

## CONCLUSION ON PESTICIDES PEER REVIEW

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### Peer review of the pesticide risk assessment of the active substance dichlorprop-P and variant dichlorprop-P-2-ethylhexyl

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#### Abstract

The conclusions of EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State Ireland and co-rapporteur Member State Poland for the pesticide active substance dichlorprop-P and the variant dichlorprop-P-2-ethylhexyl and the assessment of applications for maximum residue levels (MRLs) are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012. The conclusions were reached on the basis of the evaluation of the representative uses of dichlorprop-P as a herbicide on cereals, grassland and grass seed crops and of the variant dichlorprop-P-2-ethylhexyl as a plant growth regulator on citrus. MRLs were assessed in mandarin and lemon. The reliable end points, appropriate for use in regulatory risk assessment and the proposed MRLs, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

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## Summary

Commission Implementing Regulation (EU) No 844/2012 (hereinafter referred to as 'the Regulation') lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012. Dichlorprop-P is one of the active substances listed in Regulation (EU) No 686/2012.

In accordance with Article 1 of the Regulation, the rapporteur Member State (RMS), Ireland, and co-rapporteur Member State (co-RMS), Poland, received an application from Nufarm UK Limited for the renewal of approval of the active substance dichlorprop-P. In addition, Nufarm UK Limited submitted applications for maximum residue levels (MRLs), as referred to in Article 7 of Regulation (EC) No 396/2005. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Poland), the European Commission and the European Food Safety Authority (EFSA) about the admissibility.

The RMS provided its initial evaluation of the dossier on dichlorprop-P and the variant dichlorprop-P-2-ethylhexyl in the renewal assessment report (RAR), which was received by EFSA on 16 March 2017. The RAR included a proposal to set MRLs, submitted under Article 7 of Regulation (EC) No 396/2005. In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Nufarm UK Limited, for comments on 28 April 2017. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 29 June 2017.

Following consideration of the comments received on the RAR, it was concluded that additional information should be requested from the applicant and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour and ecotoxicology.

In accordance with Article 13(1) of the Regulation, EFSA should adopt a conclusion on whether dichlorprop-P can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council and give a reasoned opinion concerning MRL applications as referred to in Article 10(1) of Regulation (EC) No 396/2005.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of dichlorprop-P as a herbicide on cereals, grassland and grass seed crops and of dichlorprop-P-2-ethylhexyl as a plant growth regulator on citrus, as proposed by the applicant. MRLs were assessed in mandarin and lemon. Full details of the representative uses and the proposed MRLs can be found in Appendix A of this report.

The use of dichlorprop-P according to the representative uses proposed at the European Union (EU) level results in a sufficient herbicidal efficacy against the target weeds. The use of dichlorprop-P-2-ethylhexyl according to the representative uses proposed at the EU level results in a sufficient plant growth regulator efficacy.

In the area of identity, physical/chemical properties and analytical methods, data gaps were identified for experimental determination of the partition coefficient *n*-octanol/water of 2,4-dichlorophenol and for determination of the emulsion characteristics of 'CA2134' using CIPAC MT 36.3.

In the area of mammalian toxicology and non-dietary exposure, the interim criteria for endocrine disruption are not met; however, further assessment of available information is needed to conclude on the endocrine potential of dichlorprop-P. A data gap is identified for an updated literature search on published epidemiological studies on phenoxyherbicides including dichlorprop-P and dichlorprop. A risk for bystander/residents is identified for representative uses in cereals, grassland and grass seed crops but not in citrus according to the EFSA guidance on non-dietary exposure.

In the area of residue, data gaps were identified for a metabolism study in poultry, a sufficient number of field trials for cereals, grass and citrus, a study addressing the nature of the residues of dichlorprop-P-2-ethylhexyl at processing and representative of the standard hydrolysis conditions and data on residues in pollen and bee products for human consumption. Consequently, the consumer risk assessment could not be finalised and no MRL can be derived.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level for the representative uses, with the notable exception that information is missing regarding the effect of water treatment processes on the nature of the residues of the dichlorprop metabolites 2,4-dichlorophenol and 2,4-dichloroanisole that might be present in surface water, when surface water is abstracted for drinking water. Consequently, the consumer risk assessment from the consumption of drinking water could not be finalised. The potential

for groundwater exposure above the parametric drinking water limit of 0.1 µg/L consequent to the uses assessed, was assessed as low for dichlorprop-P-2-ethylhexyl, dichlorprop isomers and their soil metabolites 2,4-dichlorophenol and 2,4-dichloroanisole identified as triggering a groundwater exposure assessment, in geoclimatic situations represented by all nine FOCUS groundwater scenarios.

Several data gaps were identified in the section for ecotoxicology in relation to the risk assessments for aquatic organisms, bees and soil organisms.

## Table of contents

Abstract.....	1
Summary.....	3
Background .....	6
The active substance and the formulated product.....	7
Conclusions of the evaluation .....	7
1. Identity, physical/chemical/technical properties and methods of analysis .....	7
2. Mammalian toxicity.....	8
3. Residues.....	11
3.1. Representative use residues.....	11
3.2. Maximum residue levels .....	12
4. Environmental fate and behaviour .....	12
5. Ecotoxicology .....	13
6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 1–4) .....	15
7. Data gaps.....	17
8. Particular conditions proposed to be taken into account to manage the risk(s) identified .....	18
9. Concerns .....	18
9.1. Concerns for the representative uses evaluated .....	18
9.1.1. Issues that could not be finalised .....	18
9.1.2. Critical areas of concern.....	19
9.1.3. Overview of the concerns identified for each representative use considered.....	19
References.....	21
Abbreviations.....	22
Appendix A – List of end points for the active substance and the representative formulation.....	24
Appendix B – Used compound codes .....	25

## Background

Commission Implementing Regulation (EU) No 844/2012<sup>1</sup> (hereinafter referred to as 'the Regulation') lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009.<sup>2</sup> This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of an additional 3 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3).

In accordance with Article 1 of the Regulation, the RMS Ireland and co-RMS Poland received an application from Nufarm UK Limited for the renewal of approval of the active substance dichlorprop-P. In addition, Nufarm UK Limited submitted applications for maximum residue levels (MRLs) as referred to in Article 7 of Regulation (EC) No 396/2005<sup>3</sup>. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Poland), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on dichlorprop-P and the variant dichlorprop-P-2-ethylhexyl in the RAR, which was received by EFSA on 16 March 2017 (Ireland, 2017). The RAR included a proposal to set MRLs, submitted under Article 7 of Regulation (EC) No 396/2005.

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Nufarm UK Limited, for consultation and comments on 28 April 2017. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 29 June 2017. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA, the RMS and co-RMS on 27 September 2017. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour and ecotoxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments, is reflected in the conclusions set out in column 4 of the reporting table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

A final consultation on the conclusions arising from the peer review of the risk assessment and on the proposed MRLs took place with Member States via a written procedure in April 2018.

<sup>1</sup> Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, p. 26–32.

<sup>2</sup> Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council 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.

<sup>3</sup> Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.



