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

European Food Safety Authority (EFSA),
Alba Brancato, Daniela Brocca, Chloe De Lentdecker, Zoltan Erdos, Lucien Ferreira, Luna Greco, Samira Jarrah, Dimitra Kardassi, Renata Leuschner, Christopher Lythgo, Paula Medina, Ileana Miron, Tunde Molnar, Alexandre Nougadere, Ragnor Pedersen, Hermine Reich, Angela Sacchi, Miguel Santos, Alois Stanek, Juergen Sturma, Tarazona Jose, Theobald Anne, Benedicte Vagenende, Alessia Verani and Laura Villamar-Bouza

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 chlorpyrifos-methyl. To assess the occurrence of chlorpyrifos-methyl residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission as well as the European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Some information required by the regulatory framework was missing and a possible chronic risk to consumers was identified. Hence, the consumer risk assessment is considered indicative only, some MRL proposals derived by EFSA still require further consideration by risk managers and measures for reduction of the consumer exposure should also be considered.

© 2017 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: chlorpyrifos-methyl, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, organophosphate, insecticide, 3,5,6-trichloropyridinol (3,5,6-TCP)

Requestor: European Commission

Question number: EFSA-Q-2008-510

Correspondence: pesticides.mrl@efsa.europa.eu
Acknowledgement: EFSA wishes to thank the rapporteur Member State Spain for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Jose T, Anne T, Vagenende B, Verani A and Villamar-Bouza L, 2017. Reasoned opinion on the review of the existing maximum residue levels for chlorpyrifos-methyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(3):4734, 70 pp. doi:10.2903/j.efsajournal.efsa.2017-4734

ISSN: 1831-4732

© 2017 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

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

Chlorpyrifos-methyl was included in Annex I to Directive 91/414/EEC on 1 July 2006 by Commission Directive 2005/72/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 chlorpyrifos-methyl 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 Spain, 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 the European Commission in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission 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 chlorpyrifos-methyl was assessed for foliar treatment in tomatoes. In addition, studies performed with chlorpyrifos in radishes and peas were considered acceptable to depict the general metabolic pathway of chlorpyrifos-methyl in plants. The parent compound, the metabolite 3,5,6-trichloropyridinol (referred to as 3,5,6-TCP) and its conjugates are the main components of the residues after foliar applications. The metabolism of chlorpyrifos-methyl was also investigated for post-harvest treatment in cereals. In these crops, an additional significant metabolite (desmethyl chlorpyrifos-methyl) was observed. A study investigating the nature of chlorpyrifos residues in rotational crops indicates that significant residues uptake was not expected in rotational crops, but it should still be confirmed by a fully validated rotational crop metabolism study performed with chlorpyrifos-methyl. A study investigating the effect of processing on the nature of chlorpyrifos-methyl residues was assessed in this review; it demonstrated that the parent compound is mainly degraded into desmethyl chlorpyrifos-methyl when subject to the standard hydrolytic conditions. Toxicological data on the desmethyl metabolite are missing and should still be provided; meanwhile, this compound was considered as toxic as the parent compound. However, different toxicological reference values are available for chlorpyrifos-methyl and for its metabolite 3,5,6-TCP. Based on this information, two separate residue definitions for enforcement and risk assessment were proposed by EFSA. The first residue definition (specific to chlorpyrifos-methyl) includes the parent compound (in all crops) and its desmethyl metabolite (in cereals and processed commodities only); chlorpyrifos-methyl can be enforced in plant commodities with a limit of quantification (LOQ) of 0.01 mg/kg, while analytical methods are not available for its desmethyl metabolite. 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 chlorpyrifos-methyl, 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 was also derived for the second residue definition. An analytical method is validated for analysis of 3,5,6-TCP and its conjugates with a LOQ of 0.01 mg/kg in plant commodities, but the efficiency of this hydrolysis step to release the conjugates has not been demonstrated.

For the main residue definition, the available data allowed deriving MRLs and risk assessment values for all commodities other than peppers and rice grain. Considering that further information on the toxicity of desmethyl chlorpyrifos-methyl is still required and that an analytical method for enforcement of this compound is not available, the MRLs derived for cereal grains were considered tentative. For high oil content commodities, the MRL proposals are also all tentative, mainly due to the lack of validation data for the analytical method for enforcement, and also to the limited data set for cotton seeds. Based on the same trials, an optional list of MRLs reflecting the use of chlorpyrifos-methyl, was also derived for the sum of 3,5,6-TCP and its conjugates. However, the final list of MRLs...
proposed for this residue definition also accommodates the use of chlorpyrifos (other source of 3,5,6-TCP in plant commodities) and is therefore further extended.

Based on processing studies including data for chlorpyrifos-methyl and its desmethyl metabolite, robust processing factors were derived for juices (citrus, apples, tomatoes and wine grapes), apple sauce, raisins, wet pomace (from wine grapes) and red wine (unheated). A robust processing factor was also derived for peeled citrus. The other processing factors derived in this review are only tentative because of the limited number of data and/or because the available studies do not provide analysis for desmethyl chlorpyrifos-methyl. Based on the same studies, a separate list of processing factors was also derived for the second residue definition.

The metabolism of chlorpyrifos-methyl in animals was sufficiently investigated in ruminants and poultry. As for plant commodities, both chlorpyrifos-methyl and its metabolite 3,5,6-TCP should be considered for risk assessment purposes. For the same reason as for plant commodities, two separate residue definitions were derived. The first residue definition (specific) only includes the parent compound and the second residue definition is the sum of 3,5,6-TCP and its conjugates. The parent compound still remains the most relevant compound for monitoring purposes but two separate lists of MRLs were derived.

On the available feeding studies, MRL and risk assessment values were derived for both proposed residue definitions, in dairy ruminants, meat ruminants, laying hens and pigs. However, considering the deficiencies of these studies (especially with regard to the storage conditions of the samples), these MRLs are tentative. 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 triclopyr, 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 other substances.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated for chlorpyrifos-methyl, using revision 2 of the EFSA Pesticides Residues Intake Model (PRIMo). For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. A chronic intake concern was identified (389% of the acceptable daily intake (ADI)), with wheat and rye grain being the main contributors (203% ADI and 163% ADI, respectively). Due to the data gaps regarding the toxicity of the desmethyl metabolite (DEM) and the magnitude of residues in processed commodities, it was not possible to perform a reliable refined calculation considering the consumption of cereals processed commodities. Nevertheless, considering fall-back MRLs for wheat and rye, the highest chronic exposure declined to 61.9% of the ADI (IE adult) and the highest acute exposure amounted to 37.8% of the acute reference dose (ARfD) (rice grain).

Apart from the MRLs evaluated in the framework of this review, internationally recommended codex maximum residue limits (CXLs) have also been established for chlorpyrifos-methyl. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure remained similar to the second EU calculation (61.2% of the ADI for IE adult) and the highest acute exposure was observed for apples (54.9% of the ARfD).

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.
# Table of contents

Abstract.................................................................................................................................................. 1
Summary................................................................................................................................................ 3
Background ............................................................................................................................................ 6
Terms of Reference .................................................................................................................... 7
The active substance and its use pattern ................................................................................................. 7
Assessment............................................................................................................................................. 8
1. Residues in plants ................................................................................................................................ 8
   1.1. Nature of residues and methods of analysis in plants ........................................................................ 8
   1.1.1. Nature of residues in primary crops ................................................................................................. 8
   1.1.2. Nature of residues in rotational crops .............................................................................................. 8
   1.1.3. Nature of residues in processed commodities ................................................................................... 9
   1.1.4. Methods of analysis in plants........................................................................................................... 9
   1.1.5. Stability of residues in plants ........................................................................................................... 10
   1.1.6. Proposed residue definitions ........................................................................................................... 10
   1.2. Magnitude of residues in plants ....................................................................................................... 10
   1.2.1. Magnitude of residues in primary crops ............................................................................................ 10
   1.2.2. Magnitude of residues in rotational crops ......................................................................................... 12
   1.2.3. Magnitude of residues in processed commodities .............................................................................. 13
   1.2.4. Proposed MRLs .............................................................................................................................. 13
2. Residues in livestock .......................................................................................................................... 13
   2.1. Nature of residues and methods of analysis in livestock .................................................................... 13
   2.2. Magnitude of residues in livestock ................................................................................................... 14
3. Consumer risk assessment ............................................................................................................... 15
   3.1. Consumer risk assessment for chlorpyrifos-methyl ............................................................................ 15
   3.1.1. Consumer risk assessment without consideration of the existing CXLs ................................................ 15
   3.1.2. Consumer risk assessment with consideration of the existing CXLs ..................................................... 16
   3.2. Consumer risk assessment for the metabolite 3,5,6-trichloropyridinol ................................................. 16
Conclusions............................................................................................................................................. 17
Recommendations................................................................................................................................... 19
References.............................................................................................................................................. 25
Abbreviations .......................................................................................................................................... 27
Appendix A – Summary of authorised uses considered for the review of MRLs .................................... 29
Appendix B – List of end points .............................................................................................................. 36
Appendix C – Input values for the exposure calculations ......................................................................... 61
Appendix D – Decision tree for deriving MRL recommendations ........................................................... 68
Appendix E – Used compound codes ................................................................................................... 70
Background

Regulation (EC) No 396/20051 (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(2) of that Regulation stipulates that the European Food Safety Author (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/EEC2 before 2 September 2008. As chlorpyrifos-methyl was included in Annex I to Council Directive 91/414/EEC on 1 July 2006 by means of Commission Directive 2005/72/EC3, and has been deemed to be approved under Regulation (EC) No 1107/20094, in accordance with Commission Implementing Regulation (EU) No 540/20115, as amended by Commission Implementing Regulation (EU) No 541/20116, EFSA initiated the review of all existing MRLs for that active substance. As chlorpyrifos-methyl shares a common metabolite with chlorpyrifos and triclopyr, 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.

Spain, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for chlorpyrifos-methyl and to prepare a supporting evaluation report (Spain, 2010a). The PROFile and the supporting evaluation report were submitted to EFSA on 19 July 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 Austria, Belgium, the Czech Republic, France, Portugal, Spain, the United Kingdom and the European Union Reference Laboratories for Pesticides Residues (Austria, 2016; Belgium, 2016; Czech Republic, 2016; EURIL, 2016; France, 2016a; Portugal, 2016; Spain, 2016a,b; United Kingdom, 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 the European Commission in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission (codex maximum residue

---

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 2005/72/EC of 21 October 2005 amending Council Directive 91/414/EEC to include chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, and metiram as active substances, OJ L 279, 22.10.2005, p. 63–69.
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.
limit; CXLs) and the additional information provided by Member States, EFSA prepared in October 2016 a draft reasoned 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 report submitted by the RMS (Spain 2010a) and the evaluation reports submitted by Member States Austria, Belgium, the Czech Republic, France, Portugal, Spain, the United Kingdom and the EU Reference Laboratories for Pesticides Residues (Austria, 2016; Belgium, 2016; Czech Republic, 2016; EURL, 2016; France, 2016a; Portugal, 2016; Spain, 2016a,b; United Kingdom, 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**

Chlorpyrifos-methyl is the ISO common name for O,O-dimethyl-O-3,5,6-trichloro-2-pyridyl phosphorothioate (IUPAC).

Chlorpyrifos-methyl belongs to the group of organothiophosphate compounds which are used as insecticide or acaricide or nematicide. Chlorpyrifos-methyl acts against the pest through the inhibition of acetyl-cholinesterase (AChE inhibitor) and the subsequent accumulation of acetylcholine in the nerve endings. It is used in a wide range of crops against sucking and biting pests, including pests belonging to the Coleoptera, Diptera, Homoptera and Lepidoptera.

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

Chlorpyrifos-methyl was evaluated in the framework of Directive 91/414/EEC with Spain designated as rapporteur Member State (RMS). The representative uses supported for the peer review process were foliar applications on grape vines and the treatment of wheat grain in post-harvest storage.

Chlorpyrifos-methyl was evaluated under the first stage of the review programme of Directive 91/414/EEC when EFSA was not yet involved in the risk assessment of active substances. The evaluation resulted in the inclusion of the substance in Annex I to Directive 91/414/EEC on 1 July 2006 by Commission Directive 2005/72/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.

The EU MRLs for chlorpyrifos-methyl are established in Annexes II and IIIB of Regulation (EC) No 396/2005 and CXL(s) for chlorpyrifos-methyl were also established by the Codex Alimentarius Commission (CAC). An application to modify the existing EU MRLs for chlorpyrifos-methyl was assessed by EFSA (2011). However, it was preferred to await the outcome of the MRL review before implementing these MRLs into the EU legislation.

For the purpose of this MRL review, the critical uses of chlorpyrifos-methyl 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. The details of the authorised GAPs for chlorpyrifos-methyl 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 report accompanying the PROFile (Spain, 2010a), the draft assessment report (DAR) and its addendum prepared under Council Directive 91/414/EEC (Spain, 1997, 2002, 2003, 2004), the review report on chlorpyrifos-methyl (European Commission, 2005), the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2009b, 2013), the previous reasoned opinion on chlorpyrifos-methyl (EFSA, 2011) as well as the evaluation reports submitted during the completeness check (Austria, 2016; Belgium, 2016; Czech Republic, 2016; EURL, 2016; France, 2016a; Portugal, 2016; Spain, 2016a,b; United Kingdom, 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 546/20117 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 chlorpyrifos-methyl shares a common metabolite with chlorpyrifos and triclopyr, the review of MRLs for these three active substances has been carried out in parallel and data reported in the framework of chlorpyrifos and triclopyr may also have been relied upon in the framework of this assessment. Where applicable, reference to the reasoned opinions for chlorpyrifos (EFSA, 2017b) or triclopyr (EFSA, 2017c) 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

During the peer review, the metabolism of chlorpyrifos-methyl was assessed for foliar treatment in tomatoes (Spain, 2003) and for post-harvest treatment in cereals (Spain, 1997).

After foliar application in tomatoes, the total residues rapidly declined during the first week. Thereafter, a slower decline was observed in plants. The parent compound, 3,5,6-trichloropyridinol (referred to as 3,5,6-TCP) and polar metabolites represented the main part of the residues. No other metabolite was present at significant level. The formation of polar metabolites increased with time between application and harvest, where they represented the majority of radioactive residues at harvest (55.8% of the total radioactive residues (TRR) at 42 days after treatment (DAT)). These polar metabolites were characterised as 3,5,6-TCP, mainly conjugated with glucose and malonic acid. In maize and wheat grain subject to post-harvest treatment with chlorpyrifos-methyl, the parent compound represented 33–45% of the TRR, while 3,5,6-TCP accounted for 19–39% and desmethyl chlorpyrifos-methyl (DEM) represented 19–24% of the TRR.

Due to the structural similarity between chlorpyrifos-methyl and chlorpyrifos, additional information on the metabolism of chlorpyrifos-methyl in root crops and pulses can be provided by the studies performed with chlorpyrifos in radishes and peas (Spain, 2010b). The results of these studies are consistent with the studies performed with chlorpyrifos-methyl in tomatoes. They confirm the presence of the parent compound but also show that polar metabolites represent a significant part of the residues at harvest (pods: 42.5% TRR; radish roots: 44.7% TRR).

The metabolic pattern after foliar application is similar in all crop groups which were investigated. It involves the hydrolysis of the thiophosphate group to form 3,5,6-TCP, which is then readily conjugated. For cereals treated after harvest, an additional significant reaction is also observed, being the demethylation of the parent compound to form desmethyl chlorpyrifos-methyl (DEM). EFSA concludes that the metabolism of chlorpyrifos-methyl in primary crops is sufficiently elucidated.

1.1.2. Nature of residues in rotational crops

Some of the crops under consideration (mainly cereals and oilseeds) can be grown in rotation with other plants. The soil degradation studies demonstrated that the degradation rate of

---

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.
chlorpyrifos-methyl is rapid, with a maximum DT$_{90}$ of 47 days. However, the metabolite 3,5,6-TCP showed a moderate degradation with a DT$_{90, field}$ up to 319 days (European Commission, 2005). Hence assessment of the possible occurrence of residues in succeeding crops resulting from the use on primary crops is relevant. However, rotational crop metabolism studies performed with chlorpyrifos-methyl are not available and, according to the above considerations, such studies are required.

Meanwhile, the studies performed with chlorpyrifos (Spain, 1999) may provide useful information on the possible behaviour of chlorpyrifos-methyl in rotational crops. In the main study, wheat, carrots and lettuce were planted 30 and 132 DAT in a soil previously treated with $^{14}$C-chlorpyrifos at a rate of 5.4 kg a.s./ha. Other studies were performed with the rate of 2.24 and 5.6 kg a.s./ha with wheat, lettuce, spinach, turnips, soybean and sugar beets but they were considered supportive only. The investigated crops were analysed at various times and at maturity for uptake of the $^{14}$C activity. Nevertheless, due to the limitations identified in these studies, all these results are considered on a tentative basis only.

According to the available data, very low amounts of chlorpyrifos ($< 0.01$ mg eq/kg) or 3,5,6-TCP were observed in carrots, lettuce and wheat ($< 0.05$ mg eq/kg). Another component was identified (3,5,6-trichloro-2-methoxypyridine), but also at trace levels. The main portion of the residues appeared to be the result of incorporation into natural plant components, such as starch, cellulose and lignin. Based on this information for chlorpyrifos, it is expected that relevant residue levels of chlorpyrifos-methyl and its soil metabolites will not occur in rotational crops, but this should still be confirmed by a rotational crop metabolism study performed with chlorpyrifos-methyl.

### 1.1.3. Nature of residues in processed commodities

A study investigating the effect of processing on the nature of residues was provided to the RMS in the active substance renewal dossier. This study has been evaluated by the RMS and is therefore considered in the framework of the present review (Spain, 2016b). It covers the representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6). This study clearly demonstrates that chlorpyrifos-methyl readily degraded when subject to hydrolytic conditions. The level of degradation increases with temperature: 25% degradation under pasteurisation, 80% degradation under boiling/brewing/baking and almost 100% degradation under sterilisation. The main degradation product is desmethyl chlorpyrifos-methyl (DEM) (21.5–90.7% of the applied radioactivity (AR)) which was already observed in cereal grain (see Section 1.1.1). The metabolite 3,5,6-TCP is also observed in lower proportions: 2.1–7.7% of the AR. Although the degradation products observed in raw and processed commodities are similar, the presence of desmethyl chlorpyrifos-methyl (DEM) is expected to be more important in processed commodities.

### 1.1.4. Methods of analysis in plants

During the peer review, an analytical method using gas chromatography with flame photometric detector (GC-FPD) was validated for enforcement of chlorpyrifos-methyl in high water and high acid content commodities with a LOQ of 0.01 mg/kg (Spain, 1997, 2002). A confirmatory method and an independent laboratory validation (ILV) were available. The multiresidue QuEChERS method in combination with gas chromatography with tandem mass spectrometry (GC–MS/MS), as reported by the EURs (2016), is sufficiently validated for analysis of chlorpyrifos-methyl in high water content commodities, high acid content commodities and dry commodities, with the LOQ of 0.01 mg/kg. With regard to the enforcement of chlorpyrifos-methyl in high oil content commodities, a method using high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) was reported by France (2016a). This method is fully validated with a LOQ of 0.01 mg/kg but France highlighted that an ILV was still missing.

Hence, it is concluded that chlorpyrifos-methyl can be enforced in the four main commodity groups with a LOQ of 0.01 mg/kg. However, an ILV for high oil content commodities is still required.

Concerning metabolite 3,5,6-TCP, an analytical method using HPLC–MS/MS was reported by France and the EURs. This method is validated for analysis of 3,5,6-TCP and its conjugates with a LOQ of 0.01 mg/kg in the four main commodity groups (France, 2016b). It is highlighted that this method used a radiolabelled internal standard. In the same report, an ILV is also available for dry and high water content commodities. However, in order to release the conjugates of 3,5,6-TCP, this method involves a hydrolysis step, which is also expected to convert chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl (DEM) into 3,5,6-TCP. Therefore, this method is not specific enough to enforce 3,5,6-TCP and its conjugates separately. Furthermore, the efficiency of this hydrolysis step to release the conjugates has not been demonstrated.
Analytical methods for the analysis of desmethyl chlorpyrifos-methyl (DEM) are not available while this metabolite is a major compound in cereal grain (dry commodities) and is also expected in processed commodities (several matrices).

1.1.5. Stability of residues in plants

In the framework of this review, the RMS has provided several studies covering the storage stability of chlorpyrifos-methyl and its metabolites (Spain, 2016a).

Storage stability of chlorpyrifos-methyl was demonstrated in high water content commodities (24 months), dry commodities (24 months) and high oil content commodities (18 months) when stored deep frozen. The storage stability in high acid content commodities was assessed in two different studies (oranges and grapes). In oranges, a significant decrease (> 30%) was observed after 12 months while in grapes, residues remained stable up to 24 months.

The storage stability of metabolite 3,5,6-TCP was also evaluated in the same matrices. This compound was stable for a period of 18 months in high water content, high oil content and high acid content commodities, and up to 24 months in dry commodities. This study is also considered adequate to address storage stability of 3,5,6-TCP conjugates because a possible decline of such conjugates is only expected to release 3,5,6-TCP.

The storage stability of desmethyl chlorpyrifos-methyl (DEM) was demonstrated for a period of 22 months in dry commodities.

1.1.6. Proposed residue definitions

Based on the above data, it can be concluded that chlorpyrifos-methyl is a good marker compound for residues in plant commodities but it is not the only compound of relevance, in particular with regard to the risk assessment. Metabolite 3,5,6-TCP (free and conjugated) contributes significantly to the total residues in all investigated primary crops and desmethyl chlorpyrifos-methyl (DEM) was significant in cereal grain treated after harvest. The latter compound is also expected to be a major component of the residues in processed commodities.

Furthermore, metabolite 3,5,6-TCP is also identified to be a major metabolite of chlorpyrifos and is therefore not specific to chlorpyrifos-methyl. Also, considering that toxicological reference values derived for chlorpyrifos-methyl (European Commission, 2005) and 3,5,6-TCP (EFSA, 2014) are different, the consumer risk assessment needs to be conducted separately for chlorpyrifos and metabolite 3,5,6-TCP (and its conjugates), noting that the assessment of 3,5,6-TCP and its conjugates should also take into consideration the use of chlorpyrifos. Therefore, two separate residue definitions for risk assessment should be established. For enforcement purposes, since 3,5,6-TCP is not specific to chlorpyrifos-methyl, the parent compound remains the most relevant marker compound but, if risk managers consider that enforcement of 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.

