REASONED OPINION

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Modification of the existing maximum residue levels for dichlorprop-P in citrus fruits

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

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Nufarm España S.A. submitted an application to the competent national authority in Spain to modify the existing maximum residue levels (MRL) for the active substance dichlorprop-P in citrus fruits (except oranges). The data submitted in support of the request were found to be sufficient to derive MRL proposals for all crops under consideration. Adequate analytical methods for enforcement are available to control the residues of dichlorprop-P in citrus fruits. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of dichlorprop-P according to the reported agricultural practices is unlikely to present a risk to consumer health.

Keywords: dichlorprop-P, citrus fruits, pesticide, MRL, consumer risk assessment

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Correspondence: pesticides.mrl@efsa.europa.eu

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Nufarm España S.A. submitted an application to the competent national authority in Spain (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance dichlorprop-P in citrus fruits (except oranges). 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 23 January 2017. To accommodate for the intended uses of dichlorprop-P in the southern Europe (SEU), the EMS proposed to raise the existing MRLs in all citrus fruits, except oranges, from the limit of quantification (LOQ) to 0.3 mg/kg.

EFSA bases its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) (and its addenda) prepared under Directive 91/414/EEC, the Commission review report on dichlorprop-P, the conclusion on the peer review of the pesticide risk assessment of the active substance dichlorprop-P as well as the conclusions from previous EFSA opinions on dichlorprop-P, including the opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (hereafter MRL review).

The metabolism of dichlorprop-P following foliar application was investigated in fruit (oranges) and cereals/grasses (wheat) crop groups. Studies investigating the effect of processing on the nature of dichlorprop-P (hydrolysis studies) have not been performed and are not required as the overall chronic exposure amounts to less than 10% of the acceptable daily intake (ADI).

As the proposed use of dichlorprop-P is on permanent crops, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies and the toxicological significance of metabolites, the residue definitions for fruit crop group and cereals/grasses crop group were proposed under the MRL review as the 'sum of dichlorprop (including dichlorprop-P), its salts, esters and conjugates, expressed as dichlorprop' for enforcement and risk assessment.

EFSA concludes that for citrus fruits assessed in this application, metabolism of dichlorprop-P in primary crops has been sufficiently addressed and that the previously derived residue definitions are applicable.

A sufficiently validated analytical method based on gas chromatography with mass spectrometry (GC–MS) is available to quantify residues in citrus fruits according to the enforcement residue definition. The method enables quantification of total residues at or above 0.02 mg/kg (LOQ).

The available residue data are sufficient to propose a MRL of 0.3 mg/kg for grapefruits, lemons, limes and mandarins, derived from a combined residue data set on oranges and mandarins.

New processing studies to investigate the magnitude of dichlorprop-P residues in processed citrus commodities have not been submitted in the framework of the current application.

Dried citrus pulp may be used for feed purposes, and therefore, a potential carry-over of dichlorprop-P residue into food of animal origin has to be assessed. The MRL review assessed livestock exposure to dichlorprop-P residues from the existing uses and derived tentative MRL proposals for animal commodities based on high intake of residues in cereals and grass. It is noted that approval restrictions of dichlorprop-P according to Regulation (EU) No 1166/2013, which entered into force after the publication of MRL review opinion, envisage a withdrawal of authorisations on grasslands and a modification of use pattern on cereals (lower application rate) by Member States by 9 June 2014. Thus, the dietary burden calculated under MRL review does not anymore reflect the actual livestock exposure to dichlorprop-P residues.

In order to see the potential contribution of residues in citrus dried pulp to the livestock exposure calculated under the MRL review, EFSA recalculated the dietary burden according to OECD guidance including the new residue data on citrus fruits and excluding the contribution of grass from livestock diet. For cereals, considering that fall-back good agricultural practices (GAPs) and residue data compliant with the approval restrictions are not available to EFSA, the same input values as derived during the MRL review were considered as a worst-case scenario. The results of the dietary burden calculation demonstrated that the exposure of all livestock species to dichlorprop-P residues exceeds the trigger values and is driven by residues in cereal by-products. Overall, the livestock exposure has significantly decreased for all livestock species, except for poultry where it now exceeds the trigger value. Therefore, for all animal commodities (except poultry), existing EU MRLs are considered sufficient to account for additional residues that could occur in animal matrices from the intake of dried citrus pulp. For poultry, further investigation on the metabolism and the magnitude of residues in tissues and in eggs is in principle required. Nevertheless, since poultry are not fed with citrus by-products, this is

not considered relevant in the framework of the current application. EFSA acknowledges that the existing MRLs for animal commodities should be reconsidered in the view of approval restrictions. Lacking residue information in cereals according to fall-back GAPs, EFSA is not in the position to derive proper MRLs. This issue will be reconsidered in the framework of the renewal of the active substance approval which is in progress.