This conclusion report summarises the outcome of the peer review of the risk assessment of the active substances and the representative formulations, evaluated on the basis of the representative uses of dichlorprop-P as a herbicide on cereals, grassland and grass seed crops and of dichlorprop-P-2-ethylhexyl as a plant growth regulator on citrus, as proposed by the applicant. MRLs were assessed in mandarin and lemon. A list of the relevant end points for the active substance and the formulation and the proposed MRLs is provided in Appendix A.

In addition, a key supporting document to this conclusion is the peer review report (EFSA, 2018), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the reporting table (3 October 2017);
- the evaluation table (14 May 2018);
- the report(s) of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (Ireland, 2018), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the European Union (EU) for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

## The active substance and the formulated product

Dichlorprop-P is the ISO common name for (2*R*)-2-(2,4-dichlorophenoxy)propionic acid (IUPAC). Dichlorprop-P-2-ethylhexyl (dichlorprop-P 2-EHE) is the modified ISO common name for (2*RS*)-2-ethylhexyl (2*R*)-2-(2,4-dichlorophenoxy)propionate (IUPAC), a variant of dichlorprop-P.

The representative formulated products for the evaluation were 'Dichlorprop-P K 600 SL' a soluble concentrate (SL) containing 600 g/L dichlorprop-P as potassium salt and 'CA2134' an emulsifiable concentrate (EC) containing 25 g/L dichlorprop-P as dichlorprop-P-2-ethylhexyl.

The representative uses evaluated were: for 'Dichlorprop-P K 600 SL' conventional field spray against broad leaves weeds in winter and spring cereals (such as wheat, barley, rye, oats and triticale), permanent and rotational grassland and grass seed crops; for 'Dichlorprop-P EHE 25' high-volume spray as a plant growth regulator (to increase fruit size and to prevent plant drop) on citrus (such as oranges, mandarins and lemons). Full details of the representative uses can be found in the list of end points in Appendix A.

Data were submitted to conclude that the representative uses of dichlorprop-P and dichlorprop-P-2-ethylhexyl proposed at the EU level result in a sufficient herbicidal efficacy against the target weeds and a sufficient plant growth regulator efficacy following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014b).

## Conclusions of the evaluation

### 1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: SANCO/3029/99-rev. 4 (European Commission, 2000a), SANCO/3030/99-rev. 4 (European Commission, 2000b) and SANCO/825/00-rev. 8.1 (European Commission, 2010).

It should be noted that data for both dichlorprop-P and dichlorprop-P-2-ethylhexyl were submitted and assessed.

The proposed specification for dichlorprop-P is based on batch data from industrial scale production and quality control data. The proposed minimum purity of the technical material is 920 g/kg. 2,4-Dichlorophenol (2,4-DCP) is considered a relevant impurity with a maximum content of 5 g/kg. Polychlorinated dibenzo-*p*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) are also

considered relevant, expressed as a sum of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) toxic equivalents (TEQs) at a maximum content of 0.01 mg/kg. It is proposed the reference specification to be updated based on the data for renewal since higher minimum purity of the active substance could be set and new impurities should be included. There is no FAO specification available for dichlorprop-P. The batches used in the (eco)toxicological assessment support the proposed specification (see Sections 2 and 5).

The proposed specification for the variant dichlorprop-P-2-ethylhexyl is based on batch data from industrial scale production. The proposed minimum purity of the technical material is 920 g/kg. 2,4-DCP is considered a relevant impurity with a maximum content of 3 g/kg. PCDDs and PCDFs are also considered relevant, expressed as a sum of TCDD TEQs at a maximum content of 0.01 mg/kg. The batches used in the (eco)toxicological assessment support the proposed specification (see Sections 2 and 5).

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of dichlorprop-P or the representative formulation. However, data gaps were identified for the experimental determination of the partition coefficient *n*-octanol/water of 2,4-DCP and for the determination of the emulsion characteristics of 'CA2134' using CIPAC MT 36.3. The main data regarding the identity of dichlorprop-P and its physical and chemical properties are given in Appendix A.

Adequate methods are available for the generation of pre-approval data required for the risk assessment. Methods of analysis are available for the determination of the active substance in the technical material and in the representative formulation and for the determination of the respective impurities in the technical material. A CIPAC method is proposed for determination of 2,4-DCP in the representative formulations. Since dioxins and furans are considered as relevant impurities, analytical methods for their determination in the representative formulations are required. However, based on the very low levels demonstrated in the technical material and considering that these impurities cannot be formed during the storage, EFSA is of the opinion that a method for their determination in the formulations should not be requested.

A common residue definition for dichlorprop-P and dichlorprop-P-2-ethylhexyl in all matrices was defined and therefore post-approval monitoring methods are applicable for both substances.

Residues of dichlorprop (including dichlorprop-P), its salts, esters and conjugates can be monitored as a total phenoxy acid present in food and feed of plant origin by liquid chromatography with tandem mass spectrometry (LC-MS/MS) with a limit of quantification (LOQ) of 0.01 mg/kg in all commodity groups. Components of residue definition (dichlorprop (including dichlorprop-P), its salts, esters and conjugates expressed as dichlorprop) in food of animal origin can also be determined as a total phenoxy acid present by LC-MS/MS with LOQ of 0.01 mg/kg in all animal matrices.

Residues of dichlorprop (including dichlorprop-P) and its salts can be monitored as a total phenoxy acid present in water, soil and air by LC-MS/MS with LOQs of 0.01 µg/L, 0.01 mg/kg and 0.278 µg/m<sup>3</sup>, respectively. The LC-MS/MS method exists for monitoring of 2,4-DCP residue in soil with LOQ of 0.05 mg/kg. Although 2,4-DCP is not included in the residue definition for monitoring in water it should be noted that LC-MS/MS method with a LOQ of 0.1 µg/L is available.

The LC-MS/MS method can be used for monitoring of dichlorprop (including dichlorprop-P), its salts, esters and conjugates residues in body fluids with a LOQ of 0.05 mg/L. Dichlorprop (including dichlorprop-P), its salts, esters and conjugates residues in body tissues can be determined by using the monitoring methods for residue in food of animal origin.

## 2. Mammalian toxicity

The toxicological profile of the active substance dichlorprop-P was discussed at the Pesticides Peer Review Experts' Teleconferences TC 164 and TC 176 and assessed based on the following guidance documents: SANCO/221/2000-rev. 10-final (European Commission, 2003), SANCO/10597/2003-rev. 10.1 (European Commission, 2012), guidance on dermal absorption (EFSA PPR Panel, 2012), guidance on non-dietary exposure (EFSA, 2014a) and guidance on the application of the CLP Criteria (ECHA, 2015).

To assess the toxicological profile of the **active substance** dichlorprop-P, the applicant submitted a set of valid toxicity studies. Although most toxicity studies were performed with dichlorprop-P some studies were available with dichlorprop and dichlorprop-P 2-EHE. For risk assessment purposes bridging between dichlorprop, dichlorprop-P and dichlorprop-P 2-EHE was considered appropriate. Considering the toxicological profile of dichlorprop-P and the identity of impurities, the proposed (old and new) technical specifications for both dichlorprop-P and its ester dichlorprop-P 2-EHE are considered covered by the toxicity studies. 2,4-DCP is a relevant impurity in both dichlorprop-P and its



ester dichlorprop-P 2-EHE (5 g/kg and 3 g/kg, respectively, as maximum content is acceptable from toxicological point of view). Dioxins and furans are considered as relevant impurities in dichlorprop-P and its ester since they could be (theoretical/potentially) formed in other sources (maximum content of 0.01 mg/kg).