For cereal grain and processed commodities, a different residue definition for enforcement and risk assessment should be proposed to consider the specific degradation observed after post-harvest treatment: demethylation of the parent compound to form desmethyl chlorpyrifos-methyl (DEM). In the absence of toxicological data, this compound is considered as toxic as the parent compound (EFSA, 2011). However, further information on the toxicity of desmethyl chlorpyrifos-methyl (DEM) is still required. Meanwhile, the residue in cereal grain and processed commodities is defined as the sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl (DEM), expressed as chlorpyrifos-methyl. This proposal does not impact on the residue definition for the sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP in cereal grains and processed commodities.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of chlorpyrifos-methyl residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Spain, 2016b), including residue trials evaluated in the framework of the peer review (Spain, 1997, 2003) or in the framework of a previous MRL application (EFSA, 2011), and additional data submitted during the completeness check (Austria, 2016; Belgium, 2016; Czech Republic, 2016; France, 2016a; Portugal, 2016; Spain,
All residue trial samples considered in this framework were stored in compliance with the demonstrated storage conditions, except for grapes (table and wine) and strawberries where some samples were stored for more than 12 months. In the storage stability study performed on high acid content commodities, a significant decrease of residues was observed after 12 months in oranges but stability in grapes was demonstrated up to 24 months (see Section 1.1.5). For grapes and strawberries, it is reasonable to refer to the study performed on grapes; therefore, covering the storage conditions of the reported trials. Decline of residues during storage of the trial samples is therefore not expected.

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

Since chlorpyrifos-methyl and its metabolite 3,5,6-TCP should be assessed separately, the residue levels related to their corresponding residue definitions were reported in two separate tables (see Appendix B.1.2). In all trials considered in this review, analysis were carried out for the parent compound and for the total residue hydrolysed to 3,5,6-TCP. In addition, the residue trials performed on cereal grains also analysed for desmethyl chlorpyrifos-methyl (DEM). As the parent compound and desmethyl chlorpyrifos-methyl (DEM) can be hydrolysed to 3,5,6-TCP, the absolute levels of 3,5,6-TCP and its conjugates were calculated by subtracting the contribution of the parent compound and desmethyl chlorpyrifos-methyl (DEM) to the total residue.8

No residue trials are available to support the foliar treatment on peppers as well as for the post-harvest treatment on maize and rice grain. Therefore, the following data gaps were identified:

- **Peppers**: Eight trials compliant with the southern outdoor GAP are required.
- **Maize and rice grain**: A post-harvest treatment is authorised on these commodities but residue trials supporting this GAP are not available. For post-harvest treatment on cereals, the current guidance gives the possibility to set the MRL at the application rate without residue trials, because this kind of treatment generally produces homogeneous and persistent residues. This waiver was proposed by France (2016a) and was considered during the Member States consultation (EFSA, 2017a). EFSA highlighted that the residue trials performed with post-harvest applications on barley and wheat do not show a clear homogeneity of the residue levels (residues range between 2.4 and 5.2 mg/kg for an application rate of 5 g a.s./tonne). In addition, the application rate (as chlorpyrifos-methyl) is not considered relevant to estimate the final residues in cereal grains because the parent compound degrades into desmethyl chlorpyrifos-methyl (DEM) and 3,5,6-TCP. Therefore, EFSA is of the opinion that, in the present case, the required conditions are not met to derive a MRL without residue trials. Consequently, four trials on maize grain and four trials on rice grain supporting the post-harvest GAP are required. For maize grain, MRL and risk assessment values can still be derived from the southern outdoor GAP supported by data. For rice grain, however, MRL and risk assessment values could not be derived.

For cotton seed and small grain cereals (barley, wheat, oats and rye), the reported residue trials are overdosed compared to the authorised GAPs. Hence, these residue trials can only be considered on a tentative basis and the following considerations were made by EFSA:

- **Cotton seed**: The available residue trials were performed with an application rate of 0.69 kg a.s./ha instead of 0.36 kg a.s./ha. Although tentative MRL and risk assessment values can be derived from these data, eight residue trials compliant with the southern outdoor GAP are still required.
- **Small grain cereals (post-harvest treatment)**: The only trials that include analysis of chlorpyrifos-methyl and its desmethyl metabolite (in compliance with the residue definition for these commodities) were performed at the rate of 5 g a.s./tonne instead of 2.5 g a.s./tonne. In the absence of any other option, tentative MRL and risk assessment values are derived from these data. It is noted that the MRL proposal derived from the OECD calculator is not relevant in the case of post-harvest treatment. Considering that Rber and Rmax indicators (7.8 mg/kg and 6.3 mg/kg, respectively) may also overestimate the MRL calculation in this case, that the highest residue level observed in the trials is 5.23 mg/kg and that the trials are overdosed

---

8 The following calculation was performed: \([3,5,6-TCP\text{ and its conjugates}] = \left[\text{total residues hydrolysed as 3,5,6-TCP}\right] - \left[\text{parent compound}\right] - \left[\text{desmethyl chlorpyrifos-methyl}\right]\), taking into account the molecular mass of chlorpyrifos methyl (322.53 g/mol), desmethyl chlorpyrifos-methyl (308.6 mg/mol) and 3,5,6-TCP (198.43 g/mol).
compared to GAP, a tentative MRL of 6 mg/kg is proposed. Nevertheless, four trials (on either barley, oat, rye or wheat grain) compliant with the post-harvest GAP are still required.

For all other crops, GAPs are adequately supported by the available residue trials, at least for the parent residue definition, taking note however of the following considerations:

- **Apples, pears, table grapes (SEU), tomatoes (SEU) and aubergines (SEU):** GAPs are authorised for one application only while residue trials were all performed with two applications. In general, this deviation is not considered acceptable because this may result in an overestimation of the MRL and risk assessment values. Nevertheless, this deviation was considered acceptable in those cases because the time between the two applications performed in the residue trials was by far longer than the preharvest interval (PHI); the impact of the first application on the final residues is therefore considered negligible.

- **Mandarins, lemons:** Only two trials performed on mandarins are available. In principle, a minimum of eight trials performed on mandarins or lemons are needed to derive a MRL on these crops. Nevertheless, considering that 14 trials performed on oranges are available and that the highest residue level was observed on orange, this is considered as a minor deficiency. Six additional trials performed on mandarins or lemons are therefore desirable but not required.

- **Currants:** The authorised GAP consists of one application just after harvest (i.e. 200 days before the next harvest). As chlorpyrifos-methyl is a non-systemic active substance, its translocation through the plant is not expected and a no-residue situation regarding chlorpyrifos-methyl can be assumed for this crop. This is, however, not applicable to the metabolite 3,5,6-TCP for which the possible uptake cannot be excluded. Therefore, if risk managers intend to set MRLs for this compound, additional residue trials performed on currants and analysing for 3,5,6-TCP would be required.

- **Rapeseed (and other oilseeds):** The number of residue trials supporting the northern and southern outdoor GAPs is not compliant with the data requirements for this crop (seven trials instead of eight are available for each region). 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.

- **Barley and oat (grain and straw):** The number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for these crops (seven trials instead of eight). One additional trial is therefore desirable (minor deficiency).

### 1.2.2. Magnitude of residues in rotational crops

Significant residues are not expected in rotational crops. However, this is only a tentative conclusion based on old studies performed with chlorpyrifos and additional metabolism studies are required (see Section 1.1.2).

### 1.2.3. Magnitude of residues in processed commodities

All studies investigating the magnitude of chlorpyrifos-methyl residues in processed commodities were assessed by the RMS in its evaluation reports (Spain, 2010a, 2016a,b). These reports also include old studies evaluated during the peer review (Spain, 1997, 2003). An overview of all available processing studies is available in Appendix B.1.2.4. Since chlorpyrifos-methyl and its metabolite 3,5,6-TCP should be assessed separately, the processing factors related to the respective residue definitions were reported in two independent tables.

Regarding the main residue definition (chlorpyrifos-methyl in raw commodities other than small grain cereals and sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl (DEM) in processed commodities and small grain cereals), only the studies performed on cereals and the new studies do include data for the metabolite desmethyl chlorpyrifos-methyl (DEM). It is noted that the new studies performed with juices of apple, orange and tomatoes and apple sauce clearly indicate that desmethyl chlorpyrifos-methyl (DEM) and chlorpyrifos-methyl remain below the LOQ in these processed items. Therefore, for these commodities, results of the old studies (only analysing for the parent compound) were also considered for deriving a process factor. Hence, robust processing factors are derived for juices (citrus, apples, tomatoes and wine grapes), apple sauce, raisins, wet pomace (from wine grapes) and red wine (unheated). A robust processing factor is also derived for peeled citrus where the residue definition for raw fruit commodities (chlorpyrifos-methyl only) applies. Data for desmethyl chlorpyrifos-methyl (DEM) are also available for orange marmalade, apples dry and wet pomaces,
canned pears, tomatoes (sauce, paste, ketchup and dried) as well as for barley (malt and beer) and all processed commodities of wheat grain (bran, flours and breads). However, due to the limited number of data, only tentative processing factors were derived for these items.

In the old studies, analysis for desmethyl chlorpyrifos-methyl (DEM) was not carried out but residue levels of the parent compound and the total 3,5,6-TCP residues are available. In this case, EFSA proposed to derive tentative processing factors considering the available results for total 3,5,6-TCP residue levels instead of considering the proposed residue definition (restricted to the sum of chlorpyrifos-methyl and its metabolite desmethyl chlorpyrifos-methyl (DEM)). This approach is expected to overestimate the calculated processing factors because the total 3,5,6-TCP residues include the parent compound, desmethyl chlorpyrifos-methyl (DEM) and 3,5,6-TCP. Therefore, the following processing factors are considered tentative: wine grapes (dry pomace and must), canned tomatoes (peeled and unpeeled). These factors could still be used to perform a conservative risk assessment.

Processing factors were also derived for the second residue definition: sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP. For this list of processing factors, both old and new studies were considered relevant since analysis of 3,5,6-TCP was always carried out. As for the field residue trials, the absolute levels for 3,5,6-TCP and its conjugates were calculated by subtracting the contribution of the parent compound (and desmethyl chlorpyrifos-methyl (DEM) when available) to the total residue hydrolysed as 3,5,6-TCP.

Considering the outcome of the risk assessment, additional processing studies analysing for desmethyl chlorpyrifos-methyl (DEM) may be useful to refine the risk assessment, especially for processed commodities of wheat and rye where only tentative processing factors could be derived while these commodities are main contributors to the chronic consumer exposure. In addition, if further robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed for the other processed commodities where a tentative processing factor is derived.

1.2.4. Proposed MRLs

MRL proposals and risk assessment values were derived for the main residue definition including chlorpyrifos-methyl (and its desmethyl metabolite in cereal grains). The available data allowed deriving MRLs and risk assessment values for all commodities other than peppers and rice grain, for which GAP-compliant trials were not reported. Considering that further information on the toxicity of desmethyl chlorpyrifos-methyl (DEM) is still required and that an analytical method for enforcement of this compound is not available, MRLs derived for cereal grains should be considered tentative. For high oil content commodities, the MRL proposals are also all tentative, mainly due to the lack of validation data for the analytical method for enforcement, but also due to the limited data set for cotton seeds.

In line with the conclusion on the residue definition (see Section 1.1.6), an optional list of MRLs can also be set for the sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP. However, it is highlighted that uncertainties were identified with regard to the efficiency of the analytical method for enforcement. Tentative MRLs and risk assessment values were derived for all commodities other than peppers, rice grain and currants, for which GAP-compliant trials were not reported. It is noted that the plant MRLs derived in this section only take into account the use of chlorpyrifos-methyl. These MRLs are reported in Appendix B.4. However, the final list of optional MRLs proposed for 3,5,6-TCP should also accommodate the use of chlorpyrifos (other source of 3,5,6-TCP in plant commodities) and it is reported in the section conclusion and recommendations.

Tentative MRLs were also derived for feed crops cereal straw in view of the future need to set MRLs in feed items. It is noted that these MRLs are derived from the outdoor GAP (foliar treatment) because the post-harvest treatment is not relevant for cereal straw.

2. Residues in livestock

Chlorpyrifos-methyl is authorised for use on several crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed, both for chlorpyrifos-methyl and 3,5,6-TCP, in the 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, 2009a) and are summarised in Appendix B. The dietary burden values calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in all commodities of animal origin.
2.1. Nature of residues and methods of analysis in livestock

The metabolism of chlorpyrifos-methyl in livestock (lactating goat, sheep and laying hens) was assessed in the DAR prepared under Directive 91/414/EEC (Spain, 1997). The overall pattern of absorption and elimination was similar among the different investigated species. Chlorpyrifos-methyl was rapidly absorbed and excreted mainly via the urine. In ruminants, tissue residues were generally low (< 1 mg/kg) with little sign of accumulation. The highest levels were present in fatty tissues and consisted almost exclusively of the parent compound. In the remaining tissues, the residues were mainly identified as the parent compound and 3,5,6-TCP, either in its free or conjugated form. Desmethyl chlorpyrifos-methyl (DEM) was also observed but only in minor amounts. Residues in whole milk, comprising mainly of the parent compound and 3,5,6-TCP, were low and reached the plateau within two days; levels in milk fat were correspondingly higher and were constituted mainly of the parent compound. In hens, tissue residues were generally low and comprised very low levels of 3,5,6-TCP and desmethyl chlorpyrifos-methyl (DEM), except fat where the parent compound was the main residue. Eggs contained low levels of radioactivity (< 0.05% of AR) and comprised roughly equal amounts of parent and both metabolites.

EFSA concludes that the metabolism of chlorpyrifos-methyl in livestock is adequately elucidated, and chlorpyrifos-methyl and 3,5,6-TCP (including its conjugates) are the most relevant components of the residues in livestock commodities.

During the peer review, an analytical method using gas chromatography with negative chemical ionisation/mass spectrometry (GC-NCl/MS) was reported and evaluated. There are indications that this method allows to enforce chlorpyrifos-methyl in all animal tissues, milk and eggs with a LOQ of 0.01 mg/kg (Spain, 2002). However, during the Member State consultation, France and Germany pointed out that this method was not fully validated with regard to the current guidance document (specificity not demonstrated, insufficient recovery data for liver and insufficient number of fortified samples for milk, meat and fat). Nevertheless, the multi-residue QuEChERS method in combination with GC–MS/MS, as reported by the EURLs (2016), is sufficiently validated for analysis of chlorpyrifos-methyl in liver, kidney and eggs. Hence, it is concluded that chlorpyrifos-methyl can be enforced in liver, kidney and eggs with a LOQ of 0.01 mg/kg; a fully validated analytical method is still required for muscle, fat and milk.

During the completeness check, an analytical method using HPLC–MS/MS was reported by France (2016b). This method is fully validated for the determination of 3,5,6-TCP in all animal tissues, milk and eggs, with a LOQ of 0.01 mg/kg. It is highlighted that this method used a radiolabelled internal standard. However, in order to release the conjugates of 3,5,6-TCP, this method involves a hydrolysis step, which is also expected to convert chlorpyrifos-methyl into 3,5,6-TCP. Therefore, this method is not specific enough to enforce 3,5,6-TCP and its conjugates separately. Furthermore, the efficiency of this hydrolysis step to release the conjugates has not been demonstrated.

The storage stability of chlorpyrifos-methyl was demonstrated for a period of 3 months at −20°C in muscle, fat, liver, kidney and milk (Spain, 2003). In eggs, however, a significant decrease (40%) was observed after 3 months of storage (only sampling performed in the study). 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 chlorpyrifos-methyl 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 triclopyr, and different toxicological reference values were derived for chlorpyrifos-methyl (European Commission, 2005) 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 it conjugates should also take into consideration the use of chlorpyrifos and triclopyr.

For monitoring purposes, since 3,5,6-TCP is not specific to chlorpyrifos-methyl, 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. The parent residue is fat soluble while 3,5,6-TCP and its conjugates are not.
2.2. **Magnitude of residues in livestock**

In the framework of the peer review, several non-Good Laboratory Practice (GLP) feeding studies were performed with dairy cows, beef calves, laying hens and swine (Spain, 1997, 2003, 2004). Although these studies are not GLP compliant, they can be considered because they were conducted prior to GLP implementation.

In all these studies, chlorpyrifos-methyl was administered using five different dosing levels (1, 3, 10, 30 and 100 mg/kg feed). The studies performed on dairy cow, hens and swine were used to derive MRL and risk assessment values in milk, poultry products and pig tissues, respectively. 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. In all studies, the samples of tissues, milk or eggs were separately analysed for chlorpyrifos-methyl and its metabolite 3,5,6-TCP. Nevertheless, as the storage conditions of the samples were not reported and due to the short period covered by the storage stability study (only 3 months for the parent compound), a decline of residues during storage of the samples cannot be excluded. Therefore, further information on this matter is required and results of the available studies are considered on a tentative basis only.

Based on these studies, MRL and risk assessment values were derived (for both proposed residue definitions) for dairy ruminants, meat ruminants, laying hens and pigs, in compliance with the latest recommendations on this matter (FAO, 2009a). It is noted that significant levels of chlorpyrifos-methyl are only expected in ruminant and swine fat, while all other MRLs are proposed at the LOQ. For the metabolite 3,5,6-TCP, MRLs above LOQ are proposed in all livestock commodities except in milk and ruminant muscle. Considering the deficiencies of the studies (in particular with regard to the storage stability), all the derived MRLs should be considered tentative.

3. **Consumer risk assessment**

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

Furthermore, only the uses of chlorpyrifos-methyl reported in Appendix A were considered in the framework of this review while the use of chlorpyrifos-methyl was previously also assessed by the JMPR (FAO, 2009b, 2013). The CXLs, resulting from these assessments by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. To facilitate consideration of these CXLs by risk managers, the consumer exposure was assessed both with and without consideration of the existing CXLs.

3.1. **Consumer risk assessment for chlorpyrifos-methyl**

3.1.1. **Consumer risk assessment without consideration of the existing CXLs**

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 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, 2009a). For all commodities of plant origin, input values refer to the raw agricultural commodities, except for citrus fruits, where the peeling factor is taken into account. For those commodities where data were insufficient 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.

The exposure values calculated were compared with the toxicological reference values for chlorpyrifos-methyl, derived by the European Commission (2005) under Directive 91/414/EEC. A chronic intake concern was identified as the highest chronic exposure represented 389% of the ADI (Danish children). The main contributors to this chronic exposure were wheat grain (203% of the ADI) and rye grain (163% of the ADI). For these commodities, the most critical GAP is a post-harvest treatment for which risk assessment values were tentatively derived considering overdosed trials (see also...
Section 1.2.1). Residue trials compliant with GAPs (including analysis of parent and its desmethyl metabolite) are still required and EFSA is of the opinion that generating these data is necessary to refine the chronic exposure assessment. It is noted that an attempt to refine the chronic exposure to chlorpyrifos-methyl was previously performed by EFSA (2011). In this refined approach, EFSA considered detailed consumption data for cereals-based processed commodities and the processing factors previously derived for these commodities. However, these calculations were not sufficient to exclude a potential chronic risk for consumers. Furthermore, the additional data on the nature and magnitude of residues in processed commodities which were evaluated in the present review indicate that this refined approach is subject to a high uncertainty. The hydrolysis studies indicate that the parent compound is mainly degraded to desmethyl chlorpyrifos-methyl (DEM) in processed commodities of cereals and the toxicity of this compound still needs to be addressed (see Section 1.1.3). In addition, tentative processing factors were recalculated for all processed commodities of cereals. These processing factors are higher than the one previously derived in 2011 and most of them are supported by a limited number of data (see Section 1.2.3). Considering all of this, EFSA did not perform a refined calculation in the present review. However, such refined calculations could be proposed after the submission of the required data.

Considering that wheat and rye grain were identified as the main drivers for the chronic risk, EFSA assessed the impact of considering fall-back GAPs for these crops (i.e. foliar treatment) in a second exposure calculation. It is highlighted that consideration of these less critical GAPs does not impact on the residue levels in livestock commodities as the post-harvest treatment on barley and oat grains is still considered for the dietary burden calculations. According to the results of this second calculation (scenario EU2), the highest chronic exposure declined to 61.9% of the ADI for Irish adults; the highest acute exposure is then calculated for rice grain, representing 37.8% of the ARfD.

Based on these calculations, a potential risk to consumers was identified for the most critical GAP of chlorpyrifos-methyl on wheat and rye grain (i.e. post-harvest application). EFSA considered that the data gaps on the toxicity of the desmethyl chlorpyrifos-methyl (DEM) and on the magnitude of residues in processed commodities did not allow performing a reliable refined calculation for the chronic exposure. However, a fall-back GAP was identified for wheat and rye, for which a second risk assessment did not indicate risk to consumers. For the remaining commodities, although some major uncertainties remain due to the data gaps identified in the previous sections, the indicative exposure calculation did not indicate a risk to consumers.

### 3.1.2. Consumer risk assessment with consideration of the existing CXLs

To include the CXLs in the calculations of the consumer exposure, CXLs were compared with the EU MRL proposals in compliance with Appendix D and all data relevant to the consumer exposure assessment have been collected from JMPR evaluations. For citrus fruits and bananas, the relevant peeling factor was applied. It is noted that the CXLs on cereal grains are not compatible with the residue definition derived in this review for cereal crops because desmethyl chlorpyrifos-methyl (DEM) was not considered by JMPR. Therefore, these CXLs (rice grain, sorghum grain and wheat grain) are not considered in this risk assessment. It is noted that the data gaps identified for muscle, fat and milk (validated analytical method for enforcement missing) also applies to the CXLs existing on similar matrices. Furthermore, as a validated analytical method for enforcement in specific matrices is not available, the existing CXLs defined for spices are also considered tentative. An overview of the input values used for this exposure calculation is also provided in Appendix C.

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 chlorpyrifos-methyl. The highest chronic exposure was calculated for Irish adults, representing 61.2% of the ADI and the highest acute exposure was calculated for apples, representing 54.9% of the ARfD.

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

Metabolite 3,5,6-TCP is not specific to chlorpyrifos-methyl as it is also a major metabolism product of two other active substances: chlorpyrifos and triclopyr. Hence, 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.

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 (for chlorpyrifos, see also EFSA, 2017b). 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 present reasoned opinion as well as in the reasoned opinion of chlorpyrifos, 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 poultry is mainly driven by the dietary intake of chlorpyrifos-methyl (0.22 mg/kg body weight (bw) per day; see also Table 1). Therefore, risk assessment values derived in Section 2.2 of the present reasoned opinion were used as input values for the present exposure calculation in poultry products. 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 (see Table 1). Therefore, risk assessment values for 3,5,6-TCP were derived from the reasoned opinion of triclopyr (EFSA, 2017c).

