

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance dichlorprop-P¹

European Food Safety Authority²

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessment carried out by the competent authority of the rapporteur Member State Denmark, for the pesticide active substance dichlorprop-P are reported. The context of the peer review was that requested by the European Commission following the submission and evaluation of confirmatory data concerning the risk assessment in the areas of consumer exposure and birds and mammals. 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. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Concerns are identified.

© European Food Safety Authority, 2012

KEY WORDS

Dichlorprop-P, peer review, risk assessment, pesticide, herbicide

¹ On request from the European Commission, Question No EFSA-Q-2012-00756, approved on 5 November 2012.

² Correspondence: pesticides.peerreview@efsa.europa.eu

Suggested citation: European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance dichlorprop-P. EFSA Journal 2012;10(11):2950. [20 pp.] doi:10.2903/j.efsa.2012.2950. Available online: www.efsa.europa.eu/efsajournal

SUMMARY

Dichlorprop-P was included in Annex I to Directive 91/414/EEC on 1 June 2007 by Commission Directive 2006/74/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. It was a specific provision of the approval that the notifier was required to submit to the European Commission further studies to confirm the results on animal metabolism and the risk assessment on acute and short-term exposure for birds and on acute exposure for herbivorous mammals by 31 May 2009.

In accordance with the specific provision, the notifier, Nufarm, submitted an updated dossier in July 2009, which was evaluated by the designated RMS, Denmark, in the form of an Addendum to the Draft Assessment Report. In compliance with Guidance Document SANCO 5634/2009 rev.3, the RMS distributed the Addendum to Member States and the EFSA for comments on 22 July 2011. The RMS collated all comments in the format of a Reporting Table, which was submitted to the European Commission in October 2011.

Following consideration of the comments received, the European Commission requested the EFSA to organise a peer review of the RMS's evaluation of the confirmatory data submitted in relation to consumer exposure and birds and mammals and to deliver its conclusions on the risk assessment for birds and mammals, the residue definition and the derivation of MRLs for animal products.

The experts at the Pesticide Peer Review meeting 96 on residues in September 2012 concluded that sufficient information was available to identify the metabolite 11 in wheat straw as dichlorprop-P methyl ester and derived the residue definition for enforcement purposes and risk assessment in plant commodities as the "sum of dichlorprop (including dichlorprop-P), its salts, esters and conjugates expressed as dichlorprop". The meeting also confirmed the MRLs of 0.7 mg/kg for bovine kidney and 0.1 mg/kg for bovine liver based on the available goat metabolism study reported in the Draft Assessment Report.

The acute risk for herbivorous and insectivorous birds and herbivorous mammals was not addressed with the confirmatory data and a critical area of concern was identified.

TABLE OF CONTENTS

Abstract	1
Summary	2
Table of contents	3
Background	4
The active substance and the formulated product	6
Conclusions of the evaluation	6
1. Residues	6
2. Ecotoxicology	7
Concerns	8
1. Issues that could not be finalised	8
2. Critical areas of concern	8
3. Overview of the concerns identified for each representative use considered	8
References	9
Appendices	10
Abbreviations	20

BACKGROUND

Dichlorprop-P was included in Annex I to Directive 91/414/EEC on 1 June 2007 by Commission Directive 2006/74/EC³, and has been deemed to be approved under Regulation (EC) No 1107/2009⁴, in accordance with Commission Implementing Regulation (EU) No 540/2011⁵, as amended by Commission Implementing Regulation (EU) No 541/2011⁶. EFSA previously finalised a Conclusion on this active substance on 13 January 2006 in the EFSA Scientific Report (2005) 52 (EFSA, 2006).

It was a specific provision of the approval that the notifier was required to submit to the European Commission further studies to confirm the results on animal metabolism and the risk assessment on acute and short-term exposure for birds and on acute exposure for herbivorous mammals by 31 May 2009.