Dichlorprop-P and its ester are extensively and rapidly absorbed after oral administration in rats (> 87% based on urinary excretion). Metabolic patterns in the different species were similar. No unique human metabolite is expected.

In the acute toxicity studies, dichlorprop-P has moderate acute toxicity when administered orally and low acute toxicity when administered dermally or by inhalation to rats. Dichlorprop-P was found to be not an irritant to the skin of rabbits but it is a severe eye irritant. It is not a skin sensitiser and not phototoxic. Dichlorprop-P 2-EHE is a skin sensitiser and is of moderate acute inhalation toxicity to rats.

After (short- and long-term) oral repeated administration of dichlorprop-P in rats, mice and dogs, the target organ of toxicity included kidney, liver and blood system. In addition, reduced absolute body weight, body weight gain, food consumption and reduced grip strength were also observed in rats. The relevant short-term oral no observed adverse effect level (NOAEL) is 35 mg/kg body weight (bw) per day (90-day rat study) and the relevant long-term oral NOAEL is 6 mg/kg bw per day (18-month mouse study). In addition to systemic effects, dogs showed local effects in the oral cavity (erosion). The relevant NOAEL for local effects in dogs is 3.5 mg/kg bw per day from the 1-year study.

The weight of evidence suggests that dichlorprop-P induced polyploidy *in vitro* but it is unlikely to be genotoxic *in vivo*. Dichlorprop-P and dichlorprop showed no carcinogenic potential in mice and rats, respectively. No specific human data is available concerning epidemiological evidence for a carcinogenic potential of dichlorprop-P and/or dichlorprop. However, a data gap is identified for an updated literature search on published epidemiological studies on phenoxy herbicides including dichlorprop-P and dichlorprop. The applicant is also advised to conduct a systematic literature review on human health covering a date span from 1980 on dichlorprop and dichlorprop-P following EFSA guidance on literature review (EFSA, 2011) since relevant publications might be available.

In the multigeneration study in rats with dichlorprop, the relevant NOAEL for parental toxicity is 8.3 mg/kg bw per day based on kidney weight effect at 42 mg/kg bw per day, which represents the NOAEL for reproductive toxicity (reduced fertility index of F1 males, prolonged gestation, dams with stillborn pups and reduced number of pups/dam) and offspring toxicity (pup mortality, decreased viability, survival, reduced body weight, increased kidney weight and reduced grip reflex). In the developmental toxicity studies with dichlorprop-P, fetal skeletal variations and retardations in rats and increased number of fetuses with accessory 13th rib(s) in rabbits were observed in the presence of maternal toxicity (reduced body weight (gain) and food consumption in rat; and marginal body weight loss, reduced food consumption in rabbit). The relevant maternal NOAELs are 20 mg/kg bw per day for the rat and 50 mg/kg bw per day for the rabbit, whereas the developmental NOAELs are 80 mg/kg bw per day and 50 mg/kg bw per day, respectively. Developmental toxicity studies with dichlorprop were considered of low reliability. Overall, the experts considered that no sufficient evidence for classification and labelling for dichlorprop-P for reproductive toxicity is available.

According to the RMS, the non-GLP and non-OECD guideline mouse developmental study on dichlorprop and dichlorprop-P showed evidence of maternal toxicity and embryotoxicity including teratogenicity. However, interpretation is limited by the lack of information on the test materials and in the reporting of the maternal effects. Therefore, this study would not challenge the conclusion reached during the experts' meeting.

The substance did not show a neurotoxic potential in acute and repeated neurotoxicity studies in rats.

Dichlorprop-P is not classified or proposed to be classified as toxic for reproduction category 2 or carcinogenic category 2, in accordance with the provisions of Regulation (EC) No 1272/2008<sup>4</sup>, and therefore, the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine-disrupting properties are not met. With regard to the scientific risk assessment, the experts could not conclude since data requirement regarding endocrine disruption was not fulfilled by the applicant. A data gap and issue that could not be finalised are identified.

The reassessment of the toxicological profile of dichlorprop-P lead to a revision of some of the existing toxicological reference values (European Commission, 2013). The experts agreed to maintain

<sup>4</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

the acceptable daily intake (ADI) of 0.06 mg/kg bw per day, on the basis of the relevant long-term NOAEL of 6 mg/kg bw in the 18-month study in mice based on chronic nephropathy at 64 mg/kg bw per day. An uncertainty factor of 100 was applied. The majority of experts agreed to revise the acute reference dose (ARfD). The ARfD is 0.2 mg/kg bw based on the NOAEL of 20 mg/kg bw per day for decreased food consumption and body weight/body weight gain observed at 80 mg/kg bw per day in the developmental toxicity study in rats. An uncertainty factor of 100 was applied. The majority of experts agreed to revise the acceptable operator exposure level (AOEL). The AOEL is 0.08 mg/kg bw per day on the basis of the relevant parental NOAEL of 8.3 mg/kg bw per day in the multigeneration study in rats based on increased kidney weight at 42 mg/kg bw per day. An uncertainty factor of 100 was applied. No correction factor for oral absorption is needed to derive the AOEL. The experts agreed that the acute acceptable operator exposure level (AAOEL) should be set on the same basis as the ARfD. The resulting AAOEL is 0.2 mg/kg bw. No correction factor for oral absorption is needed to derive the AAOEL.

The RMS estimated **non-dietary exposure** (i.e. for operators, workers, bystanders and residents) according to the EFSA (2014a) and considering dermal absorption values of dichlorprop-P in 'Dichlorprop-P K 600 SL' of 19% for the concentrate and of 45% for the dilution and in 'Dichlorprop-P 2-EHE 25 g/L (CA21134)' of 75% for both the concentrate and the dilution.

Considering the representative uses with 'Dichlorprop-P K 600 SL (CA3121)' as a **herbicide** in **grassland/grass seed crops**, the operator exposure was below the AOEL (31% of the AOEL) with the use of personal protective equipment (PPE: gloves during mixing, loading and application and work wear-arms, body and legs covered, and closed cabin). Worker exposure was above the AOEL (work wear, 118% of the AOEL). Bystander<sup>5</sup> child exposure to spray drift and resident child and adult exposure were above the AAOEL/AOEL (maximum exposure 151% of the AOEL for resident child exposure to spray drift located at 2–3 m).<sup>6</sup> Estimation of recreational exposure of children and adult residents (relevant to grassland uses) was above and below the AOEL for child (122% of the AOEL) and adult, respectively (34% of the AOEL). Considering the representative uses with 'Dichlorprop-P K 600 SL (CA3121)' as a **herbicide** in **cereals**, the operator exposure was below the AOEL (25% of the AOEL) with the use of PPE (gloves during mixing, loading and application and work wear-arms, body and legs covered and closed cabin). Worker exposure was below the AOEL (work wear, 94.5% of the AOEL). Bystander child exposure and resident child exposure to spray drift and resident child entry into treated crops were above the AAOEL/AOEL (maximum exposure 120% of the AOEL; resident child exposure to spray drift if located at 2–3 m).<sup>7</sup>

Considering the representative uses with 'CA2134' as a **plant growth regulator** in **citrus trees**, the operator exposure was below the AOEL (18% of the AOEL) with the use of PPE (gloves during mixing, loading and application) and with open cabin. Worker exposure was below the AOEL with the use of PPE (work wear and gloves, 63.8% of the AOEL). Bystander and resident exposure was below the AAOEL/AOEL (5 m distance). Considering the representative uses with 'CA2134' as a plant growth regulator in citrus trees, manual/knapsack application is not envisaged in the submitted dossier.

