CONCLUSION ON PESTICIDES PEER REVIEW

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Updated conclusion on the peer review of the pesticide risk assessment of the active substance mecoprop-P

European Food Safety Authority (EFSA),
Fernando Alvarez, Maria Arena, Domenica Auteri, Marco Binaglia, Anna Federica Castoldi, Arianna Chiusolo, Angelo Colagiorgi, Mathilde Colas, Federica Crivellente, Chloe De Lentdecker, Isabella De Magistris, Mark Egsmose, Gabriella Fait, Franco Ferilli, Varvara Gouliarmou, Laia Herrero Nogareda, Alessio Ippolito, Frederique Istace, Samira Jarrah, Dimitra Kardassi, Aude Kienzler, Anna Lanzoni, Roberto Lava, Renata Leuschner, Alberto Linguadoca, Christopher Lythgo, Oriol Magrans, Iris Mangas, Ileana Miron, Tunde Molnar, Laura Padovani, Martina Panzarea, Juan Manuel Parra Morte, Simone Rizzuto, Rositsa Serafimova, Rachel Sharp, Csaba Szentes, Andrea Terron, Anne Theobald, Manuela Tiramani, Giorgia Vianello and Laura Villamar-Bouza

Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the initial competent authorities of the rapporteur Member State, the United Kingdom, and co-rapporteur Member State, Ireland, for the pesticide active substance mecoprop-P are reported. Due to the UK leaving the EU, the renewal of approval dossier on mecoprop-P was reallocated to Ireland, as RMS. 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 mecoprop-P as a herbicide on winter and spring wheat (including durum and spelt), barley, rye, oats and triticale. The conclusions were updated following the request from the European Commission to review the risk assessment as regards non-dietary exposure and the endocrine-disrupting properties of mecoprop-P. The reliable end points, appropriate for use in regulatory risk assessment are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are reported where identified.

Keywords: mecoprop-P, peer review, risk assessment, pesticide, herbicide

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Correspondence: pesticides.peerreview@efsa.europa.eu

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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. Mecoprop-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), the United Kingdom (UK), and co-rapporteur Member State (co-RMS), Ireland, received an application from Nufarm for the renewal of approval of the active substance mecoprop-P. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Ireland), the European Commission and the European Food Safety Authority (EFSA) about the admissibility.

The RMS (UK) provided its initial evaluation of the dossier on mecoprop-P in the renewal assessment report (RAR), which was received by EFSA on 1 April 2016. In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Nufarm, for comments on 6 June 2016. 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 9 August 2016.

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 and ecotoxicology.

In accordance with Article 13(1) of the Regulation, EFSA should adopt a conclusion on whether mecoprop-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.

EFSA published its conclusion on the peer review of the pesticide risk assessment of mecoprop-P on 18 May 2017 (EFSA, 2017a). On 4 December 2018, the European Commission sent a mandate to EFSA with a request to review the risk assessment as regards non-dietary exposure and endocrine-disrupting properties of mecoprop-P. The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of mecoprop-P as a herbicide on winter and spring wheat (including durum and spelt), barley, rye, oats and triticale, as proposed by the applicant. Full details of the representative uses can be found in Appendix A of this report.

The uses of mecoprop-P according to the representative uses proposed at EU level result in sufficient herbicidal efficacy against the target weeds.

A data gap was identified for a search of the scientific peer-reviewed open literature on the aqueous photolysis metabolite 2-methylphenol.

In the section **identity, physical chemical properties, analytical methods** data gaps were identified for log P data for two metabolites hydroxymethyl-mecoprop-P (HMCPP) and 2-methylphenol, for monitoring (chiral) methods for the determination of mecoprop-P residues in all matrices (open for animal matrices pending decision on the residue definition) and for an enforcement method in body fluids and tissues. It was proposed to update the reference specification of the first approval.

In the **mammalian toxicology** area, data gaps were identified with regard to the assessment of the toxicological relevance of some impurities present in the proposed renewal specification, considering that the batches used in the toxicological studies do no support all the impurities, and with regard to the toxicological data on the two metabolites carboxy-mecoprop-P (CCPP) and 4-glucosyl-MPP. The predicted exposure of residents is exceeding the acceptable operator exposure level (AOEL) for children entering treated areas (75th percentile), leading to a critical area of concern.

In the **residue** section, the consumer risk assessment cannot be finalised due to the outstanding data to confidently address the nature and magnitude of residues in plant and animal matrices. Further information is also requested on the potential residues of mecoprop-P and its degradation products in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom.

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 assessed. For the representative use on winter cereals under the vulnerable conditions represented by the Okehampton FOCUS groundwater scenario, there is the potential for the active substance mecoprop-P to be present in shallow groundwater above the parametric drinking water limit of 0.1 μg/L. A data gap was

identified as the potential for the *R* isomer to racemise to the *RS* mixture in the soil, water/sediment and air compartments was not adequately addressed.

In the area of **ecotoxicology** in the absence of a long-term toxicity study on birds, a data gap to further address the long-term toxicity and risk to birds for mecoprop-P and an issue that could not be finalised were identified. A high long-term risk to wild mammals for mecoprop-P was concluded for all representative uses (critical area of concern). Data gaps were identified for further information to address the risk to birds and mammals for the pertinent plant metabolites, the risk to aquatic organisms for mecoprop-P and for metabolite 2-methylphenol and to address the risk to soil microorganisms for mecoprop-P. Finally, a data gap was identified for a risk assessment in line with the EFSA Guidance on risk assessment for honey bees for mecoprop-P and its pertinent metabolites.

Regarding the assessment of the **endocrine disruption** (ED) properties for humans and non-target organisms, based on the available evidence, the ED criteria according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605, are not met for the oestrogen, androgen, steroidogenesis and thyroid (EATS)-modalities.

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Background

Commission Implementing Regulation (EU) No 844/2012[1] (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[2]. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant 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 up to 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, the United Kingdom (UK), and co-RMS, Ireland, received an application from Nufarm for the renewal of approval of the active substance mecoprop-P. Complying with Article 8 of the Regulation, the RMS (UK) checked the completeness of the dossier and informed the applicant, the co-RMS (Ireland), the European Commission and EFSA about the admissibility.

The RMS (UK) provided its initial evaluation of the dossier on mecoprop-P in the RAR, which was received by EFSA on 1 April 2016 (United Kingdom, 2016).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Nufarm, for consultation and comments on 6 June 2016. 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 9 August 2016. At the same time, the collated comments were forwarded to the RMS (UK) 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 (UK) 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 and the RMS (UK) on 27 September 2016. 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 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 (UK), 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 took place with Member States via a written procedure in March–April 2017.

EFSA published its conclusion on the peer review of the pesticide risk assessment of mecoprop-P on 18 May 2017 (EFSA, 2017a), in which a critical area of concern was identified for the exposure of workers when re-entering the treated fields. The models in place at the time of the application for the renewal of approval of mecoprop-P do not cover the scenario where a worker enters again a treated

[1] 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.

