Modification of the existing maximum residue levels for triclopyr in oranges, lemons and mandarins

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Agriphar SA submitted a request to the competent national authority in Ireland to modify the existing maximum residue levels (MRLs) for the active substance triclopyr in oranges, lemons and mandarins. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for these commodities. Adequate analytical methods for enforcement are available to control the residues of triclopyr in the plant matrices under consideration at the validated LOQ of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of triclopyr according to the reported agricultural practice is unlikely to present a risk to consumer health.

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Keywords: triclopyr, oranges, lemons, mandarins, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Agriphar SA submitted an application to the competent national authority in Ireland (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance triclopyr in oranges, lemons and mandarins. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 5 May 2014. To accommodate for the intended EU foliar and post-harvest uses of triclopyr, the EMS proposed to lower the existing tentative MRL from 0.1 to 0.08 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps, which were requested from the EMS. On 20 June 2022, the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments, and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of triclopyr was investigated in crops belonging to the groups of fruit crops, root crops and cereals/grasses after foliar and soil applications. A new metabolism study in fruit crops (oranges) after post-harvest drenching was submitted in the present MRL application. Studies on the effect of processing on the nature of triclopyr (hydrolysis studies) were not performed and are not deemed necessary considering that triclopyr residues in the oranges, lemons and mandarins treated according to the intended uses were found below the trigger level below 0.1 mg/kg. Investigations of residues of triclopyr in rotational crops are not required in the framework of this application.

Based on the metabolic pattern identified in the metabolism studies in primary crops, a general residue definition for plant products was proposed by the MRL review as ‘triclopyr’ both for enforcement and risk assessment after foliar applications. The results of the new metabolism study confirm that triclopyr is the only relevant residue found in post-harvest treated oranges (fruit crop). For the crops assessed in this application, EFSA concluded that the metabolism of triclopyr in primary crops has been sufficiently addressed and the previously derived residue definitions are applicable.

Sufficiently validated analytical methods are available to quantify residues according to the residue definition for enforcement. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (LOQ). The available residue trials are sufficient to derive an MRL proposal of 0.07 mg/kg for orange, lemon and mandarin fruits. Residue data allowed to derive a median peeling factor of 0.33.

The by-product citrus dried pulp can be used as feed item. Therefore, the potential carryover of residues of triclopyr into commodities of animal origin was further assessed. The livestock dietary burdens as estimated by the MRL review were recalculated according to the OECD methodology and the revised default processing factors, considering the existing uses of triclopyr. For the calculation of the exposure to triclopyr residues in citrus dried pulp, the existing MRL of 0.1 mg/kg tentatively set in grapefruits, oranges, lemons and mandarins was used as an input value. The estimated livestock dietary burdens exceeded the trigger value of 0.1 mg/kg DM for all relevant animal species, except poultry layers, and were affected by the new calculation methodology. However, citrus dried pulp is not among the major contributing commodities in the critical diets of ruminants and pigs and it is not usually fed to poultry. Moreover, the intended use on oranges, lemons and mandarins is covered by the calculations, and therefore, a modification of the existing MRL in products of animal origin is not necessary in the context of the present application. The livestock exposure to triclopyr residues and the potential carry-over of residues into commodities of animal origin will be reassessed in the framework of the MRL review confirmatory data, when full information on authorised uses of triclopyr will be available to EFSA.

The toxicological profile of triclopyr was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.03 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.3 mg/kg bw.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMO). The short-term exposure assessment was performed only with regard to the commodities assessed in the present MRL application. For oranges, lemons and mandarins, the short-term exposure accounted individually for a maximum of 0.7% of the ARfD. The long-term exposure assessment performed in the MRL review was updated using the median residue value for oranges, lemons and mandarins derived from the submitted residue trials and for kiwi fruits from a previous MRL application. To these fruits with inedible peel, the peeling factors were applied to refine the
exposure. The highest estimated long-term dietary intake accounted for 5% of the ADI (NL toddler diet). The contribution of residues of triclopyr to the overall long-term exposure was up to 0.13% of the ADI for oranges. The chronic exposure calculation should be regarded as indicative since for certain commodities, only tentative MRLs could be derived during the MRL review. Nevertheless, the margin of safety for the chronic exposure is sufficiently large to cover this lack of information in the context of the current application.

EFSA concluded that the proposed uses of triclopyr on oranges, lemons and mandarins will not result in a consumer exposure exceeding the toxicological reference values and, therefore, are unlikely to pose a risk to consumers’ health.

The peer review of the renewal of approval of triclopyr in accordance with Regulation (EC) No 1107/2009 is ongoing and, therefore, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

EFSA proposes to amend the existing MRLs as reported in the summary table below. Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------------|------------|------------------------|-------------------------|-----------------------|
| 0110020    | Oranges    | 0.1 (ft)               | Risk management decision | The submitted data are sufficient to derive an MRL proposal of 0.07 mg/kg based on the intended post-harvest use. The SEU foliar use is also supported by a less critical residue data set. Risk management decision shall be taken whether the tentative MRL of 0.1 mg/kg (with footnote) shall be maintained until the assessment of the MRL review confirmatory data is finalised or the MRL is lowered to the value of 0.07 mg/kg, which is sufficiently supported by data and for which no consumer intake concerns were identified. |
| 0110030    | Lemons     | 0.1 (ft)               | Risk management decision | The submitted data are sufficient to derive an MRL proposal of 0.07 mg/kg based on the intended post-harvest use. Risk management decision shall be taken whether the tentative MRL of 0.1 mg/kg (with footnote) shall be maintained until the assessment of the MRL review confirmatory data is finalised or the MRL is lowered to the value of 0.07 mg/kg, which is sufficiently supported by data and for which no consumer intake concerns were identified. |
| 0110050    | Mandarins  |                        | Risk management decision | |

MRL: maximum residue level; SEU: southern Europe.
\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
\(^{ft}\): The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 16 May 2020, or, if that information is not submitted by that date, the lack of it.
Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for triclopyr in oranges, lemons and mandarins. The detailed description of the intended foliar and/or post-harvest uses of triclopyr in these citrus fruits, which are the basis for the current MRL application, is reported in Appendix A.

Triclopyr is the ISO common name for 3,5,6-trichloro-2-pyridyloxycetic acid (IUPAC). The chemical structures of the active substance and its main metabolite are reported in Appendix E.

Triclopyr was evaluated in the framework of Directive 91/414/EEC1 with Ireland designated as the original rapporteur Member State (RMS) for the representative uses as a foliar treatment on pasture, non-recreational amenity grassland. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2006). Triclopyr was approved2 for the use as herbicide on 1 June 2007. Afterwards, the conditions of use of the active substance were amended, in particular by restricting its use with a total application per year of maximum 480 g active substance per hectare.3 The process of renewal of the approval is currently ongoing.