In accordance with the specific provision, the notifier, Nufarm, submitted an updated dossier in July 2009, which was evaluated by the designated rapporteur Member State (RMS), Denmark, in the form of an Addendum to the Draft Assessment Report (Denmark, 2011). In compliance with Guidance Document SANCO 5634/2009 rev.3 (European Commission, 2009), the RMS distributed the Addendum to Member States and the EFSA for comments on 22 July 2011. The RMS collated all comments in the format of a Reporting Table, which was submitted to the European Commission in October 2011. Following consideration of the comments received, the European Commission requested the EFSA to organise a peer review of the RMS's evaluation of the confirmatory data submitted in relation to consumer exposure and birds and mammals and to deliver its conclusions on the risk assessment for birds and mammals, the residue definition and the derivation of MRLs for animal products.

The Addendum and the Reporting Table were discussed at the Pesticide Peer Review Meeting and Teleconference on residues and ecotoxicology in September 2012. Details of the issues discussed, together with the outcome of these discussions were recorded in the meeting reports.

A final consultation on the conclusions arising from the peer review took place with Member States via a written procedure in October 2012.

The conclusions laid down in this report were reached on the basis of the peer review of the RMS's evaluation of the confirmatory data submitted in relation to consumer exposure and birds and mammals. A key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the compilation of comments in the Reporting Table to the conclusion. The Peer Review Report (EFSA, 2012) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the Reporting Table,
- the reports of the scientific consultation with Member State experts,

³ Commission Directive 2006/74/EC of 21 August 2006 amending Council Directive 91/414/EEC to include dichlorprop-P, metconazole, pyrimethanil and triclopyr as active substances. OJ No L 235, 30.8.2006, p. 17-22.

⁴ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ No L 309, 24.11.2009, p. 1-50.

⁵ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p.1-186.

⁶ Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p.187-188.

- the comments received on the draft EFSA conclusion.

Given the importance of the Peer Review Report, this document is considered as background document A to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Dichlorprop-P is the ISO common name for (*R*)-2-(2,4-dichlorophenoxy)propionic acid (IUPAC). The unresolved isomeric mixture of this substance has the common name dichlorprop.

Dichlorprop-P belongs to the class of phenoxypropionic acid herbicides such as mecoprop or fenoprop. Dichlorprop-P is taken up mainly via leaves and induces a series of morphological effects which include decreases in root and shoot growth by acting as a mimic of auxin.

The representative formulated product for the evaluation was "DP-P K 600" ("Optica DP"), a soluble concentrate (SL), registered under different trade names in Europe. In the formulation the active substance is present as the potassium salt variant.

The evaluated representative uses as post emergent herbicide comprise broadcast spraying to control broad-leaved weeds in cereals, grassland and grass seed crops at an application rate of 1.5 kg dichlorprop-P per hectare.

CONCLUSIONS OF THE EVALUATION

1. Residues

The conclusion in the section below is based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999) and the recommendations on livestock burden calculations stated in the 2004 and 2007 JMPR reports (JMPR, 2004 and 2007).

Dichlorprop-P was initially peer reviewed in 2005 and discussed at the EPCO experts' meeting for residues (EPCO 19) in February 2005. A conclusion was issued by EFSA in January 2006 where a data gap was identified to provide further information on the metabolism of dichlorprop-P in cereals with regard to the identification and the toxicological relevance of metabolite 11 detected in straw in order to finalise the plant residue definition for risk assessment. After the experts' meeting, the RMS submitted data to address the identity of metabolite 11. These data were evaluated by the RMS in an Addendum and further discussed at the Pesticide Peer Review meeting 96 on residues in September 2012.

Metabolite 11 was detected in the wheat metabolism study (0.5 N rate) at a significant proportion in straw (14% TRR - 0.19 mg/kg). The submitted confirmatory data showed that metabolite 11 was identified as dichlorprop-P methyl ester and its identity was confirmed by mass spectrometry. It was unclear whether this metabolite had to be considered as a genuine metabolite or as an artefact generated during the extraction procedure with acidified methanol. The meeting of experts agreed to consider this metabolite as an artefact formed during the prolonged frozen storage of the straw extracts under acidic methanol conditions where methylation reactions may occur resulting in an esterification step. The meeting reconsidered accordingly the residue definition for enforcement purposes and risk assessment in cereals as the "sum of dichlorprop (including dichlorprop-P), its salts, esters and conjugates expressed as dichlorprop". It is noted that this residue definition is covered by analytical methods that are not enantioselective and do not differentiate between residues of the acid, salts, esters and glycoside conjugates.

