EFSA Journal 2010;8(10):1718

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance diclofop (considered variant diclofop-methyl)[1]

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SUMMARY

Diclofop is one of the 79 substances of the third stage part A of the review programme covered by Commission Regulation (EC) No 1490/2002,[3] as amended by Commission Regulation (EC) No 1095/2007[4] . In accordance with the Regulation, at the request of the Commission of the European Communities (hereafter referred to as 'the Commission'), the EFSA organised a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by France, being the designated rapporteur Member State (RMS). The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of the variant diclofop in Annex I to Council Directive 91/414/EEC.

Following the Commission Decision of 5 December 2008 (2008/934/EC)[5] concerning the non-inclusion of diclofop in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Bayer Crop Science made a resubmission application for the inclusion of diclofop in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008.[6] The resubmission dossier included further data in response to the issues identified in the DAR.

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, France, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 11 August 2009.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 13 August 2009. The EFSA collated and forwarded all comments received to the Commission on 28 September 2009.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission requested the EFSA to conduct a focused peer review in the area of mammalian toxicology and deliver its conclusions on diclofop.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of diclofop as a herbicide on cereals, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

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1 On request from the European Commission, Question No EFSA-Q-2009-00950, issued on 01 September 2010
2 Correspondence: praper@efsa.europa.eu
3 OJ L224, 21.08.2002, p.25
4 OJ L 246, 21.9.2007, p.19
5 OJ L 333, 11.12.2008, p.11
6 OJ L 15, 18.01.2008, p.5

Suggested citation: European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance diclofop (considered variant diclofop-methyl). EFSA Journal 2010;8(10):1718. [74 pp.]. doi:10.2903/j.efsa.2010.1718. Available online: www.efsa.europa.eu

For physical-chemical properties there are no critical areas of concern. However, data gaps have been identified for batch data for one of the sources, a 2 year shelf-life study for the formulation, additional methods and method validation.

The preferential metabolism/degradation of each stereoisomer in plants, animals (diclofop-methyl and probably diclofop) and the environment (diclofop only), and the possible impact on the toxicity, worker and consumer risk assessment, and the environment were not investigated in the studies submitted in the dossier and needs to be addressed.

A data gap was identified in the toxicology section for a study on acute toxicity by inhalation performed with the representative formulation. No critical area of concern was raised.

The nature of the residues in cereal crops has not been confirmed because the metabolism studies submitted could not be considered acceptable. Therefore no further areas of the risk assessment could be concluded upon.

The data available on environmental fate and behaviour in the environment are sufficient to carry out the required environmental exposure assessments at the EU level. For the representative uses assessed, contamination of groundwater above the parametric drinking water standard (0.1µg/L) is not expected for diclofop-methyl, diclofop or diclofop-phenol.

The risk to herbivorous birds and mammals from potential plant metabolites remains to be addressed, based on a valid plant metabolism study. The risk to all other non-target organisms was assessed low based on the data available and the representative uses.

KEY WORDS

Diclofop, diclofop-methyl, peer review, risk assessment, pesticide, herbicide

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BACKGROUND

Legislative framework

Commission Regulation (EC) No 1490/2002,[7] as amended by Commission Regulation (EC) No 1095/2007[8] lays down the detailed rules for the implementation of the third stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC. This regulates for the European Food Safety Authority (EFSA) the procedure for organising, upon request of the Commission of the European Communities (hereafter referred to as 'the Commission'), a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the designated rapporteur Member State.

Commission Regulation (EC) No 33/2008[9] lays down the detailed rules for the application of Council Directive 91/414/EEC for a regular and accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC but which were not included in Annex I. This regulates for the EFSA the procedure for organising the consultation of Member States and the applicant for comments on the Additional Report provided by the designated RMS, and upon request of the Commission the organisation of a peer review and/or delivery of its conclusions on the active substance.

Peer review conducted in accordance with Commission Regulation (EC) No 1490/2002

Diclofop is one of the 79 substances of the third stage part A of the review programme covered by Commission Regulation (EC) No 1490/2002, as amended by Commission Regulation (EC) No 1095/2007. In accordance with the Regulation, at the request of the Commission, the EFSA organised a peer review of the DAR provided by the designated rapporteur Member State, France, which was received by the EFSA on 19 July 2007 (France 2007).

The peer review was initiated on 10 September 2007 by dispatching the DAR to Member States and the applicant Bayer Crop Science for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table.

The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of diclofop in Annex I to Council Directive 91/414/EEC.

Peer review conducted in accordance with Commission Regulation (EC) No 33/2008

Following the Commission Decision of 5 December 2008 (2008/934/EC)[10] concerning the non-inclusion of diclofop in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Bayer Crop Science AG made a resubmission application for the inclusion of diclofop in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the issues identified in the DAR, in particular taking into consideration the operator exposure.

In accordance with Article 18, France, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 11 August 2009 (France 2009)

[7] OJ L224, 21.08.2002, p.25
[8] OJ L246, 21.9.2007, p.19
[9] OJ L 15, 18.01.2008, p.5
[10] OJ L 333, 11.12.2008, p.11

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicant for comments on 13 August 2009. In addition, the EFSA conducted a public consultation on the Additional Report. The EFSA collated and forwarded all comments received to the Commission on 28 September 2009. At the same time, the collated comments were forwarded to the RMS for compilation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Tables. The comments and the applicant's response was evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 1 December 2009, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on diclofop within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were required to be submitted by the applicant in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicant in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the Commission on 24 November 2009; the applicant was also invited to give its view on the need for additional information. On the basis of the comments received, the applicant's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that the EFSA should organise a consultation with Member State experts in the area of mammalian toxicology and that further information should be requested from the applicant in the areas of residues, environmental fate and behaviour, and ecotoxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Tables. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in consultation with Member State experts, and the additional information to be submitted by the applicant, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert discussions where these took place, was reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in June 2010.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a herbicide on cereals, as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report (EFSA 2010), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report comprises the following documents:

- the comments received,
- the Reporting Table on the DAR (revision 1-1; 25 November 2009),
- the Reporting Table on the Additional Report (revision 1-1; 25 November 2009),
- the Evaluation Table 31 August 2010
- the report(s) of the scientific consultation with Member State experts (where relevant).

Given the importance of the DAR and the Additional Report including its addendum (compiled version of May 2010 containing all individually submitted addenda; France 2010) and the peer review report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Diclofop is the ISO common name for (*RS*)-2-[4-(2,4-dichlorophenoxy)phenoxy]propionate (IUPAC). Due to the fact that the diclofop-methyl, a variant of diclofop, is used in the formulated product, it should be noted that the evaluated data belong to the variant diclofop-methyl, unless otherwise specified.

The representative formulated product for the evaluation was 'Illoxan36EC' an emulsifiable concentrate (EC) containing 378 g/l.

The representative uses evaluated comprise outdoor foliar spraying to control grass weeds in cereals. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

It must be noted that diclofop-methyl is a racemic mixture of enantiomers, but the possible preferential metabolism/degradation of each enantiomer in animals, plants and the environment was not investigated in the studies submitted in the dossier and was therefore not considered during the peer review. Moreover, the analytical methods used in the studies reported through all sections were not stereo-selective, and all values mentioned as diclofop or diclofop-methyl have to be considered as "sum of enantiomers". The possible impact of each individual enantiomer on the toxicity, the consumer risk assessment and the environment was not evaluated. Data gaps, applicable for sections 2, 3, 4 and 5, were therefore identified to address the impact of the isomeric composition of the substance.

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

The minimum purity of diclofop-methyl as manufactured is not less than 980 g/kg. The specification for one source is not accepted and a data gap for new batch data has been identified. It should also be noted that the new specification proposed in the addendum to Volume 4 to the additional report of April 2010 was not considered eligible according to Commission Regulation 33/2008 (EC). Diclofop-methyl contains no known relevant impurities.

The main data regarding the identity of diclofop-methyl and its physical and chemical properties are given in Appendix A.

As there was a change of formulation a data gap was identified for a 2 year shelf-life study.

The residue definition for plants and animals could not be finalised.

The methods of analysis for plants are not acceptable. There is a non validated hydrolysis step in the method which means it extracts at least some conjugates. Also for the GC method the derivitisation step is not validated. The method of analysis for food of animal origin is also not accepted for the following reasons. As for the plant method the method includes a non validated hydrolysis step, the derivitisation step is not validated and in the ILV study there was communication with the primary laboratory. For the soil and water methods the derivitisation step was not validated. Also for water there is no method for the metabolite diclofop-phenol. For air there is a GC-MSD method available. A method for body fluids and tissues is currently not required because the active substance is not classified as toxic or very toxic. The outcome from the toxicological studies in rabbits would support a classification T R 24, "toxic in contact with skin." If the classification should change in the future then an additional data gap for a method for body fluids and tissues should be identified.

2. Mammalian toxicity

Diclofop-methyl was discussed at the PRAPeR Expert's Meeting on mammalian toxicology (PRAPeR 73) in March 2010. The technical specification agreed by section 1 on identity, physical/chemical/technical properties is supported by the toxicological assessment. It is noted that the technical specification for one source as presented in the Additional Report (August 2009) would also be covered by the toxicological assessment if it could be accepted by Section 1. A data gap was identified for the bridging profile for the new formulation Illoxan 36 EC, as the presented data were not eligible according to Commission Regulation 33/2008(EC).

Diclofop-methyl is extensively absorbed and eliminated, with bile being the main route of excretion.

Moderate to low acute toxicity is observed when diclofop-methyl is administered by the oral, dermal or inhalation routes to rats. However rabbits appear to be significantly more sensitive to diclofop-methyl as observed by a LD_{50} of about 200 mg/kg bw by the dermal route in several older studies that would indicate a classification as "toxic in contact with skin" (R24), as proposed by the expert meeting (see Appendix A). No skin irritation and mild ocular irritation were observed, but diclofop-methyl has the potential to cause skin sensitization.

The main target organ of diclofop-methyl is the liver. Upon long term exposure hepatocellular adenomas and carcinomas were observed in rats and mice. Diclofop-methyl was shown to be a potent rodent inducer of Peroxisome Proliferator-Activated Receptor-alpha (PPARα) generally agreed to be rodent specific and unlikely to pose a risk to humans. No NOAEL could be determined in rats upon long-term exposure as the toxicological relevance of lipofuscin storage in the kidneys found in the 2-year rat study could not be ruled out; the LOAEL is 0.2 mg/kg bw/day. No genotoxic potential was observed. Developmental or reproductive effects were associated with parental toxicity. The rabbit developmental study was found to have been conducted with inappropriately low doses, leaving a gap of knowledge on the potential developmental effects in this sensitive species between 3 and about 10 mg/kg bw/day dose levels. The highest dose tested of 3 mg/kg bw/day showed signs of maternal toxicity but no developmental effect. The maternal NOAEL was therefore 0.3 mg/kg bw/day and the developmental NOAEL of 3 mg/kg bw/day was used as a precautionary NOAEL for the overall acute effects of diclofop-methyl. No potential for neurotoxicity was observed in the standard toxicity studies.

The acceptable daily intake (ADI) of diclofop-methyl is 0.001 mg/kg bw/day, applying an assessment factor of 200 to the LOAEL from the 2-year rat study. The acceptable operator exposure level (AOEL) is 0.003 mg/kg bw/day derived from the maternal NOAEL of the rabbit developmental toxicity study and applying a safety factor of 100, no correction for oral absorption needed. The acute reference dose (ARfD) is 0.03 mg/kg bw derived from the developmental NOAEL of the same rabbit study, 100 safety factor applied.

A data gap was set for an acute inhalation toxicity study performed with the formulation due to its spray use.

Estimated operator exposure is below the AOEL if personal protective equipment (PPE) is worn (gloves during mixing, loading and application, and standard protective garment, sturdy footwear, hood and visor during application) according to the German model, applying geometric mean values. If no PPE is considered or according to the UK POEM model or the German model with 75^{th} percentile values (and same PPE), operator exposure exceeds the AOEL.

Worker exposure is expected to be below the AOEL if PPE is worn (gloves, long sleeved shirt and long trousers). A data gap was identified on the identification of the enantiomer ratio to which workers are exposed, or on their comparative toxicity. Calculated bystander exposure is below the AOEL.

3. Residues

The wheat metabolism study was not considered acceptable due to significant concerns about the validity of the study. Wheat grain control samples contained significant levels of radioactivity at a level of approximately 90% of the TRR found in the treated wheat grains. It is therefore unlikely that the nature of the residues elucidated in the metabolism studies is representative of the representative use.

The nature of the residues in cereal crops has not been confirmed and therefore no further areas of the risk assessment could be concluded upon.

It should be noted that the preferential metabolism of each isomer in plants and animals and the subsequent impact on the consumer risk assessment has also not been addressed.

