Modification of the existing maximum residue level for triclopyr in kiwi

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Abstract
In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Arysta LifeScience Benelux submitted a request to the competent national authority in Greece to modify the existing maximum residue levels (MRLs) for the active substance triclopyr in kiwi fruits. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for kiwi fruits. Adequate analytical methods for enforcement are available to control the residues of triclopyr in the plant matrix under consideration (i.e. high acid content commodity) at the validated limit of quantification (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, kiwi, pesticide, MRL, consumer risk assessment

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### Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Arysta LifeScience Benelux submitted an application to the competent national authority in Greece (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance triclopyr in kiwi fruits. 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 17 July 2019. To accommodate for the intended use of triclopyr, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.01 to 0.15 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified a data gap on storage stability and points which needed further clarification, which were addressed by the EMS in a revised evaluation report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous EFSA 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. Studies on the effect of processing on the nature of triclopyr (hydrolysis studies) were not performed and not deemed necessary considering that the chronic exposure to triclopyr from all dietary sources does not exceed 10% of the acceptable daily intake (ADI), and that triclopyr residues in kiwi fruits treated with the active substance were found at levels below 0.1 mg/kg. As kiwis do not grow in rotation with other crops, investigations of residues of triclopyr in rotational crops are not required in the framework of this application.

Based on the metabolic pattern identified in metabolism studies in primary crops, a general residue definition for plant products was proposed as triclopyr for enforcement and risk assessment. These residue definitions are applicable to primary crops. EFSA concluded that for the crop assessed in this application, metabolism of triclopyr in primary crops has been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectroscopy (HPLC-MS/MS) are available to quantify residues in kiwi fruits according to the residue definition for enforcement. The methods enable quantification of residues at or above 0.01 mg/kg in the crop assessed (LOQ). The available residue trials are sufficient to derive an MRL proposal of 0.15 mg/kg for triclopyr in kiwi fruits.

Residues of triclopyr in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock. Residue data provided allowed to derive a median peeling factor of 1.

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 commodity assessed in the present MRL application in accordance with the internationally agreed methodology. For kiwi fruits, the short-term exposure accounted for 1% of the ARfD. The long-term exposure assessment performed in the MRL review was updated with the risk assessment values derived from the residue trials on kiwi fruits submitted in support of the present MRL application. The highest estimated long-term dietary intake accounted for 6% of the ADI (NL toddler). The contribution of residues of triclopyr from kiwi fruits to the overall long-term exposure was up to 0.1% of the ADI.

EFSA concluded that the proposed use of triclopyr on kiwis will not result in a consumer exposure exceeding the toxicological reference values and, therefore, is 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 MRL as reported in the summary table below.

Full details of all endpoints 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                                      |
|------------|----------------|-------------------------|-------------------------|-----------------------------------------------------------|
| 0162010    | Kiwi fruits    | 0.01*                   | 0.15                    | The submitted data are sufficient to derive an MRL proposal for the SEU use. Risk for consumers unlikely |

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

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

Enforcement residue definition: Triclopyr
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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for triclopyr in kiwi fruits. The detailed description of the intended use of triclopyr in kiwi, which is the basis for the current MRL application, is reported in Appendix A.

Triclopyr is the ISO common name for 3,5,6-trichloro-2-pyridyloxyacetic 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/EEC 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 approved 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. The process of renewal of the approval is currently ongoing.

The EU MRLs for triclopyr are established in Annexes II of Regulation (EC) No 396/2005. 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, this is the first EFSA reasoned opinion on the modification of MRLs for triclopyr.

In accordance with Article 6 of Regulation (EC) No 396/2005, Arysta LifeScience Benelux submitted an application to the competent national authority in Greece (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance triclopyr in kiwi fruits. 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 17 July 2019. EFSA identified a data gap on storage stability and points which needed further clarification, which were addressed by the EMS in a revised evaluation report. To accommodate for the intended use of triclopyr, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.01 to 0.15 mg/kg.

