorpyrifos)    |
| Broccoli        | 0.01*                   | STMR (chlorpyrifos)    | 0.01*                   | HR (chlorpyrifos)    |
| Cauliflower     | 0.01*                   | STMR (chlorpyrifos)    | 0.01*                   | HR (chlorpyrifos)    |
| Brussels sprouts | 0.01*                  | STMR (chlorpyrifos)    | 0.01*                   | HR (chlorpyrifos)    |
| Head cabbage    | 0.01*                   | STMR (chlorpyrifos)    | 0.01*                   | HR (chlorpyrifos)    |
| Kale            | 0.01*                   | STMR (chlorpyrifos)    | 0.01*                   | HR (chlorpyrifos)    |
| Kohlrabi        | 0.01*                   | STMR (chlorpyrifos)    | 0.01*                   | HR (chlorpyrifos)    |
| Lamb’s lettuce  | –                       | No data available      | –                       | No data available      |
| Lettuce         | –                       | No data available      | –                       | No data available      |
| Scarole (broad-leaf endive) | – | No data available | – | No data available |
| Commodity                  | Input value (mg/kg) | Chronic risk assessment | Acute risk assessment |
|---------------------------|--------------------|-------------------------|-----------------------|
| Rocket, Rucola            | –                  | No data available       | –                     |
| Spinach                   | 0.03               | STMR (chlorpyrifos)     | 0.03 HR (chlorpyrifos) |
| Beans (fresh, with pods)  | 0.01*              | STMR (chlorpyrifos)     | 0.01* HR (chlorpyrifos) |
| Beans (fresh, without pods)| –                  | No data available       | – No data available   |
| Peas (fresh, with pods)   | –                  | No data available       | – No data available   |
| Peas (fresh, without pods)| –                  | NO data available       | – No data available   |
| Asparagus                 | –                  | No data available       | – No data available   |
| Globe artichokes          | –                  | No data available       | – No data available   |
| Beans (dry)               | 0.01*              | STMR (chlorpyrifos)     | 0.01* HR (chlorpyrifos) |
| Peas (dry)                | –                  | No data available       | – No data available   |
| Lupins (dry)              | 0.01*              | STMR (chlorpyrifos)     | 0.01* HR (chlorpyrifos) |
| Poppy seed                | 0.01*              | STMR (chlorpyrifos)     | 0.17 HR (chlorpyrifos) |
| Sunflower seed            | 0.01*              | STMR (chlorpyrifos)     | 0.01* HR (chlorpyrifos) |
| Rape seed                 | 0.01*              | STMR (chlorpyrifos)     | 0.17 HR (chlorpyrifos) |
| Soya bean                 | –                  | No data available       | – No data available   |
| Mustard seed              | 0.01*              | STMR (chlorpyrifos)     | 0.17 HR (chlorpyrifos) |
| Cotton seed               | 0.02               | STMR (chlorpyrifos-methyl) | 0.05 HR (chlorpyrifos-methyl) |
| Gold of pleasure          | 0.01*              | STMR (chlorpyrifos)     | 0.17 HR (chlorpyrifos) |
| Olives for oil production | 0.01*              | STMR (chlorpyrifos)     | 0.01* HR (chlorpyrifos) |
| Barley grain              | 0.59               | STMR (chlorpyrifos-methyl) | 1.02 HR (chlorpyrifos-methyl) |
| Buckwheat grain           | –                  | No data available       | – No data available   |
| Maize grain               | 0.01*              | STMR (chlorpyrifos)     | 0.01* HR (chlorpyrifos) |
| Millet grain              | –                  | No data available       | – No data available   |
| Oats grain                | 0.59               | STMR (chlorpyrifos-methyl) | 1.02 HR (chlorpyrifos-methyl) |
| Rice grain                | –                  | No data available       | – No data available   |
| Rye grain                 | 0.10               | STMR (chlorpyrifos)     | 0.20 HR (chlorpyrifos) |
| Wheat grain               | 0.10               | STMR (chlorpyrifos)     | 0.20 HR (chlorpyrifos) |
| Sugar beet (root)         | 0.01*              | STMR (chlorpyrifos)     | 0.06 HR (chlorpyrifos) |
| Swine meat                | 0.01*              | STMR muscle (triclopyr) | 0.01 HR muscle (triclopyr) |
| Swine fat                 | 0.01               | STMR (triclopyr)        | 0.01 HR (triclopyr)   |
| Swine liver               | 0.06               | STMR (triclopyr)        | 0.13 HR (triclopyr)   |
| Swine kidney              | 0.04               | STMR (triclopyr)        | 0.13 HR (triclopyr)   |
| Ruminant meat             | 0.03               | STMR muscle (triclopyr) | 0.05 HR muscle (triclopyr) |
| Ruminant fat              | 0.04               | STMR (triclopyr)        | 0.09 HR (triclopyr)   |
| Ruminant liver            | 0.42               | STMR (triclopyr)        | 0.95 HR (triclopyr)   |
| Ruminant kidney           | 0.31               | STMR (triclopyr)        | 0.90 HR (triclopyr)   |
| Poultry meat              | 0.02               | STMR muscle (chlorpyrifos-methyl) | 0.02 HR muscle (chlorpyrifos-methyl) |
### Commodity