[2] 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.

field of cereals post sowing and before the emergence of the plantlets. Therefore, a worst-case scenario, not matching the realistic agricultural practice, was presented by the RMS (UK) in the RAR in the case of mecoprop-P. Moreover, in the case of other herbicides recently reassessed using the same models and the same representative uses, the worst-case scenarios were refined with ad hoc calculated parameters (EFSA, 2016). In order for the European Commission to have the information required for decision-making, on 4 December 2018, the European Commission sent a mandate to EFSA in accordance with Article 31 of Regulation (EC) No 178/2002[3] with a request to review the risk assessment as regards non-dietary exposure to cover realistic agricultural practice and endocrine-disrupting properties of mecoprop-P, by proceeding as follows:

- In case the results of such update show that the non-dietary exposure assessment is still not acceptable, a statement that outlines these results should be issued by 15 March 2019 at the latest.
- If on the contrary the results of such update show that the non-dietary exposure assessment is acceptable, EFSA is requested to update the assessment as regards points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, in line with Commission Regulation (EU) 2018/605[4], applicable from 10 November 2018, with the guidance document to identify endocrine-disrupting substances (ECHA/EFSA, 2018), and with Commission Implementing Regulation (EU) 2018/1659[5]. In this case, EFSA is requested to update the EFSA conclusions on both the non-dietary exposure assessment and the assessment of the endocrine-disrupting properties of mecoprop-P.

EFSA received the updated RAR and the list of end points (LoEP) from the RMS, UK, with the revised non-dietary exposure assessment on 21 December 2018 (United Kingdom, 2018). EFSA distributed the updated documents to the Member States and the applicant, Nufarm, for consultation and comments on 7 January 2019. EFSA also provided comments. At the Pesticide Peer Review Experts' Meeting 190 Session 2 – Mammalian toxicology session (January 2019), the updated assessment showed that the non-dietary exposure assessment was acceptable. As a result, the RMS, UK, provided an updated RAR and LoEP accordingly (United Kingdom, 2019).

Due to the UK leaving the EU, the renewal of approval dossier on mecoprop-P was reallocated to Ireland, as RMS.

As stated in the mandate, EFSA proceeded with the updated assessment with respect to points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, in line with Commission Regulation (EU) 2018/605. EFSA prepared an initial assessment report on the ED properties in line with the EFSA/ECHA (2018) guidance and distributed it to the Member States and the applicant, Nufarm, for consultation and comments on 24 April 2019 (EFSA, 2019). Following a consultation with Member States in the Pesticide Peer Review Experts' Meeting TC 10 Mammalian toxicology – Ecotoxicology joint session (July 2019), it was concluded that mecoprop-P does not meet the ED criteria for humans for the thyroid (T) modality according to point 3.6.5 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) No 2018/605. However, considering that no oestrogen, androgen and steroidogenesis (EAS)-mediated adverse effects were observed based on an incomplete data set, additional testing was required to complete the data package for the EAS-modalities in relation to human health and to further investigate the ED properties of the substance for non-target organisms. Therefore, in accordance with the provisions of Commission Regulation (EU) No 2018/1659, on 9 August 2019 the applicant was given the opportunity to submit, within a period of 30 months, additional information to address the approval criteria set out in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) No 2018/605, and/or documentary evidence demonstrating that mecoprop-p may be used such that exposure is negligible, and/or the conditions for application of the derogation under Article 4(7) of Regulation (EC) No 1107/2009 are met. The additional information submitted by the applicant on 31 January 2022 was subsequently evaluated by the new RMS, Ireland.

[3] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

[4] Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

[5] Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine-disrupting properties introduced by Regulation (EU) 2018/605. OJ L 278, 8.11.2018, p. 3–6.

EFSA received the updated RAR and LoEP from the RMS, Ireland, with the revised ED assessment on 16 May 2022 (Ireland, 2022). Subsequently, a consultation on the revised RAR after the clock stop took place with Member States, the applicant, EFSA and the public in June–August 2022. All comments received were collated in the format of a reporting table and were considered during the finalisation of the peer review. In addition, as a result of the consultation, in light of the comments received, a consultation with Member States in the Pesticide Peer Review Meeting TC 92 Mammalian toxicity and Ecotoxicity session on ED was conducted in January 2023 and, as a consequence, the RMS, Ireland, provided an updated RAR and LoEP, in line with the outcome of the experts' discussion (Ireland, 2023).

A final consultation on the updated conclusions arising from the peer review following the mandate from the European Commission took place with Member States via a written procedure in September 2023.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of mecoprop-P as a herbicide on winter and spring wheat (including durum and spelt), barley, rye, oats and triticale, as proposed by the applicant, including updates following the request from the European Commission to review the risk assessment as regards non-dietary exposure and to assess the endocrine-disrupting properties of mecoprop-P. A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

In addition, a key supporting document to this updated conclusion is the peer review report (EFSA, 2017b, updated 2023), 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 tables (27 September 2016, 29 January 2019[6] and 17 October 2022[7]);
- the evaluation tables (12 April 2017, updated 30 June 2023);
- 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 EFSA endocrine disruption (ED) (16 May 2019)[8];
- the comments received on the draft EFSA conclusion and the updated EFSA conclusion.

Given the importance of the RAR, including its revisions from the initial RMS, the UK (United Kingdom, 2017; United Kingdom, 2018, updated 2019) and the new RMS after Brexit, Ireland (Ireland, 2022, updated 2023), the Peer Review Report and the EFSA ED assessment (EFSA, 2019), all these 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 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

Mecoprop-P is the ISO common name for (2*R*)-2-(4-chloro-2-methylphenoxy)propanoic acid (IUPAC).

The unresolved isomeric mixture of this substance has the ISO common name mecoprop.

The representative formulated product for the evaluation was 'Mecoprop-P K 600', a soluble concentrate (SL) containing 600 g/L mecoprop-P.

[6] Reporting table following consultation on the revised RAR (non-dietary exposure assessment) prepared by the RMS (IE) in the context of the mandate to review the non-dietary exposure assessment.

[7] Reporting table following consultation on the revised RAR on the RMS (IE) assessment of the endocrine-disrupting properties made available after the 30-month clock stop in the context of the mandate to review the endocrine-disrupting assessment.

[8] ED assessment performed by EFSA before the timepoint of the ED additional information request (stop of the clock). The ED assessment including evaluation of the newly provided additional information on the endocrine disruption properties following the ED clock stop is available in the revised RAR (Ireland, 2023) with the final outcome presented in the current EFSA Conclusion (see Section 6).

The representative uses evaluated were spray applications in winter and spring wheat (including durum and spelt), barley, rye, oats and triticale, to control broadleaved weeds. Full details of the good agricultural practices (GAPs) can be found in the list of end points in Appendix A.

Data were submitted to conclude that the use of mecoprop-P according to the representative uses proposed at EU level results in a sufficient herbicidal efficacy against the target weeds following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014b).

A **data gap** has been identified for a search of the scientific peer-reviewed open literature on the aqueous photolysis metabolite 2-methylphenol and synonyms relevant to the scope of the application for renewal, dealing with side effects the environment and non-target species and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011).

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), SANCO/825/00-rev. 8.1 (European Commission, 2010).

The new proposed reference specification for mecoprop-P is based on batch data from industrial scale production. The minimum purity of the technical material is 890 g/kg. There is no FAO specification available for mecoprop-P. The impurity 4-chloro-2-methylphenol is considered a relevant impurity with a maximum amount of 5 g/kg. The batches used in the toxicological assessment support the proposed renewal specification, but not the original reference specification (See Section 2). The batches used in ecotoxicological testing support both the proposed renewal specification and the original reference specification. As a consequence, it is recommended to update the reference specification of the first approval.