The EU MRLs for triclopyr are established in Annex II of Regulation (EC) No 396/20054. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2017) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued one reasoned opinion on the modification of the MRL for triclopyr in kiwi fruits (EFSA, 2020). The proposal from this reasoned opinion has been considered in recent MRL regulation.5

In accordance with Article 6 of Regulation (EC) No 396/2005, Agriphar SA submitted an application to the competent national authority in Ireland (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance triclopyr in oranges, lemons and mandarins. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 5 May 2014. To accommodate for the intended uses of triclopyr, the EMS proposed to lower the existing tentative MRL from 0.1 to 0.08 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps, which were requested from the EMS. On 20 June 2022, the EMS submitted a revised evaluation report (Ireland, 2013 as revised in 2022), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Ireland, 2013) as revised up to its final version in 2022, the draft assessment report (DAR) and its addendum (Ireland, 2003, 2005) prepared under Directive 91/414/EEC, the Commission review reports on triclopyr and its revision (European Commission, 2006, 2014), the conclusion on the peer review of the pesticide risk assessment of the active substance triclopyr (EFSA, 2006), as well as the conclusions from previous EFSA opinions on triclopyr, including the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2017, 2020).

For this application, the data requirements established in Regulation (EU) No 544/20116 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a,b,c,d,e,f,g, 2000, 2010a,b, 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 546/20117.

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1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2 Commission Directive 2006/74/EC of 21 August 2006 amending Council Directive 91/414/EEC to include dichlorprop-P, metconazole, pyrimethanil and triclopyr as active substances. OJ L 235, 30.8.2006, p. 17–22.
3 Commission Implementing Regulation (EU) 2015/307 of 26 February 2015 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance triclopyr. OJ L 56, 27.2.2015, p. 6–8.
4 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.
5 For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as
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. 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.
The peer review of the renewal of approval of triclopyr in accordance with Regulation (EC) No 1107/2009 is ongoing and, therefore, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

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

The evaluation report submitted by the EMS (Ireland, 2013; as revised in 2022) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of triclopyr was investigated in primary crops belonging to the group of fruit crops (foliar and soil application), root crops (foliar and soil application) and cereal/grass crops (foliar application) in the framework of the EU pesticides peer review and the MRL review (EFSA, 2006, 2017). Triclopyr, free and conjugated, was the main residue in target primary crops (68% TRR in the apple pulp, 64–75% TRR in radish, 47–78% in grass). The toxicologically relevant metabolite 3,5,6-trichloropyridinol (3,5,6-TCP) was identified in low proportions in root crops only (up to 3% TRR).

A new metabolism study after post-harvest treatment of triclopyr in fruit crops was assessed in the framework of this MRL application (Ireland, 2013). The study was conducted on orange fruits drenched in a solution containing radiolabelled triclopyr for ca. 40 s followed by drying for ca. 30 min. The treatment rate (target 2 g/L per tonne fruit) tested is representative (1 N) of the intended application rate of the current MRL request. Samples of fruits were collected after treatment and over a period of storage for up to 42 days after treatment (DAT). Samples were kept at room temperature in the dark.

The fruits were rinsed with acetonitrile/water (1/1; v/v) and separated into peel and pulp. Afterwards, the radioactivity was extracted from the homogenised peel and pulp three times with a mixture of acetonitrile/water (8/2; v/v). The solid was combusted to determine the total radioactive residues by summing it up with that of the extracts. Alkaline hydrolysis was conducted on the 42-DAT extract from orange peel. According to the EMS, the extraction and analysis techniques were capable to release conjugated forms of triclopyr. Identification and characterisation of more than 90% TRR was achieved.

In the whole unrinsed fruits, the total radioactivity accounted for 0.14, 0.17, 0.20 and 0.17 mg eq/kg at 0, 3, 14 and 42-DAT, respectively; Triclopyr was the major component (99.3% TRR at 0-DAT to 85.8% TRR at 42-DAT). The main portions of the applied radioactivity remained in the rinses and the condensate solutions, consisting mainly of parent triclopyr. In the fruit, total radioactivity was mainly distributed in the peel (0.03–0.15 mg eq/kg, from 4.5% to 25% TRR). In the pulp, radioactivity was low (≤ 0.001 mg eq/kg, 0.2–0.5% TRR depending on the sampling time) and therefore not further characterised.

The metabolism study showed that triclopyr undergoes very limited metabolisation after post-harvest application. The low-level components observed (nine unknown metabolites, individually max. 5.3% TRR, 0.009 mg eq/kg at 42-DAT) in extracts of orange peel were identified as glucoside and aspartic acid conjugates of triclopyr.

Based on the results of the study submitted, EFSA concluded that the metabolism of triclopyr after post-harvest drenching is sufficiently elucidated in fruit crops. Triclopyr was the only relevant residue found in post-harvest treated oranges. Further studies investigating the nature of triclopyr in the primary crops under consideration are therefore not required.

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8 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.
1.1.2. Nature of residues in rotational crops

Triclopyr is proposed for foliar and/or post-harvest uses on citrus fruits, which are permanent crops. Therefore, no further consideration on the nature of the active substance in rotational crops is required in the context of the present MRL application.

1.1.3. Nature of residues in processed commodities

Since residues in the raw agricultural commodities are expected to be below the trigger value of 0.1 mg/kg, investigation on the nature of residues of triclopyr in processed commodities is not required for the crops under assessment (European Commission, 1997d).

1.1.4. Analytical methods for enforcement purposes in plant commodities

Analytical methods for the determination of triclopyr residues in plants commodities were assessed during the MRL review and in a previous MRL application (EFSA, 2017, 2020). Sufficiently validated methods based on HPLC-MS/MS, including a method using QuEChERS technique, are available to determine residues of triclopyr in high-acid content commodities, to which citrus fruits belong. The methods allow quantifying residues of triclopyr at or above the LOQ of 0.01 mg/kg.

1.1.5. Storage stability of residues in plants

The storage stability of triclopyr in plants under frozen conditions was assessed in high-water content commodities in the framework of the EU pesticides peer review (EFSA, 2006) and in high-acid and high-water content commodities in a previous EFSA opinion (EFSA, 2020). Based on these studies, residues of triclopyr were found to be stable for up to 12 months at −18°C in high-acid content matrices, to which group the commodities under assessment belong.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, EFSA proposed to define the residue for enforcement and risk assessment as ‘triclopyr’ in all plant commodities (EFSA, 2017). The results of the new metabolism study confirm that triclopyr is the only relevant residue found in post-harvest treated oranges. Residue definitions were not set for rotational crops and processed products as not triggered. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

Taking into account the intended uses in the present MRL application and the results of the new metabolism study submitted, EFSA concluded that the above-mentioned residue definitions are also applicable to the post-harvest uses in fruits.