| Commodity     | Chronic risk assessment | Acute risk assessment |
|---------------|-------------------------|-----------------------|
|               | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Poultry fat   | 0.02 STMR (chlorpyrifos-methyl) | 0.02 HR (chlorpyrifos-methyl) |
| Poultry liver | 0.02 STMR (chlorpyrifos-methyl) | 0.02 HR (chlorpyrifos-methyl) |
| Ruminant milk | 0.01 STMR (triclopyr)    | 0.01 HR (triclopyr)   |
| Eggs          | 0.02 STMR (chlorpyrifos-methyl) | 0.02 HR (chlorpyrifos-methyl) |

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

Evaluation of the GAPs and available residues data at EU level

- GAP or GB = 0.1 mg/kg in EU?
  - No
  - Yes
  - MRL derived in Section 3?
    - No
    - Yes
    - MRL is recommended.

Consumer risk assessment for GAPs evaluated at EU level - EU scenarios

- Not considered for the RA
  - Risk identified?
    - Yes
    - No

- Current EU MRL is indicated in the RA
  - Risk identified?
    - Yes
    - No

- Tentative median/highest values are included in the RA
  - Risk identified?
    - Yes
    - No

- Median/highest values are included in the RA
  - Risk identified?
    - Yes
    - No

Recommenations resulting from EU authorisations and import tolerances

- (A) Specific LOD or default MRL?
- (B) Specific LOD or default MRL?
- (C) Maintain current EU MRL?
- (D) Specific LOD or default MRL?
- (E) Establish tentative EU MRL?
- (F) Specific LOD or default MRL?
- (G) MRL is recommended.

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

- **(I)** Maintain EU recommendation indicating that no CXL is available.
- **(II)** Maintain EU recommendation indicating CXL is not compatible.
- **(III)** Maintain EU recommendation indicating that CXL is covered.
- **(IV)** Maintain EU recommendation; higher CXL is not safe for consumer.
- **(V)** Maintain current CXL or EU recommendation?
- **(VI)** Maintain EU recommendation; higher CXL is not safe for consumer.
- **(VII)** CXL is recommended; EU recommendation is covered as well.

**Consumer risk assessment with consideration of the existing CXL**

- Input values for the RA remain unchanged.
- Input values for the RA remain unchanged.
- Input values for the RA remain unchanged.
- CXL is included in the RA.
- CXL is supported by data.
- CXL is recommended.
- Risk identified?

**Recommendations with consideration of the existing CXL**

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

| Code/trivial name | Chemical name/SMILES notation | Structural formula |
|-------------------|-------------------------------|--------------------|
| Triclopyr         | 3,5,6-Trichloro-2-pyridyloxyacetic acid Clc1cc(Cl)c(Cl)nc1OCC(=O)O | ![Structural formula for Triclopyr]() |
| Chlorpyrifos      | O,O-Diethyl O-3,5,6-trichloro-2-pyridyl phosphorothioate Clc1cc(Cl)c(Cl)nc1OP(=S)(OCC)OCC | ![Structural formula for Chlorpyrifos]() |
| Chlorpyrifos-methyl | O,O-Dimethyl O-3,5,6-trichloro-2-pyridyl phosphorothioate Clc1cc(Cl)c(Cl)nc1OP(=S)(OC)OC | ![Structural formula for Chlorpyrifos-methyl]() |
| 3,5,6-Trichloropyridinol (3,5,6-TCP) | 3,5,6-Trichloropyridin-2-ol Clc1cc(Cl)c(Cl)nc1O | ![Structural formula for 3,5,6-Trichloropyridinol (3,5,6-TCP)]() |

SMILES: simplified molecular-input line-entry system.