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 mecoprop-P or the representative formulation; however, **data gaps** were identified for log P data for metabolites HMCPP and 2-methylphenol (see Section 5). The main data regarding the identity of mecoprop-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 and the relevant impurity 4-chloro-2-methylphenol, in the technical material and in the representative formulation.

The residue definition for monitoring for food and feed of plant origin was set as mecoprop-P. The existing LC-MS/MS method for monitoring determines the total mecoprop content, present as acid, esters or conjugates, with a limit of quantification (LOQ) of 0.01 mg/kg, expressed as mecoprop in all commodity groups. The method is not enantioselective. As a consequence, a **data gap** was identified for a monitoring method (chiral method) for the determination of mecoprop-P in plant commodities.

The existing LC-MS/MS method for monitoring residues in food and feed of animal origin determines the total mecoprop content, present as acid, esters or conjugates, with a LOQ of 0.01 mg/kg, expressed as mecoprop. The method is not enantioselective. Pending on the final decision on the residue definition for monitoring in animal matrices, a **data gap** might be identified for a monitoring method (chiral method) of the compound of the residue definition in animal matrices.

The monitoring residue definition for soil, water and air is mecoprop-P. LC-MS/MS methods are available enabling the determination of residues of mecoprop and the corresponding esters in soil, water and air with LOQs of 0.01 mg/kg in soil, 0.02 μg/L in surface water and 0.28 $\mu g/m^3$ in the air, respectively; however, the methods are not enantioselective. As a consequence, a **data gap** was identified for monitoring (chiral) methods for mecoprop-P in the environmental matrices.

A **data gap** was identified for a monitoring method for the determination of mecoprop-P residues in body fluids and tissues.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000-rev. 10-final (European Commission, 2003a), SANCO/10597/2003-rev. 10.1 (European Commission, 2012), Guidance on non-dietary exposure assessment (EFSA, 2014) and Guidance on dermal absorption (EFSA PPR Panel, 2012).

The toxicological profile of mecoprop-P and its metabolites was discussed at the Pesticides Peer Review Experts' Meeting 151 in February 2017. The revised non-dietary exposure assessment was discussed at the Pesticides Peer Review Experts' Meeting 190 Session 2 in January 2019.

The relevance of some individual impurities in comparison with the toxicological profile of the parent compound has not been fully addressed (**data gap, see Section 8)**. The impurity 4-chloro-2-methylphenol (PCOC) is considered toxicologically relevant based on its hazardous properties (including acute toxicity by inhalation in accordance with the Regulation (EC) No 1272/2008[9]) with a maximum acceptable content of 5 g/kg. The batches used in the toxicity studies support the proposed renewal specification, but not the original reference specification.

Mecoprop-P is rapidly and extensively absorbed after oral administration being mostly eliminated with urine with a half-life under 8 h. Mecoprop-P is largely excreted as parent material and it is mainly distributed in the thyroid, kidney, blood and plasma. Acute toxicity studies were performed using mecoprop-P, while some of the long-term studies were performed on the racemate mecoprop. During the experts' consultation 151 (February 2017), it was agreed on the toxicity bridging between the two isomers of mecoprop; studies on the racemate were considered applicable to the mecoprop-P isomer because the toxicity of the isomer mixture was found to be equivalent to the toxicity of the P isomer in the repeat dose studies. Mecoprop-P has a harmonised classification.[10] Category 4 for acute oral toxicity, and Category 1 for eye damage. Low acute toxicity was observed when mecoprop-P was administered by the dermal or inhalation routes; no skin irritation and skin sensitisation were attributed to the active substance. Mecoprop-P did not have any phototoxic effect, and therefore, photomutagenicity testing is not required.

The main target organs of mecoprop-P in the repeat dose studies are the kidneys in rats, mice and dogs, liver in mice and blood cells in dogs. The relevant short-term no adverse effect level (NOAEL) is 4 mg/kg body weight (bw) per day from the 90-day study in dogs, based on decreased red blood cells and packed cell volume and supported also by the NOAEL of 4.4 mg/kg bw per day from the 7-week study in rats, based on increased absolute and relative kidney weight, increased blood urea nitrogen and decreased cholesterol. The relevant long-term NOAEL is 1 mg/kg bw per day from the 2-year study in rats, based on increased kidney weight. Mecoprop-P did not present genotoxic potential *in vivo* and had equivocal evidence of clastogenicity in mammalian cells *in vitro*. No evidence of carcinogenicity was observed in rats and the slight increase in hepatocellular carcinoma in mouse females was considered equivocal, of limited relevance for humans and not sufficient for classification. The parental, reproductive and offspring NOAELs are 500/325 ppm (corresponding to 24.3 mg/kg bw per day in the extended one-generation study. Differently from the previous evaluation, the experts agreed that criteria were met for classification[3] of mecoprop-P as developmental toxicant Category 2, based on the increased late resorptions in the rabbit study. This proposal was based on a more detailed evaluation of the late resorption findings in the developmental toxicity study in the rabbit and considering that the developmental NOAEL was lower than the maternal NOAEL. The RMS disagreed, considering that the magnitude of the effect observed was not sufficient for classification of the substance. However, more recently RAC[11] concluded that no classification for development toxicity is warranted. There was no evidence of neurotoxic effects or immunotoxicity induced by mecoprop-P treatment in the supplementary studies provided.

The metabolite hydroxymethyl-mecoprop-P (HMCPP) showed lower acute toxicity than the parent, even though just a study summary was submitted and not the full study report. In repeated dose studies, HMCPP showed to be less toxic than the parent; HMCPP was also negative in Ames test and negative in the *in vivo* micronucleus test. Insufficient information was available to conclude on the

[9] 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.

[10] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

[11] RAC Opinion, 2019, https://echa.europa.eu/documents/10162/eaa998fa-152e-79a6-4401-a98888ad4c6a

toxicity (including genotoxicity) of carboxy-mecoprop-P (CCPP) and 4-glucosyl-MPP metabolites, and therefore, a **data gap** was identified.

The acceptable daily intake (**ADI**) of mecoprop-P is 0.01 mg/kg bw per day with no change in the ADI value compared to the original approval (European Commission, 2003b), based on the NOAEL of 1 mg/kg bw per day for kidney changes in the 2-year study in rats and applying an uncertainty factor (UF) of 100. The acceptable operator exposure level (**AOEL**) is 0.04 mg/kg bw per day with no change in the AOEL value compared to the previous review report assessment (European Commission, 2003b), based on the NOAEL of 4 mg/kg bw per day for haematological changes observed in the 90-day study in dogs and applying an uncertainty factor (UF) of 100 with no correction for oral absorption. The acute acceptable operator exposure level (**AAOEL**) and acute reference dose (**ARfD**), not set in the previous review report assessment (European Commission, 2003b), are both 0.2 mg/kg bw based on the NOAEL of 20 mg/kg bw per day for the increased incidence of late resorptions in the rabbit developmental study and applying an uncertainty factor (UF) of 100.