The toxicological profile of dichlorprop-P was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.06 mg/kg body weight (b)w per day and an acute reference dose (ARfD) of 0.5 mg/kg bw.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The estimated long-term dietary intake was 2% of the ADI. The short-term exposure did not exceed the ARfD for any crops assessed in this application.

EFSA concludes that the proposed use of dichlorprop-P on citrus fruits will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumer health.

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

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: sum of dichlorprop (including dichlorprop-P), its salts, esters and conjugates, expressed as dichlorprop				
0110010	Grapefruits	0.02*	0.3	The submitted data are sufficient to derive MRL proposals for the SEU uses. No consumer health concern was identified
0110030	Lemons	0.02*	0.3	
0110040	Limes	0.02*	0.3	
0110050	Mandarins	0.02*	0.3	

SEU: Southern Europe; MRL: maximum residue level.
*: 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.

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Background

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

The applicant Nufarm España S.A.[4] submitted an application to the competent national authority in Spain, hereafter referred to as the evaluating Member State (EMS), to modify the existing MRLs for the active substance dichlorprop-P in citrus fruit (except oranges). This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the MRL regulation.

The EMS summarised the data provided by the applicant in an evaluation report which was submitted to the European Commission and forwarded to EFSA on 23 January 2017. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2017-00058 and the following subject:

Dichlorprop-P: Application to modify MRLs in various commodities

Spain proposed to raise the existing MRLs of dichlorprop-P in grapefruit, lemon, lime and mandarin from the limit of quantification (LOQ) (0.02 mg/kg) to 0.3 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

Terms of Reference

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

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

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

The evaluation report submitted by the EMS (Spain, 2016) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

The active substance and its use pattern

The detailed description of the intended southern Europe (SEU) use of dichlorprop-P in citrus fruits, which is the basis for the current MRL application, is reported in Appendix A.

Dichlorprop-P is the ISO common name for (*R*)-2-(2,4-dichlorophenoxy) propionic acid (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

[1] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

[2] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[4] Nufarm España S.A., Balmes 200, 08006, Barcelona, Spain.

Dichlorprop-P was evaluated in the framework of Directive 91/414/EEC with Denmark designated as the rapporteur Member State (RMS) for the representative use as a foliar treatment on cereals/grass crop group. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2006).

Following the peer review a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2006/74/EC[5], which entered into force on 1 June 2007. According to Regulation (EU) No 540/2011[6], dichlorprop-P is deemed to have been approved under Regulation (EC) No 1107/2009. This approval was restricted to uses as herbicide only and included a requirement for the notifier to provide further confirmatory information on livestock metabolism and risk assessment for birds and herbivorous mammals. Confirmatory data were submitted, evaluated by the RMS and a peer review was carried out by EFSA (2012). Considering that a high acute risk for birds and mammals could not be excluded by EFSA, further restrictions to the approval have been established by means of Commission Implementing Regulation (EU) No 1166/2013.[7] These restrictions stipulate that the use on grasslands shall no longer be authorised and that, as regards cereals, only applications in spring shall be authorised at application rates not exceeding 0.8 kg a.s./ha per application. Member States shall amend or withdraw authorisations in line with these restrictions by 9 June 2014 and any period of grace granted by Member States for disposal of stocks shall expire by 9 June 2015 at the latest.

The EU MRLs for dichlorprop-P are established in Annex 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, 2014) and the proposed modifications have been implemented in the MRL legislation.[8] It is noted that at the time of the MRL review the approval restrictions were still not in place. Therefore, the review included authorised uses on grasslands and uses on cereals at dose rates higher than 0.8 kg/ha.

After completion of the MRL review, EFSA has not issued any reasoned opinion on the modification of MRLs for dichlorprop-P.