4. Environmental fate and behaviour

As already discussed, the regulatory dossier provides no information on the behaviour of each individual diclofop enantiomer in the environment. It is not known if either isomer is degraded more quickly than the other or if interconversion between enantiomers occurs in the environmental matrices studied. Reference in this conclusion to diclofop is therefore to the sum of enantiomers of unknown ratio. Consequently a data gap was identified.

In soil laboratory incubations under aerobic conditions in the dark diclofop-methyl is not persistent rapidly forming the major (>10% applied radioactivity (AR)) metabolite diclofop (max. 82%AR). Diclofop-phenol (max. 5.9%AR) was also assessed for groundwater exposure. These metabolites exhibited low to medium persistence or were not persistent respectively. Mineralisation of the dichlorophenyl ring radiolabel to carbon dioxide accounted for 8-21 % AR after 120 days. The formation of unextractable residues (not extracted using acidified acetonitrile:water) for this radiolabel accounted for 41-44% AR after 120 days. In anaerobic soil incubation and in soil photolysis study the same rapid conversion of diclofop-methyl to diclofop occurred. Diclofop-methyl and diclofop-phenol are immobile in soil. Diclofop exhibits medium soil mobility with adsorption being pH dependent, with adsorption reducing as pH increases. The results of two field leaching studies carried out at 2 sites in the UK (early winter applications at a dose rate of 756g/ha diclofop-methyl, slightly higher than the representative use) with suction cup samplers in the unsaturated zone at 120 cm (pH 6.7 sandy loam) and 80cm (pH 7.3 clay), indicated it was clear that annual average recharge concentrations to groundwater of diclofop below these depths would be <0.1µg/L under the conditions at these experimental sites.

In laboratory incubations in dark aerobic natural sediment water systems, diclofop-methyl is impersistent forming the major metabolites: diclofop (max.: 84-89%AR in water and 36-44% in sediment, exhibiting moderate persistence) and diclofop-phenol which was the major sediment metabolite (max. 16-24% AR, exhibiting high persistence). The unextractable sediment fraction (not extracted using acetonitrile:water) was the major sink for the dichlorophenyl ring radiolabel accounting for 43-48 %AR after 120 days. Mineralisation of this radiolabel accounted for 17-18 % AR after 120 days. Aqueous photolysis of diclofop cannot be excluded as having the potential to result in the formation of diclofop-phenol, on the basis of the available aqueous photolysis investigations. Therefore exposure estimates in surface water as a result of potential photolytic transformation from diclofop were carried out.

For the representative uses assessed, the necessary surface water and sediment exposure assessments (Predicted environmental concentrations (PEC)) in surface water and sediment were carried out for the metabolites diclofop and diclofop-phenol using the FOCUS (2001) step 1 and step 2 approach (version 1.1 of the Steps 1-2 in FOCUS calculator). For the active substance diclofop-methyl, appropriate step 3 (FOCUS, 2001) and step 4 calculations were available [11]. The step 4 calculations appropriately followed the FOCUS (2007) guidance with just no spray drift buffer zones of up to 5m being implemented. As already noted above, levels of diclofop-phenol that might be formed as a result of aqueous photolysis of diclofop were estimated. These estimations were appropriately calculated using the results of FOCUS (2001) step 3 simulations for diclofop.

[11] Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA (2007)) and Walker equation coefficient of 0.7

The necessary groundwater exposure assessments were carried out using FOCUS (2000) scenarios and the models PEARL 3.3.3 and PELMO 3.3.2[12] for the active substance diclofop-methyl and it's soil metabolites diclofop and diclofop-phenol. The potential for groundwater exposure from the representative uses assessed by all these compounds above the parametric drinking water limit of 0.1 μg/L, was concluded to be low in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios.

The PEC in soil, surface water, sediment and groundwater agreed by the peer review, covering the representative uses assessed can be found in appendix A.

5. Ecotoxicology

A data gap remains to address the potential risk to non-target organisms from enantiomer of dichlofop (see introduction and section 4).

The risk to birds and mammals was assessed according to the Guidance Document on birds and mammals (European Commission, 2002c). Whereas the acute and short term risk to insectivorous and herbivorous birds via dietary exposure was assessed as low at tier 1 for the representative uses in cereals, higher tier refinements were required for the long-term assessment. The RMS suggested a refined long-term risk assessment for Brent goose, Skylark and Yellow wagtail as herbivorous, omnivorous and insectivorous focal species, respectively. The long-term risk to herbivorous and omnivorous birds was assessed as low based on agreed refinement of PD and measured residue levels in cereal shoots and decline therein. Whereas PD refinements were accepted for insectivorous birds (Yellow wagtail), concerns remain whether 90th percentile PT values derived from a field study conducted in North Europe would cover behaviour of Yellow wagtail in South Europe. The long-term (reproductive) risk to birds for the use in cereals could be assessed as low (see details in the list of endpoints), based on a generic tier I risk assessment following the new guidance document for Birds and Mammals (EFSA, 2009). The initial risk assessment for mammals (following the old Birds and Mammals Guidance document) indicated a potential acute and long-term risk to small herbivorous mammals. In a refined risk assessment the acute and long-term risk was as low, based on measured residue levels and their decline in cereal shoots, wood mouse and brown hare as focal species and refined PD values. The risk from metabolites was assessed as low for birds and mammals based on the data available. However, following from the data gap for a valid plant metabolism study (see section 3), a data gap was identified to assess the risk to herbivorous birds and mammals from potential unidentified plant metabolites. The risk from secondary poisoning ($logP_{ow}$ = 4.8) and from consumption of contaminated drinking water was assessed as low for birds and mammals.

Diclofop-methyl is very toxic to fish, daphnids and algae. Acute toxicity data for representative formulation showed the same toxicity as the active substance to aquatic organisms. The risk to algae and aquatic plants was assessed low for the representative uses, based on $FOCUS_{sw}$ step 2 PEC values. Risk mitigation measures, e.g. non-spray buffer zones of 5m based on worst case initial PEC values at FOCUSsw step 4, was required to identify a low risk for fish and daphnids. The chronic risk to daphnids was based on the endpoint from a more realistic semi-static chronic study with the formulation with only one renewal of the test concentration during the study. Partition of diclofop-methyl to the sediment is negligible. Bioconcentration factors up to 1700 were identified in fish. The risk of bioaccumulation in fish was however considered negligible, because of only one application

[12] Simulations complied with EFSA (2004) and correctly utilised the agreed Q10 of 2.58 (following EFSA (2007)) and Walker equation coefficient of 0.7

per year for the representative use and a fast clearance time of diclofop-methyl in fish (CT_{90} of 2.6 days).
The metabolites diclofop is harmful to aquatic organisms. Diclofop-phenol is very toxic to aquatic organisms and has a comparable toxicity to aquatic organisms as the parent substance. Both metabolites will partition to the sediment. The risk to aquatic organisms including sediment dwellers was assessed as low for diclofop and diclofop-phenol, based on $FOCUS_{sw}$ step 1 and $FOCUS_{sw}$ step 2, respectively.

Whereas tier 1 risk assessment indicated a low off-field risk to the non-target arthropods *Aphidius rhopalosiphi* and in *Typhlodromus pyri*, further refinements were required to address the risk for the in-field scenario. The measured impact of diclofop-methyl on 5 other species of the foliar and soil predator groups and of the soil parasitoid group was low under laboratory conditions. Additional extended laboratory studies and aged residue studies for *A. rhopalosiphi* and *T. pyri* were provided for the resubmission. The "in-field" risk to non-target arthropod species was considered to be low as an additional aged residue study indicated sufficient potential for recovery within season.

Based on dose-response studies on 6 dicotyledonous plants and 4 monocotyledonous plants, a risk assessment was provided for ryegrass as the most sensitive non-target plant species. The risk to off-crop non-target plants was assessed as low based on mitigation measures, e.g. in-field non-spray buffer zone of 5m.

The risk to bees, earthworms, non-target soil micro- and macro-organisms and sewage treatment processes was assessed as low based on the data available and the representative GAP uses.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
diclofop-methyl	Not persistent DT_{50} 0.2-1.1 days (DT_{90} 0.5-3.6 days, 20°C, 40-45%MWHC soil moisture)	Risk to soil living organisms assessed as low.
diclofop	Low to medium persistence biphasic DT_{50} 5.1-74 days (DT_{90} 21-246 days, 20°C, 40-55%MWHC soil moisture) biphasic DT_{50} 6.7-38 days (DT_{90} 40-241 days, field studies)	Risk to soil living organisms assessed as low.
diclofop-phenol	Not persistent DT_{50} 0.12-0.28 days (DT_{90} 0.56-1 days, 20°C, 40-55%MWHC soil moisture)	Risk to soil living organisms assessed as low.

6.2. 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 relevance	Ecotoxicological activity

diclofop-methyl	immobile K_{foc} 15084-26654 mL/g	No	Yes	Yes	Very toxic to aquatic organisms. Risk to aquatic organisms assessed as low, based on risk mitigation measures
diclofop	medium mobility K_{foc} 148-505 mL/g (pH dependent reducing adsorption as pH increases)	No	No	No data available, no data required	Harmful to aquatic organisms. Low risk to aquatic organisms.
diclofop-phenol	immobile K_{foc} 5098-9253 mL/g	No	Yes, based on comparable toxicity to aquatic organisms as a.s.	No data available, no data required	Very toxic to aquatic organisms. Low risk to aquatic organisms.

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
diclofop-methyl (water only)	Very toxic to aquatic organisms. Risk to aquatic organisms assessed as low, based on risk mitigation measures. Should be included in residue definition.
diclofop (water and sediment)	Harmful to aquatic organisms. The risk to aquatic and sediment living organisms was assessed as low. Should not be included in residue definition (See section 5)
diclofop-phenol (water and sediment)	Very toxic to aquatic organisms. The toxicity of diclofop-phenol is comparable to the toxicity of diclofop-methyl. The risk to aquatic and sediment living organisms was assessed as low. Should be included in the residue definition (See section 5).

6.4. Air

Compound (name and/or code)	Toxicology
diclofop-methyl	Rat LC_{50} inhalation > 1.36 mg/L air/4h, nose-only exposure (no classification required)

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

- Representative 5 batch analysis for the reference source (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)
- A 2 year shelf life study for New Illoxan 36 EC (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)
- Method of analysis for plants (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)
- Method of analysis for products of animal origin (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)
- Validation of the derivitisation step used in the soil method of analysis (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)
- Validation of the derivitisation step used in the water method of analysis (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)
- Method of analysis for diclofop-phenol in surface water (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)
- Diclofop-methyl consists of 2 stereoisomers. The preferential metabolism/degradation of each isomer in plants and animals and their possible impact on the toxicity and on worker and consumer risk assessment need to be addressed (relevant for all representative uses evaluated; no submission date proposed; refer to sections 2 and 3).
- A bridging profile for the new formulation Illoxan 36 EC (see section 2).
- An acute inhalation toxicity study performed with the representative formulation (relevant for all representative uses evaluated; no submission date proposed by the applicant; see section 2)
- A new metabolism study is required to support the use on cereals (relevant for the representative use on cereals; submission date proposed by the applicant: unknown, see section 3).
- An additional metabolism study may change the current conclusions in all other areas of the assessment, therefore all other studies, existing open points and points of clarification should be reconsidered in the light of a new metabolism study (relevant for the representative use on cereals; submission date proposed by the applicant: unknown, see section 3)
- Diclofop consists of 2 stereoisomers. This needs to be taken into account in the environmental risk assessments as this adds some uncertainty. Information on the toxicity and/or on the degradation of the 2 isomers in the environment is needed. (relevant for all representative uses evaluated; data gap identified after the commenting phase; no submission date proposed by the applicant; refer to sections 4 and 5).
- The risk to herbivorous birds and mammals from potential plant metabolites (including any isomers of these metabolites) remains to be addressed, based on a valid plant metabolism study (relevant for all representative uses evaluated; no submission date proposed; refer to sections 5).

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- Operator exposure is below the AOEL if personal protective equipment is worn (gloves during mixing and loading, and gloves, standard protective garment, sturdy footwear, hood and visor during application) according to the German model, using geometric mean values (see section 2).

- Worker exposure is below the AOEL if personal protective equipment is worn (gloves, long-sleeved shirt and long trousers) (see section 2).

- Appropriate risk mitigation, e.g. non-spray buffer zones of 5 m was required to identify a low risk to aquatic organisms for all representative uses;

- Appropriate risk mitigation, e.g. non-spray in-field buffer zones of 5 m was required to identify a low risk to non-target plants for all representative uses;

ISSUES THAT COULD NOT BE FINALISED

- The preferential metabolism/degradation of each stereoisomer in plants and animals (diclofop-methyl and probably diclofop) and the environment (diclofop only), and the possible impact on the toxicity, to the operator, worker and consumer risk assessment, and the environment were not finalised.

- A consumer risk assessment for cereals could not be finalised due to the absence of a reliable cereal metabolism study.