EFSA requested the RMS to provide additional calculations for all exposure groups and all representative uses according to other models than the EFSA guidance on non-dietary exposure (EFSA, 2014a). The RMS provided additional calculations using the original German Model for bystander and residents and the EUROPOEM for re-entry worker exposure (Ireland, 2018). Considering representative uses in grassland/grass seed crops and cereals, the calculations indicated that bystander and resident exposure is below the AOEL as well as the re-entry worker exposure using work wear. The calculations have not been peer-reviewed by Member States and EFSA. A preliminary assessment done by EFSA indicated that the calculations are not complete. The calculations did not include all exposure groups (i.e. operators) and all uses (i.e. citrus). The UK approach was not included in the calculations for bystander and residents. Only 10 m distance was used in the German approach. The AAOEL might not be appropriate to compare bystander exposure when using the original German approach. Input parameters from the EFSA guidance have been used when calculating worker exposure according to EUROPOEM. Therefore, the calculations are not presented in the LoEP but are available in the revised RAR (Ireland, 2018).

<sup>5</sup> The calculations for bystander exposure were compared to the AAOEL in line with the EFSA Guidance (2014a). It is noted that further distances might be considered for bystander and residents.

<sup>6</sup> Resident and bystander exposure estimates were below the AOEL/AAOEL if bystander and resident are located at 10 m (data not presented in the RAR, calculated by EFSA).

<sup>7</sup> If located at 10 m, only resident child entry into treated crops was above the AOEL (data not presented in the RAR, calculated by EFSA).

### 3. Residues

The assessment in the residue section is based on the OECD guidance document on overview of residue chemistry studies (OECD, 2009b), the OECD publication on MRL calculations (OECD, 2011), the European Commission guideline document on MRL setting (European Commission, 2011) and the Joint Meeting on Pesticide Residues (JMPR) recommendations on livestock burden calculations (JMPR, 2004, 2007) and OECD guidance document on residue definition (OECD, 2009a).

#### 3.1. Representative use residues

Metabolism of dichlorprop-P was investigated in wheat and of dichlorprop-P 2-EHE in oranges applying [ $^{14}\text{C}$ ]-ring-labelled active substance. The study on wheat was with one foliar application at 750 g a.s./ha at BBCH 31 (0.6 N rate). Identification of metabolites was not conducted in wheat grain although the total radioactive residue (TRR) amounted 0.021 mg/kg and the remained unextracted radioactive residues in wheat accounted for 60% TRR. The identified substances in mature straw were dichlorprop-P and 2,4-DCP accounted for 18.7% TRR (0.257 mg eq/kg) and 1.8% TRR (0.024 mg eq/kg), respectively. Dichlorprop-OH having a tentative structure ascribed accounted for 5.3% TRR (0.071 mg eq/kg). Only two metabolites out of 11 occurred above 10% TRR. One was characterised as multicomponent consisting of glycosides and accounting for 14.4% TRR (0.197 mg eq/kg) and the other as dichlorprop-P methyl ester accounting for 14.1% (0.193 mg eq/kg). In foliage and straw, a similar metabolic pattern was observed at maturity. In comparison to that, less metabolites were observed in ears in comparison to foliage at the same immature growth stage. Although underdosed and with limited characterisation in the edible part, the study can be used for the risk assessment.

Dichlorprop-P 2-EHE was applied to young orange trees in pots as foliar treatment at a rate of ca 7 mg a.s./tree at BBCH 71–73 (days after treatment 1 (DAT1)) and some trees were treated a second time with the same amount at BBCH 81 (DAT2). The application rate corresponds to ca 120 g a.s./ha (ca 1.6 N). Although the tree/ha ratio in this study does not represent the situation encountered in orchards, the study is found suitable to elucidate the metabolism in this crop. Dichlorprop-P 2-EHE and dichlorprop-P were the only identified compounds in extracts of pulp, peel, juice and leaves at the various growth stages from day 0 for both applications to the harvest (46 DAT2 and 159 DAT1). The remainder of the radioactivity is attributed to conjugates or to unknown compounds, each accounting for less than 10% TRR (0.01 mg eq/kg).

On the basis of the two metabolism studies, the residue definition for risk assessment and monitoring is set as sum of dichlorprop (including dichlorprop P), its salts, esters and conjugates expressed as dichlorprop for cereals and citrus fruit.

Residue trials for cereals and grass compliant with the critical good agricultural practice (GAP) were submitted. However, it is not demonstrated that the analytical method used analyses all compounds covered by the residue definition. Furthermore, samples from most of the trials with cereals were stored for longer periods than supported by storage stability for all the compounds covered by the residue definition. Therefore, a sufficient number of residue trials in cereals and grass according to the critical GAP and analysing for all compounds covered by the residue definition and covered by storage stability data in a time interval where acceptable storage stability is demonstrated is required (data gap). Residue trials for oranges and mandarins according to critical GAP and analysing for all compounds covered by the residue definition in a time interval where acceptable storage stability is demonstrated have been submitted. However, some of them were replicates resulting in a too low number of valid trials for the proposed uses in citrus (orange, mandarin and lemon). Therefore, a data gap was identified for sufficient number of residue trials for citrus.

Metabolism of dichlorprop-P under processing conditions has been investigated and the substance has been demonstrated to be stable under all processing conditions. However, a study addressing the nature of the residues at processing and representative of the standard hydrolysis conditions is required for all compounds covered by the residue definition (data gap).

