Modification of the existing maximum residue levels for chlorpyrifos-methyl in kaki/Japanese persimmon and granate apple/pomegranate

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Abstract
In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Dow Agro Sciences submitted an application to the competent national authority in Spain (evaluating Member State (EMS)) to modify maximum residue levels (MRLs) for the active substance chlorpyrifos-methyl in kaki/Japanese persimmons and granate apples/pomegranates. The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for chlorpyrifos-methyl and for the optional residue definition that refers to 3,5,6-trichloropyridinol (3,5,6-TCP) in the fruits under consideration. Adequate analytical methods for enforcement are available to control the residues of chlorpyrifos-methyl in plant matrices under consideration. For the enforcement of 3,5,6-TCP residues in the crops under consideration, the applicant has to perform validation of the hydrolysis step of analytical enforcement method and to submit an independent laboratory validation (ILV) for high acid content matrices. Based on the risk assessment results and provided that the conclusions of the MRL review are taken into consideration, EFSA concludes that the long-term and short-term intake of residues of chlorpyrifos-methyl and metabolite 3,5,6-TCP resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

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Keywords: chlorpyrifos-methyl, kaki/Japanese persimmon, granate apple/pomegranate, pesticide, insecticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Dow AgroSciences submitted an application to the competent national authority in Spain (evaluating Member State (EMS)) to modify existing maximum residue levels (MRLs) for the active substance chlorpyrifos-methyl in kaki/Japanese persimmons and granate apples/pomegranates. Spain drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 6 October 2015. To accommodate for the intended uses of chlorpyrifos-methyl in south Europe, the EMS proposed to raise the existing MRLs in kaki/Japanese persimmons and granate apples/pomegranates from the limit of quantification (LOQ) to 0.5 and 0.3 mg/kg, respectively.

EFSA based its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) (and its addendum/addenda) prepared under Council Directive 91/414/EEC, the Commission review report on chlorpyrifos-methyl as well as the conclusions from previous EFSA opinions on chlorpyrifos-methyl, including an opinion on the review of existing EU MRLs for chlorpyrifos-methyl according to Article 12 of Regulation (EC) No 396/2005 (hereafter- MRL review).

The metabolism of chlorpyrifos-methyl has been investigated following foliar application in fruit crops and for post-harvest treatment in cereals/grass. The metabolism of chlorpyrifos-methyl in root crops was considered acceptable to depict a general metabolic pathway of chlorpyrifos-methyl in plants. The parent compound, the metabolite 3,5,6-trichloropyridinol (3,5,6-TCP) and its conjugates are the main components of residues after foliar applications, whereas after post-harvest treatment in cereals additionally desmethyl chlorpyrifos-methyl is present at significant levels.

Studies investigating the effect of processing on the nature of chlorpyrifos-methyl (hydrolysis studies) demonstrated that the active substance degrades to desmethyl chlorpyrifos-methyl. Toxicological data on the desmethyl metabolite are missing and should still be provided.

As the proposed uses of chlorpyrifos-methyl are on permanent crops, investigation of residues in rotational crops was not considered under the current application.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological significance of metabolites and degradation products, the MRL review proposed two separate residue definitions for enforcement and risk assessment. The first residue definition (specific to chlorpyrifos-methyl) includes only the parent compound and applies to all crops, except cereals and processed commodities, for which also the desmethyl metabolite has to be considered. The second residue definition refers to the sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP. Since this compound is not chlorpyrifos-methyl specific, the first residue definition remains the most relevant for enforcement purpose, the second being optional in case risk managers may consider enforcement of 3,5,6-TCP residues.

EFSA concludes that for the crops assessed in this application, metabolism of chlorpyrifos-methyl in primary crops is sufficiently addressed and the residue definitions proposed by the MRL review are applicable.

Chlorpyrifos-methyl can be enforced in plant commodities, including crops under consideration, with a LOQ of 0.01 mg/kg, while analytical methods are not available for its desmethyl metabolite. An analytical method is validated for analysis of 3,5,6-TCP and its conjugates with an LOQ of 0.01 mg/kg in plant commodities, but some deficiencies regarding efficiency of hydrolysis step and specificity of the method were noted by the MRL review. An independent laboratory validation (ILV) for high acid and high oil content commodities is still required.

The available residue trials are sufficient to derive a MRL proposal of 0.5 mg/kg for kaki/Japanese persimmon and 0.3 mg/kg for granate apple/pomegranate. MRL proposals for the optional residue definition that refers to 3,5,6-TCP residues were also derived.

New studies investigating magnitude of chlorpyrifos-methyl residues in processed commodities of granate apple/pomegranate and kaki/Japanese persimmon have not been submitted. From the residue trials on granate apple/pomegranate, a peeling factor of < 0.15 could be derived for chlorpyrifos-methyl and < 0.07 for 3,5,6,-TCP residue.