The dermal absorption values have been assessed in an *in vitro* study with a different formulation than the formulation for representative uses. The read-across between the two formulations has been considered appropriate.[12] Based on pro-rata calculations, the dermal absorption values to be used for risk assessment are 22% for 3 g/L (1:200 dilution) and 11.25% for 6 g/L (1:100 dilution).

On the basis of the EFSA calculator (EFSA, 2014), the exposure of operators resulting from the proposed uses of 'Mecoprop-P K 600' on cereals was predicted to be below the (A)AOEL for an operator wearing gloves during mixing/loading. Using the EFSA calculator, the predicted exposure of residents is below the AOEL except for children entering treated areas (AOEL of 111.38%; 75th percentile) even applying a buffer strip of 10 m and a drift reduction during application (critical area of concern; see Section 10.2). In the absence of validated method to measure dermal absorption for dry residues, only the dermal absorption value for the highest dilution (22%) should be used. It is noted that applying a dermal absorption value of 11.25% (corresponding to a higher dilution of 6 g a.s./L from the application of 200 L water/ha instead of 3 g a.s./L from the application of 400 L water/ha) would result in a predicted exposure of residential children below the AOEL. However, this estimate would only cover an application volume of 200 L of water/ha while the representative uses also include 400 L water/ha. It is noted that the use of the EFSA calculator was not mandatory at the time of submission of the renewal dossier; therefore, calculations with UK model were also provided before the mandate (in 2017, with more conservative dermal absorption values). The predicted bystander and resident exposure to vapour was 10% of the AOEL for an adult and 21% for a child, while the exposure to spray drift was predicted to be 20% of the AOEL. According to the EFSA calculator, the exposure estimates for the worker inspecting treated crops (wearing workwear) are below the AOEL.

3. Residues

The assessment in the residue section is based on the OECD guidance document on overview of residue chemistry studies (OECD, 2009), the OECD publication on maximum residue level (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).

Metabolism of mecoprop-P in primary crops was investigated upon foliar application to a cereal/ grass crop (wheat) using ^{14}C-mecoprop-P labelled on the benzene ring. Mecoprop-P was applied post-emergence on wheat, at growth stage BBCH 32 at a dose rate of 1.4 kg a.s./ha (1.2 N rate). Mecoprop-P was identified at a level of 4.1% total radioactive residue (TRR) in immature green plant, 2.4% TRR in wheat grain and 22% TRR in wheat straw. Four weeks after application, the predominant compounds of the total residues in the whole green plant were identified as HMCPP (free and glucoside conjugated) (26.3% TRR; 3.06 mg eq/kg), CCPP (10% TRR; 1.16 mg eq/kg) and 4-glucosyl-MPP (26.2% TRR; 3.05 mg eq/kg). It is noted that the way the 4-glucosyl-MPP compound is formed in cereal whole plant is unclear and further clarification on the structure and the formation pathway of 4-glucosyl-MPP in plants should be provided (**data gap**). In mature wheat grain besides the identified minor metabolite CCPP (6% TRR; 0.01 mg eq/kg), the major part of the radioactive residues was characterised as a polar fraction that globally accounted for 42.4% TRR (0.07 mg eq/kg) and was shown to be constituted of several components that did not exceed each 0.013 mg eq/kg. In wheat

[12] Refer to experts' consultation 2.11 in the Report of Pesticides Peer Review Meeting 190 session 2 (EFSA, 2017b, updated 2023).

straw, metabolites HMCCP and CCPP were recovered at levels of 11.8% TRR (1.18 mg eq/kg) and 14.2% TRR (1.42 mg eq/kg), respectively. Further characterisation of the unidentified radioactive fractions in wheat grain and straw demonstrated that the residues were found to be mainly incorporated into the natural plant constituents (sugars, lignin). The metabolic pathway of mecoprop-P was considered as adequately depicted and the **residue definition for enforcement** for cereal grain is proposed as mecoprop-P only. For risk assessment, several aspects were considered to derive the residue definition: (1) the significant proportions and concentrations of HMCPP and CCPP recovered in wheat straw, the identified CCPP compound in wheat grain and (2) although HMCPP under its conjugated form and 4-glucosyl-MPP were not relevant in regard to the representative uses on cereal small grains where only grain and straw are considered as feed items, their respective contribution to the animal dietary intakes when animals are exposed to residues in grass which is an authorised use (EFSA, 2013a) and where these compounds could represent a significant part of the residues have to be considered. The **residue definition for risk assessment** for cereal whole plant, grain and straw is provisionally set as mecoprop-P, HMCPP (free and conjugated), CCPP and 4-glucosyl-MPP. A **data gap** is therefore identified for sufficient NEU and SEU GAP-compliant residue trials to address the magnitude of residues of these compounds in cereals whole plant, grain and straw and supported by acceptable storage stability data. Once the result of the requested residue trials is available, further consideration may need to be given to the toxicity profile of CCPP and 4-glucosyl-MPP and the residue definition for risk assessment of the representative uses revised accordingly. HMCPP has been demonstrated to be less toxic than mecoprop-P (see Section 2). Meanwhile provisional conversion factors for risk assessment of 4 for cereal grain, 2.2 for cereal straw and 6 for cereal whole plant (forage) were derived from the metabolism study.

Since mecoprop-P showed a very low to moderate persistence in soil (DT_{90} 20–33 days), confined rotational crop metabolism studies are not triggered.

A complete residue trial data set compliant with the SEU GAP is available on wheat and barley whilst only four residue trials on wheat and barley compliant with the NEU GAP were provided with a possible extrapolation to rye, oats and triticale. The residue data are supported by acceptable storage stability data. Because based on the metabolism data, a 'zero' residue situation cannot be concluded for cereal grain so sufficient residue trials on cereal grain compliant with the NEU and SEU GAP on cereals need to be requested for the determination of mecoprop-P residues at a lower limit of determination (0.01 mg/kg) (**data gap**). Meanwhile, a provisional MRL of 0.05* mg/kg (*At the limit of quantification (LOQ).) is derived for cereal grain.

The requirement for standard hydrolysis studies on the nature of the residues in processed cereal grain should be reconsidered pending the outcome of the requested residue trials to address the magnitude of residues of the different relevant compounds in cereal grain.

