Conclusion regarding the peer review of the pesticide risk assessment of the active substance

dichlorprop-P

finalised: 13 January 2006

(revision of 30 January 2006 with a minor editorial change in the areas of concern)

SUMMARY

Dichlorprop-P is one of the 52 substances of the second stage of the review programme covered by Commission Regulation (EC) No 451/2000[1], as amended by Commission Regulation (EC) No 1490/2002[2]. This Regulation requires the European Food Safety Authority (EFSA) to organise a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the EU-Commission.

Denmark being the designated rapporteur Member State submitted the DAR on dichlorprop-P in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 5 November 2003. Following a quality check on the DAR, the peer review was initiated on 13 February 2004 by dispatching the DAR for consultation of the Member States and the notifier, the dichlorprop-P Task Force which originally consisted of BASF AG, Aventis Crop Science (now Bayer Crop Science) and A H Marks Co. Ltd. On 20 February 2004, the Task Force membership changed. BASF and Bayer CropScience effectively divested their Task Force positions to Nufarm bv. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed in an evaluation meeting in July 2004. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in January – March 2005.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 30 September 2005 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as herbicide as proposed by the applicant which comprises broadcast spraying to control grass and broad-leaved weeds in cereals, grassland and grass seed crops at an application rate of 1.5 kg dichlorprop-P per hectare. Dichlorprop-P can be used only as herbicide.

[1] OJ No L 53, 29.02.2000, p. 25
[2] OJ No L 224, 21.08.2002, p. 25

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.

Adequate methods are available to monitor all compounds given in the respective residue definitions.
Whether or not sufficient enforcement methods are available to monitor food of plant and animal origin depends on the final residue definition. The reason is that none of the submitted method is enantio selective. The residues are determined as a sum parameter of both, the *R*- and the *S*-isomer. This means that for the determination of dichlorprop-P no specific enforcement method would be available. The methodologies used are GC with MS detection and HPLC with UV detection. None of them is enantio selective. A multi-residue method like the Dutch MM1 or the German S19 is not applicable to due the nature of the residues.
Sufficient analytical method as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible.

Dichlorprop-P is extensively and rapidly absorbed after oral administration in rats (> 88% based on urinary and faecal excretion). It is of moderate oral toxicity and low dermal toxicity as well as after inhalatory exposure. Dichlorprop-P was found to be non-irritant to the skin of rabbits but it is a severe eye irritant. Therefore, classification with Xi; R41 (Risk of serious damage to eyes) and R22 (Harmful if swallowed) is justified. It is not a skin sensitiser. Dichlorprop-P is of no genotoxic concern and does not show any carcinogenic potential. Furthermore, it does not induce reproduction toxic or neurotoxic effects.
The acceptable daily intake (ADI) is 0.06 mg/kg bw/day, the acceptable operator exposure level (AOEL) is 0.35 mg/kg bw/day, and the acute reference dose (ARfD) is 0.5 mg/kg bw/day, all with a safety factor of 100 applied. The exposure estimates for workers and bystanders is below the AOEL.

The metabolism of dichlorprop-P has been studied in cereals. In straw unchanged dichlorprop-P accounted for the majority of total radioactivity at maturity, whereas no further work on identification or characterisation of grain residue was performed due to low extractable residue levels. Two major metabolites were found in straw. One of them, metabolite 11 was not identified in the study and therefore its toxicological relevance could not be addressed. Further data on the identity of that metabolite were required (data gap). The residue definition for risk assessment was agreed by the experts' meeting for residues as sum of dichlorprop-P, its salts and conjugates expressed as dichlorprop-P. Based on information of potential conversion of dichloprop-P residues to the *S*-isomer, which became available after the experts' meeting the residue definition for consumer risk assessment would need to be reconsidered not only in terms of relevance of metabolite 11.
In supervised residue trials the sum of the *R*- and the *S*-isomer of dichlorprop was determined, however, it still needs to be clarified whether also conjugates that are part of the residue definition have been analysed in those trials.

A livestock metabolism study in lactating goats indicated that residues above LOQ could occur in edible animal matrices, and thus a feeding study on ruminants is required (data gap).
Due to the lack of the above stated information and data the consumer risk assessment cannot currently be concluded. However, a provisional assessment of consumer risk with currently proposed MRLs for cereals, which are still pending their confirmation, indicates that consumer exposure is low for all considered consumer groups (significantly less than 10% ADI and ARfD, respectively). Exposure from food of animal origin has not been considered in the assessment.

Under aerobic conditions in soil, no degradation products of dichlorprop-P that accounted for more than 10% AR were identified. Non-extractable residues reached a maximum of 33.6% AR and CO_2 maximum of 43.4% AR. Under anaerobic conditions in a water/sediment system no new metabolites were identified.
Dichlorprop-P can be considerate as moderate persistent in soil. During the peer review process, experts decided to address a general question to the PPR Scientific Panel on the use of a Q10 value based on measured data in place of the FOCUS default value of 2.2 for temperature correction of DT50 values. However, in this case the Q10 of 5 was accepted.
Only initial PECsoil values are used in the ecotoxicological risk assessment.
The batch soil adsorption/desorption studies indicate that dichlorprop-P is potentially mobile. Modelling and a lysimeter study for the representative uses evaluated indicated that dichlorprop-P is unlikely to contaminate groundwater when used as recommended. Also monitoring data in 3 different countries in EU (UK, Germany and Denmark) showed that dichlorprop-P occurrence in groundwater as well as in surface fresh water is rare.
Dichlorprop-P is expected to be stable to hydrolysis at environmental relevant pH. Photolysis can contribute to the degradation of dichlorprop-P in the environment. 2,4-dichlorophenol was the only identified metabolite (max. 23.6% day 8) in soil. Scientific literature demonstrated that 2,4-dichlorophenol is degraded by soil micro-organism in less than 10 days. However, due to its pesticidal activity, the potential groundwater contamination for 2,4-dichlorophenol should be assessed.
Dichlorprop-P should be classified as a non ready biodegradable substance.
In water/sediment systems dichlorprop-P was degraded to 5.1 and 2.3% AR in the water phase and reached maximum levels of 11.9%AR and 10.3% AR in the sediment. The maximum amounts of sediment residue that was not extracted were up to 25.4% AR and 16.0% AR (day 30). The remaining amount was recovered as volatiles (more than 80% AR two months after application). The amount of dichlorprop-P in the system was 0.1% AR or less at the end of the study.
PECsw due to contamination via spray drift were calculated for dichlorprop-P for a 30 cm deep static water body at 1 m distance for the evaluated representative use on spring cereals. PECsed values are not included in the endpoints since they are not relevant for the risk assessment.
Concentration of dichlorprop-P in the air compartment and transport through it is not expected to be significant.

A high short term risk has been identified for herbivorous birds and a high acute risk for mammals for the use of dichlorprop-P in grass and grass seed crops. Additionally a potential high acute risk to

insectivorous bird was identified considering the yellow wagtail as a representative species consuming 100% small insects as a worst case. Further data is thus needed to address the risk to birds and mammals. Additionally, a provisional data requirement was set to address the acute risk for both uses, pending the opinion of the PPR panel concerning the use of dietary short-term endpoint for the acute assessment. The opinion for pirimicarb was adopted in July 2005[3] and it is proposed by the EFSA that a risk assessment is performed in accordance with the recommendations provided in this opinion.

The diatom algae *Navicula pelliculosa* was the most sensitive of the aquatic species tested with dichlorprop-P. The predicted environmental concentration in surface water was calculated based on spray drift. The TER value for algae indicates a high risk and risk mitigation measures comparable to 5 m buffer zones are required.

The risk to bees, non-target arthropods, earthworms and other soil organism is considered low. To protect non-target plants outside the field risk mitigation measures comparable to a 5 m buffer zone is required.

Key words: dichlorprop-P, dichlorprop, peer review, risk assessment, pesticide, herbicide

[3] Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request from EFSA related to the evaluation of pirimicarb. The EFSA Journal (2005) 240, 1-21.

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BACKGROUND

Commission Regulation (EC) No 451/2000 laying down the detailed rules for the implementation of the second and third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC, as amended by Commission Regulation (EC) No 1490/2002, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Dichlorprop-P is one of the 52 substances of the second stage covered by the amended Regulation (EC) No 451/2000 designating Denmark as rapporteur Member State.

In accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, Denmark submitted the report of its initial evaluation of the dossier on dichlorprop-P, hereafter referred to as the draft assessment report, to the EFSA on 5 November 2003. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 8(5) of the amended Regulation (EC) No 451/2000 the revised version of the draft assessment report was distributed for consultation on 13 February 2004 to the Member States and the main notifier, the dichlorprop-P Task Force which originally consisted of BASF AG, Aventis Crop Science (now Bayer Crop Science) and A H Marks Co. Ltd. as identified by the rapporteur Member State On 20 February 2004, the Task Force membership changed. BASF and Bayer CropScience effectively divested their Task Force positions to Nufarm bv.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives from Member States identified and agreed in an evaluation meeting on 13 July 2004 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level. A representative of the notifier was attending this meeting.

Taking into account the information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in expert meetings organised on behalf of the EFSA by the EPCO-Team at the Federal Office for Consumer Protection and Food Safety (BVL) in Braunschweig in January – March 2005. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 30 September 2005 leading to the conclusions as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR).

In accordance with Article 8(7) of the amended Regulation (EC) No 451/2000, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received
- the resulting reporting table (rev. 1-1 of 14 July 2004)
- the consultation report

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation
- the evaluation table (rev. 2-1 of 30 September 2005)

Given the importance of the draft assessment report including its addendum (compiled version of July 2005 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B 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 phenoxyproponic aicd 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 grass and broad-leaved weeds in cereals, grassland and grass seed crops at an application rate of 1.5 kg dichlorprop-P per hectare. Dichlorprop-P can be used only as herbicide.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of dichlorprop-P as manufactured should not be less than 900 g/kg (at least 82% enaniomeric excess)[4]. This value was set under the condition that the different technical materials can be regarded as equivalent. The individual values for the different technical materials are partially higher.

At the moment no FAO specification exists.

According to the equivalence assessment of the different technical materials (three sources), the RMS concluded that they can be regarded as equivalent. The different impurities are not of toxicological and/or ecotoxicological concern (Tier II, Sanco/10597/2003 –rev. 7, Evaluation report, July, 2005). The RMS stated also that the differences in the minimum purities of the different sources are not of toxicological and/or ecotoxicological concern.

This assessment was not peer reviewed nor discussed in regular expert meetings, but discussed and confirmed after the evaluation meeting in a written procedure with the Member States prior to the final discussion at the evaluation meeting in November 2005). It was concluded that they could indeed be regarded as equivalent (see confidential part of the addendum).

The technical material could contain phenoxy acids (carry-over from other productions) as relevant impurities. The maximum content is 3 g/kg.

The content of dichlorprop-P in the representative formulation is 600 g/L (pure).

The assessment of the data package revealed no particular area of concern.

The main data regarding the identity of dichlorprop-P and its physical and chemical properties are given in appendix 1.

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of dichlorprop-P in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material.

Therefore, enough data are available to ensure that quality control measurements of the plant protection product are possible.

Adequate methods are available to monitor all compounds given in the respective residue definition, i.e. dichlorprop and its salts in soil, water and air.

[4] It should be noted that the technical material contains small amounts of the inactive *S*-isomer [(R)-2-(2,4-dichlorophenoxy)propionic acid]. However, the COM has confirmed for an comparable case (1,3-dichloro-propene) that Article 2 of Commission Regulation 2076/2002 is not applicable in this case.

Whether or not sufficient enforcement methods are available to monitor food of plant and animal origin depends on the final residue definition. The reason is that none of the submitted method is enantio selective. The residues are determined as a sum parameter of both, the *R*- and the *S*-isomer. This means that for the determination of dichlorprop-P no specific enforcement method would be available.
Furthermore, it should be noted that with the available analytical methods for food, soil and water it is not possible to differentiate between residue of the acid and its salts, esters and glycoside conjugates.
The methodologies used are GC with MS detection and HPLC with UV detection. None of them is enantio selective. A multi-residue method like the Dutch MM1 or the German S19 is not applicable to due the nature of the residues.

The discussion in the expert meeting on identity, physical and chemical properties and analytical methods (EPCO 20, March 2005) was limited to particular physical, chemical and technical properties of dichlorprop-P and the formulations the specification of the technical material and several issues on analytical methods. Required additional information is given in addenda to Volume 4 (April and July 2005).

2. Mammalian toxicology

Dichlorprop-P was discussed at EPCO experts' meeting for mammalian toxicology (EPCO 18) in February 2005.

Some MS objected on the possible toxicological differences between the racemate and the enantiomer dichlorprop-P. The possibility of bridging between studies performed with the 2 ingredients was considered during the meeting: only small differences could be observed in the studies performed. Therefore, it was concluded that the bridging concept was acceptable.

As there are three different sources for the technical material, a concern on the toxicological equivalence was raised. However, at the Evaluation meeting in November 2005 it was finally concluded that they could be regarded as equivalent, see also confidential part of the addendum.