Residues in livestock were not investigated under the current assessment since both crops under consideration or their by-products are not used as livestock feed.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the MRL review, a comprehensive long-term exposure assessment was performed separately for chlorpyrifos-methyl and metabolite 3,5,6-TCP, taking into account the existing uses at European Union (EU) level and the acceptable CXLs (for chlorpyrifos-methyl only).
refined long-term exposure assessment for chlorpyrifos-methyl, which was performed under the MRL review and considered fall-back Good Agricultural Practices (GAPs) on wheat and rye, was now updated with the STMR values derived for kaki/Japanese persimmons and granate apples/pomegranates. The estimated long-term dietary intake of chlorpyrifos-methyl residues accounted for up to 61% of the acceptable daily intake (ADI). The long-term exposure assessment for 3,5,6-TCP performed under the MRL review considered highest residues of 3,5,6-TCP that could occur in food commodities from the use of either chlorpyrifos, chlorpyrifos-methyl or triclopyr. This calculation was now updated with STMR values for 3,5,6-TCP derived from the residue trials on kaki/Japanese persimmons and granate apples/pomegranates. The estimated long-term dietary intake of 3,5,6-TCP residues accounted for up to 6% of the ADI.

The short-term exposure assessment was performed separately for chlorpyrifos-methyl and 3,5,6-TCP, considering the highest residues in kaki/Japanese persimmons and granate apples/pomegranates as derived from the residue trials submitted for the current assessment. The calculated exposure did not exceed the acute reference dose (ARfD) neither for chlorpyrifos-methyl nor for 3,5,6-TCP.

Based on the risk assessment results and provided that the conclusions of the MRL review are taken into consideration, EFSA concludes that the long-term and short-term intake of chlorpyrifos-methyl residues resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

EFSA concludes that the long-term and short-term intake of 3,5,6-TCP residues resulting from the existing uses of chlorpyrifos, chlorpyrifos-methyl and triclopyr and from the intended use of chlorpyrifos-methyl on kaki/Japanese persimmons and granate apples/pomegranates is unlikely to present a risk to consumer health.

EFSA proposes to amend the existing MRLs as reported in the summary table below.

| Code(a) | Commodity                  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|---------|----------------------------|-------------------------|-------------------------|--------------------------------------------------------------------------------------|
| 0161060 | Kaki/Japanese persimmons  | 0.05*                   | 0.5                     | The submitted data are sufficient to derive a MRL proposal for the SEU use. No consumer health concern was identified |
| 0163050 | Granate apples/pomegranates | 0.05*                  | 0.3                     |                                                                                      |

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

| Code(a) | Commodity                  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|---------|----------------------------|-------------------------|-------------------------|--------------------------------------------------------------------------------------|
| 0161060 | Kaki/Japanese persimmons  | –                       | 0.9                     | The submitted data are sufficient to derive a MRL proposal for the SEU use. No consumer health concern was identified |
| 0163050 | Granate apples/pomegranates |–                       | 0.8                     |                                                                                      |

MRL: maximum residue level; SEU: southern Europe; 3,5,6-TCP: 3,5,6-trichloropyridinol; ILV: independent laboratory validation.

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

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

(b): According to EFSA reasoned opinion on the MRL review of chlorpyrifos-methyl (EFSA, 2017).

(F): Fat soluble.
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**Background**

Regulation (EC) No 396/2005\(^1\) (hereinafter referred to as ‘the MRL regulation’) establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the MRL regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC\(^2\), repealed by Regulation (EC) No 1107/2009\(^3\), shall submit an application to a Member State to set or to modify a MRL in accordance with the provisions of Article 7 of the MRL regulation.

The applicant Dow AgroSciences\(^4\) submitted an application to the competent national authority in Spain, hereafter referred to as the evaluating Member State (EMS), to modify the existing MRLs for chlorpyrifos-methyl in kaki/Japanese persimmons and granate apples/pomegranates. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the MRL regulation.

The EMS summarised the data provided by the applicant in an evaluation report (Spain, 2015) which was submitted to the European Commission and forwarded to EFSA on 6 October 2015. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2015-00577 and the following subject:

*Chlorpyrifos-methyl: Application to modify MRLs in persimmon and pomegranate.*

Spain proposed to raise the existing MRLs of chlorpyrifos-methyl in kaki/Japanese persimmons and granate apples/pomegranates from the limit of quantification (LOQ) of 0.05 to 0.5 mg/kg and 0.3 mg/kg, respectively.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps and points which needed further clarification, which were requested from the EMS. EFSA also informed the EMS Spain, the applicant and the European Commission that the reasoned opinion on the modification of MRLs for chlorpyrifos-methyl in kaki/Japanese persimmons and granate apples/pomegranates will be issued after the finalisation of the MRL review of chlorpyrifos-methyl according to Article 12 of Regulation (EC) No 396/2005 (MRL review). On 22 December 2015, the EMS submitted the requested information in a revised evaluation report (Spain, 2015), which replaced the previously submitted evaluation report.