The animal dietary burden calculation available is provisional pending the results from valid field trials with cereals and grass. However, results from field trials with cereals which are underestimating the residue already indicated that a poultry metabolism study is triggered (data gap). A metabolism study with lactating goats using [ $^{14}\text{C}$ ]-ring-labelled dichlorprop-P and two dose rates of 0.1569 mg/kg bw per day and 1.5193 mg/kg bw per day was available. Dichlorprop-P was the only identified compound and was found in liver and kidney in the high-dosed animal at levels of 0.025 mg eq/kg and 0.419 mg eq/kg, respectively. However, enzymatic treatment released further dichlorprop-P from

the goat kidney (5%, 0.023 mg eq/kg) in the high-dose group indicating the presence of conjugates. In milk, muscle and fat radioactivity in the high-dose group was below or at 0.01 mg eq/kg in the high-dosed animal. In context of Art 12 evaluation, the residues reported in this ruminant study were used as the basis to set MRLs. In the absence of an animal dietary burden calculation due to non-valid field trials, it cannot be estimated now whether the residues from the metabolism study could be used to propose MRLs or whether a feeding study with ruminants would be triggered. Based on this metabolism study, the residue definition both for risk assessment and monitoring for ruminants is set as sum of dichlorprop (including dichlorprop P), its salts, esters and conjugates expressed as dichlorprop. It is noted that the residue definition differs from that previously set for ruminant animal products in the Article 12 MRL review (EFSA, 2014b) since it now also includes esters and conjugates which are also occurring in these matrices in line with OECD (2009a). Therefore, the revision of the Article 12 MRL review might be needed. Considering that dichlorprop-P 2-EHE has a log  $P_{o/w}$  greater than 3, a fish study would have been triggered. However, citrus that could be treated with dichlorprop-P 2-EHE is not used in fish food, so these data are not essential in the context of the representative uses being assessed.

A consumer risk assessment could not be conducted as valid field trials for all representative uses are missing.

A data gap was set with regard to potential residue levels in pollen and bee products.

A data gap set in the context of the Article 12 MRL review for a confirmatory method for enforcement in animal commodities has been addressed since the analytical method is available.

### 3.2. Maximum residue levels

No MRL has been proposed as valid field trials for all representative uses are missing.

## 4. Environmental fate and behaviour

Dichlorprop-P was discussed at the Pesticides Peer Review Experts' Teleconference TC166 in February 2018.

The rates of dissipation and degradation in the environmental matrices investigated were estimated using FOCUS (2006) kinetics guidance. In soil laboratory incubations under aerobic conditions in the dark, dichlorprop-P exhibited low to moderate persistence, forming the major (> 10% applied radioactivity (AR)) metabolites 2,4-DCP (max. 11.6% AR) and 2,4-dichloroanisole (2,4-DCA, max. 13.1% AR), which exhibited very low to moderate and low to moderate persistence, respectively. Mineralisation of the phenyl ring  $^{14}\text{C}$  radiolabel to carbon dioxide accounted for 39–43% AR after 56–90 days. The formation of unextractable residues (not extracted by acidified acetonitrile/water or acidified acetone) for this radiolabel accounted for 34–62% AR after 56–90 days. Dichlorprop-P-2-ethylhexyl (dichlorprop-P 2-EHE) exhibited very low to low persistence transforming to dichlorprop-P. Information in the published scientific literature indicated that the *R*-isomer of dichlorprop (dichlorprop-P) is converted to its *S*-isomer (dichlorprop-M) though the *S*-isomer usually degrades faster than the *R*-isomer. In anaerobic soil incubations, dichlorprop-P was essentially stable while dichlorprop-P 2-EHE exhibited very low to low persistence transforming to dichlorprop-P. In the available laboratory soil photolysis study, the route and rate of degradation of dichlorprop-P was comparable to that which occurred in the dark aerobic incubations though the maximum formation of 2,4-DCP (23.6% AR) was observed in this investigation. Dichlorprop-P/dichlorprop exhibited very high to high mobility in soil. 2,4-DCP and 2,4-DCA exhibited medium to low soil mobility. It was concluded that the adsorption of these three compounds was not pH dependent.

In laboratory incubations in dark aerobic natural sediment water systems, dichlorprop-P exhibited moderate persistence with chromatographically resolved transformation products accounting for < 5% AR. The unextractable sediment fraction (not extracted by acetonitrile/water) was a sink for the phenyl ring  $^{14}\text{C}$  radiolabel, accounting for 11–19% AR at study end (91 days). Mineralisation of this radiolabel accounted for 81–91% AR at the end of the study. In dichlorprop-P 2-EHE dosed aerobic natural sediment water systems, the ester partitioned to sediment and exhibited very low to low persistence transforming to dichlorprop-P. The rate of decline of dichlorprop-P in a laboratory sterile aqueous photolysis experiment was comparable to that occurred in the aerobic sediment water incubations. No chromatographically resolved component (excluding dichlorprop) accounted for > 5% AR. The necessary surface water and sediment exposure assessments (predicted environmental concentrations (PEC) calculations) were carried out for the soil metabolites 2,4-DCP and 2,4-DCA using the FOCUS



(2001) step 1 and step 2 approach (version 3.2 of the Steps 1-2 in FOCUS calculator). For the active substances dichlorprop-P and dichlorprop-P 2-EHE, appropriate step 3 (FOCUS, 2001) calculations were available.<sup>8</sup> For dichlorprop-P 2-EHE, adsorption end points for dichlorprop-P were used as input in the Step 3 simulations.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (European Commission, 2014a) scenarios and the models PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4.<sup>8</sup> For dichlorprop-P 2-EHE, adsorption end points for dichlorprop-P were used as input in simulations (which would overestimate actual exposure potential of dichlorprop-P 2-EHE). The potential for groundwater exposure from the representative uses by dichlorprop-P, dichlorprop-P 2-EHE, 2,4-DCP and 2,4-DCA above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios.

The applicant provided appropriate information to address the effect of water treatment processes on the nature of residues of dichlorprop that might be present in surface water, when surface water is abstracted for drinking water. The conclusion of this consideration was that dichlorprop would be transformed to small two carbon chain compounds such as acetic/oxalic acids or formic acid/carbon dioxide and chloride salts, due to oxidation at the disinfection stage of usual water treatment processes. However, the information provided was not appropriate to address the effect of water treatment processes on the nature of the 2,4-DCP and 2,4-DCA residues that might be present in surface water, when surface water is abstracted for drinking water. This has led to the identification of a data gap (see Section 7) and results in the consumer risk assessment not being finalised (see Section 9).

The PEC in soil, surface water, sediment and groundwater covering the representative uses assessed can be found in Appendix A of this conclusion. FOCUS air (FOCUS, 2008) guidance was adhered to when calculating the available PEC.

## 5. Ecotoxicology

The following documents were considered for the risk assessment: European Commission (2002), SETAC (2001), EFSA (2009), EFSA PPR Panel (2013) and EFSA (2013).

Some aspects of the risk assessment for birds and mammals and the probabilistic risk assessment for non-target terrestrial plants were discussed at the Pesticides Peer Review Experts' meeting 174.

Considering the ecotoxicological profile of dichlorprop-P and the identity of impurities, the proposed (old and new) technical specifications for both dichlorprop-P and its ester dichlorprop-P 2-EHE are considered covered by the ecotoxicological studies.

On the basis of the available data and assessments, a low risk to **birds and mammals** was concluded for all the representative uses.

Laboratory studies were available for **aquatic organisms** with the active substance dichlorprop-P as acid form or as salt form, on dichlorprop-P 2-EHE, on related formulations and on the metabolite 2,4-dichlorophenol. For the metabolite 2,4-dichloroanisole, peer-reviewed data from the conclusion of 2,4-D (EFSA, 2014c) were considered.

The data for aquatic plants indicated a magnitude of sensitivity to dichlorprop-P several orders higher than the end points for the other aquatic organisms. Therefore, the regulatory acceptable concentration (RAC) used in the risk assessment is based on the data for aquatic plants. The risk assessments resulted in a low risk for more than half of the relevant FOCUS step 3 surface water scenarios. However, a number of scenarios indicated a high risk (data gap).