2.1 Absorption, distribution, excretion and metabolism (Toxicokinetics)

Dichlorprop-P as well as its ester and amine derivatives was extensively and rapidly absorbed after oral administration (> 88% based on urinary and faecal excretion), whereas the systemic absorption following dermal application of ester or amine was limited. It mainly distributes in kidneys, plasma, thyroid, ovaries, uterus, adrenals, blood, heart and liver. The majority of absorbed radioactivity was excreted via urine (85-96 %) with very little accumulation being observed in organs and tissues. Only about 3 % of the administered dose was recovered as metabolites (at least 5 minor components of which none accounted for more than 1 % of the administered radioactivity). The structure of the metabolites could not be identified. The only significant compound detected in the urine was dichlorprop-P.

2.2 ACUTE TOXICITY

The oral LD_{50}-value was 567 mg/kg bw in rats. The acute dermal toxicity of dichlorprop-P is low (LD_{50} > 2000 mg/kg bw); the acute toxicity after inhalation exposure in rats is low. In one study, the LC_{50} value is above 2.70 mg/l. Dichlorprop-P is non-irritant to the skin of rabbits but it is a severe eye irritant. Therefore, **classification with Xn; R22 (Harmful if swallowed) and Xi; R41 (Risk of serious damage to eyes) is justified.** It is not a skin sensitizer.

2.3 SHORT TERM TOXICITY

In rats and mice, the liver was a target organ with increased absolute and relative weights, alterations in hepatocytes, and changes in a number of clinical chemistry parameters being observed in the high-dose groups. Furthermore, reduced body weights and body weight gains were observed in high-dose rats and mice, signs of mild anaemia were observed in high-dose rats and dogs.

The relevant NOAEL is 35 mg/kg bw/day from the 3-month study in rats, based on reduced body weight and body weight gain, effects in the liver, and decreases in red blood cell parameters observed in high-dose animals.

A 21-day dermal toxicity study in rabbits revealed a NOAEL of 1000 mg/kg bw/day for systemic effects. No repeated inhalation studies are available.

2.4 GENOTOXICITY

Dichlorprop-P has been assessed in a battery of *in vivo* and *in vitro* assays. All the studies gave negative results, except one test – a chromosomal aberration test in human lymphocytes without metabolic activation – giving a weak (compared to the positive control substance), but statistically significant positive response. Another *in vitro* test on clastogenic activity (also in human lymphocytes) used only one fixation time and showed a negative response both with and without metabolic activation. Since the equivocally positive results in isolated human lymphocytes was obtained only at a cytotoxic concentration and since all the other chromosomal aberration assays without metabolic activation *in vitro* and the micronucleus test *in vivo* were negative, the weakly positive response was considered to be incidental. Therefore, it was concluded that dichlorprop-P is of no genotoxic concern.

2.5 LONG TERM TOXICITY

The critical effect identified based on the chronic toxicity studies is observed in the kidneys of the three animal species tested (rat, mouse, dog). Mice appear to be more sensitive to the renal effects than the two other species as chronic nephropathy was observed in mice administered dichlorprop-P at concentrations from 400 ppm in the diet for 18 months. The liver also appears to be a target organ in rats and mice, and the haematopoietic system in rats and dogs, but the effects are observed at higher dose levels than the effects in the kidneys.

The overall NOAEL for chronic toxicity based on the chronic nephropathy observed in the kidneys is 6 and 8 mg/kg bw/day in males and females, respectively, from the 18-month study in mice. Overall, dichlorprop-P does not show any carcinogenic potential.

2.6 REPRODUCTIVE TOXICITY

In the multi-generation studies in rats the relevant NOAEL for maternal toxicity is 8.3 mg/kg bw/day based on kidney weight effect at 42 mg/kg bw/day, which represents the NOAEL for reproductive toxicity (prolonged gestation, dams with stillborn pups and reduced number of pups/dam at higher doses).

The developmental toxicity studies were performed in rats (3 studies) or in rabbits (3 studies). The relevant NOAEL for both maternal and developmental toxicity was 20 mg/kg bw/day (rats) based on reduced food consumption and body weight and foetal skeletal variation at 80 mg/kg bw/day onwards. The experts discussed the occurrence of a marginally increased number of foetuses with rudimentary cervical ribs. It was concluded that the litter incidence, very close to the control data, would have been the main basis for evaluation. As a consequence, the developmental NOAEL in rats was increased to 80 mg/kg bw/day. The relevant NOAEL was 50 mg/kg bw/day, from the rabbit study.

2.7 NEUROTOXICITY

There was no indication of delayed neurotoxicity following oral administration of dichlorprop-P either as a single dose or by repeated doses. The functional operational battery was used for testing injury to the neurological system: it only revealed significant impairment on the day of administration of dichlorprop-P at or close to lethal doses (testing under such conditions is questionable). The neuromorphology in selected organs/tissues and locations of the central and peripheral nervous system was unchanged both following single and repeated doses.

The NOAEL following oral single dose administration was 125 mg/kg bw and following 90 days oral dietary administration 35 and 42 mg/kg bw/day in male and female rats, respectively.

2.8 FURTHER STUDIES

No additional studies have been provided.

2.9 MEDICAL DATA

Epidemiological studies of workers (possibly) exposed to phenoxy herbicides, chlorophenols and dioxins showed conflicting results, both with respect to cancers in general and special cancer types (soft-tissue sarcoma (STS), Hodgkin's disease (HD) and non-Hodgkin's lymphoma (NHL)) and with respect to the need for higher chlorinated dioxins in the process.

The general health status over a six-year period of all employees of a major producer of phenoxy herbicides was reported in a medical survey. The examinations performed did not indicate any adverse effects of handling phenoxy herbicides with respect to haemoglobin, liver or kidney function or with respect to general health status. The overall epidemiological evidence for a carcinogenic potential for chlorophenoxy herbicides is considered to be suggestive and far from conclusive. No specific human data is available concerning the carcinogenic potential of dichlorprop-P.

2.10 ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) and ACUTE REFERENCE DOSE (ARfD)

ADI

The ADI is derived based on the NOAEL of 6 mg/kg bw/day for chronic nephropathy observed in the 18-month dietary study in mice, applying a SF of 100, as confirmed by the experts.

The ADI is 0.06 mg/kg bw/day.

AOEL

The proposed **AOEL is 0.35 mg/kg bw/day**, based on the 90-day study in rats, with a safety factor of 100.

ARfD

The ARfD was discussed during the meeting; the most relevant study to derive the value was considered to be the rabbit teratogenicity study, with a NOAEL of 50 mg/kg bw/day.

It was then set an **ARfD of 0.5 mg/kg bw**, with a SF of 100.

2.11 DERMAL ABSORPTION

The meeting discussed the issue on the basis of an *in vivo* rat study (performed with the ester) and an *in vitro* rat/human skin study (performed with the potassium salt). The dermal absorption values were concluded to be 1.3% for the concentrate and 11% for the dilution.

2.12 EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

Operator exposure

The representative formulation of dichlorprop-P is Optica SL formulation (600 g/L K salt formulation), intended to be used in cereals.

The potential operator exposure was estimated for the intended use in cereals and grass area with the highest recommended rate of 1.5 kg a.s./ha in 200 L water using a tractor mounted hydraulic sprayer.

Estimated exposure presented as % of AOEL (0.35 mg/kg bw/day), according to calculations with the German and UK POEM model. The default for body weight of operator is 70 kg in the German model and 60 kg in the UK-POEM model.

Model	No PPE	With PPE*
German	31	2.2
UK POEM	174	28

PPE* (personal protective equipment): gloves during M/L and application

Estimated exposure is below the AOEL even without PPE (German model, 31% of the AOEL) or with the use of gloves during M/L and application (UK POEM, 28% of the AOEL).

Worker exposure

For the intended use of dichlorprop-P (cereals and grass areas), re-entry activities are not expected shortly after spraying. Based on this and considering the rapid environmental degradation of dichlorprop-P, no exposure is envisaged.

Bystander exposure

The RMS submitted calculations (based on Lloyd and Bell, 1983) of estimated bystander exposure to dichlorprop-P, refined with the new dermal absorption value of 11%, showing negligible exposure levels (<1% of the AORL).

3. Residues

Dichlorprop-P was discussed at EPCO experts' meeting for residues (EPCO 19) in February 2005 in Braunschweig (Germany).

The residue behaviour of dichlorprop-P was studied with material of different chiral purity. The analytical methods utilised in the residue studies with dichlorprop-P have been not specific for dichlorprop-P residues and therefore the sum of dichlorprop isomers (*R*- and *S*-isomer) was determined. Based on the submitted data it is not possible to conclude whether or not conversion reactions of dichlorprop-P into the *S*-isomer occur in plant matrices or in the livestock body, as e.g. reported for environmental matrices. (refer to chapter 4). Following RMS' assumption that such a conversion does not occur, the determined dichlorprop[5] residues are referred to as dichlorprop-P in the conclusion on the section of residues presented below.

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

The metabolism of dichlorprop-P has been studied in wheat after application of radio-labelled material with a chiral purity of 90.7% *R*-isomer and 9.3% *S*-isomer. The application rate in the wheat study was 0.5N compared to the intended rate for the use on cereals.

Total radioactive residue (TRR) in grain at maturity was 0.02 mg/kg, whereof 60% was non-extractable. No further work on identification or characterisation of grain residue was done due to the low extractable residue levels (0.008 mg/kg).

In straw at maturity unchanged dichlorprop-P accounted for the majority of TRR (19%). Several metabolites are formed during the metabolism of dichlorprop-P in wheat plants, whereof metabolites 8 and 11 were the major ones, each accounting for 14% of TRR. Metabolite 8 was found to be conjugates of dichlorprop-P and released several components when treated with acid, including dichlorprop-P and the hydroxy derivate of dichlorprop-P. Metabolite 11 has not been identified. The RMS concluded that it was not possible to find arguments for the non-toxicological relevance of metabolite 11 and therefore data on identity and toxicological significance of metabolite 11 was required by the experts at EPCO

[5] *R*- and *S*-isomer, all possible ratios

19. After the experts' meeting data concerning the origin and identity of metabolite 11 have been forwarded. The RMS concludes from these data that metabolite 11 was dichlorprop-P-methyl ester and that it was an artefact resulting from the use of acidified methanol as extraction medium. It is noted that RMS' conclusion concerning metabolite 11 was reached after the experts' meeting for residues and was therefore neither peer reviewed nor discussed.

Since the analytical methods are not specific for the *R*-isomer (dichlorprop-P) a discussion on the proper residue definition was initiated in EPCO 19. The experts concluded that from a risk assessment point of view the residue of concern in cereals should be defined as sum of dichlorprop-P, its salts and conjugates expressed as dichlorprop-P for both monitoring and risk assessment purposes, subject to metabolite 11 not being relevant for consumer risk assessment. However, for monitoring and enforcement purposes an optional proposal might be the sum of dichlorprop[6], its salts and conjugates expressed as dichlorprop to determine residues arising from use of dichlorprop-P in plant protection products.
It is noted that the experts were not aware at that time that there might be the potentiality of a conversion of dichlorprop-P into the *S*-isomer in plant material, as observed in environmental matrices, and thus of a potentially higher consumer exposure to the *S*-isomer than caused by the low level of impurity present in the technical material dichlorprop-P. Furthermore it is noted that the experts' meeting of toxicology concluded that the bridging concept was acceptable for dichlorprop-P and the racemic mixture dichlorprop (refer to chapter 2) and thus the toxicological properties of both isomers could be considered as similar. However, in the light of the new information the residue definition for consumer risk assessment would need to be reconsidered not only in terms of metabolite 11.

In all submitted residue trials dichlorprop-P was applied, and, since the analytical method was not enantio selective, the sum of both dichlorprop isomers was determined. Thus, based on the residue trials it is not possible to conclude whether or not conversion reactions of dichlorprop-P into the *S*-isomer occur in plant matrices in course of time until harvest, as e.g. reported for environmental matrices. In the experts' meeting the question was raised whether the trials also cover conjugated forms of dichlorprop-P, which are part of the proposed residue definition.
Pending a decision on the relevance of metabolite 11 and the appropriateness of the residue trials to reflect the residue definitions a total of 29 residue trials in cereals according to critical GAP were submitted, 29 performed in Northern Europe and 4 in Southern Europe.
Some of the available trials indicate that residues of dichlorprop[7] in grain were below 0.05 mg/kg. However, other trials demonstrate that residue of 0.05-0.07 mg/kg can occur in grain at a PHI longer than 66 days, which was the proposed PHI. Of the four trials performed in the southern region only three involve determination of residues in grain. Later in the procedure further trials have been submitted. In total, 6 trials are available for the South, showing residues consistently being below 0.05 mg/kg (LOQ). Based on the most critical results from residue trials in the northern region a provisional

[6] *R*- and *S*-isomer, all possible ratios
[7] *R*- and *S*-isomer, all possible ratios

MRL of 0.1 mg/kg is proposed for dichlorprop-P in cereals. However, the results from the trials still need to be confirmed for their compliance with the proposed residue definitions.
Since the residues in grain were <0.1 mg/kg and the TMDI accounts for less than 10% of ADI (0.06 mg/kg bw/day) studies on the effect of processing are not required.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

DT_{90} for dichlorprop-P is shorter than 100 days and residues in rotational and succeeding crops are therefore not expected when dichlorprop-P is used according to the cGAP in relation to the representative uses.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

A livestock metabolism study in lactating goats with radio-labelled dichlorprop-P (chiral purity of 97.3% *R*-isomer and 2.7% *S*-isomer) has been submitted. This study shows that dichlorprop-P is rapidly excreted in ruminants, primarily as the unchanged compound. Excretion occurs mainly via the urine (up to 86.9% of the administered dose) indicating a high level of adsorption. Excretion via milk was minor; the total radioactivity in milk was only 0.01% of the administered dose. There is no evidence of accumulation in tissue. The highest residue of dichlorprop-P in tissues was found in kidney. In kidney dichlorprop-P was the major compound, accounting for 0.442 mg/kg (90.7% TRR) and corresponding to 0.006% of the administered dose. Since the metabolism of dichlorprop-P in goats and rats is similar no further metabolism studies are required.
Considering that the majority of the residue in animal products is constituted by unchanged dichlorprop-P it is proposed that the residue definition for dichlorprop-P in edible animal products is defined as the sum of dichlorprop-P and its salts expressed as dichlorprop-P for both, monitoring and risk assessment purposes. However, for monitoring purposes an optional proposal may be the sum of dichlorprop[8] and its salts. Again, the potentiality of a conversion of dichlorprop-P into the *S*-isomer in animal material was not considered at the time the proposals were made.