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 the results of residue field trials in oranges and post-harvest use trials on oranges and mandarins. In some of the trials, residues were also measured in the pulp and were always < LOQ, except in one residue trial after foliar application (0.04 mg/kg). Residues of triclopyr in the edible portion of these commodities are unlikely to occur as shown in the available metabolism studies and confirmed by the residue trials on fruits assessed in a previous EFSA opinion (EFSA, 2020).

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. For the HPLC-MS/MS method used to analyse residues from the field study on oranges, extraction efficiency data were provided and were considered adequate (Ireland, 2013).

It is noted that samples taken after foliar application of triclopyr on oranges were also analysed for 3,5,6-trichloropyridinol (3,5,6-TCP).9 This metabolite of triclopyr was never quantified in the pulp but occasionally detected in the peel and therefore in the whole fruit samples (at 0.02 mg/kg) of two

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9 EFSA has set specific toxicological reference values (ADI of 0.03 mg/kg bw per day and ARfD of 0.25 mg/kg bw) for 3,5,6-trichloropyridinol (EFSA, 2014). Subsequently, a higher ADI of 0.06 mg/kg bw per day was established (EFSA, 2019b).
trials. Also in three untreated samples, 3,5,6-TCP was found above the LOQ of 0.01 mg/kg (up to 0.07 mg/kg just after treatment, at 0-DAT). According to the field history, the previous use of products containing triclopyr, chlorpyrifos and/or chlorpyrifos-methyl (all forming 3,5,6-TCP metabolite) was not recorded and therefore potential contamination of untreated samples with triclopyr test item could be excluded. The EMS assumed that contamination might have occurred due to drift onto the experimental plots from neighbouring lands sprayed with these pesticides (Ireland, 2013). EFSA considered this a possible explanation since these trials resulted to be properly conducted.

**Oranges, lemons, mandarins. EU GAP: Post-harvest drench, 1 × 2 g/ton fruit, withholding interval 3 days**

The results of eight GAP-compliant residue trials on oranges (4 trials) and mandarins (4 trials) were provided. All trials were conducted in Spain on the same date in four different premises. The fruits were drenched, let dried and then subject to degreening, cleaning, brushing, waxing and packaging to simulate normal commercial practice. For the MRL setting, EFSA selected the average value of analytical replicates in line with agreed methodology (EFSA, 2015; FAO, 2016).

The applicant proposed to extrapolate the residue data on oranges and mandarins to oranges, lemons and mandarins. According to the EU guidance, an extrapolation of residue data on oranges and mandarins to the whole group of citrus is possible and, consequently, also to single commodities of the group (European Commission, 2017). The available information is sufficient to derive an MRL proposal of 0.07 mg/kg for the intended post-harvest use on oranges, lemons, mandarins. It is also noted that the existing MRL in these crops is higher (0.1 mg/kg) and derived on a tentative basis in the framework of the MRL review.

**Oranges. SEU GAP: Foliar spray, 1 × 37.5 g/ha, PHI 32 days**

The applicant submitted the results of nine field trials on oranges performed in different SEU countries. All trials were carried out in a single season but in several different geographical locations in the southern Europe and therefore the deviation from the requirement of trials being performed over two growing seasons is considered minor. The results of these trials allow deriving an MRL proposal of 0.06 mg/kg for the foliar use on oranges indicating that foliar treatment is less critical than post-harvest use in oranges in terms of residue levels.

### 1.2.2. Magnitude of residues in rotational crops

Investigation of the magnitude of residues of triclopyr in rotational crops is not required in the context of the present MRL application. The intended preharvest use is on orange fruits which are permanent crops not expected to be grown in rotation with other crops. The other intended uses are post-harvest.

### 1.2.3. Magnitude of residues in processed commodities

Specific processing studies with citrus fruits were not provided and are not required since residues of triclopyr exceeding 0.1 mg/kg were not observed in the commodities under assessment. Furthermore, their individual chronic exposure is not expected to exceed 10% of the ADI (European Commission, 1997d; see also Section 3).

Residue data submitted allow calculating peeling factors for oranges and mandarins after the intended foliar and post-harvest uses (Ireland, 2013). The peeling significantly reduces residue levels in fruits, which were always < LOQ in the fruit pulp, with the exception of one residue trial after foliar use. No significant difference regarding the distribution of residues among peel and pulp between fruits was observed. The derived median peeling factor is reported in Appendix B.1.2.3.

### 1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for oranges, lemons and mandarins. The intended foliar use on oranges showed to be less critical for residues than the intended post-harvest use.

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10 The EMS selected the highest value of the analytical replicates and thus derived a slightly higher MRL proposal of 0.08 mg/kg and median/highest residue values (Ireland, 2013).
In Section 3, EFSA assessed whether residues of triclopyr resulting in oranges, mandarins and lemons from the intended post-harvest use are likely to pose a consumer health risk.

2. Residues in livestock

The by-product citrus dried pulp may be used for feed purposes. Hence, it was necessary to investigate whether the livestock intake of residues from citrus dried pulp obtained from fruits treated according to the intended uses of triclopyr would have an impact on the residues expected in food of animal origin.

The most recent animal dietary burden was indicatively calculated in the framework of the MRL review (EFSA, 2017). It was now recalculated considering the default processing factors (PF) for various feed items and livestock feeding tables listed in the OECD Guidance (OECD, 2013) which had in a meanwhile replaced the feeding table reported in SANCO 7031/VI/95 (European Commission, 1996). It is noted that citrus dried pulp previously was not included in the list of feed items. For the calculation of the exposure to triclopyr residues from the intake of citrus dried pulp, the existing MRL of 0.1 mg/kg tentatively set in grapefruits, oranges, lemons and mandarins was used (no refined value available) since this value is higher than the median residue (0.03 mg/kg) derived from the residue trials submitted to support the intended post-harvest use on oranges, lemons and mandarins. The default PF of 10 was applied to estimate the residue level in the dried pulp. The input values for the exposure calculations for livestock are presented in Appendix D.1.

The results of the dietary burden calculations are presented in Section B.2. Considering the existing uses of triclopyr assessed in the MRL review, the new calculation methodology has an impact on the previously estimated dietary burdens. The exposure estimate is lower for ruminants and increased for 7% in pigs, but it is driven by the existing use on grass assessed in the MRL review. The dietary burden in poultry (all diets) which was not triggered under the MRL review, now exceeds the trigger value of 0.1 mg/kg DM, because of the existing use in rice and residues in its by-product bran/pollard. Citrus dried pulp is not a poultry feed item (OECD, 2013). Moreover, based on the results of the overdosed hen metabolism study with triclopyr (81 times higher the calculated dietary burden) assessed in the MRL review, quantifiable residues in poultry edible products are not expected and the setting of MRL in poultry tissues and eggs is currently not required.