- The risk to herbivorous birds and mammals from potential plant metabolites remains to be addressed, based on a valid plant metabolite study.

CRITICAL AREAS OF CONCERN

- Insufficient plant metabolism data were available to conclude on an appropriate plant residue definition, therefore all other areas of the risk assessment for this use could not be concluded upon and an exceedance of the toxicological reference values (ADI and ARfD) could not be excluded.

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[13] For further guidance documents see http://ec.europa.eu/food/plant/protection/resources/publications_en.htm#council (EC) or http://www.oecd.org/document/59/0,3343,en_2649_34383_1916347_1_1_1_1,00.html (OECD)

APPENDICES

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

The LoEP has been modified according to the comments of the member states for the initial submission (2003) and after the re submission
EFSA May 2010

Identity, Physical and Chemical Properties, Details of Uses, Further Information
Data given for Diclofop methyl except when indicated.

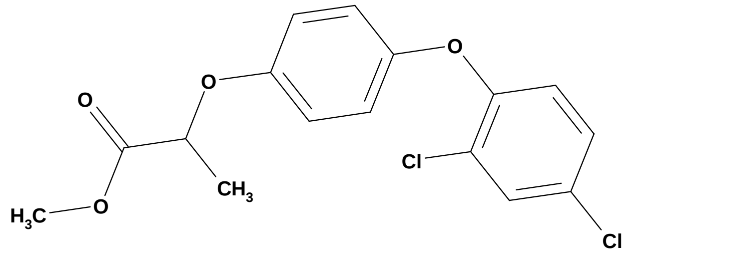
Active substance (ISO Common Name) ‡	Diclofop (ISO) (Unless otherwise stated, the following data relate to the variant diclofop-methyl)
Function (e.g. fungicide)	Herbicide

Rapporteur Member State	France
Co-rapporteur Member State	

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	Diclofop-methyl methyl (RS)-2-[4-(2,4-dichlorophenoxy)phenoxy]propionate
Chemical name (CA)	Diclofop-methyl methyl 2-[4-(2,4-dichlorophenoxy)phenoxy]propanoate
CIPAC No	358.201 (diclofop-methyl) 358 (diclofop)
CAS No	257-141-8 (Diclofop-methyl) 40843-25-2 (diclofop)
EEC No (EINECS or ELINCS)	Not available
FAO Specification (including year of publication)	No FAO specification
Minimum purity of the active substance as manufactured (g/kg)	980 g/kg reference source open
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	none
Molecular formula	$C_{16}H_{14}Cl_2O_4$
Molecular mass	341.20 g/mole

Structural formula



Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	44°C (99.0%)
Boiling point (state purity) ‡	370-395 °C (99.0%)
Temperature of decomposition	Not required as both melting and boiling points were determined
Appearance (state purity) ‡	white powdered solid, odourless (99.0%) Light brown solid (93.8%)
Vapour pressure (in Pa, state temperature) ‡	2.5 x 10^{-5} Pa at 25°C
Henry's law constant (Pa m^3 mol^{-1}) ‡	1.05 x 10^{-2} $Pa.m^3.mol^{-1}$ at 20°C
Solubility in water (g/l or mg/l, state temperature) ‡	Neutral range at 20°C : 0.39 mg/L (Diclofop-methyl does not form ions).
Solubility in organic solvents (in g/l or mg/l) ‡	solubility at 20°C n-hexane 49.7 g/l acetone > 500 g/l toluene > 500 g/l dichloromethane > 500 g/l methanol 120 g/l isopropanol 51 g/l ethyl acetate > 500 g/l polyethylene glycol 148 g/l dimethylsulfoxide > 500 g/l
Surface tension	Not tested as solubility in water below 1 mg/L.
Partition co-efficient (log P_{OW}) (state pH and temperature) ‡	Diclofop-methyl: 4.8 (neutral pH) Diclofop: 2.8 (pH 5) 0.7 (pH 7)
Dissociation constant ‡	Diclofop-methyl is neither an acid or a base Diclofop : pKa = 3.4
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength) ‡	In methanol ε = 51969 L/mol*cm (λ = 202 nm) ε = 16030 L/mol*cm (λ = 229 nm) ε = 3218 L/mol*cm (λ = 283 nm) *ε = 2495* L/mol*cm *(λ = 291 nm)* In methanol/HCl ε = 52530 L/mol*cm (λ = 202 nm) ε = 15124 L/mol*cm (λ = 229 nm) ε = 2593 L/mol*cm (λ = 279 nm) * *ε = 1895* L/mol*cm *(λ = 291 nm)* In methanol/NaOH ε = 24177 L/mol*cm (λ = 216 nm) ε = 19027 L/mol*cm (λ = 229 nm) ε = 5217 L/mol*cm (λ = 281 nm) *ε = 4448* L/mol*cm *(λ = 291 nm)* <u>For Diclofop</u> In acetonitrile ε = 14900 L/mol*cm (λ = 229 nm)

	ε = 2860 L/mol*cm (λ = 283 nm) No absorption after 290 nm
Flammability ‡ (state purity)	Not highly flammable (93.8%)
Explosive properties ‡ (state purity)	No danger of explosion (93.8%)
Oxidizing properties ‡ (state purity)	No oxidizing properties (94.6%)

Summary of representative uses evaluated (diclofop methyl)*

Summary of representative uses evaluated (*name of active substance or the respective variant*)*

Crop and/ or situation (a)	Member State or Country	Product name	F / G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application			Application rate per treatment			PHI (days) (k)	Remark: (l)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage (j)	number min max	kg as/hl min max	water l/ha min max	kg as/ha as DCM /ha min max		
Cereals	N-Europe and France	Illoxan® EC36	F	Lolium	EC	378 g/L	Ground-boom sprayer	BBCH 13-20 (Autumn) BBCH12 -31 (spring)	1		200-400	max. 0.378 max. 0.567	covered by period between latest applica-tion and harvest	[1]
Cereals	S-Europe	Illoxan® EC36	F	Lolium, Avena	EC	378 g/L	Ground-boom sprayers	BBCH 12-29 (Autumn to Spring)	1		200 - 400	max. 0.605	covered by period between latest applica-tion and harvest	[1]

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the applicant no longer supports this use(s). (a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)	(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**

(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I) (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (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 (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	(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) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha (m) PHI - minimum pre-harvest interval

- [1] Insufficient plant metabolism data were available to conclude on an appropriate plant residue definition, therefore all other areas of the risk assessment for this use could not be concluded upon and an exceedance of the toxicological reference values (ADI and ARfD) could not be excluded.

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Methods of Analysis

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

Technical as (analytical technique)	GC -FID (AL 115/96-2 method).
Impurities in technical as (analytical technique)	GC-FID (AL 016/97-2 method). Derivation with N-Methyl-N-trimethylsilyl-trifluoroacetamide (MSTFA). (Confirmation of the identity by GC/MS)
Plant protection product (analytical technique)	GC-FID (AM000903FF1method).

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Open pending submission of an acceptable plant metabolism study.
Food of animal origin		Open pending submission of an acceptable plant metabolism study.
Soil		*diclofop isomers and their salts
Water	surface	*diclofop isomers and their salts and diclofop-phenol
	drinking/ground	*diclofop isomers and their salts
Air		diclofop-methyl isomers

*diclofop isomers and their salts were selected as markers for monitoring, due to the impersistence of the diclofop-methyl isomers

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Open
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Open

Soil (analytical technique and LOQ)	GC-MSD (m/z : 281, 340 and 342) Methylation is carried out with tetrabutylammonium hydroxyde (TBAH) solution and iodomethane for diclofop extract or trimethylsulfonium hydroxyde (TMSH) solution for diclofop-methyl extract LOQ of diclofop and diclofop methyl in soil is 0.02 mg/kg Open for validation of the derivitsiation step.
Water (analytical technique and LOQ)	GC/MS (m/z= 255, 340 and 342) LOQ of diclofop and diclofop methyl in drinking and surface water: 0.05 µg/L Considering the residue definition in surface water (diclofop, diclofop-methyl and diclofop-phenol), an analytical method for the determination of diclofop-phenol validated according to SANCO/825/00 rev 7, must be provided. The LOQ of this method will not have to exceed the NOEC value of 15,6 µg/L. Moreover, in the case where this method is not specific, a confirmatory method will have to be also submitted. Open for validation of the derivitsiation step.
Air (analytical technique and LOQ)	GC-MSD (m/z : 253, 255 and 340). LOQ : 0.6 µg/ m^3. in accordance to the value of the AOEL (0.003 mg/kg bw/day)
Body fluids and tissues (analytical technique and LOQ)	None – not required

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	none

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	> 90%, based on bile, urine, blood, carcass and skin recoveries 48 h after administration
Distribution ‡	Widely distributed with low levels into the organs and tissues (rat bile excretion study). The highest residues are found in fat
Potential for accumulation ‡	none
Rate and extent of excretion ‡	Rapid and complete (97% in 4 days) Eliminated mainly via faeces (77%) and urine (16%) until 96 h; 73% excreted via bile after 48 h
Metabolism in animals ‡	2 main metabolites (cleavage of the ester moiety and hydroxylation of dichlorophenyl ring)
Toxicologically relevant compounds ‡ (animals and plants)	diclofop-methyl
Toxicologically relevant compounds ‡ (environment)	diclofop-methyl

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 512 mg/kg bw	**R22**
Rat LD_{50} dermal ‡	> 2000 mg/kg bw (rat) ~ 200 mg/kg bw (rabbit)	- **T, R24***
Rat LC_{50} inhalation ‡	> 1.36 mg/L air/4h, nose-only exposure	-
Skin irritation ‡	Non-irritant	-
Eye irritation ‡	Non- irritant	-
Skin sensitisation ‡	Sensitising (M&K)	**R43**

* No classification by the dermal route has been agreed by ECHA (see Classification and proposed labelling with regard to toxicological data)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Liver : liver enzyme activities, liver morphological changes, peroxisome proliferation (rat, mice) liver enzyme activities, increased weight liver, steatosis (dog)	
Relevant oral NOAEL ‡	90-day rat: 1.6 mg/kg bw/day 90-day mice: 0.3 mg/kg bw/day 90-day dog: 4.3 mg/kg bw/day 15-month dog: 0.44 mg/kg bw/day	

Relevant dermal NOAEL ‡	28-day rat: 5 mg/kg bw/day	
Relevant inhalation NOAEL ‡	28-day rat: 0.008 mg/L air (2.16 mg/kg bw/day)	

Genotoxicity ‡ (Annex IIA, point 5.4)

	No genotoxic potential	

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

Target/critical effect ‡	Liver toxicity with peroxisome proliferation (rat and mice) Kidney toxicity with diffuse lipofuscin storage (rat)	
Relevant NOAEL ‡	LOAEL 0.2 mg/kg bw/day; 2-year rat 0.2 mg/kg bw/day; 2-year mouse	
Carcinogenicity ‡	Liver adeno-carcinoma in rat Liver adenoma and trabecular tumours (old terminology for hepatocellular carcinoma) in mice Unlikely to pose a risk to humans: peroxisome proliferation observed is rodent specific (not relevant for human)	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Reproduction: Decrease in pups born alive Liver and kidney weight increased in parents Developmental growth delay in pups	
Relevant parental NOAEL ‡	0.7 mg/kg bw/day	
Relevant reproductive NOAEL ‡	2.0 mg/kg bw/day	
Relevant offspring NOAEL ‡	2.0 mg/kg bw/day	

Developmental toxicity

Developmental target / critical effect ‡	Rat: Reduced body weight and bodyweight gain in dams Retardation in development in pups Rabbit: Body weight loss in dams No effect observed on pups development	

Relevant maternal NOAEL ‡	Rat: LOAEL 10 mg/kg bw/day Rabbit: 0.3 mg/kg bw/day	
Relevant developmental NOAEL ‡	Rat: 10 mg/kg bw/day Rabbit: 3 mg/kg bw/day	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data - not required	
Repeated neurotoxicity ‡	No data - not required	
Delayed neurotoxicity ‡	No data - not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Diclofop-methyl was able in a few days to induce marked proliferation of peroxisomes with a typical ultra structure. Liver effects are similar to those observed with clofibrate, a known peroxisome proliferator with increase of specific liver enzymes like catalase and malate enzyme. The NOAEL for hepatomegaly and peroxisome proliferation is **0.39 mg/kg bw/day.**
Studies performed on metabolites or impurities ‡	none

Medical data ‡ (Annex IIA, point 5.9)

	No known effects

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.001 mg/kg bw/day	2-year rat	200*
AOEL ‡	0.003 mg/kg bw/day	Rabbit developmental study (maternal NOAEL)	100**
ARfD ‡	0.03 mg/kg bw	Rabbit developmental study (developmental NOAEL)	100

*increased safety factor as ADI is based on a LOAEL
** No correction for oral absorption