EFSA based its assessment on the revised evaluation report submitted by the EMS (Greece, 2019), 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 the EFSA opinion on the review of existing MRLs (EFSA, 2017).

For this application, the data requirements established in Regulation (EU) No 544/2011 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, 2017; 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.

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.

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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, pymethamif 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. 5–8.
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: http://ec.europa.eu/food/plant/pesticides/ep-pesticides-database/public/?event=pesticide.residue.selection&language=EN
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.
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, are presented in Appendix B.

The revised evaluation report submitted by the EMS (Greece, 2019) 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 in primary crops belonging to the group of fruit crops (apples), root crops (radish) and cereal/grass crops (ryegrass) was investigated after foliar and soil applications in the framework of the EU pesticides peer review and the MRL review (EFSA, 2006, 2017). Triclopyr was the main residue (68% of total radioactive residue (TRR) in the apple pulp, 64–75% of TRR in radish, 47–78% in grass) and was mainly present as free acid. The toxicologically relevant metabolite 3,5,6-TCP was only identified in root crops (radishes, 0.13 mg eq/kg; < 3% TRR).

Based on these studies, EFSA concludes that the metabolism of triclopyr is sufficiently elucidated.

1.1.2. **Nature of residues in rotational crops**

Triclopyr is proposed to be used on a permanent crop. Therefore, no further consideration on the metabolism of triclopyr in rotational crops is required in the context of the present assessment.

Nevertheless, according to the soil degradation studies evaluated in the framework of the peer review, DT90 values of triclopyr and its relevant soil metabolite (3,5,6-TCP) range between 63 and 319 days exceeding the trigger value of 100 days (EFSA, 2006). A rotational crop metabolism study is available. Samples were taken from turnip, lettuce, wheat and green bean crops grown on bare soil treated with radiolabelled triclopyr with a plant back interval of 36 days after treatment (EFSA, 2006, 2017).

1.1.3. **Nature of residues in processed commodities**

The effect of processing on the nature of residues of triclopyr was not investigated. No new information has been submitted with the MRL application (Greece, 2019). Considering, however, that the chronic consumer exposure to triclopyr is not expected to exceed 10% of the ADI (see also Section 3) and that triclopyr residues were found below the trigger value of 0.1 mg/kg in kiwi fruits treated with the active substance (see Section 1.2), there is no need to investigate the effect of industrial and/or household processing for this commodity.

1.1.4. **Methods of analysis in plants**

Analytical methods for the determination of triclopyr residues were assessed during the MRL review (EFSA, 2017). Sufficiently validated methods based on HPLC-MS/MS are available to determine residues of triclopyr in crops belonging to the group of high acid content commodities. The methods allow quantifying residues 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 high water content commodities under frozen conditions was assessed in the framework of the EU pesticides peer review and the MRL review (EFSA, 2006, 2017). A data gap regarding the validation of the method of analysis used in those studies was identified.

Information on the stability of triclopyr residues in frozen samples from high water content (apples) and high acid content (kiwi fruits and mandarins) commodities was submitted with the current application (Greece, 2019). 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 crop under assessment belongs.
1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies on primary crops, the following residue definitions were proposed for plant matrices in the framework of the MRL review (EFSA, 2017).

- residue for risk assessment: triclopyr
- residue definition for enforcement: triclopyr

Residue definitions were not set for rotational crops and processed products.

Taking into account the proposed use on a fruit crop assessed in this application, EFSA concluded that these residue definitions are appropriate 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 results from 11 GAP-compliant field trials on kiwi performed in Southern Europe (SEU) over the growing seasons 2003, 2004 and 2018 (Greece, 2019). Among the 11 submitted trials, two pairs were performed in the same place and with preharvest intervals (PHIs) differing by 1 day in both cases. EFSA considered these trials as not independent and selected the mean residue value per pair of trials in this case. Based on the above the final number of independent residue trials is 9.