The metabolism in livestock was investigated in lactating goats with ^{14}C-(U-phenyl)-mecoprop-P at nominal doses of 0.13 and 1.27 mg/kg bw per day, respectively. Mecoprop-P was extensively excreted in urine and faeces and only 0.02% and < 0.01% of the administered radioactivity was recovered, respectively, in milk and tissues. The total residues in fat and muscle were very low (< 0.01 mg eq/kg) and no further metabolites' identification was attempted in those matrices. At the highest dose, the total residues in kidney and liver amounted to 0.097 mg eq/kg and 0.031 mg eq/kg, respectively. In kidney, mecoprop-P was recovered under its free and conjugated forms (48% TRR) alongside unknown compounds that globally accounted for 13.2% TRR (0.013 mg eq/kg). Mecoprop-P was not recovered in liver and milk whilst unidentified compounds were detected at significant proportions in liver (54.7% TRR; 0.017 mg eq/kg) and in milk (29.6% TRR, 0.004 mg eq/kg). EFSA acknowledges that the goat metabolism study was not conducted in accordance with the current test guideline recommendations in view of the low rate of metabolites' identification in liver, kidney and milk and the metabolism of mecoprop-P in ruminants cannot be sufficiently depicted based on the current data. A **data gap** was set to provide all analytical evidence available in the raw data from the goat metabolism study for further metabolites' identification in ruminants' matrices. Since it cannot be concluded on whether the metabolism in rat and ruminants are similar the need for a pig metabolism study is not excluded. The need for a poultry metabolism study addressing the fate of mecoprop-P residues will be reconsidered based on the outcome of the requested NEU and SEU residue trials on cereal grain analysing mecoprop-P residues at a lower limit of determination (0.01 mg/kg) (see **data gap**). Furthermore, pending upon the respective contribution of HMCPP (free and conjugated), CCPP and 4-glucosyl-MPP to the livestock dietary burden (**data gap**) and their relative toxicity, the need for metabolism studies in poultry and ruminants addressing the potential transfer and behaviour of these compounds in animal matrices will have to be reconsidered. The need for a fish metabolism study will

also have to be reconsidered pending upon the outcome of the requested residue trials on cereal grain and analysing for all the relevant compounds. Currently residue definitions for monitoring and risk assessment for products of animal origin cannot be proposed. A ruminant feeding study conducted with mecoprop-P only was also submitted and analysing for the magnitude of residues of parent mecoprop-P, HMCPP and CCPP. It is acknowledged that if significant transfer of residues of HMCPP (free and conjugated), CCPP and 4-glucosyl-MPP into animal commodities is observed, the magnitude of these compounds or their degradation products should be further investigated in livestock feeding studies dosing with a representative mixture of mecoprop-P and all relevant compounds in feed items.

For the time being, a consumer risk assessment can only be conducted for plant matrices on a provisional basis. Long-term or short-term intake concerns were not identified for the consumers since the highest chronic and acute intakes accounted for 20.6% of the ADI (Danish child) and 1.4% of the ARfD (wheat), calculated with EFSA PRIMo rev. 3.1. The consumer risk assessment is, however, not finalised for the products of animal origin considering the outstanding data to perform a comprehensive livestock exposure assessment. Experimental information was not available regarding the potential racemisation of mecoprop-P (*R*-isomer) into the *RS*-isomer mixture of mecoprop. Although this potential might be expected to be low, a **data gap** was identified (see Sections 4 and 8). However, the impact of any potential isomeric conversion on the consumer toxicological burden can be considered of low relevance because the toxicity of the *RS*-isomer mixture (mecoprop) was found to be equivalent to the toxicity of the *R*-isomer (mecoprop-p) (see Section 2); however, depending on the extent of any potential isomerisation into the *S*-isomer, a review of the residue definitions may be triggered as currently only residues of the *R*-isomer have been considered.

The proposed provisional residue definition for risk assessment for cereal/grass crops has been changed compared to the residue definition that was agreed in the review of the existing MRLs for mecoprop-P (EFSA, 2013a). Furthermore, the livestock exposure assessment will need to be reconsidered in the light of the outcome of the data gaps identified during the peer review. Meanwhile, an acute intake concern was not identified considering the tentative MRLs and the ARfD of 0.2 mg/kg bw in the exposure calculation.

Residue data in pollen and bee products were not provided. Although cereal crops are considered of low attractiveness to bees for pollen collection, metabolism data indicate non-negligible translocation of the residues throughout the plant parts. TRRs observed in cereals grains were 0.165 mg eq/kg at an application rate of 1.41 kg/ha (1.2 N). It is therefore not excluded that residues of mecoprop-P and its relevant metabolites can be present in pollen and bee products so further information needs to be requested (**data gap**).

4. Environmental fate and behaviour

As the analytical methods used in the available fate and behaviour studies did not discriminate mecoprop-P (*R*) and mecoprop-M (*S*) isomers, the applicant was requested to address the potential for racemisation of mecoprop-P in environmental matrices under natural conditions. The only information provided on this was that racemisation was not expected as high temperatures and the presence of acidic metal species to catalyse transformation to the S isomer would be necessary. Whilst this is plausible, an expectation is not sufficient information for a regulatory assessment. Consequently, a **data gap** was identified (see Section 8). However, it is considered unlikely that the uncertainty on the contribution to the total residues levels of the *S* isomer metabolite formed would change the conclusion of high aquatic risk (see Section 5). 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, mecoprop-P exhibited very low to moderate persistence, forming no transformation products at levels that triggered identification and further assessment (all chromatically resolved components except mecoprop accounted for $< 5\%$ applied radioactivity (AR)). Mineralisation of the phenyl ring ^{14}C radiolabel to carbon dioxide accounted for 40–51% AR after 100–191 days. The formation of unextractable residues (not extracted by acidified acetonitrile) for this radiolabel accounted for 43–51% AR after 100 days.

Mecoprop-P exhibited very high to medium mobility in soil. It was concluded that the adsorption of mecoprop-P was pH dependent, with adsorption decreasing as pH increased. In a lysimeter study of 2-year duration, mecoprop-P and 4-chloro-2-methylphenol in leachate accounted for < 0.03 μg/L, in individual leachate samples. It should be noted that this study may not cover the higher leaching potential for metabolites that might be encountered under neutral or alkaline soil conditions.

In laboratory incubations in dark aerobic natural sediment water systems, mecoprop-P exhibited moderate to high persistence, forming no transformation products at levels that triggered identification and further assessment (all chromatically resolved components except mecoprop accounted for < 5% AR). The unextractable sediment fraction (not extracted by acetonitrile including Soxhlet extraction) was a sink for the phenyl ring ^{14}C radiolabel, accounting for 10–32% AR at study end (98–100 days). Mineralisation of this radiolabel accounted for 13–58% AR at the end of the study. The rate of decline of mecoprop-P in a laboratory sterile aqueous photolysis experiment was faster (low persistence) relative to that which occurred in the aerobic sediment water incubations. The photolysis metabolite 2-methylphenol was formed at a maximum of 30% AR and exhibited moderate persistence. The necessary surface water and sediment exposure assessments (Predicted environmental concentrations (PEC) calculations) were carried out for mecoprop-P and the metabolite 2-methylphenol, using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 2.1 of the Steps 1–2 in FOCUS calculator). For the active substance mecoprop-P, appropriate step 3 (FOCUS, 2001) and step 4 calculations were available.[13] The step 4 calculations appropriately followed the FOCUS (FOCUS, 2007) guidance, with no-spray drift buffer zones of up to 10 m being implemented for the drainage scenarios (representing a 38–86% spray drift reduction), and combined no-spray buffer zones with vegetative buffer strips of up to 10 m (reducing solute flux in run-off by 60% and erosion runoff of mass adsorbed to soil by 85%) being implemented for the run-off scenarios. Calculations were also presented for vegetative filter strips of 20 m (reducing solute flux in run-off by 80% and erosion run-off of mass adsorbed to soil by 95%). The SWAN tool (version 1.1.4) was appropriately used to implement these mitigation measures in the simulations. However, risk managers and others may wish to note that whilst run-off mitigation is included in the step 4 calculations available, the FOCUS (FOCUS, 2007) report acknowledges that for substances with K_{Foc} < 2,000 mL/g (i.e. mecoprop-P), the general applicability and effectiveness of run-off mitigation measures had been less clearly demonstrated in the available scientific literature, than for more strongly adsorbed compounds.