Considering dichlorprop-P 2-EHE, the available data (with the exception of an acute study for daphnids) were not sufficient to be used in the risk assessment as they did not represent appropriately the toxicity of dichlorprop-P 2-EHE (data gap for the representative uses on citrus). Nevertheless, it is noted that a long-term exposure of aquatic organisms to dichlorprop-P 2-EHE is not expected due to its rapid transformation (hydrolysis) to dichlorprop-P (DT<sub>50</sub> in water sediment systems: 0.17–0.3 days).

A low risk to aquatic organisms was concluded for the metabolites (2,4-DCP and 2,4-DCA) on the basis of the available data and FOCUS step 2 exposure estimations.

The risk to potential bioaccumulation was also considered as low.

For **honeybees**, only acute studies were available for dichlorprop-P 2-EHE. Laboratory studies as requested by EFSA (2013) were available for dichlorprop-P, except for honeybee larvae for which only a single dose study was available. Since this data indicated a higher sensitivity of larvae than adults and low risk could not be concluded for larvae for all the representative uses, a data gap was identified.

<sup>8</sup> Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2008) and Walker equation coefficient of 0.7.

The risk assessment for bees was partially conducted according to EFSA (2013). At screening step (contact and dietary oral route of exposure), a low risk was concluded for dichlorprop-P 2-EHE. It is noted that with the exception of the acute assessments, the toxicity data for dichlorprop-P was used considering a rapid decomposition of the ester form into the acid form in the environment. As regards dichlorprop-P, the tier 1 risk assessments resulted in a low risk for the use in winter cereals and spring cereals, with the exception of the weed scenario for spring cereals (data gap). For the use on grassland, the tier 1 risk assessments resulted in a low risk, with the exception of the weed scenario and the treated crop scenario (data gap).

A low risk was concluded for dichlorprop-P from the exposure via surface water. No assessment for the puddle water was available and from the screening assessment for the consumption of guttation water, a low risk could not be concluded (data gap).

As regards dichlorprop-P 2-EHE, on the basis of the acute assessments for guttation water, a low risk was concluded from the exposure via water consumption.

No risk assessment was provided for the metabolites potentially occurring in pollen and nectar (i.e. dichlorprop-OH was identified > 10% TRR in wheat foliage) (data gap).

No data were available on accumulative effects or on other species of bees.

It is noted that, considering procedural aspects, the RMS did not agree with the identified data gaps related to the risk assessment for bees.

On the basis of the available data (tier 1 and tier 2 laboratory tests), a low risk was concluded for **non-target arthropods**.

On the basis of the available data on **earthworms** and **soil macro- and microorganisms**, a low risk was concluded for the representative uses for dichlorprop-P, dichlorprop-P 2-EHE and for the soil metabolites, with the exception of the metabolite 2,4-DCP for the representative uses on spring cereal and grassland, where the risk was assessed as high for collembolan (data gap).

A low risk was concluded for **non-target terrestrial plants** for the representative use on citrus (dichlorprop-P 2-EHE). As regards the representative uses for dichlorprop-P, a low risk was concluded provided that risk mitigation corresponds to a 5 m no-spray buffer zone or 50% spray drift reduction is applied.

A low risk was concluded for the organisms involved in biological methods for **sewage treatment**.

No specific studies were available to address the **potential endocrine activity** of dichlorprop-P or dichlorprop-P 2-EHE. Pending on the outcome of the data gap in Section 2, further ecotoxicological tests might be necessary to address the potential endocrine disrupting properties of dichlorprop-P or dichlorprop-P 2-EHE. In addition, some information from the open literature were available indicating some potential for endocrine disruption (e.g. mild estrogenicity in fish) of the metabolite 2,4-DCP.



## 6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments Tables (1–4)

**Table 1:** Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Dichlorprop-P 2-EHE	Very low to low persistence Single first-order DT <sub>50</sub> 0.9–1.7 days (20°C pF 2 soil moisture)	The risk to soil organisms was assessed as low
Undefined ratio of constituent <i>R</i> - and <i>S</i> -isomers of dichlorprop with the <i>R</i> -isomer predominating	Low to moderate persistence Single first-order and biphasic kinetics DT <sub>50</sub> 3.2–17.6 days (DT <sub>90</sub> 10.7–58.4 days, 20°C 40–57% MWHC soil moisture)	The risk to soil organisms was assessed as low
2,4-dichlorophenol (2,4-DCP)	Very low to moderate persistence Single first-order and biphasic kinetics DT <sub>50</sub> 0.53–6.2 days (DT <sub>90</sub> 1.8–42.1 days, 20°C 50–57% MWHC soil moisture)	Data gap for the uses on spring cereal and grassland
2,4-dichloroanisol (2,4-DCA)	Low to moderate persistence Single first-order DT <sub>50</sub> 5.2–31.4 days (20°C 50–57% MWHC soil moisture)	The risk to soil organisms was assessed as low

DT<sub>50</sub>: period required for 50% dissipation; DT<sub>90</sub>: period required for 90% dissipation; MWHC: maximum water-holding capacity.

**Table 2:** Groundwater

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L at 1 m depth for the representative uses <sup>(a)</sup>	Pesticidal activity	Toxicological relevance
Dichlorprop-P 2-EHE	No data, dichlorprop end points used to complete assessments	No	Yes	Yes
Undefined ratio of constituent <i>R</i> - and <i>S</i> -isomers of dichlorprop with the <i>R</i> -isomer predominating	Very high to high mobility K <sub>Foc</sub> 13–84 mL/g	No	Yes	Yes
2,4-dichlorophenol (2,4-DCP)	Medium to low mobility K <sub>Foc</sub> 244–765 mL/g	No	Assessment not triggered	Assessment not triggered
2,4-dichloroanisol (2,4-DCA)	Medium to low mobility K <sub>Foc</sub> 436–1,630 mL/g	No	Assessment not triggered	Assessment not triggered

K<sub>Foc</sub>: Freundlich organic carbon adsorption coefficient.

(a): FOCUS scenarios or a relevant lysimeter.

**Table 3:** Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Dichlorprop-P 2-EHE	Data gap
Undefined ratio of constituent R and S isomers of dichlorprop with the R isomer predominating	The risk to aquatic organisms was assessed as low for several scenarios. Data gap for some other scenarios
2,4-dichlorophenol (2,4-DCP)	The risk to aquatic organisms was assessed as low
2,4-dichloroanisole (2,4-DCA)	The risk to aquatic organisms was assessed as low

**Table 4:** Air

Compound (name and/or code)	Toxicology
Dichlorprop-P 2-EHE	Acute Tox Cat. 4: H332. Harmful if inhaled
Undefined ratio of constituent R and S isomers of dichlorprop with the R isomer predominating	Low acute toxicity by inhalation
2,4-dichlorophenol (2,4-DCP)	No specific data are available by inhalation route. The substance is corrosive.

## 7. Data gaps

This is a list of data gaps identified during the peer review process, including those areas in which a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful effects).