**Terms of Reference**

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall assess the application and the evaluation report and give a reasoned opinion on the risks to the consumer and where relevant to animals associated with the setting of the requested MRLs. The opinion shall include:

- an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;
- the anticipated LOQ for the pesticide/product combination;
- an assessment of the risks of the acceptable daily intake (ADI) and acute reference dose (ARfD) being exceeded as a result of the modification of the MRL;
- the contribution to the intake due to the residues in the product for which the MRLs was requested;
- any other element relevant to the risk assessment.

In accordance with Article 11 of the MRL regulation, EFSA shall give its reasoned opinion as soon as possible and at the latest within 3 months from the date of receipt of the application.

The evaluation report submitted by the EMS (Spain, 2015) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

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

\(^3\) 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.

\(^4\) Dow AgroSciences, Park Square 3B, Milton Park, OX144RN, Abingdon, United Kingdom.
The active substance and its use pattern

The detailed description of the intended uses of chlorpyrifos-methyl in Spain on kaki/Japanese persimmons and granate apples/pomegranates, which are the basis for the current MRL application, is reported in Appendix A.

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 insecticides or acaricides or nematicides.

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. Therefore, no EFSA conclusion is available. 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\(^5\), and has been deemed to be approved under Regulation (EC) No 1107/2009. Chlorpyrifos-methyl was approved for the use as insecticide only.

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 in various crops was assessed by EFSA (2011), but it was preferred to await the outcome of the MRL review before implementing these MRLs into the EU legislation. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 has been performed (EFSA, 2017), but the proposed modifications have not been implemented yet in the MRL legislation.

Assessment

EFSA has based its assessment on the evaluation report submitted by the EMS (Spain, 2015), the draft assessment report (DAR) (and its addendum/addenda) prepared under Directive 91/414/EEC (Spain, 1997, 2002, 2003, 2004), the European Commission review report on chlorpyrifos-methyl (European Commission, 2005) as well as the conclusions from previous EFSA opinions on chlorpyrifos-methyl of which one is on the review of MRLs for chlorpyrifos-methyl according to Article 12 of the Regulation (EC) No 396/2005 (EFSA, 2011, 2017).

For this application, the data requirements established in Regulation (EU) No 544/2011\(^6\) and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2016; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011\(^7\).

A selected list of end points of the studies assessed by EFSA in the framework of the MRL review, including the end points of studies submitted in support of the current MRL application, are presented in Appendix B.

\(^5\) 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. OJ L 279, 22.10.2005, p. 63-69.

\(^6\) Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances Text with EEA relevance. OJ L 155, 11.6.2011, p. 1-66.

\(^7\) 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.
1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of chlorpyrifos-methyl in primary crops belonging to the group of fruit crops (foliar application on tomatoes) and cereals/grass (post-harvest treatment of maize, wheat) has been investigated in the framework of the EU pesticides peer review and confirmed by the MRL review (EFSA, 2017).

After foliar application in tomatoes, the total residues rapidly declined during the first week. The parent compound, 3,5,6-trichloropyridinol (3,5,6-TCP) and polar metabolites represented the main part of the residues. In maize and wheat grain subject to post-harvest treatment with chlorpyrifos-methyl, the parent compound represented 33–45% of the total radioactive residues (TRR), while 3,5,6-TCP accounted for 19–39% and desmethyl chlorpyrifos-methyl (DEM) represented 19-24% of the TRR.

In addition, the MRL review assessed studies performed with chlorpyrifos in radishes and pea, in order to depict metabolism of chlorpyrifos-methyl in root crops and pulses. The results of these studies are consistent with the studies performed with chlorpyrifos-methyl in tomatoes.

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 DEM. The MRL review concluded that the metabolism of chlorpyrifos-methyl in primary crops is sufficiently elucidated (EFSA, 2017).

For the intended use (foliar application on fruits), the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

As the proposed uses of chlorpyrifos-methyl are on permanent crops, investigations of residues in rotational crops are not required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of chlorpyrifos-methyl was considered in the framework of the MRL review (EFSA, 2017). Hydrolysis study demonstrated that chlorpyrifos-methyl degrades under hydrolysis conditions and 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 DEM (21.5–90.7% applied radioactivity (AR)) with lower amounts of 3,5,6-TCP present (up to 7.7% AR). Although the degradation products observed in raw and processed commodities are similar, the presence of DEM is expected to be more important in processed commodities (EFSA, 2017).

1.1.4. Methods of analysis in plants

Analytical methods for the determination of chlorpyrifos-methyl residues and residues of 3,5,6-TCP were assessed during the MRL review where it was concluded that chlorpyrifos-methyl can be enforced in the four main commodity groups with an LOQ of 0.01 mg/kg. An independent laboratory validation (ILV) for high oil content commodities is still required, but not relevant for the current application (EFSA, 2017).