The goat metabolism study was performed at a dose rate comparable to the estimated maximum intake of dichlorprop-P residues by cattle (*ca* 1.6 -1.8 mg/kg bw/day from green forage). Hence the results of the goat study could be used to indicate whether or not detectable residues in animal products were expected.
In the study residues above the respective LOQ (0.01 mg/kg milk; 0.02 mg/kg meat, fat; 0.05 mg/kg liver, kidney) were only observed in kidney. The total radioactive residue (TRR) in kidney amounted to 0.5 mg/kg whereas a TRR of 0.05 mg/kg was found in liver. Unchanged dichlorprop-P accounted for about 85.9% and 53.5% of TRR in kidney and liver, respectively. based on results.
From the study it could be concluded that an exposure of ruminants to dichlorprop-P residues at the assessed level may lead to residues ≤0.5 mg/kg and <0.05 mg/kg in kidney and liver, respectively. Residues above the LOQ are therefore only expected in cattle kidney. However, the estimated values are based on results obtained from one test animal in a goat metabolism study only. To get firm data on

[8] *R*- and *S*-isomer, all possible ratios

quantitative transfer of residues to edible ruminant matrices and to establish MRLs for food of animal origin EPCO 19 concluded that a feeding study on ruminants is required.

3.3. CONSUMER RISK ASSESSMENT

It is noted that currently the consumer risk assessment **cannot be concluded** due to the lack of the following information and data:

- identity and potential toxicological significance of metabolite 11
- confirmation of compliance of supervised residue trials with the proposed residue definitions, mainly regarding whether or not dichlorprop-P conjugates were covered by the trial results
- a feeding study on ruminants to address actual consumer exposure through food of animal origin (mainly cattle kidney)

Furthermore clarification is needed whether and to what extent consumer exposure to the dichlorprop *S*-isomer, potentially present due to conversion of dichlorprop-P residues, might occur. Subsequently a reconsideration of the currently proposed residue definition for risk assessment might be necessary.

However, a provisional, indicative consumer risk assessment was done by RMS, based on the currently proposed MRL for cereals. Consumer exposure from food of animal origin could not be included in the assessment. Provisionally, a theoretical maximum daily intake (TMDI) has been calculated in accordance with WHO guidelines for predicting dietary intake of pesticide residues for adults, schoolchildren and infants. Intakes of dichlorprop-P calculated for an adult weighing 60 kg on the basis of average daily consumptions according to WHO/FAO GEMS/Food European diet account for less than 1% ADI. TMDI calculated for schoolchildren and infants based on UK consumption data amounts to <2% of ADI. To estimate acute exposure, the NESTI provisionally calculated for an adult, a schoolchild and an infant on the basis of the 97.5th percentile food consumption from UK consumption data amounts to <1% of ARfD for cereals.

3.4. PROPOSED MRLS

An MRL of 0.1 mg/kg is proposed for cereals. An MRL is proposed even though dichlorprop[9] and not dichlorprop-P was determined in all the residue trials. It is noted that the proposal is **provisional** pending the final confirmation that metabolite 11 is of no concern and that the residue levels obtained in field trials include also conjugates of dichlorprop-P. Subject to whether the residue definition for monitoring and MRL purposes will be set as either dichlorprop-P or dichlorprop[10], the potential occurrence of relevant levels of the dichlorprop *S*-isomer in raw agricultural commodities needs to be clarified (as to be done for risk assessment purposes).
Since a feeding study is lacking for ruminants it is currently not possible to propose MRLs for edible animal products.

There are currently no Codex Alimentarius Commission (CAC) MRLs established for dichlorprop-P.

[9] *R*- and *S*-isomer, all possible ratios
[10] *R*- and *S*-isomer, all possible ratios

4. Environmental fate and behaviour

Dichlorprop-P was discussed at the EPCO experts' meeting for fate and behaviour (EPCO 16) in January-February 2005.

Since enantioselective methods of analysis were not employed in the fate and behaviour in the environment studies, it can not be excluded that isomerization occurs in the environment as demonstrated by scientific literature.[11] Therefore, enantioisomer of dichlorprop-P should be precautionary included in the residue definition of the different environmental compartments. This means that the residue definition will be dichlorprop (that includes *R* and *S* isomers). However this does not necessarily imply a one to one ratio of the two isomers as would be expected if the racemic product was applied.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

The route of degradation of dichlorprop-P in soil was investigated in a laboratory study (dark aerobic conditions at 24-27 ºC and 75% WHC) on a single sandy loam soil (organic matter 2.7%, pH 6.5) dosed with radiolabelled ^{14}C-dichlorprop-P. Degradation proceeded via the breaking of the ether bond and successive transformations of the phenol ring producing different soil extractable degradation products, but none of these accumulated to levels above 5% AR. Dichlorprop-P was mineralised with 43.3% of the applied radioactivity (cumulative) trapped in the NaOH solution 90 days after treatment. Minimal volatilisation of organic ^{14}C was observed. Nature of non-extractable residues (33.6% AR after 90 days) was not investigated.

No anaerobic degradation study is available for soil. However the anaerobic degradation study in a water/sediment system, showed that unidentified metabolites were formed at levels < 5.3% AR.

A study on photolysis in soil demonstrated that the rate or dichlorprop-P breakdown in the sandy loam soil as described above was faster in the irradiated samples (DT_{50}: 7.6 d) than in the dark control samples (20 d). **2,4-dichlorophenol** was the only identified metabolite (max. 23.6%AR at day 8). Evaluation Meeting (July 2004) expressed concerns on the environmental fate of this metabolite and a data requirement was set for references not included in the dossier. Three references were provided by the applicant and summarised by RMS in an addendum. The degradation of 2,4-dichlorophenol was discussed in the experts' meeting (EPCO 16, January – February 2005) and it was concluded that apart from its occurrence in the photodegradation study, the metabolite is clearly a minor one as the photolysis is very fast (in order of minutes) and it is biodegraded in less than 10 days. Consequently, the need for further assessment for this photolysis metabolite was not seen. Nevertheless, after the evidence that this metabolite has a pesticidal activity, according to the Guidance Document on the

[11] Müller, M. D. and Buser, H-R. *Environ. Sci. Technol.***1997**, *31,* 1953-1959; Buser, H-R. and Müller, M. D. *Environ. Sci. Technol.***1997**, *31,* 1960-1967.; Wink, O and Luley, U. *Pesticide Science* **1988**, *22(1)*, 31-40.

assessment of the relevance of metabolites in groundwater (SANCO/221/2000 rev10 25 Feb 2003) PEC_{gw} are necessary to complete the risk assessment on potential groundwater contamination.
An unknown peak was observed at higher concentrations in the dark control samples (5.1%) compared to the irradiated samples (3.6%), and was therefore not considered a photodegradation product.

4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

Degradation rate of dichlorprop-P under aerobic conditions was investigated in 3 soils (humic sand, sandy loam and loam soil at 20 ºC and 40% MWHC). One soil type (sandy loam) was also incubated at 10ºC. Half-lives were obtained by fitting degradation curve to first order kinetics and ranged between 6.8 and 13.8 days (normalised to 20ºC and 10kPa). At 10 ºC the single first order DT_{50} value of 37.4 days was determined.
Evaluation meeting pointed out the need to calculate the soil DT_{50} value also from the route study. Half-life for dichlorprop-P was calculated by RMS considering moisture correction and temperature correction and included in an addendum. The normalisation to 20ºC was performed using the experimental Q10 value of 5, significantly deviating from the FOCUS default value of 2.2. The use of other Q10 values based on experimental data *vs* the default value was discussed in an experts meeting (EPCO 16, January – February 2005). It was concluded that this is a general issue that must be discussed between specialists and, therefore, a question to the PPR Scientific Panel was addressed.[12] In the case of dichlorprop-P, the non-default Q10 value of 5 was accepted by MS. Based on a temperature of 25 ºC (EPCO 16 supported the use of a mean temperature for this study) and without a scaling for water content (EPCO 16 found this scaling to be inappropriate) the DT_{50} value was found to be 26.1 days.
As the risk assessments were based on initial PECsoil values, the experts meeting considered that new calculations using the revised DT_{50} were not needed.

4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

K_{OC}-values of dichlorprop-P were determined in three batch adsorption studies. The values determined ranged from 12.9 to 83.7 L/kg, and the Freundlich exponent 1/n was between 0.59 and 0.91. Dichlorprop-P can be classified as high to very high mobile. Column leaching studies on four different soil types confirmed the potential mobility of dichlorprop-P. Amounts between 11.4 to 85.0% AR and between 0.35 to 56.2% AR were found in the leachate of the un-aged soils and aged soils respectively. The extracts were analysed by LSC and HPLC-RAM and the only detectable eluting radioactive residue corresponded to dichlorprop-P. An aged residue column leaching was also available. After 30 days ageing the initially recovered radioactivity had decreased to 26.9%. 7.5% of AR was extractable and 2.06% of radioactivity submitted to leaching was recovered in the leachate, corresponding to

[12] Question Nº EFSA-Q-2005-058, Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from EFSA related to the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil

0.55% of AR. Concentration of total radioactivity in the pooled leachate was 6.8 µg/L when expressed as dichlorprop-P equivalents.

The mobility of dichlorprop-P was investigated in four lysimeter/field studies covering different soil types/treatment combinations (the first study with two German soils, the second study with four Swedish soils, the third study with 8 Swedish field lysimeters filled with two different soils, and the fourth study was a 2-year period drainage water study with three clayey soils in Denmark). The threshold value of 0.1 µg/L at 1 m depth was exceeded on individual sampling occasions in two lysimeter studies. In one study dichlorprop-P concentrations above the limit of detection (0.1 µg/L) were observed on one sampling occasion in clay lysimeters and on three occasions in sand lysimeters, reaching 16 and 26 µg/L in percolate from the respective soils. In the drainage water study, in 7 out of 65 samples dichlorprop-P was detected at concentrations above 0.1 µg/L (max. concentration 0.30 µg/L).

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

Dichlorprop-P is hydrolytically stable in sterile aqueous buffers between pH 3 and pH 9 at 25ºC±2.

The study on photodegradation in an aqueous solution buffered at pH 7 showed that dichlorprop-P is degraded under artificial sunlight irradiation conditions but not under dark conditions. Approximately 75% AR in the irradiated samples was degraded after 8 days of irradiation, corresponding to a photodegradation half-life of 4 days. In the irradiated samples two peaks, each exceeding 10% of the applied radioactivity, were detected. It was demonstrated that none of the individual components of the peaks will exceed the 10% AR.

No readily biodegradability test was available in the DAR and therefore it was proposed to classify this active substance as “non-readily biodegradable” taking into account the results of the water/sediment study.

A study with two water sediment systems was available. Dichlorprop-P was degraded to 5.1 and 2.3% AR in the water phase (day 30). In the two sediments maximum levels of dichlorprop-P were found at 11.9%AR (day 7) and 10.3% AR (day 3). The maximum amounts of sediment residue that was not extracted were up to 25.4% AR and 16.0% AR (day 30). The remaining amount was recovered as volatiles. The evaluation meeting (July 2004) had some concerns on the fact that volatile products trapped in the soda lime were carbon dioxide. The evidences supporting that trapped radioactivity were CO_2 were provided by the applicant and included in an addendum. The impact of possible volatilization on risk assessment was discussed in an experts’ meeting (EPCO 16, January – February 2005). The experts acknowledged that is not explicitly proven that the trapped volatiles are CO_2, but considered this most likely. It was concluded that in any case the exact identity of the volatiles has no influence on the risk assessment. Two months after application more than 80% AR was found in volatiles, whereas the amount of parent compound in the system was 0.1% AR or less. The total (up to 5 peaks) metabolite fractions were reported to be low (max. 3.7% AR and 2.0% AR). The degradation

can be described as tri-phasic, consisting of a lag-phase, exponential growth phase and retardation/plateau phase. Therefore, DT_{50} values for the water phase were calculated from the degradation curves, resulting in 21 days and 20 days. Half life in the total systems (15.3 and 14.6 days) was derived for the two systems based on first order kinetics.