During the previous peer review, a data gap was identified to provide a ruminant feeding study to establish MRLs for food of animal origin and this was further discussed at the Pesticides Peer Review meeting 96. Referring to the goat metabolism study, the meeting of experts noted that dichlorprop-P is rapidly excreted primarily as unchanged compound via urine, no significant accumulation is observed in tissues, and dichlorprop-P residues above the LOQ of the method are expected only in kidney. As a feeding study waiver, the notifier referred to ruminant feeding studies from other phenoxy herbicide

active substances with a similar structure to dichlorprop-P (2,4-D, 2,4-DB and MCPA). The meeting of experts considered these studies as “bridging data” since at similar dosing levels, a consistent pattern of excretion via urine was observed and residues above the LOQ are only expected in kidney after feeding with phenoxy herbicides. The meeting agreed that no further information would be gained by conducting a new feeding study with dichlorprop-P and confirmed the MRL proposals of 0.7 mg/kg for bovine kidney and 0.1 mg/kg for bovine liver.

EFSA proposes to reconsider the enforcement and risk assessment residue definition in all animal matrices, except poultry as the “sum of dichlorprop (including dichlorprop-P) and its salts, expressed as dichlorprop”.

No chronic or acute intake concerns were identified for the consumers. Based on the representative use on cereals and the EFSA PRIMo model, the TMDI was <1.1% of the ADI for all the consumer groups and the IESTI accounted for max. 0.5% of the ARfD (bovine kidney).

2. Ecotoxicology

In the framework of the confirmatory data assessment 3 position papers with revised acute risk assessments for birds and mammals were submitted by the notifier and evaluated by the RMS in an Addendum (Denmark, 2011).

Acute risk assessment to birds (herbivorous and insectivorous) and to mammals (herbivorous)

The first tier TER values were below the trigger for both birds and mammals. As a refinement of the acute risk assessment, a kinetic approach was presented where a “gavage factor” was proposed to address the risk. This factor was derived by comparing the estimated concentration of the test substance in the stomach with that in cereals based on the default RUD value. This “gavage factor” was then applied to the first tier TERs. However, it was noted that the weakness of the approach is that the concentration of the substance in the plasma may be lower than that in the stomach and therefore the concentration in the stomach may not represent a worst-case. Moreover, it was noted that no data were provided to support this approach. In addition to the “gavage factor approach” also a new 24-hour dietary study on mice was provided to refine the risk assessment for mammals. However, the experts at the Pesticides Peer Review Teleconference 76 on ecotoxicology questioned whether the exposure regime of 24-hours in this study could be considered sufficiently conservative for the acute risk assessment. It was also noted that the TER was below the trigger when using the endpoint from this study. Overall, it was concluded that the acute risk for herbivorous and insectivorous birds and herbivorous mammals was not addressed with the confirmatory data and a critical area of concern was identified.

Short-term risk to herbivorous birds

No data were provided by the notifier to address the short-term risk to herbivorous birds in the framework of submission of confirmatory data. However, according to EFSA, 2009 the short-term risk assessment is covered by the long-term risk assessment. The long-term risk is assessed as low at Tier 2.

Concerns

1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where 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 of Annex VI to Directive 91/414/EEC and where 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).

- None

2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude 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 where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude 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.

1. A high acute risk for herbivorous and insectivorous birds and herbivorous mammals could not be excluded.

3. Overview of the concerns identified for each representative use considered

Representative use		Cereals	Grassland	Grass seed crops
Consumer risk	Risk identified			
	Assessment not finalised			
Risk to wild non target terrestrial vertebrates	Risk identified		X ¹	
	Assessment not finalised			
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified			
	Assessment not finalised			
Comments/Remarks				

The superscript number in this table relate to the numbered point above under critical areas of concern.