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (Illoxan 36EC)	Concentrate (378 g/L): 1.2 % Spray dilution (1.25 g/L): 11.1 % Rat *in vivo* and comparative *in vitro* (human/rat skin)

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Tractor mounted equipment (application rate 0.605 kg a.i./ha) % of AOEL <u>German model (geometric mean values)</u> without PPE : 1479 % with PPE: (gloves: M&L/application; coverall, sturdy footwear, hood and visor: application)66.4 % <u>UK POEM model</u> without PPE : 8857 % with PPE (gloves M&L/application): 1354 %
Workers	% of AOEL Without PPE : 130 % With PPE (gloves, long sleeved shirt, long trousers): 13 %
Bystanders	19.5 % of AOEL

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	RMS/peer review proposal
Diclofop-methyl	<u>As in Annex I to Directive 67/548/EEC</u>: **Xn** “Harmful” **R22** “Harmful if swallowed” **R43** “May cause sensitization by skin contact” <u>Additional proposal by the peer review</u>: **T** “Toxic” **R24** “Toxic in contact with skin”

Residues

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

Plant groups covered	None. The wheat metabolism study was not considered acceptable. Due to the absence of an acceptable plant metabolism study all other areas of the assessment cannot be concluded upon, therefore all endpoints remain unfinalised.
Rotational crops	Open pending submission of an acceptable plant metabolism study.
Plant residue definition for monitoring	Open pending submission of an acceptable plant metabolism study.
Plant residue definition for risk assessment	Open pending submission of an acceptable plant metabolism study.
Conversion factor (monitoring to risk assessment)	

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

Animals covered	Open pending submission of an acceptable plant metabolism study.
Animal residue definition for monitoring	Open pending submission of an acceptable plant metabolism study.
Animal residue definition for risk assessment	Open pending submission of an acceptable plant metabolism study.
Conversion factor (monitoring to risk assessment)	
Metabolism in rat and ruminant similar (yes/no)	
Fat soluble residue: (yes/no)	

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

	Open pending submission of an acceptable plant metabolism study.

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

Wheat (grain, straw, bran, shorts, flour)	Open pending submission of an acceptable plant metabolism study.
Beef (whole milk, liver, muscle, eggs)	Open pending submission of an acceptable plant metabolism study.

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

Open pending submission of an acceptable plant metabolism study.

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

Open pending submission of an acceptable plant metabolism study.

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

Open pending submission of an acceptable plant metabolism study.

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

Open pending submission of an acceptable plant metabolism study.

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

Open pending submission of an acceptable plant metabolism study.

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

Mineralization after 100 days ‡	8.1 – 21.4 % (120 days, n=2)
Non-extractable residues after 100 days ‡	40.8 – 43.6 % (120 days, n=2)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Diclofop: 67.4 – 81.7 % after 1 d (n=2) Diclofop-phenol: 2.3 – 5.9 % after 7 – 22 d (n=2)

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

Anaerobic degradation ‡

Mineralization after 100 days	<0.1 % (90 days, n=1)
Non-extractable residues after 100 days	25 % (90 days, n=1)
Metabolites that may require further consideration for risk assessment – name and/or code, % of applied (range and maximum)	Diclofop (maximum 77.7 % after 2 days, n=1)

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment – name and/or code, % of applied (range and maximum)	Diclofop (77.7 % AR after 2 d), Non-extractable (25 %), No major metabolites.

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	OC (%)	pH	t. °C / % MWHC	DT_{50}/DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (χ^2)	Method of calculation
Sandy loam	2.1	6.7	20°C / 40 %	0.07 / 3.6	1.1 (from FOMC DT90/3.32)	15.5	Best fit: FOMC
Clay	1.5	7.3	20°C / 45 %	0.04 / 2.0	0.4 (from FOMC DT90/3.32)	12.8	Best fit: FOMC
Sandy loam	1.04	6.1	20°C / 60 %	0.2 / 0.8	0.2 (from SFO DT_{50})	0.4	Best fit: FOMC
Sandy loam	1.04	6.1	20°C / 40 %	0.2 / 1.7	0.4 (from FOMC DT_{90}/3.32)	3.0	Best fit: DFOP
Silt loam	1.46	6.9	20°C / 40 %	0.2 / 0.5	0.1	1.0	SFO
Loamy sand	2.91	5.0	20°C / 40 %	0.3 / 1.4	0.4 (from SFO DT_{50})	7.7	Best fit: FOMC
Sandy loam	1.45	7.2	20°C / 40 %	0.2 / 0.7	0.2	0.2	SFO
Geometric mean/median					0.31 / 0.36		

Diclofop	Aerobic conditions							
Soil type	OC (%)	pH	t. °C / % MWHC	DT_{50}/DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	St. (χ^2)	Method of calculation
Sandy loam	2.1	6.7	20°C / 40 %	53.4 / 177	0.652	53.4	16.3	FOMC for parent, SFO for metabolite
Clay	1.5	7.3	20°C / 45 %	74.0 / 246	0.801	74.0	6.7	FOMC for parent, SFO for metabolite
Sandy loam	2.9	6.0	20°C / 55 %	10.1 / 55.2	-	12.7 (from SFO DT_{50})	6.8	Best fit: FOMC
Loam	1.4	6.6	20°C / 55 %	7.0 / 23.3	-	7.0	1.8	Best fit: SFO
Loam	1.7	4.9	20°C / 55 %	11.8 / 44.6	-	12.9 (from SFO DT_{50})	2.3	Best fit: DFOP
Silt loam	2.7	6.5	20°C / 55 %	6.0 / 25.3	-	6.8 (from SFO DT_{50})	7.4	Best fit: FOMC
Silty clay loam	4.7	7.2	20°C / 55 %	5.1 / 21.5	-	5.7 (from SFO DT_{50})	4.8	Best fit: FOMC
Geometric mean/median						15.1 / 12.7		

Diclofop-phenol	Aerobic conditions							
Soil type	OC (%)	pH	t. °C / % MWHC	DT_{50}/DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	St. (χ^2)	Method of calculation
Loam	1.1	6.7	20°C / 55 %	0.12 / 0.56	-	0.13 (from SFO DT_{50})	3.7	Best fit: FOMC
Sandy loam	1.5	6.1	20°C / 55 %	0.15 / 0.7	-	0.17 (from SFO DT_{50})	3.8	Best fit: FOMC
Silt loam	1.6	6.6	20°C / 55 %	0.18 / 0.84	-	0.20 (from SFO DT_{50})	3.3	Best fit: DFOP
Clay loam	4.2	7.4	20°C / 55 %	0.28 / 1.0	-	0.28 (from SFO DT_{50})	2.7	Best fit: DFOP
Geometric mean/median						0.19 / 0.19		

Field studies ‡

Parent + diclofop	Aerobic conditions (*Residues not measured individually but as the sum of diclofop-methyl and diclofop **Only diclofop residues measured)							
Soil type	Location	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm.	Method of calculation

Silty Sand (winter wheat)	Germany	4.8	40	35.18*	116.9*	16.3	-	Best fit: SFO
Sandy Loam	Germany	6.9	40	7.9*	241.5*	22.3	-	Best fit: FOMC
Sandy Loam	Germany	5.6	40	6.7*	39.6*	11.1	-	Best fit: DFOP
Loamy Sand	Germany	5.6	40	20.2*	134.3*	17.4	-	Best fit: DFOP
Sandy Loam	England	6.7	10	33.0**	109.7**	-	-	SFO
Clay	England	7.3	10	38.5**	127.8**	-	-	SFO
Geometric mean/median				19.0 / 26.6	113.2 / 122.4			

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	Not expected

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	OC (%)	pH	t. °C / % MWHC	DT_{50}/DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (χ^2)	Method of calculation
Silt loam	3.3	6.6	20°C / 55 %	0.56 / 2.3	-	9.4	Best fit: DFOP
Geometric mean/median				-			

Diclofop	Anaerobic conditions No DT_{50} available, but degradation is slow according to the study with the parent.							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
-	-	-	-	-	-	-	-	-
Geometric mean/median								

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡ Only two values, no additional data required							
Soil type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sand	0.53	6.8	-	-	80.0	15084	1.01
Silt loam	0.59	5.9	-	-	157.3	26654	1.08

Arithmetic mean/median					-	20869	1.048
pH dependence, Yes or No			No				

Diclofop‡							
Soil type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay	0.89	7.8	-	-	1.31	148	0.819
Sand	0.42	6.9	-	-	0.76	182	0.860
Sandy loam	1.92	5.8	-	-	7.51	391.1	0.900
Silt loam	2.56	6.3	-	-	6.60	257.7	0.913
Sandy loam	1.6	5.2	-	-	8.09	505.5	0.902
Clay loam	5.47	6.9	-	-	13.54	247.5	0.900
Arithmetic mean/median						- / -	- / -
pH dependence, Yes or No			Yes (decreasing adsorption with increasing pH)				

Diclofop-phenol ‡							
Soil type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loam	1.1	6.7	-	-	56.07	5098	0.873
Sandy loam	1.5	6.1	-	-	94.95	6330	0.896
Silt loam	1.6	6.6	-	-	148.04	9253	0.908
Clay loam	4.2	7.4	-	-	254.74	6065	0.933
Arithmetic mean/median					138.5 / 121.5	6686 / 6198	0.902 / 0.902
pH dependence, Yes or No			No				

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

Column leaching ‡	No data submitted, not required
Aged residues leaching ‡	No data submitted, not required
Lysimeter/ field leaching studies ‡	Location: England (Warwickshire) Study type (e.g.lysimeter, field): field Soil properties: Sandy loam, pH = 6.7, OC= 2.1, WHC @ 1kPa (volumetric)=38.81 % Dates of application : 2nd December 1996 & 12th December 1997 Crop : /Interception estimated: Winter wheat (<25 %) Number of applications: 2 years, 1 applications per

	year Duration. 2.5 years Application rate: 756 g/ha/year Average annual rainfall (mm): 1790 mm from October 1996 to January 1999 Average annual leachate volume (mm): not measured % radioactivity in leachate (maximum/year): not relevant Individual annual maximum concentrations (e.g. 1st, 2nd, 3rd yr): 1st year 37 µg/L diclofop at 25 cm depth, 0.44 µg/L at 50 cm depth, 0.22 µg/L at 120 cm depth – 2nd year 3.7 µg/L diclofop at 25 cm depth, 0.62 µg/L diclofop at 50 cm, 0.18 µg/L diclofop at 120 cm Individual annual average concentrations (e.g. 1st, 2nd, 3rd yr): not measured, expected to be < 0.1 µg/L Amount of radioactivity in the soils at the end of the study: not relevant, no ^{14}C Location: England (Warwickshire) Study type (e.g.lysimeter, field): field Soil properties: Clay, pH = 7.3, OC= 1.5, WHC @ 1kPa (volumetric)=41.37 % Dates of application : 9th December 1996 & 23rd January 1998 Crop : /Interception estimated: Winter wheat (<25 %) Number of applications: 2 years, 1 applications per year Duration. 2.5 years Application rate: 756 g/ha/year Average annual rainfall (mm): 1650 mm from November 1996 to January 1999 Average annual leachate volume (mm): not measured % radioactivity in leachate (maximum/year): not relevant Individual annual maximum concentrations (e.g. 1st, 2nd, 3rd yr): 1st year 34 µg/L diclofop at 25 cm depth, 0.28 µg/L at 50 cm depth, 0.43 µg/L at 80 cm depth – 2nd year 11.0 µg/L diclofop at 25 cm depth, 0.25 µg/L diclofop at 50 cm, 0.10 µg/L diclofop at 80 cm Individual annual average concentrations (e.g. 1st, 2nd, 3rd yr): not measured, expected to be < 0.1 µg/L Amount of radioactivity in the soils at the end of the

	study: not relevant, no ^{14}C

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	Diclofop-methyl: DT_{50} (d): 1.07 (maximum from laboratory study, back-calculated SFO DT_{50} from FOMC, FOCUS procedure)
Application data	Crop: cereals Depth of soil layer: 5cm Soil bulk density: 1.5g/cm3 Crop interception: 25 % (BBCH growth stage 12-31) Number of applications: 1 Interval (d): not relevant Application rate(s): 605 g as/ha

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.605		-	
Short term	24h	0.317	0.461	-	-
	2d	0.166	0.362	-	-
	4d	0.045	0.244	-	-
Long term	7d	0.006	0.158	-	-
	28d	<0.001	0.044	-	-
	50d	<0.001	0.025	-	-
	100d	<0.001	0.013	-	-
Plateau concentration		-			

Metabolite I Method of calculation	Diclofop: DT_{50} (d): 35.18 (maximum from German field studies, SFO)
Application data	Crop: cereals Depth of soil layer: 5cm Soil bulk density: 1.5g/cm3 Crop interception: 25 % (BBCH growth stage 12-31) Number of applications: 1 Interval (d): not relevant Molecular ratio (-): 0.959