An anaerobic eutrophic pond study was available. The EPCO experts' meeting discussed the calculated anaerobe DT_{50} value and they concluded that since this value is not relevant for the risk assessment, no further assessment was necessary.

PECsw due to contamination via spray drift were calculated for dichlorprop-P for a 30 cm deep static water body at 1 m distance for the evaluated representative use on spring cereals. During the peer review process some concerns raised on the calculated PECsed values, however they are not included in the endpoints since they are not relevant for the risk assessment (see section 5.2). Initially FOCUSsw-PECs were provided in the DAR based on a contribution from run-off/erosion and/or drainflow of 15% of the application rate. Accordingly with the FOCUS guidance document, PECsw values were recalculated with a 10% contribution of the above mentioned entry routes and included in an addendum. Nevertheless, in the experts' meeting it was agreed that a risk assessment taking into account exposure via run off and drainage it is not needed to conclude the EU risk assessment in this case.

4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

Concentrations of dichlorprop-P in groundwater were estimated with PELMO model for FOCUS groundwater scenarios, using input parameters selected according FOCUS guidelines (addendum, December 2004). The modelling was based on post emergence application of the dichlorprop-P soluble formulation to winter cereals in spring with an application rate of 1.5 kg a.s./ha. The modelling in the original draft assessment report was disregarded as the Koc value used was higher than the mean Koc from all the reported studies, the interception factor was incorrect and a questionable DT_{50} value was used. The EPCO experts' meeting discussed the modelling input values and accepted the Q_{10} value of 5 to calculate the DT_{50} value at reference conditions (see section 4.1.2). In May 2005 the addendum was updated to take into account changes recommended at the expert meeting. However, no new FOCUS modelling for groundwater based on the acceptable and reliable DT_{50} of 14.7 days instead of 13.5 d was performed. EFSA and rapporteur Member State considers that this slight difference would not significantly affect the results. In all scenarios the predicted 80th percentile annual average concentrations are below the 0.1 µg/L regulatory threshold. The FOCUS modelling on the photolysis metabolite 2,4-dichlorophenol was considered not necessary after the RMS evaluation of references confirming that this is a minor metabolite (see section 4.1.1). Nevertheless, after the evidence that this metabolite has a pesticidal activity, according to the Guidance Document on the assessment of the relevance of metabolites in groundwater (SANCO/221/2000 rev10 25 Feb 2003) PEC_{gw} are necessary to complete the risk assessment on potential groundwater contamination.

Monitoring data in UK, Germany and Denmark were reviewed. Within this data set, dichlorprop-P occurrence in groundwater is rare (levels above 0.1 µg/L: 0.2% in Germany and 0.9% in Denmark). In

UK 1393 surface freshwater samples were analysed for the presence of dichlorprop-P, 1.4% were found to exceed 0.1µg/L.

4.3. FATE AND BEHAVIOUR IN AIR

Concentrations of dichlorprop-P in the air compartment are expected to be negligible, due to low volatility and short persistence in the atmosphere (< 0.9 d).

The degradation rate resulting from ozone attack was estimated from the OECD method to be $k_{O3} > 3.3 \cdot 10^{-18}$ cm^3 $molecule^{-1}$ s^{-1}, and the corresponding half-life was < 3.5 d.

5. Ecotoxicology

Dichlorprop-P was discussed at the EPCO experts' meeting for ecotoxicology (EPCO 17) in January - February 2005. Ecotoxicological studies with formulations were performed either with BASF DP-p potassium 600 g/L (product code DUPLOSAN BAS 044 26 H) or with BASF DP-p DMA salt 600 g/L (product code DUPLOSAN BAS 044 18 H) which the Rapporteur considered to be toxicologically comparable to the lead formulation Optica DP. This assessment is confirmed by the EFSA. As there are three different sources for the technical material, a concern on the ecotoxicological equivalence was raised. However, at the Evaluation meeting in November 2005 it was finally concluded that they could be regarded as equivalent; see also confidential part of the addendum.

5.1. RISK TO TERRESTRIAL VERTEBRATES

The risk to terrestrial vertebrates was assessed based on the use of dichlorprop-P in field crops of small grain cereals and grass, including grass seed crops in the northern EU. In the first tier assessment for birds a medium sized herbivorous bird and a small insectivorous bird were considered in accordance with the Guidance Document on Birds and Mammals (SANCO/4145/2000). The acute TER values were below the Annex VI trigger for both types of birds (2.5 and 2.9 respectively), and the long-term TER was below the trigger for insectivorous birds (TER = 3.3).

The applicant proposed to use the dietary endpoint for the acute assessment instead of the acute LD_{50} obtained by gavage exposure. The arguments given were firstly that rapid uptake and excretion would lead to no accumulation in the course of a day, secondly that small birds cannot consume their daily food requirement in one single feeding session and that signs of sublethal toxicity observed would lead to reduced food intake. The arguments were discussed in the experts' meeting. With regard to use of the dietary endpoint for the acute risk assessment it was agreed to await the opinion of the PPR panel for pirimicarb for which the same approach has been proposed. The opinion on pirimicarb was adopted in July 2005[13] and it is proposed by the EFSA that a risk assessment in accordance with the

[13] Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request from EFSA related to the evaluation of pirimicarb. The EFSA Journal (2005) 240, 1-21.

recommendations given in this opinion is performed. The applicants' proposal to use an avoidance factor based on reduced food intake in the acute study was not accepted in the experts' meeting. Furthermore, the applicant proposed to refine the short-and long-term assessment for herbivorous birds based on measured residue data in cereals and grass (the data are tabulated in Appendix 1 to the updated addendum 1, June 2005). 90th percentile of measured residue values was used for the acute and short-term TER calculations as agreed in the experts' meeting. For the long-tem mean values together with a 21-day f_{twa} were used. It was noted that in this case the measured residue values for grass were higher than the generic values in the guidance document (SANCO/4145/2000). For insectivorous birds the experts' meeting accepted the proposal to base the assessment on the yellow wagtail, *Motacilla flava*, as a representative species and to use PD factors of 0.83 for large insects and 0.17 for small insects with RUD values according to SANCO/4145/2000. A feed intake rate (FIR) of 0.91 was used for the wagtail.

Resulting TER values for herbivorous birds presented in the updated addendum 1 (June 2005) are below the Annex VI trigger for acute and short-term risk (TER_a = 5.8, TER_{st} = 7.4) in the grass scenario, while the TER values for cereals are above the trigger. The long-term risk to herbivorous birds is considered low (TER = 15.6).

For insectivorous birds (yellow wagtail) the acute/short term TER value based on the refinements is 21 and the long-term value 12 and hence the risk is considered low. However, the experts' meeting was of the opinion that as a worst case the acute risk should be based on 100% consumption of small insects since toxicity was observed in one acute study and since opportunistic feeding on one single type of food cannot be excluded. Using the feed intake rate (FIR) used for the yellow wagtail this will result in a TER of 3.3 (calculated by EFSA) if only small insects are considered, indicating a potential high acute risk. Additionally, Member States should consider if the yellow wagtail is a representative species for their landscapes.

For mammals the first tier assessment indicates a low risk to insectivorous mammals (TER_a = 43, TER_{lt} = 32), while a potential high risk was identified for small herbivorous mammals (TER_a = 1.9, TER_{lt}= 1.8). The assessment for herbivorous mammals was refined using measured residues in grass and cereals (see discussion for birds above). Furthermore, as for birds the applicant proposed to use the dietary endpoint (>683 mg/kg bw/day for male mice in 90-day dietary study) for the acute assessment instead of the acute LD_{50}. The resulting acute TERs are 2.1 and 12.8 for grass and cereals respectively, indicating a high risk in grass while the value for cereals is above the Annex trigger of 10 indicating a low risk. The long-term TER value for grass is 5, which is just at the Annex VI trigger while the value for cereals is 11 indicating that the risk is low. To further refine the assessment the applicant proposed to take typical diet of voles (15% seeds and fruits, 80% green plants and 5% insects) into consideration. Calculations of feed intake rate (FIR) are presented in the updated addendum 1 of June 2005. Maintaining the 90th percentile residue values the Rapporteur calculated a TER_a of 2.5 for grass. Taking into account the measured decline of residues in grass a long-term TER value of 5.9 was obtained. Based on these refinements the acute TER is still below the Annex trigger of 10 indicating a

high risk. The Rapporteur considers this is a worst case since the RUD was not refined to reflect the actual diet composition. The risk assessment for mammals was discussed in the experts' meeting and it was agreed that the long-term risk was addressed. The acute assessment for grass was not accepted and a data requirement for the applicant to address the risk was set, including the choice of the vole as focal species. Additionally a provisional data requirement was set to address the acute risk in cereals, pending the opinion of the PPR panel concerning the use of dietary short-term endpoint for the acute assessment.

The plant metabolite dichlorprop-OH was discussed at the experts' meeting and it was agreed that since the metabolite is more water soluble and more likely to conjugate it will be more rapidly excreted than the parent compound. Furthermore there is no reason to suspect that it is more toxic. It was therefore concluded that the potential risk is covered by the risk assessment for dichlorprop-P.

An assessment of the risk to birds and mammals due to intake of drinking water in pools within the sprayed area or pools outside the field, contaminated due to spray drift, was presented in addendum 1. The exposure via drinking water was considered minimal in comparison with dietary intake and the assessment was accepted by the experts in the EPCO meeting.

As the logPow is below 3, dichlorprop-P is not likely to bioaccumulate and the risk from secondary poisoning to birds and mammals is considered to be low.

In conclusion a high risk has been identified for herbivorous birds and mammals for the use of dichlorprop-P in grass and grass seed crops. Additionally a potential high acute risk to insectivorous bird was identified considering the yellow wagtail as a representative species consuming 100% small insects as a worst case. For both birds and mammals a provisional data requirement was set to address the acute risk in cereals, pending the opinion of the PPR panel concerning the use of dietary short-term endpoint for the acute assessment.

5.2. RISK TO AQUATIC ORGANISMS

Four algae studies including four different species were tested for toxicity of dichlorprop-P or its salt, and one test was conducted with the formulation BASF DP-p potassium 600 g/L (DUPLOSAN BAS 044 26 H). The diatom algae *Navicula pelliculosa* was the most sensitive of the aquatic species tested with dichlorprop-P (E_bC_{50}/E_rC_{50} = 0.076/>0.084 mg a.s./L). Significant effects were only seen on cell density at 120 h, with no effects at earlier time intervals or on growth rate. In a study with the same species using the formulation no effects were seen at 100 mg a.s./L. The applicant has argued that the study with the salt should be disregarded since for unexplained reasons no effect concentrations achieved in studies at the conducting laboratory at the time for this study were one to two orders of magnitude below those recorded at other laboratories. Based on the results from the formulation study and the finding that there were no effects on growth rate in the study with the salt, the Rapporteur based the risk assessment for algae on the result from a study on *Anabaena flos aquae* (E_bC_{50} =20.3 mg a.s./L). The choice of endpoint for algae was discussed at the experts' meeting. It was considered that

the data provided was not enough to disregard the study on *Navicula* with the salt, and it was agreed that the risk assessment should be based on the lowest available endpoint. The 14-day EC_{50} for *Lemna gibba* (growth inhibition) was 3.4 mg a.s./L in a study using dichlorprop-P DMA salt and the 7-day EC_{50} was 42.1 mg a.s./L in a study using the formulation. The acute and long-term toxicity towards fish and daphnids is low. Dichlorprop-P was detected in sediment above 10% of applied amount in the water/sediment study, but since the 21-d *Daphnia* NOEC is above 0.1 mg a.s./L no studies with sediment-dwelling organisms are required and the risk is considered to be low.

The predicted environmental concentration in surface water was calculated based on spray drift to a 30 cm static water body at 1 and 5 m distance to the field and an application of 1.5 kg a.s./ha. TER values based on the E_bC_{50} of 0.076 mg/L are 5.5 and 26 respectively, thus indicating that risk mitigation measures comparable to 5 m buffer zones are required.

Exposure of surface water via run off/drain flow equivalent to 15% of the applied dose was also considered in the DAR. The calculated TER values were all above the relevant Annex VI triggers at 1 m distance indicating a low risk from these routes of exposure. However, in this assessment the lowest effect value for *Navicula* was not taken into account. The EFSA therefore proposes that a risk assessment taking into account exposure via run off/drain flow is considered at Member State level.

5.3. RISK TO BEES

The available studies with dichlorprop-P indicate a low oral and contact toxicity to honeybees and the calculated HQ values were well below the Annex VI trigger indicating a low risk.

5.4. RISK TO OTHER ARTHROPOD SPECIES

Laboratory data on toxicity are available for the standard species *Aphidius rhopalosiphi* and *Thyphlodromus pyri* and two additional species, *Chrysoperla carne* and *Pardosa* spp using dichlorprop-P DMA-salt. Effects on mortality were high in the glass plate tests for the standard species, 97and 33% for *Aphidius* and *Thyphlodromus* respectively at a dose rate of 1.5 kg/ha. In an extended test exposing Aphids to treated barley at the same dose rate the mortality was 5% and the effect on fecundity was 35%. Low mortality was observed for *Chrysoperla* in a glass plate test.