Assessment

EFSA has based its assessment on the evaluation report submitted by the EMS (Spain, 2016), the DAR (and its addenda) prepared under Directive 91/414/EEC (Denmark, 2005a,b, 2011), the Commission review report on dichlorprop-P (European Commission, 2013), the conclusion on the peer review of the pesticide risk assessment of the active substance dichlorprop-P (EFSA, 2006, 2012), as well as the conclusions from previous EFSA opinions on dichlorprop-P (EFSA, 2011, 2014).

For this application, the data requirements established in Regulation (EU) No 544/2011[9] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a, b, 2016; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.[10]

As the EU pesticides peer review for the renewal of the active substance approval in accordance with Regulation (EC) No 844/2012 is not yet finalised, the conclusions reported in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the peer review.

[5] 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.

[6] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

[7] Commission Implementing Regulation (EU) No 1166/2013 of 18 November 2013 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance dichlorprop-P. OJ L 309, 19.11.2013, p. 22–24.

[8] Commission Regulation (EU) 2015/2075 of 18 November 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for abamectin, desmedipham, dichlorprop-P, haloxyfop-P, oryzalin and phenmedipham in or on certain products. OJ L 302, 19.11.2015, p. 15–50.

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

[10] 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 the MRL review, including the end points of studies submitted in support of the current MRL application, are presented in Appendix B.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of dichlorprop-P following foliar application has been investigated in cereals/grass crop group (wheat) in the framework of the EU pesticides peer review (Denmark, 2005a; EFSA, 2006) and of dichlorprop-P-EHE in the fruit crop group (oranges) in the framework of the previous MRL assessment (EFSA, 2011).

In cereal straw at maturity dichlorprop-P was the major residue (19%); 60% of the total radioactive residue (TRR) in grain was not extractable. Two metabolites (8 and 11) were identified as major metabolites accounting for 14% TRR each, and were further identified as conjugates of dichlorprop-P and dichlorprop-P methylester.

Following foliar application on oranges, dichlorprop-P-EHE undergoes de-esterification forming dichlorprop-P acid. The acid is then rapidly conjugated. At maturity, combined residues of dichlorprop-P-EHE, dichlorprop-P and conjugated dichlorprop-P accounted for a maximum of 53.6–75.6% TRR in orange leaves and 72.1–76.6% of the TRR in fruits.

For the intended use on citrus fruits, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

As the proposed use of dichlorprop-P is on permanent crops, investigations of residues in rotational crops are not required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of dichlorprop-P has not been investigated neither in the framework of the EU pesticides peer review nor MRL review. Nevertheless, investigation on the nature of residues is not required as the overall chronic exposure amounts to less than 10% of the acceptable daily intake (ADI).

1.1.4. Methods of analysis in plants

Analytical methods for the determination of dichlorprop-P residues were assessed during the EU pesticides peer review (Denmark, 2005a; EFSA, 2006) and under the previous MRL assessment (EFSA, 2011).

The method using gas chromatography with mass spectrometry (GC–MS) detection has been considered sufficiently validated for the determination of dichlorprop (including dichlorprop-P), its salts, its esters and its conjugates in plant matrices (for the sum of compounds) with an LOQ of 0.02 mg/kg in dry/high starch content (wheat grain), high acid content (citrus), high water content (wheat green) and high oil content (oil seed rape) commodities. This method involves a hydrolysis of all esters and conjugates to the parent compound and is fully validated (EFSA, 2011, 2014).

The method is sufficiently validated for the determination of residues of dichlorprop-P in the crops under consideration at the LOQ of 0.02 mg/kg.

1.1.5. Stability of residues in plants

The storage stability of dichlorprop-P and dichlorprop-P-EHE in wheat and citrus stored under frozen conditions was investigated in the framework of the EU pesticides peer review and the previous MRL application (EFSA, 2006, 2011).

It was demonstrated that in citrus fruits assessed in the framework of this application, residues are stable for at least 12 months when stored at −18°C.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions were confirmed for fruit crops and cereals/grasses crop groups by the MRL review:

- Residue definition for risk assessment: the sum of dichlorprop (including dichlorprop-P) its salts, esters and conjugates, expressed as dichlorprop.
- Residue definition for enforcement: the sum of dichlorprop (including dichlorprop-P) its salts, esters and conjugates, expressed as dichlorprop.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition.