All input values included in the exposure calculations are summarised in Appendix C.4. 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 (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 chlorpyrifos-methyl was assessed for foliar treatment in tomatoes. In addition, studies performed with chlorpyrifos in radishes and peas were considered acceptable to depict the
general metabolic pathway of chlorpyrifos-methyl in plants. The parent compound, the metabolite 3,5,6-trichloropyridinol (referred to as 3,5,6-TCP) and its conjugates are the main components of the residues after foliar applications. The metabolism of chlorpyrifos-methyl was also investigated for post-harvest treatment in cereals. In these crops, an additional significant metabolite (desmethyl chlorpyrifos-methyl (DEM)) was observed. A study investigating the nature of chlorpyrifos residues in rotational crops indicates that significant residues uptake was not expected in rotational crops, but it should still be confirmed by a fully validated rotational crop metabolism study performed with chlorpyrifos-methyl. A study investigating the effect of processing on the nature of chlorpyrifos-methyl residues was assessed in this review; it demonstrated that the parent compound is mainly degraded into desmethyl chlorpyrifos-methyl (DEM) when subject to the standard hydrolytic conditions. Toxicological data on the desmethyl metabolite are missing and should still be provided; meanwhile, this compound was considered as toxic as the parent compound. However, different toxicological reference values are available for chlorpyrifos-methyl and for its metabolite 3,5,6-TCP. Based on this information, two separate residue definitions for enforcement and risk assessment were proposed by EFSA. The first residue definition (specific to chlorpyrifos-methyl) includes the parent compound (in all crops) and its desmethyl metabolite (in cereals and processed commodities only); chlorpyrifos-methyl can be enforced in plant commodities with a LOQ of 0.01 mg/kg, while analytical methods are not available for its desmethyl metabolite. 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 chlorpyrifos-methyl, 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 was also derived for the second residue definition. An analytical method is validated for analysis of 3,5,6-TCP and its conjugates with a LOQ of 0.01 mg/kg in plant commodities, but the efficiency of this hydrolysis step to release the conjugates has not been demonstrated.

For the main residue definition, the available data allowed deriving MRLs and risk assessment values for all commodities other than peppers and rice grain. Considering that further information on the toxicity of desmethyl chlorpyrifos-methyl (DEM) is still required and that an analytical method for enforcement of this compound is not available, the MRLs derived for cereal grains were considered tentative. For high oil content commodities, the MRL proposals are also all tentative, mainly due to the lack of validation data for the analytical method for enforcement, and also to the limited data set for cotton seeds. Based on the same trials, an optional list of MRLs reflecting the use of chlorpyrifos-methyl, was also derived for the sum of 3,5,6-TCP and its conjugates. However, the final list of MRLs proposed for this residue definition also accommodates the use of chlorpyrifos (other source of 3,5,6-TCP in plant commodities) and is therefore further extended.

Based on processing studies including data for chlorpyrifos-methyl and its desmethyl metabolite, robust processing factors were derived for juices (citrus, apples, tomatoes and wine grapes), apple sauce, raisins, wet pomace (from wine grapes) and red wine (unheated). A robust processing factor was also derived for peeled citrus. The other processing factors derived in this review are only tentative because of the limited number of data and/or because the available studies do not provide analysis for desmethyl chlorpyrifos-methyl (DEM). Based on the same studies, a separate list of processing factors was also derived for the second residue definition.

The metabolism of chlorpyrifos-methyl in animals was sufficiently investigated in ruminants and poultry. As for plant commodities, both chlorpyrifos-methyl and its metabolite 3,5,6-TCP should be considered for risk assessment purposes. For the same reason as for plant commodities, two separate residue definitions were derived. The first residue definition (specific) only includes the parent compound and the second residue definition is the sum of 3,5,6-TCP and its conjugates. The parent compound still remains the most relevant compound for monitoring purposes but two separate lists of MRLs were derived.

Based on the available feeding studies, MRL and risk assessment values were derived for both proposed residue definitions, in dairy ruminants, meat ruminants, laying hens and pigs. However, considering the deficiencies of these studies (especially with regard to the storage conditions of the samples), these MRLs are tentative. 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 triclopyr, 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 other substances.
Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated for chlorpyrifos-methyl, using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. A chronic intake concern was identified (389% ADI), with wheat and rye grain being the main contributors (203% ADI and 163% ADI, respectively). Due to the data gaps regarding the toxicity of the desmethyl metabolite desmethyl chlorpyrifos-methyl (DEM) and the magnitude of residues in processed commodities, it was not possible to perform a reliable refined calculation considering the consumption of cereals processed commodities. Nevertheless, considering fall-back MRLs for wheat and rye, the highest chronic exposure declined to 61.9% of the ADI (IE adult) and the highest acute exposure amounted to 37.8% of the ARfD (rice grain).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for chlorpyrifos-methyl. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure remained similar to the second EU calculation (61.2% of the ADI for IE adult) and the highest acute exposure was observed for apples (54.9% of the ARfD).

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):** chlorpyrifos-methyl (including its desmethyl metabolite in cereal commodities). MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see Table 2). All MRL values listed as ‘Recommended’ in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 2 footnotes for details).

- **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 chlorpyrifos-methyl 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 or existing EU MRLs still need to be confirmed by the following data:

- an ILV for the determination of chlorpyrifos-methyl in high oil content commodities;
- a fully validated analytical method for the determination of chlorpyrifos-methyl in spices;
- a fully validated analytical method for the determination of desmethyl chlorpyrifos-methyl (DEM) in dry commodities;
- a fully validated analytical method for the determination of chlorpyrifos-methyl in muscle, fat and milk;
- additional residue trials supporting the GAPs on rice grain, cotton seed as well as the post-harvest treatment on barley and oat;
- additional processing studies analysing for desmethyl chlorpyrifos-methyl (DEM) for processed commodities of cereals;
- further information on the toxicity of the metabolite desmethyl chlorpyrifos-methyl (DEM) (relevant in processed commodities and in cereal grains after post-harvest treatment);
- further information on the storage conditions of the samples in the livestock feeding studies.

In addition, it is highlighted that some MRLs derived for chlorpyrifos-methyl result from a CXL or from a GAP in one climatic zone only, while other GAPs reported in this review were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- a representative study investigating metabolism of chlorpyrifos-methyl in rotational crops;
- additional residue trials supporting the GAP on peppers and the post-harvest treatment on maize grain.

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. It is also highlighted that MRLs derived in wheat and rye grain are based on the outdoor fall-back GAPs (outdoor foliar treatment) because the critical GAPs (post-harvest treatment) were shown to result in an exceedance of the ADI for the parent chlorpyrifos-methyl. It is noted that GAP-compliant residue trials supporting the post-harvest uses on wheat grain and rye grain as well as further information on the toxicity of desmethyl chlorpyrifos-methyl (DEM) may allow to refine the chronic risk assessment in the future. However, in the meantime, Member States are recommended to reconsider or withdraw their national authorisations on wheat and rye in order to ensure that the fall-back MRLs derived for the parent chlorpyrifos-methyl in these crops are not exceeded. Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- additional residue trials supporting the GAPs on mandarins and lemons and on barley oats (foliar treatment).

For the optional residue definition, the proposed MRLs also took into consideration the reasoned opinions of chlorpyrifos (for plant commodities) and triclopyr (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. For animal commodities, MRLs in poultry are derived from the chlorpyrifos-methyl dietary burden while for ruminants (dairy and meat) and pigs, tentative MRLs are derived from the reasoned opinion of triclopyr (identified as the main driver of residues intake in these groups of livestock).

It is noted that the above-mentioned data gaps for the parent compound also apply to the optional residue definition. In addition, specific data gaps for the metabolite 3,5,6-TCP were also identified. Therefore, if risk managers intend to set MRLs for this compound, the following data should be required (in addition to the above mentioned data gaps):

- 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 2: Summary table

| Code number | Commodity   | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|-------------|-------------------------|---------------------|-----------------------|---------|
|             |             |                         |                     |                       |         |
| Enforcement residue definition 1a (existing): chlorpyrifos-methyl(F) | | | | | |
| 110010      | Grapefruit  | 0.05*                   | 2                   | 2                     | Recommended(a) |
| 110020      | Oranges     | 0.5                     | 2                   | 2                     | Recommended(b) |

www.efsa.europa.eu/efsajournal 20 EFSA Journal 2017;15(3):4734
| Code number | Commodity                  | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|----------------------------|------------------------|---------------------|-----------------------|---------|
| 110030      | Lemons                     | 0.3                    | 2                   | 2                     | Recommended (b) |
| 110040      | Limes                      | 0.05*                  | 2                   | 2                     | Recommended (b) |
| 110050      | Mandarins                  | 1                      | 2                   | 2                     | Recommended (b) |
| 130020      | Apples                     | 0.5                    | 1                   | 1                     | Recommended (b) |
| 130030      | Quinces                    | 0.5                    | 1                   | 1                     | Recommended (b) |
| 130040      | Medlar                     | 0.5                    | 1                   | 1                     | Recommended (b) |
| 130050      | Loquat                     | 0.5                    | 1                   | 1                     | Recommended (b) |
| 140010      | Apricots                   | 0.05*                  | 0.5                 | 0.5                   | Recommended (b) |
| 140020      | Cherries                   | 0.05*                  | 0.5                 | 0.5                   | Recommended (b) |
| 140030      | Peaches                    | 0.5                    | 0.5                 | 0.5                   | Recommended (b) |
| 140040      | Plums                      | 0.05*                  | 0.5                 | 0.5                   | Recommended (b) |
| 151010      | Table grapes               | 0.2                    | 1                   | 1                     | Recommended (b) |
| 151020      | Wine grapes                | 0.2                    | 1                   | 1                     | Recommended (b) |
| 152000      | Strawberries               | 0.5                    | 0.06                | 0.06                  | Recommended (b) |
| 154030      | Currants (red, black and white) | 0.05*               | –                   | 0.01*                 | Recommended (c) |
| 161040      | Kumquats                   | 0.05*                  | 2                   | 2                     | Recommended (b) |
| 162010      | Kiwi                       | 0.05*                  | –                   | 0.01*                 | Recommended (c) |
| 211000      | Potatoes                   | 0.05*                  | 0.01*               | 0.01*                 | Recommended (c) |
| 231010      | Tomatoes                   | 0.5                    | 1                   | 1                     | Recommended (b) |
| 231020      | Peppers                    | 0.5                    | 1                   | 1                     | Recommended (b) |
| 231030      | Aubergines (egg plants)    | 0.5                    | 1                   | 1                     | Recommended (b) |
| 401030      | Poppy seed                 | 0.05*                  | –                   | 0.01*                 | Further consideration needed (f) |
| 401060      | Rape seed                  | 0.05*                  | –                   | 0.01*                 | Further consideration needed (f) |
| 401080      | Mustard seed               | 0.05*                  | –                   | 0.01*                 | Further consideration needed (f) |
| 401090      | Cotton seed                | 0.05*                  | –                   | 0.04                  | Further consideration needed (f) |
| 401130      | Gold of pleasure           | 0.05*                  | –                   | 0.01*                 | Further consideration needed (f) |
| 810000      | Spices (seeds)             | 1                      | 1                   | 1                     | Further consideration needed (c) |
| 820000      | Spices (fruits and berries)| 0.3                    | 0.3                 | 0.3                   | Further consideration needed (c) |
| 840000      | Spices (roots and rhizome) | 5                      | 5                   | 5                     | Further consideration needed (c) |
| 1011010     | Swine muscle               | 0.05*                  | 0.1                 | 0.1                   | Further consideration needed (c) |
| 1011020     | Swine fat (free of lean meat)| 0.05*                | 0.1                 | 0.1                   | Further consideration needed (c) |
| 1011030     | Swine liver                | 0.05*                  | 0.01*               | 0.01*                 | Further consideration needed (c) |
| 1011040     | Swine kidney               | 0.05*                  | 0.01*               | 0.01*                 | Further consideration needed (c) |
| 1012010     | Bovine muscle              | 0.05*                  | 0.1                 | 0.1                   | Further consideration needed (c) |
| 1012020     | Bovine fat                 | 0.05*                  | 0.1                 | 0.1                   | Further consideration needed (c) |
| 1012030     | Bovine liver               | 0.05*                  | 0.01*               | 0.01*                 | Further consideration needed (c) |
| 1012040     | Bovine kidney              | 0.05*                  | 0.01*               | 0.01*                 | Further consideration needed (c) |
| 1013010     | Sheep muscle               | 0.05*                  | 0.1                 | 0.1                   | Further consideration needed (c) |
| 1013020     | Sheep fat                  | 0.05*                  | 0.1                 | 0.1                   | Further consideration needed (c) |
| 1013030     | Sheep liver                | 0.05*                  | 0.01*               | 0.01*                 | Further consideration needed (c) |
| 1013040     | Sheep kidney               | 0.05*                  | 0.01*               | 0.01*                 | Further consideration needed (c) |
| 1014010     | Goat muscle                | 0.05*                  | 0.1                 | 0.1                   | Further consideration needed (c) |
| Code number | Commodity           | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment                        |
|------------|---------------------|------------------------|----------------------|-----------------------|--------------------------------|
| 1014020    | Goat fat            | 0.05*                  | 0.1                  | 0.1                   | Further consideration needed(6) |
| 1014030    | Goat liver          | 0.05*                  | 0.01*                | 0.01*                 | Further consideration needed(6) |
| 1014040    | Goat kidney         | 0.05*                  | 0.01*                | 0.01*                 | Further consideration needed(6) |
| 1016010    | Poultry muscle      | 0.05*                  | 0.01*                | 0.01*                 | Further consideration needed(6) |
| 1016020    | Poultry fat         | 0.05*                  | 0.01*                | 0.01*                 | Further consideration needed(6) |
| 1020010    | Cattle milk         | 0.01*                  | 0.01*                | 0.01*                 | Further consideration needed(6) |
| 1020020    | Sheep milk          | 0.01*                  | 0.01*                | 0.01*                 | Further consideration needed(6) |
| 1020030    | Goat milk           | 0.01*                  | 0.01*                | 0.01*                 | Further consideration needed(6) |
| 1030000    | Birds’ eggs         | 0.01*                  | 0.01*                | 0.01*                 | Further consideration needed(6) |
|            | Other commodities of plant and/or animal origin | See Reg. (EC) No 839/2008 | –                   | –                      | Further consideration needed(6) |

**Enforcement residue definition 1b (existing):** chlorpyrifos-methyl

**Enforcement residue definition 1b (proposed):** sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl

| Code number | Commodity       | MRL (mg/kg) | Comment                        |
|------------|-----------------|-------------|--------------------------------|
| 500010     | Barley grain    | 3           | Further consideration needed(7) |
| 500030     | Maize grain     | 3           | Recommended(4)                  |
| 500050     | Oats grain      | 3           | Further consideration needed(3) |
| 500060     | Rice grain      | 3           | Further consideration needed(3) |
| 500070     | Rye grain       | 3           | Recommended(6)                 |
| 500080     | Sorghum grain   | 3           | Further consideration needed(3) |
| 500090     | Wheat grain     | 3           | Recommended(6)                 |
|            | Other commodities of plant origin | See Reg. (EC) No 839/2008 | –                   | –                      | Further consideration needed(3) |

**Enforcement residue definition 2 (existing):** –

**Enforcement residue definition 2 (optional):** sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP

| Code number | Commodity | MRL (mg/kg) | Comment                        |
|------------|-----------|-------------|--------------------------------|
| 110010     | Grapefruit| –           | 0.4                            | Further consideration needed(6) |
| 110020     | Oranges   | –           | 0.8                            | Further consideration needed(6) |
| 110030     | Lemons    | –           | 0.8                            | Further consideration needed(6) |
| 110040     | Limes     | –           | 0.4                            | Further consideration needed(6) |
| 110050     | Mandarins | –           | 0.8                            | Further consideration needed(6) |
| 120010     | Almonds   | –           | 0.01*                          | Further consideration needed(6) |
| 120040     | Chestnuts | –           | 0.01*                          | Further consideration needed(6) |
| 120060     | Hazelnuts | –           | 0.01*                          | Further consideration needed(6) |
| 120080     | Pecans    | –           | –                              | Further consideration needed(6) |
| 120110     | Walnuts   | –           | 0.01*                          | Further consideration needed(6) |
| 130010     | Apples    | –           | 0.15                           | Further consideration needed(6) |
| 130020     | Pears     | –           | 0.3                            | Further consideration needed(6) |
| 130030     | Quinces   | –           | 0.15                           | Further consideration needed(6) |
| 130040     | Medlar    | –           | 0.01*                          | Further consideration needed(6) |
| 130050     | Loquat    | –           | –                              | Further consideration needed(6) |
| 140010     | Apricots  | –           | 0.01*                          | Further consideration needed(6) |
| 140020     | Cherries  | –           | 0.3                            | Further consideration needed(6) |
| 140030     | Peaches   | –           | 0.3                            | Further consideration needed(6) |
| 140040     | Plums     | –           | 0.05                           | Further consideration needed(6) |
| 151010     | Table grapes| –         | 0.4                            | Further consideration needed(6) |
| 151020     | Wine grapes| –           | 0.4                            | Further consideration needed(6) |
| Code number | Commodity                      | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | MRL (mg/kg) | Comment |
|-------------|--------------------------------|-------------------------|----------------------|-----------------------|-------------|---------|
| 152000      | Strawberries                   | –                       | –                    | 0.3                   | Further consideration needed<sup>(o)</sup> |
| 1540120     | Cranberries                    | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 154030      | Currants (red, black and white)| –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 161040      | Kumquats                       | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 162010      | Kiwi                           | –                       | –                    | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 163020      | Bananas                        | –                       | –                    | 1.5                   | Further consideration needed<sup>(g)</sup> |
| 211000      | Potatoes                       | –                       | –                    | 0.1                   | Further consideration needed<sup>(g)</sup> |
| 213010      | Beetroots                      | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 213020      | Carrots                        | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 213080      | Radishes                       | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 220010      | Garlic                         | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 220020      | Onions                         | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 220030      | Shallots                       | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 220040      | Spring onions                  | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 231010      | Tomatoes                       | –                       | –                    | 0.15                  | Further consideration needed<sup>(g)</sup> |
| 231020      | Peppers                        | –                       | –                    | 0.01*                 | Further consideration needed<sup>(g)</sup> |
| 231030      | Aubergines (egg plants)        | –                       | –                    | 0.15                  | Further consideration needed<sup>(g)</sup> |
| 233010      | Melons                         | –                       | –                    | 0.02                  | Further consideration needed<sup>(g)</sup> |
| 233020      | Pumpkins                       | –                       | –                    | 0.02                  | Further consideration needed<sup>(g)</sup> |
| 233030      | Watermelons                    | –                       | –                    | 0.02                  | Further consideration needed<sup>(g)</sup> |
| 234000      | Sweet corn                     | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 241010      | Broccoli                       | –                       | –                    | 0.01*                 | Further consideration needed<sup>(g)</sup> |
| 241020      | Cauliflower                    | –                       | –                    | 0.01*                 | Further consideration needed<sup>(g)</sup> |
| 242010      | Brussels sprouts               | –                       | –                    | 0.01*                 | Further consideration needed<sup>(g)</sup> |
| 242020      | Head cabbage                   | –                       | –                    | 0.01*                 | Further consideration needed<sup>(g)</sup> |
| 243010      | Chinese cabbage                | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 243020      | Kale                           | –                       | –                    | 0.01*                 | Further consideration needed<sup>(g)</sup> |
| 244000      | Kohlrabi                       | –                       | –                    | 0.01*                 | Further consideration needed<sup>(g)</sup> |
| 251010      | Lamb's lettuce                 | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 251020      | Lettuce                        | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 251030      | Scarole (broad-leaf endive)    | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 251060      | Rocket, rucola                 | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 252010      | Spinach                        | –                       | –                    | 0.03                  | Further consideration needed<sup>(g)</sup> |
| 260010      | Beans (fresh, with pods)       | –                       | –                    | 0.01*                 | Further consideration needed<sup>(g)</sup> |
| 260020      | Beans (fresh, without pods)    | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 260030      | Peas (fresh, with pods)        | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 260040      | Peas (fresh, without pods)     | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 270010      | Asparagus                      | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 270050      | Globe artichokes               | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 300010      | Beans (dry)                    | –                       | –                    | 0.01*                 | Further consideration needed<sup>(g)</sup> |
| 300030      | Peas (dry)                     | –                       | –                    | –                     | –           | Further consideration needed<sup>(g)</sup> |
| 300040      | Lupins (dry)                   | –                       | –                    | 0.01*                 | Further consideration needed<sup>(g)</sup> |
| Code number | Commodity                      | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review |
|-------------|--------------------------------|-------------------------|----------------------|-----------------------|
| 401030      | Poppy seed                     | –                       | –                    | 0.3                   | Further consideration needed(n) |
| 401050      | Sunflower seed                 | –                       | –                    | 0.01*                 | Further consideration needed(n) |
| 401060      | Rape seed                      | –                       | –                    | 0.3                   | Further consideration needed(n) |
| 401070      | Soya bean                      | –                       | –                    | 0.3                   | Further consideration needed(n) |
| 401080      | Mustard seed                   | –                       | –                    | 0.3                   | Further consideration needed(n) |
| 401090      | Cotton seed                    | –                       | –                    | 0.09                  | Further consideration needed(n) |
| 401130      | Gold of pleasure               | –                       | –                    | 0.3                   | Further consideration needed(n) |
| 402010      | Olives for oil production      | –                       | –                    | 0.01*                 | Further consideration needed(n) |
| 500010      | Barley grain                   | –                       | –                    | 1.5                   | Further consideration needed(n) |
| 500020      | Buckwheat grain                | –                       | –                    | –                     | Further consideration needed(n) |
| 500030      | Maize grain                    | –                       | –                    | 0.02                  | Further consideration needed(n) |
| 500040      | Millet grain                   | –                       | –                    | –                     | Further consideration needed(n) |
| 500050      | Oats grain                     | –                       | –                    | 1.5                   | Further consideration needed(n) |
| 500060      | Rice grain                     | –                       | –                    | 0.02                  | Further consideration needed(n) |
| 500070      | Rye grain                      | –                       | –                    | 0.4                   | Further consideration needed(n) |
| 500080      | Sorghum grain                  | –                       | –                    | –                     | Further consideration needed(n) |
| 500090      | Wheat grain                    | –                       | –                    | 0.4                   | Further consideration needed(n) |
| 610000      | Tea                             | –                       | –                    | –                     | Further consideration needed(n) |
| 620000      | Coffee beans                   | –                       | –                    | –                     | Further consideration needed(n) |
| 810000      | Spices (seeds)                 | –                       | –                    | –                     | Further consideration needed(n) |
| 820000      | Spices (fruits and berries)    | –                       | –                    | –                     | Further consideration needed(n) |
| 840000      | Spices (roots and rhizome)     | –                       | –                    | –                     | Further consideration needed(n) |
| 900010      | Sugar beet (root)              | –                       | –                    | 0.1                   | Further consideration needed(n) |
| 1011010     | Swine muscle                   | –                       | –                    | 0.01*                 | Further consideration needed(n) |
| 1011020     | Swine fat (free of lean meat)  | –                       | –                    | 0.015                 | Further consideration needed(n) |
| 1011030     | Swine liver                    | –                       | –                    | 0.15                  | Further consideration needed(n) |
| 1011040     | Swine kidney                   | –                       | –                    | 0.15                  | Further consideration needed(n) |
| 1012010     | Bovine muscle                  | –                       | –                    | 0.06                  | Further consideration needed(n) |
| 1012020     | Bovine fat                     | –                       | –                    | 0.09                  | Further consideration needed(n) |
| 1012030     | Bovine liver                   | –                       | –                    | 1                     | Further consideration needed(n) |
| 1012040     | Bovine kidney                  | –                       | –                    | 1                     | Further consideration needed(n) |
| 1013010     | Sheep muscle                   | –                       | –                    | 0.06                  | Further consideration needed(n) |
| 1013020     | Sheep fat                      | –                       | –                    | 0.09                  | Further consideration needed(n) |
| 1013030     | Sheep liver                    | –                       | –                    | 1                     | Further consideration needed(n) |
| 1013040     | Sheep kidney                   | –                       | –                    | 1                     | Further consideration needed(n) |
| 1014010     | Goat muscle                    | –                       | –                    | 0.06                  | Further consideration needed(n) |
| 1014020     | Goat fat                       | –                       | –                    | 0.09                  | Further consideration needed(n) |
| 1014030     | Goat liver                     | –                       | –                    | 1                     | Further consideration needed(n) |
| 1014040     | Goat kidney                    | –                       | –                    | 1                     | Further consideration needed(n) |
| 1016010     | Poultry muscle                 | –                       | –                    | 0.03                  | Further consideration needed(n) |
| 1016020     | Poultry fat                    | –                       | –                    | 0.03                  | Further consideration needed(n) |
| 1016030     | Poultry liver                  | –                       | –                    | 0.03                  | Further consideration needed(n) |
| 1020010     | Cattle milk                    | –                       | –                    | 0.015                 | Further consideration needed(n) |
| 1020020     | Sheep milk                     | –                       | –                    | 0.015                 | Further consideration needed(n) |
### Review of the existing MRLs for chlorpyrifos-methyl

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | MRL (mg/kg) | Comment |
|-------------|-----------|-------------------------|----------------------|-----------------------|-------------|---------|
| 1020030     | Goat milk | –                       | –                    | 0.015                 | Further consideration needed | (i) |
| 1030000     | Birds’ eggs | –                       | –                    | 0.03                  | Further consideration needed | (j) |
| –           | Other commodities of plant and/or animal origin | –                       | –                    | –                     | Further consideration needed | (k) |

MRL: maximum residue level; CXL: codex maximum residue limit; 3,5,6-TCP: 3,5,6-trichloropyridinol.