Based on the extended laboratory data the in-field risk to *A. rhopalosiphi* is considered low. Since all observed effects are below the ESCORT II trigger of 50% in limit tests at a dose rate proposed for the representative uses, the risk to non-target arthropods is considered low.

5.5. RISK TO EARTHWOMS

A study on the acute toxicity to earthworms from dichlorprop-P indicates a low toxicity. The acute TER value is >500 and therefore the risk to earthworms is considered to be low.

No major soil metabolites of dichlorprop-P were detected in the soil degradation studies.

5.6. RISK TO OTHER SOIL NON-TARGET ORGANISMS

No data is available and not considered necessary since dichlorprop-P degrades fast in soil and there are no major metabolites.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The effects of dichlorprop-P on soil carbon and nitrogen conversion were tested using the formulation BASF DP-p DMA salt 600 g/L (DUPLOSAN BAS 044 18 H). No deviations of more than 25% after 28 days were observed at dose rates 5 times the recommended application rate. Hence the Annex VI trigger was met indicating a low risk.

5.8. RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

Six species (*Brassica napus, Pisum sativum, Papaver somniferum, Linum usitatissimum, Avena sativa, Allium cepa*) were tested in a seedling emergence test and a vegetative vigour test for there sensitivity to the formulation BASF DP-p potassium salt 600 g/L (DUPLOSAN BAS 044 26 H. The overall most sensitive species was *Allium cepa* in the seedling emergence test with an ER_{50} of 46 g a.s./ha.

PEC values were calculated from 2.77 and 0.57% drift at 1 and 5 m distance and an application rate of 1.5 kg a.s./ha. The TER values were 1.1 and 5.3 indicating that risk mitigation measures comparable to a 5 m buffer zone is required to protect higher plants outside the treated field.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

Data from a test with dichlorprop-P DMA-salt on effects on activated sludge respiration rate are available and indicate that the risk to biological methods of sewage treatment plants is low.

6. Residue definitions

Soil

Definitions for risk assessment: dichlorprop-P and its salts, 2,4-dichlorophenol
Definitions for monitoring: dichlorprop[14] and its salts

Water

Ground water

Definitions for risk assessment: dichlorprop-P and its salts, 2,4-dichlorophenol
Definitions for monitoring: dichlorprop[14] and its salts

[14] In this case dichlorprop does not necessarily mean a ratio 1:1 (racemic mixture) of both stereoisomers since the actual rate of racemization of dichlorprop-P is not known.

Surface water

Definitions for risk assessment: dichlorprop-P and its salts

Definitions for monitoring: dichlorprop[15] and its salts

Air

Definitions for risk assessment: dichlorprop-P

Definitions for monitoring: dichlorprop[15]

Food of plant origin

Definitions for risk assessment: Sum of dichlorprop-P its salts and conjugates expressed as dichlorprop-P[16]

Definitions for monitoring: Sum of dichlorprop-P its salts and conjugates expressed as dichlorprop-P

or alternatively

Sum of dichlorprop[17] its salts and conjugates expressed as dichlorprop

Food of animal origin

Definitions for risk assessment: Sum of dichlorprop-P and its salts expressed as dichlorprop-P

Definitions for monitoring: Sum of dichlorprop-P and its salts expressed as dichlorprop-P

or alternatively

Sum of dichlorprop[18] and its salts expressed as dichlorprop

[15] In this case dichlorprop does not necessarily mean a ratio 1:1 (racemic mixture) of both stereoisomers since the actual rate of racemization of dichlorprop-P is not known.

[16] may need to be reconsidered in the light of new information on potential conversion of dichlorprop-P into the *S*-isomer (refer to chapter 3)

[17] *R*- and *S*-isomer, all possible ratios, not necessarily 1:1 ratio of the two isomers

[18] *R*- and *S*-isomer, all possible ratios, not necessarily 1:1 ratio of the two isomers

Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Dichlorprop[18]	Low to moderate persistent (Experimental DT_{50lab} = 7.4 – 16.5 d)	See 5.5, 5.6 and 5.7
2,4-dichlorophenol (2,4-DCP)	Major soil photolysis metabolite, minor aerobic metabolite not detected in lysimeter studies. Nevertheless, due to its pesticidal activity, should be included in the residue definition.	No assessment needed

Ground water

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological activity	Ecotoxicological activity
Dichlorprop	Very high to high mobility (Koc = 12.9-83.7 L/kg)	FOCUS modelling: no Lysimeter: no, all annual average concentrations < 0.1 µg/L	Yes	Yes	No exposure, no assessment needed.
2,4-dichlorophenol (2,4-DCP)	No data	FOCUS modelling: no data Lysimeter: no, all annual average concentrations < 0.1 µg/L	Yes	No data available	No exposure, no assessment needed.

[18] In this case dichlorprop does not necessarily mean a ratio 1:1 (racemic mixture) of both stereoisomers since the actual rate of racemization of dichlorprop-P is not known.

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Dichlorprop[19] (water and sediment)	See 5.2

Air

Compound (name and/or code)	Toxicology
Dichlorprop[9]	Not acutely toxic via inhalation. No data on repeated exposure.

[19] In this case dichlorprop does not necessarily mean a ratio 1:1 (racemic mixture) of both stereoisomers since the actual rate of racemization of dichlorprop-P is not known.

LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- Depending on the final residue definition for food of plant and animal origin, it could be necessary to require enantio selective methods (refer to section 1 and 3).
- Further data on metabolite 11 is required or alternatively a new metabolism study on cereals (relevant for use on grassland, cereals; data submitted to RMS but not peer reviewed; refer to 3.1.1).
- A ruminant feeding study is required (relevant for use on grassland; submission date unknown; refer to 3.2)
- Further data is required to address the short term risk to herbivorous birds (relevant for grass; submission date unknown; refer to point 5.1).
- Further data is required to address the acute risk to insectivorous birds feeding on 100% small insects (relevant for all representative uses evaluated; submission date unknown; refer to point 5.1).
- Further data is required to address the acute risk to herbivorous mammals (relevant for grass; submission date unknown; refer to point 5.1).
- A provisional data requirement was set to address the acute risk for herbivorous birds and mammals, pending the opinion of the PPR panel concerning the use of dietary short-term endpoint for the acute assessment. The opinion for pirimicarb was adopted in July 2005 and new risk assessment in line with the guidance provided in this opinion should be provided (relevant for all representative uses; submission date unknown; refer to point 5.1).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as herbicide as proposed by the applicant which comprises broadcast spraying to control grass and broad-leaved weeds in cereals, grassland and grass seed crops at an application rate of 1.5 kg dichlorprop-P per hectare. Dichlorprop-P can be used only as herbicide.

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.

Adequate methods are available to monitor all compounds given in the respective residue definitions.

Whether or not sufficient enforcement methods are available to monitor food of plant and animal origin depends on the final residue definition. The reason is that none of the submitted method is enantio selective. The residues are determined as a sum parameter of both, the *R*- and the *S*-isomer. This means that for the determination of dichlorprop-P no specific enforcement method would be available. The methodologies used are GC with MS detection and HPLC with UV detection. None of them is enantio

selective. A multi-residue method like the Dutch MM1 or the German S19 is not applicable to due the nature of the residues.
Sufficient analytical method as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible.

The oral LD_{50} of dichlorprop-P is 567 mg/kg bw in rats. The acute dermal toxicity of dichlorprop-P is low as well as the acute inhalation toxicity. Dichlorprop-P is non-irritant to the skin of rabbits but it is a severe eye irritant. Therefore, **classification with Xi; R41 (Risk of serious damage to eyes) is justified.** It is not a skin sensitiser.
The relevant NOAEL for repeated short term exposure is 35 mg/kg bw/day and the overall NOAEL for chronic toxicity is 6 mg/kg bw/day. Dichlorprop-P is of no genotoxic or carcinogenic concern.
In the multi-generation studies the relevant NOAEL for maternal toxicity is 8.3 mg/kg bw/day and the NOAEL for reproductive toxicity is 42 mg/kg bw/day. The relevant maternal and developmental NOAEL is 50 mg/kg bw/day, from the rabbit study. Dichlorprop-P gave no indication of delayed neurotoxicity. The ADI is **0.06 mg/kg bw/day** from the 18-month dietary study in mice, the **AOEL is 0.35 mg/kg bw/day**, based on the 90-day study in rat, and the **ARfD is 0.5 mg/kg bw** from the teratogenicity study in rabbit. All the reference values were applied with a safety factor of 100.
The exposure estimates for workers and bystanders are below the AOEL.

The metabolism of dichlorprop-P has been studied in cereals. In straw unchanged dichlorprop-P accounted for the majority of total radioactivity at maturity, whereas no further work on identification or characterisation of grain residue was performed due to low extractable residue levels. Two major metabolites were found in straw. One of them, metabolite 11 was not identified in the study and therefore its toxicological relevance could not be addressed. Further data on the identity of that metabolite were required (data gap). The residue definition for risk assessment was agreed by the experts' meeting for residues as sum of dichlorprop-P, its salts and conjugates expressed as dichlorprop-P. Based on information of potential conversion of dichloprop-P residues to the *S*-isomer, which became available after the experts' meeting the residue definition for consumer risk assessment would need to be reconsidered not only in terms of relevance of metabolite 11.
In supervised residue trials the sum of the *R*- and the *S*-isomer of dichlorprop was determined, however, it still needs to be clarified whether also conjugates that are part of the residue definition have been analysed in those trials.
A livestock metabolism study in lactating goats indicated that residues above LOQ could occur in edible animal matrices, and thus a feeding study on ruminants is required (data gap).
Due to the lack of the above stated information and data the consumer risk assessment cannot currently be concluded. However, a provisional assessment of consumer risk with currently proposed MRLs for cereals, which are still pending their confirmation, indicates that consumer exposure is low for all considered consumer groups (significantly less than 10% ADI and ARfD, respectively). Exposure from food of animal origin has not been considered in the assessment.

No degradation products of dichlorprop-P that accounted for more than 10% AR were identified in soil under aerobic conditions. Non-extractable residues reached a maximum of 33.6% AR and CO_2 maximum of 43.4% AR. Under anaerobic conditions in a water/sediment system no new metabolites were identified. Photolysis in soil may contribute to the environmental degradation of dichlorprop-P. 2,4-dichlorophenol was the only photoproduct found at amounts above 10% AR, but due to its fast degradation rate (in order of minutes) it is considered a minor metabolite.

Dichlorprop-P can be considerate as moderate persistent in soil ($DT_{50\ 20}$ºC = 6.8 – 26.1 d). During the peer review process, one open point was the use of Q10 value of 5 based on measured data and significantly deviating from the FOCUS default value of 2.2. The experts decided that this is a general question that must be discussed between specialists and therefore a specific question to the PPR Scientific Panel was addressed.

Field dissipation studies were not conducted.

PECs soil were calculated based on the single maximum application rate, using a DT_{50} of 26.1 days. Only initial PECsoil values are used in the ecotoxicological risk assessment.

The batch soil adsorption/desorption studies indicate that dichlorprop-P is potentially mobile (Koc = 12.9 – 83.7 L/kg). Column leaching studies confirmed the potential mobility of the dichlorprop-P. In un-aged soils 11.4 – 83.9% AR was found in the leachate of four soils. In aged leaching studies 0.35 – 56% AR was found in the leachate. The only detectable eluting radioactive residue corresponded to dichlorprop-P.

Four lysimeter/field studies are available that show exceedance of 0.1 µg/L at 1 m depth only at individual data points (in the Swedish study one sampling in clay lysimeters and three occasions in sand lysimeters, reaching 16 and 26 µg/L in percolate). In the drainage water study, in 7 out of 65 samples dichlorprop-P was detected at concentrations above 0.1 µg/L (max. concentration 0.30 µg/L).

Dichlorprop-P is hydrolytically stable in sterile aqueous buffers between pH 3 and pH 9 at 25ºC±2.

The study on photodegradation showed that dichlorprop-P is degraded under artificial sunlight irradiation conditions (DT_{50} value of 4 days) but not under dark conditions. No metabolites were found above the 10% AR.

Dichlorprop-P should be classified as a non ready biodegradable substance.

A study with two water sediment systems was available. Dichlorprop-P was degraded to 5.1 and 2.3% AR in the water phase (day 30). In the two sediments maximum levels of dichlorprop-P were found at 11.9%AR (day 7) and 10.3% AR (day 3). The maximum amounts of sediment residue that was not extracted were up to 25.4% AR and 16.0% AR (day 30). The remaining amount was recovered as volatiles. The experts had some concerns on the fact that volatile products trapped in the soda lime were carbon dioxide. It was concluded that even if is not explicitly proven that trapped volatiles are CO_2, the exact identity of the volatiles has no influence on the risk assessment. Two months after application more than 80% AR was found in volatiles, whereas the amount of parent compound in the system was 0.1% AR or less. The total (up to 5 peaks) metabolite concentrations were reported to be low (max. 3.7% AR and 2.0% AR). DT_{50} values for the water phase were calculated from the degradation curves resulting in 21 days and 20 days. Half life in the total systems (15.3 and 14.6 days) was derived for the two systems based on first order kinetics.