EFSA concludes that these residue definitions are appropriate for the crops assessed under the current application and no modification of residue definitions is needed.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted residue trials on mandarins. The fruit samples were analysed according to the residue definitions for enforcement and risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. Mandarin samples of these residue trials were stored under conditions (maximum storage of 193 days) for which integrity of the samples has been demonstrated (Spain, 2016). Decline of residues during storage of the trial samples is therefore not expected.

In support of the SEU use, 12 residue trials on mandarins were submitted. Four residue trials were disregarded as incompliant with the intended good agricultural practices (GAP) in terms of a number of applications. The remaining eight trials were conducted in Spain in 2010, 2011 and 2015.

The residue trials provide information on residues in the peel, pulp and/or whole fruit at the preharvest intervals (PHI) of 0, 14–15 and 44–45 days, thus deviating from the PHI of 20 days of the intended GAP. Nevertheless, the trials were considered acceptable as the growth stages at the time of application were consistent with the GAP. The residue values selected for the MRL estimate were those at the PHI of 14–15 days, unless higher at a longer PHI of 44–45 days.

Additionally, the applicant refers to eight residue trials on oranges that have been previously assessed by EFSA for identical GAP[11] (EFSA, 2014) and proposes to combine these data with the new residue trials on mandarins and to extrapolate the combined residue data to the whole group of citrus fruits. In accordance with the EU extrapolation rules (European Commission, 2016), such an extrapolation is acceptable and the number and quality of the trials are sufficient to derive a MRL proposal of 0.3 mg/kg for the whole group of citrus fruits.

1.2.2. Magnitude of residues in rotational crops

Not relevant for the current MRL application.

1.2.3. Magnitude of residues in processed commodities

New processing studies to investigate the magnitude of dichlorprop-P residues in processed citrus commodities have not been submitted in the framework of the current application. From five residue trials on mandarins a peeling factor of 0.42 could be derived, indicating that peeling reduces residues in the edible part of the crop. The peeling factor, however, is not proposed for risk assessment as the MRL proposal is based on a combined residue data set on oranges and mandarins.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for grapefruits, mandarins, lemons and limes (see Appendix B.1.2.1). In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

[11] An MRL of 0.3 mg/kg was proposed for oranges (EFSA, 2014).

2. Residues in livestock

Dried citrus pulp may be used for feed purposes and therefore a potential carry-over of dichlorprop-P residues into food of animal origin has to be assessed.

The MRL review according to Article 12 of Regulation (EC) No 396/2005 assessed livestock exposure to dichlorprop-P residues from the intake of orange wet pomace, apple wet pomace, cereal grain, bran and straw and grass (forage and silage), using the former agreed European methodology (European Commission, 1997e). It is, however, noted that at the time of the review, MRL proposals for cereals and grass were based on authorisations not compliant with approval restrictions laid down in Regulation (EU) No 1166/2013 (see also Section on The active substance and its use pattern).

In order to see the potential contribution of residues in citrus dried pulp to the livestock exposure calculated under MRL review, EFSA recalculated the dietary burden according to OECD guidance (OECD, 2013) including the new residue data on citrus fruits and excluding the contribution of grass from livestock diet, as currently no uses shall be still authorised in Europe. For cereals, considering that fall-back GAPs and residue data compliant with the approval restrictions are not available to EFSA, the same input values as derived during the MRL review were considered as a worst case scenario. The input values for the exposure calculations for livestock are presented in Appendix C.

The results of the dietary burden calculation are presented in Appendix B.2 and demonstrate that the exposure of all livestock species to dichlorprop-P residues exceed the trigger values and are driven by residues in cereal by-products. Overall, by excluding grass from the livestock diet and using the OECD methodology, the livestock exposure has significantly decreased for all livestock species, except for poultry where it now exceeds the trigger value. Therefore, for all animal commodities (except poultry) existing EU MRLs are currently considered sufficient to account for additional residues that could occur in animal matrices from the intake of dried citrus pulp. For poultry, further investigation on the metabolism and the magnitude of residues in tissues and in eggs is in principle required. Nevertheless, since poultry are not fed with citrus by-products this is not considered relevant in the framework of the present application.