REFERENCES

- Denmark, 2005. Final Addendum to Draft Assessment Report on dichlorprop-P, compiled by EFSA, July 2005.
- Denmark, 2011. Addendum to the Draft Assessment Report, confirmatory data, July 2011.
- EFSA (European Food Safety Authority), 2006. Conclusion regarding the peer review of the pesticide risk assessment of the active substance dichlorprop-P. EFSA Scientific Report (2005) 52, issued on 13 January 2006.
- EFSA (European Food Safety Authority), 2009. Guidance Document on Risk Assessment for Birds and Mammals on request of EFSA. EFSA Journal 2009; 7(12):1438.
- EFSA (European Food Safety Authority), 2012. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance dichlorprop-P.
- European Commission, 1999. Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, 1607/VI/97 rev.2, 10 June 1999.
- European Commission, 2006. Review Report for the active substance dichlorprop-P finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 23 May 2006 in view of the inclusion of dichlorprop-P in Annex I of Directive 91/414/EEC. SANCO/10016/2006 – rev.3, 23 May 2006.
- European Commission, 2009. Guidance document on the procedures for submission and assessment of confirmatory data following inclusion of an active substance in Annex I of Council Directive 91/414/EEC. SANCO 5634/2009 rev.3.
- JMPR, 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Rome, Italy, 20–29 September 2004, Report 2004, 383 pp.
- JMPR, 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Geneva, Switzerland, 18–27 September 2007, Report 2007, 164 pp.

APPENDICES

APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Summary of uses supported by available data (dichlorprop-P**)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
				Type (d-f)	Conc. of as (i)	method kind (f-h)	Growth Stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Cereals (wheat, barley, oats, rye, triticale and durum wheat)	North Europe/ South Europe	F	Broad leaved weeds	SL	600	High volume, Overall spray, Field crop sprayer	Spring, before BBCH 32	1 per crop per year	N/A	1-0.4	150-400	1.5	66	Both winter and summer: wheat, barley and oats
Grassland	North Europe	F	Broad leaved weeds	SL	600	as above	Spring, summer, when the grass has at least 3 leaves	1 per year	N/A	1-0.4	150-400	1.5	N/A	Livestock must be kept out of treated grassland at least 14 days after treatment
Grass Seed crops	North Europe	F	Broad leaved weeds	SL	600	as above	Spring, 4-6 weeks before head emergence	1 per year	N/A	1-0.4	150-400	1.5	28-42	

SL – soluble concentrate; N/A – Not applicable

** In the formulation the active substance is present as the potassium salt variant.

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
 (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
 (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

- (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
 (i) g/kg or g/l
 (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
- (k) Indicate the minimum and maximum number of application possible under practical conditions of use
- (l) PHI - minimum pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/restrictions

Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Cereals
Rotational crops	Studies not required since residues are not expected.
Plant residue definition for monitoring	Sum of dichlorprop (including dichlorprop-P), its salts, esters and conjugates expressed as dichlorprop
Plant residue definition for risk assessment	Sum of dichlorprop (including dichlorprop-P), its salts, esters and conjugates expressed as dichlorprop
Conversion factor (monitoring to risk assessment)	None

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Lactating goats
Animal residue definition for monitoring	Sum of dichlorprop (including dichlorprop-P) and its salts, expressed as dichlorprop (except poultry)
Animal residue definition for risk assessment	Sum of dichlorprop (including dichlorprop-P) and its salts, expressed as dichlorprop (except poultry)
Conversion factor (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Residues in succeeding crops are not expected since DT₉₀ by aerobic degradation in soil is less than 100 days.