An anaerobic eutrophic pond study was available. The EPCO experts' meeting discussed the calculated anaerobe DT_{50} value and they concluded that since this value is not relevant for the risk assessment, no further assessment was necessary.
PEC_{sw} due to contamination via spray drift were calculated for dichlorprop-P for a 30 cm deep static water body at 1 m distance for the evaluated representative use on spring cereals. PECsed values are not included in the endpoints since they are not relevant for the risk assessment.
The experts agreed that a risk assessment taking into account exposure via run off and drainage should be considered at Member State level (these routes of potential surface water contamination were considered in the DAR and recalculated in an addendum based on a contribution from run-off/erosion and drainage of 15% of the application rate).
The potential leaching of dichlorprop-P to groundwater was simulated with FOCUS PELMO for the nine $FOCUS_{gw}$ scenarios. The EPCO experts' meeting discussed the modelling input values (Koc and mean DT_{50} value including results form the metabolism study) and accepted the Q_{10} value of 5 to calculate the DT_{50} value at reference conditions. In all scenarios the predicted 80^{th} percentile annual average concentrations are below the 0.1 µg/L regulatory threshold. The FOCUS modelling for the minor metabolite 2,4-dichlorophenol is considered essential to finalise the EU risk assessment.
Monitoring data in 3 different countries in EU (UK, Germany and Denmark) showed that dichlorprop-P occurrence in groundwater and surface fresh water is rare.
Concentration of dichlorprop-P in the air compartment and transport through it is not expected to be significant.

A high short term risk has been identified for herbivorous birds and a high acute risk for mammals for the use of dichlorprop-P in grass and grass seed crops. Additionally a potential high acute risk to insectivorous bird was identified considering the yellow wagtail as a representative species consuming 100% small insects as a worst case. Further data is thus needed to address the risk to birds and mammals. Additionally, a provisional data requirement was set to address the acute risk for birds and mammals in cereals, pending the opinion of the PPR panel concerning the use of dietary short-term endpoint for the acute assessment. The opinion for pirimicarb was adopted in July 2005 and it is proposed by the EFSA that a risk assessment is performed in accordance with the recommendations provided in this opinion.

The diatom algae *Navicula pelliculosa* was the most sensitive of the aquatic species tested with dichlorprop-P. The predicted environmental concentration in surface water was calculated based on spray drift. The TER value for algae indicates a high risk and risk mitigation measures comparable to 5 m buffer zones are required.

The risk to bees, non-target arthropods, earthworms and other soil organism is considered low. To protect non-target plants outside the field risk mitigation measures comparable to a 5 m buffer zone is required.

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

- Risk mitigation measures comparable to 5 m buffer zones are required to protect the aquatic environment (refer to point 5.2).
- Risk mitigation measures comparable to 5 m buffer zones are required to protect non-target plants outside the field (refer to point 5.8).

Critical areas of concern

- ~~At the moment no statement can be given whether or not the different sources of dichlorprop-P can be regarded as equivalent (they are not from an analytical point of view, see chapter 1).~~
- No enantio selective analytical method is available for the determination of residue in food of plant and animal origin (the necessity depends on the final residue definition). Furthermore, it should be noted that with the available analytical methods for food, soil and water it is not possible to differentiate between residue of the acid and its salts, esters and glycoside conjugates.
- Consumer risk assessment cannot be finalized. Consumer exposure from use on cereals is provisional pending the confirmation that the unidentified metabolite 11 is of no toxicological significance and that the residue levels obtained in field trials include also conjugates of dichlorprop-P. Actual consumer exposure to dichlorprop-P residues from food of animal origin cannot be assessed due to lacking data. Proposed residue definition for risk assessment may need to be reconsidered also in the light of a potential conversion reaction of dichlorprop-P into the *S*-isomer in food/feed, as recently reported for environmental matrices.
- Exposure for workers during re-entry activities in amenity grass should be dealt with at MS level (the use is not included in the list of uses for inclusion in Annex I, but it represents a particular concern for exposure in sports, playing children, etc.).
- A high short term risk has been identified for herbivorous birds for the use in grass and grass seed crops.
- A high acute risk has been identified for herbivorous mammals for the use in grass and grass seed crops.
- A potential high acute risk to insectivorous bird was identified considering the yellow wagtail as a representative species consuming 100% small insects as a worst case..
- A provisional data requirement was set to address the acute risk for birds and mammals in cereals, pending the opinion of the PPR panel concerning the use of dietary short-term endpoint for the acute assessment.
- A high risk was identified for the algae and risk mitigation measures comparable to 5 m buffer zones are required to protect the aquatic environment.
- A high risk was identified for non-target plants and risk mitigation measures comparable to 5 m buffer zones are required to protect non-target plants outside the field.

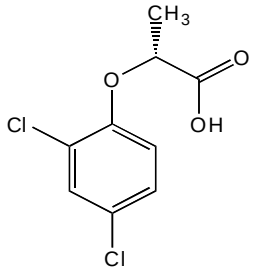
APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

(Abbreviations used in this list are explained in appendix 2)

Appendix 1.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Dichlorprop-P
Function (e.g. fungicide)	Herbicide
Rapporteur Member State	Denmark
Co-rapporteur Member State	--

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	(*R*)-2-(2,4-dichlorophenoxy)propanoic acid
Chemical name (CA) ‡	(+)-2-(2,4-dichlorophenoxy)propionic acid
CIPAC No ‡	476
CAS No ‡	15165-67-0
EEC No (EINECS or ELINCS) ‡	403-980-1 (ELINCS)
FAO Specification ‡ (including year of publication)	None for dichlorprop-P
Minimum purity of the active substance as manufactured ‡ (g/kg)	900 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	Other phenoxy acids may occur in some of the batches in some of the sources. These impurities derive from former production of other phenoxy acids in the same production line. The specific identities are given in the respective Annex C's. Maximum content is 3 kg/g of each. It is unlikely that more than one is present at detectable levels.
Molecular formula ‡	$C_9H_8Cl_2O_3$
Molecular mass ‡	235.1
Structural formula ‡	

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	122.1 – 122.9 ºC (100.0%)
Boiling point (state purity) ‡	decompose (100.0%)
Temperature of decomposition	290 °C (100.0%)
Appearance (state purity) ‡	White crystalline solid (100.0%) Off-white flakes (Tech.)
Relative density (state purity) ‡	1.42 (100.0%)
Surface tension	59.0 mN/m, 0.1% , 20 °C
Vapour pressure (in Pa, state temperature) ‡	1.8×10^{-4} Pa at 25°C (99.9%)
Henry's law constant (Pa m^3 mol^{-1}) ‡	5.6×10^{-5} Pa m^3/mole
Solubility in water ‡ (g/l or mg/l, state temperature)	590 mg/l, (20 °C) unbuffered 500 mg/L, (20 °C) pH 3, buffer 6.31g/l, (20 °C) pH 4, buffer > 250 g/l, (20 °C) pH 7, buffer > 250 g/l, (20 °C) pH 9, buffer (all 99.9%)
Solubility in organic solvents ‡ (in g/l or mg/l, state temperature)	20 °C *p*-xylene 69.6 g/kg acetone 1679 g/kg ethyl acetate 697 g/kg methanol 1631 g/kg 1,2-dichloroethane 77.2 g/kg *n*-heptane 2.9 g/kg (all 99.9%)
Partition co-efficient (log POW) ‡ (state pH and temperature)	pH 5: log P_{ow} = 1.029 (20 °C) pH 7: log P_{ow} = -0.562 (20 °C) pH 9: log P_{ow} = -0.873 (20 °C) (all 99.7%)
Hydrolytic stability (DT50) ‡ (state pH and temperature)	pH5 stable (25 °C and 50 °C) pH7 stable (25 °C and 50 °C) pH9 stable (25 °C and 50 °C)
Dissociation constant ‡	pKa = 3.67 (20 °C) (99.7%)

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

UV/VIS absorption (max.) ‡ (if absorption > 290 nm state ε at wavelength)	λ_{max} 205 nm: ε = 2.8×10^4 l x mol^{-1} x cm^{-1} λ_{min} 218 nm: ε = 7.6×10^3 l x mol^{-1} x cm^{-1} λ_{max} 230 nm: ε = 8.9×10^3 l x mol^{-1} x cm^{-1} λ_{min} 252 nm: ε = 2.2×10^3 l x mol^{-1} x cm^{-1} λ_{max} 285 nm: ε = 1.9×10^3 l x mol^{-1} x cm^{-1} $\lambda_{shoulder}$ 292 nm: ε = 1.7×10^3 l x mol^{-1} x cm^{-1} (99.9%)
Photostability (DT50) ‡ (aqueous, sunlight, state pH)	Water: 4 days (pH 7) Air: < 0.9 days
Quantum yield of direct phototransformation in water at Σ > 290 nm ‡	Φ < 0.023
Flammability ‡	Is not a highly flammable solid
Explosive properties ‡	No risk of explodability

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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, barely and oats [1]
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 [1]
Grass Seed crops	North Europe	F	Broad leaved weeds	SL	600	as above	Spring, 4-6 weeks before head emer-gence	1 per year	N/A	1-0.4	150-400	1.5	28-42	[1]

SL – soluble concentrate; N/A – Not applicable

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

[1] The risk assessment has revealed a risk in section 5.

(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)
(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

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(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
(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
(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

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.2: Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (principle of method)	The sample is analysed by HPLC with UV detection
Impurities in technical as (principle of method)	Impurities associated with the active ingredient are determined by HPLC with UV detection or by GC-MSD.
Plant protection product (principle of method)	The sample is analysed by HPLC with UV detection

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Samples are extracted with alkaline methanol and are typically cleaned up on C18 columns. Extracts are derivatized by methylation and analysed by GC-MS. LOQ (Cereals): 0.02-0.05 mg/kg (grain), 0.05 mg/kg (whole plant and straw). LOQ (grass): 0.05 mg/kg.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Samples are extracted with trifluoroacetic acid in acetonitrile and cleaned up on C18 cartridges. Extracts are then evaporated and dissolved in trifluoroacetic acid/methanol and finally analysed by HPLC. LOQ (milk): 0.01 mg/kg LOQ (Egg): 0.02 mg/kg LOQ (Fat): 0.02 mg/kg LOQ (beef and poultry meat): 0.02 mg/kg LOQ (liver and kidney): 0.05 mg/kg

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Soil (principle of method and LOQ)	The soil sample is extracted with aqueous methanol. The sample is centrifuged, filtered and extracted again. Sodium hydroxide solution is added to the extracts. The methanol is evaporated. The aqueous residue is washed with dichloromethane and acidified with H2SO4. The water fraction is extracted with dichloromethane again and discarded. The organic extracts are dried and evaporated to dryness. The dry residue is methylated using H2SO4 and methanol. Water is added and the methylated 2,4-DP-p is extracted into n-hexane. The hexane layer is dried using sodium sulphate prior to GC-MSD analysis. The column used is a DB-17, 15 m, 0.50 µm film, 0.32 ID or a DB-1 15 m, 0.25 µm film, 0.25 ID. Two ions are used for quantification and one ion is used for identification. LOQ: 0.01 mg/kg
Water (principle of method and LOQ)	Water is acidified and extracted with CH2Cl2. The organic phase is evaporated to the aqueous residue, acidified, to pH 1, and extracted with CH2Cl2. The CH2Cl2 are dried and evaporated to dryness. 5 µl of sulphuric acid, 800 µl trifluoroacetic anhydride and 200 µl trichloroethanol are added. The solution is concentrated and NaHCO3 solution is added, extracted with iso-octane and cleaned on a silica gel column The sample eluted and analysed by GC-MSD. The column used is a DB-17, 15 m, 0.50 µm film, 0.32 ID. Two ions are used for quantification and one ion is used for identification. LOQ: 0.05 µg/L, drinking water LOQ: 1 µg/L, surface water
Air (principle of method and LOQ)	Air is sucked through Tenax adsorption tubes and extracted with acetone. The extract is evaporated to dryness and dissolved in 1 mL of methanol/0.1% triflouroacetic acid (49:51, v/v). The final extract is analysed by high-performance liquid chromatography with UV detection (230nm) using a C8 column LOQ: 11 µg/m3
Body fluids and tissues (principle of method and LOQ)	Dichlorprop-P is not classified as toxic or highly very toxic, therefore analytical methods to study residues in body fluids and tissues are not required.

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	None

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.3: Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)

Rate and extent of absorption ‡	> 88% (based on urinary and faecal excretion)
Distribution ‡	Widely distributed (highest residues in blood, liver, kidney, thyroid, adrenal, heart and uterus)
Potential for accumulation ‡	No significant accumulation
Rate and extent of excretion ‡	Min. 88% excreted within 120 hours or 168 hours (low and high dose respectively) via urine. 3-12 % via faeces.
Metabolism in animals ‡	Limited metabolism. 3% unidentified metabolites.
Toxicologically significant compounds ‡ (animals, plants and environment)	Parent compound and 3 % unidentified metabolites (animals) Sum of Dichlorprop-P and isomer (plants)

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	567 mg/kg bw (methylcellulose as vehicle)	**R22**
Rat LD_{50} dermal ‡	> 4000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 7.4 mg/L	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Severe eye irritant	**R41**
Skin sensitization ‡ (test method used and result)	Not a skin sensitiser (Magnusson and Kligman)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Kidney, liver, blood system (dog, mouse and rat)
Lowest relevant oral NOAEL / NOEL ‡	35 mg/kg bw/day, 3-months, rat
Lowest relevant dermal NOAEL / NOEL ‡	1000 mg/kg bw/day, high dose; 21 day rabbit
Lowest relevant inhalation NOAEL / NOEL ‡	No data submitted.