EFSA acknowledges that the existing MRLs for animal commodities should be reconsidered in the view of approval restrictions. However, as long as cereal by-products are main contributors in all livestock diets and fall-back GAPs for cereals compliant with the approval conditions are not available, EFSA is not in the position to derive proper MRLs. Nevertheless, it is noted that livestock exposure to dichlorprop-P residues will be reassessed in the framework of the renewal of the active substance approval which is in progress.

3. Consumer risk assessment

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

The toxicological reference values for dichlorprop-P used in the risk assessment (i.e. ADI and acute reference dose (ARfD) values) were derived in the framework of the EU pesticides peer review (EFSA, 2006).

3.1. Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed only for citrus fruits in accordance with the internationally agreed methodology (FAO, 2016). The calculations were based on the highest residue (HR) value derived from supervised field trials and the complete list of input values can be found in Appendix D.2.

The short-term exposure did not exceed the ARfD for any crop assessed in this application (see Appendix B.3).

3.2. 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, 2014). EFSA updated the calculation with the relevant supervised trials median residue (STMR) values derived from the residue trials submitted in support of this MRL application for grapefruits, lemons, limes and mandarins. The input values used in the exposure calculations are summarised in Appendix D.2.

The estimated long-term dietary intake was 2% of the ADI. The contribution of residues expected in citrus fruits to the overall long-term exposure is presented in more detail in Appendix B.3.

EFSA concluded that the long-term intake of residues of dichlorprop-P resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

Conclusions and recommendations

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for all crops under consideration.

Adequate analytical methods for enforcement are available to control the residues of dichlorprop-P in citrus fruits under consideration.

Based on the risk assessment results, EFSA concluded that the short-term and long-term intakes of citrus fruit containing residues resulting from the use of dichlorprop-P according to the reported agricultural practice are unlikely to present a risk to consumer 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
CF	conversion factor for enforcement to risk assessment residue definition
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
EC	emulsifiable concentrate
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC–MS	gas chromatography with mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe
STMR	supervised trials median residue
TRR	total radioactive residue

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.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	g a.s./ha min–max		
Citrus fruits (grapefruits, oranges, lemons, limes and mandarins)	SEU (Spain)	F	Used as a plant growth regulator (1st appl. to increase fruit size and 2nd appl. to prevent fruit drop)	EC	25 g/L	Spray (atomiser)	BBCH 73 BBCH 81	1–2	Determined by growth stage	3.75 2.5	1,500–2,000	56.3–75 37.5–50	20	The same GAP but limited to oranges only assessed under Article 12 MRL review (EFSA, 2014) and in Article 10 assessment (EFSA, 2011)

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; MS: Member State; EC: emulsifiable concentrate; a.s.: active substance.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	**Crop groups**	**Crops**	**Applications**	**Sampling**
	Fruit crops	Orange	Foliar; 2 × 7.66 mg/tree (BBCH 71-73 and BBCH 81)	0, 30, 159 DAT; 0, 46 DALA
	Root crops	–	–	–
	Leafy crops	–	–	–
	Cereals/grass	Wheat	Foliar; 1 × 750 g/ha (BBCH 31)	0, 28, 89 DAT
	Pulses/oilseeds	–	–	–
	Miscellaneous	–	–	–
	Wheat: U-^{14}C- phenyl dichlorprop-P Oranges: U-^{14}C-phenyl dichlorprop-P-2-EHE (EFSA, 2006, 2011)			
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**
	Root/tuber crops	–	–	–
	Leafy crops	–	–	–
	Cereal (small grain)	–	–	–
	other	–	–	–
	Not relevant for the current application			
Processed commodities (hydrolysis study)	**Conditions**		**Investigated?**	
	Pasteurisation (20 min, 90°C, pH 4)		No	
	Baking, brewing and boiling (60 min, 100°C, pH 5)		No	
	Sterilisation (20 min, 120°C, pH 6)		No	
	Not available but not required for the current application (chronic exposure lower than 10% ADI)			

BBCH: growth stages of mono- and dicotyledonous plants; DAT: days after treatment; DALA: days after last application; PBI: plant back interval; ADI: acceptable daily intake.