Concerning metabolite 3,5,6-TCP, an analytical method using high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) is validated for analysis of 3,5,6-TCP and its conjugates with an LOQ of 0.01 mg/kg in the four main commodity groups (EFSA, 2017). The MRL review noted that the efficiency of hydrolysis step of this method to release the conjugates has not been demonstrated and the method is not specific enough to enforce 3,5,6-TCP and its conjugates separately (EFSA, 2017). An ILV for high acid (relevant for the crop under consideration) and high oil content commodities is still required and shall be provided if risk managers decide to enforce MRLs for 3,5,6-TCP.

EFSA concludes that there is a sufficiently validated method available for the determination of chlorpyrifos-methyl residues in the crops under consideration at the LOQ of 0.01 mg/kg.
1.1.5. Stability of residues in plants

The storage stability of chlorpyrifos-methyl and metabolite 3,5,6-TCP in plants stored under frozen conditions was investigated in the framework of the MRL review (EFSA, 2017). It was demonstrated that in high acid and high water content crops assessed in the framework of this application, chlorpyrifos-methyl is stable for at least 12 and 24 months, respectively, and metabolite 3,5,6-TCP (and its conjugates) for at least 18 months when stored at −18°C.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions were proposed by the MRL review:

- **Residue definition for risk assessment**
  - chlorpyrifos-methyl (for fruit crops, root crops and pulses/oilseeds)
  - sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl (cereal grain and processed commodities)
  - sum of 3,5,6-trichloropyridinol (3,5,6-TCP) and its conjugates, expressed as 3,5,6-TCP (for all crops)

- **Residue definition for enforcement**
  - chlorpyrifos-methyl (for fruit crops, root crops and pulses/oilseeds)
  - sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl (for cereal grain and processed commodities)
  - (optional) - sum of 3,5,6-trichloropyridinol (3,5,6-TCP) and its conjugates, expressed as 3,5,6-TCP (all crops).

Metabolite 3,5,6-TCP is not specific to chlorpyrifos-methyl, but if risk managers consider that the enforcement of metabolite 3,5,6-TCP is also necessary, an optional residue definition for enforcement was proposed by the MRL review.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is parent chlorpyrifos-methyl, which is identical with the above-mentioned residue definition for all crops, except cereals.

EFSA concludes that these residue definitions are appropriate for the assessment of the proposed uses on the crops under consideration and no further information is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted residue trials performed on kaki/Japanese persimmons and granate apples/pomegranates. The analytical method used to analyse crop samples converts chlorpyrifos-methyl and any 3,5,6-TCP conjugate into free 3,5,6-TCP. Results in the evaluation report were presented as chlorpyrifos-methyl alone and as the total 3,5,6-TCP (including 3,5,6-TCP from hydrolysis of chlorpyrifos-methyl). To derive residues for 3,5,6-TCP only, EFSA expressed the results of chlorpyrifos-methyl as 3,5,6-TCP by applying a molecular weight conversion factor of 1.63 and subtracted the amount from the total 3,5,6-TCP residues.

According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. The samples of residue trials were stored under conditions for which integrity of the samples has been demonstrated (Spain, 2015).

1.2.1.1. Kaki/Japanese persimmon

In support of the southern Europe (SEU) Good Agricultural Practice (GAP), the applicant submitted four GAP-compliant residue trials on kaki/Japanese persimmon. The trials were conducted in Spain over two seasons in 2012 and 2013. The number and quality of trials is sufficient to derive an MRL proposal of 0.5 mg/kg for chlorpyrifos-methyl in kaki/Japanese persimmon. Additionally, an MRL proposal of 0.9 mg/kg was derived for optional enforcement residue definition that refers to 3,5,6-TCP residues.
1.2.1.2. Granate apple/pomegranate

In support of the SEU GAP, the applicant submitted four GAP-compliant residue trials on granate apple/pomegranate. The trials were conducted in Spain over two seasons in 2011 and 2012. In all residue trials the peel and pulp of the fruit were also analysed, indicating no residues of chlorpyrifos-methyl above the limit of detection in the pulp. The number and quality of the trials is sufficient to derive a MRL of 0.3 mg/kg for granate apples/pomegranates. Additionally, an MRL proposal of 0.8 mg/kg was derived for optional enforcement residue definition that refers to 3,5,6-TCP residues.

1.2.2. Magnitude of residues in rotational crops

Not relevant for the current application.

1.2.3. Magnitude of residues in processed commodities

New studies investigating the effect of processing on the magnitude of chlorpyrifos-methyl residues in the processed fruit commodities have not been submitted in the framework of the current application. Residues trials on granate apple/pomegranate provide information on the distribution of residues between peel and pulp. In the pulp, residues are below the LOQ of 0.01 mg/kg. From the results, a peeling factor of < 0.15 could be derived for chlorpyrifos-methyl residues. For metabolite 3,5,6-TCP, a peeling factor of < 0.07 was derived.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the fruit crops under evaluation (see Appendix B.1.2.1). In Section 3, EFSA assessed whether residues on kaki/Japanese persimmon and granate apple/pomegranate resulting from the intended SEU uses are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as crops under consideration or their by-products are not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

As there are two risk assessment residue definitions proposed by the MRL review, the consumer exposure was assessed separately to chlorpyrifos-methyl and 3,5,6-TCP residues.