	% formed: 87.0 (max. from laboratory study) Application rate(s): 605 g diclofop-methyl/ha

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.505		-	
Short term	24h	0.495	0.500	-	-
	2d	0.485	0.495	-	-
	4d	0.466	0.485	-	-
Long term	7d	0.440	0.472	-	-
	28d	0.291	0.388	-	-
	50d	0.188	0.322	-	-
	100d	0.070	0.221	-	-
Plateau concentration		-			

Metabolite II Method of calculation	Diclofop-phenol: DT_{50} (d): 0.28 (maximum from laboratory studies, SFO)
Application data	Crop: cereals Depth of soil layer: 5cm Soil bulk density: 1.5g/cm3 Crop interception: 25 % (BBCH growth stage 12-31) Number of applications: 1 Interval (d): not relevant Molecular ratio (-): 0.748 % formed: 5.9 (max. from laboratory study) Application rate(s): 605 g diclofop-methyl/ha

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.027		-	
Short term	24h	0.002	0.014	-	-
	2d	<0.001	0.010	-	-
	4d	<0.001	0.006	-	-
Long term	7d	<0.001	0.004	-	-

28d	<0.001	0.001	-	-
50d	<0.001	0.001	-	-
100d	<0.001	<0.001	-	-
Plateau concentration	-			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	Diclofop-methyl: pH 5: stable at 25 °C (DT_{50} = 363 d) pH 7: hydrolysed at 25 °C (DT_{50}= 31.7 d, SFO) Metabolite: Diclofop (16.9 % after 9 days, 46.5 % after 30 days) pH 9: hydrolysed at 25 °C (DT_{50}= 0.52 d) Metabolite: Diclofop (70.8 % after 1 d, 93.7 % after 8 d)
Photolytic degradation of active substance and metabolites above 10 % ‡	Diclofop-methyl and diclofop: DT_{50} 5.7 hours at pH 7 (corresponds to 1.9 summer days in Athens, Greece); no major metabolites
Quantum yield of direct phototransformation in water at Σ > 290 nm	0.0012 and 0.0018 (2 experiments using 2 different photolysis systems)
Readily biodegradable ‡ (yes/no)	Diclofop-methyl: No Diclofop: No

Degradation in water / sediment

Parent	Distribution in water: < LoD after 1 d (n=2) Distribution in the sediment: < LoD									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50} / DT_{90} whole sys.	St. (χ^2)	DT_{50} / DT_{90} water	St. (χ^2)	DT_{50} / DT_{90} sed	St. (χ^2)	Method of calculation
Site C	6.38	6.5	20	0.08 / 0.25	18.5	-	-	-	-	SFO
Site E	6.38	6.8	20	0.04 / 0.12	16.5	-	-	-	-	SFO
Geometric mean				0.06		-		-		

Diclofop	Distribution in water: max. 83.6-89.3 after 6 h-1 d, < 3.4 % after 120 d (n=2) Distribution in sediment: max. 36.3-43.9 % after 28-43 d, 5.8-9.7 % after 120 d									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50} / DT_{90} whole sys.	St. (χ^2)	$DisT_{50}$ / $DisT_{90}$ water	St. (χ^2)	$DisT_{50}$ / $DisT_{90}$ sed	St. (χ^2)	Method of calculation
Site C	6.38	6.5	20	57.8 / 191.9	12.7	32.6 / 108.2	5.9	45.8 / 152.0	19.8	SFO

Site E	6.38	6.8	20	43.6 / 144.9	6.99	10.6 / 48.9 (DFOP)	1.7	35.0 / 116.4	14.0	SFO
Geometric mean				50.2		-		-		

Diclofop-phenol	Distribution in water: < LoD Distribution in sediment: max. 16.5-23.8 % after 120-155 d, 6.4-9.4 % after 366-397 d (n=2)									
Water / sediment system	pH water phase	pH sed	t. °C	$DisT_{50}$ / $DisT_{90}$ whole sys.	St. (χ^2)	DT_{50} / DT_{90} water	r^2 (χ^2)	DT_{50} / DT_{90} sed	St. (χ^2)	Method of calculation
Site C	6.38	6.5	20	222 / 736	11.1	-	-	-	-	SFO
Site E	6.38	6.8	20	87 / >1000	1.13	-	-	-	-	FOMC
Geometric mean				139		-		-		

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study)	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Site C	6.38	6.5	17 % after 120 d 35.9 % after 397 d	48.5 % after 120 d max 52.5 % after 275 d	47.8 % (397 d)
Site E	6.38	6.8	18.3 % after 120 d 24.6 % after 366 d	43.1 % after 120 d max 54.71 % after 275 d	53.4 % (366 d)

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

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS Steps1-2 Molecular weight (g/mol): 341.19 Water solubility (mg/L): 0.80 K_{OC} (L/kg): 15750 DT_{50} soil (d): 0.27 days (SFO) DT_{50} water/sediment system (d):0.1 (SFO) DT_{50} water (d): 0.1 (SFO) DT_{50} sediment (d): 0.1 (SFO) Crop interception (%): 25 %
Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure (Pa at 20°C): 1.2 x 10^{-5} 1/n: 0.961, Q10=2.58, Walker equation coefficient 0.7
Application rate	Crop: Cereals, winter Plant uptake coefficient : 0.5

Number of applications: 1 Interval (d): not applicable Application rate(s): 605 g as/ha Application window: N-EU October-February (Step 1&2) Start: 5 days after emergence; End: 30 days later (Step 3)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	14.73		1440	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	5.564		0.026	
	24 h	0.002	2.783	0.000	0.013
	2 d	0.000	1.392	0.000	0.007
	4 d	0.000	0.696	0.000	0.008
	7 d	0.000	0.398	0.000	0.005
	14 d	0.000	0.199	0.000	0.002
	21 d	0.000	0.133	0.000	0.002
	28 d	0.000	0.099	0.000	0.001
	42 d	0.000	0.066	0.000	0.001

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D1 Lanna ditch (application 3rd October)		0 h	3.822		1.069	
		24 h	0.258	1.353	1.049	1.065
		2 d	0.0189	0.725	1.020	1.057
		4 d	0.0016	0.365	0.964	1.035
		7 d	0.0013	0.209	0.889	0.998
		14 d	0.0010	0.105	0.748	0.918
		21 d	0.0007	0.0704	0.644	0.850
		28 d	0.0006	0.0530	0.566	0.792
		42 d	0.0004	0.0355	0.458	0.701
D1 Lanna stream		0 h	3.342		0.832	

(application 3rd October)		24 h	0.0749	1.096	0.811	0.827
		2 d	0.0011	0.556	0.788	0.818
		4 d	0.0008	0.279	0.744	0.797
		7 d	0.0007	0.160	0.686	0.767
		14 d	0.0005	0.0801	0.576	0.704
		21 d	0.0004	0.0535	0.495	0.650
		28 d	0.0003	0.0402	0.434	0.606
		42 d	0.0001	0.0269	0.350	0.535
D2 Brimstone ditch (application 3rd November)		0 h	3.817		1.017	
		24 h	0.225	1.297	0.998	1.014
		2 d	0.0148	0.690	0.970	1.006
		4 d	0.0013	0.347	0.916	0.984
		7 d	0.0004	0.199	0.844	0.949
		14 d	0.0004	0.0997	0.709	0.872
		21 d	0.0005	0.0666	0.609	0.806
		28 d	0.0005	0.0501	0.534	0.751
		42 d	0.0000	0.0335	0.432	0.664

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D2 Brimstone stream (application 3rd November)		0 h	3.284		0.598	
		24 h	0.0399	0.794	0.586	0.596
		2 d	0.0030	0.404	0.570	0.591
		4 d	0.0000	0.203	0.538	0.578
		7 d	0.0000	0.116	0.496	0.557
		14 d	0.0000	0.0580	0.416	0.511
		21 d	0.0000	0.0387	0.357	0.472
		28 d	0.0000	0.0290	0.312	0.439
		42 d	0.0000	0.0193	0.251	0.387
D3 Vreedepeel ditch (application 28th November)		0 h	3.763		0.795	
		24 h	0.0369	1.053	0.775	0.790
		2 d	0.0008	0.530	0.753	0.781
		4 d	0.0008	0.266	0.711	0.762
		7 d	0.0007	0.152	0.655	0.732
		14 d	0.0005	0.0763	0.551	0.672
		21 d	0.0004	0.0510	0.474	0.621
		28 d	0.0003	0.0384	0.415	0.578
		42 d	0.0002	0.0256	0.335	0.511
D4 Skousbo pond (application 28th September)		0 h	0.130		0.0246	
		24 h	0.0021	0.0323	0.0241	0.0245
		2 d	0.0000	0.0164	0.0235	0.0243
		4 d	0.0000	0.0082	0.0223	0.0238
		7 d	0.0000	0.0047	0.0208	0.0230
		14 d	0.0000	0.0024	0.0177	0.0213
		21 d	0.0000	0.0016	0.0154	0.0198
		28 d	0.0000	0.0012	0.0136	0.0185
		42 d	0.0000	0.0008	0.0111	0.0165

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D4 Skousbo stream (application 28th September)		0 h	3.265		0.409	
		24 h	0.0002	0.543	0.398	0.405
		2 d	0.0002	0.272	0.386	0.400
		4 d	0.0002	0.136	0.365	0.389
		7 d	0.0002	0.0777	0.336	0.374
		14 d	0.0001	0.0389	0.283	0.342
		21 d	0.0001	0.0260	0.243	0.316
		28 d	0.0001	0.0195	0.212	0.294
		42 d	0.0000	0.0130	0.171	0.260
D5 La Jailliere pond (application 27th November)		0 h	0.130		0.0344	
		24 h	0.0073	0.0437	0.0338	0.0343
		2 d	0.0004	0.0231	0.0329	0.0340
		4 d	0.0000	0.0116	0.0313	0.0334
		7 d	0.0000	0.0066	0.0291	0.0323
		14 d	0.0000	0.0033	0.0248	0.0299
		21 d	0.0000	0.0022	0.0216	0.0278
		28 d	0.0000	0.0017	0.0190	0.0261
		42 d	0.0000	0.0011	0.0155	0.0232
D5 La Jailliere stream (application 27th November)		0 h	3.523		0.597	
		24 h	0.0013	0.793	0.580	0.592
		2 d	0.0004	0.397	0.564	0.584
		4 d	0.0004	0.199	0.532	0.569
		7 d	0.0003	0.114	0.490	0.546
		14 d	0.0002	0.0570	0.412	0.500
		21 d	0.0002	0.0380	0.353	0.462
		28 d	0.0001	0.0286	0.309	0.430
		42 d	0.0000	0.0191	0.249	0.380

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6 Thiva ditch (application 6th December)		0 h	3.805		0.895	
		24 h	0.149	1.161	0.877	0.892
		2 d	0.0067	0.605	0.852	0.884
		4 d	0.0011	0.304	0.805	0.864
		7 d	0.0009	0.174	0.742	0.833
		14 d	0.0003	0.0873	0.623	0.765
		21 d	0.0002	0.0582	0.534	0.707
		28 d	0.0002	0.0437	0.467	0.658
		42 d	0.0001	0.0292	0.377	0.581
R1 Weiherbach pond (application 17th November)		0 h	0.130		0.0455	
		24 h	0.0154	0.0545	0.0448	0.0454
		2 d	0.0018	0.0307	0.0437	0.0451
		4 d	0.0000	0.0156	0.0415	0.0443
		7 d	0.0000	0.0089	0.0388	0.0430
		14 d	0.0000	0.0045	0.0331	0.0400
		21 d	0.0000	0.0030	0.0288	0.0373
		28 d	0.0000	0.0022	0.0255	0.0349
		42 d	0.0000	0.0015	0.0208	0.0312
R1 Weiherbach stream (application 17th November)		0 h	2.482		0.276	
		24 h	0.0001	0.367	0.269	0.273
		2 d	0.0001	0.184	0.261	0.270
		4 d	0.0001	0.0918	0.247	0.263
		7 d	0.0001	0.0525	0.228	0.252
		14 d	0.0000	0.0264	0.197	0.234
		21 d	0.0000	0.0176	0.170	0.217
		28 d	0.0000	0.0132	0.150	0.203
		42 d	0.0000	0.0088	0.121	0.180