Since kiwi fruits are classified as major crops in the SEU, a complete set of eight trials is required to derive an MRL (European Commission, 2017). Therefore, the data available are sufficient to derive an MRL proposal.

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.

It is noted that samples taken in the context of the trials performed in 2018 were also analysed for 3,5,6-TCP. In all samples of the whole fruit, the metabolite was found at or below the LOQ of 0.01 mg/kg (3,5,6-TCP was not quantified in the pulp) (Greece, 2019).

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 assessment, as kiwis are not expected to be grown in rotation with other crops.

1.2.3. Magnitude of residues in processed commodities

There is currently no need to investigate the magnitude of residues in processed kiwi fruits treated with triclopyr (see also Section 1.1.3). Residue data allowing to calculate a peeling factor for kiwi fruits at the intended PHI were submitted (Greece, 2019). The derived 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 the commodity under assessment (see Appendix B.4). In Section 3, EFSA assesses whether residues of triclopyr resulting from the intended use are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as kiwi fruits are not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment for the agreed residue definition for risk assessment using revision 3.1 of the EFSA PRIMO (EFSA, 2018, 2019). 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).

The input values used in the exposure calculations are summarised in Appendix D.1.

Short-term (acute) dietary risk assessment

The short-term risk assessment was performed only with regard to kiwi fruits, being the commodity assessed in the present MRL application. The estimation of the exposure is based on the highest residue (HR) derived from the supervised field trials evaluated in Section 1.2.1, multiplied by the derived peeling factor of 1.

For kiwi fruits, the short-term exposure accounted for 1% of the ARfD.

Long-term (chronic) dietary risk assessment

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed taking into account the existing uses at EU level (EFSA, 2017). EFSA updated the calculation with the supervised trials median residue (STMR) value derived from the residue trials submitted in support of this MRL application for kiwi fruits. The consumer risk assessment was performed considering the residues in the pulp, by applying the derived peeling factor of 1. 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 6% of the ADI (NL toddler). The contribution of residues expected in kiwi fruits is up to the 0.1% of the ADI.

Overall conclusions

Based on the consumer exposure assessment, EFSA concludes that the existing EU uses and the intended uses of triclopyr in kiwi 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. 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 for kiwi fruits.

Based on the consumer exposure assessment, EFSA concludes that the existing EU uses and the intended use of triclopyr in kiwi 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 MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CAC Codex Alimentarius Commission
CAS Chemical Abstract Service
CF conversion factor for enforcement to risk assessment residue definition
CIRCA (EU) Communication & Information Resource Centre Administrator
CS capsule suspension
CV coefficient of variation (relative standard deviation)
DAR draft assessment report
DAT days after treatment
DM dry matter
DP dustable powder
DS powder for dry seed treatment
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 Type(b) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min–max | Interval between application (min) | Application rate per treatment g a.s./hl | Water L/ha min–max | Rate Unit | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|-------------|-----------------------------------|---------------------|------------|------------|-----------------------------------|----------------|------------------------------------|-------------------------------|-----------------|-----------|-------------|--------|
| Kiwi fruits (green, red, yellow) | SEU | F | Increase fruit size and weight | ST | 100 g/kg | Foliar treatment – broadcast spraying | Between 70 and 100 days after full blooming | 1 | n.a. | 800–1,200 | 10 | g a.i./ha | 52 | Fruit size and weight increase |

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. 
(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 pre-harvest 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 | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                       | Apples      | Foliar  | 1 × 650 g a.s./ha | 21             | Radiolabelled active substance: ¹⁴C-triclopyr (EFSA, 2006) |
|                                   |             | Soil, 2 | 1.1 kg a.s./ha   | 14             |                |
| Root crops                        | Radishes    | Foliar  | 1 × 27 g a.s./ha  | 8              |                |
| 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 | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                     | Turnips     | Bare soil | 0.56 kg a.s./ha | 36        | Radiolabelled active substance: ¹⁴C-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 and boiling (60 min, 100°C, pH 5) | Not triggered | – |
|                                          | Sterilisation (20 min, 120°C, pH 6) | Not triggered | – |
|                                          | Other processing conditions | – | – |
Can a general residue definition be proposed for primary crops?
Yes