The toxicological reference values for chlorpyrifos-methyl used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (European Commission, 2005). The toxicological reference values for 3,5,6-TCP used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review of the active substance chlorpyrifos (EFSA, 2014). The metabolite 3,5,6-TCP can occur in food commodities as a metabolite of chlorpyrifos, chlorpyrifos-methyl and triclopyr, and therefore, 3,5,6-TCP residues occurring in plant commodities from other sources must also be considered.

3.1. Short-term (acute) dietary risk assessment

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

3.1.1. Chlorpyrifos-methyl

The short-term exposure did not exceed the ARfD for any the crops assessed in this application (see Appendix B.3.1).
3.1.2. Metabolite 3,5,6-trichloropyridinol (3,5,6-TCP)

The short-term exposure did not exceed the ARfD for any the crops assessed in this application (see Appendix B.3.1).

3.2. Long-term (chronic) dietary risk assessment

3.2.1. Chlorpyrifos-methyl

In the framework of the MRL review, a comprehensive long-term exposure assessment to chlorpyrifos-methyl was performed, taking into account the existing uses at EU level and the acceptable CXLs (EFSA, 2017). The refined exposure calculation which considered fall-back GAPs on wheat and rye (referred to in Appendix B.3.2 of the EFSA opinion on the MRL review) was now updated with the relevant STMR values derived from the residue trials on kaki/Japanese persimmon and granate apple/pomegranate submitted in support of this MRL application. The input values used in the exposure calculations are summarised in Appendix D.1.

The estimated long-term dietary intake accounted for up to 61% of the ADI. The contribution of residues expected in the fruits under consideration to the overall long-term exposure is presented in more detail in Appendix B.3.2.

Provided that conclusions of the MRL review are taken into consideration, EFSA concludes that the long-term intake of chlorpyrifos-methyl residues resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

3.2.2. Metabolite 3,5,6-trichloropyridinol (3,5,6-TCP)

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, considering highest residues of 3,5,6-TCP occurring in food commodities from the use of either chlorpyrifos, chlorpyrifos-methyl or triclopyr (EFSA, 2017). For additional assumptions regarding the choice of input values, see EFSA opinion on the MRL review. EFSA updated this calculation with the relevant STMR values derived from the residue trials submitted in support of this MRL application for kaki/Japanese persimmons and granate apples/pomegranates. There are no existing uses of chlorpyrifos or triclopyr on fruits under consideration that would result in additional residues of 3,5,6-TCP in these commodities. The input values used in the exposure calculations are summarised in Appendix D.2.

The estimated long-term dietary intake accounted for up to 6% of the ADI. The contribution of residues in the fruits under consideration to the overall long-term exposure is presented in more detail in Appendix B.3.1.

EFSA concludes that the long-term intake of 3,5,6-TCP residues resulting from the existing uses of chlorpyrifos, chlorpyrifos-methyl and triclopyr and from the intended use of chlorpyrifos-methyl on kaki/Japanese persimmons and granate apples/pomegranates is unlikely to present a risk to consumer health.

Conclusions and recommendations

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for chlorpyrifos-methyl and for the optional residue definition that refers to 3,5,6-TCP in the fruits under consideration.

Adequate analytical methods for enforcement are available to control the residues of chlorpyrifos-methyl in plant matrices under consideration. For the enforcement of 3,5,6-TCP residues in the crops under consideration, the applicant has to perform validation of the hydrolysis step of analytical enforcement method and to submit an ILV for high acid content matrices.

Based on the risk assessment results and provided that the conclusions of the MRL review are taken into consideration, EFSA concludes that the long-term and short-term intake of residues of chlorpyrifos-methyl and metabolite 3,5,6-TCP resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

The MRL recommendations are summarised in Appendix B.4.
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Abbreviations

3,5,6-TCP 3,5,6-trichloropyridinol
a.s. active substance
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
CF conversion factor for enforcement to risk assessment residue definition
CXL Codex maximum residue limit
DAR draft assessment report
DAT days after treatment
dEM desmethyl chlorpyrifos-methyl
EC emulsifiable concentrate
EMS evaluating Member State
FAO Food and Agriculture Organization of the United Nations
FID flame ionisation detector
GAP Good Agricultural Practice
GC gas chromatography
GC–MS/MS gas chromatography with tandem mass spectrometry
GS growth stage
HPLC high-performance liquid chromatography
HPLC–MS/MS high-performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEIDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LOQ limit of quantification
MRL maximum residue level
MS mass spectrometry detector
MS/MS tandem mass spectrometry detector
OECD Organisation for Economic Co-operation and Development
PBI plant back interval
PF processing factor
phi preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe
RD residue definition
RMS rapporteur Member State
SEU southern Europe
SMILES simplified molecular-input line-entry system
STMR supervised trials median residue
TRR total radioactive residue
WHO World Health Organization
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F | G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|----------------------|-------------------------|---|-----------|-----------------------------------|-------------|-------------|-----------------------------|--------------|---------|
| **Persimmon** (kaki/Japanese persimmon) | SEU (Spain) | F |  | Scales *(Planococcus citri)*, Aphids, Diptera *(Ceratitis capitata)*, Thrips, Coleoptera, Lepidoptera *(Cryptoblabes)*, Whitefly | EC 0.225 kg/L Broadcast, air-assisted foliar spray | BBCH 10-60 and/or BBCH 69-87 | 1–2 60 days | 90 1,250–1,500 | Equiv. to 1,125–1,135 | 15  No application during flowering |
| **Pomegranate** (granate apple/pomegranate) | SEU (Spain) |  |  |  |  |  |  |  |  |  |  |  |