The intended uses on oranges, lemons and mandarins assessed in the framework of this application are covered by these updated calculations which are carried out using the existing MRL on certain citrus fruits. Taking into account that citrus dried pulp is not among the major contributing commodities identified in the critical diets of ruminants and pigs, a modification of the existing MRL in products of animal origin is not necessary.

The livestock exposure to triclopyr residues and the potential carry-over of residues into commodities of animal origin and the subsequent potential formation of metabolite 3,5,6-TCP, will be reassessed in the framework of the MRL review confirmatory data, when the data gaps identified in the MRL review will be addressed and a full information on the authorised uses of triclopyr will be available to EFSA.

In animal commodities, two separate risk assessment residue definitions were proposed by the MRL review (EFSA, 2017):

- triclopyr;
- 3,5,6-TCP and its conjugates, expressed as 3,5,6-TCP.

It was noted that metabolite 3,5,6-TCP, which was observed in significant amounts in the ruminant metabolism study with triclopyr, may also be generated in animals from the use of two other active substances, chlorpyrifos and chlorpyrifos-methyl.

3. Consumer risk assessment

EFSA performed a dietary risk assessment for the agreed residue definitions for risk assessment in plant and animal matrices using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019a). 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).

The toxicological reference values for triclopyr used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (European Commission, 2006). For the metabolite 3,5,6-TCP, included in a separated residue definition for risk assessment for
products of animal origin, different toxicological reference values are set requiring a separate risk
assessment for residues in the commodities of animal origin.

In the framework of the MRL review (EFSA, 2017), EFSA performed a separate consumer risk
assessment for 3,5,6-TCP and its conjugates, from the uses of chlorpyrifos, chlorpyrifos methyl and
triclopyr. The exposure calculation did not indicate a risk to consumers. In plant commodities,
metabolite 3,5,6-TCP is unlikely to be present after the application of triclopyr. It is mainly expected to
occur following the use of chlorpyrifos or chlorpyrifos-methyl which are no longer authorised for use as
pesticides in the EU. Therefore, an update of the chronic risk assessment performed in the MRL
review for 3,5,6-TCP is not necessary.

The input values used in the exposure calculations are summarised in Appendix D.2.

- **Short-term (acute) dietary risk assessment**

  The short-term risk assessment was performed only with regard to oranges, lemons and
mandarins, being the commodities assessed in the present MRL application. The estimation of the
exposure is based on the highest residue (HR) derived from the post-harvest supervised trials
submitted, multiplied by the derived peeling factor of 0.33.

  For oranges, lemons and mandarins, the short-term exposure accounted for a maximum of 0.7% of
the ARfD (highest for oranges).

- **Long-term (chronic) dietary risk assessment**

  The comprehensive long-term exposure assessment performed in the framework of the MRL review
was recently revised in the EFSA assessment of an MRL application for kiwi fruits, (EFSA, 2020). In
that calculation, the existing tentative MRL of 0.1 mg/kg was included as an input value for
grapefruits, oranges, lemons and mandarins and the estimated long-term exposure to triclopyr
residues accounted for up to 6% of the ADI (NL toddler).

  EFSA is now updating the above-mentioned calculation by replacing the previous input value at the
existing MRL of 0.1 mg/kg with the STMR value of 0.03 mg/kg as derived for oranges, lemons and
mandarins from the residue trials submitted in support of this MRL application; the peeling factor of
0.33 was applied to the input value for oranges, lemons and mandarins and a peeling factor of 1 was
applied to the input value for kiwi fruits. The contributions of commodities for which no GAP was
reported in the framework of the MRL review were not included in the calculation.

  The estimated long-term exposure to triclopyr residues accounted for up to 5% of the ADI (NL
toddler). The contribution of residues expected in oranges, lemons and mandarins is up to the 0.13%
of the ADI (highest for oranges).

- **Overall conclusions**

  Based on the results of the consumer exposure assessment, EFSA concludes that the existing EU
uses and the intended uses of triclopyr on oranges, lemons and mandarins will not result in acute or
chronic consumer exposure exceeding the toxicological reference values for triclopyr and therefore are
unlikely to pose a risk to consumers’ health.

  The chronic exposure calculation should be regarded as indicative. An updated long-term consumer
risk assessment shall be performed in the framework of the assessment of the MRL review
confirmatory data for triclopyr when the identified missing information regarding certain authorised
uses and additional residue data will be available to EFSA. Nevertheless, the margin of safety for the
chronic exposure is sufficiently large to cover this lack of information in the context of the current
application.

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

### 4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL
proposal of 0.07 mg/kg for oranges, lemons and mandarins in support of the intended post-harvest
use; the derived MRL proposal is lower than the existing tentative MRL. A risk management decision is
required on whether to lower the existing MRL of 0.1 mg/kg derived tentatively in the framework of the
MRL review.

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11 Commission Implementing Regulation (EU) 2020/17 and Commission Implementing Regulation (EU) 2020/18.
Based on the consumer exposure assessment, EFSA concludes that the existing EU uses as well as the intended uses of triclopyr in oranges, lemons and mandarins will not result in acute or chronic consumer exposure exceeding the toxicological reference values and, therefore, are unlikely to pose a risk to consumers’ health.

The chronic exposure calculation should be regarded as indicative since for certain commodities, only tentative MRLs could be derived during the MRL review. Nevertheless, the margin of safety for the chronic exposure is sufficiently large to cover this lack of information in the context of the current application.

The peer review of the renewal of approval of triclopyr in accordance with Regulation (EC) No 1107/2009 is ongoing and, therefore, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

The MRL recommendations are summarised in Appendix B.4.