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

(F): MRL is expressed as mg/kg of fat contained in the whole product.

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

(b): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII 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): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).

(e): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level is not supported by data but the existing EU MRL is lower than the existing CXL (combination C-VII in Appendix D).

(f): 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).

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

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

(i): 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; existing CXL is covered by the tentative MRL (combination E-III in Appendix D).

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

(k): 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); CXL is not compatible with EU residue definitions (combination C-II in Appendix D).

(l): There are no relevant authorisations or import tolerances reported at EU level; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-II in Appendix D).

(m): 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; CXL is not compatible with EU residue definitions (combination G-II in Appendix D).

(n): Tentative MRL is derived from a GAP on chlorpyrifos evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available for this residue definition (although a CXL may be available for chlorpyrifos and/or chlorpyrifos-methyl).

(o): Tentative MRL is derived from a GAP on chlorpyrifos-methyl evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available for this residue definition (although a CXL may be available for chlorpyrifos and/or chlorpyrifos-methyl).

(p): There are no relevant authorisations or import tolerances reported at EU level; a CXL is available for chlorpyrifos and/or chlorpyrifos-methyl but there is no CXL for this residue definition. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered.

(q): GAP on chlorpyrifos or chlorpyrifos-methyl evaluated at EU level is not supported by data and it was not possible to derive an EU MRL for this residue definition; there is neither existing EU MRL nor CXL for this residue definition (although a CXL may be available for chlorpyrifos and/or chlorpyrifos-methyl). Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered.

(r): Tentative MRL is derived from a GAP on triclopyr evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available for this residue definition (although a CXL may be available for chlorpyrifos and/or chlorpyrifos-methyl).

### References

Austria, 2016. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for chlorpyrifos-methyl, January 2016. Available online: www.efsa.europa.eu

Belgium, 2016. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for chlorpyrifos-methyl, January 2016. Available online: www.efsa.europa.eu
Review of the existing MRLs for chlorpyrifos-methyl

Czech Republic, 2016. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for chlorpyrifos-methyl, January 2016, updated in April 2016. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers’ health arising from proposed temporary EU MRLs. EFSA Journal 2007;5(3):32r, 1141 pp. doi:10.2903/j.efsa.2007.32r

EFSA (European Food Safety Authority), 2011. Reasoned opinion on the modification of the existing MRLs for chlorpyrifos-methyl in various crops. EFSA Journal 2011;9(6):2219, 67 pp. doi:10.2903/j.efsa.2011.2219

EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide human health risk assessment of the active substance chlorpyrifos. EFSA Journal 2014;12(4):3640, 34 pp. doi:10.2903/j.efsa.2014.3640

EFSA (European Food Safety Authority), 2016. Completeness check report on the review of the existing MRLs of chlorpyrifos-methyl prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 8 November 2016. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2017a. Member States consultation report on the review of the existing MRLs of chlorpyrifos-methyl prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 30 January 2017. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2017b. Reasoned opinion on the review of the existing maximum residue levels for chlorpyrifos according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(3):4733, 77 pp. doi:10.2903/j.efsa.2017.4733

EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2017c. Reasoned opinion on the review of the existing maximum residue levels for triclopyr according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(3):4735, 77 pp. doi:10.2903/j.efsa.2017.4735

EURL (European Union Reference Laboratories for Pesticide Residues), 2016. Analytical methods validated by the EURLs and overall capability of official laboratories to be considered for the review of the existing MRLs for chlorpyrifos-methyl, 20 January 2016.

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

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev., 22 July 1996.

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

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

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

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

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

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95 – rev. 1, 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO 3029/99-rev. 4.

European Commission, 2005. Review report for the active substance chlorpyrifos-methyl. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 3 June 2005 in view of the inclusion of chlorpyrifos-methyl in Annex I of Council Directive 91/414/EEC. SANCO/3061/99 – rev. 1, 6, 3 June 2005.

European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

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

European Commission, 2016. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.2, September 2016.

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

FAO (Food and Agriculture Organization of the United Nations), 2009b. Chlorpyrifos-methyl. In: Pesticide residues in food – 2009. Evaluations, Part I, Residues. FAO Plant Production and Protection Paper 196.
FAO (Food and Agriculture Organization of the United Nations), 2013. Chlorpyrifos-methyl. In: Pesticide residues in food – 2013. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 219.

France, 2016a. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for chlorpyrifos-methyl, January 2016. Available online: www.efsa.europa.eu

France, 2016b. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for triclopyr, January 2016. Available online: www.efsa.europa.eu

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

Portugal, 2016. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for chlorpyrifos-methyl, January 2016, updated in May 2016. Available online: www.efsa.europa.eu

Spain, 1997. Draft Assessment Report (DAR) on the active substance chlorpyrifos-methyl, prepared by the rapporteur Member State Spain in the framework of Directive 91/414/EEC, September 1997.

Spain, 1999. Draft Assessment Report (DAR) on the active substance chlorpyrifos, prepared by the rapporteur Member State Spain in the framework of Directive 91/414/EEC, May 1999.

Spain, 2002. Addendum B.4 Methods of analysis to the draft assessment report on the active substance chlorpyrifos-methyl prepared by the rapporteur Member State Spain in the framework of Council Directive 91/414/EEC, September 2002.

Spain, 2003. Addendum III.B.6 Residues to the draft assessment report on the active substance chlorpyrifos-methyl prepared by the rapporteur Member State Spain in the framework of Council Directive 91/414/EEC, March 2003.

Spain, 2004. Addendum B.6 Residues to the draft assessment report on the active substance chlorpyrifos-methyl prepared by the rapporteur Member State Spain in the framework of Council Directive 91/414/EEC, April 2004.

Spain, 2010a. Evaluation report prepared under Article 8 of Regulation (EC) No 396/2005 on the modification of MRLs for chlorpyrifos-methyl in various commodities, July, 2010. Available online: www.efsa.europa.eu

Spain, 2010b. Evaluation report on the modification of MRLs for chlorpyrifos in various commodities based on data from the product Pyrinex 25 CS, prepared by the rapporteur Member State Spain under Article 8 of Regulation (EC) No 396/2005, 25 October 2010.

Spain, 2016a. Evaluation report prepared under Article 12.2 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing MRLs for chlorpyrifos-methyl, March 2016. Available online: www.efsa.europa.eu

Spain, 2016b. Evaluation report prepared under Article 12.2 of Regulation (EC) No 396/2005. Additional residue data to be considered for the review of the existing MRLs for chlorpyrifos-methyl, May 2016. Available online: www.efsa.europa.eu

United Kingdom, 2016. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for chlorpyrifos-methyl, January 2016. Available online: www.efsa.europa.eu

Abbreviations

3,5,6-TCP 3,5,6-trichloropyridinol
a.i. active ingredient
a.s. active substance
AChE acetyl-cholinesterase
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CAC Codex Alimentarius Commission
cGAP critical GAP
CXL codex maximum residue limit
DAR draft assessment report
DAT days after treatment
DB dietary burden
DEM desmethyl chlorpyrifos-methyl
DM dry matter
| Abbreviation | Definition |
|--------------|------------|
| DT$_{90}$    | period required for 90% dissipation (define method of estimation) |
| EMS          | evaluating Member State |
| eq           | residue expressed as a.s. equivalent |
| EUURLs       | European Union Reference Laboratories for Pesticide Residues (former CRLs) |
| FAO          | Food and Agriculture Organization of the United Nations |
| GAP          | Good Agricultural Practice |
| GC-FPD       | gas chromatography with flame photometric detector |
| GC–MS/MS     | gas chromatography with tandem mass spectrometry |
| GC-NCI       | gas chromatography with negative chemical ionisation |
| 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 |
| MRL          | maximum residue level |
| MS           | Member States |
| MS/MS        | tandem mass spectrometry detector |
| NEU          | northern European Union |
| OECD         | Organisation for Economic Co-operation and Development |
| 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) |
| $R_{\text{per}}$ | statistical calculation of the MRL by using a non-parametric method |
| $R_{\text{max}}$ | 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

| Crop Common name | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation Type | Content Conc. | Method | Growth stage From BBCH | Until BBCH | Number | Interval (days) Min | Max | Rate Min | Max | PHI or waiting period (days) | Comments (max. 250 characters) |
|------------------|-----------------|--------|----------------|-------------------------|-----------------|------------------|----------------|---------|---------------------|-----------|---------|---------------------|---|----------|-----|------------------------|--------------------------|
| Apples | Malus domestica | NEU | Outdoor | CZ | Aphids, codling moth, Lepidoptera | EC | 225 g/L | Foliar treatment – spraying | 10 | 87 | 1 | 0.45 | 0.90 kg | a.i./ha | 21 | No applications during flowering (BBCH 60–69) |
| Pears | Pyrus communis | NEU | Outdoor | AT | Cydia pomonella | EC | 225 g/L | Foliar treatment – spraying | 70 | 87 | 1 | 0.68 | kg | a.i./ha | 21 | See apples |
| Cherries | Prunus cerasus, Prunus avium | NEU | Outdoor | CZ | Rhagoletis cerasi | EC | 225 g/L | Foliar treatment – spraying | 10 | 87 | 1 | 0.61 | kg | a.i./ha | 21 | See apples |
| Wine grapes | Vitis vinifera | NEU | Outdoor | FR | Grape berry moth | EC | 225 g/L | Foliar treatment – spraying | 19 | 89 | 1 | 2 | 14 | 0.14 | 0.34 kg | a.i./ha | 21 | No applications during flowering (BBCH 60–69). Also, authorised in AT with 0.45 kg a.s./ha; PHI 28 days |
| Currants (red, black and white) | Ribes nigrum, rubrum | NEU | Outdoor | FR | | EC | 225 g/L | Foliar treatment – spraying | n.a. | n.a. | 1 | 0.50 | kg | a.i./ha | > 200 | Application is performed on shrubs, after harvest of the fruits, a PHI > 200 days is expected |
| Potatoes | Tuber form Solanum spp. | NEU | Outdoor | FR, CZ | Aphids, potato beetle | EC | 400 g/L | Foliar treatment – spraying | n.a. | n.a. | 1 | 0.30 | kg | a.i./ha | 21 |
| Poppy seed | Papaver somniferum | NEU | Outdoor | FR, CZ | Aphids | EC | 400 g/L | Foliar treatment – spraying | 59 | 1 | 0.30 | kg | a.i./ha | n.a. |
## Critical outdoor GAPs for northern Europe

| Crop | Common name | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Application | PHI or waiting period (days) | Comments (max. 250 characters) |
|------|-------------|-----------------|--------|----------------|--------------------------|----------------|-------------|------------|-----------------------------|---------------------------------|
| **Rape seed** | Brassica napus | *Brassica napus* | NEU Outdoor | CZ | Aphids (CEUTSP), pollen beetle (MELISP) | EC 225 g/L | Foliar treatment – spraying | 30 | 0.23 | n.a. |
| **Mustard seed** | Brassica nigra | *Brassica nigra* | NEU Outdoor | FR | Aphids | EC 400 g/L | Foliar treatment – spraying | 59 | 0.34 | 0.34 |
| **Gold of pleasure** | Camelina sativa | *Camelina sativa* | NEU Outdoor | FR | Aphids | EC 400 g/L | Foliar treatment – spraying | 59 | 0.25 | 0.30 |
| **Barley** | Hordeum spp. | *Hordeum spp.* | NEU Outdoor | FR | Aphids | EC 400 g/L | Foliar treatment – spraying | n.a. | n.a. | 0.25 |
| **Oats** | Avena fatua | *Avena fatua* | NEU Outdoor | CZ | Aphids | EC 400 g/L | Foliar treatment – spraying | n.a. | n.a. | 0.30 |
| **Rye** | Secale cereale | *Secale cereale* | NEU Outdoor | FR | Aphids | EC 400 g/L | Foliar treatment – spraying | n.a. | n.a. | 0.30 |
| **Wheat** | Triticum aestivum | *Triticum aestivum* | NEU Outdoor | CZ | Aphids | EC 400 g/L | Foliar treatment – spraying | n.a. | n.a. | 0.30 |

* Other GAP authorised in FR: 1 × 0.3 kg as.s./ha at BBCH 51

* Less critical GAPs authorised in FR: 1 × 0.25 kg as.s./ha at BBCH 51
| Crop          | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled                  | Formulation | Method                          | Application | PHI or waiting period (days) | Comments                                                                 |
|---------------|-----------------|--------|----------------|-------------------------|-----------------------------------|-------------|--------------------------------|-------------|-------------------------------|--------------------------------------------------------------------------|
| Oranges       | *Citrus sinensis* | SEU    | Outdoor ES     | Scale insects, whitefly  | EC 225 g/L Foliar treatment – spraying | 20 89 1 2 110 1.35 2.25 kg a.i./ha | 15          | No applications during flowering (BBCH 60–69) |
| Lemons        | *Citrus limon*   | SEU    | Outdoor ES     | Scale insects, whitefly  | EC 225 g/L Foliar treatment – spraying | 20 89 1 2 110 1.35 2.25 kg a.i./ha | 15          | See oranges                   |
| Mandarins     | *Citrus reticulata* | SEU   | Outdoor ES     | Scale insects, whitefly  | EC 225 g/L Foliar treatment – spraying | 20 89 1 2 110 1.35 2.25 kg a.i./ha | 15          | See oranges                   |
| Apples        | *Malus domestica* | SEU  | Outdoor ES     | Aphids, codling moth, Lepidoptera | EC 225 g/L Foliar treatment – spraying | 10 87 1 0.68 0.90 kg a.i./ha | 15          | See oranges                   |
| Pears         | *Pyrus communis* | SEU    | Outdoor ES     | Aphids, codling moth, Lepidoptera | EC 225 g/L Foliar treatment – spraying | 10 87 1 0.68 0.90 kg a.i./ha | 15          | See oranges                   |
| Quinces       | *Cydonia oblonga* | SEU  | Outdoor ES     | Aphids, codling moth, Lepidoptera | EC 225 g/L Foliar treatment – spraying | 10 87 1 0.68 0.90 kg a.i./ha | 15          | See oranges                   |
| Peaches       | *Prunus persica* | SEU    | Outdoor IT     | Aphids, Lepidoptera, Mirids, Thrips | EC 225 g/L Foliar treatment – spraying | 10 87 2 7 0.45 1.00 kg a.i./ha | 15          | No applications during flowering (BBCH 60–69). Also, authorised in ES with 1 application only |
| Table grapes  | *Vitis euvitis*  | SEU    | Outdoor IT     | Grape berry moth        | EC 225 g/L Foliar treatment – spraying | 19 89 1 0.34 0.61 kg a.i./ha | 15          | See oranges                   |
| Wine grapes   | *Vitis euvitis*  | SEU    | Outdoor IT     | Grape berry moth        | EC 225 g/L Foliar treatment – spraying | 19 89 1 0.09 0.68 kg a.i./ha | 15          | See oranges                   |
## Critical outdoor GAPs for southern Europe

| Crop Common name | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation Type | Content Conc. Unit | Method | Growth stage From BBCH | Until BBCH | Number | Interval (days) Min Max | Rate Min Max | PHI or waiting period (days) | Comments (max. 250 characters) |
|------------------|-----------------|--------|----------------|-------------------------|-----------------|------------------|-------------------|--------|------------------------|-----------|--------|------------------------|-----------|--------------------------|--------------------------------|
| Strawberries     | *Fragaria x ananassa* | SEU     | Outdoor       | ES                      | Aphids, weevils (OTIOSU) | EC 225 g/L       | Foliar treatment – spraying | 35     | 95                     | 1         | 0.34               | 0.68 kg a.i./ha  | 5                   | See oranges                  |
| Kiwi             | *Actinidia deliciosa* syn. A. chinensis | SEU     | Outdoor       | FR                      | EC 225 g/L       | Foliar treatment – spraying | n.a.  | n.a.                  | 1         | 0.45 kg a.i./ha        | 21            |
| Potatoes         | Tuber form *Solanum* spp. | SEU     | Outdoor       | IT                      | Aphids, potato beetle | EC 225 g/L       | Foliar treatment – spraying | 31     | 69                     | 1         | 0.45 kg a.i./ha        | 21            |
| Tomatoes         | *Lycopersicum esculentum* | SEU     | Outdoor       | ES                      | Aphids, thrips, Lepidoptera (Heliothis, Agrots) | EC 225 g/L       | Foliar treatment – spraying | 11     | 89                     | 1         | 0.34               | 0.72 kg a.i./ha  | 5                   | See oranges                  |
| Peppers          | *Capsicum annuum*, var. grossum and var. longum | SEU     | Outdoor       | ES                      | Aphids, thrips, Lepidoptera (Heliothis, Agrots) | EC 225 g/L       | Foliar treatment – spraying | 11     | 89                     | 1         | 0.34               | 0.72 kg a.i./ha  | 5                   | See oranges                  |
| Aubergines (egg plants) | *Solanum melongena* | SEU     | Outdoor       | ES                      | Aphids, thrips, Lepidoptera (Heliothis, Agrots) | EC 225 g/L       | Foliar treatment – spraying | 11     | 89                     | 1         | 0.34               | 0.72 kg a.i./ha  | 5                   | See oranges                  |
| Poppy seed       | *Papaver somniferum* | SEU     | Outdoor       | PT                      | Aphids           | EC 400 g/L       | Foliar treatment – spraying | 59     | 1                       |             | 0.30 kg a.i./ha        | n.a.           |
| Rape seed        | *Brassica napus* | SEU     | Outdoor       | IT                      | Weevils (CEUTSP), pollen beetle (MELISP) | EC 225 g/L       | Foliar treatment – spraying | 30     | 59                     | 1         | 0.45 kg a.i./ha        | n.a.           |
## Critical outdoor GAPs for southern Europe

| Crop | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation Type | Content Conc. | Content Unit | Method | Growth stage From BBCH | Until BBCH | Application Number | Interval (days) Min | Interval (days) Max | Rate (kg a.i./ha) Min | Rate (kg a.i./ha) Max | Rate (kg a.i./ha) Unit | Comments (max. 250 characters) |
|------|-----------------|--------|----------------|-------------------------|-----------------|------------------|-----------------|--------------|--------|----------------------|-------------|----------------------|---------------------|---------------------|----------------------|----------------------|----------------------|----------------------|
| Mustard seed | Brassica nigra | SEU | Outdoor | PT | Aphids | EC | 400 | g/L | Foliar treatment – spraying | 59 | 1 | 0.25 | kg a.i./ha | n.a. |
| Cotton seed | Gossypium spp. | SEU | Outdoor | ES | Aphids, Heliothis, Spodoptera | EC | 225 | g/L | Foliar treatment – spraying | 30 | 89 | 0.27 | 0.36 kg a.i./ha | 15 |
| Gold of pleasure | Camelina sativa | SEU | Outdoor | FR | Aphids | EC | 400 | g/L | Foliar treatment – spraying | 59 | 1 | 0.34 kg a.i./ha | n.a. |
| Barley | Hordeum spp. | SEU | Outdoor | PT | Aphids | EC | 400 | g/L | Foliar treatment – spraying | n.a. | n.a. | 0.25 | 0.30 kg a.i./ha | 28 |
| Maize | Zea mays | SEU | Outdoor | IT | Ostrinia nubilalis | EC | 225 | g/L | Foliar treatment – spraying | 12 | 59 | 0.27 | 0.90 kg a.i./ha | n.a. |
| Oats | Avena fatua | SEU | Outdoor | PT | Aphids | EC | 400 | g/L | Foliar treatment – spraying | n.a. | n.a. | 0.25 | 0.30 kg a.i./ha | 28 |
| Rye | Secale cereale | SEU | Outdoor | PT | Aphids | EC | 400 | g/L | Foliar treatment – spraying | n.a. | n.a. | 0.25 | 0.30 kg a.i./ha | 28 |

*Less critical GAPs authorised in FR with 0.25 kg a.s./ha or with 1 × 0.3 kg a.s./ha at BBCH 51.*
### Critical outdoor GAPs for southern Europe

| Crop | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Application | PHI or waiting period (days) | Comments (max. 250 characters) |
|------|--------|----------------|-------------------------|----------------|-------------|-------------|-----------------------------|--------------------------------|
| Common name | Scientific name | | | | Type | Content | Method | Growth stage From BBCH | Until BBCH | Number | Interval (days) | Rate | PHI or waiting period (days) | |
| | | | | | Concentration | Unit | | Min | Max | Min | Max | Min | Max | Unit | |
| Wheat | Triticum aestivum | SEU | Outdoor | PT | Aphids | EC | 400 g/L | Foliage treatment – spraying | n.a. | n.a. | 1 | 0.25 | 0.30 | kg a.i./ha | 28 | Less critical GAPs authorised in FR with 0.25 kg a.s./ha or with 1 × 0.3 kg a.s./ha at BBCH 51 |