Rotational crop and primary crop metabolism similar?
Inconclusive (further investigation not needed) (EFSA, 2017)

Residue pattern in processed commodities similar to residue pattern in raw commodities?
Not triggered (EFSA, 2017)

Plant residue definition for monitoring (RD-Mo)
Triclopyr

Plant residue definition for risk assessment (RD-RA)
Triclopyr

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

HPLC–MS/MS (EFSA, 2017):
- Validated in high water (grass forage), high acid (orange, lemons), high oil (sunflower, soybean grain) and dry (rice grain) commodities and in grass straw.
- ILV available for dry and high-water content commodities.
- Method validated for two different mass transitions.
- LOQ: 0.01 mg/kg

HPLC–MS/MS (EFSA, 2017):
- QuEChERS method is fully validated for high water, high acid and dry commodities.
- LOQ: 0.01 mg/kg

B.1.1.2. Storage stability of residues in plants

| Plant products (available studies) | Category                  | Commodity | T (°C) | Stability period | Compounds covered | Comment/ Source |
|------------------------------------|---------------------------|-----------|--------|------------------|-------------------|-----------------|
|                                    |                           |           |        | Value            | Unit              |                 |
| High water content                 | Grass                     | –20       | 48     | Months<sup>(a)</sup> | Parent triclopyr  | EFSA (2006)     |
| High water content                 | Apple                     | –18       | 12     | Months           | Parent triclopyr  | Greece (2019)   |
| Dry/High starch                    | –                         | –         | –      | –                | –                 | Data gap (EFSA, 2017) |
| High acid content                  | Kiwi                      | –18       | 12     | Months           | Parent triclopyr  | Greece (2019)   |
|                                    | Mandarin                  | –18       | 12     | Months           | Parent triclopyr  | Greece (2019)   |

(a): Tentative, validation of the method of analysis used in the study investigating the storage stability of triclopyr in high water content commodities (data gap) (EFSA, 2017).
### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|-----------|-----------------------------|---------------------------------------------------------------|----------------|-----------------------|----------------|----------------|----------|
| Kiwi fruits | SEU | 3 × 0.01; 2 × 0.03; 3 × < 0.05; 0.06 | Residue trials on kiwi fruits compliant with the GAP 3,5,6-TCP: 4 × < 0.01; 0.01 (5 × < 0.01 in the pulp) | 0.15 | 0.06 | 0.03 | – |

<sup>(a)</sup>: 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.

<sup>(b)</sup>: Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

<sup>(c)</sup>: Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

<sup>(d)</sup>: 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 present MRL application is a permanent crop and residues in rotational crops were not investigated |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Not triggered | The present MRL application is a permanent crop and residues in rotational crops were not investigated |

MRL: maximum residue level.

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies(a) | Processing Factor (PF) | CFp(b) | Comment/ Source |
|---------------------|---------------------------|------------------------|--------|-----------------|
| Kiwi fruit, peeled  | 5                         | 0.67, 2 x < 1.0; 2 x 1.0 | 1.0    | Greece (2019)   |