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**Abbreviations**

- 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
- CAS Chemical Abstract Service
- CCPR Codex Committee on Pesticide Residues
- CEN European Committee for Standardisation (Comité Européen de Normalisation)
- CF conversion factor for enforcement to risk assessment residue definition
- cGAP critical GAP
- CIPAC Collaborative International Pesticide Analytical Council
- CIRCA (EU) Communication & Information Resource Centre Administrator
- CIRCABC Communication and Information Resource Centre for Administrations, Businesses and Citizens
- CS capsule suspension
- CV coefficient of variation (relative standard deviation)
- CXL Codex maximum residue limit
- DALA days after last application
- DAR draft assessment report
- DAT days after treatment
- DM dry matter
- DP dustable powder
- DS powder for dry seed treatment
- DT90 period required for 90% dissipation (define method of estimation)
- dw dry weight
- EC emulsifiable concentrate
- ECD electron capture detector
EDI estimated daily intake
EMS evaluating Member State
eq residue expressed as a.s. equivalent
ESI electrospray ionisation
EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO Food and Agriculture Organisation of the United Nations
FID flame ionisation detector
FLD fluorescence detector
FPD flame photometric detector
GAP Good Agricultural Practice
GC gas chromatography
Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
GC-ECD gas chromatography with electron capture detector
GC-FID gas chromatography with flame ionisation detector
GC-FPD gas chromatography with flame photometric detector
GC-MS gas chromatography with mass spectrometry
GC-MS/MS gas chromatography with tandem mass spectrometry
GC-NPD gas chromatography with nitrogen/phosphorous detector
GLP Good Laboratory Practice
GR granule
GS growth stage
HPLC high performance liquid chromatography
HPLC-MS high performance liquid chromatography with mass spectrometry
HPLC-MS/MS high performance liquid chromatography with tandem mass spectrometry
HPLC-UVD high performance liquid chromatography with ultra-violet detector
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
IPCS International Programme of Chemical Safety
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint FAO/WHO Meeting on Pesticide Residues
Koc organic carbon adsorption coefficient
LC liquid chromatography
LOAEL lowest observed adverse effect level
LOD limit of detection
LOQ limit of quantification
MRL maximum residue level
MS Member States
MS mass spectrometry detector
MS/MS tandem mass spectrometry detector
MW molecular weight
NEU northern Europe
NOAEL no observed adverse effect level
NPD nitrogen/phosphorous detector
OECD Organisation for Economic Co-operation and Development
PAFF Standing Committee on Plants, Animals, Food and Feed
PBI plant back interval
PF processing factor
PHI pre-harvest interval
Pow partition coefficient between n-octanol and water
PRIME (EFSA) Pesticide Residues Intake Model
PROFile (EFSA) Pesticide Residues Overview File
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
Rber statistical calculation of the MRL by using a non-parametric method
| Abbreviation | Definition |
|--------------|------------|
| Rmax         | statistical calculation of the MRL by using a parametric method |
| RA           | risk assessment |
| RAC          | raw agricultural commodity |
| RD           | residue definition |
| RMS          | rapporteur Member State |
| RPF          | relative potency factor |
| SANCO        | Directorate-General for Health and Consumers |
| SC           | suspension concentrate |
| SCPAFF       | Standing Committee on Plants, Animals, Food and Feed (formerly: Standing Committee on the Food Chain and Animal Health; SCFCAH) |
| SEU          | southern Europe |
| SG           | water-soluble granule |
| SL           | soluble concentrate |
| SP           | water-soluble powder |
| STMR         | supervised trials median residue |
| TAR          | total applied radioactivity |
| TMDI         | theoretical maximum daily intake |
| TRR          | total radioactive residue |
| UV           | ultraviolet (detector) |
| WG           | water-dispersible granule |
| WHO          | World Health Organisation |
| WP           | wettable powder |
| YF           | yield factor |
| ZC           | mixed CS and SC formulation |
## 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 |
|-----------------------|-------------------------|------------|-----------------------------------|-------------|------------|--------------------------------|---------------|---------|
|                       |                         |            |                                   | Type(b)     | Conc. a.s. (g/kg) | Method kind | Range of growth stages & season(c) | Interval between application (days) min–max | g a.s./hL min–max | Water (L/ha) min–max | Rate min–max | Unit |                      |               |
| Oranges EU            | I                       | Growth Regulator | ST 100 | Post-harvest treatment - drenching | From BBCH 85 | 1 | n.a. | 2 g a.s./ton | 3 | 2 g/hL at a rate of 100 L water/ton fruit. Application 3 days before commercialisation. |
| Oranges SEU F         | Growth Regulator | ST 100 | Foliar treatment - broadcast spraying | After BBCH 80 | 1 | n.a. | 1–1.5 1,500–2,500 37.5 g a.s./ha | 32 | Just after colour break. Colour break starts at BBCH > 80. |
| Oranges SEU F         | Growth Regulator | ST 100 | Foliar treatment - broadcast spraying | After BBCH 80 | 1 | n.a. | 2000–2,500 37.5 g a.s./ha | 40 | Just after colour break. Colour break starts at BBCH > 80. |
| Mandarins EU          | I                       | Growth Regulator | ST 100 | Post-harvest treatment - drenching | From BBCH 85 | 1 | n.a. | 2 g a.s./ton | 3 | 2 g/hL at a rate of 100 L water/ton fruit. Application 3 days before commercialisation. |
| Lemons EU             | I                       | Growth Regulator | ST 100 | Post-harvest treatment - drenching | From BBCH 85 | 1 | n.a. | 2 g a.s./ton | 3 | 2 g/hL at a rate of 100 L water/ton fruit. Application 3 days before commercialisation. |

**MRL:** maximum residue level; **GAP:** Good Agricultural Practice; **NEU:** northern European Union; **SEU:** southern European Union; **MS:** Member State; **a.s.:** active substance; **ST:** water soluble tablets; **n.a.:** not applicable.

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

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

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

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

### B.1. Residues in plants

#### B.1.1. Nature of residues and analytical methods for enforcement purposes in plant commodities

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

| Primary crops (available studies) | Crop groups | Crops | Application | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|-------|-------------|----------------|----------------|
| Fruit crops                       | Apples      | Foliar, 1 × 650 g a.s./ha | 21 | Radiolabelled active substance: $^{14}$C-triclopyr (EFSA, 2006) |
|                                  |             | Soil, 2 × 1.1 kg a.s./ha   | 14 |                              |
| Oranges                          |             | Post-harvest drench, 1 × 2 g/hL per tonne fruit (rate of 100 mL/kg oranges) for ca. 40 s. | 30 min, 3, 14, 42 | Radiolabelled active substance: $[\text{pyridyl-2-}^{14}\text{C}]$-triclopyr (Ireland, 2013) |
| Root crops                       | Radishes    | Foliar, 1 × 27 g a.s./ha   | 8  | Radio-labelled active substance: $^{14}$C-triclopyr (EFSA, 2006) |
|                                  |             | Soil, 1 × 1.1 kg a.s./ha   | 7  |                              |
| Cereals/grass crops              | Ryegrass    | Foliar, 1 × 2.24 kg a.s./ha | 0, 3, 7, 14, 30, 60, 91 |  |
|                                  |             | Foliar, 1 × 4.5 kg a.s./ha  | 91 |  |

| Rotational crops (available studies) | Crop groups | Crops | Application | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|-------|-------------|-----------|----------------|
| Root/tuber crops                    | Turnips     | Bare soil, 0.56 kg a.s./ha | 36 | Radiolabelled active substance: $^{14}$C-triclopyr (EFSA, 2006) |
| Leafy crops                        | Lettuce     | Bare soil, 0.56 kg a.s./ha | 36 |  |
| Cereal (small grain)               | Wheat       | Bare soil, 0.56 kg a.s./ha | 36 |  |
| Pulses/oilseeds                    | Green beans | Bare soil, 0.56 kg a.s./ha | 36 |  |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)      | Not triggered |  |
| Baking, brewing, boiling (60 min, 100°C, pH 5) | Not triggered |  |
| Sterilisation (20 min, 120°C, pH 6)      | Not triggered |  |
| Other processing conditions              | n.a.       |  |