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R3 Bologna stream (application 6th December)		0 h	3.483		0.509	
		24 h	0.0003	0.677	0.495	0.504
		2 d	0.0002	0.338	0.481	0.497
		4 d	0.0002	0.169	0.454	0.484
		7 d	0.0002	0.0969	0.418	0.465
		14 d	0.0001	0.0487	0.359	0.428
		21 d	0.0001	0.0325	0.309	0.397
		28 d	0.0001	0.0244	0.272	0.371
		42 d	0.0001	0.0163	0.220	0.329
R4 Roujan stream (application 10th December)		0 h	2.462		0.223	
		24 h	0.0000	0.298	0.216	0.220
		2 d	0.0000	0.149	0.210	0.217
		4 d	0.0000	0.0745	0.199	0.211
		7 d	0.0000	0.0426	0.183	0.203
		14 d	0.0000	0.0219	0.193	0.194
		21 d	0.0000	0.0146	0.170	0.190
		28 d	0.0000	0.0109	0.152	0.183
		42 d	0.0000	0.0073	0.128	0.169

Step 4 with 5 meter no spray buffer zone mitigating just spray drift:

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D1 Lanna ditch (application 11th September)		0 h	1.035		0.204	
		24 h	0.0205	0.268	0.200	0.203
		2 d	0.0006	0.137	0.195	0.202
		4 d	0.0002	0.0687	0.184	0.197
		7 d	0.0002	0.0393	0.171	0.190
		14 d	0.0001	0.0197	0.144	0.175
		21 d	0.0001	0.0132	0.125	0.162
		28 d	0.0001	0.0099	0.110	0.152
		42 d	0.0001	0.0067	0.0893	0.135
D1 Lanna stream (application 11th September)		0 h	1.220		0.229	
		24 h	0.00813	0.302	0.223	0.227
		2 d	0.0002	0.152	0.217	0.225
		4 d	0.0002	0.0761	0.205	0.219
		7 d	0.0002	0.0436	0.190	0.211
		14 d	0.0001	0.0218	0.160	0.194
		21 d	0.0001	0.0146	0.138	0.180
		28 d	0.0001	0.0110	0.122	0.168
		42 d	0.0001	0.0073	0.0984	0.149
D2 Brimstone ditch (application 11th October)		0 h	1.036		0.217	
		24 h	0.0262	0.284	0.213	0.216
		2 d	0.0009	0.146	0.207	0.214
		4 d	0.0002	0.0732	0.196	0.210
		7 d	0.0002	0.0419	0.181	0.202
		14 d	0.0001	0.0210	0.153	0.186
		21 d	0.0001	0.0141	0.133	0.173
		28 d	0.0001	0.0106	0.117	0.161
		42 d	0.0000	0.0071	0.0945	0.143

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D2 Brimstone stream (application 11th October)		0 h	1.243		1.243	
		24 h	0.0314	0.341	0.255	0.259
		2 d	0.0011	0.175	0.248	0.257
		4 d	0.0003	0.0878	0.235	0.251
		7 d	0.0002	0.0503	0.217	0.242
		14 d	0.0002	0.0252	0.183	0.223
		21 d	0.0000	0.0168	0.158	0.207
		28 d	0.0001	0.0126	0.139	0.193
		42 d	0.0000	0.0084	0.112	0.171
D3 Vreedepeel ditch (application 6th November)		0 h	1.019		0.216	
		24 h	0.0103	0.286	0.211	0.215
		2 d	0.0002	0.144	0.205	0.213
		4 d	0.0002	0.0721	0.194	0.207
		7 d	0.0002	0.0413	0.180	0.200
		14 d	0.0001	0.0207	0.152	0.184
		21 d	0.0001	0.0138	0.131	0.170
		28 d	0.0001	0.0104	0.115	0.159
		42 d	0.0000	0.0070	0.0935	0.141
D4 Skousbo stream (application 10th September)		0 h	1.193		0.150	
		24 h	0.0001	0.198	0.146	0.148
		2 d	0.0001	0.0992	0.141	0.146
		4 d	0.0001	0.0496	0.134	0.142
		7 d	0.0001	0.0284	0.124	0.137
		14 d	0.0000	0.0142	0.104	0.126
		21 d	0.0000	0.0091	0.0900	0.116
		28 d	0.0000	0.0071	0.0790	0.109
		42 d	0.0000	0.0048	0.0637	0.0962

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC$_{SW}$ (µg/L)		PEC$_{SED}$ (µg/kg)	
			Actual	TWA	Actual	TWA
D5 La Jailliere stream (application 26th November)		0 h	1.287		0.218	
		24 h	0.0005	0.290	0.212	0.216
		2 d	0.0001	0.145	0.206	0.214
		4 d	0.0001	0.0725	0.195	0.208
		7 d	0.0001	0.0415	0.180	0.200
		14 d	0.0001	0.0208	0.152	0.184
		21 d	0.0001	0.0139	0.131	0.170
		28 d	0.0000	0.0104	0.115	0.159
		42 d	0.0000	0.0070	0.0930	0.141
D6 Thiva ditch (application 6th December)		0 h	1.031		0.243	
		24 h	0.0402	0.315	0.238	0.242
		2 d	0.0018	0.164	0.232	0.240
		4 d	0.0003	0.0822	0.220	0.235
		7 d	0.0002	0.0471	0.203	0.227
		14 d	0.0001	0.0236	0.172	0.209
		21 d	0.0000	0.0158	0.148	0.194
		28 d	0.0001	0.0118	0.130	0.181
		42 d	0.0000	0.0079	0.105	0.160
R1 Weiherbach stream (application 14th November)		0 h	0.906		0.101	
		24 h	0.0000	0.134	0.0983	0.1000
		2 d	0.0000	0.0670	0.0956	0.0987
		4 d	0.0000	0.0335	0.0906	0.0961
		7 d	0.0000	0.0192	0.0838	0.0924
		14 d	0.0000	0.0096	0.0715	0.0851
		21 d	0.0000	0.0064	0.0618	0.0790
		28 d	0.0000	0.0048	0.0543	0.0738
		42 d	0.0000	0.0032	0.0439	0.0655

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC$_{SW}$ (µg/L)		PEC$_{SED}$ (µg/kg)	
			Actual	TWA	Actual	TWA
R3 Bologna stream (application 17th November)		0 h	1.259		0.329	
		24 h	0.0001	0.187	0.325	0.327
		2 d	0.0000	0.0935	0.325	0.326
		4 d	0.0000	0.0468	0.319	0.324
		7 d	0.0000	0.0267	0.311	0.320
		14 d	0.0001	0.0134	0.295	0.312
		21 d	0.0000	0.0090	0.283	0.304
		28 d	0.0000	0.0067	0.273	0.298
		42 d	0.0000	0.0045	0.258	0.287
R4 Roujan stream (application 3rd November)		0 h	0.912		0.107	
		24 h	0.0000	0.142	0.104	0.106
		2 d	0.0000	0.0708	0.101	0.104
		4 d	0.0000	0.0354	0.0956	0.101
		7 d	0.0000	0.0203	0.0884	0.0976
		14 d	0.0000	0.0101	0.0748	0.0897
		21 d	0.0000	0.0068	0.0645	0.0831
		28 d	0.0000	0.0051	0.0566	0.0775
		42 d	0.0000	0.0034	0.0457	0.0687

Metabolite diclofop Parameters used in FOCUSsw step 1 and 2	Diclofop Molecular weight: 327.17 Water solubility (mg/L): 122 700 Soil or water metabolite: soil & water metabolite Koc (L/kg): 148 DT_{50} soil (d): 15.08 DT_{50} water/sediment system (d): 48.99 DT_{50} water (d): 48.99 DT_{50} sediment (d): 48.99 Crop interception (%): 25 % Maximum occurrence observed (% molar basis with respect to the parent): Water/sed: 97.7 % Soil: 87 %
Parameters used in FOCUSsw step 3 (if performed)	Not performed

Application rate	Crop: Cereals, winter Plant uptake coefficient : 0.5 Number of applications: 1 Interval (d): not applicable Application rate(s): 605 g diclofop-methyl/ha Application window: N-EU October-February (Step 1&2)
Main routes of entry	-

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	145.73		211.39	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	48.20		69.98	
	24 h	47.28	47.74	69.00	69.49
	2 d	46.62	47.35	68.03	69.00
	4 d	45.32	46.66	66.13	68.04
	7 d	43.43	45.68	63.38	66.63
	14 d	39.34	43.52	57.40	63.48
	21 d	35.63	41.49	51.99	60.54
	28 d	32.27	39.60	47.09	57.78
	42 d	26.47	36.16	38.63	52.76

Metabolite diclofop-phenol Parameters used in FOCUSsw step 1 and 2	Diclofop-phenol Molecular weight: 255.1 Water solubility (mg/L): 16 Soil or water metabolite: soil & sediment metabolite Koc (L/kg): 6686 DT_{50} soil (d): 0.19 DT_{50} water/sediment system (d): 165.82 DT_{50} water (d): 165.82 DT_{50} sediment (d): 165.82 Crop interception (%): 25 % Maximum occurrence observed (% molar basis with respect to the parent): Water/sed: 23.8 % Soil: 5.9 %

Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Crop: Cereals, winter Plant uptake coefficient : 0.5 Number of applications: 1 Interval (d): not applicable Application rate(s): 605 g diclofop-methyl/ha Application window: N-EU October-February (Step 1&2)
Main routes of entry	-

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	1.89		66.39	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.990		6.539	
	24 h	0.395	0.693	6.511	6.525
	2 d	0.217	0.499	6.484	6.512
	4 d	0.147	0.336	6.430	6.484
	7 d	0.097	0.237	6.350	6.444
	14 d	0.094	0.166	6.167	6.351
	21 d	0.092	0.142	5.989	6.260
	28 d	0.089	0.129	5.817	6.171
	42 d	0.084	0.115	5.486	5.997

PECsw for diclofop-phenol after forming by photodegradation: **1.52 µg/l**.

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: FOCUS-PEARL 3.3.3, FOCUS-PELMO 3.3.2 Scenarios (list of names): Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva Crop:Winter cereals Q10=2.58, Walker equation coefficient 0.7

	Diclofop-methyl DT_{50} = 0.27 d (median lab value at 20°C/pF2). Kfoc: 15750, 1/n = 0.961 Kom: 9136 Diclofop DT_{50} = 11.02 d Kfoc = 299.4, 1/n = 0.901 Kom: 173.7 ffM: 1 (from parent) Diclofop-phenol DT_{50} = 0.15 d Kfoc = 6686, 1/n = 0.9024 Kom: 3878 ffM: 1 (from diclofop)
Application rate	Application rate: 605 g/ha Plant interception: 25 % No. of applications: 1 Time of application (month or season): 5 days after emergence: Châteaudun 31 Oct Hamburg 6 Nov Jokioinen 25 Sep Kremsmünster 10 Nov Okehampton 22 Oct Piacenza 6 Dec Porto 5 Dec Sevilla 5 Dec Thiva 5 Dec

PEC (gw) – FOCUS modelling result (80th percentile annual average concentration at 1m)

	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			Diclofop	Diclofop-phenol
PEARL and PELMO / Winter cereals	Chateaudun	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001
	Kremsmunster	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001

	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001

PEC (gw) From lysimeter / field studies

Parent	1st year	2nd year	3rd year
Annual average (µg/L)	-	-	-

Metabolite X	1st year	2nd year	3rd year
Annual average (µg/L)	-	-	-

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

Direct photolysis in air ‡	Not studied, not required
Quantum yield of direct phototransformation	Not studied, not required
Photochemical oxidative degradation in air ‡	DT_{50} of 0.56 days derived by the Atkinson model (AOPWIN 1.90) using OH concentration of 1.5 x 10^{-6} (12 hours) DT_{50} of 0.85 days derived by the Atkinson model (AOPWIN 1.90) using OH concentration of 0.5 x 10^{-6} (24 hours)
Volatilisation ‡	Not studied, not required
Metabolites	None

PEC (air)

Method of calculation	Not calculated, not required

PEC (a)

Maximum concentration	Negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: diclofop-methyl, diclofop, diclofop-phenol Surface Water: diclofop-methyl, diclofop (from soil and water-sediment system), diclofop-phenol (from soil) Sediment: diclofop (from soil and water-sediment system), diclofop-phenol (from water-sediment system) Groundwater: diclofop-methyl, diclofop, diclofop-phenol Air: diclofop-methyl

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

Soil (indicate location and type of study)	-
Surface water (indicate location and type of study)	-
Ground water (indicate location and type of study)	-
Air (indicate location and type of study)	-

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Candidate for R53

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

Species	Test substance	Time scale	End point (mg/kg bw/day	End point (mg/kg feed)
Bird ‡				
Bobwhite quail	Diclofop-methyl	Acute	> 2250	
Japanese quail	Diclofop-methyl EC 378 g/L	Acute	> 2000 (> 718 mg a.s./kg bw)	
	Metabolite 1	Acute	-	
Mallard duck	Diclofop-methyl	Short-term	> 1104	> 5620
Bobwhite quail	Diclofop-methyl	Short-term	> 2875	> 5620
Mallard duck	Diclofop-methyl	Long-term	25	200
Bobwhite quail	Diclofop-methyl	Long-term	20	200
Mammals ‡				
Rat	Diclofop-methyl	Acute	512	
Rat	Preparation	Acute	2176 (males)	
Rat	Preparation	Acute	2029 (females)	
	Metabolite 1	Acute	No data	
Rat	Diclofop-methyl	Long-term (two generations study)	7.8	
Additional higher tier studies ‡				
-				