(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 residue trial.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

| ARfD | 0.3 mg/kg bw (European Commission, 2006) |
|------|----------------------------------------|
| Highest IESTI, according to EFSA PRIMo | Kiwi fruits: 1% of ARfD |
| Assumptions made for the calculations | The calculation is performed using PRIMo version 3.1. The short-term exposure assessment focussed on the commodities under assessment (i.e. kiwi fruits) and for which residue trials were available using the highest residue levels expected in the raw agricultural commodities. For kiwi fruits, the highest residue (HR) derived from the supervised field trials was multiplied by the estimated peeling factor of 1 |

| ADI | 0.03 mg/kg bw per day (European Commission, 2006) |
|-----|--------------------------------------------------|
| Highest IEDI, according to EFSA PRIMo | 6% of ADI (NL toddler) |
| Contribution of crops assessed: Kiwi fruits: 0.1% of ADI |
| Assumptions made for the calculations | The calculation is performed using PRIMo version 3.1. It is based on the median residue (STMR) levels derived for the crop under assessment (i.e. kiwi fruits) from the submitted residue trials and in the MRL review (EFSA, 2017). For kiwi fruits, the STMR derived from the supervised field trials was multiplied by the estimated peeling factor of 1. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation |

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; STMR: supervised trials median residue; GAP: Good Agricultural Practice.
### B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity   | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------------------|-------------|-------------------------|-------------------------|------------------------|
| 0162010          | Kiwi fruits | 0.01*                   | 0.15                    | The submitted data are sufficient to derive an MRL proposal for the SEU use. Risk for consumers unlikely |

*: 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.

**Enforcement residue definition:** Triclopyr

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### Triclopyr

**Toxicological reference values**

| ADI (mg/kg bw per day) | ARfD (mg/kg bw) |
|------------------------|-----------------|
| 0.03                   | 0.3             |

**Source of ADI:** EFSA

**Source of ARfD:** EFSA

#### LOQs (mg/kg)

Range from: 0.01 to: 0.30

#### EFSA PRIMo revision 3.1; 2019/03/19

#### Year of evaluation: 2005

#### No of diets exceeding the ADI: ---

### Calculated exposure (% of ADI)

| Commodity/group of commodities | Exposure resulting from | Chronic risk assessment: JMPR methodology (IEDI/TMDI) |
|--------------------------------|-------------------------|-----------------------------------------------------|
|                                | % of ADI                |                                                     |
|                                |                         |                                                     |

### Comments:

PL general

Apples

DK child

Oranges

GEMS/Food G10

GEMS/Food G06

IE adult

GEMS/Food G07

DE adult

GEMS/Food G11

FI general

FR child 3-15 yr

FR infant

ES adult

GEMS/Food G15

ES child

GEMS/Food G08

NL general

FR toddler 2-3 yr

FR toddler 2-3 yr

UK general

FR adult

DE child

IE child

NL toddler

NL child

FR adult

DE women 14-50 yr

SE general

GEMS/Food G11

GEMS/Food G15

GEMS/Food G07

UK infant

NL child

FR child 3-15 yr

UK adult

NL toddler

FR toddler 2-3 yr

### 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.

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**Supplementary results – chronic risk assessment**

**Input values**

**Details – chronic risk assessment**

**Details – acute risk assessment/children**

**Details – acute risk assessment/adults**

**Refined calculation mode**

**No of diets exceeding the ADI:** ---

### Exposure resulting from

| Commodity/group of commodities | Exposure resulting from | Chronic risk assessment: JMPR methodology (IEDI/TMDI) |
|--------------------------------|-------------------------|-----------------------------------------------------|
|                                | % of ADI                |                                                     |
|                                |                         |                                                     |

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**Details – acute risk assessment**

**Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

### Exposure resulting from

| Commodity/group of commodities | Exposure resulting from | Chronic risk assessment: JMPR methodology (IEDI/TMDI) |
|--------------------------------|-------------------------|-----------------------------------------------------|
|                                | % of ADI                |                                                     |
|                                |                         |                                                     |

---

**Conclusion:**

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

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**Modification of the existing maximum residue level for triclopyr in kiwi**

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EFSA Journal 2020;18(7):6191
### Acute risk assessment/children