Can a general residue definition be proposed for primary crops? Yes EFSA (2017)

Rotational crop and primary crop metabolism similar? Inconclusive Further investigation not needed (EFSA, 2017)
B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category               | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source         |
|------------------------------------|------------------------|-----------|--------|------------------|-------------------|------------------------|
|                                    | High water content     | Apple     | −18    | 12 Months        | Triclopyr         | EFSA (2020)            |
|                                    |                        | Grass     | −20    | 48 Months        | Triclopyr         | Tentative\(^{(a)}\) EFSA (2006) |
|                                    | Dry/High starch        | –         | –      | –                | –                 | –                      |
|                                    | High acid content      | Kiwi      | −18    | 12 Months        | Triclopyr         | EFSA (2020)            |
|                                    |                        | Mandarin  | −18    | 12 Months        | Triclopyr         | EFSA (2020)            |

\(^{(a)}\): The validation of the method of analysis used in the study investigating the storage stability of triclopyr was missing (data gap) (EFSA, 2006, 2017).

DAT: days after treatment; a.s.: active substance; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; ILV: independent laboratory validation; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe.
### B.1.2. Magnitude of residues in plants

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

| Commodity                      | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                                                                                                                                 | Calculated MRL (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) | CF\(^{(d)}\) |
|-------------------------------|------------------|----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|------------------|-------------------|--------|
| Oranges                       | SEU              | 4 × < 0.01; 3 × 0.01; 0.03; 0.04                                                                                           | Residue trials on oranges compliant with the GAP. Pulp: 8 × < 0.01; 0.04 mg/kg Residues of 3,5,6-TCP: 7 × < 0.01, 2 × 0.02 (9 × < 0.01 mg/kg in the pulp)                                              | 0.06                   | 0.04             | 0.01              | n.a.  |
| Oranges, lemons, mandarins   | Indoor (Po-use)  | 2 × 0.02; 5 × 0.03; 0.05                                                                                                     | Residue trials on oranges and mandarins compliant with the GAP. MRL proposal based on the options HR, mean + 4SD (OECD calculator) Pulp: 4 × < 0.01 mg/kg                                                                 | 0.07                   | 0.05             | 0.03              | n.a.  |

GAP: Good Agricultural Practice; Po-use: post-harvest use; MRL: maximum residue level; n.a.: not applicable; HR: highest residue; SD: standard deviation.

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

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

Not triggered

The intended use in the present MRL application is on permanent crops.

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

Not triggered

The intended use in the present MRL application is on permanent crops.

MRL: maximum residue level.

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies(a) | Processing Factor (PF) Individual values | Median PF | CF_P(b) | Comment/ Source |
|---------------------|----------------------------|----------------------------------------|-----------|---------|----------------|
| Orange, peeled      | 3                          | Foliar: 0.33; < 1; 1                   | 0.33(c)   | –       | – Ireland (2013) |
|                     | 2                          | Po-use: 0.33; 0.34                    |           |         |                |
| Mandarin, peeled    | 2                          | Po-use: 0.29; 0.33                    | 0.29(c)   | –       | – Ireland (2013) |

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

(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.

(c): Lowest value as best estimate of peeling factor since residues in the pulp were always < LOQ of 0.01 mg/kg, except one trial.

B.2. Residues in livestock

Dietary burden calculation according to OECD, 2013.

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day Median | Maximum | mg/kg DM Median | Maximum | Most critical diet (a) | Most critical commodity (b) | Trigger exceeded (Yes/No) | DB calculated using old feeding tables (EFSA, 2017) | Max burden mg/kg DM |
|-----------------------------|-----------------------------------------------------|---------|-----------------|---------|----------------------|--------------------------|---------------------------|-------------------------------------------------|-------------------|
| Cattle (all diets)         | 0.729                                               | 1.430   | 18.94           | 37.18   | Grass Forage (fresh) |                          | Yes                        | 77.8                             |
| Cattle (dairy only)        | 0.729                                               | 1.430   | 18.94           | 37.18   | Grass Forage (fresh) |                          | Yes                        | 76.7                             |
| Sheep (all diets)          | 0.990                                               | 1.953   | 29.70           | 58.58   | Ram/Ewe Forage (fresh) |                          | Yes                        | Not calculated                   |
| Sheep (ewe only)           | 0.990                                               | 1.953   | 29.70           | 58.58   | Ram/Ewe Forage (fresh) |                          | Yes                        | Not calculated                   |
| Swine (all diets)          | 0.148                                               | 0.288   | 6.40            | 12.48   | Swine (breeding) Grass Forage (fresh) |                          | Yes                        | 11.6                             |
| Poultry (all diets)        | 0.008                                               | 0.008   | 0.11            | 0.11    | Poultry broiler Rice Bran/pollard |                          | Yes                        | Not triggered                     |
| Poultry (layer only)       | 0.004                                               | 0.004   | 0.06            | 0.06    | Poultry layer Rice Bran/pollard |                          | No                         | Not triggered                     |

bw: body weight; DM: dry matter; DB: dietary burden.

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

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.
B.3. Consumer risk assessment

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|-------------------------|-------------------------|-----------------------|
| 0110020 | Oranges   | 0.1 (ft)                | Risk management decision | The submitted data are sufficient to derive an MRL proposal of 0.07 mg/kg based on the intended post-harvest use. The SEU foliar use is also supported by a less critical residue data set. Risk management decision shall be taken whether the tentative MRL of 0.1 mg/kg (with footnote) shall be maintained until the assessment of the MRL review confirmatory data is finalised or the MRL is... |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; GAP: Good Agricultural Practice.

B.4. Recommended MRLs

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|-------------------------|-------------------------|-----------------------|
|         | Oranges   | 0.1 (ft)                | Risk management decision | The submitted data are sufficient to derive an MRL proposal of 0.07 mg/kg based on the intended post-harvest use. The SEU foliar use is also supported by a less critical residue data set. Risk management decision shall be taken whether the tentative MRL of 0.1 mg/kg (with footnote) shall be maintained until the assessment of the MRL review confirmatory data is finalised or the MRL is... |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; GAP: Good Agricultural Practice.
| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-----------------|------------|------------------------|-------------------------|------------------------|
| 0110030         | Lemons     | 0.1                    | Risk management decision| The submitted data are sufficient to derive an MRL proposal of 0.07 mg/kg based on the intended post-harvest use. Risk management decision shall be taken whether the tentative MRL of 0.1 mg/kg (with footnote) shall be maintained until the assessment of the MRL review confirmatory data is finalised or the MRL is lowered to the value of 0.07 mg/kg, which is sufficiently supported by data and for which no consumer intake concerns were identified. |
| 0110050         | Mandarins  | 0.1 (ft)               | Risk management decision|                                                                                     |

MRL: maximum residue level; SEU: southern Europe.