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

cereals at 1 x 605 g a.s./ha (South Europe)

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Large herbivorous bird (early cereals)	Acute	37.8	59.5	10
	Short-term	20.2	54.6	10
	Long-term	10.7	**1.9**	5
Insectivorous bird (early cereals)	Acute	32.7	68.8	10
	Short-term	18.2	60.5	10
	Long-term	18.2	**1.1**	5
Worm-eating bird	Long-term	0.137	146	5
Fish-eating bird	Long-term	0.0067	2985	5

Uptake via drinking water	Acute	0.0012	2’000’000	10
Higher tier refinement (Birds)				
Small omnivorous bird [(1)]	Long-term (South Europe, 605 g a.s./ha)	3.13	6.38	5
	Long-term (North Europe, 567 g a.s./ha)	3.70	5.40	5
Large herbivorous bird [(2)]	Long-term (South Europe, 605 g a.s./ha)	1.03	19.4	5
	Long-term (North Europe, 567 g a.s./ha)	1.41	14.23	5
Small insectivorous bird	Long-term (South Europe, 605 g a.s./ha)	4.85	**4.12**[(3)]/5.7[(8)]	5
	Long-term (North Europe, 567 g a.s./ha)	4.54	**4.40**[(3)]/6.8[(8)]	5
Tier 1 (Mammals)				
Small herbivorous mammal	Acute	119.41	**4.29**	10
Small herbivorous mammal	Long-term	33.67	**0.23**	5
Worm-eating mammal	Long-term	0.170	46	5
Fish-eating mammal	Long-term	0.004	1880	5
Uptake via drinking water	Acute	0.0006	800’000	10
Higher tier refinement (Mammals)				
Medium herbivorous mammal [(4)]	Acute (South Europe, 605 g a.s./ha)	8.89	57.6	10
	Acute (North Europe, 567 g a.s./ha)	8.33	61.4	10
Small herbivorous mammal [(5)]	Acute (South Europe, 605 g a.s./ha)	44.15	11.6	10
	Acute (North Europe, 567 g	41.38	12.4	10

	a.s./ha)			
Medium herbivorous mammal (6)	Long-term (South Europe, 605 g a.s./ha)	0.656	11.9	5
	Long-term (North Europe, 567 g a.s./ha)	0.874	8.9	5
Small herbivorous mammal (7)	Long-term (South Europe, 605 g a.s./ha)	From 0.48 to 1.02	From 7.67 to 16.27	5
	Long-term (North Europe, 567 g a.s./ha)	From 0.53 to 1.09	From 7.15 to 14.62	5

(1) refined with a 50th percentile RUD of 35.2 mg a.s./kg food/kg a.s. applied, measured in cereal shoots from residue trials, DT50 = 2.28 days for North Europe, DT50= 1.65 days for South Europe, bird of 37.2 g body weight, Food Intake Rate of 0.98 g fresh weight-day/g b.w. and PD refined according a various diet.
(2) refined with a 50th percentile RUD of 35.2 mg a.s./kg food/kg a.s. applied, measured in cereal shoots from residue trials, DT50 = 2.28 days for North Europe, DT50= 1.65 days for South Europe, bird of 3000 g body weight, Food Intake Rate of 0.44 g fresh weight-day/g b.w, all other parameters at 1.
(3) refined for a bird of 17.6 g body weight, Food Intake Rate of 0.91 g fresh weight-day/g b.w, 90th percentiles PT of 0.82, 23.6% of small insects and 76.4 % of large insects. Ftwa was not refined.
(4) refined with a 90th percentile RUD of 52.5 mg a.s./kg food/kg a.s. applied, mammal of 3000 g body weight, Food Intake Rate of 0.28 g fresh weight-day/g b.w, all other parameters at 1.
(5) refined with a 90th percentile RUD of 52.5 mg a.s./kg food/kg a.s. applied, mammal of 25 g body weight, Food Intake Rate of 1.39 g fresh weight-day/g b.w (as for a small herbivorous mammal), all other parameters at 1.
(6) refined with a 50th percentile RUD of 35.2 mg a.s./kg food/kg a.s. applied, measured in cereal shoots from residue trials, DT50 = 2.28 days for North Europe, DT50= 1.65 days for South Europe, mammal of 3000 g body weight, Food Intake Rate of 0.28 g fresh weight-day/g b.w, all other parameters at 1.
(7) refined with a 50th percentile RUD of 35.2 mg a.s./kg food/kg a.s. applied, measured in cereal shoots from residue trials, DT50 = 2.28 days for North Europe, DT50= 1.65 days for South Europe, mammal of 25 g body weight, Variable Food Intake Rate and PD according to the application period, PT at 1.
(8) EFSA notes after the peer review that the long-term (reproductive) risk to birds for the use in cereals could be assessed as low, based on a generic Tier I risk assessment following the new guidance document for Birds and Mammals (EFSA, 2009). Lark as representative species for cereals (BBCH10-29); shortcut value for mean RUD = 10.9; TWA = 0.53

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 (Test type)	End point	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
L. macrochirus	Diclofop-methyl	96 hr (flow-through)	Mortality, EC_{50}	**0.15** **(mm)**
P. promelas	Diclofop-methyl	265 d (flow-through)	Growth NOEC	**0.015** **(mm)**
L. macrochirus	Diclofop-methyl EC 378 g/L	96 hr (static)	Mortality, EC_{50}	0.486 (mm) (form.) 0.173 (mm) (a.s.)
O. mykiss	Diclofop-methyl EC 378 g/L	21 d (flow-through)	Growth NOEC	0.182 (mm) (form.)

				0.083 (mm) (a.s.)
O. mykiss	Diclofop	96 hr (static)	Mortality, EC_{50}	**> 100 (nom)**
O. mykiss	Diclofop	28d (JFG, flow-through)	Growth, NOEC	**16.0 (nom)**
O. mykiss	Diclofop-phenol	96 hr (semi-static)	Mortality, EC_{50}	**0.189 (mm)**
O. mykiss	Diclofop-phenol	28d (JFG, flow-through)	Growth, NOEC	**0.025 (nom)**
Aquatic invertebrate				
Daphnia magna	Diclofop-methyl	48 h (static)	Mortality, EC_{50}	0.23 (mm)
Daphnia magna	Diclofop-methyl	21 d (semi- static)	Reproduction, NOEC	0.081 (mm)
Daphnia magna	Diclofop-methyl EC 378 g/L	48 h (static)	Mortality, EC_{50}	0.6 (mm) (form.) **0.16 (mm) (a.s.)**
Daphnia magna	Diclofop-methyl EC 378 g/L	21 d (semi- static) 8 x renewal	Reproduction, NOEC	0.025 (mm) (form.) **0.009 (mm) (a.s.)**
Daphnia magna	Diclofop-methyl EC 378 g/L	21 d (semi- static) 1 x renewal	Reproduction, NOEC	0.076 (nom) (form.) **0.027 (nom) (a.s.)**
Daphnia magna	Diclofop	48 h (static)	Mortality, EC_{50}	**48 (nom)**
Daphnia magna	Diclofop	21d (static renewal conditions)	Reproduction, NOEC	**4 (nom)**
Daphnia magna	Diclofop-phenol	48 h (static)	Mortality, EC_{50}	**0.52 (nom)**
Daphnia magna	Diclofop-phenol	21d (semi-static)	Reproduction, NOEC	**0.0156 (mm)**
Sediment dwelling organisms				
C. riparius	Diclofop	28 d (static, spiked water test)	NOEC	**10 (nom)**
C. riparius	Diclofop-phenol	28 d (static, spiked sediment test)	NOEC	**6.4 mg/kg sed (nom)**
Algae				
Pseudokirchneriella subcapitata	Diclofop-methyl	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} Yield E_yC_{50}	0.451 (mm) > 2.196 (mm) 0.487 (mm)
Pseudokirchneriella subcapitata	Diclofop-methyl EC 378 g/L	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.434 (im) (form.) 0.16 (im) (a.s.) 9.04 (im) (form.) 3.24 (im) (a.s.)

			Yield E_yC_{50}	0.390 $_{(im)}$ (fom.) **0.14** $_{(im)}$ **(a.s.)**
Pseudokirchneriella subcapitata	Diclofop	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} Yield E_yC_{50}	> **30** $_{(nom)}$
Pseudokirchneriella subcapitata	Diclofop-phenol	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} Yield E_yC_{50}	0.183 $_{(mm)}$ 0.575 $_{(mm)}$ **0.165** $_{(mm)}$
Higher plant				
Lemna gibba	Diclofop-methyl	7 d (semi-static)	Fronds, EC_{50}	**>1.12** $_{(mm)}$
	Preparation	14 d (static)	Fronds, EC_{50}	No data
Lemna minor	Diclofop	7 d (semi-static)	Fronds, E_rC_{50} Fronds, E_yC_{50}	10.7 $_{(nom)}$ **8.92** $_{(nom)}$
Lemna minor	Diclofop-phenol	7 d (semi-static)	Fronds, E_rC_{50} Fronds, E_yC_{50}	4.32 $_{(mm)}$ **3.13** $_{(mm)}$
Microcosm or mesocosm tests				
No data				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$) or initial measured $_{(im)}$. In the case of preparations indicate whether end points are presented as units of preparation or a.s.

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

Cereal at 1 x 605 g a.s./ha for diclofop-methyl and diclofop-methyl EC 378 g/L (the lowest toxicity value between the active substance and the formulation was selected for each organism group)

Test substance		**Diclofop-methyl**	**Diclofop-methyl**	**Diclofop-methyl EC 378 g/L**	**Diclofop-methyl EC 378 g/L**	**Diclofop-methyl EC 378 g/L**	**Diclofop-methyl EC 378 g/L**	**Diclofop-methyl**
Scenario	**PEC sw initial (µg L)**	**fish acute**	**fish chronic**	**Daphnia acute**	**Daphnia chronic (8 x renewal)**	**Daphnia chronic (1 x renewal)[14]**	**Algae chronic**	**Higher plant chronic**
		L. macrochirus	*P. promelas*	*Daphnia magna*	*Daphnia magna*	*Daphnia magna*	*P. subcapitata*	*Lemna gibba*
		LC_{50}	NOEC	EC_{50}	NOEC	NOEC	E_yC_{50}	EC_{50}
		0.15 mg/L	0.015 mg/L	0.16 mg/L	0.009 mg/L	0.027 mg/L	0.14 mg/L	> 1.12 mg/L
FOCUS Step 1								
	14.73	**10.2**	**1.02**	**10.86**	**0.61**	**1.83**	**9.5**	76.1
FOCUS Step 2	North Europe (worst-case for drainage and run-off). PECsw for South Europe were not calculated.							
	5.564	**26.9**	**2.7**	**28.8**	**1.62**	**4.8**	25.2	201
FOCUS Step 3								
D1 / ditch	3.822	**39.2**	**3.92**	**41.9**	**2.35**	**7.06**	36.6	293
D1 / stream	3.342	**44.9**	**4.49**	**47.9**	**2.69**	**8.08**	41.9	335
D2 / ditch	3.817	**39.3**	**3.93**	**41.9**	**2.36**	**7.07**	36.7	293
D2 / stream	3.284	**45.7**	**4.57**	**48.7**	**2.74**	**8.22**	42.6	341
D3 / ditch	3.763	**39.9**	**3.99**	**42.5**	**2.39**	**7.17**	37.2	298

[14] The chronic risk to daphnids was based on the endpoint from a more realistic semi-static chronic study with the formulation with only one renewal of the test concentration during the study

D4 / pond	0.130	1154	115.4	1231	69.2	208	1077	8615
D4 / stream	3.265	**45.9**	**4.59**	**49.0**	**2.76**	**8.27**	42.9	343
D5 / pond	0.130	1154	115.4	1231	69.2	208	1077	8615
D5 / stream	3.523	**42.6**	**4.26**	**45.4**	**2.55**	**7.66**	39.8	318
D6 / ditch	3.805	**39.4**	**3.94**	**42.0**	**2.36**	**7.09**	36.8	294
R1 / pond	0.130	1154	115.4	1231	69.2	208	1077	8615
R1 / stream	2.482	**60.4**	**6.04**	**64.5**	**3.63**	10.88	56.4	451
R3 / stream	3.483	**43.1**	**4.31**	**45.9**	**2.58**	**7.75**	40.2	321
R4 / stream	2.462	**60.9**	**6.09**	**65.0**	**3.65**	10.97	56.9	455
FOCUS Step 4	**5 m non-spray buffer zone**							
D1 / ditch	1.035	145	14.5	155	**8.70**	26.1	*safe use demonstrated at STEP 3*	
D1 / stream	1.220	123	12.3	131	**7.40**	22.1		
D2 / ditch	1.036	145	14.5	154	**8.70**	26.1		
D2 / stream	1.243	121	12.1	129	**7.24**	21.7		
D3 / ditch	1.019	147	14.7	157	**8.83**	26.5		
D4 / stream	1.193	126	12.6	134	**7.54**	22.6		
D5 / stream	1.287	117	11.7	124	**7.00**	21.0		
D6 / ditch	1.031	145	14.5	155	**8.73**	26.2		
R1 / stream	0.906	165	16.5	177	**9.93**	29.8		
R3 / stream	1.259	119	11.9	127	**7.15**	21.4		
R4 / stream	0.912	164	16.4	175	**9.87**	29.6		