### Critical indoor GAPs for northern and southern Europe (including post-harvest treatments)

| Crop | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Application | PHI or waiting period (days) | Comments (max. 250 characters) |
|------|--------|----------------|-------------------------|----------------|-------------|-------------|-----------------------------|--------------------------------|
| Common name | Scientific name | | | | Type | Content | Method | Growth stage From BBCH | Until BBCH | Number | Interval (days) | Rate | PHI or waiting period (days) | |
| | | | | | Concentration | Unit | | Min | Max | Min | Max | Min | Max | Unit | |
| Barley | Hordeum spp. | NEU/SEU | Indoor | BE, FR | Stored grain pests (Coleoptera, Lepidoptera, Acari) | KN | 225 g/L | Post-harvest – spraying | n.a. | n.a. | 1 | 2.50 | g a.i./tonne | 1 | Minimum withholding period: 1 day. Less critical GAP authorised in UK: 2.25 kg a.s./ha (WHP 60 day) |
| Maize | Zea mays | NEU/SEU | Indoor | FR | Stored grain pests (Coleoptera, Lepidoptera, Acari) | EC | 25 g/L | Post-harvest – spraying | n.a. | n.a. | 1 | 2.50 | g a.i./tonne | 1 | Minimum withholding period: 1 day |
| Oats | Avena fatua | NEU/SEU | Indoor | BE, FR | Stored grain pests (Coleoptera, Lepidoptera, Acari) | KN | 225 g/L | Post-harvest – spraying | n.a. | n.a. | 1 | 2.50 | g a.i./tonne | 1 | Minimum withholding period: 1 day. Less critical GAP authorised in UK: 2.25 kg a.s./ha (WHP 60 day) |
| Crop | Common name | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Application | PHI or waiting period (days) | Comments (max. 250 characters) |
|------|-------------|-----------------|--------|----------------|-------------------------|-----------------|--------------|-------------|-----------------------------|-------------------------------|
| Rice | Oryza sativa | Indoor FR       | Stored grain pests (Coleoptera, Lepidoptera, Acari) | EC 25 g/L | Post-harvest – spraying | n.a. | 1 | 2.50 g a.i./ tonne | Minimum withholding period: 1 day |
| Rye  | Secale cereale | Indoor BE, FR   | Stored grain pests (Coleoptera, Lepidoptera, Acari) | KN 225 g/L | Post-harvest – spraying | n.a. | 1 | 2.50 g a.i./ tonne | Minimum withholding period: 1 days. Less critical GAP authorised in UK: 2.25 kg a.s./ha (WHP 60 days) |
| Wheat | Triticum aestivum | Indoor BE, FR   | Stored grain pests (Coleoptera, Lepidoptera, Acari) | KN 225 g/L | Post-harvest – spraying | n.a. | 1 | 2.50 g a.i./ tonne | Minimum withholding period: 1 days. Less critical GAP authorised in UK: 2.25 kg a.s./ha (WHP 60 days) |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; PHI: preharvest interval; a.i.: active ingredient; a.s.: active substance; BBCH: growth stages of mono- and dicotyledonous plants.
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                      | Tomatoes    | Foliar: 1 × 0.99 kg a.s./ha (at BBCH 64–85) | 0, 5, 16, 26, 42 |
| Cereals/grass crops              | Wheat       | Post-harvest: 1 × 32 g a.s./ton             | 0, 30, 90, 180  |
|                                  | Maize       |                                                  | 0, 30, 90, 180  |

Sources: Tomatoes (Spain, 2003) and cereals (Spain, 1997)
Metabolism in root crops and pulses/oilseeds is addressed by additional metabolism studies performed on chlorpyrifos (Spain, 2010b)

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) |
|-------------------------------------|-------------|---------|----------------|-----------|
|                                     |             |         |                |           |

Study performed with chlorpyrifos-methyl is not available and is required
Meanwhile, metabolism of chlorpyrifos-methyl in rotational crops can be tentatively addressed by a study performed with chlorpyrifos on carrots, lettuce and wheat (Spain, 1999)

| Processed commodities (hydrolysis study) | Conditions | Investigated? |
|------------------------------------------|------------|---------------|
|                                          | Pasteurisation (20 min, 90°C, pH 4) | Yes |
|                                          | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes |
|                                          | Sterilisation (20 min, 120°C, pH 6) | Yes |

Source: Spain (2016b)
| Question                                                                 | Response |
|------------------------------------------------------------------------|----------|
| Can a general residue definition be proposed for primary crops?        | No       |
| Rotational crop and primary crop metabolism similar?                   | Yes (tentative conclusion) |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | No       |
| Plant residue definition for monitoring (RD-Mo)                       |          |
| Plant residue definition for risk assessment (RD-RA)                  |          |
| Conversion factor (monitoring to risk assessment)                     |          |
| Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) |          |

**RD-monitoring 1:**
- **Fruit crops, root crops and pulses/oilseeds:** chlorpyrifos-methyl
- **Cereal grain and processed commodities:** sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl (tentative)

**RD-monitoring 2 (optional):**
- **All crops:** sum of 3,5,6-trichloropyridinol (3,5,6-TCP) and its conjugates, expressed as 3,5,6-TCP

**RD-risk assessment 1:**
- **Fruit crops, root crops and pulses/oilseeds:** chlorpyrifos-methyl
- **Cereal grain and processed commodities:** sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl (tentative)

**RD-risk assessment 2:**
- **All crops:** sum of 3,5,6-trichloropyridinol (3,5,6-TCP) and its conjugates, expressed as 3,5,6-TCP

**Conversion factor (monitoring to risk assessment):** Not relevant

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

**Chlorpyrifos-methyl:**
- GC-MS/MS (EURL, 2016):
  - QuEChERS method is fully validated for high water, high acid and dry commodities
  - LOQ: 0.01 mg/kg
- HPLC-MS/MS (France, 2016a):
  - Validated in high oil content commodities
  - ILV is missing
  - Method validated for two different mass transitions
  - LOQ: 0.01 mg/kg

**Desmethyl chlorpyrifos-methyl:**
- Analytical method not available for this compound

**3,5,6-trichloropyridinol (3,5,6-TCP) and its conjugates:**
- HPLC-MS/MS (France, 2016b):
  - 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
  - Efficiency of the hydrolysis step was not validated
  - LOQ: 0.01 mg/kg
B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability (months/years) |
|-----------------------------------|----------|-----------|--------|--------------------------|
| **Chlorpyrifos-methyl**           | High water content | Tomato (and tomato juice) | −20 | 24 months | |
|                                  | High oil content | Rapeseed | −18 | 18 months | |
|                                  | Dry         | Wheat grain | −20 | 24 months | |
|                                  | High acid content | Orange | −20 | ≤ 12 months (a) | |
|                                  |             | Grape | −20 | 24 months | |
| **Desmethyl chlorpyrifos-methyl (DEM)** | Dry | Wheat grain | −20 | 22 months | |
| **3,5,6-trichloropyridinol (3,5,6-TCP) and its conjugates(b)** | High water content | Apple, peach, cabbage, tomato and potato | −18 | 18 months | |
|                                  | High oil content | Rapeseed | −18 | 18 months | |
|                                  | Dry         | Wheat grain | −18 | 24 months | |
|                                  | High acid content | Orange and grape | −18 | 18 months | |

Source: Spain (2016a)

(a): This study investigates storage stability for 24 months but a significant decrease (> 30%) was observed after 12 months.

(b): As the possible decline of conjugates is expected to proceed through 3,5,6-TCP, conjugates are also covered.
## B.1.2. Magnitude of residues in plants

### B.1.2.1. Summary of residues data from the supervised residue trials (for chlorpyrifos-methyl)

| Crop          | Region/indoor(a) | 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)(b) | STMR (mg/kg)(c) |
|---------------|------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|-----------------------|---------------|-----------------|
| Oranges       | SEU              | Oranges: 0.06; 0.18; 0.26; 0.31; 0.37(d); 0.44; 0.45; 0.47(d); 0.49; 0.49; 0.58(d); 0.6; 0.89; 0.89; Mandarins: 0.47; 0.69 | Combined data set on oranges and mandarins compliant with GAP (Spain, 2010a, 2016a,b). Extrapolation to lemons is acceptable MRL\textsubscript{OECD} = 1.43 | 1.5                   | 0.89          | 0.47            |
| Mandarins     |                  |                                                                                                  |                                                                                                              |                       |               |                 |
| Lemons        |                  |                                                                                                  |                                                                                                              |                       |               |                 |
| Apples        | NEU              | Apples: < 0.01; 0.02; 0.03; 0.05; 0.05; 0.05; 0.05; 0.05; Pears: < 0.01; 0.01; 0.02               | Combined data set on apples and pears compliant with GAP on apples; trials performed with 2 applications are deemed acceptable (Spain, 2010a, 2016a,b) MRL\textsubscript{OECD} = 0.1 | 0.1                   | 0.05          | 0.03            |
| Pears         | SEU              | Apples: 0.03; 0.03; 0.08; 0.1; 0.15; 0.19; 0.2; 0.22; Pears: 0.02; 0.02; 0.03; 0.04; 0.08       | Combined data set on apples and pears compliant with GAP on apples; trials performed with 2 applications are deemed acceptable (Spain, 2010a) MRL\textsubscript{OECD} = 0.39 | 0.4                   | 0.22          | 0.08            |
| Quinces       | NEU              | Apples: < 0.01; < 0.01; 0.01; 0.012; 0.02; 0.04; 0.04; 0.05; Pears: 0.02; 0.02; 0.02; 0.07; 0.08 | Combined data set on apples and pears compliant with GAP on pears (different GAP than apples); trials performed with 2 applications are deemed acceptable (Spain, 2010a). No northern use on quinces MRL\textsubscript{OECD} = 0.12 | 0.15                  | 0.08          | 0.02            |
| Cherries      | NEU              | 10 × < 0.01                                                                                     | Trials compliant with GAP; trials performed with 2 applications are deemed acceptable (Spain, 2010a) MRL\textsubscript{OECD} = 0.01 | 0.01*                 | 0.01          | 0.01            |
| Peaches       | SEU              | < 0.01; < 0.01; 0.01; 0.01; 0.01; 0.02; 0.02                                                     | Trials on peaches compliant with GAP (Spain, 2010a) MRL\textsubscript{OECD} = 0.03                         | 0.04                  | 0.02          | 0.01            |

Residue definition for enforcement and risk assessment: chlorpyrifos-methyl

---

(a) SEU = Southern Europe; NEU = Northern Europe

(b) HR = Harmonised Ranges

(c) STMR = Short-term Median Residue
| Crop | Region/indoor(a) | 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)(b) | STMR (mg/kg)(c) |
|------|-----------------|--------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|----------------------|---------------|-----------------|
| Table grapes | SEU | 7 × < 0.01; 0.01; 0.05; 0.07 | Trials compliant with GAP; trials performed with 2 applications are deemed acceptable (Spain, 2010a). An outlier of 0.53 mg/kg was excluded from this data set MRL_{OECD} = 0.11 | 0.15 | 0.07 | 0.01 |
| Wine grapes | NEU | 5 × < 0.01; 0.01; 0.02; 0.02; 0.02; 0.02; 0.03; 0.04 | Trials compliant with GAP (Spain, 2010a) MRL_{OECD} = 0.06 | 0.06 | 0.04 | 0.02 |
| | SEU | 7 × < 0.01; 0.01; 0.05; 0.07 | Trials compliant with GAP (Spain, 2010a). An outlier of 0.53 mg/kg was excluded from this data set MRL_{OECD} = 0.11 | 0.15 | 0.07 | 0.01 |
| Strawberries | SEU | 4 × < 0.01; 0.01; 0.02; 0.02; 0.02 | Trials compliant with GAP (Spain, 2010a) MRL_{OECD} = 0.03 | 0.04 | 0.02 | 0.01 |
| Currants (red, black and white) | NEU | – | The product is applied right after harvest, i.e. 200 days before the next harvest. As chlorpyrifos-methyl is a non-systemic active substance, transfer from soil to edible part of crops is not expected and a no residue situation can be assumed (France, 2016a) | 0.01* | 0.01 | 0.01 |
| Kiwi | SEU | 8 × < 0.01 | Trials compliant with GAP (France, 2016a); trials performed with 2 applications instead of 1 are deemed acceptable | 0.01* | 0.01 | 0.01 |
| Tomatoes Aubergines (egg plants) | SEU | 0.02; 0.03; 0.03; 0.06; 0.06; 0.06; 0.07; 0.07 | Trials on tomatoes compliant with GAP; trials performed with two applications are deemed acceptable (Spain, 2010a). Extrapolation to aubergines is applicable MRL_{OECD} = 0.16 | 0.2 | 0.07 | 0.06 |
| Peppers | SEU | – | No trials compliant with GAP | – | – | – |
| Potatoes | NEU | 8 × < 0.01 | Trials performed with a more critical GAP (1–2 applications at 0.52–0.57 kg a.s./ha; PHI 21 days) acceptable since residue are < LOQ (Spain, 2010a) | 0.01* | 0.01 | 0.01 |
| | SEU | 8 × < 0.01 | Trials performed with 1 or 2 applications at 0.52–0.58 kg a.s./ha; PHI 21 days, acceptable since residue are < LOQ (Spain, 2010a) | 0.01* | 0.01 | 0.01 |
| Rape seed | NEU | 7 × < 0.01 | Northern and southern trials on rapeseed, all compliant with GAP, can be combined to derive an MRL (Spain, 2010a). The trial resulting in 0.015 mg/kg was disregarded due to residue > LOQ in control samples (France, 2016a) | 0.01* (tentative)(h) | 0.01 | 0.01 |
| | SEU | 7 × < 0.01 | | | |

Review of the existing MRLs for chlorpyrifos-methyl

www.efsa.europa.eu/efsajournal 40 EFSA Journal 2017;15(3):4734
| Crop                        | Region/indoor(a) | 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)(b) | STMR (mg/kg)(c) |
|-----------------------------|------------------|------------------------------------------------------------------------------------------------|----------------------------------------------|-----------------------|---------------|----------------|
| Poppy seed Mustard seed     | NEU              | $7 \times < 0.01$                                                                         | Direct extrapolation from rapeseed trials, performed with 0.45 kg a.s./ha instead of 0.3 or 0.34 kg a.s./ha; acceptable since residues are $<\LOQ$ | 0.01* (tentative)(h) | 0.01          | 0.01           |
| Gold of pleasure            | SEU              | $7 \times < 0.01$                                                                         |                                              |                       |               |                |
| Cotton seed                 | SEU              | $6 \times < 0.01; 0.02; 0.02$                                                            | Overdosed residue trials performed on cotton (0.69 kg as/ha instead or 0.36) (Spain, 2010a), considered on a tentative basis $\text{MRL}_{\text{OECD}} = 0.03$ | 0.04(g, h) (tentative) | 0.02          | 0.01           |
| Barley and oats straw       | NEU              | $5 \times < 0.01; 0.02; 0.03; 0.03$                                                      | Trials performed on barley compliant with GAP; northern and southern data can be combined (France, 2016a). Extrapolation to oats is applicable $\text{MRL}_{\text{OECD}} = 0.07$ | 0.07 (tentative)(h) | 0.05          | 0.01           |
|                             | SEU              | $4 \times < 0.01; 0.01; 0.04; 0.05$                                                      |                                              |                       |               |                |
| Wheat and rye straw         | NEU              | $2 \times < 0.01; 0.02; 0.03; 0.04; 0.09; 0.13; 0.24$                                     | Trials performed on wheat compliant with GAP; northern and southern data can be combined (France, 2016a). Extrapolation to rye is applicable $\text{MRL}_{\text{OECD}} = 0.3$ | 0.3 (tentative)(h) | 0.24          | 0.02           |
|                             | SEU              | $4 \times < 0.01; 0.01; 0.01; 0.04; 0.07$                                                |                                              |                       |               |                |

**Residue definition for enforcement and risk assessment:** sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl

| Crop                        | Region/indoor(a) | 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)(b) | STMR (mg/kg)(c) |
|-----------------------------|------------------|------------------------------------------------------------------------------------------------|----------------------------------------------|-----------------------|---------------|----------------|
| Barley and oats grain       | NEU              | $6 \times < 0.01; 0.01; 0.03$                                                             | Trials performed on barley compliant with GAP; northern and southern data can be combined (France, 2016a) Extrapolation to oats is applicable. Only the parent compound was analysed as the metabolite desmethyl chlorpyrifos-methyl (DEM) is not expected after foliar treatment $\text{MRL}_{\text{OECD}} = 0.06$ | 0.07                  | 0.05          | 0.01           |
|                             | SEU              | $3 \times < 0.01; 0.01; 0.01; 0.03; 0.05$                                                |                                              |                       |               |                |
| Indoor                      | Wheat            | $3.09^{(b)}; 3.32; 3.88^{(b)}; 5.23^{(f)}$                                               | Overdosed trials on wheat and barley (5 instead of 2.5 g a.s./tonne) considered on tentative basis (Spain, 2010a). Trials not analysing desmethyl chlorpyrifos-methyl were disregarded (Spain, 2003). Outlier value of 10.6 mg/kg was disregarded $\text{MRL}_{\text{OECD}}$: not relevant for post-harvest treatment $R_{\text{ter}} = 7.76; \ R_{\text{max}} = 6.26$ | $6^{(g, h, i)}$ (tentative) | 5.23          | 3.69           |
|                             | Barley           | $3.01^{(b)}; 3.69^{(f)}; 3.76^{(f)}$                                                     |                                              |                       |               |                |
**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>**
---|---|---|---|---|---|---
Wheat and rye grain | NEU | 7 × < 0.01; 0.02 | Trials performed on wheat compliant with GAP; northern and southern data can be combined (France, 2016a). Extrapolation to rye is applicable. Only the parent compound was analysed as the metabolite desmethyl chlorpyrifos-methyl (DEM) is not expected after foliar treatment | MRL<sub>OECD</sub> = 0.02 | 0.02 | 0.01
 | SEU | 8 × < 0.01 | | | | |
Indoor | Wheat: 3.09<sup>(d)</sup>; 3.32; 3.88<sup>(e)</sup>; 5.23<sup>(f)</sup> | Overdosed trials on wheat and barley (5 instead of 2.5 g a.s./tonne) considered on tentative basis (Spain, 2010a). Trials not analysing desmethyl chlorpyrifos-methyl were disregarded (Spain, 2003). Outlier value of 10.6 mg/kg was disregarded MRL<sub>OECD</sub>: not relevant for post-harvest treatment | \( R_{\text{ber}} = 7.76; R_{\text{max}} = 6.26 \) | 5.23 | 3.69
 | Barley: 3.01<sup>(d)</sup>; 3.66<sup>(f)</sup>; 3.76<sup>(f)</sup> | | | 6<sup>(g)\,(h)\,(i)</sup> (tentative) | |
Maize grain | SEU | 8 × < 0.01 | Trials compliant with GAP (Spain, 2010a). Only the parent compound was analysed as the metabolite desmethyl chlorpyrifos-methyl (DEM) is not expected after foliar treatment | | 0.01* | 0.01 | 0.01 |
Indoor | – | No trials available. The waiver proposed by France is not acceptable (France, 2016a) | | – | – | – |
Rice grain | Indoor | – | No trials available. The waiver proposed by France is not acceptable (France, 2016a) | | – | – | – |

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

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

(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): Higher residue level observed at PHI 21 days compared to 15 days.

(e): Highest residue level was observed after a withholding period of 0 day.

(f): Highest residue level was observed after a withholding period of 6 months.

(g): MRL is tentative because the number of trials compliant with GAP is not sufficient.

(h): MRL is tentative because the analytical method for enforcement is not fully validated or not available.