Genotoxicity ‡ (Annex IIA, point 5.4)

.....	No genotoxic potential

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Increased incidence and severity of chronic nephropathy in the kidneys (mouse).
Lowest relevant NOAEL / NOEL ‡	6 mg/kg bw/day, 18-months mice
Carcinogenicity ‡	No carcinogenic potential

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	Effects on kidney weight; prolonged gestation, high number of dams with stillborn pups, reduced number of pups/dam in maternal toxic doses.
Lowest relevant reproductive NOAEL / NOEL ‡	Maternal: 8.3 mg/kg bw/day Reproductive: 42 mg/kg bw/day
Developmental target / critical effect ‡	Increased number of foetuses with accessory 13th rib(s) at maternal toxic doses in the rabbit
Lowest relevant developmental NOAEL / NOEL ‡	Maternal and developmental 50 mg/kg bw/day

Neurotoxicity / Delayed neurotoxicity ‡ (Annex IIA, point 5.7)

.....	No evidence of delayed neurotoxicity following oral single and repeated dosing.

Other toxicological studies ‡ (Annex IIA, point 5.8)

.....	No studies submitted

Medical data ‡ (Annex IIA, point 5.9)

.....	Cases of acute poisoning for chlorophenoxy herbicides have been reported. No adverse effects with respect to general health status were discovered over a six-year period in a major producer of phenoxy herbicides. Available epidemiological data are inadequate for determining an association between cancer in human and exposure.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.06 mg/kg bw/day	18-month feeding study mouse	100
AOEL ‡	0.35 mg/kg bw/day	90-day feeding study rat	100
ARfD ‡ (acute reference dose)	0.5 mg/kg bw/day	Teratogenicity study rabbit,	100

Dermal absorption (Annex IIIA, point 7.3)

Optica DP (form potassium salt)	Spray dilution: 11% Concentrate: 1.3% Based on results from *in vivo* studies (form: ester) and correction for *in vitro* data (form: potassium salt).

Acceptable exposure scenarios (including method of calculation)

Operator	Exposure below the AOEL without PPE (German model, 31% of the AOEL) or with gloves during M/L (UK POEM 28% of AOEL).
Workers	Exposure below the AOEL
Bystanders	Exposure below the AOEL

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data	Xn, Xi	Harmful, irritating
	R22	Harmful if swallowed
	R41	Risk of serious damage to eyes

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.4: 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-P, its salts and conjugates expressed as dichlorprop-P *or alternatively* Sum of dichlorprop[20], its salts and conjugates expressed as dichlorprop
Plant residue definition for risk assessment	Sum of dichlorprop-P, its salts and conjugates expressed as dichlorprop-P [21]
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-P and its salts expressed as dichlorprop-P *or alternatively* Sum of dichlorprop[22] and its salts expressed as dichlorprop
Animal residue definition for risk assessment	Sum of dichlorprop-P and its salts, expressed as dichlorprop-P [23]
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 DT_{90} by aerobic degradation in soil is less than 100 days.

[20] *R*- and *S*-isomer, all possible ratios, not necessarily 1:1 ratio of the two isomers
[21] might need to be reconsidered upon receipt of outstanding data on metabolite 11 and also in the light of a potential conversion of dichlorprop-P into the *S*-isomer
[22] *R*- and *S*-isomer, all possible ratios, not necessarily 1:1 ratio of the two isomers
[23] might need to be reconsidered upon receipt of outstanding data on metabolite 11 and also in the light of a potential conversion of dichlorprop-P into the *S*-isomer

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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 is 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
Muscle	A data requirement for a ruminant feeding study was established at the experts' meeting EPCO 19	n/a	not required*
Liver		n/a	not required*
Kidney		n/a	not required*
Fat		n/a	not required*
Milk			
Eggs		n/a	

* Residue values in animal products are based on the goat metabolism study

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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

ADI	0.06 mg/kg bw/day
TMDI (European Diet) (% ADI)	Will be finally evaluated upon receipts of outstanding data and information[24] *Provisional assessment:* 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)
NEDI (% ADI)	Not applicable
Factors included in NEDI	Not applicable
ARfD	0.5 mg/kg bw/day
Acute exposure (% ARfD)	Will be finally evaluated upon receipts of outstanding data and information[25] *Provisional assessment:* NESTI-UK cereals: <1% ARfD all consumer groups Animal products: Will be evaluated when data for the proposal of MRLs in animal products has been submitted.

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

* Calculated on the basis of distribution in the different portions, parts or products as determined through balance studies

[24] identity and toxicological significance of metabolite 11; confirmation of compliance of supervised residue trials with residue definition; feeding study on ruminants and MRL proposals for animal products
[25] identity and toxicological significance of metabolite 11; confirmation of compliance of supervised residue trials with residue definition; feeding study on ruminants and MRL proposals for animal products

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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

Cereals (Barley, oats, rye, wheat and triticale)	0.1 mg/kg[26]
Milk Meat Fat Kidney Liver Egg	A data requirement for a livestock feeding study was established at the experts' meeting EPCO 19 in February 2005. MRLs for animal products will be proposed when this study has been submitted.

*) LOQ

[26] provisional, to be confirmed

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.5: Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡	25±2 °C: 43.4% (90 d)
Non-extractable residues after 100 days ‡	33.6 % (90 d)
Relevant metabolites - name and/or code, % of applied ‡ (range and maximum)	2,4-dichlorophenol: 3.9 % (peak 7 d) 2,4-dichloroanisole: 4.2 % (peak 7 d) unidentified: 2.8 % (peak 28 d)

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡	No studies submitted
Soil photolysis ‡	DT_{50}: 7.6 d (irradiated samples) DT_{50}: 20 d (dark control samples) Metabolites: 2,4-dichlorophenol: 23.6 % (peak 8 d) An unknown peak was observed at higher concentrations in the dark control samples (5.1 %) compared to the irradiated samples (3.6 %), and was therefore not considered a photodegradation product.

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	1. order kinetics
Laboratory studies ‡ (range or median, with n value, with r^2 value)	25 ± 2 ° C, aerobic: DT_{50lab}: 14 d (n = 1) experimental 26.1 d normalised to 20 oC and 10kPa 20 °C: DT_{50lab}: 7.4 – 16.5 d (n = 3) experimental 6.8 – 13.8 d normalised to 20 oC and 10kPa For FOCUS modelling mean DT_{50lab}: 14.7 days 10 °C: DT_{50lab}: 37.4 d (n = 1) experimental, Q10 = 5

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

	Degradation in the saturated zone ‡: Data available, not considered to be relevant for the risk assessment.
Field studies ‡ (state location, range or median with n value)	No studies submitted
Soil accumulation and plateau concentration ‡	No studies With a max. DT_{50} of 26.1 d and only one application a year significant accumulation in soil is not expected, cf. PECsoil calculations below.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡ K_d ‡	Sorption: Koc: 12.9 – 83.7 L/kg (n = 10), mean 44 L/kg; 1/n: 0.589-0.908, mean 0.79 Kd: 0.105 – 6.52 (n = 10) Desorption: Koc: 21.9 – 474 L/kg (n = 4) Kd: 0.285 – 33.2 (n = 4) Adsorption values from column leaching experiments unaged soil, sorption: Koc: 2.31 – 16.3 L/kg (n = 3) Kd: 0.03 – 0.26 (n = 3) aged soil, sorption: Koc: 26.0 L/kg (n = 1) Kd: 0.338 (n = 1)
pH dependence ‡ (yes / no) (if yes type of dependence)	No

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	Soil types: sandy loam (pH 7.4), sandy loam (pH 6.3), sand (pH 6.7) and clay (pH 7.0) unaged soils: percolation rates: 0.019 (clay) – 8.60 (sand) mL/min leachate: 83.9, 11.4, 85.0 and 56.4 % (total radioactivity) aged soils: percolation rates: 0.145 (clay) – 4.19 (sand) mL/min extractable 2,4-DP-p: 51.9, 60.0, 62.8 and 66.6 % volatiles < 0.29 % leachate: 44.9, 0.354, 56.2 and 48.9 % (total radioactivity) In all soils the only detectable residue corresponded to dichlorprop-P
Aged residues leaching ‡	A sandy soil, with OC=0.6 % and pH 7.3, was treated with 5.29 mg/kg 2,4-DP and aged aerobically for 30 days at 20 °C and at a moisture content of approximately 75% of the field moisture capacity. After 30 days ageing: total soil radioactivity: 26.9% of applied RA extractable: 7.48% of applied RA 2.06% of radioactivity submitted to leaching was recovered in the leachate, corresponding to 0.55% of applied radioactivity. Concentration of total radioactivity in the pooled leachate was 6.8 µg/L, when expressed as dichlorprop-P equivalents.
Lysimeter/ field leaching studies ‡	Four lysimeter/field studies were reported. Leaching was studied in two German soils (silty loam with OM = 1.05 and pH 7.2 at the surface, and sandy silt with OM = 0.90 and pH 6.9 at the surface). The application rate was 1.69 kg a.s./ha. Results showed that for both lysimeters, the analysis of the leachates gave no indication of Dichlorprop-P above the limit of detection (LOD = 0.007 µg/L). None of the metabolites were found in

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

	the leachate at any time (LOD = 0.005 µg/L). Leaching was studied in four Swedish soils with OM ranging from 3.8 (clay) to 89% (peat) and pH 4.8-7.2, with an application rate of 1.6 kg a.s./ha. Leaching for varying soil types/treatment combinations ranged from 0.02 to 0.20% of the applied amount in the agricultural soils. Leaching was greater in clay monoliths than in sand monoliths, which was explained by macropore flow. In the leachate from peat 1.8% of the applied amount was found, this is, however, not representative of typical agricultural soils. Leaching of dichlorprop was studied in 8 Swedish field lysimeters filled with either a sandy soil or a clay soil. Application was at a rate of 1.5 kg a.s./ha. Dichlorprop concentrations above the limit of detection (0.1 µg/L) were observed on one sampling occasion in the clay lysimeters and on three occasions in the sand lysimeters, reaching 16 and 26 µg/L in percolate from the respective soils. The content of dichlorprop was measured over a 2-year period in drainage water from three clayey soils in Denmark. The application rate ranged from 1.25 to 1.6 g a.s./ha. Dichlorprop was analysed in a total of 65 samples, in 22 of these the herbicide was detected and in 7 samples the concentrations were above 0.1 µg/L. These 7 samples were divided among three locations. The maximum concentration was 0.30 µg/L in Blans Dec. 1989.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation	0% crop interception 5 cm soil incorporation Soil density 1.5 g/cm^3 Only initial value needed for the risk assessment
Application rate	Single application 1.5 kg a.s./ha, representing a normal dose for spring cereals

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	2.00	2.00		

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolysis of active substance and relevant metabolites (DT_{50}) ‡ (state pH and temperature)	Radiolabeled (+)-2,4-DP-p acid did not degrade in aqueous solutions buffered at pH 5, 7 and 9.
Photolytic degradation of active substance and relevant metabolites ‡	^{14}C-2,4-DP-p acid degraded in an aqueous solution buffered at pH 7 under artificial sunlight irradiation conditions, but not under dark conditions. Approximately 75% of the applied amount in the irradiated samples was degraded after 8 days of irradiation, corresponding to a photodegradation half-life of 4 days. Two unknown products, peaks 1 and 2, each exceeding 10% of the applied radioactivity were detected. Peak 1 reached a maximum of 45.1% of the applied radioactivity at day 8 and contained polar water-soluble materials that eluted in the void volume. Peak 1 consisted of several components, each less than 10 % of the AR. Peak 2 reached a maximum of 11.0% of the applied radioactivity at day 8. Peak 2 also appeared to contain polar products. Three minor products, i.e. peaks 3, 4 and 5, each of which did not exceed 2% of applied radioactivity were also observed in the irradiated samples only.
Readily biodegradable (yes/no)	No studies submitted, not ready degradable (supported by the water/sediment study)

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Degradation in water/sediment - DT_{50} water - DT_{90} water - DT_{50} water - DT_{90} water - DT_{50} whole system - DT_{90} whole system - DT_{50} whole system - DT_{90} whole system	DT_{50} values for the water phase are calculated from degradation curves for two water/sediment systems: DT_{50} water Krempe: 21 d DT_{50} water Ohlau: 20 d DT_{50} values for the whole system are based on 1.order kinetics: DT_{50} water Krempe: 15.3 d DT_{50} water Ohlau: 14.6 d
Mineralization	79.2-90.2% AR at 91 d (n=2)
Non-extractable residues	10.8-19.4% AR at 91 d (n=2)
Distribution in water / sediment systems (active substance) ‡	Krempe and Ohlau: max. 11.9 (7 d) and 10.3 % (3 d) of applied amount were found in the two sediments, and the remaining amount was recovered as volatiles or unextractable residues (max. 25.4 and 16 % day 30 respectively). Two months after application more than 80% of the applied radioactivity was found in volatiles, whereas the amount of parent compound in the system was 0.1% or less.
Distribution in water / sediment systems (metabolites) ‡	In the aerobic systems fractions of degradates were not reported, the total (up to 5 peaks) metabolite concentrations were reported to be low (max. 3.7 % of AR in Ohlau and max. 2.0 % AR in Krempe).