Cereal at 1 x 605 g a.s./ha for metabolites

Test substance	**Diclofop**							
Scenario	**PEC sw initial (µg L)**	**fish acute**	**fish chronic**	**Daphnia acute**	**Daphnia chronic**	**Algae chronic**	**Higher plant chronic**	**Sediment dwelling organism chronic**
		O. mykiss	*O. mykiss*	*Daphnia magna*	*Daphnia magna*	*P. subcapitata*	*Lemna minor*	*C. riparius*

		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}	NOEC
		> 100 mg/L	16.0 mg/L	48 mg/L	4 mg/L	> 30 mg/L	10.7 mg/L	10 mg/L
FOCUS Step 1								
	145.73	686	110	329	27.4	206	61.2	69
FOCUS Step 2	North Europe (worst-case for drainage and run-off). PECsw for South Europe were not calculated.							
	48.20	2075	332	996	83	622	222	207
Test substance	**Diclofop-phenol**							
Scenario		**fish acute**	**fish chronic**	**Daphnia acute**	**Daphnia chronic**	**Algae chronic**	**Higher plant chronic**	**Sediment dwelling organism chronic**
		O. mykiss	*O. mykiss*	*Daphnia magna*	*Daphnia magna*	*P. subcapitata*	*Lemna minor*	*C. riparius*
		LC_{50}	NOEC	EC_{50}	NOEC	EyC_{50}	EyC_{50}	NOEC
		0.189 mg/L	0.025 mg/L	0.52 mg/L	0.0156 mg/L	0.165 mg/L	3.13 mg/L	6.4 mg/kg sed
FOCUS Step 1								
PECsw initial (µg/L)	1.89	100	13.22	275	**8.25**	87.3	1656	-
PECsed (µg/kg sed)	66.39	-	-	-	-	-	-	96.4
FOCUS Step 2								
PECsw initial (µg/L)	1.52*	124	16.45	342	10.26	108	2059	-

* This PECsw is an estimation of PECsw for diclofop-phenol at Step 3 due to aqueous photolysis. According to the e-fate section, the PECsw of 1.52 µg/l for diclofop-phenol can be used further in risk assessment. It has to noted that this a worse case value compared to Step 2.

Bioconcentration	
	Diclofop-methyl
$logP_{O/W}$	4.8
Bioconcentration factor (BCF)[1] ‡	From 420 to 1700 X* depending on the life stage in *Pimephales promelas* From 3100 to 4700 X* (normalized for lipid content) in *Lepomis macrochirus*
Annex VI Trigger for the bioconcentration factor	1000
Clearance time (days) (CT_{50})	0.38 d (*Lepomis macrochirus*)
(CT_{90})	2.6 d (*Lepomis macrochirus*)
Level and nature of residues (%) in organisms after the 14 day depuration phase	11-12 %

[1] only required if log $P_{O/W}$ >3.
* based on total ^{14}C or on specific compounds

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
Diclofop-methyl‡	> 131 µg as/bee	> 100 µg as/bee
Diclofop-methyl EC 378 g/L	> 467 µg product /bee > 167.2 µg a.s./bee	> 279 µg product/bee > 100 µg a.s./bee
Field or semi-field tests		
not required		

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

Cereals (early growth stage) at 1 x 605 g a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
Diclofop-methyl	Contact	< 6.05	50
Diclofop-methyl	oral	< 4.62	50
Diclofop-methyl EC 378 g/L	Contact	< 5.96	50
Diclofop-methyl EC 378 g/L	oral	< 3.56	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha[1])
Typhlodromus pyri ‡	Diclofop-methyl EC 378 g/L	Mortality	> 30.24 g a.s./ha
Aphidius rhopalosiphi ‡	Diclofop-methyl EC 378 g/L	Mortality	30.12 g a.s./ha

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

Cereals (early growth stage) at 1 x 605 g a.s./ha

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field (1 m)	Trigger
Diclofop-methyl EC 378 g/L	*Typhlodromus pyri*	> 30.24 g a.s./ha	**< 20.0**	0.55	2
Diclofop-methyl EC 378 g/L	*Aphidius rhopalosiphi*	30.12 g a.s./ha	**20.1**	0.55	2

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate	Dose (g a.s./ha)[1]	End point	% effect	Trigger value
Aphidius rhopalosiphi	adults	Diclofop-methyl EC 378 g/L Lab. Test	2268	Mortality	100%	50%
Aphidius rhopalosiphi	adults	Diclofop-methyl EC 378 g/L Extended laboratory (wheat plants)	92.2, 184.4, 368.8, 737.6, 1106.4, 1475.2	Mortality Reproduction	LR_{50} = 707 g a.s./ha NOEC = 184 g a.s./ha	50%
Typhlodromus pyri	protonymphs	Diclofop-methyl EC 378 g/L Extended laboratory (bean leaves)	48.3, 95.5, 189.5, 375.3, 743.2	Mortality Reproduction	LR_{50}: 348 g a.s./ha NOEC = 190 g a.s./ha	50%
Typhlodromus pyri	protonymphs	Diclofop-methyl EC 378 g/L Extended laboratory (aged residue on sweet pepper plants)	743	Mortality (DAT0) Reproduction (DAT 0)	16% 7.5% (reduction of reproduction)	50%
Coccinella septempuncata	larvae	Diclofop-methyl EC 378 g/L Lab. Test	1134	Mortality Fertility of offspring	9.76% 20.5%	50%

Species	Life stage	Test substance, substrate	Dose (g a.s./ha)[1]	End point	% effect	Trigger value
Episyrphus balteatus	larvae	Diclofop-methyl EC 378 g/L Lab. Test	1190	Mortality Reproduction	15% no offspring fertile	50%
Episyrphus balteatus	larvae	Diclofop-methyl EC 378 g/L, Petri dish, 2 weeks	1512-1840* (a.s.) 3024-3675* (a.s.)	Mortality Fertility	8.4% (mortality, 1512-1840 g a.s./ha) -158% (fertility, 1512-1840 g a.s./ha) 12.5% (mortality, 3024-3675 g a.s./ha) 63% (fertility, 3024-3675 g a.s./ha)	50 %
Syrphus corollae	larvae	Diclofop-methyl EC 378 g/L Lab. Test	1134	Mortality Fertility	6.12% (mortality) no effect (egg production)	50 %
Pardosa amenata	adults	Diclofop-methyl EC 378 g/L Lab. Test	1134	Mortality Reproduction	15% no significant effect (predation)	50 %
Poecilus cupreus	larvae	Diclofop-methyl EC 378 g/L Lab. Test	1134	Mortality	18%	50 %
Poecilus cupreus	larvae	Diclofop-methyl EC 378 g/L Lab. Test	1190	Mortality Foraging activity	0% no effect	50 %

[1] indicate whether initial or aged residues
[3] indicate if positive percentages relate to adverse effects or not

Field or semi-field tests
Not required

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point

Test organism	Test substance	Time scale	End point
Earthworms			
Eisenia fetida	Diclofop-methyl	Acute 14 days	LC_{50} > 1000 mg a.s./kg d.w.soil
Eisenia fetida	Diclofop-methyl	Chronic 8 weeks	No data
Eisenia fetida	Diclofop-methyl EC 378 g/L	Acute	LC_{50}= 265 mg a.s./kg d.w.soil LC_{50}= 734 mg product / kg soil
Eisenia fetida	Diclofop-methyl EC 378 g/L	Chronic	No data
Eisenia fetida	Diclofop	Acute	LC_{50} > 1000 mg/kg d.w.soil
Eisenia fetida	Diclofop	Chronic	NOEC = 100 mg /kg d.w.soil
Eisenia fetida	2,4-dichlorophenoxyphenol	Acute	LC_{50} = 730 mg/kg d.w.soil
Eisenia fetida	2,4-dichlorophenoxyphenol	Chronic	NOEC = 10 mg /kg d.w.soil
Other soil macro-organisms			
Not required			
Soil micro-organisms			
Nitrogen mineralisation	Diclofop-methyl ‡	Chronic	Medium loamy sand: negligible effect at 0.756 kg a.s./ha +44.36% NO3-, significant, at day 14, which is reversible at 3.78 kg a.s./ha
	Diclofop-methyl EC 378 g/L	Chronic	Loamy sand and silt loam: negligible effect at 3, 15 and 30 L/ha
Carbon mineralisation	Diclofop-methyl ‡	Chronic	Medium loamy sand: negligible effect at 0.756 and 3.78 kg a.s./ha
	Diclofop-methyl EC 378 g/L	Chronic	Loamy sand and silt loam: negligible effect at 3 and 15 L/ha
Field studies			
Not required			

[1] indicate where end point has been corrected due to log Pow >2.0 (e.g. LC_{50corr})

Toxicity/exposure ratios for soil organisms

Cereals (on early growth stage) at 1 x 605 g a.s./ha

Test substance	Time scale	Corrected toxicity (mg/kg dry soil) [(1)]	Soil $PEC_{initial}$ (mg/kg soil)	TER	Trigger
Earthworms					

Test substance	Time scale	Corrected toxicity (mg/kg dry soil) (1)	Soil $PEC_{initial}$ (mg/kg soil)	TER	Trigger
Diclofop-methyl‡	Acute	$LC50_{CORR}$ > 500 mg a.s./kg soil	0.605	> 826	10
Diclofop-methyl emulsifiable concentrate 378 g/L	Acute	$LC50_{CORR}$ =133 mg a.s./kg soil	0.605	220	10
Diclofop	Acute	$LC50_{CORR}$ > 500 mg diclofop /kg soil	0.505	> 990	10
Diclofop-phenol	Acute	$LC50_{CORR}$ > 365 mg diclofop-phenol/kg soil	0.027	13518	10
Diclofop	Chronic	$NOEC_{CORR}$ = 50	0.505	99	10
Diclofop-phenol	Chronic	$NOEC_{CORR}$ = 5	0.027	185	5
Other soil macro-organisms					
No data					

[1] endpoint was corrected by factor 2 because LogKow for diclofop-methyl is 4.8 and LogKow of diclofop is 2.8. The Log Kow of diclofop-phenol is unknown. Therefore, it is corrected by default.

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

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided

Laboratory dose response tests
Cereals (early growth stage) at 1 x 605 g a.s./ha

Most sensitive species	Test substance	ER_{50} (g a.s./ha) vegetative vigour	ER_{50} (g a.s./ha) emergence	Exposure (g a.s./ha)	TER	Trigger
Rye grass	Diclofop-methyl	-	38	1 m : 2.77% 16.7 g a.s./ha	**2.28**	5
				5 m: 0.57% 3.45 g a.s./ha	11.01	5
Rye grass	Diclofop-methyl emulsifiable concentrate 378 g/L	116	-	1 m : 2.77% 16.7 g a.s./ha	6.95	5
				5 m: 0.57% 3.45 g a.s./ha	33.62	5

Additional studies (e.g. semi-field or field studies)

Not required

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	end point
Activated sludge	Diclofop-methyl: EC_{50} 3h > 1000 mg a.s./L
Activated sludge	Diclofop-phenol : EC_{50} 3h = 86 mg a.s./L
Pseudomonas sp.	Not required

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

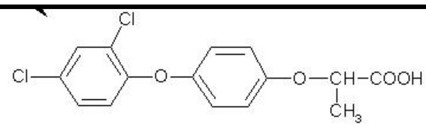
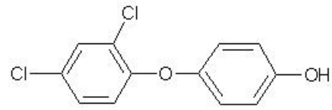
Compartment	
soil	Diclofop-methyl
water	Diclofop-methyl, diclofop-phenol
sediment	Diclofop-phenol
groundwater	Diclofop-methyl

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	N, R50/R53

	RMS/peer review proposal
Preparation	N, R50/R53

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
diclofop (The RMS used the term diclofop-acid)	(RS)-2-[4-(2,4-dichlorophenoxy)phenoxy]propionic acid	
diclofop-phenol	4-(2,4-dichlorophenoxy)phenol	

* The metabolite name in bold is the name used in the conclusion.

ABBREVIATIONS

1/n	slope of Freundlich isotherm
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstract Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)

GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	Pascal

PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year