(i): MRL is tentative because the toxicity of the desmethyl chlorpyrifos-methyl is not fully addressed.
### Summary of residues data from the supervised residue trials (sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP)

| Crop            | Region/indoor(a) | 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)(b) | STMR (mg/kg)(c) |
|-----------------|------------------|-----------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|---------------|----------------|
| **Oranges**     | SEU              | Oranges: <$0.01; <0.01; 0.03; 0.04; 0.12; 0.13; 0.16; 0.17; 0.18; 0.28; 0.36; 0.37; 0.51 |
|                 |                  | Mandarins: 0.04; 0.32                                                                      | Combined data set on oranges and mandarins compliant with GAP (Spain, 2010a, 2016a,b). Extrapolation to lemons is acceptable MRL$_{OECD}$ = 0.78 | 0.8 (tentative) | 0.51          | 0.15           |
| Mandarins       |                  |                                                                                              |                                             |                       |               |                |
| Lemons          |                  |                                                                                              |                                             |                       |               |                |
| **Apples**      | NEU              | Apples: <$0.01; <0.01; 0.01; 0.03; 0.05                                                        | Combined data set on apples and pears compliant with GAP on apples; trials performed with 2 applications are deemed acceptable (Spain, 2010a, 2016a,b) MRL$_{OECD}$ = 0.11 | 0.15 (tentative) | 0.07          | 0.03           |
|                 |                  | Pears: 0.02; 0.04; 0.07                                                                     |                                             |                       |               |                |
| **Pears**       | SEU              | Apples: <$0.01; <0.01; 0.01; 0.02; 0.04; 0.04; 0.05                                           | Combined data set on apples and pears compliant with GAP on apples; trials performed with 2 applications are deemed acceptable (Spain, 2010a) MRL$_{OECD}$ = 0.15 | 0.15 (tentative) | 0.10          | 0.04           |
|                 |                  | Pears: 0.03; 0.05; 0.05; 0.08; 0.10                                                         |                                             |                       |               |                |
| **Quinces**     | NEU              | Apples: <$0.01; 0.01; 0.01; 0.02; 0.03; 0.03; 0.11                                           | Combined data set on apples and pears compliant with GAP on pears (different GAP than apples); trials performed with 2 applications are deemed acceptable (Spain, 2010a). No northern use on quinces MRL$_{OECD}$ = 0.24 | 0.3 (tentative) | 0.15          | 0.03           |
|                 |                  | Pears: 0.02; 0.03; 0.04; 0.11; 0.11; 0.15                                                   |                                             |                       |               |                |
| **Cherries**    | NEU              | Cherries: 0.01; 0.01; 0.02; 0.04; 0.05; 0.06; 0.06; 0.08; 0.18                                  | Trials compliant with GAP; trials performed with 2 applications are deemed acceptable (Spain, 2010a) MRL$_{OECD}$ = 0.25 | 0.3 (tentative) | 0.18          | 0.05           |

Residue definition for enforcement and risk assessment: sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP

OECD = 0.78

HR (mg/kg)(b) = 0.8 (tentative)

STMR (mg/kg)(c) = 0.51
| Crop                        | Region/indoor(a) | 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)(b) | STMR (mg/kg)(c) |
|---------------------------|------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|------------------------|---------------|----------------|
| Peaches                   | SEU              | 0.01; 0.02; 0.02; 0.02; 0.08; 0.08; 0.09; 0.11                                                                                                               | Trials on peaches compliant with GAP (Spain, 2010a) MRL<sub>OECD</sub> = 0.21                                      | 0.3 (tentative)       | 0.11          | 0.05           |
| Table grapes              | SEU              | < 0.01; 0.02; 0.05; 0.06; 0.07; 0.09; 0.13; 0.13; 0.15; 0.23                                                                                                         | Trials compliant with GAP; trials performed with 2 applications are deemed acceptable (Spain, 2010a) MRL<sub>OECD</sub> = 0.36 | 0.4 (tentative)       | 0.23          | 0.08           |
| Wine grapes               | NEU              | < 0.01; 0.02; 0.05; 0.06; 0.07; 0.08; 0.08; 0.09; 0.09; 0.12; 0.13                                                                                              | Trials compliant with GAP (Spain, 2010a) MRL<sub>OECD</sub> = 0.21                                            | 0.3 (tentative)       | 0.13          | 0.08           |
|                          | SEU              | < 0.01; 0.02; 0.05; 0.06; 0.07; 0.09; 0.13; 0.13; 0.15; 0.23                                                                                                         | Trials compliant with GAP (Spain, 2010a). The trial where an outlier was identified for parent compound was also disregarded for this residue definition MRL<sub>OECD</sub> = 0.36 | 0.4 (tentative)       | 0.23          | 0.08           |
| Strawberries              | SEU              | 0.04; 0.06; 0.06; 0.09; 0.1; 0.1; 0.12; 0.16                                                                                                                  | Trials compliant with GAP (Spain, 2010a) MRL<sub>OECD</sub> = 0.27                                             | 0.3 (tentative)       | 0.16          | 0.10           |
| Currants (red, black and white) | NEU            | –                                                                                                                                                    | No residue trials available. The product is applied just after harvest, ie. 200 d before the next harvest. Although chlorpyrifos is not systemic, the possible uptake of 3,5,6-TCP and/or its conjugates cannot be excluded | –                     | –             | –              |
| Kiwi                      | SEU              | 4 × < 0.05                                                                                                                                           | Trials compliant with GAP (France, 2016a); trials performed with 2 applications instead of 1 are deemed acceptable | 0.05 (tentative)      | 0.05          | 0.05           |
| Tomatoes Aubergines (egg plants) | SEU          | < 0.01; 0.01; 0.01; 0.02; 0.04; 0.04; 0.05; 0.05; 0.06                                                                                                         | Trials on tomatoes compliant with GAP; trials performed with 2 applications are deemed acceptable (Spain, 2010a). Extrapolation to aubergines is applicable MRL<sub>OECD</sub> = 0.11 | 0.15 (tentative)      | 0.06          | 0.04           |
| Peppers                   | SEU              | –                                                                                                                                                    | No trials compliant with GAP                                                                                      | –                     | –             | –              |
### Potatoes NEU
- **Region/indoor(a)**: NEU
- **Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)**: 5 × < 0.01; 0.01; 0.01; 0.03
- **Recommendations/comments (OECD calculations)**: Trials performed with a more critical GAP (1–2 applications at 0.52–0.57 kg a.s./ha; PHI 21 days) acceptable for a conservative risk assessment (Spain, 2010a)
  - **MRL<sub>OECD</sub>** = 0.04
- **HR (mg/kg)<sup>(b)</sup>**: 0.04 (tentative)
- **STMR (mg/kg)<sup>(c)</sup>**: 0.03

### SEU
- **Region/indoor(a)**: SEU
- **Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)**: 3 × < 0.01; 0.01; 0.01; 0.04; 0.06
- **Recommendations/comments (OECD calculations)**: Trials performed with 1 or 2 applications at 0.52–0.58 kg a.s./ha; PHI 21 days, acceptable for a conservative risk assessment (Spain, 2010a)
  - **MRL<sub>OECD</sub>** = 0.10
- **HR (mg/kg)<sup>(b)</sup>**: 0.1 (tentative)
- **STMR (mg/kg)<sup>(c)</sup>**: 0.06

### Rape seed NEU
- **Region/indoor(a)**: NEU
- **Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)**: 3 × < 0.01; 0.01; 0.01; 0.02; 0.03
- **Recommendations/comments (OECD calculations)**: Northern trials and southern trials on rapeseed, all compliant with GAP, can be combined to derive an MRL (Spain, 2010a)
  - **MRL<sub>OECD</sub>** = 0.12
- **HR (mg/kg)<sup>(b)</sup>**: 0.15 (tentative)
- **STMR (mg/kg)<sup>(c)</sup>**: 0.10

### SEU
- **Region/indoor(a)**: SEU
- **Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)**: 2 × < 0.01; 0.01; 0.02; 0.03; 0.10
- **Recommendations/comments (OECD calculations)**: Northern trials and southern trials on rapeseed, all compliant with GAP, can be combined to derive an MRL (Spain, 2010a)
  - **MRL<sub>OECD</sub>** = 0.12
- **HR (mg/kg)<sup>(b)</sup>**: 0.15 (tentative)
- **STMR (mg/kg)<sup>(c)</sup>**: 0.10

### Poppy seed Mustard seed Gold of pleasure
- **Region/indoor(a)**: NEU
- **Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)**: 3 × < 0.01; 0.01; 0.01; 0.02; 0.03
- **Recommendations/comments (OECD calculations)**: Direct extrapolation from rapeseed trials, performed with 0.45 kg a.s./ha instead of 0.3 or 0.34 kg a.s./ha; acceptable for a conservative risk assessment
  - **MRL<sub>OECD</sub>** = 0.12
- **HR (mg/kg)<sup>(b)</sup>**: 0.15 (tentative)
- **STMR (mg/kg)<sup>(c)</sup>**: 0.10

### Cotton seed
- **Region/indoor(a)**: SEU
- **Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)**: < 0.01; 0.01; 0.02; 0.02; 0.04; 0.04; 0.05
- **Recommendations/comments (OECD calculations)**: Overdosed residue trials performed on cotton (0.69 kg a.s./ha instead of 0.36) (Spain, 2010a), acceptable for a conservative risk assessment
  - **MRL<sub>OECD</sub>** = 0.09
- **HR (mg/kg)<sup>(b)</sup>**: 0.09 (tentative)
- **STMR (mg/kg)<sup>(c)</sup>**: 0.05
| Crop                  | Region/indoor(a) | 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)(b) | STMR (mg/kg)(c) |
|-----------------------|------------------|-----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------|---------------|
| Barley and oats grain | NEU              | < 0.01; 0.01; 0.01; 0.01; 0.02; 0.02; 0.02; 0.02                                               | Trials performed on barley compliant with GAP; northern and southern data can be combined (France, 2016a). Extrapolation to oats is applicable. MRL_{OECD} = 0.06                                                                                           | 0.06 (tentative)     | 0.05         | 0.01          |
|                       | SEU              | < 0.01; 0.01; < 0.01; < 0.01; 0.01; 0.02; 0.02                                               |                                                                                                                                                                                                                                                |                      |              |               |
| Indoor                |                  | Wheat: 0.09(d); 0.3; 0.59(d); 0.63 Barley: 0.37; 0.58; 0.80(d); 1.02(d)                      | Overdosed trials on wheat and barley (5 instead of 2.5 g a.s./tonne) considered on tentative basis (Spain, 2010a); highest residue from withholding period (WHP) 0–6 months was considered. Trials not analysing desmethyl chlorpyrifos-methyl were disregarded (Spain, 2003). MRL_{OECD} not relevant for post-harvest treatment R_{ber} = 1.52; R_{max} = 1.48 | 1.5 (tentative)     | 1.02         | 0.59          |
| Wheat and rye grain   | NEU              | 5 × < 0.01; 0.01; 0.02; 0.02                                                                | Trials performed on wheat compliant with GAP; northern and southern data can be combined (France, 2016a). Extrapolation to rye is applicable. MRL_{OECD} = 0.02                                                                                             | 0.03 (tentative)     | 0.02         | 0.01          |
|                       | SEU              | 6 × < 0.01; 2 × 0.01                                                                       |                                                                                                                                                                                                                                                |                      |              |               |
| Indoor                |                  | Wheat: 0.09(d); 0.3; 0.59(d); 0.63 Barley: 0.37; 0.58; 0.80(d); 1.02(d)                      | Overdosed trials on wheat and barley (5 instead of 2.5 g a.s./tonne) considered on tentative basis (Spain, 2010a); highest residue from withholding period (WHP) 0–6 months was considered. Trials not analysing desmethyl chlorpyrifos-methyl were disregarded (Spain, 2003). MRL_{OECD} not relevant for post-harvest treatment R_{ber} = 1.52; R_{max} = 1.48 | 1.5 (tentative)     | 1.02         | 0.59          |
| Barley and oats straw | NEU              | 8 × < 0.1                                                                                 | Trials performed on barley compliant with GAP; northern and southern data can be combined (France, 2016a). Extrapolation to oats is applicable                                                                                               | 0.1 (tentative)      | 0.10         | 0.10          |
|                       | SEU              | 7 × < 0.1                                                                                 |                                                                                                                                                                                                                                                |                      |              |               |
### Crop Residue Levels and MRL Proposals

| Crop                  | Region/Indoor | 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> |
|-----------------------|---------------|-----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|-----------------------|--------------------------|--------------------------|
| Wheat and rye straw   | NEU           | 7 x < 0.1; 0.1                                                                                | Trials performed on wheat compliant with GAP; northern and southern data can be combined (France, 2016a). Extrapolation to rye is applicable MRL<sub>OECD</sub> = 0.11 | 0.2 (tentative)       | 0.10                     | 0.10                     |
|                       | SEU           | 8 x < 0.1                                                                                     |                                                                                              |                       |                          |                          |
| Maize grain           | SEU           | 7 x < 0.01; 0.01                                                                              | Trials compliant with GAP (Spain, 2010a) R<sub>ber</sub> = 0.02 (OECD calculator not relevant) | 0.02 (tentative)      | 0.01                     | 0.01                     |
|                       | Indoor        | –                                                                                             | No trials available. The waiver proposed by France (France, 2016a) is not acceptable        | –                     | –                        | –                        |
| Rice grain            | Indoor        | –                                                                                             | No trials available. The waiver proposed by France (France, 2016a) is not acceptable        | –                     | –                        | –                        |

**GAP:** Good Agricultural Practice; **MRL:** maximum residue level; **OECD:** Organisation for Economic Co-operation and Development; **a.s.:** active substance; **PHI:** preharvest interval; **R<sub>ber</sub>:** statistical calculation of the MRL by using a non-parametric method; **R<sub>max</sub>:** 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.

(d): Highest residue level was observed after a withholding period of 6 months.
B.1.2.3. Residues in succeeding crops

Confinement rotational crop study (quantitative aspect)
Significant residues are not expected in rotational crops
Tentative conclusion based on old studies performed with chlorpyrifos (additional metabolism studies are still required)

Field rotational crop study
Not available and not required (tentative)

B.1.2.4. Processing factors

(a) Residue definition in processed commodities: sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl

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

**Residue definition in raw agricultural commodities:** chlorpyrifos-methyl

**Robust processing factors (sufficiently supported by data)**

| Processed commodity | Number of studies\(^{(a)}\) | Individual values | Median PF |
|---------------------|-----------------------------|-------------------|----------|
| Citrus, peeled\(^{(b)}\) | 14                          | 0.01; 0.01; 0.04; 0.04; 0.05; 0.05; 0.05; 0.05; 0.06; 0.07; 0.08; Mandarin: 0.03; 0.05 |
| Citrus, juice       | 4\(^{(c)}\)                 | 0.01; 0.02; 0.04; 0.08 |
| Apples, juice       | 4\(^{(c)}\)                 | 0.03; 0.06; 0.14; 0.50 |
| Apples, sauce       | 4\(^{(c)}\)                 | 0.03; 0.06; 0.14; 0.50 |
| Table grapes, dried | 6                           | 0.52; 0.58; 1.7; 2.7; 2.8; 5.9 |
| Wine grapes, juice  | 6                           | 0.06; 0.07; 0.09; 0.40; 0.40; 0.77 |
| Wine grapes, wet pomace | 6            | 0.67; 2.0; 3.3; 3.3; 12.2; 12.8 |
| Wine grapes, red wine | 6                    | 0.05; 0.08; 0.18; 0.19; 0.32; 0.72 |
| Tomatoes, juice     | 4\(^{(c)}\)                 | 0.02; 0.02; 0.05; 0.06 |

**Indicative processing factors (limited data set)**

| Processed commodity | Number of studies\(^{(a)}\) | Individual values | Median PF |
|---------------------|-----------------------------|-------------------|----------|
| Oranges, marmalade  | 2                           | 0.04; 0.09        |
| Apples, dry pomace  | 2                           | 4.3; 19.9         | 12       |
| Apples, wet pomace  | 2                           | 1.5; 5.6          | 3.5      |
| Pears, canned       | 2                           | 0.07; 0.13        | 0.10     |
| Tomatoes, peeled and canned | 2 | 0.03; 0.04 |
| Tomatoes, unpeeled and canned | 1\(^{(d)}\) | 0.29 |
| Tomatoes, sauce     | 2                           | 0.43; 0.73        | 0.58     |
| Tomatoes, paste     | 2                           | 0.89; 0.91        | 0.90     |
| Tomatoes, ketchup   | 2                           | 0.38; 0.48        | 0.43     |
| Tomatoes, dried     | 2                           | 4.0; 5.4          | 4.7      |
| Wine grapes, dry pomace | 1\(^{(d)}\) | 33           |
| Wine grapes, must   | 1\(^{(d)}\)                 | 1.0               | 1.0      |

**Residue definition in raw agricultural commodities:** sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl

**Indicative processing factors (limited data set)**

| Processed commodity | Number of studies\(^{(a)}\) | Individual values | Median PF |
|---------------------|-----------------------------|-------------------|----------|
| Barley, brewing malt | 2                           | 0.14; 0.14        | 0.14     |
| Barley, beer        | 2                           | 0.01; 0.01        | 0.01     |
| Wheat, whole-meal flour | 2             | 1.1; 1.2          | 1.2      |
| Wheat, whole-meal bread | 2             | 0.56; 0.79        | 0.67     |
## Processed commodity Number of studies\(^{(a)}\) Individual values Median PF
| Processed commodity | Number of studies\(^{(a)}\) | Processing factor (PF) | Median PF |
|---------------------|-----------------------------|------------------------|-----------|
| Wheat, white flour  | 2                           | 0.22; 0.24             | 0.23      |
| (extrapolated to rye) |                |                        |           |
| Wheat, white bread  | 2                           | 0.14; 0.14             | 0.14      |
| (extrapolated to rye) |                |                        |           |
| Wheat, bran         | 2                           | 2.9; 3.1               | 3.0       |
| (extrapolated to rye) |                |                        |           |

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

\(^{(b)}\): The residue definition for processed commodities does not apply to peeled fruits as these processed commodities are not subject to hydrolysis. Therefore, the calculated PF refer to chlorpyrifos-methyl residue levels in both raw and processed commodities.

\(^{(c)}\): Two studies performed with analysis of desmethyl chlorpyrifos-methyl showed that this compound remained below the LOQ in these processed items. Therefore, the PF were derived considering only the residue levels of the parent compound in raw and processed commodities. It also allows using results from two other studies where only analysis of the parent compound was performed.

\(^{(d)}\): Analysis for the metabolite desmethyl chlorpyrifos-methyl was not carried out in the available studies and these PF are therefore considered indicative. However, overestimated processing factors can be derived considering the levels of total 3,5,6-TCP (which includes chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl in addition to 3,5,6-TCP) in processed commodity and the levels of chlorpyrifos-methyl in raw agricultural commodities.

## Robust processing factors (sufficiently supported by data)

| Processed commodity | Number of studies\(^{(a)}\) | Individual values | Median PF |
|---------------------|-----------------------------|-------------------|-----------|
| Citrus, peeled      | 14                          | Oranges: 0.01; 0.03; 0.08; 0.09; 0.11; 0.12; 0.12; 0.12; 0.12; 0.14; 0.14 Mandarins: 0.05; 0.11 | 0.12      |
| Citrus, juice       | 4                           | 0.05; 0.06; 0.12; 0.14 | 0.09      |
| Table grapes, dried (raisins) | 6 | 0.49; 2.0; 3.6; 3.9; 4.7; 7.9 | 3.8       |
| Wine grapes, red wine (unheated) | 7 | 0.12; 0.19; 0.19; 0.67; 0.75; 1.2; 1.8 | 0.67      |
| Wine grapes, juice  | 4                           | 0.41; 0.69; 0.91; 2.9 | 0.8       |
| Wine grapes, wet pomace | 4                   | 1.3; 4.5; 5.1; 6.6 | 4.8       |
| Wheat, whole-meal flour  | 3 | 0.35; 0.51; 0.79 | 0.51      |
| (extrapolated to rye) |                |                   |           |
| Wheat, whole-meal bread  | 3 | 0.08; 0.61; 0.76 | 0.61      |
| (extrapolated to rye) |                |                   |           |
| Wheat, white flour  | 3                           | 0.01; 0.06; 0.08   | 0.06      |
| (extrapolated to rye) |                |                   |           |
| Wheat, white bread  | 3                           | 0.12; 0.13; 0.26   | 0.13      |
| (extrapolated to rye) |                |                   |           |
| Wheat, bran         | 3                           | 0.91; 2.3; 7.2     | 2.3       |
| (extrapolated to rye) |                |                   |           |

## Indicative processing factors (limited data set)

| Processed commodity | Number of studies\(^{(a)}\) | Individual values | Median PF |
|---------------------|-----------------------------|-------------------|-----------|
| Oranges, marmalade  | 2                           | 0.05; 0.11        | 0.08      |
| Apples, juice       | 2                           | 0.11; 0.59        | 0.35      |
| (extrapolated to pears) |                |                   |           |
| Apples, dry pomace  | 2                           | 0.8; 21           | 10.8      |
| (extrapolated to pears) |                |                   |           |
| Apples, wet pomace  | 1                           | 0.08              | 0.08      |
| (extrapolated to pears) |                |                   |           |
### Processed commodity

| Processed commodity                  | Number of studies<sup>a</sup> | Processing factor (PF) | Median PF |
|-------------------------------------|-------------------------------|------------------------|-----------|
| Apples, sauce                        | 2                             | 0.39; 0.59             | 0.49      |
| Pears, canned                        | 1                             | 0.08                   | 0.08      |
| Wine grapes, dry pomace              | 3<sup>b</sup>                 | 3.4; 7.3; 8.4          | 7.3       |
| Wine grapes, must                    | 3<sup>b</sup>                 | 0.19; 0.33; 1.5        | 0.33      |
| Wine grapes, red wine (heated)       | 1                             | 0.75                   | 0.75      |
| Tomatoes, sauce                      | 2                             | 1.5; 1.7               | 1.6       |
| Tomatoes, juice                      | 2                             | 0.66; 0.86             | 0.76      |
| Tomatoes, unpeeled and canned       | 1<sup>b</sup>                 | 0.66                   | 0.66      |
| Tomatoes, peeled and canned         | 1                             | 0.51                   | 0.51      |
| Tomatoes, paste                      | 1                             | 8.3                    | 8.3       |
| Tomatoes, ketchup                    | 1                             | 0.88                   | 0.88      |
| Rape seed, crude oil                 | 1                             | 0.48                   | 0.48      |
| Rape seed, refined oil               | 1                             | 0.62                   | 0.62      |
| Rape seed, meal/press cake          | 1                             | 0.86                   | 0.86      |
| Cotton seed, crude oil               | 1                             | 1.2                    | 1.2       |
| Cotton seed, refined oil             | 1                             | 1                      | 1         |
| Cotton seed, meal/press cake        | 1                             | 0.80                   | 0.80      |
| Barley, brewing malt                | 2                             | 1.2; 2.7               | 2.0       |
| Barley, beer                         | 2                             | 0.15; 0.28             | 0.2       |
| Maize, flour                         | 1                             | 0.08                   | 0.08      |
| Maize, crude oil                     | 1                             | 0.08                   | 0.08      |

<sup>a</sup>: Studies with residues in the RAC at or close to the LOQ were disregarded.

<sup>b</sup>: Since analysis for desmethyl chlorpyrifos-methyl was not carried out, it was not possible to recalculate the absolute levels for 3,5,6-TCP and its conjugates by subtracting the contribution of the parent compound and desmethyl chlorpyrifos-methyl to the total residue hydrolysed as 3,5,6-TCP. Consequently, this processing factor may be overestimated and is therefore considered tentative.

### B.2. Residues in livestock

#### Risk assessment residue definition 1: sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl<sup>(b)</sup>, expressed as chlorpyrifos-methyl

**Scenario EU1**: All authorised GAPs are considered

| Risk assessment | Foods | Max dietary burden (mg/kg DM) | Trigger exceeded (Y/N) |
|-----------------|-------|-------------------------------|------------------------|
| EU1             | Dairy ruminants | 3.11                          | Y                      |
|                 | Meat ruminants  | 5.87                          | Y                      |
|                 | Poultry         | 4.28                          | Y                      |
|                 | Pigs            | 4.88                          | Y                      |

**Scenario EU2**: Fall-back GAPs (i.e. foliar treatment) are considered for wheat and rye grain

| Risk assessment | Foods | Max dietary burden (mg/kg DM) | Trigger exceeded (Y/N) |
|-----------------|-------|-------------------------------|------------------------|
| EU2             | Dairy ruminants | 3.05                          | Y                      |
|                 | Meat ruminants  | 5.87                          | Y                      |
|                 | Poultry         | 4.28                          | Y                      |
|                 | Pigs            | 4.88                          | Y                      |

#### Risk assessment residue definition 2: sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP

**Scenario EU2**: As scenario EU2 should be the basis for MRL calculation in livestock commodities, the dietary burden calculations for 3,5,6-TCP is directly estimated from scenario EU2

| Risk assessment | Foods | Max dietary burden (mg/kg DM) | Trigger exceeded (Y/N) |
|-----------------|-------|-------------------------------|------------------------|
| EU2             | Dairy ruminants | 0.78                          | Y                      |
|                 | Meat ruminants  | 1.30                          | Y                      |
|                 | Poultry         | 0.91                          | Y                      |
### Review of the existing MRLs for chlorpyrifos-methyl

bw: body weight; DM: dry matter; GAP: Good Agricultural Practice.
(a): Calculated for the maximum dietary burden.
(b): Desmethyl chlorpyrifos-methyl is only relevant in small cereal grain (treated post-harvest) and in processed commodities.
(c): Dietary burden is unaffected in scenario EU2 because residues resulting from post-harvest treatment on barley and oats grains are still considered in the calculations.