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 4.4.2.[13] The potential for groundwater exposure from the representative uses by mecoprop-P above the parametric drinking water limit of 0.1 μg/L was concluded to be low in geoclimatic situations that are represented by all six FOCUS scenarios for spring planted cereals and eight of the nine FOCUS groundwater scenarios for autumn planted (winter) cereals. At the scenario Okehampton, 80th percentile annual average recharge concentrations moving below 1 m were predicted to be 0.115 μg/L.

The applicant provided appropriate information to address the effect of water treatments processes on the nature of the residues that might be present in surface water, when surface water is abstracted for drinking water. The conclusion of this consideration was that both mecoprop-P and 2-methylphenol 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.

The PEC in soil, surface water, sediment and groundwater covering the representative uses assessed can be found in Appendix A of this conclusion.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002), SETAC (2001), EFSA (2009) and EFSA PPR Panel (2013).

Mecoprop-p was discussed at the Peer Review Experts' meeting 154 in February 2017.

The potential for the *R* isomer to racemise to the *RS* mixture in the soil and water compartments was not adequately addressed; however, it is considered unlikely that the uncertainty on the contribution to the total residues levels of the *S* isomer metabolite formed would change the conclusion of high aquatic risk (see Section 4).

A low acute risk to **birds** for mecoprop-P was concluded for all representative uses. The only available long-term endpoint for birds was based on a subchronic study. It is noted that a study in line with the OECD 206 Test Guideline was indicated as being under development by the applicant. Considering the uncertainties in the currently available long-term endpoint for birds, a data gap for the full report of this study, which may provide a relevant endpoint to be used in the long-term avian risk assessment, was identified (**data gap and issue not finalised, see Section 10.1**). By performing a

[13] Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2008) and Walker equation coefficient of 0.7.

provisional risk assessment with the available data and by using the LD_{50}/10, the latter being lower than the available sub-chronic endpoint, a low long-term risk to birds was concluded for all representative uses.

A low acute risk to **wild mammals** for mecoprop-P was concluded for all the representative uses. During the Peer Review Experts' meeting 154,[14] the experts agreed to use the NOAEL of 8.5 mg/kg bw per day in the long-term risk assessment for wild mammals. This endpoint was not modified after the submission of the new data on mammals, being the lowest reliable endpoint; however, this endpoint was obtained by testing the racemic Mecoprop. By using this endpoint, a high long-term risk to wild mammals was concluded for all representative uses of mecoprop-p. The available refinement, DT_{50} based on residues trials, was discussed, and agreed during the Peer Review Experts' meeting 154;[15] however, it was not sufficient to address the risk identified for small insectivorous and omnivorous mammals and large herbivorous mammals (**data gap**). A risk assessment for the exposure via bioaccumulation was not triggered for mecoprop-P. It is noted that in the case of the surface water metabolite 2-methylphenol, the available $LogP_{ow}$ (< 3) was reported as being retrieved from the literature. The relevant sources of these data were not summarised in the RAR (**data gap**). By considering the metabolites as 10 times more toxic than the parent compound, a high acute and long-term risk to birds could not be excluded for the plant metabolite HMCPP for all the representative uses whilst a high long-term risk could not be excluded for metabolite CCPP for all the representative uses (**data gap**). It is noted that the RMS disagreed with this data gap being the high risk identified exclusively for the scenario 'Large herbivorous bird 'goose' which is considered as not relevant for the representative uses by the RMS. By considering the metabolites as 10 times more toxic than the parent compound, a high acute and long-term risk to mammals could not be excluded for the plant metabolite CCPP for all representative uses (**data gap**). A low risk from consumption of contaminated water was concluded for both birds and wild mammals.

With regard to **aquatic organisms**, a high risk to aquatic plants (*Myriophyllum spicatum*) for mecoprop-P was concluded for 1/5 FOCUS scenarios for the use on spring cereals and for 2/9 FOCUS scenarios for the use on winter cereals when appropriate risk mitigation measures are considered (**data gap**). A low risk to aquatic invertebrates (acute and chronic), fish (acute and chronic) and algae was concluded for all the representative uses. Regarding the surface water metabolite 2-methylphenol, by considering it as 10 times more toxic than the parent, a low risk was concluded for aquatic invertebrates (acute and chronic), fish (acute and chronic) and algae for all representative uses whilst a high risk could not be excluded for aquatic plants. It is noted that Step 3 and 4 FOCUS exposure estimates were not available for this metabolite (**data gap**).

In the case of honey**bees**, acute toxicity data, chronic toxicity data (including an assessment of effects on the hypopharyngeal gland (HPG)) and larval single exposure data for the active substance were available. A study on brood development in line with Oomen et al. (1992) was available for the formulation 'Mecoprop-P L 600'. Only the acute risk assessment according to the European Commission Guidance (2002) was conducted. Since the EFSA Guidance Document on the risk assessment of plant protection products on bees (EFSA, 2013b) was not taken note, the RMS did not use it while performing the bees risk assessment. It is, however, noted that European Commission (2002) does not provide a risk assessment scheme addressing the chronic risk to adult honeybees and the risk to honeybee brood; the latter are covered by EFSA (2013b). In consideration of the above, and of the fact that the available high tier study on bee brood development is considered of limited use according to EFSA (2013b), a **data gap** has been identified. It is additionally noted that the examination of the HPG in the chronic toxicity study revealed statistically significant reduction in the acini diameter between all the test item groups and the control group, therefore, a no observed effect dose (NOED) could not be derived.

At the first-tier level, a high risk for **non-target arthropods** (*A. rhopalosiphi*) following in-field exposure was concluded whilst a low risk was concluded in the case of the off-field exposure. Extended and/or aged residues tests were available for *A. rhopalosiphi, C. carnea and A. bilineata*. By using these data in line with ESCORT 2, a low risk was concluded for all species except *A. bilineata*. The highest tested dose in the *A. bilineata* test was below the maximum application rate, however, considering that, at that application rate, the effects on reproduction accounted for 2.8% and that a low off-field risk was concluded, overall, a low risk to non-target arthropods could be concluded.

[14] Refer to experts' consultation 5.1 in the Report of Pesticides Peer Review Meeting 154 (EFSA, 2017b, updated 2023).
[15] Refer to experts' consultation 5.2 in the Report of Pesticides Peer Review Meeting 154 (EFSA, 2017b, updated 2023).

A low risk to **earthworm and other soil macroorganisms** was concluded for all the representative uses of mecoprop-P. In the absence of a valid study to address the effects of mecoprop-P to **soil microorganisms,** a **data gap** was identified, it is noted that the RMS disagreed with this data gap.

The probabilistic risk assessment for **non-target terrestrial plants** was discussed and agreed at the Peer Review experts' meeting 154. A low risk to non-target terrestrial plants for mecoprop-P was concluded for all the representative uses provided that mitigation measures are implemented.