PEC (surface water) (Annex IIIA, point 9.2.3)

Parent

Method of calculation	Continuous and time-weighted average surface water concentrations calculated at a distance 1 m from source (2.77 % drift) using a DT_{50} of 21 days (worst case).
Application rate	Single application 1.5 kg a.s./ha, representing a normal dose for spring cereals
Main routes of entry	Drift

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

PEC$_{(sw)}$ (mg / L)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	$1.39 \cdot 10^{-2}$	$1.39 \cdot 10^{-2}$		
Short term 4h	$1.34 \cdot 10^{-2}$	$1.36 \cdot 10^{-2}$		
2d	$1.30 \cdot 10^{-2}$	$1.34 \cdot 10^{-2}$		
4d	$1.21 \cdot 10^{-2}$	$1.30 \cdot 10^{-2}$		
Long term 7d	$1.10 \cdot 10^{-2}$	$1.24 \cdot 10^{-2}$		
14d	$8.72 \cdot 10^{-3}$	$1.11 \cdot 10^{-2}$		
21d	$6.93 \cdot 10^{-3}$	$1.00 \cdot 10^{-2}$		
28d	$5.50 \cdot 10^{-3}$	$9.04 \cdot 10^{-3}$		
42d	$3.46 \cdot 10^{-3}$	$7.49 \cdot 10^{-3}$		

PEC (sediment)

Parent

Method of calculation	Not needed for the risk assessment.
Application rate	--

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	FOCUS groundwater scenarios, using the PELMO model (3.2.2). Mean DT50 = 13.5 days*, mean Koc = 45 L/kg and mean Freundlich coef. 1/n=0.79. Experimental Q10 = 5
Application rate	1.5 kg a.s./ha on winter cereal in spring, assuming 25% crop interception

PEC$_{(gw)}$

Maximum concentration	Not available, not required
Average annual concentration (Results quoted for modelling with FOCUS gw scenarios, according to FOCUS guidance)	< 0.1 µg/l

* For PEC_{gw} calculations a reliable DT_{50} = 14.7 days should have been used in place of 13.5 days. This slight difference is not expected to have a significant impact on modelling results.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

PEC(gw) - FOCUS modelling results

Predicted 80th percentile average concentrations of Dichlorprop-P in groundwater at 1 m depth

Model /Crop	Scenario	Parent (µg/l)	Metabolite (µg/l)		
			-	-	-
	Châteaudun	0.019			
	Hamburg	0.000			
	Jokioinen	0.000			
	Kremsmünster	0.006			
	Okehampton	0.081			
	Piacenza	0.006			
	Porto	0.000			
	Sevilla	0.000			
	Thiva	0.000			

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	Degradation rate from OH-attack was found to be $k_{OH} > 11.4 \cdot 10^{-12}$ cm^3 molecule^{-1} s^{-1}. Based on this value the atmospheric degradation half-life was < 0.9 d. The degradation rate resulting from ozone attack was estimated from the OECD method to be $k_{O3} > 3.3 \cdot 10^{-18}$ cm^3 molecule^{-1} s^{-1}, and the corresponding half-life was < 3.5 d.
Quantum yield of direct phototransformation	No data submitted
Photochemical oxidative degradation in air ‡	No data submitted
Volatilization ‡	From plant surfaces: no data submitted from soil: no data submitted

PEC (air)

Method of calculation	Expected to be negligible based on physical/chemical properties

PEC$_{(a)}$

Maximum concentration	Negligible

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	**Soil** Definitions for risk assessment: dichlorprop-P and its salts, 2,4-dichlorophenol Definitions for monitoring: dichlorprop and its salts **Water** **Ground water** Definitions for risk assessment: dichlorprop-P and its salts, 2,4-dichlorophenol Definitions for monitoring: dichlorprop and its salts **Surface water** Definitions for risk assessment: dichlorprop-P and its salts Definitions for monitoring: dichlorprop and its salts **Air** Definitions for risk assessment: dichlorprop-P Definitions for monitoring: Dichlorprop In this case diochlorprop does not necessarily means a ratio 1:1 (racemic mixture) of both stereoisomers since the actual rate of racemization of dichlorprop-P is not known.

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	No data
Surface water (indicate location and type of study)	UK: 1393 samples with 1.4 % > 0.1 µg/l in 1997
Ground water (indicate location and type of study)	UK: no findings > 0.1 µg/l Germany: 10 findings in 2373 samples of which 5 exceeded 0.1 µg/l, corresponding to 0.2% Denmark: 6477 samples (GRUMO), of which 10 exceeded 0.1 µg/l, corresponding to 0.9%
Air (indicate location and type of study)	No data

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	Possible candidate for R53 May cause long-term adverse effects in the aquatic environment

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.6: Effects on non-target Species

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

Acute toxicity to mammals ‡	Rat LD_{50} = 567 mg a.s./kg bw
Acute toxicity to birds ‡	Rat NOAEL = 152 mg a.s. /kg bw day
Dietary toxicity to birds ‡	*Colinus virginianus* $LD_{50\ (14\ d)}$ = 279 mg DMA salt/kg bw (234 mg dichlorprop-P/kg bw)
Reproductive toxicity to birds ‡	*Colinus virginianus* $LC_{50\ (10\ d)}$ = 6090 ppm DMA salt (5110 ppm dichlorprop-P) ~ 701 mg DMA salt/kg bw day (589 mg dichlorprop-P /kg bw day)
	Coturnix coturnix NOEC = 847 ppm dichlorprop-P ~ 149 mg a.s./kg bw day

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

Revised based on dichlorprop-P (acid) endpoints and other refinements (see addendum January 2005- updated June 2005 - for details)

Application rate (kg a.s./ha)	Crop	Category (e.g. insectivorous bird)	Time-scale	TER	Annex VI Trigger
Birds Tier 1[1]					
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 2[2]					
1.5	Grass/Cereals	large herbivorous birds	acute/ short term	5.8 / 14.9[3]	10
1.5	Cereals	insectivorous birds	acute/ short term	7.3 / 21[4]	10
1.5	Grass/Cereals	large herbivorous birds	short term	7.4 / 34[3]	10
1.5	Cereals	large herbivorous birds	long term	15.6	5
1.5	Cereals	insectivorous birds	long term	125	5

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Application rate (kg a.s./ha)	Crop	Category (e.g. insectivorous bird)	Time-scale	TER	Annex VI Trigger
Mammals Tier 1[1]					
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 2[2]					
1.5	Grass/Cereals	small herbivorous mammals	acute / short term	>2.1 / >12.8[3]	10
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 for further details on birds and mammals respectively.
[3] Based on measured residues in short grass and cereals respectively
[4] Based in small insects and mixed insect diet respectively
[5] Based on mixed diet

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Values used in the risk assessment in the DAR are highlighted in bold				
Oncorhyncus mykiss and *L. macrochirus*	Dichlorprop-P DMA salt	96 hr (static)	Mortality	LC_{50} > 150# **LC_{50} >109 mg acid/L**
Oncorhyncus mykiss	Dichlorprop-P	28 d flow through	sublethal symptoms	**NOEC = 100**
Daphnia magna	Dichlorprop-P	48 hr (static system)	mortality	**EC_{50} >100**
Daphnia magna	Dichlorprop-P	48 hr (semi-static system)	mortality	EC_{50}>100
Daphnia magna	Dichlorprop-P DMA salt	48 hr (static)	mortality	EC_{50}>100 #
Daphnia magna	Dichlorprop-P	21 d	mortality	**NOEC>100**
Daphnia magna	Dichlorprop-P	21 d	fecundity	NOEC >100

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Anabaena flos-aquae	Dichlorprop-P	72 hr	Growth inhibition	**ErC_{50} = 26.5** EbC_{50} = 20.3
Selenastrum capricornutum	Dichlorprop-P	72 hr	Growth inhibition	ErC_{20} = 67.0
Navicula pelliculosa	Dichlorprop-P DMA salt DP-p K 600	120 hr 72 hr	Growth inhibition	E_bC_{50} = 0.091# (0.076 mg acid/l) ErC_{50} > 1 # (>0.84 mg acid/l) EC_{50} >216* (100 mg acid/l
Skeletonema costatum	Dichlorprop-P DMA salt	120 hr	Growth inhibition	NOEC ≥ 11# (9.22 mg acid/l)
Lemna gibba	Dichlorprop-P DMA salt DP-p K 600	14 d 7 d	Growth inhibition	**EC_{50} = 4.1 #** (3.4 mg acid/L)E_bC_{50} = 91.1* (**42.1 mg acid/l)**
Microcosm or mesocosm tests: Not submitted				

expressed as DMA salt
* given as mg formulated product/l

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Initial PEC values based on spray drift are 0.5 mg/L at 0 m, 0.0139 m/L at 1m and 0.0029 mg/L at 5 m

Application rate (kg a.s./ha)	Crop	Organism	Time-scale (endpoint)	Distance (m)	TER	Annex VI Trigger
1.5	field	*O. mykiss* *L. macrochirus*	96 hr (LC_{50} >109 mg acid/L)	0	> 218	100
1.5	field	*O. mykiss*	28 d (NOEC 100 mg acid/L)	0	> 200*	10

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Application rate (kg a.s./ha)	Crop	Organism	Time-scale (endpoint)	Distance (m)	TER	Annex VI Trigger
1.5	field	*N. peliculosa*	120 hr (ErC50 > 0.84 mg acid/L)	1	60	10
			120 hr (EbC50 0.076 mg acid/L)	1	5.5	10
				5	26	10
1.5	field	*Anabaena flos aquae*	72 hr (ErC50 26.5 mg acid/L)	0	53	10
			(EbC50 20.3 mg acid/L)	0	41	
1.5		*Lemna gibba#*	14 d (EC_{50} 3.4 mg acid/L)	0	6.8	10
				1	245	10
1.5	field	Daphnia magna	48 hr (EC_{50} >100 mg acid/L)	0	>200	100
1.5	field	Daphnia magna	21 d (NOEC 100 mg acid/L)	0	>200*	10

* based on PEC_i
\# based on the study with the active substance

Bioconcentration

Bioconcentration factor (BCF) ‡	not submitted, not required (log Pow < 3)
Annex VI Trigger:for the bioconcentration factor	100
Clearance time (CT_{50}) (CT_{90})	--
Level of residues (%) in organisms after the 14 day depuration phase	--

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity ‡	> 200 µg a.s./bee
Acute contact toxicity ‡	> 200 µg a.s./bee

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
1.5	Cereals	Oral	< 7.5	50
1.5	Cereals	Contact	< 7.5	50
Field or semi-field tests: Not required				

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests ‡						
Typhlodromus pyri	Juv/Adu	Dichlorprop-P DMA	1.5	Mortality Fecundity	33 18	30%
Chrysoperla carnae	Juv/Adu	Dichlorprop-P DMA	1.5	Mortality Fecundity	5 0	30%
Pardosa spp	Sub-Adu	Dichlorprop-P DMA	1.5	Mortality Feeding rate	0 13	30%
Aphidus rholosiphi	Juv	Dichlorprop-P DMA	1.5	Mortality	97	30%
Aphidus rholosiphi Extended lab. study	Juv	Dichlorprop-P DMA	1.5	Mortality Fecundity	5 35	30% ESCORT trigger 50%
Field or semi-field tests: Not required						

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity ‡	LC_{50} > 1000 mg a.s./kg
Reproductive toxicity ‡	Not required

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Application rate (kg as/ha)	Crop	Time-scale	TER	Annex VI Trigger
1.5 kg/ha	Cereals	14 d	> 500	10

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization ‡	3% effect at 7.5 kg a.s./ha. Effect less than trigger of 25% at 5 times the max. application rate.
Carbon mineralization ‡	Max. 12% effect at 1.5 kg a.s./ha. Effect less than trigger of 25%.

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Most sensitive species	Test substance	ER50 (kg as /ha) Plant weight	Exposure[1] (kg as/ha)	TER	Trigger
Laboratory dose response tests					
Onion (*Allium cepa*)	BAS 044 26H[2]	0.0457	0 m 1.5	0.03	5
			1 m 0.042	1.1	5
			5 m 0.0086	5.5	5
Additional studies: Not required					

1 based on 90th percentile drift values (Rautmann et al. 2001)
2 SC formulation containing 602 g as/L

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	Dichlorprop-P: N; Harmful to the environment R50/R53 Very toxic to aquatic organisms, may cause long term-adverse effects in the aquatic environment Formulation: Not discussed at expert meeting

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC_{50}	lethal concentration, median

LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year