#### 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 | 23                      | 10              | 85 N                      |
|                               | Lactating goat | 0.86-0.97          | 7               | 7 N/ dairy ruminants      |
|                               |         |                         |                 | 3.4 N/ meat ruminants     |
|                               | Sheep (ewe) | 100 (a)              | 1               | > 900 N/ dairy ruminants  |

Source: Spain (1997)
(a): Nominal dose of 30–34 mg/kg feed; theoretical administered dose converted in mg/kg bw per day assuming a feed intake of 2 kg DM per day and a standard body weight of 70 kg.
### B.2.1.2. Stability of residues in livestock

#### Animal products

| Animal          | Commodity                  | T (°C) | Stability (months/years) |
|-----------------|----------------------------|--------|--------------------------|
| **Chlorpyrifos-methyl** |                            |        |                          |
| Beef            | Muscle, fat, liver, kidney | –20    | 3 months                 |
| Cow             | Milk                       | –20    | 3 months                 |
| Laying hen      | Egg                        | –20    | ≤ 3 months\(^{(a)}\)     |

Source: Spain (2003)

\(^{(a)}\): This study investigates storage stability for 3 months but a significant decrease (40%) was observed.

#### 3,5,6-trichloropyridinol (3,5,6-TCP) and its conjugates\(^{(a)}\)

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

Source: Spain (2010b)

\(^{(a)}\): As the possible decline of conjugates is expected to proceed through 3,5,6-TCP, conjugates are also covered.

---

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

**Metabolism in rat and ruminant similar (Yes/No)**

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

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

**Conversion factor (monitoring to risk assessment)**

**Fat soluble residues (Yes/No)**

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

#### RD-monitoring:

1. Chlorpyrifos-methyl

2. (optional): sum of 3,5,6-trichloropyridinol (3,5,6-TCP) and its conjugates, expressed as 3,5,6-TCP

#### RD-risk assessment:

1. Chlorpyrifos-methyl

2. (optional): sum of 3,5,6-trichloropyridinol (3,5,6-TCP) and its conjugates, expressed as 3,5,6-TCP

\(^{(a)}\): This study investigates storage stability for 3 months but a significant decrease (40%) was observed.

#### References

Source: Spain (2003)

Source: Spain (2010b)
B.2.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies (for chlorpyrifos-methyl)

| 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> | 0.01 | n.a. | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(i)</sup> |
| Closest feeding level<sup>(a)</sup> | (0.36 mg/kg bw; 3 N rate) |
| Milk<sup>(e)</sup> | 0.01 | n.a. | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(i)</sup> |
| Meat ruminants<sup>(f)</sup> | 0.01 | Not available | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(i)</sup> |
| Closest feeding level<sup>(a)</sup> | (0.31 mg/kg bw; 1.2 N rate) |
| Muscle | 0.01 | Not available | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(i)</sup> |
| Fat | 0.03 | Not available | 0.02 | 0.02 | 0.03 (tentative)<sup>(i)</sup> |
| Liver | 0.01 | Not available | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(i)</sup> |
| Kidney | 0.01 | Not available | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(i)</sup> |
| Poultry<sup>(g)</sup> | 0.01 | Not available | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(i)</sup> |
| Closest feeding level<sup>(a)</sup> | (0.63 mg/kg bw; 2.3 N rate) |
| Muscle | 0.01 | Not available | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(i)</sup> |
| Fat | 0.01 | Not available | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(i)</sup> |
| Liver | 0.01 | Not available | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(i)</sup> |
| Egg | 0.01 | Not available | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(i)</sup> |
| Pig<sup>(h)</sup> | 0.01 | Not available | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(i)</sup> |
| Closest feeding level<sup>(a)</sup> | (0.40 mg/kg bw; 2 N rate) |
| Muscle | 0.01 | Not available | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(i)</sup> |
| Fat | 0.09 | Not available | 0.03 | 0.05 | 0.05 (tentative)<sup>(i)</sup> |
| Liver | 0.01 | Not available | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(i)</sup> |
| Kidney | 0.01 | Not available | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(i)</sup> |

MRL: maximum residue level; bw: body weight.
*: Indicates that the MRL is proposed at the limit of quantification.
n.a. not applicable.
(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 1 N rate for the maximum dietary burden.
(d): 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.
(e): Only the milk samples collected from day 2 to day 14 were considered (plateau level).
(f): 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.
(g): Study performed on laying hens: feeding level was recalculated as mg/kg bw considering the average feed daily consumption (0.12 kg/day) and weight (1.9 kg) of laying hens.
(h): Study performed on swine: feeding level was recalculated as mg/kg bw considering the average feed daily consumption (3 kg/day) and weight (75 kg) of swine.
(i): MRL proposal is tentative because of the deficiencies identified in the feeding studies (storage conditions of the samples).
B.2.2.1. 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 chlorpyrifos-methyl (0.11 mg/kg bw) and the feeding study analysing for 3,5,6-TCP | | | |
| Closest feeding level<sup>(a)</sup> (0.36 mg/kg bw; 3 N rate) | | | |
| Milk<sup>(e)</sup> | < 0.01 | n.a. | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(i)</sup> |
| Meat ruminants<sup>(f)</sup> | | | | |
| Based on the dietary burden of chlorpyrifos-methyl (0.25 mg/kg bw) and the feeding study analysing for 3,5,6-TCP | | | |
| Closest feeding level<sup>(a)</sup> (0.31 mg/kg bw; 1.2 N rate) | | | |
| Muscle | < 0.01 | Not available | < 0.01 | < 0.01 | 0.01* (tentative)<sup>(i)</sup> |
| Fat | < 0.05 | Not available | 0.03 | 0.04 | 0.05 (tentative)<sup>(i)</sup> |
| Liver | 0.44 | Not available | 0.28 | 0.36 | 0.4 (tentative)<sup>(i)</sup> |
| Kidney | 0.21 | Not available | 0.13 | 0.17 | 0.2 (tentative)<sup>(i)</sup> |
| Poultry<sup>(g)</sup> | | | | |
| Based on the dietary burden of chlorpyrifos-methyl (0.27 mg/kg bw) and the feeding study analysing for 3,5,6-TCP | | | |
| Closest feeding level<sup>(a)</sup> (0.63 mg/kg bw; 2.3 N rate) | | | |
| Muscle | < 0.05 | Not available | 0.015 | 0.021 | 0.03 (tentative)<sup>(i)</sup> |
| Fat | < 0.05 | Not available | 0.015 | 0.021 | 0.03 (tentative)<sup>(i)</sup> |
| Liver | < 0.05 | Not available | 0.015 | 0.021 | 0.03 (tentative)<sup>(i)</sup> |
| Eggs | < 0.05 | Not available | 0.015 | 0.021 | 0.03 (tentative)<sup>(i)</sup> |
| Pig<sup>(h)</sup> | | | | |
| Based on the dietary burden of chlorpyrifos-methyl (0.20 mg/kg bw) and the feeding study analysing for 3,5,6-TCP | | | |
| Closest feeding level<sup>(a)</sup> (0.40 mg/kg bw; 2 N rate) | | | |
| Muscle | < 0.05 | Not available | 0.01 | 0.02 | 0.03 (tentative)<sup>(i)</sup> |
| Fat | < 0.05 | Not available | 0.05 | 0.05 | 0.05 (tentative)<sup>(i)</sup> |
| Liver | 0.20 | Not available | 0.07 | 0.09 | 0.1 (tentative)<sup>(i)</sup> |
| Kidney | 0.17 | Not available | 0.07 | 0.09 | 0.1 (tentative)<sup>(i)</sup> |

MRL: maximum residue level; bw: body weight.
*: Indicates that the MRL is proposed at the limit of quantification.
n.a. not applicable.
(a): Closest feeding level and N dose rate related to the maximum dietary burden.
(b): Mean residue level, recalculated at the 1N rate for the median dietary burden.
(c): Highest residue level for tissues and eggs and mean residue level for milk, recalculated at the 1 N rate for the maximum dietary burden.
(d): 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.
(e): Only the milk samples collected from 6 to day 13 were considered (plateau level).
(f): 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.
(g): Study performed on laying hens: feeding level was recalculated as mg/kg bw considering the average feed daily consumption (0.12 kg/day) and weight (1.9 kg) of laying hens.
(h): Study performed on swine: feeding level was recalculated as mg/kg bw considering the average feed daily consumption (3 kg/day) and weight (75 kg) of swine.
(i): MRL proposal is tentative because a fully validated analytical method for enforcement of 3,5,6-TCP and its conjugates is still needed.
### B.3. Consumer risk assessment

#### B.3.1. Consumer risk assessment for chlorpyrifos-methyl without consideration of the existing CXLs

| Parameter                  | Value                                                                 |
|----------------------------|----------------------------------------------------------------------|
| ADI                        | 0.01 mg/kg bw per day (European Commission, 2005)                     |
| Highest IEDI, according to EFSA PRIMo | **Scenario EU1**: 389% ADI (DK, child)  
Main contributors: wheat grain (203% ADI) and rye grain (163% ADI)  
**Scenario EU2**: 61.9% ADI (IE, adult) |
| Assumptions made for the calculations | **Scenario EU1**: The calculation is based on the median residue levels in the raw agricultural commodities, except for citrus fruits, where the relevant peeling factor was applied.  
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.  
**Scenario EU2**: Fall-back GAPs (i.e. foliar treatment) were considered for wheat and rye grain.  
Consideration of these less critical GAPs does not impact on the residue levels in livestock commodities as the post-harvest treatment on barley and oat grains is still considered for the dietary burden calculations. All other input values remain unchanged. |
| ARfD                       | 0.1 mg/kg bw (European Commission, 2005)                              |
| Highest IESTI, according to EFSA PRIMo | **Scenario EU1**: 75.6% ARfD (wheat grain)  
**Scenario EU2**: 37.8% ARfD (rice grain) |
| Assumptions made for the calculations | **Scenario EU1**: The calculation is based on the highest residue levels in the raw agricultural commodities, except for citrus fruits, where the relevant peeling factor was applied.  
For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation.  
**Scenario EU2**: Fall-back GAPs (i.e. foliar treatment) were considered for wheat and rye grain.  
Consideration of these less critical GAPs does not impact on the residue levels in livestock commodities as the post-harvest treatment on barley and oat grains is still considered for the dietary burden calculations. All other input values remain unchanged. |

#### B.3.2. Consumer risk assessment for chlorpyrifos-methyl with consideration of the existing CXLs

| Parameter                  | Value                                                                 |
|----------------------------|----------------------------------------------------------------------|
| ADI                        | 0.01 mg/kg bw per day (European Commission, 2005)                     |
| Highest IEDI, according to EFSA PRIMo | 61.2% ADI (IE, adult)                                                |
| Assumptions made for the calculations | For those commodities having a CXL higher than the EU MRL proposal, median residue levels applied in the EU scenario were replaced by the median residue levels derived by JMPR. |
| ARfD                       | 0.1 mg/kg bw (European Commission, 2005)                              |
| Highest IESTI, according to EFSA PRIMo | 54.9% ARfD (apples)                                                  |
| Assumptions made for the calculations | For those commodities having a CXL higher than the EU MRL proposal, highest residue levels applied in the EU scenario were replaced by the median residue levels derived by JMPR. |
B.3.3. 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 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.

A second exposure calculation including the potential intake of 3,5,6-TCP driven by the CXLs of chlorpyrifos and chlorpyrifos-methyl was not carried out as this metabolite was not considered in the assessment made by Codex.

B.4. Proposed MRLs

| Code number | Commodity     | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|---------------|-------------------------|----------------------|-----------------------|---------|
| 110010      | Grapefruit    | 0.05*                   | 2                    | 2                     | Recommended(a) |
| 110020      | Oranges       | 0.5                     | 2                    | 2                     | Recommended(a) |
| 110030      | Lemons        | 0.3                     | 2                    | 2                     | Recommended(a) |
| 110040      | Limes         | 0.05*                   | 2                    | 2                     | Recommended(a) |

Enforcement residue definition 1a (existing): chlorpyrifos-methyl(F)

Enforcement residue definition 1a (proposed): chlorpyrifos-methyl(F)
| Code number | Commodity                      | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|--------------------------------|-------------------------|---------------------|-----------------------|---------|
| 110050      | Mandarins                      | 1                       | 2                   | 2                     | Recommended (b) |
| 130010      | Apples                         | 0.5                     | 1                   | 1                     | Recommended (b) |
| 130020      | Pears                          | 0.5                     | 1                   | 1                     | Recommended (b) |
| 130030      | Quinces                         | 0.5                     | 1                   | 1                     | Recommended (b) |
| 130040      | Medlar                         | 0.5                     | 1                   | 1                     | Recommended (b) |
| 130050      | Loquat                         | 0.5                     | 1                   | 1                     | Recommended (b) |
| 140010      | Apricots                       | 0.05*                   | 0.5                 | 0.5                   | Recommended (b) |
| 140020      | Cherries                       | 0.05*                   | 0.5                 | 0.5                   | Recommended (b) |
| 140030      | Peaches                        | 0.5                     | 0.5                 | 0.5                   | Recommended (b) |
| 140040      | Plums                          | 0.05*                   | 0.5                 | 0.5                   | Recommended (b) |
| 151010      | Table grapes                   | 0.2                     | 1                   | 1                     | Recommended (b) |
| 151020      | Wine grapes                    | 0.2                     | 1                   | 1                     | Recommended (b) |
| 152000      | Strawberries                   | 0.5                     | 0.06                | 0.06                  | Recommended (b) |
| 154030      | Currants (red, black and white)| 0.05*                  | –                   | 0.01*                 | Recommended (b) |
| 161040      | Kumquats                       | 0.05*                   | 2                   | 2                     | Recommended (b) |
| 162010      | Kiwi                           | 0.05*                   | –                   | 0.01*                 | Recommended (b) |
| 211000      | Potatoes                       | 0.05*                   | 0.01*               | 0.01*                 | Recommended (b) |
| 231010      | Tomatoes                       | 0.5                     | 1                   | 1                     | Recommended (b) |
| 231020      | Peppers                        | 0.5                     | 1                   | 1                     | Recommended (b) |
| 231030      | Aubergines (egg plants)        | 0.5                     | 1                   | 1                     | Recommended (b) |
| 401030      | Poppy seed                     | 0.05*                   | –                   | 0.01*                 | Further consideration needed (f) |
| 401060      | Rape seed                      | 0.05*                   | –                   | 0.01*                 | Further consideration needed (f) |
| 401080      | Mustard seed                   | 0.05*                   | –                   | 0.01*                 | Further consideration needed (f) |
| 401090      | Cotton seed                    | 0.05*                   | –                   | 0.04                  | Further consideration needed (f) |
| 401130      | Gold of pleasure               | 0.05*                   | –                   | 0.01*                 | Further consideration needed (f) |
| 810000      | Spices (seeds)                 | 1                       | 1                   | 1                     | Further consideration needed (g) |
| 820000      | Spices (roots and rhizome)     | 0.3                     | 0.3                 | 0.3                   | Further consideration needed (g) |
| 840000      | Spices (roots and rhizome)     | 5                       | 5                   | 5                     | Further consideration needed (g) |
| 1011010     | Swine muscle                   | 0.05*                   | 0.1                 | 0.1                   | Further consideration needed (b) |
| 1011020     | Swine fat (free of lean meat)   | 0.05*                   | 0.1                 | 0.1                   | Further consideration needed (b) |
| 1011030     | Swine liver                    | 0.05*                   | 0.01*               | 0.01*                 | Further consideration needed (b) |
| 1011040     | Swine kidney                   | 0.05*                   | 0.01*               | 0.01*                 | Further consideration needed (b) |
| 1012010     | Bovine muscle                  | 0.05*                   | 0.1                 | 0.1                   | Further consideration needed (b) |
| 1012020     | Bovine fat                     | 0.05*                   | 0.1                 | 0.1                   | Further consideration needed (b) |
| 1012030     | Bovine liver                   | 0.05*                   | 0.01*               | 0.01*                 | Further consideration needed (b) |
| 1012040     | Bovine kidney                  | 0.05*                   | 0.01*               | 0.01*                 | Further consideration needed (b) |
| 1013010     | Sheep muscle                   | 0.05*                   | 0.1                 | 0.1                   | Further consideration needed (b) |
| 1013020     | Sheep fat                      | 0.05*                   | 0.1                 | 0.1                   | Further consideration needed (b) |
| 1013030     | Sheep liver                    | 0.05*                   | 0.01*               | 0.01*                 | Further consideration needed (b) |
| 1013040     | Sheep kidney                   | 0.05*                   | 0.01*               | 0.01*                 | Further consideration needed (b) |
| 1014010     | Goat muscle                    | 0.05*                   | 0.1                 | 0.1                   | Further consideration needed (b) |
| 1014020     | Goat fat                       | 0.05*                   | 0.1                 | 0.1                   | Further consideration needed (b) |
| 1014030     | Goat liver                     | 0.05*                   | 0.01*               | 0.01*                 | Further consideration needed (b) |
| 1014040     | Goat kidney                    | 0.05*                   | 0.01*               | 0.01*                 | Further consideration needed (b) |
| Code number | Commodity                  | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                          |
|------------|---------------------------|-------------------------|---------------------|-------------|----------------------------------|
| 1016010    | Poultry muscle            | 0.05*                   | 0.01*               | 0.01*       | Further consideration needed(i)  |
| 1016020    | Poultry fat               | 0.05*                   | 0.01*               | 0.01*       | Further consideration needed(i)  |
| 1016030    | Poultry liver             | 0.05*                   | 0.01*               | 0.01*       | Further consideration needed(i)  |
| 1020010    | Cattle milk               | 0.01*                   | 0.01*               | 0.01*       | Further consideration needed(i)  |
| 1020020    | Sheep milk                | 0.01*                   | 0.01*               | 0.01*       | Further consideration needed(i)  |
| 1020030    | Goat milk                 | 0.01*                   | 0.01*               | 0.01*       | Further consideration needed(i)  |
| 1030000    | Birds’ eggs               | 0.01*                   | 0.01*               | 0.01*       | Further consideration needed(i)  |
|            | Other commodities of plant and/or animal origin | See Reg. (EC) No 839/2008 | –          | –            |                                  |

**Enforcement residue definition 1b (existing):** chlorpyrifos-methyl  
**Enforcement residue definition 1b (proposed):** sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl

| Code number | Commodity      | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                          |
|------------|----------------|-------------------------|---------------------|-------------|----------------------------------|
| 500010     | Barley grain   | 3                       | –                   | 6           | Further consideration needed(i)  |
| 500030     | Maize grain    | 3                       | –                   | 0.01*       | Recommended(c)                  |
| 500050     | Oats grain     | 3                       | –                   | 6           | Further consideration needed(i)  |
| 500060     | Rice grain     | 3                       | 0.1                 | 3           | Further consideration needed(i)  |
| 500070     | Rye grain      | 3                       | –                   | 0.02        | Recommended(c)                  |
| 500080     | Sorghum grain  | 3                       | 10                  | –           | Further consideration needed(i)  |
| 500090     | Wheat grain    | 3                       | 10                  | 0.02        | Recommended(h)                  |
|            | Other commodities of plant origin | See Reg. (EC) No 839/2008 | –          | –            |                                  |

**Enforcement residue definition 2 (existing):** –  
**Enforcement residue definition 2 (proposed):** sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP

| Code number | Commodity     | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                          |
|------------|---------------|-------------------------|---------------------|-------------|----------------------------------|
| 110010     | Grapefruit    | –                       | –                   | –           | Further consideration needed(i)  |
| 110020     | Oranges       | –                       | –                   | 0.8         | Further consideration needed(i)  |
| 110030     | Lemons        | –                       | –                   | 0.8         | Further consideration needed(i)  |
| 110040     | Limes         | –                       | –                   | –           | Further consideration needed(i)  |
| 110050     | Mandarins     | –                       | –                   | 0.8         | Further consideration needed(i)  |
| 130010     | Apples        | –                       | –                   | 0.15        | Further consideration needed(i)  |
| 130020     | Pears         | –                       | –                   | 0.3         | Further consideration needed(i)  |
| 130030     | Quinces       | –                       | –                   | 0.15        | Further consideration needed(i)  |
| 130040     | Medlar        | –                       | –                   | –           | Further consideration needed(i)  |
| 130050     | Loquat        | –                       | –                   | –           | Further consideration needed(i)  |
| 140010     | Apricots      | –                       | –                   | –           | Further consideration needed(i)  |
| 140020     | Cherries      | –                       | –                   | 0.3         | Further consideration needed(i)  |
| 140030     | Peaches       | –                       | –                   | 0.3         | Further consideration needed(i)  |
| 140040     | Plums         | –                       | –                   | –           | Further consideration needed(i)  |
| 151010     | Table grapes  | –                       | –                   | 0.4         | Further consideration needed(i)  |
| 151020     | Wine grapes   | –                       | –                   | 0.4         | Further consideration needed(i)  |
| 152000     | Strawberries  | –                       | –                   | 0.3         | Further consideration needed(i)  |
| 154030     | Currants (red, black and white) | –                       | –                   | –           | Further consideration needed(i)  |
| 161040     | Kumquats      | –                       | –                   | –           | Further consideration needed(i)  |
| 162010     | Kiwi          | –                       | –                   | 0.05*       | Further consideration needed(i)  |
| 211000     | Potatoes      | –                       | –                   | 0.1         | Further consideration needed(i)  |
| 231010     | Tomatoes      | –                       | –                   | 0.15        | Further consideration needed(i)  |
| 231020     | Peppers       | –                       | –                   | –           | Further consideration needed(i)  |
| Code number | Commodity                  | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review MRL (mg/kg) | Comment                                      |
|------------|----------------------------|-------------------------|---------------------|----------------------------------|---------------------------------------------|
| 231030     | Aubergines (egg plants)    | –                       | –                   | 0.15                             | Further consideration needed(6)             |
| 401030     | Poppy seed                 | –                       | –                   | 0.15                             | Further consideration needed(6)             |
| 401060     | Rape seed                  | –                       | –                   | 0.15                             | Further consideration needed(6)             |
| 401080     | Mustard seed               | –                       | –                   | 0.15                             | Further consideration needed(6)             |
| 401090     | Cotton seed                | –                       | –                   | 0.09                             | Further consideration needed(6)             |
| 401130     | Gold of pleasure           | –                       | –                   | 0.15                             | Further consideration needed(6)             |
| 500010     | Barley grain               | –                       | –                   | 1.5                              | Further consideration needed(6)             |
| 500030     | Maize grain                | –                       | –                   | 0.02                             | Further consideration needed(6)             |
| 500050     | Oats grain                 | –                       | –                   | 1.5                              | Further consideration needed(6)             |
| 500060     | Rice grain                 | –                       | –                   | –                                | Further consideration needed(6)             |
| 500070     | Rye grain                  | –                       | –                   | 0.03                             | Further consideration needed(6)             |
| 500080     | Sorghum grain              | –                       | –                   | –                                | Further consideration needed(6)             |
| 500090     | Wheat grain                | –                       | –                   | 0.03                             | Further consideration needed(6)             |
| 810000     | Spices (seeds)             | –                       | –                   | –                                | Further consideration needed(6)             |
| 820000     | Spices (fruits and berries)| –                       | –                   | –                                | Further consideration needed(6)             |
| 840000     | Spices (roots and rhizome)| –                       | –                   | –                                | Further consideration needed(6)             |
| 1011010    | Swine muscle               | –                       | –                   | 0.03                             | Further consideration needed(6)             |
| 1011020    | Swine fat (free of lean meat) | –                     | –                   | 0.05                             | Further consideration needed(6)             |
| 1011030    | Swine liver                | –                       | –                   | 0.1                              | Further consideration needed(6)             |
| 1011040    | Swine kidney               | –                       | –                   | 0.1                              | Further consideration needed(6)             |
| 1012010    | Bovine muscle              | –                       | –                   | 0.01*                            | Further consideration needed(6)             |
| 1012020    | Bovine fat                 | –                       | –                   | 0.05                             | Further consideration needed(6)             |
| 1012030    | Bovine liver               | –                       | –                   | 0.4                              | Further consideration needed(6)             |
| 1012040    | Bovine kidney              | –                       | –                   | 0.2                              | Further consideration needed(6)             |
| 1013010    | Sheep muscle               | –                       | –                   | 0.01*                            | Further consideration needed(6)             |
| 1013020    | Sheep fat                  | –                       | –                   | 0.05                             | Further consideration needed(6)             |
| 1013030    | Sheep liver                | –                       | –                   | 0.4                              | Further consideration needed(6)             |
| 1013040    | Sheep kidney               | –                       | –                   | 0.2                              | Further consideration needed(6)             |
| 1014010    | Goat muscle                | –                       | –                   | 0.01*                            | Further consideration needed(6)             |
| 1014020    | Goat fat                   | –                       | –                   | 0.05                             | Further consideration needed(6)             |
| 1014030    | Goat liver                 | –                       | –                   | 0.4                              | Further consideration needed(6)             |
| 1014040    | Goat kidney                | –                       | –                   | 0.2                              | Further consideration needed(6)             |
| 1016010    | Poultry muscle             | –                       | –                   | 0.03                             | Further consideration needed(6)             |
| 1016020    | Poultry fat                | –                       | –                   | 0.03                             | Further consideration needed(6)             |
| 1016030    | Poultry liver              | –                       | –                   | 0.03                             | Further consideration needed(6)             |
| 1020010    | Cattle milk                | –                       | –                   | 0.01*                            | Further consideration needed(6)             |
| 1020020    | Sheep milk                 | –                       | –                   | 0.01*                            | Further consideration needed(6)             |
| 1020030    | Goat milk                  | –                       | –                   | 0.01*                            | Further consideration needed(6)             |
| 1030000    | Birds’ eggs                | –                       | –                   | 0.03                             | Further consideration needed(6)             |

MRL: maximum residue level; CXL: codex maximum residue limit; 3,5,6-TCP: 3,5,6-trichloropyridinol.
*: Indicates that the MRL is set/proposed at the limit of quantification.
(F): Residue is fat soluble.
(a): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix D).