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

\(ft\): The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 16 May 2020, or, if that information is not submitted by that date, the lack of it.
## Appendix C – Pesticide Residue Intake Model (PRiMo)

### Triclopyr

| Commodity | Maximum Residue Limits (MRLs) (mg/kg) | Mean Adult Intake (mg/kg) | % of ADI | Data Source |
|-----------|-------------------------------------|--------------------------|----------|-------------|
| Pears     | 1.55                                 | 1.55                      | 2%       | JMPR        |
| Rice      | 0.7%                                 | 0.7%                      | 1.0%     | JMPR        |
| Oranges   | 1.01                                 | 1.01                      | 0.7%     | JMPR        |

### Toxicological reference values

- ADI: Acceptable Daily Intake
- ARfD: Acceptable Single-Acute Intake

### Source of ADI

- WHO: World Health Organization
- Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

### Source of ARfD

- JMPR: Joint FAO/WHO Meeting on Pesticide Residues

### Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

### Exposure resulting from commodities not under assessment

No of diets exceeding the ADI: ---

### Details – chronic risk assessment

- Calculated exposure
- Commodity/diet
- MS Diet (in % of ADI)
- 1st contributor to MS (in % of ADI)
- 2nd contributor to MS (in % of ADI)
- 3rd contributor to MS (in % of ADI)

### Input values

- Triclopyr LOQs (mg/kg): range from 0.01 to 0.3

### Conclusion

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

**Disclaimer:** Dietary data from the UK were included in PRiMo when the UK was a member of the European Union.
### Acute risk assessment/children

| Highest % of ARfD/ADI | Commodities | MRL/input (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|-------------|-------------------|---------------------|
| 3%                    | Grapefruits| 0.1/0.1           | 7.9                 |
| 2%                    | Pears      | 0.05/0.05         | 6.9                 |
| 2%                    | Apples     | 0.05/0.05         | 5.4                 |
| 2%                    | Peaches    | 0.05/0.05         | 4.8                 |
| 1%                    | Kiwi fruits| 0.15/0.06         | 3.7                 |
| 1%                    | Oranges    | 0.07/0.02         | 2.2                 |
| 1%                    | Apricots   | 0.05/0.05         | 1.7                 |
| 0.7%                  | Mandarins  | 0.07/0.02         | 0.98                |
| 0.6%                  | Bovine: Edible offals (other than liver and kidney) | 0.08/0.08 | 0.58                |
| 0.4%                  | Bovine: Liver | 0.06/0.05 | 0.40                |
| 0.4%                  | Bovine: Muscle/meat | 0.06/0.05 | 0.36                |
| 0.3%                  | Sheep: Muscle/meat | 0.06/0.05 | 0.24                |

### Acute risk assessment/adults/general population

| Highest % of ARfD/ADI | Commodities | MRL/input (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|-------------|-------------------|---------------------|
| 0.9%                  | Apples/juice| 0.05/0.05         | 2.7                 |
| 0.5%                  | Pears/juice | 0.05/0.05         | 1.6                 |
| 0.5%                  | Oranges/juice | 0.07/0.03 | 1.6                 |
| 0.5%                  | Peaches/canned | 0.05/0.05 | 1.3                 |
| 0.3%                  | Peaches/juice | 0.05/0.05 | 0.83                |
| 0.2%                  | Rice/milling (polishing) | 0.3/0.04 | 0.39                |
| 0.2%                  | Rice/milling (polishing) | 0.3/0.04 | 0.61                |
| 0.2%                  | Lemons/juice | 0.07/0.03 | 0.09                |
| 0.1%                  | Kiwi fruits/juice | 0.15/0.03 | 0.54                |
| 0.1%                  | Bovine: Liver | 0.06/0.05 | 0.40                |
| 0.1%                  | Bovine: Edible offals (other than liver and kidney) | 0.08/0.08 | 0.27                |
| 0.1%                  | Bovine: Muscle/meat | 0.06/0.05 | 0.24                |
| 0.1%                  | Other farmed animals: Muscle/meat | 0.06/0.05 | 0.24                |

### Processing commodities

| Highest % of ARfD/ADI | Processed commodities | MRL/input (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|-----------------------|-------------------|---------------------|
| 0.3%                  | Processed fruits      | 0.05/0.05         | 1.7                 |
| 0.5%                  | Processed vegetables  | 0.05/0.05         | 1.5                 |
| 0.3%                  | Processed nuts       | 0.05/0.05         | 1.5                 |
| 0.3%                  | Processed meat       | 0.05/0.05         | 1.5                 |
| 0.3%                  | Processed beverages  | 0.05/0.05         | 1.5                 |
| 0.2%                  | Other processed fruits | 0.15/0.06 | 0.54                |
| 0.2%                  | Lemons/jam            | 0.07/0.03         | 0.09                |

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

A short-term intake of residues of Triclopyr is unlikely to present a public health risk.

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

Conclusion:

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

| Results for children | Results for adults |
|----------------------|--------------------|
| No of processed commodities for which ARfD/ADI is exceeded (IESTI): | No of processed commodities for which ARfD/ADI is exceeded (IESTI): |

**Note:**
- The acute risk assessment is based on the EFSA GEMS/BIOM model.
- Data from the ARF were included in PIRGR under the condition that the EFSA buildup value is not exceeded.
- The calculation is based on the large portion of the most critical consumer group.

Details – acute risk assessment/children

Details – acute risk assessment/adults
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

| Feed commodity                     | Median dietary burden | Maximum dietary burden |
|------------------------------------|-----------------------|------------------------|
|                                    | Input value           | Comment                | Input value           | Comment                |
|                                    | (mg/kg)               |                        | (mg/kg)               |                        |
| Grass, forage (fresh)              | 7.80                  | STMR (EFSA, 2017)      | 15.40                 | HR (EFSA, 2017)        |
| Grass, hay                         | 27.30                 | STMR × PF (3.5)(a) (EFSA, 2017) | 53.90                 | HR × PF (3.5)(a) (EFSA, 2017) |
| Grass, silage                      | 12.48                 | STMR × PF (1.6)(a) (EFSA, 2017) | 24.64                 | HR × PF (1.6)(a) (EFSA, 2017) |
| Apple, pomace wet                  | 0.25                  | STMR (0.05) × PF (5)(a) (EFSA, 2017) | 0.25                 | STMR (0.05) × PF (5)(a) (EFSA, 2017) |
| Grapefruits, oranges, lemons, mandarins, dried pulp(b) | 1.00 EU MRL (EFSA, 2017) | 1.00 EU MRL (0.1) × PF (10)(a) (EFSA, 2017) |
| Rice, bran/pollard                 | 1.00 STMR (10)(a) (EFSA, 2017) | 1.00 STMR (10)(a) (EFSA, 2017) |

**Risk assessment residue definition:** Triclopyr

- STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
- (a): In the absence of processing factors supported by data, default processing factors (in bracket) were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.
- (b): For the dried pulp of citrus, the calculation is performed with the tentative existing MRL of 0.1 mg/kg (no refined value available) since it is higher than the STMR of 0.03 mg/kg derived for oranges, lemons and mandarins according to the intended uses assessed in this application.