On the basis of the available data, the risk was considered low for **organisms in sewage treatment plants.**

6. Endocrine disruption properties

The assessment of the endocrine disruption (ED) potential of mecoprop-P was discussed at the Pesticides Peer Review Experts' TC 10 Mammalian Toxicology – Ecotoxicology joint session in July 2019. According to the ECHA/EFSA ED (2018) guidance, the experts concluded that mecoprop-P does not meet the ED criteria for **humans** for the thyroid (T) modality according to point 3.6.5 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) No 2018/605. However, additional testing was required to complete the data package available at that time for adverse human health effects due to the oestrogen, androgen and steroidogenesis (EAS)-mediated adverse effects and to further investigate the ED properties of the substance for **non-target organisms.**[16]

In the context of the Mandate and following submission of additional information on ED by the applicant, mecoprop-P was discussed at the Pesticides Peer Review Experts' Meeting TC 92 on Mammalian Toxicology and Ecotoxicology joint session on ED (January 2023) for both humans and non-target organisms.

Regarding **humans**, when integrating and weighting the results of the new study submitted in the WoE for T-modality, there is no pattern of adversity for the T modality and ED criteria were not met for the T modality (Scenario 1 a). This is in line with the former conclusion on T modality held in the PR meeting 10/2019. With regard to the EAS-modalities, the data set was also considered complete, and a pattern of EAS-mediated adversity was not observed.[17]

The outcome of the assessment reported above for humans also applies to **wild mammals as non-target organisms**.

Regarding **non-target organisms other than wild mammals**, an Amphibian Metamorphosis Assay (AMA, OECD TG 231), and a Fish Short-Term Reproduction Assay (FSTRA, OECD TG 229) were made available. Both studies were discussed at the Pesticide Peer-Review Experts' meeting TC 92.[18]

Regarding the T-modality, although some positive findings were observed in the AMA, all experts agreed that those were not suggesting a pattern of T-mediated endocrine activity.

Regarding the EAS-modalities, all experts agreed that the FSTRA study was reliable with restriction due to some malformations observed both in the control and treated animals. Nevertheless, the experts agreed that the study could still be used in the ED assessment. Overall, the experts concluded that there was no pattern of activity with regard to the EAS-modalities.

In conclusion, based on the available information and according to the ECHA/EFSA (2018) guidance, the ED criteria according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/ 2009, as amended by Commission Regulation (EU) 2018/605, are not met for the EATS-modalities for the active substance mecoprop-P for humans and non-target organisms.

[16] Refer to the expert consultation point 2 of the report of the Pesticides Peer Review Experts' meeting 10 (July 2019; EFSA 2023).

[17] Refer to the experts' consultation point 2.3 of the Report of Pesticides Peer Review Meeting TC 92 (January 2023; EFSA, 2017b, updated 2023).

[18] Refer to the Expert consultation points 5.1 and 5.2 of the Report of the Pesticides Peer Review Meeting TC 92 (January 2023; EFSA, 2017b, updated 2023).

7. 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
Mecoprop-P	Very low to moderate persistence Single first-order and biphasic kinetics DT_{50} 6–10.1 days (DT_{90} 19.9–33.6 days, 20°C, 75% 1/3 bar WHC)	Data gap

Table 2: Groundwater

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L at 1 m depth for the representative uses[(a)]	Pesticidal activity	Toxicological relevance
Mecoprop-P	Very high to medium mobility K_{Foc} 12–167 mL/g, pH dependent	For winter cereals 1/9 FOCUS groundwater scenarios at 0.115 µg/L	Yes	Yes

(a): At least one FOCUS scenario or relevant lysimeter.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Mecoprop-P	High risk for 1/5 FOCUS scenarios (use on spring cereals) High risk for 2/9 FOCUS scenarios (use on winter cereals)
2-methylphenol	Data gap

Table 4: Air

Compound (name and/or code)	Toxicology
Mecoprop-P	Rat inhalation LC_{50} > 2.13 mg/L (4 h exposure, whole body), no classification required

8. 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).

- A search of the scientific peer-reviewed open literature regarding the aqueous photolysis metabolite 2-methylphenol and synonyms relevant to the scope of the application for renewal, dealing with side effects on the environment and non-target species and published within the last 10 years before the date of submission of dossier, conducted and reported in accordance with (EFSA, 2011) was not available (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section on the active substance and formulated product).
- Log P data for metabolites hydroxymethyl-mecoprop-P (HMCPP) and 2-methylphenol (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 1 and 5)
- Monitoring method (chiral method) for the determination of mecoprop-P residues in plant commodities (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1)
- Monitoring methods (chiral methods) for the determination of mecoprop-P residues in soil, water and air (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1)
- Enforcement method for the determination of mecoprop-P residues in body fluids and tissues (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1)
- Two impurities in the proposed renewal specification have not been adequately assessed because they were not shown to be present in adequate levels in batches used in the toxicological studies and there is insufficient information on their toxicity. The toxicity and relevance of these impurities in the technical specification should be addressed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- Toxicological data on the carboxy-mecoprop-P (CCPP) and 4-glucosyl-MPP metabolites (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- Clarification on the structure and the formation pathway of 4-glucosyl-MPP compound in plants (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- Sufficient NEU and SEU GAP-compliant residue trials on cereals whole plant, grain and straw to address the magnitude of residues of mecoprop-P, HMCPP (free and conjugated), CCPP and 4-glucosyl-MPP and supported by acceptable storage stability data (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- NEU and SEU GAP-compliant residue trials on cereal grain for the determination of mecoprop-P residues at a lower limit of determination (0.01 mg/kg) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- The livestock dietary burden calculation to be revised based on the outcome of the requested residue trials to determine the magnitude of mecoprop-P, HMCPP (free and conjugated), CCPP and 4-glucosyl-MPP in feed items and considering also their relative toxicity (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- All analytical evidence available in the raw data from the goat metabolism study for further metabolites' identification in ruminants' matrices (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- Determination of the residues in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom with regard to mecoprop-P and its degradation products (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).

- The potential for the *R* isomer to racemise to the *RS* mixture in the soil, water/sediment and air compartments, plants and animals was not adequately addressed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 3 and 4).
- Full report of the study performed according to OECD 206 Test Guideline to further address long-term endpoint and risk to birds (relevant for all representative uses evaluated, submission date proposed by the applicant: first-second quarter of 2017; see Section 5).
- Further information to address the long-term risk to small insectivorous and omnivorous mammals and large herbivorous mammals for mecoprop-P and to fish-eating birds and mammals for 2-methylphenol (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 5).
- Further information to address the acute and long-term risk to wild mammals for the plant metabolite CCPP (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 5).
- Further information to address the acute and long-term risk to birds for the plant metabolite HMCPP and the long-term risk to birds for the plant metabolite CCPP (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 5).
- Further information to address the risk to aquatic plants (*Myriophyllum spicatum*) for mecoprop-P and metabolite 2-methylphenol (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 5).
- A risk assessment for mecoprop-P and its pertinent metabolites for honeybees according to EFSA (2013b) (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 5).
- Further information to address the risk to soil microorganisms for mecoprop-P (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 5).

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

Operators should wear PPE (gloves) during mixing/loading (see Section 2).

Mitigation measures (e.g. 5 m non-spray buffer zone or 5 m vegetated buffer strip) are necessary to mitigate the risk to aquatic organisms for the use on winter cereals for FOCUS scenarios D3, D4, D5, D6, R1, R3, R4 and for FOCUS scenarios D3, D4, D5, R4 for the use on spring cereals (see Section 5).