- Experimental determination of the partition coefficient *n*-octanol/water of 2,4-DCP (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1).
- Determination of the emulsion characteristics of 'CA2134' using CIPAC MT 36.3 (relevant for formulation 'CA2134', use as a plant growth regulator; submission date proposed by the applicant: unknown; see Section 1).
- Weight of evidence approach on endocrine disruption of dichlorprop-P and dichlorprop taking into account deviations of level 4/5 studies according to OECD guideline studies and studies submitted under ESDP21 and TOX21 and potential relevant publications. Pending on the outcome of the data gap in Section 2, further ecotoxicological tests might be necessary to address the potential endocrine disrupting properties of dichlorprop-P or dichlorprop-P 2-EHE. (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 2 and 5).
- Updated literature search on published epidemiological studies on phenoxyherbicides including dichlorprop-P and dichlorprop (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- Metabolism study in poultry (relevant for uses in cereals; submission date proposed by the applicant: unknown; see Section 3).
- A sufficient number of field trials for cereals, grass, citrus (oranges, mandarins and lemon) analysing for all compounds covered by the residue definition and performed in a timeframe for which storage stability for all compounds covered by the residue definition is demonstrated (relevant for uses in cereals, grass and citrus; submission date proposed by the applicant: unknown; see Section 3).
- Determination of residues as proposed for risk assessment residue definition in pollen and bee products for human consumption (relevant for use on cereals and grass; submission date proposed by the applicant: unknown; see Section 3).
- A study addressing the nature of the residues at processing and representative of the standard hydrolysis conditions is required (relevant for uses in citrus fruit; submission date proposed by the applicant: unknown; see Section 3).
- An OECD 309 aerobic mineralisation study was not available (not relevant for any representative uses evaluated at EU level following EU FOCUS exposure guidance; submission date proposed by the applicant: unknown; see Section 4 of the evaluation table contained in the peer review report (EFSA, 2018)).
- Information to address the effect of water treatment processes on the nature of the metabolite residues (2,4-DCP and 2,4-DCA) that might be present in surface water, when surface water is abstracted for drinking water was not available. Probably in the first instance, a consideration of the processes of ozonation and chlorination would appear appropriate. Should this consideration indicate novel compounds might be expected to be formed from water treatment, the risk to human or animal health through the consumption of drinking water containing them should be addressed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4).
- A chronic or long-term study for fish which fulfils the data requirement as set in Commission Regulation (EU) 283/2013 (not relevant for the representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5 of the evaluation table contained in the peer review report (EFSA, 2018)).
- Further information on the toxicity of dichlorprop-P to algae (not relevant for the representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5 of the evaluation table contained in the peer review report (EFSA, 2018)).
- Further information on the toxicity of dichlorprop-P 2-EHE on aquatic organisms and for an appropriate risk assessment (relevant for the representative use on citrus; submission date proposed by the applicant: unknown; see Section 5).

- Further risk assessments for dichlorprop-P for situations represented by R4 FOCUS surface water scenario for the use on spring cereals, for situations represented by D1, D2, R1 and R3 FOCUS surface water scenarios for the use on winter cereals, and for situations represented by D1 and D2 FOCUS surface water scenarios for the use on grassland (relevant for the representative use on cereals and grassland; submission date proposed by the applicant: unknown; see Section 5).
- Further information on the toxicity of dichlorprop-P to honeybee larvae (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Further information to address the risk to honeybees (relevant for the representative use on spring cereals and grasslands; submission date proposed by the applicant: unknown; see Section 5).
- Further information to address the risk to non-target soil macroorganisms other than earthworms of the metabolite 2,4-DCP (relevant for the representative use on spring cereals and grasslands; submission date proposed by the applicant: unknown; see Section 5).

## 8. Particular conditions proposed to be taken into account to manage the risk(s) identified

- Considering the representative uses with 'Dichlorprop-P K 600 SL' as a **herbicide in grassland/grass seed crops**, operators should use PPE (gloves during mixing, loading and application and work wear-arms, body and legs covered, and closed cabin) to reduce exposure below the AOEL. Resident and bystander exposure estimates should be located at 10 m to reduce exposure below the AOEL. However, estimation of recreational exposure of children was above the AOEL (122% of the AOEL) (see Section 2).
- Considering the representative uses with 'Dichlorprop-P K 600 SL' as a **herbicide in cereals**, operator should use PPE (gloves during mixing, loading and application and work wear-arms, body and legs covered, and closed cabin) to reduce exposure below the AOEL (25% of the AOEL) (see Section 2).
- Considering the representative uses with 'CA2134' as a **plant growth regulator in citrus trees**, operator should use PPE (gloves during mixing, loading and application) to reduce exposure below the AOEL. Workers should use gloves to reduce exposure below the AOEL (63.8% of the AOEL) (see Section 2).
- Considering the representative uses with 'CA2134' as a plant growth regulator in citrus trees, manual/knapsack application is not envisaged in the submitted dossier (see Section 2).
- As regards to the representative uses for dichlorprop-P, a low risk for non-target terrestrial plant was concluded only when a risk mitigation measure with an efficiency equivalent to a 5 m no-spray buffer zone or to 50% spray drift reduction was taken into consideration (see Section 5).

## 9. Concerns

### 9.1. Concerns for the representative uses evaluated

#### 9.1.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011<sup>9</sup> and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

<sup>9</sup> Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

- 1) Dichlorprop-P is not classified or proposed to be classified as toxic for reproduction category 2 or carcinogenic category 2, in accordance with the provisions of Regulation (EC) No 1272/2008, and therefore, the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine-disrupting properties are not met. However, further assessment of available information is needed to conclude on the endocrine potential of dichlorprop-P (see Section 2).
- 2) A consumer risk assessment could not be conducted as valid field trials for all representative uses are missing, i.e. covering the uses on cereals, cereals undersown with rotational grass, grassland, grass seed crops, and citrus. Also, the absence of final animal feedstuff residue levels precludes accurate estimates of animal intake calculations that are needed to estimate residues levels in animal products. Data are missing regarding poultry metabolism and more information might be needed regarding investigation of ruminant animal transfer (see Section 3).
- 3) The consumer risk assessment from the consumption of drinking water could not be finalised, whilst satisfactory information was missing on the effect of water treatment processes on the nature of the residues 2,4-DCP and 2,4-DCA (metabolites of dichlorprop) that might be present in surface water, when surface water is abstracted for the production of drinking water (see Section 4).

### 9.1.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29 (6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

No critical area of concern has been identified.