#### Unprocessed commodities

| Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|-------------|--------------------------|---------------------|-----------------------|-------------|--------------------------|---------------------|
| 4%                    | Oranges     | 0.10/0.1                 | 13                  | 1%                    | Oranges     | 0.10/0.1                 | 3.1                  |
| 3%                    | Grapefruits| 0.10/0.1                 | 7.9                 | 0.6%                  | Mandarin   | 0.10/0.1                 | 1.8                  |
| 2%                    | Pears       | 0.005/0.05               | 6.9                 | 0.6%                  | Grapefruits| 0.10/0.1                 | 1.8                  |
| 2%                    | Mandarin    | 0.10/0.1                 | 5.9                 | 0.5%                  | Pears       | 0.005/0.05               | 1.5                  |
| 2%                    | Apples      | 0.05/0.05                | 5.4                 | 0.5%                  | Apples      | 0.05/0.05                | 1.4                  |
| 2%                    | Peaches     | 0.05/0.05                | 4.8                 | 0.3%                  | Peaches     | 0.05/0.05                | 0.94                 |
| 1%                    | Kiwi fruits (green, red, yellow) | 0.15/0.06 | 3.7 | 0.3% | Lemons | 0.10/0.1 | 0.90 |
| 1%                    | Lemons      | 0.10/0.1                 | 3.4                 | 0.3%                  | Rice        | 0.30/0.1                 | 0.85                 |
| 0.6%                  | Apricots    | 0.05/0.05                | 1.7                 | 0.3%                  | Kiwi fruits (green, red, yellow) | 0.15/0.06 | 0.84 |
| 0.4%                  | Rice        | 0.3/0.1                  | 1.3                 | 0.2%                  | Apricots    | 0.05/0.05                | 0.54                 |
| 0.4%                  | Milk: Cattle| 0.01/0.01               | 1.2                 | 0.1%                  | Milk: Cattle| 0.01/0.01             | 0.39                 |
| 0.1%                  | Bovine: Liver| 0.06/0.05              | 0.40                | 0.09%                 | Bovine: Muscle | 0.06/0.05 | 0.28 |
| 0.1%                  | Bovine: Muscle/meat | 0.06/0.05 | 0.36 | 0.08% | Sheep: Muscle/meat | 0.06/0.05 | 0.24 |
| 0.09%                 | Bovine: Kidney | 0.08/0.07           | 0.26                | 0.07%                 | Bovine: Liver | 0.06/0.05 | 0.20 |
| 0.09%                 | Sheep: Muscle/meat | 0.06/0.05 | 0.27 | 0.06% | Milk: Goat | 0.01/0.01 | 0.18 |

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

### Acute risk assessment/adults/general population

#### Unprocessed commodities

| Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|-------------|--------------------------|---------------------|-----------------------|-------------|--------------------------|---------------------|
| 2%                    | Oranges     | 0.10/0.1                 | 5.3                 | 0.6%                  | Apples      | 0.05/0.05                | 1.3                  |
| 0.9%                  | Apples      | 0.05/0.05                | 2.7                 | 0.5%                  | Oranges     | 0.10/0.1                 | 1.5                  |
| 0.5%                  | Pears       | 0.05/0.05                | 1.6                 | 0.4%                  | Grapefruits| 0.10/0.1                 | 1.1                  |
| 0.4%                  | Peaches/canned | 0.05/0.05 | 1.3 | 0.1% | Peaches/canned | 0.05/0.05 | 0.41 |
| 0.3%                  | Peaches/juice | 0.05/0.05 | 0.83 | 0.1% | Rice/milling (polishing) | 0.30/0.04 | 0.39 |
| 0.2%                  | Rice/milling (polishing) | 0.30/0.04 | 0.61 | 0.06% | Lemons/juice | 0.10/0.1 | 0.19 |
| 0.2%                  | Kiwi fruits/juice | 0.15/0.03 | 0.54 | #NUM! | #NUM! | #NUM! | #NUM! |
| 0.1%                  | Lemons/jam   | 0.1/0.1                  | 0.30                | #NUM! | #NUM! | #NUM! | #NUM! |
| 0.0%                  | Limes/juice  | 0.01/0.01                | 0.00                | #NUM! | #NUM! | #NUM! | #NUM! |
| #NUM!                 | #NUM!       | #NUM!                    | #NUM!               | #NUM! | #NUM! | #NUM! | #NUM! |
| #NUM!                 | #NUM!       | #NUM!                    | #NUM!               | #NUM! | #NUM! | #NUM! | #NUM! |
| #NUM!                 | #NUM!       | #NUM!                    | #NUM!               | #NUM! | #NUM! | #NUM! | #NUM! |
| #NUM!                 | #NUM!       | #NUM!                    | #NUM!               | #NUM! | #NUM! | #NUM! | #NUM! |