(b): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII 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): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).

(e): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level is not supported by data but the existing EU MRL is lower than the existing CXL (combination C-VII in Appendix D).

(f): 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).

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

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

(i): 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; existing CXL is covered by the tentative MRL (combination E-III in Appendix D).

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

(k): 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); CXL is not compatible with EU residue definitions (combination C-II in Appendix D).

(l): There are no relevant authorisations or import tolerances reported at EU level; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-II in Appendix D).

(m): 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; CXL is not compatible with EU residue definitions (combination G-II in Appendix D).

(n): There are no relevant authorisations or import tolerances reported at EU level; although a CXL is available for chlorpyrifos-methyl, there is no CXL for this residue definition. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered.

(o): Tentative MRL is derived from a GAP on chlorpyrifos-methyl evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available for this residue definition (although a CXL may be available for chlorpyrifos-methyl).

(p): GAP evaluated at EU level is not supported by data and it was not possible to derive an EU MRL for this residue definition; there is neither existing EU MRL nor CXL for this residue definition (although a CXL may be available for chlorpyrifos-methyl). Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered.
## 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                |
| **Risk assessment residue definition 1a: chlorpyrifos-methyl** | | | | |
| Citrus pomace  | 1.2                   | STMR \times 2.5\(^{(a)}\) | 1.2                   | STMR \times 2.5\(^{(a)}\) |
| Apple pomace   | 0.28                  | STMR \times PF         | 0.28                  | STMR \times PF         |
| Barley and oat straw | 0.01*                 | STMR                   | 0.05                  | HR                     |
| Wheat and rye straw | 0.02                  | STMR                   | 0.24                  | HR                     |
| Potatoes       | 0.01*                 | STMR                   | 0.01*                 | HR                     |
| Rapeseed meal  | 0.02                  | STMR \times 2\(^{(a)}\) | 0.02                  | STMR \times 2\(^{(a)}\) |
| Cotton seed    | 0.01*                 | STMR                   | 0.01*                 | STMR                   |
| Cotton seed meal | 0.013                 | STMR \times 1.3\(^{(a)}\) | 0.013                 | STMR \times 1.3\(^{(a)}\) |
| Maize grain    | 0.01*                 | STMR                   | 0.01*                 | STMR                   |
| **Risk assessment residue definition 1b: sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl** | | | | |
| Barley and oat grain | 3.7                   | STMR                   | 3.7                   | STMR                   |
| Wheat and rye grain | 3.7                   | STMR                   | 3.7                   | STMR                   |
| Wheat and rye bran | 0.01*                 | STMR (fall-back)\(^{(b)}\) | 0.01*                 | STMR (fall-back)\(^{(b)}\) |
| Maize grain    | 0.02                   | STMR \times PF         | 0.03                   | STMR (fall-back)\(^{(b)}\) \times PF |

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

(a): For citrus pomace, rapeseed meal (50% oil content) and cotton seed meal (20% oil content), in the absence of processing factors supported by data, default processing factors of 2.5, 2 and 1.3 were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.

(b): In the scenario EU2 (excluding the post-harvest treatments on wheat and rye grains), input values for wheat and rye commodities are derived from the fall-back GAP (i.e. outdoor foliar treatment).

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

### Risk assessment residue definition 2: sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP

| Feed commodity | Median dietary burden | Maximum dietary burden |
|----------------|-----------------------|------------------------|
|                | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment                |
| Citrus pomace  | 0.37                  | STMR \times 2.5\(^{(a)}\) | 0.37                  | STMR \times 2.5\(^{(a)}\) |
| Apple pomace   | < 0.01                | STMR \times PF         | < 0.01                | STMR \times PF         |
| Barley and oat straw | 0.1                   | STMR                   | 0.1                   | HR                     |
| Wheat and rye straw | 0.1                   | STMR                   | 0.1                   | HR                     |
| Potatoes       | 0.01*                 | STMR                   | 0.06                  | HR                     |
| Rapeseed meal  | < 0.01                | STMR \times PF         | < 0.01                | STMR \times PF         |
| Cotton seed    | 0.02                  | STMR                   | 0.02                  | STMR                   |
| Cotton seed meal | 0.02                  | STMR \times PF         | 0.02                  | STMR \times PF         |
| Maize grain    | 0.01*                 | STMR                   | 0.01*                 | STMR                   |
| Barley and oat grain | 0.59                  | STMR                   | 0.59                  | STMR                   |
| Wheat and rye grain | 0.01*                 | STMR (fall-back)\(^{(b)}\) | 0.01*                 | STMR (fall-back)\(^{(b)}\) |
| Wheat and rye bran | 0.02                  | STMR (fall-back)\(^{(b)}\) \times PF | 0.02                  | STMR (fall-back)\(^{(b)}\) \times PF |

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

(a): For citrus pomace, in the absence of processing factors supported by data, default processing factors of 2.5 were, respectively, included in the calculation to consider the potential concentration of residues in this commodity.

(b): For the dietary burden calculations of 3,5,6-TCP, input values for wheat and rye grains are directly derived from the fall-back GAP identified in scenario EU2.

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
### C.2. Consumer risk assessment without consideration of the existing CXLs (chlorpyrifos-methyl)

| Commodity                        | Chronic risk assessment | Acute risk assessment |
|----------------------------------|-------------------------|-----------------------|
|                                  | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| **Risk assessment residue definition 1a: chlorpyrifos-methyl** |                         |                       |                      |                       |
| Oranges                          | 0.02                    | STMR × PF             | 0.04                | HR × PF               |
| Lemons                           | 0.02                    | STMR × PF             | 0.04                | HR × PF               |
| Mandarins                        | 0.02                    | STMR × PF             | 0.04                | HR × PF               |
| Apples                           | 0.08                    | STMR                  | 0.22                | HR                    |
| Pears                            | 0.08                    | STMR                  | 0.22                | HR                    |
| Quinces                          | 0.08                    | STMR                  | 0.22                | HR                    |
| Cherries                         | 0.01*                   | STMR                  | 0.01*               | HR                    |
| Peaches                          | 0.01*                   | STMR                  | 0.02                | HR                    |
| Table grapes                     | 0.01*                   | STMR                  | 0.07                | HR                    |
| Wine grapes                      | 0.02                    | STMR                  | 0.07                | HR                    |
| Strawberries                     | 0.01*                   | STMR                  | 0.02                | HR                    |
| Currants (red, black and white)  | 0.01*                   | STMR                  | 0.01*               | HR                    |
| Kiwi                             | 0.01*                   | STMR                  | 0.01*               | HR                    |
| Potatoes                         | 0.01*                   | STMR                  | 0.01*               | HR                    |
| Tomatoes                         | 0.06                    | STMR                  | 0.07                | HR                    |
| Peppers                          | 0.50                    | EU MRL                | 0.50                | EU MRL                |
| Aubergines (egg plants)          | 0.06                    | STMR                  | 0.07                | HR                    |
| Poppy seed                       | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Rape seed                        | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Mustard seed                     | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Cotton seed                      | 0.01*                   | STMR (tentative)      | 0.02                | HR (tentative)        |
| Gold of pleasure                 | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Swine meat                       | 0.01                    | 0.8 × STMR muscle + 0.2 × STMR fat (tentative) | 0.02                | 0.8 × HR muscle + 0.2 × HR fat (tentative) |
| Swine fat (free of lean meat)    | 0.03                    | STMR (tentative)      | 0.05                | HR (tentative)        |
| Swine liver                      | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Swine kidney                     | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Ruminant meat                    | 0.01                    | 0.8 × STMR muscle + 0.2 × STMR fat (tentative) | 0.01                | 0.8 × HR muscle + 0.2 × STMR fat (tentative) |
| Ruminant fat (free of lean meat) | 0.02                    | STMR (tentative)      | 0.02                | HR (tentative)        |
| Ruminant liver                   | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Ruminant kidney                  | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Poultry meat                     | 0.01*                   | 0.9 × STMR muscle + 0.1 × STMR fat (tentative) | 0.01*               | 0.9 × HR muscle + 0.1 × HR fat (tentative) |
| Poultry fat                      | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Poultry liver                    | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Ruminant milk                    | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Eggs                             | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
Commodity | Chronic risk assessment | Acute risk assessment |
--- | --- | --- |
**Input value (mg/kg)** | **Comment** | **Input value (mg/kg)** | **Comment** |
--- | --- | --- | --- |
**Risk assessment residue definition 1b:** sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl

| Commodity | Chronic risk assessment | Acute risk assessment |
--- | --- | --- |
Barley and oats grain | 3.7 | STMR (tentative) | 5.2 | HR (tentative) |
Maize grain | 0.01* | STMR | 0.01* | HR |
Rice grain | 3.0 | EU MRL\(^{(a)}\) | 3.0 | EU MRL\(^{(a)}\) |
Wheat and rye grain | 3.7 | STMR (tentative) | 5.2 | HR (tentative) |

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

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

(a): Use reported by the RMS is not supported by data; the existing EU MRL is used for indicative exposure calculations.

(b): In the scenario EU2 (excluding the post-harvest treatments on wheat and rye grains), input values for wheat and rye grains are derived from the fall-back GAP (i.e. outdoor foliar treatment).

### C.3. Consumer risk assessment with consideration of the existing CXLs (chlorpyrifos-methyl)

| Commodity | Chronic risk assessment | Acute risk assessment |
--- | --- | --- |
**Input value (mg/kg)** | **Comment** | **Input value (mg/kg)** | **Comment** |
--- | --- | --- | --- |
**Risk assessment residue definition 1a:** chlorpyrifos-methyl

| Commodity | Chronic risk assessment | Acute risk assessment |
--- | --- | --- |
Grapefruit | 0.01 | STMR × PF (CXL) | 0.04 | HR × PF (CXL) |
Oranges | 0.01 | STMR × PF (CXL) | 0.04 | HR × PF (CXL) |
Lemons | 0.01 | STMR × PF (CXL) | 0.04 | HR × PF (CXL) |
Limes | 0.01 | STMR × PF (CXL) | 0.04 | HR × PF (CXL) |
Mandarins | 0.01 | STMR × PF (CXL) | 0.04 | HR × PF (CXL) |
Apples | 0.07 | STMR (CXL) | 0.56 | HR (CXL) |
Pears | 0.07 | STMR (CXL) | 0.56 | HR (CXL) |
Quinces | 0.07 | STMR (CXL) | 0.56 | HR (CXL) |
Medlar | 0.07 | STMR (CXL) | 0.56 | HR (CXL) |
Loquat | 0.07 | STMR (CXL) | 0.56 | HR (CXL) |
Apricots | 0.02 | STMR (CXL) | 0.26 | HR (CXL) |
Cherries | 0.02 | STMR (CXL) | 0.26 | HR (CXL) |
Peaches | 0.02 | STMR (CXL) | 0.26 | HR (CXL) |
Plums | 0.02 | STMR (CXL) | 0.26 | HR (CXL) |
Table grapes | 0.01 | STMR (CXL) | 0.53 | HR (CXL) |
Wine grapes | 0.01 | STMR (CXL) | 0.53 | HR (CXL) |
Strawberries | 0.01 | STMR (CXL) | 0.04 | HR (CXL) |
Currants (red, black and white) | 0.01* | STMR | 0.01* | HR |
Kumquats | 0.21 | STMR (CXL) | 0.89 | HR (CXL) |
Kiwi | 0.01* | STMR | 0.01* | HR |
Potatoes | 0.01* | STMR | 0.01* | HR |
Tomatoes | 0.06 | STMR (CXL) | 0.92 | HR (CXL) |
Peppers | 0.06 | STMR (CXL) | 0.72 | HR (CXL) |
Aubergines (egg plants) | 0.06 | STMR (CXL) | 0.72 | HR (CXL) |
Poppy seed | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
Rape seed | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
Mustard seed | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
Cotton seed | 0.01* | STMR (tentative) | 0.02 | HR (tentative) |

www.efsa.europa.eu/efsajournal 63 EFSA Journal 2017;15(3):4734
| Commodity                                      | Chronic risk assessment | Acute risk assessment |
|-----------------------------------------------|-------------------------|-----------------------|
|                                               | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Gold of pleasure                              | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Spices (seeds)                                | 0.05                    | STMR (CXL, tentative) | 0.39                | HR (CXL, tentative)   |
| Spices (fruits and berries)                   | 0.10                    | STMR (CXL, tentative) | 0.12                | HR (CXL, tentative)   |
| Spices (roots and rhizome)                    | 0.77                    | STMR (CXL, tentative) | 2.9                 | HR (CXL, tentative)   |
| Swine meat                                    | 0.01                    | 0.8 × STMR muscle + 0.2 × STMR fat (CXL) (tentative) | 0.02 | 0.8 × HR muscle + 0.2 × HR fat (CXL) (tentative) |
| Swine fat (free of lean meat)                 | 0.03                    | STMR (CXL, tentative) | 0.06               | HR (CXL, tentative)   |
| Swine liver                                   | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Swine kidney                                  | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Ruminant meat                                 | 0.01                    | 0.8 × STMR muscle + 0.2 × STMR fat (CXL) (tentative) | 0.02 | 0.8 × HR muscle + 0.2 × HR fat (CXL) (tentative) |
| Ruminant fat (free of lean meat)              | 0.03                    | STMR (CXL, tentative) | 0.06               | HR (CXL, tentative)   |
| Ruminant liver                                | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Ruminant kidney                               | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Poultry meat                                  | 0.01*                   | 0.9 × STMR muscle + 0.1 × STMR fat (tentative) | 0.01* | 0.9 × HR muscle + 0.1 × HR fat (tentative) |
| Poultry fat                                   | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Poultry liver                                 | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Ruminant milk                                 | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Eggs                                          | 0.01*                   | STMR (tentative)      | 0.01*               | HR (tentative)        |
| Risk assessment residue definition 1b: sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl |
| Barley and oats grain                         | 3.7                     | STMR (tentative)      | 5.2                 | HR (tentative)        |
| Maize grain                                   | 0.01*                   | STMR                    | 0.01*               | HR                    |
| Rice grain                                    | 3.0                     | EU MRL<sup>(a),(b)</sup> | 3.0                | EU MRL<sup>(a),(b)</sup> |
| Sorghum grain                                  | –                       | No compatible CXL<sup>(b)</sup> | –                  | No compatible CXL<sup>(b)</sup> |
| Rye grain                                      | 0.01*                   | STMR (fall-back)<sup>(c)</sup> | 0.02               | HR (fall-back)<sup>(c)</sup> |
| Wheat grain                                    | 0.01*                   | STMR (fall-back)<sup>(b),(c)</sup> | 0.02               | HR (fall-back)<sup>(b),(c)</sup> |

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

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

(a): Use reported by the RMS is not supported by data; the existing EU MRL is used for indicative exposure calculations.

(b): As the residue definition of CXL is not compatible with EU residue definition, CXL for cereals cannot be taken into account.

(c): In the scenario CX1, input values for wheat and rye grains are directly derived from the fall-back GAP identified in scenario EU2.
### C.4. Consumer risk assessment for the metabolite 3,5,6-trichloropyridinol (3,5,6-TCP)

| Commodity           | Input value (mg/kg) | Comment                      | Input value (mg/kg) | Comment                      |
|---------------------|--------------------|------------------------------|--------------------|------------------------------|
| **Risk assessment residue definition 2:** sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP (all risk assessment values are tentative) |
| Grapefruit          | 0.02               | STMR (chlorpyrifos) × PF     | 0.05               | HR (chlorpyrifos) × PF       |
| Oranges             | 0.02               | STMR (chlorpyrifos-methyl) × PF | 0.06              | HR (chlorpyrifos-methyl) × PF |
| Lemons              | 0.02               | STMR (chlorpyrifos) × PF     | 0.05               | HR (chlorpyrifos) × PF       |
| Limes               | 0.02               | STMR (chlorpyrifos) × PF     | 0.05               | HR (chlorpyrifos) × PF       |
| Mandarin            | 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)            |
| Commodity                              | Chronic risk assessment | Acute risk assessment |
|---------------------------------------|-------------------------|-----------------------|
| **Input value** (mg/kg)               | **Comment**             | **Input value** (mg/kg) |
| **Chronic risk assessment**           |                         | **Comment**           |
| 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   |
| Rocket, Rucola                         | – No data available     | – 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)    |
### Commodity Risk Assessment

| Commodity        | Chronic risk assessment | Acute risk assessment |
|------------------|-------------------------|-----------------------|
|                  | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Ruminant kidney  | 0.31 STMR (triclopyr)   |                       | 0.90 HR (triclopyr) |
| Poultry meat     | 0.02 STMR muscle (chlorpyrifos-methyl) | 0.02 HR muscle (chlorpyrifos-methyl) |
| 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 DB > 0.1 mg/kg DM in EU?
  - Yes: MRL derived in Section 3?
  - No: Maintain current EU MRL?
- MRL derived in Section 3?
  - Yes: MRL fully supported by data?
  - No: MRL is recommended.
- GAP or DB > 0.1 mg/kg DM in EU?
  - No: Current EU MRL is included in the RA.
  - Yes: Median/highest values are included in the RA.

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

- Risk identified?
  - Yes: Median/highest values are included in the RA.
  - No: Fall-back MRL available?
    - Yes: MRL is recommended.
    - No: Not considered for the RA.

Recommendations resulting from EU authorisations and import tolerances

- Comparison with CXLs

(A) Specific LOQ or default MRL?
(B) Specific LOQ or default MRL?
(C) Maintain current EU MRL?
(D) Specific LOQ or default MRL?
(E) Establish tentative EU MRL?
(F) Specific LOQ or default MRL?
(G) MRL is recommended.
Comparison of the EU recommendation with the existing CXL

- CXL available?
  - Yes
    - RD comparable?
      - Yes
        - CXL higher?
          - Yes
          - No
          - No
          - No
      - No
    - No
  - No

Consumer risk assessment with consideration of the existing CXL

- CXL supported by data?
  - Yes
    - Yes
    - No
  - No

Recommendations with consideration of 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 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.
### Appendix E – Used compound codes

| Code/trivial name                   | Chemical name/SMILES notation                                      | Structural formula |
|-------------------------------------|-------------------------------------------------------------------|--------------------|
| Chlorpyrifos-methyl                 | O,O-Dimethyl O-3,5,6-trichloro-2-pyridyl phosphorothioate Clc1cc(Cl)c(Cl)nc1OP(=S)(OC)OC | ![Chlorpyrifos-methyl](image) |
| Chlorpyrifos                        | O,O-Diethyl O-3,5,6-trichloro-2-pyridyl phosphorothioate Clc1cc(Cl)c(Cl)nc1OP(=S)(OCC)OCC | ![Chlorpyrifos](image) |
| Triclopyr                           | 3,5,6-Trichloro-2-pyridyloxyacetic acid Clc1cc(Cl)c(Cl)nc1OCC(=O)O | ![Triclopyr](image) |
| 3,5,6-Trichloropyridinol (3,5,6-TCP) | 3,5,6-Trichloropyridin-2-ol Clc1cc(Cl)c(Cl)nc1O                  | ![3,5,6-Trichloropyridinol](image) |
| Desmethyl chlorpyrifos-methyl (DEM) | O-Methyl O-(3,5,6-trichloropyridin-2-yl) hydrogen phosphorothioate Clc1cc(Cl)c(Cl)nc1OP(O)(=S)OC | ![Desmethyl chlorpyrifos-methyl](image) |
| 3,5,6-Trichloro-2-methoxypyridine    | 3,5,6-Trichloro-2-methoxypyridine Clc1cc(Cl)c(Cl)nc1OC            | ![3,5,6-Trichloro-2-methoxypyridine](image) |

SMILES: simplified molecular-input line-entry system.