Can a general residue definition be proposed for primary crops?	No
Rotational crop and primary crop metabolism similar?	Not considered under current assessment
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Inconclusive but not relevant for the current application
Plant residue definition for monitoring (RD-Mo)	The sum of dichlorprop (including dichlorprop-P), its salts, esters and conjugates, expressed as dichlorprop (fruit and cereal/grass crop groups only)
Plant residue definition for risk assessment (RD-RA)	The sum of dichlorprop (including dichlorprop-P), its salts, esters and conjugates, expressed as dichlorprop (fruit and cereal/grass crop groups only)
Conversion factor (monitoring to risk assessment)	Not applicable
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content, high oil content, high acid content and dry/high starch content matrices: GC-MS, LOQ 0.02 mg/kg. ILV available (EFSA, 2014)

GC–MS: gas chromatography with mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability (months/years)**
	High water content	Cereal forage	−18	18
	Dry/high starch	Cereal grain	−18	18
	High acid content	Citrus	−18	12
	In citrus, the stability was investigated on dichlorprop-P-EHE (EFSA, 2014)			

B.1.2. Magnitude of residues in plants

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

Crop (supervised trials)	Region/ indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo}[b] (mg/kg)	$STMR_{Mo}$[c] (mg/kg)	CF[d]
Mandarins	SEU	0.06[e]; 0.06[e];0.06; 0.07; 0.08[e]; 0.08[e]; 0.12[e]; 0.17 Pulp: 0.02[e]; 0.03[e]; –; –; 0.03[e];0.05[e]; 0.05[e]; –	Residue populations on mandarins and oranges similar according to *U*-test and were combined to derive MRL proposal which is **extrapolated to mandarins, grapefruits, limes and lemons**	**0.3**	0.17 (pulp: 0.05)	0.08 (pulp: 0.03)	1
Oranges	SEU	0.05; 2 × 0.06; 0.07[e]; 0.08[e]; 0.10[e]; 0.11; 0.15 (EFSA, 2011, 2014)					

OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue according to the residue definition for monitoring.
(c): Supervised trials median residue according to the residue definition for monitoring.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(e): Residues higher at a longer PHI of 44–45 days.

B.1.2.2. Residues in succeeding crops

Not relevant for the current MRL application.

B.1.2.3. Processing factors

New processing studies on citrus fruits have not been submitted. Residue trial samples were analysed for residues in pulp, allowing to derive a peeling factor of 0.42 for mandarins, which cannot be applied for risk assessment purposes as the MRL for mandarins is based on a combined residue data set on mandarins and oranges.

B.2. Residues in livestock

Relevant groups	Dietary burden expressed in			Trigger exceeded (Y/N)	Most critical commodity[a]	Previous assessment maximum burdens[g] (mg/kg DM) (EFSA, 2014)
	mg/kg bw per day		mg/kg DM			
	Median	Maximum	Maximum			
Cattle (all diets)	0.009	0.094	2.44[b]	Y	Barley straw	44[f]
Cattle (dairy only)	0.009	0.094	2.44	Y	Barley straw	43
Sheep (all diets)	0.01	0.197	4.64[c]	Y	Barley straw	n.c.
Sheep (ewe only)	0.01	0.197	4.64	Y	Barley straw	n.c.
Swine (all diets)	0.007	0.007	0.23[d]	Y	Barley straw	6.6
Poultry (all diets)	0.009	0.06	0.87[e]	Y	Wheat milled by-products	0.07
Poultry (layer only)	0.009	0.06	0.87	Y	Wheat straw	

n.c.: not calculated; bw: body weight; DM: dry matter.
(a): Calculated for the maximum dietary burden.
(b): The highest dietary burdens expressed in mg/kg (dry matter) DM result from dairy cattle diet.
(c): The highest dietary burdens expressed in mg/kg DM result from ram/ewe diet.
(d): The highest dietary burdens expressed in mg/kg DM result from finishing pig diet.
(e): The highest dietary burdens expressed in mg/kg DM result from layer poultry diet.
(f): The highest dietary burdens expressed in mg/kg DM result from beef cattle.
(g): Based on more critical registered uses in Europe (EFSA, 2014) than permitted according to approval restrictions in Regulation (EU) No 1166/2013.

B.2.1. Nature of residues and methods of analysis in livestock

Not considered in the framework of the MRL application.