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

Dichlorprop-P residues in grain, whole plants and straw are stable for at least 18 months when stored at -18°C.
Dichlorprop-P residues in grass are stable for at least 120 days when stored at -5°C

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: yes	Poultry: no	Pig: yes
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	43 mg/kg diet (DM basis) – Dairy cattle: 1.56 mg/kg bw per day Beef cattle: 1.84	0.041 mg/kg diet (DM basis)	0.047 mg/kg diet (DM basis)

Potential for accumulation (yes/no):

Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)

Muscle

Liver

Kidney

Fat

Milk

Eggs

mg/kg bw per day		
Residue levels (mg/kg) in milk and tissues derived from the goat metabolism study		
No	n/a	n/a
Yes		
<0.02		
0.047		
0.488		
<0.02		
<0.01		
	n/a	

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL (mg/kg)	STMR (b)
Barley	Northern	Grain: <0.02; 5 x <0.05; 0.05; 0.07 Straw: 0.03; <0.05; 0.07; 0.11;	Used application rate: 1.2-1.5 kg as/ha and PHI: 66-108 days	0.1	Grain: 0.05* Straw: 0.07
Wheat	Northern	Grain: 4 x <0.05 Straw: <0.05; 0.11; 0.35	Used application rate: 1.2-1.5 kg as/ha and PHI: 102-134 days	0.1	Grain: 0.05* Straw: 0.11
Barley	Southern	Grain: 4 x <0.05 Straw: 0.06, 2 x 0.07, 1.06,	Used application rate: 1.2-1.5 kg as/ha and PHI: 60-79 days	0.1	Grain: 0.05* Straw: 0.07
Wheat	Southern	Grain: 5 x <0.05 Straw: <0.05; 0.08, 0.97, 1.45, 6.64,	Used application rate: 1.5 kg as/ha and PHI: 94-103 days	0.1	Grain: 0.05* Straw: 0.97
Grass (grassland)	Northern	3.25; 3.49; 4.14; 6.0; 6.1; 6.2; 7.14; 8.6;	Used application rate: 1.4-1.5 kg as/ha and PHI: 14 days	Not applicable	6.1

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17

(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical GAP

* When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.06 mg/kg bw per day
TMDI (European Diet) (% ADI)	1.0% of ADI for an adult (60 kg) 0.4% of ADI for a schoolchild (30 kg) 1.5% of ADI for an infant (7.5 kg)
TMDI (% ADI) – EFSA PRIMo Model	<1.1% of the ADI (DK child)
NEDI (% ADI)	Not applicable
Factors included in NEDI	Not applicable
ARfD	0.5 mg/kg bw
Acute exposure (% ARfD) – EFSA PRIMo Model	0.5% ARfD (bovine kidney) 0.2% ARfD (milk) 0.2% ARfD (bovine liver)

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/processed crop	Number of studies	Transfer factor	% Transference*
Studies not required	n/a	n/a	n/a

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Cereals
(Barley, oats, rye, wheat and triticale)

0.1 mg/kg

Milk

0.01* mg/kg

Meat

0.02* mg/kg

Fat

0.02* mg/kg

Kidney

0.7 mg/kg

Liver

0.1 mg/kg

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Acute toxicity to mammals ‡

Rat LD₅₀ = 567 mg a.s./kg bw

Acute toxicity to birds ‡

Rat NOAEL = 152 mg a.s./kg bw per day

Colinus virginianus LD₅₀ (14 d) = 279 mg DMA salt/kg bw (234 mg dichlorprop-P/kg bw)

Dietary toxicity to birds ‡

Colinus virginianus LC₅₀ (10 d) = 6090 ppm DMA salt (5110 ppm dichlorprop-P)
~ 701 mg DMA salt/kg bw per day (589 mg dichlorprop-P /kg bw per day)