- Mitigation measures (e.g. 5 m non-spray buffer zone) are necessary to mitigate the risk to non-target terrestrial plants for all the representative uses (see Section 5).

10. Concerns

10.1. 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[19] 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.

[19] 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) The consumer risk assessment cannot be finalised due to the outstanding data to confidently address the nature and magnitude of residues in plant and animal matrices (see Section 3).
2) The long-term risk to birds for mecoprop-P cannot be finalised (see Section 5).

10.2. 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.

Using the EFSA calculator, the predicted exposure of residents (sum of all exposure pathways) is below the AOEL except for children entering treated areas (75th percentile) even applying a buffer strip of 10 m and a drift reduction during application.[20]

A high long-term risk to wild mammals for mecoprop-P was concluded for all representatives uses (see Section 5).

10.3. 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		Spring cereals	Winter cereals
Operator risk	Risk identified		
	Assessment not finalised		
Worker risk	Risk identified		
	Assessment not finalised		
Resident/bystander risk	Risk identified	X[3]*	X[3]*
	Assessment not finalised		
Consumer risk	Risk identified		
	Assessment not finalised	X[1]	X[1]
Risk to wild non-target terrestrial vertebrates	Risk identified	X[4]	X[4]
	Assessment not finalised	X[2]	X[2]
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified		
	Assessment not finalised		

[20] It is noted that applying a dermal absorption value of 11.25% (corresponding to a higher dilution of 6 g a.s./L from the application of 200 L water/ha instead of 3 g a.s./L from the application of 400 L water/ha) would result in a predicted exposure of residential children below the AOEL. However, this estimate would only cover an application volume of 200 L of water/ha while the representative uses include also 400 L water/ha.

Representative use		Spring cereals	Winter cereals
Risk to aquatic organisms	Risk identified	1/5 FOCUS scenarios	2/9 FOCUS scenarios
	Assessment not finalised		
Groundwater exposure to active substance	Legal parametric value breached		1/9 FOCUS scenarios
	Assessment not finalised		
Groundwater exposure to metabolites	Legal parametric value breached		
	Parametric value of 10 μg/L breached		
	Assessment not finalised		

The superscript numbers relate to the numbered points indicated in Sections 10.1 and 10.2. Where there is no superscript number, see Sections 2–6 for further information.

*: It is noted that applying a dermal absorption value of 11.25% (corresponding to a higher dilution of 6 g a.s./L from the application of 200 L water/ha instead of 3 g a.s./L from the application of 400 L water/ha) would result in a predicted exposure of residential children below the AOEL. However, this estimate would only cover an application volume of 200 L of water/ha while the representative uses include also 400 L water/ha.

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Abbreviations

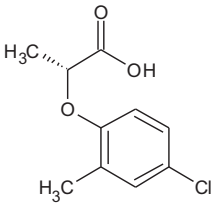
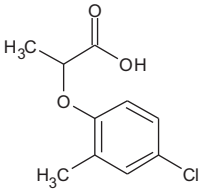
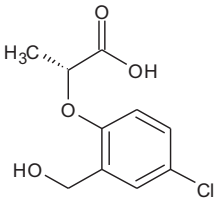
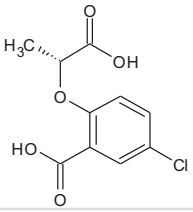
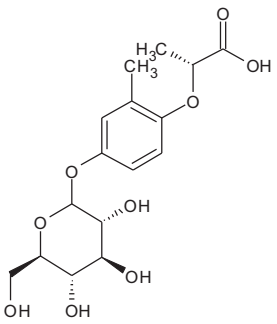
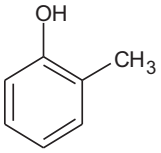
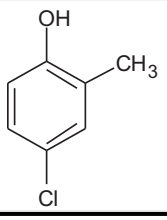
1/*n*	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
a.s.	active substance
AAOEL	acute acceptable operator exposure level
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AMA	Amphibian Metamorphosis Assay
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
bw	body weight
CFU	colony forming units
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
dw	dry weight
ECHA	European Chemicals Agency
EEC	European Economic Community
EAS	oestrogen, androgen and steroidogenesis modalities
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FSTRA	Fish Short-Term Reproduction Assay
GAP	Good Agricultural Practice
HPG	hypopharyngeal glands
HQ	hazard quotient
$HQ_{contact}$	hazard quotient for contact exposure
HR	hazard rate
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
iv	intravenous
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)
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography–mass spectrometry
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDD_{50}	lethal dietary dose; median
LOQ	limit of quantification
mm	millimetre (also used for mean measured concentrations)
mN	milli-Newton
MRL	maximum residue level
NOAEL	no observed adverse effect level

NOED	no observed effect dose
OECD	Organisation for Economic Co-operation and Development
Pa	pascal
PEC	predicted environmental concentration
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
QSAR	quantitative structure–activity relationship
r^2	coefficient of determination
SL	soluble concentrate
SMILES	simplified molecular-input line-entry system
SPG	specific protection goal
T	thyroid modality
$t_{1/2}$	half-life (define method of estimation)
TRR	total radioactive residue
UF	uncertainty factor
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.2023.8344

Appendix B – Used compound codes

Code/trivial name[(a)]	Chemical name/SMILES notation/INCHIKEY[(b)]	Structural formula[(c)]
mecoprop-P	(2*R*)-2-(4-chloro-2-methylphenoxy)propanoic acid Clc1cc(C)c(O[C@H](C)C(=O)O)cc1 WNTGYJSOUMFZEP-SSDOTTSWSA-N	
mecoprop	(2*RS*)-2-(4-chloro-2-methylphenoxy)propanoic acid CC1=C(C=CC(=C1)Cl)OC(C)C(=O)O WNTGYJSOUMFZEP-UHFFFAOYSA-N	
HMCPP or hydroxymethyl-mecoprop-P	(2*R*)-2-[4-chloro-2-(hydroxymethyl)phenoxy] propanoic acid Clc1cc(CO)c(O[C@H](C)C(=O)O)cc1 PQIATGPQELCUPX-ZCFIWIBFSA-N	
CCPP or carboxy-mecoprop-P	2-[(1*R*)-1-carboxyethoxy]-5-chlorobenzoic acid Clc1cc(c(O[C@H](C)C(=O)O)cc1)C(=O)O KLQFDKXRMORTPA-RXMQYKEDSA-N	
4-glucosyl-MPP	(2*R*)-2-[4-(D-glucopyranosyloxy)-2-methylphenoxy] propanoic acid O=C(O)[C@@H](C)Oc1ccc(OC2O[C@H](CO)[C@@H](O)[C@H](O)[C@H]2O)cc1C GSHOJMWWYZJRHU-FFKZRIAESA-N	
2-methylphenol (*o*-cresol)	2-methylphenol Cc1ccccc1O QWVGKYWNOKOFNN-UHFFFAOYSA-N	
4-chloro-2-methylphenol (4-chloro-*o*-cresol) (PCOC)	4-chloro-2-methylphenol Cc1cc(Cl)ccc1O RHPUJHQBPORFGV-UHFFFAOYSA-N	

(a): The compound name in bold is the name used in the conclusion.
(b): ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 7 July 2021).
(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).