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

### Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity. For processed commodities, the exceedance of the ARfD/ADI was identified.
### Appendix D – Input values for the exposure calculations

#### D.1. Consumer risk assessment

| Commodity        | Chronic risk assessment | Acute risk assessment |
|------------------|-------------------------|-----------------------|
|                  | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment                   |
| Kiwi fruits      | 0.03                    | STMR × PF (1)         | 0.06                | HR × PF                   |
| Oranges          | 0.10                    | EU MRL (EFSA, 2017)   |                     |                           |
| Grapefruits      | 0.10                    | EU MRL (EFSA, 2017)   |                     |                           |
| Lemons           | 0.10                    | EU MRL (EFSA, 2017)   |                     |                           |
| Mandarins        | 0.10                    | EU MRL (EFSA, 2017)   |                     |                           |
| Apples           | 0.05                    | STMR (tentative) (EFSA, 2017) | |                          |
| Pears            | 0.05                    | STMR (tentative) (EFSA, 2017) | |                          |
| Apricots         | 0.05                    | STMR (tentative) (EFSA, 2017) | |                          |
| Peaches          | 0.05                    | STMR (tentative) (EFSA, 2017) | |                          |
| Rice grain       | 0.10                    | STMR (tentative) (EFSA, 2017) | |                          |
| Swine meat       | 0.01                    | STMR (LOQ) muscle (EFSA, 2017) | |                          |
| Swine fat        | 0.01                    | STMR (LOQ) (EFSA, 2017) | |                          |
| Swine liver      | 0.01                    | STMR (LOQ) (EFSA, 2017) | |                          |
| Swine kidney     | 0.01                    | STMR (LOQ) (EFSA, 2017) | |                          |
| Ruminant meat    | 0.03                    | STMR muscle (EFSA, 2017) | |                          |
| Ruminant fat     | 0.03                    | STMR (EFSA, 2017)     | |                          |
| Ruminant liver   | 0.03                    | STMR (EFSA, 2017)     | |                          |
| Ruminant kidney  | 0.03                    | STMR (EFSA, 2017)     | |                          |
| Milk             | 0.01                    | STMR (LOQ) (EFSA, 2017) | |                          |

MRL: maximum residue level; STMR: supervised trials median residue; HR: highest residue; PF: processing factor; LOQ: limit of quantification.
# Appendix E – Used compound codes

| Code/trivial name | Chemical name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|-------------------|-----------------------------------------------------|---------------------------------|
| Triclopyr         | [(3,5,6-trichloro-2-pyridyl)oxy]acetic acid Clc1cc(Cl)c(Cl)nc1OCC\(=\)O REEQLXCGVXDSQ\-UHFFFAOYSA\(-N\) | ![Structural formula](image) |
| 3,5,6-Trichloropyridinol (3,5,6-TCP) | 3,5,6-trichloropyridin-2-ol Clc1cc(Cl)c(Cl)nc1O WCYYAQFQZQUEN\-UHFFFAOYSA\(-N\) | ![Structural formula](image) |

<sup>(a)</sup>: ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).

<sup>(b)</sup>: ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).