### 9.1.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 5.)

**Table 5:** Overview of concerns

Representative use		Winter cereals including cereals undersown with rotational grass	Spring cereals including cereals undersown with rotational grass	Grassland (permanent and rotational)	Grass seed crops	Citrus (oranges, mandarins, lemons)
<b>Operator risk</b>	Risk identified					
	Assessment not finalised					
<b>Worker risk</b>	Risk identified			X	X	
	Assessment not finalised					
<b>Resident/ bystander risk</b>	Risk identified	X	X	X	X	
	Assessment not finalised					
<b>Consumer risk</b>	Risk identified					
	Assessment not finalised	X <sup>2,3</sup>	X <sup>2,3</sup>	X <sup>2,3</sup>	X <sup>2,3</sup>	X <sup>2,3</sup>
<b>Risk to wild non-target terrestrial vertebrates</b>	Risk identified					
	Assessment not finalised					
<b>Risk to wild non-target terrestrial organisms other than vertebrates</b>	Risk identified	X	X	X	X	
	Assessment not finalised					
<b>Risk to aquatic organisms</b>	Risk identified	4/9 FOCUS SW scenarios	1/5 FOCUS SW scenarios	2/7 FOCUS SW scenarios	2/7 FOCUS SW scenarios	
	Assessment not finalised					
<b>Groundwater exposure to active substance</b>	Legal parametric value breached					
	Assessment not finalised					
<b>Groundwater exposure to metabolites</b>	Legal parametric value breached					
	Parametric value of 10 µg/L <sup>(a)</sup> breached					
	Assessment not finalised					

Columns are grey if no safe use can be identified. The superscript numbers relate to the numbered points indicated in Section 9.1.1. Where there is no superscript number, see Sections 2–6 for further information.

(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission, 2003.



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## Abbreviations

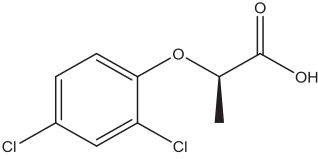
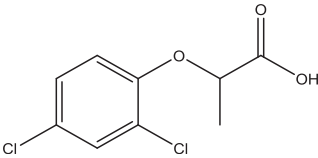
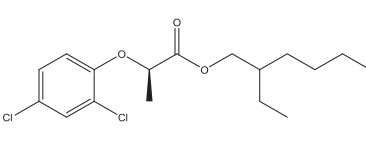
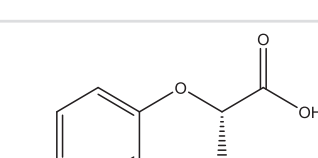
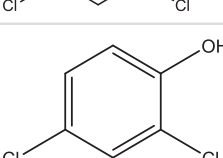
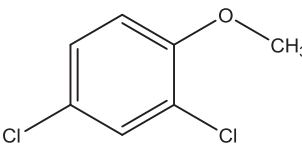
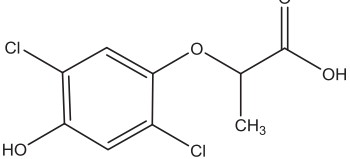
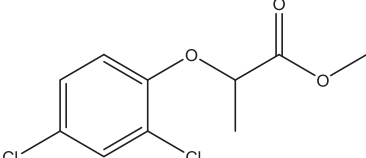
a.s.	active substance
AOEL	acceptable operator exposure level
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
bw	body weight
CIPAC	Collaborative International Pesticides Analytical Council Limited
DAT	days after treatment
DCA	dichloroaniline
DCP	dichlorophenol
DT <sub>50</sub>	period required for 50% dissipation (define method of estimation)
DT <sub>90</sub>	period required for 90% dissipation (define method of estimation)
EC	emulsifiable concentrate
ECHA	European Chemicals Agency
EEC	European Economic Community
EUROPOEM	European Predictive Operator Exposure Model
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
GLP	good laboratory practice
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K <sub>Foc</sub>	Freundlich organic carbon adsorption coefficient
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue level

MWHC	maximum water-holding capacity
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PCDD	polychlorinated dibenzo- <i>p</i> -dioxin
PCDF	polychlorinated dibenzofuran
PEC	predicted environmental concentration
PEC <sub>air</sub>	predicted environmental concentration in air
PEC <sub>gw</sub>	predicted environmental concentration in groundwater
PEC <sub>sed</sub>	predicted environmental concentration in sediment
PEC <sub>soil</sub>	predicted environmental concentration in soil
PEC <sub>sw</sub>	predicted environmental concentration in surface water
P <sub>ow</sub>	partition coefficient between <i>n</i> -octanol and water
PPE	personal protective equipment
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
RMS	rapporteur Member State
SL	soluble concentrate
SMILES	simplified molecular-input line-entry system
TCDD	2,3,7,8-tetrachlorodibenzo- <i>p</i> -dioxin
TEQ	toxic equivalent
TRR	total radioactive residue
WHO	World Health Organization

## **Appendix A – List of end points for the active substance and the representative formulation**

Appendix A can be found in the online version of this output ('Supporting information' section):  
<https://doi.org/10.2903/j.efsa.2018.5288>

## Appendix B – Used compound codes

Code/trivial name <sup>(a)</sup>	IUPAC name/SMILES notation/ InChiKey <sup>(b)</sup>	Structural formula <sup>(b)</sup>
<b>dichlorprop-P</b>	(2 <i>R</i> )-2-(2,4-dichlorophenoxy)propionic acid <chem>C[C@@H](OC1=CC=C(Cl)C=C1Cl)C(=O)O</chem> MZHCEGPTKEIGP-RXMQYKEDSA-N	
<b>dichlorprop</b>	(2 <i>RS</i> )-2-(2,4-dichlorophenoxy)propionic acid <chem>CC(OC1=CC=C(Cl)C=C1Cl)C(=O)O</chem> MZHCEGPTKEIGP-UHFFFAOYSA-N	
<b>dichlorprop-P-2-ethylhexyl dichlorprop-P 2-EHE</b>	(2 <i>RS</i> )-2-ethylhexyl (2 <i>R</i> )-2-(2,4-dichlorophenoxy)propionate <chem>C[C@@H](OC1=CC=C(Cl)C=C1Cl)C(=O)OCC(CC)CCCC</chem> CEEDFYRUPAWDOU-PZORYLMUSA-N	
<b>dichlorprop-M</b>	(2 <i>S</i> )-2-(2,4-dichlorophenoxy)propionic acid <chem>C[C@H](OC1=CC=C(Cl)C=C1Cl)C(=O)O</chem> MZHCEGPTKEIGP-YFKPBYRVSA-N	
<b>2,4-dichlorophenol 2,4-DCP</b>	2,4-dichlorophenol <chem>OC1=CC=C(Cl)C=C1Cl</chem> HFZWRUODUSTPEG-UHFFFAOYSA-N	
<b>2,4-dichloroanisole 2,4-DCA</b>	2,4-dichloro-1-methoxybenzene <chem>CIC1=CC(Cl)=CC=C1OC</chem> CICQUFBZCADHHX-UHFFFAOYSA-N	
<b>dichlorprop-OH</b>	2-(2,5-dichloro-4-hydroxyphenoxy)propanoic acid <chem>CC(C(=O)O)OC1=CC(Cl)=C(O)C=C1Cl</chem> MXBDBDHZOJCWDW-UHFFFAOYSA-N	
<b>dichlorprop-P methyl ester</b>	methyl 2-(2,4-dichlorophenoxy)propanoate <chem>CC(C(OC)=O)OC1=CC=C(Cl)C=C1Cl</chem> SCHCPDWDIOTCMJ-UHFFFAOYSA-N	

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

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

(b): Names, SMILE codes and InChi Keys are generated by ChemBioDraw ver. 13.0.2.3021.