B.2.2. Magnitude of residues in livestock

Not considered in the framework of the MRL application.

B.3. Consumer risk assessment

ARfD	0.5 mg/kg bw (EFSA, 2006)
Highest IESTI, according to EFSA PRIMo	Oranges: 4% of ARfD Grapefruit: 3% of ARfD
Assumptions made for the calculations	The calculation is based on the highest residue levels expected in raw agricultural commodities

ADI	0.06 mg/kg bw per day (EFSA, 2006)
Highest IEDI, according to EFSA PRIMo	2% ADI (NL child diet) Contribution of crops assessed: Grapefruit: 0.09% of ADI Oranges: 0.5% of ADI Lemons: 0.04% of ADI Limes: 0.02% of ADI Mandarins: 0.1% of ADI
Assumptions made for the calculations	The calculation is based on the median residue levels derived for raw agricultural commodities. The contributions of commodities where no GAP was reported in the framework of Article 12 MRL review were not included in the calculation

ARfD: acute reference dose; IESTI: international estimated short-term intake; PRIMo: Pesticide Residues Intake Model; bw: body weight; ADI: acceptable daily intake; IEDI: international estimated daily intake.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: sum of dichlorprop (including dichlorprop-P), its salts, esters and conjugates, expressed as dichlorprop				
0110010	Grapefruits	0.02*	0.3	The submitted data are sufficient to derive MRL proposals for the SEU uses. No consumer health concern was identified
0110030	Lemons	0.02*	0.3	
0110040	Limes	0.02*	0.3	
0110050	Mandarins	0.02*	0.3	

SEU: southern Europe; MRL: maximum residue level.
*: 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.

Appendix C – Pesticide Residue Intake Model (PRIMo)

Dichlorprop-P			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.06**	ARfD (mg/kg bw):	**0.5**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2005**	Year of evaluation:	**2005**

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	0 2
No. of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
2	NL child	0.5	Milk and cream	0.4	Oranges	0.4	Wheat	
2	DE child	0.5	Oranges	0.4	Apples	0.3	Wheat	
1	FR toddler	0.7	Milk and cream	0.3	Oranges	0.2	Wheat	
1	WHO cluster diet B	0.7	Wheat	0.1	Oranges	0.1	Bovine: Edible offal	
1	DK child	0.5	Wheat	0.4	Rye	0.2	Milk and cream	
1	UK infant	0.6	Milk and cream	0.2	Wheat	0.2	Oranges	
1	ES child	0.4	Wheat	0.3	Oranges	0.2	Milk and cream	
1	UK toddler	0.3	Milk and cream	0.3	Wheat	0.3	Oranges	
1	WHO cluster diet D	0.5	Wheat	0.1	Milk and cream	0.1	Bovine: Edible offal	
1	IE adult	0.2	Wheat	0.1	Oranges	0.1	Barley	
1	WHO cluster diet F	0.3	Wheat	0.1	Oranges	0.1	Milk and cream	
1	FR infant	0.4	Milk and cream	0.1	Oranges	0.1	Apples	
1	WHO cluster diet E	0.3	Wheat	0.1	Barley	0.1	Oranges	
1	SE general population 90th percentile	0.3	Wheat	0.2	Milk and cream	0.1	Oranges	
1	IT kids/toddler	0.6	Wheat	0.1	Oranges	0.0	Apples	
1	NL general	0.2	Oranges	0.2	Wheat	0.1	Milk and cream	
1	WHO regional European diet	0.2	Wheat	0.1	Milk and cream	0.1	Bovine: Edible offal	
1	ES adult	0.2	Wheat	0.2	Oranges	0.1	Milk and cream	
0	FR all population	0.3	Wheat	0.0	Milk and cream	0.0	Bovine: Edible offal	
0	PT general population	0.3	Wheat	0.1	Oranges	0.0	Apples	
0	IT adult	0.3	Wheat	0.0	Oranges	0.0	Apples	
0	DK adult	0.2	Wheat	0.1	Milk and cream	0.1	Rye	
0	FI adult	0.1	Oranges	0.1	Milk and cream	0.1	Wheat	
0	UK vegetarian	0.2	Wheat	0.1	Oranges	0.1	Milk and cream	
0	LT adult	0.1	Rye	0.1	Wheat	0.1	Milk and cream	
0	UK Adult	0.1	Wheat	0.1	Oranges	0.0	Milk and cream	
0	PL general population	0.1	Apples	0.0	Pears	0.0	Lemons	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Dichlorprop-P is unlikely to present a public health concern.