Reproductive toxicity to birds ‡

Coturnix coturnix NOEC = 847 ppm dichlorprop-P
~ 149 mg a.s./kg bw per day

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Application rate (kg a.s./ha)	Crop	Category (e.g. insectivorous bird)	Time-scale	TER	Annex VI Trigger
Birds Tier 1¹					
1.5	Cereals	large herbivorous birds	acute	2.5	10
1.5	Cereals	insectivorous birds	acute	2.9	10
1.5	Cereals	large herbivorous birds	short-term	11.7	10
1.5	Cereals	insectivorous birds	short-term	13.0	10
1.5	Cereals	large herbivorous birds	long-term	5.6	5
1.5	Cereals	insectivorous birds	long-term	3.3	5
Birds Tier 2²					
1.5	Grass/Cereals	large herbivorous birds	acute/ short term	5.8	10
1.5	Cereals	insectivorous birds	acute/ short term	7.3	10
1.5	Grass/Cereals	large herbivorous birds	short-term	7.4	10
1.5	Cereals	large herbivorous birds	long-term	15.6 ³	5
1.5	Cereals	insectivorous birds	long-term	125 ⁴	5
Mammals Tier 1¹					
1.5	Cereals	small herbivorous mammals	acute	1.9	10
1.5	Cereals	insectivorous mammals	acute	43	10
1.5	Cereals	small herbivorous mammals	long-term	1.8	5
1.5	Cereals	insectivorous mammals	long-term	32	5
Mammals Tier 2²					
1.5	Grass/Cereals	small herbivorous mammals	long-term	5/11 ³	5

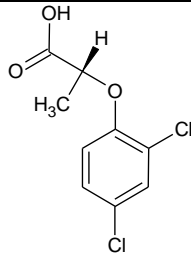
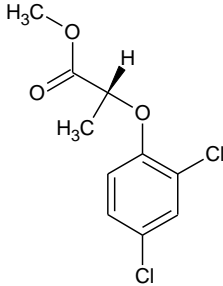
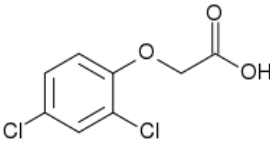
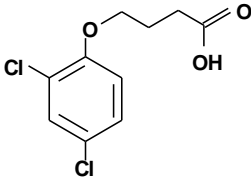
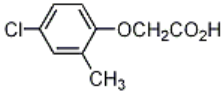
¹ At tier 1 the risk assessment is performed for the standard scenarios suggested for grassland and cereals in the Guidance Document on Risk Assessment for Birds and Mammals.

² At tier 2 the risk assessment is based on measured residue values in grass and cereal, refined endpoints, specific scenarios/indicator species – see addendum 1 to B9 (updated June 2005), section B.9.1.8 and B.9.3.2 (Denmark, 2005) for further details on birds and mammals respectively.

³ Based on measured residues in short grass and cereals respectively

⁴ Based on small insects and mixed insect diet respectively

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
Dichlorprop-P	(2 <i>R</i>)-2-(2,4-dichlorophenoxy)propionic acid (IUPAC)	
Dichlorprop-P methyl ester Metabolite 11	methyl (2 <i>R</i>)-2-(2,4-dichlorophenoxy)propionate (IUPAC)	
2,4-D	(2,4-dichlorophenoxy)acetic acid (IUPAC)	
2,4-DB	4-(2,4-dichlorophenoxy) butyric acid (IUPAC)	
MCPA	4-chloro- <i>o</i> -toloxyacetic acid (IUPAC)	

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
d	day
DAR	draft assessment report
DM	dry matter
DMA	dimethylamine
DT ₉₀	period required for 90 percent disappearance (define method of estimation)
EPCO	European Pesticides Coordination
EU	European Union
g	gram
GAP	good agricultural practice
h	hour(s)
ha	hectare
hL	hectolitre
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on 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)
kg	kilogram
L	litre
LD ₅₀	lethal dose, median; dosis letalis media
LOQ	limit of quantification (determination)
mg	milligram
mL	millilitre
MRL	maximum residue limit or level
NEDI	national estimated daily intake
NESTI	national estimated short-term intake
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
PHI	pre-harvest interval
PRIMo	pesticide residue intake model
ppm	parts per million (10 ⁻⁶)
RMS	rappporteur Member State
RUD	residue per unit dose
SL	soluble concentrate
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
TRR	total radioactive residue