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

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI: minimum preharvest interval.
Appendix B – List of end points

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crops | Applications | Sampling (DAT) |
|----------------------------------|-------------|-------|--------------|----------------|
| Fruit crops                     | Tomatoes    | Foliar: 1 $\times$ 0.99 kg a.s./ha (at BBCH 64-85) | 0, 5, 16, 26, 42 |
| Cereals/grass                   | Wheat       | Post-harvest: 1 $\times$ 32 g a.s./tonne | 0, 30, 90, 180 |
|                                  | Maize       |                                                | 0, 30, 90, 180 |

Metabolism in root crops and pulses/oilseeds is addressed by additional metabolism studies performed on chlorpyrifos (EFSA, 2017)

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

Main degradation product is desmethyl chlorpyrifos-methyl (EFSA, 2017)

DAT: days after treatment; PBI: plant back interval.

Can a general residue definition be proposed for primary crops?

- No

Rotational crop and primary crop metabolism similar?

- Yes (tentative) (EFSA, 2107)

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

- No

Plant residue definition for monitoring (RD-Mo)

- **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

Plant residue definition for risk assessment (RD-RA)

- **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:                                                                                   |
| - QuEChERS method is fully validated for high water, high acid and dry commodities          |
| - LOQ: 0.01 mg/kg                                                                          |
| HPLC–MS/MS:                                                                                |
| - 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:                                                                                |
| - 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                                                                          |

(�FSA, 2017)
### 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       |

(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. (EFSA, 2017).
### B.1.2. Magnitude of residues in plants

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

| Crop (supervised trials) | Region/indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments (OECD calculations) | MRL proposals (mg/kg) | HR\(_{\text{MO}}\)(\(^{(b)}\)) (mg/kg) | STMR\(_{\text{MO}}\)(\(^{(c)}\)) (mg/kg) | CF\(^{(d)}\) |
|--------------------------|--------------------------|---------------------------------------------------------------|----------------------------|----------------------|--------------------------------|--------------------------------|--------|
| **Residue definition for enforcement and risk assessment (1): chlorpyrifos-methyl** | | | | | | | |
| Persimmon | SEU | 0.077; 0.093; 0.113; 0.250 | Trials compliant with the GAP MRL\(_{\text{OECD}}\) = 0.45 | 0.50 | 0.25 | 0.10 | 1 |
| Granate apple/pomegranate | SEU | 0.042; 0.049; 0.094; 0.122 | Trials compliant with the GAP MRL\(_{\text{OECD}}\) = 0.23 | 0.30 | 0.12 | 0.07 | 1 |

**Residue definition for enforcement and risk assessment (2): sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP**

| Persimmon | SEU | 0.182; 0.271; 0.275; 0.368 | Trials compliant with the GAP MRL\(_{\text{OECD}}\) = 0.89 | 0.90 | 0.37 | 0.27 | 1 |
| Granate apple/pomegranate | SEU | 0.108; 0.128; 0.144; 0.398 | Trials compliant with the GAP MRL\(_{\text{OECD}}\) = 0.74 | 0.80 | 0.40 | 0.14 | 1 |

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

(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 according to the residue definition for monitoring.

(c): Supervised trials median residue according to the residue definition for monitoring.

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2.2. Residues in succeeding crops
Not relevant for the current application.

B.1.2.3. Processing factors
New studies not submitted. According to residue trials on granate apple/pomegranate, residues in pulp are below the LOQ of 0.01 mg/kg both for chlorpyrifos-methyl and 3,5,6-TCP.

| Processed commodity                   | Number of valid studies | Processing factor (PF) | Individual values | Median PF |
|---------------------------------------|-------------------------|------------------------|-------------------|-----------|
| Residue definition for enforcement and risk assessment: chlorpyrifos-methyl |                         |                        |                   |           |
| Granate apple/pomegranate, peeled     | 4                       | < 0.08; < 0.11; < 0.20; < 0.24 | < 0.15            |           |
| Residue definition for enforcement and risk assessment: sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP |                         |                        |                   |           |
| Granate apple/pomegranate, peeled     | 4                       | < 0.03; < 0.07; < 0.08; < 0.09 | < 0.07            |           |

B.2. Residues in livestock
Not relevant for the current application.