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.
In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
4	Oranges	0.15 / -	3.0	Grapefruit	0.17 / -	0.8	Oranges	0.15 / -	0.6	Oranges	0.15 / -
3	Grapefruit	0.17 / -	2.9	Oranges	0.15 / -	0.7	Grapefruit	0.17 / -	0.5	Grapefruit	0.17 / -
2	Mandarins	0.17 / -	1.4	Mandarins	0.17 / -	0.5	Mandarins	0.17 / -	0.4	Mandarins	0.17 / -
1	Lemons	0.17 / -	0.9	Lemons	0.17 / -	0.2	Lemons	0.17 / -	0.2	Lemons	0.17 / -
1	Limes	0.17 / -	0.5	Limes	0.17 / -	0.2	Limes	0.17 / -	0.2	Limes	0.17 / -
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
		***)				***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL
***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:
For Dichlorprop-P IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of dichlorprop (including dichlorprop-P), its salts, esters and conjugates, expressed as dichlorprop				
Citrus dried pulp	0.8	STMR × PF[(a)]	0.8	STMR × PF[(a)]
Apple pomace	0.1	STMR × PF[(a)] (EFSA, 2014)	0.1	STMR × PF[(a)] (EFSA, 2014)
Wheat, barley, oat, rye, triticale grain	0.05	STMR (EFSA, 2014)	0.05	STMR (EFSA, 2014)
Wheat, barley, oat, rye, triticale straw	0.08	STMR (EFSA, 2014)	6.64	HR (EFSA, 2014)
Brewers grain (dried); distiller's grain (dried)	0.17	STMR grain (EFSA, 2014) × PF[(a)]	0.17	STMR grain (EFSA, 2014) × PF[(a)]
Wheat gluten meal	0.09	STMR grain (EFSA, 2014) × PF[(a)]	0.09	STMR grain (EFSA, 2014) × PF[(a)]
Wheat milled by-products	0.35	STMR grain (EFSA, 2014) × PF[(a)]	0.35	STMR grain (EFSA, 2014) × PF[(a)]

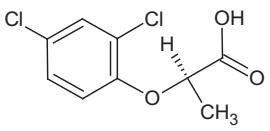
(a): STMR: supervised trials median residue; HR: highest residue; PF: processing factor. For dried citrus pulp, apple pomace, brewer's grain(dried)/distiller's grain (dried), wheat gluten meal and wheat milled by-products in the absence of processing factors supported by data, default processing factors of 10, 5, 3.3, 1.8 and 7 were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.

D.2. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition plant commodities: sum of dichlorprop (including dichlorprop-P), its salts, esters and conjugates, expressed as dichlorprop				
Grapefruits, mandarins, lemons, limes	0.08	STMR	0.17	HR
Oranges	0.08	STMR (EFSA, 2014)	0.15	HR (EFSA, 2014)
Apples, pears, cherries, plums, barley, oats, rye, wheat	STMR	EFSA (2014)	Calculated only for commodities under consideration in the MRL application	
Risk assessment residue definition animal commodities: sum of dichlorprop (including dichlorprop-P), its salts, expressed as dichlorprop				
Meat, fat, liver and kidney of swine and ruminants, milk	STMR	EFSA (2014)	Calculated only for commodities under consideration in the MRL application	

STMR: supervised trials median residue; HR: highest residue.

Appendix E – Used compound codes

Code/trivial name	Chemical name/SMILES notation	Structural formula
Dichlorprop-P	(2*R*)-2-(2,4-dichlorophenoxy)propionic acid Clc1cc(Cl)ccc1O[C@H](C)C(=O)O	
dichlorprop-P-2-ethylhexyl dichlorprop-P-2-EHE dichlorprop-P-EHE	(2*RS*)-2-ethylhexyl (2*R*)-2-(2,4-dichlorophenoxy)propionate Clc1cc(Cl)ccc1O[C@H](C)C(=O)OCC(CC)CCCC