D.2. Consumer risk assessment

| Commodity                          | Chronic risk assessment | Acute risk assessment(a) |
|------------------------------------|-------------------------|--------------------------|
|                                    | Input value (mg/kg)     | Comment                  | Input value (mg/kg)     | Comment                  |
| Oranges                            | 0.01                    | STMR (0.03) × PF (0.33)  | 0.02                    | HR (0.05) × PF (0.33)    |
| Grapefruits                        | 0.10                    | EU MRL (EFSA, 2017)      | 0.10                    | EU MRL (EFSA, 2017)      |
| Lemons                             | 0.01                    | STMR (0.03) × PF (0.33)  | 0.02                    | HR (0.05) × PF (0.33)    |
| Mandarins                          | 0.01                    | STMR (0.03) × PF (0.33)  | 0.02                    | HR (0.05) × PF (0.33)    |
| Apples(b)                          | 0.05                    | STMR (EFSA, 2017)        | 0.05                    | HR (EFSA, 2017)          |
| Pears(b)                           | 0.05                    | STMR (EFSA, 2017)        | 0.05                    | HR (EFSA, 2017)          |
| Apricots(b)                        | 0.05                    | STMR (EFSA, 2017)        | 0.05                    | HR (EFSA, 2017)          |
| Peaches(b)                         | 0.05                    | STMR (EFSA, 2017)        | 0.05                    | HR (EFSA, 2017)          |
| Kiwi fruits                        | 0.03                    | STMR (0.03) × PF (1) (EFSA, 2020) | 0.06                    | HR (0.06) × PF (1) (EFSA, 2020) |
| Rice grain(b)                      | 0.10                    | STMR (EFSA, 2017)        | 0.21                    | HR (EFSA, 2017)          |
| Swine meat                         | 0.01                    | STMR (LOQ) (EFSA, 2017)  | 0.01                    | HR (LOQ) (EFSA, 2017)    |
| Swine fat                          | 0.01                    | STMR (LOQ) (EFSA, 2017)  | 0.01                    | HR (LOQ) (EFSA, 2017)    |
| Swine liver                        | 0.01                    | STMR (LOQ) (EFSA, 2017)  | 0.01                    | HR (LOQ) (EFSA, 2017)    |
| Swine kidney                       | 0.01                    | STMR (LOQ) (EFSA, 2017)  | 0.01                    | HR (LOQ) (EFSA, 2017)    |
| Swine, ed. offal(c)                | 0.01                    | STMR (LOQ) (EFSA, 2017)  | 0.01                    | HR (LOQ) (EFSA, 2017)    |
| Ruminant meat                      | 0.03                    | STMR (EFSA, 2017)        | 0.05                    | HR (EFSA, 2017)          |
| Ruminant fat                       | 0.03                    | STMR (EFSA, 2017)        | 0.05                    | HR (EFSA, 2017)          |
| Ruminant liver                     | 0.03                    | STMR (EFSA, 2017)        | 0.05                    | HR (EFSA, 2017)          |
| Ruminant kidney                    | 0.03                    | STMR (EFSA, 2017)        | 0.08                    | HR (EFSA, 2017)          |
| Ruminant, ed offal(d)              | 0.03                    | STMR (EFSA, 2017)        | 0.08                    | HR (EFSA, 2017)          |
| Commodity                                              | Chronic risk assessment | Acute risk assessment<sup>(a)</sup> |
|--------------------------------------------------------|-------------------------|-------------------------------------|
|                                                        | Input value (mg/kg)     | Comment                            | Input value (mg/kg) | Comment          |
| Equines, other farmed animals' meat<sup>(c)</sup>       | 0.03                    | STMR (EFSA, 2017)                  | 0.05               | HR (EFSA, 2017)  |
| Equines, other farmed animals' fat<sup>(c)</sup>        | 0.03                    | STMR (EFSA, 2017)                  | 0.05               | HR (EFSA, 2017)  |
| Equines, other farmed animals' liver<sup>(c)</sup>      | 0.03                    | STMR (EFSA, 2017)                  | 0.05               | HR (EFSA, 2017)  |
| Equines, other farmed animals' kidney<sup>(c)</sup>     | 0.03                    | STMR (EFSA, 2017)                  | 0.08               | HR (EFSA, 2017)  |
| Equines, other farmed animals' ed. offal<sup>(c)</sup>  | 0.03                    | STMR (EFSA, 2017)                  | 0.08               | HR (EFSA, 2017)  |
| Milks                                                  | 0.01                    | STMR (LOQ) (EFSA, 2017)            | 0.01               | HR (LOQ) (EFSA, 2017) |

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

<sup>(a)</sup>: Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

<sup>(b)</sup>: Input values for these commodities were set on a tentative basis from GAPs evaluated in the MRL review, which are not fully supported by data (EFSA, 2017).

<sup>(c)</sup>: To comply with Regulation (EU) 2021/590 where the MRL set for pigs and ruminant kidney was extrapolated to edible offal and the MRLs set for ruminant tissues extrapolated to equines and other farmed animals, EFSA applied in the calculation the STMRs derived in the MRL review.
## Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChIKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|--------------------------------|-------------------------------------------------|-------------------------------|
| Triclopyr                     | [(3,5,6-trichloro-2-pyridyl)oxy]acetic acid Clc1cc(Cl)c(Cl)nc1OCC(=O)O REEQLXCGVXDJSQL-UHFFFAOYYSA-N | ![Structural formula for Triclopyr](image) |
| 3,5,6-Trichloropyridinol (3,5,6-TCP) | 3,5,6-trichloropyridin-2-ol Clc1cc(Cl)c(Cl)nc1O WCYYAFOQZQEOUEN-UHFFFAOYYSA-N | ![Structural formula for 3,5,6-Trichloropyridinol](image) |

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

(a): The metabolite name in bold is the name used in the conclusion.

(b): ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).

(c): ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).