B.2.1. Nature of residues and methods of analysis in livestock
Not relevant for the current application.

B.2.2. Magnitude of residues in livestock
Not relevant for the current application.

B.3. Consumer risk assessment

B.3.1. Consumer risk assessment for chlorpyrifos-methyl

| ARfD | 0.1 mg/kg bw (European Commission, 2005) |
|------|----------------------------------------|
| Highest IESTI, according to EFSA PRIMo | kaki/Japanese persimmon: 10% of ARfD granate apple/pomegranate: 3% of ARfD |
| Assumptions made for the calculations | The calculation is based on the highest residue levels expected in kaki/Japanese persimmon and granate apple/pomegranate only, according to the intended GAP reported in the current MRL application |
| ADI  | 0.01 mg/kg bw per day (European Commission, 2005) |
| Highest IEDI, according to EFSA PRIMo | 61% ADI (IE adult diet) Contribution of crops assessed: kaki/Japanese persimmon: 0.03% of ADI granate apple/pomegranate: 0.02% of ADI |
| Assumptions made for the calculations | The calculation updates the refined exposure calculation performed in the framework of the MRL review considering fall-back GAPs on wheat and rye (see Appendix B.3.2.) (EFSA, 2017) with the median |
residue levels derived for kaki/Japanese persimmon and granate apple/pomegranate for the GAPs reported in the framework of the current application. The contributions of commodities where no GAP was reported in the framework of MRL review were not included in the calculation.

B.3.2. Consumer risk assessment for metabolite 3,5,6-trichloropyridinol (3,5,6-TCP)

| ARfd          | 0.25 mg/kg bw (EFSA, 2014) |
|---------------|----------------------------|
| Highest IESTI, according to EFSA PRIMo | Kaki/Japanese persimmon: 6% of ARfd Granate apple/pomegranate: 4% of ARfd |
| Assumptions made for the calculations | The calculation is based on the highest residue levels expected in kaki/Japanese persimmons and granate apples/pomegranates only, according to the intended GAP reported in the current MRL application |
| ADI           | 0.03 mg/kg bw per day (EFSA, 2014) |
| Highest IEDI, according to EFSA PRIMo | 6% ADI (DE child diet) Contribution of crops assessed: kaki/Japanese persimmon: 0.02% of ADI granate apple/pomegranate: 0.02% of ADI |
| Assumptions made for the calculations | The calculation updates the exposure calculation performed in the framework of the MRL review (see Appendix B.3.3.) (EFSA, 2017) with the median residue levels derived for kaki/Japanese persimmons and granate apples/pomegranates for the GAPs reported in the framework of the current application |

B.4. Recommended MRLs

| Code(a) | Commodity                  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                      |
|---------|----------------------------|-------------------------|-------------------------|---------------------------------------------------------------------------|
| 0161060 | Kaki/Japanese persimmons   | 0.05*                   | 0.5                     | The submitted data are sufficient to derive a MRL proposal for the SEU use. No consumer health concern was identified |
| 0163050 | Granate apples/pomegranates| 0.05*                   | 0.3                     | The submitted data are sufficient to derive a MRL proposal for the SEU use. No consumer health concern was identified. EFSA notes that the hydrolysis step of enforcement method is not validated and an ILV for high acid content matrices is not available |

MRL: maximum residue level; SEU: southern Europe; 3,5,6-TCP: 3,5,6-trichloropyridinol; ILV: independent laboratory validation.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): According to EFSA reasoned opinion on the MRL review of chlorpyrifos-methyl (EFSA, 2017).
(F): Fat soluble.
### Appendix C – Pesticide Residue Intake Model (PRIMo)

**Chlorpyrifos-methyl**

| Status of the active substance | Code no. | LOQ (mg/kg bw) | proposed LOQ | Toxicological end points |
|--------------------------------|----------|----------------|--------------|--------------------------|
| ADI (mg/kg bw/per day)         | 0.01     | EC             | 0.1          | Source of ADI: EC        |
| Source of ADI:                 |          |                |              | Source of ARfD: EC       |
| Year of evaluation:            | 2005     |                |              | Year of evaluation: 2005 |

#### Chronic risk assessment - refined calculations

| Commodity/group of commodities | TMDI (range) in % of ADI | No of diets exceeding ADI | Highest calculated TMDI values in % of ADI | Highest contributor to MS diet (in % of ADI) | 2nd contributor to MS diet (in % of ADI) | 3rd contributor to MS diet (in % of ADI) | pTMRLs at LOQ (in % of ADI) |
|--------------------------------|--------------------------|---------------------------|--------------------------------------------|---------------------------------------------|------------------------------------------|---------------------------------------------|-----------------------------|
| Barley                         | 5.0                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Rice                           | 5.0                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Oats                           | 5.0                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Milk and cream                 | 4.0                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Oats                           | 4.0                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Tomatoes                       | 3.0                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Oats                           | 3.0                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Apples                         | 2.0                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Oats                           | 2.0                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Barley                         | 1.0                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Tomatoes                       | 1.0                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Apples                         | 1.0                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Oats                           | 1.0                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Barley                         | 0.9                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Tomatoes                       | 0.9                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Apples                         | 0.9                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Oats                           | 0.9                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Barley                         | 0.8                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Tomatoes                       | 0.8                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Apples                         | 0.8                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Oats                           | 0.8                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Barley                         | 0.7                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Tomatoes                       | 0.7                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Apples                         | 0.7                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Oats                           | 0.7                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Barley                         | 0.6                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Tomatoes                       | 0.6                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Apples                         | 0.6                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Oats                           | 0.6                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Barley                         | 0.5                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Tomatoes                       | 0.5                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Apples                         | 0.5                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Oats                           | 0.5                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Barley                         | 0.4                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Tomatoes                       | 0.4                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Apples                         | 0.4                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Oats                           | 0.4                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Barley                         | 0.3                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Tomatoes                       | 0.3                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Apples                         | 0.3                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Oats                           | 0.3                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Barley                         | 0.2                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Tomatoes                       | 0.2                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Apples                         | 0.2                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Oats                           | 0.2                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Barley                         | 0.1                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Tomatoes                       | 0.1                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Apples                         | 0.1                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Oats                           | 0.1                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Barley                         | 0.0                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Tomatoes                       | 0.0                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Apples                         | 0.0                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |
| Oats                           | 0.0                      | 61                        | 61                                         | 46                                          | 30                                       | 16                                         | 41                          |

**Conclusion:**

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs, were below the ADI.

A long-term intake of residues of chlorpyrifos-methyl is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD. For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculation, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

For processed commodities, no exceedance of the ARfD/ADI was identified.

The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

pTMRL: provisional temporary MRL.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

Conclusion:
For chlorpyrifos-methyl, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.
### Appendix D – Input values for the exposure calculations

#### D.1. Consumer risk assessment for chlorpyrifos-methyl

| Commodity                                    | Chronic risk assessment | Acute risk assessment |
|----------------------------------------------|-------------------------|-----------------------|
|                                              | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| **Risk assessment residue definition:** chlorpyrifos-methyl |                         |                       |                      |
| Kaki/Japanese persimmon                      | 0.10 STMR               |                       | 0.25 HR              |
| Granate apple/pomegranate                    | 0.07 STMR               |                       | 0.12 HR              |
| Other commodities of plant and animal origin | STMR Appendix C.3 of EFSA opinion on MRL review (EFSA, 2017) | Performed only for the crops under consideration |                      |

**Risk assessment residue definition:** sum of chlorpyrifos-methyl and desmethyl chlorpyrifos-methyl, expressed as chlorpyrifos-methyl

| Commodity                                                  | Chronic risk assessment | Acute risk assessment |
|------------------------------------------------------------|-------------------------|-----------------------|
|                                                            | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Barley, oat, maize, sorghum, rye and wheat grain           | STMR/MRL Appendix C.3 of EFSA opinion on the MRL review (EFSA, 2017) | Performed only for the crops under consideration |  |

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

#### D.2. Consumer risk assessment for the metabolite 3,5,6-trichloropyridinol (3,5,6-TCP)

| Commodity                                    | Chronic risk assessment | Acute risk assessment |
|----------------------------------------------|-------------------------|-----------------------|
|                                              | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| **Risk assessment residue definition:** sum of 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP |                         |                       |                      |
| Kaki/Japanese persimmon                      | 0.27 STMR               |                       | 0.37 HR              |
| Granate apple/pomegranate                    | 0.14 STMR               |                       | 0.40 HR              |
| Other commodities of plant and animal origin | STMR Appendix C.4 of EFSA opinion on the MRL review (EFSA, 2017) | Performed only for the crops under consideration |  |

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level.
### 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 \(\text{Clc1cc(Cl)c(Cl)nc1OP(=S)(OC)OC}\) | ![](image1)         |
| Chlorpyrifos                 | \(O,O\)-Diethyl \(O\)-3,5,6-trichloro-2-pyridyl phosphorothioate \(\text{Clc1cc(Cl)c(Cl)nc1OP(=S)(OCC)OCC}\) | ![](image2)         |
| Triclopyr                    | 3,5,6-Trichloro-2-pyridyloxyacetic acid \(\text{Clc1cc(Cl)c(Cl)nc1OCC(=O)O}\)               | ![](image3)         |
| 3,5,6-Trichloropyridinol     | 3,5,6-Trichloropyridin-2-ol \(\text{Clc1cc(Cl)c(Cl)nc1O}\)                                    | ![](image4)         |
| Desmethyl chlorpyrifos-methyl (DEM) | O-Methyl \(O\)-(3,5,6-trichloropyridin-2-yl) hydrogen phosphorothioate \(\text{Clc1cc(Cl)c(Cl)nc1OP(O)(=S)OC}\) | ![](image5)         |

SMILES: simplified molecular-input line-entry system.